UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

SALT INSTITUTE, *et al.*, Plaintiffs, v. TOMMY THOMPSON, Secretary, Department of Health and Human Services Defendant.	)	CIVIL ACTION NO. 04-359 GBL

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MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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A. INTRODUCTION

This is a case about administrative agency accountability to Congressional requirements of transparency, sound science, and accuracy, in the dissemination of government information.

The Information Quality Act and the Shelby Amendment are, perhaps, the most significant advancements in the pursuit of transparency, honesty and openness in the Federal government that have been made in the past 40 years. These statutes require Federal agencies that disseminate information to the public, not only as part of a formal rulemaking, but as part of almost any facet of agency activity, to meet clear and specific quality standards.

By Act of Congress, administrative agencies are now required to use only valid, demonstrably accurate and empirically supported scientific and technical data in any information they disseminate. They must truthfully inform the public, and disclose and provide all underlying data and methods the public needs to test and verify the accuracy of such information, including data generated by federally-funded grant research. And, most significantly, the public has the right to seek and obtain correction of government disseminated information that does not meet the requisite quality standards.

Plaintiffs in this case are Salt Institute and The Chamber of Commerce of the United States of America ("Plaintiffs"). They seek relief under the Information Quality Act ("IQA"), the Shelby Amendment ("Shelby") and the Administrative Procedure Act ("APA") from the refusal of the National Heart Lung and Blood Institute (the "Institute"), a unit of the U.S. Department of Heath and Human Services, to disclose data and methods used by the Institute in and to support the dissemination of public information concerning the health effects of salt in the human diet, and to correct the information that fails the quality test. *See* Plaintiffs' First Amended Complaint ("Compl.")(Ex. 1). Plaintiffs have brought this case to obtain redress from final agency action that denies them the important rights Congress has conferred

There is no doubt the Institute has refused to disclose the data and methods it relied upon to support disseminated public information. There is no doubt that the Institute refused to

correct erroneous information and refused to allow Plaintiffs' to meaningfully exercise their rights. There is no doubt that the Institute has disregarded the plain language and intent of the IQA and Shelby, and disseminated influential information about human health risks that does not meet the relevant quality standards.

Government behind closed doors is not acceptable to the Congress and it should not be accepted in this Court. The Institute's Motion To Dismiss for all its detail is, fundamentally, predicated upon the premise that the doors will stay closed and that there is no power in this Court to find otherwise. The Institute's arguments, however, are supported by almost nothing. They mischaracterize the dispute and ask the Court to apply well known principles of standing and judicial review in ways that are utterly incompatible with statutory language and intent, and well-established jurisprudence. Congress did not waste its breath in enacting the IQA and Shelby, and this Court should not join the Defendants in their efforts to diminish and undermine the important principles embodied in the enactments at issue here.

The Institute has given no valid reason to dismiss this lawsuit and the Court should not do so.

B. BACKGROUND

In 1946, Congress enacted the APA, 5 U.S.C. § 551 et seq. to rein in arbitrary agency action, and to rationalize and to standardize administrative processes and behavior.[1] The APA's centerpiece is judicial review. Judicial review has been the only effective check on administrative agencies to assure agency fidelity to statutory dictates and principles of fairness to

[1] Under the APA, administrative agencies must not (among other things) exceed the limits of the authorizing legislation, ignore a Congressional command, violate the law, exercise discretion in an arbitrary and capricious manner, or refuse to act when action is called for. *See* 5 U.S.C. §706; Mary M. Cheh, *An Essay on Marbury v. Madison, Executive Inaction, and the Duty of the Courts to Enforce the Law*, 72 GEO. WASH. L. REV. 253, 263-64 (2003) (citations omitted).

regulated persons, to ensure agencies use sound scientific data in an appropriate and defensible way, or to maintain the principle of legislative supremacy.[2]

1. The Federal Information Quality Regime

The new Federal information quality regime - - perhaps the most fundamental change in administrative law since the APA's enactment - - has two primary components. One is the IQA, which sets quality standards for information disseminated by federal agencies, and requires agencies to disclose enough information about data and methods that interested persons may test and verify the government's scientific claims. Most significantly, IQA creates a new right; affected persons are entitled to seek and obtain correction of information that does not meet quality standards. *See* Section 515 of the Treasury, Postal Service, and General Government Appropriations Act for Fiscal Year 2001, 44 U.S.C. § 3516 note (Ex. 2); 67 Fed. Reg. 8452, 8452-58 (the "OMB Preamble") and 8459-60 (the "OMB Guidelines") (Feb. 22, 2002) (collectively, Ex. 3). The other is Shelby, a disclosure statute. *See* Pub. L. No. 105-277. Shelby requires agencies to make available federally-funded research through the Freedom of Information Act ("FOIA") procedures.

2. The Information Quality Act

When Congress enacted the APA, it contemplated agencies would generally operate via either a "rulemaking" or an "adjudication."[3] It did not anticipate federal agencies would accomplish regulatory and policy goals by disseminating "free-standing" information (that is, information about matters within the agency's jurisdiction but not linked to a particular rule), particularly through the Internet."[4] According to one former EPA General Counsel, the

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[2] *See* Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1200 (1982).

[3] *See* 5 U.S.C. §§ 553-554 (2000).

[4] Although administrative agencies have always published information, the nature, extent, and impact of free-standing information dissemination have radically changed in recent years. One cause of this change has been the enactment of statutes requiring disclosure of information in the service of the public's "right to know." *See, e.g.*, the Emergency Planning & Community

dissemination of free-standing information "can be a supplement, sometimes even an alternative, to regulation. When broadly available, information can change behavior."[5] Such "regulation by information" historically evaded judicial review.[6]

By the late 1990s, the extent of this problem had been recognized, and some solutions proposed, by the Senate Appropriations Committee,[7] the General Accounting Office,[8] and the American Bar Association.[9] In 1998, the House of Representatives reported a bill "urging" the Office of Management and Budget to develop rules providing "policy and procedural guidance to Federal agencies" for ensuring the quality of disseminated information, and allowing "affected persons to petition for correction of information that does not comply with the rules."[10] The

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Right-to-Know Act, 42 U.S.C. § 11001 et seq. (2000). Another has been the advent of the Internet and the ubiquity of computers. As a result, free-standing information dissemination occurs more often, on matters of more substantive importance, and with less time for agency review and analysis, than ever before. *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).

[5] Environmental Law Institute, *The Environmental Forum* 36 (July/August 1998).

[6] *See* Ernest Gelhorn, *Adverse Publicity by Administrative Agencies*, 86 HARV. L. REV. 1380, 1426-27 (1973); Conrad, *supra*. Judicial review of agency action keeps agencies accountable. Congress's anachronistic presumption that agencies would speak to matters of policy almost entirely through either regulations or adjudications has led many courts to find persons affected by agency dissemination of free-standing information did not have APA protection.

[7] S. Rep. No. 106-161 at 81 (1999).

[8] The General Accounting Office in 1998 recommended that EPA develop guidance and standards to "address obtaining stakeholders' involvement in [information] projects' design and development," General Accounting Office, Pub No. GAO/RCED-98-245, ENVIRONMENTAL INFORMATION: AGENCYWIDE POLICIES AND PROCEDURES ARE NEEDED FOR EPA'S INFORMATION DISSEMINATION, at 19 (Sept. 1998).

[9] *See* "Recommendation concerning significant agency information dissemination activities intended to promote policy goals," *ABA House of Delegates 2001 Annual Meeting,* DAILY J. OF THE AM. BAR ASSOC., Report No. 107c, at 17, 20 (Aug. 6-7, 2001).

[10] H.R. REP. NO. 105-592, at 49-50 (1998).

United States Environmental Protection Agency ("EPA") even began to voluntarily implement some mechanisms to advise potentially affected parties of information products in the pipeline.[11]

In December, 2000, the Congress enacted IQA, requiring government information to meet quality standards, providing "affected persons" with the right to seek and obtain correction of disseminated information, and directing agencies to provide those persons with an administrative mechanism that could be used to obtain the requisite relief. The statute states:

> (a) IN GENERAL – [OMB] shall...issue guidelines...that shall 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....
>
> (b) CONTENT OF GUIDELINES – The guidelines under subsection (a) shall - -
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> (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)

After notice and comment, the implementing OMB Guidelines and explanatory Preamble were issued on February 22, 2002. The Guidelines are specific, detailed, and clear:

- They define the "information" subject to quality standards. OMB Guidelines at §§V(5), (6), (9).
- They define a triggering "dissemination." *Id.* at §§V(7),(8).
- They define quality standards that become more demanding as information importance increases. There is a primary test for basic information, an intermediate test for

[11] EPA, INFORMATION PRODUCTS BULLETIN, *See* www.epa.gov/ipbpages.

"influential information," as defined in §V(9), *Id.* at §§V(3)(b)(ii)(setting high transparency standard governing "influential scientific, financial, or statistical information"); and the most rigorous test for influential information that addresses "risks to human health, safety, and the environment." *Id.* at V(3)(b)(ii)(C) (for influential information regarding human health, safety, and environment risks, agencies "shall" adopt or adapt quality principles established by Congress for risk information relating to national drinking water standards under the Safe Drinking Water Act).[12]

- They define mandatory agency responsibilities pre- and post-dissemination and detail specific agency obligations regarding correction procedures. *Id.* at §§III, III(3), IV(2).

As implemented, IQA is also an information disclosure statute. *Id.* at §V(3)(a)(agency must identify sources of disseminated information so public can assess for itself the objectivity of that information, and have access to full, accurate, transparent documentation and error sources affecting data quality). Agencies responsible for disseminating influential scientific, financial, or statistical information (such as the information at issue here) must provide a "high degree of transparency about data and methods to facilitate reproducibility of such information by qualified third parties." *Id.* at §V(3)(b)(ii). The data and methods used by an agency must be sufficiently transparent that "an independent reanalysis could be undertaken by a qualified member of the public." *Id.* Consequently, agencies must generally[13] make available the "data and methods needed" to determine whether scientific results reported in government information are reproducible in any given case. *Id.* at §V(3)(ii)(B).[14] This standard applies both to agency

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[12] The information at issue in this case, which relates to the human health risks of dietary salt, is subject to the highest IQA quality standard, as it is clearly "influential" information bearing on human health risk. Compl. ¶¶ 1, 11-16, 45.

[13] Information disclosure is qualified only privacy, trade secrets, intellectual property, or "other confidentiality protections." OMB Guidelines at §V(3)(ii)(B)(*i*). If data and methods are withheld due to these "compelling interests," then the agency must "apply especially rigorous robustness checks to [disseminated] analytic results and document what checks were undertaken." *Id.* at §V(3)(ii)(B)(*ii*). However, "Agency guidelines **shall, in all cases**, require a disclosure of the specific data sources that have been used, and the specific quantitative methods and assumptions that have been employed." *Id.* (emphasis added).

[14] Here, the Institute had to disclose the mean blood pressures, standard deviations, and sample sizes of the relevant subgroups on each of the three levels of sodium intake used for both the control and low-salt diet in a useable form. *See* Compl. ¶¶ 3, 20-23, 26-27, 33.

analysis of data from a single study, and to analyses that combine information from multiple studies. *Id.*

The explanatory OMB Preamble speaks to a number of the issues in this case:

- It is "crucial" that Federal agencies follow the OMB Guidelines, because "The fact that the Internet enables agencies to communicate quickly and easily not only offers great social benefits, but also increases the potential harm that can result from information that does not meet basic information quality principles." 67 Fed. Reg. at 8452.

- The OMB Guidelines apply to a wide variety of government information dissemination activities that may range in importance and scope, while being generic enough to fit "all media." (2) Agencies must meet "basic information quality standards" for all information, but the more important the information, the higher the information quality requirements. (3) The Guidelines are designed so agencies can implement them in a common-sense and workable manner. 67 Fed. Reg. at 8452-53.

- Subsequent agency dissemination of information prepared by third parties requires that the underlying information adhere to the quality guidelines. 67 Fed. Reg. at 8454.

- Scientific information must be transparent and reproduceable by interested third parties. Agencies may not rely on undifferentiated "weight of science" claims to support disseminated information, and peer review, without more, is not dispositive of information quality. 67 Fed. Reg. at 8456-57.

3. The Shelby Amendment

In 1997, U.S. Senator Richard Shelby requested that the EPA Administrator produce the scientific data. He found that EPA did not have the data, that EPA had never reviewed the underlying research, that EPA formulated its policy based on the findings reported in "peer reviewed" studies,[15] and that the data itself was FOIA-exempt because it was in the possession of third party researchers, not the agency.[16] Congress responded:

> ... Provided further, That the Director of OMB amends Section ___.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the

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[15] *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).

[16] *See Forsham v. Harris,* 445 U.S. 169, 179 (1980).

> procedures established under the Freedom of Information Act: Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data...

FY 1999 Omnibus Appropriations Act (144 CONG. REC., H11178 (daily ed. Oct. 19, 1998)).

Shelby's drafters specifically intended to "make **all** federally funded research accessible" under FOIA. Shelby, *supra,* at 378-79 (emphasis added). OMB, after notice and comment, amended Circular A-110 to limit FOIA access to new studies funded after April 17, 2000 that were cited publicly and officially in support of an agency action with the force of law. 64 Fed. Reg. 54926 (Oct. 8, 1999). These limitations cannot be found in Shelby's plain language, and were contrary to the drafters' intentions.

C. STATEMENT OF THE CASE

1. The Disclosure Request.

In October 2002, the Institute began disseminated and continues to disseminate articles, press releases, and website postings advising *all* Americans, including persons with healthy diets and normal blood pressure, to severely restrict salt intake to avoid the risk of high blood pressure, disseminations said to be based on the conclusions of the DASH-Sodium study that it had previously funded (the "Sodium Trial"). There is only a limited amount of published data on the relationship between salt intake and human health outcomes, or "hard endpoints," such as heart attacks, strokes, and other cardiovascular events.[17] *See* Compl. ¶11. Consequently, Plaintiffs – whose members have an obvious, particular economic and research interest in the human health consequences of dietary salt - sought to test and verify the science behind the Institute's disseminations, and turned to the IQA. Compl. ¶¶ 7-9. [18]

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[17] This data suggests a diet with too little salt does not improve human health, and may in fact increase the risk of dangerous cardiovascular and other ailments, particularly in otherwise healthy persons over the age of 65. Compl. ¶ 11.

[18] Plaintiffs believe the disseminated information were based entirely on two scientific publications that selectively reported data from the government-funded Sodium Trial, resulting in inaccurate and misleading results. Compl. ¶¶ 17-28. In violation of the law, the Institute did not make available full, accurate, useful, and transparent documentation of the Sodium Trial data, or identify all of the scientific studies it relied upon, so Plaintiffs can only speculate.

On May 14, 2003, Plaintiffs filed an IQA petition asking the Institute to disclose the data and methods on which it relied, and to correct disseminated information. (Compl. Ex. 1.) Upon information and belief, these data were readily available in useful form at all times relevant, and were needed to effectively analyze what the Institute said. The Institute rejected Plaintiffs' petition by letter dated August 19, 2003, stating: "This petition seeks correction of information disseminated..." It mistakenly asserted that because Plaintiffs sought access to data produced in grant-funded research, IQA did not apply. It also claimed the disseminated information was not influential, and that external peer review satisfied IQA. It further stated that its claim all Americans would benefit from sodium reduction was not based solely on the research data requested that were acquired in studies called "the Sodium Trial", but rather on the "totality of the scientific evidence." (Prior to this time, the agency had specifically cited solely the Sodium Trial as scientific support.) However, in violation of the IQA, it never identified the data it believed constituted the allegedly supportive "totality of the scientific evidence." (Compl. Ex.2).

On September 3, 2003, the Institute advised Plaintiffs that it was, sua sponte, treating their Petition as a FOIA request. It then denied the Petition because the Institute did not have the requested data, and advised that it would not forward a request for access to third-party investigators unless the request was for access to data that were first produced under a new or competing grant after April 17, 2000, and that were "Cited publicly and officially by the Federal Government in support of an agency action that has the force of law." (Compl. Ex. 3). The Institute did not and does not have procedures in place under which Plaintiffs could obtain federally-funded research through FOIA.

Plaintiffs timely appealed the Institute's refusal to correct or disclose on September 22, 2003. (Compl. Ex. 4). In January 2004, the Institute listed the Sodium Trial on the "Limited Access Data Set" (the "LADS") website. The LADS website provides researchers with limited,

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Compl. ¶¶ 21-23, 25-27, 29, 32-34, 38, 46; OMB Guidelines §§ V(3)(a),(b)(ii); 67 Fed. Reg. at 8455.

and tightly controlled, access to raw data sets. Upon information and belief, the Institute placed the raw data in LADS, in whole or in part, to frustrate Plaintiffs' efforts to test, in a reasonable time and at reasonable cost, the scientific validity of the Institute's human health risk claim that all Americans should reduce sodium intake.[19] Compl. ¶ 38.

The Institute finally denied Plaintiffs' Appeal on or about February 11, 2004. (Compl. Ex. 5) This suit followed.

2. The Consequences Of The Agency's Disregard For The Law

IQA was enacted to ensure government information is objective and supported by scientifically sound data, and that the public has meaningful access to the data and methodological information needed to test and reproduce the government's results. OMB Guidelines §§ III(2), (3); V(3); 67 Fed. Reg. at 8455-57. It stands for the principle that the quality of government-disseminated scientific information is a direct function of the information's objectivity and reproducibility. OMB Guidelines §V(3). The law also recognizes that the public's capacity to test the objectivity and reproducibility of government information depends entirely upon the quality of an agency's scientific data and research methods disclosure. *Id.* at §V(3)(b); 67 Fed. Reg. at 8455-58. By mandating good science, IQA encourages sound government decision-making, and promotes scientific discourse by deterring agencies from relying on flawed studies, drawing scientifically unwarranted conclusions, and disseminating inaccurate information.

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[19] The fact that raw data is in the LADS website does not moot this case, as Defendant seemingly suggests. *See* Def's Mem., p. 19, fn. 14. The data is not readily accessible; it was not produced under FOIA, as required by Shelby, and it was not provided under IQA, as required by the OMB Guidelines. Access to the LADS data base is by application only. Moreover, as noted above, plaintiffs do not have the method or methods that the agency used to manipulate the raw data. Lacking that methodology, plaintiffs cannot assess the quality of the government's information in a reasonable time and at a reasonable cost. Even if that additional information were available in the database, and even if Plaintiffs could have access, Plaintiffs' claims under ¶¶47(a),(c)-(i), 52-54, and 56-61 remain to be reviewed.

The human health impact of dietary salt is an important scientific issue. However, the Institute's disregard for the law, specifically its failure to respect the principles of transparency, reproducibility, and sound science enshrined in IQA, has materially impaired further scientific investigation. Compl. ¶¶14, 32.[20] Among other things:

- Because key data have been wrongfully withheld, Plaintiffs are unable to undertake an independent reanalysis of the Institute's conclusions, a violation of OMB Guidelines § V(3)(b)(ii)(B).

- Plaintiffs cannot test or verify the Institute's human health risk analysis, or determine if it considered data showing the specific populations addressed in the Sodium Trial, the expected risk or central estimate of risk for each, the appropriate upper or lower bound estimate of risk, all significant uncertainties, peer reviewed studies regarding the claimed effect, and disclosed the methodologies used to reconcile inconsistencies in the scientific data, as required. *Id.* at §V(3)(b)(ii)(C).

- The Institute refused to make available the information needed to determine whether the peer review it relied on government met the general criteria for competent and credible peer review, violating §V(3)(b)(i).

- The Institute refused to identify, much less make available or provide information regarding the data obtained and methods used to therein, all of the studies it relied on, violating §V(3)(b)(ii).

Verification and testing is particularly important here because the limited amount of scientifically sound Sodium Trial data that is in the public realm suggests, that for most Americans, normal consumption of dietary salt in a healthy diet has no statistically verifiable adverse effect on blood pressure levels. Compl. ¶ 11. In other words, it seems the Institute's claim that all persons should limit salt intake regardless of their pre-existing cardiovascular risk

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[20] The consequences of the Institute's disregard for the law to Plaintiffs, and to the public their members serve, is significant and concrete. The Institute (1) has denied the Plaintiffs' right to obtain the science needed to disseminate accurate information to consumers, thereby allowing those consumers and their medical providers to make informed judgments about the consumption of salt, (2) has prejudiced Plaintiffs' members' ability to market their products without the stigma created by the government's negative dissemination of information that does not meet basic quality standards, and (3) it has deprived the association Plaintiffs' of their ability to carry out their essential activities, which include public education and advocacy, and research and investigation into the genetic and nutritional factors that govern individual response to dietary salt. Compl.¶¶ 7-9.

is unsupported by sound science, potentially harmful to many Americans, and, quite simply, wrong. *See* Compl. ¶¶ 11,13.[21]

On March 31, 2004, Plaintiff filed suit to enforce their rights under the IQA, Shelby and the APA. A First Amended Complaint was filed on June 10, 2004. Plaintiffs seeks the judgment of the Court ordering the Institute to comply in full with the IQA, and directing the Institute to make available federally-funded research data under FOIA, as required by Shelby. In response, the Defendant has filed a Motion to Dismiss pursuant to Rules 12 (b) (1) and 12 (b) (6) of the Federal Rules of Civil Procedures. Its Motion is entirely without merit, and should be denied by this Court.

D. QUESTIONS PRESENTED

1. Whether Plaintiffs Have Standing to Pursue Their Remedies in this Court.

2. Whether The IQA and The Administrative Procedure Act Afford Plaintiffs a Remedy For The Institute's Final Actions Denying Their Rights to Disclosure and Correction Under The IQA.

3. Whether the Institute's Denial of Plaintiffs' Appeal Constitutes "Final Agency Action for Which There is No Other Adequate Remedy in a Court" Within the Meaning of Section 10 (d) of the APA, 5 U.S.C. § 704.

4. Whether the Institute's Denial of Plaintiffs' Petition and Appeal and/or the Dissemination of Information are Matters "Committed to Agency Disclosure by Law" Under Section 10 (a) of the APA, 5 U.S.C. § 701(a)(2).

5. Whether Plaintiffs' Right to a FOIA Procedure to Obtain Data Generated Through Federally-Funded Research, as Guaranteed by the Shelby Amendment, is Enforceable in this Court in a Suit Against the Agency.

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[21] The Institute's extensive discussion of scientific articles possibly bearing on the validity of the information disseminated to the public is irrelevant to their Motion to Dismiss, and most likely to this lawsuit in general. *See* Def.'s Mem., pp. 10-12, 13 n. 10, 21. Defendant's Memorandum provides the only transparency the Institute has provided to date. It is indeed a sad commentary on the Defendant's commitment to principles of sound science – but good evidence as to why IQA and Shelby are so important – that it took a law suit for the Institute even to begin to identify the full scientific basis for its health risk claims.

ARGUMENT

This is the first case in which a court will adjudicate claims under IQA and Shelby.[22] Although matters of first impression are presented, the underlying administrative law principles are basic and clear. First, a person has the presumptive right to judicial review of an agency's final denial of his petition for relief, absent specific statutory language, reliable legislative history, or a fairly discernable congressional intent in the detail of the legislative scheme to preclude judicial review. *Bowen v. Michigan Academy of Family Physicians,* 476 U.S. 667, 670-73 (1984). Defendant does not, and in the face of clear IQA and OMB Guideline language, cannot, defeat this presumption.

Second, when a court reviews an agency's construction of a statute, it is confronted with two questions. The predicate question, always, is whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter, for the court and agency must give effect to Congress's unambiguously expressed intent. Shelby is crystal clear – when the Institute failed to make available to Plaintiffs a procedure under FOIA to obtain federally-funded data, it violated the law.

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[22] To the best of Plaintiffs' knowledge, there are no cases interpreting Shelby's meaning or effect. There is one case that briefly reviews what appears to have been a "throw in" IQA claim in the final stages of the massive Missouri River environmental litigation. *See In Re Operation of the Missouri River System Litigation,* No. 03-MD-1555 (PAM) (D. Minn. June 21, 2004) p.49. However, as Defendant at least tacitly acknowledges, this case is not instructive much less controlling, of the issues at bar. First, it appears the IQA was never properly before the court, as there is no evidence the particular *Missouri River* plaintiff that raised an IQA claim (and there were over two dozen plaintiffs who raised a dozen or so issues) filed a correction request. Second, the *Missouri River* court's "analysis," spanning approximately 200 words, never mentions the OMB Guidelines, much less analyzes their impact. Def's Mem., p.31. This is a major analytical defect. Third, although the *Missouri River* court states in bare dicta that "the language of the IQA indicates the Court may not review an agency's decision to deny a party's information quality complaint," it does not cite the language that supports such a conclusion. After making this bald statement, the Court has a one paragraph APA analysis, without citations, asserts that there is no law to apply, and then concludes not that APA judicial review is unavailable, but that "Congress did not intend the IQA to provide a private cause of action."

This case involves significant issues. The positions taken by the agency in denying Plaintiffs' Petition and Appeal, and by the Defendant in this case, run directly counter to the express intent of Congress, and to the public interest in government transparency, scientific objectivity, and agency accountability. On the plain language of the relevant statutes, on basic principles of administrative law, and for the public interest, Defendant's Motion should be denied.

I. STANDARD OF REVIEW.

Defendant's 12(b)(6) motion should not be granted unless it appears beyond a doubt that Plaintiffs can prove no set of facts that would entitle them to relief. The Court must construe the Complaint in the light most favorable to the Plaintiffs, take the facts pled as true, and make all reasonable inferences in Plaintiffs' favor. *In re Cable and Wireless PLC,* 2004 U.S. Dist. LEXIS 11509, *21-22 (E.D. Va. 2004) (citations omitted); *see also Ibarra v. United States,* 120 F.3d 472, 473 (4th Cir. 1997).[23]

II. PLAINTIFFS HAVE STANDING.

Defendant challenges Plaintiffs' standing. He claims the Complaint fail to allege a concrete or particularized injury, fairly traceable to the agency's action, that is likely to be redressed by a favorable court decision. Def.'s Mem., pp. 17-23. He asserts that Plaintiffs have failed to articulate a justiciable interest in receiving information and obtaining correction. This attack is meritless, ignoring the fundamental language and purpose of IQA and Shelby.

Plaintiffs have standing under at least four separate, individually sufficient legal theories:

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[23] The Complaint's central purpose is to provide Defendant fair notice of the claim and the grounds upon which it rests. *Cable and Wireless at* 22 (citation omitted). The Complaint meets this test.

- Plaintiffs are entitled to APA judicial review of final agency action, specifically, the denial of their IQA petition and appeal. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997); *Air Brake Systems, Inc. v. Mineta,* 357 F.3d 632, 641 (6th Cir. 2004).

- The denial of Plaintiffs' request for correction and information independently creates standing. *See Sargeant v. Dixon,* 130 F.3d 1067, 1070 (D.C. Cir. 1997) (citation omitted); *Public Citizen v. FTC,* 869 F. 2d 1541, 1548, n.13 (D.C. Cir. 1989) (citations omitted).

- Plaintiffs has standing because the Institute's actions in withholding data caused direct, redressable injury, by impairing Plaintiffs' ability to conduct research and disseminate information to their members and the public. *See* Compl. ¶7; *Competitive Enterprise Institute v. National Highway Safety Admin.,* 901 F. 2d 107, 122-23 (D.C. Cir. 1990).

- Plaintiffs have appropriately pled associational standing, because their members have a particular interest in, and will be harmed by the dissemination of, poor quality information regarding dietary salt. Compl. ¶¶ 7-9, 11, 13, 32-39. Put another way, Plaintiffs' members would otherwise have standing to sue in their own right, the interests at stake are germane to the organizational purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *See Friends of the Earth, Inc. v. Laidlaw Environmental Services, Inc.,* 528 U.S. 167, 180-81 (2000); *Warth v. Seldin,* 422 U.S. 490 (1975); *Hunt v. Washington State Apple Advertising Commission,* 432 U.S. 333 (1977).

III. COUNT I STATES A CLAIM.

A. Judicial Review Is Presumed.

APA judicial review of Count I is presumed. *See Regional Management Corporation, Inc. v. Legal Services Corporation,* 186 F.3d 457, 467 (4th Cir. 1999) (judicial review of federal agency action is presumed) (citations omitted); *see also Inova Alexandria Hospital v. Shalala,* 244 F.3d 342, 346 (4th Cir. 2001) (citations omitted). This presumption may be defeated only by clear and convincing evidence of specific statutory language, reliable legislative history, or a fairly discernable congressional intent in the detail of the legislative scheme to preclude judicial review. *Bowen,* 476 U.S. at 670-73; *Regional Management*, 186 F.3d at 467-68 (citations omitted). Where Congressional intent is in doubt, judicial review is presumed. *Bowen,* 476 U.S.

at 351.[24] The Institute has made no showing that the language of the IQA or any other source of authority reveals congressional intent to preclude or limit judicial review of a key action under the IQA. Indeed all available authority points to a purpose of encouraging vigorous judicial oversight. *See supra* at 1-4.

B. The OMB Guidelines Are Binding.

1. The OMB Guidelines are legislative rules.

Congress mandated that agency-disseminated information must meet OMB Guidelines' quality standards, and that "affected persons" be given the right *to seek and obtain* correction of disseminated information that did not meet the statutory requirements. IQA §§515(a),(b). It directed each agency provide an "administrative mechanism" through which this right could be exercised. IQA §515(b). Finally, it directed OMB to issue the OMB Guidelines under 44 U.S.C. § 3516, the section of the Paperwork Reduction Act ("PRA") captioned "Rules and Regulations" that grants OMB the authority to promulgate rules and regulations to carry out its PRA responsibilities, while specifying, in reasonably precise terms, the content thereof. *Id.*

Specifically authorized by statute, and adopted through formal notice and comment rulemaking, the OMB Guidelines create legally enforceable rights. *See Chasse v. Chasen*, 595 F. 2d 5961 (1st Cir 1979); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir.

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[24] The presumption applies with particular force in APA cases:

> The Supreme Court has traditionally not been sympathetic to arguments that judicial review is not available in APA cases. For example, the Court has stressed that the APA's " 'generous review provisions' must be given a 'hospitable' interpretation." It has often reiterated that "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." And more recently the Court has pointed out that it "will not lightly interpret a statute to confer unreviewable power on an administrative agency."

American Friends Service Committee v. Webster, 720 F. 2d 29, 39 (D.C. Cir. 1983) (citations omitted); *see also Regional Management Corporation,* 186 F.3d at 467 (citations omitted).

2000) ("A 'legislative rule' is one that the agency has promulgated in compliance with the procedures laid down in the statute or in the Administrative Procedure Act").[25] The OMB Guidelines surely are "substantive" and "legislative" in character, and have the force of law.[26]

2. Even if the OMB Guidelines are not legislative rules, Congress intended that they be binding on agencies as a matter of law.

Congress has made clear that the OMB Guidelines are legally binding on the federal agencies.[27] Section 515(b) provides that the Guidelines "s*hall* apply to the sharing by Federal

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[25] It is important to note that an agency's disclaimer that it has not issued a legislative rule, but rather guidance, is not dispositive of its legal effect on affected persons. *See infra* note 27.

[26] In *Chrysler Corp. v Brown*, 441 U.S. 281, 301-303 (1979), the Court characterized a "substantive" or "legislative-type rule" having the "force and effect of law" as one "affecting individual rights and obligations" and promulgated by the agency in accordance with a grant by Congress to it of "quasi-legislature" authority and the procedural requirements of the APA. Substantive rules "create law, usually implementary to an existing law" and "grant rights" or "impose obligations," in contrast to interpretive rules, which "merely clarify or explain existing law or regulations" and are "essentially hortatory and instructional." *American Hospital Association v. Bowen,* 834 F. 2d 1037, 1045 (D.C. Cir. 1987) (citations omitted). Substantive rules having the force of law are distinguishable general agency policy statements, which announce agencies' "tentative intentions for the future" and do not establish a "binding norm," and from procedural rules adopted by agencies for "organizing their internal operations." *Id,* at 1046-47 (internal quotations omitted).

One important characteristic of a legislative rule is whether the agency measure fills a "legislative gap" that is necessary in order to make the statutory scheme operative. *See American Mining Congress v. United States Department of Labor*, 995 F. 2d 1106, 1112 (D.C. Cir. 1993). In this case, the OMB guidelines were the method for implementing Congress' information quality program. Also, OMB provided the opportunity for notice and comment on the Guidelines, with publication in the Federal Register. APA.§ 553 provides notice and comment procedures are applicable to legislative rules, but not to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A); *see also* R. Stewart Breyer, C. Sunstein & M. Spitzer, *Administrative Law And Regulatory Policy*, 614-628 (4th ed 1999). By any test, the OMB Guidelines are substantive "legislative rules."

[27] Defendant seems to suggest that because IQA directs OMB to set information quality standards through "guidelines," and refers to them as providing "policy and procedural guidance," these provisions do not have the force of law and represent only non-binding guidance. This suggestion is meritless. In directing OMB to issue "guidelines" for information quality, Congress repeated a word used in PRA §3506(a), which provides OMB must issue