IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

ALEXANDRIA DIVISION

SALT INSTITUTE and the CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA Plaintiffs, v. TOMMY G. THOMPSON, Secretary, U.S. Department of Health and Human Services, Defendant.	Civil Action No. 04-359 (GBL)

MEMORANDUM ORDER

THIS MATTER is before the Court on Defendant's Motion to Dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). This case involves Plaintiffs Salt Institute and Chamber of Commerce of the United States of America's allegations that the National Heart, Lung and Blood Institute ("NHLBI") violated the Information Quality Act ("IQA") and the Shelby Amendment by failing to disclose the data and methods underlying the Dietary Approaches to Stop Hypertension-Sodium Trial conducted by an NHLBI grant recipient, the DASH-Sodium Collaborative Research Group. 44 U.S.C. § 3516, note (2000); 64 Fed. Reg. 54926 (Oct. 8, 1999). Plaintiffs also allege that NHLBI violated the IQA by reporting the results of the DASH-Sodium Trial on its website and in medical journal articles and

by recommending that people limit their sodium intake to moderately low levels. The issues before the Court are:

(1) whether Plaintiffs' claims should be dismissed because Plaintiffs lack standing to pursue their claims in federal court due to an absence of an injury in fact,

(2) whether Plaintiffs' claims should be dismissed because no private right of action arises under the IQA,

(3) whether Plaintiffs fail to state a claim that NHLBI, violated the Shelby Amendment by failing to implement procedures through which the public could obtain the DASH-Sodium Trial data under the Freedom of Information Act ("FOIA").

I. BACKGROUND

The plaintiffs in this case are the Salt Institute, a trade association of companies that "produce and market salt for food and other uses," and the Chamber of Commerce of the United States of America ("Chamber"), a business federation which includes "companies that use, market, and/or sell food products containing salt," First Am. Compl. ¶¶ 7,8. Plaintiffs seek declaratory and injunctive relief from this Court on their claims that the NHLBI, which is one part of the National Institutes of Health ("NIH"), an agency of the Department of Health and Human Services ("HHS"), violated the IQA and the Shelby Amendment. Plaintiffs assert that NHLBI violated the IQA and the Shelby Amendment by failing

to disclose the data and methods underlying the Dietary Approaches to Stop Hypertension-Sodium Trial ("DASH-Sodium Trial") conducted by an NHLBI grant recipient-the DASH-Sodium Collaborative Research Group. The Salt Institute and the Chamber also allege that NHLBI violated the IQA by reporting the results of the DASH-Sodium Trial on its website and in medical journal articles and by recommending that people limit their sodium intake to moderately low levels.

A. The Information Quality Act ("IQA")

The IQA is located in Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 and directs the Office of Management and Budget ("OMB") to issue guidelines 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..." Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515] (Dec. 21, 2000) (published at 44 U.S.C. § 3516 note). The IQA also directs OMB to include three specific requirements in its guidelines: (1) that federal agencies develop their own information quality guidelines, (2) administrative mechanisms for affected persons to seek correction of information that does not comply with OMB's guidelines, and (3) that federal agencies report periodically to OMB on the number and nature of complaints they receive regarding

the accuracy of the information they disseminate. § 515(B)(2). Neither the Act itself nor its very limited legislative history provide a mechanism for judicial review of information quality or any avenue for judicial relief.

1. OMB Guidelines

The OMB published final guidelines on implementing the IQA on February 22, 2002. *See* 67 Fed. Reg. 8452 (Feb. 22, 2002). The Guidelines require federal agencies to undertake four principal responsibilities: (1) to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate;" (2) to "develop a process for reviewing the quality ... of information before it is disseminated;" (3) to "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;" and (4) to provide OMB with reports regarding the agencies' information quality guidelines and any information quality complaints they receive. 67 Fed Reg. at 8458-59. Furthermore, the OMB guidelines encourage agencies that are responsible for disseminating influential scientific, financial, or statistical information to provide a "high degree of transparency about data and methods to facilitate reproducibility of such information by qualified third parties." *Id.* at 8460.

The OMB guidelines also address administrative correction mechanisms and require agencies to "specify appropriate time periods for agency decisions on whether and how to correct information" and to "establish an administrative appeal process to review the agency's initial decision." *Id.* at 8459. OMB states that the agencies should correct information only "where appropriate" and that "these administrative mechanisms shall be flexible" and "appropriate to the nature and timeliness of the disseminated information." *Id.* Agencies maintain significant discretion in ensuring the quality of the information of the information they disseminate.

2. HHS Guidelines

On October 1, 2002, pursuant to the IQA and the OMB guidelines, HHS implemented its own "Guidelines for Ensuring the Integrity of Information Disseminated by HHS agencies." U.S. DEPT. OF HEALTH AND HUMAN SERVICES, GUIDELINES FOR ENSURING THE INTEGRITY OF INFORMATION DISSEMINATED TO THE PUBLIC, *available at http://www.aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml (last revised Nov. 12, 2003)*. The HHS guidelines include both department-wide and agency-specific guidelines, including the guidelines of the NIH. HHS indicates that it generally favors public access to the data underlying agency-sponsored scientific studies when the data is available. *Id.* Such public disclosure of data, however, may not always be permissible, due for example,

to confidentiality requirements, proprietary restrictions, or resource availability. *Id.* The NIH guidelines state that generally "grantees own the data generated by or resulting from a grant-supported project." *Id.* at § II.2 and n.1. Consequently, although data sharing is encouraged, NIH recognizes that it may be limited by confidentiality concerns and other factors that preclude data dissemination. *Id.* at § V.1.

The HHS guidelines also establish a process for information correction requests and appeals. *Id.* at § VI. HHS reminds complainants that they bear the burden of proof to establish the need for and the type of correction sought. *Id.* A correction request must include specific reasons for asserting that the information at issue violates OMB, HHS, or agency-specific guidelines and "specific recommendations for correcting the information." *Id.* The agency aims to respond to correction requests within 60 days of receipt, and a party may appeal the agency's decision within 30 days after that. The agency aims to decide any appeals within 60 days. *Id.*

B. The Shelby Amendment

In 1998, Congress added two sentences to the Fiscal Year 1999 Omnibus Consolidated Emergency Supplemental Appropriations Act that are designed to require federal agencies to make available to the public research data

produced by federal grantees under FOIA in certain circumstances. Termed the Shelby Amendment, the entire provision provides:

> ...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 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 data.

FY 1999 Omnibus Appropriations Act (144 CONG. REC. H11178 (daily ed. Oct. 19, 1998)). OMB, after publishing two proposed revisions and receiving over 12,000 comments, published the final revision of Circular A-110 in October of 1999, 64 Fed. Reg. 54926 (October 8, 1999), which became effective April 17, 2000. *See Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, 65 Fed. Reg. 14406 (March 16, 2000). OMB's final revision, in pertinent part, provides the following:

> ...in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under FOIA.

Id. at 14407. The revised circular applies only to data

that is published and used by the Federal agency in support of an action that has the force and effect of law. *Id.* Additionally, the circular is applicable only to data first produced under new or competing continuing grants awarded after April 17, 2000, the regulation's effective date. *See* 64 Fed. Reg. 54926.

C. DASH-Sodium Trial

In recent years, scientists supported and funded by Defendant have conducted studies focusing on the relationship between diet quality and blood pressure. The first clinical study, conducted in 1997, was called the Dietary Approaches to Stop Hypertension ("DASH study"). The results of the DASH study were published in the *New England Journal of Medicine* in 1997, and the study findings indicated that a diet rich in fruits, vegetables, and low-fat dairy products, coupled with reduced saturated and total fat intake, could reduce blood pressure ("DASH diet"). The DASH diet did not severely restrict dietary salt intake. *See* Compl. ¶ 17; L.J. Appel, T.J. Moor, E. Obarzanelk, et al., *A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure*, 336 NEW ENG. J. MED. 1117 (1997).

In 2000, as a follow-up to an earlier clinical study on the effects of a healthy diet on blood pressure, researchers examined the effects of different levels of dietary sodium

on the blood pressure rates of persons eating a healthy diet and persons eating a typical diet. The study was performed by the DASH-Sodium Collaborative Research Group (hereinafter "Group"), a large group of research scientists from hospitals and universities around the country that received a grant from NHLBI to perform the trial. *See* Compl. ¶¶ 18-19.

The DASH study involved 412 participants who were randomly assigned to eat a typical U.S. diet or the DASH diet. On January 4, 2001, the DASH-Sodium Collaborative Research Group published its findings in the *New England Journal of Medicine*. *See* Compl. ¶ 19; Frank M. Sacks, MD et al., *Effects of Blood Pressure on Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension Diet*, 344 NEW ENG. J. MED. 3, 5 (January 4, 2001). The Group concluded that lower levels of blood pressure corresponded to lower levels of sodium intake in all participants. *Id.* The Group later performed a more detailed subgroup analysis of the DASH-Sodium Trial Data and published its results in the December 18, 2001 edition of the *Annals of Internal Medicine*. William M. Vollmer, PhD, Frank M. Sacks, MD, 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 (December 18, 2001) In this

article, the research scientists confirmed and extended their earlier findings and concluded that decreases in blood pressure associated with reduced sodium intake were present in all subgroups. *See* Def.'s Mem. Supp. Def. Mot. Dis. at 11 [hereinafter "Def's Mot. Dismiss"]; *Id.*

After the results of the DASH-Sodium Trial had been published in these peer reviewed medical journals, NHLBI reported the conclusions of the Group in various website press releases and publications. *See* Def.'s Mot. to Dismiss at 12.

D. Administrative Proceedings Related to Plaintiffs' Request for Data Disclosure and Information Correction

On May 14, 2003, Plaintiffs filed an IQA petition with the NHLBI asking the it to make publicly available all the data and methods on which it relied in the DASH-Sodium Trial. Compl. Ex. 1. Plaintiffs complained about various statements contained in six NHLBI-related documents discussing the results of the DASH-Sodium Trial and the effect of salt intake on blood pressure. Plaintiffs asserted that the information in the six documents "directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in all individuals." First Am. Compl., Ex. 1 at 2. Plaintiffs stated, "[t]his petition seeks correction of information

disseminated by NHBLI..." Plaintiffs, however, also noted that they did "not at this time request or recommend that the challenged information be removed from public view." *Id.* at 15. Instead, Plaintiffs limited their request for relief to the disclosure of the DASH-Sodium Trial Data, including mean blood pressures, standard deviations, and sample sizes for the relevant subgroups on each of the three levels of sodium intake for both the control and the DASH diet. *See* First Am. Compl. ¶33; *Id.* at 14-15.

On August 19, 2003, NHLBI responded by letter to Plaintiffs' petition and noted that since Plaintiffs were not seeking a correction of any disseminated information but instead were seeking access to data generated by Federal grantees, the request should be made under FOIA, not through an IQA petition. *See* First Am. Compl., Ex. 2 at 2. The letter further stated that the agency would forward Plaintiffs' request for data to the appropriate FOIA officials. *See id.* NHLBI also noted that the challenged information satisfied NIH's information quality standards and that the information was subjected to extensive review under NHLBI's procedures for publication. The NHLBI explained that the Group already honored two similar requests for the data and was preparing a public access data set of the study results for release in January 2004. *Id.*

at 5.

On September 3, 2003, the NHLBI sent Plaintiffs a letter advising them that it was treating their petition as a FOIA request. It then denied Plaintiffs' petition because the NHLBI did not have the requested data. The letter stated that the grants for the DASH studies "were Cooperative Agreements which did not require the investigators to share their data with the National Institutes of Health." *See* First Am. Compl., Ex. 3 at 1. NHLBI also stated that it would not forward a request for access to third-party investigations unless the request was for data covered by the Shelby Amendment, as implemented in OMB's revised Circular A-100. It further stated that the Shelby Amendment applies only to data that is (1) first produced under a new or competing grant awarded after April 17, 2000; and (2) cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law. First Am. Compl., Ex. 3 at 2. NHLBI indicated that the DASH-Sodium grants were competitively awarded in February 1997 and were extended for five subsequent years through non-competitive continuing grants, thus making the Shelby Amendment inapplicable to the DASH-Sodium Trial data. *Id.* at 2.

On September 22, 2003, Plaintiffs appealed the NHLBI's

refusal to correct or disclose the data. *See* First Am. Compl., Ex. 4. Plaintiffs reiterated both their request for access to the DASH-Sodium Trial data and their complaints regarding the various statements made by NHLBI regarding sodium intake and the results of the DASH-Sodium Trial. *See id.* In January 2004, the Institute listed the Sodium Trial on the "Limited Access Data Set" ("LADS") website. The LADS website provides researchers with limited and tightly controlled access to raw data sets. Plaintiffs allege that the Institute placed the raw data in LADS to frustrate Plaintiffs' efforts to gain access to all of the data. Compl. ¶ 38.

On February 11, 2004, NHLBI denied Plaintiffs' appeal. *See* First Am. Compl., Ex. 5. NHLBI advised the Plaintiffs that they could request the data from the DASH-Sodium Collaborative Research Group and explained that a public access data set of the DASH-Sodium Trial was available through the Internet. *See id.* at 2. NHBLI also reiterated its conclusion that the statements regarding sodium intake in the challenged documents satisfied the information quality guidelines. Plaintiffs filed their initial complaint on March 31, 2004. They filed their First Amended Complaint on June 10, 2004.

On July 15, 2004, the Dash-Sodium Trial investigators

published the specific data requested by Plaintiffs in an article in The American Journal of Cardiology, known as the "Bray Paper." *See* G.A. Bray et. al., *A Further Subgroup Analysis of the Effects of the DASH Diet and Three Dietary Sodium Levels on Blood Pressure: Results of the DASH-Sodium Trial, 94 J. CARDIOLOGY* 222, 223-25 (July 15, 2004); Reply Mem. Supp. Def.'s Mot. Dismiss. Ex. 1. The Defendants have submitted to the Court the Bray Paper along with a declaration of Nancy L. Geller, Director of Biostatistics Research in the Division of Epidemiology and Clinical Applications of the NHLBI at the NIH, asserting in summary, "[i]t appears to me that the data Plaintiffs requested, and more, is available in the Subgroup Analysis [Bray] paper." Geller Declaration ¶ 11. Plaintiffs, however, assert that the Bray Paper does not provide the data requested. Pls. Sur-Resp. to Def.'s Reply Supp. Mot. Dismiss at 2. In support of their position, Plaintiffs submit a declaration from David McCarron, M.D., an expert consultant to Plaintiffs, stating that the Bray Paper does not provide all of the data requested by Plaintiffs.

II. DISCUSSION

A. Standard of Review

A Federal Rule of Civil Procedure 12(b)(6) motion

should not be granted unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief. FED. R. CIV. P. 12(b)(6); *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). In considering a Rule 12(b)(6) motion, the Court must construe the complaint in the light most favorable to the plaintiffs, read the complaint as a whole, and take the facts asserted therein as true. *Mylan Labs, Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). Conclusory allegations regarding the legal effect of the facts alleged need not be accepted. *See Labram v. Havel*, 43 F.3d 918, 921 (4th Cir. 1995). Because the central purpose of the complaint is to provide the defendant "fair notice of what the plaintiff's claim is and the grounds upon which it rests," the plaintiff's legal allegations must be supported by some factual basis sufficient to allow the defendants to prepare a fair response. *Conley*, 355 U.S. at 47.

B. Analysis

1. Plaintiffs Lack Standing

Plaintiffs Salt Institute and Chamber of Commerce lack standing to pursue their claims in federal court.[1] In order

[1]Because Plaintiffs allege that the Bray Paper does not provide them with all the information they requested, their claim is not moot. Nevertheless, Plaintiffs claims are dismissed because they lack standing.

to satisfy the three-part test for standing under Article III of the U.S. Constitution, the plaintiff must show: (1) it suffered an "injury in fact" that is (a) concrete and particularized, (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant, and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992); *Friends of Ferrell Parkway, LLC v. Stasko*, 282 F.3d 315, 320 (4th Cir. 2002); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. Inc.*, 528 U.S. 167, 180-181 (2000). The party invoking federal jurisdiction bears the burden of establishing the elements of standing. *Steel Company v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998). Plaintiffs must demonstrate that they are not merely asserting a "generally available grievance" about the government, unconnected with a threatened concrete interest of their own. *See Lujan*, 504 U.S. at 573-574.

a. Injury in Fact

i. Concrete and Particularized Injury

Plaintiffs fail to allege that they have suffered a concrete and particularized injury, and at most, assert no more than a generalized grievance shared by members of the

public at large. See, e.g., Taubman Realty Group Ltd. P'ship v. Mineta, 320 F.3d 475, 480-81 (4th Cir. 2003) (finding shopping center developers' alleged injuries not sufficiently concrete or particularized to confer standing). Plaintiffs also fail to demonstrate that they are not merely asserting a "generally available grievance" about government, unconnected with a threatened concrete interest of their own. *See Lujan*, 504 U.S. at 573-574. Plaintiffs must allege that they suffered some specific injury, and it must be more than the merely theoretical injury that all persons may suffer. *See Lujan*, 504 U.S. at 573-574. Plaintiffs allege generally that they have standing to sue because "they have suffered actual or threatened injury due to Defendant's conduct." First Am. Compl. ¶ 9. Plaintiffs, however, make no specific assertions of injury caused by NHLBI's recommendations regarding dietary intake or NHLBI's inability to provide them with the DASH-Sodium data. Thus, none of the Plaintiffs' alleged harms is sufficiently concrete and particularized to confer standing. *See, e.g., Baur v. Veneman*, 352 F.3d 625, 636-37 (2d Cir. 2003).

ii. Actual and Imminent

Plaintiffs might contend that they are injured by NHLBI's dissemination of the results of the DASH-Sodium Trial because this information might cause consumers to

reduce their consumption of salt, thus decreasing the Plaintiffs' constituent members' sales. Even assuming *arguendo* that Plaintiffs had included this theory in their complaint, which they did not, such an injury is based on the hypothetical actions of third parties and is too speculative to constitute the type of "certainly impending" injury necessary to have standing under Article III. *See Whitmore v. Arkansas*, 495 U.S. 149, 150, 155, 158 (1990) (indicating that the injury alleged cannot be "conjectural or hypothetical," "remote" "speculative" or "abstract" but must be "certainly impending").

b. Injury is Not Traceable to NHLBI's Actions

Plaintiffs fail to allege that their purported injury is fairly traceable to the challenged conduct of NHLBI and not attributable to some independent third party not before the Court. Plaintiffs must establish that there is a causal connection between the injury and the alleged violations of the law. *See, e.g., Friends for Ferrell Parkway*, 282 F.3d at 323-24 (finding that a city's failure to build a road and increased traffic, noise, and fumes were not fairly traceable to the United States Fish and Wildlife Services' acquisition of land; since many other factors may have caused Plaintiffs' alleged injuries). Plaintiffs allege that they are somehow injured by the statements and

recommendations of NHLBI regarding the importance of limiting dietary salt intake to moderate levels stemming from the results of the DASH-Sodium Trial and other research, and by their inability to gain access to the trial data. NHLBI's recommendations, however, are not new or unique. Numerous other scientific studies have reached the conclusion that reducing sodium intake reduces blood pressure. *See, e.g., F.J. He and G.A. MacGregor, Effect of Modest Salt Reduction on Blood Pressure: A Meta-Analysis of Randomized Trials*, Implications for Public Health, 16 J. HUMAN HYPERTENSION 761 (2002); *J.A. Cutler, D. Follmann, and P.S. Allender, Randomized Trials of Sodium Reduction: An Overview*, 65 AM. J. CLINICAL NUTRITION 643 (Suppl.) (1997); *M.R. Law, C.D. Frost, and N.J Law, By How Much Does Dietary Salt Reduction Lower Blood Pressure? III. Analysis of Data from Trials of Salt Reduction*, 302 BRITISH MEDICAL JOURNAL 819 (1991). Additionally, the U.S. Dietary Guidelines have made the same recommendation as NHLBI to limit sodium intake to approximately 2400 mg per day. *See* U.S. DEP'T OF AGRIC. AND DEP'T OF HEALTH AND HUMAN SERVICES, NUTRITION AND YOUR HEALTH, DIETARY GUIDELINES FOR AMERICANS (5th ed. 2000). Furthermore, the findings of the 1989 U.S. National Academy of Sciences' (NAS) *Recommended Dietary Allowances* report affirmed the safety and efficacy of a dietary sodium intake of 2400 mg

per day or less. *See* SUBCOMMITTEE ON THE TENTH EDITION OF THE RECOMMENDED DIETARY ALLOWANCES, FOOD AND NUTRITION BOARD, COMMISSION ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, RECOMMENDED DIETARY ALLOWANCES (10th ed. 1989). Any potential claim of injury by Plaintiffs cannot be fairly traceable to the NHLBI, because any one of these numerous other studies or agency reports making the same recommendations could be responsible for Plaintiffs' undefined injury.

The published results of the DASH-Sodium Trial themselves are more likely the cause of any injury allegedly suffered by the Plaintiffs rather than NHLBI's mere dissemination of Dash-Sodium Trial results. The conclusions of the independent scientists who conducted the DASH-Sodium Trial were reported in articles in both the January 4, 2001 issue of the *New England Journal of Medicine* and the December 18, 2001 issue of the *Annals of Internal Medicine*. Plaintiffs are not, however, seeking a correction or any other relief regarding the published results of the DASH-Sodium Trial. Furthermore, the DASH-Sodium Trial scientists are third parties not presently before the court. Plaintiffs have failed to establish that NHLBI's withholding of the data is the cause of their purported injury.

c. Redressability

Plaintiffs purported injuries would not be redressed

even if they received their desired remedies of access to the DASH-Sodium Trial data and amendment of NHLBI's statements and recommendations regarding salt intake. In determining whether a plaintiff has a sufficient injury to establish standing, courts ask whether a ruling favorable to the plaintiff would eliminate the harm to him. *See, e.g., Friends for Ferrell Parkway*, 282 F.3d at 323-324 (indicating that plaintiffs' injuries likely would not be redressed by relief requested due to other causes of injuries). If a court order declaring a government action illegal or unconstitutional (and ending that government action) would not eliminate the harm to the litigant, then that individual does not have the type of specific injury that would grant him standing to challenge the government action. *See Id.* at 320-321 (indicating that plaintiffs' injury must be "caused by the challenged conduct of the defendant, and not by the independent actions of third parties not before the court"). The numerous other scientific studies, the DASH-Sodium Trial results themselves, the U.S. Dietary Guidelines, and the NAS Recommended Dietary Allowances' recommendations to limit salt intake would all remain unchanged, in circulation, and potentially influencing the public to reduce its consumption of salt. Plaintiffs' purported injury is not likely to be redressed by a favorable decision from this Court, and

Plaintiffs therefore lack standing to sue.

d. Organizational Standing

Plaintiffs do not have organizational standing. An organization has standing to challenge government action that causes injury to the organization itself. *Hunt v. Washington State Apple Adver.* 432 U.S. 333, 343 (1977). An organization also has standing to challenge government actions that cause injury in fact to its members if the organization can demonstrate the following three facts:

> (i) An injury in fact has occurred to the members of the organization that would give individual members a right to sue on their own behalf;
>
> (ii) The injury to the members is related to the organization's purpose; and
>
> (iii) Neither the nature of the claim nor the relief requested requires participation of the individual members in the lawsuit.

Id. at 343.

Plaintiffs have not properly alleged an injury in fact because they have not alleged that their members have suffered a concrete and particularized injury that would give them the right to sue on their own behalf. Therefore, Plaintiffs have not properly alleged organizational

standing. Plaintiffs lack the requisite legal standing to assert their claims in federal court.

2. Judicial Review of NHLBI's Actions Regarding the DASH-Sodium Trial

Generally, there are two possible avenues for judicial review of federal agency action: (1) a substantive statute may provide a private right of action for judicial review of an agency action or (2) the provisions of the Administrative Procedure Act may provide for judicial review. *Regional Mgmt. Corp. Inc. v. Legal Serv. Corp.* 186 F.3d 457, 461 (4th Cir. 1999). In this case, judicial review does not exist under the IQA because there is no private right of action. Furthermore, there exists no final agency action, so the presumption of judicial review does not apply.

a. Private Right of Action Under the Information Quality Act

There is no private right of action under the IQA and an agency's decision to deny a party's information quality complaint is not reviewable by this Court. For a plaintiff to enforce the provisions of a federal law in court, Congress must first have afforded the party a private right of action. *See Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("private rights of action to enforce federal law must be created by Congress"). The most important factor in

determining whether Congress intended to create a private right of action is whether the statute's text provides such a right. *See id.* There is nothing in the IQA that provides a right of action in a court of law for alleged violations of its provisions. The IQA simply directs OMB to provide "policy and procedural guidance" to federal agencies "for ensuring and maximizing the quality, objectivity, utility, and integrity of information" that those agencies disseminate and to require each agency to issue guidelines to achieve those same purposes. Pub. L. No. 106-554, § 1 (A)(3) [Title V, § 515(A)] (*published at* 44 U.S.C. § 3516 note). The statute also prescribes the process to be followed if a party complains that an agency has failed to adhere to the established guidelines. The IQA requires each federal agency 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 the guidelines..." *Id.* at § 515(b)(2)(B). The language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts. The first and only court to address this issue determined that the IQA does not provide for a private

cause of action. *In re: Operation of the Missouri River Sys. Litig.*, No. 03-MD-1555 at 49, 2004 WL 1402563 (D. Minn. June 21, 2004) (order granting summary judgment).

b. Administrative Procedure Act Judicial Review

The presumption of APA judicial review only applies only if two underlying prerequisites are met: (1) final agency action must have occurred and (2) the agency action is not committed to agency discretion by law. *See* 5 U.S.C. §§ 701(a)(2); *Transactive Corp v. United States*, 91 F.3d 232, 236 (D.C. Cir. 1996) (indicating presumption of APA judicial review does not apply if agency action is committed to agency discretion by law or if action is not final).

i. Final Agency Action

The NHLBI's actions in this case do not constitute a final agency action necessary for judicial review under the APA. A final agency action is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997). In this case, NHLBI merely described the results of the DASH-Sodium trials, the findings of research scientists, and made recommendations to limit sodium intake to moderate levels. Agency dissemination of advisory information that has no legal impact has consistently been found inadequate

to constitute final agency action and thus is unreviewable by federal courts under the APA. *See, e.g., Franklin v. Massachusetts*, 505 U.S. 788, 798 (1992) (finding agency report on census data was not final agency action because it carried no direct legal consequences); *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852, 859-62 (4th Cir. 2002) (EPA report on health hazards of second-hand tobacco smoke not final agency action); *Industrial Safety Equip. Ass'n Inc. v. EPA*, 837 F.2d 1115, 1117, 1119 (D.C. Cir. 1988) (EPA report recommending use of certain asbestos protection respirators not final agency action). NHLBI's actions do not constitute final agency action and therefore are not reviewable by this Court.

ii. Agency Discretion

Judicial review is also precluded because the informal agency decisions concerning NHLBI's statements and recommendations regarding the DASH-Sodium Trial were matters "committed to agency discretion by law." There is a strong presumption of reviewability under the APA. *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967). The APA, however, expressly precludes judicial review of agency action "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). "Agency action is committed to the discretion of the agency by law when 'the statute is drawn so that a court

would have no meaningful standard against which to judge the agency's exercise of discretion.'" *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (*quoting Heckler v. Chaney*, 470 U.S. 821, 830 (1984)). If no "judicially manageable standard" exists by which to judge the agency's action, meaningful judicial review is impossible and the courts are without jurisdiction to review that action. *Id.*

Neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised its discretion in deciding a request to correct a prior communication. In fact, the guidelines provide that "[a]gencies, 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." 67 Fed. Reg. at 8458. Courts have determined that regulations containing similar language granted sufficient discretion to agencies to preclude judicial review under the APA. *See Steenholdt*, 314 F.3d at 638 (holding that agency's decision under a regulation allowing an agency to take an action "for any reason the Administration considers appropriate" is committed to agency discretion and not

reviewable under APA). Judicial review of NHLBI's discretionary decisions is not available under the APA because the IQA and OMB guidelines at issue insulate the agency's determinations of when correction of information contained in informal agency statements is warranted.

c. APA and Shelby Amendment

Plaintiffs lack standing to assert that NHLBI violated the Shelby Amendment. Plaintiffs allege that NHLBI violated the Shelby Amendment, Pub. L. No. 105-277, 1998 HR 4328, which directs OMB to amend its Circular A-110 to require federal agencies to give the public access to all data generated by federally funded studies. *See* First Am. Compl. ¶¶ 55-61. Plaintiffs claim that NHLBI exceeded its statutory discretion by granting public access only to data from new studies funded after April 17, 2000, that was cited publicly and officially in support of agency action with the force of law. *See id.* ¶ 58. Plaintiffs generally allege that they are "adversely affected and aggrieved by this final agency action, and have no other adequate remedy at law." Compl. ¶ 61. 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.

Furthermore, Plaintiffs fail to state a claim because

OMB, not NHLBI, is responsible for implementing the Shelby Amendment. In their claim, Plaintiffs assert that NHLBI exceeded its statutory discretion under the Shelby Amendment and "restricted public access only to data from new studies funded after April 17, 2000 that was cited publicly and officially in support of an agency action with the force of law." First Am. Compl. ¶ 58. Contrary to Plaintiffs' assertion, OMB, not NHLBI, restricted access to grantee data in the manner described pursuant to its authority under the Shelby Amendment. The Shelby Amendment directs OMB, not NHLBI, to amend OMB Circular A-110 to require federal agencies to make data produced by federal grant recipients available to the public under FOIA procedures. Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 1998 HR 4328 (1998). OMB implemented the Shelby Amendment and NHLBI merely applied the terms of OMB's revised Circular A-110. Accordingly, Plaintiffs' claim that NHLBI violated the Shelby Amendment fails to state a claim on which relief can be granted.

III. CONCLUSION

The Defendants Motion to Dismiss is granted because the Plaintiffs lack standing to sue, there is no private right of action under the Information Quality Act, and the NHLBI's actions regarding the DASH-Sodium Trial data are not subject

to judicial review under the Administrative Procedure Act.

For the foregoing reasons, it is hereby

ORDERED that Defendant's Motion to Dismiss is GRANTED.

The Clerk is directed to forward a copy of this Order to counsel.

Entered this 15th day of November, 2004.

Gerald Bruce Lee
United States District Judge

Alexandria, Virginia
11/15/04