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

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CLERK U.S. DISTRICT COURT
ALEXANDRIA, VIRGINIA

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.	)	Case No. 04-CV-359 GBL

MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

(6)

INTRODUCTION

This case arises out of Plaintiffs' displeasure with the results of a scientific study that concluded that reducing sodium intake, in conjunction with either a typical or a healthy diet, reduces blood pressure for most people, including those with or without hypertension. Plaintiffs make an unprecedented attempt to have a federal court second-guess an administrative agency's decision to endorse the study under the Information Quality Act ("IQA") and the so-called Shelby Amendment. Plaintiffs assert that the agency violated its statutory duties by allegedly failing to produce the scientific data that was collected and possessed by the private research group that performed the study and by disseminating the results of the group's study, which the plaintiffs challenge generally as lacking sufficient scientific quality.

The plaintiffs in this case are the Salt Institute, a trade association of companies that "produce and market salt for food and other uses," First Am. Compl. ¶ 7, and the Chamber of Commerce of the United States of America (the "Chamber"), a business federation which includes "companies that use, market, and/or sell food products containing salt," First Am. Compl. ¶ 8. They seek declaratory and injunctive relief from this Court on their claims that the National Heart, Lung, and Blood Institute ("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 produce the data underlying the Dietary Approaches to Stop Hypertension-Sodium Trial (the "DASH-Sodium Trial") conducted by an NHLBI grant recipient--the DASH-Sodium Collaborative Research Group. The Salt Institute and the Chamber also complain 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, based, in part, on the DASH-Sodium Trial results. Pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, Plaintiffs' claims should be dismissed.

Plaintiffs lack standing to challenge the results of the DASH-Sodium Trial and the related statements that NHLBI disseminated. Plaintiffs fail even to articulate a specific theory of how the dissemination of the results of the DASH-Sodium Trial and NHLBI's public health recommendations injure them. At most, Plaintiffs assert a generalized grievance regarding the results of the DASH-Sodium Trial. Moreover, Plaintiffs cannot trace their purported injury specifically to NHLBI's statements regarding the DASH-Sodium Trial results and sodium intake or establish that their requested but unspecified "correction" of such statements would redress their injury because any causal connection to NHLBI's statements is broken by countless other scientific studies and policy statements that also indicate that reducing salt intake helps to reduce blood pressure. Clearly, Plaintiffs do not have standing to invoke this Court's jurisdiction under Article III.

Even if this Court had subject matter jurisdiction (which it does not), Plaintiffs' claims should still be dismissed because there is no statutory basis for federal court review of them. The thrust of Plaintiffs' IQA claim is that the DASH-Sodium Trial is based on flawed scientific methods and lacks sufficient quality, objectivity, and utility. Federal courts, however, are generally not proper forums for determining the quality of scientific research studies performed by federal grantees, and the IQA contains no provision granting private parties a right to enforce its statutory terms in federal court. Instead, the Act leaves such determinations to the administrative agencies.

Similarly, neither the DASH-Sodium Trial nor NHLBI's dissemination of information

related to it are subject to judicial review under the Administrative Procedure Act ("APA"). Because NHLBI's mere dissemination of the study results and related information triggers no legal consequences, imposes no obligations, and creates no rights, it does not constitute final agency action, which is a prerequisite for judicial review under the APA. Even if NHLBI's conduct were deemed to qualify as final agency action, judicial review still would be precluded in this case. The determination as to whether the information in NHLBI's informal statements regarding the DASH-Sodium Trial lacks sufficient "quality" and requires a correction is committed to agency discretion and not subject to judicial review.

Plaintiffs' additional 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 also must be dismissed. Plaintiffs have not alleged that they have suffered a sufficiently concrete and particular injury to have standing to bring this claim, and nothing in the two-sentence-long Shelby Amendment indicates that its terms are judicially enforceable by private parties. Moreover, Plaintiffs fail to state an actionable claim because the Shelby Amendment directs the Office of Management and Budget ("OMB"), not NHLBI, to establish the terms and conditions under which federal agencies are required to produce data developed by federal grantees. OMB fulfilled its obligations under the Shelby Amendment and developed the procedures governing the production of data from grant recipients. OMB's procedures and NHLBI's compliance with those procedures were reasonable and are entitled to deference.

For the above reasons, Plaintiffs' claims are wholly without merit and should be dismissed.

BACKGROUND

A. The Information Quality Act

The Information Quality Act[1] resides in section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 and directs 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 within one year of the issuance of OMB's guidelines; (2) that federal agencies establish 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 that they receive regarding the accuracy of the information they disseminate. See id. at § 515(b)(2). Notably, neither the Act itself nor its scant legislative history provide a mechanism for judicial review of the quality of information or any avenue for judicial relief.[2]

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1 The Act is also commonly referred to as "The Data Quality Act."

2 The only legislative history regarding the IQA is found in a single sentence in the Conference Report and Committee Report accompanying the omnibus appropriations bill. The Conference Report states: "The conferees include a new provision requiring OMB to develop guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies as proposed by the House." H.R. Conf. Rep. No. 106-1033, at 396 (2000); see also H.R. Rep. No. 106-756, at 83 (2000) (committee report providing nearly identical language).

1. OMB Guidelines

OMB issued proposed guidelines implementing the IQA on June 28, 2001, 66 Fed. Reg. 34489 (June 28, 2001), then, after a period for public comment, published revised guidelines on September 28, 2001, 66 Fed. Reg. 49718 (Sept. 28, 2001). Following another period for additional comment, OMB published final guidelines on February 22, 2002. See 67 Fed. Reg. 8452 (Feb. 22, 2002). In its final guidelines, OMB provides guidance to federal agencies for ensuring and maximizing the quality of the information they disseminate to the public. Generally, 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.[3]

The consistent theme throughout the guidelines is that "agencies must apply these standards flexibly," "in a common-sense and workable manner," and that the "guidelines . . . [do] not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of

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3 The OMB guidelines explain that an agency's "pre-dissemination review" of information applies only "to information that the agency first disseminates on or after October 1, 2002," while the "agency's administrative mechanisms . . . apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information." Id. at 8458.

great benefit and value to the public." Id. at 8453. For example, the OMB guidelines provide that federal agencies are to "adopt a basic standard of quality . . . as a performance goal," and "[q]uality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated." Id. Recognizing that the guidelines "cannot be implemented by each agency in the same way," OMB directs agencies to "incorporate [quality standards] into their existing agency information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes." Id. Agencies thus maintain substantial discretion in determining how best to ensure the quality of the information they disseminate.

With respect to the administrative correction mechanisms, the OMB guidelines require agencies to "specify appropriate time periods for agency decisions on whether and how to correct the information" and to "establish an administrative appeal process to review the agency's initial decision." Id. at 8459. OMB makes clear, however, that agencies should correct information only "where appropriate," and that "[t]hese administrative mechanisms shall be flexible" and "appropriate to the nature and timeliness of the disseminated information." Id. As explained in the preamble to the OMB guidelines:

> Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and **are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved,** and explain such practices in their annual fiscal year reports to OMB.

Id. at 8458 (emphasis added).

By their terms, the OMB guidelines apply only to "information" that is "disseminated" by a federal agency. Id. The term "information" includes "any communication or representation of

knowledge such as facts or data," but "does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views." Id. at 8460. The term "dissemination" means "agency initiated or sponsored distribution of information to the public," but "does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." Id.

2. HHS Guidelines

On October 1, 2002, pursuant to the IQA and the OMB guidelines, the Department of Health and Human Services implemented its own "Guidelines for Ensuring the Quality of Information Disseminated to the Public." See www.hhs.gov/infoquality.[4] The HHS guidelines include department-wide umbrella guidelines and agency-specific guidelines, including the guidelines of the National Institutes of Health.[5]

In its guidelines, HHS declares its commitment "to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination." Id. at § A. HHS recognizes that it has flexibility in implementing its guidelines given that OMB understood that OMB's guidelines could not be implemented in the same way by all agencies and wanted agencies, instead, to apply their guidelines "in a common sense, workable manner." Id. at § B. HHS views its guidelines as "an evolving document and process." Id. at § D.1. Consistent with OMB guidance, the HHS

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4 HHS initially posted draft guidelines on May 1, 2002 and solicited public comments for a sixty day period. See 67 Fed. Reg. 61343, 61344 (Sept. 30, 2002).

5 The NIH information quality guidelines implement and reiterate the directives of the OMB and HHS guidelines. See www.hhs.gov/infoquality/NIHinfo2.htm.

guidelines do not apply to press releases, archival material, or opinions. Id.

HHS also indicates that it generally favors public access to the data underlying agency-sponsored scientific studies when the data is available. Id. at § D.4.e. Such public disclosure of data, however, may not be permissible at times due, for example, to confidentiality requirements, proprietary restrictions, or resource availability. Id. The NIH guidelines are more specific. They state that generally "grantees own the data generated by or resulting from a grant-supported project." www.hhs.gov/infoquality/NIHinfo2.htm, 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 § E. 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 a two-sentence rider to the Fiscal Year 1999 Omnibus Consolidated Emergency Supplemental Appropriations Act that was designed to require federal agencies to make research data produced by federal grantees available to the public under FOIA in certain circumstances. Termed the Shelby Amendment, the entire provision provides:

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 the data.

Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 1998 HR 4328 (1998). Nothing in the Shelby Amendment provides for judicial review of its limited provisions.

The Shelby Amendment provides OMB wide latitude to implement its directives by amending Circular A-110. After publishing its first proposed revision in February of 1999 and receiving over 9,000 comments, and then publishing a revised proposal in August of 1999 and receiving over 3,000 comments, OMB published its final revision of Circular A-110 in October of 1999, see 64 Fed. Reg. 54926 (October 8, 1999), and the rule became effective on 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 of Circular A-110, in pertinent part, provides the following:

> [I]n 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 the FOIA.

Id. at 14407. Thus, the revised circular applies only to data cited publicly and officially by a Federal agency in support of an action that has the force and effect of law. Id. Moreover, 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 at 54929

(October 8, 1999); 65 Fed. Reg. 14406; 45 C.F.R. 74.36(d) (HHS regulations adopting OMB's revised Circular A-110).

C. The DASH-Sodium Trial

In 2000, as a follow-up to an earlier clinical study on the effects of a healthy diet on blood pressure,[6] 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, titled the DASH-Sodium Trial, was performed by a large group of research scientists from several hospitals and universities around the country, collectively known as the DASH-Sodium Collaborative Research Group. The DASH-Sodium Collaborative Research Group received a grant from NHLBI to perform the DASH-Sodium Trial.

The DASH-Sodium Trial involved 412 participants who were randomly assigned to eat either a typical U.S. diet or the DASH diet. Participants ate their assigned diet for three consecutive 30-day feeding periods, during which their sodium intake varied from high (3300 milligrams of salt per day) to intermediate (2400 milligrams of salt per day) to low (1500 milligrams of salt per day).[7] On January 4, 2001, the DASH-Sodium Collaborative Research Group published its findings in the New England Journal of Medicine and concluded that "[t]he reduction of sodium intake significantly lowered systolic and diastolic blood pressure in a

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6 The earlier study was called the Dietary Approaches to Stop Hypertension (DASH) trial. The results of the DASH trial were published in the New England Journal of Medicine in 1997, and they indicated that a diet rich in fruits, vegetables, low-fat dairy products, coupled with reduced fat intake (the "DASH diet") lowers blood pressure as compared to a typical U.S. diet. See L.J. Appel, T.J. Moore, E. Obarzanek, et al., *A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure*, 336 New Eng. J. Med. 1117 (1997).

7 The sequence of the participants' salt intake levels varied randomly.

stepwise fashion, with both the control diet and the DASH diet." Frank M. Sacks, MD, et al., *Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) Diet*, 344 New Eng. J. Med. 3, 5 (January 4, 2001). Lower levels of blood pressure at the lower levels of sodium intake were seen in all participants including those with or without hypertension, in both women and men, and across races. See id. at 3, 6.

The DASH-Sodium Collaborative Research 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. In this article, the research scientists confirmed and extended their earlier findings and concluded that "[t]he decreases in blood pressure associated with reduced sodium intake were present in all subgroups and were clinically relevant," and that "the beneficial effects of . . . reduction of dietary sodium intake are broadly generalizable across groups." 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).[8]

After the results of the DASH-Sodium Trial had been published in the above-referenced peer reviewed medical journals, NHLBI reported the conclusions of the DASH-Sodium Collaborative Research Group in various website press releases and publications. For instance, in a December 17, 2001, press release, NHLBI announced that the detailed subgroup analysis of the DASH-Sodium Trial would be published in the Annals of Internal Medicine, and NHLBI

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8 In this action, Plaintiffs do not seek a correction or any other relief with respect to the information regarding the results of the DASH-Sodium Trial contained in both the January 4, 2001 New England Journal of Medicine article and the December 18, 2001 Annals of Internal Medicine Article.

Director Dr. Claude Lenfant explained the significance of the scientific study by stating, "[n]ow, we can say that cutting back on dietary sodium will benefit Americans generally and not just those with high blood pressure." See www.nhlbi.nih.gov/new/press/01-12-17.htm. Similarly, in May 2003, NHLBI released "The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" ("JNC 7"), documenting findings of 46 expert scientists from in and outside of the government. Based on the published results of the DASH-Sodium Trial and other studies, the JNC 7 suggests reducing dietary sodium intake to no more than 2400 milligrams per day (the intermediate level) as one of several proposed lifestyle modifications to manage hypertension. JNC 7 at 8 and n. 25-27.[9] NHLBI reported the results of the DASH-Sodium Trial and offered similar recommendations in several other press releases and publications but did not promulgate any binding rules or regulations based on the DASH-Sodium Trial.

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

On May 14, 2003, Plaintiffs filed an Information Quality Act petition with NHLBI in which they sought access to the data underlying the DASH-Sodium Trial and complained about various statements contained in six NHLBI-related documents discussing the results of the DASH-Sodium Trial and the

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9 The JNC 7 is available at www.nhlbi.nih.gov/guidelines/hypertension. The Journal of the American Medical Association also published the JNC 7. See A.V. Chobanian, G.I. Bakris, et al., *The Seventh Report of the Joint National Committee on Prevention, Evaluation, and Treatment of High Blood Pressure*, Journal of the American Medical Association (May 21, 2003) at 2560-72.

effect of salt intake on blood pressure.[10] Plaintiffs asserted that, in sum, the information in these six documents "directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals." First Am. Compl., Exh. 1 at 2. Although Plaintiffs complained that the information in the six documents failed to satisfy the objectivity standards of the IQA, Plaintiffs did not at that time request a correction of that information, but rather limited their request for relief to the disclosure of the DASH-Sodium Trial data, including specifically the data for each subgroup of participants at each of the three levels of dietary

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10 The six documents and the particular statements are: (1) the aforementioned December 17, 2001 NHLBI news release stating that "[t]he DASH diet plus reduced dietary sodium lowers blood pressure for all persons, according to the first detailed subgroup analysis of the DASH study results" and quoting NHLBI Director Dr. Lenfant's statement that "we can say that cutting back on dietary sodium will benefit Americans generally and not just those with high blood pressure"; (2) an October 15, 2002 NHLBI news release describing recommendations by the National High Blood Pressure Education Program (NHBPEP) to appear the next day in the Journal of the American Medical Association (JAMA) stating that "limiting daily dietary sodium intake to less than 2,400 mg of sodium (about 1 teaspoon of salt) per day helps lower or control blood pressure"; (3) an October 16, 2002 article in JAMA by NHBPEP indicating that the findings of the DASH-Sodium Trial "are consistent with current national recommendations for a moderately low intake of dietary sodium (no more than 100 mmol/d; approximately 6 g of sodium chloride or 2.4 g of sodium day) by all Americans and suggest that an even lower level of dietary sodium intake may result in a greater reduction in blood pressure." The article also includes a box stating that reducing dietary sodium intake to no more than 2.4 g of sodium per day is a proper lifestyle modification for primary prevention of hypertension; (4) a document released on NHLBI's website titled "Facts About the DASH Diet" indicating that the results of the DASH-Sodium Trial "showed that reducing dietary sodium lowered blood pressure . . . at each sodium level"; (5) a document previously released on NHLBI's website (though no longer distributed by the agency) titled "Facts About Lowering Blood Pressure" which noted the DASH-Sodium Trial researchers' conclusions that "[t]he less sodium consumed, the lower the blood pressure" and that "[t]he effects of sodium reduction were seen in all study participants – those with and without high blood pressure, men and women, and African Americans and others"; and (6) NHLBI's aforementioned May 2003 "Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" stating that "[a]doption of healthy lifestyles by all persons is critical for the prevention of high BP and is an indispensable part of the management of those with hypertension." The JNC 7 suggests reducing dietary sodium intake to no more than 2400 mg a day as one of several proposed lifestyle modifications to manage hypertension. First Am. Compl. ¶ 29, Exh. 1 at 5-6.

sodium intake. See id. Exh. 1 at 14-15.

On August 19, 2003, NHLBI responded to Plaintiffs' petition and noted that Plaintiffs' request for access to data generated by federal grantees should be made through a FOIA request (as indicated in the Shelby Amendment), not through an IQA petition, and that the agency would forward Plaintiffs' request for data to the appropriate FOIA officials. See First Am. Compl., Exh. 2 at 2. The agency explained that the Plaintiffs could simply ask the grantee, the DASH-Sodium Collaborative Research Group, for the data, as it had 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. Although Plaintiffs did not specifically request correction of the information cited in their petition, NHLBI addressed their complaints and concluded that the challenged information in the six documents satisfied information quality standards.[11] The agency indicated that all six documents were subject to extensive review under NHLBI's procedures for publications.[12] NHLBI emphasized that the Dash-Sodium Trial methodologies and analyses themselves were carefully evaluated and approved by many experts in statistics, clinical trials, and hypertension, and the results were subject to extensive independent peer review before publication in the New England Journal of Medicine and the Annals of Internal Medicine. Id. at 4-5. The agency also

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11 NHLBI also correctly recognized that the two press releases were not covered by the guidelines. First Am. Compl., Exh. 2 at 2 n.3; see also 67 Fed. Reg. 8452, 8460 § V. 8 (OMB Guidelines inapplicable to press releases); www.hhs.gov/infoquality § D. 3 (HHS Guidelines inapplicable to press releases).

12 NHLBI's process involves review and approval by: (1) the National Education Program Coordinator; (2) the Senior Manager for Health Communications and Information Science in the NHLBI's Office of Prevention, Education, and Control (OPEC); (3) relevant involved scientists; (4) the OPEC Director; (5) the NHLBI Director; and (6) the HHS Public Affairs Office. First Am. Compl., Exh. 2 at 3.

explained that its recommendations regarding sodium intake were not based solely on the DASH-Sodium Trial but also stemmed from "a substantial body of evidence developed over more than a decade show[ing] a clear causal relationship between sodium intake and blood pressure." Id. at 5.

On September 3, 2003, NHLBI responded to Plaintiffs' request for the DASH-Sodium Trial data under FOIA, pursuant to the Shelby Amendment, and denied their claim. First Am. Compl., Exh. 3 at 1. NHLBI explained that it did not have the data in its possession, because the DASH-Sodium Trial was funded under grants which did not require the grantees to share their data with NHLBI. Id. Additionally, the agency explained that the Shelby Amendment, as implemented in OMB's revised Circular A-110, applies only to data that is (1) first produced under a new or competing continuing grant awarded after April 17, 2000; and (2) cited publically and officially by the Federal Government in support of an agency action that has the force and effect of law. Id. at 2. NHLBI indicated that the DASH-Sodium grants were competitively awarded in February 1997 and were, thereafter, extended through non-competitive continuing grants, thus making the Shelby Amendment inapplicable to the DASH-Sodium Trial data.

On September 22, 2003, Plaintiffs appealed the denial of their IQA petition. See First Am. Compl., Exh. 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.

On February 11, 2004, NHLBI denied Plaintiffs' appeal. See First Am. Compl., Exh. 5. The agency again 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 at http://www.nhlbi.gov. See id. at 2. NHLBI reiterated its conclusion that the statements regarding sodium intake in the six challenged documents satisfied the information quality guidelines given the extensive review process that the documents went through and the vast array of scientific evidence, including the DASH-Sodium Trial, supporting the ameliorative effects of reduced sodium intake on blood pressure. See id. at 2-4.

E. Plaintiffs' Complaint in this Action

The Salt Institute and the Chamber filed their initial complaint in this action on March 31, 2004. Plaintiffs filed their First Amended Complaint on June 10, 2004, in which they reassert their previously rejected theories as violations of the IQA, the Shelby Amendment, and the Administrative Procedure Act ("APA"). See First Am. Compl. ¶¶ 40-61.

ARGUMENT

I. PLAINTIFFS' CLAIMS THAT NHLBI VIOLATED THE IQA AND THE APA MUST BE DISMISSED.

A. Plaintiffs Lack Standing to Pursue Their Claims in Federal Court.

The doctrine of "standing is an essential and unchanging part of the case-or-controversy requirement of Article III," Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992), and "the party invoking federal jurisdiction bears the burden of establishing its existence." Steel Company v. Citizens for a Better Environment, 523 U.S. 83 104 (1998). At the pleadings stage, "'[i]t is the responsibility of the complainant clearly to allege facts demonstrating that he is a proper party to invoke . . . the exercise of the court's remedial powers.'" Renne v. Geary, 501 U.S. 312, 315 (1991), quoting Bender v. Williamsport Area School Dist., 475 U.S. 534, 546 n.8

(1986).

The familiar three-part test for standing is whether the plaintiff has demonstrated that it has (1) suffered a concrete and particularized injury that is (2) fairly traceable to the Defendant's action and that is (3) likely to be redressed by a favorable court decision. See, e.g., Lujan, 504 U.S. at 560-61; Friends for Ferrell Parkway, LLC v. Stasko, 282 F.3d 315, 320 (4th Cir. 2002). In addition to those three irreducible, constitutional minima, plaintiffs also must demonstrate that they are not merely asserting a "generalized grievance." See Lujan, 504 U.S. at 573-74; United States v. Richardson, 418 U.S. 166, 176-77 (1974).

In this case, the Salt Institute and the Chamber lack the requisite legal standing to assert their claims in federal court. Plaintiffs fail even 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. Plaintiffs also fail to satisfy the traceability and redressability components of standing.

In their First Amended Complaint, Plaintiffs' allegations of injury consist in their entirety of vague, unelaborated assertions that they "are adversely affected or aggrieved by NHLBI's final agency action," that they "have suffered actual or threatened injury due to the Defendant's conduct," and that they "have suffered legal wrong and are adversely affected and aggrieved by final agency action for which there is no other adequate remedy at law." First Am. Compl. ¶¶ 7-9, 46, 61. Plaintiffs offer no explanation whatsoever of *how* they specifically are injured by the actions of NHLBI. Plaintiffs make no specific assertion that NHLBI's recommendations regarding dietary salt intake injure them or that NHLBI's inability to provide them with the DASH-Sodium data injures them. Thus, none of the Plaintiffs' alleged harms is sufficiently

concrete and particular to confer standing. See, e.g., Baur v. Veneman, 352 F.3d 625, 636-37 (2d Cir. 2003) ("[A] plaintiff cannot rely solely on conclusory allegations of injury or ask the court to draw unwarranted inferences in order to find standing."); Arkansas Right to Life v. Butler, 146 F.3d 558, 560 (8th Cir. 1998).

At most, Plaintiffs allege only a generalized grievance regarding the quality and availability of data underlying a government-funded study. As the Supreme Court has made clear, Plaintiffs must demonstrate more than just "a genuine interest" in the results of the DASH-Sodium Trial; they must show that they are "in danger of suffering [a] particular concrete injury" that is not "undifferentiated and common to all members of the public." Richardson, 418 U.S. at 176-77 (internal quotation marks omitted). "[A] mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem" is not sufficient to confer standing. Sierra Club v. Morton, 405 U.S. 727, 739 (1972). Plaintiffs' mere interest in ensuring that the government complies with the requirements of the IQA is not sufficiently particularized to grant them standing in this case.[13]

The fact that NHLBI's actions in this case have no binding legal effect also highlights the illusory nature of Plaintiffs' claims of injury. Despite the agency's denial of Plaintiffs' request to obtain the DASH-Sodium Trial data through the IQA, Plaintiffs have always been free to request such data from the Trial investigators, which NHLBI itself recommended. Today, Plaintiffs can

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13 The IQA's instruction that "affected persons" be given an "administrative mechanism" to seek correction of information does not provide such persons with standing to raise IQA claims in federal court. See, e.g., Gettman v. DEA, 290 F.3d 430, 434 (D.C. Cir. 2002) (indicating that "contrary to petitioners' suggestion, it is not at all anomalous that Congress could permit them as 'interested part[ies]' (assuming they are) to participate in agency proceedings, and yet they be unable to seek review in federal courts.").

seek access to the data from NHLBI directly, either through the public access data set website or under FOIA.[14] And, while the agency determined that the DASH-Sodium Trial and its recommendations regarding dietary sodium intake satisfied the information quality guidelines, Plaintiffs are free to criticize the study publicly, challenge its methodologies, and dispute NHLBI's recommendations. Plaintiffs have not been concretely and particularly injured by NHLBI's actions. 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 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 if Plaintiffs had alleged this theory (which they have 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"); Friends for Ferrell Parkway, LLC v. Stasko, 282 F.3d 315, 320-21 (4th Cir. 2002) (explaining that the plaintiff's injury must be "caused by the challenged conduct of the defendant, and not by the independent actions of

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14 The Plaintiffs' ability to access the data through the Trial investigators, the website, or FOIA (subject to applicable privacy and confidentiality laws) suggests that their complaint for the data in this case is moot. See, e.g., Schering Corp. v. Shalala, 995 F.2d 1103, 1106 (D.C. Cir. 1993) (finding that a case is moot when it "has lost its character as a present, live controversy of the kind that must exist if [the court] is to avoid advisory opinions on abstract questions of law."). NHLBI remains willing to provide Plaintiffs the data under FOIA procedures.

third parties not before the court"); Gettman, 290 F.3d at 436 (finding that "such speculative claims dependent upon the actions of third parties do not create standing for the purposes of establishing a case or controversy under Article III").

The allegations in Plaintiffs' First Amended Complaint also fail to establish that Plaintiffs' purported injury is fairly traceable to NHLBI's actions and that their injury would be redressed by the remedies they seek. 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. But NHLBI's recommendations are hardly new or unique. As NHLBI noted, numerous other scientific studies have reached the commonplace 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 Journal of Human Hypertension 761 (2002); J.A. Cutler, D. Follmann, and P.S. Allender, *Randomized Trials of Sodium Reduction: An Overview*, 65 American Journal of 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). Any one of these or numerous other studies could be responsible for Plaintiffs' purported and undefined injury.

The published results of the DASH-Sodium Trial themselves are more likely the cause of any injury allegedly suffered by the Plaintiffs than NHLBI's mere dissemination of those results. As mentioned, 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. But Plaintiffs are not seeking a correction or any other relief regarding the published results of the DASH-Sodium Trial, and those articles and their conclusions regarding the beneficial effects of reducing salt intake on blood pressure have been and will remain in circulation potentially influencing health care providers and the public to reduce salt intake.

Additionally, the U.S. Dietary Guidelines have made the same recommendation as NHLBI to limit sodium intake to approximately 2400 mg per day. See United States Department of Agriculture and Department of Health and Human Services, *Nutrition and Your Health, Dietary Guidelines for Americans*, (5th ed. 2000). This recommendation is also consistent with the findings of the 1989 U.S. National Academy of Sciences' (NAS) *Recommended Dietary Allowances* report, which 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). The U.S. Dietary Guidelines and the Recommended Dietary Allowances are likely even more influential on American diets than statements made in NHLBI publications or on its website. Thus, any potential injury claimed by the Plaintiffs cannot be fairly traceable to the actions of NHLBI given that many other scientific studies, the DASH-Sodium Trial itself, and other organizations have reached the same conclusions and made similar recommendations regarding the need to limit salt intake to reduce blood pressure. See, e.g., Friends for Ferrell Parkway, 282 F.3d at 323-24 (finding that city's failure to build a road and increased traffic, noise, and fumes were not fairly traceable to the United States Fish and Wildlife Service's acquisition of land; many other factors caused