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

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| SALT INSTITUTE and the CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA<br><br>Plaintiffs,<br><br>v.<br><br>TOMMY G. THOMPSON, Secretary, U.S. Department of Health and Human Services<br><br>Defendant. | ) | Case No. 04-CV-359 GBL |

**MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS**

## 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

plaintiffs' alleged injuries).

Accordingly, the Plaintiffs' purported injuries likely 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. See Friends for Ferrell Parkway, 282 F.3d at 323-24 (indicating that plaintiffs' injuries likely would not be redressed by relief requested due to other causes of injuries). The numerous other scientific studies, the DASH-Sodium Trial results themselves, and the U.S. Dietary Guidelines' and the NAS Recommended Dietary Allowances' recommendations to limit salt intake would all remain unchanged, in circulation, and potentially influence the public to reduce its consumption of salt as much as, if not more than, the NHLBI press releases and other statements listed in Plaintiffs' complaint. Plaintiffs' injury, whatever it might be, thus is not likely to be redressed by a favorable decision from this court, and Plaintiffs therefore lack standing to assert their claims.

**B. There is No Private Right of Action Under the Information Quality Act.**

Even assuming for the sake of argument that plaintiffs could somehow establish standing to pursue their claims, their claims under the IQA still would fail because the statute provides no private right of action. In order 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) (finding that "private rights of action to enforce federal law must be created by Congress."); Touche Ross & Co. v. Redington, 442 U.S. 560, 578 (1979) (remedies available are those "that Congress enacted into law"). Thus, "[t]he judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy." Alexander, 532 U.S. at 286 (citing Transamerica Mortgage

Advisors, Inc. v. Lewis, 444 U.S. 11, 15 (1979)). "Statutory intent on this latter point is determinative," and "[w]ithout it, a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." Id. at 286-87.

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 private right. See id. at 288-89 ("We ... begin (and find that we can end) our search for Congress's intent with the text and structure of [the statute in question]."); Touche Ross & Co., 442 U.S. at 568 ("[O]ur analysis must begin with the language of the statute itself."). Nothing in the Information Quality Act provides anyone a right of action in a court of law for an alleged violation of any 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 OMB's guidelines. In that regard, 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 issued [by OMB]." Id. at § 515(b)(2)(B) (emphasis added). Plainly, nothing in the text of the statute indicates that Congress intended for the *federal courts* to serve as ongoing monitors of the "quality" of information maintained and disseminated by federal agencies. Rather, the language and structure of the IQA reflects Congress's intent that any challenge to the quality of information

disseminated by a federal agency should take place in administrative proceedings before federal agencies. Simply put, Congress nowhere provided a new judicial avenue for private parties to enforce the terms of the IQA. The first and only court to address this issue recently 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 (D. Minn. June 21, 2004) (order granting motions for summary judgment).

Nor can Plaintiffs demonstrate that an "implied" private right of action is inferable from some source of congressional intent other than the Act's text.[15] For example, the IQA's legislative history, which is sparse in general, is completely silent with respect to the particular question of judicial relief. See Touche Ross & Co., 442 U.S. at 571 (concluding that, where "the plain language of the provision weighs against implication of a private remedy," silence in the legislative history "reinforces our decision not to find such a right of action implicit within the section"); Regional Mgmt. Corp. Inc., 186 F.3d at 463 n.7 (indicating that "[w]here neither the language nor legislative history of a statute suggests any intent to create a private right of action, there is no need to inquire further."). Moreover, "[i]t is an 'elemental canon' of statutory construction that where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." Karahalios v. National Federation of Federal Employees, 489 U.S. 527, 533 (1989); Transamerica Mortgage Advisors, 444 U.S. at 19 ("where a statute

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15 Courts have noted that finding such "implied" private rights of action have become increasingly disfavored. See, e.g., Regional Mgmt. Corp. Inc. v. Legal Serv. Corp., 186 F.3d 457, 461 (4th Cir. 1999) (indicating that burden is on plaintiff to establish implied private right of action and requirements are stringent); Cline v. Rogers, 87 F.3d 176, 182 (6th Cir. 1996) ("The Supreme Court has been increasingly reluctant to find an implied cause of action where Congress had the opportunity to create a private right explicitly but did not do so.").

expressly provides a particular remedy or remedies, a court must be chary of reading others into it."). "[I]n the absence of strong indicia of contrary congressional intent, [the courts] are compelled to conclude that Congress provided precisely the remedies it considered appropriate." Karaholias, 489 U.S. at 533 (quoting Middlesex County Sewerage Authority v. Sea Clammers, 453 U.S. 1, 15 (1981)). Here, the language of the IQA compels the conclusion that Congress believed "administrative mechanisms" created by individual federal agencies (rather than a private cause of action in federal court) would be the most appropriate vehicle for achieving the purposes of the Act. In these circumstances, implication of a private right would not further the intent of Congress; to the contrary, it "would undercut the specific administrative remedy prescribed by Congress in that statute." Government of Guam v. American President Lines, 28 F.3d 142, 145 (D.C. Cir. 1994). Also telling is that other federal statutes, by contrast, do contain explicit provisions for private judicial relief, indicating that when Congress desires to provide for private enforcement in the federal courts, it can and will do so. See, e.g., 16 U.S.C. § 1540(g) (Endangered Species Act's citizen-suit provision). In sum, Congress evinced no intent, express or implied, to create a private cause of action for alleged violations of the IQA; thus, Plaintiffs' claims must be dismissed.

### C. NHLBI's Actions Regarding the DASH-Sodium Trial Are Not Subject to Judicial Review Under the Administrative Procedure Act.

Given the absence of a private right of action under the IQA, Plaintiffs also invoke the provisions of the Administrative Procedure Act ("APA") to assert their claims. However, two separate APA limitations each preclude judicial review of the Plaintiffs' claims that NHLBI's actions violated the IQA.

### 1. NHLBI's Dissemination of Information Regarding the DASH-Sodium Trial Is Not Final Agency Action.

The APA authorizes judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. 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) (internal quotation marks and citations omitted); see also Reliable Automatic Sprinkler Co, Inc. v. Consumer Product Safety Comm'n, 324 F.3d 726, 731 (D.C. Cir. 2003) (finding that "[a]gency action is considered final to the extent that it imposes an obligation, denies a right, or fixes some legal relationship.").

NHLBI's actions regarding the DASH-Sodium Trial plainly do not constitute "final agency action" within the meaning of the APA. NHLBI's dissemination of the results of the DASH-Sodium Trial, its recommendations to reduce dietary salt intake, and its inability to produce the DASH-Sodium Trial data do not determine any rights or obligations or result in any legal consequences. To the contrary, the DASH-Sodium Trial simply consists of the findings of research scientists which conclude that reducing sodium intake lowers blood pressure, and NHLBI's statements regarding the Trial merely consist of descriptions of the Trial's results and *recommendations* to limit sodium intake to moderate levels, which, in and of themselves, have no legal force or effect whatsoever.

For precisely these reasons, courts have consistently concluded that agency dissemination of such advisory information cannot be viewed as "final agency action." See, e.g., Franklin v. Massachusetts, 505 U.S. 788, 798 (1992) (holding that Secretary of Commerce's report conveying census data to the President carried "no direct consequences" and thus was not "final

agency action"). The Fourth Circuit, for example, has determined that the EPA's issuance of a report on the health hazards of second-hand tobacco smoke was not final agency action because it carried no direct and appreciable legal consequences and therefore was not reviewable under the APA. Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 859-62 (4th Cir. 2002); see also Air Brake Sys., Inc. v. Mineta, 357 F.3d 632, 639-40 (6th Cir. 2004) (finding that opinion letters on agency's website written by NHTSA's chief counsel were not final agency action because they stated only tentative conclusions based on limited information); Aerosource, Inc. v. Slater, 142 F.3d 572, 580 (3d Cir. 1998) (holding that FAA's advisory reports regarding safety concerns with repair work performed by certified aircraft parts repair station were not final agency action because they "imposed no obligations, denied no right, and did not fix or alter a legal relationship."); Guerrero v. Clinton, 157 F.3d 1190, 1194-95 (9th Cir. 1998) (finding that submission of a report to Congress "triggers no legal consequences" at all and it was "simply a document submitted to Congress that Congress ha[d] no obligation to consider, let alone act upon."); Industrial Safety Equipment Ass'n, Inc. v. EPA, 837 F.2d 1115, 1117, 1119 (D.C. Cir. 1988) (holding that a government report issued by the Environmental Protection Agency did not constitute "agency action" at all, let alone "final agency action"); American Trucking Ass'n, Inc. v. United States, 755 F.2d 1292, 1297 (7th Cir. 1985) (holding that statements contained in an Interstate Commerce Commission report did "not purport to announce rules of law nor do they impose an obligation, determine a right or liability or fix a legal relationship," thus the report was not final agency action subject to review); but cf. Tozzi v. U.S. Dep't of Health and Human Serv.,

271 F.3d 301, 310-11 (D.C. Cir. 2001).[16] Because NHLBI's dissemination of its statements regarding the DASH-Sodium Trial and its inability to produce the Trial's underlying data do not constitute "final agency action" within the meaning of the APA, this Court is precluded from determining whether the agency's actions comply with the IQA or its implementing guidelines.

Additionally, NHLBI's denial of Plaintiffs' administrative petition and appeal seeking the production of the DASH-Sodium Trial data and correction of the agency's statements regarding the Trial does not qualify as "final agency action" under the APA. See Aerosource, Inc., 142 F.3d at 579 ("[I]f a court treated the denial of an application to reconsider an action which is not in itself a final order as a final order, then a petitioner simply by asking for reconsideration could convert a nonfinal action into a final order. Of course, this conversion should not be permitted."). In other words, parties cannot manufacture final agency action simply by lodging an administrative challenge to otherwise non-final agency actions and wait for the agency's denial of their protest. Such an end-run around the final agency action requirement would open a gaping loophole in the APA's finality requirement and is clearly prohibited. For example, in rejecting the contention that the Federal Trade Commission's denial of a party's administrative request to dismiss a complaint constituted "final agency action," the Supreme Court explained:

> By requesting the Commission to withdraw its complaint and by awaiting the Commission's refusal to do so, [the plaintiff] may well have exhausted its administrative

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16 In Tozzi, the court found that HHS's decision to upgrade dioxin to the category of "known" carcinogens in the HHS Report on Carcinogens had a sufficiently binding legal effect to be reviewable under the APA. 271 F.3d at 310-11. The court's decision, however, was based on the fact that (1) listing a substance as a human carcinogen triggers other legal obligations under OSHA, Department of Labor, and state regulations; (2) a notice proposing the dioxin upgrade was formally published in the Federal Register; and (3) the carcinogen classification scheme is mandated by the Public Health Service Act. See id. None of NHLBI's challenged actions in this case share any of these characteristics.

> remedy . . . . But the Commission's refusal to reconsider its issuance of the complaint does not render the complaint a "definitive" action . . . [and] does not augment the complaint's legal force or practical effect.

Federal Trade Commission v. Standard Oil Company of California, 449 U.S. 232, 243 (1980). Just as the Supreme Court found in Standard Oil, Plaintiffs' administrative request to "correct" NHLBI's statements and recommendations regarding the DASH-Sodium Trial and to obtain the study data may well have exhausted Plaintiffs' administrative remedies. But NHLBI's denial of Plaintiffs' request has not made the agency's statements and recommendations any more "definitive"; nor has it "augment[ed]" their "legal force or practical effect." NHLBI's inability to produce the data and its statements and recommendations regarding reduced salt intake had no legal force before the agency refused to modify those actions, and they continue to have no legal force today. Because NHLBI's actions regarding the DASH-Sodium Trial are not final agency actions, the APA provides no basis for judicial review of the Plaintiffs' claims and they must be dismissed.

**2. The Decisions Regarding Whether a Correction Should be Made to NHLBI's Informal Statements Relating to the DASH-Sodium Trial and Whether the Trial's Underlying Data Must be Produced Under the IQA are Committed to Agency Discretion By Law.**

Judicial review is also foreclosed in this case under 5 U.S.C. § 701(a)(2), on the ground that the informal agency decisions at issue here were on matters "committed to agency discretion by law." "Agency action is committed to agency discretion 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. (internal quotation omitted).

As noted above, Plaintiffs' complaint focuses on NHLBI's informal statements and recommendations regarding the DASH-Sodium Trial, which were found in various press releases and publications. NHLBI did not undertake any formal notice and comment procedure or promulgate any rule or regulation with respect to the DASH-Sodium Trial. Nor did it conduct a formal adjudication or issue a binding order related to the DASH-Sodium Trial. NHLBI merely issued informal statements regarding the Trial results and recommendations pertaining to salt intake. Judicial review is improper here because the decision whether corrections should be made (or underlying data disclosed) as to this informal agency speech – speech lacking the force and effect of formal agency rules, regulations, or orders – is committed to agency discretion under the IQA.[17]

The language of the IQA confirms that Congress did not intend to enlist the judicial branch in policing agencies' discretion in communicating information in informal speech. The statute does not impose its own standard of "quality" on agency information; instead, it merely requires 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 disseminated by those agencies. Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515(a)],

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17 As elaborated further below, a different question might be presented in a case in which a plaintiff challenges an agency's dissemination of information in connection with its formal rules or regulations. In that context, the IQA might conceivably be relevant to "arbitrary and capricious" and "substantial evidence" reviews under the APA. Here, however, Plaintiffs challenge only informal agency speech – plain and simple – and in this context the question whether the agency should correct its speech is committed to the discretion of the agency by law.

114 Stat. 2763, 2763A-153 (Dec. 21, 2000). Congress's use of the word "guidelines," and the phrase "policy and procedural guidance," plainly reflect an intention to preserve discretion. See id. And – of special importance in this case – Congress's decision not to specify when information must or should be corrected by agencies, whether agencies must cease dissemination of information that does not meet the (unspecified) standard of quality, or whether data must be disclosed indicates that Congress did not intend to disturb the discretionary nature of agency information flow. See generally In re: Operation of the Missouri River Sys. Litig., No. 03-MD-1555 at 49 (D. Minn. June 21, 2004) (noting the absence of standards in the text of the IQA without addressing the significance of the guidelines).

The structure of the IQA confirms that Congress did not wish to supplant agency discretion regarding informal communications. Although the IQA includes specifications as to the "content" of the guidelines to be issued by OMB, Pub. L. No. 106-554, § 515(b), those specifications require only that the OMB "guidelines" direct individual agencies to issue their own "guidelines," that each agency "establish administrative mechanisms" allowing "affected persons to seek and obtain correction" of poor quality information, and that agencies periodically report to OMB on the "complaints" they have received concerning information quality and how those complaints have been "handled." See id. at § 515(b)(2). In other words, far from reflecting an intention to have courts sit in judgment of agencies' compliance with IQA "guidelines," the structure of the IQA reveals Congress's preference for self-policing by agencies and by OMB.

The OMB's guidelines do provide definitions for some of the terms (e.g., "quality,"

"utility," "objectivity," and "integrity") that Congress left undefined in the IQA.[18] But other aspects of the OMB guidelines confirm that an agency's discretion concerning whether or not to make corrections to agency statements or other information, and to what extent, generally was not to be disturbed. Indeed, the OMB guidelines themselves indicate that they do not apply in any respect to agency "correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes," or to agency opinions. 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002). As mentioned, two of the complained-of statements were contained in NHLBI press releases announcing the publication of the results of the DASH-Sodium Trial. The other four documents were merely health recommendations released either on NHLBI's website or in medical journals. See supra note 9. The fact that the guidelines do not even apply to informal agency materials such as correspondence, press releases, and opinions indicates that informal agency statements, such as health recommendations, were neither intended to be reviewed by courts, nor susceptible to such judicial review when divorced from formal agency process.

Additionally, even as to formal agency communications, the OMB guidelines preach flexibility, exhorting federal agencies to "adopt a basic standard of quality . . . *as a performance goal*." 67 Fed. Reg. 8458 (emphasis added). The guidelines make clear that "[q]uality is to be ensured and established *at levels appropriate to the nature and timeliness of the information to*

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18 Some of OMB's definitions, however, are devoid of content that could manageably be applied by a court in reviewing a challenge under the IQA. For example, the OMB guidelines indicate that "'[u]tility' refers to the usefulness of the information to its intended users, including the public." 67 Fed. Reg. at 8459. This definition does not provide meaningful standards for a court to determine whether certain agency information violates the IQA.

*be disseminated.*" Id. (emphasis added). Given the wide variety of information that agencies disseminate, OMB determined that its guidelines "cannot be implemented in the same way by each agency." Id. at 8453. Instead, the guidelines call for agencies to exercise independent judgment in fulfilling the objectives of the IQA– to "weigh the costs . . . and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held." Id.

The OMB guidelines show special solicitude for agency discretion in handling the very type of request at issue here – a request for "correction" under the agency's own guidelines. In particular, the OMB guidelines explain that agencies "are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved." Id. at 8458. The OMB guidelines do not purport to impose in all instances an inflexible requirement on agencies to cease dissemination of – or correct – information contained in informal agency statements that might arguably fall short of the goals of the IQA.[19] Rather,

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19 The HHS guidelines also afford agencies considerable deference in determining correction requests. For instance, the HHS guidelines counsel its agencies to consider "the nature and timeliness of the information involved and such factors as *the significance of the correction on the use of the information*, the magnitude of the correction and *the resource requirements for the correction.*" www.hhs.gov/infoquality § E (emphases added). The reference to "resource requirements" should make courts particularly cautious, as the Supreme Court has found agency resource allocation determinations (and determinations that rest on discretionary resource allocations) committed to agency discretion by law. See, e.g., Lincoln v. Vigil, 508 U.S. 182 (1993) (Indian Health Service decision to terminate a particular Indian children's health program based on resource constraints held committed to agency discretion by law; "Like the decision against instituting enforcement proceedings, . . . an agency's allocation of funds from a lump-sum appropriation requires 'a complicated balancing of a number of factors which are peculiarly within its expertise': whether its 'resources are best spent' on one program or another; whether it 'is likely to succeed' in fulfilling its statutory mandate; whether a particular program 'best fits the agency's overall policies'; and, 'indeed, whether the agency has enough resources to fund a program 'at all.'" (quoting Heckler v. Chaney, 470 U.S. 821 (1984))). There is no manageable way in which a court could evaluate an agency's determination not to correct because of its

the guidelines call on agencies to apply the IQA's standards "flexibly," id. at 8453, and to exercise discretion in determining whether correction of information is appropriate in any given case, id. at 8458, 8459.[20] When, as here, the quality of the information challenged is contained in informal agency statements or recommendations, rather than incorporated into binding rules or regulations, it stands to reason that the agency's discretion to determine whether correction is necessary is at its apex.

Courts have interpreted language similar to that included in the above-referenced OMB guidelines as granting discretion to agencies sufficient to preclude judicial review under the APA. In Steenholdt v. FAA, 314 F.3d 633, 638 (D.C. Cir. 2003), the D.C. Circuit concluded that a regulation that authorizes an agency official to take an action for any reason the official "considers appropriate" confers discretion on the agency and leaves the Court with "no law to apply." Accord Madison-Hughes v. Shalala, 80 F.3d 1121, 1128 (6th Cir. 1996). Here, the OMB guidelines indicate that "[a]gencies, in making their determination of whether or not to correct information . . . 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. 8452, 8458 (emphasis added). The HHS guidelines likewise counsel flexibility, indicating that the discretionary determination whether to "correct" prior agency speech will depend upon the agency's evaluation of, among other things, "the significance of the correction on the use of the

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judgment concerning the "significance of the correction on the use of the information" (at issue in this case), as well as concerning "the resource requirements for the correction." www.hhs.gov/infoquality § E.

20 OMB's IQA guidelines do not address whether agencies must produce data generated by federal grantees. The appropriate vehicle for demanding disclosure of records from agencies, generally, is a request under FOIA. And agency obligations to produce, and authority to obtain, data specifically from federal grantees are directly addressed in the Shelby Amendment, which itself provides for disclosure of such data pursuant to FOIA procedures. The Shelby Amendment is discussed in greater detail below in Section II.

information, the magnitude of the correction and the resource requirements for the correction." www.hhs.gov/infoquality § E. Thus, NHLBI's decision to decline to revise its prior informal agency statements and health recommendations is a decision that is NHLBI's to make. Where, as here, the applicable OMB and agency guidelines leave reviewing courts without manageable judicial standards, judicial review is precluded under the APA.

Clearly, neither the IQA nor the OMB guidelines contemplate federal court review of the quality of information referenced in informal agency statements outside the context of formal rulemaking or adjudication.[21] Indeed, if such informal agency statements, recommendations, or opinions were subject to information quality challenges in federal courts, the floodgates would open and courts would be inundated with claims that all sorts of agency statements relied on information that was not of sufficient quality. Courts would be ill-equipped to determine whether an agency acted arbitrarily or capriciously in issuing an informal agency statement alleged to contain information of insufficient scientific quality (or in declining to correct such a statement) without having the context and record of formal agency rulemaking or adjudication as a backdrop to inform the determination. See, e.g., Satellite Broad. and Communications Ass'n v. FCC, 275 F.3d 337, 370 (4th Cir. 2001) (indicating that the arbitrary and capricious standard requires courts to determine if an agency has articulated a "satisfactory explanation for its action [that demonstrates] a rational connection between the facts found and the choice made.")

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21 This challenge to the court's jurisdiction may leave open the possibility of judicial review in an appropriate case involving bonafide agency action, such as a formal agency rule or order clarifying rights or imposing obligations. Such agency actions are generally subject to review under the APA's "arbitrary and capricious" and "substantial evidence" review standards. The question of whether an agency's alleged non-compliance with the IQA in that context can influence the ultimate determination of whether the agency's action is unlawful – for example, in relying on scientific data that has not been generated using "sound statistical and research methods," 67 Fed. Reg. at 8459 – is not presented here, and therefore is not addressed in any detail. In this respect, the position of the United States here is less sweeping than the approach announced by the court in Missouri River, No. 03-MD-1555 at 49 (D. Minn. June 21, 2004).

(internal quotations omitted); cf. Public Citizen v. National Advisory Comm. on Microbiological Criteria for Foods, 886 F.2d 419, 426, 432 (D.C. Cir. 1988) (Silberman, J. concurring in judgment) (finding that Federal Advisory Committee Act's requirement that advisory committees be fairly balanced was not reviewable under the APA because "[t]he relevant points of view on issues to be considered by an advisory committee are virtually infinite and, therefore, the judgment as to what constitutes an appropriate or "fair" balance of these views must be a political one . . . .").[22]

Because the IQA and the OMB guidelines at issue here preserve the discretion of the agency to determine when correction of information contained in informal agency statements or recommendations is "appropriate," and do not address whether grantee data must be produced, judicial review of NHLBI's discretionary decisions is not available and the complaint should also

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22 The non-justiciability of Plaintiffs' demand for correction of NHLBI's informal communications is perhaps best understood in the context of the allegations of the complaint, which call on the Court to delve deeply into disputed questions of scientific judgment, and thereafter assume an "executive editing" function in conforming the agency's speech to the Court's scientific conclusions. For example, Plaintiffs seek the Court's determination on, among other things, (1) whether "normal consumption of dietary salt in a healthy diet has [a] statistically verifiable adverse effect on blood pressure levels," and whether the agency's health recommendations on salt intake are "unsupported by sound science, the product of a statistically invalid interpolation of clinical data, and, quite simply, wrong," First Am. Compl. ¶ 13; (2) whether the study relied on by NHLBI was improperly "skewed toward persons with salt sensitivity," and was not based on a sufficiently "representative sample of adult Americans," id. at ¶ 20; (3) whether the "Sodium Trial was methodologically suspect," id. at ¶ 22; (4) whether "Sodium Trial investigators breached accepted scientific methodological norms by dropping the middle data set from the analysis," and by "assuming a linear relationship, and then 'modeling' accordingly," id. at ¶ 25; (5) whether "[g]ood science required the Sodium Trial's reported results be supported by a properly controlled multivariate statistical analysis for each subgroup studied," id. at ¶ 26; and (6) whether the information in the agency's statements and recommendations was sufficiently "comprehensive," "objective," or "useful," in light of the above issues, id. at ¶ 32(a). The problem is that, even assuming there are judicially manageable tools available to permit the Court to revisit these scientific judgments, neither the IQA itself, nor the applicable OMB and agency guidelines, contain standards that would allow the Court intelligently to determine whether correction of NHLBI's statements is "appropriate" in light of "the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction." www.hhs.gov/infoquality § E.

be dismissed under section 701(a)(2) of the APA.[23]

## II. PLAINTIFFS' CLAIM THAT NHLBI VIOLATED THE SHELBY AMENDMENT AND THE APA MUST BE DISMISSED.

Plaintiffs also 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 awarding agencies to make data produced by federal grant recipients available to the public. See First Am. Compl. ¶¶ 55-61. Plaintiffs contend that NHLBI, not OMB, exceeded its statutory discretion under the Shelby Amendment and restricted public access only to data from studies funded after April 17, 2000 and cited publically and officially in support of an agency action with the force and effect of law. See id. ¶ 58. This claim also should be dismissed.

### A. Plaintiffs Lack Standing to Assert that NHLBI Violated the Shelby Amendment.

In their claim that NHLBI violated the Shelby Amendment, Plaintiffs generically allege that they are injured because they "are adversely affected and aggrieved by this final agency action, and have no other adequate remedy at law." Id. ¶ 61. Even if NHLBI were responsible for limiting public access to grantee data as indicated (which it is not, as discussed below), such an injury is not sufficiently particular or concrete to satisfy the constitutional requirements for

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23 Even assuming arguendo that NHLBI's decision denying Plaintiffs' administrative request for data production and correction could somehow be deemed reviewable, NHLBI's decision was certainly not arbitrary, capricious, or an abuse of discretion. See 5 U.S.C. § 706 (2)(A). NHLBI acted well within its discretion under its own and OMB's information quality guidelines in concluding that its statements regarding the results of the DASH-Sodium Trial were of sufficient quality, that its health recommendations were appropriate, and that it could not produce the data because it did not possess it. Additionally, NHLBI's indication that Plaintiffs' request for the study data was governed by the Shelby Amendment, not the IQA, also was reasonable, given that the Shelby Amendment specifically addresses the production of data from federal grant recipients and the IQA merely addresses the quality of information generally. See, e.g., United States v. Smith, 812 F.2d 161, 166 (4th Cir. 1987) (indicating that "[i]t is a basic rule of statutory construction that a more specific statute will be given precedence over a more general one.") (internal citations omitted).

standing, as explained in Part I. A. above. As with their claims under the IQA, at most, Plaintiffs allege a generalized grievance, shared by members of the public at large, that access to grantee data is limited in the manner indicated in OMB's revised Circular A-110. Plaintiffs' purported injury is even more suspect in light of the fact that the DASH-Sodium Trial data has been available for some time from the DASH-Sodium Collaborative Research Group and a public access data set was made available in January 2004 through the internet as well. Accordingly, Plaintiffs' injury is not sufficiently concrete or particularized to confer them standing to assert their Shelby Amendment claim.[24]

### B. Plaintiffs Fail to State a Claim On Which Relief Can Be Granted Because OMB, not NHLBI, Is Responsible for Implementing the Shelby Amendment.

In their claim, Plaintiffs inaccurately 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' allegation, OMB, not NHLBI, restricted access to grantee data in the manner described pursuant to its delegated authority under the Shelby Amendment. As mentioned previously, 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. Ominbus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 1998 HR 4328

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24 Even if Plaintiffs were somehow found to have standing to assert their Shelby Amendment claim, the claim must still be dismissed because the Shelby Amendment does not create a private right of action for alleged violations of its provisions. Nothing in the Amendment's two-sentence-long text or its legislative history even suggests that Congress intended for private parties to be able to petition federal courts to remedy potential violations of the Amendment. See Alexander v. Sandoval, 532 U.S. 275, 288-89 (2001) (indicating that text of statute is most important factor in determining Congressional intent to provide a private right of action); see also Section I. B. above. Accordingly, Plaintiffs' claim under the Shelby Amendment fails for this reason as well.

(1998) (indicating 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.") (emphasis added). In its revision of Circular A-110, OMB noted that "Congress entrusted OMB with the authority to resolve statutory ambiguities, the obligation to address implementation issues the statute did not address, and the discretion to balance the need for public access to research data with protections of the research process." 64 Fed. Reg. 54926 (October 8, 1999).

After publishing its first proposed revision in February of 1999 and receiving over 9,000 comments, OMB reasonably exercised its discretion to implement the broad terms of the Shelby Amendment and amended Section .36 of OMB Circular A-110 to provide:

> . . . 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 the FOIA

65 Fed. Reg. 14406, 14407. In implementing the Amendment in this manner, OMB reasonably determined that "we have decided not to extend the scope of the revision to agency guidance documents and other issuances that do not have the force and effect of law. We continue to believe that the public interest in such access is less than where the agency is taking action that has the force and effect of law, and that the revision would not be workable in those circumstances." 64 Fed. Reg. 54926, 54928-29. Moreover, OMB also limited the Shelby Amendment to data first produced under new or competing continuing grants awarded after April 17, 2000 – the revised circular's effective date. See 64 Fed. Reg. 54926 at 54929; 65 Fed. Reg.

14406. OMB's implementation of the Shelby Amendment's broad terms is eminently reasonable and entitled to deference. See Chevron, USA v. Natural Resources Defense Council, 467 U.S. 837 (1984) (finding that courts must defer to agencies' reasonable interpretations of statutes).

As demonstrated, OMB, not NHLBI, implemented the Shelby Amendment in the manner described. NHLBI merely applied the terms of OMB's revised Circular A-110 and reasonably concluded that it was not required to request the grantee to produce the DASH-Sodium Trial data because the DASH grants were first awarded in February of 1997 and were funded for five subsequent years *without further competition.* See First Am. Compl., Exh. 3 at 2 (emphasis added).[25] Accordingly, Plaintiffs' assertion that NHLBI violated the Shelby Amendment fails to state a claim on which relief can be granted and should be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

## CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss should be granted and this action should be dismissed with prejudice.

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25 Additionally, the Shelby Amendment, as implemented in OMB's revised Circular A-110, does not apply to the DASH-Sodium Trial data, because the data was not cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law. As discussed above, NHLBI did not issue any legally binding rules, regulations, or orders based on the DASH-Sodium Trial results, it merely publicized the results and made recommendations to limit dietary sodium intake on its website and in certain publications.

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Respectfully submitted,

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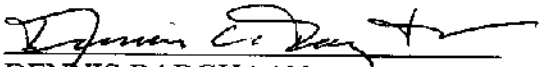

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**CERTIFICATE OF SERVICE**

I hereby certify that on this date, a true copy of the foregoing was served on plaintiff by first class mail and electronic mail addressed to:

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