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

ALEXANDRIA DIVISION

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

MEMORANDUM ORDER

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

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

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

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

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

I. BACKGROUND

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

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

A. The Information Quality Act ("IQA")

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

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

1. **OMB Guidelines**

The OMB published final guidelines on implementing the IQA on February 22, 2002. *See* 67 Fed. Reg. 8452 (Feb. 22, 2002). The Guidelines require federal agencies to undertake four principal responsibilities: (1) to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate;" (2) to "develop a process for reviewing the quality ... of information before it is disseminated;" (3) to "establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines;" and (4) to provide OMB with reports regarding the agencies' information quality guidelines and any information quality complaints they receive. 67 Fed Reg. at 8458-59. Furthermore, the OMB guidelines encourage agencies that are responsible for disseminating influential scientific, financial, or statistical information to provide a "high degree of transparency about data and methods to facilitate reproducibility of such information by qualified third parties." *Id.* at 8460.

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

2. HHS Guidelines

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

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

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

B. The Shelby Amendment

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

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

> ...Provided further, That the Director of OMB amends Section -.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining data.

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

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

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

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

C. DASH-Sodium Trial

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

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

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

The DASH study involved 412 participants who were randomly assigned to eat a typical U.S. diet or the DASH diet. On January 4, 2001, the DASH-Sodium Collaborative Research Group published its findings in the *New England Journal of Medicine*. *See* Compl. ¶ 19; Frank M. Sacks, MD et al., *Effects of Blood Pressure on Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension Diet*, 344 NEW ENG. J. MED. 3, 5 (January 4, 2001). The Group concluded that lower levels of blood pressure corresponded to lower levels of sodium intake in all participants. *Id.* The Group later performed a more detailed subgroup analysis of the DASH-Sodium Trial Data and published its results in the December 18, 2001 edition of the *Annals of Internal Medicine*. William M. Vollmer, PhD, Frank M. Sacks, MD, et al., *Effects of Diet and Sodium Intake on Blood Pressure: Subgroup Analysis of the DASH-Sodium Trial*, 135 ANNALS OF INTERNAL MEDICINE 1019, 1025-26 (December 18, 2001) In this

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

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

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

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

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

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

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at 5.

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

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

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

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

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

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

II. DISCUSSION

A. Standard of Review

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

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

B. Analysis

1. Plaintiffs Lack Standing

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

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

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