No. 05-1097

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

SALT INSTITUTE and THE CHAMBER OF COMMERCE OF THE UNITED STATES,

Plaintiffs-Appellants,

v.

MICHAEL O. LEAVITT, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

# BRIEF FOR THE APPELLEE

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**STATEMENT OF JURISDICTION**

Plaintiffs invoked the jurisdiction of the district court under 5 U.S.C. §§ 701-706 and 28 U.S.C. § 1331. The district court dismissed the complaint for lack of subject matter jurisdiction. Final judgment was entered on November 15, 2004. Plaintiffs filed a notice of appeal on January 11, 2005. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

## STATEMENT OF THE ISSUE

In a fiscal year 2001 appropriations provision known as the Information Quality Act (IQA) (codified as a note following 44 U.S.C. § 3516), Congress directed the Office of Management and Budget (OMB) to issue guidelines addressing the quality of information disseminated by federal agencies. Plaintiffs allege violations of the IQA and the implementing guidelines. The question presented is whether the district court correctly held that plaintiffs do not present a justiciable claim.

## STATEMENT OF THE CASE

The plaintiffs in this action are the Salt Institute, an association of companies that produce and market salt for food purposes, and the Chamber of Commerce of the United States, whose members include companies that produce and market food products containing salt. The defendant is the Secretary of the Department of Health and Human Services (HHS), named in his official capacity.

In May of 2003, plaintiffs filed a petition with the National Heart, Blood, and Lung Institute (NHBLI), one of HHS's National Institutes of Health (NIH). The petition purported to invoke the administrative mechanisms established by the agency pursuant to the Information Quality Act for

seeking the correction of information disseminated by the agency. The petition cited various NHLBI statements recommending, based in part on the results of a federally funded study known as the DASH-Sodium Trial, that dietary sodium intake be limited to 2,400 milligrams per day to reduce blood pressure. However, the petition disclaimed any challenge to the accuracy of those statements and requested no correction. Instead, the petition asserted that specified data needed to validate the conclusions of the study were not publicly available, and urged the agency to make those data available.

In response, the agency explained that since plaintiffs were not seeking the correction of any information disseminated by the agency, but were instead seeking access to data produced in federally funded research, the appropriate mechanism for their request was not the IQA but the Freedom of Information Act (FOIA). The agency advised plaintiffs that it had conducted a search and found no records responsive to plaintiffs' request, explaining that the pertinent grant agreements did not require the recipients to share their data with NIH. The agency explained that OMB Circular A-110, which had been revised in response to a provision known as the Shelby Amendment to require agencies to obtain and release

grantee data through the FOIA under specified circumstances, was inapplicable by its terms. Finally, the agency explained that its statements were in any event consistent with its information quality guidelines. The agency's determinations were affirmed on plaintiffs' administrative appeal.

Plaintiffs then filed this lawsuit, invoking the judicial review provisions of the Administrative Procedure Act (APA) and alleging that the agency had withheld data and disseminated information in violation of the IQA and implementing guidelines. The complaint also alleged that the agency had withheld data in violation of the Shelby Amendment. The complaint sought an order requiring the agency to produce specified data and to correct NHLBI's statements concerning the relationship between dietary sodium and blood pressure.

The district court dismissed the complaint. The court rejected plaintiffs' contention that the agency had violated the Shelby Amendment, explaining that NHLBI had correctly concluded that the revisions to OMB Circular A-110 were inapplicable to the data that plaintiffs sought. The court held that plaintiffs presented no justiciable claim for the correction of information under the IQA. The court concluded that plaintiffs lacked standing because they had neither alleged nor shown that they were injured by the statements

they purported to challenge, as distinct from the various other similar recommendations regarding sodium intake. In addition, the court held that neither the APA nor the IQA provided a basis for judicial review of the challenged statements. The court observed that agency statements without legal effect do not constitute "final agency action" under the APA, and explained that the IQA itself contemplated that challenges to the accuracy of agency information would be made administratively, not in court.

On appeal, plaintiffs have abandoned their Shelby Amendment claim. See Pl. Br. 12-13 n.4.

## STATEMENT OF FACTS

### I. Statutory And Regulatory Background.

#### A. Provisions governing public access to data generated by federal grant recipients.

1. The Freedom of Information Act.

The Freedom of Information Act, 5 U.S.C. § 552, provides the statutory mechanism for obtaining records from a federal agency. The statute vests the district courts with jurisdiction to order the production of "agency records" that were requested but improperly withheld. Id. § 552(a)(4)(B).

Materials do not constitute "agency records" within the meaning of the FOIA unless they were created or obtained by the agency. Department of Justice v. Tax Analysts, 492 U.S.

136, 144-46 (1989). Accordingly, "written data generated, owned, and possessed by a privately controlled organization receiving federal study grants are not 'agency records' within the meaning of the Act when copies of those data have not been obtained by a federal agency subject to the FOIA." Forsham v. Harris, 445 U.S. 169, 171 (1980). An agency's right to obtain a grant recipient's data does not alter this result because the FOIA "applies to records which have in fact been obtained, and not to records which merely could have been obtained." Id. at 186.

2. The Shelby Amendment.

In appropriations legislation for fiscal year 1999, Congress included a provision addressing public access to data produced by federal grant recipients. Termed the Shelby Amendment, the two-sentence provision did not amend the FOIA directly. Instead, it directed the Office of Management and Budget to amend Section _.36 of OMB Circular A-110 to require awarding agencies to ensure that data produced under a federal grant will be made available to the public through the procedures established under the FOIA. See Omnibus

Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 112 Stat. 2681 (1998).[1]

After issuing two proposed revisions to Circular A-110 and receiving more than 12,000 comments, OMB published a final revision to Circular A-110 in October of 1999. See 64 Fed. Reg. 54926 (Oct. 8, 1999). In pertinent part, the revised Circular states:

> [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 54930.

By its terms, the revised Circular applies only to data cited publicly and officially by a federal agency in support of an agency action that has the force and effect of law. See

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[1] In full, the Shelby Amendment stated:

> 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 the data[.]

ibid. (definitions). Moreover, the Circular applies only to data first produced under new or competing continuing grants awarded after April 17, 2000, the effective date of the regulation that codified the revised Circular. See 64 Fed. Reg. at 54929; 65 Fed. Reg. 14406 (March 16, 2000); 45 C.F.R. 74.36(d) (HHS regulations adopting revised Circular A-110).

In issuing the revised Circular, OMB explained that it took an approach that balanced the public interest in obtaining information needed to validate federally-funded research findings with the need to establish a workable access provision that does not interfere with the traditional scientific process. See 64 Fed. Reg. at 54926, 54928-29.

**B. Provisions governing the quality of information disseminated by the federal government.**

1. The Information Quality Act.

One of the aims of the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., is to "ensure the greatest possible benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government." Id. § 3501(2). The statute vests OMB with authority to develop and oversee the implementation of policies, principles, standards, and guidelines to apply to federal agency dissemination of public information. See id. § 3504(d)(1).

To that end, Congress included in appropriations legislation for fiscal year 2001 a provision known as the Information Quality Act, which directed 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] (2001) (codified as a note following 44 U.S.C. § 3516). The provision indicated that the OMB guidelines should require each covered federal agency to:

> (A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);
>
> (B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and
>
> (C) Report periodically to the director [of OMB]-
>
> (i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and
>
> (ii) how such complaints were handled by the agency.

Ibid.

2. OMB guidelines implementing the IQA.

After issuing two sets of guidelines for public comment, OMB published final guidelines in February of 2002. See 67 Fed. Reg. 8452 (Feb. 22, 2002). The guidelines set out four general responsibilities for the covered agencies: (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 (including the objectivity, utility, and integrity) 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 report annually to OMB "on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved." OMB Guidelines § III(1)-(4).[2]

In the preamble to the guidelines, OMB explained that it had "sought to avoid the problems that would be inherent in developing detailed, prescriptive, 'one-size-fits-all'

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[2] The OMB Guidelines are reproduced in the addendum to plaintiffs' opening brief (SR 10-12) and are published at 67 Fed. Reg. 8452, 8458-8460 (Feb. 22, 2002).

government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner." 67 Fed. Reg. at 8452. OMB observed that "information quality comes at a cost," and urged agencies to "weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) 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. at 8453. OMB explained that agencies, "in making their determination 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.

## II. Factual Background And Proceedings Below.

### A. The DASH-Sodium Trial.

In recent years, researchers supported with grants from the National Institutes of Health have studied the relationship between diet and blood pressure. In 1997, researchers published the results of a clinical study called

the Dietary Approaches To Stop Hypertension (DASH) Trial. JA 9. The results, which were published in the New England Journal of Medicine, indicated that a diet rich in fruits, vegetables, and low-fat dairy products, coupled with reduced fat intake, was effective in reducing blood pressure. See JA 9, 27; see also 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).

In 2000, as a follow-up to the DASH Trial, researchers examined the effects of different levels of dietary sodium on blood pressure. JA 10. The results of that clinical study, termed the DASH-Sodium Trial, were published in the New England Journal of Medicine in January of 2001. See JA 10; see also 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 (2001). The researchers concluded that the reduction of sodium intake significantly lowered blood pressure. See Sacks, et al., supra, at 3, 5. 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 researchers later performed a more detailed subgroup analysis of the DASH-Sodium Trial data and published its results in the December 2001 edition of the Annals of Internal Medicine. See JA 11. In that article, the research scientists 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 (2001).

After the results of the DASH-Sodium Trial had been published in these peer reviewed medical journals, NIH's National Heart, Lung, and Blood Institute reported the conclusions of the DASH-Sodium Trial in various publications and press releases. See JA 12-14. For example, in May of 2003, NHLBI released "The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure" (JNC 7).[3] Based on the

[3] The JNC 7 was published by the Journal of the American Medical Association, 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 (2003) at 2560-72,

published results of the DASH-Sodium Trial and other studies, the report recommended that dietary sodium be limited to 2,400 milligrams per day. JA 14; see also JNC 7 at 8 & nn. 25-27.

**B. Proceedings before the agency.**

1. Plaintiffs' IQA petition.

Plaintiffs are the Salt Institute, an association of companies that produce and market salt for food purposes, and the Chamber of Commerce of the United States of America, whose members include companies that produce and market food products containing salt. See JA 6, 7. In May of 2003, plaintiffs filed a petition with the National Heart, Lung and Blood Institute purporting to seek "correction" of information pursuant to the Information Quality Act. JA 25-39. The petition cited various agency statements concerning the relationship between sodium intake and blood pressure, including the JNC 7 report. See JA 29-30.

Although styled as a request for "correction of information disseminated by NHLBI," JA 26, the petition disclaimed any challenge to the accuracy of the agency's statements. See JA 32 ("we are not at this time directly challenging the substantive accuracy of the enumerated

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and it is also available at www.nhlbi.nih.gov/guidelines/hypertension.

statements"). Likewise, the petition indicated that plaintiffs were not asking the agency to retract or qualify any statements. See JA 39. Instead, the petition asserted that specified data needed to validate the conclusions of the DASH-Sodium Trial were not publicly available, see JA 32-38, and urged the agency to make additional data available, see JA 38-39.

2. The agency's response to the IQA petition.

In response, the National Heart, Lung and Blood Institute explained that because plaintiffs were "not seeking the correction of any agency-disseminated information, but [were] instead seeking access to data produced in grant-funded research, the appropriate administrative mechanism of the Freedom of Information Act (FOIA), which specifically governs requests from the public for government records." JA 43. The agency explained that under the revisions to OMB Circular A-110, individual requests for data produced under grants awarded by NIH are handled through the FOIA. See JA 43 & n.4. Accordingly, the agency indicated that it would forward plaintiffs' request for data to the agency's FOIA officials. See JA 43.

The agency also explained that its statements satisfied NIH's information quality standards. See JA 43-44.[4] The agency observed that the results that plaintiffs claimed were not reported (those pertaining to the study participants whose sodium intake was limited to 2,400 milligrams per day and those pertaining to subgroups within the study participants) were, in fact, included in the paper published in the New England Journal of Medicine article in January of 2001. See JA 45 (discussing Figures 1 and 2). Likewise, the agency explained that the paper published in the Annals of Internal Medicine in December of 2001 provided the unadjusted data for all subgroups examined (subgroups defined by hypertension status, ethnicity, and sex). See JA 45 (discussing Table 2). The agency noted that the investigators' approach to subgroup analysis and reporting was carefully evaluated and approved by many experts in statistics, clinical trials, and hypertension, through their participation in an NIH peer review group, an independent Protocol Review Committee, an independent Data and Safety Monitoring Committee, and the journals' peer review

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[4] The agency noted that the two press releases cited by plaintiffs were not covered under the relevant guidelines. See JA 43 n.3; see also OMB Guidelines § V(8) (excluding press releases from the definition of information "dissemination").

processes. See JA 45-46. None of those groups requested additional post-hoc subgroup analysis. See JA 46.

The agency added that NHLBI's recommendations on sodium intake were based on the totality of available scientific evidence, and noted that a substantial body of evidence developed over more than a decade shows a clear causal relationship between sodium intake and blood pressure. See JA 46. Indeed, the recommendation of a goal of consuming not more than 2,400 milligrams of sodium per day was the same as the sodium goal in the U.S. Dietary Guidelines issued by the Department of Agriculture, which, in turn, was consistent with a 1989 statement of the National Academy of Sciences affirming the efficacy and safety of a dietary sodium intake of 2,400 milligrams per day or less. See JA 46.

Finally, the agency noted that the steering committee of the DASH-Sodium trial had already honored two requests for access to data and that the investigators were preparing a public access data set for release in 2004. See JA 46.

3. The agency's FOIA search.

The agency's FOIA official subsequently advised plaintiffs that the NHLBI had conducted a search for documents relevant to their request and had determined that no such documents were in its possession. See JA 49. The official

explained that the DASH grants were cooperative agreements that did not require the grant recipients to share their data with NIH. See JA 49.

The FOIA official explained that the revisions to OMB Circular A-110 were inapplicable because the requested data were not first produced under a new or continuing grant awarded after April 17, 2000. See JA 50. Rather, the DASH grants were competitively awarded in February of 1997 and were funded for five subsequent years without further competition. See JA 50.

4. Plaintiffs' administrative appeal.

Plaintiffs did not appeal the agency's FOIA determination. See JA 49 (procedures for FOIA appeal). Instead, plaintiffs challenged the agency's response to their IQA petition, contending that the FOIA and OMB Circular A-110 were irrelevant because, in their view, the OMB guidelines implementing the IQA required the release of all data underlying any information that is disseminated by an agency.

Plaintiffs asserted that, "[i]n simple terms, a partial release of data can never be 'complete' and can never be 'objective'" within the meaning of the OMB guidelines implementing the IQA. JA 57. They argued that the FOIA and OMB Circular A-110 do not limit the "more extensive"

disclosure obligations that, in their view, were imposed under the OMB guidelines implementing the IQA. JA 59. Plaintiffs' appeal did not address the agency's observation that the data they had requested (pertaining to subgroups and to participants consuming 2,400 milligrams of sodium per day) had in fact been publicly released in 2001. See JA 45, JA 57.

5. The agency's decision on plaintiffs' appeal.

The Acting Director of the NHLBI rejected plaintiffs' contentions on appeal. JA 69-73. The Acting Director confirmed that the agency's information quality guidelines do not require the agency to obtain and release grantee data, and reaffirmed that a request for data is properly evaluated under the FOIA. See JA 69-70, 72.

**C. Proceedings in district court.**

Plaintiffs then brought this action, alleging violations of the IQA and its implementing guidelines, as well as violations of the Shelby Amendment. The complaint sought an order requiring the Department of Health and Human Services "to produce, in a useable and scientifically valid form," specified data from the DASH-Sodium Trial. JA 21-22. In addition, the complaint sought an order requiring HHS "to correct" the NHLBI statements cited in the petition. JA 22.

The district court dismissed the complaint. The court rejected plaintiffs' contention that the agency had violated the Shelby Amendment, explaining that NHLBI had correctly concluded that the revisions to OMB Circular A-110 were inapplicable because the data that plaintiffs requested were not from a new study funded after April 17, 2000. JA 28-29.

The court held that plaintiffs presented no justiciable claim for the correction of information under the IQA. The court held that plaintiffs lack standing because they had neither alleged nor shown that they were injured by the statements they purported to challenge, as distinct from the various other similar recommendations regarding sodium intake. See JA 88-96. In addition, the court held that neither the APA nor the IQA provides a basis for judicial review of the challenged statements. The court observed that the IQA itself contemplated that challenges to the quality of information disseminated by an agency would be addressed in administrative proceedings, not in the courts. See JA 97. And the court explained that agency statements without legal effect do not constitute "final agency action" subject to judicial review under the APA. JA 98-99 (citing Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 859-62 (4th Cir. 2002)). Indeed, the court concluded that determinations about

information quality were committed to an agency's discretion by law, noting that the OMB guidelines require agencies to undertake only the degree of correction that they conclude is appropriate. JA 100.[5]

**SUMMARY OF ARGUMENT**

In an appropriations provision commonly known as the Information Quality Act, Congress directed the Office of Management and Budget to issue guidelines addressing the quality of information disseminated by federal agencies. The IQA indicated that the guidelines should require the agencies to establish "administrative mechanisms" to seek and obtain correction of information disseminated by an agency; and should require each agency to report periodically to OMB regarding the number, nature, and handling of any complaints

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[5] While the case was pending in district court, another article concerning the DASH-Sodium trial was published. 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 The American Journal of Cardiology 222, 223-25 (2004). In response to the government's declaration suggesting that the request for data was moot, plaintiffs submitted a declaration stating that the data were still inadequate because they provided changes in blood pressure for the subjects of the study but not the mean and standard deviations. See JA 86-87; see also Docket Entry #14 (declaration of Nancy L. Geller, Ph.D.); Docket Entry #22 Exh.1 (declaration of David McCarron, M.D.). The district court thus held that the case was not moot. See JA 15 n.1.

received regarding the accuracy of information that it disseminated.

As the district court held, an agency's rejection of a request for correction of information is not subject to judicial review. It is well established that agency reports and other statements lacking the force of law are not "final agency action" within the meaning of the APA. As this Court has stressed, such statements "'are properly challenged through the political process and not the courts.'" Invention Submission Corp. v. Rogan, 357 F.3d 452, 459 (4th Cir.), cert. denied, 125 S. Ct. 415 (2004) (quoting Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 861 (4th Cir. 2002)). Consistent with this principle, the IQA expressly provided that challenges to the quality of an agency's information would be considered administratively, with oversight from OMB. Plaintiffs offer no basis to supplement this scheme with a judicial remedy.

As a threshold matter, however, there is no evident reason for this Court to decide whether an agency's resolution of a correction request would be subject to judicial review. Before the agency, plaintiffs disclaimed any challenge to the accuracy of the statements that they cited. Instead, they sought access to data produced by a federal grant recipient.

As the agency explained, such a request is properly handled through the FOIA, not through an IQA petition. And as plaintiffs do not dispute, the data that they seek are not available under the FOIA.

## ARGUMENT

## PLAINTIFFS DO NOT PRESENT A JUSTICIABLE CLAIM

### I. The Information Quality Act Does Not Provide A Mechanism For Obtaining A Grant Recipient's Data From A Federal Agency.

#### A. Public Access To A Grant Recipient's Data Was Specifically Addressed By The Shelby Amendment And By Revised OMB Circular A-110.

Plaintiffs purport to seek the "correction" of information disseminated by a federal agency, pursuant to the procedures established under the Information Quality Act. Before the agency, however, plaintiffs disclaimed any challenge to the accuracy of the statements they cited, and requested no retraction or modification of those statements. See JA 32, 38-39. Instead, the petition asserted that data needed to validate the conclusions of a grant recipient's study were not publicly available, and urged the agency to make additional data available. See JA 26, 27-28.

As the agency explained, the Information Quality Act did not establish a mechanism for obtaining a grant recipient's data. The statutory mechanism for obtaining agency records is

the FOIA. Access to a grant recipient's data under the FOIA was specifically addressed by the Shelby Amendment and by OMB's implementing revisions to Circular A-110, which do not apply to the data that plaintiffs have requested.

It is long established that a grant recipient's data do not constitute "agency records" within the meaning of the FOIA unless they have actually been obtained by the agency. Forsham v. Harris, 445 U.S. 169 (1980). Working within this framework, Congress in the Shelby Amendment directed OMB to amend Circular A-110 to require agencies to ensure that data produced under a federal grant will be made available to the public through the procedures established under the FOIA.

OMB, in turn, amended Circular A-110 to require that agencies obtain and release grantee data under specified circumstances. Upon receipt of a 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 agency shall request and the grant recipient shall provide the data so that they can be made available to the public through the procedures under the FOIA. 64 Fed. Reg. 54926, 54930 (Oct. 8, 1999). By its terms, revised Circular A-110 applies only when an agency "publicly and officially

cites the research findings in support of agency action that has the force and effect of law." Ibid. (definitions). Moreover, the revised Circular applies only to data first produced under new or competing continuing grants awarded after April 17, 2000, the effective date of the regulation that codified the revised Circular. See id. at 54929; 65 Fed. Reg. 14406 (March 16, 2000); 45 C.F.R. 74.36(d).

As OMB stressed in issuing the revised Circular, it chose a "balanced approach" that furthered the public interest in obtaining the information needed to validate federally-funded research findings, while establishing a public access process that would be "workable in practice" and that would not interfere with the traditional scientific process. See 64 Fed. Reg. 54926. As OMB explained, it "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," noting that even some commenters urging broader public access "were sympathetic to OMB's desire that the public access provision be workable." Id. at 54928-29.

### B. The IQA And OMB's Implementing Guidelines Did Not Create Any Mechanism For Obtaining Access To A Grant Recipient's Data.

In response to plaintiffs' request for data pertaining to the DASH-Sodium Trial, the agency advised plaintiffs that it

had no documents responsive to plaintiffs' request. See JA 49. The agency explained that the DASH grants did not require that the investigators share their data with NIH, see ibid., and explained that revised OMB Circular A-110 was inapplicable because the requested data were not first produced under a new or continuing grant awarded after April 17, 2000, see JA 50.

Plaintiffs do not contest these determinations. Indeed, on appeal they have abandoned their claim under the Shelby Amendment (which, in any event, provided no mechanism for judicial enforcement). See Pl. Br. 12-13 n.4.

Plaintiffs nonetheless insist that the Information Quality Act gave them a right to the data produced in connection with the DASH-Sodium Trial. But as the agency explained, the IQA did not address public access to grantee data at all. Unlike the Shelby Amendment, which specifically addressed public access to a grant recipient's data, the IQA broadly addressed the quality of information disseminated by a federal agency. The IQA contemplated that agencies would establish administrative mechanisms allowing persons to seek the "correction" of such information. By contrast, the IQA did not contemplate any mechanism - much less a judicial mechanism - for obtaining information from the government.

Nor did OMB, in implementing the Information Quality Act, address public access to a grant recipient's data. Contrary to plaintiffs' apparent belief, OMB did not, in issuing its IQA guidelines, abandon the carefully calibrated approach that it took in revising Circular A-110. As explained above, in revising Circular A-110, OMB required agencies to obtain and release grantee data only for data produced under new grants issued after April of 2000 and only when the findings were publicly and officially cited in support of agency action that has the force and effect of law. As OMB made explicit, the limitations on the scope of the revised Circular were designed to ensure that the public access provision would be "workable," a widely-recognized concern. 64 Fed. Reg. 54926, 54929; see also Forsham, 445 U.S. at 186 n.17 (noting that even if public access to grantee data were required only when the agency had a contractual right of access to the data, the class of documents subject to disclosure would still be "staggering").

Like the IQA itself, the OMB guidelines implementing the IQA contemplate public involvement in federal information policy only to the extent of allowing members of the public to seek and, where appropriate, obtain administrative correction of information disseminated by an agency. See OMB Guidelines

§ III(3). As we explain in Part II below, this administrative correction process is not subject to judicial review. But even apart from that obstacle, plaintiffs could not properly invoke an administrative "correction" process with a petition that disavowed any challenge to the accuracy of agency information and instead demanded grantee data. As NIH advised the plaintiffs and as NIH's own IQA guidelines reflect, requests for grantee data are properly handled through the FOIA. See JA 43 & n.4; JA 69-70 & n.4; see also SR 55 (NIH Guidelines § VI(3)).

## II. Challenges To The Quality Of Information Disseminated By A Federal Agency Are Resolved In Administrative Proceedings, Not In Court.

### A. The Issues That Plaintiffs Purport To Raise On Appeal Are Not Presented On The Facts Of This Case.

In district court, plaintiffs not only sought the production of data; they also sought an order requiring the agency "to correct" the various NHLBI statements concerning sodium intake that plaintiffs had cited in their petition. JA 22; see also JA 12-14. On appeal, plaintiffs appear to renew the contention that the agency should be ordered to correct these statements, although they acknowledge that "[n]either the district court nor this Court have been asked to fashion a specific correction." Pl. Br. 28.

It is difficult to fathom how plaintiffs could seek a court order requiring NHLBI to correct its statements, having disavowed before the agency any challenge to the "substantive accuracy" of those statements. JA 32. Plaintiffs' petition made absolutely no effort to show that the NHLBI's statements regarding the relationship between dietary sodium intake and blood pressure were wrong, and it did not ask the agency to retract or qualify those statements. Even plaintiffs do not suggest that the IQA would allow a party to bypass an agency's administrative correction mechanisms and proceed directly to court with a challenge to the accuracy of agency information. Thus, the issues that plaintiffs purport to raise on appeal are not actually presented on the facts of this case.

Assuming that the issues are presented, however, the district court correctly held that there is no basis for judicial review of the accuracy of information disseminated by a federal agency. Consistent with this Court's admonition in Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852 (4th Cir. 2002), we address the alleged statutory basis for jurisdiction before addressing the issue of standing. See id. at 857 & n.6 ("Because we conclude that the [agency report] was not final agency action, and therefore, that the district court lacked subject matter jurisdiction to hear

plaintiffs' claims, [citation], we do not reach the standing issue.") (citing Ashwander v. Tennessee Valley Authority, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring), and noting that standing is a constitutional issue).[6]

### B. Agency Statements Lacking The Force And Effect Of Law Are Not Subject To Judicial Review Under The APA.

Plaintiffs contend that the statutory basis for their suit is Section 704 of the APA, which authorizes judicial review of "final agency action" for which there is no other remedy in a court. See Pl. Br. 31 (quoting 5 U.S.C. § 704). It is well established, however, that an agency's reports and other statements lacking the force and effect of law do not constitute final agency action within the meaning of the APA.

In Flue-Cured Tobacco, tobacco manufacturers sought to challenge a report issued by the Environmental Protection Agency (EPA) that classified secondhand smoke as a known human carcinogen and concluded that such smoke was responsible for approximately 3,000 nonsmoker, lung-cancer deaths in the United States each year. See 313 F.3d at 854, 856. The report was issued pursuant to EPA's authority under the Radon

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[6] In light of this Court's discussion in Flue-Cured Tobacco, plaintiffs are clearly wrong to assert that the district court should not have considered the availability of judicial review under the APA. See Pl. Br. 31.

Act to research indoor air pollutants and disseminate the findings of the research. See id. at 855, 856. Plaintiffs urged and the district court held that the EPA had violated the Radon Act by failing to include a tobacco-industry representative on the agency's advisory committee. See id. at 857. The district court ordered that the relevant chapters of the report should be vacated. See ibid.

This Court reversed, holding that there was no statutory basis for subject matter jurisdiction. The Court explained that, because the Radon Act did not create a specific private right of action, the plaintiffs had based their claims for relief on the APA's general review provisions, 5 U.S.C. §§ 702, 704. See id. at 857. The Court held that the APA's review provisions were unavailable because the EPA report was not final agency action.

The Court explained that for agency action to be "final" for purposes of the APA, two criteria must be met.

> "First, the action must mark the 'consummation' of the agency's decisionmaking process - it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'"

Id. at 858 (quoting Bennett v. Spear, 520 U.S. 154, 177-78 (1997)). As the Court observed, the parties did not dispute that the EPA report marked the consummation of the agency's

decisionmaking process. See ibid. Thus, the critical issue was whether the report gave rise to legal consequences, rights, and obligations. See ibid.

The Court held that it did not. Although the Court did not dispute that the report's "persuasive value may lead private groups to impose tobacco-related restrictions," id. at 861, the Court explained that "these decisions are attributable to independent responses and choices of third parties." Ibid. Such "actions and consequences" do not legally flow from the report and thus provide no basis for APA review. Ibid.

This Court stressed that "as a practical matter and of considerable importance, if [it] were to adopt the position that agency actions producing only pressures on third parties were reviewable under the APA, then almost any agency policy or publication issued by the government would be subject to judicial review." Ibid. The Court declared:

> We do not think that Congress intended to create private rights of actions to challenge the inevitable objectionable impressions created whenever controversial research by a federal agency is published. Such policy statements are properly challenged through the political process and not in the courts.

Ibid.

The Court reaffirmed these principles in Invention Submission Corp. v. Rogan, 357 F.3d 452 (4th Cir.), cert. denied, 125 S. Ct. 415 (2004), holding that an agency's advertising campaign could not be regarded as final agency action even if it were assumed that the agency's intent was to target the plaintiff company in order to put it out of business. See id. at 454, 458-60. The Court explained that the agency's "advertising did not create 'legal consequences' for [the plaintiff] or any other member of the public cognizable as final agency action, and the campaign itself did not determine any right or obligation of any party." Id. at 460. The Court declared: "If the [agency's] advertising made business more difficult for [the plaintiff] by raising the public's awareness, the decisions of members of the public 'are attributable to independent responses and choices of third parties' and cannot be imputed to the [agency] for purposes of determining whether its conduct was final agency action." Ibid. (quoting Flue-Cured Tobacco, 313 F.3d at 861). Accord Aerosource v. Slater, 142 F.3d 572, 581 (3d Cir. 1998) (although FAA reports warning the aviation community that the plaintiff may have improperly maintained aircraft parts had a "severe adverse impact" on the plaintiff's business, the

reports were not subject to judicial review because they did not impose a legal obligation).

In light of these precedents, plaintiffs cannot contend that the NHLBI statements they purport to challenge are final agency action. As we explain below, nothing in the IQA transforms these otherwise unreviewable statements into final agency action subject to judicial review under the APA.

### C. The IQA Does Not Transform An Agency's Otherwise Unreviewable Statements Into Final Agency Action Reviewable Under The APA.

Plaintiffs concede that the IQA provides no mechanism for judicial enforcement. See Pl. Br. 31. They nonetheless believe that the passage of the IQA radically altered the prerequisites for APA review recognized in Flue-Cured Tobacco and Invention Submission (although the revolution apparently went unnoticed by the parties and the Court in those cases). Thus, plaintiffs assert that while the "district court may have believed that an agency's failure to correct publicly disseminated information based upon bad science has no 'legal effect,' ... such a conclusion plainly cannot stand following enactment of the IQA." Pl. Br. 33. Plaintiffs are mistaken.

As the district court explained, the IQA by its terms contemplated that the accuracy of agency information would be challenged before the agency, not in court. The IQA directed

OMB to issue guidelines requiring agencies to establish "administrative mechanisms" to allow affected persons to seek and obtain correction of information disseminated by the agency. 44 U.S.C. § 3516 note. Although plaintiffs "cannot conjure any known rule of statutory construction" to support the district court's conclusion that these remedies are exclusive, Pl. Br. 33 n.17, the Supreme Court has supplied the maxim. See Kissinger v. Reporters Committee For Freedom of the Press, 445 U.S. 136, 148-49 (1980) (The Federal Records Act "expressly provides administrative remedies for violations of the duties it imposes, implicating our conclusion in [Transamerica Mortgage Advisors, Inc. v. Lewis, 444 U.S. 11, 19 (1979)] that it is 'an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it.'").

If there could be any doubt on that score, the IQA expressly set out the mechanism by which the agency's handling of correction requests would be reviewed. The IQA provided that agencies should be required to "[r]eport periodically to the director [of OMB] - (i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and (ii) how such

complaints were handled by the agency." 44 U.S.C. § 3516 note. Thus, by its terms, the IQA provided that the agencies' implementation of OMB's information quality guidelines would be reviewed by OMB, not by the courts. See Regional Management Corp. v. Legal Service Corp., 186 F.3d 457, 462 n.6 (4th Cir. 1999) ("The presence of a nonjudicial means of enforcement is indicative of a congressional intent not to create an implied private right of action.") (internal quotation marks and citation omitted).

Moreover, OMB eschewed "detailed, prescriptive, 'one-size-fits-all' government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner," and underscored the "flexibility" that its guidelines gave the agencies. 67 Fed. Reg. at 8452. In particular, OMB stressed that agencies, "in making their determination 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; see also OMB Guidelines § III(3) (agencies shall establish administrative mechanisms allowing affected persons

to seek and obtain, "where appropriate," correction of agency information). Thus, the agency's response to the correction request was "committed to agency discretion by law." 5 U.S.C. § 701(a)(2).

In insisting that they must have a right to judicial review, plaintiffs observe that NHLBI denied their (purported) request for correction and their administrative appeal, "leaving no place for Plaintiffs to go to seek relief from the agency." Pl. Br. 33. Contrary to plaintiffs' apparent premise, however, "it is not at all anomalous that Congress could permit them ... to participate in agency proceedings, and yet they be unable to seek review in federal courts." Gettman v. DEA, 290 F.3d 430, 434 (D.C. Cir. 2002). As the Supreme Court and this Court have explained, exhaustion and finality are distinct requirements, and the exhaustion of administrative remedies does not make otherwise non-final agency action final. See FTC v. Standard Oil Co., 449 U.S. 232, 243 (1980) (holding that plaintiffs' exhaustion of administrative remedies did not transform the FTC's issuance of a complaint into final agency action, and explaining that the plaintiff had "mistaken exhaustion for finality"); Regional Management Corp. v. Legal Services Corp., 186 F.3d 457, 462 n.6 (4th Cir. 1999) ("the existence of a right of

action and of an exhaustion requirement are separate issues"); Eastman Kodak Co. v. Mossinghoff, 704 F.2d 1319, 1324 (4th Cir. 1983) ("Even assuming arguendo that Kodak had exhausted its administrative remedies on the abandonment question, that does not ipso facto mean that the decision is a final agency action.") (citing Standard Oil). Accord Aerosource v. Slater, 142 F.3d 572, 579 (3d Cir. 1998) ("After all, if 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.") (citing Standard Oil).

In sum, the IQA by its terms contemplated that challenges to the accuracy of an agency's information would be heard before the agency, not in court. Thus, the IQA reflected the established principle that freestanding agency statements are not subject to judicial review.

### D. Plaintiffs Lack Standing To Challenge The Accuracy Of The NHLBI's Statements.

For largely the same reasons, plaintiffs lack standing to bring this suit. The district court held that plaintiffs had neither alleged nor shown that they were injured by the NHLBI statements they purported to challenge, as distinct from the various other similar recommendations regarding sodium intake.

See JA 88-96. Plaintiffs do not dispute this point on appeal and, indeed, disavow any reliance on the commercial impact of the NHLBI statements. See, e.g., Pl. Br. 26 ("Plaintiffs' injury ... was not alleged to have arisen from the commercial impact of the information disseminated[.]").

Plaintiffs instead allege that they were "denied their statutory rights because the Defendant failed to follow its procedures, violating the IQA, the OMB Guidelines, and its own Guidelines." Pl. Br. 29. Such a generalized grievance would not be actionable. See, e.g., Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 149, 156 (4th Cir. 2000) (en banc) ("The injury in fact requirement precludes those with merely generalized grievances from bringing suit to vindicate an interest common to the entire public."). In any event, as we have already shown, Congress did not create through the IQA any judicially enforceable rights. Thus, plaintiffs present no justiciable claim.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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I hereby certify pursuant to Fed. R. App. P. 32(a)(7)(C) that the foregoing brief is monospaced, has 10.5 or fewer characters per inch and contains 7,856 words, according to the count of Corel WordPerfect 9.

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**CERTIFICATE OF SERVICE**

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