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." Karahalios, 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); Acrosource, 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,"

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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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

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.

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).

(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.

Dated: June 25, 2004

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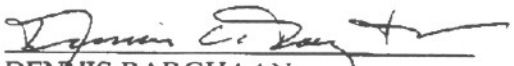

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CERTIFICATE OF SERVICE

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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