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

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

REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

Despite Plaintiffs' portrayal of the Information Quality Act and the Shelby Amendment as "the most significant advancements" in administrative law in the last 40 years, they cannot establish the judicial enforceability of these provisions in this case, or even this court's jurisdiction to decide their claims. First, Plaintiffs' claims for access to the DASH-Sodium Trial data are entirely moot because the data, in the format requested by Plaintiffs, was recently published in a medical journal article. Plaintiffs also have not articulated a viable theory of standing. Plaintiffs inappropriately conflate the principle of judicial review with standing. Their reliance on informational injury is ineffective because they cannot demonstrate a link between NHLBI's decision not to correct its information and Plaintiffs' alleged injury of being deprived of the DASH-Sodium Trial data. Moreover, Plaintiffs do not have associational standing because their members do not have standing to sue in their own right. Nor can Plaintiffs establish the constitutional standing prerequisites of traceability and redressability.

Plaintiffs have also failed to demonstrate that they are entitled to judicial review of NHLBI's actions. They have not refuted the fact that the IQA provides merely for "administrative mechanisms" for parties to seek correction of information, not judicial review of such determinations. Moreover, Plaintiffs' heavy reliance on the presumption of judicial review under the APA is unavailing, because that presumption assumes the existence of final agency action and judicially manageable standards, which are not present in this case. NHLBI's denial of Plaintiffs' administrative correction request is not sufficient to convert non-final action into final action, and the IQA and the OMB guidelines afford agencies substantial discretion in deciding correction requests, particularly requests involving informal agency statements. Finally, Plaintiffs fail to establish that they have standing to pursue their claim under the Shelby Amendment and neglect to rebut the fact that OMB,

not NHLBI, implemented the Shelby Amendment in the manner that Plaintiffs find objectionable. Because the Court lacks jurisdiction over Plaintiffs' claims, this action should be dismissed.

ARGUMENT

I. PLAINTIFFS' CLAIMS THAT NHLBI VIOLATED THE IQA AND THE APA IN COUNTS I AND II SHOULD BE DISMISSED FOR LACK OF JURISDICTION.

A. Plaintiffs' Claim for the DASH-Sodium Trial Data is Moot.

To the extent that Plaintiffs assert a right to obtain the DASH-Sodium Trial data under the IQA, such a claim has clearly become moot. Not only has the data generally been available from the Trial investigators and the public access data website long before now, but the Trial investigators recently published the specific data requested by Plaintiffs in an article in The American Journal of Cardiology. 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 (July 15, 2004) (attached as Exhibit A). Tables in the article contain the mean blood pressure, standard deviation, and sample size for each relevant subgroup, including race, hypertension status, sex, age, income, and body mass index, as Plaintiffs requested. See First Am. Compl. ¶¶ 20-21, 26, Relief Req. ¶ C. The data presented in the article are in a more useful format for the Plaintiffs' purposes than what NHLBI itself could provide to Plaintiffs. Declaration of Nancy L. Geller (attached as Exhibit B). Accordingly, Plaintiffs' claim for the data in a useful form is moot and should be dismissed.[1] See, e.g., Schering Corp. v. Shalala, 995 F.2d 1103, 1106 (D.C. Cir. 1993).

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[1] Contrary to their suggestions, Plaintiffs have had ready access to the methods of the Trial investigators as well. These methods are described in the published articles detailing the results of the DASH-Sodium Trial. See, e.g., Laura P. Svetkey, et al., *The DASH Diet, Sodium Intake and Blood Pressure Trial (DASH-Sodium): rationale and design*, J. Am. Diet. Assn. 1999; 8 (suppl): S96-S104.

B. Plaintiffs Do Not Have Standing To Pursue Their Claims in Federal Court.

Plaintiffs essentially ignore the arguments in Defendant's Memorandum in Support of his Motion to Dismiss ("Mem.") that they lack constitutional standing under Article III because they have not (1) suffered a concrete and particularized injury that is (2) fairly traceable to the Defendant's action and that is (3) likely to be redressed by a favorable court decision. See, e.g., Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992); Mem. at 16-22. Plaintiffs merely assert in abrupt and conclusory fashion that four theories support their standing to assert their claims in this case. See Plaintiffs' Memorandum in Opposition to Motion to Dismiss ("Opp. Mem.") at 15-16. The burden is on Plaintiffs, however, to establish standing. See Steel Company v. Citizens for a Better Environment, 523 U.S. 83, 103-04 (1998). And mere "conclusory allegations" are insufficient to satisfy this burden. Baur v. Veneman, 352 F.3d 625, 636-37 (2d Cir. 2003). None of Plaintiffs' theories confers standing on the Plaintiffs to challenge in federal court NHLBI's administrative decisions under the IQA that its informal statements relating to hypertension and the results of the DASH-Sodium Trial did not warrant correction, and that it was unable to produce the study's underlying data.

Plaintiffs first allege that they have standing simply because they claim (incorrectly) that the final agency action requirement of judicial review under the APA is satisfied by NHLBI's denial of their administrative petition and appeal. Id. at 16. Without any reasoning, Plaintiffs assert that if judicial review under the APA is available, they must necessarily have standing. In this manner, Plaintiffs unjustifiably conflate the doctrine of standing with the doctrine of judicial review under the APA. Plaintiffs cite two cases, Bennett v. Spear, 520 U.S. 154, 178 (1997) and Air Brake Sys. Inc. v. Mineta, 357 F.3d 632, 641 (6th Cir. 2004), in support of this proposition. Neither of these cases, however, provides any support for Plaintiffs' theory of standing. Although both decisions discuss the

requirements for final agency action, nowhere do they suggest that if APA judicial review of final agency action is available (which it is not in this case), a party thus has standing to assert a claim. See Bennett, 520 U.S. at 178; Mineta, 357 F.3d at 641. To the contrary, every plaintiff must establish constitutional standing as a prerequisite to invoking the court's jurisdiction under the APA or otherwise. See Renne v. Geary, 501 U.S. 312, 315 (1991). Plaintiffs' manufactured theory thus provides no basis for their standing in this case.[2]

Plaintiffs' next two theories of standing assert that "[t]he denial of Plaintiffs' request for correction and information independently creates standing" and "Plaintiffs ha[ve] standing because the Institute's actions in withholding data caused direct, redressable injury, by impairing Plaintiffs' ability to conduct research and disseminate information to their members and the public." See Opp. Mem. at 16. Both of these allegations appear to assert standing based on "informational" injury, which typically arises where an organization is deprived of information and that lack of information renders the organization's activities infeasible. See Competitive Enterprise Institute v. National Highway Safety Admin., 901 F.2d 107, 122 (D.C. Cir. 1990).[3] To establish standing under this theory, a plaintiff must demonstrate the presence of a "link between the agency's action, the

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[2] To the extent Plaintiffs are asserting that they have Article III standing to sue in federal court simply because under the IQA they have a right to file an administrative complaint and appeal with the agency seeking correction of information, this theory also fails to confer Plaintiffs standing. See, e.g., Gettman v. DEA, 290 F.3d 430, 434 (D.C. Cir. 2002) (finding that "contrary to petitioners' suggestion, it is not at all anomalous that Congress could permit them as 'interested part[ies]' (assuming that they are) to participate in agency proceedings, and yet they be unable to seek review in federal courts.").

[3] Given the paucity of analysis that Plaintiffs offer in support of their standing theories, it is difficult to develop a clear understanding of each of them. The relevant portions of the three cases cited in Plaintiffs' second and third standing theories, however, each refer to principles of "informational standing." See Sargeant v. Dixon, 130 F.3d 1067, 1070 (D.C. Cir. 1997); Public Citizen v. FTC, 869 F.2d 1541, 1548 n.13 (D.C. Cir. 1989); Competitive Enterprise Institute, 901 F.2d at 122-23.

informational injury, and the organization's activities." Id.

This theory of standing is unavailing to these Plaintiffs, because there is no link between the agency's action and Plaintiffs' alleged informational injury. NHLBI's action under the IQA in this case was its decision that its statements regarding the DASH-Sodium Trial did not warrant correction. The agency's decision not to correct its information did not deprive Plaintiffs of the study's underlying data. Indeed, NHLBI did not even possess the data at the time of Plaintiffs' request. Plaintiffs' alleged "informational" injury has more to do with their own failure to request the data directly from the DASH-Sodium Trial researchers, or seek access through the public access data website. Moreover, as explained above, the Trial investigators recently published the data requested by Plaintiffs in this case in a readily useable format. See Exhibit A (attached). The fact that this data is now published in an easily accessible journal article indicates that Plaintiffs' claim for the data in this case is moot and any informational injury suffered non-existent.

Moreover, the IQA does not provide for information production. Rather, the IQA requires that agencies rely on information of sufficient quality and provides for "administrative mechanisms" to correct disseminated information when appropriate. As a result, there is no basis to request the production of information under the IQA, which makes the Plaintiffs' theory of standing inapplicable.

Plaintiffs' final theory of associational standing also fails because their members would not have standing to sue in their own right. Plaintiffs' assertion that their members have been injured because they lack the "ability to market their products without the stigma created by the government's negative dissemination of information that does not meet basic quality standards," Opp. Mem. at 12 n. 20, is not the type of concrete and particularized injury required under Article III. See, e.g., Newdow v. Eagen, 309 F. Supp.2d 29, 37 (D.D.C. 2004) (finding that "threat of future stigmatic injury is too speculative to qualify as an injury in fact . . . ."). And, to the extent Plaintiffs claim that

their members are injured by NHLBI's dissemination of the results of the DASH-Sodium Trial because this information might cause consumers to reduce their consumption of salt and decrease their members' sales, such an injury is based on the hypothetical actions of third parties and is far too speculative to qualify as a concrete injury necessary to confer standing. See, e.g., Friends for Ferrell Parkway, LLC v. Stasko, 282 F.3d 315, 320-21 (4th Cir. 2002) (indicating that plaintiff's injury must be "caused by the challenged conduct of the defendant, and not by the independent actions of third parties not before the court").

Finally, Plaintiffs assert that the numerous other scientific studies, the published results of the DASH-Sodium Trial themselves, and the recommendations in the U.S. Dietary Guidelines and the Recommended Dietary Allowances–all of which indicate that reducing salt intake reduces blood pressure (Mem. at 20-22)--are "irrelevant" to an analysis of traceability and redressability. See Opp. Mem. at 13 n. 21. To the contrary, these publications are highly relevant because they also make it impossible for Plaintiffs to trace their purported injuries to NHLBI's recommendations and statements regarding the DASH-Sodium Trial as distinct from any one of these independent publications and pronouncements. Furthermore, Plaintiffs' IQA request for correction of NHLBI's statements would not redress their alleged injuries because these other publications and their findings would remain unchanged. Because Plaintiffs have failed to demonstrate that they have standing to assert their IQA claims in federal court, their claims should be dismissed.

C. NHLBI's Actions Regarding the DASH-Sodium Trial Are Not Subject to Judicial Review.

Despite Plaintiffs' frequent invocation of their alleged presumptive right to judicial review, there is no basis for judicial review of any of NHLBI's actions in this case. Neither its dissemination of the results of the DASH-Sodium Trial, its recommendations to reduce dietary salt intake, its

inability to produce the DASH-Sodium Trial data, nor its denial of Plaintiffs' administrative challenge under the IQA to the foregoing conduct warrant judicial review. Generally, there are two possible avenues for judicial review of federal agency action: (1) "a substantive statute may provide a private right of action for judicial review of an agency action;" or (2) the provisions of the Administrative Procedure Act may provide for judicial review. Regional Mgmt. Corp., Inc. v. Legal Serv. Corp., 186 F.3d 457, 461 (4th Cir. 1999). In the case at hand, judicial review of NHLBI's actions is not available directly under the IQA, nor under the APA, and the presumption of judicial review does not apply.

1. There is No Explicit or Implied Private Right of Action Under the Information Quality Act.

Plaintiffs acknowledge that the "IQA does not explicitly authorize a direct private right of action," but they urge the court to read one into the statute. Opp. Mem. at 30. The Supreme Court has recently made clear, however, that a statute's text is the most important factor in determining whether Congress intended to create a private right of action to enforce a statute's terms in court. See, e.g., Alexander v. Sandoval, 532 U.S. 275, 288-89 (2001) ("We ... begin (and find that we can end) our search for Congress's intent with the text and structure of [the statute in question]."). Moreover, "implied" private rights of action are increasingly disfavored. See, e.g., Regional Mgmt., 186 F.3d at 461 (indicating that burden is on plaintiff to establish implied private right of action and requirements for doing so are stringent). The Sixth Circuit has explained that "[t]he 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." Cline v. Rogers, 87 F.3d 176, 182 (6th Cir. 1996). As recognized by Plaintiffs, nothing in the IQA provides anyone a right of action in a court of law for alleged violations of its provisions, indicating that such a right should not be implied.

Plaintiffs nevertheless resort to the Supreme Court's dated decision in Cort v. Ash, 422 U.S. 66, 78 (1975), which discusses factors for determining whether a private right of action should be implied under a statute. See Opp. Mem. at 30. The decision in Cort, however, has been effectively overtaken by the Court's decisions in Touche Ross & Co. v. Redington, 442 U.S. 560, 575-76 (1979) and Transamerica Mortg. Advisors, Inc. v. Lewis, 444 U.S. 11, 23-24 (1979), which converted "one of [Cort's] four factors (congressional intent) into *the determinative factor*, with the other three merely indicative of its presence or absence." Thompson v. Thompson, 484 U.S. 174, 189 (1988) (Scalia, *J.*, concurring) (emphasis in original); see also Park National Bank of Chicago v. Michael Oil Co., 702 F. Supp. 703, 704 (N.D. Ill. 1989).

Nothing in the IQA, its legislative history, or its structure provides a basis for concluding that Congress intended to provide a private right of action to enforce its terms in federal court. Plaintiffs' unsubstantiated assertion that Congress enacted the IQA in response to other court decisions finding that parties were not entitled to judicial remedies for information-related complaints is baseless and conclusory. See Opp. Mem. at 31. Nothing in the Act's language or even its scant legislative history supports this conclusion or indicates that judicial relief was contemplated. To the contrary, the language of the Act actually disclaims Congress's intention to provide a cause of action enforceable in federal court by explicitly requiring OMB's and other agencies' IQA guidelines to contain *administrative mechanisms* for affected persons to seek information corrections when warranted. Clearly, Congress believed that issues regarding the quality of agency information and whether corrections are necessary are best determined by the expertise of federal agencies, not federal courts. As a result, inferring a private right of action would not further the intent of Congress, but rather "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).

Finally, the only court to have addressed a claim under the IQA has ruled that "Congress did not intend the IQA to provide a private cause of action . . . ." In re: Operation of the Missouri River Sys. Litig., 2004 WL 1402563 at * 24 (D. Minn. 2004). While the court's analysis is brief, its decision is instructive and supports the conclusion that there is no private right of action, explicit or implied, under the IQA. Accordingly, judicial review of Plaintiffs' claims is not available through a private right of action under the IQA.

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

a. Presumption of APA Judicial Review Applies Only When Prerequisites of Final Agency Action and Judicially Manageable Standards Are Present.

Plaintiffs rely heavily on their assertion that judicial review under the APA is presumed and "may be defeated only by clear and convincing evidence of specific statutory language, reliable legislative history, or a fairly discernable congressional intent in the detail of the legislative scheme to preclude judicial review." Opp. Mem. at 16. The presumption of APA judicial review, however, applies only if two underlying prerequisites are met: (1) final agency action and (2) action that is not committed to agency discretion by law. See 5 U.S.C. §§ 701(a)(2), 704; Transactive Corp. v. United States, 91 F.3d 232, 236 (D.C. Cir. 1996) (indicating that presumption of APA judicial review does not apply if an agency action is committed to agency discretion by law or if the action is not final). If either of these requirements is not satisfied, the APA does not apply, judicial review is not allowed, and the presumption does not become effective.[4]

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[4] Moreover, the presumption of APA judicial review typically arises when an assertion is made that a statute precludes APA judicial review. See 5 U.S.C. § 701(a)(1). Defendant does not assert that Congress explicitly prohibited APA judicial review of IQA compliance in all cases. In fact, Defendant has acknowledged that in certain circumstances (not implicated here), APA judicial review of IQA claims may be available. See Mem. at 30 n. 17, 35 n. 21.

The cases that Plaintiffs cite in support of the presumption of APA judicial review are distinguishable from the facts of this case, because each of those cases involved review of final agency action determining rights and obligations. See Bowen v. Michigan Acad. of Family Physicians, 476 U.S. 667, 668 (1986) (reviewing validity of agency's Medicare regulation); Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 345-46 (4th Cir. 2001) (reviewing validity of agency's dismissal of appeal challenging fiscal intermediary's disallowance of hospital's Medicare reimbursement request); Regional Mgmt. Corp. Inc. v. Legal Serv. Corp., 186 F.3d 457, 459-60 (4th Cir. 1999) (denying judicial review of agency's decision upholding validity of lobbying efforts which resulted in legislation and determinations that directly and adversely affected plaintiff). As demonstrated below, NHLBI's exercise of discretion not to correct freestanding agency statements regarding the DASH-Sodium Trial is not final agency action and is committed to agency discretion by law, thus preventing the application of the general presumption in favor of APA judicial review and precluding such review itself.

b. None of NHLBI's Actions Regarding the DASH-Sodium Trial Qualifies as Final Agency Action.

Plaintiffs attempt to distance themselves from their own allegations focusing on NHLBI's dissemination of the DASH-Sodium Trial results, its recommendations to limit salt intake to moderate levels, and its inability to produce the Trial data. See First Am. Compl. ¶¶ 12, 29-32. But despite their attempt now to recast their complaint as exclusively targeting NHLBI's denial of Plaintiffs' IQA petition and appeal, the fact remains that none of NHLBI's actions in this case constitutes final agency action necessary for judicial review under the APA.

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). As explained previously, the DASH-Sodium Trial results simply

consist of the findings of research scientists who concluded that reducing sodium intake lowers blood pressure, and NHLBI's statements regarding the Trial merely consist of descriptions of these findings and *recommendations* to limit sodium intake to moderate levels. None of these underlying actions determines rights or obligations or has any legal effect on the Plaintiffs or anyone else.[5] Agency dissemination of such advisory information that has no legal impact has consistently been found not to constitute final agency action and thus is unreviewable by federal courts under the APA. See, e.g., Franklin v. Massachusetts, 505 U.S. 788, 798 (1992) (finding agency report on census data was not final agency action because it carried no direct consequences); Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 859-62 (4th Cir. 2002) (EPA report on health hazards of second-hand tobacco smoke not final agency action)[6]; Industrial Safety Equip. Ass'n, Inc. v. EPA, 837 F.2d 1115, 1117, 1119 (D.C. Cir. 1988) (EPA report recommending use of certain asbestos protection respirators was not final agency action).[7]

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[5] Plaintiffs' argument that the OMB Guidelines are binding and have the force of law is irrelevant to the inquiry of whether the *challenged* agency action is final for purposes of APA judicial review. Plaintiffs do not challenge the validity of the OMB Guidelines or assert that the Guidelines have somehow injured them. Accordingly, the finality of the OMB Guidelines is not an issue in this case. Rather, the question is whether NHLBI undertook an action from which "legal consequences will flow" in merely distributing the DASH-Sodium Trial results and its recommendations to lower salt consumption.

[6] Plaintiffs' attempt to distinguish the decision in Flue-Cured Tobacco is not persuasive. See Opp. Mem. at 20 n. 28. NHLBI's distribution of the DASH-Sodium Trial results and its recommendations to limit salt intake are comparable to the health advisory in Flue-Cured Tobacco in that they do not create any legal rights, obligations, or consequences. As demonstrated below, Plaintiffs' focus on NHLBI's denial of their administrative challenges does not alter the advisory nature of the agency's underlying actions in this case.

[7] Plaintiffs' reliance on Tozzi v. U.S. Dep't of Health and Human Serv., 271 F.3d 301, 310-11 (D.C. Cir. 2001) is unavailing. As noted in Defendant's initial memorandum, while the court in Tozzi determined that HHS's decision to upgrade dioxin to the category of "known" carcinogens qualified as final agency action, the court's conclusion rested on the fact that (1) such a classification triggered 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

In apparent recognition of the lack of any legal effect resulting from NHLBI's underlying actions of distributing the results of the DASH-Sodium Trial, making recommendations to limit salt intake, and informing Plaintiffs that it did not possess the Trial data, Plaintiffs attempt to manufacture final agency action by focusing on NHLBI's denial of their administrative petition and appeal, which focused solely on the agency's underlying actions listed above. See First Am. Compl. Exhs. 1, 4; Opp. Mem. at 20-23. Courts have rejected such attempts to create final agency action where none exists. The Supreme Court in Federal Trade Commission v. Standard Oil Co. of California, 449 U.S. 232, 243 (1980), rejected the contention that the FTC's *denial* of a party's administrative request to dismiss a complaint constituted "final agency action" where the complaint itself had no binding legal effect. The 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 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.

Id.; see also Regional Mgmt. Corp., Inc. v. Legal Serv. Corp., 186 F.3d 457, 462-63 n. 6 (explaining that merely exhausting administrative remedies does not entitle a plaintiff to seek judicial review of an agency action). The Third Circuit has also rejected Plaintiffs' theory of manufactured finality in finding that there was no final agency action in the Federal Aviation Administration's *denial,* and its refusal to reconsider its *denial*, of a plaintiff's administrative request to rescind FAA's advisory reports regarding safety concerns with repair work performed by plaintiff. Aerosource, Inc. v. Slater, 142 F.3d 572, 580-81 (3d Cir. 1998). In reaching that conclusion, the court noted that FAA's denial of plaintiff's administrative requests "did not impose

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Act. See id. The Tozzi case thus involved much more than the dissemination of advisory information and triggered actions that ultimately had binding legal effects, unlike the present case.

an obligation, deny a right, or fix some legal relationship." Id. The court went on to explain the folly of Plaintiffs' theory:

> [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.

Id. at 579. Plaintiffs' contention that Federal Trade Commission and Aerosource, Inc. are distinguishable because these cases did not involve agency denials of administrative petitions "that had been specifically authorized by an act of Congress" is simply an attempt to back-door the argument that Congress provided a right of action in the IQA.[8] Congress did no such thing, as Defendant has previously established. In any event, Plaintiffs cite no authority for the proposition that Congress's contemplation of the administrative mechanism that Plaintiffs engaged to ventilate their concerns regarding the DASH-Sodium Trial means that NHLBI's refusal to correct a freestanding, advisory dissemination – that in no way determines private rights or obligations – somehow qualifies as final, reviewable agency action.

Plaintiffs cannot cite any authority to support their theory that final agency action can be fabricated simply by lodging an administrative challenge to the non-final underlying action they find objectionable and waiting for the agency to deny their challenge. Instead, Plaintiffs cite Bennett v. Spear, 520 U.S. 154, 178 (1997),[9] and Air Brake Sys., Inc. v. Mineta, 357 F.3d 632,

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[8] Plaintiffs appear also to claim that the IQA provides them with a right to correction and disclosure of information, and that NHLBI's denial of their correction request denied them that right. The IQA, however, merely provides persons with a right to use *administrative mechanisms* to *seek* correction of information that is not of sufficient quality. Plaintiffs exercised their right under the IQA to lodge an administrative challenge to NHLBI's statements regarding the DASH-Sodium Trial. The fact that the agency denied their challenge did not deny Plaintiffs any of their "rights" and is not final agency action.

[9] While the Court in Bennett found final agency action present, this finding was based on the fact that the Fish and Wildlife Service's biological opinion did have "direct and appreciable

641 (6th Cir. 2004),[10] for the uncontroversial principle that final agency action requires action that determines rights, obligations, or legal consequences. See Opp. Mem. at 20. Because there is no support for Plaintiffs' theory of manufactured final agency action, and because the decisions in Federal Trade Commission and Aerosource, Inc. directly reject such a theory, none of NHLBI's freestanding communications regarding the DASH-Sodium Trial qualifies as final agency action. Thus, the agency's actions are not judicially reviewable under the APA on this basis alone, and the Plaintiffs' claims should be dismissed.[11]

c. 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 under the APA is also precluded on the ground that the agency decisions in this case are on matters "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). "Agency

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legal consequences" because it imposed substantial penalties for any taking of endangered fish that violated the opinion's provisions. Id. at 1168-69. By contrast, NHLBI's statements regarding the DASH-Sodium Trial impose no penalties on anyone and have no legal consequences.

[10] The Mineta decision actually supports Defendant's contention that there is no final agency action. The court determined that opinion letters on NHTSA's website were not final agency action because they stated only tentative conclusions based on limited information. Id. at 639-40.

[11] Plaintiffs' Opposition betrays that their real agenda is to remedy what they perceive to be the obsolete coverage of the APA. They explain that "[w]hen Congress enacted the APA, it contemplated agencies would generally operate via either a 'rulemaking' or an 'adjudication'," and "did not anticipate federal agencies would accomplish regulatory and policy goals by disseminating 'free-standing' information . . . ." Opp. Mem. at 4. The IQA, they contend, was Congress's response to concerns about "regulation by information." Id. at 5. But the fact remains that Congress has not amended the APA to correct the discrepancy Plaintiffs purport to identify. And absent express statutory language establishing that Congress intended to allow litigants to enlist the judiciary to police freestanding agency communications regarding "almost any facet of agency activity," id. at 1, courts should be reluctant to infer such an extraordinary intention in the IQA.

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)).[12]

With respect to freestanding agency communications transmitting information outside the context of formal rules, regulations, or orders, such as NHLBI's statements and recommendations relating to the DASH-Sodium Trial, neither the IQA nor the OMB Guidelines provide judicially manageable standards to determine whether an agency properly exercised its discretion in deciding a request for correction of such information.[13] Plaintiffs do not dispute the fact that the IQA itself, given its brevity, does not provide meaningful standards. Plaintiffs, instead, assert that the OMB guidelines provide clear standards to judge the quality of NHLBI's information in this case, and that the guidelines identify examples of appropriate *methods* of correction once an

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[12] Plaintiffs overstate the requirements of the "committed to agency discretion" exception in § 701(a)(2). Contrary to Plaintiffs' suggestion, a statute does not have to "commit the decision making to the 'agency's judgment absolutely'" in order for the exception to apply. See Opp. Mem. at 23-24 (quoting Heckler, 470 U.S. at 830). The cases cited by Plaintiffs do not support the proposition that agency discretion must be absolute for there to be no law to apply. Rather, the cases indicate that the § 701(a)(2) exception applies, as indicated, when "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." Heckler, 470 U.S. at 830; Steenholdt, 314 F.3d at 638 (quoting Heckler). The Court, in Heckler, merely goes on to indicate that in such circumstances, "the statute ("law") can be taken to have 'committed' the decisionmaking to the agency's judgment absolutely." Id.

[13] Plaintiffs' arguments to the contrary are unavailing. Initially, Plaintiffs assert that the IQA and the OMB guidelines apply to formal and informal, freestanding agency communications alike. See Opp. Mem. at 24-25. Defendant, however, is not arguing that the IQA or the OMB Guidelines do not apply to informal, freestanding statements (except to the extent that the statements are contained in press releases, in which case the IQA and the Guidelines clearly do not apply, see 67 Fed. Reg. at 8460 (OMB Guidelines § V. 8.). Rather, Defendant is explaining that the *discretion* afforded to agencies under the applicable IQA and OMB Guidelines is at its zenith when a correction of freestanding agency speech is sought, thus precluding judicial review in cases involving freestanding agency statements.

agency has determined that a correction is warranted. See Opp. Mem. at 26-27; 67 Fed. Reg. 8452, 8459 (OMB Guidelines § IV. 2.).

The question of whether the guidelines contain intelligible standards to judge the "quality" of a given body of information, however, is distinct from the question of whether the guidelines provide judicially manageable standards for judging an agency's determination of whether and how to correct a prior communication. On the latter question, the OMB guidelines define the agencies' discretion in the broadest terms. The guidelines provide that "[a]gencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that *they conclude is appropriate* for the nature and timeliness of the information involved." 67 Fed. Reg. at 8458 (emphasis added); see also HHS guidelines, www.hhs.gov/infoquality § E (indicating that in determining correction requests agencies should 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.").[14] Courts have determined that regulations containing similar language granted sufficient discretion to agencies to preclude judicial review under the APA. See, e.g., Steenholdt v. FAA, 314 F.3d 633, 638 (D.C. Cir. 2003) (concluding that a regulation authorizing an agency official to take an action for any reason the official "considers appropriate" confers discretion on the agency and leaves the court with "no law to apply"). And given that the nature of the information involved in

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[14] Plaintiffs' earlier argument that the OMB guidelines are binding, see Opp. Mem. at 17-20, has no bearing on whether they provide judicially manageable standards to evaluate agency discretion in deciding IQA complaints. Because the guidelines themselves grant agencies significant discretion in determining whether informal agency information distribution requires a correction, the fact that the guidelines are "binding" on the agencies does not inform the issue of whether they provide clear criteria to apply.

this case consists of non-binding freestanding NHLBI statements and recommendations, the agency's discretion to determine whether a correction is warranted is at its peak.[15]

Plaintiffs' heavy reliance on the decision in Inova Alexandria Hosp. v. Shalala, 244 F.3d 342 (4th Cir. 2001), is also unavailing. Although the court in Inova concluded that a rule promulgated by HHS's Provider Reimbursement Review Board provided a meaningful standard against which to judge the Board's decision to dismiss a hospital's administrative appeal challenging the disallowance of a portion of the hospital's Medicare reimbursement request, the rule at issue was more concrete and specific than the provisions governing correction requests under the IQA and the OMB guidelines. The rule governing the Board's authority to dismiss appeals provided, "'If [the provider] fail[s] to submit [a] final position paper to the Board by the due date, the Board may dismiss the appeal.'" Inova, 244 F.3d at 347 (quoting terms of rule). The rule's condition that a provider fail to file its paper on time provides a clearer standard than the OMB guideline that informs the agencies "to undertake only the degree of correction that *they conclude is appropriate* for the nature and timeliness of the information involved." 67 Fed. Reg. at 8458 (emphasis added). The decision in Inova thus is distinguishable and does not preclude a finding that NHLBI's decision not to correct its informal information and recommendations regarding sodium intake is committed to its discretion by law.

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[15] Plaintiffs' suggestion that the standards of judicial review contained in the APA supply the court with law to apply in this case is misguided. See Opp. Mem. at 27. Plaintiffs simply confuse the presence of a standard of review with the existence of law to apply. If the mere presence of a standard of review were sufficient to provide meaningful criteria under the APA, then there would be law to apply to every agency action and no agency action could ever be committed to agency discretion, thus eviscerating the exception in § 701(a)(2). Steenholdt, 314 F.3d at 639 (rejecting similar assertion that the "substantial evidence" standard of review provides law to apply). As demonstrated, neither the IQA nor the OMB guidelines provide underlying standards for a court to determine whether an agency's discretionary determination of whether to correct its prior freestanding statements was, for example, arbitrary and capricious. Standards of review do not fill this void.

Finally, the only case to address this issue has determined that an agency's decision to deny an IQA complaint is committed to agency discretion under § 701(a)(2). In re: Operation of the Missouri River Sys. Litig., 2004 WL 1402563 at * 24 (D. Minn. 2004). Although the Missouri River decision does not discuss the OMB guidelines, its conclusion nevertheless supports the proposition that there is no law to apply to NHLBI's decision not to correct its informal statements regarding the DASH-Sodium Trial, thus precluding judicial review of this agency decision under the APA.[16]

II. PLAINTIFFS' CLAIM IN COUNT III THAT NHLBI VIOLATED THE SHELBY AMENDMENT AND THE APA SHOULD BE DISMISSED.

A. Plaintiffs' Claim for the DASH-Sodium Trial Data is Moot.

To the extent Plaintiffs seek access to the DASH-Sodium Trial data under the Shelby Amendment, such a claim is moot for the same reasons their claim for the data under the IQA is moot. See § I. A. above. As discussed, the Trial investigators recently published the requested data in a readily useable format in a medical journal article. See Exhibit A (attached). The data presented in the journal article matches the Plaintiffs' request more closely than what NHLBI could provide to Plaintiffs. See Declaration of Nancy L. Geller (attached as Exhibit B). Any production of data from NHLBI would at best be redundant. Plaintiffs' claim thus is moot and should be dismissed.

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

Plaintiffs' entire support for their standing to assert their claim under the Shelby

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[16] As mentioned in Defendant's initial memorandum, Defendant's argument here is limited to the assertion that neither the IQA nor the OMB guidelines contemplate federal court review of the quality of information referenced in informal agency statements unconnected to formal rulemaking or adjudication. Defendant leaves open the possibility of APA judicial review of the quality of information referenced in formal agency rules or orders which clarify rights or impose obligations.

Amendment consists of one sentence flatly asserting that simply because they "requested and were denied correction and information, [they] thus have standing." Opp. Mem. at 32. This vacuous allegation of standing is not sufficient under Article III. See, e.g., Baur v. Veneman, 352 F.3d 625, 636-37 (2d Cir. 2003) (stating that "a plaintiff cannot rely solely on conclusory allegations of injury or ask the court to draw unwarranted inferences in order to find standing.").

Assuming this statement is an attempt to rely on informational standing, as they apparently have done to support their standing to assert their IQA and APA claims, see Opp. Mem. at 16, Plaintiffs do not have informational standing for their Shelby Amendment claim any more than they do for their IQA claims. As explained above in section I. B., Plaintiffs' alleged information injury is suspect because the Trial data has been available from the Trial investigators for some time, a public access data set was made available through the internet in January 2004, and the specific data in the particular format Plaintiffs requested was published recently in The American Journal of Cardiology. See Exhibit A (attached). Plaintiffs have failed to provide a persuasive theory of standing to assert their Shelby Amendment claim, and therefore it should be dismissed.

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

Plaintiffs' assertion that NHLBI is the proper defendant in their Shelby Amendment claim is based on the faulty premise that NHLBI possessed the Trial data and ignores the fact that their claim is clearly focused on OMB's implementation of the Shelby Amendment in Circular A-110. NHLBI did not possess the Trial data at the time Plaintiffs requested it. First Am. Compl., Exh. 2 at 1. More importantly, Plaintiffs' claim in Count III does not complain directly about their lack of access to the Trial data, but rather targets the *requirements* governing the production of grantee data found in OMB's Circular A-110. First Am. Compl. ¶ 58 (alleging that "Defendant, in excess of his statutory discretion and contrary to law, instead restricted public access only to data from

new studies funded after April 17, 2000 that was cited publicly and officially in support of an agency action with the force of law."), ¶ 59 (alleging that "NHLBI did not make available to Plaintiffs or the public a *procedure* through which the Sodium Trial data, or other similar data, could be obtained through the Freedom of Information Act.") (emphasis added). Clearly, OMB's Circular A-110 is the target and cause of any potential injury suffered by Plaintiffs in this claim.[17] Therefore, regardless of how much judicial deference should be afforded to the Circular, *OMB*, not NHLBI, is responsible for its implementation and is the appropriate defendant for any claim that might be asserted regarding the Circular. Even if Plaintiffs could demonstrate that the restrictions in Circular A-110 are unreasonable, NHLBI could not provide Plaintiffs with their requested relief because NHLBI is not authorized to modify the terms of Circular A-110, only OMB is. Because Plaintiffs incorrectly allege that NHLBI, not OMB, exceeded its statutory discretion by enacting Circular A-110, Plaintiffs fail to state a claim on which relief can be granted.

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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[17] In essence, Plaintiffs are demanding NHLBI to ignore Congress's directive that *OMB* implement the Shelby Amendment and urging NHLBI to develop its own policies for implementing the broad terms of the Amendment. NHLBI is not authorized to do so and is bound by Congress's enactments and OMB's Circular A-110.

Dated: July 30, 2004

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this date, a true copy of the foregoing REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS was served on Plaintiffs by first class mail and electronic mail addressed to:

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