to satisfy the three-part test for standing under Article III of the U.S. Constitution, the plaintiff must show: (1) it suffered an "injury in fact" that is (a) concrete and particularized, (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant, and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992); *Friends of Ferrell Parkway, LLC v. Stasko*, 282 F.3d 315, 320 (4th Cir. 2002); *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. Inc.*, 528 U.S. 167, 180-181 (2000). The party invoking federal jurisdiction bears the burden of establishing the elements of standing. *Steel Company v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998). Plaintiffs must demonstrate that they are not merely asserting a "generally available grievance" about the government, unconnected with a threatened concrete interest of their own. *See Lujan*, 504 U.S. at 573-574.

a. Injury in Fact

i. Concrete and Particularized Injury

Plaintiffs fail to allege that they have suffered a concrete and particularized injury, and at most, assert no more than a generalized grievance shared by members of the

public at large. See, e.g., Taubman Realty Group Ltd. P'ship v. Mineta, 320 F.3d 475, 480-81 (4th Cir. 2003) (finding shopping center developers' alleged injuries not sufficiently concrete or particularized to confer standing). Plaintiffs also fail to demonstrate that they are not merely asserting a "generally available grievance" about government, unconnected with a threatened concrete interest of their own. *See Lujan*, 504 U.S. at 573-574. Plaintiffs must allege that they suffered some specific injury, and it must be more than the merely theoretical injury that all persons may suffer. *See Lujan*, 504 U.S. at 573-574. Plaintiffs allege generally that they have standing to sue because "they have suffered actual or threatened injury due to Defendant's conduct." First Am. Compl. ¶ 9. Plaintiffs, however, make no specific assertions of injury caused by NHLBI's recommendations regarding dietary intake or NHLBI's inability to provide them with the DASH-Sodium data. Thus, none of the Plaintiffs' alleged harms is sufficiently concrete and particularized to confer standing. *See, e.g., Baur v. Veneman*, 352 F.3d 625, 636-37 (2d Cir. 2003).

ii. Actual and Imminent

Plaintiffs might contend that they are injured by NHLBI's dissemination of the results of the DASH-Sodium Trial because this information might cause consumers to

reduce their consumption of salt, thus decreasing the Plaintiffs' constituent members' sales. Even assuming *arguendo* that Plaintiffs had included this theory in their complaint, which they did not, such an injury is based on the hypothetical actions of third parties and is too speculative to constitute the type of "certainly impending" injury necessary to have standing under Article III. *See Whitmore v. Arkansas*, 495 U.S. 149, 150, 155, 158 (1990) (indicating that the injury alleged cannot be "conjectural or hypothetical," "remote" "speculative" or "abstract" but must be "certainly impending").

b. Injury is Not Traceable to NHLBI's Actions

Plaintiffs fail to allege that their purported injury is fairly traceable to the challenged conduct of NHLBI and not attributable to some independent third party not before the Court. Plaintiffs must establish that there is a causal connection between the injury and the alleged violations of the law. *See, e.g., Friends for Ferrell Parkway*, 282 F.3d at 323-24 (finding that a city's failure to build a road and increased traffic, noise, and fumes were not fairly traceable to the United States Fish and Wildlife Services' acquisition of land; since many other factors may have caused Plaintiffs' alleged injuries). Plaintiffs allege that they are somehow injured by the statements and

recommendations of NHLBI regarding the importance of limiting dietary salt intake to moderate levels stemming from the results of the DASH-Sodium Trial and other research, and by their inability to gain access to the trial data. NHLBI's recommendations, however, are not new or unique. Numerous other scientific studies have reached the conclusion that reducing sodium intake reduces blood pressure. *See, e.g., F.J. He and G.A. MacGregor, Effect of Modest Salt Reduction on Blood Pressure: A Meta-Analysis of Randomized Trials*, Implications for Public Health, 16 J. HUMAN HYPERTENSION 761 (2002); *J.A. Cutler, D. Follmann, and P.S. Allender, Randomized Trials of Sodium Reduction: An Overview*, 65 AM. J. CLINICAL NUTRITION 643 (Suppl.) (1997); *M.R. Law, C.D. Frost, and N.J Law, By How Much Does Dietary Salt Reduction Lower Blood Pressure? III. Analysis of Data from Trials of Salt Reduction*, 302 BRITISH MEDICAL JOURNAL 819 (1991). Additionally, the U.S. Dietary Guidelines have made the same recommendation as NHLBI to limit sodium intake to approximately 2400 mg per day. *See* U.S. DEP'T OF AGRIC. AND DEP'T OF HEALTH AND HUMAN SERVICES, NUTRITION AND YOUR HEALTH, DIETARY GUIDELINES FOR AMERICANS (5th ed. 2000). Furthermore, the findings of the 1989 U.S. National Academy of Sciences' (NAS) *Recommended Dietary Allowances* report affirmed the safety and efficacy of a dietary sodium intake of 2400 mg

per day or less. *See* SUBCOMMITTEE ON THE TENTH EDITION OF THE RECOMMENDED DIETARY ALLOWANCES, FOOD AND NUTRITION BOARD, COMMISSION ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, RECOMMENDED DIETARY ALLOWANCES (10th ed. 1989). Any potential claim of injury by Plaintiffs cannot be fairly traceable to the NHLBI, because any one of these numerous other studies or agency reports making the same recommendations could be responsible for Plaintiffs' undefined injury.

The published results of the DASH-Sodium Trial themselves are more likely the cause of any injury allegedly suffered by the Plaintiffs rather than NHLBI's mere dissemination of Dash-Sodium Trial results. The conclusions of the independent scientists who conducted the DASH-Sodium Trial were reported in articles in both the January 4, 2001 issue of the *New England Journal of Medicine* and the December 18, 2001 issue of the *Annals of Internal Medicine*. Plaintiffs are not, however, seeking a correction or any other relief regarding the published results of the DASH-Sodium Trial. Furthermore, the DASH-Sodium Trial scientists are third parties not presently before the court. Plaintiffs have failed to establish that NHLBI's withholding of the data is the cause of their purported injury.

c. Redressability

Plaintiffs purported injuries 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. In determining whether a plaintiff has a sufficient injury to establish standing, courts ask whether a ruling favorable to the plaintiff would eliminate the harm to him. *See, e.g., Friends for Ferrell Parkway*, 282 F.3d at 323-324 (indicating that plaintiffs' injuries likely would not be redressed by relief requested due to other causes of injuries). If a court order declaring a government action illegal or unconstitutional (and ending that government action) would not eliminate the harm to the litigant, then that individual does not have the type of specific injury that would grant him standing to challenge the government action. *See Id.* at 320-321 (indicating that plaintiffs' injury must be "caused by the challenged conduct of the defendant, and not by the independent actions of third parties not before the court"). The numerous other scientific studies, the DASH-Sodium Trial results themselves, the U.S. Dietary Guidelines, and the NAS Recommended Dietary Allowances' recommendations to limit salt intake would all remain unchanged, in circulation, and potentially influencing the public to reduce its consumption of salt. Plaintiffs' purported injury is not likely to be redressed by a favorable decision from this Court, and

Plaintiffs therefore lack standing to sue.

d. Organizational Standing

Plaintiffs do not have organizational standing. An organization has standing to challenge government action that causes injury to the organization itself. *Hunt v. Washington State Apple Adver.* 432 U.S. 333, 343 (1977). An organization also has standing to challenge government actions that cause injury in fact to its members if the organization can demonstrate the following three facts:

> (i) An injury in fact has occurred to the members of the organization that would give individual members a right to sue on their own behalf;
>
> (ii) The injury to the members is related to the organization's purpose; and
>
> (iii) Neither the nature of the claim nor the relief requested requires participation of the individual members in the lawsuit.

Id. at 343.

Plaintiffs have not properly alleged an injury in fact because they have not alleged that their members have suffered a concrete and particularized injury that would give them the right to sue on their own behalf. Therefore, Plaintiffs have not properly alleged organizational

standing. Plaintiffs lack the requisite legal standing to assert their claims in federal court.

2. Judicial Review of NHLBI's Actions Regarding the DASH-Sodium Trial

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 this case, judicial review does not exist under the IQA because there is no private right of action. Furthermore, there exists no final agency action, so the presumption of judicial review does not apply.

a. Private Right of Action Under the Information Quality Act

There is no private right of action under the IQA and an agency's decision to deny a party's information quality complaint is not reviewable by this Court. 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) ("private rights of action to enforce federal law must be created by Congress"). 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 right. *See id.* There is nothing in the IQA that provides a right of action in a court of law for alleged violations 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 established guidelines. 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..." *Id.* at § 515(b)(2)(B). The language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts. The first and only court to address this issue 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, 2004 WL 1402563 (D. Minn. June 21, 2004) (order granting summary judgment).

b. Administrative Procedure Act Judicial Review

The presumption of APA judicial review only applies only if two underlying prerequisites are met: (1) final agency action must have occurred and (2) the agency action is not committed to agency discretion by law. *See* 5 U.S.C. §§ 701(a)(2); *Transactive Corp v. United States*, 91 F.3d 232, 236 (D.C. Cir. 1996) (indicating presumption of APA judicial review does not apply if agency action is committed to agency discretion by law or if action is not final).

i. Final Agency Action

The NHLBI's actions in this case do not constitute a final agency action necessary for judicial review under the APA. A 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). In this case, NHLBI merely described the results of the DASH-Sodium trials, the findings of research scientists, and made recommendations to limit sodium intake to moderate levels. Agency dissemination of advisory information that has no legal impact has consistently been found inadequate

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 legal 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); *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 not final agency action). NHLBI's actions do not constitute final agency action and therefore are not reviewable by this Court.

ii. Agency Discretion

Judicial review is also precluded because the informal agency decisions concerning NHLBI's statements and recommendations regarding the DASH-Sodium Trial were matters "committed to agency discretion by law." There is a strong presumption of reviewability under the APA. *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967). The APA, however, expressly precludes judicial review of agency action "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). "Agency action is committed to the discretion of the agency 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.*

Neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised its discretion in deciding a request to correct a prior communication. In fact, 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. Courts have determined that regulations containing similar language granted sufficient discretion to agencies to preclude judicial review under the APA. *See Steenholdt*, 314 F.3d at 638 (holding that agency's decision under a regulation allowing an agency to take an action "for any reason the Administration considers appropriate" is committed to agency discretion and not

reviewable under APA). Judicial review of NHLBI's discretionary decisions is not available under the APA because the IQA and OMB guidelines at issue insulate the agency's determinations of when correction of information contained in informal agency statements is warranted.

c. APA and Shelby Amendment

Plaintiffs lack standing to assert that NHLBI violated the Shelby Amendment. Plaintiffs allege that NHLBI violated the Shelby Amendment, Pub. L. No. 105-277, 1998 HR 4328, which directs OMB to amend its Circular A-110 to require federal agencies to give the public access to all data generated by federally funded studies. *See* First Am. Compl. ¶¶ 55-61. Plaintiffs claim that NHLBI exceeded its statutory discretion by granting public access only to data from new studies funded after April 17, 2000, that was cited publicly and officially in support of agency action with the force of law. *See id.* ¶ 58. Plaintiffs generally allege that they are "adversely affected and aggrieved by this final agency action, and have no other adequate remedy at law." Compl. ¶ 61. As with their claims under the IQA, Plaintiffs lack standing because they have not alleged an injury that is sufficiently particularized and concrete to satisfy the constitutional requirements for standing.

Furthermore, Plaintiffs fail to state a claim because

OMB, not NHLBI, is responsible for implementing the Shelby Amendment. In their claim, Plaintiffs assert that NHLBI exceeded its statutory discretion under the Shelby Amendment and "restricted public access only to data from new studies funded after April 17, 2000 that was cited publicly and officially in support of an agency action with the force of law." First Am. Compl. ¶ 58. Contrary to Plaintiffs' assertion, OMB, not NHLBI, restricted access to grantee data in the manner described pursuant to its authority under the Shelby Amendment. The Shelby Amendment directs OMB, not NHLBI, to amend OMB Circular A-110 to require federal agencies to make data produced by federal grant recipients available to the public under FOIA procedures. Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, 1998 HR 4328 (1998). OMB implemented the Shelby Amendment and NHLBI merely applied the terms of OMB's revised Circular A-110. Accordingly, Plaintiffs' claim that NHLBI violated the Shelby Amendment fails to state a claim on which relief can be granted.

III. CONCLUSION

The Defendants Motion to Dismiss is granted because the Plaintiffs lack standing to sue, there is no private right of action under the Information Quality Act, and the NHLBI's actions regarding the DASH-Sodium Trial data are not subject

to judicial review under the Administrative Procedure Act.

For the foregoing reasons, it is hereby

ORDERED that Defendant's Motion to Dismiss is GRANTED.

The Clerk is directed to forward a copy of this Order to counsel.

Entered this 15th day of November, 2004.

Gerald Bruce Lee
United States District Judge

Alexandria, Virginia
11/15/04