OMB did not comply.

Therefore, on June 22, 1998, the FY 1999 Treasury and General Government Appropriations Act (H.R. 4104) was reported in the House, accompanied by House Report No. 105-592. House Report No. 105-592, ultimately enacted as a non-binding part of the FY 1999 Omnibus Appropriations Act (Pub. Law No. 105-277) stated:

> **RELIABILITY AND DISSEMINATION OF INFORMATION**
> The Committee urges the Office of Management and Budget (OMB) to develop, with public and Federal agency involvement, rules providing policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies, and information disseminated by non-Federal entities with financial support from the Federal government, in fulfillment of the purposes and provision of the Paperwork Reduction Act of 1995 (P.L. 104-13). The Committee expects issuance of these rules by September 30, 1999. The OMB rules shall also cover the sharing of, and access to, the aforementioned data and information, by members of the public. Such OMB rules shall require Federal agencies to develop, within one year and with public participation, their own rules consistent with the OMB rules. The OMB and agency rules shall contain administrative mechanisms allowing affected persons to petition for correction of information which does not comply with such rules; and the OMB rules shall contain provisions requiring the agencies to report to OMB periodically regarding the number and nature of petitions or complaints regarding Federal, or Federally-supported, information dissemination, and how such petitions and complaints were handled. OMB shall report to the Committee on the status of implementation of these directives no later than September 30, 1999.

See H.R. Rep. No. 105-592, at 49-50 (1998).[9]

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[9] The House and Senate versions of the FY 1999 Treasury and General Government Appropriations Act were merged in H.R. 4104 on September 3 (legislative day, August 31) 1998. The bill was ultimately sent to a Conference

Again, OMB did not comply.

Representative Thomas Bliley (R-VA), chairman of the House Commerce Committee sent a letter to the OMB reiterating the need to comply with the law and reminding it of the previous year's House report language. Bliley expressed frustration over the OMB's failure to act, stating: "I am concerned about OMB's performance in this matter, because the Paperwork Reduction Act of 1995 required OMB to issue such regulations on data quality, and OMB seems to have accomplished little over the last nearly four years" in moving to comply. (Letter from Rep. Thomas Bliley to OMB of 5/20/99; available at www.thecre.com/quality/letter-blibley-lew.html) In May 1999 and March 2000, Representative Jo Ann Emerson (R-MO), a primary IQA sponsor, also sent letters reminding the OMB of its obligations. (Letters from Rep. Jo Ann Emerson to OMB of May 6, 1999 and March 20, 2000; available at www.thecre.com/quality/letter-emerson-lew.html, and www.thecre.com/quality/EmersonLetter20000320.html)

In April 2000, OMB responded to Representative Emerson's inquiries, declining to issue the required guidelines, stating, "At the present time, OMB is not convinced that new 'one-size-fits all' rules will add much to the existing OMB

Committee. Conference Report 105-789 included the House Report's information quality provision.

guidance and oversight activity." (Letter from John T. Spotila, Administrator of the Office of Information and Regulatory Affairs, to Rep. Jo Ann Emerson of April 18, 2000; available at www.thecre.com/quality/20041012_letter.htm)

Congress responded swiftly to OMB's refusal to act. On December 14, 2000, the FY 2001 Treasury General Government Appropriations Act (H.R. 5658) was reported in the House. This time, Congress made the information quality and correction provisions mandatory. H.R. 5658 §515 stated:

> (a) IN GENERAL – The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504 (d)(1) and 3516 of title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of chapter 35 of title 44, United States Code, commonly referred to as the Paperwork Reduction Act.
>
> (b) CONTENT OF GUIDELINES – The guidelines under subsection (a) shall– (1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and (2) require that each Federal agency to which the guidelines apply—(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a); (B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and (C) report periodically to the Director—(i) the number and nature of complaints received by the agency

> regarding the accuracy of information disseminated by the agency; and (ii) how such complaints were handled by the agency.

H.R. 5658 was ultimately incorporated into H.R. 4577, the FY 2001 Consolidated Appropriations Act. As finally enacted, the IQA provided:

> (a) IN GENERAL –[OMB] shall...issue guidelines...that shall provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information)disseminated by Federal agencies....
>
> (b) CONTENT OF GUIDELINES – The guidelines under subsection (a) shall - - (1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and (2) require that each Federal agency to which the guidelines apply – (A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a); (B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a).

V. SUMMARY OF ARGUMENT

The IQA is an important and necessary development in administrative law. Through this statute, Congress imposed enforceable accuracy and quality standards on the executive branch, and granted persons affected by information disseminated in violation of quality standards a judicially reviewable right to seek and obtain a correction.

The IQA's long legislative gestation shows Congress' determination to change business as usual, and to expand the public accountability of federal agencies in the dissemination of influential, non-regulatory information to the

public at large. Neither the statute, nor the OMB Guidelines nor the HHS/NIH Guidelines reflect a lack of conviction in this regard; nor do they convey any sense that agencies are free to tell affected members of the public to mind their own business, and evade judicial review, as the court below apparently believed to be the case.

The principal conceptual error in the district court's analysis of this case lies in the court's failure or unwillingness to appreciate the significance and enforceability of informational rights. It wrongly assumes that the right to information, whether to obtain disclosure of it, or correct it, or protect it or have some other influence on it, does not have equal constitutional status with other rights recognized by Congress and enacted into law, no matter how clearly that right has been conferred by Congress.

The court below is simply wrong from the beginning of its analysis to the end. Congress surely may create and expect the judicial enforcement of informational rights. It has done so before, and has done so here, in enacting the IQA.

In this case, Plaintiffs make a request for the correction of publicly disseminated information in an area of undisputed concern to them. They sought to commence the correction process prescribed by the IQA and agency Guidelines. The Defendant denied the request. Constitutional and prudential standing is established here as clearly as it would be if this was a request for disclosure of information under the Freedom of Information Act which was finally denied.

The district court's further conclusion that the APA provides no remedy is neither tenable nor supported by the relevant authorities. The court's finding that the agency decision is not final is inexplicable. The administrative process is exhausted and there is no conceivable avenue of relief short of judicial review.

Plaintiff's legal rights under the IQA have been denied. No element needed to make the agency decision final is missing.

The court's further conclusion that the decision to correct or commence the correction process is purely discretionary and thus committed to agency discretion by law is equally unsupported. The law itself makes no such statement and there is not a single word in the statute rebutting the presumption of reviewibility under the APA. Moreover, judicial review is guided by an abundance of detailed standards that apply in judging whether disseminated information meets quality criteria. The discretionary function exception never has been applied in a case like this involving statutorily conferred private rights and the district court offers no rationale for extending the doctrine to a statutory rights case like this case. The APA plainly provides an avenue for review of the rights abridged here.

The decision of the district court should be reversed.

VI. ARGUMENT

A. Standard Of Review

Questions concerning jurisdiction and standing are questions of law which the Court reviews *de novo*. See American Canoe Ass'n Inc. v. Murphy Farms Inc., 326 F.3d 505, 512 (4th Cir. 2003). In considering a motion to dismiss, all factual allegations of the Complaint must be taken to be true and the allegations of the Complaint must be viewed in the light most favorable to the Plaintiff. GE Inv. Private Placement Partners II v. Parker, 247 F.3d 543 (4th Cir. 2003).

B. Plaintiffs Have Standing To Seek Judicial Review Of The Denial Of Their IQA Complaint

1. Introduction.

The district court's holding that Plaintiffs have no standing to seek judicial review of Defendant's denial of their IQA Complaint is premised, fundamentally, on the theory that the IQA, and its congressionally created informational rights are jurisprudentially irrelevant. The court below wandered in a thicket of non-germane inquiries, investigating presumed economic affects, speculating on the hypothetical behavior of the public, and perusing the general literature on sodium consumption and blood pressure, without once acknowledging that this case is about an agency's refusal to acknowledge, much less satisfy, the informational rights conferred directly upon Plaintiffs by Congress in the IQA. The agency said "no" and, for the district court, that was the end of the matter.

The IQA is one of several statutes Congress has enacted to control the flow and use of governmental information. The Supreme Court has repeatedly recognized that a statutory right to information confers constitutional standing. Courts have affirmed the public's right to obtain information possessed by the government under the FOIA; to challenge an agency's failure to collect information, see Federal Election Commission v. Akins, 524 U.S. 11, 20-21 (1998) (holding "injury in fact" consists of inability to obtain information that, on respondents' view of the law, must be publicly disclosed by statute); its right to challenge the disclosure of information held by the government; Chrysler Corp. v. Brown, 441 U.S. 281, 318 (1979) ("reverse-FOIA" case standing for the proposition that an agency's breach of a substantive obligation causes an injury in fact); its right to obtain disclosure of information concerning public health and safety; American Canoe Association Inc. v. City of Louisa Water and Sewer Comm'n, 389 F.3d 536 (6th Cir. 2004); the right to expect protection of personal privacy (The Privacy Act § 5 U.S.C. §§ 552(a)); the right to privacy of certain health information (the Health Insurance Portability and Accountability Act of 1996, 48 U.S.C. § 1320 (d)) and other laws. See generally Cass R. Sunstein,

Informational Regulation and Informational Standing: Akins and Beyond, 147 U. PA. L. Rev. 613, 643 n.15.

The IQA provides:

[§ 515]

> (b) The guidelines under subsection (a) shall-
>
> (1) apply to the sharing of and access to, information disseminated by Federal agencies; and
>
> * * * *
>
> (2)(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a).

Given the plain text of the IQA, it is difficult to understand how a court could conclude that an "affected person" who is denied the opportunity to seek and obtain a correction of information being disseminated does not have standing to complain about it and is not in the very same position as the Plaintiffs in the many cases in which informational standing has been recognized.

The controlling cases very strongly support the premise that the IQA confers judicially enforceable rights and the necessary standing to pursue those rights on the Plaintiffs here.

2. Constitutional Standing is Established

Article III of the Constitution precludes public access to the federal courts in the absence of a true "case" or "controversy." Bennett v. Spear, 520 U.S. 154, 162 (1997). To satisfy this requirement, the Plaintiff must "demonstrate that he has suffered 'injury in fact', that the injury is 'fairly traceable' to the actions of Defendant, and that the injury will likely be remedied by a favorable decision."

Bennett at 162 citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)[and other authorities].

In an "informational" case the injury required need not be the deprivation of a personal or economic right as suggested by the court below, but may be satisfied by the deprivation of the right to protect, influence, or, under the IQA, obtain agency data and methods, and to correct the information at issue. See Akins, 511 U.S. at 21 (inability to obtain information that must be disclosed is injury in fact). The Supreme Court held,

> the refusal to permit appellants to scrutinize [the information requested] to the extent [the statute] allows constitutes a sufficiently distinct injury to provide standing to sue. Our decisions interpreting the Freedom of Information Act have never suggested that those requesting information under it need show more than they sought and were denied specific agency records. [citations omitted]

Public Citizen, 491 U.S. at 449.

There is no doubt that Congress has constitutional authority to create a remedy for informational injury and that such injury is "sufficiently concrete to easily pass the constitutional test." Akins, 524 U.S. at 25. However, the district court here demanded far more than is required for Article III standing. J.A.87-90. It denied standing solely for the reason that Plaintiffs "make no specific assertion 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 Plaintiff's alleged harms is sufficiently concrete to confer standing." J.A.90[10]

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[10] The district court held Plaintiffs had not pled injury in fact: (1) because they had only asserted a generalized grievance, not a concrete injury, making "no specific assertions of injury caused by NHLBI's recommendations regarding dietary intake of salt or NHLBI's inability to provide them with the [requested] data;" and (2) because the theory Plaintiffs might have pled, but did not, to show injury was based on the hypothetical actions of third parties in the marketplace.

Plaintiffs' injury, however, was not alleged to have arisen from the commercial impact of the information disseminated, but from NHLBI's refusal to follow the IQA, to respect the relevant Guidelines, and to allow for an investigation of the quality, objectivity and reproducibility of information it disseminated to the public. See Compl. ¶¶ 13, 32-39, 42-49, 52; J.A.9,14-20. Plaintiffs did not need to show that people eat less salt or that any economic or business impact flowed from the dissemination of information. Uniformly consistent Supreme Court authorities addressing the characteristics of informational injury fully support the conclusion that the NHLBI IQA violations pled by Plaintiffs are more than enough to satisfy Article III case or controversy requirements. Akins, 524 U.S. at 21; Public Citizen, 491 U.S. at 449; Chrysler Corp., 441 U.S. at 318; see also Havens Realty Corp. v. Coleman, 455 U.S. 363, 373-374 (1982) (deprivation of information about housing availability constitutes "specific injury" permitting standing).

The district court concluded also that standing was defective because the injury alleged was not "actual or imminent" in the sense that the injury as defined by the district court was the hypothetical action of third parties who might elect to reduce salt consumption. The district court missed the point. The informational injury alleged arose from NHLBI's refusal to disclose the necessary data or to consider the necessity of a correction in accordance with the criteria set forth in the IQA and HHS and NIH Guidelines. That injury already had occurred, and the "actual or imminent" element of Article III standing is met *per se*. See Akins, 524 U.S. at 20; Public Citizen, 491 U.S. at 449.[11]

J.A.89-90. The direct, concrete, and particular injury Plaintiffs actually pled, however, was the violation of their IQA data disclosure and correction rights, and that is enough. Public Citizen, 491 U.S. at 449-50; Akins, 511 U.S. at 21.

[11] Defendant's initial motion to dismiss on mootness grounds was made allegedly on the premise that other blood pressure articles would support the

The district court also found defective standing because the Complaint failed the tests of causation and redressability. J.A.89-96. Again, the district court mischaracterized the informational character of Plaintiffs' rights. If the injury in fact was the NHLBI's violation of Plaintiffs' IQA rights, then it can hardly be said that the injury was not caused by, or "traceable" to, Defendant's final agency action. See e.g., Akins, 511 U.S. at 23. Defendant's violation of the law was the sole cause of the injury alleged in this case.

The same line of analysis also clearly applies to the redressability question. Redress of the injury can be obtained in full here by an order of the court directing NHLBI to follow its own procedures, and invoke the full IQA correction process. There is nothing exceptional afoot when a court orders and agency to follow its own regulations and that is all that is required here for full redressability; such a remedy is well within the power of the judicial branch. See Akins, 511 U.S. at 25 (citations omitted).

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disseminated information even if the DASH-Sodium study did not. This grounds for dismissal was expanded after the DASH-Sodium investigators published a new article purporting to show the beneficial effect of a reduction in dietary sodium across sub-groups. Defendant alleged this new article responded fully to Plaintiffs' data needs as well. 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: Result of the DASH-Sodium Trial, 94 J. Cardiology 222 (July 15, 2004). In response, Plaintiffs filed an affidavit prepared by a well qualified researcher refuting the statement that the Bray article truly addressed their objections. With these matters in dispute, NHLBI dropped its mootness claim during oral argument. Transcript of Oral Argument at 4-5. Nevertheless, judging from the analysis of redressability and causation in the district court's opinion it seems that the court wrongly relied upon a mootness related theory to conclude that Plaintiffs' harm was not caused by Defendant and could not be remedied. On this account, the district court's conclusions are based impermissibly upon disputed facts that cannot properly be resolved in the context of a motion to dismiss.

Neither the district court nor this Court have been asked to fashion a specific correction. However, it appears the district court's sense of the matter was that proving the invalidity of the conclusions drawn from the DASH-Sodium Trial and even the retraction of the information disseminated, would probably not influence public behavior. J.A.89-96.

The district court's mode of analysis jumps the gun. It concluded through an improper prejudgment of the underlying dispute that the information Defendant disseminated is correct and therefore not in need of more investigation, independent testing, or correction. This prejudgment of the matter is reinforced, according to the court by other research articles.[12] J.A.92.

None of these conclusions made by the district court is relevant to Article III standing under the IQA. The district court's prejudgments about the final outcome of the IQA process are speculative, unsupported by any direct and validated authorities, contradicted by authoritative sources cited in the original Complaint for a correction[13] and irrelevant. All Plaintiffs need to show to meet the requirements of Article III standing with respect to redressability is that "they might gain significant relief if they prevail...Appellants' potential gain is undoubtedly sufficient to give them standing." Public Citizen, 491 U.S. at 451.

It is far from a forgone conclusion that the Plaintiffs are wrong in their criticism of the disseminated information at issue. The district court's implicit belief that Plaintiffs cannot obtain relief on the merits is unsupported by the record. In any event, the problem here, as in Bennett, is that the district court has impermissibly confused (and perhaps wrongly evaluated) the likelihood of ultimate

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[12] None of the articles is in the record except to the extent they are generally cited by NHLBI in a letter denying Plaintiffs IQA Complaint.

[13] See J.A.35-38. Excerpts from the statement of Dr. John Laragh, Application For Correction, May 14, 2003.

success of Plaintiffs' correction request with the relevant issues, namely Plaintiffs' right to have the prescribed procedure followed. See Bennett, 520 U.S. at 172.

In this case, Plaintiffs were denied their statutory rights because the Defendant failed to follow its procedures, violating the IQA, the OMB Guidelines, and its own Guidelines. This surely constitutes an injury in fact under the law for which Defendant is solely responsible and it is readily redressable on judicial review. The district court's denial of constitutional standing must be reversed.[14]

C. Prudential Standing Is Established

The Supreme Court has recognized a set of prudential principles that must be satisfied in addition to the irreducible Article III requirements, as a predicate to federal court jurisdiction. The Taubman Realty Group v. Mineta, 320 F.3d 475, 480-81 (4th Cir. 2004). Although the district court did not rely upon the prudential

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[14] The district court denied organizational standing to Plaintiffs. This holding must fall as well. See Hunt v. Washington State Appl. Adv., 432 U.S. 333, 343 (1977); see also Sunstein supra at 654 (recognizing the independent standing of organizations that have a "demonstratable intent in the [subject matter]..."; American Canoe, 389 F.3d at 545-6; Competitive Enterprise Institute v. National Highway Traffic Safety Administration, 901 F.2d 107 (D.C. Cir. 1990). Congress imposed broad IQA obligations on federal agencies, and conferred a broad right to agency compliance with those obligations on the public. Consequently, Appellants' members could bring their own action against Defendant. As the Sixth Circuit noted: "where some actual injury [e.g. the deprivation of an information right] befalls every member of the community, Congress can create standing regardless of the universality of that injury." American Canoe, 389 F.3d at 545 (citations omitted). Germaneness is satisfied by a "mere pertinence" between litigation subject and an organization's purpose. CEI, 901 F.2d at 111 (citations omitted). The subject of this litigation – production and analysis of government information and data related to the human health effects of dietary salt – is germane to the Plaintiffs' organizational purposes. Compl. ¶¶ 7-8, J.A.6-7. Finally, no circumstances exist that would require individual members to participate in the case. CEI, 901 F.2d at 111 (citation omitted).

elements of standing, they were raised below and are properly considered by this Court. They are also easily met here.

The most relevant prudential requirement is the doctrine "that a plaintiff's grievance must arguably fall within the zone of interest protected or regulated by the statutory provisions..." Nat'l Credit Union Admin. v. First Nat'l Branch & Trust Co., 522 U.S. 479, 488 (1998) (citations omitted). It is difficult to make a plausible argument as a practical matter that organizations involved to a substantial degree in medical research, food processing, salt mining and manufacturing, are outside the IQA's zone of interest regarding the government's dissemination of information about salt. There is nothing remote or attenuated about the relevant relationships here; far less involvement in the zone than Plaintiffs have would be sufficient.

The best source of authority for determining whether the zone of interest requirement is satisfied is the statute. Here, as often is the case, the statutory text is the beginning and ending point of the inquiry. See Alexander v. Sandoval, 532 U.S. 275, 287-88 (2001); Touche Ross v. Redington, 442 U.S. 560, 68-69, 578 (1979). The IQA defines the identity of the parties that may seek and obtain a correction of previously disseminated information. It provides that "affected persons" may invoke the statutory remedy, and are invested with statutory rights.

This broad formulation does not necessarily require an "adverse" effect, but is satisfied, according to the plain language, if there is any effect.[15] In any event, statutes identifying an "aggrieved" or "adversely affected" party as the bearer of rights to seek enforcement reflect a "congressional intent to cast the standing net broadly-beyond the common-law interests and substantive statutory rights upon

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[15] It bears mention that any "effect" should also sufficient to establish an injury in fact for purposes of Article III standing, just as the denial of a FOIA request is sufficient to meet all Article III requirements.

which prudential standing traditionally rested." Akins, 524 U.S. at 19 (citations omitted).

There surely is no prudential reason to deny standing in this case. Both Plaintiffs credibly allege that they are affected by denial of their IQA rights regarding the agency's disseminated information concerning salt consumption. Compl. ¶ 7, 8, 13, 30, 31, 33-39, 46, 52; J.A. 6-7, 9, 10, 16-20. Nothing more is necessary. Indeed, if the Plaintiffs are not "affected" by NHLBI's action no one is, and if they do not satisfy the prudential requirements for standing, no one could.

D. The APA Provides A Remedy For Defendant's Denial Of Access To The Correction Process

Having held that Article III criteria are not met in this lawsuit, the district court lacked jurisdiction to consider the merits in any way. See Bell v. Hood, 327 U.S. 678, 682 (1946) (holding that a motion to dismiss may only be decided once the court establishes subject matter jurisdiction over the claims). The court's denial of an APA remedy was, therefore, dictum at best. The court's decision denying APA review of NHLBI's refusal to consider Plaintiffs' IQA Complaint on the merits was, however, clear error and should be reversed as well.

The absence of a specific provision authorizing judicial review of an agency's IQA adjudication carries no implication of an intent to preclude judicial review. A right of action in U.S. district court is expressly created by the APA in any case of "final agency action for which there is no other adequate remedy in a court ...", 5 U.S.C. § 704, and "applied universally" "except to the extent that (1) statutes preclude judicial review or (2) agency action is committed to agency discretion by law." Id. § 701(a); Bennett, 520 U.S. at 175-76. The APA's promise of judicial review is generous, liberally construed, and readily available in the absence of powerful authority to the contrary. See Japan Whaling Ass'n. v. American Cetacean Soc., 478 U.S. 221, 230 n.4 (1986); Block v. Community

Nutrition Institute, 467 U.S. 340, 345 (1984); Inova Alexandria Hospital v. Shalala, 244 F.3d 342, 346 (4th Cir. 2001). There is "a strong presumption that Congress intends judicial review of administrative action." Id. quoting Bowen v. Mich. Acad. Of Family Physicians, 476 U.S. 67, 670 (1986).

The district court held that judicial review under the APA was, nevertheless, unavailable here because (1) Defendant's action is not final agency action and (2) the agency action complained of is committed to agency discretion by law, citing 5 U.S.C. § 701 (a)(2). The court applied the discretionary function exception to the normal presumption of judicial review on the theory that "the IQA and OMB Guidelines insulate the agency's determination of when a correction of information contained in informal agency statements is warranted." J.A.101.[16] Thus, it held there are no "judicially manageable standards by which to review an agency's refusal to make a correction and judicial intervention is inappropriate." J.A.100.

The district court's denial of APA review is not in accordance with law and must be reversed.

There is no factual or legal basis for the conclusion that Defendant's denial of any IQA relief to Plaintiffs was not a final agency action. Final agency action first "must mark the 'consummation' of the agency's decision making process - it must not be of a tentative or merely interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined' or from which 'legal consequences will flow.'" Flue Cured Tobacco Cooperative Stabilization

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[16] In support of this conclusion, the court cites Preamble language in the Federal Register introducing the OMB Guidelines that agencies may reject correction requests that are frivolous or made in bad faith, and generally are not required to make any correction considered untimely or unwarranted. 67 Fed. Reg. 8458. The Preamble language may not, however, be construed to undermine the rights conferred on the public in the IQA, and the district court's reliance on this language is inappropriate for that reason.

Corp. v. EPA, 313 F.3d 852, 858 (4th Cir. 2002) quoting Bennett 520 U.S. at 177-78.

NHLBI denied the request for a correction (more accurately, denied even its obligation to consider the need for a correction), denied Plaintiffs' appeal from that first denial, leaving no place for Plaintiffs to go to seek relief from the agency. It is difficult to understand how this could be described as anything other than the "consummation" of the administrative decision making process, making the matter ripe for judicial review. The district court relies mostly on the notion that the agency's action in refusing to remove or modify the recommendation to restrict salt use has no legal consequences to Plaintiffs. Here again the district court misses the point. The legal consequence of the agency's final action denying the application and appeal is that Plaintiffs are deprived of their rights to seek and obtain correction of incorrect information. The agency's denial of an IQA application is itself a legally germane "consequence," just as is an agency's denial of a request for the disclosure of information under FOIA.

The district court may have believed that an agency's failure to correct publicly disseminated health information based upon bad science has no "legal impact," but such a conclusion plainly cannot stand following enactment of the IQA.

The district court's further conclusion that the agency action is committed to agency discretion by law, similarly ignores the significance of the new informational rights created in the IQA.[17] This Court has held that the exception to

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[17] The district court held that the reference in the IQA to the development of "administrative mechanisms" implied Congress' intent to limit the review of correction complaints to an agency adjudication to the exclusion of judicial review. We cannot conjure any known rule of statutory construction to support this interpretation. Moreover, this statutory phrase is far short of the necessary "express supercedure" that is required to override the applicability of APA provisions. 5

judicial review in play here "is a 'very narrow one,' reserved for 'those rare instances' where statutes are drawn in such broad terms that in a given case there is no law to apply." Inova Hospital, 244 F.3d at 346, quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971). "There is no law to apply 'if the statute is drawn so that a court would have no meaningful standard against which to judge an agency's exercise of discretion.'" Id. quoting Hechler v. Chaney, 470 U.S. 821, 830 (1985). "In other words, judicial review is foreclosed if the 'agency action of which Plaintiff complains fails to raise a legal issue which can be reviewed by a court by reference to statutory standards and legislative intent.'", Id.; however, regulations can provide "standing for judicial review," of agency action if the statute lacks judicially manageable standards for such review. Id. quoting CC Distrib., Inc. v. United States, 883 F.2d 146, 154 (D.C. Cir. 1989); see also Center for Auto Safety v. Dole, 846 F.2d 1532, 1534 (D.C. Cir. 1988).

The discretionary function exception has not been applied by the Supreme Court, or any other court, to our knowledge, to a private party's direct exercise of express statutory rights. It is appropriately applied to, for example, an agency decision to initiate enforcement proceedings, reconsider an action taken absent a statutory obligation to do so, agency personnel decisions, national security matters, the setting of agency priorities, or other decisions of a housekeeping or management nature. Lincoln v. Vigil, 508 U.S. 182, 191-93 (1993) (collecting authorities). In none of these circumstances is a congressionally-bestowed public right implicated. The district court gives no good reason for enlarging the discretionary function exception to a case like this one.

U.S.C. § 559; see also Professional Reactor Operator Soc. v. N.R.C., 939 F.2d 1047, 1052 (D.C. Cir. 1991) (Ruth Bader Ginsberg); 92 Cong. Rec. 2148, 2159 (1946) ("[I]mplied amendments [to the APA] shall be precluded.")

The district court found no standards to apply in reviewing Defendant's denial of Plaintiffs' IQA rights, but surely did not look very hard to find the applicable standards. They are present in abundance.

If, for example, the agency outright refuses to institute a correction process because the request is considered frivolous or otherwise not worth the effort, that would be reviewable under 5 U.S.C. § 706 where the reviewing court could decide to "compel agency action unlawfully withheld" and would test the agency's reasoning to determine whether its actions are "arbitrary and capricious, an abuse of discretion or otherwise not in accordance with law." Courts conduct this kind of review every day.

If the agency commences a correction process in response to a more substantial correction request, the agency must be guided by the statutory standards for the public dissemination of information set forth in the IQA and elaborated upon in detail in the OMB and agency-specific guidelines implementing the statute. The IQA provides that there shall be a process for "ensuring and maximizing the quality, objectivity, utility and integrity of information...disseminated by an agency." 44 U.S.C. § 3516(b)(2) note. The Guidelines explain at great length and implement what is meant by each statutory quality test mandated. This is hardly a standard-less environment.

If, for example, an agency disseminated science or health information to the public that was not supported by any science, the quality standards prescribed here surely would not be met and if the agency refused a correction, its action would be arbitrary and capricious, in the same sense that an agency's action in promulgating a regulation addressing matters requiring scientific support would be arbitrary and capricious if the science did not support the rule. Courts regularly test agency regulations of a scientific or technical nature against their support in the record, and may strike down rules that are not supported. See e.g. Leather Ind. Of

America v. EPA, 40 F.3d 392, 403-05 (D.C. Cir. 1994); American Trucking Assn. v. EPA, 175 F.3d 1027, 1055 (D.C. Cir. 1999); Horsehead Resource Dev. Co. v. Browner, 16 F.3d 1246, 1269 (D.C. Cir. 1994).

Courts may, of course, accord some degree of deference to agency choices or interpretation, but demonstrably bad science is not properly relied upon by an agency whether it is reflected in a regulation or in publicly disseminated information. There is no mystery to this process and no substance to the district court's claim that there are no judicially manageable standards to apply in determining whether an agency was arbitrary or capricious in refusing to make a correction or consider a request to commence the process of determining whether a correction is appropriate.

Here there is no doubt that Defendant was arbitrary and capricious because it refused to consider a request to commence the correction process without making a finding that the request was frivolous or in bad faith. This conduct should constitute a violation of IQA rights by Defendant, if the IQA is to have any force at all.

It surely is true that there will be an experimental period in the IQA's implementation. It is a new law, and it will take creativity on the part of the agency, the judiciary and the requesters to evolve the best approach toward fashioning an appropriate remedy framework. But the need for time and additional cases to work out the contours and details of that framework is no reason to nullify the substantive rights and protections afforded to the public by the IQA. Federal agencies did not, at first, have much affection for the APA, substantially resisting its implementation. It is not surprising to see the same reaction here; but the solution should by no means be the nullification of the public's, and the Plaintiffs', IQA's rights.

VI. CONCLUSION

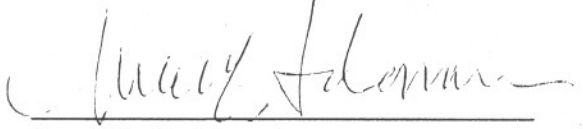
The decision of the district court should be reversed.

VII. REQUEST FOR ORAL ARGUMENT

This is a case of national significance for which oral argument is appropriate.

Respectfully submitted,

SALT INSTITUTE
THE CHAMBER OF COMMERCE
OF THE UNITED STATES



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STATUTORY AND REGULATORY ADDENDUM

INDEX

Item	Date	Page
44 U.S.C. §3516 note	Amended December 21, 2000	S.R.1
Office of Management and Budget – Guidelines for Ensuring and Maximinzing the Quality, Objectivity, Utility, and Intergrity of Information Disseminated by Federal Agencies; Notice; Republication	February 22, 2002	S.R.3
United States Department of Health & Human Services Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public	Last Revised November 13, 2003	S.R.13
United States Department of Health & Human Services, National Institutes of Health Guidelines for Ensuring the Quality of Information Disseminated to the Public	Last Revised November 12, 2003	S.R.34