No. 05-1097

IN THE

# United States Court of Appeals

FOR THE FOURTH CIRCUIT

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

*Appellants/Plaintiffs,*

v.

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

*Appellee/Defendant.*

ON APPEAL FROM A FINAL DECISION OF
THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF VIRGINIA, ALEXANDRIA DIVISION

## APPELLANTS' REPLY BRIEF


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## INTRODUCTION AND SUMMARY OF ARGUMENT IN REPLY

This case presents an important issue of first impression: whether agency denials of petitions filed under the Information Quality Act (IQA), 44 U.S.C. § 3516, note (2000), are subject to judicial review under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. As described at length in the opening briefs filed by plaintiffs and their amici, the IQA was passed in December 2000 after years of efforts by Congress to have the Office of Management and Budget (OMB) implement previously enacted information-quality mandates. The IQA—and guidelines promulgated pursuant thereto—establish clear and objective standards for ensuring information quality and integrity, and administrative mechanisms for adjudicating IQA petitions. An agency's denial of an IQA petition under the administrative review process established pursuant to the statute has all the hallmarks of a prototypical "final agency action" subject to APA judicial review.

Defendant has fundamentally abandoned the district court's holding and reasoning. Virtually the entirety of its brief is now premised on its assertion that "there is no evident reason for this Court to decide whether an agency's resolution of [an IQA] correction request would be subject to judicial review," because, defendant argues, plaintiffs did not file a proper IQA request. Appellee's Br. at 22. Defendant's eleventh-hour effort to recast this case fails for several reasons.

First, defendant never argued below that the judicial review issue was not presented on the ground that plaintiffs' IQA request was deficient, and, "[a]s this court has repeatedly held, issues raised for the first time on appeal generally will not be considered." Muth v. United States, 1 F.3d 246, 250 (4th Cir. 1993).

Second, defendant's argument fails to account for the procedural posture of this case. This appeal is from the Federal Rule of Civil Procedure 12(b) dismissal of plaintiffs' complaint. As a result, for this appeal, all facts pleaded by plaintiffs must be accepted. Because the complaint alleges that plaintiffs filed an IQA petition seeking both "data disclosure and information correction," J.A. 16, nothing more is now required to establish plaintiffs' right to judicial review. Defendant's challenge on the merits to the adequacy of the allegations and demand in plaintiffs' IQA petition—if not already waived—may be addressed to the District Court on remand, but for now, that challenge provides no basis for holding APA judicial review is unavailable vel non.

Third, even if defendant's argument were properly before this Court, plaintiffs followed IQA procedure and submitted a valid IQA petition seeking information and information correction. Defendant's arguments to the contrary, and the shell game it attempts to play with plaintiffs' IQA petition and request for reconsideration, simply highlight the reasons why judicial review is needed.

On the merits, defendant has strikingly little to say. Like the District Court, defendant's principal response is to recharacterize plaintiffs' complaint as a challenge merely to "an agency's report[] or other statement[]." Appellee's Br. at 22, 30. As plaintiffs and their amici have explained, however, the complaint at issue in this case is not some abstract challenge to an agency's report, as in Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 430 (4th Cir. 2002). Rather, the complaint at issue challenges the agency's denial of plaintiffs' IQA requests following exhaustion of the statutorily mandated administrative review process. Under well-established principles of administrative law, the denial of plaintiffs' petition and request for reconsideration constitutes "final agency action" that is subject to APA judicial review, because it challenges the consummation of an agency's determination regarding the plaintiffs legal right to "obtain correction" under the IQA. The District Court's contrary decision should be reversed.

## I. THE COURT SHOULD DISMISS DEFENDANT'S BELATED EFFORT TO AVOID CONSIDERATION OF THE QUESTION DECIDED BELOW AND PRESENTED TO THIS COURT

### A. Defendant's Primary Argument Was Waived

The District Court below held that judicial review of an agency's denial of an IQA petition is categorically unavailable under the APA. Defendant's principal response in this Court is not to defend that ruling, but rather to assert—in terms suggesting that defendant itself recognizes the weakness of the lower court's

ruling—that "there is no evident reason for this Court" to decide that issue. Appellee's Br. at 22. The reason that defendant provides for side-stepping the question presented is that plaintiffs' underlying petition purportedly failed to present a proper IQA request. See id. at 22. That argument, however, fails at the most basic level because it was not presented either in agency proceedings or in the District Court and it therefore has been waived. Plaintiffs' administrative complaint was styled, filed, and adjudicated as an IQA petition. In addressing that petition before the agency and District Court, defendant responded substantively, in great detail, to the IQA arguments, but it never once argued that plaintiffs' initial request was not an IQA petition.

In the proceedings before the District Court, defendant presented a number of arguments in support of its motion to dismiss, including that (1) plaintiffs lacked standing, (2) the IQA does not provide for a private right of action, and (3) the requirements for judicial review under the APA were not satisfied. See Mem. in Supp. of Def.'s Mot. to Dismiss at 2-3. Nowhere did defendant assert that plaintiffs' underlying IQA petition failed to qualify as such, or was insufficient, because the petition purportedly failed to seek correction of the challenged disseminations. Indeed, defendant expressly acknowledged before the District Court that plaintiffs' IQA petition did in fact seek correction of the challenged

disseminations.[1] The District Court clearly relied upon defendant's representations and framing of the issues, deciding the matter based on the understanding that there was no challenge to the validity of the underlying IQA petition. J.A. 75 (listing the issues presented by the parties as (1) whether plaintiffs lacked standing, (2) whether there is a private right of action under the IQA, and (3) whether plaintiffs failed to state a claim with respect to the Shelby Amendment).

Not until the filing of its brief in this Court has defendant asserted that plaintiffs' request is deficient in such a way as to not qualify for treatment as an IQA petition. Indeed, as noted above, defendant took the precise opposite position below. Accordingly, this argument has been waived and should not be considered by this Court. See, e.g., Holland v. Big River Minerals Corp., 181 F.3d 597, 605 (4th Cir. 1999) ("Generally, issues that were not raised in the district court will not be addressed on appeal."); Muth, 1 F.3d at 250 ("As this court has repeatedly held, issues raised for the first time on appeal generally will not be considered.").

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[1] See, e.g., Reply Mem. in Supp. of Def.'s Mot. to Dismiss at 1 (referring to defendant's administrative decision as a "denial of Plaintiffs' administrative correction request") (emphasis added); id. at 5 (noting that NHLBI determined that "its statements regarding the DASH-Sodium Trial did not warrant correction" and asserting that "[t]he agency's decision not to correct its information did not deprive Plaintiffs of the study's underlying data") (emphasis added); id. at 6 (referring to plaintiffs' petition as a "request for correction of NHLBI's statements") (emphasis added); id. at 10 (referring to defendant's administrative ruling as an "exercise of discretion not to correct freestanding agency statements") (emphasis added); id. at 17 (referring to defendant's administrative decision as a "decision not to correct") (emphasis added); id. at 18 (same). Furthermore, as defendant itself admits in its brief to this Court, the complaint filed in the District Court clearly sought correction as well. Appellee's Br. at 19 (noting that "the complaint sought an order requiring HHS 'to correct' the NHLBI statements cited in the petition").

### B. Even If Not Waived, Defendant's Argument Is Improper In Light Of The Procedural Posture Of This Case

Even if defendant's challenge to the validity of plaintiffs' underlying IQA petition had not been waived, the argument fails in view of the current procedural posture of this case. This appeal is from the District Court's Rule 12(b) dismissal of plaintiffs' action. Accordingly, the pleading before the Court is plaintiffs' complaint—not plaintiffs' underlying IQA petition. All facts pleaded in the complaint therefore must be accepted as true and construed in plaintiffs' favor. Mayes v. Rapoport, 198 F.3d 457, 460 (4th Cir. 1999); Goldstar (Panama) S.S. v. United States, 967 F.2d 965, 967 (4th Cir. 1992). Thus, the Court need—and should—look no further than the facts alleged in the complaint in order to determine whether the overriding question of judicial review is properly before it.

Plaintiffs' First Amended Complaint alleges, inter alia, that (1) defendants violated the IQA, J.A. 5, 12-14; (2) plaintiffs filed an IQA petition seeking both "data disclosure and information correction," J.A. 16; (3) defendant denied plaintiffs' IQA petition based, inter alia, on purported compliance with the requirements of the IQA, J.A. 16-17; (4) plaintiffs timely appealed defendant's denial of their IQA petition, J.A. 17; and (5) defendant denied plaintiffs' administrative appeal, J.A. 18. Accepting these allegations as true ends the inquiry and squarely forecloses analysis of the merits of the underlying IQA petition.

Defendant's arguments with respect to these issues—if not already waived—are contested by plaintiffs on the facts and law and therefore must be raised and presented in the first instance to the District Court on summary judgment or at a trial following remand.

### C. Plaintiffs' Underlying IQA Petition Presents A Valid Claim

In any event, as defendant recognizes, plaintiffs' IQA petition explicitly "sought 'correction' " of information pursuant to the [IQA]." Appellee's Br. at 14.[2] To begin this process, plaintiffs sought release of the data underlying the challenged statements—to which they clearly were entitled under the IQA. S.R. 19 (HHS Guidelines at § D(2)(c)(2)) ("[A]gency guidelines, in all cases, shall require a disclosure of the specific data sources that have been used and the specific

[2] See, e.g., J.A. 26 ("This petition seeks correction of information disseminated by NHLBI, which directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in *all* individuals."); J.A. 28 (containing a section heading entitled "A Description of the Information for Which Correction is Sought"); J.A. 29-30 (containing a list of statements made by defendant that "form the basis of th[e] petition and constitute the specific information being challenged as a violation of the Data Quality Act"); J.A. 32 ("The disseminated information being challenged by this petition is in violation of both the presentation and substance prongs of the objectivity standard."); J.A. 33 ("The information being challenged by this petition, in combination with the lack of publicly available data on the DASH-Sodium study, has resulted in a clear public message being presented by NHLBI, i.e., all individuals can reduce their blood pressure by reducing sodium intake."); J.A. 34 ("[T]he agency's release of the information for which correction is being sought is inconsistent with the agency's obligations under the [IQA's] basic substantive objectivity standard.").

quantitative methods and assumptions that have been employed.") (emphasis added).[3]

Rather than directly address plaintiffs' express request for correction of information and assertion that access to such information is an integral part of the IQA, defendant again attempts to obfuscate the issue. First, defendant contends that plaintiffs expressly "disavowed" any challenge to the substantive accuracy of the statements at issue; second, it chastises plaintiffs for purportedly making no effort to demonstrate that the challenged statements were wrong; and finally, it accuses plaintiffs of attempting to bypass the agency's correction mechanisms. Appellee's Br. at 28-29. Each of these contentions is without merit.

First, plaintiffs did not disavow any challenge to the substantive accuracy of the information at issue. As noted above, the IQA requires disclosure of

[3] See also S.R. 11 (67 Fed. Reg. 8452, 8459 (Feb. 22, 2002)) ("Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation."); id. ("[T]he agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified an disclosed to users."); S.R. 18 (HHS Guidelines at § D(2)(c) (same); S.R. 25 (HHS Guidelines at § D(4)(f) ("In the case of analytical studies, HHS agencies will make provisions for sufficient transparency about data and methods so that an independent reanalysis could be undertaken by a qualified member of the public."); S.R. 57 (NIH Guidelines at §VII) (stating, with respect to influential information, that, "[a]fter publication, research data, any unique reagents, and any supporting data that form the basis of any research communication should be made available promptly and completely to any person who seeks further information.").

underlying data. A fair reading of plaintiffs' IQA petition—and certainly the reading intended by plaintiffs—establishes that plaintiffs sought correction of the challenged statements, with release of the underlying data being the logical first step in the correction process. The portion of the petition selectively quoted by defendants—which states that "we are not at this time directly challenging the substantive accuracy of the enumerated statements," J.A. 32 (emphasis added)—was simply a recognition of the unremarkable fact that plaintiffs would not be in a position to directly challenge the substantive accuracy of the disseminated information until the underlying data was released and tested.

Second, defendant's criticism of plaintiffs' inability to affirmatively demonstrate that the challenged statements were incorrect—or to propose specific qualifications to those statements—is disingenuous.[4] Plaintiffs obviously could not conclusively demonstrate the inaccuracy of the disseminated information or suggest specific qualifications until they had received and independently tested the underlying data defendant was obligated to provide to meet IQA transparency requirements. The critical role that Congress intended the IQA to play in ensuring the quality of information disseminated by the government would be gutted if an

[4] Defendant's hyper-technical treatment of the language in appellants' initial IQA petition is also not in keeping with the language or spirit of the statute and the IQA guidelines. In fashioning guidelines to implement the IQA, OMB explicitly recognized that its implementation would be an "evolutionary process." S.R. 10.

agency could respond to an IQA petition seeking correction of the data by simply refusing to release the data in the first place.[5]

Third, the suggestion that plaintiffs attempted to bypass the agency's correction mechanisms is nonsensical. Plaintiffs filed a detailed IQA petition that fully identified the challenged agency disseminations. It then sought disclosure of the underlying data as the first step in the correction process. This request was denied.

Having been denied the information their IQA petition sought for purposes of testing the validly of the agency's disseminated recommendations on sodium intake, plaintiffs included in their request for reconsideration explicit requests for correction:

> CONCLUSION AND RELIEF REQUESTED
>
> For the reasons stated above, Petitioners request that their Petition be granted. Petitioners further request: (1) that the NHLBI correct the disseminating information by removing it from its publications and website, and (2) that NHLBI be ordered to cease disseminating the subject information until the requested data is produced.

[5] The IQA requires, *inter alia*, that the analysis of the data relied upon by the government be capable of being replicated. This test cannot be met where the government has refused to release the necessary data.

J.A. 61. Responding to plaintiffs' request for reconsideration, defendant expressly acknowledged the correction requests and denied them:

> Dear Messrs. Kovaks [sic; Kovacs] and Hanneman:
>
> I am responding, on behalf of the National Heart, Lung and Blood Institute (NHLBI), to your request for reconsideration (Appeal) under the National Institutes Health "Guidelines for Ensuring the Quality of Information Disseminated to the Public" (NIH Guidelines). The Appeal concerns NHLBI's denial of your May 14, 2003 request for correction (Correction Request) seeking copies of NHLBI grantee data. The Appeal asks that NHLBI: (1) "correct the disseminating information by removing it from its publications and website" and (2) "be ordered to cease disseminating the subject information until the requested data is produced." The data at issue is from the NHLBI grant-funded DASH-Sodium trial and, as described in the Correction Request, concerns "DASH-Sodium blood pressure data for each subgroup... at each of the three levels of dietary sodium intake, including the missing 2,400 mg/day intake level, on both the control diet and the DASH diet." The Appeal claims that NHLBI, in failing to supply you with copies of the requested data, has violated the NIH Guidelines. Upon review of the relevant documents and consideration of all the issues and arguments raised, I affirm the agency's denial of your Correction Request.

J.A. 69 (footnotes omitted; emphasis added).[6] Thus, the administrative proceedings plainly resulted in an unequivocal denial of explicit correction requests made by plaintiffs in addition to their information requests. The government's belated argument to the contrary simply seeks to ignore what is in the record. Far from attempting to bypass the agency's correction mechanisms, plaintiffs have followed the prescribed procedures to the letter and have been stonewalled by defendant at every step of the process.

Ultimately, the shell game that defendant attempts to play with plaintiffs' IQA petition in order to preclude the Court from reaching the threshold issue of judicial review serves only to reinforce the need for such review. For example, defendant's primary assertion on appeal—that plaintiffs' IQA petition is insufficient because plaintiffs initially took the prudent step of invoking their right to obtain and study supporting data prior to suggesting specific corrections or retractions—is, at best, disingenuous.

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[6] In addition to data disclosure, the request for reconsideration raised IQA challenges to the agency's determinations that the disseminated information was not "influential", the underlying data need not be reproducible, the disseminated information was "objective", peer review was enough to bar an IQA petition, the agency could use the "totality of scientific evidence" to deny plaintiffs' request without disclosing what the evidence was, and the Freedom of Information Act (FOIA) limited IQA obligations. J.A. 57-60.

IQA petitioners bear the burden of proof in seeking relief under the statute. S.R. 26 (HHS Guidelines at § E) ("Complainants should be aware that they bear the 'burden of proof' with respect to the necessity for correction as well as with respect to the type of correction they seek."); S.R. 53 (NIH Guidelines at §VI) (same). Had plaintiffs taken the approach now suggested by defendant and filed an IQA petition proposing specific corrections or retractions without first obtaining and testing the underlying data, defendant almost certainly would have denied plaintiffs' petition for failure to satisfy their burden of proof. As illustrated by defendant's denial of plaintiffs' IQA appeal, however, plaintiffs fare no better by taking the prudent approach, because defendant purports to have the authority to withhold underlying data and then insist on upholding the dismissal of IQA petitions that do identify specific requests for correction or retraction. Thus, as this case clearly illustrates, agencies acting without the prospect of independent judicial review may take a "heads I win, tails you lose" approach to adjudicating IQA petitions—denying such petitions for any number of reasons, all while refusing to provide petitioners with access to the underlying data needed to meet their burden of proof in seeking correction.

Equally troubling is defendant's apparent belief that it may unilaterally construe plaintiffs' IQA petition as something other than an IQA petition. Defendant argues at length that plaintiffs should have invoked the disclosure

provision of the Shelby Amendment, not the IQA. In so doing, defendant further asserts that, because Shelby is inapplicable, plaintiffs are not entitled to relief, and the IQA cannot be invoked. The unsupported claim that plaintiffs' request for scientific transparency—guaranteed by the IQA and required by defendant's own IQA guidelines—unwittingly transformed a request for IQA correction into an untimely Shelby/FOIA request for grantee data is groundless. Supplying the data, sources and methods needed to determine scientific reproducibility is an integral IQA requirement, and is not superseded or otherwise affected by either Shelby or FOIA.

Defendant's effort to unilaterally reclassify plaintiffs' IQA petition in order to deprive plaintiffs of judicial review only reinforces the need for judicial oversight of agency handling of IQA petitions. Just like a plaintiff in court, a petitioner in administrative proceedings is the master of its own pleadings. The fact that an agency believes that a given request should have been made in a different pleading does not permit the agency to unilaterally recast an IQA petition to terminate plaintiffs' right to judicial review. If defendant believes that plaintiffs' IQA petition is defective or insufficient in some manner (assuming this argument is not waived), that is a defense to the merits of the petition. Just as a FOIA request seeking documents within one of the FOIA's enumerated exemptions is subject to the same administrative appeal and judicial review

procedures as any other FOIA request, an IQA petition—even if seeking data to which the agency believes the petitioner is not entitled—is subject to the same administrative and judicial review procedures that any other IQA petition would receive.

## II. AN AGENCY'S DENIAL OF AN IQA PETITION FOLLOWING THE EXHAUSTION OF THE ADMINISTRATIVE APPEALS PROCESS IS SUBJECT TO JUDICIAL REVIEW UNDER THE APA

When it comes to addressing the central question presented by this appeal—whether an agency's denial of an IQA request is subject to judicial review under the APA—defendant not only has very little to say, but it again attempts to avoid the question altogether by mischaracterizing the adjudicated denial of an IQA petition as a free-standing objection to the contents of an agency report or statement. Defendant's effort is unavailing.

### A. The "Final Agency Action" Requirement Is Readily Met

Agency action is considered final under the APA when it (1) is not "of a merely tentative nature," but instead "mark[s] the consummation of the agency's decisionmaking process"; and (2) is "one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (citations omitted). Here, plaintiffs' IQA petition was denied. The administrative appeal of this decision also was subsequently denied, thereby unquestionably "mark[ing] the consummation of the agency's

decisionmaking process." Id. at 178. This denial determined plaintiffs' rights—as well as the agency's obligations—under the IQA vis-à-vis the challenged disseminations. Thus, both finality elements are met. Id. See also Br. for Amicus Curiae Grocery Manufacturers of America (GMA) at 16-20.

In response, defendant points to this Court's decisions in Flue-Cured Tobacco, 313 F.3d at 430, and Invention Submission Corp. v. Rogan, 357 F.3d 452 (4th Cir. 2004), and argues that agency statements lacking the force of law cannot constitute final agency action. Defendant's reliance on those cases overlooks a critical fact: plaintiffs have never contended that the challenged statements—standing alone—constitute final agency action. Rather, the final agency action at issue in this case is defendant's denial of plaintiffs' IQA petition and subsequent administrative appeal. Neither Flue-Cured Tobacco nor Invention Submission Corp. involved a challenge to an agency action that represents the culmination of a statutorily created administrative appeals process under an Act establishing objective criteria ensuring the quality and integrity of information disseminated by the government. Instead, those cases involved free-standing challenges to the release of a government report (Flue-Cured Tobacco) and an advertising campaign (Invention Submission Corp.). Neither case remotely resembles the facts here.

Next, defendant argues that the IQA cannot transform non-final agency statements into final agency action. That argument also fails. Again, defendant

miscasts plaintiffs' argument. Plaintiffs do not assert that passage of the IQA directly affected the finality of agency disseminations.[7] Rather, it is the denial of an IQA petition and request for reconsideration that is APA final agency action. This position is wholly unremarkable and it has been adopted by nearly every commentator that has addressed this issue. See Br. for Amicus Curiae GMA at 19 n.4.

Defendant further asserts—apparently as part of the same argument—that the agency's administrative mechanism is plaintiffs' exclusive remedy. The Supreme Court's decision in Kissinger v. Reporters Committee For Freedom of the Press, 445 U.S. 136, 148-49 (1980)—the sole precedent relied upon by defendant to support this point—is readily distinguishable. Reporters Committee is not an APA case. Rather, the question before the Court in that case was whether to imply a private right of action under either the Federal Records Act of 1950, 44 U.S.C. § 2901 et seq., or the Records Disposal Act. 445 U.S. at 148-49. The Court, applying one of its tools of statutory construction, concluded that, because these

[7] Defendant's continued citation of Flue-Cured Tobacco and Invention Submission Corp.—and its parenthetical suggestion that, under plaintiffs' theory, the IQA somehow should have affected the outcome of these cases despite the fact that its procedures were never invoked, see Appellee's Br. at 34—again mischaracterizes the issue before the Court. Plaintiffs have never suggested that the IQA somehow affects the finality of agency disseminations, or that it may lead to final agency action, in cases in which it is never invoked.

statutes provided for particular remedies, it should not read the statutes to imply additional remedies. Id.

Defendant's attempt to apply this maxim to a case involving the APA is squarely foreclosed, however, by the "well-settled presumption favoring interpretations of statutes that allow judicial review of administrative action." McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479, 496 (1991); see also Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967) ("[J]udicial review of final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of congress."); Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 346 (4th Cir. 2001) (this Court must begin its analysis "with the strong presumption that Congress intends judicial review of administrative action"). Thus, Reporters Committee does not preclude judicial review of defendant's denial of plaintiffs' IQA petition.[8]

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[8] The presumption in favor of judicial review under the APA also defeats defendant's suggestion that judicial review is unavailable because the IQA refers to "administrative mechanisms" for challenging the denial of an IQA petition. See Appellee's Br. at 34. See also Br. for Amicus Curiae National Association of Home Builders (NAHB) at 12-13 (citing reverse FOIA cases). Congress is presumed to be aware of the well-settled presumption of the availability of judicial review of final agency action under the APA when it legislates. That Congress expressly provides for administrative review of an agency action in no way precludes judicial review of that action. Indeed, courts have had no trouble finding an APA right to judicial review of final agency action taken under the National Environmental Policy Act (NEPA) despite the fact that NEPA (1) contains no express statutory right to such review, and (2) provides for administrative oversight

Defendant's only other argument with respect to finality is its assertion that it is not uncommon for parties that participate in agency proceedings to be denied access to subsequent review in federal court. Defendant cites a number of cases purportedly supporting this argument. Appellee's Br. at 37. As explained below, none of these cases applies here.

First, Gettman v. DEA, 290 F.3d 430 (D.C. Cir. 2002)—the primary case relied upon by defendant—has nothing to do with APA finality. The issue in Gettman was whether the petitioners, who sought to initiate DEA rulemaking proceedings, met the standing requirements of Article III. It therefore has no bearing on this Court's determination of whether defendant's denial of plaintiffs' IQA petition was APA final agency action.

Second, the party claiming finality in FTC v. Standard Oil Co., 449 U.S. 232 (1980), was challenging the agency's issuance of a complaint that commenced agency proceedings, while those proceedings were still being adjudicated. Id. at 242. Thus, the Court declined to intervene because "[j]udicial intervention into the agency process denies the agency an opportunity to correct its own mistakes and to apply its expertise," and "also leads to piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been

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by the Council of Environmental Quality. See, e.g. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410-11 (1971).

unnecessary." Id. By contrast, defendant here already has declined to "correct its own mistakes" or "apply its expertise," and proceedings before the agency unquestionably are complete.

Third, the agency at issue in Regional Mgmt. Corp. v. Legal Serv. Corp., 186 F.3d 457 (4th Cir. 1999), was held by this Court not to be a federal agency. Id. at 462. It therefore was not subject to the APA, id., and this Court accordingly had no occasion to addresses the issue of finality. The portion of the opinion relied upon by defendant addresses the question whether the statute at issue nevertheless provides the basis for an implied right of action separate and apart from the APA. Id. at 462-463 & n.6. The question here, by contrast, is whether a party may obtain APA judicial review of an IQA petition denial.

Fourth, like the party in Standard Oil, the party claiming finality in Eastman Kodak Co. v. Mossinghoff, 704 F.2d 1319 (4th Cir. 1983), also was engaged in related, ongoing proceedings before the agency. Id. at 1323 ("The agency action for which Kodak seeks judicial review involves a question, which under the circumstances of this case, is properly to be decided in the pending interference proceedings according to Patent Office Rules of Practice."). Thus, the portion of the opinion cited by defendant simply recognizes the unremarkable proposition that exhaustion of a single issue within a pending administrative proceeding does

not amount to final agency action. Id. at 1324. There can be no such claim here, as defendant denied plaintiffs' IQA petition in its entirety.

Finally, Aerosource, Inc. v. Slater, 142 F.3d 572 (3d Cir. 1998)—the last case cited by defendant with respect to this issue—simply recognizes the unremarkable proposition that filing a motion for reconsideration cannot convert an otherwise non-final agency action into final agency action. Id. at 579. Plaintiffs' position is by no means to the contrary. Rather, plaintiffs assert the normally uncontroversial proposition that completion of a petition process and administrative appeal required by statute amounts to final agency action.

In short, defendant has pointed to nothing that undermines the straightforward argument made in plaintiffs' opening brief: defendant's denial of plaintiffs' IQA petition and administrative appeal both "mark[ed] the consummation of the agency's decisionmaking process" and was a ruling "by which rights or obligations have been determined" and "from which legal consequences . . . flow." Bennett, 520 U.S. at 177-178 (citations and quotations omitted). That is all that is needed to establish final agency action.

### B. The Denial Of An IQA Petition Is By No Means Committed To Agency Discretion

As explained in the opening briefs filed by plaintiffs and their amici, the District Court's conclusion that the resolution of an IQA petition is committed to

agency discretion by law is entirely without merit.[9] See Appellants' Br. at 33-36; Br. for Amicus Curiae GMA at 20-30; Br. for Amicus Curiae NAHB at 14-20. In its brief before this Court, defendant again abandons the theories argued below and accepted by the District Court, fails to address the points raised by plaintiffs and their amici, and elects instead to press a new theory as to why this matter should be treated as having been committed to agency discretion. As with defendant's other newly-minted defenses, its argument with respect to the committed-to-agency-discretion exception to judicial review under the APA was waived because it was not presented below. See Holland, 181 F.3d at 605.

This argument fares no better on the merits. Defendant's current position appears to be that simply because it required agencies to periodically provide OMB with statistics regarding the disposition of IQA petitions, Congress intended to overcome the strong and well-established presumption in favor of judicial review of administrative action under the APA. However, only a clear expression of Congress's intent is sufficient to overcome the presumption in favor of judicial review. See 5 U.S.C. § 559 (any effort to supersede or modify the APA must be express); Ninilchik Traditional Council v. United States, 227 F.3d 1186, 1193 (9th Cir. 2000) (citing section 559 for the proposition that "challenges to agency actions

[9] While agencies are afforded discretion under the OMB Guidelines regarding when and how to correct information, Congress gave them no authority in the IQA to decide whether to correct information that conflicts with the IQA's standards. See Br. for Amicus Curiae NAHB at 19-20.

are subject to the APA's judicial review standards unless Congress specifies a contrary intent"). The fact that Congress called for statistical reports on the dispositions of IQA requests underscores that it was concerned about how those complaints were being administratively adjudicated. That concern bolsters—rather than undermines—the conclusion that Congress presumed that the APA's default rule of judicial review would apply to final agency denials of IQA petitions. In addition, no amount of administrative oversight can substitute for judicial review where, as here, OMB—the agency defendant claims fulfills this role—has no direct authority to require an agency to carry out a statutory function or to correct an agency's improper decision.[10]

The suggestion that the IQA's statistical reporting requirement was intended to replace substantive judicial oversight by Article III courts is also flatly inconsistent with the legislative history and subsequent judicial construction of the APA. The authors of the APA spoke clearly with respect to what would be required in order to remove agency action from the scope of judicial review:

> To preclude judicial review under this bill a statute if not specific in withholding such review must upon its face give clear and convincing evidence of an intent to withhold it. The

[10] OMB has no scientific staff or adjudicatory unit to evaluate IQA compliance, nor could it likely withhold funds or otherwise punish an agency with a poor IQA track record.

> mere failure to provide specifically by statute for judicial review is certainly no evidence of an intent to withhold it.

APA Legislative History, S. Doc No. 79-248.[11]

More to the point, however, an issue is committed to agency discretion by law only in "'those rare instances where statutes are drawn in such broad terms that in a given case there is no law to apply.'" Inova Alexandria Hosp., 244 F.3d at 346 (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971)). The government does not even argue that there is no law to apply. As explained in plaintiffs' opening brief, the IQA and implementing regulations established concrete criteria for adjudicating IQA requests. See Appellants' Br. 35-36; Br. for Amicus Curiae GMA at 21-24; Br. for Amicus Curiae NAHB at 18-19. Accordingly, the sole ground asserted on appeal by defendant in support of its contention that resolution of IQA petitions is committed to agency discretion by law clearly fails.[12]

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[11] In providing an example of the type of statute that precludes review, The Attorney General's Manual on the Administrative Procedure Act, (1947)—a document long considered an authoritative source for interpreting the APA, see Darby v. Cisneros, 509 U.S. 137, 148 n.10 (1993)—cites 38 USC 705 (1933), which states: "all decisions rendered [by the agency] . . . shall be final and conclusive on all questions of law and fact and no other official or court of the United States shall have jurisdiction to review by mandamus or otherwise any such decision." Attorney General's Manual at 94.

[12] Defendant—cavalierly and without support—suggests a number of times in its brief that the IQA somehow "contemplate[s]" that IQA challenges to agency disseminations will be heard by agencies, not courts. See, e.g., Appellee's Br. at

## III. PLAINTIFFS HAD STANDING TO CHALLENGE THE AGENCY'S DENIAL OF THEIR IQA PETITION

Lastly, defendant argues—almost as an afterthought—that plaintiffs lack standing to pursue this matter. It is not surprising that defendant makes only a half-hearted attempt to defend the District Court's standing ruling. Indeed, much of defendant's standing argument collapses with its argument that judicial review is unavailable to challenge the denial of an IQA petition in the first place. Accordingly, if this Court concludes that judicial review is available, then it follows that defendant's standing argument fails as well.

In any event, as explained in plaintiffs' opening brief, see Appellant's Br. at 22-31, it is well established that informational injury is sufficient to satisfy the requirements of Article III. See, e.g., Federal Election Comm'n v. Akins, 524 U.S. 11, 21 (1998) ("The 'injury in fact' that respondents have suffered consists of their inability to obtain information . . . that, on respondents' view of the law, the statute requires" be made public.); Public Citizen v. United States Dep't of Justice, 491 U.S. 440, 449 (1989) ("Our decisions interpreting the Freedom of Information Act have never suggested that those requesting information under it need show more

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20, 34, 38. The text above clearly forecloses this assertion, as the removal of a matter from the scope of judicial review under the APA may not be done through contemplation. Rather, Congress must do so clearly, either by expressly precluding judicial review or by providing no law for courts to apply. Neither is the case here.

than that they sought and were denied specific agency records. There is no reason for a different rule here.") (citations omitted). Defendant makes no attempt whatsoever to distinguish—or even address—these cases.

Instead, defendant's only argument with respect to this issue is its assertion that plaintiffs' claim constitutes only a generalized grievance, and therefore is not actionable. Appellee's Br. at 38-39. Tellingly, this precise argument was made—and rejected—in Akins. In finding this argument unavailing, the Court noted that the generalized grievance concept "invariably appears in cases where the harm at issue is not only widely shared, but is also of an abstract and indefinite nature—for example, harm to the common concern for obedience to law." 524 U.S. at 23 (citation and internal quotations omitted).

There is no such abstract and indefinite harm here. Plaintiffs invoked informational rights created by the IQA. Their IQA petition was denied. Plaintiffs filed a timely appeal of this denial, which defendant also denied. Thus, plaintiffs' injury stemmed from the denial of their IQA petition and concomitant denial of their statutory right to information and information correction—injuries that were particular to plaintiffs and not shared by the public at large. This is all Article III requires. See Warth v. Seldin, 422 U.S. 490, 500 (1975) ("The actual or threatened injury required by Art. III may exist solely by virtue of statutes creating legal

rights, the invasion of which creates standing") (citation and internal quotations omitted).

Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 149 (4th Cir. 2000)—the only case cited by defendant in support of its argument regarding standing—is not to the contrary. As this Court noted in that case, a plaintiff cannot be said to assert a generalized grievance if he "somehow differentiate[s] himself from the mass of people who may find the conduct of which he complains to be objectionable only in an abstract sense," thereby demonstrating that the alleged injury "'affects the plaintiff in a personal and individual way.'" Friends of the Earth, 204 F.3d at 156 (citation omitted).

Here, as explained above, plaintiffs do not seek to vindicate a generalized grievance similar to those found wanting in other cases by the Supreme Court. See Akins, 524 U.S. at 23-24 (citing cases in which plaintiffs failed to establish standing where they (1) sought to ensure that certain procedures are followed, (2) sought to vindicate an alleged injury common to others, or (3) failed to show injury to a personal right separate and apart from the general interest in the administration of law). Instead, plaintiffs seek to vindicate their statutory right to, inter alia, seek correction of government-disseminated information plaintiffs believe is harmful to their interests. Plaintiffs' invocation of the informational rights created by the IQA—and defendant's denial of plaintiffs' rights thereunder—unquestionably

differentiate plaintiffs from others who may find defendant's dissemination of such information objectionable in an abstract sense and results in an injury that "affect[s] the plaintiff in a personal and individual way." Id. at 156. Defendant's argument to the contrary therefore fails.[13]

## CONCLUSION

For the reasons set forth above and in plaintiffs' opening brief, the decision of the District Court should be reversed.

[13] As explained both in plaintiffs' opening brief and in the briefs filed by their amici, the Court must review the above-discussed arguments regarding standing prior to reaching the merits of the appeal. See Appellants' Br. at 31; Br. for Amicus Curiae NAHB at 24-28; Br. for Amicus Curiae GMA at 5 n.2. As stated above, plaintiffs clearly have standing to pursue the claims at issue. If the Court were to conclude otherwise, however, it must vacate the remainder of the District Court's opinion. Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 93-102 (1998).

Respectfully submitted,

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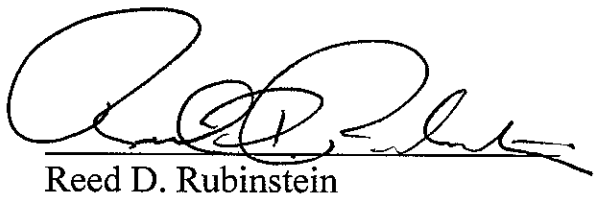

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**UNITED STATES COURT OF APPEALS**
**FOR THE FOURTH CIRCUIT**

**No.** 05-1097 **Caption:** Salt Institute et al. v. Michael O. Leavitt, Health & Human Services

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Attorney for Appellants

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## CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2005, a copy of Appellants' Reply Brief was served on the following parties by first-class mail, postage prepaid:

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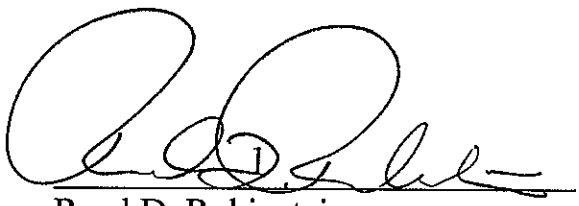

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