No. 05-1097

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

SALT INSTITUTE; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Plaintiffs-Appellants,

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

On Appeal From The United States District Court
For The Eastern District Of Virginia
Alexandria Division

BRIEF FOR THE GROCERY MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING APPELLANTS AND REVERSAL

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Dated: April 21, 2005

DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER ENTITIES WITH A DIRECT FINANCIAL INTEREST IN LITIGATION

Only one form need be completed for a party even if the party is represented by more than one attorney. Disclosures must be filed on behalf of individual parties as well as corporate parties. Disclosures are required from amicus curiae only if amicus is a corporation. Counsel has a continuing duty to update this information. Please file an original and three copies of this form.

No. 05-1097 Caption: Salt Institute et al. v. Leavitt

Pursuant to FRAP 26.1 and Local Rule 26.1,

Grocery Manufacturers of America who is Amicus Curiae ,
(name of party/amicus) (appellant/appellee/amicus)

makes the following disclosure:

1. Is party/amicus a publicly held corporation or other publicly held entity?
☐ YES ☒ NO

2. Does party/amicus have any parent corporations?
☐ YES ☒ NO
If yes, identify all parent corporations, including grandparent and great-grandparent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity?
☐ YES ☒ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))?
☐ YES ☒ NO
If yes, identify entity and nature of interest:

5. Is party a trade association?
☒ YES ☐ NO
If yes, identify all members of the association, their parent corporations, and any publicly held companies that own 10% or more of a member's stock:

Please see attached list and accompanying Motion of the Grocery Manufacturers of America for Partial Relief From Local Rule 26.1.

6. If case arises out of a bankruptcy proceeding, identify any trustee and the members of any creditor's committee:

Gregory G. Garre
(signature)

4/21/05
(date)

Rule 26.1.5 Disclosure

GMA Member Companies and Parents (if applicable)

ACH Food Companies (parent: Associated British Foods plc)
Ajinomoto U.S.A., Inc. (parent: Ajinomoto Co., Inc.)
Alberto-Culver Company
Alcoa Consumer Products Company (parent: Alcoa)
Allen Canning Company
Altria Group Inc.
Archer Daniels Midland

B&G Foods Inc.
Barilla America, Inc.
Basic American, Inc.
Bimbo Bakeries, U.S.A. (parent: Grupo Bimbo, S.A. de C.V.)
Birds Eye Foods
Blue Diamond Growers
Brach's Confections
Bruce Foods Corporation
Buena Vista Home Entertainment (parent: The Walt Disney Company)
Bush Brothers & Company

C.H. Guenther & Son, Inc.
Cadbury Schweppes Americas Beverages (parent: Cadbury Schweppes plc)
Campbell Soup Company
Cargill Inc.
Carvel Corporation (parent: Roark Capital Group)
Chicken of the Sea International (parent: Thai Union International, Inc.)
Church & Dwight Company, Inc.
Clorox Company, The
Coca-Cola Company, The
Coca-Cola Enterprises Inc.
Colgate-Palmolive Company
Comag Marketing Group, LLC
ConAgra Foods, Inc.
Continental Mills Inc.

Daisy Brand, Inc.
Dannon Company, Inc., The (parent: Group Danone)
Dean Foods Company
Del Laboratories, Inc.
Del Monte Foods
Dial Corporation, The (parent: Henkel Group)

Diamond of California
Dole Packaged Foods Company (parent: Dole Food Company)
Domino Foods Inc.
DSM Nutritional Products, Inc.
Dreyer's Grand Ice Cream (parent:: Nestlé USA Inc.)
Dunkin' Brands, Inc. (parent: Allied Domecq plc)

E. & J. Gallo Winery
Energizer Holdings, Inc.

Fairmount Food Group, LLC
Faultless Starch/Bon Ami Company
Flowers Foods

General Mills, Inc.
George Weston Bakeries, Inc.(parent: George Weston Limited)
Georgia-Pacific Corporation
Gillette Company, The

H. J. Heinz Company
Hallmark Cards, Inc.
Harmony Foods Corporation
Hershey Foods Corporation
Hormel Foods Corporation

J. M. Smucker Company, The
Jarden Corporation
Johnson & Johnson
Johnsonville Sausages, LLC

Kellogg Company
Kikkoman Foods(parent: Kikkoman Corporation)
Kimberly-Clark Corporation

Lance, Inc.
Land O' Lakes, Inc.

Mariani Packing Company, Inc.
Marine Harvest USA, Inc.
Mars, Incorporated
McCain Foods USA, Inc. (parent: McCain Foods Limited)
McCormick & Company, Inc.
McIlhenny Company
McKee Foods Corporation
Melitta USA (parent: Melitta Group)
Meow Mix

Merisant Company
Miller Brewing Company (parent: SABMiller plc)
Molson Coors Co.
Morton International, Inc.
Musco Family Olive Co., The

N.K. Hurst Company
Nestlé USA (parent: Nestlé SA)
Nestlé Waters North America, Inc. (parent: Nestlé SA)
Novartis Consumer Health North America (parent: Novartis AG)

Ocean Spray Cranberries, Inc.
OSEM Group of Companies
Owens-Illinois, Inc.

PepsiCo, Inc.
Pepsi Bottling Group, Inc., The
Pfizer, Inc.
Pharmavite, LLC
Playtex Products, Inc.
Plochman, Inc.
Procter & Gamble Company, The

Reckitt Benckiser plc
Reily Foods
Rich Products Corporation
Richelieu Foods
Ross Products Division (parent: Abbott Laboratories, Inc.)

S.C. Johnson & Son, Inc.
Sara Lee Corporation
Schwan Food Company, The
Signature Brands, LLC
Solo Cup Company
Specialty Brands
Steuben Foods, Inc.
Sun Maid Growers of California

Tasty Baking Company
Tetley USA, Inc. (parent: Tata Tea Limited)
Time, Inc. (parent: Time Warner)

Ubiquity Brands
Unilever Bestfoods (parent: Unilever N.V.)

Ventura Foods, LLC

Welch Foods, Inc.
Williams Foods, Inc.
Wise Foods, Inc.
Wm. Wrigley Jr. Company

Yofarm Company, The

In addition, GMA states as follows:

The Coca-Cola Company (a GMA member) owns greater than 10% of the stock of Coca-Cola Enterprises (also a GMA member).

PepsiCo, Inc. (a GMA member) owns greater than 10% of the stock of The Pepsi Bottling Group, Inc. (also a GMA member).

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ISSUE PRESENTED FOR REVIEW

Amicus curiae Grocery Manufacturers of America (GMA) will address the following issue:

Whether a federal agency's denial of a petition filed pursuant to the Information Quality Act (IQA), 44 U.S.C. § 3516 note, and guidelines thereunder, is subject to judicial review under the Administrative Procedures Act, 5 U.S.C. § 704.

STATEMENT OF INTEREST

GMA was founded in 1908 and is today the world's largest association of food, beverage, and consumer-brand companies. 1/ GMA has more than 140 companies among its membership with annual sales totaling some $460 billion. From the wheat harvested on the farm, to the computers used to run our plants, to the trucks transporting products, GMA companies touch nearly every sector within the U.S. economy and make and market trusted brand-name products found in millions of American homes. GMA applies legal, scientific, and political expertise from its member companies to vital public policy issues affecting the industry, and speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues.

GMA and its members have a direct and substantial interest in the question whether judicial review is available of an agency's denial of a petition filed pursuant to the IQA seeking the correction or release of data. We live in an information age -- a day in which information may instantaneously reach hundreds of millions of individuals over the Internet, not to mention by way of more conventional forms of technology such as broadcast, cable television, and print. The federal government

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1/ Pursuant to Federal Rule of Appellate Procedure 29(a), GMA states that all parties have consented to this brief.

and in particular administrative agencies are in a unique position to accumulate and disseminate information because of the breadth of issues reached by federal law and scope of resources available to federal agencies to investigate issues.

Through agencies such as the Department of Health and Human Services (HHS), Department of Agriculture (USDA), and National Institute of Health (NIH), the federal government regulates numerous issues of vital importance to GMA members and consumers alike, including issues related to the safety of food products manufactured by GMA companies. The NHLBI study on the dietary affects of sodium -- i.e., salt -- underlying this case illustrates the tremendous influence that the federal government may have on the consumer choices of millions of Americans concerning products sold by GMA's members. A government-backed study advising that a low-sodium diet may lower the risk of heart disease may affect millions of dietary decisions each day.

It is critical that such a study be subject to careful scrutiny to ensure that the data relied on by the government is sound. Moreover, although the dispute in this case centers on the quality of the data underlying NHLBI's sodium trial, the resolution of this case may affect the quality of information created and disseminated by the government with respect to virtually any ingredient or constituent in food and beverage

products manufactured by GMA members, including carbohydrates, sugar, fat, and caffeine -- ingredients that are the subject of ongoing scientific debate.

For GMA members, a single government-issued report creating health concerns about an ingredient or constituent in a food product can have dramatic economic and regulatory consequences. USDA's Agricultural Research Service (ARS) -- the self-described "in-house research arm of the [USDA]" with an annual budget of approximately $1 billion -- partially funds and reports on numerous food-related or dietary studies each year. Likewise, the Dietary Guidelines for Americans disseminated by HHS and USDA not only form the basis for USDA's Food Guidance System for Americans, but also affect federal, state, and private consumer education materials and have the potential to affect the content of food labeling and advertising as well. The quality, integrity, and transparency of the information disseminated by the federal government on such matters is therefore of vital importance to GMA members, as well as to the millions of Americans who consume their products on a daily basis.

The IQA and guidelines established pursuant to the IQA are a critical and overdue step toward ensuring that information released by the federal government reflects the best available science, accurately assesses health risks, and is based on sound

data and analyses. As explained below, judicial review of agency decisions denying petitions filed pursuant to the express terms of the IQA is necessary to fulfill the vital objectives of the IQA and is conferred under the same provisions of the Administrative Procedure Act (APA) that permit the judicial review of countless other final administrative actions. 2/

2/ Although the focus of this brief is on the judicial-review issue, GMA agrees with plaintiffs that, as a threshold matter, the District Court fundamentally erred in holding that plaintiffs lack standing to pursue this action. See Salt Inst. Br. 22-31. If this Court concludes, however, that plaintiffs lack standing, then it should vacate that portion of the District Court's decision addressing whether judicial review was available on the merits of plaintiffs' claims. Under the fundamental principles reiterated by the Supreme Court in Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 109-110 (1998), the District Court erred in going beyond the standing issue to the merits of the IQA issue (assuming that the District Court properly held that plaintiffs lack standing). The importance of the question whether judicial review is available in this context heightens the need to follow the principles articulated by Steel Company and to leave that question for another day in a case in which there is no threshold jurisdictional obstacle to addressing that issue.

SUMMARY OF ARGUMENT

The federal government possesses an extraordinary ability to influence American life through the dissemination of information, including information concerning the health or safety of food and other consumer products. The IQA represents a critical check on the reliability of information disseminated by administrative agencies. For several reasons, the District Court erred as a matter of law in holding that an agency's denial of an IQA petition is immune from judicial review.

First, the "strong presumption" against which Congress legislates is that administrative action is subject to judicial review. Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 346 (4th Cir. 2001). Congress enacted the IQA after the Office of Management and Budget's (OMB) repeated failures to comply with Congress' directions to adopt information-quality guidelines. The IQA requires OMB to issue guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information," and to establish "administrative mechanisms" to ensure that information collected and disseminated by federal agencies is reliable. 44 U.S.C. § 3516 note. The availability of judicial review of an agency's denial of an IQA petition is key to ensuring that the goals of the IQA are met. Moreover, especially in view of OMB's refusal to heed Congress's

directives before the IQA, there is no reason to conclude that Congress intended implementation of the IQA to be solely a matter of administrative discretion or grace.

Second, an agency's denial of an IQA petition constitutes "final agency action" under the APA, and therefore is subject to judicial review under the express terms of the APA. The IQA and agency guidelines promulgated thereunder establish a process by which individuals affected by the dissemination of information by the federal government may file a petition seeking correction of such information and release of data supporting the publicly-disseminated information. The District Court focused on the agency's release of challenged information, rather than the agency's denial of plaintiffs' IQA petition, as the purported final agency action. That was error. The denial of an IQA petition clearly satisfies the criteria for final agency action under applicable Supreme Court and Circuit precedent.

Third, the District Court erred in holding that -- even if final agency action is present -- resolution of IQA petitions is committed to agency discretion by law. Steenholdt v. Federal Aviation Admin., 314 F.3d 633 (D.C. Cir. 2003) -- the sole case cited by the District Court to support that conclusion -- is readily distinguishable. The regulation at issue in Steenholdt granted unfettered discretion to the agency in ruling on the

merits of the issue before it. By contrast, the guidelines promulgated under the IQA establish a clear goal of improved information quality and set concrete standards to be applied in reviewing IQA petitions. Indeed, the same standards that Congress mandated to ensure that interested parties may obtain administrative review of IQA petitions also guarantee that standards exist for the judicial review of an agency's denial of an IQA petition.

Finally, judicial review is needed to advance the objectives of the IQA. The available evidence regarding implementation of the IQA suggests that agencies are finding errors in the initial analysis of IQA petitions, that IQA petitions are languishing far beyond the time permitted for disposition, and that none of the dire predictions made by critics of the IQA regarding the potential negative impact of information-quality petitions on the regulatory system has come to pass. Judicial oversight of agency disposition of IQA petitions would have the effect of ensuring the timeliness and accuracy of agencies' disposition of IQA petitions without leading to any of the dire consequences predicted by critics. Accordingly, compelling policy concerns also support the conclusion that agency denials of IQA petitions are subject to judicial review.

ARGUMENT

THE DISTRICT COURT ERRED IN HOLDING THAT AN AGENCY DECISION TO DENY AN IQA PETITION IS IMMUNE FROM JUDICIAL REVIEW

Plaintiffs Salt Institute and Chamber of Commerce of the United States of America filed a petition pursuant to the IQA with NHLBI seeking the disclosure of data and correction of information disseminated by NHLBI in connection with NHLBI's sodium trial. NHLBI denied that petition as well as plaintiffs' subsequent administrative appeal. The District Court held that an agency's denial of a request under the IQA is categorically immune from judicial review. As explained below, that ruling is fundamentally at odds with the (1) traditional presumption in favor of judicial review of agency action; (2) history and purpose of the IQA; (3) judicial-review provisions of the APA; and (4) compelling public policy considerations. It should not be allowed to stand.

I. THE "STRONG PRESUMPTION" AGAINST WHICH CONGRESS LEGISLATES IS THAT ADMINISTRATIVE ACTION IS SUBJECT TO JUDICIAL REVIEW

Congress is presumed to be aware of "basic rules of statutory construction" when it legislates, including 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). Thus, in enacting the IQA, Congress is presumed to have known that Supreme Court precedent requires this Court to begin its analysis "with the strong presumption that Congress intends judicial review of administrative action." Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 346 (4th Cir. 2001) (quoting Bowen v. Michigan Acad. of Family Physicians, 476 U.S. 667, 670 (1986)). Indeed, "judicial 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." Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967) (emphasis added). Nothing in the IQA or its history suggests, much less compels the conclusion, that Congress intended to deviate from the traditional rule in enacting the IQA. To the contrary, all signs point to the conclusion that Congress intended the traditional rule of judicial review to apply under the IQA.

II. THE HISTORY AND PURPOSE OF THE IQA SUPPORT THE CONCLUSION THAT JUDICIAL REVIEW IS AVAILABLE HERE

1. The history of the IQA seriously undermines the argument that Congress intended the implementation of the IQA to be left solely to the discretion of OMB and individual agencies -- with no opportunity whatsoever for affected parties to obtain judicial review of an agency's denial of an IQA petition.

As Members of Congress observed, "[i]t is vital that government information * * * be valid," as "it often underpins regulatory and resource-allocation decisions by federal agencies -- as well as laws made by Congress." United States Senate Republican Policy Comm., The Data Quality Act: History and Purpose (Jan. 18, 2005) (Senate RPC Report) at 1. Indeed, "[t]he use of poor-quality data or bad science can lead to costly mistakes." Ibid. Moreover, the government's dissemination of unsound data or information about products can have a devastating economic impact on American businesses that produce such goods.

The IQA was the culmination of Congress's efforts over many years to improve the quality and transparency of information disseminated by federal agencies -- efforts that had, until that time, been largely ignored by these agencies. The IQA has its origins in the Paperwork Reduction Act (PRA). Ibid. The PRA required OMB to establish information-quality measures aimed at

ensuring the accuracy and integrity of information disseminated to the public by federal agencies. See 44 U.S.C. § 3504(d). Notwithstanding that clear legislative directive from Congress, however, OMB essentially ignored the data-quality provisions contained in the PRA. Senate RPC Report at 2. In response to OMB's inaction, Congress reiterated its commitment to improved information quality in 1998, when it passed a non-binding resolution "urging OMB to develop policy and procedural guidance 'in fulfillment of the purposes and provisions of the [PRA].'" Ibid. (quoting House Rep. No. 105-592).

The 1998 resolution set forth specific deadlines for federal agencies to issue the required guidelines. See House Rep. No. 105-592 at 49. Once again, OMB ignored those directives. As a result, Members of Congress issued a series of letters referring OMB to its obligations under the PRA and requesting updates regarding OMB's progress in establishing the required information-quality guidelines. 3/ In response, OMB again thumbed its nose at Congress, stating that -- despite the clear intent of Congress -- OMB saw no need for either

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3/ See Letter from Congress Member Emerson to J. Lew, Director, OMB (May 6, 1999) available at http://www.thecre.com/quality/letter-emerson-lew.html; Letter from Congress Member Bliley to J. Lew, Director, OMB (May 20, 1999) available at http://www.thecre.com/quality.letter-bliley-lew.html; Letter from Congress Member Emerson to J. Spotila, Director, OMB (Mar. 20, 2000) available at http://www.thecre.com/quality/EmersonLetter20000320.html.

additional information-quality guidelines or for a petition process by which affected members of the public could seek correction of information disseminated by executive-branch agencies. See Letter from J. Spotila, Director, OMB to Congress Member Emerson (Apr. 18, 2000) available at http://www.thecre.com/quality/20041012_letter.htm.

In the light of OMB's recalcitrance on this issue, Congress was left with no choice but to pass the IQA. The IQA reiterated the information-quality directives contained in the PRA and, this time, set a mandatory deadline for compliance by OMB. Passage of the IQA was, as Members of Congress later explained, "compelled" by OMB's "repeated lack of compliance" with its obligations under the PRA. Senate RPC Report at 2. There is no basis for concluding that the Congress that enacted the IQA after OMB's repeated refusal to implement information-quality measures would have intended to insulate from judicial review agency decisions to disregard the statutory requirements of the IQA. To the contrary, the history of the IQA leads to the conclusion that Congress intended the traditional rule to apply.

2. The important purposes of the IQA also support the conclusion that Congress intended for judicial review of agency decisions denying IQA petitions. The IQA establishes a mechanism by which affected individuals may challenge the

accuracy of information released by the federal government. This is important because "[b]ad information and/or 'junk science' disseminated by the federal government can be costly if it leads to unnecessary regulations or policies that fail to correct, or even exacerbate, the problem being addressed." Senate RPC Report at 6. Furthermore, the IQA was intended to prevent the practice of "regulation by publication," in which agencies "publish unsupportable claims that achieve a regulatory impact without having to go through the regulatory process." Senate RPC Report at 6.

To accomplish those objectives, the IQA requires agencies to "ensur[e] and maximize[e]" the "quality, objectivity, utility, and integrity of information" they disseminate. 44 U.S.C. § 3516 note. But equally important, the IQA requires agencies 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 Act's requirements. Ibid. The IQA thus not only directs agencies to ensure the quality and integrity of information disseminated by the government, but also provides for greater public transparency of the manner in which agencies arrive at their recommendations and conclusions. Among other things, an "important benefit of [such] transparency is that the public

will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency." 67 Fed. Reg. 8452, 8456 (Feb. 22, 1987).

Agencies are presumed to discharge their responsibilities in good faith. As in the case of numerous other agency decisions, however, the availability of judicial review of agency decisions denying IQA petitions serves as a critical check on agency decision making to ensure that the statutory requirements of the Act are met. Holding that judicial review is unavailable would undermine the important objectives of the IQA by leaving to the agencies that disseminate information the sole and final say over whether that information satisfies the criteria set forth in the IQA.

III. LIKE COUNTLESS OTHER AGENCY DECISIONS, AN AGENCY'S DECISION TO DENY A REQUEST FOR DATA OR CORRECT INFORMATION UNDER THE IQA IS SUBJECT TO JUDICIAL REVIEW UNDER THE APA

Under the APA, any "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The challenged action must be "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The APA's time-honored avenue "for judicial review of agency action is grounded in concerns about constraining the exercise of discretionary

power by administrative agencies." Bowen v. Massachusetts, 487 U.S. 879, 908 n.46 (1988) (quoting Delaware Div. of Health & Social Servs. v. United States Dep't of Health & Human Servs., 665 F. Supp. 1104, 1117-18 (D. Del. 1987)). The availability of such judicial review "promotes fidelity to statutory requirements, and, when congressional intent is ambiguous, it increases the likelihood that the regulatory process will be a responsible exercise of discretion." Ibid. A person who has properly filed an IQA petition and exhausted his administrative remedies is "entitled" to judicial review under APA § 704.

A. Denial Of An IQA Petition Is Final Agency Action

To meet the APA's finality requirement, an agency action must satisfy two conditions. "First, the action must mark the consummation of the agency's decisionmaking process -- it must not be of a merely tentative nature." Bennett v. Spear, 520 U.S. 154, 177-178 (1997) (citations and quotations omitted). "[S]econd, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Id. at 178. The finality requirement is met here.

The IQA directs agencies to establish "administrative mechanisms" for processing IQA petitions. 44 U.S.C. § 3516 note. The NIH Guidelines that govern the IQA petition in this case (1) instruct those seeking "correction of information disseminated

by the NIH or its components" to submit IQA petitions to the office that disseminated the information, see NIH Guidelines for Ensuring the Quality of Information Disseminated to the Public (Nov. 12, 2003) (NIH Guidelines) ¶ VI(1); (2) establish principles and procedures by which responding offices may determine appropriate responses to such petitions, see id. ¶ VI(2) & (3); (3) establish procedures for tracking and reporting the results of IQA petitions, see id. ¶ VI(4); and (4) provide for intra-agency appellate review of IQA petition denials, including a requirement that NIH resolve all such appeals within sixty days of receipt, see id. ¶ VI(5).

Plaintiffs here filed a petition pursuant to the IQA with respect to information compiled and disseminated by NHLBI in connection with its sodium trial and followed the procedures established by NIH for processing IQA petitions. Plaintiffs' petition was denied by NHLBI. Plaintiffs filed an administrative appeal and that appeal was denied by the agency as well. The agency's denial of plaintiffs' IQA petition -- pursuant to the administrative complaint process established by NIH -- undeniably "mark[ed] the consummation of the agency's decisionmaking process" with respect to plaintiffs' petition because there is nothing more for the agency to do with respect to plaintiffs' petition under NIH's rules. Bennett, 520 U.S. at

178. As a result, the first element of the "finality" test set forth in Bennett is satisfied in this case and will be with respect to an agency's denial of any IQA petition under the administrative review process required by IQA. Id.

The second element of Bennett is also met in this case because the agency's denial of plaintiffs' IQA petition is an act from "which rights or obligation have been determined." Ibid. The IQA and the regulations promulgated thereunder grant the right to members of the public to challenge the quality of information disseminated by executive-branch agencies, including the right to request that such information be corrected and that supporting evidence be released to the public. Plaintiffs invoked both rights. The agency's denial of their IQA petition both denied plaintiffs' claim to those rights and conclusively determined that the agency had no obligation to correct the challenged information or release the supporting data. It is difficult to imagine a clearer example of an agency action from "which rights or obligations have been determined." Ibid.

In concluding that there was no final agency action, the District Court simply misunderstood the issue before it. The court did not consider the administrative process mandated by IQA for reviewing IQA petitions. Instead, relying on Flue-Cured Tobacco Coop. Stabilization Corp. v. United States Envtl.

Protection Agency, 313 F.3d 852 (4th Cir. 2002), the District Court concluded there was no final agency action in this case on the ground that "[a]gency 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." 345 F. Supp. 2d at 602. That analysis, however, is fundamentally flawed. In Flue-Cured Tobacco, the challenged agency action consisted solely of the release of a government report. Here, by contrast, the challenged action is the agency's denial of plaintiffs' petition seeking the release and correction of information pursuant to the IQA. Accordingly, proper application of the Supreme Court's ruling in Bennett leads to the conclusion that agency denials of IQA petitions constitute final agency action under the APA. 4/

4/ Commentators who have considered whether judicial review is available under the APA have similarly concluded that the denial of an IQA petition constitutes final agency action for purposes of the APA. See, e.g., Sidney A. Shapiro, The Information Quality Act and Environmental Protection: The Perils of Reform By Appropriations Rider, Wm. & Mary Envtl. L. & Pol'y Rev. 339, 370 (2004) (noting that the reasoning of Flue-Cured Tobacco does not extend to the IQA because the focus of a reviewing court's inquiry is the rejection of the IQA petition, which qualifies as final agency action under the APA); Michelle V. Lacko, The Data Quality Act: Prologue To A Farce Or A Tragedy?, 53 Emory L.J. 305, 328 (2004) (noting that, "[a]ccording to one commentator, about 90 percent of administrative law experts believe * * * [IQA] petitions, if denied by [an agency] and appealed and denied again, would be considered final agency actions the [sic] therefore judicially reviewable.") (footnote and internal quotations omitted); James W. Conrad, Jr., The Information

B. Congress Did Not Commit The Resolution Of IQA Petitions Purely To Agency Discretion

The District Court alternatively held that, even assuming the denial of an IQA petition constitutes final agency action, judicial review is unavailable under the APA on the ground that the decision whether to grant or deny an IQA petition is committed to agency discretion by law. That, too, was error.

1. As discussed in Part I above, the "strong presumption" is that Congress intends for judicial review of agency action to be available under the APA. Inova Alexandria Hosp., 244 F.3d at 346. The exceptions to the standing presumption in favor of judicial review are few: "[T]he APA provides for review 'except to the extent that (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law.'" Ibid. (quoting 5 U.S.C. § 701(a)). Nothing in the IQA purports to preclude judicial review of IQA petitions. Accordingly, the

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Quality Act -- Antiregulatory Costs of Mythic Proportions?, 12 Kan. J.L. & Pub. Pol'y 521, 539 (Spring 2003)(stating that "[t]here should be no question that the denial by an agency's administrative appeal mechanism of an affected person's appeal of an adverse initial decision on a correction request constitutes final agency action"); Alan C. Raul & Julie Z. Dwyer, "Regulatory Daubert": A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles Into Administrative Law, 66-Fall Law & Contemp. Probs. 7 (Autumn 2003) at 17 (stating that the creation of the IQA petition process "gives rise to a legitimate claim that final agency decisions on such complaints should be subject to further review in the federal courts").

only possible bar to judicial review is that the adjudication of IQA petitions is committed to agency discretion by law.

The committed-to-agency-discretion exception to judicial review "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.'" Ibid. (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971)). To fall within the exception, a statute must be "'drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.'" Ibid. (quoting Heckler v. Chaney, 470 U.S. 821, 830 (1985)).

Significantly, the standards to be applied by a court need not come explicitly from the statute itself. Rather, "even if the underlying statute does not include meaningful (or manageable) standards, 'regulations promulgated by an administrative agency in carrying out its statutory mandate can provide standards for judicial review.'" Ibid. (quoting CC Distribs., Inc. v. United States, 883 F.2d 146, 154 (D.C. Cir. 1989)). See also Safe Energy Coalition of Mich. v. United States Nuclear Regulatory Comm'n, 866 F.2d 1473, 1478 (D.C. Cir. 1989); Center for Auto Safety v. Dole, 846 F.2d 1532, 1534 (D.C. Cir. 1988). Moreover, a sufficient basis for judicial review exists if the regulatory scheme simply establishes a general

goal. See Robbins v. Reagan, 780 F.2d 37, 45 (D.C. Cir. 1985) ("Even when there are no clear statutory guidelines, courts often are still able to discern from the statutory scheme a congressional intention to pursue a general goal.").

At a minimum, the regulatory guidelines mandated by the IQA -- and developed through notice-and-comment rulemaking -- clearly define the standards established by the IQA and provide ample teeth for a court to enforce the IQA. The HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (Nov. 13, 2003) (HHS Guidelines) (¶ D(2)) define in detail the key statutory terms set forth in the IQA for policing information requests, including "quality," "utility," "objectivity," and "integrity." OMB's IQA guidelines similarly direct agencies to establish clear, readily-applicable standards for resolution of IQA petitions. See 67 Fed. Reg. at 8458-59 (instructing agencies to establish "a basic standard of quality," that takes into account "objectivity, utility, and integrity" -- all of which are defined in detail in the regulations).

To be sure, OMB's guidelines also take into account that agencies subject to the guidelines have wide-ranging areas of responsibility, and therefore must apply the guidelines to a wide variety of information and information-dissemination

techniques. 5/ But the fact that OMB's guidelines appropriately call for some administrative flexibility in applying the IQA does not mean that the implementation of the IQA is committed entirely to the discretion of agencies by law.

More to the point, the IQA guidelines provide no such discretion in determining when a challenged agency dissemination has run afoul of the IQA in the first instance. Rather, as stated by OMB, "[t]he guidelines provide definitions that attempt to establish a clear meaning so that both the agency and the public can readily judge whether a particular type of information to be disseminated does or does not meet [the quality, utility, objectivity, and integrity attributes established by the IQA]." Id. at 8453 (emphasis added). See also id. at 8459 (stating that mechanisms must be established for handling IQA correction petitions in order "[t]o facilitate public review") (emphasis added).

5/ See, e.g., id. at 8458-59 (instructing agencies to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate"); id. at 8459 (stating that agencies must establish administrative procedures to handle IQA correction petitions, but allowing such mechanisms to be "flexible" and "appropriate to the nature and timeliness of the disseminated information"); id. (allowing agencies some flexibility in determining how best to correct disseminated information, and noting that "appropriate responses include personal contacts via letter or telephone, form letters, press releases or mass mailings").

These detailed definitions, together with the statute and other applicable regulatory pronouncements, provide objective, readily-applicable standards for adjudication of IQA petitions, and thus preclude a finding that IQA decisions are committed to agency decision by law. Indeed, the fact that OMB and HHS have spelled out the requirements of the IQA for adjudication of administrative claims under the IQA alone seriously if not fatally undercuts the District Court's conclusion that concrete standards do not exist for judicial review of IQA claims. 6/

2. The District Court pointed to a statement in OMB's comments to its guidelines -- as opposed to the guidelines themselves -- to the effect that agencies are "required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved." 345 F. Supp. 2d at 602 (quoting 67 Fed. Reg. at 8458). That statement, coupled with a citation to the D.C. Circuit's opinion in Steenholdt v. Federal Aviation Admin., 314 F.3d 633 (D.C. Cir. 2003), led the District Court to conclude that there was no meaningful basis for judicial review.

6/ Moreover, even if this Court were to conclude that the standards established by the regulations are not specific enough, it is beyond dispute that the IQA and the regulations promulgated thereunder reflect a clear intent to set minimum quality standards for all information disseminated by the executive branch, which alone is a sufficient basis for finding that there are standards to apply. See Robbins 780 F.2d at 45.

Specifically, the District Court reasoned that both the regulation at issue in this case and the one at issue in Steenholdt permitted the respective agencies to take or refrain from taking certain actions based on what the agency believed was "appropriate." See 345 F. Supp. 2d at 602-603.

That analysis is deeply flawed. To begin with, the D.C. Circuit's decision in Steenholdt is not only not binding on this Court, but readily distinguishable. Steenholdt involved a regulation promulgated under the Federal Aviation Act that governed the Federal Aviation Administration's (FAA) certification of private engineers to examine aircraft for airworthiness. 314 F.3d at 634-35. The regulation called for annual evaluations of such engineers and permitted FAA to refuse to re-certify a private engineer "[f]or any reason the [agency] considers appropriate." Id. at 635 (quoting 14 C.F.R. § 183.15(6)) (emphasis added). In other words, the regulation at issue in Steenholdt by its terms granted the agency a blank check to deny recertification for any reason at all.

Here, by contrast, neither the statute nor the guidelines promulgated pursuant to the IQA permit an agency to deny an IQA petition "for any reason the agency considers appropriate." To the contrary, as explained, the OMB and HHS guidelines establish specific, judicially-applicable standards for analyzing when

information should be corrected or disseminated under the IQA, but provide limited flexibility for the agency only to determine how such correction should be handled. In view of that distinction, this case is much closer to this Court's decision in Inova Alexandria Hospital and the D.C. Circuit's decision in Marshall County Health Care Auth. v. Shalala, 988 F.2d 1221 (D.C. Cir. 1993).

The Medicare Act provision at issue in Inova Alexandria Hospital granted the agency "full power and authority to make rules and establish procedures, not inconsistent with the provisions of this subchapter or regulations of the Secretary, which are necessary and appropriate to carry out the provisions of this section." 244 F.3d at 346 (quoting 42 U.S.C. § 1395oo(e)) (emphasis added). This Court rejected the argument that such language committed decisions regarding dismissal of agency proceedings for failure to comply with procedural obligations to agency discretion as a matter of law. Id. at 347.

The Court reached that conclusion based on three factors. First, the type of decision at issue -- the dismissal of an appeal -- "is not the kind of decision that is ordinarily committed to agency discretion by law." Ibid. Rather, "[t]he decision to dismiss an administrative appeal is similar to the kind of dismissal decisions that courts routinely review for

error." Id. at 348. Second, there was "no affirmative evidence that the [agency] intended to insulate its decisions to dismiss appeals from judicial review." Ibid. Third, the Court was "hesitant to interpret the [agency's] rule as precluding judicial review in light of the substantial interests at stake in the provider reimbursement arena," which were "served by a provider appeals process that is fair and evenhanded." Ibid.

So too here. First, it is clear that the type of review at issue -- review of the final decision produced by an agency's internal appeals process -- is the type of review federal courts conduct under the APA on a routine basis. Second, there is no evidence that either Congress, in establishing the IQA, or OMB and HHS, in promulgating regulations thereunder, intended to insulate final agency orders resolving IQA petitions from judicial review. Third, there can be little doubt that substantial interests are at stake. Indeed, as discussed above, Congress went to great lengths to pass the IQA and force OMB to comply with its requirements because of the dramatic effect information disseminated by federal agencies can have on regulated and non-regulated entities alike.

The regulation at issue in Marshall County also used similar language: it set reimbursement rates under Medicare based on average costs for a given geographic area, but allowed

the agency to make certain exceptions at the margins "as the [agency] deems appropriate." 988 F.2d at 1223 (quoting 42 U.S.C. § 1395ww(d)(5)(C)(iii)) (emphasis added). Like this Court in Inova Alexandria Hospital, the D.C. Circuit in Marshall County held that the delegation of discretion quoted above did not render the determination at issue "completely unreviewable." Id. at 1224. Rather, the court concluded that a "specific norm" existed "to guide the [agency's] judgment," and that it could hypothesize scenarios that would clearly be unreasonable under the regulatory scheme at issue. Ibid. The court therefore concluded that judicial review was appropriate. Id. at 1225.

Accordingly, both Inova Alexandria Hospital and Marshall County lead a fortiori to the conclusion that agency decisions denying IQA petitions are not committed to the discretion of administrative agencies by law.

3. The District Court's conclusion that the handling of IQA petitions is committed to agency discretion by law is also inconsistent with the history of the Act. As explained above, Congress enacted the IQA after OMB's repeated refusal to heed its previous demands to adopt information-quality standards. Indeed, it strains credulity to suggest that Congress authorized federal agencies to administer the IQA free from any judicial oversight after these same agencies ignored the express will of

Congress and fought implementation of the information-quality standards mandated by Congress for years prior to IQA.

Finally, the subject matter of IQA petitions provides no basis for denying judicial review either. Federal courts routinely make determinations about the quality and reliability of scientific evidence in applying Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), and its progeny in the context of expert testimony. More to the point, analysis of the quality of evidence underlying agency action has long been part-and-parcel of reviewing courts' inquiry under the "arbitrary and capricious" standards established by the APA, including in a variety of complex regulatory fields such as environmental law and food and drug law. See, e.g., Motor Vehicle Manuf. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983) (holding that the arbitrary and capricious standard requires agencies to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choices made," and noting that an agency's rule will normally be considered arbitrary and capricious "if the agency * * * offered an explanation for its decision that runs counter to the evidence before the agency"); aaiPharma, Inc. v. Thompson, 296 F.3d 227, 242 (4th Cir. 2002), cert. denied, 538 U.S. 923 (2000) (applying

the Supreme Court's ruling from State Farm). 7 / And, as discussed, in considering whether an agency has improperly denied an IQA petition, the federal courts may apply the concrete standards established pursuant to the IQA.

C. Judicial Review Of The Denial Of IQA Petitions Advances The Fundamental Objectives Of The IQA And Other Compelling Public Policy Considerations

Judicial review is necessary to fulfill the objectives of the IQA. If judicial review is unavailable under the APA, the IQA is almost entirely toothless. Agencies may either wrongly deny valid IQA petitions or delay ruling on them indefinitely without fear of consequence, much like they ignored Congress' prior attempts to implement information-quality guidelines. Statistics indicate that both scenarios are not uncommon.

First, OMB itself concedes that initial reports indicate that intra-agency appellate review of IQA petitions has been "critical" in demonstrating to agencies that correction of challenged information is in fact required in certain instances under the IQA. Information Quality: A Report to Congress, Fiscal Year 2003 (2003 Report to Congress) available at http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq at 10.

7/ See also Alan C. Raul & Julie M. Zampa, Deeper Judicial Scrutiny Needed For Agencies' Use of Science, Washington Legal Foundation, Legal Backgrounder, Vol. 17 No. 7 (Jan. 25, 2002) (discussing the application of Daubert and State Farm).

Yet, in most agencies the same office that issues the challenged information also rules on the initial IQA petition and subsequent appeal; there is no point in the process in which such petitions are considered by independent administrative law judges. See James W. Conrad, Jr., Seeking Better Science -- Early Returns From Information Quality Correction Requests, 35 No. 1 ABA Trends 10, 11 (Sept./Oct. 2003). It is logical to assume that, just as in countless other administrative contexts, corrective action required by the IQA may not occur absent independent judicial oversight -- or, equally important, without the prospect of judicial review looming over an agency.

Second, in a recent letter to OMB, the Center for Regulatory Effectiveness (CRE) noted that "a number of agencies are circumventing the [IQA] and OMB's government-wide implementation guidelines by granting themselves numerous extensions in reaching decisions on Requests for Correction (RFCs) and RFC appeals." Letter from J. Tozzi, Center for Regulatory Effectiveness to J. Graham, OMB (Feb. 22, 2005) available at http://www.thecre.com/quality/2005/20050228_regweek.html at 1. Indeed, according to CRE, 13 of 18 then-pending RFCs and RFC appeals had been awaiting agency action longer than permitted under the agency's own guidelines, with 6 of the 13 overdue RFCs/RFC appeals open longer than 200 days -- and two

that were pending longer than 300 days. Id. at 1-2. Moreover, Members of Congress have expressed their concern with agencies' compliance with the IQA on more than one occasion. See, e.g., H.R. Conf. Rep. No. 108-401. (noting Congress's "concern[] that agencies are not complying fully with the requirements of the Federal Data Quality Act"); Letter from Congress Member Barton to United States Dep't of Energy (Jan. 13, 2005) available at http://energycommerce.house.gov/108/News/01132005_1422.htm at 1-2 (seeking additional information so Congress can assess whether agencies "are implementing and following data-quality procedures as Congress intended").

Finally, OMB has itself concluded that none of the dire predictions made by critics of the IQA prior to its implementation have come to pass. In 2003, OMB issued a formal report to Congress containing initial appraisals of the information-quality petition procedures established by the IQA and the regulations promulgated thereunder. See 2003 Report to Congress. Among other things, OMB concluded that the IQA has not (1) opened the floodgates to vast numbers of information-quality petitions; (2) become a tool used only by industry; (3) slowed down the pace of agency regulation; or (4) chilled dissemination of information by agencies. See id. at 8-9. There is no reason to conclude that judicial review of the

limited number of IQA petitions filed annually would produce any of these effects either. Rather, judicial review of agency denials of IQA petitions would provide the necessary oversight to ensure that such petitions are timely and appropriately resolved by federal agencies.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment of the District Court and hold that agency denials of IQA petitions are subject to judicial review.

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UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 05-1097 **Caption:** Salt Institute; Chamber of Commerce of the United States of America

v.

Michael O. Leavitt, Secretary, of Health and Human Services

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