agencies of, and access to, information disseminated by Federal agencies" and requires "each Federal agency *to which the guidelines apply"* to issue its own guidelines, establish administrative mechanisms for the correction of information, and periodically report to OMB (emphasis added). Under well-established principles of statutory construction, Congress' use of the term "shall" in a statute indicates Congress' intent that a provision be construed as mandatory. *Chavez,* 627 F. 2d at 954-955.

IQA §515(a) directs that the OMB Guidelines be issued pursuant to PRA §§ 3504 and 3516. PRA §3504(d)(1) provides that the OMB "shall develop and oversee the implementation of policies, principles, and guidelines to apply to Federal agency dissemination of public information, regardless of the form or format in which such information is disseminated." Section 3516 grants OMB the authority to promulgate rules and regulations necessary to carry out its responsibilities under the PRA. The OMB Guidelines are an exercise of OMB's PRA rule-making authority to oversee the implementation of mandatory information dissemination by Federal agencies.

Agency compliance with the PRA is not discretionary. The PRA expressly directs federal agencies to comply with policies established by the OMB. 44 U.S.C. § 3506 (a) provides that "Each agency *shall be responsible …for complying with* the information policies, principles, standards and *guidelines* prescribed by [OMB]." Disclosure and correction are neither

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"guidelines" with which federal agencies must comply. Also, the Guidelines themselves emphasize that they are binding on Federal agencies. *See* 67 Fed. Reg. at 8452. In determining the legal status and effect of a measure, one must look to substance, not to labels. *Anderson v. Butz*, 550 F. 2d 459, 463 (4th Cir. 1977) (courts "must inquire into the substance and effect [of the agency measure]. The label attached is not controlling"). In *Appalachian Power Co.*, 208 F.3d at 1015, the court concluded that an EPA document entitled "Periodic Monitoring Guidance" had, in substance, the force and effect of law and therefore was subject to judicial review. And, of course, the "guidelines" issued by the United States Sentencing Commission are legally binding.

discretionary nor optional and there is neither textural nor historical support for the Institute's contrary argument.

3. The Denial Was Final Agency Action.

Exercising their Congressionally-mandated right, Plaintiffs filed a Petition for correction and disclosure in accordance with Institute requirements. Compl. ¶ 33. The Institute rejected the Petition, and Plaintiffs appealed. *Id.* ¶ 34. That Appeal, in turn, was denied. *Id.* ¶ 35.

The denial was final agency action. Strictly speaking, it was an "order" arising "in a matter other than rulemaking" - an informal adjudication. 5 U.S.C. §§ 551(4), (6), (7); Breyer et al., supra at 567-68.[28] The denial marked the consummation of the Institute's decision making process, and established the rights and obligations of both parties. *See Bennett*, 520 U.S. at 178; *Mineta,* 357 F.3d at 641 (stating rule that an agency's determination of rights or obligations that is "final" for purposes of APA review "generally stems from an agency action that is directly binding on the party seeking review…").

As a result, Plaintiffs have suffered legal wrong. *See* Compl. ¶47. Plaintiffs are aggrieved, for what was previously an open question has been finally adjudicated, to their

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[28] The binding nature of the agency's denial, and its direct legal effect on the Plaintiffs, is what distinguishes this case from *Flue-Cured Tobacco Cooperative Stabilization Corporation v. EPA*, 313 F.3d 852 (4th Cir. 2002) and the line of Supreme Court cases cited therein. As the Fourth Circuit noted:

> Both *Franklin* and *Dalton* involved agency recommendations which carried persuasive value with the President who was the final decision maker. However, the persuasive value and practical barriers associated with the agencies' recommendations were insufficient to create reviewable agency action under the APA because the challenged agency actions, although they might have influenced the President's decision, did not create any legal rights, obligations, or consequences. Instead, it was the actions of the President which had a direct legal effect on the parties.

*Flue-Cured Tobacco,* 313 F.3d at 860 (citations omitted). Here, it was the actions of the agency, not some third party, that had a direct legal effect on the parties. Therefore, judicial review is available. *Id.* at 857-58.

detriment. *Mineta,* 357 F.3d at 641 (stating rule that an agency's determination of rights or obligations that is "final" for purposes of APA review "generally stems from an agency action that is directly binding on the party seeking review..."). Thus, judicial review is appropriate. The Institute's theory for this case is about Plaintiff's "displeasure with the results of a scientific study" is preposterous. *See* Def.'s Mem. at 1. The Case is about Plaintiff's report to obtain informational data from the Institute and the Institute's refusal to supply it. The Institute mislead the Court here because there simply is no good argument to deny judicial review of the Institute find decision and no good reason to shield their decision for judicial scrutiny.

4. Defendant's Arguments Fail.

Defendant apparently concedes judicial review of IQA claims would be appropriate in a case "involving bonafide agency action, such as a formal agency rule or order clarifying rights or imposing obligations." Def.'s Mem., p.35, n.21. However, it argues that the denial was not "bonafide" agency action, and asserts two grounds for dismissal: (1) since the dissemination of information at issue in this case was not "final agency action," the denial of an IQA petition and appeal seeking correction of such information cannot be "final agency action,"[29] and (2) Congress committed IQA compliance regarding "informal" communications to agency discretion by law. Def.'s Mem., pp. 25-29. Both arguments fail.

**1. The denial, not the dissemination, is relevant, and the refusal to disclose is final.**

Defendant erroneously discusses (at length) whether the Institute's actions in disseminating the DASH-Sodium Trial results or recommending reduced salt intake are "final agency action." He also spends several pages attempting to justify the scientific basis for the

[29] Defendant concedes that there are circumstances in which the dissemination of information, without more, is final agency action. Def.'s Mem., p28, n.16 *citing Tozzi v. United States Dep't of Health and Human Serv.,* 271 F.3d 310, 310-11 (D.C. Cir. 2001).

disseminated information. These points are irrelevant to this case. The gravamen of Count I is the Institute's arbitrary and capricious denial of Plaintiffs' Appeal. Moreover, the existence of studies that allegedly support the disseminated information is absolutely irrelevant – at issue in this motion is the Institute's failure to provide Plaintiffs with information, and make corrections, as required by IQA. *See* Compl. ¶¶ 33-47.

Defendant errs even more seriously by asserting that Institute's denial of a petition and appeal for correction under IQA is "final agency action" only if the underlying dissemination of information itself is "final agency action," and contending that Plaintiffs have "manufacture[d] agency action simply by lodging an administrative challenge to otherwise non-final agency action . . . ." Def.'s Mem., p.28. Plaintiffs did not invent the administrative correction process -- Congress did. Congress explicitly mandated an administrative mechanism allowing affected persons to seek and obtain correction of information disseminated by an agency that does not comply with IQA guidelines to create a mechanism for judicial review, in cases where the right to such review previously had been uncertain. *Bowen,* 487 U.S. at 896 (there is a well settled presumption that Congress is aware of the state of the law at the time it legislates).

Defendant cites *Federal Trade Commission v. Standard Oil Company of California,* 449 U.S. 232 (1980) and *Aerosource, Inc. v. Slater*, 142 F.3d 572 (3d Cir. 1998) as supporting authority. Factually, these cases are inapposite. Neither case involved an agency's final adjudication and denial of a petition for relief that had been specifically authorized by act of Congress.

Analytically, application of "derivative finality" to IQA appeals is simply unsupportable. Dissemination of information constituting "final agency action" is, and always has been, subject to judicial review. *See Tozzi,* 271 F.3d at 310-11. What Congress did through IQA was clarify

affected persons' right to seek and obtain correction of **any** disseminated information, as a matter of law. Imposing a derivative finality barrier to judicial review, as Defendant suggests, would effectively eviscerate IQA, and improperly render the statute a nullity. The denial, and not the disseminated information, is the relevant focus for a *Bennett* analysis.

**2. The 5 U.S.C. §701(a)(2) exception does not apply.**

Defendant bears the burden of demonstrating by clear and convincing evidence that Congressional intent to preclude judicial review is fairly discernable in the detail of the legislative scheme. *Bowen,* 476 U.S. at 670-73; *see also Southern Railway Co. v. Seaboard Allied Milling Corp.,* 442 U.S. 444, 454 (1979) (noting that Court should not lightly interpret a statute to confer unreviewable power on an administrative agency). Seeking to carry this burden, the Institute asserts judicial review is foreclosed under 5 U.S.C. § 701(a)(2), for "the informal agency decisions at issue here were on matters 'committed to agency discretion by law.'" Def.'s Mem., p.29.

The § 701(a)(2) exception is very narrow, applicable only in those rare instances when statutes are drawn so broadly there is no law to apply in a given case. *Citizens to Preserve Overton Park v. Volpe,* 401 U.S. 402, 410 (1971). "No law" means there is no "judicially manageable standard" by which an agency's actions may be judged. *See Inova Hospital,* 244 F.3d at 346. Even if the underlying statute does not include meaningful (or manageable) standards, agency pronouncements in the form of regulations, and/or formal and informal policy statements that impose rights or obligations on the parties can support judicial review. *Id.* (citations omitted).

Courts disfavor 701(a)(2) claims. *See id.*; *Heckler v. Chaney,* 470 U.S. 821, 830 (1985) §701(a)(2) requires that the authorizing statute commit the decision making to the "agency's

judgment absolutely"); *Steenholdt v. Federal Aviation Administration*, 314 F.3d 633, 638 (D.C. Cir. 2003); *see also Chrysler Corp.*, 441 U.S. at 317 (where limits are placed on agency action by statute, there is law to apply). The mere fact that an agency has *some* discretion does not make agency action unreviewable. Courts routinely conclude that judicial review is available notwithstanding statutory language that seemingly allows for unlimited discretion. *Inova Hospital,* 244 F.3d at 348 (citations omitted).

Defendant has three arguments for 701(a)(2) application: (a) The structure of the IQA confirms Congress did not wish to supplant agency discretion regarding "informal communications," (Def.'s Mem., p.31); (b) the OMB Guidelines do not provide manageable judicial review standards (*Id.* p.35); and (c) courts are ill-equipped to determine whether an agency acted arbitrarily or capriciously in declining to correct information without the context and record of formal agency rulemaking or adjudication (*Id.*). These arguments all fail.

*a. IQA applies to all disseminated information.*

Without authority, Defendant asserts "The structure of the IQA confirms that Congress did not wish to supplant agency discretion regarding *informal* communications…" and that the "structure" of the IQA reveals Congress's preference for self-policing by agencies and OMB. Def.'s Mem. at 29-30. Yet, IQA's plain language does not distinguish between "formal" and "informal" agency communications. In truth, there is absolutely nothing in the "structure" of IQA, much less clear and convincing evidence, that "confirms" Congress intended to supplant agency discretion regarding "informal," or have the agencies "self-police."

The OMB Guidelines – to which the Institute was bound in any event - do not distinguish between "formal" and informal communications." Instead, they apply to "**any** communication or representation of knowledge such as facts or data, in any medium or form…"

OMB Guidelines §V(5); OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, INFORMATION QUALITY: A REPORT TO CONGRESS, p.6-7 (2003) (the Guidelines' scope is very broad, spanning information related to regulatory, statistical, research, and benefits programs, covering all Federal agencies subject to the Paperwork Reduction Act, distinguishing only between ordinary information and "influential information" – that is, scientific, financial and statistical information having a clear and substantial impact on important public policy or important private sector decisions).

The OMB Guidelines carve out certain kinds of dissemination from IQA compliance, but "informal communications" - - a concept Defendant seems to have fabricated especially for this case - - are not on the list.[30] In advocating a creation of a legal distinction between "formal" and "informal" agency communications, Defendant improperly seeks to rewrite both IQA and the OMB Guidelines. *See United States v. Mo. Pac. R.R. Co.,* 278 U.S. 269, 278 (1929) (where language of an enactment is clear, and construction according to its terms does not lead to absurd or impractical consequences, the words employed are to be taken as the final express of the meaning intended); *see also INS v. Cardoza-Fonesca,* 480 U.S. 421, 452-53 (1987) (Scalia, J., concurring) (advocating textual approach to interpretation). There is simply no support for the agreement that Congress intended to limit IQA review to formal regulatory action and, indeed, the argument makes no sense because rulemaking always has been subject to intense judicial scrutiny. The IQA was designed principally to address precisely the information presented at issue here.

*b. There are manageable standards for judicial review.*

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[30] *See* 67 Fed. Reg. at 8460.

The law in the Fourth Circuit is clear – even if an agency purports to reserve for itself complete discretion, if that discretion is circumscribed by the provisions of a statute or rule, there are manageable standards for judicial review. *Inova Hospital,* 244 F.3d at 347.[31] The Institute has claimed it has such discretion. In fact, the IQA and the OMB Guidelines limit the Institute's discretion.

As demonstrated above, the OMB Guidelines provide clear and detailed standards against which the Institute's denial may be tested. Plaintiffs' Petition for correction devotes five and a half pages to explaining why the Institute's recommendations failed to comply with the OMB and NIH guidelines requirements regarding "objectivity" alone. Defendant's claim that the Institute has absolute discretion in this case because this comprehensive implementation of the statute provides no basis for meaningful judicial oversight, simply does not stand up.[32]

Defendant also argues there is no law to apply because the OMB Preamble suggests agencies are entitled to some deference in fashioning a correction. *See* Def.'s Mem. at 32-34, citing 67 Fed. Reg. at 8458. He overstates his case. *See Inova Hospital,* 244 F.3d at 346 citing

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[31] In a case involving an agency claim that the Medicare Act did not contain sufficient standards for judicial review, the Fourth Circuit stated:

> Even if the Board purports to give itself complete discretion by rule to dismiss an appeal…the Board's power to dismiss is nevertheless circumscribed by the provisions of the Medicare Act. Because the Hospital's Medicare Act claim turns on the scope of the Act, there is a judicially manageable standard for analyzing this claim.

*Inova Hospital,* 244 F.3d at 347.

[32] As previously noted, even if the underlying statute does not include meaningful (or manageable) standards, agency pronouncements in the form of regulations, and/or formal and informal policy statements that create binding norms by imposing rights or obligations on the parties can provide standards for judicial review. *See Inova Hospital,* 244 F. 3d at 346 (citations omitted); *Heckler,* 470 U.S. at 830 (§701(a)(2) requires that the authorizing statute commit the decision making to the "agency's judgment absolutely"). In this case, however, the IQA's plain language limits agency discretion by mandating Institute compliance with the OMB Guidelines, and by requiring the Institute to maximize the quality, objectivity, utility, and integrity of disseminated information. *See* IQA §515(b).

*Beno v. Shalala,* 30 F.3d 1057, 1066 (9th Cir. 1994); *Robbins v. Reagan,* 780 F. 2d 37, 45 (D.C. Cir. 1985). The Preamble does state: "Agencies...are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB." 67 Fed. Reg. at 8458. However, the OMB Guidelines --which clearly control -- specify:

> The agency shall respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate responses include personal contacts...form letter, press releases, or mass mailings that correct a widely disseminated error or address a frequently raised complaint.

OMB Guidelines §IV(2). In other words, while an agency might in fact have some discretion in determining the method of correction, its obligation to do so, and to do so in a manner that fairly meets the nature of the original information dissemination, is explicitly required by law, and be can be quite substantial when the impact of the error is also substantial, as it was in this case.

The Institute claim that there are no standards for judicial review is strange indeed. Under the APA, the standards for judicial review are set forth in detail. 5 U.S.C. §706. For decades, the Courts have applied their standards to review agency action based upon scientific and empirical data and have determined over and over again that an agency's action was or was in arbitrary, capricious an abuse of discretion, or otherwise not in accordance with law." *Id.* The Institute offers no credible theory to explain a court's inability to apply this well known standard to the circumstances of this case.

Defendant makes the remarkable statement, without supporting citation, that "[t]he OMB guidelines do not purport to impose in all instances an inflexible requirement on agencies to cease dissemination of – or correct – information contained in informal agency statements that might arguably fall short of the goals of the IQA. Def.'s Mem., p.33. IQA, and the OMB

Guidelines, clearly say otherwise. OMB Guidelines, §§II, III, IV, V(5)-(8).[33] As directed by Congress, the OMB Guidelines require agencies to provide a mechanism through which affected persons may vindicate their right to obtain correction of any non-compliant information. *See, e.g.,* OMB Guidelines §§ II(2) (agencies "**shall**" establish administrative mechanisms allowing affected persons to seek and obtain correction of "information maintained and disseminated by the agency that does not comply with these OMB Guidelines"); III(1) (agencies "**shall**" adopt specific standards of quality that are appropriate for the various categories of information they disseminate); IV(2) (the "agency **shall** respond to complaints in a manner appropriate to the nature and extent of the complaint").

For all of these reasons, the court should hold there is law to apply. *Compare Inova Hospital,* 244 F.3d at 346-48; *Chrysler Corp.,* 441 U.S. at 317.

*c. "Floods of litigation" fears and claims of judicial ineffectiveness, are not valid reasons for depriving Plaintiffs of their IQA rights.*

Invoking the hoariest of defenses, Defendant warns (without citation or analysis) that if Plaintiffs succeed in this case, "the floodgates would open and courts would be inundated with claims that all sorts of agency statements relied on information that was not of sufficient

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[33] The OMB Preamble states Federal agencies are obligated to comply with the guidelines and protect affected persons' right to seek and obtain correction. 67 Fed. Reg. at 8452-53. Responding to draft agency guidelines that it felt reserved undue discretion to agencies (and in response to assertions of unreviewability), OMB stated:

> Regardless of what kinds of litigation-oriented disclaimers the agencies may include, agency guidelines should not suggest that agencies are free to disregard their own guidelines. [W]e ask that you not include extraneous assertions that appear to suggest that the OMB and agency guidelines are not statements of government-wide policy, i.e., government-wide quality statements which an agency is free to ignore based on unspecified circumstances.

OMB memorandum entitled "OIRA Review of Information Quality Guidelines Drafted by Agencies" (June 10, 2002) at 14-15.

quality." Def.'s Mem., p. 35. This false premise is disproved by the empirical evidence. According to OMB, "[t]he assumption that certain agencies would be overwhelmed by the volume of correction requests was one of the most common early perceptions. To the surprise of many, that has not been the case." *See* OFFICE OF INFORMATION AND REGULATORY AFFAIRS, p. 8. Since 2002, the federal government has received a grand total of **thirty-five** correction requests. Id. at 8-9. In any event, fear of a litigation flood is not a legally cognizable basis for rewriting IQA, and is, frankly, hardly compelling. It could be raised to deny enforcement or compliance with a wide variety of statutes where, as here, Congress has precluded agency activity from occurring behind closed doors.

Additionally, Defendant claims without authority that courts are "ill-equipped to determine whether an agency acted arbitrarily or capriciously...without having the context and record of formal agency rulemaking or adjudication as a backdrop to inform the determination." Def.'s Mem., p.35. Courts routinely evaluate propriety of agency action without a "context and record of formal agency rulemaking or adjudication." *See Tozzi,* 271 F. 3d at 310-11; *Blaustein & Reich, Inc.v. Buckles,* 220 F. Supp. 2d 235 (E.D. Va.) aff'd ___ F. 3d ___ (4th Cir. 2004). In any event, this case has an ample record that provides sufficient "backdrop" for judicial review.

IV. COUNT II STATES A CLAIM.

If the Court finds for Plaintiffs on Count I, it need not reach the issues raised in Count II. But if, for whatever reason the Court finds that Defendant carried his burden, and demonstrated Congress intended to foreclose judicial review under the APA, then the viability of the new federal information quality regime will depend entirely on the ability of affected parties (like Plaintiffs) to seek and obtain judicial review directly under the IQA.

IQA does not explicitly authorize a direct private right of action; a right of action would have to be, and should be implied. *See Cort v. Ash,* 422 U.S. 66, 78 (1975) (stating test) *cited in Regional Management,* 186 F.3d at 463; *contra Missouri River, supra* (finding no private right of action, but failing to mention or apply the *Cort* factors and failing to engage in any depth analysis of the law). The *Cort* test has four factors: (1) is the plaintiff one of the class for whose benefit the statute was enacted; (2) is there any indication of legislative intent either to create a remedy or deny one; (3) is a private right of action consistent with the underlying purposes of the legislation; and (4) is the cause of action traditionally relegated to state law.

A. Plaintiffs Are Part Of The Covered Class.

IQA was enacted to ensure substantive information that does not meet a basic level of quality should not be disseminated by federal agencies. *See* 67 Fed. Reg. at 8452. According to OMB: "It is crucial that information Federal agencies disseminate meets these guidelines...the fact that the Internet enables agencies to communicate information quickly and easily...increases the potential harm that can result from dissemination of information that does not meet basic information quality guidelines." *Id.* Plaintiffs have been directly and adversely affected and aggrieved by the dissemination of poor quality information, and by the agency's refusal to make available the data necessary to evaluate the quality and objectivity of that information. *See* Compl. ¶¶ 7-9, 31-46, 53. They are within the class of persons for whom the statute was enacted.

B. Legislative Intent Should Be Implied.

If, as Defendant claims, agency denials of IQA appeals are immunized from judicial review, then the only logical reading of IQA is one that provides for a private right of action.

Legal context matters to the extent it clarifies text. *Alexander v. Sandoval,* 532 U.S. 275, 288 (2001). Here, IQA's text, history, and structure provide affirmative evidence Congress intended the statute to provide a private right action. As noted *supra,* the APA categorized all agency action as rulemaking or adjudication, and did not contemplate "regulation by information." Courts therefore have tended not to afford protections for persons injured by government information activities, generally finding lack of finality. *See* Def.'s Mem., pp. 26 – 27 (citing cases). Congress imposed information quality requirements on federal agencies in the Paperwork Reduction Act. Nevertheless, courts generally refused to afford persons affected by the dissemination of poor quality government information with a remedy, unless the dissemination itself could be characterized as "final agency action." *See, e.g., Industrial Safety Equipment Association Inc. v. EPA*, 837 F. 2d 1115 (D.C. Cir. 1988) (denying review).

IQA was Congress's response to this problem. *Bowen,* 487 U.S. at 896 (there is a well settled presumption that Congress is aware of the state of the law at the time it legislates). Its plain language shows Congress intended persons adversely affected by dissemination of poor quality government information could seek and obtain correction when the information in question was not otherwise subject to judicial review. Within this context, and given IQA's text, the only rational reading of the statute is one that concludes Congress intended to grant Plaintiffs a private right of action to enforce their correction rights.[34]

3. Implication Is Consistent With The Legislative Scheme.

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[34] The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right, but also a private remedy. *Sandoval,* 532 U.S. at 286 (citations omitted). In this case, especially given the fact that IQA was a response to the absence of effective recourse for persons harmed by government dissemination of poor quality or false information, it would be illogical in the extreme to hold that Congress created a statutory right without providing an effective remedy. In any event, *Sandoval,* decided by a 5-4 vote, did not overrule *Cort*. Therefore, the Court should consider all of the *Cort* factors in evaluating Plaintiffs' implied private right of action claim.

As set forth *supra,* implication of a private right of action to seek correction is consistent with the statutory language and the legislative scheme, which speaks of "requir[ing] that each Federal agency . . . allow affected parties to seek and obtain correction of information" that does not meet OMB's Guidelines. IQA §515(b); OMB Guidelines §III. **Some** resort to judicial review must exist for this entitlement to have any practical meaning.

4. The Cause Of Action Is Not Traditionally Relegated To State Law.

The cause of action – correction of information disseminated by a federal agency – is not traditionally relegated to state law.

V. COUNT III STATES A CLAIM.

Count III seeks relief under the APA, alleging Defendant violated the Shelby Amendment, illegally failing to make available to Plaintiffs a procedure through which the Sodium Trial data could be obtained under FOIA. *See* Compl. ¶59. Defendant seeks dismissal because Plaintiffs lack standing; because OMB, not the agency, was responsible for implementing the Shelby Amendment through revised Circular A-110; and because OMB's determination was entitled to *Chevron* deference. Def.'s Mem., pp. 38 - 40. None of these claims have merit.

First, Plaintiffs requested and were denied correction and information, and thus have standing. *See supra* at § II; *Sargeant,* 130 F.3d at 1070 (citation omitted); *Public Citizen,* 869 F. 2d at 1548, n.13 (citations omitted). Second, Defendant may not hide behind Circular A-110. It, and not OMB, had the data and refused Plaintiffs access. As a result, Defendant, and not OMB, caused the injury, and is the proper party defendant.[35] Third, Circular A-110 is not entitled to

[35] It was Defendant, not OMB, that failed to make available FOIA procedures to obtain the data, and ultimately denied Plaintiffs access thereto.

*Chevron* deference, as Defendant claims nor is it properly construed to reduce Plaintiff's clearly articulated statutory right to disclosure.

The Supreme Court has made quite clear that *Chevron* is limited to legislative rules -- i.e., rules that agencies issue to implement legislation delegating to them some measure of discretion (and to formal adjudications). *See United States v. Mead*, 533 U.S. 218, 226-230 (2001); *Christensen v. Harris County,* 529 U.S. 576, 587 (2000). *Chevron* does not apply to interpretive rules, or other agency statements of policy or guidance, where Congress has not delegated such legislative authority. *Mead*, 533 U.S. at 226-27. Cases in this category are governed by the *Skidmore* standard, under which an agency's statements are only due some amount of "respect," depending on such factors as "the validity of its reasoning . . and all those factors which give it power to persuade, if lacking power to control." *Skidmore v. Swift &Co.*, 323 U.S. 134, 140. See Mead, 533 U.S. at 221.

The IQA clearly authorizes OMB to issue legislative rules, as it instructs OMB to issue guidelines covering a range of substantive and procedural topics, and fleshing out broad authorizations regarding information quality standards. . Shelby, by contrast, does not delegate any legislative power or discretion to OMB. Rather, Congress' direction in Shelby was crystal clear and ministerial in nature: "require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under [FOIA]" is a precise instruction that leaves no room for the exercise of legislative discretion. Consequently, the agency's impositions of limits on public access is not entitled to *Chevron* deference or any deference or respect at all.[36]

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[36] And even if it was, *Chevron* stands for the proposition that the limitations should be struck down. When a court reviews an agency's construction of a statute, it is confronted with two questions. The predicate question, always, is whether Congress has directly spoken to the

Because these limitations can be found nowhere in Shelby, and are inconsistent with both the statute's language and the drafters' intent, *Skidmore* deference is inapplicable. The Court must therefore strike down the challenged limitations on the agency's duty to disclose, for the temporal and substantive limitations imposed by OMB are manifestly contrary to plain statutory language and undeniable intent. *See* Shelby, *supra.* at 387-89 (stating that final OMB revisions were much narrower than the drafters' original intent, and that "the severe limitations...are contrary to the plain meaning of the statute and Congress's intent in passing the law") (citations omitted).

Shelby must be implemented as written. Defendant's failure to make available FOIA procedures for obtaining the Sodium Trial data was a violation of law. Count III states a claim.

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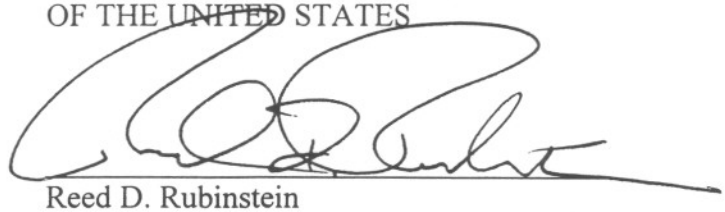
precise question at issue. If the intent of Congress is clear, that is the end of the matter, for the court and agency must give effect to Congress' unambiguously expressed intent. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842-43 (1984). If the statute is silent, or ambiguous, then the question for the court is whether the agency's answer is based on a permissible construction of the statute. *Id.* Congress's direction in Shelby was crystal clear: "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under [FOIA]" is a precise instruction that left no room for the exercise of interpretative judgment. Consequently, OMB did not have the authority to "interpret" Congress' directive by limiting data access only to data from new studies funded after April 17, 2000 that were cited publicly and officially in support of agency action with the force of law. *Id.* at 842-43; *see also Christensen,* 529 U.S. at 596-97 (Breyer, J., dissenting) (stating rule that where it is in doubt that Congress intended to delegate interpretative authority, *Chevron* is inapplicable).

Moreover, even if Shelby is deemed ambiguous, the court must nevertheless strike down the challenged limitations on the agency's duty to disclose, for the temporal and substantive limitations imposed by OMB are manifestly contrary to Congressional intent. *Household Credit Servs. v. Pfennig,* ___ U.S. ___ , 124 S. Ct. 1741, 1748 (2004) (Under *Chevron*, if a statutory term "is ambiguous, the [agency's] regulation implementing [it] 'is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute'"); Shelby, *supra* at 387-89 (stating that final OMB revisions were much narrower than the drafters' original intent, and that "the severe limitations...are contrary to the plain meaning of the statute and Congress's intent in passing the law") (citations omitted).

## CONCLUSION

For the foregoing reasons Defendant's Motion to Dismiss should be denied.

Respectfully submitted,
SALT INSTITUTE
THE CHAMBER OF COMMERCE
OF THE ~~UNITED~~ STATES



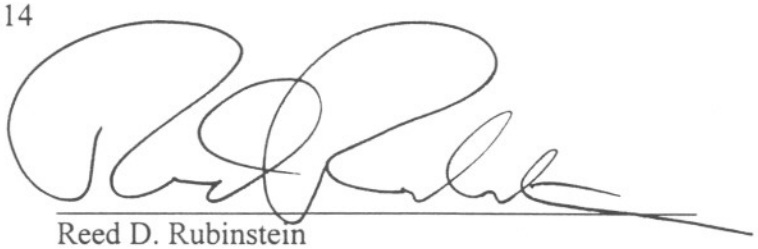
Reed D. Rubinstein
Mark E. Solomons
Greenberg Traurig, LLP
800 Connecticut Avenue, N.W.
Suite 500
Washington, D.C. 20006
(202) 331-3100

OF COUNSEL FOR THE CHAMBER OF COMMERCE OF THE
UNITED STATES
Stephen A. Bokat
Ellen Bryant
National Chamber Litigation Center, Inc.
1615 H Street, N.W.
Washington, D.C. 20062
(202) 462-5337

CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2004, a true copy of the foregoing was served, via First Class Mail, on Defendant, and addressed to its counsel of record:

Dennis C. Barghaan, Jr.
Assistant United States Attorney
2100 Jamieson Avenue
Alexandria, Virginia 22314
(703) 299-3891
Attorney for Defendant



Reed D. Rubinstein