IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

THE ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., et al.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. H-01-2963
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

REPLY MEMORANDUM IN SUPPORT
OF DEFENDANTS' MOTION TO DISMISS

STATEMENT

1. Nature and State of the Proceeding

This case presents a legal challenge to the Privacy Rule adopted under provisions of the Health Insurance Portability and Accountability Act of 1996 ('HIPAA"). Defendants U.S. Department of Health and Human Services and Tommy Thompson ("HHS or "the Secretary" or "the Agency") moved to dismiss this case on December 3, 2001, arguing that plaintiffs' complaint in its entirely lacked subject matter jurisdiction and failed to state a claim upon which relief could be granted. Fed. R. Civ. P. 12(b)(1) & (b)(6). The Court conducted an initial pretrial conference on January 4, 2001, noting the pendency of defendants' motion to dismiss.

Plaintiffs opposed the motion on January 11, 2002. Plaintiffs' opposition is most remarkable for the great effort it expends addressing arguments not raised by defendants' motion, and for the very little resistence it offers to the arguments that defendants did make. Plaintiffs' melding of

irrelevant legal argument together with abstract policy discussions succeeds more in obfuscating the issues than opposing them. With this submission, defendants hereby reply.

2. Statement of the Issues

The issues presented by the government's motion to dismiss and the standards for their review are set forth in the Memorandum of Points and Authorities in Support of Defendants' Motion to Dismiss ("Def. Mem."), at pp. 2-4.

3. Summary of the Argument

Plaintiffs pay great attention to establishing the Court's jurisdiction over their statutory claim, a proposition undisputed by defendants, and focus little on the jurisdictional failings of their constitutional claims. The Fourth Amendment requires for its invocation some coercive conduct by the government. Only one provision of the Privacy Rule requires that, under certain conditions, covered entities provide the government access to protected health information for purposes of enforcing the Privacy Rule. A claim that such access represents an unreasonable search and seizure is premature absent an enforcement action and a factual context in which to assess the government's actions. Because the enforcement provisions (among others) of the Privacy Rule may change prior to the April 14, 2003 compliance date, and because it is highly speculative that these plaintiffs' health information would ever be accessed, plaintiffs' Fourth Amendment claim is unripe. The "permissive" provisions of the Privacy Rule, upon which plaintiffs primarily rely to establish ripeness, cannot give rise to a Fourth Amendment injury. Those sections are neither coercive nor mandatory, but merely permit covered entities to comply with already existing laws.

Plaintiffs also fail to establish their Article III standing under the First Amendment. Indeed, plaintiffs' declarations further cement their lack of standing by establishing that even in the absence

of the Privacy Rule, their grievances will remain unredressed. Plaintiffs offer no cognizable injury separate and apart from their alleged "chill" emanating from the existence of the Privacy Rule, and therefore fall squarely within the line of cases prohibiting standing based on chill alone. Moreover, the objective unreasonableness of their claim is not open to factual dispute, but is easily susceptible to judicial notice, and established by plaintiffs' own declarations.

Plaintiffs' claim that the Secretary exceeded his statutory authority in extending the Privacy Rule to nonelectronic information fails because the Secretary's interpretation of the statute he was entrusted to administer is reasonably related to the enabling statute and entitled to deference. Plaintiffs point to Congress' concern in promoting the efficiencies of electronic transactions, but point to no language establishing that Congress intended to limit privacy protection to electronic transactions only. Plaintiffs' dispute with the Secretary's choices is ultimately one of policy, the wisdom of which is not appropriately at issue. Plaintiffs also fail to bring the Court's attention to legislation passed December 27, 2001 (two full weeks before plaintiffs filed their opposition), which takes note of the Privacy Rule and expressly declines to extend its compliance date beyond the current April 14, 2003 date. Congress' instruction to comply with the Privacy Rule further supports the conclusion that the Secretary acted within his authority, and correctly interpreted congressional will.

Finally, plaintiffs provide little rebuttal to the government's motion to dismiss their Tenth Amendment and procedural claims. Plaintiffs' complaint should, therefore, be dismissed in its entirety.

ARGUMENT

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER PLAINTIFFS' FOURTH AND FIRST AMENDMENT CLAIMS

A. Policy Disputes Are Insufficient to Invoke the Court's Jurisdiction

Plaintiffs begin their opposition with a discussion (unrelated to any particular cause of action) of several provisions of the Privacy Rule with which they disagree. *See* Pl. Mem., pp. 10-13. This discussion is both beside the point and misleading. It is beside the point, because courts "are not concerned . . . with the wisdom, need or appropriateness of . . . legislation." *Olsen v. State of Nebraska, et al.*, 313 U.S. 236, 246, 61 S. Ct. 862, 865 (1941). Plaintiffs' opening discussion is misleading, because it substantively misstates several of the Privacy Rule's provisions.

1. Plaintiffs claim that the Privacy Rule imposes a "federally mandated delay of several months" in order for a patient to gain access to his or her own medical records." Pl. Mem., p. 10. The Privacy Rule, however, does no such thing. To the contrary, the rule generally guarantees patient access to his or her own medical records, and imposes a deadline by which access must be provided: Unless the information is not maintained or accessible on-site,[1] "the covered entity must act on a request for access no later than 30 days after receipt of the request . . . ."[2] 45 C.F.R. § 164.524(b)(2); *see also* 65 Fed. Reg. 82556 ("The time limitation is intended to be an outside

[1] In such a case, "the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt off such a request." 45 C.F.R. § 164.524(b)(2)(ii).

[2] Absent a showing that the agency acted arbitrarily or capriciously, such policy decisions are left to the sound discretion of the agency. *See, e.g. Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416, 91 S.Ct. 814, 823 (1971), *overruled on other ground by Califano v. Sanders*, 430 U.S. 99, 105, 97 S.Ct. 980 (1977); *NLRB v. J.M. Wood Manufacturing Co.*, 466 F.2d 201, 202 (5th Cir.1972); 65 Fed. Reg. 82731-36 (Dec. 28, 2000) (HHS discussion of comments regarding § 164.524).

deadline, rather than an expectation.") Covered entities are free, of course, to provide access within a shorter time. Moreover, state laws that require access within a shorter time frame would still apply, because the Privacy Rule does not preempt state laws which are not contrary to the Privacy Rule.[3] For those states that do not provide any time limit by which covered entities must provide access to patients' own health information, the Privacy Rule provides such a time limit. *See, e.g.*, Pl. Mem., Exh. B (Fla. Stat. § 456.057, requiring access only in "a timely manner" and providing no firm deadline); Pl. Mem., Exh. D (Mo. Stat. § 191.227, providing only for access within "reasonable time"). Thus, rather than delay patient access, the Privacy Rule either does not change existing rights of access or increases them, and plaintiffs' argument to the contrary is baseless.

2. Plaintiffs mistakenly represent that the Privacy Rule "denies timely access by patients who are subjects of medical research . . . ." Pl. Mem., p. 12, 8. In fact, as the regulation makes plain, patients who are undergoing clinical research may temporarily be denied access to their records only if the patient has agreed to such denial of access. Section 164.524(a)(2)(iii), which plaintiffs partially quote at page 12 of their opposition, states as follows:

> An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, **provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon**

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[3] Plaintiffs mistakenly characterize the Privacy Rule as mandating the "preemption of state laws that provide greater rights of access to individuals to their own medical information." Pl. Mem., pp. 8, 11-12. The Privacy Rule does not preempt state laws that are not contrary to the federal rule (i.e., compliance with both is possible), and even contrary state laws are not preempted if they are more protective of patient privacy. Pub.L. No. 104-191, Sec. 264(c)(2), 110 Stat. 2033-34 (Aug. 21, 1996); 45 C.F.R. §§ 160.203(b), 160.202 (defining the term "more stringent" to include any law that provides greater right of access by the individual who is the subject of the information).

completion of the research.

45 C.F.R. § 164.524(a)(2)(3) (bolded portion omitted by plaintiffs); Pl. Mem., p. 12; *see also* 65 Fed. Reg. 82734 (explaining that "only restriction on access to patient information applies where individual agrees in advance to denial of access when consenting to participate in research that includes treatment."); 65 Fed. Reg. 82555 (Dec. 28, 2000). But where such prior agreement exists, it is the patient's agreement, and not the Privacy Rule, that accounts for any delay in access.

3. Plaintiffs err when they broadly proclaim that the Privacy Rule "prevents access by patients to learn how their records have been disclosed to others." Pl. Mem., p. 12, 8. The Privacy Rule provides as one of its standards the right to an accounting of certain disclosures of protected health information. 45 C.F.R. § 164.528(a). Covered entities must temporarily suspend an accounting when doing so would interfere with health oversight and law enforcement investigations. Even then, however, the health oversight or law enforcement official must provide the covered entity with a statement "that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required." 45 C.F.R. § 164.528(a)(2)(i). *See also* 65 Fed. Reg. 82741 (agreeing with commenters' concerns that an accounting could tip off subjects of investigations).[4]

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[4] Plaintiffs also fundamentally misconstrue the nature of the Privacy Rule's "permissive" access provisions. Pl. Mem., pp. 5, 8, 15, 28-29. That point is addressed in connection with plaintiffs' Fourth Amendment claim, *infra*, at pp. 10-11. Similarly, plaintiffs misapprehend 45 C.F.R. §§164.502(d)(2) and 164.514(c). Those provisions simply provide that protected health information which is "de-identified" in accordance with specific regulatory requirements is no longer individually identifiable health information, and that a covered entity can re-identify it for its own use. 45 C.F.R. §§ 164.502(d)(2), 164.514(c). Once re-identified, however, the information is again subject to the Privacy Rule. 45 C.F.R. §§ 164.502(d)(2)(ii), 164.514(c)(2). These provisions are entirely voluntary, and there is certainly no government access to confidential information (mandatory or otherwise) associated with them. They cannot provide the basis for a constitutional challenge.

B. The Government Has Not Contested the Court's Jurisdiction to Hear The Statutory Claim Contained In Plaintiffs' Fourth Claim For Relief.

1. This Court lacks jurisdiction over plaintiffs' constitutional claims under the Fourth and First Amendments due to a lack of standing and ripeness. Defendants did not dispute in their motion to dismiss plaintiffs' standing to bring their statutory claim, nor did defendants claim that plaintiffs' statutory claim was unripe. Yet, the bulk of plaintiffs' opposition is devoted to establishing the standing and ripeness of their statutory claim. *See* Memorandum of Points and Authorities in Opposition to Defendants' Motion to Dismiss ("Pl. Mem."), pp. 4, 5, 11, 12, 16-24, 28-33. This entire discussion is irrelevant, because no one has disputed the Court's jurisdiction to decide plaintiffs' statutory claim.

2. For this same reason, the district court decision in *AAPS v. FDA*, Civ. Action No. 00-2898 (HHK) (D.D.C 2001) (Pl. Exh. A), the decision upon which plaintiffs' jurisdictional argument primarily relies, has no bearing on this case. The district court judge in that case merely found that standing and ripeness did not bar plaintiffs' statutory challenge to a regulatory scheme where enforcement had already begun. Pl. Exh. A, pp. 1, 21-22. No constitutional challenge was even presented. Since defendants have lodged no objection to the adjudication of plaintiffs' statutory claim, plaintiffs' repeated reliance on this decision is simply beside the point.[5]

C. Plaintiffs' Fourth Amendment Claim is Not Ripe for Review

1. In contrast to the effort spent on undisputed issues, plaintiffs barely touch upon the

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[5] Plaintiffs' discussion of associational standing in connection with AAPS' representation of its member physicians is also irrelevant. Pl. Mem., pp. 18-22. Defendants did not dispute AAPS' organizational standing with respect to its member physicians. Rather, defendants questioned AAPS' ability to represent its members as patients, *see* Def. Mem., p. 25, n.18, since AAPS describes itself as a physician organization. Plaintiffs do not address this point, other than to describe it as "moot." Pl. Mem., p. 20.

jurisdictional failings that defendants raised in their motion to dismiss. *See* Pl. Mem., pp. 25-28. As an initial matter, plaintiffs fail to recognize the distinction between the virtually insurmountable jurisdictional barriers facing a pre-enforcement, facial challenge under the Fourth Amendment, and the standards governing an ordinary challenge to agency rulemaking. As defendants stressed in their opening memorandum, constitutional issues should never be decided in the absence of an actual factual setting that makes the decision necessary. *See* Def. Mem., p. 16 (citing cases). Pre-enforcement, facial challenges under the Fourth Amendment are particularly disfavored, since the reasonableness of a search and seizure depends on the particular factual setting.[6] *Id*., pp. 17-18. There has been no enforcement of the Privacy Rule, and thus no application of its enforcement mechanisms, since covered entities are not required to come into compliance until April 14, 2003 (April 14, 2004 for small health plans). *Id*., p. 18. Moreover, to sustain a facial challenge under the Fourth Amendment, plaintiffs must show that the Privacy Rule is not capable of a valid application, a standard plaintiffs cannot meet in the instant case. *Id*., n.12.

Plaintiffs fail to dispute any of these fundamental propositions. Indeed, plaintiffs all but abandon their Fourth Amendment claim based on the only provision of the Privacy Rule that mandates government access to protected health information.[7] *See* 45 C.F.R. § 160.310(c)

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[6] In addition to those cases cited in Defendants' opening memorandum, *see* Def. Mem., pp. 17-18, the Supreme Court recently reiterated that whether the government's actions are reasonable under the Fourth Amendment is an intensely factual inquiry. *United States v. Arvizu*, __ S. Ct. __, 2002 WL 46773 (Jan. 15, 2002) (attached at Exh. 1) (unanimously holding that whether police officer had a reasonable suspicion sufficient to stop vehicle under the Fourth Amendment could only be decided on the totality of the circumstances.)

[7] Because plaintiffs cannot refute the prematurity of their Fourth Amendment claim with respect to 45 C.F.R. § 160.310(c), they never address that provision directly, choosing instead to refer generally to the "broad access" to patient records that the Privacy Rule allegedly allows. *See, e.g.*, Pl. Mem., p. 8, 10, 13-15.

(providing HHS with authority to access health records for purpose of enforcing the Privacy Rule). Although plaintiffs generally insist that the Court need not wait for an enforcement action to act on plaintiffs' claims, and that there is "no chance that resolution of this dispute may ultimately prove unnecessary," Pl. Mem., pp. 30-31, the opposite is true. The only provision of the Privacy Rule that requires covered entities to permit government inspection of covered health information is the oversight authority contained in 45 C.F.R. § 160.310(c). Since there is no possibility of the government invoking this provision prior to the Privacy Rule's compliance date of April 14, 2003, and since such invocation is necessary in order for the court to weigh the reasonableness of the government's actions, plaintiffs' Fourth Amendment claim cannot be ripe in its current posture.

Moreover, contrary to plaintiffs' assertions, plaintiffs' Fourth Amendment claim may never be ripe. As explained previously, HHS could issue an entirely new enforcement rule that would replace the current subpart C of 45 C.F.R. Part 160. Def. Mem., p. 17. HHS has also stated that it will issue other proposed modifications to the Privacy Rule "in one or more rulemakings to ensure that patients' privacy needs are appropriately met." *Id.*, Exh. D, p. 1. These forthcoming modifications to the Privacy Rule are directly relevant to plaintiffs' claim here, because they affect how and under what circumstances the Privacy Rule will be enforced, and, even more fundamentally, what actions will constitute violations at all. *See* Def. Mem., Exh. D (HHS Guidance on privacy standards).

Changes to the rule, therefore, directly affect the enforcement landscape, of which 45 C.F.R. § 160.310(c) is an integral part. Even without modification, the likelihood that these patients' medical records will ever be accessed by the government is exceedingly remote. The government has a number of options from which to choose in exercising its oversight and enforcement

responsibility. Among them, HHS may elect to use administrative subpoenas, it may elect to review only a covered entity's policies and procedures, or it may elect to inspect a covered entity's records that do not contain individually identifiable health information. *See* Def. Mem., pp. 20-21; *United Transportation Union v. Foster*, 205 F.3d 851, 857-58 (5th Cir. 2000). In its current posture, plaintiffs' claim is hypothetical and speculative, and unripe.

2. Having failed to articulate why their Fourth Amendment challenge to 45 C.F.R. § 160.310(c) is not fatally premature, plaintiffs are left to argue that their "privacy harm results immediately from permissive dissemination. . . ." Pl. Mem., p. 28 (emphasis added). The notion, however, that a covered entity's voluntary disclosure of health information could ever constitute an unconstitutional search and seizure is fundamentally misconceived. For an activity to implicate the Fourth Amendment, there must be, at a minimum, some government coercion. *Florida v. Bostick*, 501 U.S. 429, 439, 111 S. Ct. 2382, 2389 (1991) ("The Fourth Amendment proscribes unreasonable searches and seizures; it does not proscribe voluntary cooperation."); *Skinner v. Railway Labor Executives Ass'n*, 489 U.S. 602, 614, 109 S.Ct. 1402, 1411 (1989) (Fourth Amendment implicated only if there is government compulsion).

The provisions in the Privacy Rule which permit disclosure of individually identifiable health information where otherwise required by law are not coercive, and are not mandatory under the rule. Indeed, they do not affect the status quo whatsoever, but exist simply so that covered entities may comply with other laws without violating the Privacy Rule in the process. *See* Def. Mem., pp. 22-23. Whether a covered entity chooses to comply with or to challenge these other laws is entirely the decision of the covered entity. *See e.g.*, 45 C.F.R. §§ 164.510, 164.512, 164.514.

The fallacy of plaintiffs' argument is perfectly illustrated by their own declarations. Plaintiff

Dawn Richardson, for example, claims that she was confronted "by a lawyer from our state health department" who apparently gained access to her children's medical records and discovered that she elected not to vaccinate her children against chicken pox. Declaration of Dawn Richardson, ¶ 5, attached to Pl. Mem. at Exh. H. From this, plaintiff Richardson concludes that the "Privacy Rule discourages patients, including myself, from providing medical history to physicians that can be used against them in this and other ways." *Id.* It is plain, however, that plaintiffs' complaint is not with the Privacy Rule at all, but with the State of Texas, which collected the information at issue. Indeed, whatever disclosures of patient information the State of Texas requires of physicians remain the same whether or not the federal Privacy Rule exists.[8] *See also* Declaration of Melvin E. Edwards, ¶¶ 1-5 (describing injury due to Texas Health Department's gathering of data from children's medical records), attached to Pl. Mem. at Exh. H; Texas Annotated Statutes, attached hereto as Exhibit 2.

In short, the "permissive" disclosures contained in the Privacy Rule merely allow covered entities to comply with pre-existing legal requirements without violating the Privacy Rule in the process. Because these provisions do not themselves compel any disclosure of information, they cannot form the basis of a Fourth Amendment claim.

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[8] The declarations submitted by the plaintiff patients highlight yet another reason why plaintiffs lack Article III standing. In addition to actual or imminent injury, a plaintiff must establish that his or her claimed injury will be redressed by the relief sought. *Lujan v. Defenders of Wildlife*, 504 U.S. 555 , 112 S. Ct. 2130 (1992) (redressability a required element of standing). In this case, plaintiffs have demonstrated in sworn declarations that their alleged injury would not be redressed even if they succeeded in invalidating the Privacy Rule. Irrespective of the Privacy Rule, the State of Texas's access to plaintiffs' medical records would be unchanged. Plaintiffs' claim of standing because "[p]atients seeking real privacy must find and use a paper-only-based physician beyond the reach of the Privacy Rule," thereby limiting their market choice, is similarly flawed. Pl. Mem., p. 19. Paper-based physicians are still subject to state laws, like those in Texas, that currently require the very disclosures about which plaintiffs complain.

D. Plaintiffs' Alleged Chill Is Insufficient To Establish Standing Under The First Amendment

HHS has established that plaintiffs lack standing to bring a First Amendment claim based on allegations of subjective "chill" resulting from the mere existence of the Privacy Rule. First, plaintiffs fail to allege any actual chill. *Laird v. Tatum*, 408 U.S. 1, 14, n.7, 92 S. Ct. 2318, 2326 (1972). Second, even had plaintiffs succeeded in establishing an actual chill, chill alone is insufficient to establish standing absent another cognizable injury. *Laird v. Tatum*, 408 U.S. at 13-14; *United Presbyterian Church in the U.S.A. v. Reagan*, 738 F.2d 1375, 1378 (D.C. Cir. 1984) (Scalia, J.). Third, plaintiffs' allegation of a chilling effect is not objectively reasonable in light of the widespread disclosure to which their information is already subject in the absence of the Privacy Rule. *Whalen v. Roe*, 429 U.S. 589, 602, 97 S. Ct. 869 (1977). Plaintiffs' opposition fails to cure any of these jurisdictional defects.

1. Plaintiffs' declarations fail to establish any actual chill.[9] For the most part, the declarations merely repeat the conclusory allegations of the complaint. They state generally, for example, that "[m]y communications with our health care providers have already been chilled by the Privacy Rule . . . ," Richardson Decl., ¶ 2; Rex Decl., ¶ 2 (Pl. Mem., Exh. H). To the extent plaintiffs provide any specifics, however, the injury about which they complain cannot be redressed by the relief sought in this case, *i.e.*, invalidation of the Privacy Rule. *Lujan v. Defenders of*

[9] According to the complaint and the declarations, the alleged "chill" stems from the government's allegedly improper access to patients' confidential medical information. Pl. Mem., Exh. H (Richardson Decl., ¶ 2; Rex Decl., ¶ 2); Complaint, ¶¶ 2, 7, 23, 32; Pl. Mem., p. 25; Def. Mem., pp. 19, 22, n. 14-15. Any claim of injury by the plaintiff physicians based on this allegation of improper access to patient records is derivative of the patients' claim, and therefore no stronger than the patients' claim. *Whalen v. Roe*, 429 U.S. at 604, n.14. Plaintiffs do not dispute this point. Thus, the plaintiff patients' inability to establish standing based on chill alone disposes of any physician claim on this same ground.

Wildlife, 504 U.S. at 560-61 (standing requires that injury be redressed by favorable decision); *Allen v. Wright*, 468 U.S. 737, 751, 104 S. Ct. 3315, 3324 (1984) (same). Plaintiff Richardson, for example, complains that she has been personally harmed by the disclosure to the "state health department" of her decision not to vaccinate her children against chicken pox. Richardson Decl., ¶¶ 4-5. Similarly, plaintiff Edwards states that the "Texas Health Department" gathered data about his son's emergency room visits, and that his daughter is in the state "ImmTrac" system. Edwards Decl., ¶¶ 2-4.

The Privacy Rule, however, has no bearing on the state of Texas' laws requiring that children be fully vaccinated, or on any Texas laws requiring the disclosure of medical records. *See*, *e.g.*, Exh. 2 (Texas Code § 161.004; § 181.103). Even if the plaintiffs prevail in this case, and the Privacy Rule is invalidated, the Texas laws would remain, and the disclosures about which plaintiffs complain would be unaffected. Plaintiffs' declarations, therefore, do establish any actual chill relevant to the Privacy Rule.

2. Plaintiffs cannot refute the substantial body of authority holding that subjective allegations of chill, without more, will not suffice to confer standing.[10] Although plaintiffs cite to the Supreme Court's decision in *Meese v. Keene*, 481 U.S. 465, 107 S. Ct. 1862 (1987) as "confirm[ation] that potential victims of the chill can sue," that decision is, in fact, in full accord with *Tatum* and its progeny.

The question presented in *Keene* was whether a U.S. citizen who wanted to use and exhibit

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[10]*See Laird v. Tatum, 408 U.S. at 13-14; United Presbyterian Church in the U.S.A. v. Reagan*, 738 F.2d at 1378; *The California Bankers Assn. v. Shultz*, 416 U.S. 21, 56-57, 94 S. Ct. 1494, 1515-16 (1974); *American Library Assn v. Barr*, 956 F.2d 1178, 1192-93 (D.C. Cir. 1992); *Poe v. City of Humble, Texas,* 554 F. Supp. 233, 237 (S.D. Tex. 1983).

Canadian films had standing to challenge their designation under the Foreign Agents Registration Act as "political propaganda." One of plaintiff's claims was that he wished to exhibit to the films, but was deterred from doing so due to the designation of films as political propaganda. Citing *Laird v. Tatum*, the Court stated:

> If Keene had merely alleged that the appellation deterred him by exercising a chilling effect on the exercise of his First Amendment rights, he would not have standing to seek its invalidation.

Keene, 481 U.S. at 473 (emphasis added). The plaintiff in *Keene*, however, unlike the plaintiff in *Laird v. Tatum*, and the plaintiffs here, did not rely solely on a chilling of First Amendment rights. He also established concrete injury separate from the chill itself. Keene alleged, for example, that as an attorney and member of the California State Senate who was running for reelection, exhibiting films that the Department of Justice had classified as "political propaganda" would hurt his reputation in the community and his chances for reelection. *Keene,* 481 U.S. at 473-74.

The only other attempt plaintiffs make to distinguish *Tatum* and *United Presbyterian Church* is to note that plaintiffs in those cases were not directly regulated by the law they were challenging. Pl. Mem., p. 27. Plaintiffs' claim that "[h]ere, plaintiffs are themselves subject to the regulation they challenge," i*d*., is only partially correct. While physicians who are covered entities are certainly subject to the regulation, the patients, who claim to be chilled by governmental access to their confidential medical information, Pl. Mem., pp. 25-26, are not. Their allegation of "chill" flows simply from the existence of the Privacy Rule. Accordingly, they fall squarely within the *Laird v. Tatum* line of cases.[11]

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[11] Citing *Public Citizen v. FTC*, 869 F.2d 1541 (D.C. Cir. 1989), plaintiff patients also claim that they can establish standing because they "suffer from a chilling of physician advice due to third-party intrusion." Pl. Mem., p. 26. *Public Citizen*, however, did not concern a claim

3. Plaintiffs do not dispute that even absent the Privacy Rule, plaintiffs' medical information is subject to wide-ranging dissemination, making plaintiffs' claim of chill objectively unreasonable. Instead, plaintiffs claim that such a "factual defense" cannot support a Rule 12 (b) motion. Pl. Mem., p. 28. The Supreme Court, however, has already established this unremarkable proposition. It stated that, in addition to routine disclosures of personal health information to hospital personnel, insurance companies and public health agencies, states commonly require reporting relating to venereal disease, child abuse, injuries caused by deadly weapons, and certifications of fetal death. *See Whalen v. Roe*, 429 U.S. at 602, n.29; Def. Mem., pp. 27-28. [12] State reporting laws are a matter of public record of which this Court can take judicial notice. Fed. R. Evid. 201(b). Plaintiffs themselves established this very fact through their declarations. Pl. Mem., Exh. H. Absent the

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of chill, and is not on point here. In that case, plaintiffs established standing to challenge regulations exempting certain products from carrying warning labels about smokeless tobacco. Some plaintiffs had actually used smokeless tobacco products because they were not fully aware of the health risks associated with them. 869 F.2d at 1546. Attestations that the Privacy Rule conflicts with the Hippocratic Oath, Pl. Mem., pp. 26-27, Exh. J, are also insufficient to imbue plaintiffs with standing under the First Amendment. Unlike the attorney-client privilege, Pl. Mem., pp. 26-27, there is no common law or federal physician-patient privilege (other than for psychotherapy). *Whalen v. Roe*, 429 U.S. at 602 n.28; *United States v. Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1311 (5th Cir. 1987); *United States v. Lindstrom*, 698 F.2d 1154, 1167, n.9 (11th Cir. 1983); Def. Mem., p. 25, n.19.

[12] Plaintiffs attempt to distinguish *Whalen v. Roe* by emphasizing that the disclosure of confidential medical information sanctioned in that case was protected from further disclosure by safeguards not present here. Pl. Mem., pp. 14-15. The Privacy Rule, however, provides substantial safeguards preventing information HHS acquires from further dissemination. Indeed, the one (and only) provision mandating government access to protected health information includes a concomitant provision requiring the safeguarding of the information. *See* 45 C.F.R. § 160.310(c)(3); Def. Mem., p. 28. Even more importantly, records collected by an agency and kept in a system of records are subject to the Privacy Act of 1974. 5 U.S.C. § 552a. The Privacy Act, enacted two years after the statute that gave rise to *Whalen*, provides for both civil and criminal penalties for violations. Thus, far greater safeguards protect health information that the Secretary might access under the Privacy Rule than existed in *Whalen v. Roe.*

Privacy Rule, plaintiffs would still be subject to all the Texas laws regarding immunization and child abuse reporting about which they specifically complain. *Id*; *see supra*, p. 10-11.

4. In a final effort to establish standing, plaintiffs rely on *Whalen v. Roe*, *supra*, arguing that because the plaintiffs in that case had standing, so too must plaintiffs in this case. Pl. Mem., p. 4. This argument makes little sense, since standing is an individualized inquiry that must be assessed on a case-by-case basis. *See U.S. v. Hays*, 515 U.S. 737, 746, 115 S. Ct. 2431 (1995). In *Whalen v. Roe*, the Court found that plaintiffs there had incurred actual injury. For example, due to the reporting requirements of the New York State Controlled Substances Act of 1972, one plaintiff had taken his child off Schedule II medication. Another plaintiff had gone to another state to obtain Schedule II drugs. *Whalen v. Roe*, 429 U.S. at 595, n.16. Plaintiffs here cannot establish this kind of concrete injury. Moreover, as explained above, the future chill that they allege is neither attributable to Privacy Rule, nor redressable by its invalidation.[13] *See supra*, pp. 10-11, 13; Pl. Mem., Exh. H. Lacking any Article III injury, plaintiffs' First Amendment claim must be dismissed.

III. PLAINTIFFS' TENTH AMENDMENT CLAIM MUST BE DISMISSED

Plaintiffs lack standing to bring their Tenth Amendment claim because, as the Supreme Court has held, "absent the states or their officers," private individuals "have no standing . . . to raise any question under the [Tenth A]mendment." *Tennessee Elec. Power Co. v. TVA*, 306 U.S. 118, 144, 59 S. Ct. 366, 372-73 (1939). Plaintiffs point to no case explicitly overturning that decision of the Supreme Court. Absent such an express disavowal, *Tennessee Elec. Power Co.* remains good law.

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[13] Plaintiffs also rely on *Whalen v. Roe* in an effort to recast their challenge to the Privacy Rule as a violation of an undefined constitutional right to privacy. Pl. Mem., pp. 13-16. Regardless of the constitutional label, however, plaintiffs are still required to establish Article III standing.

Hohn v. United States, 524 U.S. 236, 252-253, 118 S. Ct. 1969, 1978 (1998); *Agostini v. Felton*, 521 U.S. 203, 237, 117 S. Ct. 1997, 2017 (1997).

1. Plaintiffs err in their reliance on *United States v. Morrison*, 529 U.S. 598, 120 S. Ct. 1740 (2000), and *United States v. Lopez*, 514 U.S. 549, 115 S. Ct. 1624 (1995), for the proposition that the Supreme Court recognizes individual standing in Tenth Amendment cases. Pl. Mem., pp. 34-35. Neither of those cases was brought under the Tenth Amendment. Rather, they were brought directly under the Commerce Clause. U.S. Const., Art. I, § 8, cl. 3. In *Reno v. Condon*, 528 U.S. 141, 120 S. Ct. 666 (2000), which did present a claim under the Tenth Amendment, the party advancing the claim was, appropriately, the State of South Carolina and its Attorney General.

2. Even if standing were established, plaintiffs' Tenth Amendment claim would fail. No "factual development," Pl. Mem., p. 35, is necessary to recognize that the business of health care administration falls squarely within Congress' Commerce Clause powers as a matter of law. Indeed, courts have already so held. Def. Mem., pp. 31-32. As opposed to the noneconomic, violent criminal conduct at issue in *Lopez* (possession of firearms in school zones), and *Morrison* (gender-based violence), here Congress has regulated the business practices of an industry whose effect on interstate commerce is beyond dispute. Def. Mem., pp. 32-33; *Morrison*, 529 U.S. at 617. Moreover, federal statutes regulating privacy are commonplace. Def. Mem., p. 33; 65 Fed. Reg. 82468-69 (Dec. 28, 2000). The Supreme Court had little trouble, for example, upholding the Driver's Privacy Protection Act, a privacy protection statute regulating the disclosure and resale of drivers' personal information. *Reno v. Condon*, 528 U.S. 141 (2000). This Court should similarly, and summarily, sustain the privacy protection provisions of HIPAA as an appropriate exercise of Congress' Commerce Clause powers.

IV. THE SECRETARY WAS WITHIN HIS STATUTORY AUTHORITY IN APPLYING THE PRIVACY RULE TO INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION IN NON-ELECTRONIC FORM

A. The Statute Does Not Limit The Secretary's Authority Exclusively To Electronic Transactions, And His Reasonable Interpretation Of The Statute Is Entitled To Great Deference

Nothing in the language of section 264 of HIPAA limits the regulation of individually identifiable health information to electronic form only, and by covering both electronic and non-electronic records, the Secretary is effectuating the statutory purposes of protecting privacy, encouraging electronic transactions and simplifying health care administration. Def. Mem., pp. 33-45. Plaintiffs' attempt to argue otherwise is misplaced.

1. Plaintiffs go to lengths to establish that Congress sought to enable electronic transactions. Pl. Mem., pp. 37-38. But that point is undisputed. It is also undisputed that Congress instructed HHS to issue regulations protecting the privacy of individually identifiable health information. The issue is whether, in so doing, Congress expressly limited the Secretary to protecting the privacy of electronic transactions only. Plaintiffs can cite no such express limitation.[14]

On the other hand, there are several indications that Congress did not intend to limit the Secretary to the regulation of electronic transactions only:

(i) Section 264(c)(1) gives the Secretary authority to promulgate regulations "containing" the standards set forth in subsection 1173(a), thereby setting a regulatory floor;

(ii) section 264(c)(1) provides that the Secretary address "at least" the subjects described in subsection (b) of section 264;

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[14] Nor has the Secretary conceded such a limitation. Pl. Mem., p. 38. The language that plaintiffs quote at 65 Fed. Reg. 82567 was directed to the definition of "covered entity." In response to comments seeking to broaden the definition, the Secretary responded that its jurisdiction over who was covered by the rule was limited, because the statute expressly defined who was to be a covered entity. 42 U.S.C. § 1320d-1(a)(2).

(iii) subsection (b) of section 264 contains no express limitation to electronic transactions, and affirmatively instructs the Secretary to regulate "individually identifiable health information"; and

(iv) Congress defined "health information" to include information that is "oral or recorded in any form or medium;"

See Def. Mem., pp. 35-38.

Plaintiffs ignore nearly all of this language, relying exclusively on the "principle of *ejusdem generis*" to argue that the definition that Congress gave to the term "health information" is merely there to ensure that all, and not just some, electronic transmissions are governed by the Rule." Pl. Mem., p. 41. The definition of "health information," however, is antithetical to such a limited interpretation.[15] Health information specifically "means any information, whether oral or recorded in any form or medium. . . ." 42 U.S.C. § 1320d(4). It is unnatural to assume that "oral" refers to an electronic transaction, or to assume that "any form or medium" means only an electronic form or medium. The appropriate principle of statutory construction here is not, therefore, "*ejusdem generis,*" but the more fundamental principle that words in a statute should be given their natural, plain, ordinary and commonly understood meaning.[16] *See U.S. v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972).

Overall, plaintiffs fail to confront the bedrock principle that, because the statute does not

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[15] The term "health information" is not defined in the context of electronic transmissions at all, Pl. Mem., p. 41, but is contained in a general definitions section, applicable to all of the Administrative Simplification provisions. *See* 42 U.S.C. § 1320d(4).

[16] To counter Latin with Latin, the principle of *expressio unius est exclusio alterius* also acts to exclude plaintiffs' interpretation. (Where Congress has carefully employed a term in one place and not used it in another, it should not be implied where not used). Congress limited other provisions of HIPAA to electronic transactions, *see, e.g.*, 42 U.S.C. § 1320d-1(a)(3), and its failure to so limit the definition of health information, or Section 264 generally, must be taken as deliberate. *See* Def. Mem., pp. 36-37.

expressly limit the Secretary's authority to electronic records, the Secretary's interpretation of the statute is entitled to great deference. "We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer . . . " *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 104 S. Ct. 2778 (1984) (citations omitted).[17]

2. Nor do plaintiffs dispute that so long as the Secretary's interpretation is reasonably related to the purposes of the enabling statute, it must be sustained. Pl Mem., p. 41 (declaring this an "unremarkable proposition"). The Secretary has already explained why the inclusion of non-electronic information within the Privacy Rule promotes the purposes of HIPAA. Def. Mem., pp. 42-43. Limiting the Privacy Rule to electronic information would leave enormous gaps in privacy protection. *See* Pl. Mem., pp. 38-39 (conceding that most medical records are paper records). It would also create a disincentive to compliance with the electronic transactions standards required by HIPAA, since covered entities could avoid the Privacy Rule altogether by using paper instead of computerized record systems – a result plainly contrary to HIPAA's stated purpose of promoting the efficient and effective administration of the health care system. By closing this loophole, and removing the disincentive to computerization, the Privacy Rule promotes the Act's objective of enabling health information to be exchanged electronically. *Id.*

Plaintiffs disagree mightily, arguing that "there are compelling interests against extending the Privacy Rule to the much larger category of paper records." Pl. Mem., pp. 42-43. The role of this

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[17] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 120 S. Ct. 1291 (2000), is not to the contrary. There, the Court reaffirmed that an agency's construction of a statute that it administers is entitled to deference, but found that Congress, in the case before it, had unambiguously spoken to the issue of tobacco regulation. 529 U.S. at 131-32.

Court, however, is not to choose between different policies, or to determine which is the wisest or the best one. That task is committed to Congress, and to the agency to which Congress has delegated regulatory authority.[18] Even if the Court disagrees with the agency's ultimate decision, so long as it reasonably effectuates the purpose of the enabling statute, the Secretary has not exceeded his legal authority as a matter of law.[19] *Mourning v. Family Publication Service, Inc.,* 411 U.S. 356, 372-74, 93 S. Ct. 1652, 1661-63 (1973); *see also Diefenthal v. CAB*, 681 F.2d 1039, 1043-44 (5th Cir. 1982). Plaintiffs have had the opportunity to express their views both to Congress directly through their lobbying efforts, and to the Agency through the rulemaking process. It is in those fora that plaintiffs' policy concerns should be addressed.

B. Congress Has Expressly Endorsed the Privacy Rule

Congress, through its own General Accounting Office ("GAO"), was specifically made aware that the scope of the Privacy Rule extended beyond electronic transactions. Moreover, the GAO agreed with the Secretary that nothing in the statute precluded such an extension, and that absent the inclusion of non-electronic records, the purpose of statute would be undermined. Def. Mem., pp. 43-

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[18] *See Chevron*, 467 U.S. at 866 ("The responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones."); *Rust v. Sullivan*, 500 U.S. 173, 187, 111 S. Ct. 1759 (1991) (agency has greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated).

[19] Plaintiffs off-handedly refer to "discovery in this action," as if the Court's function here were to undertake *de novo* review. It is a fundamental principle of administrative law, however, that in a legal challenge to an agency's rulemaking authority (or to agency action under Administrative Procedure Act), plaintiffs are not entitled to go behind the public rulemaking record absent a credible allegation of bad faith. Even were the Court to deny defendants' motion, therefore (which it should not), discovery in this case would be inappropriate. *Department of Interior and Bureau of Indian Affairs v. Klamath Users Protective Assn.*, 532 U.S. 1, 121 S. Ct 1060, 1065 (2001); *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 149 (1975); *U.S. v. Morgan*, 313 U.S. 409, 422 (1941); *Franklin Savings Assn. v. Ryan*, 922 F.2d 209, 211 (4th Cir. 1991).

44 & Exh. H, I. Plaintiffs, relying on *Boys Market, Inc. v. Retail Clerks Union*, 398 U.S. 235, 90 S. Ct. 1583 (1970), argue that congressional silence should not interpreted as congressional approval. Pl. Mem., pp. 43-44. The government agrees that this is the general rule, and indeed, cited to *Boys Market* in its opening brief. Def. Mem., p. 43, n.31. However, when Congress is expressly made aware of an agency interpretation, through, for example, congressional hearings, the reverse inference applies. Def. Mem., p. 43-44.[20] Plaintiffs fail to address any of these cases, discounting the GAO's endorsement of the Secretary's interpretation as "isolated testimony." Pl. Mem., p. 44. Congress, plaintiffs argue, has simply been too busy to bother with the Privacy Rule. *Id*., p. 43. Plaintiffs are wrong.

Congress has managed to find time for further consideration of HIPAA and the Privacy Rule. On December 27, 2001, Congress passed the "Administrative Simplification Compliance Act," Pub. L. 107-105, 115 Stat. 1003 (attached hereto as Exh. 3). The legislation provides a mechanism by which covered entities may extend the time to comply with the transactions and code set rules adopted under HIPAA, contained in 42 U.S.C. 1320d-4. *See* Pub L. 107-105, Sec. 2(a)(1); Cong. Record, Jan. 3, 2002, p. E2525 (legislative history) (attached hereto as Exh. 4). At the same time, however, Congress declined to extend the date by which covered entities must comply with the Privacy Rule. *See* Pub. L. 107-105 (b)(1)-(2) (providing that "nothing in this section shall be construed as modifying the April 14, 2003, deadline for [covered entities] to comply with the

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[20] *See United Hospital Center v. Richardson*, 757 F.2d 1445, 1451-52 (4th Cir. 1985) (citing *United States v. Sheffield Bd. of Comm'rs*, 435 U.S. 110, 131-32 , 98 S. Ct. 965, 979 (1978)); *CBS v. FCC*, 453 U.S. 367, 385, 101 S. Ct. 2813, 2824 (1981)*; Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381, 89 S. Ct. 1794, 1802 (1969); *Zemel v. Rusk*, 381 U.S. 1, 11-12, 85 S. Ct. 1271, 1278 (1965); *Fredericks v. Kreps*, 578 F.2d 555, 563 (5th Cir. 1978) (en banc); *State of Florida v. Mathews*, 526 F.2d 319, 324 (5th Cir. 1976).

requirements of subpart E of part 164 of title 45, Code of Federal Regulations," and affirmatively providing that the privacy standards shall apply to covered entities regardless of when they comply with the transactions standards).

The legislative history of Pub. L. 107-105, in a section subtitled "Scope and Application of Confidentiality Rule," explains that "[i]n this legislation, the Committee has sought to ensure that entities become compliant with the April 14, 2003 HIPAA confidentiality requirements despite the fact that the final transaction standards will not be effective until six months later." Cong. Record, Jan. 3, 2002, p. E2526 (Exh.4). Given this legislation's express recognition of the Privacy Rule, and Congress' expressed intention to have compliance with the rule effecuated within the time frame originally established, there is no room to argue that Congress is not fully apprised of the full scope of the Privacy Rule. Moreover, the law's express instruction that the Privacy Rule become effective on schedule is strong evidence that the Secretary regulated within his statutory authority.[21] Such evidence further warrants the dismissal of plaintiffs' fourth cause of action.

V. THE SECRETARY FULLY COMPLIED WTH THE REGULATORY FLEXIBILITY ACT

Plaintiffs do not refute that the Secretary's compliance with the Regulatory Flexibility Act is reviewed only "to determine whether an agency has made a 'reasonable, good-faith effort' to carry out [its] mandate . . . ." *Alenco Communications, Inc., et al., v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000), quoting *Associated Fisheries, Inc. v. Daley*, 127 F.3d 104, 114 (1st Cir. 1997). *See* Def. Mem., p. 46. Contrary to plaintiffs' assertions, the ultimate wisdom of the Secretary's choices are not

[21] Although the Administrative Simplification Compliance Act became law on December 27, 2001, a full two weeks before plaintiffs submitted their opposition memorandum, plaintiffs fail entirely to address it.

at issue, but only his compliance with the Act's procedural requirements. *Alenco*, 201 F.3d 608 at 625. Nor is discovery appropriate – the entire Regulatory Flexibility Analysis, as well as the Final Regulatory Impact Analysis, are set forth in full in the Privacy Rule, and provide the sole basis to determine the reasonableness of the Agency's procedural compliance. *See* 65 Fed. Reg. 82782-93; 65 Fed. Reg.82758-79; Def. Mem., pp. 46-47.

Plaintiffs' insistence that the Secretary failed to consider the impact of the Privacy Rule on small businesses is belied by the record. Contrary to plaintiffs' contention, for example, the Secretary considered and responded to many proposals for alternative treatment of small businesses. For example, the Secretary considered giving small businesses a longer time to comply with the Privacy Rule. He concluded, however, that he was prohibited from doing so by the express statutory language mandating that all covered entities, except for small health plans, come into compliance within two years. 65 Fed. Reg. 82752, 82779, 82782. The Secretary also considered exempting small businesses from the Privacy Rule altogether. However, "[s]mall entities constitute the vast majority of all entities that are covered; to exempt them would essentially nullify the purpose of the rule." 65 Fed. Reg. 82779.[22]

With respect to implementation of the Privacy Rule, the Secretary embraced a flexible approach called "scalability." 65 Fed. Reg. 82782. Under this principle, the rule generally permits a covered entity, wherever possible, the opportunity to create its own procedures for complying with the rule that are best suited to its size and sophistication. For example, section 164.530, requires that

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[22] Plaintiffs wrongly claim that only "now" has the Secretary disclosed his retaining of an outside consultant to assist in assessing the cost of systems compliance for small businesses. Pl. Mem., p. 46. This, along with the abundant consideration of the rule's impact on small business, is addressed in the Regulatory Flexibility Analysis. *See, e.g.*, 65 Fed. Reg. 82757.

a covered entity designate a privacy official. It is left up to the covered entity, however, to determine how best to comply. A small physician practice may choose to designate the existing office manager as the privacy official. A large health plan may prefer a privacy staff or board. 65 Fed. Reg. 82782, 45 C.F.R. § 164.530(a)(1). Plaintiffs may disagree with the Secretary's approach. Such disagreement, however, does not constitute a violation of the Regulatory Flexibility Act. The Secretary fully complied with his obligations, and plaintiffs' claim should, accordingly, be dismissed.[23]

CONCLUSION

For all the foregoing reasons, and those set forth in defendants' opening memorandum, plaintiffs' complaint should be dismissed.

Respectfully submitted,

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[23] Plaintiffs fail entirely to respond to the express statutory language in the Paperwork Reduction Act that precludes the remedy they seek in their complaint. Def. Mem., p. 48. Citing two interrelated judicial decisions, plaintiffs argue that courts have reviewed "private party claims challenging agency action under the PRA." Pl. Mem., p. 47. The cases cited by plaintiffs, however, are inapplicable, because they were not challenges to an agency's compliance with the Paperwork Reduction Act. Rather, they addressed a legal question as to the scope of the PRA itself, specifically whether OMB had authority under the PRA to countermand agency regulations. *See, e.g., Dole v. United Steelworkers of Am.*, 494 U.S. 26, 110 S. Ct. 929 (1990).