

No. 02-20792

IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIFTH CIRCUIT

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THE ASSOCIATION OF AMERICAN  
PHYSICIANS & SURGEONS, INC., *et al.*,

Plaintiffs-Appellants,

vs.

UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES, *et al.*,

Defendants-Appellees.

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**CERTIFICATE OF INTERESTED PARTIES**

The undersigned counsel of record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the Judges of this Court may evaluate possible disqualification or recusal.

**A. Parties:**

**Plaintiffs-Appellants:**

1. The Association of American Physicians and Surgeons, Inc. (“AAPS”)
2. Congressman Ron Paul, M.D.

3. Dawn Richardson
4. Rebecca Rex
5. Darrell McCormick

**Defendants-Appellees:**

6. United States Department of Health and Human Services
7. Tommy G. Thompson,  
Secretary of the U.S. Department of Health and Human Services

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## **STATEMENT REGARDING ORAL ARGUMENT**

Plaintiffs-Appellants request oral argument to address the important issue of medical record privacy, and the standing and ripeness existent in this action.

Plaintiffs-Appellants respectfully submit that oral argument would assist in the resolution of this matter.

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Karen Tripp

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Plaintiffs-Appellants,	)	
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	)	
Defendants-Appellees.	)	
	)	

**MEMORANDUM OF PLAINTIFFS-APPELLANTS**

Plaintiffs-Appellants The Association of American Physicians & Surgeons, Inc. (“AAPS”), Congressman Ron Paul, M.D., Dawn Richardson, Rebecca Rex and Darrell McCormick respectfully submit this memorandum in order to reverse the decision below.

**JURISDICTIONAL STATEMENT**

The district court has original jurisdiction in this action under the Constitution of the United States and 28 U.S.C. §§ 1331, 1337. This Court has jurisdiction pursuant to 28 U.S.C. § 1291. This appeal is from a final judgment entered on June 17, 2002, which disposed of all claims in this case. Plaintiffs filed a timely notice of appeal on July 11, 2002. *See* Fed. R. App. Proc. 4(a)(1).

## **STATEMENT OF ISSUES**

1. Whether the district court erred in failing to apply *Whalen v. Roe*, which establishes standing and ripeness for plaintiffs' claims.
2. Whether the district court erred in categorically denying standing to private individuals who challenge violations of federalism and the Tenth Amendment.
3. Whether the district court erred in failing to apply the Regulatory Flexibility Act to defendants' refusal to consider meaningful alternatives for small practitioners.

## **STATEMENT OF THE CASE**

On December 28, 2000, the Secretary of the Department of Health and Human Services (the "Secretary" or "HHS") published the so-called "Privacy Rule," which constitutes the unprecedented federal regulation of personal medical records and subjects them to broad governmental access. 65 Fed. Reg. 82462. A massive regulatory scheme, the Privacy Rule creates substantial new costs without any relief for small medical practices. The Privacy Rule became effective as of April 14, 2001. *See id.* ("The final rule is effective on February 26, 2001," later postponed to April 14, 2001, *see* 66 Fed. Reg. 12434).

A physicians' organization, a Congressman-physician, and several patients filed this lawsuit on August 30, 2001. Complaint ¶¶ 11-15 (hereinafter, "Comp.

\_\_\_”), Appellants Record Excerpts, Tab 5 (hereinafter, “Tab \_\_\_”). Plaintiff AAPS, founded in 1943, is a nonprofit organization of thousands of physicians in all specialties, many already directly injured by costs and intrusions caused by the Privacy Rule. AAPS has defended medical record privacy, and its privacy survey was even cited by the Secretary in issuing the Privacy Rule. 65 Fed. Reg. 82468. The motto of AAPS is “omnia pro aegroto,” which means “all for the patient.”

Plaintiff Ron Paul, M.D., is an individual physician who also serves in the U.S. Congress on behalf of a Texas district. The patient plaintiffs are Dawn Richardson, Rebecca Rex, and Darrell McCormick, the first two of whom reside in Texas. They all suffer from the invasion of their medical record privacy wrought by the Privacy Rule.

Plaintiffs challenged the Privacy Rule based on the First, Fourth and Tenth Amendments. Comp. ¶¶ 31-43 (Tab 5). Plaintiffs also objected to the failure by HHS to consider meaningful alternatives for small practitioners, in violation of the Regulatory Flexibility Act. *Id.* ¶¶ 51, 52-54. Plaintiffs asserted additional claims not pursued on this appeal.

On December 3, 2001, defendants moved to dismiss the Complaint, primarily arguing lack of standing and ripeness. Plaintiffs opposed this motion by memorandum dated and filed January 11, 2002. The district court granted

defendants' motion to dismiss on primarily procedural grounds, by order entered on June 17, 2002.

In dismissing this action, the lower court held “that plaintiffs’ pre-enforcement Fourth Amendment claims are premature and not ripe for judicial review.” 2002 U.S. Dist. LEXIS 15857, \*19 (S.D. Tex. June 14, 2002) (Tab 4). As to plaintiffs’ First Amendment claims, the court dismissed them for lack of an “actual chill”: “Because plaintiffs have not shown that the Privacy Rule itself has directly caused their alleged injuries, they have failed to establish any actual chill ensuing from the Privacy Rule.” *Id.* at \*21.

Plaintiffs’ Tenth Amendment claims met a similar fate, but for a different reason. The court below categorically denied standing to private individuals on federalism or Tenth Amendment grounds. “[T]he court concludes that plaintiffs have no standing as private individuals to pursue their claims under the Tenth Amendment.” *Id.* at \*23. The district court also dismissed plaintiffs’ claims under the Regulatory Flexibility Act (RFA), which requires agencies to give explicit consideration to less onerous regulatory options for small businesses, and to address meaningful alternatives. In addition, the district court dismissed plaintiffs’ statutory challenge to the Privacy Rule, but that issue is not appealed here. Nor do plaintiffs appeal the ruling below concerning the Paperwork Reduction Act.

The district court expressly styled its order as a “Final Judgment,” inducing this appeal. *Id.* at \*34. Plaintiffs filed a timely notice of appeal on July 11, 2002.

### **STATEMENT OF FACTS**

On August 21, 1996, Congress enacted the Health Insurance Portability and Accountability Act (“HIPAA”), also known as the Kassebaum-Kennedy Bill. Pub. L. No. 104-191, 110 Stat. 2021 (Aug. 21, 1996). Its genesis was the desire of retiring Senator Nancy Kassebaum to protect the portability and continuation of health insurance coverage for employees after termination of their jobs. On its way to passage, however, this major legislation attracted numerous sections unrelated to portability, including many provisions for the billing and processing of health insurance claims, as well as special federal funding for the prosecution of caregivers. 42 U.S.C. §§ 1320d, 1398i; 18 U.S.C. § 1347.

Section 261 of HIPAA sets forth the purpose that led to the Privacy Rule: to improve the health care system by establishing standards and requirements for “the electronic transmission of certain health information.” 42 U.S.C.A. § 1320d-note. HHS was directed to act if Congress did not. “If language governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act ... is not enacted by [August 21, 1999], the Secretary ... shall promulgate final regulations containing such standards ....” Section 264(c)(1) of

HIPAA, 42 U.S.C.A. § 1320d-2-note. Section 1173(a), the object of this limited grant of authority, is expressly entitled “Standards to Enable Electronic Exchange” and mandates that the “Secretary shall adopt standards for transactions, and date elements for such transactions, to enable health information to be exchanged electronically ....” 42 U.S.C. § 1320d-2.

HHS went far beyond this purpose. It developed a labyrinthine regulation that it formally proposed on November 3, 1999, for which plaintiff AAPS submitted extensive objections dated December 29, 1999. 64 Fed. Reg. 59918. AAPS objected, *inter alia*, to regulatory restrictions on patients’ accessing their own medical records, and the broad access to such records by government without meaningful safeguards. Subsequently, HHS published its Privacy Rule, greatly expanded in scope, on December 28, 2000. 65 Fed. Reg. 82462. After the change in Administrations, new comments were allowed until March 30, 2001. Plaintiff AAPS again submitted detailed comments dated March 26, 2001, including objections to: 45 C.F.R. Section 160.203 (possible preemption of state laws that provide greater rights of access to individuals to their own medical information), Sections 160.310(c) and 164.502 (broad access by government to medical records), Section 164.524(a)(2)(iii) (preventing patient access to his own medical research records), Section 164.524(b)(2) (delaying patient access to own records by 30 days or more), and Section 164.528(a)(2) (suspending patients’ right to accountings).

None of AAPS's objections, nor apparently those of anyone else, caused any meaningful modifications to the Privacy Rule. To the surprise of many, the Secretary abruptly announced on April 12<sup>th</sup> that the Privacy Rule would be implemented unchanged two days later. Since then there has been no modification to the Rule in any relevant respect, nor is there any reason to expect such revision.

The Privacy Rule mandates government searches through personal medical records without a warrant or showing of cause or other meaningful safeguard. 45 C.F.R. §§ 160.310(c), 164.502(a)(2)(ii), 164.502(b)(2)(iii),(iv), 164.512(b),(d). Physicians are compelled, in violation of their Oath of Hippocrates, to aid and abet such invasions of their patients' privacy. 45 C.F.R. §§ 160.310(c)(1), 164.502(a), 164.508(a)(2)(ii), 164.512. Institutions are allowed to disseminate with impunity highly personal medical records to other local, state or federal entities or agents engaged in surveillance. *Id.* §§ 160.310(c)(3), 164.502, 164.512.

The Privacy Rule represents a significant expansion in federal regulatory power. The proposed regulation applied only to individually identifiable health information that is or has been electronically transmitted or maintained by a covered entity, and "would not have applied to information that was never electronically maintained or transmitted by a covered entity." 65 Fed. Reg. 82488. As promulgated, however, the Privacy Rule does "extend the scope of protections to all individually identifiable health information in any form, electronic or non-

electronic, that is held or transmitted by a covered entity. This includes individually identifiable health information in paper records that never has been electronically stored or transmitted.” *Id.* The effect of this 11<sup>th</sup> hour expansion, upheld below, is that ***all*** medical records possessed by a physician who engages in ***any*** electronic transactions is subject to the Rule and its broad governmental access. That includes medical information provided to physicians even years before the Rule was suggested.

### **SUMMARY OF ARGUMENT**

The Privacy Rule injects the federal government into the very local and personal domain of medical records, past and future. It impacts everything from patient employability to insurability, and its casualty is true patient privacy. Plaintiffs, a collection of physicians and patients, have standing to complain about this intrusion on their personal privacy and on federalism. Because the Rule is already in effect, it is fully ripe for review. Yet the court below dismissed this action on procedural grounds, avoiding the substance of this challenge.

The controlling Supreme Court precedent of *Whalen v. Roe* requires reversal. 429 U.S. 589 (1977). *Whalen* concerned a procedurally indistinguishable challenge to a medical record statute. The parties agreed below that it applies here and repeatedly invoked it in their briefs. Yet the district court did not reference it even once, hence unjustifiably overruling it *sub silentio*. See, e.g., *Thurston Motor*

*Lines, Inc. v. Jordan K. Rand, Ltd.*, 460 U.S. 533, 535 (1983) (per curiam) (“Needless to say, only this [Supreme] Court may overrule one of its precedents.”); *see also Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 486 (1989) (Stevens, Brennan, Marshall and Blackmun, JJ., dissenting) (departing from Supreme Court precedent is an “indefensible brand of judicial activism”). As in *Whalen*, plaintiffs fully satisfy the requirements of standing and ripeness, and the court below should not have terminated this action prior to discovery.

Reversal is also warranted on federalism grounds. The district court held that plaintiffs have “no standing as private individuals to pursue their claims under the Tenth Amendment.” 2002 U.S. Dist. LEXIS 15857, \*23 (Tab 4). This contravenes recent Supreme Court teachings on federalism, which have recognized that private individuals have standing to contest overreaching by the federal government. *See United States v. Morrison*, 529 U.S.598 (2000); *United States v. Lopez*, 514 U.S. 549 (1995). Plaintiffs have every right to complain about federal intrusions into the purely local matter of their medical records, and to challenge such regulations as inconsistent with federalism.

Finally, the decision below should be reversed based on the Regulatory Flexibility Act (RFA). HHS did not consider any meaningful alternatives to the Privacy Rule to alleviate its disproportionately high cost for small practitioners. The RFA requires the Secretary “to give explicit consideration to less onerous

options” with respect to small businesses. *Associated Fisheries of Maine v. Daley*, 127 F.3d 104, 114 (1<sup>st</sup> Cir. 1997). Here, the Secretary simply imposed a one-size-fits-all requirement without considering more sensibly tailored schemes. Dismissal of plaintiffs’ RFA claim, without even allowing discovery, was unjustified below.

Plaintiffs do not appeal on certain issues due to key concessions by defendants below. For example, the Privacy Rule allows entities to withhold medical records for up to 90 days from the patients themselves, and the Rule does not defer to State guarantees of quicker access. 65 Fed. Reg. 82556. AAPS submitted comments on this defect, which the Secretary implicitly rejected. In its reply brief below, however, the government conceded that State laws guaranteeing patients faster access remain effective, and the court agreed by holding that “State laws requiring access within a shorter time frame are still valid, since the Privacy Rule does not preempt state laws that are not contrary to the Rule.” 2002 U.S. Dist. LEXIS 15857, \*19 n.5. In addition, defendants admitted in their initial brief below that “[t]he proverbial country doctor who deals only in paper, or who has a computer but conducts none of the transactions referred to in section 1173(a) electronically, would not be a covered entity, and would not be subject to this legislation.” Memorandum of Points and Authorities in Support of Defendants’ Motion to Dismiss, Part II.B (Nov. 30, 2001) [hereinafter, “Govt. Mem.

Supporting Mot. To Dismiss”] (Docket No. 23). Plaintiffs rely on these concessions in omitting these issues from this appeal.

In sum, the Privacy Rule’s grant of unrestricted governmental access to medical records without safeguards, and its heavy burden on small practices, are subject to judicial review. Standing and ripeness exist for plaintiffs to complain about the lack of safeguards, as in *Whalen*, especially given the retroactive effect of the Rule on pre-existing records. Reversal and remand are necessary so that a factual record may be developed in the court below.

### **STANDARD OF REVIEW**

In reviewing the decision below, this Court should accept as true all allegations in the Complaint, and construe it liberally in favor of plaintiffs. “For the purposes of a motion to dismiss, the material allegations of the complaint are taken as admitted. And, the complaint is to be liberally construed in favor of plaintiff. The complaint should not be dismissed unless it appears that appellant could prove no set of facts in support of his claim which would entitle him to relief.” *Jenkins v. McKeithen*, 395 U.S. 411, 421-22 (1969) (citations and quotations omitted). *See also Meason v. Bank of Miami*, 652 F.2d 542, 544 (5<sup>th</sup> Cir. 1981), *cert. denied*, 455 U.S. 939 (1982). This same standard of review applies to all of the issues on this appeal.

## ARGUMENT

### **I. *WHALEN v. ROE* REQUIRES REVERSAL OF THE DECISION BELOW IN ORDER TO ALLOW PLAINTIFFS TO PROVE THEIR CLAIMS THROUGH DISCOVERY.**

The Privacy Rule applies to medical records already created, chills patient-physician communications now, and burdens medical practices now. Comp. ¶¶ 2-6 (Tab 5). The Rule already provides mandatory and permissive governmental access to personal medical records without a warrant or showing of cause. *Id.* ¶¶ 32-33. Plaintiffs allege direct injury from the Rule. *Id.* ¶¶ 35, 53. The Rule has been final in all relevant respects and expressly effective since April 2001. Facts concerning current governmental access to medical records are uniquely known to defendants, yet no discovery or factfinding was allowed below.

*Whalen v. Roe*, cited extensively by the parties below, requires reversal. 429 U.S. 589 (1977). The *Whalen* Court granted standing to an almost identical collection of physicians and patients who were challenging a medical record statute less intrusive and burdensome than the Privacy Rule. *Id.* at 595. There, as here, plaintiffs challenged a regulation mandating governmental access to highly personal medical information. *Id.* at 596. There, as here, plaintiffs complained about the loss of privacy to the government. *Id.* at 596 n.16. Plaintiffs there were allowed discovery and a trial on their claims. The Supreme Court ultimately relied extensively on the factual record developed through trial. *Id.* at 593-95. Here, the

district court dismissed the claims without allowing the development of a factual record.

Substantively, *Whalen* concerned whether the State of New York may build a database of names and addresses of patients receiving specific drugs that are often illegally used. *Id.* at 591. Here plaintiffs contest governmental access to all personal medical records without a showing of cause or a warrant. Standing existed in *Whalen*, and it exists here. *Id.* at 595 & n.14. Defendants repeatedly argued below that *Whalen* applies. Govt. Mem. Supporting Mot. To Dismiss at 19 n.14, 22 n.15, 25 n.19, 27, 28 (Docket No. 23). It was reversible error for the lower court to fail to apply *Whalen*.

Indeed, the case for standing and ripeness is even stronger here than in *Whalen* because the Privacy Rule has a retroactive application: all past-recorded medical information is subject to its terms. Everything plaintiffs provided to their doctors in the past is open, under the Privacy Rule, to government review. 65 Fed. Reg. 82805 (45 C.F.R. § 164.501). This contrasts sharply with the statute in *Whalen*, which only made the government privy to medical records created in the future. 429 U.S. at 593 (“[T]he Act requires that all prescriptions for Schedule II drugs be prepared by the physician in triplicate on an official form. ... One copy of the form is retained by the physician, the second by the pharmacist, and the third is forwarded to the New York State Department of Health in Albany.”) (footnote

omitted). In *Whalen*, individuals had notice of the new law and at least retained the option of avoiding disclosure by not seeing a doctor in the State, while individuals lack that prior notice here.

The *Whalen* Court relied heavily on the developed facts to find the following safeguards decisive:

[T]he [medical records] are returned to the receiving room to be retained in a vault for a five-year period and then destroyed as required by the statute. The receiving room is surrounded by a locked wire fence and protected by an alarm system. The computer tapes containing the prescription data are kept in a locked cabinet. When the tapes are used, the computer is run “off-line,” which means that no terminal outside of the computer room can read or record any information. Public disclosure of the identity of patients is expressly prohibited by the statute and by a Department of Health regulation. ... At the time of trial there were 17 Department of Health employees with access to the files; in addition, there were 24 investigators with authority to investigate cases of overdispensing which might be identified by the computer.

429 U.S. at 593-95 (footnotes deleted). Defendants fail to cite any such safeguards applicable to government here, nor does the Privacy Rule provide any.

The Privacy Rule authorizes numerous mandatory and permissive disclosures to government, without the *Whalen* safeguards. No warrant or even a showing of cause is required for compelled government searches through personal medical records. 45 C.F.R. §§ 160.310(c), 164.502(a)(2)(ii), 164.502(b)(2)(iii),(iv), 164.512(b),(d). Physicians are forced to aid and abet such invasions of their patients’ privacy, in violation of their sworn Oath of Hippocrates that “[a]ll that may come to my knowledge in the exercise of my profession or

outside of my profession or in daily commerce with men, which ought not to be spread abroad, **I will keep secret and never reveal.**” <http://www.aapsonline.org/ethics/oaths.htm> (emphasis added). 45 C.F.R. §§ 160.310(c)(1), 164.502(a), 164.508(a)(2)(ii), 164.512; 65 Fed. Reg. 82462-829 (Privacy Rule, in 368 pages, omits any reference to the Oath). Institutions are allowed to disseminate highly personal medical records to other entities pursuant to local, state or federal surveillance, database or disclosure laws. *Id.* §§ 160.310(c)(3), 164.502, 164.512. Given the lack of safeguards, these provisions collectively violate patients’ constitutional rights. *See Soto v. City of Conford*, 162 F.R.D. 603, 618 (N.D. Cal. 1995) (“The Supreme Court has recognized a limited privacy interest in the confidentiality of one’s medical records, derived implicitly from the United States Constitution.”) (citing *Whalen*).

Particularly objectionable is the laundry list of permitted disclosures without patient consent. Section 164.512(d)(1). One of the enumerated items allows virtually any disclosure to any public official: “activities necessary for appropriate oversight of ... [t]he health care system.” 45 C.F.R. § 164.512(d)(1) & (d)(1)(i); *see also* § 164.512(b). Once disclosed to a non-covered entity, repeated disclosures are then unlimited. “We do not have the authority to regulate persons other than covered entities, so we cannot affect attempts by entities outside of this rule to” violate privacy by identifying personal medical records. 65 Fed. Reg.

82712. These permissive disclosures plainly lack the requisite “concomitant statutory or regulatory duty to avoid unwarranted disclosures” emphasized in *Whalen*. 429 U.S. at 605.

The court below never addressed the lack of safeguards at the heart of this case. The court did not deny that individuals would thereby be harmed, but merely found the probability to be low that plaintiffs themselves would be harmed. 2002 U.S. Dist. LEXIS 15857, at \*17 (discussed in Point II, *infra*). As to the permissive governmental access, the court upheld it on the theory that it “merely makes it possible for entities to comply with existing laws without violating the Privacy Rule in the process.” *Id.* at \*17 n.4 (citing 45 C.F.R. § 512(c)). But that misconstrues the broad scope of the disclosures made permissive by the Privacy Rule. It authorizes disclosures even where no existing law requires it, as for the undefined “oversight activities” allowed by 45 C.F.R. § 164.512(d)(1) & (d)(1)(i) (quoted above). Once information is so disclosed, there is then no limitation on re-disclosures.

This Circuit has broadly construed *Whalen*’s protection of medical record privacy. “This Court has interpreted [*Whalen*] to confer a right to protect from disclosure confidential or sensitive information held by the government.” *Sherman v. United States Dep’t of the Army*, 244 F.3d 357, 361 n.5 (5<sup>th</sup> Cir. 2001) (citing *Fadjo v. Coon*, 633 F.2d 1172, 1175 (5<sup>th</sup> Cir. 1981)). Other Circuits have held

likewise. See *Anderson v. Romero*, 72 F.3d 518, 522 (7th Cir. 1995) (Posner, J.) (reaffirming a “constitutional right to conceal one’s medical history”); *Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 578 (3d Cir. 1980); see also *Ferm v. United States Trustee (In re Crawford)*, 194 F.3d 954, 958-59 (9<sup>th</sup> Cir. 1999), *cert. denied*, 528 U.S. 1189 (2000); *Flanagan v. Munger*, 890 F.2d 1557, 1570-71 (10th Cir. 1989); cf. *Kallstrom v. City of Columbus*, 136 F.3d 1055, 1063 (6<sup>th</sup> Cir. 1998) (denying enforceability to a waiver of this right).

Justice Brennan’s concurrence in *Whalen* is particularly apt here, in its rejection of the approach adopted by the court below:

What is more troubling about this scheme, however, is the central computer storage of the data thus collected. Obviously, as the State argues, collection and storage of data by the State that is in itself legitimate is not rendered unconstitutional simply because new technology makes the State’s operations more efficient. **However, as the example of the Fourth Amendment shows, the Constitution puts limits not only on the type of information the State may gather, but also on the means it may use to gather it.** The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity of some curb on such technology.

429 U.S. at 606-07 (Brennan, J., concurring) (emphasis added).

## II. THE COURT BELOW ERRED IN REJECTING PLAINTIFFS' STANDING TO ASSERT THEIR FOURTH AND FIRST AMENDMENT CLAIMS.

Plaintiffs include (i) an organization of thousands of practicing physicians (AAPS) governed by the Privacy Rule, (ii) a practicing physician serving as a Congressman (Ron Paul, M.D.), and (iii) three patients (Dawn Richardson, Rebecca Rex and Darrell McCormick) – a group legally indistinguishable from the *Whalen* plaintiffs. 429 U.S. at 595 & n.14. Since standing was found in *Whalen*, the Supreme Court has even expanded associational standing further. *See Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 281 (1986) (“It has long been settled that even in the absence of injury to itself, an association may have standing solely as the representative of its members.”) (quotations omitted). *See also United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 688-89 (1973) (finding that the environmental group had standing to challenge an agency decision that adversely affected the group’s members); *National Lime Ass’n v. EPA*, 233 F.3d 625, 636-37 (D.C. Cir. 2000) (holding that a trade association had standing to challenge EPA rulemaking). *Cf. Pennell v. San Jose*, 485 U.S. 1, 8 (1988) (granting standing to landlords for their facial challenge to a rule that was likely to reduce their collected rent).

The court below failed to address plaintiffs' claim that the Privacy Rule limits patients' market choice. "I am limiting my practice to avoid doing any electronic transmissions. ... To avoid the substantial regulatory costs and invasions of privacy imposed by the Rule for all my records, I must avoid doing any electronic transmissions." Declaration of Philip M. Catalano, M.D., ¶ 2 (Tab 6). Patients seeking real privacy must now find and use a paper-only-based physician beyond the reach of the Privacy Rule. "My market choice is thereby restricted with respect to the decisions most important to me: protecting the health of my family." Declaration of Patient Dawn Richardson ¶ 6 (Tab 7); Declaration of Patient Rebecca Rex ¶ 5 (Tab 8). This limitation in market options comfortably satisfies the standing requirements for consumer choice. *See Competitive Enter. Inst. v. NHTSA*, 901 F.2d 107, 113 (D.C. Cir. 1990) ("We determined that a lost opportunity to purchase vehicles of choice is sufficiently personal and concrete to satisfy Article III requirements."); *Center for Auto Safety (CAS) v. NHTSA*, 793 F.2d 1322, 1332-33 (D.C. Cir. 1986) (holding that a decrease in opportunity to purchase certain types of vehicles constituted injury-in-fact and established standing). Such injury alone suffices for standing. "The injury need not be substantial. A trifle is enough for standing." *Joseph v. United States Civil Serv. Comm'n*, 554 F.2d 1140, 1145 (D.C. Cir. 1977). The court below failed to address this argument or any of these cited precedents.

Plaintiffs also have standing due to the Rule's chilling effect on patient-physician communications and behavior. *See Whalen*, 429 U.S. at 602 (“**Unquestionably**, some individuals’ concern for their own privacy may lead them to avoid or to postpone needed medical attention.”) (emphasis added); *Swidler & Berlin et al. v. United States*, 524 U.S. 399, 407 (1998) (in attorney-client context, confidentiality “encourages the client to communicate fully and frankly with counsel”). The mandatory and permissive governmental access established by the Privacy Rule has already injured plaintiffs, as set forth in the Complaint and the declarations. Comp. ¶ 35 (Tab 5); Declaration of Gregory N. Laurence, M.D., ¶¶ 3-5 (Tab 9); Declaration of Philip M. Catalano, M.D., ¶¶ 2-3 (Tab 6). The facial invalidity of such infringement on confidential speech is sufficient to establish standing under the First Amendment. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 333-34 (D.C. Cir. 2000); *Wash. Legal Found. v. Kessler*, 880 F. Supp. 26, 31 (D.D.C. 1995) (HHS conceding that “there exists an enforceable First Amendment right to receive information”).

The lower court held that “[b]ecause these ‘unwarranted disclosures’ have not yet occurred and plaintiffs have suffered no actual injury, the court concludes that plaintiffs lack standing to pursue this claim, and the claim is not ripe for review.” 2002 U.S. Dist. LEXIS 15857, at \*17. But by its own admission, the Privacy Rule imposes substantial costs on practicing physicians. The Privacy Rule

expressly acknowledges that physicians, including members of plaintiff AAPS, face monetary obligations and regulatory duties by virtue of the Rule. 65 Fed. Reg. 82789 (Section V of the Rule estimates a cost of compliance for small businesses of \$4,188 per establishment in the first year and approximately \$2,217 thereafter.). These costs, which are already being incurred, suffice. *See Joseph*, 554 F.2d at 1145 (“A trifle is enough for standing.”); Declaration of Gregory N. Laurence, M.D., ¶ 5 (Tab 9) (“I have determined that my costs amount to at least six thousand dollars in the form of consultants, office training and software changes.”).

The district court mistakenly extended a decision concerning the rather impersonal Endangered Species Act to the highly personal issue of medical records. “An interest shared generally with the public at large in the proper application of the Constitution and laws will not suffice.” 2002 U.S. Dist. LEXIS 15857, at \*15 (relying on *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)). In *Lujan*, the Supreme Court reinstated a summary judgment *after discovery*, in sharp contrast to the dismissal here. Moreover, the claim in *Lujan* consisted of an alleged injury from harm to endangered species in foreign countries. *See id.* at 564. That injury is far more remote than the highly personal harm alleged here. The district court erred in suggesting that the generality of the harm here somehow operates to deprive plaintiffs of standing. The extension by the court below of a

recent Establishment Clause decision to the medical record context is untenable. *See, e.g.*, 2002 U.S. Dist. LEXIS 15857, at \*19 (relying on the Establishment Clause decision of *Henderson v. Stalder*, 287 F.3d 374, 380 (5<sup>th</sup> Cir. 2002)).

### **III. THE COURT BELOW ERRED IN DISMISSING PLAINTIFFS' FOURTH AND FIRST AMENDMENT CLAIMS FOR LACK OF RIPENESS.**

The lower court erred in agreeing with defendants that “this action is premature because actual compliance with the Privacy Rule is not mandated until April 14, 2003 (or April 14, 2004, in the case of small health care entities).” 2002 U.S. Dist. LEXIS 15857, at \*18. The Rule has, in fact, been effective since April 14<sup>th</sup> of last year, and it impacts current and past medical records immediately. Patient choice has already been harmed, and physicians are already incurring substantial costs. Entities are already allowed by the Privacy Rule to disseminate medical records to third parties. 65 Fed. Reg. 82829 (allowing immediate compliance). Only enforcement penalties are postponed until April 14, 2003, which are not the subject of plaintiffs’ claims. And although any regulation may be subject to change, defendants provide no basis for arguing that any relevant aspect of the Privacy Rule will be modified. “[I]t is clear beyond peradventure that the validity of a rule can be ripe for review whether or not it has actually been improperly applied and enforced in a concrete factual setting.” *Eagle-Picher Indus. v. EPA*, 759 F.2d 905, 917-18 (D.C. Cir. 1985).

Plaintiffs satisfy the four-pronged test for ripeness of this Circuit. *See Dresser Indus., Inc. v. United States*, 596 F.2d 1231 (5th Cir. 1979). As repeated in the decision below, these factors include: “(1) whether the issues are purely legal; (2) whether the issues are based on final agency action; (3) whether the controversy has a direct and immediate impact on the plaintiff; and (4) whether the litigation will expedite, rather than delay or impede, effective enforcement by the agency.” 2002 U.S. Dist. LEXIS 15857, at \*14 (citing *Dresser Indus.*, 596 F.2d at 1235). *See also Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967); *Louisiana Env'tl. Action Network v. EPA*, 172 F.3d 65, 69 (D.C. Cir. 1999) (“Fitness for judicial review is based on whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency’s action is sufficiently final.”). Only cases that are demonstrably unripe should be dismissed. “Courts confronted with close questions of ripeness are appropriately guided by the presumption of reviewability.” *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 434 (D.C. Cir. 1986). As demonstrated below, judicial review on the merits is warranted here.

**A. HHS’s Issuance of the Rule Constitutes Final Agency Action and Its Lack of Adequate Safeguards is Immediately Reviewable.**

The district court misread the nature of plaintiffs’ action, which is not based on enforcement of the Privacy Rule. Rather, plaintiffs complain about compliance

with the Rule without adequate safeguards. Compliance began when the Rule became effective, in April of 2001. It makes no difference that “HHS may promulgate new rules related to the Privacy Rule,” an observation that is always true about every regulation. 2002 U.S. Dist. LEXIS 15857, at \*18. It was incorrect for the district court to conclude that “for the court now to adjudicate plaintiffs’ claims in their present pre-enforcement stage would pose a risk that the court would render an impermissible advisory opinion.” *Id.* (citation omitted). The *Whalen* decision by the Supreme Court in an analogous procedural posture was surely not advisory.

HHS itself declared that the Privacy Rule constituted a final agency action “effective on February 26, 2001,” later postponed to April 14, 2001. 65 Fed. Reg. 82462; 66 Fed. Reg. 12434. A regulation issued as a Final Rule, after a notice-and-comment period, is sufficiently “final” to warrant judicial review. *See, e.g., Abbott Labs.*, 387 U.S. at 151 (finding finality where the challenged regulation was “promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties”); *Eagle-Picher*, 759 F.2d at 917 (finding regulation to be final where it was issued “after notice-and-comment proceedings, and contains no equivocal or tentative language as to the [agency’s] intention to employ it”). “[A]n agency’s interpretation of its governing statute, with the expectation that regulated parties will conform to and rely on this

interpretation, is final agency action fit for judicial review.” *Indep. Bankers Ass’n of Am. v. Smith*, 534 F.2d 921, 929 (D.C. Cir.), *cert. denied*, 429 U.S. 862 (1976).

**B. The Issues are Largely Legal and Hence Ripe for Review.**

The Privacy Rule deprives patients of their rights to speak confidentially to their physicians, and this facial invalidity under the First Amendment is fully ripe. The Supreme Court upheld standing for a merely potential exhibitor of foreign films to challenge a government designation of those films as “political propaganda” under federal law. *Meese v. Keene*, 481 U.S. 465, 474-75 (1987). There the Court confirmed that potential victims of the chill can sue. *See also R. A. V. v. St. Paul*, 505 U.S. 377, 395, 414 (1992) (Justice Scalia, for the Court, deploring the “danger of censorship,” *Leathers v. Medlock*, 499 U.S. 439, 448 (1991), and invalidating an ordinance the concurrence described as “fatally overbroad and invalid on its face”). Declarations of Patients Dawn Richardson and Rebecca Rex (Tabs 7-8).

The Privacy Rule deprives patients of confidentiality in their communications with physicians, a 2500-year-old privilege. *See* Oath of Hippocrates, quoted Point II *supra*; *Whalen v. Roe*, discussed in Point I *supra*; Declarations of Physicians Beverly B. Nuckols, M.D., Philip M. Catalano, M.D., Melissa Kline Clements, M.D. and Gary S. Mirkin, M.D. (Tabs 6, 10-12). The Supreme Court found an analogous chilling effect for reduced confidentiality in

attorney-client communications. Chief Justice Rehnquist so held:

Knowing that communications will remain confidential even after death encourages the client to communicate fully and frankly with counsel. While the fear of disclosure, and the consequent withholding of information from counsel, may be reduced if disclosure is limited to posthumous disclosure in a criminal context, it seems unreasonable to assume that it vanishes altogether. Clients may be concerned about reputation, civil liability, or possible harm to friends or family. Posthumous disclosure of such communications may be as feared as disclosure during the client's lifetime.

*Swidler & Berlin et al.*, 524 U.S. at 407.

The court below relies on two precedents of this Circuit, unrelated to sensitive medical records, but neither dictates unripeness here. 2002 U.S. Dist. LEXIS 15857, at \*12 - \*13. In *Orix Credit Alliance, Inc. v. Wolfe*, 212 F.3d 891 (5<sup>th</sup> Cir. 2000), this Court declined enjoining the filing of all future lawsuits connected with a matter. The relief sought was an advisory opinion about unarticulated future litigation, which is nothing like the immediate invasion of privacy and chilling effect here. *See* Declarations of Patients Dawn Richardson and Rebecca Rex (Tabs 7-8). In *United Transp. Union v. Foster*, 205 F.3d 851 (5<sup>th</sup> Cir. 2000), this Court found lack of ripeness because the chain of events required an unlikely train wreck, producing evidence not quite rising to the level of probable cause of alcohol or drug misuse, followed by a request for testing, which the worker could nevertheless have refused without penalty, rendering the entire exercise to be fruitless. *See id.* at 858-59. Here, privacy harm results immediately

from permissive dissemination, in sharp contrast to *Orix* and *United Transp. Union*.

**C. Plaintiffs Suffer a Direct and Immediate Impact Sufficient to Establish Ripeness.**

Plaintiffs have suffered direct and immediate impact. The Privacy Rule imposes substantial costs on the physician-plaintiffs now. Comp. ¶ 53 (Tab 5) (“This overall cost of compliance would total between about \$16,000 and \$23,000 for the first year alone, and substantially more if an additional employee or consultant is necessary to manage the new software.”); Declaration of Gregory N. Laurence, M.D., ¶ 5 (Tab 9) (“I have determined that my costs amount to at least six thousand dollars in the form of consultants, office training and software changes.”); *see also* Declarations of Beverly B. Nuckols, M.D., Philip M. Catalano, M.D., Melissa Kline Clements, M.D., Gary S. Mirkin, M.D. (Tabs 6, 10-12). The patient-plaintiffs lose their privacy and full choice of physicians now. Declarations of Plaintiff Patients Dawn Richardson and Rebecca Rex (Tabs 7-8) quoted Point II *supra* (describing their injury through loss of market choice). The Privacy Rule’s retroactive application to pre-existing medical records causes harm now.

Only by overlooking the above injuries, and lack of adequate safeguards, did the district court find a lack of injury. None of the above declared statements or allegations are cited by the decision below. It merely dismisses a statement in one

declaration about harmful disclosure of vaccination information, finding “that the Privacy Rule has no bearing on Texas or other state laws governing the vaccination of children or other health matters.” 2002 U.S. Dist. LEXIS 15857, at \*21. But the Privacy Rule does expressly authorize disclosure of this and other medical information to virtually any governmental agency, as discussed in Point I above and disapproved by *Whalen*. 45 C.F.R. Section 164.512(d)(1), for example, grants federal and apparently state agencies broad new power to receive and process health information for any lawful oversight activity, including any function “necessary for appropriate oversight of [t]he health care system; [g]overnment benefit programs for which health information is relevant to beneficiary eligibility; [and e]ntities subject to government regulatory programs for which health information is necessary for determining compliance with program standards.” The Privacy Rule thereby opens up everyone’s medical records to any oversight function, including everything from schools to social security benefits to vaccination programs. The Rule itself does not create all these agencies and their oversight functions, but allows dissemination of plaintiffs’ personal medical records to them. That impact and resultant injury falls squarely within the prohibition of *Whalen*. 429 U.S. at 605-06 (quoted in Part I, *supra*).

As to the chilling effect, the court below dismissed what the Supreme Court held to be “[u]nquestionably” true: “some individuals’ concern for their own

privacy may lead them to avoid or to postpone needed medical attention.” 429 U.S. at 602; 2002 U.S. Dist. LEXIS 15857, at \*20 - \*22. For pleading purposes, plaintiffs have alleged adequate injury from the chilling effect in their Complaint and in their Declarations. Comp. ¶ 35 (“patients can no longer communicate with their physicians in a truly privileged manner”) (Tab 5); Declaration of Melvin E. Edwards ¶ 7 (Tab 13) (“I also can no longer obtain medical care for myself or my children with the assurance that our records won’t be released into a government database without my permission to strangers or even political adversaries.”).

At bottom, the district court relied on a probability assessment uninformed by an evidentiary record. The court declared that:

A number of unlikely events must occur in order for plaintiffs to sustain an injury. The Secretary of HHS would have to elect to exercise his oversight responsibilities pursuant to 45 C.F.R. § 160.310(c) to request access to protected health information. The Secretary would then have to proceed directly against the specific covered entity that possessed the protected health information of the plaintiffs. Even in such a scenario, plaintiffs’ particular health information might not be accessed or disclosed. It is therefore highly speculative and unlikely that plaintiffs would ever be injured by the Privacy Rule.

*Id.* at \*16 - \*17. The first step above – that the Secretary will exercise his oversight responsibilities – is a virtual certainty. As to the Secretary proceeding against specific covered entities and accessing plaintiffs’ particular health information, that evidence is uniquely known to defendants and properly subject to discovery and factfinding. There is no need to speculate about the probability of

something that can be assessed through factfinding. In *Whalen*, the court relied on evidence adduced through discovery and even at trial before making determinations about the adequacy of the safeguards. 429 U.S. at 593-95. Dismissal for this reason on the pleadings, pre-discovery, is unjustified.

Such speculation about likelihoods cannot justify defendants' Rule 12(b)(6) motion, where the allegations are taken as true and this Court must construe the complaint "in the light most favorable to the non-moving party." *American Waste & Pollution Control Co. v. Browning Ferris Inc.*, 949 F.2d 1384, 1386 (5th Cir. 1991). The Privacy Rule itself cites harm from governmental access that has already occurred. 65 Fed Reg. 82468 (citing government retaliation against a 30-year FBI veteran and derailment of a candidacy for Congress from unconsented medical disclosures).

The injury of restricting patient choice and inflicting costs on physicians is adequate under Fifth Circuit precedent -- even outside the heightened scrutiny of medical record privacy. *See Allandale Neighborhood Ass'n v. Austin Transp. Study Policy Advisory Comm.*, 840 F.2d 258 (5<sup>th</sup> Cir. 1988). There this Court held that even unrealized losses are sufficient for standing and ripeness where "a market devaluation has present adverse consequences short of realization through sale. The knowledge that sale of the property may bring in fewer proceeds will influence and restrict the willingness to sell. ... We conclude therefore that these two

Plaintiffs have satisfied the constitutional standing requirement (and, with it, any constitutional ripeness requirement).” *Id.* at 263 (footnote omitted). Here, the “knowledge” that one’s medical records may be disclosed pursuant to the Privacy Rule to virtually any governmental agency “will influence and restrict the willingness to” see a doctor and obtain the best treatment through unfettered communication. *Id.* The district court did not reference *Allandale* decision, though argued by plaintiffs below.

**D. Postponing Judicial Review Would Create Hardship.**

Judicial review is also warranted now to avoid “the hardship to the parties of withholding court consideration.” *New Orleans Pub. Serv., Inc. v. Council of New Orleans*, 833 F.2d 583, 586 (5th Cir. 1987) (quotations omitted). *See also TRT Telecomms. Corp. v. FCC*, 876 F.2d 134, 140 (D.C. Cir. 1989) (“[T]he central judicial interest in deferring resolution of th[e] question lies in the possibility that if the issue is not adjudicated at this time, it may not require adjudication at all.”) (quotations omitted). Delay here only magnifies the problems and harm for later resolution; no further action by HHS is needed to clarify its position with respect to the merits of this litigation. Rather, HHS has already detailed its legal position concerning the challenged elements of the Privacy Rule. Where a rule represents an agency’s final position, “review [will not] . . . waste[] the court’s time.” *Eagle-Picher*, 759 F.2d at 917. The “court has an interest in conserving its own resources

by resolving challenges to agency action” as soon as they are ripe “rather than stretching them out over an indefinite period of time.” *Id.*

There is no chance that resolution of this dispute may ultimately prove unnecessary. HHS implicitly rejected plaintiff AAPS’s comments dated March 26, 2001, and physicians must endure expenses now to comply. Therefore “no purpose would be served by delaying [this Court’s] decision.” *Chem. Waste Mgmt., Inc. v. EPA*, 869 F.2d 1526, 1534 (D.C. Cir. 1989) (finding issue ripe for review). HHS itself has anticipated legal review by providing for severability in its expansive definition of “protected health information”: “The definition of protected health information is set out in this form to emphasize the severability of this provision. ... We have structured the definition this way so that, if a court were to disagree with our view of our authority in this area, the rule would still be operational, albeit with respect to a more limited universe of information.” 65 Fed. Reg. 82496. Accordingly, HHS “can only profit from an early determination that eliminates the cloud of uncertainty surrounding” the agency’s disputed authority. *See Indep. Bankers Ass’n*, 534 F.2d at 929.

#### **IV. THE LOWER COURT ERRED IN CATEGORICALLY DENYING PLAINTIFFS THE RIGHT TO CHALLENGE THE PRIVACY RULE ON THE GROUNDS OF ITS VIOLATION OF FEDERALISM AND THE TENTH AMENDMENT.**

The Supreme Court, the other Courts of Appeals, and the text of the Tenth Amendment itself recognize that private individuals like plaintiffs have rights

based in our constitutional structure of federalism. Yet the court below, omitting reference to any of these, declared that “plaintiffs have no standing as private individuals to pursue their claims under the Tenth Amendment.” 2002 U.S. Dist. LEXIS 15857, at \*23. This was reversible error.

**A. Individual Plaintiffs Have the Right to Invoke the Tenth Amendment.**

For starters, the Tenth Amendment expressly states that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, **or to the people.**” U.S. Const., Amend. X (emphasis added). (The government omitted the key phrase “or to the people” in its argument below. Govt. Mem. Supporting Mot. To Dismiss at 30.) (Docket No. 23). “The powers of the legislature are defined, **and limited**; and that those limits may not be mistaken, or forgotten, the constitution is written.” *Marbury v. Madison*, 5 U.S. 137, 176 (1803) (Marshall, C.J.) (emphasis added). This limitation on the federal government includes the Commerce Clause itself: “[L]imitations on the commerce power are inherent in the very language of the Commerce Clause.” *United States v. Lopez*, 514 U.S. 549, 553 (1995) (citing *Gibbons v. Ogden*, 22 U.S. (Wheat.) 1, 189-90, 6 L. Ed. 23 (1824)).

In affirming the right of citizens to invoke the Tenth Amendment, the

Supreme Court has emphasized that:

The Constitution does not protect the sovereignty of the States for the benefit of the States or state governments as abstract political entities, or even for the benefit of the public officials governing the States. To the contrary, **the Constitution divides authority between federal and state governments for the protection of individuals.** State sovereignty is not just an end in itself: “Rather, federalism secures to citizens the liberties that derive from the diffusion of sovereign power.” *Coleman v. Thompson*, 501 U.S. 722, 759 (BLACKMUN, J., dissenting). “Just as the separation and independence of the coordinate branches of the Federal Government serves to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.” *Gregory v. Ashcroft*, 501 U.S. [452], at 458 (1991). *See* The Federalist No. 51, p. 323 (C. Rossiter ed. 1961).

*New York v. United States*, 505 U.S. 144, 181-82 (1992) (emphasis added, citations omitted).

In *Lopez*, a private individual prevailed on his argument that federalism invalidated the statute at issue. 514 U.S. at 567-68 (invalidating a congressional statute because otherwise “there will never be a distinction between what is truly national and what is truly local”). Indeed, this bedrock principle has been applied repeatedly. In *Morrison*, it was again a private individual who argued and prevailed in striking a statute based on federalism. 529 U.S. 598, 627 (2000) (“under our federal system th[e] remedy must be provided by the [State], and not by the United States”). As one commentator observed, “the Tenth Amendment is no longer in a ‘dormant state,’ and challenges based on this constitutional amendment now bear the Supreme Court’s imprimatur.” Ara B. Gershengorn,

*Note: Private Party Standing to Raise Tenth Amendment Commandeering Challenges*, 100 Colum. L. Rev. 1065, 1077 (May 2000).

The Seventh Circuit followed these rulings, rejecting the view of the court below. *Gillespie v. City of Indianapolis*, 185 F.3d 693 (7<sup>th</sup> Cir. 1999), *cert. denied*, 528 U.S. 1116 (2000). “[T]he Tenth Amendment, although nominally protecting state sovereignty, ultimately secures the rights of individuals. **Gillespie consequently has standing to raise the Tenth Amendment violation notwithstanding what state or local officials themselves may have to say about the propriety of the statute.**” 185 F.3d at 703-04 (emphasis added). That court explained, as the Supreme Court has held, that the Tenth Amendment protects federalism regardless of whether states consent to its violation. *See also Seniors Civil Liberties Ass'n v. Kemp*, 965 F.2d 1030 (11th Cir. 1992); *Atlanta Gas Light Co. v. United States Dep't of Energy*, 666 F.2d 1359 (11th Cir.), *cert. denied*, 459 U.S. 836 (1982). As the *Atlanta Gas Light* court explained, “during the New Deal era the Supreme Court granted such standing by implication in considering the merits of the Tenth Amendment claims brought by private parties.” 666 F.2d at 1368 n.16 (citing *Helvering v. Davis*, 301 U.S. 619, 637, 640 (1937); *Steward Machine Co. v. Davis*, 301 U.S. 548, 573 (1937)). Moreover, the *Atlanta Gas Light* court noted that the Supreme Court expressly limited the nexus requirement

for standing. 666 F.2d at 1368 n.16 (citing *Duke Power Co. v. Carolina Env. Study Group*, 438 U.S. 59 (1978)).

Yet the court below did not reference any of these precedents. Instead, it reached way back to the 1939 precedent of *Tennessee Elec. Power Co. v. TVA*, 306 U.S. 118 (1939). But, as Justice Powell observed, “standing barriers have been substantially lowered” in the many decades since *Tennessee Elec. Power Co.* was decided. *United States v. Richardson*, 418 U.S. 166, 193 (1974) (Powell, J., concurring). The Seventh Circuit noted that both the Fourth and Eleventh Circuits concur. *Gillespie*, 185 F.3d at 700 n.3 (citations omitted).

The court below relied heavily on *Gaubert v. Denton*, 1999 U.S. Dist. LEXIS 8207 (E.D. La. May 28, 1999), *aff'd without opinion*, 210 F.3d 368 (5th Cir. 2000). But there the plaintiff attempted to use the Tenth Amendment in order to compel the State to act. Specifically, plaintiff Gaubert sued the State of Louisiana and invoked the Tenth Amendment to compel it to produce documents in violation of a privilege required by the Federal Highway Safety Act (FHSA). 1999 U.S. Dist. LEXIS 8207, at \*4 - \*14. That attempt to use the Tenth Amendment against a State is inapplicable here, and at any rate this Circuit never embraced the reasoning in *Gaubert*.

**B. Whether the Privacy Rule Exceeds Commerce Clause Authority is an Issue of Fact Unsuitable for Disposition on the Pleadings.**

Once plaintiffs' standing is recognized, further factual development is necessary in order to determine if the Privacy Rule exceeds Commerce Clause authority. Recent Supreme Court precedents emphasized the limits on federal power, and invalidated federal overreaching into the state domain. After implicitly recognizing standing, the *Lopez* Court rejected the argument, akin to defendants' here, that Congress could regulate gun possession based on an alleged connection to economic productivity. The Court likewise refused to allow federal intrusion into other state jurisdictional matters like "family law and direct regulation of education." 514 U.S. at 565. In *Morrison*, the Court invalidated a federal statute creating a cause of action for domestic violence, rejecting the argument that economic productivity could justify such federal interference. 529 U.S. at 618 ("The regulation and punishment of intrastate violence that is not directed at the instrumentalities, channels, or goods involved in interstate commerce has always been the province of the States.").

States have traditionally enjoyed exclusive jurisdiction over regulating medical practice and protecting patient-physician confidentiality. *See, e.g.*, Cal. Const. Art. I, Section I ("All people . . . have inalienable rights. Among these are enjoying and defending life and liberty, . . . and pursuing and obtaining safety, happiness, and privacy."); Confidentiality of Medical Information Act, Civil Code

§ 56 et seq. In particular, California requires that “any waiver by a patient of the provisions of this part, except as authorized by Section 56.11 or 56.21 or subdivision (b) of Section 56.26 shall be deemed contrary to public policy and shall be unenforceable and void.” *Id.* § 56.37; *see also id.* § 56.20. The Constitution of the State of Florida, where plaintiff McCormick resides, includes a Declaration of Rights. Its Section 23, entitled “Right to Privacy,” guarantees that: “Every natural person has the right to be let alone and free from government intrusion into the person’s private life except as otherwise provided herein. This section shall not be construed to limit the public’s right of access to public records and meetings as provided in law.” Under *Lopez* and *Morrison*, plaintiffs’ allegations, taken as true at this preliminary stage, adequately plead a cause of action. Comp. ¶¶ 38-43 (Tab 5).

## **V. THE PRIVACY RULE VIOLATES THE REGULATORY FLEXIBILITY ACT.**

Regulatory Flexibility Act (“RFA”) “provides for judicial review of the final regulatory flexibility analysis,” which includes scrutiny of the requisite “description of the steps the agency has taken to minimize the significant economic impact on small entities ... including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule.” 5 U.S.C. §§ 611(a)(1), 604(a)(5). This requires more than mere window dressing. *See generally* Thomas O. Sargentich, *The Small Business Regulatory Enforcement Act*,

49 Admin. L. Rev. 123, 128 (1997) (noting that the congressional sponsors of the 1996 amendment strengthening the RFA observed that “many agencies gave the RFA lip service at best”). HIPAA itself requires that “[t]he Secretary shall adopt standards that ... take into account ... the needs and capabilities of small health care providers and rural health care providers ....” 42 U.S.C. § 1320d-2.

Plaintiffs have stated a valid cause of action under the RFA. Comp. ¶¶ 51, 52-54 (Tab 5); *see also* Declarations of Plaintiffs cited and discussed in Point III.C, *supra*. The Privacy Rule defiantly requires that its “privacy standard must be implemented by all covered entities, **regardless of size.**” *Id.* at 82782 (emphasis added). The regulatory flexibility analysis of the Privacy Rule glaringly omits meaningful alternatives for reducing its burden. 65 Fed. Reg. 82779-793 (complete text of RFA analysis); Comp. ¶ 54 (Tab 5). It also underestimates the regulatory costs on small practices. *Id.* ¶ 53. It devotes less than four pages to discussing alternatives to reduce this burden, and most of that discussion is inconsequential boilerplate. 65 Fed. Reg. 82782-785. This directly violates the RFA, which requires that meaningful exceptions and modifications be considered for small businesses. The Secretary should have considered removing for small practices many of the objectionable provisions cited by plaintiffs, such as the costly last-minute expansion to the paper medical records that admittedly dominate small practices. *Id.* at 82608.

The court below held that the Secretary’s analysis “appears to address all of the substantive issues required by the RFA, including ... a description of the steps taken by HHS to minimize the economic impact on small entities.” 2002 U.S. Dist. LEXIS 15857, at \*29 - \*30 (citations omitted). But as the above quote demonstrates, HHS did not take any steps to alleviate the burden of the Privacy Rule on small practitioners. The district court added that “plaintiffs have alleged no specific facts indicating that HHS failed to make a good-faith effort otherwise to satisfy the requirements of the RFA.” *Id.* at \*30. But discovery is necessary to produce evidence of bad faith in this context. *See, e.g., Harrods Ltd. v. Sixty Internet Domain Names*, 2002 U.S. App. LEXIS 17530, \*81 (4<sup>th</sup> Cir. Aug. 23, 2002) (agreeing with plaintiffs that “further evidence of bad faith is uniquely in the possession of defendants, and Harrods [UK] will need to seek and obtain discovery, which is only beginning, before it can present further evidence on bad faith and other issues.”). Where, as here, the Secretary flatly refuses to create **any** exceptions for small business, judicial scrutiny and discovery are warranted. The Secretary simply failed to “give explicit consideration to less onerous options” and “address significant” alternatives. *Alenco Comm., Inc. v. FCC*, 201 F.3d 608, 625 n.20 & n.21 (5<sup>th</sup> Cir. 2000) (citation omitted). *See also Associated Fisheries*, 127 F.3d at 116.

Defendants argued below that “HHS retained an outside consultant to assess concerns raised in the public comments about the cost of systems compliance for small business.” Govt. Mem. Supporting Mot. To Dismiss at 47 (Docket No. 23). What that consultant actually analyzed and concluded, and whether he had any conflicts-of-interest, is properly the subject of discovery, not dismissal under Rule 12(b)(6). The Privacy Rule itself concedes that the “actual costs of particular providers might vary **considerably** based on their current practices and technology.” 65 Fed. Reg. 82756 (emphasis added). The RFA requires a meaningful analysis of that considerable variance, and amelioration of its costly extremes. This the Privacy Rule failed to do.

## **VI. CONCLUSION**

For the foregoing reasons, the decision below should be reversed and remanded for discovery to proceed.

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Dated: September 10, 2002

## CERTIFICATE OF SERVICE

I hereby certify that on this 10<sup>th</sup> day of September, 2002, I caused two true and correct copies (on paper) of **Memorandum of Appellants**, a computer disk containing same, and one copy (paper only) of **Record Excerpts** to be served by first class mail, postage prepaid, on each counsel of record listed below, pursuant to Fed. R. App. P. 25(b), and that the same documents were filed, by mailing an original and seven copies (on paper and computer disk) of **Memorandum of Appellants** and an original and four copies (paper only) of **Record Excerpts** by first class mail, postage prepaid, to the Clerk of the Court, pursuant to Fed. R. App. P. 25(a)(2)(B)(ii), at the following addresses:

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## CERTIFICATE OF COMPLIANCE

Pursuant to 5th Cir. R. 32.2 and .3, the undersigned certifies this brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B), because it contains no more than \_\_\_\_\_ words as defined by that rule. This brief has been prepared using Microsoft Word 2002 in proportionally spaced typeface having font of Times New Roman, size 14. The undersigned understands a material misrepresentation in completing this certificate, or circumvention of the type-volume limits in Fed. R. App. P. 32(a)(7) may result in the Court's striking the brief and imposing sanctions against the person signing the brief.

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