TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES .... (ii)

SUMMARY OF ARGUMENT. 1

ARGUMENT. 5

I. PLAINTIFFS' CLAIMS UNDER THE FIRST AND FOURTH AMENDMENTS HAVE THE REQUISITE STANDING AND RIPENESS 6

1. Fourth Amendment Claim 8

2. First Amendment Claim 15

II. AS DEFENDANTS CONCEDE, PLAINTIFFS HAVE STANDING TO CHALLENGE THE SCOPE OF THE PRIVACY RULE FOR EXTENDING BEYOND FEDERAL POWER 20

III. HHS FAILED TO MAKE THE REQUISITE "GOOD FAITH" EFFORT TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT. 24

IV. CONCLUSION 28

SIGNATURE OF COUNSEL 28

CERTIFICATE OF SERVICE 29

CERTIFICATE OF COMPLIANCE 30

TABLE OF AUTHORITIES

Page

CASES

Abbott Labs. v. Gardner, 387 U.S. 136 (1967) 10

Alenco Comm., Inc. v. *FCC*, 201 F.3d 608 (5th Cir. 2000).......... 24

Allandale Neighborhood Ass'n v. Austin Transp. Study Policy Advisory Comm., 840 F.2d 258 (5th Cir. 1988).......... 17, 18

Anderson v. Romero, 72 F.3d 518 (7th Cir. 1995).......... 9

Associated Fisheries of Maine v. Daley, 127 F.3d 104 (1st Cir. 1997) 24

Association of Am. Physicians & Surgeons v. HHS, 2002 U.S. Dist. LEXIS 15857 (S.D. Tex. June 14, 2002) 2

Atlanta Gas Light Co. v. United States Dep't of Energy, 666 F.2d 1359 (11th Cir.), *cert. denied*, 459 U.S. 836 (1982) 24

Center for Auto Safety (CAS) v. NHTSA, 793 F.2d 1322 (D.C. Cir. 1986).. 18

Competitive Enter. Inst. v. NHTSA, 901 F.2d 107 (D.C. Cir. 1990).......... 18

Conant v. Walters, 309 F.3d 629 (9th Cir. 2002).......... 15, 16

Ferm v. United States Trustee (In re Crawford), 194 F.3d 954 (9th Cir. 1999), *cert. denied*, 528 U.S. 1189 (2000). 9

Doe v. City of New York, 15 F.3d 264 (2d Cir. 1994).......... 9

Doe v. United States, 253 F.3d 256 (6th Cir. 2001).......... 12, 13

Fadjo v. Coon, 633 F.2d 1172 (5th Cir. 1981) 9

Flanagan v. Munger, 890 F.2d 1557 (10th Cir. 1989)........ 9

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) 23

Gillespie v. City of Indianapolis, 185 F.3d 693 (7th Cir. 1999), *cert. denied*, 528 U.S. 1116 (2000) 23, 24

Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc., 452 U.S. 264 (1981)........ 24

Hohn v. United States, 524 U.S. 236 (1998) 12

Indep. Bankers Ass'n of Am. v. Smith, 534 F.2d 921 (D.C. Cir.), *cert. denied*, 429 U.S. 862 (1976) 6

Kallstrom v. City of Columbus, 136 F.3d 1055 (6th Cir. 1998) 9

Ker v. California, 374 U.S. 23 (1963) 11

Laird v. Tatum, 408 U.S. 1 (1972)........ 18, 19

Linder v. United States, 268 U.S. 5 (1925)........ 21

Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992) 14

McCarthy v. Briscoe, 553 F.2d 1005 (5th Cir.), *cert. denied*, 434 U.S. 985 (1977) 13

Meese v. Keene, 481 U.S. 465 (1987)........ 19

National Council for Improved Health v. Shalala, 122 F.3d 878 (10th Cir. 1997) 19

New Hampshire Right to Life Political Action Comm. v. Gardner, 99 F.3d 8 (1st Cir. 1996)........ 17

Ornelas v. United States, 517 U.S. 690 (1966) 11

Pennzoil Co. v. FERC, 742 F.2d 242 (5th Cir. 1984)........ 14

Reno v. Condon, 528 U.S. 141 (2000) 21, 22

Rowan Cos., Inc. v. Griffin, 876 F.2d 26 (5th Cir. 1989) 12

Seniors Civil Liberties Ass'n v. Kemp, 965 F.2d 1030 (11th Cir. 1992) 24

Sherman v. United States Dep't of the Army, 244 F.3d 357 (5th Cir. 2001) 9, 15

Steel Co. v. Citizens for a Better Environment, 523 U.S. 83 (1998) 20

Tennessee Elec. Power Co. v. TVA, 306 U.S. 118 (1939) 24

Terry v. Ohio, 392 U.S. 1 (1968) 11

Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967) 13

Trammel v. United States, 445 U.S. 40 (1980) 16

Trustees for Alaska v. EPA, 749 F.2d 549 (9th Cir. 1984) 10, 11

United Presbyterian Church v. Reagan, 738 F.2d 1375 (D.C. Cir. 1984) 19

United States Cellular Corp. v. F.C.C., 254 F.3d 78 (D.C. Cir. 2001) 25

United States v. Evans, 928 F.2d 858 (9th Cir. 1991) 21, 23

United States v. Lopez, 514 U.S. 549 (1995) 4, 21, 22, 23

United States v. Ramsey, 503 F.2d 524 (7th Cir. 1974), *cert. denied*, 420 U.S. 932 (1975) 19, 20

United States v. Richardson, 418 U.S. 166 (1974) 24

United States v. Salerno, 481 U.S. 739 (1987) 14

United Transp. Union v. Foster, 205 F.3d 851 (5th Cir. 2000) 11

United States v. Westinghouse Electric Corp.,
638 F.2d 570 (3d Cir. 1980) 9

Village of Hoffman Estates v. Flipside, 455
U.S. 489 (1982) 11

Whalen v. Roe, 429 U.S. 589 (1977) .... *passim*

FEDERAL STATUTES

5 U.S.C. § 604(a)(5) 25

5 U.S.C. § 611(a)(1) 25

42 U.S.C. § 1320d-2 25

REGULATIONS

45 C.F.R. § 160.310(c). 8, 13

45 C.F.R. § 160.310(c)(1). 7

45 C.F.R. § 160.310(c)(3). 7

45 C.F.R. § 164.502. .... 6, 7

45 C.F.R. § 164.502(a)(2)(ii). 8

45 C.F.R. § 164.502(b)(2)(iii),(iv). 8

45 C.F.R. § 164.512(b). 8

45 C.F.R. § 164.512(d)(1). 8

45 C.F.R. § 164.512(d)(1)(i). 8

65 Fed. Reg. 82462. .... 1, 10

65 Fed. Reg. 82488 21

65 Fed. Reg. 82496 6

65 Fed. Reg. 82608 27

65 Fed. Reg. 82641. .... 27, 28

65 Fed. Reg. 82712 .... 5, 8

65 Fed. Reg. 82782 27

65 Fed. Reg. 82783 26

66 Fed. Reg. 12434 10

PUBLIC LAWS

Pub. L. No. 104-191, 110 Stat. 2021 (Aug. 21, 1996).................... 1

MISCELLANEOUS

Fed. R. Evid. 501 16

Letter of John R. Lumpkin, M.D., M.P.H., Chair, National Committee on Vital and Health Statistics to defendant Secretary Thompson, HHS (dated Nov. 25, 2002, posted at http://www.ncvhs.hhs.gov/021125lt.htm) 26

U.S. Const., Amend. I.................... 14, 15, 16

U.S. Const., Amend. IV 8, 11, 14, 15

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

THE ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., *et al.*,	
Plaintiffs-Appellants,	
vs.	**No. 02-20792**
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	
Defendants-Appellees.	

REPLY 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 Reply Memorandum for reversal of the decision below, in response to the Defendants-Appellees' Brief.

SUMMARY OF ARGUMENT

The so-called "Privacy Rule," promulgated under the Health Insurance Portability and Accountability Act ("HIPAA"), exposes personal medical records to broad mandatory and permissive disclosures to government, without any meaningful safeguards protecting their confidentiality. Pub. L. No. 104-191, 110 Stat. 2021 (Aug. 21, 1996); 65 Fed. Reg. 82462. The Rule also imposes

substantial and unnecessary costs on small medical practices. It already operates to limit patient choice in the market. Nevertheless, plaintiffs' challenge to the Rule was dismissed below on procedural grounds on June 14, 2002. 2002 U.S. Dist. LEXIS 15857 (S.D. Tex. June 14, 2002) (Tab 4).

Plaintiffs appealed on three grounds. First, the district court erred in failing to apply *Whalen v. Roe*, 429 U.S. 589 (1977), which establishes standing and ripeness for plaintiffs' claims. Second, the district court erred in categorically denying standing to private individuals who challenge violations of federalism and the Tenth Amendment. And third, it was mistaken in failing to apply the Regulatory Flexibility Act to defendants' refusal to consider meaningful alternatives for small practitioners.

Defendants-Appellees United States Department of Health and Human Services ("HHS") and Tommy G. Thompson (the "Secretary"), oppose this appeal by largely ignoring *Whalen*, as did the court below. That decision plainly mandates substantive judicial review of government schemes to access highly personal medical records. "[T]he 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 [medical] 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 607 (Brennan, J., concurring) (emphasis added).

It is that "means it may use to gather it," and the impact of the federal intrusion on small practices, federalism and patient choice of physicians, which plaintiffs challenge here. The Privacy Rule commands essentially unlimited means, allowing dissemination of personal medical records in broad circumstances and even requiring their distribution in others. It bypasses well-established protections of judicial process for the Secretary to seize medical records. In effect for more than a year, the Rule is plenty ripe for challenge. It even has a retroactive effect in subjecting past medical records to the same loss of privacy as future ones.

The district court committed reversible error in ignoring *Whalen* and disposing of this action on procedural grounds, without reaching the merits. There is immediate harm – both financial and medical – attendant to governmental access to personal medical records without adequate safeguards. The "means" adopted by the Privacy Rule is ripe for challenge now. 429 U.S. at 607 (Brennan, J., concurring).

The Privacy Rule imposes suffocating burdens on small practices to comply immediately. As demonstrated by declarations submitted in the proceeding below, physicians are already incurring enormous expense due to the Rule. Other physicians are electing the "country doctor" exemption conceded by defendants

below. Choice of physicians by patients, who need privacy protection against the governmental access allowed by the Rule, is reduced. Though enforcement will not occur until April 2003, there is immediate harm to patients, physicians and patient choice of physicians resulting from ongoing compliance with the Rule.

Defendants' opposition brief fails to address these central issues. Though *Whalen* found standing and ripeness on claims procedurally identical to those here, defendants simply declare that it "has no precedential value." Defs. Br. at 33. Defendants attempt to distinguish it on the grounds that there "one had stopped taking a regulated medication as a result of the statute." *Id.* (citing 429 U.S. at 595 n.16). But here, declarations by patients submitted below demonstrate similar adverse effect. Declaration of Dawn Richardson, ¶¶ 2-4 (Tab 7); Declaration of Rebecca Rex, ¶¶ 2-4 (Tab 8).

On federalism, defendants concede that "federal courts routinely entertain claims of this sort." Defs. Br. at 35 (citing *United States v. Lopez*, 514 U.S. 549 (1995)). But inexplicably, three pages later, defendants argue that "plaintiffs lack standing to pursue this sort of Tenth Amendment claim." Defs. Br. at 38. Defendants' first statement was correct, and the decision below should be reversed in this respect.

Nor do defendants adequately address the Regulatory Flexibility Act (RFA), which requires more than a perfunctory invocation to justify the onerous new

regulatory burdens. The RFA requires agencies to give explicit consideration to less burdensome regulatory options for small businesses, and to address meaningful alternatives, which defendants failed to do. This defect leaves small medical practices with no realistic way to comply with the burdensome regulations and remain in business, and is cause for reversal and remand.

ARGUMENT

The Privacy Rule creates federal power to access personal medical records without a warrant or showing of cause. The records seized need not be connected with any federal program. The communications by patients to physicians subject to this access can be unrelated to payment for services. Once accessed, there are no meaningful protections against further dissemination of the information. The Privacy Rule even forswears any ability to stop publication once the information falls into the hands of a non-covered entity, such as an employer, insurer, or adversary of the patient or physician. 65 Fed. Reg. 82712.

Defendants insist that the Rule purports "to protect medical privacy." Defs. Br. at 21. In reality, the Rule expands government access without adequate safeguards. The Secretary's traditional authority utilizes administrative subpoenas subject to judicial process; but under the Privacy Rule the Secretary can seize records without cause or judicial process. The Rule also constitutes a massive

federal intrusion into the traditionally state domain of professional regulation. Additionally, it places impermissible burdens on small medical practices.

The Secretary expected legal review and even provided 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 dispute. *Indep. Bankers Ass'n of Am. v. Smith*, 534 F.2d 921, 929 (D.C. Cir.), *cert. denied*, 429 U.S. 862 (1976).

I. PLAINTIFFS' CLAIMS UNDER THE FIRST AND FOURTH AMENDMENTS HAVE THE REQUISITE STANDING AND RIPENESS.

Whalen conclusively establishes standing and ripeness by plaintiffs here. There, as here, plaintiffs challenged the adequacy of the safeguards against intrusions on medical record privacy. *Whalen* precludes dismissal of this action on the purely procedural grounds of standing and ripeness, as explained in plaintiffs' initial appellate brief.

It is illustrative to contrast the lack of safeguards here to those found so essential by the *Whalen* Court. Here, there is no "vault" to guard against improper

access. 429 U.S. at 593. Here, there is no destruction of records gathered by the government. *Id.* Here, there is no "locked wire fence and protect[ion] by an alarm system." *Id.* at 594. Nor must the government keep its records in "a locked cabinet." Its computers need not be "run 'off-line,' meaning that no terminal outside of the computer room can read or record any information." *Id.* The Privacy Rule does not prohibit "disclosure of the identity of patients" by the government, with "[w]illful violation of these prohibitions [] a crime punishable by up to one year in prison and a $ 2,000 fine." *Id.* at 594-95.

The number of those having government-mandated access to personal medical records under the Privacy Rule is unlimited, in contrast to the *Whalen* decision. "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. Twenty months after the effective date of the Act, the computerized data had only been used in two investigations involving alleged overuse by specific patients." *Id.* at 595. Here, in sharp contrast, there are no such restrictions.

Though plaintiffs applied *Whalen* at length below and here on appeal, the lower court completely ignored it and defendants here barely touch it. The reason is clear: *Whalen* requires reversal of the decision below.

1. Fourth Amendment Claim.

The Privacy Rule violates the Fourth Amendment by authorizing searches of medical records without a warrant or even a showing of cause. "A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable requirements …. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice." 45 C.F.R. § 160.310(c). *See also id.* §§ 164.502(a)(2)(ii), 164.502(b)(2)(iii),(iv). The Rule further violates the Amendment by authorizing intrusive permissive searches. *Id.* § 164.512(d)(1) & (d)(1)(i) (allowing disclosure to any public official for "activities necessary for appropriate oversight of … [t]he health care system"); *see also id.* § 164.512(b). The permissive disclosures enable personal medical records to be disseminated to the many thousands of non-covered entities lacking obligations to the patients. The Secretary concedes that he does "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 disseminating personal medical records. 65 Fed. Reg. 82712. Once accessed, there are no security precautions or meaningful penalties with respect to government control of the information.

Under *Whalen*, a plaintiff need not await a loss of job or insurance or political career before having a valid cause of action to protect his medical record privacy. Defendants argue that "patients have at no time had an absolute expectation of privacy in their medical records," Defs. Br. at 22, but this Circuit has already construed *Whalen* to establish significant informational privacy rights. "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 (5th Cir. 2001) (citing *Fadjo v. Coon*, 633 F.2d 1172, 1175 (5th Cir. 1981)). Other Circuits have also affirmed this right. *See Anderson v. Romero*, 72 F.3d 518, 522 (7th Cir. 1995) (Posner, J.) (affirming "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 (9th 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 (6th Cir. 1998) (denying enforceability to a waiver of this right).

Defendants fail to distinguish or even cite any of these Circuit decisions, and give scant attention to *Whalen* itself. Like the court below, defendants do not address the inadequate safeguards at the heart of this case. Instead, defendants

argue that "to succeed, [plaintiffs] must demonstrate that the enforcement provision of the Privacy Rule can *never* be applied in a constitutionally permissible manner." Defs. Br. at 24. But plaintiffs challenge the mandatory and permissive *compliance* with the Privacy Rule, not merely its enforcement. Compliance is immediate and indisputable. HHS itself declared that the Privacy Rule constituted a final agency action. 65 Fed. Reg. 82462; 66 Fed. Reg. 12434 (Privacy Rule is "effective on February 26, 2001," later postponed to April 14, 2001). A regulation issued as an effective rule, after a notice-and-comment period, is sufficiently "final" to warrant judicial review. *See, e.g.*, *Abbott Labs. v. Gardner*, 387 U.S. 136, 151 (1967). The Privacy Rule was immediately effective and compliance is already occurring; only penalties for non-compliance have been delayed until April 14, 2003. Defendants misstate this. Defs. Br. at 25 n.10.

None of defendants' citations undermine the ripeness and standing established in *Whalen* for the sensitive issue of medical records. Defendants rely, for example, on a Ninth Circuit decision dismissing a Fourth Amendment claim in *Trustees for Alaska v. EPA*, 749 F.2d 549 (9th Cir. 1984). Plaintiffs there challenged the power of the Environmental Protection Agency (EPA) to inspect the records of miners operating under certain permits. But "[u]pon a company's refusal to comply with a request for information, the EPA must seek a court enforcement order under section 1319(a)(3)(b)." *Id.* at 560-61. This judicial

process is utterly lacking in the Privacy Rule. Moreover, the power to inspect records was a condition of the permit, while the Privacy Rule permits the government to search records unrelated to any federal program here. *Id.* at 560.

Nor can defendants find refuge in *Village of Hoffman Estates v. Flipside*, 455 U.S. 489 (1982). Defs. Br. at 27. There the Supreme Court declined to consider a Fourth Amendment challenge to a requirement for merchants selling drug paraphernalia, obviously associated with illegal activity, to maintain customer names and addresses. 455 U.S. at 504 n.22. That decision did not implicate any of the medical record privacy rights established in *Whalen*. Nor are the other Fourth Amendment precedents cited by defendants controlling here. *See Ornelas v. United States*, 517 U.S. 690, 696 (1966) (addressing reasonable suspicion to stop and question petitioners as they entered their car, and probable cause to remove the interior panel of petitioners' car to find a package of cocaine); *Terry v. Ohio*, 392 U.S. 1 (1968) (reviewing a stop and frisk based on a suspicion of planned criminal activity, with respect to the admissibility of a seized gun); *Ker v. California*, 374 U.S. 23, 33 (1963) (considering entry of an apartment and seizure of a marijuana brick in plain view); *United Transp. Union v. Foster*, 205 F.3d 851 (5th Cir. 2000) (reviewing a planned test for alcohol or drug misuse after an unlikely combination of (i) a train wreck and (ii) suspicion not rising to the level of probable cause). Defs. Br. at 24-27. These decisions are simply too remote from the issue of

medical record privacy, and do not contradict *Whalen* in any way. When the Supreme Court has directly addressed an issue, as it has in *Whalen*, then it must be applied directly unless and until the Court overrules it. *See, e.g.*, *Hohn v. United States*, 524 U.S. 236, 252-253 (1998) (Supreme Court decisions "remain binding precedent until we see fit to reconsider them ….").

Particularly puzzling is defendants' reliance on *Rowan Cos., Inc. v. Griffin*, 876 F.2d 26 (5th Cir. 1989) (cited by Defs. Br. at 27). That decision, by this Court, *reversed* a dismissal of an action for lack of ripeness. This Court held that the case should proceed "to provide a means of settling an actual controversy before it ripens into a violation of the civil or criminal law, or a breach of a contractual duty." *Id.* at 28. Plaintiffs likewise seek declaratory relief here to protect the privacy of their medical records before someone's career is ruined, which is as compelling as the complaint in *Rowan*. *See id.* at 27 (allowing plaintiff to seek judicial declaration of its future obligations to provide reimbursement for medical expenses).

Defendants observe that they have subpoena power apart from the Privacy Rule, which gives them an alternate means of obtaining medical records from physician offices. Defs. Br. at 25 n.11. That power, however, is subject to all-important judicial review prior to compelling a physician to produce the records. *See Doe v. United States*, 253 F.3d 256 (6th Cir. 2001). In *Doe*, the Department of

Justice served a subpoena on a podiatrist seeking, *inter alia*, "all documents and patient files evidencing Doe's referral of patients for certain electrodiagnostic tests after April 2, 1998." *Id.* at 261. The statutory authority for the subpoena was Section 248 of HIPAA. Doe was able to file a motion for a protective order, and even appeal an adverse ruling. *Id.* That judicial process is lacking in the Privacy Rule.

Yet defendants argue that the availability of administrative process renders this action unripe, because it is not completely certain which means the Secretary will use. But the Privacy Rule enables the Secretary to bypass judicial process altogether, providing unfettered access to medical records without a subpoena. 45 C.F.R. § 160.310(c). Irreversible loss of privacy occurs from the mandatory and permissive access authorized by the Rule, and judicial review need not wait until it is too late. *See Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967) (denying standing based expressly on a finding that "no irremediable adverse consequences flow from requiring a later challenge to this regulation" – which is untrue here); *McCarthy v. Briscoe*, 553 F.2d 1005, 1007 (5th Cir.), *cert. denied*, 434 U.S. 985 (1977) ("Moreover, a denial of injunctive relief at this stage would not subject appellants to any immediate or irreparable injury. Whatever imminent hardship existed at the time this suit was filed has already been avoided by the injunction directed at the 1976 Texas ballot.").

Defendants also rely on decisions addressing standing after discovery, unlike here. *See, e.g.*, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (cited at Defs. Br. at 19, 31, 32). The *Lujan* Court denied standing only *after* plaintiffs obtained discovery from the government. "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presume that general allegations embrace those specific facts that are necessary to support the claim.' In response to a summary judgment motion, however, the plaintiff can no longer rest on such 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts,' Fed. Rule Civ. Proc. 56(e), which for purposes of the summary judgment motion will be taken to be true." *Id.* at 561 (citations omitted). Plaintiffs have not yet obtained discovery here, and evidence of government invasion of medical record privacy remains exclusively in its possession. *See also Pennzoil Co. v. FERC*, 742 F.2d 242, 244 (5th Cir. 1984) (declining, for lack of ripeness, an appeal of a denial of a motion for summary judgment rather than a motion to dismiss).

Plaintiffs' Fourth Amendment claim is intertwined with its First Amendment claim, discussed below, and thus is not precluded by *United States v. Salerno*, 481 U.S. 739, 745 (1987) (noting that the Supreme Court has "not recognized an 'overbreadth' doctrine outside the limited context of the First Amendment"). Moreover, this Court has recognized a general right of privacy in one's personal

information, in reliance on *Whalen. See Sherman*, 244 F.3d at 361 n.5 (quoted *supra*). At any rate, the court below did not reach the merits of plaintiffs' challenge, and this appeal need not resolve it at this stage. The issue is whether plaintiffs have standing and ripeness to challenge the intrusion of the Privacy Rule on First and Fourth Amendment rights. Under *Whalen* and the First Amendment precedents below, standing and ripeness exist here.

2. First Amendment Claim.

The chilling effect of the Privacy Rule on patient-physician communications is severe. No longer may a patient rely on the protections of judicial process, such as a warrant, to guard against undesired disclosures to the government and third parties. The Privacy Rule permits and sometimes requires physicians and medical institutions to disseminate highly personal medical communications to third parties without the patients' consent. Such disclosure can destroy the ability to obtain insurance, employment, engage in public activism, and even marital relationships. Patients will say less to doctors, and vice-versa, if government and others have such unguarded access to what is said.

Just recently, the Ninth Circuit enjoined the federal government on these grounds from investigating a physician based solely on his recommendation. *Conant v. Walters*, 309 F.3d 629, 2002 U.S. App. LEXIS 22492 (9th Cir. Oct. 29, 2002). "An integral component of the practice of medicine is the communication

between a doctor and a patient. Physicians must be able to speak frankly and openly to patients." *Id.* at *15. The appellate court noted that this "has been recognized by the courts through the application of the common law doctor-patient privilege." *Id.* (citing Fed. R. Evid. 501). There the underlying communications concerned the controversial use of marijuana, while the communications at stake here concern lawful and salutary activities.

The Supreme Court has emphasized that "the imperative need for confidence and trust" between the patient and his or her physician, such that "a physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment." *Trammel v. United States,* 445 U.S. 40, 51 (1980). Simply put, there are "core First Amendment values of the doctor-patient relationship," and "[b]eing a member of regulated profession does not, as the government suggests, result in a surrender of First Amendment rights." *Conant*, 2002 U.S. App. LEXIS 22492, *16, *17. The Ninth Circuit enjoined the federal government from infringing on this speech, even in the absence of a specific enforcement action.

This Court need not go as far as the *Conant* court. It is indisputable that the threat of a career-ending breach of medical information privacy is enough to restrict speech by patients and doctors alike. *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); Declaration of Gregory N. Laurence, M.D., ¶¶ 3-5 (Tab 9); Declaration of Philip M. Catalano, M.D., ¶¶ 2-3 (Tab 6). It is "objectively reasonable," using the term of defendants' own authority, for patients and physicians to be chilled by the governmental access without cause mandated by the Privacy Rule. Defs. Br. at 29 (citing *New Hampshire Right to Life Political Action Comm. v. Gardner*, 99 F.3d 8, 14 (1st Cir. 1996)). Defendants assume that there is an "absence of any immediate harm or threat of future harm," but the Supreme Court has already resolved that issue in favor of plaintiffs: there is undeniable harm in providing access to medical records without adequate safeguards. *Whalen*, 429 U.S. at 602; Defs. Br. at 30.

The chilling effect immediately limits economic choice, which alone suffices to establish standing. Declaration of Philip M. Catalano, M.D., ¶ 2 (Tab 6) ("I am limiting my practice to avoid doing any electronic transmissions."); Declaration of Patient Dawn Richardson ¶ 6 (Tab 7) ("My market choice is thereby restricted with respect to the decisions most important to me: protecting the health of my family."). *See Allandale Neighborhood Ass'n v. Austin Transp. Study Policy Advisory Comm.*, 840 F.2d 258, 262-63 (5th Cir. 1988) ("[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).") (footnote omitted); *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). Yet defendants offer nothing meaningful in rebuttal. They merely say that "[t]aken seriously, the plaintiffs' concerns should also lead them to avoid seeking federal disability and Medicare benefits, because such statutes require disclosure to the government of sensitive medical information." Defs. Br. at 32-33. That analogy fails because the Privacy Rule authorizes governmental access to medical records **outside of** government programs. Even the records of patients who pay cash are exposed to governmental access under the Privacy Rule.

Defendants' numerous citations outside of the medical record context add little to the analysis. Defs. Br. at 29-31. They rely heavily on *Laird v. Tatum*, 408 U.S. 1 (1972), but the *Whalen* Court itself implicitly rejected applying it to the sensitive issue of medical record privacy. *Laird* merely concerned data collection of information that "is nothing more than a good newspaper reporter would be able to gather by attendance at public meetings and the clipping of articles from publications available on any newsstand." *Id.* at 9 (quotations omitted). That is a

far cry from the gathering of highly personal medical information. Also, in contrast to the Privacy Rule, the scheme challenged in *Laird* was an alleged practice rather than a formally promulgated regulation. *Id.* at 2 n.1 ("The complaint filed in the District Court candidly asserted that its factual allegations were based on a magazine article ...."). *See also United Presbyterian Church v. Reagan*, 738 F.2d 1375, 1378 (D.C. Cir. 1984) (unlike the Privacy Rule, "Executive Order No. 12333 issues no commands or prohibitions to these plaintiffs, and sets forth no standards governing their conduct"). In contrast, standing typically exists to challenge sweeping formal rules, as here. *See Meese v. Keene*, 481 U.S. 465 (1987) (finding standing in a challenge to a statute labeling certain films as "political propaganda," despite lack of specific, incurred injury).

Similarly, defendants rely on the Tenth and Seventh Circuit decisions to no avail. Defs. Br. at 31. Here plaintiffs do specifically allege that the regulations impose unjustified restrictions on their speech, in contrast with defendants' precedents. *See National Council for Improved Health v. Shalala*, 122 F.3d 878, 884 n.9 (10th Cir. 1997) ("Plaintiffs have not specifically argued that the regulations chill their own speech."); *see also United States v. Ramsey*, 503 F.2d 524, 526 n.5 (7th Cir. 1974), *cert. denied*, 420 U.S. 932 (1975) (rejecting defendant's argument that the "very existence of wiretapping authority has a

chilling effect on free speech," because if "this argument were valid, no statutory authorization of electronic eavesdropping would be constitutional").

It was the dismissal of this action prior to discovery that prevented plaintiffs from enumerating further intrusions of privacy caused by the Rule. The *Whalen* Court relied heavily on the factual record developed by plaintiffs in discovery and at trial, with respect to the safeguards of the regulatory scheme. 429 U.S. at 595. That ruling was not, in the colorful words employed by defendants, merely a "drive-by jurisdictional ruling[that] … has no precedential effect." Defs. Br. at 33 (quoting *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 91 (1998)). The patient and physician declarations, quoted above and in plaintiffs opening brief, demonstrate the chilling effect and its immediate harm. The regulatory scheme of the Privacy Rule is reviewable on its merits, and the decision below should be reversed.

II. AS DEFENDANTS CONCEDE, PLAINTIFFS HAVE STANDING TO CHALLENGE THE SCOPE OF THE PRIVACY RULE FOR EXTENDING BEYOND FEDERAL POWER.

Defendants expressly concede that "[p]laintiffs have standing to pursue their Tenth Amendment claim only to the extent that they contend that HIPAA's provisions fall outside Congress' Commerce Clause authority. The federal courts **routinely entertain claims of this sort**." Defs. Br. at 35 (emphasis added). But then defendants suggest that every medical practice "has a 'substantial relation' to

interstate commerce, and can therefore be regulated by Congress under the Commerce Clause." *Id.* (quoting *United States v. Lopez*, 514 U.S. at 559). This violates federalism to transfer the regulation of medical recordkeeping, traditionally within the exclusive jurisdiction of the states, to the federal government. *See Linder v. United States*, 268 U.S. 5, 18 (1925) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government."). *Linder* and *Lopez* do not permit this massive federal intrusion into the state domain.

Had the Privacy Rule confined itself to electronic transactions, as it did initially, this would not be an issue. 65 Fed. Reg. 82488 (The Rule "would not have applied to information that was never electronically maintained or transmitted by a covered entity."). But the Rule transgressed federalism when it extended to all paper records of any physician who files merely a single electronic claim. Defendants respond that "the conversion to electronic health care information transactions may be delayed if patients perceive that the system threatens their privacy." Defs. Br. at 36. That rationale does not justify the extension of the Privacy Rule to paper records.

Defendants rely primarily on two decisions concerning federalism. *Reno v. Condon*, 528 U.S. 141, 148-49 (2000) (cited by Defs. Br. at 37); *United States v. Evans*, 928 F.2d 858, 862 (9th Cir. 1991) (cited by Defs. Br. at 36). But both

support plaintiffs here. In *Reno*, the Supreme Court addressed whether federal law may restrict state sales of driver registration information. The Court held that "the personal, identifying information that the [federal statute] regulates is a 'thing in interstate commerce,' and that the sale or release of that information in interstate commerce is therefore a proper subject of congressional regulation." 528 U.S. at 148 (quoting *Lopez*, 514 U.S. at 558-59). The basis of the Court's decision is illustrative here: "The motor vehicle information which the States have historically sold is used by insurers, manufacturers, direct marketers, and others engaged in interstate commerce to contact drivers with customized solicitations. The information is also used in the stream of interstate commerce by various public and private entities for matters related to interstate motoring. Because drivers' information is, in this context, an article of commerce, its sale or release into the interstate stream of business is sufficient to support congressional regulation." *Id.*

Paper records preserved in small rural practices, in contrast, are **not** in the "interstate stream of business" emphasized in *Reno v. Condon*. They have not been historically used to solicit customers. The federal government lacks power to intrude into or otherwise regulate these records. The Privacy Rule illogically asserts federal control over those records if the physician engages in **any** electronic transaction with respect to **any** patient. It is akin to the Federal Communications

Commission attempting to regulate all actions of any individual who ever placed an interstate telephone call. This is simply beyond federal power.

United States v. Evans also fails to support defendants' position. In *Lopez*, the Supreme Court cited and rejected the very argument that defendants reassert here. "[I]f we were to accept the Government's arguments, we are hard pressed to posit any activity by an individual that Congress is without power to regulate." 514 U.S. at 564 (responding to governmental reliance on *Evans*). Moreover, *Evans* itself has little to offer here. The Ninth Circuit relied on factual findings by Congress in support of its power to regulate, holding that "they carry great weight in this court's analysis." 928 F.2d at 862. Here, defendants do not, and cannot, cite any findings by Congress or HHS in support of authority to regulate paper records of all doctors.

Defendants also misplace reliance 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). Defs. Br. at 39 n.14. There plaintiff Gaubert attempted to use the Tenth Amendment to compel action by the State of Louisiana. 1999 U.S. Dist. LEXIS 8207, at *4 - *14. Using the Tenth Amendment against a State has obvious difficulties, and is inapposite to plaintiffs' challenge to overreaching by the federal government here. As most Circuits have confirmed, individuals have standing to assert this type of claim. *Gillespie v. City of Indianapolis*, 185 F.3d 693 (7th Cir.

1999), *cert. denied*, 528 U.S. 1116 (2000); *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). *See also United States v. Richardson*, 418 U.S. 166, 193 (1974) (Powell, J., concurring) (noting that "standing barriers have been substantially lowered" in the many decades since *Tennessee Elec. Power Co. v. TVA*, 306 U.S. 118 (1939)).

At a minimum, a factual record is necessary to resolve the plaintiffs' federalism claim. Even defendants' own cited authority, *Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc.*, entailed a 13-day trial to develop a factual record. 452 U.S. 264, 273 (1981) (cited by Defs. Br. at 28). A remand to the court below is necessary to determine how much the federal government is intruding on exclusive state jurisdiction over medical practice and patient-physician confidentiality.

III. HHS FAILED TO MAKE THE REQUISITE "GOOD FAITH" EFFORT TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT.

Defendants concede that HHS must make a "'reasonable, good-faith effort to carry out [its] mandate'" under the RFA. Defs. Br. at 40 (quoting *Alenco Comm., Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000) and *Associated Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 114 (1st Cir. 1997)). But defendants provide nothing

to disprove plaintiffs' allegations that there was no good-faith effort. Plaintiffs' claims should not have been dismissed.

Defendants fail to satisfy the following requirement of the RFA: "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 requirement is reinforced by HIPAA itself, which mandates 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.

Defendants seek to avoid any meaningful application of the RFA by insisting that its requirements are "purely procedural," such that **any** feigned compliance is adequate. Defs. Br. at 40 (quoting *United States Cellular Corp. v. F.C.C.*, 254 F.3d 78, 88 (D.C. Cir. 2001)). But defendants' own precedent scrutinized the work of the agency, and only denied the challenge under the RFA after finding that the agency's "reasons for dismissing alternatives … were entirely reasonable." *Id.* at 89. Here, it was not reasonable for the Privacy Rule to impose its costly burdens on all medical practices that engage in merely a single electronic transaction. 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* Letter of John R. Lumpkin, M.D., M.P.H., Chair, National Committee on Vital and Health Statistics to defendant Secretary Thompson, HHS (dated Nov. 25, 2002, posted at http://www.ncvhs.hhs.gov/021125lt.htm) (“[P]roviders may drop out of the system of providing care to indigent patients because they cannot afford to absorb the costs of complying with the Privacy Rule … Millions of health care workers will need to be trained in the next few months, but there is a dire shortage of expertise, materials, and funding.”).

Defendants’ opposition brief contains very little in substantive defense of their conduct with respect to the RFA, and only a few citations in support. Defs. Br. at 39-41. Defendants first claim that the Rule was modified “‘to ease the burden on small businesses.’” Defs. Br. at 40-41 (quoting 65 Fed. Reg. 82783). In fact, the Rule does nothing to alleviate the general requirement that small entities must comply with all aspects of the Privacy Rule. What defendants reference is the dropping of the recertification proposal, but that is meaningless because the employer remains responsible for ensuring up-to-date training -- with or without recertification.

Defendants concede that the Secretary completely rejected exemptions for small businesses. Defs. Br. at 41. Without explanation or justification, the Privacy Rule insists that its “privacy standard must be implemented by all covered entities,

regardless of size." 65 Fed. Reg. 82782. 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.

Defendants' other cited bases for asserting RFA compliance are even less helpful. The Privacy Rule requires actual knowledge of violations by covered entities in order to hold them responsible for the conduct of business associates, because of complaints that a lower standard would be "too vague or difficult to apply." *Id.* at 82641. Some commented that small entities would have trouble monitoring much larger business associates, which HHS cited. *Id.* But the Rule for business associates applies across-the-board, to big and small entities alike.

Small businesses complained bitterly about the inflexible and unjustified application of the Rule to them, and HHS acknowledged their comments. *Id.* at 82641. "One respondent believed that the initial and ongoing costs for small provider offices could be as much as 11 times higher than the estimates provided in the proposed rule. Other commenters stated that the estimates for small entities are 'absurdly low.'" *Id.* Defendants cite to these comments as evidence of compliance with the RFA, but HHS did not act on them. Instead it simply declared, by fiat, that "the Department does not agree with the assertion that small entities will be disproportionately affected." *Id.* Whether the impact on small businesses is

disproportionate or not, defendants were obliged to make a good-faith effort on their behalf. Defendants failed to do so.

IV. CONCLUSION.

Plaintiffs have stated a valid cause of action, and discovery should proceed. For the foregoing reasons, the decision below should be reversed and remanded.

Respectfully submitted,

Andrew Schlafly, Esq.
AAPS General Counsel
939 Old Chester Road
Far Hills, NJ 07931
(908) 719-8608 (phone)
(212) 214-0354 (fax)

Karen Tripp
Attorney-in-charge
Texas Bar No. 03420850
Southern District Bar No. 2345
P.O. Box 1301
Houston, Texas 77251-1301
(713) 658-9323 (phone)
(713) 658-9410 (fax)
ATTORNEYS FOR PLAINTIFFS

Dated: December 3, 2002

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of December, 2002, I caused two true and correct copies (on paper) of **Reply Memorandum of Appellants**, a computer disk containing same, 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 **Reply Memorandum of Appellants** 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:

Mr. Mark B. Stern
Mr. Michael S. Raab
Mr. Charles W. Scarborough
Mr. Sambhav N. Sankar
U.S. Department of Justice
Civil Division, Appellate Staff
Patrick Henry Building
601 D Street, N.W., Room 9108
Washington, D.C. 20530-0001

Mr. Charles R. Fulbruge III
Clerk of the Court
United States Court of Appeals
for the Fifth Circuit
600 Camp Street
New Orleans, Louisiana 70130

____
Karen B. Tripp, Esq.

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 6,266 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.

____
Karen Tripp