IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Docket No. 04-2550

CITIZENS FOR HEALTH *et al.*	
Plaintiffs-Appellants,	
vs.	
TOMMY G. THOMPSON, SECRETARY OF UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,	
Defendant-Appellee.	

BRIEF OF GUENTER L. SPANKNEBEL, M.D., LEONARD MORSE, M.D., WAYNE, GLAZIER,M.D., GRAHAM L. SPRUIELL, M.D. AND THE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

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STATEMENT OF IDENTITY, INTEREST, AUTHORITY TO FILE AND CORPORATE DISCLOSURE STATEMENT

The Association of American Physicians and Surgeons, Inc. ("AAPS")[1] and Doctors Guenter L. Spanknebel, Leonard Morse, Wayne Glazier and Graham L. Spruiell (collectively, the "*Amici*") authorize this *amici curiae* brief to be filed. Doctors Morse and Spanknebel are past presidents of the Massachusetts Medical Society, the nation's oldest medical society. Doctor Morse also served as a past-chair of the American Medical Association's Council on Ethical and Judicial Affairs. Doctor Glazier is President of the Massachusetts Independent Physicians' Association. Doctor Spruiell is active in various psychiatric associations and is a clinical instructor at the Harvard Medical School.

The essence of the physician-patient relationship is trust. It allows patients to reveal the most intimate details of their lives to their physicians who hold the information in confidence. Without absolute trust, patients cannot honestly reveal themselves and physicians cannot properly understand the patient's condition.[2]

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[1] AAPS is a nationwide association of thousands of physicians in all types of practices and specialties. AAPS is a non-profit Indiana corporation founded in 1943 and dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship. The corporation has no parents, subsidiaries or shareholders.

[2] Massachusetts Medical Society, Background: MMS Policy on Patient Privacy and Confidentiality: Health Policy (10/14/2000)(As adopted by MMS House of

When a patient fears a disclosure, he or she may withhold the disclosure of certain symptoms or facts from the physician. Thus, the physician may be without knowledge of the symptoms needed for a proper diagnosis. Furthermore, physicians who expect disclosure may record information selectively. In other words, the process of healing is harmed because either the patient or physician may withhold essential information[3].

As a result of Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 *et seq.* (August 21, 1996)("HIPAA")[4] and the regulations issued by the United States Department of Health and Human Services ("HHS")(the "Regulations") pursuant to that provision, 65 Fed. Reg. 82462 *et seq.* (December 28, 2000)("Original Regulations") and 67 Fed. Reg. 53182 (August 14, 2002)("Modifications"), that trust has been jeopardized. Under Section 264(c) and the Regulations patients lose the ability to control access to and dissemination of their medical records. Although the Regulations attempt to preserve the traditional confidentiality

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Delegates, November 8, 1996)("Trust is the essence of the patient-physician relationship.")("MMS Background").

[3] MMS Background, *supra* note 2; *See also,* U.S. Congress, Office of Technology Assessment, *Protecting Privacy in Computerized Medical Information,* OTA-TCT-576 (Washington, D.C.: U.S. Gov't. Printing Office, Sept. 1993) ("PROTECTING PRIVACY") at 30; Original Regulations, 65 Fed. Reg. at 82467-80.

[4] Unless otherwise specified all "section" or "§" references refer to HIPAA.

principles attributed to Hippocrates approximately 2,400 years ago, they contain broad exceptions to the consent and authorization requirements. The exceptions to the consent and authorization requirements for payment, treatment and healthcare operations consume virtually the entire general rule. Under these exceptions, a covered entity may choose not to seek a patient's permission prior to using or disclosing that patient's information if it involves payment, treatment or healthcare operations. The locus of decision-making regarding access to and dissemination of information is shifted from the patient to the covered entity.[5] This obliterates the very foundation of the medical profession – the trust between a patient and his or her physician and reduces patient candor resulting in increased diagnostic and treatment risks. *Amici* are alarmed and disturbed by these developments and believe they can be of particular assistance to the Court regarding the nature and importance of the patient-physician relationship.[6]

Amici question the very power and process by which Congress purportedly authorized HHS to issue the Regulations. Whether HHS ever had any power to

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[5] Medical records of this appellate panel may be at risk. The Regulations apply to "health plans" which is defined to include the "Federal Employees Health Benefits Program…." 45 C.F.R. §160.103.

[6] "A trusting patient-physician relationship is the fundamental beginning for appropriate health care…." Leonard Morse, Comments from Physicians, in MMS Background, *supra* note 2.

regulate health privacy is the real issue before this Court. *Amici* contend that, in fact, HHS had no authority at all to regulate health privacy. *Amici* believe that immediate relief from the damage caused by HHS' misuse of power is necessary. Delaying relief could hurt the health of thousands, if not millions, of patients. In the age of the Internet, electronic records may be transmitted and retransmitted worldwide in an instant. Once a patient's electronic records are released, it is too difficult or impossible to reverse the breach of privacy. The records are no longer private. They become public.

Unless the decision below is immediately reversed, HHS will continue to act without legislative authority, permanently changing medical care and putting patients at risk.

BACKGROUND

Physicians have long had a duty to maintain the confidences of their patients. This fundamental tenet of the medical profession was first expressed in the Hippocratic Oath. For the last 2,400 years, those who have entered the medical profession have subscribed to this oath which provides:

> What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself.…[7]

[7] PROTECTING PRIVACY, *supra* note 3 at 38.

For centuries physicians throughout the world have adhered to similar non-disclosure principles.[8] These principles appear in current[9] and historical[10] medical ethical codes. These principles apply to other health professionals and institutions.[11]

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[8] *See e.g.,* Bioethics – Codes, Oaths, Guidelines and Position Statements *reprinted at* www.library.dal.ca/kellogg/Bioethics/codes/codes.htm

[9] *See, infra,* notes 11-12 and accompanying text.

[10] PROTECTING PRIVACY, *supra*, note 3 at 38. In 1803 Thomas Percival, an English physician published an ethics code for physicians regarding fidelity and honor in connection with observations made during interactions with patients. At its inaugural meeting in 1847, the American Medical Association ("AMA") issued its first ethical code regarding confidentiality. That code incorporated Percival's language, with little change. It provided:

> The obligation of secrecy extends beyond the period of professional services-none of the privacies of personal and domestic life, not infirmity of disposition or flaw of character observed during professional attendance, should ever be divulged by [the physician] except when he is imperatively required to do so. The force and necessity of this obligation are indeed so great, that professional men have, under certain circumstances, been protected in their observance of secrecy by courts of justice.

Id.

[11] Robert E. DeWitt, Anita Ellis Harton, William E. Hoffmann, Jr., Robert M. Keenan, III, & Marie B. Ellis, *Patient Information and Confidentiality*, in TREATISE ON HEALTH CARE LAW, ¶16.01[1](A. Capron & I. Birnbaum eds. 2001)(discussing ADA, Principles of Ethics and Code of Professional Conduct ("Dentists shall guard the confidentiality of patient records."); APA, Principles of Medical Ethics ("Confidentiality is essential to psychiatric treatment."); ANA, Code for Nurses with Interpretive Statements ("The nurse safeguards the client's right to privacy by judiciously protecting information of a confidential nature.");

Until HIPAA was enacted and the Regulations were issued, the general practice regarding the release of a patient's medical record was that the information contained in that record could only be released to a third party with the consent of the patient. For example, a patient's express consent was required to release his or her medical record to any of the following parties: patient's attorney, insurance company, family member (unless there is a durable power of attorney), federal or state agencies, employer (unless there is a worker's compensation claim), and other third parties.[12]

With open accessibility of medical records, patients suffer concrete harm. They may be denied life or health insurance, lose jobs, lose credit, fail to obtain security clearance, or suffer other biases, without knowing why. The Massachusetts Medical Society describes the essence of the trust relationship in its Policy on Patient Privacy and Confidentiality. The "General Principles" listed in that policy statement include:

AHA, American Hospital Association's Bill of Rights, Article 6 ("The patient has the right to expect that all communications and records pertaining to his care should be treated as confidential.")

[12] American Medical Association, Office of General Counsel, Division of Health Law, Patient Confidentiality (1998) *reprinted @* www.ama-assn.org/ama/pub/category/4610.html.

> 1- The patient has a fundamental right to privacy and confidentiality in his/her relationship with a physician…
>
> 2- Privacy and confidentiality are the privileges of the patient, so only he or she may waive them, in a meaningful and non-coerced fashion. Release of information for a specific purpose such as insurance payment should not require waiver of the total right to privacy and confidentiality.[13]

As we move into the twenty-first century, access to confidential patient information has become more pervasive making it more difficult to maintain the patient's trust. Physicians in integrated delivery systems or networks can have access to the confidential health records of all patients within their system or network. Confidential information can also be disseminated through clinical repositories and shared databases. The challenge for physicians is to reconcile new technologies with the duty to maintain confidentiality.

In light of the history and practice of the medical profession[14], the right to limit access to one's personally identifiable health information should not be eliminated by regulatory fiat. This court must prevent unwarranted intrusions into

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[13] Massachusetts Medical Society, MMS Policy on Patient Privacy and Confidentiality (3-22-02)(emphasis added) *reprinted at* www2.mms.org/pages/privacy.asp.

[14] To the extent that the Original Regulations and Modifications permit or encourage the transmittal of medical records without the consent of the patient, those regulations run counter to the philosophical and ethical foundation of the medical profession.

such information, which may include one's medical, family, psychological, sexual and genetic histories as well as current medical conditions and treatments. Limiting access to personally identifiable health information allows everyone to be more secure in their person and property.[15]

Finally, this court should consider ramifications of its decision outside of the healthcare context. It must be remembered that the Hippocratic Oath was the first professional code of ethics. Numerous ethical codes have evolved since the time of Hippocrates in medicine, law, business and elsewhere. Rena Gorlin, Codes of Professional Responsibility: Ethics Standards in Business, Health and Law (4th ed. 1999). In order to generate trust in their professions, those other codes emulate Hippocrates' concern regarding confidentiality. If HHS regulations can eliminate medical confidentiality, other federal regulations could soon eliminate confidentiality in other contexts. With the loss of confidentiality, trust between an attorney and client, a priest and penitent, or between an accountant and client will decrease and the patient, client or penitent will be the victim.

SUMMARY OF ARGUMENT

[15] With open access to medical records, as permitted by the payment, treatment and operations exceptions in the Modifications, the risk of disclosure to the community in general, and to employers and insurers, in particular, increases.

Acting without Congressional authority, HHS has changed the rights of every patient and every provider and has obliterated more than 2,400 years of accepted medical practice.

Section 264(c) violates the Constitution's bicameral and presentment requirements in two ways. First, it statutorily amended the Constitution's lawmaking requirements by adding a time constraint to Article I, Section 7. Second, Congress ignored the holding of *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919 (1983) and authorized regulations to supplant legislation without fulfilling the bicameral and presentment requirements.

The Court should void the delegation to HHS because Congress may only delegate power it received from the People and because Congress failed to satisfy the "intelligible principles" test in its attempt to delegate authority to issue privacy regulations. First, the 104th Congress was powerless to effect a delegation beyond the expiration of its term. Second, Congress did not provide a general policy or boundary to limit the regulations. In fact, Congress allowed HHS to address an infinite number of subjects. Third, under the Constitution, Congress has no power to impair a patient-physician contract and no power to "take" private property for public use without compensating the property owner. Fourth, under the Fourth,

Ninth and Tenth Amendments, a patient has the right to control access to and dissemination of his or her medical record.

ARGUMENT

I. SECTION 264(C) IGNORED THE CONSTITUTION'S LAWMAKING PROCEDURES

A. Section 264 Unconstitutionally Limits The Time For Congress To Pass A Law

Since our nation was founded more than 200 years ago, a "single, finely wrought and exhaustively considered, procedure" has been used to enact federal legislation. That procedure is laid out in the Constitution's Bicameral and Presentment Clauses. Strict compliance with those procedures is required. When Congress delegates its lawmaking function to another branch or independent agency, it may not legislatively alter that procedure. If it does, the delegation is unconstitutional. For example, the legislative veto and the line item veto were declared unconstitutional. *Immigration and Naturalization Service v. Chadha*, 462 U.S. 919 (1983); *Clinton v. City of New York*, 524 U.S. 417 (1998). Similarly, when Congress conditions the delegation of its lawmaking function upon the

restriction of its own time to consider legislation, it alters the legislative process. Section 264(c) contains such a delegation.

The Bicameral and Presentment Clauses require passage of exactly the same text by both Houses and presentment to the President. *Clinton*, 524 U.S. at 448. Those procedures may not be statutorily supplemented or modified. They may be altered only by a constitutional amendment. *Clinton*, 524 U.S. at 449; *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 837 (1995); *Oregon v. Mitchell*, 400 U.S. 112, 128 (1970). Section 264(c) alters the procedure without ratifying a constitutional amendment in accordance with Article V. Pursuant to Section 264(c), once three years had elapsed without passage of new health privacy legislation, HHS had six months to regulate (unless the House, Senate and the President had agreed otherwise). In contrast, without Section 264(c), HHS could not have regulated health privacy unless the House, Senate and President agreed on new health privacy legislation.

A law such as §264(c), which completely delegates legislative responsibility to an executive department or independent administrative agency, violates the Constitution's letter and spirit. Lawmaking under the guise of rulemaking involves neither agreement of both Houses nor presentment to the President. Section 264(c) failed to provide HHS with rulemaking authority with respect to the privacy of

individually identifiable health information ("IIHI") upon and immediately after enactment. Rather, §264(c) provided that such rulemaking authority might later pass to HHS. That authority would pass to HHS only if legislation with respect to that subject matter failed to be enacted by the statutory deadline.

The abdication of Congressional responsibility encouraged by Section 264(c) is philosophically at odds with the Constitution. *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring)("Abdication of responsibility is not part of the constitutional design"). Section 264(c) turns the legislative process on its head and conditions rulemaking authority solely upon the failure of Congress to take action between two specified dates. It allows Congress to avoid tough decisions. The scope of delegation was set by HHS rather than by agreement of both Houses and the President.

B. Congressional Lawmaking Is Supplanted By HHS Privacy Regulations

Although not every action taken by Congress is subject to the bicameralism and presentment requirements, those requirements must be met when Congress exercises legislative power. Whether particular actions are an "exercise of legislative power depends not on their form but upon 'whether they contain matter

which is properly to be regarded as legislative in its character and effect.'" *Chadha,* 462 U.S. at 952 *quoting* S. Rep. No. 1335, 54th Cong., 2d Sess., 8 (1897).

The legislative character of an action may be established by an examination of the Congressional action that it supplants. This "Supplantation Principle" was used to analyze the constitutionality of the legislative veto in *Chadha*. *Id.* at 952 ("The legislative character of the one-House veto in these cases is confirmed by the character of the congressional action it supplants"). That principle should be extended to apply to actions undertaken by independent agencies and other branches of government. There is no reason not to extend this principle to evaluate non-Congressional exercises of legislative power.

In *Chadha*, the constitutionality of the legislative veto provision in §244(c)(2) of the Immigration and Nationality Act was examined. The Supreme Court examined §244(c)(2) and found that it had an essentially legislative purpose and effect. Although the Court acknowledged that §244(c)(2) authorized one house, by resolution, to require the Attorney General to deport an alien whose deportation otherwise would be canceled under Section 244, the Court reasoned that "the House took action that had the *purpose and effect of altering the legal rights, duties, and relations of persons*, including the Attorney General, Executive Branch officials and Chadha, all outside the Legislative Branch." *Chadha*, 462

U.S. at 952 (emphasis added). The Court explained that without the House's action, Chadha would remain in the United States. Congress had acted and that action had altered Chadha's status. Without the challenged provision, Chadha's deportation could have been accomplished only by legislation requiring deportation, if at all. *Id.* at 953-54.

Section 264(c) is legislative in both character and effect in two ways. First, by its own terms, it is equivalent to legislation. The alleged authority of HHS to promulgate regulations arose only after Congress failed to pass legislation governing standards with respect to the privacy of IIHI within 36 months of the enactment of HIPAA. Second, the regulations had the purpose and affect of altering the rights, duties, and relations of persons, including patients, providers, health care clearinghouses, health plans, HHS, Office of Civil Rights and others, all outside of Congress. Section 264(c)(1)("Such regulations shall address at least the subjects described in subsection (b)").

Subsections "a" and "b" reinforce this conclusion. They directed the Secretary of HHS to make legislative recommendations regarding privacy of IIHI. They set a limited agenda for the Secretary: to make recommendations for future legislation. The difficult policy choices regarding rights, procedures, and uses and disclosure of IIHI were left to Congress. Subsection "a" explicitly directed the

Secretary of HHS to submit "detailed recommendations on standards with respect to the privacy of [IIHI]." Those recommendations were to be received by a Senate Committee and a House Committee. As used, the word "recommendations" contemplated future Congressional action. In the context of §264, "recommendations" were sought solely for a legislative purpose- to propose and possibly enact future legislation. The subjects contained in §264(b) are legislative in nature and include the rights an individual should have, §264(b)(1), the procedures for exercising those rights, §264(b)(2), and the determination of permitted "uses and disclosures", §264(b)(3).[16] If Congress had enacted the recommendations with respect to those rights, everyone in the United States would have been affected. Similarly, the Original Regulations and Modifications affect everyone in the United States - people and parties outside Congress.

The language seeking recommendations from HHS set forth in Subsections "a", "b", and "d", as well as the language of Subsection "c", suggests that no laws governing privacy standards existed when HIPAA was enacted or prior thereto. Congress wrote on a blank slate. It needed to be better informed before legislating.

[16] A "right" is "[a] power, privilege, or immunity guaranteed under a constitution, statutes or decisional laws, or claimed as a result of long usage" or "[a] legally enforceable claim of one person against another, that the other shall do a given act, or shall not do a given act." *Black's Law Dictionary* 1189 (5th ed. 1979).

This understanding is consistent with Subsections "a", "b", and "d" under which Congress explicitly sought recommendations from HHS regarding those standards. Subsections "a", "b", and "d" reveal that Congress had not yet made any policy determination or value judgment regarding the standards for privacy of IIHI when it enacted HIPAA. Marci Hamilton, *Representation and NonDelegation: Back to Basics*, 20 Cardozo L. Rev. 807, 820 (1999)("The legislature holds primary responsibility to make the national policy choices, and the President may not take on those choices."); *See, Clinton*, 524 U.S. at 442-445, 445n.38. Congress had not balanced the interests of various constituencies regarding that subject matter.[17] However, Congress recognized that it needed further advice. HHS rulemaking

[17] Institutionally, Congress is better able to balance multiple viewpoints than a single agency or department. *See,* Hamilton, 20 Cardozo L.Rev. at 814 ("The legislative branch serves the people by filtering the factions in the society and distilling those laws that will best serve the nation … [P]ositions must be funneled through a large number of ports before becoming governing law … As a result, it is capable of reaching more nuanced compromises on national issues"). In contrast, when lawmaking is delegated to the President, there is only one port of entry, one viewpoint, albeit representing the entire nation. When lawmaking is delegated to an agency or executive department, the viewpoint is even narrower and without electoral accountability. *Id.* at 819-21. The best evidence of why there should be a Congressional filter and why Congress should set national policy is the fact that HHS received approximately 52,000 comments in connection with its issuance of the Original Regulations. 67 Fed. Reg. 14776, 14777 (March 27, 2002).

authority under §264(c) was equated to legislation and carved-out from the remainder of §1173 rulemaking authority.[18]

II. CONGRESS MAY NOT DELEGATE AUTHORITY IT LACKS

It is axiomatic that Congress may only delegate power it receives from the People. Thus, Congress cannot delegate any power which Congress itself cannot exercise. *Loving v. United States,* 517 U.S. 748,758 (1996)("This Court established long ago that Congress must be permitted to delegate to others at least some authority that it could exercise itself. *Wayman v.Southard,* [23 U.S. 1, 42] (1825)"); *Clinton,* 534 U.S. at 481 (Stevens, J., dissenting). Therefore, the court must first analyze whether Congress has the power to enact a specific piece of legislation before it analyzes the validity of the delegation authorized by that legislation.[19]

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[18] 65 Fed. Reg. at 82469-70. Section 1173 authorized HHS to promulgate uniform national standards regarding transactions, unique health identifiers, code sets, security and electronic signatures. § 1173 of the Social Security Act, 110 Stat. 2024-26 *codified* at 42 U.S.C. §1320d-2. In conference, privacy of IIHI was moved out of Section 1173. 65 Fed. Reg. at 82469.

[19] This initial analysis is based on two separate concepts. First, the federal government is one of enumerated powers. Second, a principal may not delegate authority it lacks.

A. A Congress Cannot Delegate Authority Beyond The End Of Its Own Term

Since our nation's first days, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000); *McCulloch v. Maryland*, 4 Wheat. (17 U.S.) 316, 405 (1819). Those powers are constrained by the Constitution's procedural requirements, s*ee e.g.*, U.S. CONST. art. I, § 7, cl.2, and substantive requirements, *see e.g.* U.S. CONST. art. I, § 9. In this case, another constraint is the temporal limit on the Congressional franchise.

The President and members of the Senate and members of the House of Representatives represent different geographic constituencies, have different modes of election, and have different requirements for holding office. U.S. CONST. art. I, §§ 2 & 3, U.S. CONST. art. II, §1 and U.S. CONST. amend. XVII. The Constitution further diffuses power by limiting the terms of the President and members of the Senate and House of Representatives and by making those terms of different lengths, *i.e.* they have different temporal mandates. Senators are elected for six years. U.S. CONST. art. I, § 3, cls. 1&2 and U.S. CONST. amend. XVII. The President is elected for four years. U.S. CONST. art. II, § 1, cl. 1. Members of the House of Representatives are elected for two years. U.S. CONST. art. I, §2, cl. 1. The authority of each Representative, each Senator and the President does not

extend beyond the expiration of his or her term in office, respectively.[20] Any extension of authority beyond the end of those terms would unconstitutionally transfer from the People the power to choose their own representatives.[21] One commentator characterized the holding of elective offices as a "temporary lease" from the nation's citizens. Alan Morrison, *A Non-Power Looks at Separation of Powers*, 79 Geo. L.J. 281, 282 (1990). Expressed in real estate terms, the Constitution does not allow "holdovers".

When Congress "delegates" its power to "make law"[22], the delegation must occur before the Congressional term ends, *i.e.* the end of the term for which the House members are elected. The reasoning is simple. A principal may delegate to its agent only the authority within its possession. Conversely, a principal may not delegate authority that the principal does not have. Each House and Senate

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[20] *See* Joseph Story, C*ommentaries on the Constitution of the United States* (Carolina Academic Press) Book III §263 .

[21] George Washington said: "The power under the Constitution will always be in the People. *It is entrusted* for certain defined purposes, *and for a certain limited period, to representatives of their own chusing*; and whenever it is executed contrary to their Interest, or not agreeable to their wishes, their Servants can, and undoubtedly will be, recalled." *Thornton*, 514 U.S. at 814n.26 (emphasis added)(internal citations omitted).

[22] The power to "make law" stands in contrast to the power to "fill-in details" or otherwise "execute" legislation. *See, Loving,* 517 U.S. at 771.

member loses all authority from his or her constituents at term-end. Consequently, the end of a Congressional term ends **subsequent legislative actions** by that Congress. Similarly, the President has no authority to sign or veto legislation once his or her term expires.[23] If Congress, as principal, cannot exercise its legislative power, then an agent of that Congress may not exercise that power.

Section 264(c) attempts an impermissible delegation of the power to legislate beyond the end of the Congressional term. Rulemaking authority under §264(c) was not permitted to occur upon or even immediately after enactment. Rather, it was deferred until 36 months after enactment of HIPAA. Indeed, rulemaking would not have occurred if Congress had enacted health privacy legislation within 36 months. Once the 105th Congress began in January 1997, the 104th Congress had no power. After that date, the 104th Congress had no power to legislate with respect to the standards for the privacy of IIHI or for anything else. Consequently, the agent of the 104th Congress, HHS, lacked that power as well.

B. Congress Provided No Policy or Boundary to Limit HHS Authority

Under the "intelligible principles" test, a delegation is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency

[23] Similarly, Article I judges have no judicial authority after their terms expire. *See e.g.* 28 U.S.C. §152(a)(Bankruptcy judges serve 14 year terms, extendible to a maximum of 14.5 years).

which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States*, 488 U.S. 361, 372-373 (1989)(*quoting American Power & Light Co. v. S.E.C.*, 329 U.S. 90, 105 (1946)). It has been suggested that delegation to administrative agencies leaves a gaping hole in the Constitution's balanced structure of checks and balances because agencies are prone to be arbitrary and unaccountable.

> "The nondelegation doctrine in this scenario is crucial to liberty, because it prohibits general lawmaking from occurring in a structure both capable of arbitrary action and removed from the national scrutiny to which both Congress and the President are exposed by the constitutional structure."

Hamilton, 20 Cardozo L.Rev. at 821.

Section 264(c) fails to meet two of the three "intelligible principle" criteria. First, there is no clearly delineated general policy. Second, there is no boundary on the delegated authority.

Neither the general policy statement contained in the preamble to HIPAA nor the policy statement articulated as §261 of the Administrative Simplification provisions of HIPAA "clearly delineates" a general policy that is applicable to the privacy of IIHI.

First, HIPAA's Preamble provides that HIPAA is:

> "[a]n act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual

> markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes."

110 Stat. at 1936. Privacy of IIHI is not referable to any of the specified purposes.

The Administrative Simplification provisions comprise subtitle F of HIPAA. The first section, §261, contains a statement of the purpose of subtitle F. 110 Stat. at 2021 (not codified but *appears* at 42 U.S.C. § 1320d note).

The argument that "standards with respect to the privacy of IIHI" is encompassed by the language appearing at the end of §261 (*i.e.* "through the establishment of standards and requirements for the electronic transmission of certain health information") is untenable. A fair reading of that language points to §1173, which is entitled "STANDARDS TO ENABLE ELECTRONIC EXCHANGE". It does not point to Section 264, which is entitled "RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION." Section 264 directed the Secretary of HHS to make recommendations. It did not direct the Secretary to establish any standard or requirement with respect to privacy of IIHI upon enactment. The only authority to issue such standards was contingent authority if Congress failed to enact legislation. The policy and purpose with respect to privacy of IIHI were to be

determined by later legislation. HIPAA contained no delineation of a policy or purpose with respect to privacy of IIHI.

Although, another circuit concluded these provisions amount to a statement of "general policy", *South Carolina Medical Association v. Thompson*, 327 F.3d 346 (4th Cir.) *cert. denied* __ U.S. ___, 124 S.Ct, 464 (2003), the statute and Regulations do not support this conclusion. First, neither the patient nor a surrogate designated by the patient is required as a control or check point to limit information transfer. Second, HIPAA contains no private right of action for patients to protect themselves.[24] Third, HIPAA and the Regulations do not necessarily apply to individuals and entities that wrongfully obtain IIHI. Fourth, HHS has created exceptions to the consent and authorization requirements for transactions involving payment, treatment and healthcare operations and HHS could conceivably create further exceptions in the future. Fifth, the Regulations do not apply to all of a patient's personal and medical information but only to IIHI that is within the scope of section 1173. If privacy were truly the policy, HHS

[24] Under the common law, it was the right of every Englishman to apply to the "courts of justice for redress of injuries". William Blackstone, Commentaries 1:137-38 (1765) *reprinted in* 5 The Founders' Constitution 311 (Philip Kurland and Ralph Lerner, eds. 1987). *See also,* Sir Edward Coke, Second Initiative 45, 55 (1641)("…[E]very subject of the realme, for injury done to him *in bonis, terris, vel persona*...may take his remedy by the course of the law, and have justice, and right for the injury done to him…") *reprinted in* 5 The Founders' Constitution 309-310.

would not have been able to lower the confidentiality bar from that encompassed by the Hippocratic Oath and practiced by physicians throughout our nation's history.

Section 264 provides no marker or check to determine whether HHS has exceeded the authority authorized by Congress. *See*, *Yakus v. United States*, 321 U.S. 414, 423-424 (1944); *Chadha*, 462 U.S. at 953.

The phrase "shall address at least" is used both to list the subjects of legislative recommendations to be submitted by HHS and to list the subjects of rulemaking authority to be delegated if Congress failed to pass legislation by the statutory deadline. The use of that phrase removed all limits on HHS's authority. In *A.L.A. Schechter Poultry Corporation v. United States*, the Supreme Court struck down, as overly broad, a delegation that merely affected all industries. 295 U.S. 495 (1935). The delegation in §264(c) is much broader. Its impact is not limited to the healthcare industry or even to all industries. It affects everyone. Its impact is pervasive.

Congress omitted boundaries from Section 264 which contains a minimal set of subjects to be recommended to Congress and a minimal set of subjects to be included in future regulations in the event that Congress does not enact legislation in connection with those recommendations by the specified future date. Because

the words "address at least" appear in §264(b) and §264(c)(1), there is nothing in Section 264 to constrain HHS rulemaking authority. There are only three subjects that must be addressed. HHS was permitted to address an infinite number of subjects.[25] In *Whitman v. American Trucking Associations, Inc.,* the Supreme Court said, "[t]he very choice of which portion of the power to exercise--that is to say, the prescription of the standard that Congress had omitted--would *itself* be an exercise of the forbidden legislative authority." 531 U.S. 457, 473 (2001) (Scalia, J.). HHS has exercised such forbidden legislative authority.

C. Congress Lacks Authority to Legislate With Respect to Health Privacy

It is black letter law that "the powers of the legislature are defined, and limited." *Marbury v. Madison*, 1 Cranch 137, 176 (1803)(Marshall, C.J.); *See also,* The Federalist, No. 45, at 292 (Madison)(Clinton Rossiter, ed. 1961) ("The powers delegated by the proposed Constitution to the federal government are few and

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[25] To clarify this point, we assume *arguendo* that section 264 dealt with the Department of Agriculture ("DoA") and the three subjects were regulations concerning apples, bananas and celery. Under the construction adopted by HHS and the court below, DoA would be allowed to regulate those three items as well as an infinite number of other items (*e.g.* dates, eggplants, figs, green beans, … zucchini) even if Congress and the President never agreed to regulate the items that DoA ultimately regulated. Similar arguments could be made with respect to regulations issued by other Executive Departments and Independent Agencies.

defined"). Under the Constitution, Congress has no power to impair the obligations of a contract and no power to take private property for public use, without just compensation. Section 264(c) attempts both. Furthermore, the right to control access to and dissemination of a person's medical records is precisely the type of right retained by the people under the Ninth Amendment and reserved to the people under the Tenth Amendment. The Supreme Court has recently examined the Fourth Amendment and indicated that the government may not use any device that can record what is happening inside a house without physically entering that house. *Kyllo v. United* States, 533 U.S. 27 (2001). The Fourth Amendment protects persons, papers and effects as well as houses. Surely, this Amendment protects individuals from having information regarding what is happening inside their bodies from being accessed by the government or private parties accessing that information pursuant to regulatory permission.

1. Congress has no power to impair a patient – physician contract.

Typically, contract is formed when a patient receives care from a physician or other health professional. The patient promises to pay or have a third party pay. The physician promises to diagnose or treat the patient. The physician also promises to keep the confidences of his or her patients. Dr. Benjamin Rush,

founder of Philadelphia Medical Society and signer of the Declaration of Independence[26], said: "[t]he most important contract that can be made, is that which takes place between a sick man and his doctor. The subject is human life…" Benjamin Rush, Selected Writings of Benjamin Rush 299 (D.D. Runes, ed. 1947) *reprinted in* American College of Physicians, Medicine in Quotations Online @ www.acponline.org/cgi-bin/medquotes.pl?subject=Medical%20ethics.

According to Article I, Section 10 of the Constitution, the states are prohibited from changing or "impairing" contractual obligations. U.S. CONST. art. I, §10, cl. 1 ("No State shall…pass any…Law … impairing the Obligation of Contracts…."). Here, federal law, section 264(c) of HIPAA and the Regulations, acts to impair the obligation of confidentiality from a physician to a patient.[27] No

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[26] Dr. Rush was a prominent physician during and after the Revolutionary Era. He was among the initial five faculty members at the College of Philadelphia (later merged with the University of Pennsylvania Medical School) and served on the staff of Philadelphia's Pennsylvania Hospital, the nation's first hospital. www.cr.nps.gov/history/online_books/declaration/bio42.htm; www.med.upenn.edu/history.html.

[27] Our founders understood the importance of the obligation of confidentiality. In 1791, the New Hampshire Medical Society was founded with Dr. Josiah Bartlett (not the character on West Wing) serving as its first president. Having Paul Revere in mind as the silversmith, the Society commissioned the production of its seal. Appearing at the bottom of that seal is the word "confide" which means "to have complete trust in". New Hampshire Medical Society, "New Hampshire Medical Society Seal" @ www.nhms.org/about/seal.html. Dr. Bartlett had an enormous

power for Congress to impair a contractual obligation was enumerated in the Constitution other than the Bankruptcy Clause. U.S. CONST. art. I, § 8, cl. 4. This lack of Congressional power to impair contractual obligations is confirmed by the need to include a provision in the Fourteenth Amendment in order to extinguish debts and obligations incurred in aid of the confederacy. U.S. CONST. amend. XIV, §4.

Without a constitutional provision authorizing Congress to enact laws impairing the obligation of contracts, HIPAA and the Regulations may not impair a physician's obligation to keep a patient's confidences.

2. The Fifth Amendment prohibits takings without compensation.

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influence in the formation of our nation. As New Hampshire's representative to the Continental Congress, he was the first to vote for the Declaration of Independence, first to sign the Declaration after John Hancock, first to vote for the Articles of Confederation, and was on numerous committees that drafted both documents. With his help, New Hampshire became the ninth state to ratify the Constitution thereby creating the United States of America. Jim Bishop, The Birth of the United States 201, 233,244, 252 (1976); www.nhms.org/about/seal.html; www.cr.nps.gov/history/online_books/declaration/bio3.htm; and www.ushistory.org/declaration/signers/bartlett.htm.

Under the Fifth Amendment, the government cannot take private property for public use unless it pays the owner.[28] For example, the government cannot take a farmer's land and construct a building or pave a highway unless it pays the owner "just compensation". Similarly, the government must pay an owner "just compensation" if it condemns land and turns it over to a private developer. Blackstone eloquently explained these ideas 250 years ago.

> So great moreover is the regard of the law for private property, that it will not authorize the least violation of it … not even for the general good of the whole community. If a new road, for instance, were to be made through the grounds of a private person, it might perhaps be extensively beneficial to the public; but the law permits no man, or set of men, to do this without consent of the owner of the land. In vain may it be urged, that the good of the individual ought to yield to that of the community; for it would be dangerous to allow any private man, or even any public tribunal, to be the judge of the common good, and to decide whether it be expedient or no. Besides, the public good is nothing more essentially interested, than in the protection of every individual's private rights … In this, and similar cases the legislature alone can, and indeed frequently does, interpose, and compel the individual to acquiesce. But how does it interpose and compel? Not

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[28] The Takings Clause places no limitation on the type of property taken. There is no question that the Takings Clause applies to personal property as well as real property. The historical antecedent for the Takings Clause may be found in Chapter 28 of the Magna Carta which provides that "the King 'could not take grain or other chattels of any one without immediate payment thereof ….'" Magna Carta art. 28, *reprinted in* 1 Bernard Schwartz, The Bill of Rights: A Documentary History 8,11(1971) *reprinted in* Andrew Gold, Regulatory Takings and Original Intent: The Direct Physical Takings Thesis "Goes to Far", 49 American University Law Review 181, 208 (1999)("Gold").

> by absolutely stripping the subject of his property in an arbitrary manner; but by giving him a full indemnification and equivalent for the injury thereby sustained….

1 William Blackstone, COMMENTARIES *135 *reprinted in* Gold at 222.

In this case, the Fifth Amendment applies. Here, the property that is "taken" is a patient's medical information.[29] Compensation is owed to the patient for the taking of that property. Empowered by HIPAA and the Regulations, patient medical information is "taken" by the Federal Government and its deputies, the covered entities (including insurance companies, providers and healthcare clearing houses) and their business associates. It is clear that property is taken by HIPAA and the Regulations because the Federal Government and these other third parties may access, control, use and disclose a patient's highly "private" medical information without input or the consent of the patient. HIPAA and the Regulations allow patient information to enter the "Information Super-Highway" and become a commodity traveling freely along the most highly traveled of any "public road". Unless a patient consents, Congress cannot legislate and HHS cannot regulate to authorize the use or disclosure of a patient's medical information.

[29] Without question no property is more "private" and valuable than a person's medical information.

CONCLUSION

Under the Constitution, the power to make the law rests squarely in the hands of Congress. Congress may not voluntarily relinquish its basic duty – to determine what the law shall be. Section 264 of HIPAA took that role from Congress and handed it to HHS. This Court must protect Congress from itself.

Compliance with Section 264 and the Regulations has already altered the nature of medical practice. Action by the Court is needed now. Unless the Court grants relief and declares Section 264 unconstitutional and the Regulations void, patients will be unable to keep their records confidential. Whether a single electronic medical record or a million records is at issue, once confidentiality is lost, nothing can restore it.

CONSENT

All Appellants and Appellee consent to the filing of this brief.

Respectfully submitted,

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