

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CITIZENS FOR HEALTH)
5 Thomas Circle NW, Suite 500)
Washington, D.C. 20005)

and)

AMERICAN ASSOCIATION FOR)
HEALTH FREEDOM)
P.O. Box 458)
Great Falls, Virginia 22066)

and)

AMERICAN ASSOCIATION OF)
PRACTICING PSYCHIATRISTS)
P.O. Box 2102)
Kensington, Maryland 20891)

and)

AMERICAN MENTAL HEALTH)
ALLIANCE-USA)
6829 Gravois Avenue)
St. Louis, Missouri 63116)

and)

AMERICAN PSYCHOANALYTIC)
ASSOCIATION)
309 East 49th Street)
New York, New York 10017)

and)

NATIONAL COALITION OF MENTAL)
HEALTH PROFESSIONALS AND)
CONSUMERS)
P.O. Box 438)
Commack, New York 11725)

and)

NEW HAMPSHIRE CITIZENS FOR)
HEALTH FREEDOM)
8 Green Acres Road)
Keene, New Hampshire 03431)

individual's life can be used and disclosed routinely without the individual's consent and against his or her will. Defendant's own findings show that the rule affects the medical privacy rights of "virtually every American" and the privacy obligations of "over 600,000 entities." 66 Fed. Reg. 12,739.

2. On April 14, 2001, Defendant put into effect Standards for Privacy of Individually Identifiable Health Information (the "Original Privacy Rule", 65 Fed. Reg. 82,462) which was one of a number of sets of regulations designed to interpret and implement sections 261 through 264 of the Health Insurance Portability and Accountability Act of 1996. (known as "HIPAA") (Pub. L. 104-191). See generally, Attachment A. One purpose of HIPAA was to improve the efficiency and effectiveness of the health care system by facilitating the greater use of electronic technology to maintain and transmit health information. See section 262 of HIPAA and 65 Fed. Reg. at 82,469. Congress also recognized, however, that the efficiencies that might be achieved through greater computerization of health information could not be realized unless strong federal protections were put in place to preserve the public's trust and confidence that their right to health privacy would not be eroded or eliminated by the greater computerization of health information. 65 Fed. Reg. at 82,469-70. Accordingly, Congress authorized the Defendant, under section 264 of HIPAA, to issue Health Information Privacy Standards to set forth a federal "floor" of health information privacy protections which Defendant had determined were the minimum national standards necessary to preserve the traditional privacy rights of individuals as the maintenance and transmission of health information became more computerized. 65 Fed. Reg. at 82,471. In issuing the Original Privacy Rule, Defendant noted:

Unless public fears are allayed, we will be unable to obtain the full benefits of electronic technologies. The absence of national standards for the confidentiality of health information has made the health care industry and the population in general uncomfortable about this primarily financially-driven expansion of the use of electronic data.

65 Fed. Reg. at 82,466.

3. A “key” element of the federal floor of privacy protections contained in the Original Privacy Rule was recognition of the traditional right of individuals to give or withhold consent before their personal health information is used or disclosed for most routine purposes. 45 C.F.R. § 164.506(a) at 65 Fed. Reg. at 82,810; see also, 65 Fed. Reg. at 82,472. In incorporating the right of consent, Defendant observed

Most direct treatment providers today obtain some type of consent for some uses and disclosures of health information. Our regulation will ensure that those consents cover the routine uses and disclosures of health information, and provide an opportunity for individuals to obtain further information and have further discussion, should they so desire.

65 Fed. Reg. at 82,474.

“Routine uses and disclosures” were defined broadly to include “treatment, payment and health care operations” of covered entities so as to confer broad privacy protections for the most common types of uses and disclosures of health information. As the Defendant noted,

The same technological advances that make possible enormous administrative savings for the industry as a whole have also made it possible to breach the security and privacy of health information on a scale that was previously inconceivable.

65 Fed. Reg. at 82,474.

4. On August 14, 2002, however, Defendant issued the “Amended Privacy Rule” (67 Fed. Reg. 53,182) that flatly reversed his initial interpretation of HIPAA by:
 - (A) Repealing the right of individuals to not have their identifiable health information used or disclosed for routine purposes without their consent as guaranteed by the Original Privacy Rule, the United States Constitution and federal common law; and
 - (B) Granting blanket “regulatory permission” for thousands of organizations and individuals (“covered entities” and their “business associates”) to use and disclose individuals’ identifiable health information for routine purposes without their knowledge or consent and against their will.

See 67 Fed. Reg. at 53,211, Attachment B.

Defendant thereby turned the health information “privacy” rule into a health information “disclosure” rule since the reversal of policy and interpretation applied to the same broad routine uses and disclosures that previously enjoyed the privacy protection conferred by the right of consent.

4. The Amended Privacy Rule became effective on October 15, 2002, a year and a half after the Original Privacy Rule guaranteeing the right of consent, had become effective. 67 Fed. Reg. at 53,182. Most entities covered by the rule must be in compliance with it by no later than April 14, 2003. 67 Fed. Reg. at 53,183.
5. On February 20, 2003, Defendant issued another set of regulations required by HIPAA establishing Security Standards to be used by covered entities and their business associates in computer systems operated by these entities. 68 Fed. Reg. 8,333. Defendant acknowledged that “security and privacy are inextricably linked” and that the confidentiality and integrity of health information held in, and transmitted by, computerized systems cannot be protected without implementing these standards. 68 Fed. Reg. at 8,335. Yet, Defendant did not require covered entities and business associates to comply with these Security Standards until more than two years after the compliance date for the Amended Privacy Rule. 68 Fed. Reg. at 8,362. Further, Defendant acknowledged in issuing the Security Rule that privacy protections under the Privacy Rule as well as the Security Rule, to the extent any exist, cannot be effective without the implementation of the enforcement measures under HIPAA. 68 Fed. Reg. at 8,342. However, Defendant has failed even to propose rules implementing the enforcement provisions of HIPAA.
6. Taken together, Defendant’s actions in issuing regulations under HIPAA have:
 - (a) stripped citizens of the power to exercise their right to medical privacy;
 - (b) expressly authorized, in effect licensed, thousands of entities and their business

associates to use and disclose the most personal health information regardless of the individuals' wishes or expectations; and

- (c) ensured that the confidentiality and integrity of this personal health information will not be protected by failing to put adequate Security and Enforcement measures into effect on a timely basis.
7. The Amended Privacy Rule has the following effects on individuals, including Plaintiffs and their members:
- (A) It eliminates the ability of individuals to exercise their right to medical privacy by limiting or withholding their consent for the use and disclosure of personal health information for most purposes.
 - (B) It effectively permits and authorizes "covered entities" to use and disclose individuals' identifiable health information without their knowledge or consent.
 - (C) It permits and authorizes covered entities to use and disclose identifiable health information even over the individual's objection and against his or her will.
 - (D) It permits and authorizes covered entities to use and disclose identifiable health information that has been provided by individuals to their physicians in the past with

an expectation and an understanding that such information would remain private and would only be further used or disclosed with the individual's consent.

- (E) It eliminates the ability of individuals to protect the privacy of their identifiable health information by paying out-of-pocket, refraining from filing insurance claims, or by choosing to avoid medical treatment altogether in the future.
- (F) The blanket "regulatory permission" conferred on all covered entities creates a federal presumption that all identifiable health information is available for use and disclosure for routine purposes unless the individual can rebut the presumption under some other federal or state law.
- (G) It erodes and undermines the privacy and trust necessary in the physician-patient relationship for quality health care to be provided.
- (H) It has a "chilling" effect on communications between patients and their health care practitioners that are essential for quality health care.

All of the plaintiffs, as individuals, patients, and providers of health care, have a concrete interest in the continued right to medical privacy and the continued access to, and opportunity to provide, quality health care, all of which are threatened by the Amended Privacy Rule.

8. In issuing the Amended Privacy Rule, the Secretary unlawfully eliminated the right of consent in the Original Privacy Rule in violation of the Administrative Procedure Act, 5 U.S.C. sec. 553 and sec. 706, by failing to provide an adequate explanation for reversing his interpretation of HIPAA, repealing the right of consent and replacing it with federal "regulatory permission"; failing to provide adequate notice of this major policy reversal, failing to address significant comments and less radical alternatives that would have preserved the right of consent set forth in the Original Privacy Rule; and by taking action that is arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law, including HIPAA.

9. By issuing the Amended Privacy Rule, the Secretary violated the medical privacy rights of Plaintiffs under the Constitution and federal common law; expressly and specifically authorized covered entities to violate the medical privacy of Plaintiffs and the sanctity of the physician-patient relationship; provided significant encouragement and direction to covered entities to violate the medical privacy rights of Plaintiffs; acted jointly with covered entities to eliminate the right of medical privacy; authorized covered entities to take action detrimental to plaintiffs' privacy rights that can be subject to the enforcement provisions under HIPAA; placed the power, property and prestige of the federal government behind a policy of eliminating the right to medical privacy for Plaintiffs; and impaired and threatened the Constitutional rights of law-abiding individuals to liberty and private communications within the context of the physician-patient relationship.
10. In summary, the Amended Privacy Rule issued by Defendant violates two of the most fundamental principles of our system of law and medicine:
 - (A) The right of law-abiding individuals "to be let alone," L. Brandeis, S. Warren, "The Right to Privacy" 4 Harv. L. Rev. 193 (1890); and
 - (B) The ethical standard under the centuries-old Hippocratic Oath to not "spread abroad" information disclosed in confidence to a physician without consent.
11. Plaintiffs seek declaratory judgment that the amendments to the Original Privacy Rule violate the Administrative Procedure Act, sections 261 through 264 of HIPAA, and the First and Fifth Amendments of the United States Constitution to the extent that they eliminate the right of consent for the use and disclosure of identifiable health information. Further, Plaintiffs seek to enjoin the implementation of provisions of the amendments that eliminate or jeopardize their right of consent and confer "regulatory permission" for covered entities to use and disclose identifiable health information without individuals' consent.

JURISDICTION

12. This Court has jurisdiction under 28 U.S.C. § 1331, and 28 U.S.C. § 2201.

VENUE

13. Venue lies properly in this District under 28 U.S.C. § 1391(e).

PARTIES

14. Citizens for Health is a national organization with more than 4000 consumer members committed to advancing consumer access to safe food, clean water, and informed health choices, including whether an individual's health information should be used or disclosed without their consent.
15. American Association for Health Freedom is a member association with approximately 500 members nationwide who are practitioners such as medical doctors, osteopaths, dentists, chiropractors and other health care practitioners as well as consumers. The Association has members in all 50 states and the Eastern District of Pennsylvania. The Association is dedicated to ensuring that their members and their members' patients have health care freedom and access to a full range of health promotion, disease prevention and treatment methods. The Association's consumer members are damaged by the loss of the federal right of privacy over, and consent for, the use and disclosure of health information, and the Association's practitioner's members are hampered in their ability to provide quality health care to their patients due to the patients' fear that their health information may be disclosed without their consent.
16. American Association of Practicing Psychiatrists is a professional association of practicing psychiatrist and have approximately 1000 members. They believe that the elimination of the right of consent and the granting of "regulatory permission" for the use and disclosure of identifiable health information will impair their ability to provide effective psychotherapy

services and jeopardize the mental health of their patients.

17. American Mental Health Alliance-USA is an association of licensed mental health professionals of all disciplines. The association has 1000 members in 15 states including Eastern Pennsylvania. The Association and its members believe that the amendments to the Privacy Rule will negatively impact the ability of its members to provide effective treatment to patients suffering from emotional and substance abuse disorders by increasing distress, reducing access to care and increasing the stigma associated with these disorders.
18. American Psychoanalytic Association is a member association with approximately 3500 members and 42 affiliated state and local societies as well as 29 accredited psychoanalytic institutes. Members are graduates or candidates at accredited institutes. The association is dedicated to the study and advancement of psychoanalysis and psychotherapy as well as the preservation of conditions essential for effective psychotherapy including privacy, confidentiality and security of health information. The association filed extensive comments on the Amended Privacy Rule and proposed less drastic alternatives other than eliminating the right of consent, but Defendant ignored or failed to address most of those comments. The association includes members who reside and/or practice in Philadelphia and Eastern Pennsylvania.
19. National Coalition of Mental Health Professionals and Consumers (NCMHPC) is a member association of over 1600 consumers, professionals of all mental health disciplines, and consumer advocates who are dedicated to improving the quality and availability of health services for treating mental and emotional distress. NCMHC works to remove barriers to access to quality mental health and substance abuse care such as the loss of health information privacy. NCMHC has concluded that the Amended Privacy Rule has already contributed to incalculable harm to all in our nation, including members of the Coalition, by eliminating privacy rights and protections. NCMHC filed extensive comments on the Amended Privacy

Rule and proposed alternatives to eliminating the right of consent, but Defendant ignored most of those comments. NCMHC has members who reside in 41 states and in the Philadelphia area and eastern Pennsylvania.

20. New Hampshire Citizens for Health Freedom is a member organization with approximately 100 members residing in New Hampshire who are consumers, physicians and health care practitioners. The organization and its members believe that the Amended Privacy Rule unlawfully deprives them of their right to medical privacy by eliminating the right of consent.
21. Sally Scofield is a health care consumer who is concerned about the loss of her right of consent and medical privacy, as conferred by the Original Privacy Rule after its effective date of April 14, 2001, and who complained to the State and to Defendant that her rights under HIPAA had been violated. In July 2002, the State notified her that it had concluded, after an investigation, that her complaint that her rights under the Original Privacy Rule had been violated was valid. Approximately two weeks later, Ms. Scofield was notified by Defendant that her rights under the Privacy Rule had not been violated, citing the amendments to the Rule eliminating the right of consent even though those amendments would not be issued in final form for another week and would not go into effect for more than two months.
22. Tedd Koren is a health care consumer who objects to the elimination of his right of consent for the routine use and disclosure of his identifiable health information. He is a resident of Eastern Pennsylvania. The elimination of his right of consent for the use and disclosure of his health care information is detrimental to his right to privacy and ability to obtain quality health care. The elimination of this right under federal regulations and the granting of “regulatory permission” for covered entities to use and disclose his health information regardless of his wishes violates his federal right to privacy.
23. Micheale Dunlap is a licensed psychotherapist and health care consumer residing in Oregon. She opposes the elimination of the right of patient consent both as a consumer and as a

practitioner of psychotherapy. She also is aware of bills pending in the Oregon legislature that would conform state law to the amended federal law by eliminating the right of consent under state law in order to avoid the conflict and confusion caused to practitioners by the Amended Privacy Rule.

24. Morton Zivan, Ph.D. is a psychologist who resides and practices in Philadelphia, Pennsylvania, and he is also a health care consumer. He opposes the elimination of the right of consent both as a consumer and as a practitioner of psychotherapy and believes that the elimination of the right of consent and the conferring of “regulatory permission” on covered entities for the use and disclosure of personal health information regardless of the individual’s wishes impairs his access to quality health care and his ability to provide quality health care to his patients.
25. The actions of Defendant in eliminating the right of consent under the Original Privacy Rule violate the rights of all Plaintiffs and their members, under the Administrative Procedure Act, to full and fair notice of proposed changes in their medical privacy rights, an analysis of the implications for their rights to liberty and privacy as well as their access to quality health care as described in the findings that supported the Original Privacy Rule, and a thorough explanation of the basis for reversing Defendant’s initial privacy policy and statutory interpretation. Defendant’s actions also violate the rights of Plaintiffs and their members under HIPAA to stronger federal privacy protections to prevent personal health information from being disclosed against their will as a result of the greater computerization of medical information facilitated by the statute. Defendant’s actions also violate the rights of Plaintiffs and their members to privacy of highly sensitive personal information under the U.S. Constitution.
26. Defendant Tommy G. Thompson is the Secretary of the U.S. Department of Health and Human Services and is charged with adopting, implementing, and enforcing medical privacy

standards under HIPAA. Section 264(c)(1) of HIPAA; section 1176 of the Social Security Act.

LEGISLATIVE AND PROCEDURAL BACKGROUND

27. On August 21, 1996, Congress enacted HIPAA, P.L. 104-191. Subtitle F of HIPAA, entitled “Administrative Simplification,” required the establishment of standards for the transmission of health information to improve “the efficiency and effectiveness of the health care system.” See HIPAA section 261.
28. In enacting HIPAA, however, Congress recognized that “administrative simplification cannot succeed if we do not also protect the privacy and confidentiality of personal health information.” 65 Fed. Reg. at 82,463. Although the provision of high quality health care requires the exchange of personal, often-sensitive information between a patient and a practitioner, “[v]ital to that interaction is the patient’s ability to trust that the information shared will be protected and kept confidential.” *Id.*
29. In recognition of the need to protect the privacy of personal medical information while facilitating the electronic transmission of health information, Congress included section 264 in the Administrative Simplification section of HIPAA. See 65 Fed. Reg. at 82,469.
30. Section 264 requires the establishment of nationwide, federal standards with respect to:
 - (A) The rights that an individual who is the subject of individually identifiable health information should have;
 - (B) The procedures that should be established for the exercise of such rights; and
 - (C) The uses and disclosures of such information that should be authorized or required.Section 264(b).
31. As a further indication that Congress intended for the privacy standards to enhance rather than erode existing medical privacy protections, section 264(c)(2) provides that the new

federal privacy regulations “shall not supercede a contrary provision of State law” if the State law imposes requirements or standards that are “more stringent” in their protection of medical privacy.

32. In further recognition of the importance of privacy protections, Congress set forth in section 264 a detailed process and strict timetable for putting these medical privacy standards into place. The Secretary of Health and Human Services was to submit recommendations to Congress “not later than” 12 months after the date of enactment (August 21, 1997). Section 264(a). If legislation governing the standards of privacy of individually identifiable health information were not enacted within 36 months of the date of enactment of HIPAA (August 21 1999), the Secretary was to promulgate final regulations containing such standards “not later than” 42 months after the date of enactment (August 21, 2000). Section 264(c)(1).
33. In fact, the privacy standards were established under the following schedule:
 - (A) The Secretary submitted privacy recommendations to Congress on September 11, 1997. 65 Fed. Reg. at 82,470.
 - (B) Congress did not enact legislation with respect to privacy standards.
 - (C) The Secretary issued proposed rules setting forth privacy standards on November 3, 1999 providing a 60-day comment period. 64 Fed. Reg. at 59,918.
 - (D) The comment period was extended by 43 days due to the scope of the proposed rule, the significant implications for the health care system, substantial public interest in the proposed rule, and the belief that “additional time would allow for more informative and thoughtful comments.” 64 Fed. Reg. 69,981 (December 15, 1999).
 - (E) The final Original Privacy Rule required by Section 264 was issued on December 28, 2000. 65 Fed. Reg. 82,462.

See generally, 65 Fed. Reg. at 82,470.

34. The effective date of the final Original Privacy Rule was February 26, 2001, and the “compliance date” (the latest date by which covered entities had to be in compliance) was February 26, 2003 (February 26, 2004 for small health plans). 65 Fed. Reg. at 82,462, 82,829. On February 26, 2001, however, the current Secretary of Health and Human Services issued a notice stating that the effective date of the Original Privacy Rule was being changed to April 14, 2001 and the compliance date was being changed to April 14, 2003 (April 14, 2004 for small health plans). 66 Fed. Reg. 12,434. Two days later, on February 28, 2001, the Secretary announced that the Original Privacy Rule that had been published in final form on December 28, 2000, was being “convert[ed] to a final rule with request for comments” and that the comment period would be reopened for a period of 30 days ending on March 30, 2001. 66 Fed. Reg. 12,738.
35. After reviewing the comments, the current Secretary “decided that it was appropriate for the [Original] Privacy Rule to become effective on April 14, 2001” (67 Fed. Reg. at 53,183). In announcing that the Original Privacy Rule would become effective April 14, 2001, Defendant issued the following statement:

President Bush wants strong patient protections put in place now. Therefore, we will immediately begin the process of implementing the patient privacy rule that will give patients greater access to their own medical records and more control over how their personal information is used.... The President considers this a tremendous victory for American consumers....

Accordingly, the Original Privacy Rule, which included recognition of individuals’ right of consent, was put into effect by the current Secretary on April 14, 2001.

36. Nearly a year later, on March 27, 2002, the Secretary issued a notice of proposed “modification” of the Original Privacy Rule, the effect of which was to eliminate the right of consent for routine uses and disclosures of identifiable health information. 67 Fed. Reg. 14,776. The Original Privacy Rule had been adopted after one of the most extensive

rulemaking proceedings in the history of the Department of Health and Human Services spanning 18 months and generating approximately 65,000 comments. However, the current Secretary indicated that “only 30 days” would be provided for comments on the proposed reversal of policy, because public concerns had already been communicated to the Department “through a wide variety of sources” outside of the rulemaking record since the Original Privacy Rule had been published in final form (67 Fed. Reg. at 14,778).

37. In fact, 30 days was not provided for public comment since the comment period closed on Friday, April 26, 2002, only 29 days after the date of the notice. 67 Fed. Reg. at 14,776. By contrast, the “30 day comment period” for the converted Original Rule with opportunity for comment was a full 30 days from the date of notice. See 66 Fed. Reg. at 12,738 (February 28, 2001).
38. The notice of the proposed rule indicated that the Department was proposing to make “mandatory” consent “optional” but did not notify members of the public that their right of consent and ability to protect the privacy of their identifiable health information for most routine uses, as recognized in the Original Privacy Rule, was to be rescinded and eliminated. 67 Fed. Reg. at 14,780-81. At least two plaintiffs, the American Psychoanalytic Association and the National Coalition of Mental Health Professionals and Consumers, filed comments reminding Defendant of the many findings in the rulemaking record to the Original Privacy Rule supporting the conclusions that privacy and the right of consent were “fundamental rights” essential for liberty and quality health care.
39. On August 14, 2002, the defendant published final amendments to the Original Privacy Rule which adopted in final form, without change, the proposal that eliminated the right of consent for the use and disclosure of identifiable health information and replaced the individuals’ right of consent with “regulatory permission” conferred on all covered entities to use and disclose identifiable health information regardless of the individuals’ wishes. 67

Fed. Reg. at 53,211. In reversing his position on the right of consent, Defendant ignored the comments that raised the findings in the Original Rule that supported the right of consent.

40. The notice of the Amended Privacy Rule also stated that the elimination of the right of consent and the granting of “regulatory permission” would be retroactive since the amendments “would apply to any protected health information held by a covered entity whether created or received before or after the compliance date.” Id.
41. The effective date of the amendments to the Privacy Rule was October 15, 2002, and the April 14, 2003 final compliance date of the Original Privacy Rule was retained. 67 Fed. Reg. at 53,182-83.
42. On February 20, 2003, Defendant issued another set of regulations in the “suite” of regulations required by HIPAA. 68 Fed. Reg. 8,334. These regulations set forth Security Standards to be adopted by covered entities and their business associates to protect the “integrity and confidentiality” of identifiable health information stored or transmitted by computer or electronic means. 68 Fed. Reg at 8,334. In issuing these regulations, Defendant set forth the following findings:

The confidentiality of health information is threatened not only by the risk of improper access to stored information, but also by the risk of interception during electronic transmission of the information.

Id. at 8,334.

Currently, no standard measures exist in the health care industry that address all aspects of the security of electronic health information while it is being stored or during the exchange of that information between entities.

Id.

As many commenters recognized, security and privacy are inextricably linked. The protection of the privacy of information depends in large part on the existence of security measures to protect that information.

Id. at 8,335.

These protections are necessary to maintain the confidentiality, integrity and availability of patient data. A covered entity that lacks adequate protections risks inadvertent disclosure of patient data, with the resulting loss of public trust, and potential legal action.

Id. at 8,344.

However, the compliance date set forth by the Defendant for these concededly essential standards is not until April 21, 2005, more than two years after the compliance date for the Amended Privacy Rule that authorizes the use and disclosure of identifiable health information without notice or consent. 68 Fed. Reg. at 8,334. Defendant acknowledges that “whether or not to implement [the Security Standards] before the compliance date is a business decision that each covered entity must make.” 68 Fed. Reg. at 8,362.

43. Defendant also acknowledges that the Security Standards, even after the compliance date, will not cover much of the identifiable health information that is covered by the Amended Privacy Rule. Defendant states that “this final rule requires protection of the same scope of information as that covered by the Privacy Rule, except that it only covers that information if it is in electronic form.” 68 Fed. Reg. at 8,342. By contrast, the Amended Privacy Rule permits the routine use and disclosure, without notice or consent, of individually identifiable health information transmitted or maintained in any “form or medium.” 45 C.F.R. § 164.501; 65 Fed. Reg. at 82,805. Thus, the identifiable health information that is subject to use and disclosure without the individual’s knowledge or consent is far broader than the information that may be protected by the Security Standards at some point in the distant future. Defendant also acknowledges that privacy cannot be assured even for health information covered by the Security Standard because “there is no such thing as a totally secure system that carries no risk to security.” 68 Fed. Reg. at 8,346. This acknowledged failure and inability to protect the privacy of identifiable health information under the Security Standards illustrates the importance of individuals retaining the right to exercise their own right to privacy by withholding consent for the use and disclosure of their

sensitive health information.

44. Further, Defendant acknowledged in the Security Standards regulations that “some form of sanction or punishment activity must be instituted” in order for the health information safeguards required by HIPAA to have some effect. 68 Fed. Reg. at 8,346. Defendant, however, has failed even to propose enforcement regulations stating merely that “it is expected that enforcement provisions applicable to all Administrative Simplification rules will be proposed in a future rulemaking.” 68 Fed. Reg. at 8,363.
45. Accordingly, Defendant has stripped individuals of the ability to prevent their personal health information from being used and disclosed and then failed to provide standards to prevent the inappropriate use of that information while in the hands of those who have been given federal permission to use and disclose it.

RULEMAKING FINDINGS

46. The rulemaking that led to the Original Privacy Rule was one of the largest in the history of the Department of Health and Human Services. The rulemaking proceedings that culminated in the publication of the December 28, 2000 final rule generated more than 52,000 comments, and the additional comment period that resulted in the Original Privacy Rule being put into effect on April 14, 2001 generated an additional 11,000 comments. 67 Fed. Reg. at 14,777. Thousands of additional comments were submitted during the truncated comment period that led to the Amended Privacy Rule. Most, if not all, of the comments addressed the issue of consent. 65 Fed. Reg. at 82,472.
47. The findings cited by the Department of Health and Human Services in support of the recognition of the right of consent in the Original Privacy Rule were detailed, numerous, unequivocal and were based on fundamental human rights and medical ethics throughout the history of this country. The right of consent was also found essential to accomplishing the purpose of Administrative Simplification under HIPAA to improve the efficiency and

effectiveness of the health care system. See generally, 65 Fed. Reg. at 82,463-74.

48. Findings supporting recognition of the right of consent included the following:
- (A) “Privacy is a fundamental right.” 65 Fed. Reg. at 82,464
 - (B) “All fifty states today recognize in tort law a common law or statutory right to privacy.” Id.
 - (C) “Some states, such as California and Tennessee, have a right to privacy as a matter of state constitutional law.” Id.
 - (D) “In the Declaration of Independence, we asserted the ‘unalienable right’ to ‘life, liberty, and the pursuit of happiness’. Many of the most basic protections in the Constitution of the United States are imbued with an attempt to protect individual privacy while balancing it against larger social purposes of the nation.” Id.
 - (E) “[T]he Fourth Amendment to the United States Constitution guarantees that ‘the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated’ The need for security of ‘persons’ is consistent with obtaining patient consent before performing invasive medical procedures. The need for security in ‘papers and effects’ underscores the importance of protecting information about the person, contained in sources such as personal diaries, medical records or elsewhere.” Id.
 - (F) “The Supreme Court has upheld the constitutional protection of personal health information.” The Court has recognized two different kinds of interests that are within the constitutionally protected “zone of privacy.” “One is the individual interest in avoiding disclosure of personal matters,’ such as this regulation principally addresses.” Id.
 - (G) “Individuals’ right to privacy in information about themselves is not absolute....But many people believe that individuals should have some right to control personal and

sensitive information about themselves. Among different sorts of personal information, health information is among the most sensitive. Id.

- (H) “Informed consent laws place limits on the ability of other persons to intrude physically on a person’s body. Similar concerns apply to intrusions on information about the person.” Id.
- (I) There is also significant intrusion on the right to privacy “when records reveal details about a person’s mental state, such as during treatment for mental health. If in Justice Brandeis’ words, the ‘right to be let alone’ means anything, then it likely applies to having outsiders have access to one’s intimate thoughts, words and emotions.” Id.
- (J) “Little in life is as precious as the freedom to say and do things with people you love that you would not say or do if someone else were present. And few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material.” Id.
- (K) “Privacy covers many things... It allows us the independence that is part of raising a family... Privacy also encompasses our right to self determination and to define who we are. Although we live in a world of noisy self-confession, privacy allows us to keep certain facts to ourselves if we so choose. The right to privacy, it seems, is what makes us civilized.” 65 Fed. Reg. at 82,465.
- (L) “[T]he right to privacy is: ‘the claim of individuals, groups, or institutions to determine for themselves when, how and to what extent information about them is communicated.’” Id.
- (M) “Americans’ concern about the privacy of their health information is part of a broader anxiety about their lack of privacy in other areas.” Id.
- (N) A number of national surveys showed that loss of personal privacy is one of the top

concerns for Americans. “This growing concern stems from several trends, including the growing use of interconnected electronic media for business and personal activities, our increasing ability to know an individual’s genetic make up, and, in health care, the increasing complexity of the system.” Id.

- (O) “The electronic information revolution is transforming the recording of health information so that the disclosure of information may require only the press of a button. In a matter of seconds, a person’s most profoundly private information can be shared with hundreds, thousands, even millions of individuals and organizations at a time.” Id.
- (P) The greater ease of health information sharing has enhanced the ability to provide better health care. “At the same time, these advances have reduced or eliminated many of the financial and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals.” Id.
- (Q) “The comments to the proposed privacy rule indicate that many persons believe that they have a right to live in society without having these details of their lives laid open to unknown and possibly hostile eyes.” Id.
- (R) “Hence a national policy with consistent rules is necessary to encourage the increased and proper use of electronic information while also protecting the very real needs of patients to safeguard their privacy.” 65 Fed. Reg. at 82,466
- (S) Numerous studies and cases were cited showing that most Americans believe that medical privacy is “absolutely essential” in any health reform and that there are many examples where the right to medical privacy is being breached today (65 Fed. Reg. at 82,467).
- (T) Medical privacy is key value of our society, but “[it] is also necessary for the effective delivery of health care, both to individuals and to populations... In short,

the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.” 65 Fed. Reg. at 82,467.

- (U) “Individuals cannot be expected to share the most intimate details of their lives unless they have confidence that such information will not be used or shared inappropriately. Privacy violations reduce consumers’ trust in the health care system and institutions that serve them.” 65 Fed. Reg. at 82,467-68.
- (V) Numerous surveys and studies were cited showing that, in order to protect their medical privacy, many Americans have taken some sort of evasive action such as “providing inaccurate information to a health care provider, changing physicians, or avoiding care altogether.” Id. at 82,468. In one study, 78% of physicians surveyed indicated that they had withheld information from patients’ medical records for privacy concerns and 87% reported having been requested by patients to withhold information from their medical records. Id.
- (W) “Comments from individuals revealed a common belief that, today, people must be asked permission for each and every release of their health information.” 65 Fed. Reg. at 82,472
- (X) “Our review of professional codes of ethics revealed partial, but loose, support for individuals’ expectations of [medical] privacy. Id. For example, the American Medical Association’s Code of Ethics states that, “conflicts between a patient’s right to privacy and a third party’s need to know should be resolved in favor of the patient, except where that would result in serious health hazard or harm to the patient or others.” The findings also incorporated the principles from the Massachusetts Medical Society which state, “Patients enter treatment with the expectation that the information they share will be used exclusively for their clinical

care. Protection of our patients' confidences is an integral part of our ethical training." Id.

- (Y) The findings acknowledged that some consents may be coerced by some providers refusing to provide treatment without the patient's consent to use and disclose health information, however, the findings noted that, "many comments that we received from individuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained... Many health care practitioners and their representatives argued that seeking a patient's consent to disclose confidential information is an ethical requirement that strengthens the physician-patient relationship." 65 Fed. Reg. at 82,473
- (Z) Accordingly, the Department of HHS decided to reject the idea of protecting individuals' rights to privacy merely by requiring a detailed notice of privacy practices and providing patients with an opportunity to request restrictions on uses and disclosures of health information. The basis for this determination was that, "it is clear from the comments that many practitioners and patients believe the approach proposed in the NPRM [not requiring consent] is not an acceptable replacement for the patient providing consent." Id.
- (AA) "The comments and the fact-finding indicate that our approach will not significantly change the administrative aspect of consent as it exists today. Most direct treatment providers today obtain some type of consent for some uses and disclosures of information. Our regulation will ensure that those consents cover the routine uses and disclosures of health information, and provide an opportunity for individuals to obtain further information and have further discussion, should they so desire." Id. at

82,474.

49. Based on the above findings, the Department concluded that recognizing and preserving the time-honored right of consent was consistent with the statutory objective of reducing administrative costs, as well as with the objective of promoting more effective health care. The basis and purpose statement to the Original Privacy Rule stated as follows:
“The same technological advances that make possible enormous administrative cost savings for the industry as a whole have also made it possible to breach the security and privacy of health information on a scale the was previously inconceivable. The Congress recognized that adequate protection of the security and privacy of health information is a *sine qua non* of the increased efficiency of information exchange brought about by the electronic revolution, by enacting the security and privacy provisions of the law.” *Id.* at 82,474.
Based on these detailed and voluminous findings with respect to the fundamental nature of the right to privacy and accepted standards of medical practice, the Department of HHS included the right of consent in the floor of federal privacy protections set forth in the Original Privacy Rule.
50. The current Secretary adopted the Original Privacy Rule and gave it an effective date of April 14, 2001 after an additional 30-day comment period and, presumably, re-reviewing all of the findings and comments from the initial rulemaking proceeding (67 Fed. Reg. at 53,183).
51. In the August 14, 2002 amendments, however, Defendant reversed this policy decision and conferred “regulatory permission” on all covered entities to use and disclose identifiable health information, retroactively and prospectively regardless of patient consent. 67 Fed. Reg. at 53,211.
52. In announcing this reversal of established policy, the Defendant failed to address most if not all of the findings supporting the right of consent in the Original Privacy Rule even

though they were expressly brought to his attention in major comments filed by at least two of the plaintiffs.

53. The “most troubling, pervasive problem” cited by the Defendant in reversing the original policy was that of, “first encounters,” that is, some providers might have difficulty providing services to patients they have never seen before if they had to first obtain consent to use and disclose their health information. 67 Fed. Reg. at 53,209. Defendant inconsistently stated that the right of informed consent before treatment as provided, however, would remain intact. 67 Fed. Reg. at 53,214. Defendant elected the option of entirely eliminating the right of consent for all individuals and creating a blanket right of access to protected health information for thousands of covered entities for most routine uses because “[t]he Department desired a global approach to resolving the problems raised by the prior consent requirement, so as not to add complexity to the Privacy Rule or to apply different standards to different types of direct treatment providers.” 67 Fed. Reg. at 53,212. There was no analysis of the prior findings with respect to individuals’ fundamental right to privacy including the right of consent, the near universal expectation by patients that their information would not be used without their consent, or the necessity of the right to medical privacy and consent for quality health care.
54. Further, all of the points relied on by Defendant in reversing his prior interpretation of the statute had been considered and rejected repeatedly during the three comment periods that led to the final adoption of the Original Privacy Rule. In fact, the course of action taken by the Secretary in the Amended Privacy Rule (substituting notice provisions for the right of consent) had been specifically considered and rejected in the adoption of the Original Privacy Rule. See 65 Fed. Reg. at 82,473 (stating that “it is clear from the comments that many practitioners and patients believe the approach proposed in the NPRM is not an acceptable replacement for the patient providing consent.”) .

FIRST CAUSE OF ACTION—VIOLATION OF ADMINISTRATIVE PROCEDURE ACT

55. Defendant's action in proposing a change in the use and disclosure of identifiable health information for routine purposes did not provide adequate notice and opportunity for public comment in accordance with the rulemaking requirements of the Administrative Procedure Act:
- (A) Defendant failed to inform the public that it was proposing to rescind the right and power of individuals to control the use and disclosure of their personal health information;
 - (B) Defendant failed to clearly notify the public that the amendments would repeal the rights to privacy and consent that had vested and been put into effect on April 14, 2001 by the Original Privacy Rule, which the President had hailed as "a tremendous victory for American consumers."
 - (C) Defendant failed to provide the full 30-day comment period which he represented he was providing;
 - (D) Defendant failed to alert Plaintiffs and other interested parties in the "Summary" of the proposed rule that he was rescinding regulatory recognition of fundamental federal rights with respect to the privacy of health information and, instead, misled the public with statements in the Summary and elsewhere that he was "maintain[ing] strong protections for the privacy of individually identifiable health information" and providing increased control by individuals over the use and disclosure of their identifiable health information; and
 - (E) Defendant also misled the public and members of Congress by contending that, in eliminating the right of consent, he was taking a "patient oriented approach" to medical privacy when Defendant's own rulemaking record shows that patients want and expect to have the right of consent and control over the use and disclosure of

their identifiable health information for most routine purposes.

Defendant's failure to provide adequate notice of his actions has deceived the public into believing that the Amended Privacy Rule provides them with greater control over the use and disclosure of their identifiable health care information, when, in fact, it deprives them of the power to exercise their right to medical privacy for routine purposes. Defendant's actions deprived members of the public, including some of the plaintiffs and their members, of an opportunity to file comments objecting to Defendant's proposed course of action.

56. Defendant failed to provide an adequate basis and purpose statement as required by the Administrative Procedure Act that addressed major comments and alternatives suggested in major comments. Among other defects, Defendant failed to provide an adequate basis for reversing a published policy and interpretation of the authorizing statute by failing to address the effect of eliminating the right of consent on individuals' recognized "fundamental right" to privacy, the importance of consent in exercising that right, the impact of the amendments on individuals' settled reasonable expectations of privacy as well as the impact on the quality of health care.

57. Defendant violated the Administrative Procedure Act by:

- (A) Failing to provide a reasoned analysis of the policy reversal with respect to medical privacy and consent;
- (B) Failing to consider important aspects of the privacy issue, many of which were addressed in the preamble to the Original Privacy Rule;
- (C) Providing an explanation of his action that runs counter to the evidence in the rulemaking record; and
- (D) Providing an explanation that is implausible based on the evidence in the record.

58. Defendant violated Congressional intent behind the Health Insurance Portability Act of 1996, including section 264, by failing to establish a floor of federal privacy protections

that will improve the efficiency and effectiveness of the health care system.

59. Defendant also failed to provide “adequate protection of the security and privacy of health information” that Congress recognized under HIPAA is “a *sine qua non* of the increased efficiency of information exchange brought about by the electronic revolution...” 65 Fed. Reg. at 82,474. Instead, Defendant has issued amendments to the Privacy Rule that provide for the greater use and disclosure of individuals’ identifiable health information without their knowledge or consent and has failed to implement adequate Security Standards and enforcement measures on a timely basis.
60. Defendant’s actions in eliminating the right of consent for individuals and substituting a right of disclosure for covered entities also violated the Administrative Procedure Act in that they were arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.

**SECOND CAUSE OF ACTION—VIOLATION OF RIGHTS TO PRIVACY
AND PROPERTY PROTECTED BY U.S. CONSTITUTION**

61. Defendant has violated Plaintiffs’ rights to liberty under the Fifth Amendment to the United States Constitution by repealing, as a matter of federal law and policy, Plaintiffs’ vested right of consent for the use and disclosure of their identifiable health information for most routine purposes. Defendant has further violated Plaintiffs’ rights under the Fifth Amendment by conferring a federal license and express authorization and “regulatory permission” upon all covered entities and their business associates to use and disclose even the most sensitive of Plaintiffs’ health information without their permission and against their will, retroactively and prospectively.
62. Defendant’s actions are contrary to his own findings that Plaintiffs have a long-standing, well-established expectation that their identifiable health information will not be used without their knowledge and consent, that this right is an integral part of the fundamental

right of privacy, and that the preservation and protection of this right is essential for quality health care as well as the efficiency and effectiveness of the health care system.

63. Defendant's actions also violate Plaintiffs' rights to familial integrity and privacy in that it violates the rights of parents to raise their children without undue state interference. Much of the personal health information that Defendant has given covered entities the authorization to use and disclose without consent pertains to intimate issues of marriage, procreation and childrearing which are traditionally the province of the private family relationship.
64. Defendant's action deprives Plaintiffs of any practical power to exercise the most fundamental of all privacy rights — "the right to be let alone."
65. Defendant has failed to show any compelling governmental interest in the wholesale elimination of the right of privacy and consent for routine uses and has failed to seriously consider alternatives suggested in comments that would preserve individuals' traditional rights to privacy while facilitating access to health care.
66. Defendant has also violated Plaintiff's right to privacy for highly sensitive personal information as it is protected by other amendments to the U.S. Constitution including the Fourth, Ninth and Tenth.
67. Defendant has also violated Plaintiffs' property interests in privacy and their personal health information as protected under the Fifth Amendment and other Amendments to the U.S. Constitution.

**THIRD CAUSE OF ACTION—VIOLATION OF RIGHT TO
PRIVATE SPEECH UNDER THE FIRST AMENDMENT**

68. Defendant's action granting "regulatory permission" to thousands of covered entities and individuals to have access to sensitive health information about individuals without their consent violates Plaintiffs rights under the First Amendment to the United States

Constitution to have private conversations and other communications within the context of the physician-patient relationship without having the content and subjects of those communications disseminated outside of that relationship. Defendant's own findings show that individuals have a reasonable expectation that these communications will not be communicated to anyone other than their practitioners without their knowledge and consent and that honoring this expectation is essential for quality health care.

69. Defendant's national policy eliminating the right to medical privacy for most routine uses is having, and will have, a "chilling" effect on Plaintiffs' First Amendment rights in the future as evidenced by Defendant's own findings and other evidence.

**FOURTH CAUSE OF ACTION—VIOLATION OF FEDERAL COMMONLAW
PRIVILEGE FOR THERAPIST-PATIENT COMMUNICATIONS**

70. Defendant's authorization for the use and disclosure of health information without consent violates Plaintiffs' rights to the "therapist-patient privilege" recognized by the U.S. Supreme Court in Jaffee v. Redmond, 116 S. Ct. 1923 (1996). The Amended Privacy Rule, by its terms, may permit the use and disclosure of communications between psychotherapists and their patients that the Supreme Court has found, based on the "reason and experience" of the country, must not be disclosed without the patient's consent if access to effective psychotherapy is to be preserved.

**FIFTH CAUSE OF ACTION—THE HEALTH INSURANCE PORTABILITY AND
ACCOUNTABILITY ACT OF 1996**

71. Defendant violated Congressional intent behind the Health Insurance Portability and Accountability Act of 1996, and specifically section 264, by failing to establish a floor of federal privacy protections that will improve the efficiency and effectiveness of the health care system.
72. Unless relief is granted by this court, Plaintiffs will suffer severe, irreparable, concrete

harm to their rights to privacy and their ability to obtain and/or provide quality health care. Plaintiff consumers and practitioners cannot rely on the privacy of identifiable health information which is essential to quality health care under the Amended Privacy Rule. 65 Fed. Reg. at 82,467. Many of the breaches of medical privacy that Defendant listed as eroding quality health care will occur with Defendant's permission and assistance under the Amended Privacy Rule. The privacy of identifiable health information, once lost, cannot be regained.

WHEREFORE, Plaintiffs request that this Court:

- A. Declare void Defendant's action of August 14, 2002, eliminating the right of consent for routine uses of identifiable health information and granting "regulatory permission" for covered entities to use and disclose that information, as a violation of Plaintiff's rights under the United States Constitution, the Administrative Procedure Act and the Health Insurance Portability and Accountability Act of 1996.
- B. Preliminarily and permanently enjoin the Defendant from further implementing, applying or enforcing the August 14, 2002 amendments to the Privacy Rule to the extent that they rescind or eliminate individuals' rights to give or withhold consent for routine uses of their identifiable health information and provide "regulatory permission" for covered entities to use and disclose identifiable health information without the individuals' consent or against the individuals' will.
- C. Award Plaintiffs their reasonable costs, expenses, and attorney's fees under 28 U.S.C. § 2412 and any other applicable law; and

D. Grant all other appropriate relief.

Respectfully submitted,

TRUJILLO RODRIGUEZ & RICHARDS, LLC

Kenneth I. Trujillo, Esq.
Ira Neil Richards, Esq.
Peter Winebrake, Esq.
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Phone: (215) 731-9004
Fax: (215) 731-9044

POWERS PYLES SUTTER & VERVILLE, PC

James C. Pyles, Esq.
Twelfth Floor
1875 Eye Street, N.W.
Washington, D.C. 20006-5409
Phone: (202) 466-6550
Fax: (202) 785-1756

Counsel for Plaintiffs

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