

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

CITIZENS FOR HEALTH, et al.	)	
	)	
Plaintiffs,	)	No. 03-2267 (MAM)
	)	
v.	)	
	)	
TOMMY G. THOMPSON, Secretary	)	
U.S. Department of Health and Human	)	
Services	)	
	)	
Defendant	)	
	)	

**PLAINTIFFS' BRIEF**  
**IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

**I. INTRODUCTION**

This action is brought by ten national and state associations, seven individuals and two individual intervenors representing nearly three-quarters of a million people. Plaintiffs include individual health care consumers and practitioners, patient advocacy groups, and organizations of concerned medical professionals challenging a rule issued by the Secretary of the U.S. Department of Health and Human Services (the "Secretary") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), P.L. 104-191, which eliminates the right to privacy of individuals for their past and future personal medical records and jeopardizes the privacy of past and future communications between patients and their physicians and practitioners within the context of the patient-physician relationship (hereinafter the "Amended Privacy Rule"). 67 Red. Reg. 53,182 (August 14, 2002). Under the Secretary's action, virtually all personal health information about every aspect of an individual's life

can be used and disclosed routinely without notice, 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," as well as countless thousands of their, "business associates." 66 Fed. Reg. 12,739.

The complaint in this case was initially filed on April 10, 2003, four days before the April 14, 2003 "compliance date" of the Amended Privacy Rule. An amended complaint was filed on May 5, 2003.

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 HIPAA. See generally, Appendix I. 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 Defendant, under section 264 of HIPAA, to issue Health Information Privacy Standards to set forth a federal "floor" of health information privacy protections which were to be 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.

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.” (emphasis supplied) 65 Fed. Reg. at 82,474.

“Routine” uses and disclosures meant “treatment, payment and health care operations” which, along with other terms in the Original Privacy Rule, were defined broadly so as to confer basic privacy protections for the most common types of uses and disclosures of health information. See 65 Fed. Reg. at 82,488-89, 82,489-91, 82,495-98.<sup>1</sup> As 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.” 5 Fed. Reg. at 82,474.

On August 14, 2002, however, Defendant issued the, “Amended Privacy Rule,”

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<sup>1</sup> “Treatment” was defined to include: the provision, management, coordination or management of health care, consultation between health care providers relating to a patient, or the referral of a patient for health care from one provider to another. 45 CFR 164.501 App. I.

“Payment” was defined to mean activities undertaken (a) by a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits to the individual (including determining eligibility and coverage, risk adjusting based on health status, billing claims management and collection activities, review for medical necessity, and utilization review including precertification and preauthorization of services); or (b) by a covered health care provider or health plan to obtain or provide reimbursement for services to an individual. 45 CFR 164.501.

“Health care operations” was defined to include any of the following activities of covered entities related to covered functions: conducting quality assessment and improvement activities related to improving health care or reducing health care costs, reviewing the competence, or qualifications of health care professionals, evaluating practitioner and provider performance and conducting training programs, underwriting, premium rating and other activities relating to the creation, renewal or replacement of a contract of health insurance, conducting or arrangement for medical review, legal services and auditing functions, business planning and development, business management and general administrative activities of the entity including customer service, resolution of internal grievances, due diligence in connection with the potential sale or transfer of assets, and creating de-identified health information. 45 164.501.

Thus, “treatment and payment” uses relate to providing health care to the individual while “health care operations” uses relate to operations of the covered entity. 65 Fed. Reg. at 82,489/3, 82,495/1, 82,497/3.

(67 Fed. Reg. 53,182) and 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) Affirmatively 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 purpose’s without their knowledge or consent and against their will.

See 67 Fed. Reg. at 53,211. App. I. <sup>2</sup>

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 of identifiable health information that previously enjoyed the privacy protection conferred by the right of consent.

The Amended Privacy Rule became effective on October 15, 2002, a year and a half after the Original Privacy Rule guaranteeing the traditional right of consent, had become effective. 67 Fed. Reg. at 53,182. Most entities covered by the rule were required to be in compliance with it by no later than April 14, 2003. 67 Fed. Reg. at 53,183. The Amended Rule provided however, that, “business associates,” who entered into contracts with covered entities prior to the October 15, 2002 effective date of the Amended Rule, could continue to use and disclose personal health information until April 14, 2004 without having to comply with the requirements of the Rule. 45 CFR 164.532(d) (amended); 67 Fed. Reg. at 53,250/1. Defendant acknowledged that creating this, “transition,” provision in the final Amended Rule issued on August 14, 2002 would create an incentive for covered entities and their, “business associates,” to enter into agreements

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<sup>2</sup> “Covered entities” are defined as “health plans, health care clearinghouses, and health care providers who transmit health information in electronic form” in connection with a transaction referred to in section 1173(a)(1) of HIPAA. 45 CFR 164.104. “Business associates” of covered entities means anyone who provides a service on behalf of or to a covered entity involving the use or disclosure of personal health information. 45 CFR 164.103. Services typically provided by business associates include legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, and financial services. Id. Business associates do not include members of the covered entity’s work force.

prior to the October 15, 2002 effective date, “solely,” to avoid the effect of the Rule. 67 Fed. Reg. at 53,251/1.

On February 20, 2003, Defendant issued another set of regulations required by section 262 of 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; 42 U.S.C. 1320d. 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 April 21, 2005, more than two years after the compliance date for the Amended Privacy Rule. 68 Fed. Reg. at 8,362.

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 failed even to propose rules implementing the enforcement provisions of HIPAA.

On April 17, 2003, seven days after the original complaint in this action was filed, Defendant issued an, “interim final rule,” on an expedited basis that he described as the, “first installment,” of an Enforcement Rule to be issued in the future to implement the enforcement measures of HIPAA. 68 Fed. Reg. at 18,895, 18,897. That publication states that it is not intended to be the enforcement rule necessary to implement the enforcement provisions in the statute because it does not contain any substantive provisions, but that it is merely intended to alert covered entities and the public to Defendant’s, “general approach to enforcement.” 68 Fed. Reg. at 18,897. Defendant’s intent is, “to seek and promote voluntary compliance,” with the HIPAA Privacy Rule, “to resolve matters by informal means before issuing findings of non-compliance,” and to, “provide opportunities to demonstrate compliance or submit a corrective action plan.” 68 Fed. Reg. at 18,897. In any event, Defendant stated that he planned to revise even this rule by September 16, 2003. *Id.* On April 28, 2003, Defendant issued yet another notice in the Federal Register stating that the prior notice was in error and that he actually plans to

revise the interim final rule by September 16, 2004. 68 Fed. Reg. at 22,453. This non-substantive, expedited, interim final, temporary, revised first installment of the Enforcement Rule does little to protect the privacy of identifiable health information. Defendant's relaxed "general approach" to enforcement totally ignores the potentially devastating and permanent damage to Plaintiffs and to the health care system from the unwanted disclosure of sensitive health information. Taken together, Defendant's actions in issuing the Amended Privacy Rule have:

- (A) Stripped Plaintiffs 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 Plaintiffs' wishes or expectations;
- (C) Permitted and provided an incentive for covered entities to enter into contracts with business associates in order to avoid having to comply with the privacy standards for up to one year after the compliance date; and
- (D) Ensured that the confidentiality and integrity of Plaintiffs' personal health information will not be protected by failing to put adequate Security and Enforcement measures into final force and effect until months or years after authorizing the use and disclosure of identifiable health information.

The Amended Privacy Rule has the following effects on individuals, including Plaintiffs and their members:

- (A) It eliminates the ability of Plaintiffs 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 Plaintiffs' identifiable health information without their knowledge or consent;
- (C) It permits and authorizes covered entities to use and disclose identifiable health information, under the guise of federal authority, even over Plaintiff's objections and against their will;

- (D) It permits and encourages covered entities to enter into agreements with business associates who may use and disclose personal health information without complying with the federal privacy standards;
- (E) It permits and authorizes covered entities to use and disclose identifiable health information that has been provided by Plaintiffs to their physicians and practitioners 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 Plaintiffs' consent;
- (F) It eliminates the ability of Plaintiffs 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;
- (G) 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 Plaintiffs can rebut the presumption under some other federal or state law;
- (H) It erodes and undermines the privacy and trust necessary in the physician-patient relationship for quality health care to be provided; and
- (I) It has a "chilling" effect on communications between Plaintiff-patients and their Plaintiff-health care practitioners that are essential for quality health care.

**A. The Plaintiffs in This Case**

The Plaintiffs in this case, whether participating individually or through Plaintiff organizations, are all consumers of health care services, and many are medical practitioners. See Verified Amended Complaint, paragraphs 17-33 and Affidavits of Plaintiffs at Appendix III. As organizations and as individuals, Plaintiffs represent approximately 750,000 citizens from every state in the Union. Id. The medical privacy rights of all Plaintiffs and their patients are currently being violated and jeopardized by the Amended Privacy Rule. All of the Plaintiffs, as individuals, patients and providers of health care, have a concrete interest in the continued right to medical privacy, the continued access to, and opportunity to provide, quality health care, and the right to rely

on the lawfully adopted regulatory right of consent that vested in all of them on the April 14, 2001 effective date of the Original Rule. All of these rights and interests are damaged by Defendant's action in issuing the Amended Privacy Rule Verified Amended Complaint at paragraph 9.

Several Plaintiffs reported that even before the April 14, 2003 compliance date, they or their members were already taking measures to protect their health care privacy in anticipation of the Amended Privacy Rule. See Verified Amended Complaint at paragraphs 19, 25, 27, 32, 33. Those measures include withholding information from their practitioners and avoiding needed health care.

In the three and a half months since the April 14, 2003 compliance date, nearly all Plaintiffs, or their members, have received notices from covered entities informing them that, as permitted and authorized under the Amended Privacy Rule, Plaintiffs' personal health information is being used and disclosed for routine purposes without their permission and that they have no right to object or protest. See Appendix III.<sup>3</sup> Those notices are from virtually every kind of covered entity including physicians, hospitals, dental offices, insurance companies, and pharmacies. They also span the country, including the states of Pennsylvania, California, Massachusetts, New Jersey, New York, New Hampshire, and Oregon. They include virtually every kind of health information including the mental health information that is of concern to Plaintiffs such as the American Psychoanalytic Association and the National Coalition of Mental Health Professionals and Consumers, health information involving senior citizens that is of

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<sup>3</sup> See, for example, the notice from the Office of Employee Group Insurance ("EGI") of the University of Texas System Administration for UT Dental, "Health care operations are activities that federal law considers important to EGI's successful operation;" notice from the Texas Bone & Joint Institute, "Federal law provides that we may use your medical information for health care operations without further specific notice to you, or written authorization from you;" model privacy notice of Texas Medical Association, "We are permitted to use and disclose your medical information for ...[treatment, payment and health care operations];" affidavit of Deborah Peel, M.D., notice from Providence Health System, Oregon Region, "...Providence Health Systems may use and disclose your health information to carry out treatment, payment and health care operations and for other purposes that are permitted or required by law;" affidavit of Michele Dunlap, Psy. D., notice from Eckerd Drugs, "We will use PHI [protected health information] for treatment...payment...and health care operations;" notice from Delaware Health & Social Services/Division of Public Health, "Delaware Health & Social Services/Division of Public Health is authorized to use PHI without your authorization or written permission for...[routine purposes];" affidavit of Janis Chester, M.D., notice from Kaiser Permanente, "Sometimes we are allowed by law to use and disclose certain PHI without your written permission...How much PHI is used or disclosed without your written permission will vary, depending for example, on the intended purpose of the use and disclosure." Affidavit of California Consumer Health Care Council. App. III.

concern to The Congress of California Seniors, breast cancer survivor files that are of concern to Plaintiffs like Jane Doe, and the hospital records of concern to Plaintiffs like Sally Scofield. See Verified Amended Complaint at paragraphs 20, 24, 25, 27 and 33.

Few of the notices offer the, “optional,” consent process that Defendant promised in the preamble to the Amended Privacy Rule would be made available. 67 Fed. Reg. at 53,211/1. Some providers appear to believe that state law requires consent for uses and disclosures while others who are closely associated do not.<sup>4</sup>

Not a single notice received by Plaintiffs so far has made any mention of the fact that patient consent for the disclosure of personal health information is required as part of the Hippocratic Oath and the ethical standards of nearly every professional medical association. See, e.g. 65 Fed. Reg. at 82,472/3. When some Plaintiffs asserted their right of consent under state statutory and common law and the traditional standards of medical ethics, practitioners still refused to provide a consent process. See affidavit of Deborah Peel, M.D.

A few of the notices included references to “more stringent” state and federal laws that require consent for purposes such as (a) sharing information about genetic testing, (b) sharing information about HIV testing or test results, (c) sharing information from substance abuse rehabilitation treatment programs, (d) sharing information about sexually transmitted diseases, (e) using and sharing health information for research and research preparation, and (f) obtaining information that state law recognizes as privileged. App. III. See notice of Massachusetts General Hospital, affidavit of American Psychoanalytic Association. See also notice of The Mount Sinai Hospital of Queens requiring consent to disclose information pertaining to HIV-related information, alcohol and substance abuse treatment, mental health information and psychotherapy notes and genetic information, affidavit of National Coalition of Mental Health Professionals and Consumers. But most notices did not include information about more stringent state laws. See, e.g., notice of North Shore Long Island Jewish Health System, affidavit of National Coalition of Mental Health Professionals and Consumers.

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<sup>4</sup> See, for example, notice of Main Line Health, “...we will ask you to sign a general consent, as required by Pennsylvania law, so that we may use and disclose your protected health information for [treatment, payment and health care operations]” and notice of Bryn Mawr Medical Specialists Association, “We may use and disclose your protected health information...[for treatment, payment and health care operations]” without consent. Affidavit of American Psychoanalytic Association.

Nearly all the notices inform patients that under the Privacy Rule, they have a right to request restrictions but all are careful to state that the covered entities do not have to grant such a request. Several emphasize this point in a manner that could be intimidating to patients. (See notice from Gynics Associates, “[w]e do NOT have to agree to this restriction...,” and notice from Austin Internal Medicine Associates, “[w]e do NOT have to agree to this restriction...” ) Affidavit of Deborah Peel, M.D. App.III.

One major health insurer and provider indicated clearly that the right to request restrictions, which Defendant has cited to show that patients retain some control over their health information, is meaningless. The notice states that the individual may request restrictions on the use and disclosure of personal health information, but “it is our policy to *not* agree to requests for restrictions.” Notice of Kaiser Permanente, at 6, affidavit of California Consumer Health Care Council. Further, a request for restrictions made by intervenor, Janis Chester, M.D., was summarily denied. See affidavit of Janis Chester, M.D. App. III. In effect, the notices of privacy practices under the Amended Privacy Rule are informing patients that they have a right to request restrictions for routine uses and disclosures, but that covered entities have the right to refuse to provide them for any information, for any reason.

Plaintiff Sally Scofield has not received any privacy notices since April 14, 2003 because she has ceased to receive all medical care, “as a result of the Amended Privacy Rule.” However, her health information is still subject to use and disclosure without her knowledge or consent because the Amended Privacy Rule has eliminated her ability to limit the use and disclosure of the information that is already in her medical record.

Every day that the Amended Privacy Rule remains in effect, further damage is caused to the privacy rights of the Plaintiffs in this case.

## **II. LEGISLATIVE AND PROCEDURAL BACKGROUND**

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 by encouraging the development of a health information system through the establishment of standards and requirements for the

electronic transmission of certain health information.” See HIPAA section 261. App. I.

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.

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. 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). App. I.

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.

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). 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. See 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. App. II.

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). See 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). See 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.

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. 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, after conducting his own rulemaking proceeding.

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).

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. 12,738 (February 28, 2001).

The notice of the proposed rule indicated that the Department was proposing to make 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. App. V.

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 comments that brought to his attention the numerous findings in the Original Rule that supported the right of consent.

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." 67 Fed. Reg. at 53,211.

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. See 67 Fed. Reg. at 53,182-83.

On February 20, 2003, Defendant issued another set of regulations in the, "suite," of regulations required by HIPAA. See 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. See 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. See 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.

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.

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. A hastily issued rule issued on April 17, 2003 is admittedly not the Enforcement Rule required by HIPAA. 68 Fed. Reg. at 18,897.

Accordingly, Defendant has stripped Plaintiffs 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 to whom he has granted federal permission to use and disclose it.

### **III. ARGUMENT**

#### **A. The Amended Privacy Rule Reverses a Settled Course of Behavior and Is Invalid Under the Rulemaking Requirements of the Administrative Procedure Act**

After one of the largest rulemaking proceedings in its history, the Department of Health and Human Services published the final Original Privacy Rule on December 28, 2000 which recognized, as its core principle, that individuals have a right to medical privacy which cannot be waived without their consent. 65 Fed. Reg. 82, 462. The Department included this basic privacy right as part of the floor of federal privacy protections based on a detailed analysis and extensive findings with respect to the right to medical privacy under the Constitution, federal and state statutory and common law, ethical standards of practice, longstanding tradition, near universal public expectations, and voluminous comments by individuals and practitioners. 65 Fed. Reg. at 82,463-82,474. App. II. The Original Privacy Rule had an effective date of February 26, 2001. 65 Fed. Reg. at 82,462/1.

After the change in Administrations, the White House issued a directive to all executive departments on January 20, 2001 ordering them to, “temporarily postpone,” for

60 days the effective dates of any regulations that had been published in the Federal Register but whose effective date had not yet arrived. See Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, from Andrew H. Card, Jr., Assistant to the President and Chief of Staff, 66 Fed. Reg. at 7702. (the “Card Memorandum”). The stated purpose of the delay was, “to ensure that the President’s appointees have the opportunity to review any new or pending regulations,” in order to avoid any “costly, burdensome, or unnecessary regulation.” Id.

On the February 26, 2001 effective date, the Department of Health and Human Services, under the new leadership of Defendant, issued a notice in the Federal Register announcing that a report to Congress on the Original Privacy Rule that was required by the Congressional Review Act, 5 U.S.C. 801(a)(1), had not been, “received,” as previously thought and that the effective date of the Rule would have to be, “corrected,” to April 14, 2001 to comply with that statute. 66 Fed. Reg. 12,434. HHS stated that because the extension in the effective date was required by law, it was waiving the requirements for notice and opportunity for public comment.

Two days later, Defendant issued a notice in the Federal Register, “to convert [the Original Privacy Rule] to a final rule with request for comments.” 66 Fed. Reg. 12,738 (February 28, 2001). He stated that the purpose of this action was, “to permit public comment on the final rule for a limited period before the rule becomes effective.” Id. The stated reason for soliciting another round of comments on the final rule was that, “following publication of the final rule,” HHS had received, “approximately a thousand inquiries about the impact and operation of the Privacy Rule on numerous sectors of the economy.” 66 Fed. Reg. at 12,739/2. Defendant stated that he was limiting the additional comment period to 30 days because HHS had already received telephone calls, e-mails and “other contacts” about the “complexity and workability” of the Original Rule over the two months since it was published and, therefore, “we believe that many of the public’s concerns about the Privacy Rule have already crystallized.” 66 Fed. Reg. at 12,739/2-3. Thus, it appears that those who had been unsuccessful in convincing the prior Administration to eliminate the right of consent renewed their failed efforts with the new Administration in January and February 2001 after the final Original Rule was published, and Defendant collaborated by retroactively converting the Original final rule

into a final rule with request for comments in order to permit those entities to create a stronger record in support of their position. On April 12, however, Defendant issued the following statement:

“Today, I am pleased to announce that the President is taking a bold and definitive step to protect the rights of citizens to keep their medical records confidential.

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....

This rule makes sure that private health information doesn't fall victim to the progress of the information and technology age, where an array of data is readily available in computer systems and too often just a keystroke away from being accessed. We are giving patients peace of mind in knowing that their medical records are indeed confidential and their privacy is not vulnerable to intrusion.

The President considers this a tremendous victory for American consumers, who will continue to receive high-quality health care without sacrificing the confidentiality of their private health matters.

As a result of President Bush's decisive action today, our citizens finally will have the peace of mind of knowing their health records are safe and protected.” (emphasis supplied) Statement By Tommy G. Thompson, Secretary, Department of Health and Human Services, “Regarding the Patient Privacy Rule” (April 12, 2001). App. I

Defendant also indicated in the statement that HHS had received more than 24,000 comments in the additional comment period that ended on March 30 and that his staff had, “expedited the review of these comments as they have come in,” and that this review, “pave[d] the way for a decision this week.”

Accordingly, the President and Defendant decided to put the Original Privacy Rule into effect, including the right of consent, after receiving and considering extra-record communications and the comments received from an additional comment period. Presumably this decision was also made in accordance with the Card Memo requiring

that the Original Privacy Rule not be “costly, burdensome, or unnecessary.” Defendant thereby adopted, or at least acquiesced in, the findings supporting the Original Rule.

Thus, the Original Privacy Rule was put into effect by the current, rather than the prior, Administration based on HHS’ prior, as well as Defendant’s own, rulemaking proceedings.<sup>5</sup> Further, the statement issued by Defendant conveyed the unmistakable message that the Privacy Rule would ensure that individuals would have more control over how their health information is used and disclosed under an increasingly computerized health information system.

When the Original Privacy Rule was put into effect by Defendant on April 14, 2001, the right of consent vested in Plaintiffs and in all Americans, as a matter of federal regulation. Defendant expressly stated that the, “new effective date,” of the Rule was April 14, 2001. 66 Fed. Reg. at 12,434/1. As Defendant noted, the HIPAA statute provides that covered entities have two years to come into compliance “following initial adoption of a HIPAA standard.” 66 Fed. Reg. at 12,434/2, citing section 1175 of the Social Security Act, 42 U.S.C. 1320d-4. While the statute provides a two-year grace period for compliance, the standards mandated by HIPAA, including the rights defined in them, vested on the effective date established by Defendant. This intent and understanding is reflected in the above sections of the HIPAA statute as well as the Defendant’s statement on April 12, 2001 that the President wants strong patient privacy protections, “put in place now.”

The right of consent under the Original Privacy Rule remained in effect for a year and a half, until October 15, 2002, when it was repealed and eliminated under the Amended Privacy Rule issued by Defendant on August 14, 2002. 67 Fed. Reg. 53,183/1.

### **1. The Right of Consent Under the Original Privacy Rule**

The Original Privacy Rule set forth a simple privacy standard, that “[with certain exceptions] a covered health care provider must obtain the individual’s consent, in

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<sup>5</sup> The decision by the President and Defendant was described at the time as, “a blow to the health-care industry whose lobbyists reportedly, ‘were stunned by the decision,’ saying that the public and private signals from Mr. Thompson were that the rules’ effective date would likely be delayed....” “Patient-data Rules To Go Into Effect,” The Wall Street Journal, A 18, (April 12, 2001).

accordance with this section, prior to using or disclosing protected health care information to carry out treatment, payment, or health care operations.” 45 CFR 164.506(a).

Two types of providers are exempted from the consent requirement: those with an “indirect treatment relationship with the individual” and those providing services to inmates of prisons. 45 CFR 164.506(a)(2)(i) and (ii).<sup>6</sup>

There are three exceptions to the consent requirement for “emergency treatment situations” where treatment is “required by law” and where consent cannot be obtained due to “substantial barriers to communicating with the individual.” 45 CFR 164.506(a)(3)(i)(A), (B), and (C). The exception for emergency treatment applies if the provider makes an attempt to obtain consent “as soon as reasonably practicable after the delivery of the treatment.” 65 Fed. Reg. at 82,510/2. The “required by law” exception applies if the provider makes any attempt to obtain consent. *Id.* And the “substantial barriers” exception applies if the provider makes any effort to obtain consent and determines, “in the exercise of professional judgment, that the individual’s consent to receive treatment is clearly inferred from the circumstances.” *Id.* The third exception encompasses any situation where health care providers are permitted to provide actual treatment without first obtaining the individual’s consent for that treatment. *Id.* According to the explanation, HHS, “[did] not intend to impose unreasonable barriers to individuals’ ability to receive, and health care providers’ ability to provide, health care.” 65 Fed. Reg. at 82,510/3.

In addition, the Original Rule makes exceptions to the consent requirement where it appears that disclosure of health information to a family member or other person is in the patient’s best interest. Health information directly relevant to a person’s involvement in the patient’s care or payment for the care can be disclosed to a family member, other relative, a close personal friend “or any other person identified by the individual” without prior consent. 45 CFR 164.510(b)(1)(i). Further, health information can be used or disclosed without consent to notify or assist in notifying a family member, personal

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<sup>6</sup> An “indirect treatment relationship” referred to a situation where the health care provider delivers health care to the individual based on the orders of another health care provider, and reports the results of that diagnosis or health care to the other health care provider. 45 CFR 164.501.

representative, or another responsible person of the patient's location, general condition or death. 45 CFR 164.510(b)(1)(ii).

If the individual is available for, or prior to, a use or disclosure, the covered entity can use and disclose the information if (a) it obtains the individual's agreement, (b) provides the individual with an opportunity to object and no objection is made, or (c) reasonably infers from the circumstances "based on the exercise of professional judgment" that the individual does not object. 45 CFR 164.510(b)(2). If the individual is not present prior to the use and disclosure, or the opportunity to agree or object cannot practicably be provided "the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual, and if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care." 45 CFR 164.510(b)(3).

Finally, the Original Rule states that, "[a] covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information." *Id.* As the above provisions show, the right of consent is recognized and preserved while affording providers the opportunity to exercise their professional judgment to ensure that patients receive the health care they need while not compromising their right and expectation of medical privacy.

The preamble to the Original Rule explains that the above provisions permitted the following uses and disclosures without consent; health information could be provided without prior consent to those involved in the individual's care such as, "blood relatives, spouses, roommates, boyfriends and girlfriends, domestic partners, neighbors, and colleagues," but this list was to be illustrative and not exclusive. 65 Fed. Reg. at 82,522/3. Under these provisions covered entities, for example, would be permitted to notify a patient's adult child that his father had suffered a stroke and that the father is in the intensive care unit. 65 Fed. Reg. at 82,523/1. Covered entities could infer an individual's agreement to disclose information when, for example, a patient brings a spouse into the doctor's office when treatment is being discussed and when a colleague or friend has brought the individual to the emergency room for treatment. 65 Fed. Reg. at

82,523/1. The preamble expressly notes under these provisions, “pharmacists may release a prescription to a patient’s friend who is picking up the prescription for him or her.” 65 Fed. Reg. at 82,523/2. It was further explained that, “the final rule does not require covered entities to verify the identity of relatives or other individuals involved in the individual’s care.” 65 Fed. Reg. at 82,523/3. The fact that an individual arrives at a pharmacy and asks to pick up a specific prescription for another individual, “effectively verifies that the friend is involved in the individual’s care, and the rule allows the pharmacist to give the filled prescription to the friend.” *Id.* The preamble states that, “[w]e encourage the exercise of professional judgment in determining the scope of the person’s involvement in the individual’s care and the time period for which the individual is agreeing to the other person’s involvement.” *Id.*

Further flexibility in the consent requirement was provided by permitting joint consents to be obtained by entities in an “organized health care arrangement.” 45 CFR 164.506(f).<sup>7</sup> A consent obtained by one entity in an organized health care arrangement would provide consent for all entities in the arrangement. 65 Fed. Reg. at 82,513/1. For example, a single joint consent could be obtained for a hospital, a clinical laboratory and an emergency department participating in an organized health care arrangement. *Id.*

Moreover, HHS found that the opportunity for informed consent was assured by the provisions in the Original Rule that required the consent form to notify the individual that he or she had a “right to review” the notice of privacy practices prior to signing the consent. 65 Fed. Reg. at 82,473/3; 45 CFR 164.506(c)(2).

Finally, the Original Privacy Rule allowed health information that was created or received prior to the compliance date to be used and disclosed for routine purposes but only “pursuant to a consent, authorization, or other express legal permission obtained from the individual” prior to the compliance date or a new consent signed after that date. 45 CFR 164.532(b). Thus, the consent provisions of the Original Privacy Rule did not affect privacy rights retroactively but only prospectively from the compliance date. 65 Fed. Reg. at 82,564/3.

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<sup>7</sup> Organized health care arrangements are defined under the Rule to include (a) a clinically integrated setting where individuals receive care from more than one provider and (b) an organized system of health care involving a number of entities that hold themselves out to the public as participating in a joint arrangement and share certain other activities jointly (e.g., utilization review, quality assessment or payment). 45 CFR 164.501.

## 2. Revocation of the Right of Consent and the Grant of “Regulatory Permission”

On August 14, 2002, Defendant issued the Amended Privacy Rule which changed section 164.506(a) to read as, “...a covered entity may use or disclose protected health information for treatment, payment, or health care operations....”

Defendant explained the effect of this change as follows: “The consent provisions in section 164.506 are replaced with a new provision at section 164.506(a) that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment and health care operations.” (emphasis supplied) 67 Fed. Reg. at 53,211/2.<sup>8</sup> Defendant also noted that the provision eliminating the right of consent and conferring blanket regulatory permission on covered entities, “would apply to any protected health information held by a covered entity whether created or received before or after the compliance date.” (emphasis supplied) 67 Fed. Reg. at 53,211/3. Thus, the Amended Privacy Rule changed the medical privacy rights of individuals and the duties of covered entities both prospectively and retrospectively.

The Amended Rule also added a requirement to the notice of privacy practice provisions which states that providers with direct treatment relationships must make a, “good faith effort,” to obtain written acknowledgement of receipt of the notice. 45 CFR 164.520(c)(2)(ii) (as amended). Defendant explained that the acknowledgement could not be oral but had to be in writing. 67 Fed. Reg. at 53,240/2. If an individual refuses to provide the written acknowledgement, the provider is required to document its good faith efforts to obtain it and the reasons why the acknowledgement was not obtained. 67 Fed. Reg. at 53,240/2. Providers are also required to retain this documentation for six years. 67 Fed. Reg. at 53,240/3; 45 CFR 164.530(j)(as amended).

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<sup>8</sup> The preamble to the Amended Rule explains that while the consent provision applied only to covered health care providers, “regulatory permission” for the use and disclosure of health information for routine purposes, was being extended to all covered entities. 67 Fed. Reg. at 53,211/1. Defendant also expanded the definition of, “health care operations,” to permit covered entities to disclose personal health information to other covered entities for the purpose of their health care operations and to their business associates. 67 Fed. Reg. at 53,216/3. By expanding the scope of routine uses and disclosures, Defendant thereby indirectly further eliminated individuals’ medical privacy rights.

The Amended Rule states that the notice of privacy practices must be given to the individual, “[n]ot later than the date of the first service delivery,” after the compliance date. 45 CFR 164.520(c)(2)(i)(A) (as amended). For patients whose first treatment encounter is over the telephone, the notice and acknowledgement requirement can be satisfied under the Amended Rule if the notice is mailed to the patient on the date of the telephone contact with a tear off sheet asking the patient to mail back the acknowledgement. 67 Fed. Reg. at 53,240/3.

However, the Amended Rule contains no provision for any notice to the individual of the actual use and disclosure of his or her personal health information for routine purposes. Indeed, an individual’s health information may be used and disclosed without notice prior to the first service delivery after the compliance date and even regardless of whether the individual provides written acknowledgement of receipt of the notice of privacy practices.

Further, the Amended Privacy Rule provides no opportunity or mechanism for individuals to object to or refuse to have their personal health information used and disclosed for routine purposes repeatedly. This inability of the individual to exercise some control over the use and disclosure of his or her health information is exacerbated by the Amended Rule’s retention of the provision that exempts routine uses and disclosures from the provision that gives individuals the “right to receive an accounting” of the disclosures of their health information. 45 CFR 164.528(a)(1).

Thus, the Amended Privacy Rule eliminates the right of consent in the Original Rule, grants “regulatory permission” to covered entities to use and disclose personal health information prospectively and retrospectively with unlimited frequency, provides no mechanism by which individuals can effectively object, permits these uses and disclosures without notice to the individual and deprives the individual of any opportunity to find out how his or her health information has been used and disclosed by not requiring any accounting. In effect, the right to health information privacy for routine purposes has been eliminated.

**B. Defendant Failed to Provide an Adequate Basis for Reversing and Repealing the Right of Consent**

## 1. The Presumption in Favor of a “Settled Course of Behavior”

The standard for determining whether a federal agency has provided a sufficient basis under the Administrative Procedure Act for the reversal of a settled policy is set forth in Motor Vehicle Manufacturers Association v. State Farm Mutual, 463 U.S. 29, 103 S. Ct. 2856 (1983). See Pennsylvania Department of Public Welfare v. U.S. Dept. of Health and Human Services, 101 F.3d 939, 943 (3d Cir. 1996); Donovan v. Adams Steel Erection, Inc., 766 F.2d 804, 807 (3d Cir. 1985). The Court in Motor Vehicle held that regulatory standards may be invalidated and set aside if they are, “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. section 706(2)(A). (citations omitted) 463 U.S. at 41, 103 S. Ct. at 2865. Further, the Court outlined the approach that should be taken where a regulatory standard is being revoked:

“...the revocation of an extant regulation is substantially different than a failure to act. Revocation constitutes a reversal of the agency’s former views as to the proper course. A ‘settled course of behavior’ embodies the agency’s informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to.’ [citation omitted] Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.” emphasis supplied) 463 U.S. at 41-42, 103 S. Ct. at 2866.

The Court noted that under the APA, “If Congress established a presumption from which judicial review should start, that presumption, ...is not *against* safety regulation, but *against* changes in current policy that are not justified in the rulemaking record.” 463 U.S. at 42, 103 S. Ct. at 2866.

Applying that principle, the Court in Motor Vehicle invalidated action taken by a federal agency that rescinded a highway safety standard on the grounds that it failed to meet the requirements for such decisions under the APA. The fact pattern in this case is strikingly analogous to that in Motor Vehicle, and Defendant’s reversal of the agency’s

position on the right of consent should be invalidated for even stronger reasons under the rationale of that decision.

The Court in Motor Vehicle considered a modified standard for automobile safety that had experienced a “complex and convoluted history” over a period of four years. 463 U.S. at 34-38, 103 S. Ct. at 2862-64. The National Highway Traffic Safety Administration (NHTSA) published an automobile safety standard (Standard 208) that provided for mandatory passive restraint systems (seat belts or airbags) to be installed in new cars. The Secretary of Transportation delayed the effective date, conducted another rulemaking and proposed testing the standard through a demonstration project. A successor Secretary disagreed, and within months of assuming office, cancelled the demonstration project and issued a new passive restraint requirement that was to be phased in beginning with large cars in 1982. In February 1981, yet another Secretary of Transportation reopened the rulemaking, delayed the compliance date for the modified passive restraint standard and conducted another rulemaking. 463 U.S. at 37-38, 103 S. Ct. at 2863-64. After that round of public comments, the then Secretary of Transportation rescinded the modified rule before the final compliance date on the grounds that he could no longer conclude that the automatic restraint requirement would produce significant safety benefits. Id.

In holding the agency action invalid under the APA, the Court noted that NHTSA had eliminated the entire standard based on the finding that only one means of meeting it (automatic seat belts) would not produce the desired safety results because they could be detached. The agency had failed to explain why another available option for meeting the requirement (mandatory installation of air bags) was not adopted. While there was serious doubt that detachable automatic seatbelts would not enhance automobile safety, even if that conclusion were valid, the Court held that it justified nothing more than an amendment of the standard to require airbags given the undisputed effectiveness of airbags in saving lives. 463 U.S. at 47-48, 103 S. Ct. at 2869. According to the Court, the required use of airbags was, “a technological alternative within the ambit of the existing standard,” and should have been considered. 463 U.S. at 51, 103 S. Ct. at 2871. The Court further noted that the automobile industry had, “waged the regulatory equivalent of war against the airbag (footnote omitted) and lost,” and that they could not now obtain a

reversal by focusing the agency's attention on a limited option for meeting the requirement and contending that this option is problematic or ineffectual. 463 U.S. at 49, 103 S. Ct. at 2869-70.

## 2. **The Presumption In Favor of the Right of Consent**

Recognition of the right of consent for routine uses and disclosures of personal health information has had a similarly complex and convoluted history under the HIPAA Privacy Rule. The Notice of the Proposed Rule Making (NPRM) for the Original Privacy Rule would have permitted covered entities to use and disclose health information for routine purposes without consent while requiring a detailed notice of privacy practices. 65 Fed. Reg. at 82,473/3. However, in response to extensive public comments, Defendant's predecessor issued the final Original Privacy Rule which rejected that proposed approach and included recognition of a right of consent. *Id.*

When Defendant took office, he delayed the effective date of the Original Privacy Rule, conducted his own rulemaking proceeding, and put the Original Rule into effect. Before the compliance date, he conducted yet another rulemaking and reversed the agency's position on the right of consent contained in the Original Rule and adopted essentially the position that HHS had rejected when the Original Rule was adopted.

As shown by the findings to the Original Privacy Rule, medical privacy is at least as essential to liberty and quality health care as passive restraint systems are to automobile safety. 65 Fed. Reg. at 82,464-465 and 82,467-68. Defendant's findings in support of the Amended Privacy Rule, that the right of consent could create problems under certain "first encounter" circumstances for some patients, is at least as questionable as NHTSA's conclusion that detachable seatbelts would not produce significant safety results. Defendant never analyzed the perceived problems under the flexibility for consent provided in the Original Rule and never explained why such access problems had not been prevalent in the 2500 years that consent was part of the ethical standard of medical practice under the Hippocratic Oath, and more recently, under the many state laws and the ethical standards of most professional medical organizations. *See infra* at III.E.

In any event, Defendant unreasonably restricted himself to considering only single “global fixes” that furthered Defendant’s goal of simplifying the Rule for covered entities. 67 Fed. Reg. at 53,210/3 and 53,212/2. Defendant professed that he considered, “targeted,” and other, “global,” approaches to addressing the alleged access problems but indicated that he dismissed them for the reason that no one approach, “would address all of the issues that were brought to the Department’s attention,” and that each of the global approaches, “had some flaw or failed to address all of the treatment-related concerns,” brought to his attention. (emphasis supplied) 67 Fed. Reg. at 53,212/1 and /2.

Thus, as with the agency in Motor Vehicles, Defendant has limited his own review of available options in such a way that he could only seriously consider the option he selected. In so doing, Defendant failed to consider “technological alternatives within the ambit of the existing standard.” 463 U.S. at 51, 103 S. Ct. at 2871. For example, Defendant failed to consider whether a combination of targeted and/or more general options would have addressed all of the perceived problems while preserving the traditional right of consent. Defendant concedes that he did not consider such an approach because of his interest in a single, “global fix.” 67 Fed. Reg. at 53,212/2.

Just as questions about the efficacy of one automobile safety system does not cast doubt on the need for a passive restraint standard, doubts about the ability of a single alternative to resolve the perceived consent problems do not cast doubt on the need for medical privacy and a right of consent. Given the well-established importance and effectiveness of the right of consent in preserving the public’s trust in the health delivery system, the “logical response” to the alleged consent problems would have been to adopt a solution that preserved the right of consent while addressing the alleged problems. Compare, 463 U.S. at 48, 103 S. Ct. at 2869.

As Defendant has found, Congress intended for the privacy standards under HIPAA to “enhance” privacy protections in order to give individuals “peace of mind,” that the increased use of computers to store and transmit health information intended by the statute would not intrude on the privacy of their health information. 65 Fed. Reg. at 82,463/2; 82,469/3; and 82,471/2. As in Motor Vehicle, the presumption from which judicial review should start is not *against* health information privacy but *against* any erosion in current privacy protections and practices. 463 U.S. at 42, 103 S. Ct. at 2866.

Certain facts in this case support invalidation of the Amended Privacy Rule’s elimination of the right of consent for even stronger reasons under rationale of Motor Vehicle. First, the agency’s “settled course” in this case has, in fact, been reversed rather than merely rescinded.<sup>9</sup> Second, the regulatory standard at issue in this case involves a fundamental privacy right grounded in the history and experience of medicine and the nation’s system of government. See 65 Fed. Reg. at 82,464/1; and infra at III.G. Third, Defendant in this case reversed his own action as well as that of his predecessor in office. Thus, it would seem especially important for Defendant to address the agency’s findings that supported recognition of the right of consent and explain his action in light of those findings before reversing himself. Fourth, Defendant has done more than simply reverse the regulatory right of consent that he put into effect. He has also conferred blanket regulatory authority on covered entities to use and disclose personal health information regardless of individuals’ wishes.<sup>10</sup> Finally, Defendant has adopted essentially the same course of action (permitting unauthorized use and disclosure with notice of privacy practices) that was rejected previously when the Original Privacy Rule was issued.

**3. Defendant Failed to Address the Agency’s Findings in Reversing Its Course of Behavior**

**a. HHS’ Findings in Support of Medical Privacy and Consent**

According to the preamble of the Original Privacy Rule:

“The comments and 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 health information. Our regulation will ensure that those consents cover the routine uses and disclosures of health

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<sup>9</sup> Defendant cannot contend that the consent provision in the Original Privacy Rule was not a “settled course” of action because the compliance date had not arrived at the time of the Amended Rule. The effective date of the Original Privacy Rule had long since passed, and the consent requirement was every bit as “settled” a course of action as was the safety standard in Motor Vehicle which was rescinded before its compliance date. 463 U.S. at 38, 103 S. Ct. at 2864

<sup>10</sup> Defendant states that such permission is, “most typically,” treated as a waiver of rights. 67 Fed. Reg. at 53,213/2. Thus, Defendant admittedly has waived the privacy rights of Plaintiffs and all Americans by granting blanket regulatory permission for the use and disclosure of personal health information.

information, and provide an opportunity for individuals to obtain further information and have further discussion, should they so desire.” (emphasis supplied) 65 Fed. Reg. at 82,474/1.

The findings that HHS made in the preamble to the Original Privacy Rule led directly and inexorably to the conclusion that it was essential to include recognition of the right of consent in the floor of federal health information privacy protections that HIPAA intended individuals “should have.” See HIPAA, section 264. App. I. Defendant failed to address those findings when he reversed his position on the right of consent even though they were expressly brought to his attention in the comments of plaintiffs in this action. See comments of American Psychoanalytic Association and the National Coalition of Mental Health Consumers and Practitioners (April 26, 2002) App. V.

i. **The Major Purposes of the Privacy Rule Are To Enhance Protections and Restore the Public’s Trust**

When HHS issued the Original Privacy Rule, it found that privacy standards authorized by the Administrative Simplification provisions of HIPAA were to have three major purposes:

- (1) “To protect and enhance the rights of consumers by providing them access to their health information and controlling the appropriate use of that information;
- (2) To improve the quality of health care in the U.S. by restoring trust among consumers health care professionals and the multitude of organizations and individuals committed to the delivery of care; and
- (3) To improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on the efforts by the states, health systems, and individual organizations and Individuals.” (emphasis supplied) 65 Fed. Reg. at 82,463/2.

According to HHS, Congress recognized that administrative simplification under HIPAA, “cannot succeed if we do not also protect the privacy and confidentiality of personal health information.” 65 Fed. Reg. at 82,463/3. High quality health care depends on the exchange of personal, often sensitive information between the “individual and a skilled practitioner” and “vital to that interaction” is the patient’s trust that the information will be kept private. 65 Fed. Reg. at 82,463/3.

HHS found that rules protecting the privacy of health information have been enacted primarily by the states, but, “state laws with a few notable exceptions, do not extend comprehensive protections to people’s medical records.” 65 Fed. Reg. at 82,464/1. Further, prior to the Original Privacy Rule, “no federal rules existed to protect the privacy of health information...” *Id.* Accordingly, HHS noted that the Original Privacy Rule, “...establishes, for the first time, a set of basic national privacy standards and fair information practices that provides all Americans with a basic level of protection and peace of mind that is essential to their full participation in their care.” 65 Fed. Reg. at 82,464/1.

**ii. Privacy is a “Fundamental Right”**

HHS examined the nature and history of the privacy that should be recognized in the national health privacy framework to be established under HIPAA. It found that, “[p]rivacy is a fundamental right,” and that while the costs and benefits of a regulation must be considered, “it is important not to lose sight of the inherent meaning of privacy: it speaks to our individual and collective freedom.” *Id.* The Department noted that, “[a]ll fifty states today recognize in tort law a common law or statutory right to privacy.” *Id.*

HHS found that, “[t]hroughout our nation’s history we have placed the rights of the individual at the forefront of our democracy.” It was also noted that the most basic protections in our Constitution, “are imbued with an attempt to protect individual privacy while attempting to balance it against the larger social purposes of the nation.” 65 Fed. Reg. at 82,464. HHS cited as support the reference to life, liberty and the pursuit of happiness in our Declaration of Independence, the Fourth Amendment protections against unreasonable searches and seizures, and the Supreme Court’s recognition of the right to

medical privacy under the Fifth Amendment in Whalen v. Roe, 429 U.S. 589 (1977). 65 Fed. Reg. at 82,464/2. HHS noted that the Fourth Amendment’s protection of security of, “persons,” is consistent with obtaining consent before performing invasive medical procedures, and that its protection of, “papers and effects,” includes personal information contained in medical records. Id. HHS concluded that the concerns that form the basis for informed consent laws that place limits on the ability to intrude physically on a person’s body similarly, “apply to intrusions on information about the person.” 65 Fed. Reg. at 82,464/3.

HHS acknowledged that, “there is also significant intrusion when records reveal details about a person’s mental state, such as during treatment for mental health.” Id. It concluded that if the, “right to be let alone,” means anything, “it likely applies to having outsiders have access to one’s intimate thoughts, words and emotions.” Id. It also noted that the Supreme Court had made the following finding in recognizing a psychotherapist-patient privilege under the Federal Rules of Evidence: “[The psychotherapist-patient privilege] serves the public interest by facilitating the appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance.” 65 Fed. Reg. at 82,464/3.<sup>11</sup>

HHS noted that many scholars have emphasized the link between privacy and liberty as in the following example:

“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 information.” (emphasis supplied) 65 Fed. Reg 82,464/3.<sup>12</sup>

HHS also noted that another writer had defined the right of privacy as, “the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated.” (emphasis supplied) 65 Fed. Reg. at

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<sup>11</sup> Citing, Jaffee v. Redmond, 518 U.S. 1, 11, 116 S. Ct. 1923, 1929 (1996).

<sup>12</sup> Citing, “Privacy Matters: In Defense of the Personal Life,” J. Smith, at 240-241 (1997).

82,465/1.<sup>13</sup> These findings vividly illustrate that the right to medical privacy cannot exist unless the individual has an ability to exercise it.

**iii. Consumers Are Increasingly Concerned About Personal Health Privacy**

HHS found that Americans' concern about the privacy of their medical information was, "part of a broader anxiety about the lack of privacy in an array of areas." 65 Fed. Reg. at 82,465/1. It cited a number of surveys that showed the following:

- The percentage of Americans expressing concern over the loss of privacy increased from 64% in 1978 to 82% in 1995;<sup>14</sup>
- Over 80% of those surveyed in 1999 felt that they had "lost all control over their personal information";<sup>15</sup> and
- 29% of respondents in a 1999 survey put the "loss of personal privacy" as their first or second concern in the coming century.<sup>16</sup> 65 Fed. Reg. at 82,465/1 and/2.

The overall concern over the threat to personal privacy stemmed from three trends: (a) the growing use of interconnected electronic media for business and personal activities, (b) the increasing ability to know an individual's genetic make-up, and (c) the increasing complexity of the health care system. *Id.* at 82,465/2.

First, with respect to the impact of electronic technology, HHS noted that it has always been difficult to protect the privacy of health information, but that the financial and logistical obstacles of compiling and transmitting health information in paper form, "served to protect the confidentiality of health information and the privacy interests of individuals." 65 Fed. Reg. at 82,465/3. However, recent developments in electronic information technology have made it possible to disseminate a person's "most profoundly

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<sup>13</sup> Citing, "Who Knows: Safeguarding Your Privacy in a Networked World," A. Cavourkian, D. Tapscott, Random House (1995).

<sup>14</sup> Citing, Harris Equifax, Health Information Privacy Study (1993).

<sup>15</sup> *Id.*

<sup>16</sup> Citing, Wall Street Journal/ABC poll (September 16, 1999).

private information” to “hundreds, thousands, even millions of individuals and organizations” in a matter of seconds. 65 Fed. Reg. at 82,465/2. According to HHS, “the growing level of trepidation about privacy in general...has tracked the rise in electronic information technology.” 65 Fed. Reg. at 82,466/1. In fact, HHS noted a recent survey that showed that 75% of consumers seeking health information on the internet are concerned or very concerned about the health sites they visit sharing their personal health information with a third party. 65 Fed. Reg. at 82,466/1.

HHS noted that there is a, “patchwork of State laws and regulations,” in this area that are incomplete and inconsistent. According to HHS, “[t]hese laws fail to provide a consistent or comprehensive legal foundation of health information privacy.” 65 Fed. Reg. at 82,466/1. Moreover, HHS noted, the transmission of health information is, “becoming increasingly ‘national’” and can have value far beyond the community where the individual resides.” 65 Fed. Reg. at 82,466/2. According to HHS, “[t]he 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 in the use of electronic data.” (emphasis supplied) 65 Fed. Reg. at 82,466/1.

The evidence of the public’s growing concern about the threat posed by the greater use and capacity of electronic information systems caused HHS to conclude: “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 82,466/2.

Second, with respect to the increased availability of genetic information, HHS also found that the absence of privacy protections was inhibiting new opportunities to identify and prevent many leading causes of death and disability through genetic testing. 65 Fed. Reg. at 82,466/2. It noted the following survey information:

- A 1995 national survey found that 85% of those surveyed were either “very concerned” or “somewhat concerned” that insurers and employers might gain access and to and use genetic information.<sup>17</sup>

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<sup>17</sup> Citing, Harris Poll, #34 (1995).

- A 1997 national survey found that 63% of participants said that they would not take genetic tests if insurers and employers could gain access to the results.<sup>18</sup>
- In genetic testing studies at the National Institutes of Health, 32% of eligible people who were offered a test for a predisposition for breast cancer declined to take it, citing concerns about the loss of privacy. 65 Fed. Reg. at 82, 466/2.<sup>19</sup>

Finally, with respect to the growing public concern over the increasing complexity of the health delivery system, HHS noted that the number of entities maintaining and transmitting health information has, “increased significantly over the past ten years.” 65 Fed. Reg. at 82,466/3. One survey found that an average of 150 people have access to a patient’s medical records during the course of a typical hospitalization. *Id.* While many of these people may have a legitimate interest need to see all or part of a patient’s records, “no laws govern who these people are, what information they are able to see, and what they are and are not allowed to do with that information once they have access to it.” 65 Fed. Reg. at 82,466/3. HHS noted the following data reflecting the public’s growing concern:

- A 1993 survey found that 75% of those surveyed were worried that medical information from a computerized national health information system will be used for many non-health reasons, and 38% were, “very concerned”.<sup>20</sup>
- 85% of the respondents in the above survey felt that protecting the confidentiality of medical records is, “absolutely essential,” or “very essential,” in health reform.<sup>21</sup>

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<sup>18</sup> Citing, “Genetic Information and the Workplace,” Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission (January 20, 1998).

<sup>19</sup> Citing, Senator Patrick Leahy’s comments on the introduction of the Medical Information Privacy and Security Act, (March 10, 1999).

<sup>20</sup> Citing, a 1993 Lou Harris poll.

<sup>21</sup> Citing, *Id.*

- A 1994 poll found that 75% of those surveyed were concerned a, “great deal,” or a, “fair amount,” about insurance companies putting medical information about them into a computer information bank to which others have access.<sup>22</sup>
- Another survey found that 35% of Fortune 500 companies look at people’s medical records before making hiring and promotion decisions. 65 Fed. Reg. at 82,467/1.<sup>23</sup>

HHS noted that the growing threats to medical privacy were not merely theoretical, and cited seven widely reported examples of breaches of the privacy of individuals’ health information. Those breaches involved the disclosure individuals’ medical records to some or many members of the public including information concerning the results of tests for HIV, prescriptions and all medications taken by individuals, the names of women suffering from incontinence, and the results of testing for high cholesterol. 65 Fed. Reg. at 82,467/2.

Based on these findings, HHS concluded that, “[i]n the face of industry evolution, the potential benefits of our changing health care system, and the real risks and occurrences of harm, protection of privacy must be built into the routine operations of our health care system.” (emphasis supplied) 82,467/2.

**iv. Medical Privacy is Necessary for Quality Health Care**

HHS then made extensive findings that showed that ensuring the privacy of medical records is necessary to secure effective, high quality health care. 65 Fed. Reg. at 82,467/2. Among those were the following:

“The need for privacy of health information, in particular, has long been recognized as critical to the delivery of needed health medical care. More than anything else, the relationship between a patient and a clinician is based on trust. The clinician must trust the patient to give full and truthful information about their health, symptoms and medical history. The patient must trust the clinician to use that information to improve his or her health

<sup>22</sup> Citing, an ACLU poll in 1994.

<sup>23</sup> Citing, Starr, Paul, “Health and the Right to Privacy”, American Journal of Law and Medicine, vol. 25, pp. 193-201 (1999).

and to respect the need to keep such information private.” (emphasis supplied) 65 Fed. Reg. at 82,467/3.

While HHS noted that health information is necessary to improve the quality of health care, it also made the following finding:

“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. Such a loss of faith can impede the quality of the health care they receive, and can harm the financial health of health care institutions.” 65 Fed. Reg. at 82,467/3-82,468/1.

HHS then reviewed existing evidence that showed the types of actions patients typically take when they feel that their health information may be used and disclosed without their permission. According to HHS, “[r]ecent studies show that a person who does not believe his privacy will be protected is much less likely to participate fully in the diagnosis and treatment of his medical condition.” 65 Fed. Reg. at 82,468/1. HHS cited numerous examples of such studies:

- A national survey in January 1999 found that 1 in 5 Americans believe their health information is being used inappropriately.<sup>24</sup>
- “More troubling,” according to HHS, was the fact that 1 in 6 Americans reported that they had taken some sort of evasive action to keep their health information private such as, “providing inaccurate information to a health care provider, changing physicians, or avoiding care altogether.”
- Another recent survey noted by HHS found that 78% of the physicians belonging to a professional medical association, “reported withholding information from a patient’s record due to privacy concerns.”
- The same survey reported that 87% of member physicians, “reported having had a patient request to withhold information from their medical records.”<sup>25</sup>

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<sup>24</sup> See California HealthCare Foundation, “National Survey: Confidentiality of Medical Records” (1999) at <http://www.chfc.org>.

<sup>25</sup> Citing survey conducted by the Association of American Physicians and Surgeons.

- Similar evasive actions were noted in surveys of adolescents.<sup>26</sup>
- HHS noted that a coalition of stakeholders including consumers, health care professionals, health plans and experts in public health, medical ethics, information systems and health policy, had found that, “To protect their privacy and avoid embarrassment, stigma, and discrimination, some people withhold information from their health care providers, provide inaccurate information, doctor-hop, to avoid a consolidated medical record, pay out-of-pocket for care that is covered by insurance, and — in some cases — avoid care altogether.”<sup>27</sup> 65 Fed. Reg. at 82,468/1-82,468/2.

HHS then cited various examples of how reported breaches of certain individual’s health information privacy had caused other damage to them including, “the loss of a job, alienation of family and friends, the loss of health insurance and public humiliation.” Id. HHS noted the following:

- Individuals diagnosed with cancer had their mortgages called by a banker who gained access to their medical records.<sup>28</sup>
- A physician’s surgical privileges were suspended after he was diagnosed with AIDS at the hospital where practiced medicine.<sup>29</sup>
- A candidate for Congress nearly had her campaign derailed when newspapers published the fact that she had sought psychiatric treatment after a suicide attempt.<sup>30</sup>
- A 30-year old FBI veteran was put on administrative leave when, “without his permission,” his pharmacy released information about his treatment for depression.<sup>31</sup> 65 Fed. Reg. at 82,468/2

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<sup>26</sup> Citing, “Foregone Health Care Among Adolescents,” Drs. Bearman, Ford, and Moody, JAMA. vol. 282, no. 23 (1999) and “Confidentiality in Health Care: A Survey of Knowledge, Perceptions, and Attitudes Among High School Students,” T.L. Cheng, et al., JAMA, vol. 269, no. 11, at 1404-1407 (1993).

<sup>27</sup> Citing, “Best Principles for Health Privacy,” at 9, Health Privacy Working Group (July 1999).

<sup>28</sup> Citing, the National Law Journal (May 30, 1994).

<sup>29</sup> Citing, *Estate of Behringer v. Medical Center at Princeton*, 249 N.J. Super. 597.

<sup>30</sup> Citing, The New York Times, Section 1, p. 25 (October 10, 1992).

<sup>31</sup> Citing, The Los Angeles Times (September 1, 1998).

HHS also noted a finding by Consumer Reports that, “40 percent of insurers disclose personal health information to lenders, employers, or marketers without customer permission.” (emphasis supplied) Id.<sup>32</sup>

v. **Congress Intended to Enhance Medical Privacy**

HHS determined that the answer to the growing concerns about the loss and breach of health information privacy is not for individuals to have to withdraw from the health care system. Rather, HHS concluded, establishing national standards specifically stating the uses and disclosures that can and cannot be made of an individual’s health information: “can help to restore and preserve trust in the health care system and the individuals and institutions that comprise that system.” 65 Fed. Reg. at 82,468/3. Thus, HHS found that the intent of Congress under HIPAA was to, “enhance,” the privacy protections for health information, and to, “restore,” the public’s eroding trust in the health delivery system to protect their privacy.

HHS then noted that at least since 1965, there has been a growing concern in Congress that the increasing use of electronic technology to store and transmit personal information has posed an increasing threat to individual privacy. 65 Fed. Reg. at 82,468/3-82,469/1. The agency noted that the most recent laws, regulations, and legislative proposals, “come against the backdrop of decades of privacy-enhancing statutes passed at the federal level to enact safeguards in fields ranging from government data files to video rental records.” 65 Fed. Reg. at 82,469/1.

HHS also found that, “it also is important for the U.S. to join the rest of the developed world in establishing basic medical privacy protections” such as those required by the Data Privacy Directive of the European Union. 65 Fed. Reg. at 82,469/2. The EU directive became effective in October of 1998 and prohibits European Union countries from transmitting personal data to another country without ensuring, “an adequate level of protection,” unless it is pursuant to an , “unambiguous consent or to fulfill a contract

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<sup>32</sup> Citing, “Who’s Reading Your Medical Records,” Consumer Reports, at 628 (October 1994).

with the individual.” (emphasis supplied) 65 Fed. Reg. at 82,486/3.<sup>33</sup> HHS noted that while the United States is not a signatory to the EU Directive, the European Commission determined in July 2000 that the U.S. Safe Harbor Privacy Principles constitute, “adequate protection.” Those Privacy Principles include a requirement for “Choice (i.e., consent).” 65 Fed. Reg. at 82,468/3, n.1.<sup>34</sup>

HHS then examined the statutory objective of HIPAA in light of the privacy concerns of the public and Congress when it was enacted. It noted that in section 262 of HIPAA, Congress, “primarily sought to facilitate the efficiencies and cost savings for the health care industry that the increased use electronic technology affords.” 65 Fed. Reg. at 82,469/3. At the same time, HHS noted:

“...Congress recognized the challenges to the confidentiality of health information presented by the increasing complexity of the health care industry, and by advances in health information systems technology and communications. Section 262 thus also directs HHS to develop standards to protect the security, including the confidentiality and integrity, of health information.

Congress has long recognized the need for protection of health information privacy generally, as well as the privacy implications of electronic data interchange and the increased ease of transmitting and sharing individually identifiable health information.” 65 Fed. Reg. at 82,469/3.

HHS also noted that Congress required in section 264 of HIPAA that the law implementing the electronic storage and transmission provisions of the statute must be accompanied by provisions setting forth (a) the privacy rights that an individual who is the subject of individually identifiable health “should have,” (b) the procedures for the

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<sup>33</sup> The European Data Privacy Directive (95/46/EC) finds that the right to informational privacy is one of the, “fundamental rights and freedoms,” of all persons that must be protected by member countries. See section (2). It further states that, “Whereas data which are capable by their nature of infringing fundamental freedoms or privacy should not be processed unless the data subject gives his explicit consent;...” Section (33) (emphasis supplied). Personal data is defined as, “any information relating to an identified or identifiable natural person.” Article 2(a).

<sup>34</sup> In fact, the Safe Harbor Privacy Principles require organizations that seek obtain medical or health information from individuals in EU countries to employ an “opt-in” process so that the information will not be disclosed without the individual’s permission except where needed for treatment. 65 Fed. Reg. at 45,667-68. App. VI.

exercise of those rights, and (c) the uses and disclosures that should be authorized or required. 65 Fed. Reg. at 82,469/3-82,470/1.

According to HHS, “[t]he Congress further recognized the importance of such standards by providing the Secretary with authority to promulgate regulations on health care privacy in the event that lawmakers were unable to act within the allotted three years.” 65 Fed. Reg. at 82,469/2. HHS concluded that, “[t]he 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.” (emphasis supplied) 65 Fed. Reg. at 82,474/2.

Bringing all these findings to bear on the privacy standards to be developed HHS stated that, “[o]ur goal is to enhance privacy protections in ways that do not impede this evolution [of the health care industry].” (emphasis supplied) 65 Fed. Reg. at 82,471/2. HHS noted that the statute does not provide it with jurisdiction over, “many key stakeholders who receive ...health information from a covered entity,” and while broader legislative authority would be desirable it, “cannot justify abandoning any effort to enhance privacy.” (emphasis supplied) 65 Fed. Reg. at 82,471/3.

vi. **HHS Determined that the Privacy Standards Were “Workable”**

HHS noted that it intended to combine, “workability,” with the new privacy protections and that balancing the need for privacy against demands for health information, “causes much of the complexity of the rule.” 65 Fed. Reg. at 82,472/1. According to HHS, much of the complexity of the rule resulted from the fact that, “the rule must track current practices and current practices are complex.” *Id.* HHS concluded, “We believe that the complexity entailed in reflecting those [current] practices is better public policy than a perhaps simpler rule that disturbed important information flows.” *Id.*

Further HHS noted that some individuals might feel that the standard is complex because they will be receiving, for the first time, a notice of how their information may be used and disclosed but “[t]he additional complexity for the individual is the price of

expanding their understanding and their rights.” (emphasis supplied) 65 Fed. Reg. at 82,472/2. A part of those expanded rights was the ability, “to exercise some control,” over the uses and disclosures of their health information. Id.

**vii. The Right of Consent is Essential for the Health Privacy That Citizens Expect**

HHS then turned to an analysis of current law and practice with respect to the right of consent. It noted that this was the issue that was the subject of the most comments. 65 Fed. Reg. at 82,472/2. The comments revealed a, “common belief,” that individuals today must be asked for each and every release of their health information. Id. HHS also found that the public has, “strong expectations,” that their personal health information will not be used or disclosed without their consent. 65 Fed. Reg. at 82,473/1.<sup>35</sup> HHS noted that while current law and practice do not entirely support that view, “[o]ur review of professional codes of ethics revealed partial, but loose, support for individuals’ expectations of privacy.” 65 Fed. Reg. at 82,472/3.

HHS found that state laws with respect to consent, “vary dramatically,” just as they do for personal privacy protections generally. However, HHS noted that approximately half of the states have a, “general law,” that prohibits disclosure of health information without patient permission and, “some,” of those laws apply only to hospital records. 65 Fed. Reg. at 82,473/1. It noted that some state laws that prohibit uses and disclosures without consent have exemptions for various types of activities. However, HHS noted that, “most state health care professional licensure laws,” include general prohibitions against, “breaches of confidentiality.” Id. at 82,473/2. Furthermore, in some states, individuals can hold providers accountable for some unauthorized disclosures of health information under tort theories such as, “invasion of privacy and breach of a confidential relationship.” Id.

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<sup>35</sup> This strong expectation of privacy with respect to health information is consistent with HHS’ findings with respect to personal information more generally. HHS found that, “many people believe that individuals should have some right to control personal and sensitive information [including health information] about themselves.” 65 Fed. Reg. at 82,464/2. HHS further found that, “[m]any people,” believe that personal details about their physical self should not be put on display, against their will, for others to see. 65 Fed. Reg. at 82,464/2-3.

HHS found that in the many cases where neither state law nor professional ethical standards exist, privacy protection is often limited to policies and procedures of corporate entities. HHS concluded, based on a study that, “these policies are not adequate to provide appropriate privacy protections and alleviate public concern.” 65 Fed. Reg. at 82,473/2. HHS also noted the focus of public concern, “The greatest concern regarding the privacy of health information derives from widespread sharing of patient information throughout the health care industry and the inadequate federal and state regulatory framework for systematic protection of health information.” (emphasis supplied) 65 Fed. Reg. at 82,473/2.<sup>36</sup>

viii. **The Right of Consent is a Privacy Right Citizens “Should Have”**

Finally, HHS addressed how these findings culminated in its recognition of the right of consent as part of the floor of federal privacy protections that citizens, “should have,” under section 264(c) of HIPAA. According to HHS, “[p]roviding and obtaining consent clearly has meaning for patients and practitioners.” 65 Fed. Reg. at 82,473/3. HHS further found 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.” *Id.* As stated at the outset, HHS found that requiring consent for routine uses and disclosures is consistent with individuals’ longstanding expectations and the prevailing practice among direct treatment providers. 82,474/1. HHS also found that including a right of consent was the best way to ensure that individuals, “have the ability to negotiate restrictions or otherwise have a meaningful discussion,” with direct treatment providers regarding health privacy practices. *Id.*

HHS also considered and rejected the option of requiring consent to be obtained from covered entities that are not direct treatment providers, such as insurers and health care clearinghouses. It was decided that the consent requirement should apply only to direct treatment providers since they are the ones, “who create the health information in

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<sup>36</sup> Citing, “*For the Record: Protecting Electronic Health Information*, National Academy Press, Washington, D.C. (1997).

the first instance.” 65 Fed. Reg. at 82,474/1. HHS noted that, “global consents,” obtained by insurers at the time of the individual’s enrollment are not really, “informed,” or voluntary. Thus, health information privacy could be protected more effectively and efficiently by requiring consent by direct treatment providers who are essentially in the position of “gatekeepers” for information sought by other covered entities. *Id.* As support for its conclusion, HHS found that, “virtually all hospitals,” and 90% of non-hospitals obtain patient consent for routine uses and disclosures. 65 Fed. Reg. at 82,771/2.

HHS also found that the enhanced privacy protections under the Original Privacy Rule would generate savings and better health care because, “[f]ear of disclosure of treatment is an impediment to health care for many Americans.” 65 Fed. Reg. at 82,776/3. HHS cited a 1993 study that found that 7% of respondents said that they or a member of their family had chosen not to seek medical services, “due to fear of harm to job prospects or other life opportunities.” *Id.* About 2% reported not filing an insurance claim, “because of concerns of lack of privacy or confidentiality.”<sup>37</sup> HHS concluded that greater confidence by patients that they could protect their medical privacy would lead to, “increased treatment among people who delay or never begin care, as well as among people who receive treatment but pay directly....” *Id.*

HHS analyzed the savings and other benefits that the Original Privacy Rule could produce for individuals suffering from four medical conditions: cancer, HIV/AIDS, sexually transmitted diseases (STDs) and mental health conditions. Those were selected because, “they are representative of widespread and serious health problems, and because they are areas where reliable and relatively complete data are available....” 65 Fed. Reg. at 82,777/1.

HHS estimated that the Original Privacy Rule could improve access to health care for 586,000 individuals suffering from cancer but, “who did not seek earlier cancer treatment due to privacy concerns.” 65 Fed. Reg. at 82,777/3. HHS calculated that \$1.6 billion in lost wages could be saved each year, “by encouraging more people to seek early cancer treatment through enhanced privacy protections.” *Id.*

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<sup>37</sup> Citing, *Health Information Survey*, Harris-Equifax, pp. 49-50 (1993).

HHS found that privacy concerns likely would deter some people from getting tested for HIV/AIDS. 65 Fed. Reg. at 82,778/1. Most states have passed some sort of law protecting the privacy of HIV status. However, HHS observed that information often can be revealed indirectly through the therapy a patient receives or the drugs he or she uses. Studies have shown that only 15% of patients who receive early treatment develop, “an ADE (AIDS defining event),” after five years while 29% of patients develop such a condition if treatment is delayed. Early treatment has been found to prolong life by 6.2%. Id.

HHS found that seeking treatment for a potentially embarrassing diseases such as STDs, “requires trust in both the provider and the health care system for confidentiality of such information.” 65 Fed. Reg. at 82,778/1-2. HHS further found that greater trust should lead to more testing and more effective treatment. Earlier treatment of curable STDs, HHS concluded, “can mean a decrease in morbidity and the costs associated with complications,” including, “expensive fertility problems, fetal blindness, ectopic pregnancies, and other reproductive complications.” Id.

With respect to mental illness, HHS estimated that 2.07 million people in the adult population per year do not seek needed mental health treatment due to privacy fears. 65 Fed. Reg. at 82,779/1. HHS calculated that the enhanced privacy protections provided to those individuals by the Original Privacy Rule could produce savings of from \$497 million to \$795 million annually. 65 Fed. Reg. at 82,779/1.

**b. Defendant Ignored HHS’ Findings**

In reversing HHS’ position on the right of consent in the Amended Privacy Rule, Defendant addressed virtually none of the numerous findings by his own agency that led to recognition of the right in the Original Privacy Rule. As was the case in Motor Vehicle, Defendant has not addressed the basis the agency previously cited in establishing the rule. As the Court in that case noted, “[t]he agency must explain the evidence which is available, and must offer a ‘rational connection between the facts found and the choice made’.” 463 U.S. at 53, 103 S. Ct. at 2871. Defendant has completely failed in this case to establish a rational connection between the agency’s own

findings that supported the Original Privacy Rule and the choice made in the Amended Rule.

For example, Defendant did not dispute that including a right of consent for routine uses and disclosures is “consistent with the administrative aspect of consent as it exists today.” Nor did he dispute that most Americans today, and historically, have had an expectation that their personal health information will not be used or disclosed without their knowledge and consent. Neither did Defendant explain how the repeal of the regulatory right of consent would be consistent with those expectations.<sup>38</sup>

Defendant also did not address why he was embracing an option in the Amended Privacy Rule (use and disclosure without consent with a notice of privacy practices) which the agency had considered and expressly rejected in adopting the Original Rule. Neither did Defendant address how the decision to eliminate the ability of individuals to have some control over the routine use and disclosure of their personal health information was consistent with his statement when he put the Original Rule into effect that the Administration’s objective was to provide individuals with, “more control over how their personal information is used,” and to give patients, “peace of mind,” in knowing that, “their privacy is not vulnerable to intrusion.” Thompson Statement (April 12, 2001).

In reversing the agency’s settled course of action, Defendant made no mention of the three major purposes of the Privacy Rule under HIPAA: (a) to enhance the rights of consumers to better control the use and disclosure of their health information, (b) to improve quality and restore trust among consumers and health care professionals in the health delivery system, and (c) to create a national framework for health privacy protection that builds on the efforts by the states and others.

Defendant failed to address how repealing a core provision of the floor of federal privacy protections and leaving this issue to the incomplete and inconsistent “patchwork” of state laws would further the objective of providing comprehensive basic privacy protections that would apply to the increasingly national (and even international) use and

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<sup>38</sup> In the background portion prior to the basis and purpose statement on consent, Defendant vaguely stated that, “[g]iven public expectations,” with respect to uses and disclosures for such purposes, “the Department’s goal is, as it has always been, to permit these activities to occur with little or no restriction.” 67 Fed. Reg. at 53,209/1. It is unclear, however, what expectations Defendant was referring to, and no evidence was cited, since all of the findings and survey data cited in the basis and purpose statement to the Original Rule showed that individuals are, and always have been, particularly concerned about the unrestricted use and disclosure of their personal health information within the health delivery system.

disclosure of personal health information. While Defendant noted in the basis and purpose statement of the Amended Rule that the repeal of the right of consent would not repeal the right of consent set forth in state laws (67 Fed. Reg. at 53,212/3), he did not address the effect of the repeal on individuals in states referenced in the preamble to the Original Rule that do not afford a right of consent at all or do not provide that right comprehensively.<sup>39</sup>

There is not one word in Defendant's basis and purpose statement for the Amended Privacy Rule that mentions the "fundamental" nature of the right to privacy, how consent is essential to an individual's ability to exercise that right, its recognition and protection under our Constitution and the cases interpreting it or why Defendant believes (assuming he does) that this right is not violated by the Amended Rule.<sup>40</sup> Nor does Defendant explain why his amendment does not narrow or eliminate basic rights to liberty and privacy as defined by the scholars cited in HHS' findings supporting the Original Rule.

Defendant completely ignores his agency's prior findings concerning the growing anxiety exhibited by consumers in numerous surveys that their personal privacy is increasingly threatened by the growing computerization of personal information, the increasing ability to determine and disseminate an individual's genetic information, and the increasing number of individuals and entities in the health care system that seek access to personal health information. Defendant fails to show how his decision to eliminate the right of individuals to control the use and disclosure of their health information for routine purposes will enhance privacy protections and reduce the anxiety of individuals who believe that their privacy rights with respect to personal health information, including their genetic information, are being eroded.<sup>41</sup>

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<sup>39</sup> Interestingly Defendant tacitly concedes that the Amended Rule will weaken privacy protections for individuals by taking the position that state consent laws will not be preempted because they provide, "more stringent," privacy protections. 67 Fed. Reg. at 53,212/3. Thus, even Defendant concedes the obvious fact that removing a right of consent from the federal law weakens rather than, "enhances," individuals' privacy protections.

<sup>40</sup> This, and many of the other findings, were expressly brought to Defendant's attention in comments by Plaintiffs American Psychoanalytic Association and the National Coalition for Consumers and Mental Health Professionals, at 5 (April 26, 2002) App. V.

<sup>41</sup> Even if Defendant had tried to provide such an explanation, the Amended Rule would still be arbitrary and capricious because the explanation would be, "counter to the evidence before the agency, or is so

Defendant also failed to address the agency's own findings that individuals are particularly concerned about the dissemination of their personal health information to insurers and to others throughout an increasingly complex health delivery system.

Defendant also failed to address the findings with respect to widely reported breaches of health information privacy that led to the conclusion that there is a need for greater privacy protections for "routine" uses and disclosures. It is noteworthy that all of the information involved in the privacy breaches cited by HHS (the results of HIV tests, prescriptions and medications, the names of women suffering from incontinence, the results of cholesterol testing and medical records generally) can be used and disclosed broadly, under the authority of federal regulatory permission, for routine purposes under the Amended Rule.

Defendant failed to show how repealing the only mechanism available to individuals to exercise their right to privacy will reduce the incidence of patients taking evasive actions to protect their health privacy including supplying inaccurate information to a provider, requesting physicians to withhold information from the medical record, frequently changing physicians to avoid a consolidated medical record and paying out of pocket rather than filing a claim for covered health care. In short, Defendant failed to show how the wholesale elimination of the right to privacy and consent for routine purposes would result in an overall improvement in access to quality health care.

Defendant also failed to show how the use and disclosure of personal health information without the individual's knowledge or consent and without any requirement for an accounting of those uses and disclosures would reduce the chances of that information being used (a) by bankers to deny mortgages to cancer patients, (b) to suspend staff privileges for physicians who test positive for AIDS, (c) to prevent citizens who have suffered from depression at some point in their lives from serving in Congress, (d) to prevent pharmacies from releasing information about public servants' treatment for depression, and (e) to allow employers to use personal health information in hiring and promotion decisions.

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implausible that could not be ascribed to a difference in view or product of agency expertise." Motor Vehicle, 463 U.S. at 43, 103 S. Ct. at 2867.

The basis and purpose statement for the Amended Rule also fails to explain how the elimination of the right of consent from federal health privacy protections is consistent with the provisions of the European Data Privacy Directive that identifies the rights to privacy and consent as, “fundamental rights and freedoms,” and requires, “explicit consent,” for the use and disclosure of personal information. Further, the basis and purpose statement to the Amended Rule fails to show how it is consistent with the U.S. Safe Harbor Privacy Principles that require individuals’ consent for the disclosure of personal information. There is also no mention of why Defendant feels that it is no longer important for the United States to “join the rest of the developed world” in establishing this type of basic medical privacy protection.

Defendant failed to show why he apparently no longer feels that the right to privacy of health information used and disclosed for routine purposes is one of the privacy rights that Congress believed that individuals, “should have,” under section 264 of HIPAA. There is a similar failure to show why protection of the privacy and security of this health information is no longer viewed as the “sine qua non” of the increased efficiency of information exchange brought about by the electronic revolution.

Neither did Defendant explain, for example, how the privacy and security of personal health information can be protected when he has conferred “regulatory permission” on covered entities and their business associates to use and disclose that information for at least two years before those entities have any obligation to comply with the security standards published on February 20 of this year. 68 Fed. Reg. at 8,334. Further, Defendant failed to explain how he plans to enforce effectively whatever privacy and security measures are in effect when he has failed to issue the final enforcement rules.

The basis and purpose statement to the Amended Rule also failed to consider or address the agency’s findings with respect to cost savings and the improved access to health care which the preamble to the Original Rule set forth. Those savings amounted to \$2.4 billion each year for cancer and mental health patients alone according to HHS’ own findings. Defendant merely noted in the basis and purpose statement to the Amended Rule that HHS had received no further information and that it estimated that all of the changes in the Amended Rule would produce savings of at least \$100 million over ten

years. 67 Fed. Reg. at 53,255/2. Thus, the changes do not appear to be consistent with HHS' finding that one of the statutory objectives of HIPAA was reducing costs. 65 Fed. Reg. at 82,474/1.

Defendant acknowledged that he received many comments that, “confused the net savings associated with the Administrative Simplification provisions with cost savings associated with the Privacy Rule,” and that they relied upon this “misinformation” to argue in favor of retaining the right of consent for routine uses. Defendant refused to consider these comments because they were “essentially propounding a policy choice and not making a comment on the validity of the estimates for cost savings associated with the elimination of the consent requirement.” 67 Fed. Reg. at 53,256/1. Defendant’s refusal to consider these comments ignored the agency’s own analysis which found that, “[t]he privacy and security standards are the platform on which the remaining standards rest...” 65 Fed. Reg. at 82,474/1. Further, Defendant found that the privacy standards are, “an integral and necessary part,” of the suite of Administrative Simplification standards and therefore, “as a matter of policy as well as law, the administrative standards should be viewed as a whole in determining whether they are ‘consistent with’ the objective of reducing administrative costs.” 65 Fed. Reg. at 82,474/2. Thus, Defendant’s failure to consider the agency’s own prior findings prevented him from considering comments and evidence that were material to the proposed amendment.

Finally, Defendant failed to address the impact that the retroactive elimination of the right of consent would have on patients and other individuals who have, heretofore, permitted their sensitive health information to be included in their medical records with the understanding and reasonable expectation that this information would not be further used and disclosed without their knowledge and permission. 65 Fed. Reg. at 82,472/3.

**4. Defendant Failed to Adequately Consider and Respond to Significant Comments and Alternatives Presented**

In order for a rule to be valid under the Administrative Procedure Act, particularly where it changes the legal rights and duties of interested parties, the accompanying basis and purpose statement, “must address, with some precision, the major comments

received.” Action on Smoking and Health v. Civil Aeronautics Board, 699 F.2d 1209, 1216 (D. C. Cir. 1983). In addressing those comments, the agency must explain why, “significant points raised by the public,” and particular proposals are inconsistent with the objectives of the regulation. Id. at 1218. The agency must also provide evidence in support of why it rejected alternatives that were within the ambit of the standard it seeks to revoke or reverse. Motor Vehicle, 463 U.S. at 51, 103 S. Ct. at 2871. As is well established, “The APA guarantees the public an opportunity to comment on proposed rules. That opportunity is meaningless unless the agency responds to significant points raised by the public.” Action on Smoking and Health, supra at 1217.

In Action on Smoking and Health, the court considered another situation where a new administration had come into office and rescinded a rule by a prior administration that limited smoking aboard airplanes. The new rule, similar to the Amended Rule’s treatment of consent in this case, removed most of the regulatory restrictions and left it to the airlines’ discretion to decide if restrictions on smoking should be implemented. The court invalidated the new rule on the grounds that the basis and purpose statement failed adequately to address and discuss significant comments and alternatives suggested. Id. at 65. In reaching its decision, the court cited the following established principle for review of APA rulemaking:

“An agency need not respond to every comment, but it must ‘respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how the resolution led the agency to the ultimate rule...The basis and purpose statement is inextricably intertwined with the receipt of comments.’ [footnote omitted] Thus, while the standard for review is whether the agency acted in an arbitrary and capricious manner, [footnote omitted] the detail required in a statement of basis and purpose depends on the subject of the regulation and the nature of the comments received.” Id. at 64.

The subject of the Privacy Rule and nature of the comments received could hardly demand a more detailed basis and purpose statement.<sup>42</sup> By eliminating the right of

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<sup>42</sup> As the Court in Motor Vehicle noted, “unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.” 463 U.S. 48, 103 S. Ct. at 2869.

consent, the Amended Rule radically changed the fundamental rights of virtually every American and the duties of numerous covered entities and their business associates since the date the Original Rule was made effective, as well as over the course of the nation's history.

Defendant failed to address and analyze the comments and alternatives on the proposed Amended Rule in the context of the voluminous comments that had been submitted on the Original Rule and in the February 2001 comment period.

HHS received, "over 52,000 public comments," during the public comment period on the Original Privacy Rule. 66 Fed. Reg. at 12,739/2; see also, 67 Fed. Reg. at 53,182/3. During the comment period conducted by Defendant that extended from February 28, 2001 to March 30, 2001, Defendant indicated that he received, "in excess of 11,400 additional comments." 67 Fed. Reg. at 53,183/3.<sup>43</sup> Defendant has filed a certified administrative record with this court showing that another approximately 11,000 comments were filed on the proposed March 27, 2002 Amended Privacy Rule. Susan McAndrew, Certification of Administrative Record, Department of Justice.

The issue of the right of consent, "drew the most comments," in the rule-making on the Original Rule. 65 Fed. Reg. at 82,472/2. In the comment period on the Amended Rule, "[t]he vast majority of of commenters addressed the [elimination of] consent proposal." 67 Fed Reg. at 53,210/1. Thus, it is logical to assume that most of the comments in the February - March 2001 comment period also addressed the right of consent.

HHS found that, "many," if not most, patients, consumers and practitioners strongly supported recognition of the right of consent in the rulemaking on the Original Rule. 65 Fed. Reg. at 82,473/3. It must be assumed that a similar proportion of the comments in the February 2001 comment period supported retaining the right of consent since Defendant decided, based on his staff's review of those comments, to implement the Original Rule immediately, in order to give patients more control over their health information. Thompson statement, at 2 (April 12, 2001).

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<sup>43</sup> Curiously, Defendant stated on April 12, 2001 that his Department had received, "more than 24,000 written comments," on the Privacy Rule, "during the past two months." See Statement of Tommy G. Thompson, at 2 (April 12, 2001).

The comments on the proposed Amended Rule filed with this court shows that strong support remained among consumers and practitioners for retaining the right of consent. That record shows that 149 organizations filed comments supporting retaining the right of consent. A list of those organizations is set forth at Appendix IV.<sup>44</sup> Those organizations represented the views of approximately 219,027,019 individuals. See Record Review Affidavit, paragraph 3.B. Most of those individuals were consumers and practitioners. Another 3,398 comments were submitted by individuals in support of retaining the right of consent. Record Review Affidavit paragraph 3.C. Again, most of these comments were submitted by consumers and practitioners with 2,353 of them being submitted by consumers. Id.

By contrast, the record reveals that approximately 4,053 comments were submitted opposing retaining the right of consent. Record Review Affidavit at 3. D. Appendix IV. Of those comments, approximately 3,119 were submitted by hospitals, health care facilities and insurers. Id. Of the comments from individuals opposing the right of consent, most appeared to be form letters on the letterheads of insurance companies, or healthcare facilities and systems often with the individual writing in his or her capacity as an employee of the company. Record Review Affidavit, paragraph 3. E. and F. Some of these letters still had labels on them such as, “Sample Letter,” and instructions such as “name, address”<sup>45</sup> App. V. A precise count of these comments is difficult to determine because many were copies of the same letter from the same individual that were given individual numbers by Defendant indicating that they probably had been counted numerous times.

Thus, the record reveals that again there was overwhelming support among consumers and practitioners for the preservation of the right of consent, and efforts to

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<sup>44</sup> The list shows that those organizations included such significant organizations, in addition to several of the Plaintiffs, as the American Association of Retired Persons (AARP), the American Bar Association, the American Psychiatric Association, the American Psychological Association, Consumer’s Union, Families USA, the Massachusetts Medical Society, the Medical Society of New York, the National Depressive and Manic-Depressive Association, the National Multiple Sclerosis Society, the Ohio State Medical Association, People Against Cancer, Renewal for Victims of Family Violence, the Women’s Law Project and the Offices of the Attorney’s General for the States of California, Massachusetts, New York and Vermont.

<sup>45</sup> A list of the organizations most commonly responsible for the form letters in the record is found at Record Review Affidavit at paragraph 3.F. App. IV.

eliminate that right appeared to be engineered principally by a relatively small group of insurance companies, hospitals and their associations. This continued strong public support is remarkable in view of the facts that: (a) this was the third rulemaking proceeding on the consent issue in three years, (b) Defendant had issued a public statement when he put the Original Rule into effect in April 2001 that he and the President were committed to protecting the rights of citizens to keep their medical records confidential, and (c) the NPRM for the Amended Rule did not alert the public that Defendant proposed to eliminate individuals' ability to control the use and disclosure of their personal health information for routine purposes. Under these circumstances, it would have been reasonable for members of the public to assume that the issue had been permanently resolved in favor of the consumer's right to privacy.

In his basis and purpose statement analyzing the comments, Defendant merely noted that there were, "many," comments in favor of retaining the right of consent and, "many," that were opposed. 67 Fed. Reg. at 53,210/1. Defendant concluded that there was, "a substantial amount of support from commenters for the approach taken in the NPRM...[t]herefore, the Department has adopted [that approach]." 67 Fed. Reg. at 53,212/3. Nowhere did Defendant analyze the comments in the context of the three, "major goals," of the Privacy Rule identified in the preamble to the Original Rule: (a) to protect and enhance the rights of consumers, (b) improving the quality of health care by restoring trust in the health care system among consumers and (c) creating a national health privacy framework by building on the efforts of the states and organizations. 65 Fed. Reg. at 82,463/2. Neither did Defendant attempt to reconcile the Amended Rule with the numerous surveys and studies cited in the basis and purpose statement of the Original Rule that show strong and near universal support among citizens and consumers for medical privacy and the right of consent.<sup>46</sup> Instead, Defendant developed an approach and method of analysis that allowed him to simply disregard the comments and views of

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<sup>46</sup> Defendant also ignored a significant and reputable national survey submitted during the February - March 2001 comment period which showed that: (a) 78% of Americans feel that it is "very important" that their medical records be kept confidential, (b) 93% indicated that genetic information should not be disclosed to medical or government researchers without prior consent, (c) 92% objected to government agencies seeing their medical records without their permission, and (d) 82% objected to insurance companies gaining access to their medical records without their permission. See comments of the Institute for Health Freedom (March 29, 2001) enclosing the results of a survey by The Gallup Organization entitled, "Public Attitudes Toward Medical Privacy" (September 2000). App. V.

most consumers and many practitioners. Defendant thereby effectively denied more than 200 million Americans the right to have their views seriously considered as contemplated under the Administrative Procedure Act. For those individuals, the public notice and comment provisions of the APA were rendered meaningless.

In his responses to the comments, Defendant also failed to consider an important aspect of the problem. Motor Vehicle, 463 U.S. at 43, 103 S. Ct. at 2867. He states generally that the reason that he adopted the approach of eliminating the right of consent and providing federal regulatory permission for the use and disclosure of health information is that it was the only approach that solves the operational problems, “in a simple and uniform manner.” 67 Fed. Reg. at 53,211/1. Defendant vaguely addressed how the rule might ease some administrative burdens for certain types of covered entities but failed entirely to address or analyze how the rule makes it far more complex and difficult for consumers, patients and physicians to protect individuals’ rights to privacy.

The Amended Privacy Rule establishes a nationwide presumption that virtually all personal health information (whether created in the past, present or future) will be used and disclosed for routine purposes unless the individual or the physician can locate a “more stringent” state law that rebuts that presumption. Thus, an individual who wants to ensure that his or her health information is not used and disclosed without his or her consent faces the daunting task of researching the law in his or her state to determine if it provides a right of consent for the particular type of health information to be protected as well as the particular use at issue; if his or her information were being used or disclosed by a covered entity in another state (or another country for that matter), the individual would have to research the law there as well. Of course, even this remote opportunity to protect medical privacy would not be available to many individuals because the Amended Rule does not require any notice to be given before the information is used or disclosed, nor does it provide for an accounting.

As some of the Plaintiffs in this case stated in their comments, the Amended Rule actually increases rather than decreases the burdens on providers.<sup>47</sup> As Defendant concedes, the Amended Rule does not eliminate the requirement for, “informed consent,”

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<sup>47</sup> See comments of the American Psychoanalytic Association and the National Coalition of Mental Health Professionals and Consumers, 10-11 (April 26, 2002) App. V.

for treatment which is routinely obtained and tracked to make sure it has not been revoked. 67 Fed. Reg. at 53,214/1. If direct treatment providers, as the gatekeepers of personal health information, can no longer assert their patients' right to privacy in the absence of consent, they will become the information collection conduits for an unlimited amount of personal health information demanded by insurers and others. 65 Fed. Reg. at 82,474.<sup>48</sup> If they seek to establish a "discretionary" consent process, the insurers will place them in an untenable conflict of interest position where they will have to elect between honoring their patients' wishes and being excluded from the insurance plan or ignoring their patients' wishes and preserving their livelihood.<sup>49</sup>

Further, direct treatment providers are required by the Amended Rule to either obtain written acknowledgement of notice of privacy practices or document their good faith efforts to obtain such an acknowledgement and the reasons why it was not obtained. 45 CFR 164.520(c)(2). Defendant fails to address or explain why obtaining consent to treat a patient and obtaining written acknowledgement of receipt of privacy notices or documenting good faith efforts to provide that notice is any less burdensome than simply obtaining consent for the use and disclosure of health information.

The added complexity of the Amended Rule has also created significant confusion among practitioners and consumers because it is inconsistent with many state laws, traditional practice standards, patient expectations and the ethical standards of most professional medical organizations. Defendant does not dispute these inconsistencies but fails to address their adverse impact. The confusion is compounded by the requirement in the Amended Rule that providers set forth in their privacy notices the uses and disclosures permitted by the Amended Rule regardless of the privacy practices that they actually follow. If a provider were to exercise his or her discretion, to have a consent process, as Defendant says is permitted under the Amended Rule (67 Fed. Reg. at 53,211/1), he or she must still provide the individual with a notice setting forth the uses

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<sup>48</sup> Plaintiffs also expressly brought this issue to Defendant's attention in their comments. Id. at 11.

<sup>49</sup> This was the dilemma faced by Plaintiff Daniel Shrager, M.D. in Shrager v. Magellan Behavioral Health, No. G.D. 00-015809 (Ct. of Common Pleas of Allegheny County, March 11, 2003) where the court ruled that a health plan acted unlawfully when it terminated Dr. Shrager's contract as a participating psychiatrist because he refused to disclose his patient's psychiatric records in identifiable form without their consent.

and disclosures that the Amended Rule permits for routine purposes without consent or other permission. 45 CFR 164.520(b)(1)(A).<sup>50</sup>

The Amended Rule's inconsistency with traditional medical practice, and the required notice logically might be expected to generate confusion among patients and practitioners – and that is, in fact, occurring. Many of the notices being used to implement the Amended Privacy Rule, dutifully inform the patients that they have no right of consent for the use and disclosure of their health information for treatment, payment and health care operations, but few, if any, mention the, “optional,” consent process which Defendant maintained was available. 67 Fed. Reg. at 53,211/1. No notices that Plaintiffs have been able to locate make any mention of the fact that consent for the use and disclosure of personal health information (particularly to third party insurers) is required by the ethical standards of most medical professions. Furthermore, few of these notices inform patients of their rights to consent under state statutes and common law. These types of notices have become common practice in the three months since the Amended Rule's compliance date despite the fact that the Rule requires privacy notices to contain a description of any use or disclosure that is, “prohibited or materially limited,” under other law, including state law. 45 CFR 164.520(b)(1)(ii)(C).<sup>51</sup>

Defendant received a comment on the proposed Amended Rule raising the concern that, “the removal of the consent requirement from the Privacy Rule will become the de facto industry standard and supplant professional ethical duties to obtain consent....” 67 Fed. Reg. at 53,212/3. Defendant brushed that concern aside by stating that more stringent state laws remain in force, and professional standards that are more protective of privacy, “retain their vitality.” *Id.* The privacy notices received by the Plaintiffs in this case show that the concern is valid.

To appreciate the confusion that is caused by the Amended Privacy Rule, it is useful to consider the information that a prospective psychiatric patient might receive under the Amended Rule. An individual suffering from depression and paranoia who consults a psychiatrist for treatment must be given a notice of privacy practices that

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<sup>50</sup> This requirement was in the Original Rule, but there it would have allayed the individual's privacy concerns because the notice would have said that personal health information could not be used or disclosed for these purposes without the individual's consent. That notice under the Amended Rule essentially informs the patients that they have no privacy rights for routine purposes.

<sup>51</sup> See affidavits regarding the privacy notices received by Plaintiffs. App. III.

informs him that federal law gives his therapist the authority to use and disclose his health information without his permission for treatment, payment and health care operations, complete with at least one example of each use. The therapist would also have to inform the patient that any information that falls within the definition of, “psychotherapy notes,” would be exempt from this authority.<sup>52</sup> Then the therapist must inform the patient of the extent of the federal therapist-patient privilege and how that interacts with the Amended Privacy Rule (if he knows).<sup>53</sup> He would also be required to inform the patient of any state law privileges or other more stringent privacy protections in state statutory or common law. He should inform the patient that the ethical standards of the American Psychiatric Association prohibit the disclosure of health information without consent, but that those standards do not have the effect of law. The psychiatrist can then tell the patient about his own privacy practices but should caution the patient that his privacy practices do not apply to other covered entities and their business associates to which he discloses health information, and that those covered entities have regulatory permission from the federal government to use and disclose his information as many times as they please for treatment, payment and health care operations without notice, permission or an accounting. It is difficult to imagine that any patient would feel comfortable disclosing sensitive health information to a practitioner after receiving such confusing and conflicting messages.

Thus, the only affects of the Amended Rule that are “simple and uniform” are that the traditional rights of individuals and patients to control the routine use and disclosure of their personal health information have been simply and uniformly eliminated under federal law. Further, covered entities and their business associates “simply and uniformly” have been given federal regulatory permission to use and disclosure personal health information without the individual’s knowledge or consent.

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<sup>52</sup> The Privacy Rule requires authorization for the use and disclosure of, “psychotherapy notes,” for treatment, payment and health care operations. 45 CFR 164.508(a)(2). The special protection for this information is not available, however, if the therapist fails to keep the information in a separate part of the medical record, a decision outside of the patient’s control. 45 CFR 164.501. Further, the definition contains 11 exceptions for certain types of information, but none are defined.

<sup>53</sup> See Jaffee v. Redmond, 518 U.S. 1, 116 S. Ct. 1923 (1996).

5. **Defendant’s Explanation of His Policy Reversal Runs Counter to the Evidence in the Record and Is Implausible**

The explanation given by Defendant for abolishing the right of consent not only ignored the comments of most consumers and practitioners but “runs counter to the evidence in the record” and “is so implausible it could not be ascribed to difference in view of the product of agency expertise.” Motor Vehicle, 463 U.S. at 43, 103 S. Ct. at 2867.

Defendant’s principal stated reason for eliminating the right of consent in the Amended Rule was in order to avoid, “compromising timely access to quality health care.” 67 Fed. Reg. at 53,210/2. This was the, “most troubling, pervasive problem” that was caused by, “first encounters,” — the need by some providers to gain access to patient information, “before their initial face-to-face contact with the patient.” 67 Fed. Reg. at 53,209/2. Defendant however, does not dispute HHS’ prior findings that: (a) many state laws require consent, (b) the ethical standards of many professional medical organizations require consent for the disclosure of health information, and (c) the Original Rule’s approach, “will not significantly change the administrative aspect of consent as it exists today.” 65 Fed. Reg. at 82,474. Yet, Defendant does not cite a single example where the right of consent has posed a barrier to timely access to health care under existing laws and professional standards.<sup>54</sup> In fact, Defendant says that covered entities are free to have consent processes and comply with state laws and ethical standards that provide for consent. 67 Fed. Reg. at 53,211/1, 53,212/3. Either the right of consent poses no barrier to timely access to health care, or Defendant does not care if it does as long as the decision is not made by the federal government.

As at least two of the Plaintiffs demonstrated to Defendant in their comments, the alleged problems could be resolved by application and interpretation of the existing regulations with no amendments or could be resolved more specifically by a minor amendment. See comments of the American Psychoanalytic Association and the National Coalition of Mental Health Professionals and Consumers, at 11 (April 26, 2002) App. V.

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<sup>54</sup> Thus, all of the “operational problems” on which Defendant relies for eliminating the right of consent are speculative and not consistent with long-standing practice and experience.

Preliminarily, Defendant asked for comments with respect to whether the right to medical privacy would be, “unduly compromised,” by the elimination of the right of consent. 67 Fed. Reg. at 14,778. Plaintiffs cited the agency’s own extensive findings as evidence that medical privacy would be unduly compromised, but Defendant failed to discuss or address the very comments he requested.

Furthermore, Plaintiffs showed that the consent process in the Original Rule had already been determined by Defendant and most providers to be, “workable.” In fact, Plaintiffs cited a national survey of covered entities presented by the California HealthCare Foundation at a hearing on April 16, 2002 before the Senate Health, Education, Labor and Pensions Committee that found that in February and March of 2002 80% of responding covered entities believed that the consent provisions of the Original Privacy Rule were, “very workable,” “workable,” or “somewhat workable.” Comment at 11. See survey at App. VI. The survey also found that hospitals and physician groups were even more likely to feel that the consent provisions were very workable, workable, or somewhat workable, but that insurers were less likely to feel that the consent provisions were workable. Id.

Defendant failed to address this survey in the basis and purpose statement despite the fact that: (a) Deputy Secretary of HHS Claude Allen was present at and testified at the same hearing, (b) Plaintiffs brought that fact and the survey to Defendant’s attention in the comments,<sup>55</sup> and (c) Defendant cited a different survey conducted by the same organization in January 1999 in the basis and purpose statement of the Amended Rule. 67 Fed. Reg. at 53,210/3. Defendant appears to have blinded and deafened, himself, to evidence that ran counter to the conclusion he wished to reach.

An examination of the Original Rule shows that the alleged problems could have been addressed without an amendment. For example, there was no requirement in the Original Rule that the consent be obtained in a “face-to-face” encounter. In fact, Defendant addressed the acknowledgement of notice requirement in the Amended Rule stating that acknowledgement could be obtained over the telephone and confirmed by

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<sup>55</sup> Comments of American Psychoanalytic Associations and National Coalition of Mental Health Professionals and Consumers, at 11 (April 26, 2002). App. V.

mail. 67 Fed. Reg. at 53,240/3. Defendant did not explain why a similar process could not be used for consent.

Further, the Original Rule contained a limited exception under which health information could be used and disclosed without consent if the provider made an attempt to obtain consent but was unable to obtain it, “due to substantial barriers to communicating with the individual,” and the provider determined, in the exercise of professional judgment, that consent is, “clearly inferred from the circumstances.” 45 CFR 164.506(a)(3)(i)(C). There was no language in the Original Rule that would have prevented this exception from addressing the “first encounter” situation.<sup>56</sup>

Similarly, Defendant failed to explain why the “first encounter” issue could not have been addressed by the provision in the Original Rule that allowed health information to be used without a written consent where the patient was not present by allowing the covered entity to exercise its professional judgment to determine whether the disclosure would be in the patient’s best interest. 45 CFR 164.510(b)(2).

The advantage to these approaches is that they would have resolved the “first encounter”/ timely access issue by doing what the patients want done. They also would have been consistent with the three major goals of the Privacy Rule identified in the basis and purpose statement to the Original Rule. 65 Fed. Reg. at 82,463/2. These approaches also would have been more consistent with the approach Defendant and his staff told Congress they were taking. As the above referenced comments noted, Deputy Secretary Allen told the Senate HELP Committee on April 16, 2002 that HHS was taking a patient oriented approach to the amendments. Comment of American Psychoanalytic Association and National Coalition for Mental Health Professionals and Consumers, at 11.<sup>57</sup> Based on the evidence in the record, however, it appears that Defendant took the one course of action most uniformly opposed by patients and consumers. Thus, the Amended Rule, issued four months later on August 14, 2002, was anything but patient oriented.

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<sup>56</sup> An example in the preamble suggests that this exception was intended to encompass situations where the patient is mentally incapacitated, but there appears to be no reason why the exception also could not apply to “substantial barriers” due to not being able to contact the patient. 65 Fed. Reg. at 82,510/3.

<sup>57</sup> Specifically with respect to the consent issue, Deputy Secretary Allen testified, “Ultimately, we tried to put ourselves in the shoes of the patient and do what made the most sense from his or her perspective.” Testimony of Claude A. Allen, Deputy Secretary, HHS, on Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) and the Proposed Modifications to those Standards, Senate Health, Education, Labor, and Pensions Committee (April 16, 2002).

Another “operational problem” that allegedly influenced Defendant’s decision to eliminate the right of consent was that emergency medical providers would have to try to obtain consent even if that was inconsistent with appropriate emergency medicine. 67 Fed. Reg. at 53,209/2. The Original Rule however, had an express exception to the prior consent requirement for, “emergency treatment situations.” 45 CFR 4.506(a)(1)(3)(i)(A).

Some emergency treatment providers apparently objected to the requirement in the exception that they attempt to obtain consent as soon as reasonably practicable after the delivery of emergency care. However, the requirement was not that they “obtain” the consent but merely that they make an, “attempt,” to obtain it. This would not seem to be a particularly onerous burden. In any event, the exception clearly prevented this consent requirement from being a barrier to access to “timely” care since the duty to attempt to obtain consent did not arise until after the services were rendered. As a practical matter, it seems highly unlikely that a patient whose information is used on a limited basis in order to provide him or her needed and desired health services is going to complain if the consent is not obtained precisely on time.

Defendant also cited the alleged problem of consent being obtained by providers that are required by law to treat patients. 67 Fed. Reg. at 53,209/3. Again, however, Defendant failed to note or discuss that the Original Rule included a specific exception for treatment without consent where it is, “required by law,” if the provider merely makes some attempt to obtain consent. 45 CFR 164.506(a)(1)(3)(i)(B). The preamble to the Original Rule indicated that this situation might arise with, “certain publicly funded providers.” 65 Fed. Reg. at 82,510/2. As with the alleged concern about emergency treatment, this does not appear to have been a potential threat to timely access to care but rather a concern about sending “mixed messages” and interfering with the physician-patient relationship. 67 Fed. Reg. at 53,209/3. The “mixed message” concern was that providers would have to ask for consent but could use and disclose the information even if the patient says, “no.” Id. Defendant failed to discuss the fact that the Amended Rule with its mandatory notice requirement creates a much broader “mixed message” problem by requiring all patients to be notified that federal law permits their health information to be used and disclosed without their consent even where state law and the provider’s privacy practices require a consent process. Further, the Amended Rule permits and

authorizes the covered entities to use and disclose personal health information even where the individual says, “no” and even where the patient is not contacted. It would be difficult to imagine a process that is more destructive to the physician-patient relationship.

Defendant also mentioned the alleged concern that oncologists often obtain information from, “other doctors, hospitals, labs, etc., speak with patients by telephone, identify treatment options, and develop preliminary treatment plans,” before the initial patient visit. 67 Fed. Reg. at 53,210/1; 53,210/2. There was no discussion by Defendant of the extent to which this concern could have been resolved by the use of joint consents which the Original Rule permitted for, “organized health care arrangements.” 45 CFR 164.506(f). Under that provision a single consent suffices for hospitals, laboratories, and other providers in such arrangements. 65 Fed. Reg. at 82,513/1. Defendant also neglected to examine the extent to which the issue could have been addressed by the exemption from the consent requirement for “indirect treatment” providers (those who provide consultation services in response to a referral from another provider).<sup>58</sup>

Defendant also mentioned that the right of consent could present problems for hospices which often provide psychological and support services over, “long distances.” 67 Fed. Reg. at 53,210/1. Again, Defendant failed to explain how this alleged problem has been handled in states with consent laws or under the federal common law psychotherapist-privilege recognized by the Supreme Court in Jaffee v. Redmond.<sup>59</sup> Further, there was no consideration of why this “problem” could not have been resolved by obtaining consent by telephone and confirmation by mail as Defendant has provided for obtaining acknowledgement of notice of privacy practices. It appears that Defendant did not explore and analyze whether the alleged operational problems could be resolved under the Original Privacy Rule because he wanted to eliminate the right of consent in response to lobbying pressure from the insurance and hospital industries.

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<sup>58</sup> The preamble to the Original Rule illustrates this exemption with the following example: “...a covered provider that provides consultation services to another provider without seeing the patient would have an indirect treatment relationship with that patient and would not be required to obtain the patient’s consent to use protected health information about the patient for the consultation.” 65 Fed. Reg. at 82,510/1.

<sup>59</sup> The Court in that case expressly extended the privilege to “licensed social workers in the course of psychotherapy.” Jaffee v. Redmond, 518 U.S. at 16, 116 S. Ct. at 1931. Such individuals are often involved in the counseling provided to hospice patients.

Defendant also failed to consider significant alternatives that were much more consistent with the facts and findings contained in the administrative record and the major goals of the Privacy Rule that HHS had identified. For example, two of the Plaintiffs in this case submitted comments stating that, if Defendant found that the alleged problems could not be resolved under the Original Privacy Rule, they could be addressed through specific minor modifications that would preserve the right of consent. Comments of the American and NCMHPC, p.11. App. V. Consistent with Defendant's past statements to the public and Congress that he desired a, "patient oriented," approach that would allow citizens, "more control," over their health care information, Plaintiffs suggested that any change start from the well-established premise that consumers do not want their health information used or disclosed routinely without their consent. Thus, as Plaintiffs pointed out, the inquiry in the "first encounter" situations should be whether there is a way to ascertain what the patient would want. The clearest indication of the patient's desires would be a physician's order. A pharmacist cannot dispense drugs without an order from a physician, and a hospital cannot schedule a surgical procedure without such an order.<sup>60</sup> So Plaintiffs suggested that Defendant consider adding the following language to 164.506(a)(3)(C), the exception to consent for, "substantial barriers": "The individual's consent to receive treatment will be inferred by the receipt of a physician's order for care until such time as written consent can be obtained." Comments of the American and NCMHPC, at 12. This minor expansion of the "substantial barriers" exception would appear to resolve all of the operational problems identified by Defendant that allegedly interfered with "timely access" to health care.

Defendant does not appear to have seriously considered this rather obvious and simple alternative. See 67 Fed. Reg. at 53,212/1. Defendant merely states that, "[t]he suggestion to allow certain uses and disclosures prior to first patient encounter would not address concerns of tracking consents, use of historical data for quality purposes, or the concerns of emergency treatment providers." 67 Fed. Reg. at 53,212/2. However, none of these issues relate to the timely access to health care concern that Defendant indicated activated his decision to amend the rule. Further, Defendant never explained why the

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<sup>60</sup> These were two other, "operational problems," Defendant indicated were brought to his attention. 67 Fed. Reg. at 53,209/2.

“tracking” of consent for use and disclosure of health information to determine whether they are still in effect was any more difficult than tracking the consents that are still required for treatment. Defendant also ignored the fact that such “tracking” of consents does not seem to be an insurmountable problem in half the nation’s states that require consent or for practitioners who, over the past 2,500 years, have adhered to such a requirement in their ethical standards of practice.

With respect to the need for historical data for quality purposes, Defendant never explained why “de-identified” data could not be used as some Plaintiffs suggested.<sup>61</sup> Comments of the American and NCMHPC, at 15. App. V. With respect to emergency treatment providers, HHS had already indicated in the preamble to the Original Rule that “[w]e intend covered health care providers that legally provide treatment without the individual’s consent to that treatment to be able to use and disclose protected health information resulting from that treatment to carry out treatment, payment and health care operations without obtaining the individual’s consent for such use and disclosure.” 65 Fed. Reg. at 82,510/3. Consistent with that stated intent, Plaintiffs suggested that the exception to consent for emergency services at 164.506(a)(3)(i)(A) could be revised to provide that consent would not be required, “In emergency treatment situations where prior consent cannot be reasonably obtained prior to treatment.” As Plaintiffs pointed out, this is consistent with current practice and probably would not erode the patient’s trust in the health delivery system.

In the basis and purpose statement to the Amended Rule, Defendant noted that some commenters pointed out that eliminating the right of consent left individuals with no control over their health information and that the notice of privacy practices was “meaningless” if individuals have no right to withhold consent since they would have no power to negotiate a consent process that fits their needs. 67 Fed. Reg. at 53,213/1 and 53,213/3. Defendant responded that he disagreed; however, his explanation does not deny the essential allegation, but rather, takes the position that individuals had no negotiating power under the Original Privacy Rule either. *Id.* at 53,213/3. He stated that

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<sup>61</sup> None of the Privacy Rule’s requirements are triggered unless the health information at issue is “identifiable.” 45 CFR 164.502(a) and 164.514(a). Defendant has stated that, “[t]he Department continues to encourage covered entities to use de-identified information wherever possible.” 67 Fed. Reg. at 53,214/1.

the commenters may not understand the consent process under the Original Rule, and explained the patient's options under the two rules as follows: According to Defendant, a patient who disagreed with the covered entity's information practices under the Original Rule "could withhold consent and not receive treatment, or could sign the consent form and obtain the treatment despite concerns about the information practices." 67 Fed. Reg. at 53,213/3. Under the Amended Rule, according to Defendant, the patient who disagrees with the covered entity's information practices can choose not to receive treatment from that provider, or can obtain treatment despite the concerns. *Id.* According to Defendant, "[t]he result, for the patient, is the same." Unfortunately, it appears to be Defendant who does not understand his own rules and the agency's prior interpretations.

First, the language of the consent provision in the Original Rule does not prohibit a provider from furnishing services to an individual if the individual does not sign a consent form. Rather, it states that a provider may not use the individual's health information for routine purposes without obtaining the individual's consent. 45 CFR 164.506(a). Thus, an individual confronted with a consent form that he felt was broader than necessary could refuse to sign it and negotiate a revision of the form with the provider (e.g., the individual might agree to the use and disclosure of orthopedic information needed to set his or her broken leg, but not consent to the use and disclosure of his or her psychiatric records). The provider could then apply his or her professional judgment to decide whether sufficient health information was being disclosed in order for the specific treatment to be furnished.

Second, as has been the case traditionally, individuals and providers had the flexibility under the Original Rule to negotiate a consent that fits their needs and circumstances. As HHS noted in the preamble to the Original Rule, the covered entity would have to determine which of the routine uses to include in the consent: "use and/or disclosure; treatment, payment, and/or health care operations." 65 Fed. Reg. at 82,511/3. As HHS noted, the consent requirement, "only applies to the extent the covered provider uses and discloses protected health information." (emphasis supplied) 65 Fed. Reg. at 82,512/1. The preamble states, for example, that if the covered entity conducted all of its health care operations with its own workforce, it would not need to obtain consent for disclosure for that purpose and, "may choose to obtain consent only for uses, not

disclosures, of protected health information to carry out treatment, payment and health care operations.” Id.

The preamble also noted that, “[i]f an individual pays out-of-pocket for all services received from the covered provider and the provider will not disclose any information about the patient to the third party payor, the provider may choose not to obtain the individual’s consent to disclose information for payment purposes.” HHS concluded, “[i]n order for a covered provider to be able to use and disclose information for all three purposes, however, all three purposes must be in the consent. (emphasis supplied) Id.

HHS also gave another example that illustrates the flexibility permitted under the consent process in the Original Rule. In that example, HHS stated that if a physician received a request for a patient’s medical record from a nursing home and the physician had obtained a consent to disclose information for treatment, “but the consent obtained by the physician excludes [genetic] information,” the physician may not disclose the individual’s genetic information without getting a new consent that encompasses that information. 65 Fed. Reg. at 82,512/3. This explanation clearly shows that the Original Rule permitted individuals to retain the power to shape consents to cover the health information that they desired to disclose and to have it used in accordance with their wishes.

Unfortunately, Defendant’s description of the Amended Rule is also inaccurate. He implies that an individual could protect the privacy of his or her health information by simply choosing not to receive treatment from that provider. In fact, the individual’s health information already in his or her medical record can be used and disclosed under the Amended Rule regardless of the action taken by individual. The provider can use and disclose the information if the patient chooses to receive or not to receive services and even if the individual never obtains services again from any provider. Even worse, due to the Rule’s retroactivity, the provider can use and disclose virtually all health information from throughout the individual’s life even if it was created or received prior to the Amended Rule’s compliance date and even if the individual seeks no further services from that provider. Defendant’s overly rigid interpretation of the Original Rule appears

to be both unnecessary and inaccurate while his interpretation of the Amended Rule is simply inaccurate.

Defendant maintains that, under the Amended Rule, individuals will have the opportunity to, “discuss privacy practices and concerns with providers.” 67 Fed. Reg. at 53,211/1. As the commenters noted, however, such opportunities are meaningless when individuals and patients have no right to control the use and disclosure of their health information. Moreover, the Amended Rule gives covered entities permission to use and disclose personal health information even if the patient does not seek any other services and, therefore, does not receive a notice of privacy practices. By contrast, HHS previously determined that having a right of consent would give individuals, “[t]he ability to negotiate restrictions or otherwise have a meaningful discussion,” with providers about their health privacy. 65 Fed. Reg. at 82,474/1.<sup>62</sup>

So, the rights of individuals under the Original and the Amended Privacy Rule are dramatically different. Under the Original Rule, the personal health information of an individual could not be used or disclosed for routine purposes without his or her consent. An individual’s health information that was created or received in the medical record prior to the April 14, 2003 compliance date could be used and disclosed in accordance with consents signed prior to April 14, 2003 and new consents obtained after the April 14 compliance date. 45 CFR 164.506 and 164.532. Those consents could be negotiated and tailored to the wishes and needs of the individuals and the providers. If a provider refused to negotiate a consent that met the individual’s wishes, the individual could seek services from another provider with the “peace of mind” that his or her information would only be used and disclosed for routine purposes in accordance with his or her permission.

Under the Amended Rule, by contrast, the individual has no control over the uses and disclosures of his or her health information for routine purposes. The individual may change providers or avoid seeking health care altogether, but his or her health information is still subject to use and disclosure without his or her permission and over

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<sup>62</sup> The notices received by Plaintiffs show that the Amended Rule permits little, if any, opportunity for negotiation or meaningful discussion. Typically covered entities are informing patients that the covered entities have a new federal right to use and disclose personal health information for routine purposes, and there is no opportunity for objection or discussion about what the patient wants. See App. III.

his or her objection. Paying for services out of pocket offers no privacy protection because use of information for “health care operations” is not limited to information necessary for payment. Even avoiding services altogether confers no protection for information already in the medical record.

Accordingly, all of the measures that HHS found that individuals have typically taken in the past to protect their health information privacy are negated by the Amended Rule. The only power the individual retains to protect his or her health privacy under the Amended Rule is to avoid seeking health care or avoid disclosing information to his or her practitioner, and even these measures do not protect the privacy of information that has already been disclosed. This is precisely the result which HHS previously found that the Privacy Rule was intended to prevent. 65 Fed. Reg. at 82,467/3.

Defendant also contends that the elimination of the right of consent is consistent with a newly stated goal to make changes that, “simplify rather than add complexity to the Rule.” 67 Fed. Reg. at 53,210/3. Defendant, however, never reconciled that statement with the finding in the Original Rule that a certain amount of complexity is necessary in order to, “track current practices,” and to give individuals the ability to exercise some control over their health information. 65 Fed. Reg. at 82,472/1.

Defendant also stated that the Department, “reviewed State laws,” in deciding whether to eliminate the right of consent, however, he only found one state law to be “[o]f note,” and that was the California Confidentiality of Medical Information Act, Cal. Code section 56. 67 Fed. Reg. at 53,210/3.<sup>63</sup> According to Defendant, the California statute permits health care providers and health plans to disclose health information for treatment, payment, and, “certain types,” of health care operations without individual consent, and a 1999 survey by the California HealthCare Foundation found that, “consumers in California did not have greater concerns about confidentiality than other health care consumers.” This was true, according to Defendant, with respect to the level of trust individuals had for both providers and health plans. 67 Fed. Reg. at 53,210/3. The actual State statute and survey results reveal a significantly different picture.

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<sup>63</sup> Defendant thereby ignored HHS’ prior finding that half of the states have medical privacy consent statutes and many require consent under common law principles. 65 Fed. Reg. at 82,473/1. Defendant also ignored the Supreme Court’s finding that all 50 states and the District of Columbia have enacted some form of psychotherapist-patient privilege law. Jaffee v. Redmond, 581 U.S. at 12, n.11, 116 S. Ct. 1929, n. 11.

First, the California statute cited by Defendant establishes a general rule that no provider, health service plan, or contractor shall disclose medical information regarding a patient or enrollee, “without first obtaining an authorization, with certain exceptions.” Cal. Civil Code, section 56.10(a). So the “default position” under the California statute is that an individual’s permission is required for disclosure of health information, while the “default” position under the Amended Rule is that an individual’s health information may be both used and disclosed for routine purposes without the individual’s permission.

Second, the California statute requires an individual’s permission to be obtained by health care service plans and contractors as well as direct treatment providers, while the Amended Rule confers blanket federal regulatory permission on all covered entities and their business associates to use and disclose health information without regard to the individual’s wishes. *Id.*

Third, the exceptions to the general rule under the California statute requiring permission do not include many of the activities included under the definition of, “health care operations,” in the Amended Rule such as business planning and development, business management and general administrative activities including customer service, the sale, transfer, merger or consolidation of the organizations and the due diligence related to such potential transactions. Compare Cal. Civil Code, section 56.10(c) and 45 CFR 164.501 (amended). Thus, the California statute would appear to offer more protection for health information privacy than the Amended Privacy Rule. In any event, the California law is hardly an analogue to the Amended Rule as Defendant implies.<sup>64</sup>

Furthermore, the lead conclusion from the California HealthCare Foundation study on which Defendant relied was that, “Americans trust their doctors and hospitals with confidential medical information, but fear disclosure when it is handled and stored by private health insurance plans and others.” (emphasis supplied) Americans Worry About the Privacy of Their Computerized Medical Records, Press Release California HealthCare Foundation (January 28, 1999). App. VI. The survey also found that, “there is...a pervasive distrust of private and government health insurers to keep personal information confidential.” Thus, the Amended Rule authorizes the nearly unrestricted

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<sup>64</sup> To the extent that the California statutes, or other state statutes, do not protect the privacy of personal health information, federal law will be the sole determinant of whether citizens in those jurisdictions retain a right to medical privacy.

use and disclosure of personal health information by the very organizations that this study shows that Americans most distrust with their health information.

In addition, the study showed that the concern over the threat to medical privacy was high among both citizens of the United States generally and citizens of California. Over half of those surveyed in the United States (54%) and in California (52%) said that the shift from paper to computer-based record systems made it more difficult to keep personal medical information private and confidential. Some concerns were actually higher in California. For example, 18% of Californians said that they had done something out of the ordinary to keep medical information confidential while only 15% of individuals nationally said they had taken such action. Nationally 55% of those surveyed worried about hackers breaking into computerized medical information systems while 58% of Californians expressed that worry. Among U.S. adults, 18% believed that their health information had been improperly disclosed, while 20% of California adults held that belief. Seven percent of citizens nationally said that they had suffered personal embarrassment or harm as a result of an improper disclosure of their health information while 9% of Californians said they had suffered such damage from a violation of their medical privacy. Among U.S. adults, 38% of those reporting a breach of their medical privacy had taken one or more steps to protect themselves while 44% of such California adults had taken comparable action.

It is surprising that Defendant would cite the January 1999 California HealthCare Foundation study to support his elimination of the right of consent because, when asked to rate the safeguards that would be the most effective in protecting medical privacy, 44% of Americans generally and 49% of Californians specified, “requiring someone’s permission to release personal information.” Defendant’s reliance on this study is additionally surprising because this same study was cited by HHS in the preamble to the Original Rule as support for strong privacy protections, including the right of consent. 65 Fed. Reg. at 82,468/1. Accordingly, Defendant’s reversal of position would seem to be a classic example of a situation where the decision runs counter to the evidence in the record, and the explanation provided is so implausible that it cannot be ascribed to a difference in view or the product of agency expertise.

Accordingly, the administrative record shows that Defendant has not come close to rebutting the presumption that his agency's settled course of behavior represents the best way of carrying out the policies that the agency itself has identified as being given priority by Congress.<sup>65</sup> As the Court in Motor Vehicle noted, agencies must be given latitude to adapt their rules to the demands of changing circumstances but, "the forces of change do not always or necessarily point in the direction of deregulation." 463 U.S. at 42, 103 S. Ct. at 2866. And as the court in Action on Smoking and Health observed, "[a] general desire for a bare minimum of regulation cannot justify rejecting specific regulatory proposals." 699 F.2d at 1217. The Amended Privacy Rule revoking the time-honored right of consent for the use and disclosure of personal health information deserves the same fate as the ill-considered rules that sought to eliminate airbags as a safety feature in automobiles and to permit smoking on airplanes.

#### **6. Defendant Failed to Consider The Broader Significance of Medical Privacy**

As HHS concluded, personal privacy is a "fundamental right," and medical privacy in particular, is essential for high quality health care. 65 Fed. Reg. at 82,464/1 and 82,467/2. The failure to preserve the right of law-abiding individuals to control and protect the privacy of their personal health information also can undermine our system of government.

The country's recent history is strewn with examples of public officials and private citizens attempting to use personal health information to damage individuals for political gain. For example, HHS cited a case in the basis and purpose statement to the Original Privacy Rule where a candidate for Congress nearly had her campaign derailed when newspapers disclosed that she had sought psychiatric treatment after a suicide attempt. 65 Fed. Reg. at 82,468/2. Defendant failed to consider the adverse impact of the

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<sup>65</sup> As this Circuit has held, agency interpretations of statutes issued contemporaneously with statutes are entitled to greater deference. Madison v. Resources for Human Development, Inc., 233 F.3d 175, 187 (3d Cir. 2000) citing Skidmore v. Swift, 323 U.S. 134, 65 S. Ct. 161 (1944) and more recent Supreme Court decisions. Thus, in this case, HHS' interpretation in 2000 of the privacy rights required by HIPAA is entitled to greater deference than Defendant's reinterpretation of that requirement in 2002.

Amended Rule on quality government in the context of this and other examples from the country's recent history.

During the Democratic presidential primaries in 1960, Senator Lyndon Johnson reportedly contacted future President John Kennedy's physician to see if he could confirm rumors that the candidate suffered from Addison's disease, so that he could block Mr. Kennedy's nomination as the Democratic candidate.<sup>66</sup>

One author and researcher has recently noted:

"As we know now, Kennedy feared that his Addison's disease, colitis, back troubles and prostatitis would be used against him in the 1960 campaign. More to the point, he worried that disclosure of his repeated hospitalizations in the 1950s and his reliance on steroids to combat the debilitating effects of Addison's disease and on antispasmodics, painkillers, testosterone, antibiotics and sleeping pills to help him cope with collateral problems would almost certainly block him from becoming president...Looking backward from today, we can conclude that full disclosure of Kennedy's ailments would, as he believed, have barred him from the White House. (emphasis supplied) "An Unfinished Life", p. 704-705.

Only a year ago, Congress solicited testimony on the implications of failing to permit individuals to protect the privacy of their genetic information at a time when genetic testing is becoming more accurate and commonplace. In response to a question about whether legislation is needed to prohibit discrimination based on genetic information, a physician-witness responded:

"I think it's absolutely critical. In my practice, I have several people who are very worried about getting Alzheimer's disease because they have a parent with Alzheimer's disease, and they will not get the testing, even though this would be very important information for themselves and taking care of themselves, because they understand, having already been discriminated against for having a mental illness, you know, what that would mean for employment and insurance in the future, and for all of their other close family relatives, close relatives.

And so I don't think that the impact of protecting or not protecting privacy is theoretical. That's what I am here to tell you....

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<sup>66</sup> "If Johnson had known the full story of Jack's poor health, he would undoubtedly have leaked it to the press. But the Kennedy's had managed largely to keep Jack's health problems a secret." R. Dalleck, "An Unfinished Life, John F. Kennedy 1917-1963, p. 261 Little, Brown, and Co. (2003).

The chilling effect is real I'm here to tell you. It's a big factor. And think about the impact on the person, the course of their therapy, worrying if they're going to lose their mind.

And if we think about it, this is truly going to be an election issue. Suppose we had known that Ronald Reagan had a risk of Alzheimer's, a genetic risk of Alzheimer's disease, would he have been elected President? I mean, I think these health issues, the privacy of health information, is going to become—and genetic information—is going to really become critical for the leaders of our country.” (Emphasis supplied)

Testimony of Deborah C. Peel, M.D., “Privacy Concerns Raised by the Collection and Use of Genetic Information by Employers and Insurers,” Hearing before the Subcommittee on the Constitution, Committee on the Judiciary, House of Representatives, 2d Sess. Serial No. 100, pp. 106-108 (September 12, 2002)<sup>67</sup>

Thus it is quite possible and, according to the above statements, even probable that two of the country's most popular and influential presidents in modern history would not have been elected if they had been unable to protect the privacy of their personal health information.

History shows that the failure to provide strong privacy protections for health information will result in its inevitable abuse. On April 16, 1973, Watergate Prosecutor Earl Silbert gave a note to Assistant Attorney General Henry E. Petersen in Daniel Ellsberg's trial on the disclosure of the Pentagon Papers which read: “This is to inform you that on Sunday, April 15, 1973, I received information that at a date unspecified, Gordon Liddy and Howard Hunt burglarized the offices of a psychiatrist of Daniel Ellsberg to obtain the psychiatrist's files relating to Ellsberg.” D. Ellsberg, “Secrets: A Memoir of Vietnam and the Pentagon Papers,” at p. 444-445, Viking Press (2002). The burglary actually occurred on September 3, 1971, over the Labor Day weekend, almost exactly 32 years ago.

In a meeting on June 30, 1971 between President Nixon, Attorney General John Mitchell and Henry Kissinger, the following exchange reportedly took place:

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<sup>67</sup> As noted, the rapid developments in the area of genetic testing was one of the reasons cited in the basis and purpose statement of the Original Rule for finding a need for stronger medical privacy protections. 65 Fed. Reg. at 82,466/2.

*“President: We’ve got to get him...Don’t worry about his trial. Just get everything out. Try him in the press. Try him in the press. Everything, John, that there is on the investigation, get it out, leak it out. We want to destroy him in the press. Press. Is that clear?”*

*Kissinger and Mitchell: Yes.”*

“Secrets,” at 432.<sup>68</sup>

At his sentencing hearing after pleading guilty to authorizing the break-in at the office of Dr. Ellsberg’s psychoanalyst, former White House official Egil Krogh explained the purpose of the operation:

“Primary, of course, was preventing further disclosures by Dr. Ellsberg and putting an end to whatever machinery for disclosure might have been developed. It was also thought, particularly by E. Howard Hunt, that the sought information could be useful in causing Dr. Ellsberg himself to disclose his true intentions. Finally, there is the point that has been most stressed in the current investigative process—the potential use of the information in discrediting Dr. Ellsberg as an anti-war spokesman....

To discredit Dr. Ellsberg would serve to discourage others who might be tempted to emulate him in disclosing information. It would also make him less able to mobilize opposition to President Nixon’s chosen Vietnam policy. The freedom of the President to pursue his chosen foreign policy was seen as the essence of national security.” “Secrets”, at 441.<sup>69</sup>

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<sup>68</sup> And on July 1, 1971, President Nixon, reportedly made the following statement to H.R. Haldeman, Charles Colson and Robert Ehrlichman:

“The difficulty is that all the good lawyers around here...they’re always saying, well, we’ve got to win the court case through the court. We’re *through* with this sort of court case. It’s our position — I don’t want that fellow Ellsberg to be brought up until after the election. I mean, just let — convict the son of a bitch *in the press. That’s the way it’s done...*”

“Secrets,” at 435.

<sup>69</sup> President Nixon had the following instructions for Acting Attorney Richard Kleindienst on April 25, 1971 with respect to the explanation that was to be given by the government to the judge in Daniel Ellsberg’s trial:

The Amended Privacy Rule coupled with the provisions of HIPAA that facilitate the nationwide storage and transmission of personal health information make it far more likely that personal health information will be used to damage individuals and corrupt the political process. This is because the Amended Rule permits and authorizes the routine use and disclosure of a virtually unlimited range of past and future personal health information for an unlimited number of times without the knowledge or permission of the individual, it requires no accounting for those disclosures, and it does not require basic security measures to be implemented. Under the Amended Rule, if a president wanted to gain access to a citizen’s psychiatric records, he need not resort to “plumbers” using crow bars — he need only rely on “covered entities” using computers.

**C. Defendant Failed to Provide Adequate Notice of the Proposed Reversal of Policy**

Defendant also failed to provide the public with adequate notice of the issues affected by his proposal to eliminate one of the core principles of the Original Privacy Rule. Defendant thereby violated the notice requirements of the Administrative Procedure Act, 5 U.S.C. 553. In the Notice of Proposed Rulemaking for the Amended Rule, Defendant summarized the developments that led the Department to include the right of consent in the Original Rule rather than omitting consent as initially proposed. Defendant summarized public reaction the initial proposal and the Department’s response as follows:

The Department received a strong public response opposing this proposal. Health care providers and patients argued that consent provides individuals with a sense of control over how their information will be used and disclosed, is a current practice of many health care providers, and is

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“Let me say one other thing. I don’t know how you can get this to the judge, but I think it’s very important for him to know that this is a national security investigation of the highest importance. It really is, you see...you know that and I know it.”

“Secrets” at p. 448

expected by patients. Providers explained that they would face an ethical conflict from a prohibition on obtaining consent. The consent requirement for direct treatment providers was a direct response to these comments.” (emphasis supplied) 67 Fed. Reg. at 14,779.

Thus, Defendant understood that three key issues raised in the strong response in favor of a right of consent were: (a) control, (b) current practice and (c) patient expectations.

In proposing to reverse the Department’s position and eliminate the established regulatory right of consent, Defendant did not mention or describe any of those issues or the proposed action’s impact on them. Instead, Defendant merely stated that he was proposing to make consent, “optional,” in order to enhance access to needed health care. Defendant provided the following explanation of his proposed action:

Accordingly, the Department proposes an approach that protects privacy interests by affording patients the opportunity to engage in important discussions regarding the use and disclosure of their health information, while allowing activities that are essential to provide access to quality health care to occur unimpeded. Specifically, the Department proposes to make optional the obtaining of consent to use and disclose protected health information for treatment, payment or health care operations on the part of all covered entities, including providers with direct treatment relationships. Under this proposal, health care providers with direct treatment relationships with individuals would no longer be required to obtain an individual’s consent prior to using and disclosing information about him or her for treatment, payment or health care operations. 67 Fed. Reg. at 14,780.

Defendant did not mention the impact his proposal would have the individual’s ability to control the use and disclosure of his or her health information or whether it was consistent with current practice and patient expectations.

Defendant made it even less likely that the public would understand the impact of his proposal on those issues by issuing a statement to the public seven days before the proposed rule appeared in the Federal Register which read as follows:

**HHS PROPOSES CHANGES THAT PROTECT PRIVACY, ACCESS TO CARE  
Revisions Would Enhance Federal Privacy Protections While Removing Obstacles  
To Care.**

HHS Secretary Tommy G. Thompson today proposed changes to HHS' health information privacy regulations to ensure strong privacy protections while correcting unintended consequences that threatened patients' access to quality health care. See HHS News Release (March 21, 2002) App. I.

Again, nothing in this press release would have alerted citizens that Defendant was proposing to eliminate their control over their health information for routine purposes or that his position was contrary to current practice, ethical standards and patient expectations.

The legislative history to the Administrative Procedure Act indicates that agency notice, "must be sufficient to fairly apprise interested parties of the issues involved." (emphasis supplied) MCI Telecommunications Corp. v. Federal Communications Commission, 57 F.3d 1136, 1141 (D. C. Cir. 1995) citing, Senate Judiciary Committee, Administrative Procedure Act, S. Rep. No. 752, 77<sup>th</sup> Cong., 1<sup>st</sup> Sess. 14 (1945). The purpose of requiring such a notice is to (a) "reintroduce public participation and fairness" to the rulemaking process and (b) assure that the "agency will have before it the facts and information relevant to a particular administrative problem." Id. See also, Simmons v. Interstate Commerce Commission, 757 F.2d 296, 300 (D.C. Cir. 1985).

Furthermore, someone reading the summary of the proposed rule in the Federal Register is likely to have been misled by the following statement:

"The purpose of this action is to propose changes that maintain strong protections for the privacy of individually identified health information while clarifying misinterpretations, addressing the unintended negative effects of the Privacy Rule on health care quality or access to health care, and relieving unintended administrative burden created by the Privacy Rule." 67 Fed. Reg. at 14,776.

Again, the Summary contains no mention of the impact on the core issues of control, current practice, or patient expectations. The Summary even fails to mention the right of consent or the fact that this right vested in all Americans when the Original Rule became effective on April 14, 2001. As one court has held, the Administrative Procedure Act does not permit an agency to introduce a proposed rule in such a, “crabwise,” fashion. McLouth Steel Products Corp. v. Thomas, 838 F.2d 1317, 1323 (D. C. Cir.1988). For this reason as well, the elimination of the right of consent in the Amended Privacy Rule must be set aside for failure to comply with the requirements of the Administrative Procedure Act.

**D. The Amended Privacy Rule Is Invalid Because It Exceeds the Authority Granted By Congress Under HIPAA**

As previously demonstrated, HHS determined when it issued the final Original Privacy Rule that the authority granted by Congress only permitted it to issue regulations that, “enhanced,” the privacy and security for personal health information as the standards facilitating greater use of electronic technology to store and transmit health information went into effect. 65 Fed. Reg. at 82,463/2; 82,469/3 and 82,474/2 Defendant has violated that mandate by reducing personal medical privacy protections and failing to require basic security measures to be put into place by covered entities on a timely basis.

Furthermore, Defendant has issued a retroactive rule in violation of HIPAA and the Administrative Procedure Act. In the Amended Privacy Rule, Defendant has eliminated any right of an individual to stop the use and disclosure of his or her personal health information and has granted regulatory permission for covered entities and their business associates to use and disclose that information. He has also made it clear that this action applies, “to any protected health information held by a covered entity whether created or received before or after the compliance date,” of April 14, 2003. (emphasis supplied) 67 Fed. Reg. at 53,211/3. Clearly, the right of consent vested in all Americans as a regulatory matter on the April 14, 2001 effective date of the Original Rule. Plaintiffs also believe that they have a Constitutional right to privacy of their health information

that predated the Original Rule (*see infra*). In any event, HHS has found that it is a, “common belief,” resting in part, on professional codes of conduct that a person’s health information cannot be used and disclosed for routine purposes without his or consent. 65 Fed. Reg. at 82,472/3. Further, Defendant acknowledged in the Original Privacy Rule that individuals have disclosed health information prior to the compliance date under many types of limited consents and restrictions. 65 Fed. Reg. at 82,564/1. Yet, Defendant has sought to supplant whatever rights and duties that existed on the federal level with respect to medical privacy both prospectively and retroactively. All of that information, regardless of when it was created or disclosed is governed by the Amended Privacy Rule.

As the Supreme Court held in Bowen v. Georgetown University Hospital, 488 U.S. 204, 109 S. Ct. 468 (1988), a statute will not be construed to encompass the power to promulgate retroactive rules, “unless that power is conveyed by Congress in express terms.” 488 U.S. at 209, 109 S. Ct. at 472. There is no such expression of authority in HIPAA with respect to the privacy standards.

Indeed, the statute contains a converse intent. Section 1174(b)(1) provides that the Secretary cannot modify standards adopted under HIPAA more than once every 12 months. Any addition or modification is to be, “completed in a manner that minimizes the disruption and cost of compliance.” Section 1175(a)(3) provides that health plans are not to be required to comply with any standard or modification of a standard at any time prior to the compliance date. Section 1175(b) states that each person to whom a standard applies shall comply with it, “[n]ot later than 24 months” after the date the standard is adopted or established.” With respect to modifications of standards, the statute provides that the Secretary may set the compliance date, but must take into account the, “nature and extent,” of the modifications, and individuals cannot be required to comply with the modification, “earlier than the last day of the 180-day period beginning on the date such modification is adopted.” Section 1175(b)(2). Defendant has taken the position that these limitations on modifying standards apply to the privacy standards. 67 Fed. Reg. at 53,210/2. Thus, HIPAA appears to contemplate that standards will have a future effect only. Accordingly, there is no authority under HIPAA for retroactive rulemaking, and none can be implied.

Further, retroactive rulemaking is unlawful under the Administrative Procedure Act. See, Bowen v. Georgetown University Hospital, 488 S. Ct. at 204, 109 S. Ct. at 475, Scalia, J. concurring; Bowen v. Georgetown Univ. Hosp., 821 F.2d 750, (D.C. Cir. 1987). The APA permits the issuance of rules by an agency of “future effect” designed to implement, interpret or prescribe law. 5 U.S.C. 551(4). Thus, a rule that an agency may issue under the APA, “is a statement that has legal consequences only for the future.” 488 U.S. at 216, 109 S. Ct. at 476. Under the regime established by the APA, “an agency cannot act with retroactive effect without some special congressional authorization.” 488 U.S. at 224, 109 S. Ct. at 479. There is no such special authorization under HIPAA.

Retroactive rules are those that, “change what the law was in the past.” *Id.* at 221. The Amended Privacy Rule clearly does that. As HHS has determined, most people have disclosed personal health information to their physicians and practitioners with the reasonable expectation that the information would not be further used and disclosed further without their consent. Even if HHS were correct in assuming that prior to the Original Rule, “virtually no federal rules existed,” with respect to medical privacy (65 Fed. Reg. at 82,464), the Amended Privacy Rule now seeks to provide or change that law. Congress has not given Defendant any such authority.

## **E. The Amended Privacy Rule Violates Plaintiffs’ Constitutional Right to Privacy**

### **1. Issues and impact**

The Amended Privacy Rule raises two issues with respect to the constitutional right to privacy:

- a. Whether the Rule violates a constitutionally protected right for citizens, including plaintiffs, to decide whether their personal health information will be used and disclosed for routine purposes; and
- b. Whether the federal government has the constitutional authority to grant blanket “regulatory permission” to public and private individuals

and entities for the routine use and disclosure of individuals' health information regardless of their wishes and against their will.

In analyzing whether the Amended Privacy Rule violates plaintiff's rights under the Constitution, it is important to keep in mind what the Rule does:

- a. It establishes a nationwide federal policy that expressly permits the use and disclosure of virtually all health information for all individuals for routine purposes without notice of those disclosures or consent;
- b. It provides regulatory permission for private entities and individuals ("covered entities") to use and disclose an individual's personal health information regardless of the individual's wishes and against his or her will;
- c. It creates a presumption that virtually all personal health information will be used and disclosed unless the individual can assert some protection under state law to prevent it;
- d. It permits the use and disclosure of personal health information that was included in the individual's medical record prior to the effective and implementation dates of the Rule, even if the disclosure was originally made with the expectation and understanding that the information would not be further used and disclosed without the patient's consent;
- e. It permits the use and disclosure of even the most personal and sensitive health information about an individual's physical and mental health including information concerning genetic diseases and predispositions, abortion, procreation, fertility, sexual orientation and emotional disorders and treatments; and
- f. It allows this information about "virtually every American" to be used and disclosed to both the government and private entities.

## 2. **The Constitutional Right to Privacy**

The right to liberty is one of the core concepts of our system of government. Our Declaration of Independence recognizes liberty as one of three, “unalienable rights,” that belong to all persons.<sup>70</sup> The Declaration further notes that it is, “to secure these rights” that governments are instituted among individuals.

The preamble to our Constitution states that it was established to, among other purposes, “secure the Blessings of Liberty to ourselves and our posterity.”<sup>71</sup> Liberty is expressly protected by the Due Process Clauses of the Fifth and Fourteenth Amendments.<sup>72</sup> It is also protected by certain other amendments including the First, Fourth and Ninth Amendments. See Roe v. Wade, 410 U.S. 113, 152-153, 93 S. Ct. 705, 726-727 (1973).

The Due Process Clause protects substantive rights in addition to procedural rights beyond those recognized by the Bill of Rights and by the specific states. Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 849, 112 S. Ct. 2791, 2806 (1992). See also, Washington v. Glucksberg, 521 U.S. 702, 719, 117 S. Ct. 2258, 2267 (1997). The right to liberty under the Constitution establishes a “sphere,” or “realm,” or “zone,” of personal privacy which the government may not enter. Lawrence v. Texas, 539 U.S. \_\_\_, 123 S. Ct. 2472 (June 26, 2003); Planned Parenthood of Southeastern Pennsylvania, 112 S. Ct. at 2805; Thornburg v. Amer. College of

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<sup>70</sup> “We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights; that among these are Life, Liberty, and the Pursuit of Happiness.”

<sup>71</sup> “We the people of the United States in order to form a more perfect union, establish Justice, insure domestic Tranquility, provide for the common defense, promote the general Welfare, and Secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America.” Preamble, Constitution of the United States. This intent is poignantly reflected in a letter to the, “Citizens of Philadelphia,” on November 3, 1787 from a former officer of the Continental Army urging adoption of the Constitution: “Let not a set of aspiring despots, who make us slaves and tell us ‘tis our Charter, wrest from you those invaluable blessings, for which the most illustrious sons of America have fought and died — but exert yourselves, like men, like freemen and like Americans, to transmit unimpaired to your latest posterity those rights, those liberties, which have ever been so dear to you, and which it is yet in your power to preserve.” The Debate on the Constitution, Part One, 104, The Library of America (1993).

<sup>72</sup> “No person shall...be deprived of life, liberty or property, without due process of law,” Fifth Amendment. “No State shall...deprive any person of life, liberty, or property, without due process of law.” Fourteenth Amendment.

Obstetricians and Gynecologists, 476 U.S. 747, 772, 106 S. Ct. 2169, 2184; Roe v. Wade, 410 U.S. at 153, 93 S. Ct. at 726-27.<sup>73</sup>

While the boundaries of liberty and privacy rights protected by the Due Process Clause have not been clearly delineated, they include both the right to make certain decisions about personal matters and the right to avoid disclosure of personal medical information. Planned Parenthood of Eastern Pennsylvania, 112 S. Ct. at 2806; Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. 747, 772, 106 S. Ct. 2169, 2184-85; Whalen v. Roe, 429 U.S. 589, 599, 97 S. Ct. 869, 876 (1973); Sterling v. Borough of Minersville, 232 F.3d 190, 194 (3d Cir. 2000). This case involves both types of privacy rights — the right of individuals to decide for themselves whether their most personal and sensitive health information may be used and disclosed and the right to not have that information disclosed to others against their will.

### **3. Medical Privacy Is a Fundamental Right**

While the right to privacy protected by the Due Process Clause is not absolute, government action infringing on certain privacy rights is subject to heightened scrutiny if “fundamental rights” are involved. Roe v. Wade, U.S. 113, 155, 93 S. Ct. 705, 728. Rights recognized as fundamental are those that are, “implicit in the concept of ordered liberty,” or, “deeply rooted in the Nation’s history and tradition.” Washington v. Glucksberg, 521 U.S. 702, 719, 117 S. Ct. 2268; Lawrence v. Texas, 123 S. Ct. at 2489, J. Scalia dissenting. Those “fundamental” privacy rights often relate to marriage,

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<sup>73</sup> The approach taken by the Supreme Court in Due Process privacy cases has evolved from examining specific conduct to determine whether it should receive Constitutional protection to recognizing and applying a more general right to liberty that protects the “autonomy of self” for individuals to decide how to conduct their personal lives. See Lawrence, 123 S. Ct. at 2475 and Planned Parenthood of Eastern Pennsylvania, 505 U.S. at 851, 112 S. Ct. at 2807. Increasingly, the issue in Due Process cases has become, not whether individuals have a constitutionally protected right to specific activities (sodomy in Lawrence or abortion in Planned Parenthood of Eastern Pennsylvania), but whether substantive Due Process protects their right to make this type of personal decision about their lives without government interference. Compare the majority opinion in Lawrence, 123 S. Ct. at 2477, with the issue as framed in Bowers v. Hardwick, 478 U.S. 186, 190, 106 S. Ct. 2841 (1986) and in the dissent in Lawrence, 123 S. Ct. at 2488. Liberty guaranteed by the Due Process Clause, “is not a series of isolated points...[i]t is a rational continuum which, broadly speaking, includes freedom from all substantial arbitrary impositions and purposeless restraints...and which also recognizes...that certain interests require particularly careful scrutiny...” Planned Parenthood of Eastern Pennsylvania, 505 U.S. at 848, 112 S. Ct. at 2805, quoting Poe v. Ullman, 367 U.S. 497, 543, 81 S. Ct. 1752, 1777 (1961) Harlan J., dissenting.

procreation, contraception, family relationships, child rearing, and education.” Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 852, 112 S. Ct. 2807 (1992). The right to avoid disclosure of medical information, particularly to nongovernmental entities, has also been recognized as a “fundamental right” protected by the Due Process Clause. Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. 747, 772, 106 S. Ct. 2169, 2184-85; Whalen v. Roe, 429 U.S. 599, n. 23, 97 S. Ct. 869, 876 n. 23; Sterling v. Borough of Minersville, 232 F.3d 190, 196 (3d Cir. 2000); Gruenke v. Seip, 225 F.3d 290, 301 (3d Cir. 2000).

Thus, privacy rights that have been identified as “fundamental” under the Constitution include the right to make independent decisions about such highly personal and intimate matters as whom to marry, whether to use contraception, the ability to bear children, family relationships, child rearing and education, whether to have an abortion and the type of relationship to have with another person. See Supreme Court decisions summarized in Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 852, 112 S. Ct. at 2805-06; Roe v. Wade, 410 U.S. 113, 153, 93 S. Ct. 705, 726-27. See also, Lawrence v. Texas, 123 S. Ct. at 2476. Logically, the right to decide whether personal information reflecting those intensely personal decisions should be made available to members of the public on a routine basis must be included in the zone of fundamental privacy interests. Otherwise, individuals will be reluctant to exercise their choice with autonomy and without governmental interference. Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. 747, 772, 106 S. Ct. at 2182 (“It is inherent in the right to make the abortion decision that the right may be exercised without public scrutiny and in defiance of the contrary opinion of the sovereign or other third parties.”, quoting, J. Stevens concurring in Bellotti v. Baird, 443 U.S. 622, 99 S. Ct. 3035 (1979)). As noted, the Amended Privacy Rule permits and authorizes the routine use and disclosure of the most personal health information to private parties, including information about contraception, the ability to bear children, family relationships, child rearing and education, abortion, sexual orientation and many other personal issues.

Also, included among the fundamental liberty interests protected by substantive due process is the right to avoid disclosure of certain highly personal information and

particularly medical information.<sup>74</sup> This includes information about abortion, Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. 747, 772, 106 S. Ct. at 2182; prescription drugs, Whalen v. Roe, 429 U.S. at 593, 97 S. Ct. at 873; pregnancy tests, Gruenke v. Seip, 225 F. 3d 290, 302 (2000); and sexual orientation, Lawrence v. Texas, 539 U.S. \_\_\_\_ ; Sterling v. Borough of Minersville, 232 F.3d at 194.<sup>75</sup>

This Circuit has concluded that whether personal information will be afforded heightened protection under substantive due process can depend on the individual's expectation that the information will not be disclosed to members of the public ("the more intimate or personal the information, the more justified is the expectation that it will not be subject to public scrutiny." Sterling v. Borough of Minersville, 232 F.3d at 195). Of course, the Amended Privacy Rule permits and authorizes the use and disclosure of the most intimate and personal health information to, "covered entities," and their, "business associates," who are members of the public. 45 CFR 164.506.

There can be no doubt, based on the administrative record that most individuals have a reasonable expectation that their personal health information will not be used or disclosed without their consent. In the preamble to the Original Privacy Rule, Defendant found that:

- a. "All fifty states today recognize in tort law a common law or statutory right to privacy." 65 Fed. Reg. at 82464/1.
- b. "Some states, such as California and Tennessee, have a right to privacy as a matter of state constitutional law." Id.

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<sup>74</sup> As noted supra, The European Union in its Data Privacy Directive of 1995 also identified the right to privacy of highly personal information as one of the, "fundamental rights and freedoms," possessed by all natural persons. EU Data Privacy Directive at (2). App. VI. The recognition of such rights was found to be significant by the Court in Lawrence v. Texas, 539 U.S. \_\_\_, 123 S. Ct. at 2481.

<sup>75</sup> This Circuit reached its decision in Sterling while noting the Supreme Court's decision in Bowers v. Hardwick, 478 U.S. 186, 106 S. Ct. 2841 (1986) "gives us pause," and the dissent was based on the fact that Bowers concluded that there was no constitutionally protected right to privacy in sexual orientation. However, the Supreme Court expressly overruled Bowers in its decision in Lawrence v. Texas, holding that the right to decide on the type of consensual relationship to have with another person is protected under the Due Process right to liberty. 123 S.Ct. at 2484. Therefore, the basis for the dissenting opinion in Sterling has been eliminated.

- c. "...many people believe that individuals should have some right to control personal and sensitive information about themselves." 65 Fed. Reg. at 82464/2.
- d. "Many people believe that details about their physical self should not be generally put on display for neighbors, employers and government officials to see." 65 Fed. Reg. at 82,464/3.
- e. "The comments to the proposed rule indicate that many persons believe that they have a right to live in society without having these details of their lives (their physical and mental treatments) laid open to unknown and possibly hostile eyes." 65 Fed. Reg. at 82,465/3.
- f. "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 82,472/3
- g. "Our review of professional codes of ethics revealed partial, but loose, support for individuals' expectations of privacy." *Id.*
- h. "The comments and fact-finding indicate that our approach [recognizing a right of consent] will not significantly change the administrative aspect of consent as it exists today." 65 Fed. Reg. at 82,474/1.

None of these findings was disputed when Defendant issued the Amended Privacy Rule.

Approximately three months after Defendant published these findings (and three weeks before he put the Original Privacy Rule into effect), the Supreme Court issued its decision in Ferguson v. City of Charleston, 532 U.S. 67, 121 S. Ct. 1281 (March 21, 2001), holding that the use and disclosure of diagnostic tests on pregnant women for law enforcement purposes without their consent was a violation of the Fourth Amendment prohibition on warrantless searches. In reaching its conclusion, the Court made the following observation:

"The reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with non-medical personnel without her consent (citing

briefs from the American Medical Association and the American Public Health Association). In none of our prior cases was there any intrusion upon that kind of expectation.” 532 U.S. at 78, 1281 S. Ct. at 1288.

The Amended Privacy Rule issued by Defendant on August 14, 2002 clearly conflicts with that reasonable expectation by permitting and authorizing the widespread use and disclosure of, not just the results of specific diagnostic tests, but all tests and a virtually unlimited scope of personal health information to governmental and nongovernmental entities and individuals. Thus, the Amended Privacy Rule constitutes an intrusion on the privacy expectations of individuals beyond that in any case ever decided by the Supreme Court.<sup>76</sup>

Nor can it be doubted that the right to privacy of highly personal health information is “implicit in the concept of ordered liberty” or “deeply rooted in the Nation’s history and tradition.” In the preamble to the Original Privacy Rule, Defendant made the following findings:

- a. “Privacy is a fundamental right.” 65 Fed. Reg. at 82,464.
- b. “And few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material.” (quoting J. Smith, “Privacy Matters: In Defense of the Personal Life, 240-241 (1997)). 65 Fed. Reg. at 82,464/3.
- c. “...the 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’.” (quoting A. Cavourkian,

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<sup>76</sup> Defendant cannot rationally dispute that the threat and damage to Plaintiffs’ constitutional rights to medical privacy have occurred as a result of his actions. Plaintiffs’ medical privacy is being violated as direct consequence of Defendant’s elimination of the right of consent and Defendant’s grant of, “regulatory permission,” to covered entities and their business associates to the use and disclose Plaintiffs’ personal health information without their permission. See notices of privacy practices implementing the Amended Rule since the April 14, 2003 compliance date. App. III. Thus, there is an obvious “close nexus” between the express permission and authorization granted by Defendant under the Amended Privacy Rule and the violations of Plaintiffs’ rights to medical privacy. See Brentwood Academy v. Tennessee Secondary School Athletic Association, 531 U.S. 288, 295, 121 S. Ct. 924, 930 (2001). Moreover, the Amended Privacy Rule’s requirement that providers supply their patients with an explicit notice of the uses and disclosures permitted under the Rule regardless of their own privacy practices, makes physicians and other providers essentially agents of the government. For a similar finding with respect to a Pennsylvania abortion statute, see Thornburgh v. Amer. Coll. Of Ost., *supra*, 476 U.S. at 763, 106 S. Ct. at 2180.

D. Tapscott, “Who Knows: Safeguarding Your Privacy in a Networked World” Random House (1995).) 65 Fed. Reg. at 82,465/1.

The preamble to the Original Rule also relied on Justice Brandeis’ often quoted dissent, analyzing the basis for the privacy protections afforded by the Fourth and Fifth Amendment as follows:

“The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man’s spiritual nature, of his feelings, and his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone — the most comprehensive of rights and the right most valued by civilized men.” *Olmstead v. U.S.*, 277 U.S. 438, 478, 48 S. Ct. 564, 572 (1928) (emphasis supplied). 65 Fed. Reg. at 82,464/3.

According to Defendant’s findings in support of the Original Rule, “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.” 65 Fed. Reg. at 82,464/3. Yet, with limited exceptions, this is precisely the kind of information that Defendant’s Amended Rule permits private entities to use and disclose routinely without the individual’s permission. The Supreme Court reiterated this theme nearly 65 years later in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 852, 112 S. Ct. at 2807: “At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.”

Again, Defendant did not rebut, or even address, these findings when he reversed his policy recognizing the right of consent in the Amended Privacy Rule. The Amended Privacy Rule clearly eliminates the right of individuals to control when, how, to whom

and where their personal health information will be used and disclosed for routine purposes.<sup>77</sup>

Further, strong evidence of the right and reasonable expectation of individuals that their personal health information will not be used or disclosed for routine purposes without their consent comes from ethical standards that pre-date the founding of the nation. The Hippocratic Oath, dating from the Fifth Century B.C., is the basis for most standards of medical ethics today. It states, “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 no account may be spread abroad, I will keep to myself holding such things shameful to be spoken about.” “The Hippocratic Oath, Text, Translation, and Interpretation”, L. Edelstein, 3, The Johns Hopkins Press (1943).<sup>78</sup> As shown by the following examples, most major professional medical associations have incorporated this principle into their ethical standards and principles:

- a. “The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law.” Principles of Medical Ethics, E-5.05 Confidentiality, American Medical Association (2001).
- b. “A psychiatrist may release confidential information only with the authorization of the patient or under proper legal compulsion.”

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<sup>77</sup> Defendant expressly indicated that his intent in the Amended Rule was to eliminate the individual’s ability to control the use and disclosure of his or her health information for routine purposes when he distinguished the continued right to give or withhold “authorization” for non-routine uses and disclosures. Defendant stated, “The authorization requirement is intended to give the individual some control over uses and disclosures of protected health information that are not otherwise permitted or required by the Rule.” (emphasis supplied) 67 Fed. Reg. at 53,222/3.

<sup>78</sup> The Hippocratic Oath has been viewed as, “the nucleus of all medical ethics,” but some portions, such as the prohibition against assisting in abortion, have not been uniformly followed. See Roe v. Wade, 410 U.S. at 131, 93 S. Ct. at 716. The prohibition against the disclosure of health information does not appear to have been one of those provisions about which there is doubt or uncertainty. In 1993, 98% of all medical schools administered some form of the Oath, and all such forms appear to include a promise of health information privacy. R. Orr, M.D. and N. Pang, M.D., The Use of the Hippocratic Oath: A Review of 20<sup>th</sup> Century Practice and a Content Analysis of Oaths Administered in Medical Schools in the U.S. and Canada in 1993.” See also, Principles of Medical Ethics, American Medical Association. History, which notes that the Oath of Hippocrates, conceived in the Fifth Century B.C. is a, “living statement of ideals to be cherished by the physician,” and has remained, “an expression of ideal conduct by the physician.”

Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry, American Psychiatric Association, Section 4.2 (2001).

- c. “The psychoanalyst should never share confidential information about a patient with non-clinical third parties (e.g., insurance companies) without the patient’s, or in the case of a minor patient, the parent’s or guardian’s informed consent.” Principles and Standards of Ethics for Psychoanalysts, Standards Applicable to the Principles of Ethics for Psychoanalysts, IV. Confidentiality, section 2, American Psychoanalytic Association.
- d. “Social workers may disclose confidential information when appropriate with valid consent from a client or a person legally authorized to consent on behalf of a client.”  
“Social workers should not disclose confidential information to third-party payers unless clients have authorized such disclosure.” Code of Ethics, Ethical Standards, Social Workers’ Ethical Responsibilities to Clients, 1.07(b) and (h), National Association of Social Workers (1999).<sup>79</sup>

These and other professional codes of conduct were cited by Defendant when he issued the Original Privacy Rule that included recognition of the right of consent. 65 Fed. Reg. at 82,472.<sup>80</sup> While he elected to follow those ethical standards in the Original Rule, Defendant correctly noted that the codes, “do not have the force of law.” *Id.*

The preamble to the Original Privacy Rule further notes that: “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

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<sup>79</sup> The national organization that accredits most hospitals and many other health care facilities in the United States indicates that health care organizations are also to be guided by the principles of the Hippocratic Oath and, “must obtain proper authorization (consent) from the individual receiving care for the release of any personally-identifiable health information to any party other than the individual.” Protecting Confidentiality, Joint Commission on the Accreditation of Healthcare Organizations, 1 and 106-107 (2001).

<sup>80</sup> In fact, Defendant noted in the preamble to the Original Privacy Rule that the American Medical Association’s Code of Ethics provides 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.” 65 Fed. Reg. at 82,472/3.

training.” 65 Fed. Reg. at 82,472/3, quoting Patient Privacy and Confidentiality, at 14, Massachusetts Medical Society (1996).

The Amended Privacy Rule by contrast, permits and authorizes the use and disclosure of personal health information without permission, as a matter of law for, “health care operations,” which relate to, “the covered entity’s functions,” rather than to the patient’s clinical care. 65 Fed. Reg. at 82,490/2.

So when Defendant reversed the policy in the Original Rule recognizing the right of consent as essential to liberty and medical privacy, he established a nation-wide law that is inconsistent with one of the most fundamental principles of medical ethics. This had the effect of plunging individuals and health practitioners into confusion with respect to whether they should shape their conduct to fit what that law permits and promotes or what standards of medical ethics provide.<sup>81</sup>

Judging from the fact that many of the Notices of Privacy Practices make no mention of an opportunity for individuals to give or withhold consent for the routine use and disclosure of their health information, it would appear that in practice, Defendant’s new “law” is displacing a fundamental standard for liberty and quality health care which has been honored for 2,500 years. See App. III.

In addition, the Supreme Court has found that all 50 states and the District of Columbia have enacted into law some form of psychotherapist-patient privilege and that the, “reason and experience,” of the country supports such a privilege which cannot be waived, in routine cases without the approval of the patient. Jaffee v. Redmond, 518 U.S.1,12, 116 S. Ct. 1923, 1929-30 (1996).

Accordingly, there can be no doubt that the right to privacy for sensitive medical information under routine circumstances is a fundamental right which is well within the “zone of privacy” protected by substantive Due Process and is grounded in the nation’s

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<sup>81</sup> Such ambiguity itself threatens the right to liberty as one of the founding fathers noted: “The internal effects of a mutable policy are still more calamitous. It poisons the blessings of liberty itself. It will be of little avail to the people that the laws are made by men of their own choice, if the laws be so voluminous that they cannot be read, or so incoherent that they cannot be understood; if they be repealed or revisited before they are promulgated, or undergo such incessant changes that no man who knows what the law is to day can guess what it will be tomorrow. Law is defined to be a rule of action; but how can that be a rule, which is little known and less fixed?” Federalist Papers LXII, James Madison, The Debate on the Constitution, Part Two, 249, The Library of America (1993).

history and medical tradition. As the Supreme Court noted with respect to privacy in the marital relationship in Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 71, n. 10, 96 S. Ct. 2831, 2841, n. 10 (1976), “[w]e deal with a right of privacy older than the Bill of Rights, older than our political parties, older than our school system.” The information included in an individual’s medical record commonly includes every type of sensitive health information that is encompassed in the marital relationship. For that information to be made available for use and disclosure on a routine basis regardless of the individual’s wishes deprives individuals, including Plaintiffs, of a “venerable” right. Sterling v. Borough of Minersville, 232 F.3d at 195.

#### **4. The Amended Privacy Rule Does Not Further A Compelling Governmental Interest**

Where, as here, fundamental rights are involved, the Supreme Court has held that, “regulations limiting these rights may be justified only by a ‘compelling [governmental] interest.” Roe v. Wade, U.S. at 157, 93 S. Ct. at 728. See also, Planned Parenthood of Eastern Pennsylvania v. Casey, 505 U.S. at 871, 112 S. Ct. at 2817. Government regulation affecting fundamental personal rights and liberties must be, “narrowly drawn to prevent the supposed evil, ... and cannot be dealt with in an, ‘unlimited and indiscriminate’ manner.” Doe v. Bolton, 410 U.S. at 216, 93 S. Ct. at 760, Douglas J., concurring (quoting Cantwell v. Connecticut, 310 U.S. 296, 307, 60 S. Ct. 900, 905 (1940) and Sheldon v. Tucker, 364 U.S. 479, 490, 81 S. Ct. 247, 253 (1960)). As the Court noted 30 years ago:

“The right to seek advice on one’s health and the right to place reliance on the physician of one’s choice are basic to [Due Process] values. We deal with fundamental rights and liberties, which as already noted, can be contained or controlled only by discretely drawn legislation that preserves the ‘liberty’ and regulates only those phases of the problem of compelling concern.” Doe v. Bolton, 410 U.S. 179, 219-220, 93 S. Ct. 739, 761-762, Douglas J., concurring (1973).

Defendant's principal stated interest in eliminating the right of consent was to avoid compromising, "timely access to quality health care." 67 Fed. Reg. at 53,210. This interest hardly rises to the level of the states' interests in protecting existing and potential life in Roe, Doe, Danforth, and Thornburg, and the states' interests in those cases were not sufficiently compelling to override the individuals' liberty interests. Further, the compelling need for Defendant's action is highly doubtful in view of his concession that consent for the use and disclosure of health information has been required for years under the statutory or common laws of many states, by the ethical standards of most medical professions, and is a reasonable expectation of most Americans. Defendant fails to explain why this traditional right of consent for the use and disclosure of health information has not compromised timely access to quality health care in the past.

Defendant also acknowledges in the administrative record that he could have addressed the, "supposed evil[s]," asserted by some covered entities and preserved the general right of consent for individuals under routine situations but that he decided to reject that approach in favor of a, "global fix to the consent problems." 67 Fed. Reg. at 53,210/3. For example, the preamble to the Amended Privacy Rule states that:

"The Department could address these problems by adopting a single solution that would address most or all of the concerns, or could address these problems by adopting changes targeted to each specific problem that was brought to the attention of the Department...the options that the Department most seriously considered were those that would provide a global fix to the consent problems." (emphasis supplied) 67 Fed. Reg. at 53,210/3.

Defendant also acknowledged that, in fact, "[s]ome commenters provided global options," that would have preserved the core concept of consent for routine uses and/or disclosures. 67 Fed. Reg. at 53,210/3. Defendant rejected those options, however, because he, "[did] not believe that any would address all of the issues that were brought to the Department's attention during the comment period or would be the best approach for regulating in this area." 67 Fed. Reg. at 53,212/1. Defendant stated that this global approach was consistent with the, "basic goal of the Rule," to provide flexibility for, "covered entities." 67 Fed. Reg. at 53,212/2, 53,213/1. Defendant failed to analyze whether two or more of the targeted or global approaches could have been used to

address the asserted problems while preserving the right of consent. Defendant also failed to address the adverse effects that the Original Rule had found would occur if the right to medical privacy were not protected. See generally, “Privacy Is Necessary to Secure High Quality Health Care.” 65 Fed. Reg. at 82,467-68.

Accordingly, the preamble to the final Amended Privacy Rule demonstrates that Defendant did not seriously consider targeted approaches to the “supposed evils” proposed by commenters nor did he seriously consider adopting a combination of two or more of the proposed targeted or global approaches that would have addressed the alleged problems while preserving individuals’ fundamental right to medical privacy. Therefore the approach selected by Defendant was a “global fix” rather than the type of “narrowly drawn” regulation which was necessary, and possible, to avoid broadly eliminating the right to medical privacy for most individuals in routine situations. Defendant states that his approach, “is the only one that resolves the operational problems that have been identified in a simple and uniform manner.” 67 Fed. Reg. at 53,211/1. It is nearly always the case that broadly eliminating civil liberties is more efficient for those who owe duties as a consequence of those rights.

##### **5. The Amended Privacy Rule Imposes an Undue Burden on the Right to Medical Privacy**

The “compelling interest” test essentially prohibits any government efforts to influence decisions with respect to the exercise of “fundamental rights.” Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. at 874, 112 S. Ct. at 2820. The Supreme Court has found however, that where the government’s interest is, “important and legitimate,” and involves protecting existing or potential human life, it is appropriate to apply an, “undue burden,” test. 505 U.S. at 876-877; 112 S. Ct. at 2820-21. See also, Stenberg v. Carhart, 530 U.S. 914, 930, 120 S. Ct. 2597, 2609 (2000). According to the Court, “an undue burden is an unconstitutional burden.” 530 U.S. at 877, 112 S. Ct. at 2821. Regulations which do no more than establish a structure for a fundamental right to be freely exercised are permitted where the state has such an interest, but regulations even under such circumstances will be deemed unconstitutional

where they present, “a substantial obstacle,” to the individual’s ability to exercise the right. 530 U.S. 878, 112 S. Ct. at 2821.”<sup>82</sup>

The government’s interest in this case is not as “important or legitimate” as the interest of the states in protecting the health of the mother or the potential life of the fetus in Roe, Doe, Danforth, Thornburg and Planned Parenthood of Southeastern Pennsylvania, so the compelling interest test is appropriate for assessing the constitutionality of the Amended Privacy Rule. However, applying the “undue burden” test to the Rule reveals that it does not establish a structure for individuals to exercise their right to medical privacy. Rather, it entirely eliminates the right of individuals to make decisions about the use and disclosure of their health information for routine purposes and makes the opportunity for individuals to give or withhold consent entirely dependent upon the discretion of third parties. Thus, the Amended Privacy Rule fails this test of constitutionality as well.

As the preamble to the Amended Rule states, the decision-making right of the individual is, “replaced,” with, “regulatory permission for covered entities to use or disclose [an individual’s] health information for treatment, payment or health care operations [routine purposes].” 67 Fed. Reg. at 53,211/2. The regulatory language of the Amended Rule itself affirmatively grants covered entities the right to, “use or disclose protected health information for treatment, payment or health care operations,” without any structure or mechanism for the individual to protest or assert his or her right to decide whether the information should be used or disclosed. 45 CFR 164.506. Thus the, “purpose and effect,” of the Amended Rule does far more than present a substantial obstacle to the right of the individual to decide whether his or her health information can be used or disclosed; it entirely abrogates that right.

**6. Defendant Has Imposed Unconstitutional Restrictions on the Right to Medical Privacy**

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<sup>82</sup> Unnecessary health regulations that have the purpose or effect of presenting a substantial obstacle [to the exercise of a liberty right] impose an undue burden on that right.” Id.

In defense of his decision to eliminate the individual’s traditional right of consent, Defendant contends that the Amended Rule merely, “makes the obtaining of consent optional on the part of all covered entities.” 67 Fed. Reg. at 53,211/1.<sup>83</sup> Further, Defendant asserts that the Amended Rule retains the provision in the Original Privacy Rule affording a right of individuals, “to request restrictions,” on the use and disclosure of their health information. *Id.* The Rule clearly provides however, that covered entities have complete discretion to refuse to grant a request for restrictions from an individual. 45 CFR 164.522(a)(1)(ii). Finally, Defendant states that the Amended Rule, “strengthens the notice requirements to preserve the opportunity for individuals to discuss privacy practices and concerns with providers.” 67 Fed. Reg. at 53,211/1. None of these asserted options can obscure the fact that the Amended Privacy Rule prevents individuals from exercising a fundamental liberty right.

Conditioning the exercise of a basic liberty right on a third party’s approval has been invalidated repeatedly. In *Doe v. Bolton*, the Supreme Court struck down a Georgia law that conditioned a woman’s right to decide whether to have an abortion on the approval of a hospital abortion committee. 410 U.S. at 197-198, 93 S. Ct. at 749-750. The Court concluded that the interposition of the committee’s discretion was, “unduly restrictive of the patient’s rights and needs.” For similar reasons, the Court also struck down a provision that conditioned a woman’s decisional autonomy on the approval of two physicians licensed in Georgia. 410 U.S. at 198-199, 93 S. Ct. at 751.

In *Planned Parenthood of Central Missouri v. Danforth*, the Court invalidated a statute that conditioned a woman’s right to make a decision about abortion on obtaining the consent of her spouse. 428 U.S. at 69-70, 96 S. Ct. at 2841. The Court also invalidated a statutory provision that imposed a, “blanket provision,” requiring approval of a parent or person in loco parentis as a condition for an unmarried minor to elect to have an abortion. 428 U.S. at 74, 96 S. Ct. at 2843. According to the Court, there is no constitutional authority for a government to give a third party, “an absolute, and possibly arbitrary, veto,” over the decision of the patient.

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<sup>83</sup> The Amended Rule also gives covered entities, “complete discretion,” in designing the consent process. 67 Fed. Reg. at 53,211/2.

In Planned Parenthood of Southeastern Pennsylvania v. Casey, the Court invalidated a provision of the Pennsylvania statute that conditioned a woman's right to decide whether to have an abortion on spousal notification. Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. at 893-898, 112 S. Ct. at 2829-31. According to the Court, "The Constitution protects all individuals, male or female, married or unmarried, from the abuse of government power, even where that power is employed for the supposed benefit of a member of the individual's family." 505 U.S. at 898, 112 S. Ct. at 2831.

The discretion conferred on covered entities by the Amended Privacy Rule exceeds the "veto" power found constitutionally deficient in the above cases and is even more unduly restrictive of the exercise of a basic right to liberty. Under the Amended Rule, covered entities are given blanket permission to use and disclose virtually all of an individual's health information for routine purposes without any opportunity for the individual to express his or her views or concerns. Because a consent process and the opportunity to restrict the use and disclosure of health information is totally at someone else's discretion, the Rule affords third parties the very kind of absolute power to make arbitrary decisions which the Court has repeatedly found unconstitutional.

Nor do the notice requirements of the Amended Rule cure its constitutional defects. First, the opportunity that the notice purportedly gives the individual to, "discuss privacy practices and concerns," is a hollow opportunity at best since the individual has no power in these discussions to exercise his or her right to privacy.

Second, the notice that the Amended Rule requires all covered entities to provide, is designed to obscure and discourage any claim to medical privacy that the individual might otherwise wish to assert. The required notice must contain a, "header," which states that, "THIS NOTICE DESCRIBES HOW INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED..." 45 CFR 164.520(b)(1)(i). The notice must also contain, "A description, including one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for treatment, payment, and health care operations." 45 CFR 164.520(b)(1)(ii)(A) (emphasis supplied). So, regardless of the privacy practices that the covered entities actually decides to adopt, it must first and foremost provide a notice to each individual that his or her personal health information

may be used and disclosed for routine purposes without permission, as a matter of federal law.

The Supreme Court invalidated an analogous notice requirement in Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. at 761-763, 106 S. Ct. at 2179-80, that under the guise of facilitating, “informed consent,” sought, “to wedge the Commonwealth’s message discouraging abortion into the privacy of the informed-consent dialogue between the woman and her physician.” 476 U.S. at 762, 106 S. Ct. at 2179. In finding the requirement unconstitutional, the Court noted that it, “officially structures — as it was obviously intended to do — the dialogue between the woman and her physician,” and it required, “the physician to recite its litany ‘regardless of whether in his judgment the information is relevant to [the patient’s] personal decision.’” 476 U.S. at 763-764, 106 S. Ct. at 2180. According to the Court, the, “very rendition,” of such information when a patient is suffering from a life-threatening condition, “may be cruel as well as destructive of the physician-patient relationship.” 476 U.S. at 763, 106 S. Ct. at 2180.

Similarly in this case, the notice of privacy practices required by the Rule officially structures, as it was intended to do, the discussion of privacy practices between the patient and the physician and conveys the impression that the patient has no right to control the use and disclosure of his or her health information for routine purposes. There is no requirement that the notice inform the patient that a consent process is an option that he or she may request. Although Defendant contends that traditional ethical standards requiring consent, “retain their vitality,” under the Amended Rule, (67 Fed. Reg. at 53,212/3) there is no requirement for the notice to make the patient aware of those standards to counterbalance the permitted and authorized uses and disclosures. Not surprisingly, the notices currently being used make no mention of an optional consent process or the traditional ethical standards that require patient consent for the routine use and disclosure of personal health information. App. III.

Further, the notice requires the provider to recite the Rule’s litany of uses and disclosures that are permitted by federal law even if the provider wishes to provide a consent process for the routine use and disclosure of health information, and the patient unquestionably does not want his or her health information used or disclosed without

consent. As in Thornburg, the very rendition of the required notice is cruel and destructive of the physician-patient relationship (in the case of a mental health patient suffering from paranoia, for example).

**7. The Scope of Uses and Disclosures Authorized by the Amended Privacy Rule and the Lack of Adequate Security Violate Plaintiffs' Right to Medical Privacy**

The Supreme Court in Whalen v. Roe confirmed that the privacy of medical information is a fundamental right which, when significantly threatened by governmental action, can only be overridden by a compelling governmental interest. 429 U.S. at 599, 97 S. Ct. at 876 and 429 U.S. at 606, 97 S. Ct. at 880, Brennan J., concurring. See also, Sterling v. Borough of Minersville, 232 F.3d at 195. However, the Court determined that the New York State program at issue in Whalen did not pose a, “significantly grievous threat,” to trigger the heightened scrutiny of the compelling interest test. 429 U.S. at 601, 97 S. Ct. at 877. The state program in Whalen was limited to requiring physicians prescribing certain drugs to file a copy of the prescription with the state so that the information could be recorded in a centralized computer file in order to further the state’s “vital interest” in controlling the distribution of dangerous drugs. Id. at 600 and 876. As part of the basis for the conclusion that the privacy rights of individuals had not been significantly threatened by the program, the Court noted that (a) the limited information disclosed was not significantly different from that which was required to be disclosed under prior law, and those disclosures were not challenged; (b) state law prohibited disclosure of the information beyond a limited number of government officials unless it was subject to a judicial subpoena in a criminal proceeding; and (c) there was no evidence that judicial supervision of the disclosure of the information would not provide adequate protection.

Accordingly, the Court was careful to describe the issues it had, and had not decided as follows:

“We therefore need not, and do not, decide any question which might be presented by the unwarranted disclosure of accumulated private data [to the public] whether intentional or unintentional or by a system that did not contain comparable security provisions. We simply hold that this record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment.” 429 U.S. at 605-609, 97 S. Ct. at 879-880.

Justice Brennan provided his understanding of the decision in a concurring opinion which stated:

“Broad dissemination by state officials of such information,...would clearly implicate constitutionally protected privacy rights, and would presumably be justified only by a compelling state interest...Of course, a statute that did effect such a deprivation [by permitting disclosure of health information to the public] would only be consistent with the Constitution if it were necessary to promote a compelling state interest.” 429 U.S. at 607, 97 S. Ct. at 880.

The security measures which the Whalen Court found avoided a “significantly grievous threat” to medical privacy included the following:

1. Public disclosure of the individual’s identity was expressly prohibited by state statute and regulations, and willful violations were punishable as crimes. 429 U.S. at 594, 97 S. Ct. at 873-874.
2. A total of only 41 state employees had access to the information. 429 U.S. at 595, 97 S. Ct. at 874.
3. The forms were delivered to a receiving room and were removed only to permit the information to be put on a magnetic tape, and then the forms were returned to the receiving room where they were retained in a vault for five years and then destroyed. 429 U.S. at 594, 97 S. Ct. at 873.
4. The receiving room was surrounded by a locked wire fence and protected by an alarm system. Id.
5. The computer tapes containing the data were kept in a locked cabinet. Id.

6. When the tapes were used they were run, “off line,” which meant that no computer outside of the computer room could read or record the information. Id.

Even with all of these security measures, Justice Brennan found the central computer storage of the information, “more troubling” and stated: “The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity for some curb on such technology.” 429 U.S. at 607, 97 S. Ct. at 880.

Also, in dicta, the Court noted that some individuals may avoid or postpone needed health care out of a concern for medical privacy but, “[n]evertheless, disclosures of private medical information to doctors, to hospital personnel, to insurance companies and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient.” 429 U.S. at 602, 97 S. Ct. at 878. In a footnote the Court gave, “familiar examples,” of what it meant, which included statutory reporting requirements, “relating to venereal disease, child abuse, injuries caused by deadly weapons and certifications of fetal death,” and cited the Court’s approval of certain reporting requirements in Planned Parenthood of Central Missouri v. Danforth. 429 U.S. at 602, n.29, 97 S. Ct. at 878, n. 29.

Unlike the drug prescription program in Whalen, the Amended Privacy Rule expressly permits and authorizes the use and disclosure of private health information of virtually every kind to members of the public (e.g., covered entities and their business associates) as well as to the government. Further, one of the purposes of the Administrative Simplification provisions of HIPAA was to encourage the development of a health information system that would facilitate the storage and transmission of health information (without compromising the individual’s right to privacy) from one computer to another electronically. See section 261 of HIPAA, 65 Fed. Reg. at 82,469/3. Thus, the system that the statute encourages is the very type that the concurring opinion in Whalen noted, “vastly increase[s] the potential for abuse.”

Also, Defendant has not implemented security measures that are even remotely “comparable” to those required under the state program at issue in Whalen. The

Amended Rule merely provides that covered entities must have in place, “appropriate...safeguards,” to protect the privacy of personal health information. 45 CFR 164.530(c)(1).

In fact, the statute requires Defendant to adopt both, “security standards,” as well as, “safeguards,” to protect the privacy of health information stored and transmitted electronically. 42 U.S.C. 1373(d)(1) and (2). Defendant did not issue the final security standards required by the statute until February 20, 2003, more than five months after he issued the final Amended Privacy Rule. 68 Fed. Reg. at 8,334. However, Defendant provided that covered entities would not be required to adopt the security standards for more than two years, until April 21, 2005. According to Defendant, “whether or not to implement [the Security Standards] before the [2005] compliance date is a business decision that each covered entity must make.” 68 Fed. Reg. at 8,342.<sup>84</sup>

Defendant acknowledged that the privacy of health information is currently threatened by the lack of security standards and that, “security and privacy are inextricably linked.” 68 Fed. Reg. 8,335. Further, Defendant noted that, “no standard measures exist in the health 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. Defendant then concluded that:

“The protection of the privacy of information depends in large part on the existence of security measures to protect that information...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 8,335 and 8,344.

Thus, Defendant’s own official statements show that he is authorizing the use and disclosure of personal health information under the Amended Privacy Rule without

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<sup>84</sup> 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. He 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.

implementing the security measures which he has determined are necessary to protect the privacy of that information and preserve the public's trust in the health delivery system.

Defendant also acknowledged in issuing the Security Rule that, "there is no such thing as a totally secure system that carries no risk to security." 68 Fed. Reg. at 8,346. The greater potential for abuse created by the computerization of health information noted in Whalen is corroborated in recent studies conducted by this Administration. In February 2003, (ironically just six months before the Amended Privacy Rule was published) President Bush released a study entitled, "The National Strategy to Secure Cyberspace," that assessed the vulnerability of the nation's electronic data storage and transmission systems to hacking and other types of intrusions.

**<http://www.whitehouse.gov/pcipb>** The report found that, "not only are the numbers of cyber incidents and attacks increasing at an alarming rate, so too are the numbers of vulnerabilities that an attacker could exploit." Study at 8. The study noted that in a recent study by the Computer Security Institute, 90% of the participants reported using anti-virus software on their networks, yet 85% of their systems had been damaged by computer viruses. The same survey found that 89% of respondents had installed computer firewalls and 60% had intrusion detection systems, yet 90% reported that security breaches had taken place and 40% of their systems had been penetrated from outside their network. Study at 8-9.

Further, another recent report shows that the federal government's commitment and ability to protect the privacy of sensitive information it collects is highly questionable. See "Privacy Act, OMB Leadership Needed to Improve Agency Compliance," GAO-03-304 (June 30, 2003). The report was the product of a survey by the General Accounting Office of compliance with the federal Privacy Act of 1974 by 25 Federal Departments and agencies, including the Department of Health and Human Services. The report found numerous deficiencies and concluded that, "[u]ntil these issues are addressed by agencies and OMB and compliance with the Privacy Act across the government is improved, the government cannot adequately assure the public that all legislated individual privacy rights are being protected." GAO Report at 30. The root of

the problem, according to GAO, is a long-standing lack of commitment by OMB to make enforcement of the Privacy Act a priority. *Id.* at 26 and 30<sup>85</sup>.

Again ironically, the General Accounting Office presented testimony to Congress on April 8, 2003, less than a week before the compliance date for the Amended Privacy Rule that included the following findings:

- a. "...significant information security weaknesses at 24 major [federal] agencies continue to place a broad array of federal operations and assets at risk of fraud, misuse and disruption;"
- b. Assets found to be at risk include, "sensitive information such as taxpayer information, social security records, medical records and proprietary business information...;"
- c. "As the number of individuals with computer skills has increased, more intrusion or "hacking" tools have become readily available and relatively easy to use. A hacker can literally download tools from the internet and "point and click" to start an attack;"
- d. "Experts also agree that there has been a steady advance in the sophistication and effectiveness of attack technology. Intruders quickly develop attacks to exploit vulnerabilities discovered in products, use these attacks to compromise computers, and share them with other attackers;"

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<sup>85</sup> GAO noted that a prior study had found that, "Interest in the Privacy Act at [OMB] has diminished steadily since 1975. Each successive Administration has shown less concern about Privacy Act oversight." GAO Report at 9. In fact, GAO has issued a series of reports and findings detailing longstanding and widespread security weakness in both government and nongovernmental computer systems. *See, e.g.*, "Critical Infrastructure Protection, Significant Challenges in Safeguarding Government and Privately Controlled Systems from Computer-Based Attacks, Testimony of J. Willemsen, 8-9, Before Subcommittee on Government Efficiency, Financial Management and Intergovernmental Relations, Committee on Government Reform, House of Representatives, GAO-01-1168T (September 26, 2001); "Weaknesses Continue to Place Critical Federal Operations and Assets at Risk, Testimony of R. Dacey, 4 ("Evaluations published since July 1999 show that federal computer systems are riddled with weaknesses that continue to put critical operations and assets at risk."), Before Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, GAO-01-600T (April 5, 2001); "Medicare: Improvements Needed to Enhance Protection of Confidential Information," 21-24, 30, Report to Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/HEHS-99-140 (July 1999).

- e. “In addition, they [hackers] can combine these attacks with other forms of technology to develop programs that automatically scan the network for vulnerable systems, attack them, compromise them, and use them to spread the attack even further;”
- f. In addition to increasing threats, the number of reported computer security incidents has risen dramatically from 9,859 in 1999 to 82,094 in 2002; and
- g. These are only the reported attacks; it is estimated that, “as much as 80 percent of actual security incidents goes unreported because: (1) the organization was unable to recognize that its systems had been penetrated or there were no indications of penetration or attack; or (2) the organization was reluctant to report.” (emphasis supplied)  
Testimony of Robert F. Dacey, Director, Information Security Issues, General Accounting Office, “Information Security, Progress Made, But Challenges Remain to Protect Federal Systems and the Nation’s Critical Infrastructures,” Testimony before the Subcommittee on Technology, Information Policy, Intergovernmental Relations and the Census, Committee on Government Reform, House of Representatives, 3, 12-13, 22 (April 8, 2003).<sup>86</sup>

The preamble to the Original Privacy Rule listed 13 widely reported examples of breaches of medical privacy. 65 Fed. Reg. at 82,467-68.<sup>87</sup> On June 24, 2003, an official from Defendant’s Office of Civil Rights (OCR) (which is charged with enforcing the Privacy Rule) stated publicly that they have received 637 complaints under the Privacy Rule, have 513 open cases and have closed 124 cases. This official explained that many of the cases that were closed involved privacy violations that occurred prior to April 14, 2003, over which the OCR believes it does not have jurisdiction, so it is not known

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<sup>86</sup> Breaches of medical information security are far too numerous to list but several illustrate the magnitude of the problem. A hacker from Finland down loaded medical records and social security numbers of 5,000 patients at a large medical center in the Northwest, simply in order to demonstrate how easily it could be done. *See* Hacker Accesses Patient Records, The Washington Post, E. 1, (December 9, 2000).

<sup>87</sup> Interestingly, the Amended Privacy Rule would permit the use and disclosure of to covered entities of all of the types of health information that were the subjects of those articles, without the patients’ permission.

whether these complaints were meritorious. This is a significant number of potential privacy violations in a relatively short period of time given the complexity of the privacy notices, the absence of any information about privacy rights that might be available to individuals and the fact that the Amended Rule authorizes the use and disclosure of health information without any notice to the individual. See statement of Susan Kaminsky, OCR to National Committee on Vital and Health Statistics, Privacy Rule Compliance and Issues - Including Enforcement. Available at <http://ncvhs.hhs.gov/030624tr.htm>].

Evidence of widespread and increasing vulnerability of computerized information systems to such attacks illustrates the validity of an early statement by OMB with respect to the implementation of the Privacy Act, “In simplest terms, information not collected about an individual cannot be misused.” GAO Report on OMB Leadership at 14. The Amended Privacy Rule however, eliminates the opportunity for individuals to elect this option.

Thus, it is clear that Defendant cannot assure individuals that their personal health information that he has authorized be used and disclosed under the Amended Privacy Rule will be adequately protected from unwarranted and unwanted disclosure. Further, based on Defendant’s failure to implement security standards contemporaneously with the Amended Rule and the lack of interest shown in protecting the privacy of personal information it collects, it appears that Defendant has neither the will nor the way of protecting the privacy of individuals’ personal health information as did the state in Whalen.

Furthermore, the disclosures which the Whalen Court’s dicta noted were an essential part of modern medical practice (statutory reporting requirements relating to venereal disease, child abuse, injuries caused by deadly weapons and certifications of fetal death), are far different from the broad uses and disclosures to members of the public permitted and authorized for routine purposes under the Amended Privacy Rule.<sup>88</sup>

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<sup>88</sup> These special uses and disclosures that are otherwise required by law are treated separately under the Privacy Rule. 45 CFR 164.512(a) (required by law); (b) (public health activities); (c) (domestic violence, abuse or neglect); and (g) (uses and disclosures about decedents). While plaintiffs do not concede the constitutional validity of these provisions, they are not part of the challenge before this court.

The Supreme Court has recognized this distinction in the Danforth decision cited in Whalen.

The Court in Planned Parenthood of Central Missouri v. Danforth upheld certain recordkeeping and reporting requirements with respect to abortions on the basis that they: (a) were, “reasonably directed to the preservation of maternal health;” and (b) “properly respect[ed] a patient’s confidentiality and privacy.” 428 U.S. at 81, 96 S. Ct. at 2846. Specifically, the Court noted that the statute prohibited the use and disclosure of the health information by anyone other than public health officers of the state. Id. The Court clarified its position on this point in Thornburg v. Amer. College of Obstetricians and Gynecologists, 476 U.S. at 765, 106 S. Ct. at 2181, where it invalidated a Pennsylvania state recordkeeping and reporting requirement on constitutional grounds because it required such detailed information as, “method of payment,” the, “woman’s personal history,” and, “the bases for medical judgments.” Id. The state statute also allowed reports based on that information to be made available to the public. Id. The statutory provision was found constitutionally deficient even though no information, including the woman’s name, could be disclosed to the public that might lead to the disclosure of the identity of the patient. According to the Court, the patient and her physician, “will necessarily be more reluctant to choose an abortion if there exists a possibility that her decision and her identity will become known publicly.” 476 U.S. at 765, 106 S. Ct. at 2182.<sup>89</sup> The Court revisited this issue in Planned Parenthood of Southeastern Pennsylvania v. Casey where it upheld the constitutionality of a Pennsylvania recordkeeping and reporting statute that ensured that the identify of the woman would not be disclosed to the public, but struck down the portion of the statute that required the reporting to the state of the reason for not notifying her husband. 505 U.S. at 900, 112 S. Ct. at 2832-33.

In this case, the Amended Privacy Rule permits and authorizes the reporting to members of the public as well as to the federal government the most detailed and personal health information including the patient’s name, extensive demographic information, and every detail about communications between spouses to the extent that

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<sup>89</sup> Similarly, the Court found in Jaffee v. Redmond that, “the mere possibility of disclosure [of confidential communications during psychotherapy sessions] may impede development of the confidential relationship necessary for successful treatment.” 518 U.S. at 10, 116 S. Ct at 1928.

they are reflected in the patients' medical records. Thus, the Amended Privacy Rule violates Plaintiffs' constitutional right to privacy under the rationale of Danforth, Whalen, Thornburg and Planned Parenthood of Southeastern Pennsylvania.

**8. The Threat to Plaintiffs' Medical Privacy by the Amended Privacy Rule Violates Their Right to Liberty**

The opening statement in the Supreme Court's decision in Planned Parenthood of Central Missouri v. Danforth applies with equal force to this case: "Liberty finds no refuge in the jurisprudence of doubt." 505 U.S. 844, 112 S. Ct. at 2803. For similar reasons, the Court Jaffee v. Redmond refused to apply a balancing of interests test to determine whether a patient-therapist privilege should be recognized under the Federal Rules of Evidence and held that, "the participants in the confidential [psychotherapist-patient] conversation 'must be able to predict with some degree of certainty whether particular discussions will be protected. An uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all.'" 518 U.S. at 18, 116 S. Ct. at 1932.

Under the Amended Privacy Rule, privacy protections are uncertain at best. The Rule permits and authorizes the use and disclosure of virtually any personal health information to covered entities and their business associates as long as they contend that it is needed for treatment, payment or health care operations. The preamble clearly states that covered entities and their business associates can exercise this authority under the Rule even with respect to information, "created or received," prior to the compliance date of the Amended Privacy Rule. 67 Fed. Reg. at 53,211. How far back may the covered entity and its business associates go? To the individual's birth? To prior generations?

The Amended Privacy Rule would appear to permit and authorize the use and disclosure of an individual's health information even if he or she never seeks another health care service after April 14, 2003, compliance date. May an individual protect the privacy of his or her health information by avoiding the health delivery system altogether in the future? The Amended Rule would also appear to permit and authorize the use and disclosure of health information even where the individual paid out of pocket for the

services. Could an individual protect his or her health information privacy in this manner?

Would an individual who is fortunate enough to find a provider that agrees to enter into an agreement to restrict the use and disclosure of the individual's health information be able to enforce that agreement against insurance companies and other covered entities which were not a party to it? Can mental health patients feel confident that their inner most thoughts, fears and emotions reflected in communications with their psychotherapists will remain private without their consent when the federal common law therapist-patient privilege is nowhere incorporated into the Rule? Can insurers coerce providers to ignore their ethical standards and disclose their patients' personal health information as a condition of being able to remain a participating provider in the plan as occurred with plaintiff Daniel Shrager, M.D.? Will genetic information be used to set insurance rates that are out of the reach of some individuals and curtail equal opportunity for them under the law? Can individuals feel that their personal health information will not be used and disclosed against their wishes under the health information technology system that is being created under HIPAA?

The Amended Privacy Rule would appear to permit and authorize the use and disclosure, without the individual's knowledge or permission, of virtually all health information relating to personal decisions that have been found to be protected by the Constitution in privacy cases decided over the past 30 years: (a) whether married individuals may elect to use contraception (Griswold v. Connecticut, 381 U.S. 479, 85 S. Ct. 1678 (1965)); (b) whether unmarried individuals may elect to use contraception (Eisenstadt v. Baird, 405 U.S. 438, 92 S. Ct. 1029 (1972)); (c) whether a woman may elect to have an abortion (Roe, Doe, Danforth, Thornburgh, Planned Parenthood of Eastern Pennsylvania); (d) whether an individual may elect to have psychotherapy services that are not disclosed to members of the public (Jaffee); (e) whether a young woman may decide whether to have pregnancy test and not have the results disclosed to members of the public (Gruenke v. Seip); (f) whether expectant mothers may have diagnostic tests performed on their urine samples and not have the results disclosed without their informed consent (Ferguson) ; and (g) whether a young man has had, or is

contemplating having, an intimate relationship with a consenting adult of the same sex (Lawrence v. Texas and Sterling v. Borough of Minersville).

By establishing a federal policy with respect to consent that runs counter to the history and tradition of the country and the expectations and desires of its citizens, Defendant has cast a shadow of doubt over the health privacy and liberty rights of all individuals. As Justice Brandeis stated, “It is not the breaking of his doors and the rummaging of his drawers, that constitutes the essence of the offense [violation of liberty and security]; but it is the invasion of his indefeasible right of personal security, personal liberty and private property, where that right has never been forfeited by his conviction of some public offense...” Olmstead v. United States, 277 U.S. at 474-475, 48 S. Ct. at 571. Justice Douglas stated similarly in his concurring opinion in Doe v. Bolton: “That right [of privacy] includes the privilege of an individual to plan his own affairs, for ‘outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, do what he pleases, go where he pleases.’” 410 U.S. at 213, 93 S. Ct. at 758 (citing Kent v. Dulles, 357 U.S. 116, 126 (1958)). The Amended Privacy Rule infringes on the privacy of individuals who have committed no public offense, who have not engaged in any harmful conduct and who pose no threat to society by having infectious diseases or by engaging in violent conduct. They simply wish to engage in the routine activities of daily life and to retain the right to be let alone.

Defendant will undoubtedly contend that he reversed his policy with respect to the right of consent for laudable reasons. As Justice Brandeis wisely noted over 75 years ago:

“Experience should teach us to be most on our guard to protect liberty when the government’s purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.” Olmstead v. United States, 277 U.S. at 479, 48 S. Ct. at 572-573.

**9. The Amended Privacy Rule Violates Plaintiffs’ Rights to Private Communications and Has a “Chilling” Effect on Those Communications in the Physician-Patient Relationship**

The First Amendment to the Constitution protects individuals against federal laws “abridging the freedom of speech.” The First Amendment has been found to protect freedom of thought and expression which, “includes both the right to speak freely and the right to refrain from speaking at all.” Wooley v. Maynard, 430 U.S. 705, 714, 97 S. Ct. 1428, 1435 (1977). The Court has also adopted a further refinement of this principle:

“The essential thrust of the First Amendment is to prohibit improper restraints on the *voluntary* public expression of ideas; it shields the man who wants to speak or publish when others wish him to be quiet. There is necessarily, and within suitably defined areas, a concomitant freedom *not* to speak publicly, one which serves the same ultimate end as freedom of speech in the affirmative aspect.” Harper and Roe, Publishers, Inc. v. Nation Enterprises, 471 U.S. 539, 559, 105 S. Ct. 2218, 2230 (1985). See also, Turner Broadcasting System, Inc. v. FCC, 512 U.S. 622, 641 (1994) (“At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence.”)

As Justice Douglas observed in his concurring opinion in Doe v. Bolton, the Court has traditionally recognized the right under the First Amendment of autonomous control over the expression of one’s intellect, interests, tastes, personality and the right to remain silent. These rights are, “absolute, permitting of no exceptions.” 410 U.S. at 211, 93 S. Ct. at 757. Justice Douglas further noted that, “The right of privacy has no more conspicuous place than in the physician-patient relationship, unless it be in the priest-penitent relationship.” 410 U.S. at 219, 93 S.Ct. at 761.

The basis for these protections conferred by the First Amendment were discussed over a century ago by Samuel Warren and Louis Brandeis as follows:

“The common law secures to each individual the right of determining, ordinarily, to what extent his thoughts, sentiments, and emotions shall be communicated to others. Under our system of government, he can never be compelled to express them (except upon the witness stand); and even if he has chosen to give them expression, he generally retains the power to fix the limits of the publicity which shall be given to them. The existence of this right does not depend upon the particular method of expression adopted. It is immaterial whether it be by word, or by signs, in painting, by sculpture, or in music...The same protection is accorded to a casual

letter or an entry in a diary, and to the most valuable poem or essay, to a botch or daub and to a masterpiece. In every such case the individual is entitled to decide whether that which is his shall be given to the public. No other has the right to publish his productions in any form, without his consent.” (emphasis supplied) *The Right to Privacy*, S. Warren and L. Brandeis, 4 Harv. L. Rev. (1890).

The “regulatory permission” given by Defendant under the Amended Privacy Rule to all covered entities to use and disclose individuals’ health information beyond their medical record and beyond their physician permits the publication of private “thoughts, sentiments and emotions” contained in those records without the individuals’ consent and even against their will. Numerous plaintiffs have alleged that these unauthorized disclosures of private health information have violated their rights to limit the dissemination of this information and will have a chilling effect on the access to quality health care in the future. See allegations by Citizens for Health (paragraph 17); American Association for Health Freedom (paragraph 18); California Consumer Health Care Council (paragraph 19); Health Administration Privacy Project (paragraph 21); National Coalition of Mental Health Professionals and Consumers (paragraph 25); New Hampshire Citizens for Health Freedom (paragraph 26) and individual plaintiffs (paragraphs 27-33).

As noted, Defendant has conceded that his intent in the Amended Privacy Rule is to deprive individuals of control over the use and disclosure of their health information for routine purposes and that granting “regulatory permission” to covered entities essentially waives individuals’ rights to privacy. Numerous studies cited by Defendant in issuing the Original Privacy Rule show that individuals who are concerned about the privacy of their health information, “often take steps to protect their privacy.” 65 Fed. Reg. at 82,468/1. Those documented steps include (a) refusing to participate fully in the diagnosis and treatment of their medical condition; (b) taking some sort of evasive action to avoid the inappropriate use of their information including providing inaccurate information, changing physicians or avoiding care altogether; (c) withholding information from their medical record or requesting physicians to withhold such information; (d) “doctor-hopping” to avoid a consolidated medical record; and (e) paying out of pocket for care that is covered by insurance. 65 Fed. Reg. at 82,468/1 and /2.

These self-preservation tactics documented by Defendant were not occurring with only a few patients (see e.g., Whalen v. Roe, 429 U.S. at 595, n. 16, 97 S. Ct. at 874, n. 16 where the record showed that only two individuals had taken some action to protect their privacy under the state plan). Defendant's own findings show that, "one in six Americans," had taken evasive action to avoid disclosure of their private health information. Seventy-eight percent of physicians reported withholding information from a patient's medical record due to privacy concerns and 87% reported having had patients request withholding information from their records. 65 Fed. Reg. at 82,468/1. Since these widespread actions were taken by patients to protect their health information prior to the issuance of the Amended Rule eliminating patients' rights to control the use and disclosure of their health information for routine purposes, it is likely that these actions are even more commonplace today.

Thus, the record in this case contains undisputed evidence that Defendant is authorizing and encouraging the publication of Plaintiffs' personal health information against their will and without their permission in violation of their rights to private communications within the physician-patient relationship. That type of unwanted publication is having a "chilling" effect on plaintiffs' access to quality health care and their ability to communicate their thoughts, sentiments and emotions to their physicians that are necessary for their health care. As Defendant observed in the Original Rule:

"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 system and institutions that serve them. Such a loss of faith can impede the quality of the health care they receive and can harm the financial health of health care institutions." 65 Fed. Reg. at 82,467/3-82,468/1.

Accordingly, the Amended Privacy Rule violates plaintiffs' First Amendment rights to private communications and impedes access to quality health care.

#### **IV. CONCLUSION**

The cumulative effect of (a) the elimination of the right of consent, (b) the grant of federal “regulatory permission” to covered entities and their business associates to use and disclose health information regardless of Plaintiffs’ wishes, (c) the failure to require an accounting for routine uses and disclosures, (d) the authority to allow covered entities to use business associates that do not have to comply with the Amended Privacy Rule, (e) the failure to implement basic security measures on a timely basis and (f) the failure to issue full and final enforcement regulations for the Rule, produces precisely the effect that HHS found that Congress intended to avoid when it enacted section 264 of HIPAA — the health care information of citizens, including Plaintiffs, is being more commonly stored and disseminated by computers, and they have far less ability to control the routine use and disclosure of that information, both prospectively and retrospectively, than prior to the Amended Rule. 65 Fed. Reg. at 82,463. Law abiding citizens who pose no threat to society in any way are deprived of their right to be let alone — “the right most valued by civilized men.” Furthermore, the Amended Rule undermines Plaintiffs’ trust in the health delivery system which 2500 years of medical ethics shows is based on the assurance that an individual’s personal health information will not be used or disclosed for routine purposes without his or her knowledge and consent.

For these reasons, Plaintiffs’ right of privacy and consent should be upheld and the provisions of the Amended Rule that are inconsistent with that right should be enjoined.

Respectfully submitted,

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