United States Court of Appeals

for the

Third Circuit

Case No. 04-2550

Citizens for Health; American Association for Health Freedom; American Association of Practicing Psychiatrists; American Metal Health Alliance-USA; American Psychoanalytic Association; National Coalition of Metal Health Professionals and Consumers; New Hampshire Citizens for Health Freedom; Sally Scofield; Ted Koren, DC; Michaele Dunlap, Phy.D.; Morton Zivan, Ph.D.; California Consumer Healthcare Council; Congress of California Seniors; Health Administration Responsibility Project; Daniel S. Shrager; Eugene B. Meyer; Jane Doe; Janis Chester; Deborah Peel,

Appellants,

– v. –

Tommy G. Thompson, Secretary U.S. Department of Health and Services.

Appeal from the Judgment of The United States District Court for the Eastern District of Pennsylvania, Civil Action No. 03-2267

BRIEF FOR *AMICUS CURIAE* PROGRAM FOR PSYCHIATRY AND THE LAW AT HARVARD MEDICAL SCHOOL

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IDENTITY OF THE *AMICUS CURIAE*, STATEMENT OF ITS INTEREST IN THE CASE, AND SOURCE OF ITS AUTHORITY TO FILE

The Program in Psychiatry and the Law at Harvard Medical School was founded in 1979 to serve as a training program for forensic psychiatrists. It is a think tank, consultation service, and clinical research unit that addresses issues involving the intersection of medicine and law. Program participants include forensic psychiatrists, forensic psychologists, attorneys, multiple-degree (e.g., clinical and legal) professionals, psychiatrists, psychologists, research methodologists, policy analysts, writers, and students, who work together to conduct empirical research and to discuss, and write about topics such as patient confidentiality and consent, the health care provider-patient relationship, and education risk management.

Because the Program's work focuses in part on the ethical, legal, and medical aspects of patient confidentiality, it has a special interest in the implications of the regulations at issue in this lawsuit, which substantially diminish medical confidentiality by removing the patient consent requirement.

Pursuant to Fed. R. App. P. 29(a), this Brief is being filed without a motion seeking leave of the Court, because both the appellants and the appellees have consented to its filing.

INTRODUCTION

It is universally recognized that the success of psychotherapy depends in large part upon the inviolability of the confidential relationship between the therapist and the patient. Consider, for example, the following explanation by the United States Supreme Court:

> Effective psychotherapy . . . depends upon an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of confidential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment.

Jaffee v. Redmond, 518 U.S. 1, 10 (1996) (recognizing the psychotherapist-patient privilege under federal law).

State courts and legislatures have made similar pronouncements. In Pennsylvania, for example, the state supreme court has noted that "[t]he foundation for any successful psychiatric treatment is trust by the patient and confidentiality in communications with the provider." Althaus v. Cohen, 756 A.2d 1166, 1170 (Pa. 2000). Consistent with that realization, the Pennsylvania legislature, like other state legislatures, has created a psychotherapist-patient evidentiary privilege. See

42 Pa. Cons. Stat. Ann. § 5944; Jaffee, 518 U.S. at 12 n.11 (citing state psychotherapist privilege legislation in all 50 states).

Notwithstanding the irrefutable connection between patient confidentiality and effective treatment, the Secretary of the United States Department of Health and Human Services ("Secretary") ("HHS") has taken action to remove protections of patient confidentiality previously approved under the information consent requirement, published as the "Standards for Privacy of Individually Identifiable Health Information," 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at former 45 C.F.R. pts. 160, 164 (2002)) (the "Original Rule"), pursuant to the regulatory framework of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Specifically, in purported pursuit of improving efficiencies in the delivery of health care, the Secretary has promulgated amended regulations ("Amended Regulations") eliminating the requirement that an entity covered by the regulations obtain patient consent before using or disclosing an individual's health information. Effectively, the Secretary has put the federal government's imprimatur on the use and disclosure of patient information without consent.

In so doing, the Secretary not only has trampled upon the best interests of patients seeking mental health care, but he has eviscerated patients' constitutional right to privacy in their health information. For nearly thirty years,

the fact that an individual's medical information is subject to constitutional protection has been recognized by our courts. See, e.g., Whalen v. Roe, 429 U.S. 589, 598-600 (1977). Indeed, in the course of issuing the first iteration of regulations under HIPAA, the Secretary concluded that a patient's control over the use and disclosure of his health information is an essential element of the privacy necessary for high quality health care. 65 Fed. Reg. at 82,467. That conclusion was initially approved by both the Clinton and the George W. Bush administrations.

The identified government interest in providing for the disclosure without consent of a patient's medical records is that the consent requirement "impeded the efficient delivery of healthcare." Citizens for Health v. Thompson, Civ. No. 03-2267, 2004 WL 765356, at *14 (E.D. Pa. Apr. 2, 2004). In certain narrowly tailored circumstances, the interest in the efficiency and efficacy of health care might be compelling.[1] Yet the Secretary has failed to show any interest that is compelling or furthered by taking away a patient's right to confidentiality in

[1] For example, in instances of medical emergency or imminent risk of harm, disclosure of personal health information without consent might be appropriate or necessary to avoid serious physical harm. See generally Tarasoff v. Regents of the Univ. of Cal., 551 P.2d 334, 442 (Cal. 1976) (concluding that public policy favoring protection of the confidential character of patient-psychotherapist communications must yield to extent to which disclosure is necessary to avert danger to others).

his private health information. To the contrary, eliminating patient consent will substantially harm the delivery of effective mental health care.

ARGUMENT

The Program's special interest in patient confidentiality is consistent with the treatment of the subject in constitutional law, evidentiary law, and medical codes.

I. RECOGNITION OF THE RIGHT OF MEDICAL PRIVACY IN CONSTITUTIONAL LAW, EVIDENTIARY LAW, AND MEDICAL CODES

A. Constitutional Law

Aptly foreshadowed by Justice Brandeis in 1928 as the "right to be let alone," Olmstead v. United States, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting), the right to privacy has been a well established, if not always well defined, part of American constitutional jurisprudence since Griswold v. Connecticut, 381 U.S. 479 (1965) (declaring unconstitutional a state law prohibiting use of contraceptives by married couples). The Supreme Court has identified two categories of privacy interests: "the individual interest in avoiding disclosure of personal matters," and "the interest in independence in making certain kinds of important decisions." Whalen v. Roe, 429 U.S. at 598-600. See Sterling v. Borough of Minersville, 232 F.3d 190, 194 (3d Cir. 2000) (recognizing the privacy interests identified in Whalen); Paul P. v. Verniero, 170 F.3d 396, 400 (3d Cir. 1999) (same); United States v. Westinghouse Elec. Corp., 638 F.2d 570, 577 (3d Cir. 1980) (same).

As to the first category of privacy interests—the one at issue here—this Court's "jurisprudence takes an encompassing view of information entitled to a protected right to privacy." Sterling, 232 F.3d at 195. With specific respect to medical information, the Supreme Court and this Court have "long recognized" an individual's constitutional right to privacy. Ferguson v. City of Charleston, 532 U.S. 67, 78 (2001); Doe v. Delie, 257 F.3d 309, 315 (3d Cir. 2001); see also Whalen, 429 U.S. at 599-600.

Because "[i]nformation about one's body and state of health is matter which the individual is ordinarily entitled to retain within the 'private enclave where he may lead a private life,'" this Court has held that "[t]here can be no question that employee medical records, which may contain intimate facts of a personal nature, are well within the ambit of materials entitled to privacy protection." Westinghouse, 638 F.2d at 577 (quoting United States v. Grunewald, 233 F.2d 556, 581-82 (2d Cir. 1956). Similarly, this Court has recognized that individuals have a constitutional right to privacy in medical information responsive to police officer candidate applications and medical prescription records. See Doe v. Southeastern Pa. Transp. Auth., 72 F.3d 1133, 1137-38 (3d Cir. 1995) (medical prescription records); Fraternal Order of Police, Lodge No. 5 v. City of

Philadelphia, 812 F.2d 105, 112-113 (3d Cir. 1987) (police officer application information).[2]

Consistent with this line of cases, the health information at issue here is entitled to constitutional protection. The information subject to the Amended Regulations includes any information that "[r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual." 45 C.F.R. § 160.103 (defining "health information," "individually identifiable health information," and "protected health information"). Such information indisputably relates to "one's body and state of health." Westinghouse, 638 F.2d at 577. As such, it "has a special character," and is of the very type that this Court has found to be protected by the right to privacy. Id.

B. Evidentiary Law

In Jaffee v. Redmond, 518 U.S. 1, 18 (1996), the Supreme Court established a federal "psychotherapist privilege" under Rule 501 of the Federal Rules of Evidence. In so doing, the Court directly recognized the vital components of confidence and trust to the value of the therapeutic relationship components that

[2] This Court also has recognized a privacy interest in information "less intimate" than medical information. See, e.g., Fraternal Order of Police, 812 F.2d at 115 (recognizing privacy interest in certain financial information).

will be destroyed by implementation of the Amended Regulations. Specifically, the Jaffee Court held that a privilege protecting confidential communications between a patient and her therapist promoted interests so strong that they outweighed the need for probative evidence in a civil case involving that patient. See id. at 9-10, 15. Like the long-established attorney-client and spousal privileges, the psychotherapist-patient privilege is one "rooted in the imperative need for confidence and trust" and is essential for effective psychotherapy. Id. at 10.

This privilege, emphasized the Court, serves both private and public ends. Private interests are served by protecting what is undoubtedly private, confidential communications between patient and psychotherapist. See id. at 11. The psychotherapist privilege also serves the public interest by making it more likely that those individuals suffering from mental or emotional problems will seek to obtain appropriate treatment. "The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance." Id. at 11. As the Court recognized, denial of such a privilege would "surely . . . chill[]" confidential communications between psychotherapists and their patients. Id. at 12.

In recognizing the psychotherapist privilege, the Court emphasized that all fifty states and the District of Columbia had enacted some form of the

privilege into law. See id. at 12. Both the Pennsylvania and New Jersey legislatures have established a psychotherapist privilege that protects confidential relations and communications between a psychotherapist and patient on the same basis as those provided between attorney and client.[3] See 42 Pa. Cons. Stat. Ann. § 5944; N.J. Stat. Ann. 45:14B-28. The other state legislatures in this Circuit, as well as the legislature in Massachusetts, where the Program is located, also have rules of law recognizing the psychotherapist privilege. See Del. R. Evid. 503; 27 V.I. Code Ann. § 169j; Mass. Gen. Laws Ann. c. 233 §20B. Several courts have emphasized the vital public policy interests on which this privilege is founded. See Commonwealth v. Counterman, 719 A.2d 284, 295 (Pa. 1998) (identifying "strong public policy that confidential communications made by a patient to a psychiatrist or psychologist should be protected from disclosure, absent consent or waiver"). See also Barrett v. Vojtas, 182 F.R.D. 177, 180 (W.D. Pa. 1998) ("The statute

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[3] The attorney-client privilege is among the oldest of recognized privileges for confidential communications, see Upjohn Co. v. U.S., 449 U.S. 383, 389 (1981); Hunt v. Blackburn, 128 U.S. 464, 470 (1888), and is intended to encourage "full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and the administration of justice." See Upjohn, at 389. The strength of the attorney-client privilege is such that it survives the death of the client, Swidler & Berlin v. United States, 524 U.S. 399, 411 (1998). In so holding, the Court emphasized the importance of confidentiality in allowing a client to speak freely to his attorney: "Knowing that communications will remain confidential even after death encourages the client to communicate fully and frankly with counsel." Id. at 407.

establishes the strength of Pennsylvania's privilege equating it with the attorney-client privilege"); Althaus v. Cohen, 756 A.2d 1166, 1170 (Pa. 2000).

In making the determination to establish the psychotherapist privilege in the federal courts, the Supreme Court relied heavily upon "the importance of the patient's understanding that her communications with her therapist will not be publicly disclosed" and the states' corresponding promise of confidentiality in that respect through psychotherapist privilege legislation. See Jaffee, 518 U.S. at 13. Significantly, the Court rejected the idea proposed by the Seventh Circuit that the psychotherapist privilege should be subject to a balancing component. As the Court cautioned:

> Making the promise of confidentiality contingent upon a trial judge's later evaluation of the relative importance of the patient's interest in privacy and the evidentiary need for disclosure would eviscerate the effectiveness of the privilege. . . if the purpose of the privilege is to be served, the participants in the confidential 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.

Id. at 17-18 (internal citation omitted).

Subsequent cases applying Jaffee have similarly recognized that "confidentiality is the foundation upon which the psychotherapist-patient privilege rests." Barrett v. Vojtas, 182 F.R.D. 177, 179 (W.D. Pa. 1998); see also Caver v.

City of Trenton, 192 F.R.D. 154, 162 (D.N.J. 2000); Kinsella v. Kinsella, 696 A.2d 556, 566 (N.J. 1997).

The Amended Regulations turn this promise of confidentiality on its head. The expectation of privacy is now contingent upon the whim of third parties who are now entitled by an express grant of federal authority to use and disclose a wide array of a person's individual health information without such person's permission and even over such person's objection. As such, the promise of confidentiality becomes an empty one, full of uncertainty and contingency. The result, to paraphrase the Supreme Court, is little better than no promise at all.

C. Medical Codes and Practices

The concept of medical privacy also finds its basis in medical codes and practices. Medical confidentiality in the therapeutic relationship rests upon an ancient foundation. Indeed, the concept originated with the Hippocratic Oath, articulated some 2,500 years ago. The oath established confidentiality as the *sine qua non* for effective medical treatment. The oath declares that

> whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

Oath of Hippocrates, in 38 Harvard Classics (P.F. Collier and Son 1910). Today, virtually all medical schools adhere to the basic principles of Hippocrates, and

most administer some form of professional oath that includes the recognition that confidentiality is an essential element of medical treatment.[4]

The policies underlying the oath have been formalized into the ethical codes of numerous professional medical organizations. For instance, in 1847, the American Medical Association instituted the "Principles of Medical Ethics," a doctrine of ethical statements developed primarily for patient benefit. See Am. Med. Ass'n, Principles of Medical Ethics, at http://www.ama-assn.org/ama/pub/category/2512.html. The Principles instruct that "[a] physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law." Id. at IV. The Principles further declare: "[A] physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self." Id. at Preamble.

Similarly, the American Psychoanalytical Association describes the therapeutic relationship as "predicated on respecting human dignity." See Am. Psychoanalytical Ass'n, Principles and Standards of Ethics for Psychoanalysts,

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[4] In 1993, 98% of all medical schools in the U.S. and Canada administered some form of the oath, and all included a pledge of health information privacy. See Robert D. Orr, M.D. et al., The Use of the Hippocratic Oath: A Review of Twentieth Century Practice and a Content Analysis of Oaths Administered in Medical Schools in the U.S. and Canada in 1993, 8(4) J. Clinical Ethics 374-85 (1997).

Preamble, at http://www.apsa.org/ethics901.htm. With respect to the concept of confidentiality, the Association's Principles and Standards of Ethics state:

> Confidentiality of the patient's communications is a basic patient's right and an essential condition for effective psychoanalytic treatment and research. A psychoanalyst must take all measures necessary to not reveal present or former patient confidences **without permission**, nor discuss the particularities observed or inferred about patients outside consultative, educational or scientific contexts.

Id. at IV. (emphasis added). In the same vein, the American Psychological Association emphasizes in its code of ethics that "psychologists have a primary obligation and take reasonable precautions to protect confidential information obtained through or stored in any medium." See Am. Psych. Ass'n, Ethical Principles of Psychologists and Code of Conduct § 4.01, at http://www.apa.org/ethics/code2002.html#4.

The Hippocratic Oath, then, as well as virtually all the various medical professional codes and principles of ethics, evidence the collective recognition of, and commitment to, patient privacy in the field of mental health care. Further, the Hippocratic Oath and ethical requirements for consent are incorporated into many state licensure regulations that have the force of law. Traditional standards of ethical medical practice vest control over medical treatment in the patient. See Richard Sobel, A New Wound to Medical Privacy: Administration Rules Eviscerate Patient Consent, L.A. Times, Aug. 23, 2002.

Respect for patient autonomy extends to the clinician's duty to maintain confidentiality of medical information. See University of Washington School of Medicine, Ethics in Medicine: Physician-Patient Relationship, at http://eduserv.hscer.washington.edu/bioethics/topics/physpt.html#ques10. As HHS itself asserted, "few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal information." 65 Fed. Reg. at 82,464 (Dec. 28, 2000) (quoting Janna Malamud Smith, Private Matters: In Defense of the Personal Life 240-41 (1997)); see also Sobel, A New Wound to Medical Privacy, supra. While clinicians endeavor to provide the most complete and optimal treatment, their ability to do so is dependent upon whether patients feel confident in making a full disclosure. See American Medical Association, Current Opinions of the Council on Ethical and Judicial Affairs, § E-5.05 (2002). The removal of the patient consent requirements from the HHS regulations effectively undermines these professional codes and standards of patient care, and ultimately diminishes the quality of patient care. See 65 Fed. Reg. at 82,474.

II. THE AMENDED REGULATIONS HAVE A SUBSTANTIAL NEGATIVE IMPACT ON THE DELIVERY OF HEALTH CARE SERVICES AND WILL DETER MANY FROM SEEKING HEALTH CARE

A. By Eliminating Confidentiality in the Psychotherapist-Patient Relationship, the Amended Regulations Substantially Harm the Quality and Effectiveness of Health Care.

Because the Amended Regulations essentially eliminate the promise of confidentiality from the psychotherapist-patient relationship, the effective delivery of mental health care is severely threatened.

1. In the initial stages of rulemaking to implement HIPAA, HHS recognized the fundamental need for privacy in providing effective health care.

In acknowledging the mutual trust that is inherent in the psychotherapist-patient relationship, HHS directly tied the concepts of privacy and confidentiality to the effective delivery of health care services.[5] In fact, HHS declared in the preamble to the Original Rule not only that privacy is fundamental right, but also that it is crucial to the effective delivery of healthcare. See 65 Fed. Reg. at 82,467. Furthermore, HHS specifically emphasized the importance of confidentiality in the area of mental health care in light of the significant invasion of an individual's most private thoughts when personal health information is

[5] 65 Fed. Reg. at 82,467. HHS noted that providers need to trust their patients to disclose all relevant information and patients need to trust that the provider will use the information for their benefit but guard the information as confidential.

exposed. HHS underscored this concept by reference to the jurisprudence of the United States Supreme Court in this area, cautioning that if Justice Brandeis' famous phrase, the "right to be let alone," has any importance then it must apply to the prevention of outsider access to an individual's "intimate, thoughts, words, and emotions." See 65 Fed. Reg at 82,464.

2. Confidentiality and trust are essential to effective treatment.

Although medical professionals themselves are subject to professional and ethical codes of confidentiality, third parties such as insurers and HMOs, to which clinicians are often required to provide information for payment purposes, are not subject to such codes. The impact of the Amended Regulations is that such entities are now permitted to disclose personal identifiable health information for routine purposes without the consent and even against the will of patients. The net result for health care is that confidentiality between psychotherapist and patient is completely undermined.

The impact of eliminating patient confidentiality on the interactions between psychotherapist and patient, and the delivery of effective mental health care, is clear. As one court has recognized, "There would be no reasonable expectation of confidentiality, and therefore no confidential intent, if a party to a conversation was aware that the other party may report on the conversation to a

third party." Barrett v. Vojtas, 182 F.R.D. 177, 179 (W.D. Pa. 1998). This need is especially acute in the psychotherapist-patient relationship:

> Among physicians, the psychiatrist has a special need to maintain confidentiality. His capacity to help his patients is completely dependent upon their willingness and ability to talk freely. This makes it difficult if not impossible for him to function without being able to assure his patients of confidentiality and, indeed, privileged communication. . . [T]here is wide agreement that confidentiality is a sine qua non for successful psychiatric treatment. The relationship may well be likened to that of the priest-penitent or the lawyer-client. Psychiatrists not only explore the very depth of their patients' conscious, but their unconscious feelings and attitudes as well. Therapeutic effectiveness necessitates going beyond a patient's awareness and, in order to do this, it must be possible to communicate freely. A threat to secrecy blocks successful treatment.

Proposed Federal Rules of Evidence, 56 F.R.D. 183, 242 (1973). Thus, without the promise of confidentiality, the psychotherapist-patient relationship is severely threatened.

In order for psychotherapists (and all physicians) to diagnose accurately and prescribe proper treatment, patients must fully disclose all relevant information. In many instances arising in psychotherapy, such information is extremely personal, and the prospect that such information might be disclosed creates a heightened sense of anxiety. Only by establishing trust, through the vehicle of a confidential relationship in which patients consent to any disclosures, can that anxiety be overcome and effective treatment provided. See Am. Psychiatric Ass'n, The Principles of Medical Ethics with Annotations Especially

Applicable to Psychiatry (2001), at http://www.psych.org/psych_pract/ethics/ppaethics.cfm.

Specifically, the therapeutic relationship begins by creating an environment in which the psychotherapist and patient can develop that bond of trust. That trust is itself an element in the healing process, and it is reciprocal: clinicians must trust patients to disclose all information, and patients must trust clinicians to use the information for patient benefit and know that it will remain confidential. See Richard Sobel, No Privacy For All? Serious Failings in the HHS Medical Records Regulations, 5(2) J. Biolaw & Bus. 45 (2002).

The level of patients' trust in the security of their confidential information directly affects the establishment and development of beneficial therapeutic relationships. See Carolyn I. Polowy & Carol Gorenberg, Client Confidentiality and Privileged Communications (NASW Press 1997); Confidentiality, at http://www.4therapy.com/consumer/about_therapy/item.php?uniqueid=32&categoryid=27. Patients must feel confident that their conversations will be secure in the therapeutic space. Without the promise of confidentiality, now compromised by the Amended Regulations, many individuals in need of treatment would be afraid to seek it. See Barbara A. Weiner & Robert Wettstein, Legal Issues In Mental Health Care 201-202 (Kluwer Academic/Plenum Publishers 1993). "The very

essence of psychotherapy is confidential personal revelations about matters which the patient is and should be normally reluctant to discuss. Frequently, a patient in analysis will make statements to his psychiatrist which he would not make even to the closest members of his family." Ralph Slovenko, Psychiatry and a Second Look at the Medical Privilege, 6 Wayne L. Rev. 175, 184-85 (1960).

3. Where disclosure may be necessary, informed consent is essential.

An essential element of psychotherapist-patient confidentiality is the right of the patient to be advised of any potential disclosure of confidential information, and the right to consent or object to such disclosure. The right to give, or withhold, informed consent is essential. Without it, the right of confidentiality is no more than a mirage -- an appearance of privacy that can be dispelled at any time without the patient's consent. Indeed, it is no right at all, since it is contingent upon the whim of third parties.

Patient consent implicates two interrelated rights: the right of informational privacy, and the right to decisional privacy, in which the individual patient is vested with the right to control the release of personal health information. Decisional privacy, or patient consent, solidifies the foundation of the therapeutic relationship, because the patient controls disclosure. Patient consent not only strengthens the therapeutic relationship and furthers patient trust, but it also ensures personal control over what information is disclosed. Simply put, this

fundamental right of privacy is "the claim of individuals, groups or institutions to determine for themselves when, how, and to what extent information about them is communicated." Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,465 (Dec. 28, 2000) (quoting Ann Cevoukian & Don Tapscott, Who Knows: Safeguarding Your Privacy in a Networked World (Random House 1995)).

4. The exception for "psychotherapy notes" is far too narrow to protect patient confidentiality, and will diminish the effective delivery of health care.

The attempts of HHS to recognize a patient's right to privacy through the "psychotherapy notes" exception is inadequate because the definition of "psychotherapy notes" is too narrow. The Amended Regulations define psychotherapy notes as: "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record." 65 Fed. Reg. at 82,805.

This exception fails entirely to meet its stated purpose, because it does not cover vast categories of information of a confidential and private nature in psychotherapy apart from notes, such as information about diagnosis, tests, and treatment. Much important medical documentation is not included in the definition

"psychotherapy notes" such as medication prescriptions and monitoring, the start and stop times of counseling sessions, modalities and frequencies of treatment results of clinical tests, and summaries of diagnoses, functional status, treatment plan, symptoms, prognosis, and progress to date. 65 Fed. Reg. at 82, 805. Yet, each of these records reveals important and frequently stigmatizing information about a patient's state of mind and mental or emotional condition. Indeed, the fact of treatment is a piece of knowledge most patients would prefer to keep confidential. If these types of information are not protected to the same degree as "psychotherapy notes," patients will either censor the information they disclose in psychotherapy or refuse to seek treatment altogether. Without the guarantee of confidentiality in personal health information, secured by the requirement of patient consent, protection of "psychotherapy notes" is ineffective.

B. The Amended Regulations Will Deter Many Persons from Seeking and Continuing Therapy

The Amended Regulations depart dramatically from all conventional understandings of patient confidentiality, and will deter patients from initiating and continuing needed therapy and intervention, harming both the patients themselves and society at large.

1. Confidentiality is essential to overcoming bias and stigma.

Seeking medical or therapeutic treatment can be a traumatizing experience for patients because of the stigma associated with many diseases.

Concern about stigma is even stronger in the context of mental illness than it is with opposed to physical illness, because mental illness poses an increased risk of prejudice, bias and stigmatization. Many people who would have few qualms admitting to having diabetes or hypertension would be much more hesitant to admit battling alcoholism or depression. "The psychiatrist, by the nature of his work, becomes privy to sensitive information of high potential value to, among others, employers, creditors, legal adversaries, law-enforcement agencies, and insurance carriers. Yet he cannot perform his work properly unless he can assure his patient of real confidentiality." Beigler, Psychiatric Confidentiality and the American Legal System: An Ethical Conflict, in Psychiatric Ethics 221 (Sidney. (1981).

Several courts, including the Third Circuit, have specifically recognized that a stigma still exists in connection with receiving mental health services. See Jaffee, 518 U.S. at 10. See also Board of Trustees of Univ. of Ala. v. Garrett, 531 U.S. 356, 375 (2001) ("[t]here can be little doubt, then, that persons with mental or physical impairments are confronted with prejudice which can stem from indifference or insecurity as well as from malicious ill will.") (Kennedy, J., concurring); Pa. Psychiatric Soc'y v. Green Spring Health Serv., Inc., 280 F.3d 278, 290 (3d Cir. 2002) (granting associational standing to psychiatrists' association to pursue claim on behalf of patients whose mental health problems

significantly hindered them from suing); Humphreys v. Drug Enforcement Admin., 96 F.3d 658, 662 (3d Cir. 1996) (recognizing that "psychiatric patients suffer a stigma in society").

Confidentiality between patients and clinicians is essential to addressing perceived stigmas associated with mental illness and is the key factor in alleviating some of the stresses associated with stigma. As difficult as it may be for patients to reveal their symptoms to clinicians, it becomes impossible if patients feel that their health information may be disclosed or distributed in the public, non-private, realm. See Richard Sobel, No Privacy For All? Serious Failings in the HHS Medical Records Regulations, 5(2) J. Biolaw & Bus. 45 (2002). A patient's ability to overcome a sense of helplessness in the face of prejudice and stigma is mitigated chiefly by having control over whether and how confidential information is released.

As two noted experts have commented on the importance of confidentiality to treatment:

> Many psychotherapists emphasize that without the perception of confidentiality, patients will postpone treatment-perhaps making their problems more serious and expensive to treat-or will avoid sharing highly personal information because of fear of public exposure and social consequences.

Howard B. Roback and Mary Shelton, Effects of Confidentiality Limitations on the Psychotherapeutic Process," 4(3) J. Psychotherapy Prac. and Res. 185-193 (1995).

2. Patients consider confidentiality to be integral to treatment.

A variety of research studies illustrate the extent of patient fears over breaches in confidentiality in psychotherapy – even in the pre-Amended Regulations era, in which it was almost universally understood that personal health information was confidential. A study of attitudes about confidentiality among 76 psychiatric outpatients found that 45% of them reported concern that a psychiatrist might divulge confidential information and 22% reported that such concerns were the basis for their reluctance to initially seek treatment. See Jacob J. Lindenthal & Claudewell S. Thomas, Psychiatrists, the Public and Confidentiality, 170 J. Nervous & Mental Disease 319 (1982).

There is a longstanding expectation that privacy in the therapist-patient relationship will be respected, and it is reflected in numerous public opinion surveys that consistently indicate that Americans believe patient consent is essential in the use of personal health information. A 1994 Wirthlin Group survey revealed that 83% of Americans believed that patient approval should be required for the release of any medical information for any purpose. Similarly, a 2000 Gallup survey showed 71% of Americans required patient approval for other physicians to even review their medical records. A 1993 Lou Harris Poll showed that the majority of Americans believe that the protection of confidentiality of medical records is "absolutely essential" or "very important" in health care reform.

Medical Privacy Public Opinion Polls, at http://www.epic.org/privacy/medical/polls.html. Indeed, 85% of Americans also believed that laws should be established to protect the privacy of medical records. See Press Release, California HealthCare Foundation, Americans Worry About the Privacy of Their Computerized Medical Records (Jan. 28, 1999), at http://www.chcf.org/press/view.cfm?itemID=12267. Moreover 75% of Americans are concerned a "great deal" or a "fair amount" about health insurance companies putting medical information about them into a computer information bank to which third parties have access. Medical Privacy Public Opinion Polls, at http://www.epic.org/privacy/medical/polls.html. The scope and breadth of these public perceptions underscore the widespread understanding and reasonable expectation among Americans that their confidential medical information is private, and will remain private unless patients choose to consent to its disclosure. Further, clinicians overwhelmingly agree that when they confirm with their patients that confidential disclosures will remain confidential, it aids in strengthening the therapeutic relationship.

3. The loss of confidentiality deters many from seeking health care in the first instance.

The elimination of patient consent requirements from the Amended Regulations undermines the psychotherapist-patient relationship and directly diminishes the quality of care. Many patients will be deterred from seeking

medical care at all, creating serious health risks to both themselves and society at large. "Society . . . has a discernible interest in fostering the therapeutic treatment of those of its members experiencing emotional turbulence. This interest consists not only in our altruistic concern for our neighbors' well-being, but in our more selfish interest in the effective treatment of those in the community who may pose a threat because of mental illness or drug addiction." In re Grand Jury Subpoena (Psychological Treatment Records), 710 F. Supp. 999, 1010 (D.N.J. 1989). Even where patients do seek care, they may be deterred from sharing sensitive information that is vital to successful treatment by the fear that such information will be disclosed, despite their objections, to third parties. Moreover, clinicians, aware that they cannot assure confidentiality, may be reluctant to elicit important revelations essential to obtaining a full history on their patients and dispensing quality care.

Logic and experience demonstrate that those patients who hold the most stigmatizing kinds of information, and, as such, may be in greatest need of professional treatment, will now be least likely to obtain that treatment because of fear of disclosure of their confidential information.

Studies have repeatedly shown that the loss of confidentiality has the effect of inhibiting the scope and effectiveness of health care delivery, thereby increasing costs for the health system as a whole. When patients lack confidence

in the security of their personal information, they often limit their disclosures, thus requiring clinicians to order unnecessary and expensive tests that drive up health care costs. See Richard Sobel, Maintaining Informed Consent for Doctor-Patient Confidentiality: More Serious Failings in the HHS Medical Records Regulations, 6(2) J. Biolaw & Bus. 61, 63-64 (2003). The California HealthCare Foundation survey discovered that one out of six patients undertook measures to ensure the protection of their medical privacy that could undercut good health care. See id. Examples of such measures include paying out-of-pocket even though insured, restricting doctor visits, providing incomplete or inaccurate information, and avoiding treatment altogether. See id. Of course, avoiding treatment altogether ultimately results in much greater costs borne by the patient, and often society as a whole. Arguments that removing consent reduces costs and produces "efficiencies" are belied by the increased costs and inefficiencies to the medical system caused by incomplete information needed for full histories, diagnoses and treatment.

Thus, effective mental health care, particularly psychotherapy, relies upon establishing an environment in which patients are willing and able to reveal personal thoughts, memories, and emotions. See Jaffee, 518 U.S. at 10. As one noted expert has stated:

> Confidentiality is a prime condition in enabling the establishment of an effective therapeutic relationship. In

> no other medical specialty is so much private information required for establishing an accurate diagnoses and treatment plan.

Philip Beck, MD, FRCPC, The Confidentiality of Psychiatric Records and the Patient's Right to Privacy, 46(3) Can. J. Psychiatry 6 (2000). Absent sufficient assurances of confidentiality, patients are reluctant to discuss the most sensitive information that often can be the most crucial to a clinician's diagnosis. See 65 Fed. Reg. at 82,467. As a result, patients do not receive adequate treatment, and health care costs increase.

In addition, the elimination under the Amended Regulations of patient consent to disclosure of personal health information for purposes of medical research, diminishes the quality and effectiveness of medical research because patients are likely to withhold information that they fear may be disclosed without their knowledge. By contrast, if the right to give informed consent is upheld, this same information might be willingly disclosed, with appropriate protections, for purposes of general health care research.

> When patients suspect that their information will be obtained inappropriately or potentially used against them, they are likely to withhold or distort information whose accuracy might contribute to better research.

Richard Sobel, Maintaining Informed Consent for Doctor-Patient Confidentiality, supra, at 63. The elimination of patient confidentiality imposes numerous other societal costs, in addition to those outlined herein, that diminish the effective

delivery of health care and deter many persons from seeking health care in the first instance.

4. Psychotherapy is an ongoing process, and the loss of confidentiality harms effective health care services at each stage of the process.

Patients can be deterred from seeking treatment at any point in the therapeutic process as a result of the loss of confidentiality. The principles of confidentiality and trust have repeatedly been recognized as fundamental to the therapist-patient relationship not only at the outset of that relationship, but over time. Specifically, as the relationship between clinician and patient develops and gets stronger, the patient feels more comfortable in making additional disclosures, frequently of more sensitive and potentially embarrassing information, that are required for the healing process to be effective. Without the promise of confidentiality throughout the relationship, an open line of communication cannot be maintained:

> Breaches or potential breaches of confidentiality in the context of therapy seriously jeopardize the quality of information communicated between patient and psychiatrist and also compromise the mutual trust and confidence necessary for effective therapy to occur.

See Philip Beck, supra. When the therapeutic relationship is compromised by disclosures, the therapist is left unable to provide effective treatment and the patient often is left feeling "humiliated and betrayed." See id.

5. The loss of confidentiality reduces the effectiveness of health care services and drives up financial and societal costs.

Breaches in confidentiality pose yet another threat to the therapeutic relationship, adversely affecting not only individuals but society at large. Those most in need of therapy are frequently the ones most reluctant to seek it in the absence of assurances of complete privacy. For instance, many individuals with anti-social characteristics are able to manage their behavior with ongoing professional treatment. Such patients often make progress when the confidentiality of their treatment process is assured. Where it is not assured, patients are reluctant to attend therapy and are left without means to manage their potentially dangerous behavior.

Breaches of health privacy can have dramatic harmful effects on patients beyond the physical and mental health of patients. These include the loss of a job, the loss of health insurance, alienation from friends and family, public humiliation and shame, and inaccurate health research. See 65 Fed. Reg. at 82,468. For example, a disclosure that one received a diagnosis of adjustment disorder (one of the mildest mental health diagnoses) could result in a rejection of both health and life insurance. See Bernard McDowell, Confidentiality: Therapeutic Importance, Legal Definitions, and Loopholes (2003), at http://www.pcez.com/~therapy/id131.htm. Moreover, a University of Illinois study found that at least 35% of Fortune 500 companies check medical records

prior to hiring or promoting employees. See Richard Sobel, Maintaining Informed Consent for Doctor-Patient Confidentiality, supra, at 63.

CONCLUSION

By vesting third parties with a federal grant of permission to disclose sensitive and private medical information, the Amended Regulations threaten to destroy the foundation of trust upon which the psychotherapist-patient relationship is built. The Amended Regulations remove the protection of confidentiality in a patient's private health information. The Secretary has failed to explain why the government's interest in doing so is compelling, nor has he explained how this action furthers any related government interest. Rather, the Secretary has not appropriately considered the overwhelming evidence directly contrary to his conclusions. Rather than increasing efficient and effective health care, infringing upon patient confidentiality makes effective health care impossible, especially in the mental health field.

For all of the reasons set forth above, *amicus* Program in Psychiatry and the Law respectfully requests that the district court's judgment be reversed.

Respectfully submitted,

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CERTIFICATION RESPECTING BAR MEMBERSHIP

Pursuant to Third Circuit Local Appellate Rule 46.1(e), I hereby certify that Joseph A. Sullivan and I are members of the Bar of this Court.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I certify that this Brief for *Amicus Curiae* Program in Psychiatry and the Law complies with the type – volume limitation, because excluding the Table of Contents, the Table of Citations, the Certificate Respecting Bar Membership, the Proof of Service, and this Certificate of Compliance, and according to the word processing system used to prepare the Brief (Microsoft Word), the Brief contains 6,791 words.

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PROOF OF SERVICE

I hereby certify that on September 1, 2004, two copies of the foregoing Brief for *Amicus Curiae* Program in Psychiatry and the Law were served by first-class mail on the following attorneys:

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