Boston University School of Law

Scholarly Commons at Boston University School of Law

Faculty Scholarship

1974

Psychosurgery: The Law's Response

George J. Annas

Follow this and additional works at: https://scholarship.law.bu.edu/faculty_scholarship

Part of the Medical Jurisprudence Commons



PSYCHOSURGERY: THE LAW'S RESPONSE

GEORGE J. ANNAS* LEONARD H. GLANTZ**

I. INTRODUCTION

Participants in the psychosurgery controversy generally espouse one of three competing points of view. First, there are the surgeons who argue that psychosurgical procedures have developed beyond the experimental stage to the point where they may be considered therapeutic for certain types of patients.¹ Second, there are those who support further research in the area in the hope of developing genuinely therapeutic procedures, but who recognize the importance of safeguarding against potential abuses in the course of this development.² Finally, there are the anti-psychosurgeons, who argue for the total prohibition of psychosurgery on ethical, spiritual, or political grounds independent of its characterization as experimental or therapeutic.³

It is the purpose of this article to examine this controversy from a legal perspective with a view toward determining what legal control mechanisms are presently available or should be created to ensure that the rights of the patient and of society are adequately protected. For the purposes of this discussion, the term "psychosurgery" will be used to mean any procedure that destroys brain tissue for the primary purpose of modifying behavior.⁴

¹ See, e.g., V. Mark & F. Ervin, Violence and the Brain (1970); Hearings on S. 974, S. 878 and S.J. Res. 71 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 93d Cong., 1st Sess., pt. 2, at 348-57, 363-68 (remarks of Drs. Orlando Andy and Robert Heath).

2 Hearings, supra note 1, at 338-47 (remarks of Dr. Bertram Brown, Director of the National Institute of Mental Health).

³ Id. at 357-63 (remarks of Dr. Peter Breggin, presently Director of the Center for the Study of Psychiatry).

4 Other definitions of psychosurgery follow:

Psychosurgery can best be defined as a surgical removal or destruction of brain tissue or the cutting of brain tissue to disconnect one part of the brain from another, with the intent of altering behavior, even though there may be no direct evidence of structural disease or damage in the brain.

Id. at 339 (remarks of Dr. Bertram Brown).

Psychosurgery is a term which has been loosely used to identify brain operations performed for the treatment of behavioral and related neurological disorders.

Id. at 348 (remarks of Dr. Orlando Andy).

The definition of psychosurgery is to destroy normal brain tissue to control the emotions or behavior or, a diseased tissue when the disease has nothing to do with behavior . . . the man is trying to control.

Id. at 359 (remarks of Dr. Peter Breggin).

"Psychosurgery" means any operation designed to irreversibly lesion or destroy brain tissue for the primary purpose of altering thoughts, emotions or behavior of a human

[•] Director, Center for Law and Health Sciences, Boston University School of Law. A.B., Harvard College, 1967; J.D., Harvard Law School, 1970; M.P.H., Harvard School of Public Health, 1972.

^{**} Staff Attorney, Center for Law and Health Sciences, Boston University School of Law. Boston University, A.B., 1970; J.D., 1973.

II. HISTORICAL OVERVIEW

The first procedure fitting this definition was the prefrontal lobotomy developed by Egas Moniz in 1935.⁵ It was first performed in the United States in 1936, by Drs. Walter Freeman and James Watts of George Washington University.⁶ Schizophrenic patients who had been habitually hospitalized and who were irritable and helpless became, after the operation, "quiet, more cooperative, clean, able to eat by themselves, capable of working in the hospital, and could even be sent home to their families."⁷ In addition, the patients lost their ability to solve simple problems, to reason abstractly and to relate to their family members.⁸ It was the side effect of extreme passivity,⁹ however, that eventually brought the procedure to the attention of a criminal court.

In 1945, Millard Wright was arrested for 10 house-breakings and robberies in Pittsburgh, Pennsylvania. Six weeks after his arrest, he refused to eat or converse, seemed confused and apparently attempted suicide. He was therefore transferred to a hospital for the criminally insane until he was placed on trial in 1947. At that time both Wright's lawyer and the local district attorney requested that the defendant be lobotomized in an attempt to cure him of his criminal tendencies. The judge agreed, but upon Wright's return to court two months after his lobotomy a different judge was presiding. Both the surgeon and the defendant were eager to have an opportunity to test the efficacy of the procedure, but the new judge was not convinced

being. "Psychosurgery" does not include procedures which may irreversibly lesion or destroy brain tissues when undertaken to cure well-defined disease such as brain tumor, epileptic foci and certain chronic pain syndromes.

Ch. 616, § 1(6) [1973 Ore. Reg. Sess.] (S. Bill 298), amending Ore. Rev. Stat. 677.190 (1971).

The term "psychosurgery" means those operations currently referred to as lobotomy, psychiatric surgery, and behavioral surgery and all other forms of brain surgery if the surgery is performed for the purpose of—

(A) modification of thoughts, feelings, actions, or behavior rather than the treatment of a known and diagnosed physical disease of the brain;

(B) modification of normal brain function or normal brain tissue in order to control thoughts, feelings, action, or behavior; or

(C) treatment of abnormal brain function or abnormal brain tissue in order to modify thoughts, feelings, actions, or behavior when the abnormality is not an established cause for those thoughts, feelings, actions, or behavior. Such term does not include electroshock treatment, the electrical stimulation of the brain, or drug therapy, except when substances are injected or inserted directly into brain tissue.

H.R. 5371, 93d Cong., 1st Sess. § 1 (1973).

For a discussion of the various types of psychosurgical procedures see Andy, Neurosurgical Treatment of Abnormal Behavior, 252 Am. J. Med. Sci. 232 (1966), reprinted in Hearings, supra note 1, at 417. For another definition of psychosurgery see Stedman's Medical Dictionary 1040 (22d ed. 1972).

⁵ The Age of Madness 157 (T. Szasz ed. 1973), *reprinting in part* Moniz, How I Came to Perform Prefrontal Leucotomy, *in* Congress of Psychosurgery 7 (Lisboa: Edicoes Atica 1948).

6 Freeman, Frontal Lobotomy in Early Schizophrenia Long Follow-up in 415 Cases, 119 Brit. J. Psychiat. 621 (1971).

7 Goldstein, Prefrontal Lobotomy: Analysis and Warning, Scientific Am., Feb. 1950, at 44.

8 Id. at 46-47; Holden, Itil & Hofstatter, Prefrontal Lobotomy: Stepping-Stone or Pitfall?, 127 Am. J. Psychiat. 591 (1970).

9 Goldstein, supra note 7, at 46-47.

that Wright should be allowed to go free. However, because of Wright's demonstrated desire to help medical science, he received the comparatively light sentence of two to 12 years instead of the possible 40 years to life. Wright later committed suicide while in prison.¹⁰

In 1949, the Stanford Law Review addressed the problems involved in drafting a statute to regulate the use of lobotomy and concluded that "the greater good will be achieved by avoiding legislative fetters and relying for protection on the high standards of the medical profession and the individuals who compose it."11 The Soviet Union demonstrated its disagreement with this conclusion by its prohibition of the performance of lobotomy in 1951.¹² As N. I. Oserezki, a Soviet psychiatrist, told the World Federation of Mental Health, the procedure is "an anti-physiological method that violates the principles of humanity [and] makes the patient an intellectual invalid" Through lobotomy, he argued, "an insane person is changed into an idiot."13 Arguing the contrary position in the United States, Drs. Freeman and Watts wrote that "[i]t is better for the patient to have a simplified intellect capable of elementary acts, than an intellect where there reigns the disorder of subtle synthesis. Society can accommodate itself to the most humble laborer, but it justifiably distrusts the mad thinker."14 Thus, Freeman was satisfied when he could reflect upon his operations and comment that "[o]n the whole, lobotomized patients make rather good citizens."15

Throughout the 1950s and 1960s, psychosurgery was ignored by the legal community. During this time, however, there existed and continued to develop a general system of control over medical practice. It is to this system that any attempt to regulate psychosurgery as a specific medical practice must first turn.

III. LEGAL CONTROL OF MEDICAL PRACTICE

A. Private Actions

The best known course of action available to a dissatisfied patient is the malpractice suit.¹⁶ A psychosurgical patient might successfully sue for mal-

14 Brown, Wienckowski & Bivens, Psychosurgery: Perspective on a Current Issue 3 (DHEW Pub. No. HSM 73-9119, 1973).

15 Silbermann & Ransohoff, supra note 10, at 808.

18 Although doctors argue that malpractice suits have reached crisis proportions, the most recent statistics reveal that one suit is filed for every 226,000 doctor-patient encounters. Report of the Secretary's Comm. on Medical Malpractice 12 (DHEW Pub. No. OS 73-88, 1973). See also Dietz, Baird & Berul, The Medical Malpractice Legal System 97 (Appendix to DHEW Pub. No. OS 73-88, 1973).

¹⁰ The case is discussed in Mayer, Prefrontal Lobotomy in the Courts, 38 J. Crim. L.C. & P.S. 576 (1948). See also Silbermann & Ransohoff, Medico-Legal Problems in Psychosurgery, 110 Am. J. Psychiat. 801, 806 n.4 (1954); Time, July 14, 1947, at 53, col. 3.

¹¹ Note, Lobotomy: Surgery for the Insane, 1 Stan. L. Rev. 463, 474 (1949).

¹² Trotter, A Clockwork Orange in a California Prison, 101 Sci. News 174, 175 (1972). 13 Scientific Am., Oct. 1953, at 60. It is well-known, however, that the Soviet Union continues to treat political dissidents as if they were insane. See, e.g., Chorover, Big Brother and Psychotechnology, Psychology Today, Oct. 1973, at 43, 44.

practice on any one of the following three grounds: (1) the performance of the procedure was negligent; (2) the patient did not give informed consent to the procedure; or (3) the method of review constituted negligence.

1. Negligent Performance of the Procedure

A claim that the performance of a psychosurgical procedure was negligent may actually involve one or more of three individual questions: (1) what procedure was used; (2) what were the qualifications of the person performing the procedure; and (3) was the chosen procedure performed without negligence. Doctors have a legal duty to perform on at least the level of the "average practitioner"¹⁷ or, if they are specialists, on the level of the "average specialist."18 If the violation of this duty results in injury to the patient, he is entitled to compensation. Certainly this duty requires, at a minimum, that the physician not employ discredited procedures. The classical lobotomy, as exemplified by the techniques of Dr. Walter Freeman, involved the insertion of a device shaped like an ice pick into the patient's orbital cavity while the patient was anesthetized through electro-shock treatment. This device was then moved around within the cranial cavity to grossly cut tissue.¹⁹ In view of the general agreement among contemporary surgeons that the performance of the classical lobotomy is unjustifiable, it would seem that any patient subjected to such a procedure should be successful in a malpractice suit. As Dr. Bertram Brown, Director of the National Institute of Mental Health, has said: "I think I can state unequivocally that no responsible scientist today would condone a classical lobotomy operation."20

More generally, of course, there is the question whether the performance of any psychosurgical procedure is justified. Apart from the controversy over the therapeutic value of psychosurgery, there is the further consideration that the United States has an oversupply of neurosurgeons.²¹ Thus, there is tremendous pressure on each neurosurgeon to justify his specialization, a phenomenon that may generally lead to the performance

¹⁷ D. Harney, Medical Malpractice 91 (1973).

¹⁸ Id. at 116. See also Brune v. Belinkoff, 354 Mass. 102, 235 N.E.2d 793 (1968); McCoid, The Care Required of Medical Practitioners, 12 Vand. L. Rev. 549 (1959); Note, The Standard of Care in Malpractice Cases, 4 Osgoode Hall L.J. 222 (1966).

¹⁹ Freeman estimated that he had lobotomized more than 3,500 persons. Freeman, supra note 6, at 622; see W. Freeman & J. Watts, Psychosurgery 51-57 (2d ed. 1950).

²⁰ Hearings, supra note 1, at 340. According to the National Institute of Mental Health, some lobotomized patients showed improvement, but the classical lobotomy was a "therapy of desperation." Brown, Wienckowski & Bivens, supra note 14, at 2. See also Scoville, Psychosurgery and Other Lesions of the Brain Affecting Human Behavior, in Psychosurgery 5, 8 (E. Hitchcock, L. Laitinen & K. Vaernet eds. 1972); Sweet, Treatment of Medically Intractable Mental Diseases by Limited Frontal Leucotomy-Justifiable?, 289 New Eng. J. Med. 1117 (1973).

²¹ See Bergland, Neurosurgery May Die, 288 New Eng. J. Med. 1043 (1973). The average neurosurgeon in 1970 in the United States performed an average of only five or six major operations per month. *Id.* at 1045, *quoting* Odom, Neurological Surgery in Our Changing Times: The 1972 AANS Presidential Address, 37 J. Neurosurg. 255 (1972).

of unnecessary surgery²² and may be responsible for the expansion of indications for surgery. Indeed, psychosurgery has been performed to treat homosexuality,²³ violent behavior²⁴ and marijuana use.²⁵

Another avenue of attack relates to the psychosurgeon's professional qualifications. The states license docoors to practice medicine,²⁶ but do not directly oversee their work. Thus, if a licensed doctor can obtain an operating room, he may perform whatever form of surgery he desires even if he has had no surgical training. Two-thirds of all the surgeons practicing in the United States today are either certified by the American Board of Neurological Surgery or by a specialty board or are currently in training leading to such certification.²⁷ The remaining one-third, however, are self-designated surgeons. Dr. Walter Freeman, for example, was a psychiatrist.²⁸ He disagreed with the view of his colleague Dr. James Watts "that any procedure involving cutting of brain tissue is a major operation and should remain in the hands of the neurological surgeon."²⁹ Freeman's view notwithstanding, it would seem that the performance of psychosurgery by any physician lacking either certification to perform neurosurgery or equivalent training should constitute malpractice.

A psychosurgeon may also be negligent in the performance of the procedure. A recent case in Kentucky, for example, involved a surgeon who missed the temporal lobe connections and destroyed the patient's optic nerve instead. A settlement was reached out of court for a substantial but undisclosed amount.³⁰

2. The Absence of Informed Consent

The concept of informed consent is presently being redefined by the courts.³¹ This redefinition is designed to give the patient more power and to

23 Shoemaker, Operation to Relieve Perversion, 97 Sci. News 50 (1970).

24 V. Mark & F. Ervin, supra note 1, at 69-91.

²⁵ Hearings, supra note 1, at 368; Trotter, Psychosurgery, the Courts and Congress, 103 Sci. News 310, 311 (1973).

28 See W. Curran & E. Shapiro, Law, Medicine, and Forensic Science 522 (2d ed. 1970); see, e.g., Mass. Gen. Laws Ann. ch. 112, §§ 2 et seq. (1965).

²⁷ Child, Surgical Intervention, Scientific Am., Sept. 1973, at 98. There are presently 1,500 certified neurosurgeons and 600 in specialty training in neurosurgery. Bergland, *supra* note 21, at 1044. Prior to taking the Board examination, an applicant must have completed one year's training in general surgery, a minimum of four years graduate study in neurological surgery and two years of independent practice in neurological surgery. Directory of Medical Specialists 603-04 (15th ed. 1972).

28 See Trotter, supra note 12, at 174; cf. W. Freeman & J. Watts, supra note 19, at x. 29 Id.

30 Hearings, supra note 1, at 384.

31 See Karchmer, Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug,"

²² See Gonzales v. Nork (Super. Ct., Sacramento County, Cal., Nov. 19, 1973) (awarding \$1.7 million in compensatory and \$2 million in punitive damages against a doctor who performed an unnecessary laminectomy); Bunker, Surgical Manpower: A Comparison of Operations and Surgeons in the United States and in England and Wales, 282 New Eng. J. Med. 135 (1970); Lewis, Variations in the Incidence of Surgery, 281 New Eng. J. Med. 380 (1969); Vayda, A Comparison of Operations and Surgeons in the United States and England and Wales, 289 New Eng. J. Med. 1224 (1973); Comment, Unnecessary Surgery: Doctor and Hospital Liability, 61 Geo. L.J. 807 (1973).

thereby equalize the doctor-patient relationship, a development consistent with judicial innovation in the landlord-tenant,³² seller-buyer,³³ employeremployee,⁸⁴ creditor-debtor,³⁵ warden-prisoner³⁶ and police-suspect³⁷ areas. Medical treatment in the absence of consent has traditionally been regarded as a battery, a touching by the doctor not consented to by the patient.³⁸ More recently, the courts have begun to find an affirmative duty on the part of the physician to inform the patient of the risks involved in a suggested procedure and the available alternatives. A breach of this duty may form the basis of a suit for negligence.³⁹

Since 1972, certain courts have gone even further by holding that expert testimony is not required to define the duty of disclosure. The emphasis, instead, is on the patient's perception of his situation.⁴⁰ In the words of one court, "the patient's right of self-decision is the measure of the physician's duty to reveal . . . [and] the test for determining whether a potential peril must be divulged is its materiality to the patient's decision."⁴¹ Employing this perspective, a leading case has held a doctor liable for not disclosing to the patient that laminectomy carries a one percent risk of paralysis.⁴² There seems to be almost uniform agreement that the risks of psychosurgery are not fully known and that they are therefore unquantifi-

31 Mo. L. Rev. 29 (1966); Oppenheim, Informed Consent to Medical Treatment, 11 Clev.-Mar. L. Rev. 249 (1962); Waltz & Scheuneman, Informed Consent to Therapy, 64 Nw. U.L. Rev. 628 (1970); Note, Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship, 79 Yale L.J. 1533 (1970); Comment, Informed Consent in Medical Malpractice, 55 Calif. L. Rev. 1396 (1967).

32 See, e.g., Boston Housing Authority v. Hemingway, 1973 Mass. Adv. Sh. 339, 293 N.E.2d 831.

33 See, e.g., Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960).

34 See, e.g., Bunting v. Oregon, 243 U.S. 426 (1917); Labor-Management Relations Act of 1947, 29 U.S.C. §§ 141 et seq. (1970).

35 See, e.g., Unico v. Owen, 50 N.J. 101, 232 A.2d 405 (1967).

36 See D. Rudovsky, The Rights of Prisoners (1973).

37 See, e.g., Miranda v. Arizona, 384 U.S. 436 (1966).

38 W. Prosser, The Law of Torts § 32, at 165 (4th ed. 1971).

39 D. Harney, supra note 17, at 83; W. Prosser, supra note 38; Annas, Informed Consent: When Good Medicine May Not Be Good Law, 1 Medicolegal News 3 (1973). See, e.g., Wilkenson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972).

⁴⁰ Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Fogal v. Genesee Hosp., 41 App. Div. 2d 468, 344 N.Y.S.2d 552 (1973); Wilkenson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972); Trogun v. Fruchtman, 58 Wis. 2d 569, 207 N.W.2d 297 (1973). But see Tatro v. Lukin, 512 P.2d 529 (Kan. 1973).

41 Cobbs v. Grant, 8 Cal. 3d 229, 245, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972), citing Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

42 Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). Accord, Wilson v. Scott, 412 S.W.2d 299 (Tex. 1967) (failure to disclose one percent risk of loss of hearing in a stapedectomy). See also Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966) (duty of drug manufacturer to warn doctors of the possibility of serious side effects in a small percentage of patients); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991 (D.N.D. 1966), aff'd, 411 F.2d 1390 (8th Cir. 1969) (duty of drug manufacturer to give adequate warning of small percentage of risk in case involving first reported incidence of injury). able.⁴³ Thus, a patient's consent to psychosurgery could not be informed unless he were aware of the dangers that have been documented, the fact that unknown side effects may develop and the possibility of death.

Additional problems are introduced when the patient's competency is called into question. Arguably, no patient who can be considered a candidate for psychosurgery is capable of giving informed consent to the procedure because, in the physician's view, his brain is either damaged or malfunctioning. In such cases, the law usually gives the patient's legal guardian the power to consent to treatment,⁴⁴ but recent cases have made it clear that there are limits to the exercise of proxy consent. For example, parents have been required to obtain court approval for their consent to kidney⁴⁵ and bone marrow⁴⁶ transplants involving healthy minor siblings who act as donors'.

Dr. Peter Breggin, perhaps this country's most ardent opponent of psychosurgery, claims that psychosurgery is no more "a medical procedure . . . than the mutilation of an arm as punishment of a crime is a medical procedure."⁴⁷ This argument has legal implications because neither individuals nor their legal guardians may consent to a procedure that may be considered a maim or mutilation.⁴⁸ The ancient rationale for this rule was the king's right to the aid of his subjects. The rule survives, however, due to the state's interest in maintaining the health of its citizens. Maiming is therefore analogous to murder in that consent on the part of the victim is not a valid defense.⁴⁹ In the modern case of *State v. Bass*,⁵⁰ for example, a doctor was convicted as an accessory before the fact to the crime of mayhem for an-

43 See Kaimowitz v. Department of Mental Health, Civil No. 73-19434-AW, slip op. at 16 (Cir. Ct., Wayne County, Mich., July 10, 1973); Edson, The Psyche and the Surgeon, N.Y. Times, Sept. 30, 1973, § 6, pt. 1 (Magazine), at 14, 88-89. In one series, however, Dr. Walter Freeman reported eight deaths in 415 patients, or a two percent mortality rate. Freeman, *supra* note 6, at 622.

44 See J. Waltz & F. Inbau, Medical Jurisprudence 172 (1971).

⁴⁵ See Hart v. Brown, 29 Conn. Super. 368, 289 A.2d 386 (1972); Howard v. Fuiton-DeKalb Hosp. Authority, 42 U.S.L.W. 2322 (Ga. Super. Ct., Nov. 29, 1973); Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969). Three unreported Massachusetts decisions are discussed in Curran, A Problem of Consent: Kidney Transplantation in Minors, 34 N.Y.U.L. Rev. 891 (1959).

48 See Smith v. Smith, Eq. No. 43919 (Md. Cir. Ct., July 14, 1972); Camitta v. Fager, Eq. No. 73-171 (Mass., Sept. 5, 1973).

47 Hearings, supra note 1, at 359.

48 See 4 Blackstone, Commentaries *205; Annot., 86 A.L.R.2d 268 (1962).

⁴⁹ See State v. Bass, 255 N.C. 42, 46-47, 120 S.E.2d 580, 583 (1961). Cf. Physical Manipulation of the Brain, Hastings Center Report 7 (Special Supp., May 1973) (remarks of Dr. Robert Michels):

Does a person have the right to informedly consent to anything that might be done to him? Suicide raises the question most clearly. Does the individual have the moral, legal, ethical, or social right to kill himself if he fully understands the nature and meaning of his act and weighs the consequences thereof? Our law says no. Well, if you can't kill yourself, can you cut out 98 percent of your brain? Or 97 percent? Or 0.38 percent? Where is the line? If you can't kill yourself to relieve pain, can you destroy your essential humanity to relieve pain? What are the limits of essential humanity? Are there any? Does the concept mean anything?

⁵⁰ 255 N.C. 42, 120 S.E.2d 580 (1961).

esthetizing the fingers of an individual who desired to amputate them to obtain insurance proceeds. The actual amputation was performed by the individual when the doctor refused to perform the procedure himself.

The argument could be made that psychosurgery, like the amputation in *Bass*, involves the removal of nonpathological tissue and thus constitutes the common law crime of mayhem. The counterargument would be that psychosurgery may be performed for the sound medical purpose of alleviating aberrant behavior. However, there are more direct ways to modify behavior. Should the result in *Bass* have been different if the patient sought the removal of his fingers to render himself incapable of using a gun during periods of violence? Alternatively, should the result have been different if, instead of aiding the amputation of the patient's fingers, the defendant had paralyzed them through a neurological procedure?

The paralysis or removal of portions of an individual's brain in an antiseptic and highly sophisticated operating room has seemed so far removed from the early mayhem cases that the analogy has rarely been mentioned more than in passing.⁵¹ Although this mayhem argument would not apply to those psychosurgical operations that involve an underlying brain pathology, it would cover the removal or destruction of healthy brain tissue for the sole purpose of modifying behavior. Whether or not liability should follow directly from this analogy, it is certainly compelling enough to indicate that stringent safeguards must be instituted to protect patients before psychosurgical procedures are performed. The current emphasis on such protective procedures suggests yet another ground for a malpractice action.

3. Negligence in the Method of Review

[I]n most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.⁵⁴

⁵¹ See Kidd, Limits of the Right of a Person to Consent to Experimentation on Himself, 117 Science 211, 212 (1953); Note, Experimentation on Human Beings, 20 Stan. L. Rev. 99, 116 (1967).

⁵² W. Prosser, supra note 38, § 33, at 166.

^{53 60} F.2d 737 (2d Cir.), cert. denied, 287 U.S. 662 (1932).

⁵⁴ Id. at 740.

Thus, a tug boat company was held negligent for not having radio communications aboard even though it was acting in conformance with the prevailing standards within the industry. This rationale has also been employed to hold a hospital liable for its failure to ensure that a general practitioner call in an orthopedic consultant in a particular case, although such supervision was not customary.⁵⁵ In light of the known dangers involved in psychosurgical practice, courts would be justified in imposing upon hospitals where psychosurgery is performed a duty to provide exhaustive scientific and lay review even though such procedures are not as yet customary.⁵⁶

(b) Inadequate Review. If there is an established review committee, it may be liable for negligence in the performance of its duties.⁵⁷ If it could be demonstrated that a committee breached a duty to protect the interests of prospective psychosurgical candidates by allowing the operation to be performed on inappropriate subjects, the committee itself as well as the hospital may be liable under traditional negligence theory.

The one court case involving psychosurgery, Kaimowitz v. Department of Mental Health,⁵⁸ may provide a specific illustration of negligence on the part of review committee members. One member of the review committee in that case failed to attend any of the meetings relating to the proposed surgery on the plaintiff. It was his view that:

As a layman I am unqualified to comment on any of the technical aspects which are involved in the project. Therefore we must all trust the good intentions and technical competence of the Hospital Medical Committee, psychologists, psychiatrists, neurologists, etc. who have reviewed and evaluated John Doe's case.⁵⁹

⁵⁵ Darling v. Charleston Community Memorial Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), cert. denied, 383 U.S. 946 (1966).

⁵⁶ A federal court has imposed sterilization guidelines on Alabama state-run institutions. Included in the guidelines is the requirement of approval of the procedures by a sterilization review committee which must include a patient from the institution, a doctor, a lawyer, at least two women, and two minority group members. Med. World News, Feb. 1, 1974, at 4.

The authors are aware of the existence of only two psychosurgery review committees. One has been established in Oregon under statutory mandate, see text accompanying note 88 infra, and the other has been established at the request of the Board of Trustees at Boston City Hospital. See note 109 and accompanying text infra. However, the medical community is familiar with the use of review committees in other contexts. See Dagi, The Ethical Tribunal in Medicine, 54 B.U.L. Rev. 268 (1974); Kayes, Selection of Recipients and Donors for Renal Transplantation, 123 Arch. Inter. Med. 511 (1969); Mishkin, Multidisciplinary Review for the Protection of Human Subjects in Biomedical Research: Past and Prospective HEW Policy, 54 B.U.L. Rev. 278 (1974); Packer & Gampell, Therapeutic Abortion: A Problem in Law and Medicine, 11 Stan. L. Rev. 417 (1959); Rostenberg, The Ethics and Sociology of Peer Review, 27 J. Am. Med. Womens Ass'n 318 (1972); Slee, Streamlining the Tissue Committee, 44 Bull. Am. College of Surgeons 518 (1959).

57 Cf. Purcell v. Zimbelman, 18 Ariz. App. 75, 500 P.2d 335 (1972).

58 Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich., July 10, 1973).

⁵⁹ Letter from Frank Moran, Complaint, exhibit F, Kaimowitz v. Department of Mental Health, Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich., July 10, 1973).

If it was clear to this committee member what his responsibilities were, then such evasion of them is morally unjustifiable. And if, as appears necessary for responsible action on their part, a duty to protect the patient is imposed on such committees, such inaction would constitute its breach.⁶⁰

B. Public Actions

1. The Need for Regulation

Before a new drug is put on the market, the manufacturer is required to demonstrate to the satisfaction of the Food and Drug Administration that it is both safe and effective.⁶¹ If one wishes to experiment with a new surgical technique, however, no prior approval from a governmental or professional agency is generally needed before its use is promoted. The history of heart transplant procedures illustrates the absence of regulation over surgical innovation. The first human heart transplant was performed in South Africa on December 3, 1967.⁶² In a race to match this performance, more than 100 transplants were performed within the following year.⁶³ The fad ended rather quickly, however, because of the operation's high cost and low success rate. Both the initiation of the craze and its demise were governed solely by the actions of individual surgeons.

The growth of psychosurgical practice has taken place in much the same fashion. Psychosurgeons reporting their own results on their own scales have claimed amazing rates of success.⁶⁴ Although these self-evaluated "before and after" studies reveal some of the dangers involved, their anecdotal nature destroys their utility for the purpose of determining whether psychosurgery is a therapeutic medical procedure. A review of the medical literature reveals only two well-designed retrospectively controlled studies of psychosurgery, both of which conclude that lobotomy does not improve one's chances of leaving a mental institution.⁶⁵ The only prospective case-controlled studies that exist support the efficacy of psychosurgery in only the most limited of ways.⁶⁶ Finally, there are no controlled

⁶⁵ McKenzie & Kaczanowski, Prefrontal Leukotomy: A Five-Year Controlled Study, 91 Can. Med. Assoc. J. 1193 (1964); Robin, A Controlled Study of the Effects of Leucotomy, 21 J. Neurol. Neurosurg. Psychiat. 262 (1958).

⁶⁶ Marks, Birley & Gelder, Modified Leucotomy in Severe Agoraphobia: A Controlled

⁶⁰ The committee's duty would be derived from its purpose of protecting the prospective patient. It could be established by legislation, judicial declaration, hospital policy, the promulgation of regulations, or standards of professional organizations. To encourage their active participation, committee members should be reimbursed for their expenses and should receive some compensation for their time.

⁶¹ For a detailed discussion of the law in this area see H. Toulmin, A Treatise on the Law of Foods, Drugs & Cosmetics (2d ed. 1963).

⁶² T. Thompson, Hearts 278 (1971).

⁶³ Id. at 278-90.

⁶⁴ In one study, Freeman and Watts reported that 45 percent of their patients had good results, 33 percent were fair and 19 percent were poor. W. Freeman & J. Watts, *supra* note 19, at 494. In a later study, Freeman reported that 87 percent of the patients were able to leave the hospital. Sixty-five percent of this group were considered successes because of their ability to be employed or keep house. The other 22 percent live in a "state of idle dependency" either at home or in a nursing institution. Freeman, *supra* note 6, at 623. For a discussion of other studies showing high success rates see Sweet, *supra* note 20.

studies of the more modern forms of psychosurgery such as amygdalectomy and cingulotomy.⁶⁷

Dr. Henry Beecher has demonstrated the importance of such controlled studies in the evaluation of surgical techniques.⁶⁸ His research presents convincing evidence that there is a placebo effect in surgery comparable to that in drug therapy. In a prospectively controlled study of ligation of the mammary artery to relieve angina, for example, it was discovered that those receiving placebo surgery—that is, an incision was made, the artery was located but not ligated; and then the incision was closed—improved in clinical and objective terms as much as those receiving the actual mammary ligation. Also citing other studies of surgical treatments now in disrepute, Beecher was able to suggest that the placebo effect in surgery is approximately 35 percent.

Beecher also discovered other relevant variables affecting the "success" of placebo operations. These variables included the patient's frame of mind, usually one of stress due to pain or illness, and the relative enthusiasm of the surgeon for the procedure. Thus, in a study of gastroenterostomies for the treatment of duodenal ulcers, for example, skeptical surgeons obtained only half as many cures and 20 times as many marginal ulcers as did the enthusiasts.

These studies are particularly relevant to the debate over the efficacy of psychosurgical procedures. First, the candidate for psychosurgery is likely to be strongly motivated toward recovery. Second, the surgeons currently performing psychosurgery are enthusiasts who strongly believe in the ability of their procedures to alleviate symptoms.⁶⁹ Finally, the placebo effect is

67 Sweet, supra note 20.

⁶⁸ Beecher, Surgery as Placebo, 176 J.A.M.A. 1102 (1961). See Beecher, Evidence for Increased Effectiveness of Placebos with Increased Stress, 187 Am. J. Physiol. 163 (1956); Cobb, Thomas, Dillard, Meredino & Bruce, An Evaluation of Internal-Mammary-Artery Ligation by a Double-Blind Technic, 260 New Eng. J. Med. 1115 (1959); Dimond, Kittle & Crockett, Comparison of Internal Mammary Artery Ligation and Sham Operation for Angina Pectoris, 5 Am. J. Cardiol. 483 (1960). But see Livingston, Cingulate Cortex Isolation for the Treatment of Psychoses and Psychoneurosis, 31 Psychiatric Treatment: Proceedings of the Association for Research on Nervous and Mental Diseases, 374, 377 (1953) (reports four placebo cingulotomies that had no effect upon patient behavior).

⁶⁹ See, e.g., Psychosurgery (E. Hitchcock, L. Laitinen & K. Vaernet eds. 1972).

Serial Inquiry, 112 Brit. J. Psychiat. 757 (1966); Tan, Marks & Marset, Bimedial Leucotomy in Obsessive-Compulsive Neurosis: A Controlled Serial Enquiry, 118 Brit. J. Psychiat. 155 (1971). Dr. William H. Sweet has argued that one "carefully designed and executed" prospective study of lobotomy revealed significant beneficial results. Sweet, *supra* note 20, at 1118, *citing* Ball, Klett & Gresock, The Veterans Administration Study of Prefrontal Lobotomy, 20 J. Clin. Exp. Psychopathol. Q. Rev. Psychiat. Neurol. 205 (1959). However, Sweet neglects to point out the following: (1) the study disclosed no significant differences between the two groups in years one, two, three and five, *id.* at 208; (2) the lobotomized patients were more compliant, submissive and self-deprecating than the controls, *id.*; (3) almost half of the 373 patients were lost during the five-year evaluation period, *id.*; (4) the method used to match the controls was not discussed; (5) all conclusions relating to discharged patients were made on the basis of only 27 lobotomized patients and 18 controls, *id.*; and (6) the researchers evaluating the results were aware of which patients had been lobotomized and which had not, *id.* at 214.

particularly prevalent when subjective, psychological states rather than pathological entities are being treated. Thus, when Dr. Orlando Andy estimates his own success rate at 19 percent,⁷⁰ the efficacy of his procedures is called into serious question because one might anticipate even better results on the basis of the placebo effect alone.

2. Modest Beginnings

The absence of reliable medical data suggests that independent review of psychosurgical practice is required. Under present government policy, psychosurgeons' protocols are reviewed only when they are funded by grants or contracts from the National Institutes of Health (NIH) or when the facility in which their studies are being conducted receive such funds.⁷¹ Although these categories may seem rather inclusive, most psychosurgeons in the United States operate on patients outside the framework of an experimental design.⁷² Thus, for example, Dr. Thomas Ballantine of the Massachusetts General Hospital regularly performs cingulotomies for depression, anxiety states, obsessional neurosis and intractable pain without independent review of either his surgical protocols or his consent procedures.73 Dr. Orlando Andy also used to operate without committee review, but in the summer of 1973 the University of Mississippi Medical Center, through its Human Investigation Committee, decided that his surgery is basically investigative and experimental. Accordingly, a moratorium was imposed upon his performance of phychosurgery until an acceptable research protocol is submitted to the Committee.74

Even this limited form of institutional review is a relatively new development. It was not until 1966 that NIH first promulgated a policy requiring such review for the purpose of determining whether (1) the rights and welfare of individual patients were protected, (2) informed consent was procured, and (3) the potential medical benefits either to the patient or to society outweighed the risks of the suggested procedure.⁷⁵ But since the

72 Cf. Hearings, supra note 1, at 343.

⁷³ Ballantine, Cassidy, Brodeur & Giriunas, Frontal Cingulotomy for Mood Disturbance, *in* Psychosurgery, *supra* note 69, at 221. During the past year, Dr. Ballantine's patients have been evaluated by a psychiatrist and a neurologist, usually the day before surgery is scheduled to be performed.

⁷⁴ Memorandum from Dr. Albert Breland, Chairman, to the Committee on Surgical Therapy of Behavioral Disorders, Aug. 27, 1973 (on file at Center for Law and Health Sciences, Boston University School of Law).

⁷⁵ Curran, Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies, 98 Daedalus 542, 578 (1969). Cf. U.S. Dep't of Health, Education & Welfare, *supra* note 71, at 5-8.

⁷⁰ National Broadcasting Co., Should Man Play God? (Educational Enterprises Documentary Film, 1973).

⁷¹ U.S. Dep't of Health, Education & Welfare, Institutional Guide to DHEW Policy on Protection of Human Subjects 1 (1971). As of March 31, 1973, however, the federal government is no longer funding any clinical psychosurgery. *Hearings, supra* note 1, at 344 (remarks of Dr. Bertram Brown, Director of the National Institute of Mental Health). *See also* N.Y. Times, Feb. 15, 1974, at 54, col. 1.

required review committees could be composed solely of doctors,⁷⁶ NIH policy promoted merely another form of peer review, a mechanism of control that has generally proven ineffective.⁷⁷

Thus, until 1973, patients could protect their rights only through traditional malpractice actions while the medical profession was allowed to police itself. During the past year, however, significant new steps have been taken toward the regulation of psychosurgery.

IV. LEGAL RESPONSES

A. Judicial Action

The only case that has addressed the current issues in the psychosurgery debate is *Kaimowitz v. Department of Mental Health.*⁷⁸ Although this lower court opinion has no binding precedential effect in Michigan or any other jurisdiction, it is likely to influence future judicial and legislative activity if only because it is the first judicial pronouncement in this area.

In 1972, two psychiatrists at the Lafayette Clinic sought and obtained state funds to study the effects of amygdalotomy and cyproterone acetate, an anti-androgen, on male aggression in institutional settings. The study protocol was approved both by a scientific review committee and by a multidisciplinary "human rights committee." Twenty-four candidates were originally sought, but only one, Louis Smith, was considered suitable. For 17 years he had been confined in a Michigan state hospital as a criminal sexual psychopath after being charged with murder and rape. The researchers presented Smith and his parents a detailed consent form, which they both signed.⁷⁹

78 Civil No. 73-19434-AW (Cir. Ct., Wayne County, Mich., July 10, 1973). The case is discussed in greater detail in Comment, Kaimowitz v. Department of Mental Health: A Right to Be Free from Experimental Psychosurgery?, 54 B.U.L. Rev. 301 (1974).

79 The form reads:

Since conventional treatment efforts over a period of several years have not enabled me to control my outbursts of rage and anti-social behavior, I submit an application to be a subject in a research project which may offer me a form of effective therapy. This therapy is based upon the idea that episodes of anti-social rage and sexuality might be triggered by a disturbance in certain portions of my brain. I understand that in order to be certain that a significant brain disturbance exists, which might relate to my anti-social behavior, an initial operation will have to be performed. This procedure consists of placing fine wires into my brain, which will record the electrical activity from those structures which play a part in anger and sexuality. These electrical waves can then be studied to determine the presence of an abnormality.

In addition electrical stimulation with weak currents passed through these wires will be done in order to find out if one or several points in the brain can trigger my episodes of violence or unlawful sexuality. In other words this stimulation may cause me to want to commit an aggressive or sexual act, but every effort will be made to have a sufficient number of people present to control me. If the brain disturbance is limited to a small area, I understand that the investigators will destroy this part of my brain with an electrical current. If the abnormality comes from a larger part of my brain, I agree that it should be surgically removed, if the doctors determine that it can be done so, without risk of side effects. Should the electrical activity from the parts of my brain into which the wires have been placed reveal that there is no significant abnormality the wires will simply be withdrawn.

I realize that any operation on the brain carries a number of risks which may be

⁷⁶ U.S. Dep't of Health, Education & Welfare, supra note 71, at 4.

⁷⁷ Compare id. with U.S. Dep't of Health, Education & Welfare, National Institutes of Health, Protection of Human Subjects, Policies and Procedures, 38 Fed. Reg. 31738, 31741 (1973).

However, before the researchers were able to proceed with the implantation of electrodes, the Medical Committee on Human Rights filed a petition on behalf of Smith and similarly situated patients challenging the proposed research. It was ultimately discovered that Smith was being held unconstitutionally, and he was therefore ordered to be released.⁸⁰ In addition, publicity resulting from the case led the state's Department of Mental Health to withdraw its approval of the project. Nevertheless, a three-judge panel decided that the question involved was likely to arise again and proceeded to determine whether involuntarily confined individuals could ever legally consent to experimental brain surgery designed to ameliorate aggressive behavior.

After evaluating, with the help of expert testimony, the risks and potential benefits of the proposed procedure, the court concluded:

there is no scientific basis for establishing that the removal or destruction of an area of the limbic brain would have any direct therapeutic effect in controlling aggressivity or improving tormenting personal behavior, absent the showing of a well defined clinical syndrome such as epilepsy.⁸¹

On the other hand, however, the known risks to the physical and mental condition of the patient were great, including loss of reasoning ability and memory and general apathy.⁸² In light of this evidence, the court felt that psychosurgery must be regarded as highly experimental.

Proceeding to the question of consent, the court cited the entire text of the Nuremburg Code⁸³ and concluded that the inherently coercive atmosphere of lengthy institutionalization so greatly diminishes an individual's capacity to make a reasoned and voluntary decision about an experimental and irreversible surgical procedure that it is impossible to give legally valid consent in such circumstances.⁸⁴

Although the case is an important victory for proponents of the regulation of psychosurgery, the court's reasoning seems contradictory. On the one hand, the court emphasized the effects of institutionalization on the capacity of the patient to give informed and voluntary consent. On the other hand, however, it limited its holding to experimental situations. If amygdalotomy were to be considered an accepted neurosurgical practice, the involuntarily detained mental patient could, in the court's view, give

⁸¹ Id. at 17-18.

82 Id. at 17.

slight, but could be potentially serious. These risks include infection, bleeding, temporary or permanent weakness or paralysis of one or more of my legs or arms, difficulties with speech and thinking, as well as the ability to feel, touch, pain and temperature. Under extraordinary circumstances, it is also possible that I might not survive the operation.

Fully aware of the risks detailed in the paragraphs above, I authorize the physicians of Lafayette Clinic and Providence Hospital to perform the procedures as outlined above.

Civil No. 73-19434-AW, slip op. at 4 n.5 (Cir. Ct., Wayne County, Mich., July 10, 1973). 80 Id. at 6.

⁸³ Id. at 23-24.

⁸⁴ Id. at 31.

legally adequate consent to the performance of the procedure on his brain.⁸⁵ The nonexperimental status of a procedure may increase the prospective patient's knowledge concerning the risks and benefits involved, but it in no way counteracts the effects of institutionalization on his ability to consent in a truly informed fashion.

The case also raises serious questions concerning the efficacy of both scientific and human rights review committees. In *Kaimowitz*, such committees approved the protocol, but failed to maintain sufficient supervision to cancel the study when only one appropriate subject could be found. At least one member of the multidisciplinary committee personally interviewed Smith to determine the voluntariness and competency of his consent. Smith did, in fact, assure that member of his willingness to participate in the experiment, but upon his release from custody he withdrew his previously given consent.⁸⁶ It is therefore questionable whether even wellmeaning human rights committees can adequately evaluate the coercive effect of institutionalization on prospective candidates for controversial procedures. The promotion of such mechanisms of review in this context may only provide false comfort to our consciences.

B. Legislative Action

The state legislature of Oregon has already enacted a statute regulating the performance of psychosurgery in that state.⁸⁷ The statute provides that psychosurgery may be performed only with the affirmative vote of at least six members of a state-wide nine-member review board.⁸⁸ The function of this panel is to determine, according to statutory guidelines, whether the consent of the patient or his legal guardian is "informed" and "voluntary" and whether the proposed procedure is "appropriate treatment for the specific patient."⁸⁹

However, the provisions of the statute are insensitive to certain problems raised by psychosurgery. At least a majority and as many as seven members of the nine-member board may be physicians.⁹⁰ Only one need be an attorney and only one is designated as a "member of the general public."⁹¹ The board is thus heavily biased toward the scientific research community and may approve the performance of psychosurgery even against the dissent of all the "lay" members.

Another problem with the statute relates to the nature of the hearing. If the patient has a legal guardian, the board is required to review only

89 Id. § 8(1).

90 Id. § 3.

⁸⁵ Id. at 40.

⁸⁶ Id. at 29-30 n.23.

⁸⁷ Ch. 616 [1973 Ore. Reg. Sess.] (S. Bill 298), amending Ore. Rev. Stat. 677.190 (1971). The entire statute is reprinted as an appendix to Atkins & Lauriat, Psychosurgery and the Role of Legislation, 54 B.U.L. Rev. 288 (1974).

⁸⁸ Ch. 616, § 3(4) [1973 Ore. Reg. Sess.] (S. Bill 298), amending Ore. Rev. Stat. 677.190 (1971).

⁹¹ Id. § 3(f).

the consent of the guardian and the appropriateness of the proposed procedure. The patient himself need not testify, and the board may approve the procedure even if the prospective patient specifically opposes it.⁹² Unlike Kaimowitz, then, the statute can be read to sanction the performance of psychosurgery on a nonconsenting, involuntarily committed mental patient under guardianship so long as six of the nine board members approve. It seems certain that the sponsors of the statute were responding to the emerging concept of the "right to treatment" in allowing this result. But, as Wyatt v. $Stickney^{93}$ made clear, involuntarily committed mental patients are entitled to "a realistic opportunity to be cured or to improve [their] mental condition."⁹⁴ Moreover, the Wyatt court has specifically addressed the problem of psychosurgery in the following manner:

Patients have a right not to be subjected to treatment procedures such as lobotomy, electro-convulsive treatment, adversive reinforcement conditioning or other unusual or hazardous treatment procedures without their express and informed consent after consultation with counsel or interested party of the patient's choice.⁹⁵

In its attempt to establish a unified approach to psychosurgery, the Oregon legislature oversimplified the problems of consent by failing to make any distinctions among voluntarily or involuntarily confined mental patients, prisoners, children or competent adults. Finally, a lawyer need not be appointed for any class of patients unless one is affirmatively requested.⁹⁶ This choice or oversight substantially weakens the protection provided by the statute to the mentally disabled.

The psychosurgery controversy has also captured the attention of federal legislators. Senator J. Glenn Beall, Jr., for example, has introduced legislation calling for a two-year moratorium on the use of federal funds and facilities for projects involving psychosurgery.⁹⁷ During this time, the Secretary of Health, Education and Welfare would be required to compile and analyze the available data and present to Congress his views and recommendations concerning the appropriate use of such procedures.⁹⁸

Representative Louis Stokes has introduced a bill that would prohibit all forms of psychosurgery designed to alter behavior from being performed in federally connected health care facilities.⁹⁹ The performance of such procedures in violation of this legislation would subject doctors and institutions to fines of up to \$10,000 per operation to be assessed by a psy-

95 344 F. Supp. at 380.

⁹² Id. § 7.

⁹³ The developments in this case are reported at 325 F. Supp. 781 (M.D. Ala. 1971); 334 F. Supp. 1341 (1971); 344 F. Supp. 373 (1972).

^{94 325} F. Supp. at 784 (emphasis added).

⁹⁶ Ch. 616, § 11 [1973 Ore. Reg. Sess.] (S. Bill 298), amending Ore. Rev. Stat. 677.190 (1971).

⁹⁷ S.J. Res. 86, 93d Cong., 1st Sess. (1973).

⁹⁸ Id. § 2.

⁹⁹ H.R. 5371, 93d Cong., 1st Sess. (1973).

chosurgery commission.¹⁰⁰ The bill would, in addition, open the district courts to civil actions by patients.¹⁰¹ Finally, violators of the proposed statute would be barred from receiving any government contracts, grants or loans for a period of five years.¹⁰²

The statute most likely to be enacted has been introduced by Senator Edward Kennedy and has already passed the Senate.¹⁰³ It covers human experimentation in general but specifically calls for the establishment of a commission for the purpose of studying psychosurgery. In the meantime, however, no moratorium on its practice would be imposed.

C. Administrative Action

In response to intense congressional and public pressure, the Department of Health, Education and Welfare (DHEW) has recently proposed significant modifications of its currently required review of human research. On October 9, 1973, DHEW proposed that all institutional review committees be composed of "not less than five persons with varying backgrounds."¹⁰⁴ If promulgated as currently proposed, the regulations would require the committees to be composed in a manner enabling them "to determine the acceptability of the [research] proposal in terms of the organization's commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes."¹⁰⁵

In addition, NIH, the component of DHEW that sponsors most of its research on human beings at risk, has proposed changes in the review process relating to experiments on children, prisoners or the mentally infirm.¹⁰⁶ Essentially, these proposed regulations establish two additional committees to pass upon particular research proposals. Each DHEW agency would be required to appoint an Ethical Review Board to consider "ethical issues and questions of societal acceptability in relation to scientific value."¹⁰⁷ The institution at which the research is being conducted would be responsible for the creation of a Protection Committee whose function it would be to oversee the selection of subjects, monitor their continued willingness to participate and intervene on their behalf if necessary.¹⁰⁸

It is important to note that however significant such administrative action is, it fails to reach directly most of the psychosurgery currently being performed in the United States. On the other hand, however, if such procedures are widely adopted by hospitals and mental institutions, they may

105 Id.

¹⁰⁰ Id. § 3(a)(1).

¹⁰¹ Id. § 3(c)(1).

¹⁰² Id. § 3(d).

¹⁰³ S. 2071 & S. 2072, 93d Cong., 1st Sess. (1973). In the House of Representatives the bill is H.R. 7724, 93d Cong., 1st Sess. (1973).

¹⁰⁴ U.S. Dep't of Health, Education & Welfare, Protection of Human Subjects: Proposed Policy, 38 Fed. Reg. 27882, 27883 (1973).

¹⁰⁶ U.S. Dep't of Health, Education & Welfare, supra note 77.

¹⁰⁷ Id. at 31741.

¹⁰⁸ Id. at 31741-42.

establish a new standard of care binding on operations performed in nonresearch settings as well. It was with such a potential development in mind, in addition to pressure from the community, that the Trustees of Boston City Hospital established a multidisciplinary review committee to review candidates for psychosurgery.¹⁰⁹

V. CONCLUSION: THE REFINEMENT OF LEGAL RESPONSES

Dr. Franz Ingelfinger has argued that informed consent is not meaningful in the hospital setting because of the control doctors exercise over their patients. In his view, "the subject's only real protection . . . depends on the conscience and compassion of the investigator and his peers."¹¹⁰ Although our society has been willing to rely on this form of protection in the past, recent developments in medical technology and an increasing awareness of past abuses have made imperative the establishment of more stringent safeguards. Community sensibilities will no longer allow, for example, the unregulated research of scientists who respond to suggestions concerning the special nature of the human brain as opposed to other organs with the argument that "[t]he inviolability of the brain is only a social construct, like nudity."¹¹¹

One of the law's responses to this dilemma has been to enlarge the concept of informed consent by compelling the physician to disclose all information necessary for the patient to become meaningfully involved in the decision-making process. This development, coupled with the increased frequency of malpractice litigation, has prompted doctors to call for nofault malpractice insurance and for binding arbitration of malpractice claims.¹¹² However, the medical profession's demonstrated inability to police itself in controversial areas like psychosurgery suggests that malpractice litigation must be retained as the consumer's only available method of controlling the quality of medical care.

Another response that has been proposed and that deserves further experimentation is the involvement of community representatives and nonmedical professionals in the decision-making process. The problems posed

110 Ingelfinger, Informed (But Uneducated) Consent, 287 New Eng. J. Med. 465 (1972). 111 Physical Manipulation of the Brain, *supra* note 49, at 11 (remarks of Dr. José Delgado).

(

¹⁰⁹ Dr. Vernon Mark, Director of Neurosurgical Service at Boston City Hospital, performs stereotactic psychosurgery on patients with diagnosable temporal lobe epilepsy. The hospital's Board of Trustees appointed Dr. David F. Allen, a psychiatrist, to establish and chair a multidisciplinary committee for the purpose of reviewing Dr. Mark's patients. In addition to Dr. Allen, the committee is composed of a medical doctor, a lawyer, a political scientist, a minister, a medical student, a sociologist, a research biogeneticist and two representatives from the local community. All of the members were chosen by the chairman on the basis of experience, ability and willingness to attend meetings; and all serve without compensation. Two consulting neurologists and an administrator were made available to the committee.

¹¹² See Baker, Proposal for a Medical Malpractice Arbitration Plan Using Cleveland, Ohio as a Model, Ill. Ins. L.J. 625 (1972); Henderson, Arbitration & Medical Services, 28 Arb. J. 15 (1973); Medical Malpractice (D. McDonald ed. 1971); Med. World News, Jan. 25, 1974, at 66.

by psychosurgery and many other medical procedures are not capable of resolution merely on the basis of medical considerations. It is for this reason, and because of the tendency of peer review committees to act as rubber stamps for the research protocols of members of their own profession, that significant nonmedical representation on review committees should be assured.

Our experience with multidisciplinary committees, however, is so limited that we must guard against their becoming a mechanism merely serving a legitimizing function on the basis of inadequate consideration. The criteria they employ and the decisions they reach should receive constant scrutiny to assure that the rights of patients are being protected. For this purpose, certain procedural safeguards should be built into the review process. First, a prospective patient should always be represented by legal counsel during committee proceedings and should have the right to cross-examine witnesses and challenge documents presented against him. Second, the committees should follow written standards for review, keep minutes of their meetings and record individual votes for every decision. The keeping of detailed minutes and the recording of votes should act as a safeguard against the diffusion of personal responsibility.¹¹³ If the research proposal and the consent of the patient are reviewed according to such procedures, individuals legally competent to give their informed consent should be allowed to undergo psychosurgical operations.

Certain classes of prospective patients, however, require more stringent protection. The confinement or status of prisoners, institutionalized mental patients and children makes them especially vulnerable. Thus, in addition to committee review and approval, there should be established a presumption, rebuttable only in a court of law, that psychosurgery cannot be performed on them. To rebut this presumption, the proponent of psychosurgery should be required to demonstrate beyond a reasonable doubt that the patient's consent is both voluntary and informed, and that there is a reasonable probability that the procedure will produce the desired effect. Although this proposal may amount to a de facto ban on the performance of psychosurgery on members of these groups, it would permit such operations under extremely compelling circumstances.

It is much too early in our experience with the mechanism of multidisciplinary review to reach any final conclusions with respect to its ability to regulate potentially abusive medical procedures. It is clear, however, that the current system of regulation is not only woefully inadequate, but practically nonexistent. For the present, then, the establishment of review committees along the lines suggested above offers a regulatory approach that permits the medical community to proceed with necessary research on the human brain without sacrificing the individual rights of patients.

¹¹³ Stanley Milgram's experiments have demonstrated that the fragmentation of responsibility may lead average individuals to commit inhuman acts. Milgram, The Perils of Obedience, Harper's, Dec. 1973, at 62. See also S. Milgram, Obedience to Authority (1974). Thus, the proliferation of committees proposed by NIH may prove self-defeating. See text accompanying notes 106-08 supra.