Judicial Review of Medical Treatment Programs

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Physicians have long enjoyed autonomy in their decisions about medical treatment. But in recent years a rise in professional liability suits,[1] vigorous efforts by hospital-accrediting agencies to develop standards for care of hospitalized patients,[2] enactment of a law mandating peer review of physicians who are reimbursed under federal programs,[3] and broadening of legislative and administrative regulation of drug prescriptions and clinical research activities[4] have brought home to physicians the concept of accountability for their actions. In malpractice suits, expanded application of the doctrines of informed consent[5] and res ipsa loquitor[6] have reinforced this sense of exposure.

As these trends have developed, the question of the limits of judicial power with respect to medical decision-making has assumed growing importance. For example, in a widely-publicized case, a Michigan county court held that brain surgery on an involuntary mental patient is unlawful where the goal of surgery is to control the patient's violent behavior.[7] The court reached

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1. *See* DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, PUB. No. 05-73-88, REPORT OF THE SECRETARY'S COMM'N ON MEDICAL MALPRACTICE 12 (1973).

2. JOINT COMM'N ON ACCREDITATION OF HOSPITALS, ACCREDITATION MANUAL FOR HOSPITALS 35-49 (1973) (setting forth standards for hospital accreditation which are designed to encourage high level of professional performance by physicians).

3. Social Security Amendments of 1972, 42 U.S.C. §§ 1320c-20c-19 (1972). For a doctor's analysis of the law, see Welch, *Professional Standards Review Organizations—Problems and Prospects*, 289 N. ENG. J. MED. 291 (1973).

4. *See* National Research Service Act of 1974, 42 U.S.C. § 2891 (1974) (mandating establishment of a federal commission to protect human subjects of medical research). *See generally* W. CURRAN & E. SHAPIRO, LAW, MEDICINE, AND FORENSIC SCIENCE 728-38 (2d ed. 1970) (summarizing the colloquy between a medical pharmacologist and representatives of the Food and Drug Administration over alleged excesses of the agency in attempting to regulate prescribing practices of physicians); Regier, *Labeling Regulations: 'Prescribe as Directed,'* 2 J. LEGAL MED. 48 (1974) (criticizing proposed FDA regulations of prescription drugs as being too restrictive).

5. *See* Karchmer, *Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug,"* 31 MO. L. REV. 29 (1966), Comment, *Patient's Rights and Informed Consent: An Emergency Case for Hospitals?*, 12 CALIF. WEST. L. REV. 406 (1976).

6. *See* Rubsamen, *Res Ipsa Loquitor in California Medical Malpractice Law —Expansion of a Doctrine to the Bursting Point*, 14 STAN. L. REV. 251 (1962).

7. Kaimowitz v. Department of Mental Health, Civ. No. 73-19434-AW (Cir.

this result even though the patient had signed a detailed consent form and the surgery had been approved by two review committees of physicians and laymen. In reaching its decision, the court found that brain surgery is not an established therapy for violent behavior and that, in any event, the patient's long institutionalization made a truly voluntary consent impossible.

While this decision by itself does not necessarily portend increasing judicial scrutiny of the merits of medical treatments, some commentators have suggested that one of its effects will be to halt the use of surgery as a means of controlling disturbed behavior.[8] If this is indeed the significance of this case, a single lower court decision will have placed off limits a form of treatment which has helped many in the past and which, with refinements, might be of even greater value in the future.[9] A more moderate view might be that since the issues of uncertain efficacy and possible exploitative use as a technique of social control have now been widely ventilated,[10] physicians may still lawfully perform psychosurgery on selected patients in accordance with rigorous scientific and legal criteria. This view would accommodate both the interests of individual patients and the broader goal of achieving better therapy than that which now exists for disturbed behavior.

Psychosurgery is but one of a number of innovative or controversial medical treatments which may engage judicial attention. Others include shock therapies, large scale drug treatment programs, and behavior or conditioning therapies—all of which may have lasting and harmful effects on mentation or behavior. Also included are open heart surgery and transplant surgery, which may carry appreciable risks of death. Although these disparate forms of treatment raise different medical issues and involve different populations of patients, they have certain features in common. They are frequently carried on in large medical centers and involve several physicians and other medically-oriented persons. They are frequently part of clinical research activity for which special protocols have been designed. The results of treatment may be presented at scientific meetings and published in medical jour-

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Ct., Wayne County, Mich., July 10, 1973), *summarized at* 42 U.S.L.W. 2063 (July 31, 1973).

8. Note, *Kaimowitz v. Department of Mental Health: A Right to be Free From Experimental Psychosurgery*, 54 B.U.L. REV. 301, 323 (1974).

9. *See* Mark, *Psychosurgery Versus Anti-Psychiatry*, 54 B.U.L. REV. 217 (1974); Sweet, *Treatment of Medically Intractable Mental Disease by Limited Frontal Leucotomy—Justifiable?*, 289 N. ENG. J. MED. 1117 (1973).

10. *See* Chorover, *Psychosurgery: A Neuropsychological Prospective*, 54 B.U.L. REV. 231 (1974); MEDICAL COMMITTEE FOR HUMAN RIGHTS, PSYCHOSURGERY: ABUSE OF MEDICINE FOR SOCIAL CONTROL (mimeograph on file with the author).

nals, thereby becoming a basis for treatment decisions by others. These common features justify amalgamation of diverse medical procedures in considering judicial review of medical treatment programs.

This Article will review three aspects of medical treatment programs. The first is the range of therapeutic abuses which may occur. The second is the existence of non-judicial constraints on the behavior of participating physicians. The third is the scope of judicial review of these programs. The thesis of this Article is that the focus of judicial review should be on the process by which decisions about medical treatment are made and when innovative or controversial treatments are weighed, courts should resist letting the nature of the treatment determine the legal issues. A treatment itself is seldom inherently bad. The important considerations are who prescribes it and on what evidence they rely in selecting it. The rule that no patient should receive an innovative or controversial treatment without a full and coherent explanation of anticipated risks and benefits and available therapeutic alternatives will not be questioned.[11] The shared goal of most physicians and lawyers is to assure that medical treatment is well conceived and executed and that patients are not subjected to inappropriate risks. Allocating to the judiciary or the legislative branch the role of making ultimate decisions about the value of brain surgery, shock therapy, heart surgery and other such treatments could lead to both unsound decisions and unfortunate strictures on progress in medical therapy.

Rather than consider the gamut of therapies that may be employed in treatment programs, this Article will concentrate on treatments which are directed at disturbed behavior, particularly violent behavior. They may be broad in scope and include drugs, shock treatments, brain surgery, brain stimulation, psychotherapy and behavior-modification techniques which depend on conditioning. They are frequently proposed for those individuals who may be unable to protect themselves and who especially need the law's protection such as hospitalized mental patients, prisoners, children and the mentally retarded. Moreover, the goals of these

11. For an example of a code of ethics concerning the use of humans as experimental subjects, see the Declaration of Helsinki listed in 67 AN. INTERNAL MED., 74, 75 (Supp. 7 1967). It is noteworthy that Doctor Vernon Mark, a neurosurgeon who has been strongly criticized for his advocacy of psychosurgery for some patients, firmly supports the principle of informed consent to psychosurgery. In addition, he would enlist the support of an impartial review committee to assess the propriety of a psychosurgical procedure and would not in any event perform psychosurgery on prisoners. Mark & Neville, *Brain Surgery in Aggressive Epileptics*, 226 J.A.M.A. 765, 772 (1973).

treatments underscore the sensitive and heavily polemicized issue of the extent to which medical treatment should be used to manage socially offensive behavior.[12] It is hoped that emphasizing problems of treatment in this particular area will illustrate factors involved in the process of medical treatment, and will assist formulation of an approach to judicial review of medical treatment programs in general.

I. MEDICAL TREATMENT AND ITS ABUSE

A. Empiricism in Treatment

Medical treatments range from the wholly empirical to those based on a precise understanding of biological mechanisms. The latter situation is the ideal because it allows for rational choices of treatment and minimizes the risks of blunderbuss prescribing. But, surprising as it may seem, many established medical treatments work in ways that are poorly understood. Such widely prescribed drugs as aspirin, morphine and cortisone derivatives evoke their definite, and at times, spectacular therapeutic effects through mechanisms that remain to be clarified.[13] The effectiveness of electroshock, a pillar of psychiatric treatment, is even less well understood.[14] The lack of knowledge about how these treatments work, however, does not obscure the fact that they *do* work. Thus, while imperfect understanding of treatment may contribute to inappropriate prescriptions in some instances, therapeutic diffidence might result if physicians were to insist upon impeccable definitions of therapeutic mechanisms before prescribing. The consequence in terms of human suffering would likely far outweigh the reduction in adverse reactions to treatment or the lessened costs of strictly rational prescribing. Therefore, empirical or "nonrational" prescribing has become an accepted element of medical treatment.

The problems associated with empirical treatment may be accentuated in the realms of mental illness and disturbed behavior. One factor is that formidable difficulties exist in defining the biological disturbances, if any, which underlie aberrant behavior. Thus, while many scientists believe that the major forms of psychosis,

12. *See generally* B. ENNIS, PRISONERS OF PSYCHIATRY (1972); N.N. KITTRIE, THE RIGHT TO BE DIFFERENT (1971). For novelistic viewpoints, see M. CRICHTON, THE TERMINAL MAN (1972); K. KESEY, ONE FLEW OVER THE CUCKOO'S NEST (1962).

13. *See* THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 237-55 (morphine), 314-29 (aspirin), 1629-35 (cortisone and related compounds) (4th ed. L. Goodman & A. Gilman eds. 1970).

14. *See* L. KOLB, NOYES' MODERN CLINICAL PSYCHIATRY 590-602 (7th ed. 1968).

such as the schizophrenias and severe forms of depression, reflect alterations in the biological functions of the brain, the tantalizing suggestions still outweigh the hard data.[15] Because some psychotic patients improve when tranquillizing or anti-depressant drugs are given or after shock treatments are administered, it has been suggested that the treatments are correcting specific biological disturbances.[16] But until the nature of these disturbances is demonstrated, the mode of action of the drugs or shock therapy must remain speculative. Another factor complicating evaluation of treatment of psychiatric patients is that many exhibit wide fluctuations in behavior in the untreated state, and at times may appear free from mental illness. It may be hazardous to conclude that a therapy has modified behavior unless the period of observation is prolonged and the criteria for evaluating effectiveness of treatment have been carefully developed and applied.[17] Also, it is frequently important that those who are responsible for evaluating responses to treatment either not be aware of what treatment has been administered, or at least not participate in formulating the clinical research protocol or in publishing the results of the study. In other words, the possibility of biased observations or mispercep-

15. Akiskal & McKinney, *Depressive Disorders: Toward a Unified Hypothesis,* 182 SCIENCE 20 (1973); Snyder, Banerjee, Yamamura & Greenberg, *Drugs, Neurotransmitters, and Schizophrenia,* 184 SCIENCE 1243 (1974); UCLA INTERDEPARTMENTAL CONFERENCE, *Schizophrenia,* 70 AN. INTERNAL MED. 107 (1969).

16. *See* Schildkraut, *Neuropsychopharmacology and the Affective Disorders,* 281 N. ENG. J. MED. (pts. 1-3) 197, 248, 302 (1969).

17. The great challenge of clinical research is to design a study which will yield interpretable and defensible results. The investigator must not only possess the knowledge of where medical uncertainties lie, but he or she must also be imaginative enough to create a protocol which provides answers to the question at hand. *See generally* Schumacher, *Critique of Experimental Trials in Multiple Sclerosis,* 24 NEUROLOGY 1010 (1974) (emphasizing the problems of evaluating therapeutic efficacy in a neurological disease of notoriously variable progression).

Where humans are involved, it may be difficult to enlist enough subjects to obtain statistically significant results or to control the extent to which they participate in a particular project. Thus, if the effects of a specific treatment are being evaluated, the researcher must convince a large number of persons to accept the treatment and then make certain that they in fact take the treatment as prescribed for the duration of the study. These goals are easier to achieve where the subjects of the study are already hospitalized and can thus be carefully monitored. This explains why evaluation of treatments affecting behavior are more often carried on in large psychiatric hospitals. Moreover, if a specific treatment is to be weighed in comparison to other treatments or to no treatment, it is important that the group under study be as comparable as possible to groups receiving other treatments or no treatment with respect to age, sex, general health, and nature of the disease process for which treatment is offered. It is the failure to develop such control groups for comparison purposes that doubt is cast upon many reports of favorable responses to treatment. Thus, one of the greatest perjoratives a clinical investigator uses in criticizing the work of another is that it is "anecdotal;" that is, it is based on observations of individual cases or groups of cases which are made without reference to comparable groups that received different treatment. For a detailed but readable critique by a neurophysiologist of the allegedly favorable results of psychosurgery, see E. VALENSTEIN, BRAIN CONTROL 294-335 (1973). For a lawyer's critique, see Annas & Glantz, *Psychosurgery: The Law's Response,* 54 B.U.L. REV. 249 (1974).

tions must be minimized if reports of therapeutic efficacy are to be credible.

Treatment of disturbed behavior is frequently classified as somatic or non-somatic. The somatic treatments presumptively have direct biological effects. Examples include drugs, surgery, shock therapies and electrical stimulation. The non-somatic treatments encompass psychotherapy and behavior therapy. While some non-somatic treatments may ultimately evoke biological changes, current usage stresses their effects on the psyche, almost as if it were divorced from the biological functioning of the brain. In any event, it is not unusual for a patient concurrently to receive both somatic and non-somatic treatments.

B. Somatic Treatments

1. Drugs.—Physicians regularly prescribe drugs to modify disturbed behavior or to alter discomforting moods. The choice of drug depends on the nature of the disturbance and the objective of treatment. An agitated, fearful schizophrenic may benefit from a major tranquillizer such as trifluoperazine (Stelazine) or haloperidol (Haldol), while a deeply withdrawn or suicidal patient may respond to an anti-depressant such as amitriptyline (Elavil) or imipramine (Tofranil).[18] Where a patient experiences a severe manic state, lithium salts are frequently helpful.[19] Amphetamines or methylphenidate (Ritalin), which are classed as stimulant drugs, may paradoxically suppress the extreme hyperactivity that afflicts some young children.[20] Anti-convulsant drugs, such as diphenylhydantoin (Dilantin) or phenobarbital, may be appropriate where behavioral disturbances are manifestations of an underlying epilepsy.[21]

Proper use of drugs requires diagnostic precision. Giving a tranquillizer to a severely depressed person may only deepen melancholy and accentuate suicidal impulses. Failure to perceive that

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18. Anderson & Kuehnle, *Strategies for the Treatment of Acute Psychosis*, 229 J.A.M.A. 1884 (1974).

19. Schou, *Lithium in Psychiatric Therapy and Prophylaxis*, 6 J. PSYCHIATRIC RES. 67 (1968).

20. *See* Pincus & Glaser, *The Syndrome of "Minimal Brain Damage" in Childhood*, 275 N. ENG. J. MED. 27 (1966); Eisenberg, *The Clinical Use of Stimulant Drugs in Children*, PEDIATRICS 709 (1972). *But see*, Conners, *Psychological Effects of Stimulant Drugs with Minimal Brain Dysfunction*, PEDIATRICS 702 (1972), where the author indicated that this is not a "paradoxical" situation. The fact that chronic amphetamine use may lead to a psychosis which mimics schizophrenia further illustrates the complexity of drug effects on the brain. S. SNYDER, MADNESS AND THE BRAIN 200-14 (1974).

21. Goldensohn & Gold, *Prolonged Behavioral Disturbances as Ictal Phenomena*, 10 NEUROLOGY 1 (1960); Slater & Beard, *The Schizophrenia-like Psychoses of Epilepsy*, 109 BRIT. J. PSYCHIA. 95 (1963).

paroxysmal rage reactions or amnesic episodes are epileptic phenomena may lead to fruitless provision of tranquillizers or psychotherapy, in lieu of anti-convulsant drugs that might afford complete control of symptoms. Thus, physicians seek to achieve as much diagnostic certainty as possible before prescribing. Where diagnostic uncertainty exists, the help of other physicians may be sought. For example, if a psychiatrist is uncertain as to the cause of a patient's paroxysmal outbursts of rage, he may ask a neurologist for an opinion as to whether the patient has epilepsy or some other form of identifiable brain disease and, if so, what further studies are indicated.

Implicit in every prescription of drugs is the risk of unexpected side-effects. The range of adverse reactions for most drugs is so great that it is the rare physician indeed who can quote all the reported side-effects of a particular compound.[22] These side-effects may include disturbances in mental function, mood or behavior and may raise the issue of whether a patient is becoming worse because of disease or because of treatment. Moreover, there is often no basis for predicting that a patient will be particularly vulnerable to the development of side-effects. There are, of course, side-effects which are so common that physicians anticipate their occurrence and are vigilant in observing for them. For example, one of the well-known side effects of phenothiazine (e.g. chlorpromazine) and butyrophenone (e.g. haloperidol) tranquilizers is the development of abnormal body movements.[23] These may range from involuntary tongue and facial movements (orofacial dyskinesias) to a full-blown Parkinsonian syndrome with tremor, rigidity, slowed movements, stooped posture and poor balance. Occasionally these disorders of movement persist after discontinuing the offending drugs, and they may impose severe physical incapacity.[24]

Where the goal of drug treatment is the moderation of violent or aggressive behavior, tranquillizers are a likely choice.[25] In suitable

22. For example, diphenylhydantoin (Dilantin), a drug which is widely used in the treatment of epilepsy, may have side effects ranging from mild nausea to hepatitis, anemia, destructive skin rashes and a form of brain damage that causes loss of coordination. ANTI-EPILEPTIC DRUGS 219-26 (D. Woodbury, J. Perry & R. Schmidt eds. 1972). For a view that recognition of adverse drug reactions is as important as recognizing malignancy, infection or metabolic abnormality, see Irey, *Adverse Reactions to Drugs and Chemicals,* 230 J.A.M.A. 596 (1974).

23. AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY—FDA TASK FORCE, *Neurologic Syndromes Associated with Anti-Psychotic Drug Use,* 289 N. ENG. J. MED. 20 (1973).

24. Schmidt & Jarcho, *Persistent Dyskinesias Following Phenothiazine Therapy,* 14 ARCH. NEUROL. 369 (1966).

25. *See* Anderson & Kuehnle, *supra* note 18, at 1884.

doses these may calm the patient, either through a general relaxing effect or by eliminating frightening hallucinations or delusions that trigger violent outbursts. Whether tranquillizers are of lasting value often depends on the underlying illness. A severely brain-damaged patient or a deteriorated chronic schizophrenic may not be manageable unless dosages are prescribed that produce somnolence or stupor. Another factor influencing the success or failure of drug treatment is the quality of other aspects of care. Merely giving tranquillizers may be of little value if a patient is ignored by physicians and other staff, or is subjected to persistent abuse or deprivations.

In the unusual case where violent outbursts are manifestations of epilepsy,[26] anti-convulsant therapy may be effective.[27] However, extensive neurological investigation may be required to establish the epileptic basis of the behavior, and the link may go unperceived for a considerable time. Once a diagnosis is established, the success of treatment depends on several factors, including the efficacy of the anti-convulsant drug, the nature of the process causing the epilepsy, the quality of follow-up by the physician, and the capacity of the patient to accept treatment. Anti-convulsant drugs must be taken regularly, usually daily, for optimum effectiveness, and the patient who is forgetful, erratic or defiant of the physician risks persistent seizures.[28] Outbursts of violence may, of course, be related to brain diseases other than epilepsy.[29] In these instances anti-convulsant therapy is of no specific value and surgery or other forms of treatment may be indicated.

2. *Shock Therapies.*—These forms of treatment are emphatically empirical. The reasons why electroshock or insulin shock produce therapeutic benefit are quite obscure. Yet it is generally accepted that electroshock treatment relieves some serious depressions[30] and that insulin shock has been useful in treating some

26. *See generally* V. MARK & F. ERVIN, VIOLENCE AND THE BRAIN 69-124 (1970); Currie, Heathfield, Henson & Scott, *Clinical Course and Prognosis of Temporal Lobe Epilepsy*, 94 BRAIN 173 (1971).

27. *See* note 21 *supra* and accompanying text.

28. It is now possible, through measurements of the amounts of anticonvulsant drugs in the blood, to determine if a patient needs adjustments in dosage or if he is taking the prescribed dosage. Kutt and Penry, *Usefulness of Blood Levels of Antiepileptic Drugs*, 31 ARCH. NEUROL. 283 (1974).

29. *See* Malamud, *Psychiatric Disorder With Intracranial Tumors of Limbic System*, 17 ARCH. NEUROL. 113 (1967); Reeves & Plum, *Hyperphagia, Rage and Dementia Accompanying a Ventromedial Hypothalamic Neoplasm*, 20 ARCH. NEUROL. 616 (1969).

30. L. KOLB, *supra* note 14 at 594. For a view that one of the advantages of electroshock in treating schizophrenia is that it allows a busy psychiatrist to handle more patients than would ordinarily be possible through use of drugs and psychotherapy, see Sullivan, *Treatment of Acute Schizophrenia: The Place of ECT*, 35 DIS. NERV. SYS. 467 (1974).

schizophrenic reactions.[31] Electroshock is still rather widely used. But the use of insulin shock has declined because of the known adverse effects on brain function of the lowered blood sugar levels (hypoglycemia) which follow administration of insulin.[32]

Despite the fact that electroshock produces rather dramatic physiological and chemical changes, including convulsions, sharp rises in blood pressure, brain blood flow, heart rate, and accelerated use of oxygen and blood sugar,[33] there are few reports of long-term adverse effects from its use.[34] Before use of anesthesia and muscle relaxant agents as adjuncts to shock therapy, fractures of vertebrae, hips and extremities were the most common complications. Fractures are now rather rare, as are cardiovascular complications such as heart attack and stroke.[35] The most disturbing complication now appears to be memory impairment. Most patients who undergo electroshock experience a transient amnesia for recent events and newly-acquired knowledge.[36] But some patients experience a severe and permanent enough loss of memory to prevent resumption of previous vocations.[37] The cause of the more chronic memory impairment is uncertain, but it is probable that repetitive seizures induced by electroshock interfere with blood flow to, or metabolism in, portions of the "limbic" brain that are essential to retention of information.

Electroshock or insulin shock would seem to be of little value in the treatment of violent or aggressive behavior per se, although these therapies probably have benefitted some chronic psychotics whose behavioral aberrations include outbursts of violence. In any event, violent behavior as a phenomenon is not an accepted indication for the use of shock therapy.

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31. L. KOLB, *supra* note 14, at 601-02.

32. *See* Courville, *Late Cerebral Changes Incident to Severe Hypoglycemia (Insulin Shock)*, 78 ARCH. NEUROL. & PSYCHIA. 1 (1957); Kolb & Vogel, *The Use of Shock Therapy in 305 Mental Hospitals*, 99 AM. J. PSYCHIA. 90 (1942).

33. R. SCHMIDT & B. WILDER, EPILEPSY, 100-03 (1968).

34. *See* L. KALINOWSKY & H. HIPPIUS, PHARMACOLOGICAL, CONVULSIVE AND OTHER SOMATIC TREATMENTS IN PSYCHIATRY 178 (1969).

35. Beresford, *Legal Issues Relating to Electroconvulsive Therapy*, 25 ARCH. GEN. PSYCHIA. 100 (1971).

36. Cronholm & Ottosson, *The Experience of Memory Function after Electroconvulsive Therapy*, 109 BRIT. J. PSYCHIA. 251 (1963).

37. Despite the obvious importance of the question as to whether patients receiving electroshock therapy develop permanent memory deficits, there is a dearth of careful studies on this point. Perhaps this is because most patients receiving electroshock tolerate it remarkably well. On the other hand, the consequences of a permanent loss of the capacity to recall may be quite devastating. For a vivid example of such as described in a non-medical publication, see THE NEW YORKER, Sept. 9, 1974 at 84 (portraying the apparently permanent loss by an economic analyst of the capacity to recall data essential to the performance of her job, following a series of eight electroshock treatments). While this account is admittedly "anecdotal," it stands as a detailed and perceptive narrative of the subjective impact of impaired memory.

3. Surgery.—The current furor over psychosurgery[38] suggests that this is a new form of treatment. However, brain operations to alter behavior have been performed for many years, and it has been estimated that in the 1940's and 1950's as many as 50,000 such operations were performed.[39] The classic operation was a so-called frontal lobotomy. This was sometimes used for patients who were unmanageably violent, but it was also performed in schizophrenics and in patients who exhibited disabling compulsive or obsessive behaviors. It was not limited to involuntarily hospitalized mental patients, but most of the subjects were in this category. Many beneficial results were reported, but the quality of the evaluations of therapeutic efficacy was often unimpressive. Side effects, when mentioned, were seldom described in any detail.[40] In any event, the procedure fell into disrepute until neurosurgical techniques evolved to the point where precise destruction of small areas of brain could be achieved without major morbidity.

It is now possible for a neurosurgeon to place a tiny lesion (destructive focus) in a patient's brain via a thin electrode or cannula which can be passed through brain tissue without apparent ill-effect. The lesion can be made by electrical coagulation, freezing, or the infusion of a chemical toxin and it can be precisely localized using radiographic and stereotactic techniques. Moreover, the procedure can frequently be achieved under local anesthesia.

With this sort of methodologic improvement, several neurosurgeons have reported on brain surgery that has altered behavior without physical injury to patients.[41] Assuming that largely risk-free neurosurgery is possible, the problems which remain are to determine what areas of the brain must be ablated in order to achieve the desired behavioral results and what the long term effects on mental function and adaptive capacities will be. Experimental studies in animals suggest that destruction of certain areas of the "limbic" brain, especially amygdala and hypothalamus, may reduce natural aggressiveness.[42] In man, there are reports to the

38. Definitions of the term psychosurgery vary but a generally accepted one states that it is a procedure which "destroys brain tissue for the primary purpose of modifying behavior." Annas & Glantz, *supra* note 17, at 249.

39. Chorover, *supra* note 10, at 235.

40. Plum, Book Review, 28 ARCH. NEUROL. 213-14 (1974). *See generally* E. VALENSTEIN, *supra* note 17.

41. *See, e.g.*, Falconer, *Reversibility by Temporal-Lobe Resection of the Behavioral Abnormalities of Temporal Lobe-Epilepsy*, 289 N. ENG. J. MED. 451 (1973); Sweet, *supra* note 9. *See generally* SURGICAL APPROACHES IN PSYCHIATRY 39-214 (1973) [hereinafter cited as LIVINGSTON].

42. E. VALENSTEIN, *supra* note 17, at 49. L. Latinen & K. Livingston eds. These studies are also summarized in Goldstein, *Brain Research and Violent Behavior*, 30 ARCH. NEUROL. 1, 23-26 (1974).

effect that selective destruction of portions of the frontal lobe, hypothalamus, thalamus, cingulate gyrus and amygdala, dampens violent or aggressive behavior.[43] In addition, operations to remove diseased brain tissue, especially in the temporal lobes, have on occasion led to improved behavior.[44] Because of such reports, some neurologically-oriented physicians and scientists have concluded that further study of the therapeutic potential of brain surgery is appropriate, provided that clinical protocols include assurance of informed consent, advance review by screening committees (which include persons not participating in the research project), and careful long-term follow-up to determine what, if any, adverse side effects result from the surgery itself.[45] Other students of the problem, however, hold that human behavior has many determinants other than the biological functioning of the brain and that surgery is a poor solution.[46]

While controversy surrounds the issue of surgery on non-diseased areas of brain for the purposes of altering behavior, there is a consensus that surgery is a proper means of treating localized brain disease, such as tumor or vascular malformation, even if one by-

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43. *See* Goldstein, *supra* note 42, at 26-34; LIVINGSTON, *supra* note 41.

44. *See* Falconer, note 41 *supra* and accompanying text.

45. *See, e.g.*, Brody, *On the Legal Control of Psychosurgery*, 157 J. NERV. MENTAL DIS. 151 (1973) (editorial); Geschwind, *Effects of Temporal-Lobe Surgery on Behavior*, 289 N. ENG. J. MED. 480 (1973) (editorial). Even those who are generally regarded as proponents of psychosurgery counsel restraint in its use. Thus, the organizers of an international symposium on psychosurgery have declared:

> Psychosurgery is not, and must not become, a method for manipulation of the mind. Its only aim is to relieve individual, intractable suffering. It should be applied only when conventional psychiatric methods have not given sufficient help. Even then, psychosurgery must not be such a blunting procedure that it prevents the patient from reacting to his problems in a normal way. If psychosurgery is used wisely, it aims at, and can succeed in, relieving the patient from pathological suffering of the mind and restoring his ability to enjoy and suffer as normal human beings do.

LIVINGSTON, *supra* note 41, at xii.

46. Insofar as the causes of social conflict actually lie in the domain of social affairs, psychotechnological treatment of deviants should be regarded as a perversion of medicine and a distinct threat to individual liberty.

Chorover, *supra* note 10, at 247.

Valenstein states the problem less passionately:

> The surgical procedures that may at times eliminate aggression and rage in humans are not affecting innate, stereotyped response patterns, their mode of action is much more global; they seem to be reducing responsiveness to many significant aspects of the environment. It is very unlikely that any of the ablation or stimulation techniques, or for that matter drugs, presently being investigated are capable of reducing undesirable aggression in a normal population without also reducing such qualities as sensitivity, ambition, and intellectual alertness.

E. VALENSTEIN, *supra* note 17, at 352. *See generally* VIOLENCE AND THE STRUGGLE FOR EXISTENCE (D. Daniels, M. Gilula & F. Ochberg eds. 1970) (summarizing the many factors which contribute to violent behavior, including humiliation, provocation, drugs, parental deprivation, personal loss, influence of peers).

product of the surgery is a change in the patient's behavior.[47] Few physicians would regard this as unjustifiable "tinkering" with the mind. The hard case is where subtle disturbances are suspected in a particular area of the brain but a specific disease process cannot be identified. In the now notorious case of Julia S, recordings from electrodes in the amygdala of the temporal lobes suggested that epileptic activity there was causing her outbursts of rage.[48] Because of these findings the amygdala were destroyed by electrocautery. This case is difficult to classify because, although the electrical recordings suggested focal pathology, the nature of the pathologic process was never determined. In other words, the evidence that diseased brain tissue was being destroyed was inconclusive. This underscores the question of how convincing the evidence of focal brain disease must be before removal or destruction of the area of suspected pathology is justified. The answer, of course, depends on the clinical facts, and it may not be easy to determine even with the most advanced technology.

4. Electrical Stimulation.—Electrical stimulation of focal areas of the brain to achieve behavioral modification may be considered a variant of psychosurgery. It involves the precise placement of electrodes in brain tissue. Specially designed electrodes can be used both to record brain wave activity from the area of interest and to stimulate the area. The stimulator may be handled remotely by a person other than the patient through use of telemetry, or the patient may engage in self-stimulation in response to certain inner feelings, such as a rising fear or anger. Although it is clearly possible to modify animal behavior by stimulation techniques,[49] their utility for this purpose in humans remains debatable.

C. Non-Somatic Treatments

1. Psychotherapy.—Virtually any non-somatic treatment that utilizes psychological techniques may be included under the term psychotherapy. If there is a distinctive element, it is that psychotherapy involves a direct contact between patient and physician with the goal of relieving psychic distress. Many variables enter into what form psychotherapy takes, including the nature of the patient's mental disturbance, the capacity of the patient to communicate, the time available for treatment, and the physician's concept of what is the most promising approach to therapy. Group thera-

47. *See* Falconer, note 41 *supra* and accompanying text; Walker, *Man and His Temporal Lobes*, 1 SURG. NEUROL. 69 (1973).
48. V. MARK & F. ERVIN, *supra* note 26, at 97-108.
49. *See* Goldstein, *supra* note 42, at 23-26; E. VALENSTEIN, *supra* note 17, at 64-124.

py may be viewed as a form of psychotherapy, at least to the extent that the therapist participates in the activities of the group and attempts to influence the interactions of the members in a way that gives promise of helping the individual members. Whether psychotherapy extends to include so-called milieu therapy is open to debate because of the lack of direct contact between patient and therapist which characterizes this form of treatment.

A major problem with respect to psychotherapy in any form is designing a method for determining its efficacy. Precise indices of improvement in emotional state are difficult to construct, and there is the continual problem of deciding whether an observable improvement relates to factors other than therapy, such as a reduction in environmental stress, coincident somatic treatments, or fluctuations in the natural history of the disease process.[50] Often relatively crude measures of success of treatment must be employed, such as discharge from hospitalization or return to work. Imprecise as they are, however, they are at least identifiable ciircumstances which may be valid indices when applied to large numbers of patients.

2. *Behavior Therapy.*—A variety of techniques have been developed for modifying behavior which rest on the notion that it is possible to facilitate some forms of conduct and prevent others through concentrated training or learning experiences.[51] These techniques largely derive from animal experimentation, and may carry labels such as classical conditioning, operant conditioning and aversion therapy. The initial step is for the experimenter to select what conduct to condition, whether positively or negatively. The next step is to determine what means to use to facilitate or extinguish the conduct. The opportunity for innovation is great at this stage and a number of ingenius, even bizarre approaches have evolved. Finally, in the ideal situation, each time the wanted or unwanted conduct occurs it evokes either a reinforcing or inhibiting response. The ultimate goal is to achieve a change in behavior which outlasts the term of the experiment.

A number of problems arise with respect to conditioning as a means of therapy.[52] One is selecting the target behavior. For

50. One author has suggested that, although imprecise, it is possible to measure improvement in terms of the patient's capacity to achieve "greater responsibility and less dependency." D. DAWIDOFF, THE MALPRACTICE OF PSYCHIATRISTS 21-27 (1973).

51. *See* L. KOLB, *supra* note 14, at 561-64. *See generally* J. WOLPE & A. LAZARUS, BEHAVIOR THERAPY TECHNIQUES: A GUIDE TO THE TREATMENT OF NEUROSES (1966).

52. *See generally* Singer, *Psychological Studies of Punishment*, 58 CALIF. L. REV. 405 (1970); Wexler, *Token and Taboo: Behavior Modification, Token Eco-*

example, if the goal is to stop a hospitalized patient from committing violent acts, is there a way of preventing only unprovoked violence without disabling the patient from self-defense or asserting his rights by less physically-oriented means? Another lies in the choice of means for modifying behavior. At what point does alleged therapy become punishment or brutalization?[53] Largely unknown is whether conditioning humans to avoid certain behaviors will lead to other forms of undesired conduct. For example, if conditioning leads to a reduction in externally-directed violence, might not a patient direct violence towards himself in the form of suicide or self-maiming? Implicit in these questions is the uncertainty as to whether it is proper to regard conditioning as therapy at all. While it may occasionally succeed in altering specific patterns of behavior, it is therapeutic for the patient only if he or she desires a change in behavior or derives reasonable personal benefit from it. Otherwise it becomes just another technique for social control of undesired behavior.

D. *Therapeutic Abuse*

1. General Nature.—In the context of this Article an abuse of treatment encompasses selecting or countenancing a treatment which has no reasonable prospect of helping a patient or imposes a risk of harm which clearly exceeds any reasonable chance of benefit. The abuse need not occasion liability in a malpractice suit since demonstrable harm to the patient may not ensue. Thus, it would be an abuse of treatment for a physician to prescribe electroshock for insomnia. Even if the patient tolerates electroshock without adverse effect, insomnia is not a sufficient justification for exposing one to the risks of electroshock. On the other hand, the fact that a treatment is innovative or controversial does not create an inference of therapeutic abuse. The real issue is whether there exists a reasonable scientific basis for the treatment either from animal experimentation or previous clinical trial in humans.[54]

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nomics, and the Law, 61 CALIF. L. REV. 81 (1973); Note, *Conditioning and Other Technologies used to "Treat?" "Rehabilitate?" "Demolish?" Prisoners and Mental Patients,* 45 S. CAL. L. REV. 616 (1972).

53. *Cf.* Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973) (allegation that administration of paralytic drug to prisoner as part of behavior therapy program was cruel and unusual punishment stated valid claim for relief under civil rights laws).

54. *See* J. WALTZ & F. INBAU, MEDICAL JURISPRUDENCE 179-202 (1971). The authors maintain that existing legal rules are adequate to resolve disputes relating to the propriety of medical treatment, and that no useful purpose is served by sharp distinctions between "customary" treatment and "experimental" treatment or "innovation." They believe that the important determinant should be whether treatment is reasonable in light of the risks and benefits and the condition of the patient. They would first discover the level of a physician's knowledge of a pro-

An abuse of treatment may involve failure to establish a reasonable diagnosis before prescribing, failure to fit the treatment to the diagnosis, improper administration of the treatment or failure to monitor or treat adverse reactions to treatment. It may also involve an attempt to achieve non-therapeutic goals, such as enhancing the reputations of institutions or physicians and regulating behavior solely for punishment or reasons of administrative convenience. A failure to inform patients or their representatives of the nature, indications and risks of treatment also constitutes an abuse of treatment.

All of these abuses offend medical ethics[55] and most would be actionable in a malpractice suit.[56] Of primary importance here, however, is the extent to which they derive from the process by which treatment decisions are made. If the environment in which treatment is selected and administered fosters these abuses, whether based on ignorance or on lack of concern for the patient, the treatment program itself is suspect even though specific harms to patients are not readily identifiable. On the other hand, if treatment decisions are the product of careful review of clinical and scientific data and are tailored to the needs of the individual patient, the fact that an individual patient is not helped by treatment, or even incurs harm, does not by itself indicate that the treatment program itself is unsound. Even the best treatments may fail to help some patients or may cause adverse side-effects.

2. *Improper Diagnosis.*—The nature of treatment ordinarily depends on diagnosis, and a diagnostic error may lead to inappropriate therapy. Accordingly, an initial step in evaluating a medical treatment program is to ascertain if reasonable diagnostic studies are done before treatment is started. Disturbed behavior, for example, may derive from psychological stresses or may reflect a

posed treatment and then consider whether such treatment is medically justifiable in the context of more generally applied alternative therapies.

55. The Hippocratic Oath requires that the physician "follow that method of treatment which according to my ability and judgment I consider for the benefit of my patients" and "abstain from whatever is deleterious and mischievous." For an analysis and statement of the Hippocratic Oath, see Edelstein, *The Hippocratic Oath,* BULL. HIST. MED. 1 (Supp. 1943). With respect to therapies of uncertain value, the Nuremberg Code and Declaration of Helsinki command that therapies be scientifically justifiable, that they be administered only by qualified persons, that they not impose risks which outweigh potential therapeutic value, that they be discontinued if it appears that they are likely to be harmful, and that voluntary and informed consent be obtained. In addition, the Declaration of Helsinki stresses that special care should be taken to avoid treatments which alter the personalities of subjects and to avoid conducting pure research under the guise of therapy. For a discussion of these two ethical codes, see Vaughan, *Histories, Mirrors, and Crystal Balls,* PHAROS 130, 131-33 (October 1974).

56. *See generally* McCoid, *The Care Required of Medical Practitioners,* 12 VAND. L. REV. 549 (1959); Beresford, *Professional Liability of Psychiatrists,* 21 DEF. L.J. 123 (1972).

disease of the brain, or may enbody a mix of psychological and biological elements. Failure to explore the possibility that an identifiable disease of the brain accounts for disturbed behavior may deprive a patient of an opportunity for cure or great improvement. Thus, benign brain tumors or scars from previous injuries to the brain may cause profound behavioral changes which are curable by surgery[57] but which are unaffected or even worsened by drugs, electroshock or psychotherapy. Use of available technology, including electroencephalography, angiography, radionuclide brain scanning and computerized radiographic techniques, allows precise localization of areas of diseased brain and may be appropriate for some patients. Neurological or neurosurgical consultations may be indicated in some instances, either to screen patients before they enter a treatment program or to consider special problems which may arise.

If it appears that brain disease has been reasonably excluded as a cause of disturbed behavior, the next step is to determine the basis of any psychiatric diagnosis that is made. Most psychiatric diagnoses rest on rather general criteria. The observations and the intuitions of the examining physician influence diagnosis more than in other areas of medicine where laboratory and radiographic studies play such a large role. The relative subjectivity of the psychiatric diagnosis may make it difficult to assess whether the diagnosis is reasonably founded.[58] Thus, when evaluating psychiatric treatment programs, it may be important to ascertain if diagnoses reflect the opinion of a single examining physician or if other physicians have concurred in the diagnosis. While an astute psychiatrist may make many correct diagnoses, the chance of inappropriate treatment increases if treatment decisions rely on the diagnosis of only one psychiatrist. Even a committee approach to diagnosis may be wanting if the physicians spend little time with patients.

3. Inappropriate Treatment.—Assuming a correct diagnosis, treatment may still be inappropriate. For example, the initial treatment for epilepsy is seldom brain surgery, and it would be unreasonable, in most instances, to operate without a prior trial of

57. *See* Falconer, *supra* note 41; Walker, *supra* note 47.

58. *See* Rosenhan, *On Being Sane in Insane Places*, 179 SCIENCE 250 (1973). The author describes eight "pseudopatients" who secured admission to twelve different psychiatric hospitals by feigning auditory hallucinations. All were diagnosed as "schizophrenic" and were hospitalized from seven to fifty-two days, with an average of nineteen days. Review of the hospital records did not disclose that non-insanity was suspected during the period of hospitalization, even though the "pseudopatients" dropped their symptom of auditory hallucinations once they were hospitalized. *See also* E. VALENSTEIN, *supra* note 17, at 346-48.

drug therapy. On a more complex level, several physicians may agree that a patient has schizophrenia, a condition for which various treatments may be used. To proceed forthwith to insulin shock, with its risks of brain damage,[59] before a trial of tranquillizer therapy may be an abuse of treatment. Although insulin shock has been useful in treating some schizophrenics, tranquillizers are generally safer than insulin shock and are at least as effective in most cases.[60] In other words, once diagnosis is determined, the least hazardous effective treatment seems appropriate.[61] If this fails, the more hazardous treatment may be justifiable.

In weighing whether treatment is reasonably matched to diagnosis, a court need not burden itself with trying to decide what is the best treatment. Medical evidence is often inconclusive as to what is the optimal treatment for a given condition but may at least indicate the range of effective treatments and the collateral risks of each. These data may allow a court to decide if patients are subjected to risks that could be avoided without therapeutic disadvantage. Thus, if all schizophrenics in a particular hospital were routinely given insulin shock in lieu of other treatments, a court might infer a lack of concern for the welfare of individual patients. This does not imply that there should be a rule of law that is wrong to treat schizophrenia with insulin shock because tranquillizers are safer. But it does suggest that the relative safety of a specific treatment is a factor to consider in determining the orientation of a treatment program towards the interests of patients.

4. Improperly Administered Treatment.—Determining whether treatment has been properly administered may raise a host of technical questions: Was a drug given by the correct route? Were muscle relaxants administered in connection with electroshock? Were sufficient precautions taken to prevent bleeding during therapeutic brain surgery? Detailed medical testimony may be required to answer such questions and a court may find the data confusing. Nevertheless, it is often possible to establish with some precision the standards for administering a given treatment. Information about dosages and routes of administration of drugs are usually included in the manufacturer's package insert which accompanies the drug or in texts or medical journals.[62] Most facilities which

59. *See* note 32 *supra* and accompanying text.
60. L. KOLB, *supra* note 14, at 397-98.
61. *Cf.* Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971), *enforced* 344 F. Supp. 373 (M.D. Ala. 1972); Wyatt v. Aderholt, 503 F.2d 1305 (5th Cir. 1974) (involuntary mental patients should receive least restrictive form of available therapies).
62. *Cf.* Koury v. Follo, 272 N.C. 366, 158 S.E. 548 (1968) (physician's liability for injury from administration of anti-biotic combination based on failure

employ electroshock treatment prepare written schema which describe the current and voltage to be applied, the placement of electrodes, the positioning of the patient, possible complications and adjunctive drugs.[63] Surgery may present special problems, however. Although there is some standardization with respect to given surgical procedures, technical errors may be so subtle as to elude precise identification. Only through careful review of operative reports and the testimony of the surgeon may the occurrence of a technical error be detected.[64]

The quality of medical records plays a key role in evaluating whether a treatment has been properly administered.[65] Good records will include exact details about drug treatments, full operative reports, and descriptions of other forms of treatment. They also indicate what persons were involved in giving a particular treatment, and will disclose what, if any, problems arose during treatment. While one might surmise that records which clearly describe a treatment will ease the task of discovery of technical errors in a way that may be disadvantageous to an institution or its physicians, incomplete or unintelligible records raise an inference of sub-standard care and may evoke questions about the overall merits of a treatment program. Moreover, poor records may increase the burden of defending against a charge of a specific technical error.

5. Improperly Evaluated Treatment.—The areas of improperly evaluated treatment include complications and therapeutic effectivness.

a. Complications.—Virtually any medical treatment has the potential for causing harm. The harm may range from a surgical catastrophe with death or severe permanent disability to slowly evolving adverse drug reactions. The way in which complications are managed often determines if permanent harm results.[66] Antic-

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to heed data about dosage in package insert); Mulder v. Parke Davis & Co., 288 Minn. 332, 181 N.W.2d 882 (1970) (physician's liability for antibiotic toxicity based on failure to follow recommendations in package insert with respect to monitoring for toxicity).

63. *Cf.* Stone v. Proctor, 259 N.C. 633, 131 S.E.2d 297 (1963) (psychiatrist's liability for failure to detect complication of electroshock therapy based upon failure to follow written procedures relative to use of electroshock).

64. *Cf.* Belshaw v. Feinstein, 258 Cal. App. 2d 711, 65 Cal. Rptr. 788 (1968) (neurosurgeon's liability for complication of stereotactic brain surgery determined on basis of data in operative report).

65. *See* Schwitzgebel, *Right to Treatment for the Mentally Disabled: The Need for Realistic Standards and Objective Criteria,* 8 HARV. CIV. RIGHTS CIV. LIB. L. REV. 513 (1973) (periodic review of records of treatment programs useful both to courts and administrative agencies that evaluate these programs and to medical audit committees which seek data about epidemiology of disease and types of treatment).

66. The management of anaphylaxis, for example, a rapidly developing allergic

ipating a complication is important because it fosters prompt identification and treatment. The capacity to anticipate in turn depends on the completeness of a physician's knowledge of a particular treatment. Similarly, identifying a complication as such requires an awareness that it might occur. Thus, if a physician were unaware that liver damage is a complication of treatment with a certain drug, he might be slow to recognize deepening jaundice, a cardinal sign of liver disease, or slow to discontinue the drug after the existence of liver damage became apparent.[67]

Because proper handling of complications is an essential means of protecting patients, a court may seek to determine the extent to which physicians are prepared to manage complications of therapy. This search may entail inquiry into the number and content of staff conferences, the availability of books and reference materials, the existence of defined procedures for treating complications and the accessibility of intensive care units or other specialized services. If a written treatment protocol exists it may be inspected to determine whether explicit mention is made of complications and the ways to handle them. Information of this sort may greatly assist a court in deciding whether a treatment program is designed to afford maximum protection to patients. A finding that a program pays little heed to the problem of complications of treatment implies a lack of therapeutic orientation.

b. Therapeutic Effectiveness.—Conclusions about the efficacy of a specific treatment is obviously important both for those receiving and those who may later receive it. But determining the efficacy of treatment may be deceptively difficult, particularly if criteria for evaluation are poorly formulated or if observations are biased, careless or incompletely recorded. Moreover, prolonged observation may be necessary to decide whether treatment is of more than transitory value. Thus, one of the major criticisms of psychosurgery is that claims of its efficacy rest on inadequate evaluations of follow-up studies,[68] and one of the shortcomings of some studies of responses to drug treatments has been the failure to compare treated subjects with non-treated subjects who are otherwise similar to the treated group.[69] Thus, a treatment program which does not rigorously investigate and criticize its own results not only deludes participating physicians and perhaps patients, but

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reaction to a drug or other agent, may literally determine the difference between life and death. *See* Kelly and Patterson, *Anaphylaxis*, 227 J.A.M.A. 1431 (1974).

67. *See* Ishak and Irey, *Hepatic Injury Associated with the Phenothiazines*, 93 ARCH. PATH. 283 (1972).

68. *See* notes 17 & 40 *supra* and accompanying text.

69. Chalmers, Block & Lee, *Controlled Studies in Clinical Cancer Research*, 287 N. ENG. J. MED. 75 (1972).

may also perpetuate ineffective or dangerous treatment by causing publication of ostensibly good results that rest on invalid data.

It has been suggested that effectiveness is the most meaningful standard of determining the legal sufficiency of medical treatment.[70] However, a reviewing court may encounter major hurdles in trying to evaluate the effectiveness of an innovative treatment. Except in circumstances where initial therapeutic results are clear-cut and statistically significant, physicians themselves may be unable to decide with reasonable certainty about efficacy of a specific treatment until a prolonged trial has been accomplished. The question may then become how much uncertainty about effectiveness must be apparent before a court will conclude that a treatment is inappropriate for a patient or group of patients. For example, while brain surgery has undeniably helped some patients whose disturbed behavior stems from underlying brain disease,[71] it is uncertain whether brain surgery can predictably alter behavior in patients without identifiable brain disease.

In *Kaimowitz v. Department of Mental Health*,[72] the court invoked therapeutic uncertainty as one ground for barring psychosurgery in a violent patient without demonstrable brain disease. Suppose, however, that there were credible medical evidence that brain surgery may predictably improve behavior of violent persons without known brain disease and that such surgery may be accomplished without major risk to the patient. Suppose further that some well-qualified experts express a minority view to the effect that brain surgery cannot predictably alter behavior or that it poses great risks of permanent harm. In these circumstances would it be justifiable for a court to conclude, after weighing the conflicting medical evidence, that such surgery is not appropriate and therefore should be barred? Or, put more generally, if a treatment is safe and probably effective, based on the best available medical data, may it still be barred, assuming, of course, a proper informed consent? One would think not. But if the implications of the treatment are profound, such as possible permanent alterations of behavior, a court may be tempted, as in *Kaimowitz*, to assume a restrictive stance. While this may constitute an infusion of a court's views on social policy into the process of medical decision-making, it has some support in medical ethics.[73]

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70. Schwitzgebel, *supra* note 65, at 528.
71. *See generally* authorities cited in note 41 *supra*.
72. Civ. No. 73-19434-AW (Cir. Ct., Wayne County, Mich., July 10, 1973), *summarized at* 42 U.S.L.W. 2063 (July 31, 1973).
73. The Declaration of Helsinki, stresses the need to avoid treatments which alter the personalities of subjects. *See* note 11 *supra*.

Whatever views a court holds about the ultimate acceptability of a given treatment, it should consider at least two aspects relating to its selection. One is the data which support its use. The other is the criteria by which responses are evaluated. Medical evidence that there is a reasonable basis for the treatment and that it is being evaluated in a reasonable way should allay concerns about the appropriateness of the treatment and spare the court from immersing itself in the nuances of the biologic effects of the treatment or of the statistical methods used to determine its efficacy. Where medical opinions are divided, a court may either require a fuller exposition of the relevant data, recognizing the limits of its own expertise, or may take the conservative view that efficacy is unproven.

6. Non-Therapeutic Goals.— Two additional therapeutic abuses are the non-therapeutic goals of social control and self-interest.

a. Social Control.—Physicians who prescribe treatments which alter behavior may be vulnerable to the criticism that the goals of treatment are non-therapeutic. Thus, prescribing a tranquillizer for an agitated psychotic or an amphetamine for a hyper-active child may arguably make the patient easier to handle without touching the underlying biological or psychological disturbance. However, these criticisms may be overly simplistic. An agitated psychotic, although hard to handle, may also be miserable because of threatening delusions or hallucinations. A hyperactive child, *albeit* a trial to teachers and family, may also be unable to learn, socialize or participate in play. Drugs which relieve symptoms may thus also allay discomfort or enhance functional capacities.[74] Moreover, physicians, families and teachers may be both more inclined and better able to provide emotional and other forms of support if troubling symptoms are relieved.

Where the issue of non-therapeutic goals arises, a court may properly require of physicians an articulation of the objectives of treatment and the relevance of treatment to attaining these objectives. If this inquiry casts doubt on therapeutic means or ends, the treatment program itself becomes suspect. How far a court delves beyond articulated goals of treatment may depend on the nature of the treatment. For example, if the goal of treatment is to control rage reactions during which a patient injures himself or others, a court may be less inclined to question the use of tranquillizers or anti-convulsants than it would the use of brain surgery or electro-

74. *See generally* authorities cited in notes 18 & 20 *supra.*

shock. Or, if the goal of treatment is to reduce disruptive behavior in children, a court may take a more critical view of drug therapy than psychotherapy or behavioral therapy.

Behavioral or conditioning therapies may present special problems. Their stated goals may be to help a person learn more adaptive behavior as a means to a happier life or to unlearn or extinguish disruptive behavior which prevents social living. Laudable as these goals may appear, they may rest on the therapists' personal notions as to what constitutes proper behavior. Whether achieving such behavior will help a particular patient may be debatable. Moreover, because the techniques used to achieve behavioral change may involve considerable stress or even danger to the patient, it may be difficult to separate therapy from punishment.[75] The use of the drug succinycholine (Anectine) in a behavior modification program provides an instructive example. Such a program, carried on within the California penal system, involved giving a paralytic drug to inmates when they engaged in specific acts of misconduct, usually violent or aggressive behavior.[76] The effect of the drug is to paralyze movement without altering consciousness, an overwhelmingly unpleasant experience. While under the influence of the drug, the subject would be exhorted by a psychiatrist to avoid future misconduct that might occasion re-administration of the drug. This bizarre project was rather quickly terminated, but it has resulted in at least one legal action.[77] It exemplifies what can emerge from unrestrained use of so-called behavior therapy.

b. Self-Interest.—Although it may go unrecognized, treatment programs may become devices for advancing the reputations and financial status of physicians or institutions. Obviously, the fact that a physician or hospital, through operation of a treatment program, gains fame, fortune or an increase in the number and amount of research grants does not alone indicate unethical, sinister or unlawful behavior. Indeed, it would be surprising if an apparently successful treatment program, at least one on a large scale, did not yield those consequences. But those very consequences may, perhaps in a most subtle way, undermine the thera-

75. *See* authorities cited in note 52 *supra.*

76. For a detailed discussion of this program, see Note, *Conditioning and Other Technologies Used to "Treat?" "Rehabilitate?" "Demolish?" Prisoners and Mental Patients,* 45 S. CAL. L. REV. 616, 633 (1972). The theoretical justification for the treatment was that it created a parent-child paradigm wherein the "bad" child (prisoner) was counselled and admonished by the parent (therapist). However, there was no control group for comparison, the "treatment" was given to subjects carrying a wide variety of psychiatric diagnoses, and there was a great degree of unpredictability as to when a subject would receive the "treatment."

77. Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973).

peutic focus of a program. Indications for the use of treatment may be relaxed, more patients may be accepted than can be properly evaluated or followed and the need continually to re-evaluate and criticize may be neglected. The net effect may be that some who don't need treatment receive it, that complications of treatment increase and that the treatment gains broader general acceptance than is warranted.

While these concerns about the insidious corruption of treatment programs may be largely hypothetical, the proliferation of transplant programs, open-heart surgery programs, cancer therapy programs and behavioral modification programs, often accompanied by major institutional public relations efforts,[78] seem to justify their mention. Should a court find itself reviewing an issue arising out of such a program, it may need to carefully determine what specific safeguards exist to assure that individual patients receive appropriate therapy. Are complete diagnostic studies performed? Are the opinions of consultants utilized? Is the treatment chosen more or less risky than available alternatives? If less risky alternative treatments are available, are they tried first? Did a review committee participate in the selection of the patient for treatment?

7. Lack of Informed Consent.—The issue of informed consent vexes both physicians[79] and legal commentators.[80] It may be extraordinarily difficult to determine whether a patient has gained a clear and balanced account of the indications and risks of treatment. Moreover, the question most frequently arises in medical malpractice cases where it may be in the claimant's interest to show

78. Although ethical constraints prevent physicians from advertising, hospitals and other institutions where physicians work may engage in some forms of "informational" advertising. These might include, for example, circulating descriptive brochures about the institution's open heart surgery, organ transplant, or behavior modification programs, or seeking publicity in newspapers and electronic media about the existence of such programs.

79. The editor of a major medical journal has stated that, in the context of research involving humans:

> [T]he process of obtaining "informed consent," with all its regulations and conditions, is no more than an elaborate ritual, a device that, when the subject is uneducated and uncomprehending, confers no more than the semblance of propriety on human experimentation. The subject's only real protection, the public as well as the medical profession must recognize, depends on the conscience and compassion of the investigator and his peers.

Ingelfinger, *Informed (But Uneducated) Consent*, 287 N. ENG. J. MED. 465, 466 (1972) (editorial).

80. In commenting on recent trends in the law of informed consent which make what is "reasonable" rather than what is customary as the standard for evaluating a consent, a lawyer-physician predicts that: "[I]n most, if not all jurisdictions in the future, physicians will face increasing risk of being second-guessed in court as to whether their disclosures were reasonable or not." Mills, *Whither Informed Consent*, 229 J.A.M.A. 305 (1974). For a discussion on recent trends in the law of informed consent, see Comment, *supra* note 5 at 406.

that he or she was not adequately informed about treatment. Contemporaneous writings are often sketchy and inconclusive and may consist only of release forms which disclose little, if anything, about the nature of treatment. Also, the physician may be unable to recall precisely what information was imparted to the patient.[81] The result is that decisions about the existence of informed consent may rest on unreliable foundations.

There are probably few instances where a physician consciously fails to inform a patient about treatment. One is when the physician is convinced that the patient urgently requires the treatment and believes that the patient may refuse it if it is fully portrayed.[82] In this instance the physician is probably convinced that the patient's interests are kept foremost. However, it still may be proper to inquire whether the indications for treatment were as urgent as stated, and whether the physician had reasonable grounds for the belief that the patient would refuse treatment if fully informed.[83] Another instance of conscious failure to inform may be where a physician believes that the prescribed treatment is clearly preferable to available alternatives. The physician may then simply not mention the alternatives. For example, a physician who believes that electroshock is clearly superior to drug therapy for managing depression may only inform a patient about the indications and risks of electroshock and not mention that drug therapy is preferred by some physicians. In this way the physician may deprive the patient of an opportunity to consider a treatment that the patient might prefer. But, because electroshock is an accepted treatment for depression, the physician may still believe that the patient's interests are being protected. Finally, a physician may believe that a risk of therapy is so remote that it does not bear mentioning. For example, death may result from electroshock,[84] but that result is a most infrequent complication and may go unmentioned, particularly where the patient is deeply depressed and fearful. A clearly abusive instance of failure to inform would be a knowing distortion of indications or risks of a procedure for the principal purpose of inducing a patient to accept treatment. The abuse might occur, for example, where a treatment program

81. *Cf.* Gray v. Grunnagle, 423 Pa. 144, 223 A.2d 663 (1966) (the defendant neurosurgeon testified that while he usually informed his patients that paralysis was a risk of spinal surgery, he could not recall the content of his communications to the plaintiff).

82. *See* Lester v. Aetna Cas. & Sur. Co., 240 F.2d 676 (5th Cir. 1957) (informed consent to electroshock therapy not required where full disclosure may worsen the patient's psychiatric state).

83. *See* Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

84. Lewis, Richardson & Gahagan, *Cardiovascular Disturbances and Their Management in Modified Electrotherapy for Psychiatric Illness*, 252 N. ENG. J. MED. 1016 (1955).

was trying aggressively to enlist enough patients so that results of treatment would appear numerically impressive in publications about the program.

In reviewing a treatment program a court should seek to identify those features which may result in poorly-founded consents. Most hospitals have regulations which require staff physicians to obtain informed consent before treatment is begun. Moreover, if the treatment program is part of a research study, a hospital may require that a review committee approve those parts of the protocol relating to informed consent. After determining what institutional procedures exist to encourage informed consent, medical records may be reviewed to determine the extent of implementation. Entries in records may indicate the substance of conversations between patient and physician about treatment or there may be an executed consent form which describes the treatment, its risks, and perhaps even the available alternatives. The consent form or the records may also confirm that the physician personally discussed the treatment with the patient rather then delegating the matter to another. Without such documentation a court may be unable to ascertain if a routine aspect of a treatment program is to assure a dialogue between patient and physician about treatment.

II. NON-JUDICIAL CONSTRAINTS ON TREATMENT

A. Institutional

The effectiveness of non-judicial constraints on medical treatment programs depends heavily on the nature of the institutions in which the programs are administered. In a teaching hospital with a medical school affiliation, programs which involve controversial or innovative treatments are usually subject to some form of peer review. For example, a treatment program may be reviewed for its scientific worth by an institutional human research committee. This review may include a close critique of the proposed treatment and the methods to be followed. Such a committee may also address itself to the issue of informed consent. The existence of a review committee, however, does not assure a thorough review of each treatment program which comes before it. Members of the committee may be unenthusiastic about taking time from their other activities to pursue what they regard as an administrative nuisance. Or, the work load of the committee may be too great to allow careful review of each program. Hence, *pro forma* approval of treatment programs may occur. Nevertheless, a properly functioning review committee may effectively screen out programs which lack scientific merit or are carelessly designed.

In non-teaching hospitals, review mechanisms may be less elaborate or even non-existent. In addition, there may be too few physicians available to conduct review proceedings. While treatment programs which involve large numbers of patients or complex technology are less likely to be conducted in non-teaching than teaching hospitals, the non-teaching hospital may occasionally carry on such programs. For example, some controversial forms of treatment of disturbed behavior, such as electroshock, insulin shock and aversion therapy, have been administered in large psychiatric hospitals which have small professional staffs, lack an affiliation with medical schools and have no training programs for young physicians.[85] In this setting, peer review of treatment programs may be minimal, except to the limited extent mandated by hospital accreditation agencies.

Some controversial and innovative treatments require a degree of scientific and technical expertise that is available only in a large medical center. Open heart surgery and organ transplantation are examples. These complex therapies involve both surgical and non-surgical specialists, and there is usually opportunity for interchange of ideas about the merits of a given treatment. By contrast, electroshock therapy does not require elaborate technology or the participation of physicians from many disciplines. With respect to psychosurgery, the neurosurgeon has been the main actor. However, selection of cases for surgery may involve non-surgical specialists such as psychiatrists and neurologists. Since many of the concerns about psychosurgery relate to the criteria for selecting patients, constraining factors, if any, should derive from the selection process. In this regard there seems to be a growing consensus that there should be some form of advance review mechanism for weighing proposals relating to psychosurgery.[86] Membership on these committees may include both neurosurgeons and neurologists, as well as non-physicians such as lawyers, clergymen and community representatives. If these committees fulfill their projected roles, they may effectively screen out proposals that are scientifically or ethically doubtful.

B. Individual

The ultimate constraint on abuse of medical treatment lies within the physician. If the physician honors traditional ethical precepts[87] and is knowledgeable and dispassionate, the chances of inappropriate or improperly managed treatment are sharply dimin-

85. *See generally* Beresford, *supra* note 35.
86. *See* authorities cited in notes 11 & 45 *supra.*
87. *See* notes 11 & 55 *supra.*

shed. Also, if the physician functions in a setting where his work is subject to appraisal by other physicians, sensitivity to opinions of peers may dampen any tendencies towards therapeutic adventurism. However, even if a physician assigns high priority to the interests of patients, deficient knowledge may lead to inappropriate treatment or an unreasonable risk of complications. If the physician does not have ready access to means of attaining adequate knowledge, such as well-informed associates or a well-stocked library, he may succumb to the temptation of treating where the better approach would be to refer the patient to another physician or institution. The scenario which appears to carry the greatest potential for therapeutic abuse involves an unethical or unknowing physician who functions in isolation from other physicians.

III. THE SCOPE OF JUDICIAL REVIEW

A. Circumstances of Review

In past years judicial review of medical treatment has most often been evoked by medical malpractice suits. While this general pattern will undoubtedly continue, a variety of other disputes may be anticipated to trigger judicial review. Current litigation over the right to treatment of involuntarily hospitalized mental patients is one such area.[88] Thus, *Wyatt v. Stickney*[89] involved a searching judicial appraisal of treatment programs for involuntary mental patients and an attempt to develop standards of proper treatment. Litigation over the rights of patients to refuse treatments may also involve scrutiny of treatment programs.[90] Where controversial or innovative treatments are involved, courts may be called upon to bar or penalize specific therapies. In *Kaimowitz v. Department of Mental Health* psychosurgery was at issue. In *Karp v. Cooley*,[91] the issue was whether use of a mechanical heart in a patient with advanced heart disease was unlawful experimentation. Although the federal court chose to apply traditional rules relating to medical malpractice suits, it devoted much attention to the specific provisions of the operative consent form and the degree to which it portrayed the state of the art with respect to the mechanical heart. Accordingly, as medical science continues to spin off new technologies for treating disease, it seems predictable that disputes will arise as to the correctness of medical decisions about such new therapies

88. *See, e.g.*, O'Connor v. Donaldson, 422 U.S. 563 (1975) (non-dangerous, civilly committed mental patient must either be given treatment or released from hospitalization); Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971).

89. 325 F. Supp. 781 (M.D. Ala. 1971).

90. *Cf.* New York City Health & Hosp. Corp. v. Stein, 70 Misc. 2d 944, 335 N.Y.S.2d 461 (1972) (denial of application by hospital director to administer electroshock to schizophrenic patient over her objections).

91. 493 F.2d 408 (5th Cir. 1974), *cert. denied*, 419 U.S. 845 (1974).

or as to the extent to which programs that employ such therapies protect the interests of patients.

Disputes about medical treatments may be cast in terms of public policy. For example, *Kaimowitz* may be read as implying that there are some medical treatments, in that case, psychosurgery, which are so inherently dangerous or of such uncertain efficacy that courts should prohibit them outright. In such a context the question whether a patient gave a duly informed consent and was involuntarily hospitalized would not be at issue. The treatment is *malum in se*. However, even if physicians prescribe such treatments, a question might arise as to who has standing to sue to prevent or penalize their use. An injured patient might contend after the fact that the nature of the treatment was such that willing consent to the treatment should be discounted. Aside from an aggrieved patient, a district attorney or a civil liberties lawyer might seek to intervene to bar a specific treatment on the grounds that it threatens public health and welfare or violates relevant medical practice laws.[92] It is perhaps conceivable that a consumer group might seek to bar a hospital from administering a particular treatment. This situation might arise, for example, where all patients admitted to a psychiatric ward of a hospital serving a particular catchment area were routinely given electroshock.

It bears noting, of course, that courts are not the only agencies which monitor medical treatment programs. Legislatures may place limitations on the use of some forms of treatment, including a requirement of screening committees.[93] Regulatory agencies may develop rules which define the ways in which certain treatments are

92. Several states have enacted laws which regulate "intrusive" treatments such as psychosurgery, usually by requiring that advance consent be given. For a summary of these laws, see Note, *Civil Commitment of the Mentally Ill*, 87 HARV. L. REV. 1190, 1347 n.129 (1974). The existence of these laws supports the argument that there is a strong public interest in restraining certain medical treatments and that representatives of the public should be granted access to the courts to ensure that the spirit of these laws is carried out. In *Kaimowitz*, a suit to enjoin psychosurgery was brought by a civil liberties lawyer on behalf of a person who had already consented to surgery and on behalf of all those similarly situated.

93. *See* note 92 *supra* and accompanying text. Oregon has recently enacted a law that requires an institution obtain advance approval of psychosurgery from a review board. Ch. 616, §§ 1-17 [1973 Ore. Reg. Sess.] (S. Bill 298), *amending* Ore. Rev. Stat. 677.190 (1971). The board is required to hold hearings to determine if all conventional treatments have been tried, if psychosurgery offers hope of therapeutic benefit, and if the patient has given a competent, voluntary and informed consent. Similar legislation has been offered in Massachusetts. For a discussion of this legislation see Atkins & Lauriat, *Psychosurgery and the Role of Legislation*, 54 B.U.L. REV. 288 (1974). Where the review board mechanism exists, however, members of the committee "should be selected not only on the basis of their knowledge and the special interest they represent, but also on their professional, economic, and psychological independence from the physician whose case is being reviewed." E. VALENSTEIN, *supra* note 17, at 338.

given.[94] Hospital accreditation agencies may impose standards for patient care that inhibit the use of hazardous treatments.[95] Even third-party payors may play a role by refusing to reimburse hospitals which attempt to conduct some types of treatment programs, such as open heart surgery. Nevertheless, where injuries occur or gaps in legislative and administrative coverage exist, courts become the forum in which competing views are resolved.

B. Standards for Review

The nature of judicial review of a medical treatment program hinges in part on a court's conception of the extent of its duty to evaluate a specific treatment. If a court interprets its role as being an arbiter of the merits of a particular treatment it may find itself enmeshed in a scientific inquiry for which it is ill-suited. A debate as to the biological basis or efficacy of a treatment may not even be resolvable by a forum of medical experts, and a court may be on shaky grounds if it renders a judgment based on its own resolution of the debate. Thus, it may not be medically defensible to conclude that brain surgery is an ineffective or inappropriate treatment for violent behavior that resists control by other means, or that certain forms of heart surgery are not medically indicated for treating advanced heart disease. Yet a court may be asked to draw those conclusions from a welter of conflicting medical testimony. Faced with such a circumstance, a court may undertake its own balancing of the apparent risks and benefits of a particular treatment, or it may assume a more restrained or detached role of seeking to determine whether treatment decisions are rational and compassionate.

1. Risk-benefit analysis.—If a treatment is allegedly injurious a court may seek to determine whether its potential benefits outweigh the risks. Putting the issue in another semantic framework, the inquiry may focus upon whether the treatment is of such uncertain value as to be deemed experimental. These approaches to evaluation of treatment are frequently followed in medical malpractice cases where the issue is cast in terms of the acceptability of treatment in light of existing standards of medical practice. However, these approaches may not be useful where treatment is ad-

94. The Massachusetts Department of Mental Health has promulgated regulations which impose quite specific limitations on the use of electroshock treatment. For example, the regulations bar shock therapy for alcoholism or drug abuse, forbid more than thirty-five treatments per year without prior approval of the commissioner, require that an anesthetist be present for each treatment, and require prior written consent of the patient or his representative and an "independent physician." Atkins & Lauriat, *supra* note 93, at 290.

95. *See* note 2 *supra* and accompanying text.

ministered as part of a clinical research project or under a specific treatment protocol. The mere fact that a treatment is of uncertain efficacy does not mean that its administration is medically unsound. Nor should it mean that a physician must be penalized if it results in harm to a patient.[96] Many anti-cancer drugs, while effective in experimental animals, are of uncertain value in humans until extensive clinical trials in human subjects are carried out.[97] Moreover, many of these drugs are quite toxic. Yet few would hold that treatment programs using these drugs should not be conducted in an effort to improve therapy of a particularly menacing disease process.[98]

Rather than attempt to label a treatment as experimental or non-experimental or to engage in judicial balancing of risks and benefits, it would seem preferable for the court to review only the process by which a controversial or innovative treatment is selected, given and monitored, and to determine the extent to which this process protects the interests of patients. If the process seems to serve this protective goal, a court may conclude that reasonable steps have been taken to prevent harm and that the occurrence of harm is not actionable. Of course such a result assumes the existence of lawful consent to treatment, including an explicit recognition by patients that therapeutic efficacy is not established.

2. *Administrative Review Standard.*—Judicial review of medical treatment has been analogized to judicial review of the action of an administrative agency.[99] Thus, in reviewing an allegation that an involuntary mental patient received inadequate treatment, a federal circuit court has recognized that:

> The court's function here resembles ours when we review agency action. We do not decide whether the agency has made the best decision, but only make sure that it has made

96. Karp v. Cooley, 493 F.2d 408 (5th Cir. 1974), *cert. denied*, 419 U.S. 845 (1974) (use of mechanical heart not unlawful experimentation). *See* Curran, *The First Mechanical Heart Transplant: Informed Consent and Experimentation*, 291 N. ENG. J. MED. 1015 (1974); J. WALTZ & F. INBAU, *supra* note 54.

97. *See* Chalmers, Block & Lee, *supra* note 69.

98. The early American case of Carpenter v. Blake, 75 N.Y. 12 (1878), implies a principle of strict liability for the physician who deviates from customary treatment of a particular disease. This case has been criticized for seeming "to lump together legitimate experimentation and abject quackery, imposing strict liability for a bad result in either case." J. WALTZ & F. INBAU, *supra* note 54, at 184. Trying a new drug that has never been used in humans is hardly "abject quackery" if the drug has shown promise in animal experiments. To impose strict liability in the face of an informed consent seems patently unreasonable. Therefore, letting the novelty of a treatment determine the question of liability would effectively stifle medical advances that require clinical trials in humans.

99. *See* Note, *supra* note 92, at 1342-44.

> a permissible and reasonable decision in view of the relevant information and within a broad range of discretion.[100]

Under this standard, "a court would not interfere with the discretion of a hospital as long as the court be convinced that the hospital was performing its duties by utilizing its expertise in the treatment of each patient."[101]

One of the attractions of this approach is that it seems to emphasize that physicians' decisions be evaluated in light of the evidence on which they rely and the quality of their judgments rather than upon the nature or the outcome of treatment. Results of treatment are obviously important because, if bad, they should be fed back into the decision-making process as evidence against further use of a given treatment.[102] But until it is apparent that bad results are reasonable indicia of faulty approaches to treatment, their occurence should not alone determine the outcome of a legal proceeding. In addition, this approach recognizes that physicians should be afforded discretion in choice of therapy so long as there is substantial evidence to support its use.[103] If therapeutic discretion is too closely circumscribed, it is difficult to envision many therapeutic advances, particularly those which require testing in human subjects. Coupling a reasonable grant of therapeutic discretion with a strict informed consent requirement should, in general, strike a balance between promoting advances in treatment and protecting interests of patients.

3. Role Allocation Standard.—Professor Tribe has suggested, in the context of constitutional analysis, that there are certain areas of privacy where parties should be free to make decisions without legislative or governmental interference.[104] Thus, with respect to abortion, the role of decision-making may be allocated to a patient and her physician, and the state should be barred from participating

100. Tribby v. Cameron, 379 F.2d 104, 105 (D.C. Cir. 1967). *See also* Nason v. Superintendent of Bridgewater State Hosp., 353 Mass. 601, 614, 233 N.E.2d 908, 914 (1968), where the court stated that: "[A]ppropriate treatment is to be determined by competent doctors in their best judgment within the limits of permissible medical practice and is to be followed diligently" (citations omitted). Under an administrative review model, violation by physicians of the provisions of a treatment protocol would be justifiable only if the violation did not affect the interests of patients. *See generally* Note, *Violations by Agencies of Their Own Regulations*, 87 HARV. L. REV. 629 (1974).

101. Note, *supra* note 92, at 1343 (citations omitted).

102. Both the Nuremberg Code and the Declaration of Helsinki require that an "experimental" treatment be discontinued when evidence emerges that it is likely to be harmful. *See* notes 11 & 55 *supra* and accompanying text.

103. *See* Bazelon, *Forward* to *The Right to Treatment*, 57 GEO. L.J. 676 (1969).

104. *See* Tribe, *Forward* to *Toward a Model of Roles in the Due Process of Life and Law*, 87 HARV. L. REV. 1 (1973) (discussing the 1972 Supreme Court term).

in the decision.[105] He prefers this approach to "interest balancing" which, in his mind, unduly emphasizes the outcome of a particular decision over the more important concern of who should make it.

Taking some liberties, the concept of role-allocation may be useful in sketching the outlines of judicial review of medical treatment. The formulation might run as follows: (1) Medical treatment is an intensely private matter which affects physical and emotional well-being; (2) decisions about it lie with persons who seek or require it and those who possess the knowledge to administer it; and (3) courts or legislatures should not participate in or usurp these decisions unless they are unsupported by substantial medical evidence. From this approach it might follow, *arguendo*, that harms resulting from these decisions should be actionable only if there is convincing evidence of therapeutic abuse or a failure to obtain informed consent. In other words, the outcome of decisions within a protected area of activity is less important than who makes them and how they are generated.

Formulating role-allocation in these terms would enable physicians to administer an innovative or controversial treatment without the threat of irrational penalty, provided they are knowledgeable and skillful and that they fairly inform their patients. The resolution of a dispute over any ensuing harm to patients would not turn on a classification of the treatment as experimental, or on a close analysis of conflicting scientific data. At the same time the requirement of informed consent would be given full sway and the medical basis for a given treatment would be carefully investigated. This should protect against therapeutic over-reaching. However, role-allocation may not be workable where treatment of involuntary patients is at issue. It is difficult to envision courts or legislatures refraining from participation in treatment decisions involving such patients, many of whom have suffered from either neglect or inappropriate treatment.[106] On the other hand, if a patient is adequately represented in the decision-making process by a guardi-

105. In discussing Roe v. Wade, 410 U.S. 113 (1973), Professor Tribe asserts that while the Supreme Court spoke in terms of interest balancing, it was in reality "*[C]hoosing among alternative allocations of decisionmaking authority*, for the issue it faced was whether the woman and her doctor, rather than an agency of government, should have the authority to make the abortion decision at various stages of pregnancy." Thus, despite what the Court said, "[t]he result it reached was not the simple 'substitution of one non-rational judgment for another concerning the relative importance of a mother's opportunity to live the life she has planned and a fetus's opportunity to live at all,' but was instead a decision about *who should make judgments of that sort*." *Id.* at 11 (emphasis added) (citations omitted).

106. *See* O'Connor v. Donaldson, 422 U.S. 563 (1975); Wyatt v. Aderholt, 503 F.2d 1305 (1974); Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971).

an, monitor or ombudsman, role-allocation may still be a viable approach to reviewing treatment of involuntary patients.

4. Informed Consent.—It is easy to agree on the principle that patients should give informed consents to treatment, and that the elements should include a competent patient, a balanced disclosure by a physician and a non-coercive atmosphere.[107] However, determining what should be the content of an informed consent or how one proves its existence may be difficult. Recent decisions, especially in California[108] and the District of Columbia,[109] have stressed the importance of looking at the patient's perception of what he or she has been told, recognizing that there may be a great gap in understanding between patient and physician. But if too much stress rests on a patient's comprehension of medical data, one may conclude, perhaps with some desperation, either that it is impossible to ever fully inform a patient about a treatment[110] or that the only workable approach is to make a *pro forma* disclosure and hope that no harm eventuates from treatment.

Definitional problems notwithstanding, an indispensable part of judicial review of a medical treatment program is an evaluation of the procedures for obtaining consent. The importance of these procedures goes not only to a recognition of the patient's autonomy in making decisions about his or her person, but also to the integrity of the entire treatment program. A program which countenances short cuts in the consent procedure may also push a particular treatment to the exclusion of equal or superior alternatives. Where the atmosphere favors coercive consents, as in mental hospitals or prisons, the inquiry must be especially searching. Occasionally a court may even find, as in *Kaimowitz*, that a voluntary or knowledgeable consent is simply not obtainable. However, the consequence may be that a patient is deprived of a treatment which may be his or her only remaining chance for therapeutic gain.

C. Elements of Review

The format of judicial review of medical treatment will be affected by what a court perceives as the goal of review. Medical evidence will be required in any event. If the focus is on the

107. *See* Mills, *supra* note 80; *Note: Kaimowitz v. Department of Mental Health: A Right to be Free From Experimental Psychosurgery*, 54 B.U.L. REV. 301 (1974).

108. Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

109. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972).

110. *See* Ingelfinger, *supra* note 79.

scientific merits of a given treatment, however, the parties must pick their experts with care, especially if the treatment is innovative or controversial. Moreover, a court may wish to encourage *amici curiae* to participate so as to assure a broad range of medical opinion.[111] The courtroom may then be treated to a full-scale scientific debate, replete with slides, charts and statistical presentations. If a court seeks a more modest goal of determining whether there is a reasonable or substantial basis for a given treatment, it may suffice to have one or two well-qualified medical experts who can testify to the medical justifications for a treatment and to the acceptable alternatives.

Judicial evaluation of a treatment program may begin with whatever treatment protocol exists. One that has survived review by institutional screening committees and federal or other granting agencies is likely to be detailed and explicit. By contrast, one that has been developed outside the range of review committee, or which does not require budgetary support from outside agencies, may be quite general. In either case, testimony of physicians, patients and other participants will be required to confirm that the terms of the protocol are fully observed. With respect to the more general protocol, rather extensive testimony may be needed to define what procedures were followed in selecting, administering and evaluating treatment. Review of a protocol will also entail assessing the qualifications of the participating physicians both in terms of general background and specific expertise with respect to a particular treatment.[112]

Once having determined the procedures relating to treatment, a court may require medical evidence about the treatment itself, including its indications, risks, mechanisms of action and results of its use in experimental animals and analogous clinical situations. Evidence of this nature may clarify issues relating to appropriateness of treatment or its inherent dangers. Thus, with respect to

111. The federal district judge in *Wyatt v. Stickney* formulated his recommendations about treatment in partial reliance on standards suggested by various amici curiae. Amici included the United States of America, the American Orthopsychiatric Association, the American Psychological Association, the American Civil Liberties Union, and the American Association on Mental Deficiency.

112. Weighing the qualifications of physicians may be as difficult for a court as weighing a treatment. Neither a long bibliography nor membership in a plethora of medical organizations are conclusive indications of competence or compassion. However, it may be fruitful to inquire into the nature and extent of a physician's specialty training, whether certification by a specialty board has been obtained, whether he or she is experienced in administering a particular treatment, whether he or she is experienced in conducting clinical research, and whether he or she has published scientific articles relating to the treatment in question. Such an inquiry may yield enough data to form a reasonable impression about a physician's expertise, or lack thereof.

psychosurgery, a court may hear evidence that brain surgery may control behavioral disturbances that reflect an underlying epilepsy or that it does or does not produce permanent change in behavior. Medical evidence may also indicate whether a treatment is purely empirical, as with electroshock, or rational in the sense of surgical removal of diseased tissue.

If there is evidence that a treatment and the rules governing its use are reasonable, a court may then turn to the issue of whether any actual or alleged harm is actionable. Thus, it might find that informed consent was not obtained as required by the treatment protocol; that an improper dose of drug was given; that a surgeon placed a lesion in the wrong part of the brain; or that procedures set forth for the use of electroshock were not followed. As to potential harms, a court might find that "institutionalization" prevents a patient from giving an adequate consent; that procedures in a protocol for evaluating responses to treatment are not being followed; that participating physicians lack relevant background or experience; that medical record keeping is so inadequate that determining compliance with the protocol is impossible; or that there are too few physicians involved in the program to assure that treatment is administered as required by the protocol. Faced with such potential harms, a court may bar the continued operation of a treatment program or mandate steps to comply with the protocol, including the appointment of a monitor, ombudsman or a supervisory review committee.[113]

If a court finds that there is not substantial evidence to support use of a given treatment or that the procedures associated with its use are not designed to protect patients, it has adequate grounds for barring further conduct of the program or for imposing liability on those administering the treatment.[114] Suppose, however, that there is not substantial evidence to support use of a given treatment and, with full knowledge of this, a patient nevertheless consents to treatment. Thus, assume that a patient with an obsessive-compul-

113. Despite its obvious importance, detailed consideration of the matter of judicial remedies with respect to legally suspect treatment programs is beyond the scope of this Article. For useful discussions of possible approaches, see Broderick, *One-Legged Ombudsman in a Mental Hospital: An Over-the-Shoulder Glance at an Experimental Project*, 22 CATH. U.L. REV. 517 (1973); Note, *Monitors: A New Equitable Remedy?*, 70 YALE L.J. 103 (1960). *See also* Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971) (court-appointed "Human Rights Committee," consisting of lawyers, doctors, patients and local citizens, to monitor treatment plan developed by court). For a discussion of the pitfalls to be avoided by review committees see E. VALENSTEIN, *supra* note 17, at 338-42.

114. *Cf.* O'Connor v. Donaldson, 422 U.S. 563 (1975) (unless he is immune from suit by reason of reliance upon state law authorizing confinement of patients, a hospital psychiatrist may be personally liable for violating a patient's right to liberty).

sive neurosis consents to psychosurgery after being informed that there is only a verly slight chance it will be helpful and that it might result in additional psychiatric problems. After surgery the patient remains neurotic and, in addition, is apathetic and less able to meet his vocational demands. Would it be a proper exercise of judicial power to allow him to recover against the surgeon? Those who favor an outright ban on psychosurgery might say yes.[115] Yet, if psychosurgery is inherently unlawful, how does it differ from insulin shock or certain types of open heart surgery which are controversial and risk brain damage or death? There seems to be no general movement to ban those treatments. Perhaps the difference lies in the fact that psychosurgery involves a direct physical intrusion on the brain. It is questionable, however, whether issues relating to informed consent or lawfulness of treatment should hinge so directly on the means by which the brain is approached. After all, insulin shock and the failure of brain blood flow during open heart surgery may both result in profound permanent brain damage with accompanying alterations of behavior. Thus, another of the pitfalls of allowing the nature of a treatment to determine its legal consequences is the evoking of irrational distinctions.

IV. CONCLUSION

For many disease processes a variety of treatments are available. The more precise the diagnosis, the more selective or rational treatment may be. However, many treatments are empirical in nature and a trial of therapy is necessary to determine efficacy. Moreover, some conditions have not yielded to conventional therapies, and a need exists to find better modes of treatment. The development of a new treatment requires imagination, knowledge of the condition to be treated, animal experimentation when feasible and design of a protocol that will assure proper administration and evaluation of treatment. Whether one calls a clincial trial of a new therapy experimentation or treatment may depend on how much data are available with respect to the treatment. Regardless of terminology the situation may be that a treatment of uncertain efficacy is offered for a condition that lacks satisfactory therapy.

Where disturbed behavior is the target of treatment, sensitive issues emerge. The disturbed behavior may reflect a specific disease process, such as epilepsy or brain tumor or may be a complex response to multiple environmental factors. Accordingly, great care must be taken to determine whether diagnosable brain disease exists so that treatment will be specific for the disease

115. *See generally* Chorover, *supra* note 10.

rather than directed primarily at its behavioral manifestations. The controversies about treatments which affect behavior concern both the relevance of treatment and its side effects or collateral risks. Thus, those who criticize use of psychosurgery or electroshock contend that these treatments may be given without adequate characterization of whatever biological disturbances exist, or may be administered without due regard to their long-term impact on mental function and behavior. On the other hand, both forms of treatment have been effective enough in some instances to warrant their use in carefully selected patients. It falls to physicians to identify these patients and to articulate standards for determining whether such controversial or innovative treatments are appropriate on medical and scientific grounds. It is difficult to see how non-physicians, no matter how enlightened, can make the often fine judgments that are required to match patient and disease with treatment.

If treatment is innovative or controversial, physicians have a special obligation to assure that treatment is appropriate to the disease process and does not impose risks which outweigh potential therapeutic gains. This duty attaches whether the treatment is psychosurgery for violent behavior or open-heart surgery for progressive heart failure or intractable chest pain. If a physician does not meet this obligation the patient is wronged—regardless of whether the therapy is labeled "experimentation." If the obligation is met and harm nevertheless ensues, the harm should be actionable only on a showing of a specific act of misfeasance or misconduct. The nature of the treatment, because innovative or controversial, should not alone determine the outcome. If it does, law becomes an irrational deterrent to advances in medical therapy.

Even so, courts may play a major role in assuring that patients receive appropriate treatment and a realistic opportunity to participate in decisions about treatment. Where treatment becomes a legal issue, a court may insist that physicians produce substantial evidence of its potential value to patients, of their qualifications to administer it, and of the reasonableness of their decisions to employ it. One may analogize the role of a court here to the one it asserts in reviewing the actions of an administrative agency. In this capacity, a court may determine the relevant guidelines to decision-making, weigh whether decisions comply with the guidelines, and ascertain if the expertise of the decision-maker has in fact been utilized. The judicial approach would be the same regardless of the nature of treatment or the persons involved. An alternative theory of review is a form of role-allocation under which a court accepts that patient and physician have a protected

interest in decisions about treatment and that judicial intrusions must rest on convincing evidence of therapeutic abuse, including lack of informed consent. This approach would seem more appropriate to situations where the risk of coerced treatment is small than compared to those involving involuntary mental patients, prisoners and children. In any event, courts may properly require that physicians follow procedures which at every stage serve the primary goal of helping or healing patients.

Courts should not become forums for arguing and deciding the general merits of a particular treatment. Such a decision may require a lengthy accumulation of scientific data, including basic research in animals and skillfully designed therapeutic trials in humans. It does not lend itself to forensic analysis. Concededly, a court may hear arguments for and against the use of a particular treatment for a given patient or group of patients and may conclude that a treatment was improperly selected or administered. However, a court should refrain from allowing its own characterization of a treatment as experimental, innovative, or controversial obscure the issue of whether specific treatment decisions were reasonable. While psychosurgery may not be a reasonable treatment for hyperactivity in children, it may be a reasonable treatment for a psychotic patient who suffers from painful delusions and paroxysmal outbursts of assaultive behavior. To bar or penalize psychosurgery in both situations would be to exalt the potential implications of a treatment over the very specific issue of its possible utility for a sick individual. The same can be said with respect to any other treatment which may injure, but which when applied by reasonable and compassionate physicians, may be truly therapeutic.