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**MONDAY, MAY 23, 1977**

**PART III**



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**DEPARTMENT OF  
HEALTH,  
EDUCATION, AND  
WELFARE**

**Office of the Secretary**



**PROTECTION OF  
HUMAN SUBJECTS**

**Use of Psychosurgery in Practice and  
Research: Report and Recommendations  
for Public Comment**

**DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE**

Office of the Secretary

**PROTECTION OF HUMAN SUBJECTS**

**Use of Psychosurgery in Practice and Research: Report and Recommendations of National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of report and recommendations for public comment.

SUMMARY: This report recommends the psychosurgery be used only to meet the health needs of individual patients, and then only under strict limitations and controls, with added safeguards where the patient is a prisoner, minor, or in a mental institution.

DATES: Written comments on the Commission's recommendations are requested and should be received on or before July 22, 1977, if they are to receive full consideration.

ADDRESSES: Send comments to: Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014. Additional copies of this Report and Recommendations may be obtained from the same address. All comments received will be available for inspection at Room 303, Westwood Building, 5333 Westbard Avenue, Bethesda, Maryland, weekdays (Federal holidays excepted) between the hours of 9 a.m. and 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:**

D. T. Chalkley, Ph. D., Director, Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014 (301-496-7005).

**SUPPLEMENTARY INFORMATION:** On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to conduct an investigation and study of the use of psychosurgery in the United States, to determine the appropriateness of such use, and to recommend to the Secretary of Health, Education, and Welfare policies defining any circumstances under which its continued use might be appropriate. The Secretary is required to publish any such recommendation of the Commission in the FEDERAL REGISTER, which he does herewith, and to provide an opportunity for interested persons to submit written comments, views, arguments, and data with respect to these recommendations. Comments should be identified by the number of the recommendation (1-8) and, to the extent feasible, distinguish between application of the recommendations to (a) medical practice and (b) medical research.

The Secretary is further required to consider the Commission's recommendations and any relevant comments or other matter submitted to him and, on or before November 21, 1977, to (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or sponsored under programs administered by him, and (2) if he determines that such action is not so appropriate, publish in the FEDERAL REGISTER such determination together with an adequate statement of the reasons for his determination. Since the Department has not yet completed its own review of this report, the views set forth in it are not necessarily those of the Department of Health, Education, and Welfare. The Department will be evaluating the report during the comment period.

Dated: May 2, 1977.

**JAMES F. DICKSON,**  
*Acting Assistant  
Secretary for Health.*

Approved: May 13, 1977.

**JOSEPH A. CALIFANO, Jr.,**  
*Secretary.*

**THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH**

**PSYCHOSURGERY REPORT AND  
RECOMMENDATIONS**

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MARCH 14, 1977.

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**INTRODUCTION**

In response to widespread public concern, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was directed to investigate and to recommend policies that should govern the use of psychosurgery. Specifically the Commission's mandate under section 202(c) of the National Research Act (Pub. L. 93-348) requires that:

The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. For purposes of this paragraph; the term "psychosurgery" means brain surgery on (1) normal brain tissue of an individual who does not suffer from any physical disease, for the purpose of changing or controlling the behavior or emotions of such individual, or (2) diseased brain tissue of an individual if the sole object of the performance of such surgery is to control, change, or affect any behavioral or emotional disturbance of such individual. Such term does not include brain surgery designed to cure or ameliorate the effects of epilepsy and [sic] electric shock treatments.

To discharge its duties under this section of the mandate, the Commission: (1) Convened a group of scientific consultants; (2) on the basis of the consultants' recommendations, contracted for studies to survey the recent literature on psychosurgery and to evaluate patients who had undergone psychosurgical operations; (3) held public hearings; (4) supported the National Minority Conference on Human Experimentation, which provided recommendations on the use of psychosurgery; (5) deliberated the issues surrounding the use of psychosurgery, in the light of the views presented to the Commission and the results of the studies performed under contract; and (6) adopted the recommendations that are set forth at the end of this report.

The Commission expanded the statutory definition of psychosurgery by replacing the word "sole" with "primary," so that the definition would read: "Psychosurgery means brain surgery on (1) normal brain tissue \* \* \* or (2) diseased brain tissue of an individual, if the primary object of the performance of such surgery is to control, change, or affect any behavioral or emotional disturbance of such individual." Under this wording, surgery with a dual purpose (e.g., relief of seizures as well as relief of emotional disorders) falls within the definition of psychosurgery if the predominant reason for performing the operation is to affect the behavioral or emotional disturbance.

The Commission also specified, for clarification, that psychosurgery includes the implantation of electrodes, destruction or direct stimulation of brain tissue by any means (e.g., ultra-sound, laser beams), and the direct application of substances to the brain, when the primary purpose of such intervention is to change of control behavior or emotions. Further, the Commission made clear that surgery for the relief of various movement disorders, such as epilepsy and parkinsonism, are not included within the definition of psychosurgery. (The legislative mandate mentioned only epilepsy. In addition, the Commission followed the Congressional exclusion of "electric shock treatments" from the definition of psychosurgery and, thus, from its investigation and report. Finally, with respect to pain, the legislative definition was silent and there is no agreement in the medical or scientific community as to whether brain surgery for relief of pain should or should not be considered psychosurgery. The Commission, on the advice of its scientific and medical consultants, specified that surgery or other invasions of the brain which interrupt the transmission of pain along sensory pathways should not be considered psychosurgery; however, when such procedures are applied to relieve the emotional response to persistent pain, without affecting the transmission of pain, they would fall within the definition of psychosurgery.

The period studied by the Commission was extended from five to ten years (1965-1975), in order to obtain a larger patient population and to permit the evaluation of patients over a longer post-operative period.

Chapters 1, 2, and 3, of this report provide a short history of the use of psychosurgery and the focus of public concern in this area, a description of the issues that have been raised in the literature, and a discussion of various legal approaches that have been taken. The results of the studies performed under contract for the Commission are summarized in Chapter 4. Proceedings and recommendations of the National Minority Conference on Human Experimentation and views presented at the Commission's public hearings on psychosurgery are summarized in Chapter 5. The Commission's recommendations defining the appropriate circumstances for the use of psychosurgical procedures are set forth in Chapter 6. The dissenting opinion of one member of the Commission is set forth in the final chapter. The full text of the survey of current literature on psychosurgery and of the reports of the two teams that evaluated psychosurgical patients under Commission contracts appear in the Appendix to this report.

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#### CHAPTER 1—BACKGROUND

##### BRIEF HISTORY OF PSYCHOSURGERY

The earliest account of psychosurgery was published in 1891 by Burckhardt, who had tried to calm very excitable patients by destroying a strip of cerebral cortex. In spite of his belief that some patients improved, the operations were discontinued due to vigorous opposition. The widespread adoption of psychosurgery is generally attributed to the Portuguese neuropsychiatrist, Egas Moniz. In 1935, after hearing a report of the calming effect of frontal lobe ablation on monkeys and chimpanzees, Moniz and a surgical colleague, Almeida Lima, operated on the frontal lobes of psychiatric patients. Moniz' monograph describing the generally favorable results obtained on his first twenty patients encouraged neuropsychiatrists and neurosurgeons around the world to adopt similar procedures. In 1936, Freeman, a neurologist, and Watts, a neurosurgeon, introduced psychosurgery into the United States, and by 1950 they had operated on over 1,000 patients. Freeman later indicated that up to the time of his retirement he had performed or supervised psychosurgical procedures on more than 3,500 patients.

The urgent need for efficient treatment of many psychiatrically disturbed veterans of World War II and optimistic reports of the results of psychosurgery resulted in its wide-scale adoption following the war. It is estimated that 40,000 prefrontal lobotomies were performed in the United States, the majority of them in the decade following 1945. By the late 1950's, reports of undesirable side effects from the operations and the introduction of psychoactive drugs produced a sharp decline in lobotomies, although a few such operations have been performed up to the present. In the 1960's, however, the accumulation of knowledge of the neuroanatomical regions that regulate emotionality and the refinement of surgical techniques encouraged the belief that crippling psychiatric symptoms could be alleviated with a minimum of risk by making small and very localized lesions. The numerous attempts over the last decade to focus psychosurgery on precise targets have generated public concern and legislative responses.

##### RISE OF PUBLIC CONCERN

Coinciding with the development of refined techniques for psychosurgery, the climate of political unrest in the late 1960's, general fear of behavior control and concern about abuse of minorities provided the background against which Dr. Peter Breggin (a Washington, D.C., psychiatrist) began to publish articles warning about the "new wave of psychosurgery" and the "return of the lobotomy." These appeared in popular as well as scientific publications; two lengthy articles were entered in the "Congressional Record" in February and March

1972.<sup>1</sup> Breggin expressed alarm about the increased incidence of psychosurgery (which, he said, was undertaken without scientific justification or proper evaluation) and about the political implications of suggestions by Mark, Sweet and Ervin that urban riots and other acts of "senseless violence" might be prevented (at least in part) by appropriate diagnostic techniques and surgical intervention. Mark et al. had made such a suggestion in a letter to the "Journal of the American Medical Association" in September 1967, and again in their book, "Violence and the Brain," which appeared in 1970.<sup>2</sup> The movie "Clockwork Orange" and Crichton's novel *The Terminal Man* (1972) added fuel to the fire, as did reports that three prisoners in California had received psychosurgery,<sup>3</sup> and that the Justice Department was supporting research that might involve further operations on prisoners in California facilities.<sup>4</sup> In February 1973, these issues received wide circulation in an article by B. J. Mason in "Ebony" magazine.

Beginning in the fall of 1972 and throughout 1973, Senator Sam Ervin, Chairman of the Subcommittee on Constitutional Rights of the Senate Judiciary Committee, conducted a lengthy correspondence with officials of the Department of Health, Education, and Welfare and the Law Enforcement Assistance Administration (LEAA) in the Department of Justice, regarding the nature and extent of federal involvement in behavior modification in general and psychosurgery in particular.<sup>5</sup> In February 1974, LEAA terminated its support of research involving the performance of psychosurgery.<sup>6</sup>

In January 1973, Gabe Kaimowitz of Michigan Legal Services intervened on behalf of a mental patient who was to become the first subject in a research project designed to compare the effects of psychosurgery with the effects of hormone treatments in reducing aggression. The research had been funded by the Michigan state legislature, and both a scientific and a human rights review committee at the clinic where the operation would be performed had approved the procedure. In July 1973, a three-judge Michigan court held that an involuntarily confined mental patient cannot give valid consent to participate in an experiment of such a hazardous and irreversible nature.<sup>7</sup>

In September 1973, during the Senate floor debate on the bill which became the National Research Act, Senator Beall offered an amendment which provided for a two-year moratorium on the performance of psychosurgery in facilities that receive federal funds, until the Commission completed a study of the use of psychosurgery during the recent past, as well as a case-by-case study "of a sufficient number of cases (together with followup information thereon) to provide the basis for an objective scientific evaluation" of the results of such operations. During the debate, the moratorium provision was deleted on the grounds that Congress had insufficient information to justify such a measure. The

amendment was further modified in conference to require simply that the Commission study the use of psychosurgery in the United States and recommend to the Secretary, DHEW, the circumstances "if any" under which its use may be appropriate.

The scientific community also became concerned about psychosurgery. In 1973, the National Institute of Mental Health undertook to study the issues surrounding the use of psychosurgery, and the National Institute of Neurological Diseases and Stroke empaneled a multidisciplinary committee to report on biomedical research aspects of, brain and aggressive behavior. In August 1973, the American Psychological Association's Division of Physiological and Comparative Psychology held a symposium on the legal, ethical and scientific aspects of psychosurgery. A multidisciplinary conference on the same subject was held in December 1973 by the Boston University Center for Law and Health Sciences. The American Psychiatric Association appointed a task force to determine the extent of psychosurgery in the United States and to study the issues; and the Society for Neurosciences polled its members as a preliminary to drafting a position paper on the subject.

By the time the Commission was created, therefore, much had been written on the scientific, legal and ethical issues surrounding the use of psychosurgery; but relatively little was known about the nature and extent of its use, the kinds of patients receiving operations, or the safety and efficacy of the various procedures.

## FOOTNOTES

NOTE.—The following publications contain many of the papers listed below:

"B.U. Symposium": Boston University Center for Law and Health Sciences, *Psychosurgery—A Multidisciplinary Symposium*, Boston University Law Review, Lexington Books, 1974.

"Individual Rights Report": U.S. Senate, Judiciary Committee, Subcommittee on Constitutional Rights, "Individual Rights and the Federal Role in Behavior Modification," U.S. Government Printing Office, November 1974.

"Health Care Hearings": U.S. Senate Committee on Labor and Public Welfare, Subcommittee on Health, "Quality of Health Care—Human Experimentation," Part 2, February 23, 1973.

<sup>1</sup> Peter Breggin, "Congressional Record," February 24, 1972, p. 5567 and March 30, 1973, p. 11396, reprinted in *Health Care Hearings*, pp. 437 and 455.

<sup>2</sup> Vernon Mark, William Sweet and Frank Ervin, *The Role of Brain Disease in Riots and Urban Violence*, "J.A.M.A.," Vol 201, No. 11, Sept. 11, 1967; Mark and Ervin, "Violence and the Brain," Harper and Row, New York, 1970 (Chs. 11 and 12 reprinted in *Individual Rights Report*, p. 596 ff.)

<sup>3</sup> Leroy Aarons, *Brain Surgery is Tested on 3 California Convicts*, "The Washington Post," February 25, 1973.

<sup>4</sup> See *Individual Rights Report*, p. 299 ff.

<sup>5</sup> *Ibid.*, pp. 49-70, 299-313.

<sup>6</sup> *Ibid.*, p. 308.

<sup>7</sup> *Kaimowitz v. Department of Mental Health*, Civil No. 73-19434-AW Circuit court for the County of Wayne, State of Michigan, July 10, 1973; reprinted in *Individual Rights Report*, p. 501 ff.

## CHAPTER 2—ISSUES SURROUNDING THE USE OF PSYCHOSURGERY

A central issue surrounding psychosurgery has been the underlying scientific justification. Breggin<sup>8</sup> and Chorover<sup>9</sup> have argued, for example, that the risks of psychosurgery are high, especially because the procedures are irreversible, and that the data regarding the effects of surgical intrusion on the brain are inconclusive and contradictory. They have observed, further, that for the most part the safety and efficacy of psychosurgery have been evaluated and reported by surgeons who lack either the expertise or objectivity to conduct reliable assessments of changes in psychiatric status or of cognitive function. These critics have cited the imprecision of psychiatric diagnosis and assessment as a further handicap in evaluating the effects of psychosurgery. Thus, they have argued, reliable categorization of patients with respect to their illnesses and precise assessment of behavioral change are not possible. In addition, as Valenstein has observed,<sup>10</sup> most psychosurgery is performed in the context of practice (i.e., without a research protocol or review), and there have been few systematic attempts to measure preoperative status against postoperative gains or losses, or even to have evaluations performed by persons who have no vested interest in the outcome. Another criticism voiced by Chorover, Valenstein and others is that surgeons are applying techniques to humans on the basis of selective attention to the results of animal research, i.e., without full knowledge or appreciation of the complexity and implications of the animal data.<sup>11</sup> They have referred, for example, to reports that lesions in the limbic system in animals produce unreliable and unpredictable results, often either increasing aggression or producing marked abnormalities in behavior.<sup>12</sup>

Concerns of a different nature center around the problem of obtaining informed consent. A question that has been raised in this context is whether an individual who is an appropriate candidate for psychosurgery is able to give valid consent to the surgery; and if not, whether potential conflicts of interest should bar third parties from consenting on behalf of another, for it may be the caretaker or society, rather than the patient, who stands to benefit from performance of the surgery.<sup>13</sup> This concern has led to suggestions that psychosurgery not be performed on children, prisoners and patients who are involuntarily confined in institutions.<sup>14</sup>

A related concern is that it may not be acceptable for an individual to consent to permanent alteration of the bodily organ which is generally thought to be the locus of that which we call the "self" or the "mind." Whether or not psychosurgery differs significantly in this regard from other therapies for behavior disorders, however, is an article of debate. Chorover has described psychosurgery as brain surgery performed upon specific cerebral structures in such

a way as to effect changes in thought processes, personality characteristics, behavior patterns, and other aspects of subjective experience.<sup>15</sup> Breggin has gone even further, suggesting that such intrusion constitutes "mutilation" of the sort which is generally prohibited in the common law.<sup>16</sup> On the other hand, Neville (a philosopher) has observed that:

Psychosurgery does not affect the brain as much as do many procedures for treating tumors or aneurysms. It does not affect nearly so many people as does the prescription of psychoactive drugs. It does not affect people as profoundly, at the heart of their character, as does psychoanalysis. Furthermore, in comparison with these other methods of altering behavior, psychosurgery is practiced in no greater ignorance of how and why it works. Yet, it seems far more drastic in its directness, more variable in its possible outcomes, and surely irreversible in the sense that it destroys brain tissue.<sup>17</sup>

In this regard, it has been observed that prolonged drug therapy and electroshock treatments both may have irreversible effects with respect to brain pathology as well as with respect to behavior and cognitive function.<sup>18</sup>

Breggin and Chorover, among others, have voiced deep concerns that psychosurgery will be used (or misused) as a social or political tool, applying socially determined definitions of "abnormal" behavior to justify controlling dissidents or subduing individuals whose behavior is disruptive or otherwise bothersome. They charge that psychosurgery has been, or will be, used selectively against blacks, women, other minorities, and person who are institutionalized.<sup>19</sup> On the other hand, Frank Ervin has argued that for purposes of manipulating the behavior of large groups of people, or of individuals over a prolonged period of time, the best technique is clearly biochemical. Drugs, he has said, can be applied surreptitiously and on a broad scale with dependable effects and with relative ease, whereas surgery is difficult to apply either in secret or on a wide scale because it involves elaborate procedures, equipment and personnel.<sup>20</sup> Willard Gaylin, President of the Hastings Institute, testified in the same vein before Senator Kennedy's subcommittee:

It seems unlikely, if there were some plot to take over the country by a totalitarian, \* \* \* that psychosurgery would be the method of choice. I doubt that they would find the most efficient technique for mass control would be planting electrodes on a population of 200 million, or psychosurgery, when they have access to a limited (sic) national television, and to schools with compulsory education, to psychological inputs and to drugs, all of which afford a more convenient, cheaper, economic mass method of manipulation.

\* \* \* [W]hile I think the problem of psychosurgery is less pressing than other aspects of behavior control, \* \* \* it is a lightning rod issue and it does deserve great attention because it focuses on some problems that transcend itself.<sup>21</sup>

A final issue is the status of psychosurgery as a therapeutic device. While some surgeons, notably Andy, have argued that psychosurgery is accepted therapy for certain behavioral dis-

orders,<sup>22</sup> others, including Heath,<sup>23</sup> have agreed with Brown and the NIMH<sup>24</sup> that psychosurgery should be considered experimental and should be conducted only within the context of research, subject to all the review provisions and procedures for the protection of human subjects which that implies. Judicial and legislative approaches to the resolution of these issues are discussed in the following chapter.

## FOOTNOTES

<sup>8</sup> Peter Breggin, Testimony in Health Care Hearings, also in articles reprinted therein.

<sup>9</sup> Stephen Chorover, Psychosurgery: A Neuropsychological Perspective, in B.U. Symposium, p. 15.

<sup>10</sup> Elliot Valenstein, "Brain Control," John Wiley & Sons, New York, 1973, p. 296; see also Valenstein, "The Practice of Psychosurgery: A Survey of the Literature (1971-1976)," submitted to the Commission in June 1976 (included in the Appendix to this report).

<sup>11</sup> See especially Valenstein, "Brain Control," pp. 326-366.

<sup>12</sup> Chorover, in B.U. Symposium, p. 22; National Institute of Neurological Diseases and Stroke, "Report on the Biomedical Research Aspects of Brain and Aggressive Behavior" (hereinafter "NINDS Report"), October 23, 1973, Part I-C: Behavioral Studies, pp. 110-122; Valenstein, "Brain Control," p. 137 ff.

<sup>13</sup> George Annas and Leonard Glantz, Psychosurgery—The Law's Response, In B.U. Symposium, p. 33.

<sup>14</sup> Chorover, in B.U. Symposium, p. 31; Alan A. Stone, M.D., et al., "Task Force Report—Psychosurgery in Massachusetts" (majority report) and proposed regulations, June 1975.

<sup>15</sup> Chorover, in B.U. Symposium, p. 21.

<sup>16</sup> Breggin, in Health Care Hearings, pp. 358-359.

<sup>17</sup> Robert Neville, Pots and Black Kettles: A Philosopher's Perspective on Psychosurgery, in B.U. Symposium, p. 128.

<sup>18</sup> Vernon Mark, Psychosurgery Versus Anti-Psychiatry, in B.U. Symposium, especially pp. 9-10, citing American College of Neuro-psychopharmacology—FDA Task Force, Neurological Syndromes Associated with Antipsychotic Drug Use: A Special Report, "Arch. Gen. Psychiatry," Vol. 28, 1973, p. 463. See also report to the Commission by Teuber, et al., "The Effects of Cingulotomy in Man," June 1976, pp. 8, 10-11, 75-76 (included in the Appendix to this report).

<sup>19</sup> See especially Breggin, in Health Care Hearings, p. 438; Chorover, in B.U. Symposium, p. 29; and Neville, in B.U. Symposium, p. 136. See also, "Report and Recommendations of the Minority Conference on Human Experimentation," pp. 21-22.

<sup>20</sup> Frank Ervin, Biological Intervention Technologies and Social Control, "American Behavioral Scientist," Vol. 18, No. 8, May/June 1975, p. 627.

<sup>21</sup> Willard Gaylin, in Health Care Hearings, p. 374.

<sup>22</sup> Orlando J. Andy, in Health Care Hearings, p. 350.

<sup>23</sup> Robert G. Heath, in Health Care Hearings, p. 365.

<sup>24</sup> Bertram S. Brown, in Health Care Hearings, p. 342; National Institute of Mental Health, "Psychosurgery—Perspective on a Current Issue," 1973, p. 8.

## CHAPTER 3—LEGAL CONSIDERATIONS

Oregon and California have enacted legislation providing for the regulation of psychosurgery, and courts in Michigan and California have explored a number of informed consent and constitutional issues raised by certain regulatory

requirements and by the performance of psychosurgery under certain conditions. Chief among these issues are the constitutionality of mandatory review boards and the validity of consent given by the involuntarily confined or their proxies.

## LEGISLATION

In 1973 Oregon enacted the first comprehensive legislation for the regulation of psychosurgery.<sup>25</sup> The Oregon statute provides that psychosurgery may be performed only if a Psychosurgery Review Board ("Review Board") has approved the performance of the operation on the individual patient. The Review Board is composed of nine members appointed by the governor from specified medical, psychological, neuroscientific and lay backgrounds.<sup>26</sup>

A physician seeking to perform psychosurgery must first file a petition with the Review Board stating that the patient or legal guardian, if any, has consented and that the proposed treatment has "legitimate clinical value" and is "needed" by the patient. The Review Board is composed of nine members hearing, giving notice to the concerned parties, to determine whether the patient or legal guardian has given and continues to give a "voluntary and informed" consent. If the patient is believed to lack the capacity for voluntary and informed consent, and there is no legal guardian, the Review Board must request that one be appointed. The patient and guardian must be notified of their respective right to legal representation at the consent hearing. Indigent persons are entitled to appointed counsel upon request.

If the Review Board finds that adequate consent has been given, it must then determine whether the proposed operation has clinical merit and is an "appropriate" therapy for the specific patient. Several requirements must be met before an operation may be deemed appropriate:

(1) All conventional therapies must have been attempted;

(2) Criteria for selection of the patient must have been met;

(3) The operation must offer hope of saving life, reestablishing health or alleviating suffering; and

(4) All other viable alternative methods of treatment must have been tried and have failed to produce satisfactory results.

The Review Board may conduct site visits or consultations with experts in the field during the course of its deliberations. The Review Board itself may undertake a specific diagnostic evaluation to aid in its determination. If the operation is permitted, a written report of the outcome must be transmitted to the Review Board.

In 1974 California enacted two somewhat differing approaches to the regulation of psychosurgery. The first is legislation covering the availability of therapies to have involuntarily confined pursuant to the penal code, wherever institutionalized,<sup>27</sup> and the second legisla-

tion upon all other persons, whether institutionalized or not.<sup>28</sup> The latter legislation has been replaced by a substantially similar 1976 act (to become effective in 1977)<sup>29</sup> in response to a court decision discussed below.

The preambles to the penal legislation and the 1976 act state their intent to protect the constitutional rights of privacy and freedom from enforced interference with thought processes and states of mind through the use of "organic" therapies.<sup>30</sup> The principal distinction between the California and Oregon legislation is that California does not recognize proxy or guardian consent to psychosurgery; rather, the performance of psychosurgery upon individuals who lack the capacity for informed consent as defined in the California statutes is prohibited.<sup>31</sup> This prohibition extends to minors under the age of 18 years.<sup>32</sup>

Both California acts recognize that a person under guardianship, having been adjudicated legally incompetent as a general matter, may nevertheless retain the specific capacity for informed consent to psychosurgery. Conversely, an otherwise legally competent patient may lack such capacity and would therefore be ineligible for psychosurgery. The two acts also explicitly reject the notion that a person lacks the capacity for informed consent solely as a consequence of being diagnosed as "mentally ill, disordered, abnormal or mentally defective."

The distinctive feature of the California penal legislation is a provision for mandatory judicial review. The warden or superintendent of the confining institution must petition a court for an order authorizing psychosurgery, specifying what "mental illness, disorder, abnormality, or defect justifies" the psychosurgery. The court must appoint both an independent medical expert and a public defender for the indigent. The court must first determine whether the person has the capacity for informed consent and has manifested that capacity in the process of consenting to psychosurgery. If the court so finds, it then must review the merits of the proposed operation. To authorize psychosurgery, the court must find that the operation would be "beneficial"; that there is a "compelling interest justifying" the operation; that there are "no less onerous alternatives"; and that the operation "is in accordance with sound medical-psychiatric practice."

The 1976 California act does not require judicial review of proposed psychosurgery on persons outside of the criminal justice system. It relies instead upon a committee's review of both the patient's consent and the merits of the operation. The California legislation differs from the Oregon approach in that the review committee is decentralized and composed only of physicians. A committee of three physicians, one appointed by the facility where the operation is to take place and two appointed by the local mental health director, must include two psychiatrists or neurosurgeons who are board-certified or eligible. Because the committee is composed only of physicians, its proceedings are clearly covered

by the physician/patient privilege. After personally examining the patient and agreeing that the patient has the capacity for informed consent, the committee must also agree with the attending physician that "all other appropriate treatment modalities have been exhausted," and that the operation "is definitely indicated and is the least drastic alternative available" for treatment at the time. There is also a "cooling-off" period; no psychosurgery may be performed for at least 72 hours after the patients written consent.

#### CASE LAW

Shortly after the enactment of the Oregon legislation, a well-publicized case involving psychosurgery was decided by a Michigan state court in "Kaimowitz v. Department of Mental Health."<sup>33</sup> "Kaimowitz" involved an involuntarily detained adult mental patient who was confined as a criminal sexual psychopath. The patient and his parents had all signed consent forms for his participation in a study of the effects of amygdalotomy on aggression; but the court held that there could be no legally adequate consent to the operation.

The court first reasoned that the combined effects of institutionalization and the hazardous and unknown effects of the proposed amygdalotomy precluded the finding of a factually adequate consent by the patient. The "inherently coercive environment" was said to prevent consent to such an experimental procedure from being "competent" and "voluntary," while the lack of a scientific basis for predicting the outcome was stated to render the consent "unknowledgeable."

Some commentators have construed the opinion to find the factors of institutionalization and unfavorable risk/benefit ratio to be separate and independent reasons for invalidating the consent.<sup>34</sup> However, the court noted that its holding did not prevent involuntarily confined patients from giving adequate consent to neurological procedures or even to amygdalotomy should it become an accepted, nonexperimental procedure. The court stated that its conclusion was based upon the expert opinion presented during the 1973 trial on the probable effects of amygdalotomy, that it would flatten emotional responses, lead to impairment of memory, learning and abstract reasoning ability, and cause general apathy, leaving open the possibility of reaching a different result in the future if presented with different evidence on the effects of amygdalotomy.

The "Kaimowitz" court also stated alternative, constitutional reasons for not recognizing the patient's consent. The court reasoned that the First Amendment freedom of speech necessarily protects the freedom to generate ideas.<sup>35</sup> Thus, if the psychosurgery would interfere with memory or affect, it would impair the right "to be free from interference with \* \* \* mental processes." Similarly, the court argued that the constitutional right of privacy protects the privacy of the mind as much as it does the well-established privacy of the

marital bed.<sup>36</sup> The court then concluded that these constitutional protections prevented the state from accepting the patient's consent to the proposed psychosurgery.

With respect to the consent of the parents, "Kaimowitz" refused to acknowledge third-party consent on the unelaborated ground that a guardian may not consent to psychosurgery to which the patient may not consent.

The informed consent and constitutional rulings of "Kaimowitz" have not been universally accepted. "Kaimowitz" argument that in voluntarily detained persons do not have the capacity for informed consent to psychosurgery has been criticized by commentators.<sup>37</sup> Moreover, the California penal legislation, enacted after the "Kaimowitz" decision, rejected the theory that involuntary confinement by itself precluded capacity for consent to risky experimental therapy. The constitutional barriers to valid consent set up by "Kaimowitz" have been greeted even more skeptically. It is not clear whether the court was concluding that (1) an involuntarily confined patient's free speech and privacy rights prevented the patient, regardless of his or her capacity for informed consent, from giving a valid consent, or (2) the constitutional protections required a conclusive presumption that all such patients be considered incompetent to consent. The first interpretation is severely questioned when applied to patients who would otherwise have the capacity for informed consent. Commentators have argued that the Constitution can no more preclude consent to psychosurgery than it can forbid consent to standard psychotherapy. In both cases, the Constitution protects the competent individual's right to choose whether or not to permit interference with his or her mental activity.<sup>38</sup> The second interpretation has also been criticized harshly. A "conclusive or irrebuttable presumption" of incompetency would appear to conflict with First Amendment and privacy cases which require that individuated rulings must be made on claims which involve infringement of fundamental rights.<sup>39</sup>

A recent California appellate case, *Aden v. Younger*,<sup>40</sup> has implicitly rejected the "Kaimowitz" constitutional arguments. The court was reviewing the 1974 legislation regulating psychosurgery on individuals outside the criminal justice system (see above); the legislation also had provisions concerning electroconvulsive therapy (ECT). The legislation was challenged as an unconstitutional infringement of first Amendment and privacy rights of access to such therapies. The most difficult issues faced by the court were raised by the provision for mandatory approval by a review committee.

The "Aden" court accepted the premise that patients' freedom of thought "intimately touched upon by any regulation of procedures affecting thought and feelings", is protected by the First Amendment and the constitutional right

of privacy.<sup>41</sup> Because a requirement for review committee approval may result in the denial of treatment to some patients who both need and desire it, their freedom of thought would remain impaired. Thus the provision for committee review must be justified by a "compelling state interest," as do all state regulations which impair fundamental constitutional rights. It should be noted that the First Amendment and privacy issues are not dependent upon finding psychosurgery (or ECT) to have a direct effect upon high order cognitive processes;<sup>42</sup> rather, psychosurgery is likely to implicate these constitutional protections because the primary purpose of the surgery, by definition, is to control or affect the motions of an individual.

In determining whether there are compelling state interests to uphold the mandatory review committee provisions, the court distinguished between review of the consent and review of the substantive merits of the therapy, and also between treatment of involuntarily detained patients and of all others.

With respect to committee review of consent, the state interest in protecting the right to refuse treatment was found clearly to justify a review procedure for ensuring the competency and voluntariness of a patient's consent. Committee review of a mental patient's competence was reasoned to be constitutional because there is reason to suspect incompetence, whether or not the patient is involuntarily detained.

In analyzing the requirement of substantive review of psychosurgery, the court recognized that the legislation was designed to protect individual autonomy.<sup>43</sup> Substantive committee review was then upheld as a means of ensuring the wisdom of the involuntarily detained patient's consent. Thus, the state's compelling interest in preventing involuntary administration of psychosurgery could be implemented by adding a protective layer of administrative review, rather than by categorically rejecting the consent of all involuntarily detained patients, as did "Kaimowitz".

With respect to substantive committee review for patients who are not involuntarily detained and are found competent to consent, the "Aden" court distinguished between psychosurgery and ECT. The court found psychosurgery to be experimental, and more hazardous and intrusive than ECT. The more intrusive a treatment, the stronger the state's interest in its regulation becomes. Thus, the court concluded that the compelling state interest in preventing unnecessary administration of experimental and intrusive treatment justified regulating psychosurgery as a "treatment of last resort," which must be approved by a committee even when the adequacy of the patient's consent has been confirmed.

By contrast, ECT was described as nonexperimental and relatively less intrusive. The court therefore concluded that mandatory committee review of the merits of proposed ECT upon competent patients was an unconstitutional in-

fringement of their right of privacy. Thus, "Aden" apparently left open, as did "Kaimowitz," the possibility that validation of psychosurgical techniques would warrant a different approach to its regulation.

Aside from "Kaimowitz," which refused to recognize proxy consent to amygdalotomy, there have been no cases that have decided the difficult issues raised by third-party consent to psychosurgery.<sup>45</sup> A complete prohibition of psychosurgery upon patients lacking the capacity for consent, however, may not be a permissible approach. "Aden," for example, found a constitutional issue in legislation which may deny patients access to psychosurgery.<sup>46</sup> Although that court found a compelling interest in support of a ban on proxy consent in order to protect the incompetent patient, a flat prohibition may become less compelling if psychosurgical procedures become validated as safe and effective.

#### CONCLUSION

The "Kaimowitz" approach might not prevail today. With new data indicating that certain psychosurgical procedures are less hazardous than previously thought and potentially of significant therapeutic value, the Oregon model (requiring committee review of both consent and the merits of the therapy, as well as a reporting system recognizing proxy consent, and permitting psychosurgery on involuntarily detained patients) should be secure from constitutional or informed consent doctrine challenges.

#### FOOTNOTES

- <sup>25</sup> 35 Ore. Rev. Stat. § 426.700 et seq.  
<sup>26</sup> 35 Ore. Rev. Stat. § 426.750-755.  
<sup>27</sup> Cal. Penal Code § 2670 et seq. (West Supp. 1976).  
<sup>28</sup> Cal. Welfare & Institutions Code § 5325 et seq. (West Supp. 1976).  
<sup>29</sup> A.B. No. 1032, amending *ibid.*, and adding § 5326.6.  
<sup>30</sup> See *Stanley v. Georgia*, 394 U.S. 557 (1968); see generally Michael H. Shapiro, *Legislating the Control of Behavior Control: Autonomy and the Coercive Use of Organic Therapies*, "S. Cal. L. Rev.," Vol. 47, 1974, p. 237. Cf. *Mackey v. Procnier*, 477 F. 2d 877 (9th Cir. 1973).  
<sup>31</sup> See also Ohio Rev. Code §§ 5122.271 (A) (7), (B). (Psychosurgery may not be performed upon patients of a hospital for the mentally ill who lack the capacity for informed consent.)  
<sup>32</sup> Tennessee has also enacted a statute prohibiting all psychosurgical procedures upon minors. Ch. 489, §§ 1f, 2 (1976) Tenn. Pub. Acts.  
<sup>33</sup> *Kaimowitz v. Department of Mental Health*, Civil No. 73-19434-AW, Circuit Court for the County of Wayne, State Of Michigan, July 10, 1973; reprinted in *Individual Rights Report*, p. 510 ff.  
<sup>34</sup> George Annas and Leonard Glantz, *Psychosurgery—The Law's Response*, in B.U. Symposium, pp. 46-47.  
<sup>35</sup> See note 6 *supra*.  
<sup>36</sup> See generally Roy G. Spece, Jr., *Conditioning and Other Technologies Use to "Treat?" "Rehabilitate," "Demolish?" Prisoners and Mental Patients*. "S. Cal. L. Rev.," Vol. 45, 1972, p. 616.  
<sup>37</sup> E.g., Jeffrie Murphy, *Total Institutions and the Possibility of Consent to Organic Therapies*, "Human Rights," Vol. 5, 1975, p. 25.

<sup>38</sup> See, e.g., John R. Mason, *Kaimowitz v. Department of Mental Health: A Right to Be Free from Experimental Psychosurgery?*, in B.U. Symposium, pp. 113-117.

<sup>39</sup> Michael H. Shapiro, *Therapeutic Justifications for Interventions into Mentation and Behavior*, "Duquesne L. Rev.," Vol. 13, 1975, pp. 673, 738-45.

<sup>40</sup> 57 Cal. App. 3d 662 (1976).

<sup>41</sup> *Ibid.* at 678-85.

<sup>42</sup> It is an open question whether, for example, psychosurgery to ameliorate severe depression has an effect upon abstract thinking. Compare David L. Braff & Aaron T. Beck, *Thinking Disorder in Depression*, "Arch. Gen. Psychiatry," Vol. 31, 1974, p. 456, with Nancy C. Andreasen, *Do Depressed Patients Show Thought Disorder?*, "J. Nervous & Mental Disease," Vol. 163, 1976, p. 186.

<sup>43</sup> Contrast with the severe anti-autonomy approach of Alan A. Stone, M.D., et al., "Task Force Report—Psychosurgery in Massachusetts" (Majority report) and proposed regulations, June 1975, §§ 220.15(D), 220.18(d) (flat ban on psychosurgery on prisoners; guardian consent recognized where non-prisoner patient has been adjudicated legally incompetent, regardless of capacity for informed consent to psychosurgery).

<sup>44</sup> Citing *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton*, 410 U.S. 179 (1973) (abortion decisions).

<sup>45</sup> Two cases currently in litigation are challenging the validity of proxy consent to psychosurgery; one involves a first Amendment challenge to a prefrontal lobotomy performed with the consent of the patient's uncle. "Three Court Tests for Psychosurgery," "Medical World News," Vol. 17, Oct. 18, 1976, p. 27. Cf. Steve Knowles, *Beyond the "Cuckoo's Nest": A Proposal for Federal Regulation of Psychosurgery*, "Harv. J. Legis.," Vol. 12, 1975, pp. 610, 630-32.

<sup>46</sup> See Shapiro, *supra* note 6, "S. Cal. L. Rev.," Vol. 47, 1974, pp. 256-57, 324-34.

<sup>47</sup> A centralized reporting system which provided for confidential processing of patients' identities was upheld against constitutional challenge in *Aden v. Younger*, 57 Cal. App. 3d at 681.

#### CHAPTER 4—STUDIES PERFORMED FOR THE COMMISSION

The Commission recognized that the existence of a large body of literature relevant to the scientific, legal and ethical issues surrounding the use of psychosurgery obviated the necessity of preparing further papers on these topics. Rather, the need clearly was to obtain data on which to base a response to the issues presented. Information was required regarding the nature and extent of psychosurgery performed in recent years in this country, the characteristics of patients receiving the operations, and the effects of the procedures. In fact, the legislative history of the charge to the Commission regarding psychosurgery indicated that the specific intent was to conduct a systematic examination of patients who had undergone psychosurgery in order to obtain a scientifically valid assessment of outcome.

On June 9, 1975, a group of consultants and Dr. Eliot Stellar, a member of the Commission, met with Commission staff to determine the best way to meet the Commission's need for data.<sup>48</sup> The con-

<sup>48</sup> Consultants included: David Allen, M.D., Department of Mental Health, Boston; Jesse Barber, M.D., Chief, Department of Neurosurgery, Howard University; Lyle Bivens, Ph. D., Chief, Neuropsychology Section, Behavioral Sciences Research Branch, National

Institute of Mental Health; John Donnelly, M.D., Psychiatrist in Chief, Institute of Living, Hartford; Irwin Feinberg, M.D., Chief, Psychiatry Service, Veterans' Administration Hospital, San Francisco; Murray Goldstein, D.O., Chief, Extramural Programs, National Institute of Neurological and Communicative Disorders and Stroke (NINCDS); Warren Huber, M.D., Director, Neurology Service, Veterans Administration; Paul Leaverton, Ph. D., Associate Director for Research, National Center for Health Statistics; Allan Mirsky, Ph. D., Department of Psychiatry, Boston University School of Medicine; Mortimer Mishkin, Ph. D., Laboratory of Neuropsychology, National Institute of Mental Health; Ayub Ommaya, M.D., Acting Chief, Surgical Neurology Branch, NINCDS; Janice Stevens, M.D., Professor of Neurology and Psychiatry, University of Oregon.

consultants recommended that the Commission support two studies: First, a literature search (supplemented by Personal contacts with surgeons) to attempt to determine the nature and extent of psychosurgery performed in this country in recent years,<sup>49</sup> and second, an objective evaluation of operated patients by a team consisting of a psychologist, a neurologist, a psychiatrist, a neurosurgeon, and a social worker. The examination of patients was proposed notwithstanding the acknowledged limitations of a retrospective study: that there would be no pre-operative evaluation of the patients, performed by the same team, against which to measure gains or losses of function clearly attributable to the surgical intervention. Such preoperative data as would exist might be uneven both in quantity and in quality, since the data would be obtainable only through medical records provided by psychiatrists and surgeons directly responsible for the patients' care. Nevertheless, the consultants believed that a retrospective study could provide preliminary answers to some of the most pressing questions regarding the outcome of psychosurgery.

#### PRACTICE OF PSYCHOSURGERY: SUMMARY OF THE LITERATURE

The Commission contracted with Elliot Valenstein, Professor of Psychology at the University of Michigan, to perform a literature survey to ascertain the nature of psychosurgery performed in recent years in the United States and the purposes for which it was undertaken. This survey was designed to supplement data previously reported in Valenstein's book "Brain Control," which was published in 1973. A library computer search of the English language literature from 1970 to the present yielded approximately 700 articles about psychosurgery or related scientific or ethical issues. Of these articles, 152 were written by individuals having direct contact with either the patients or their medical records and contained information on the results of psychosurgery; 56 additional articles reported on surgery purely for relief of pain or on electrical stimulation of the brain. Of the 152 articles reporting on psychosurgery, 26

Institute of Mental Health; John Donnelly, M.D., Psychiatrist in Chief, Institute of Living, Hartford; Irwin Feinberg, M.D., Chief, Psychiatry Service, Veterans' Administration Hospital, San Francisco; Murray Goldstein, D.O., Chief, Extramural Programs, National Institute of Neurological and Communicative Disorders and Stroke (NINCDS); Warren Huber, M.D., Director, Neurology Service, Veterans Administration; Paul Leaverton, Ph. D., Associate Director for Research, National Center for Health Statistics; Allan Mirsky, Ph. D., Department of Psychiatry, Boston University School of Medicine; Mortimer Mishkin, Ph. D., Laboratory of Neuropsychology, National Institute of Mental Health; Ayub Ommaya, M.D., Acting Chief, Surgical Neurology Branch, NINCDS; Janice Stevens, M.D., Professor of Neurology and Psychiatry, University of Oregon.

<sup>49</sup> It was understood that a survey conducted for the American Psychiatric Association would be completed in time to provide basic data in this area.

referred to operations performed in the United States and 39 referred to operations performed in the United Kingdom.

Valenstein contacted scientists and professional organizations in other countries in order to determine, as best possible, the nature and extent of psychosurgery performed throughout the world. In addition, he incorporated and analyzed the results of two questionnaire surveys conducted by others in an effort to determine with some reliability the incidence and nature of psychosurgical operations performed in this country. One of those surveys had been conducted by Dr. John Donnelly, M.D., for the American Psychiatric Association.

Dr. Donnelly had sent questionnaires to the 1,901 active members of the American Association of Neurological Surgeons and the American Congress of Neurological Surgeons, and had received responses from 1,428 (78 percent). The data indicate that relatively few members had performed psychosurgery in the years under survey, and that these surgeons had, on the average, performed few operations. Specifically, 75 surgeons reported having performed psychosurgery in 1971, while the figures for 1972 and 1973 were 71 and 59, respectively. The total number of reported psychosurgical operations in an average year in this period was 324. By extrapolating from these figures to take account of the neurosurgeons who did not return the questionnaire, one can estimate the number of operations performed annually in the United States to be 414. By comparison, approximately 200-250 such operations are performed annually in the United Kingdom, and approximately 83 in Australia. Based upon population, psychosurgery is performed in the United Kingdom at twice the rate it is in the United States, and in Australia at three times the rate in the United States.

An important aspect of the data compiled by Donnelly and analyzed by Valenstein is that approximately 25 percent of the total number of operations performed in the United States are performed by surgeons doing no more than three operations per year, and many surgeons who perform psychosurgery average only one per year. Valenstein suggests that this raises serious questions about the ability of the surgeons to maintain adequate skill or competence. By contrast, four surgeons were responsible for 48 percent of the procedures reportedly performed in this country in 1973. Further, at most only about 27 percent of the neurosurgeons performing psychosurgery in this country publish their results; thus, a considerable amount of experience with psychosurgery does not become part of the scientific literature.

The published reports on the effects of psychosurgery are generally of limited usefulness. Valenstein evaluated each report and found, for example, that 54 percent of the articles published worldwide contained no information obtained from objective tests. Of the 70 articles (out of 152) which reported the results of any objective tests, 16 referred only to an IQ test. In the United States, 56

percent of the published articles mentioned no objective tests, 11 percent report on only one, 8 percent report on two, and approximately 25 percent report results from three or more. Further, when the reports were analyzed with respect to (1) the independence of the personnel performing the postoperative evaluations from those performing the treatment, (2) the use of standardized tests, (3) the statistical treatment of data, and (4) the duration of postoperative follow-ups, the results are equally disappointing. Using a rating scale<sup>50</sup> from 1 to 6 (in which a rating of 1 represents the best scientific design and use of data, and a rating of 6 represents a report presenting only descriptive information and lacking comparison groups) almost 90 percent of the United States articles received a rating of 4 or higher, and 41 percent received a rating of 6.

Valenstein found apparent general agreement in the literature that the patients most likely to improve following psychosurgery are those with severe disturbances of mood and emotion (e.g., the severely depressed, anxious, and the obsessive-compulsive neurotic). Patients with serious impairments of thought processes are reported to be less likely to improve. Many psychiatrists and surgeons have concluded that psychosurgery is ineffective for schizophrenic patients, although others have reported significant improvement in these patients following surgery. Valenstein suggests that some of the disagreement may be due to a lack of clarity in psychiatric diagnosis, especially with respect to schizophrenia, which has become a catch-all diagnostic category in this country. There is also disagreement in the literature as to whether criminals, psychopaths, sexual offenders, and aggressive individuals lacking clear evidence of brain damage benefit from psychosurgery.

Valenstein reports that with the exception of operations for intractable pain, the majority of psychosurgical operations performed in the United States are on patients suffering from fear and anxiety, obsessive-compulsive disorders, and neurotic depression (despite the relative overuse of schizophrenia as a diagnosis).

Valenstein also reports that most patients are referred to neurosurgeons by psychiatrists in private practice whose patients are primarily middle class. Women, he found, comprised 56 percent of the operated patients, a proportion that does not differ significantly from the sex ratio distribution in the diagnostic categories for which psychosurgery is performed. (Valenstein explicitly refrains from discussing possible sex discrimination in the diagnosis of mental illness or as a precipitating factor.) Minorities account for very few of the psychosurgical patients. In fact, based upon correspondence with some of the most active psychosurgeons in the country, Valenstein reports that in a combined total of 600 patients, one was black, two were Oriental Americans, and

six were Hispanic Americans. Valenstein was able to identify only 7 operations performed on children since 1970, and he found no specific reports of psychosurgery performed on prisoners except for the three in Vacaville in 1972 (referred to on page 3 of this report). No data are available that would yield reliable information on the proportion of psychosurgical patients who are institutionalized.

#### INDEPENDENT EVALUATIONS OF THE EFFECTS OF PSYCHOSURGERY

The Commission contracted for an evaluation of psychosurgical patients to be conducted by a team of psychologists, psychiatrists, neurologists and social workers. This team, headed by Allan F. Mirsky, Ph. D., and Maressa H. Orzack, Ph. D., neuropsychologists at Boston University, undertook to enlist the cooperation of surgeons with sufficiently large patient populations who would be willing to write their patients to inquire first, whether they would consent to having their medical records examined by the team, and second, whether they would consent to be examined themselves. Cooperating surgeons signed consent forms indicating their understanding that their names would not be revealed by the evaluating team but that because of the kinds of surgery they performed, their identities might nevertheless be clear to persons familiar with the scientific literature. Care was taken to ensure that patients were identified to the team only if they had signed and mailed in the consent forms indicating their willingness to have their records examined and/or to be examined themselves. Each patient who was examined was also asked for permission to interview a family member or close friend; such permission was indicated on a separate consent form. All aspects of the study and all consent forms were reviewed and approved by two Institutional Review Boards, a contract review committee and Commission staff.

The Commission also provided for the acceleration and expansion of a study already under way at the Massachusetts Institute of Technology under the direction of Professor Hans-Lukaa Teuber, Ph. D., and Suzanne Corkin, Ph. D., two neuropsychologists, with Thomas Twitchell, M.D., a neurologist. They were examining patients who had undergone cingulotomies for various psychiatric disorders as well as for persistent pain. These cases were all drawn from one surgeon, and because of contacts that had previously been made, Teuber had been able to see a number of patients preoperatively as well as postoperatively while remaining scrupulously independent from the surgeon and from involvement in any decisions that were made regarding the surgery.<sup>51</sup>

In total, therefore, the Commission was able to obtain independent evaluations

<sup>51</sup> Teuber's study was funded in part by the National Institute of Mental Health and had been reviewed and approved by the Institutional Review Board at M.I.T. as well as by various committees at NIMH.

<sup>50</sup> Developed by Man and Van Putten.



of patients operated upon by four different surgeons. Some of the patients in Teuber's sample were seen both pre- and postoperatively; in Mirsky's study, which was by necessity a retrospective one, controls (matched for age, sex, nature and duration of illness) were compared with the operated patients for performance on various behavioral and cognitive tasks. Teuber tested normal controls on some of his tasks, as well. The results of the two evaluation studies are remarkably compatible both with each other and with the claims regarding safety and efficacy which appear in the scientific literature.

**Subjects.** Teuber examined 34 adult patients who had undergone bilateral, stereotactic lesions in the anterior cingulate region; 18 were seen both pre- and postoperatively, and 16 were examined only postoperatively. This group included 12 males and 22 females; 4 additional males had undergone the operation but declined to be tested. Of the patients examined, 11 had suffered from persistent pain and depression and 23 had other psychiatric disorders. (Patients referred for surgery because of pain frequently presented a mixed picture of pain and depression or of pain and conversion reactions.) In Mirsky's study, there were 27 adult patients; eight had undergone orbital undercutting, seven had received bilateral cingulate lesions (sometimes in conjunction with lesions in the amygdala, and/or the *substantia innominata*), ten had received prefrontal sonic lesions, and two had undergone anterior prefrontal leucotomies. There were 11 males and 16 females in the operated group, with a preponderance of preoperative diagnoses of depressive or affective illness or of obsessive-compulsive disorders. Mirsky's control group consisted of eight patients (three males, five females). It should be noted that the patients in both studies were all white, predominantly middle-aged, and with illnesses of long standing.

A number of patients in both groups had undergone more than one psychosurgical operation. Of the 34 patients in Teuber's study, five had two cingulotomies, four had three cingulotomies, and one had a cingulotomy in addition to a multitarget operation (performed by another surgeon). Of the 27 patients in Mirsky's study, ten had more than one operation including one patient who underwent three surgical procedures. With one exception (a patient who had a cingulotomy followed by an orbital undercutting), however, patients whose first lesion was in the limbic system received subsequent lesions in the limbic system, and patients with frontal lobe lesions received subsequent lesions in the frontal lobe.

**Outcome: Effectiveness of psychosurgery.** The effectiveness of psychosurgery in alleviating symptoms or in restoring normal functioning was assessed in both studies by standard psychiatric tests, examination of patients, and interviews with close friends or family members. In Mirsky's study, 14 of the 27 patients had very favorable outcomes, were enthusiastic about the surgery, and would undergo the operation again under sim-

ilar circumstances. The remainder of the patients had results which ranged from only moderate improvement to worsening of their condition, and their feelings about the surgery were mixed. If the number of those who experienced moderate improvement is added to those who were very much improved, however, the success rate in Mirsky's study would be 21 out of 27 (78 percent), which is compatible with many reports in the literature. In Teuber's group, nine out of the 11 patients whose presenting symptom was persistent pain experienced complete or nearly complete relief, and five out of the seven whose primary symptom was depression experienced full or partial relief. All but two of these patients would recommend the surgery to others, and all expressed great preference for the surgery over electroshock treatments. In the remaining 16 cases (patients diagnosed as obsessive-compulsive or with other psychiatric disorders), the outcome was mixed, but patients' attitudes toward the surgeon were supportive, nonetheless.

There were no significant changes in marital or employment status in Mirsky's group following surgery. In Teuber's group, a total of 18 patients were employed postoperatively compared to 15 preoperatively, but women gained more than men. Seven women were employed preoperatively; 11 were employed postoperatively. (One male, employed preoperatively was unemployed postoperatively.) Teuber reports no significant changes in marital status following surgery.

**Outcome: Safety of psychosurgery.** The patients in both studies underwent a series of psychological, neurological, and electroencephalographic (EEG) examinations designed to measure functional capacities in a number of areas including intelligence, attention, memory (verbal and nonverbal), visual-spatial abilities, verbal and nonverbal fluency, ability to shift sets in categorization, and motor function. In the battery of tests administered to Mirsky's patients (examined two to nine years postoperatively) the majority of scores yielded no significant differences between operated groups and controls. The exception was in tasks considered to be sensitive to frontal lobe dysfunction.<sup>52</sup> In the Wisconsin Card Sorting Task, the operated patients had more difficulty shifting from one category to another (i.e., they made more perseverative errors) than did unoperated controls. In a vigilance task, the operated group with less favorable outcomes responded to uncritical stimuli more frequently than did either the operated group with more favorable outcomes or the control subjects; but the psychosurgical patients with more favorable outcomes made fewer errors of this sort than did the control patients.

In the group of patients that Teuber examined (four to 18 months postoperatively) there were no losses following

surgery as compared with preoperative scores or control subjects, except for an impairment in learning the tactual stylus maze. This deficit, however, generally diminishes with time; thus, additional examinations will be necessary in order to assess the implications of this finding. On I.Q. tests and the Hidden Figures Test, patients tested more than four months after surgery improved over preoperative scores. In general, where significant differences were found, they were related to the electroshock treatments (ECT) which the patients had undergone prior to surgery. Patients who had undergone ECT were inferior both to normal subjects and to patients who had not undergone ECT on the following tasks: Verbal and nonverbal fluency, delayed alternation, tactual maze learning, continuous recognition of verbal and nonverbal material, delayed recall of a complex drawing, recognition of faces and houses, and identification of famous public figures. On some tasks, notably recent memory (both verbal and nonverbal) and remote memory, patients who had undergone more than 50 ECT treatments were severely impaired as compared both to normal subjects and to patients who had undergone fewer than 50 ECT. Teuber emphasizes, however, that these findings do not demonstrate that such deficits are necessarily the result of shock treatments. Since the patients' ages, as well as the considerable severity and duration of their illnesses, may well have been contributing factors.

Neither Mirsky nor Teuber found neurological deficits following surgery other than those associated with the patients' underlying illnesses and chemotherapy. Mirsky reports one case and Teuber, two, in which patients with no history of brain injury or convulsive disorder prior to surgery suffered seizures postoperatively. Of these, one had only one seizure, another had three over a period of months following surgery; the third patient requires anticonvulsant medication on a continuing basis to control his seizures. Mirsky also reports some changes in electrophysiological activity (as recorded on EEG's) related to attention and reaction time, which may be attributable to the surgical interventions.<sup>53</sup>

Overall, Mirsky and Teuber report finding no significant psychological or cognitive deficits attributable to psychosurgery in the patients they examined, with the exception of an impairment (in Mirsky's patients) on the Wisconsin Card Sorting task and (in Teuber's patients) in the tactual stylus maze. As Teuber notes, however, the same operations performed by different surgeons, or on other patients, or on a healthy brain might produce different results. Indeed, it is not clear which of several factors contribute principally to the successful outcome; for example, the noteworthy and continuing concern and attentiveness of the surgeons for their patients, and the recipro-

<sup>52</sup> This finding may or may not reflect the circumstance that removal of frontal tissue in many of these patients was more extensive than in the patients studied by Teuber.

<sup>53</sup> It should be noted that the sample on which this finding is based consisted of 15 patients with prefrontal lesions and 5 who had lesions in the limbic system.

cal devotion of the patients to their surgeons, may play a central role in determining the success of the therapy. In the hands of a disinterested surgeon, the result could be less favorable. To the extent that the mechanisms underlying the effects remain unclear, the benefit directly attributable to the surgical intervention will remain conjectural. An additional aspect in evaluating the effects of psychosurgery is clearly to determine the level of functioning in patients who have sustained years of illness and who have undergone extensive trials of electroshock treatment and various chemical therapies. As Teuber emphasizes:

\* \* \* the operation added its effects not only to those of a persistent illness that preceded it, but to the cumulative impact of the massive earlier treatment efforts, which by themselves seemed to be interfering with certain higher functions, and often to an extent where it appeared futile to expect that the effect of (the surgery) as such might have become discernible, within the welter of other handicaps that already weighed upon the patients as they entered upon this surgical course. (p. 15 of Teuber's report.)

#### CHAPTER 5—MINORITY CONFERENCE AND PUBLIC HEARINGS

##### MINORITY CONFERENCE

In order to assure that minority viewpoints would be heard, the Commission contracted with the National Urban Coalition to organize a conference on human experimentation. The conference was held on January 6-8, 1976, at the Sheraton Conference Center, Reston, Virginia. Attended by over 200 representatives, it provided a format for presentations of papers and workshop discussions from which a set of recommendations emerged. One section of the Minority Conference on Human Experimentation was devoted to the issues surrounding the use of psychosurgery. Two black neurosurgeons presented papers to a work group which, following further discussion, developed recommendations to be forwarded to the Commission.

Dr. Jesse Barber of Howard University emphasized that psychosurgery does seem to be effective in relieving certain symptoms without serious side effects, and that to the extent that it is a useful therapy, it should be available to blacks and other minorities. In his view, the current opposition to psychosurgery has prevented minorities from receiving such operations from which they might benefit. He suggested that minorities should participate at every level of decision making in order to ensure both that blacks are not inappropriately subjected to psychosurgery and that blacks who might properly be treated are not deprived of its benefits. Dr. Ernest Bates, of the University of California at San Francisco, agreed with Dr. Barber that there is no evidence that blacks or other minorities predominate in any of the groups receiving psychosurgery. He emphasized, also, that care must be taken to assure that such operations do not become the tools of social or political institutions. Both surgeons recommended that psychosurgery be performed as part

of a research protocol designed to provide valid information regarding its effects on brain function as well as on the behavioral disorders it is designed to ameliorate. In addition, they recommended that the protocols undergo stringent review for scientific design as well as to assure appropriate selection of subjects and adequate procedures for informed consent. Both recommended against the use of psychosurgery on prisoners.

The recommendations of the Minority Conference reflected the prevalent concern that psychosurgery might be used for social or political ends, and they included provisions to protect minority individuals from such abuse. They called for psychosurgery to be considered experimental, to be performed only under careful scrutiny of scientific design as well as of selection of subjects, and to be performed in accordance with procedures for ensuring informed consent. They also recommend that accumulated data regarding outcome should go to a central repository. The Conference recommended, in addition, that the committees reviewing and monitoring the research be multidisciplinary and composed of members who are "economically, professionally and emotionally independent from all individuals involved in the patient's care." Minorities should be represented among both the scientific and lay members of such committees, which should have authority to prevent the performance of psychosurgery when they believe that it is not advisable in particular cases. (Patients, however, should be able to appeal their decision to a national commission.) Finally, the Conference recommended that psychosurgery should not be performed on prisoners, persons involuntarily confined in institutions, sexual deviants, political deviants, or social deviants, and that funds for research involving psychosurgery should not be accepted from law enforcement agencies, pharmaceutical companies or other institutions "that do not hold paramount the patient's personal care."

##### PUBLIC HEARING

On June 11, 1976, the Commission held a public hearing on the use of psychosurgery. Announcements were sent to several hundred professional organizations, public interest groups and individuals. All persons who requested to appear were heard; a few preferred to submit written testimony in lieu of an oral presentation. Summaries of both oral and written testimony follow.

*John Donnelly, M.D.* (representing the Task Force on Psychosurgery of the American Psychiatric Association) reported on a survey conducted for the Task Force which revealed that in the United States, approximately 500 psychosurgical procedures were performed in each of the years 1971, 1972 and 1973. The appropriate population of such surgery, he suggested, is a small number of psychiatric patients who are refractory to nonsurgical interventions and who may be further incapacitated by the administration of psychotropic drugs over

a long period of time. Since there is evidence that modern psychosurgical techniques do not produce the personality changes which would outweigh the benefits of the procedure itself, psychiatric patients who are unresponsive to other available treatments have a right to request psychosurgery as a last resort provided adequate safeguards are established. In such cases, even modest improvement represents a substantial benefit. Special mechanisms should be established to ensure that all the rights of involuntarily confined mental patients are protected, including the right to adequate treatment. Dr. Donnelly emphasized that there is no evidence of intentional misuse of psychosurgery for social or political purposes or of disproportionate involvement of minority groups or women. The extent to which violent behavior is a sign of psychiatric illness rather than a manifestation of political or social action remains unknown, but it is a proper subject for further investigation, he said. Since psychosurgery is undertaken as a treatment of last resort, even a modest improvement represents a substantial benefit when compared to the alternative. Dr. Donnelly testified that the position of the American Psychiatric Association is that:

1. Psychosurgery is a treatment of last resort and should be performed only in facilities having a highly qualified team of specialists to conduct pre- and post-operative evaluations. Their data should be available to other professionals.

2. A federally supported national registry of psychosurgical patients should be established under the auspices of a national medical organization.

3. Peer Review Committees should screen potential candidates for psychosurgery, and interdisciplinary consent committees should review the adequacy of patients' consent.

4. For the present, psychosurgery should not be performed on minors or prisoners if, in the case of the latter, the purpose is to alter their criminal behavior.

5. Psychosurgery should be performed on involuntarily confined psychiatric patients only with the approval of a consent committee which is independent of the psychiatric hospital.

6. Patients with recognized psychiatric disorders and a propensity for violent behavior should be evaluated as surgical candidates only in the context of their illness.

*Mr. Abdullah Ahmad Bey* (representing the North Central Unity Non-Profit Community Corporation, Inc.) expressed his concern about the potential dangers of psychosurgery and the inequities of the health care delivery system in general. He recommended that the Commission scrutinize any medical procedure or research proposal that threatens people's life or dignity, particularly procedures with the potential to control people's lives. The rights of patients to adequate health care should be protected, and informed consent should be given by all participants in medical research. Health care policy should not be con-

trolled by the health care providers; rather, consumers should constitute at least 60 percent of the governing boards of health agencies or delivery systems. The Department of Health, Education, and Welfare should adopt the World Health Organization's definition of health for the "total human being." Federal funding should not be used by health care agencies for unspecified purposes. Candidates for psychosurgery should not be forced to waive their legal right to redress, and legislation should be enacted to protect people from potential abuses of psychosurgery, such as the control and exploitation of racial, ethnic, religious, political, economic or sexual minority groups.

*Ayub K. Ommaya, M.D., F.R.C.S.* (Acting Chief, Surgical Neurology Branch, National Institute of Neurological and Communicative Diseases and Stroke, National Institutes of Health). Speaking for himself, Dr. Ommaya gave a brief history of the use of psychosurgery emphasizing that it continues today because psychiatry has been unsuccessful in treating certain types of mental patients. He suggested that the surgeon's interest in this procedure is twofold: to relieve suffering and to discover the truth about a theory which forms the basis for the therapy. Dr. Ommaya said of the "Kaimowitz" case that the scientific hypothesis underlying the research was very weak, and that many people have misinterpreted what was really at stake by overlooking the fact that the subject involved was being held as a sexual psychopath. He emphasized that for effective patient management, both a compassionate regard for the patient's problems and continuous communication between the parties involved are crucial. Dr. Ommaya proposed that after all non-surgical therapies have been given a fair trial, the decision regard psychosurgery should be made by the patient and his or her physicians, without any interference by the state; and he stressed the importance of preserving the flexibility of medical decision-making. Further, he believes it is difficult, if not impossible, to conduct clinical trials on psychosurgery; however, he recommends that pre- and postoperative evaluations be performed by psychologists, and that physicians be vigilantly critical in evaluating both the decision to operate and the value of a given procedure for relief of a particular patient's problem. Dr. Ommaya added that patients' freedom of choice must be preserved.

*Congressman Louis Stokes* (Member, House of Representative) explained his bill to prohibit psychosurgery in federally supported health care facilities. The legislation is based upon the following three premises:

1. Psychosurgery has no therapeutic value because the indications for it do not depend upon the presence of identifiable brain pathology; further, he said, there have been no successful psychosurgical operations and many failures. Congressman Stokes cited three instances in which persons reportedly had undergone psychosurgery with poor results.

2. It is impossible to give informed consent to psychosurgery because of the experimental nature of the procedure, as stated in the "Kaimowitz" decision. Further, he said that institutionalization erodes the ability of an involuntarily confined person to render informed consent. Congressman Stokes would carry the constitutional argument in "Kaimowitz" one step further by adding that psychosurgery prevents the patient from obtaining proper redress of grievances and violates his or her First Amendment rights. As a result, the victims of psychosurgery are relegated to the status of subcitizens.

3. Psychosurgery has the potential of becoming a tool for the social and political repression of minority groups, political dissenters and the poor. Congressman Stokes cited a few instances where this allegedly had occurred.

He concluded that in the present context of racial and social mistrust, the practice of psychosurgery is not amenable to effective regulation by either the public or private sector, and therefore must be prohibited.

*Richard F. Thompson, Ph.D. and John P. Flynn, M.D.* (testifying for the Division of Comparative and Physiological Psychology of the American Psychological Association) stated that:

1. The animal research literature does not provide compelling data or rationale to support the conduct of psychosurgery.

2. The human clinical literature does not provide compelling evidence for the use of psychosurgery as an accepted medical procedure.

3. Psychosurgery should be labeled an experimental procedure.

They recommended that psychosurgery should be permitted, but regulated by stringent safeguards and by the supervision of experts in all relevant fields. In addition, a comprehensive evaluation of the effects of psychosurgical procedures should be undertaken, since studies in the existing literature generally lack sufficient data to permit critical assessment of the efficacy of procedures. Thus, although it is possible that patients suffering from specific illnesses benefit from psychosurgery, the evidence provided thus far is not convincing.

*Kenneth Heilman, M.D.* (representing the International Neuropsychological Society, Inc.) posed the following questions:

1. What is the clinician's role in altering behavior? Dr. Heilman suggests that physicians are violating the Hippocratic oath if they use their art for political or social purposes. Psychosurgery should not be performed on prisoners, and criminality should not be considered a sickness. Psychosurgery for the relief of intractable seizures or pain, however, is within the purview of sound medical practice. Dr. Heilman stated that psychosurgery should not be performed on children because they should be given every opportunity to improve by nonsurgical means, and that includes the process of maturation.

2. Can focal brain lesions alter behavior? Dr. Heilman noted that there is evidence that localized brain lesions pro-

duce specific cognitive and emotional defects and that to his knowledge there has never been a spontaneous lesion (e.g., stroke, tumor, trauma) that has improved cognitive function. He said that ablative neurosurgery (which removes brain tissue) always produces a defect of behavior; however, proponents of psychosurgery suggest that it may help to reestablish homeostasis at a lower level of organization, in persons with behavioral disorders.

3. Does psychosurgery work? There have been few controlled studies of psychosurgery to date; but with respect to the standard lobotomies, indications are that the physiological, intellectual and emotional complications argue against its therapeutic utility.

4. What should be done in the future? Members of the Society are almost evenly split as to whether or not brain surgery which diminishes the intensity of emotion would be acceptable in some psychiatric cases. Most agree that further research, including basic animal research, is needed and should be supported under the auspices of NIH. Clinicians should participate in the animal research and the animal investigators should collaborate in the human research. This might be achieved by the establishment of interdisciplinary research centers. In any case, psychosurgery should be considered an experimental procedure, and protocols should be reviewed by a human experimentation committee or similar review board.

*Charles A. Fager, M.D.* (representing the American Association of Neurological Surgeons and the Congress of Neurological Surgeons) indicated that there is an international consensus that psychosurgery should be restricted to small, intracerebral structures for the purpose of ameliorating disabling emotional and neurotic conditions rather than as a treatment for major psychoses. Dr. Fager reviewed recent studies of the safety and efficacy of psychosurgery and stated that based upon the current literature, neurosurgeons and other concerned neuroscientists no longer regard stereotactic psychosurgical procedures as experimental, having concluded that the benefits of these procedures far outweigh the risks. Because the procedures are still controversial, however, the neurosurgical community would cooperate with a national registry for the purpose of accumulating data regarding outcome in order to resolve some of the remaining questions. Surgery for psychiatric disorders should be conducted only at institutions providing adequate committee review of protocols and interdisciplinary study of efficacy. However, the decision to undertake psychosurgery should remain with the physician and the patient, in accordance with the following guidelines endorsed by the International Society of Psychiatric Surgery:

1. Neurological intervention for psychiatric disease should be considered only after all other generally accepted methods of treatment have failed.

2. Such surgery should be performed only for the relief of suffering and in an attempt

to restore a disabled individual to effective functioning in society—never for social or political purposes.

3. There should be a prior history of being able to function effectively and of subsequent continuous disability which has proved refractory to nonsurgical treatment.

4. The decision to employ neurosurgery for a patient with psychiatric disease should be made by the psychiatrist and neurosurgeon after consultation and acceptance by a small group of persons with the appropriate experience, insight and humane concerns.

5. Both the patient and next of kin must agree to the surgery after they have been fully informed of the risks and possible benefits.

*Robert W. Doty Ph.D.* (representing the Society for Neuroscience) discussed the results of a recent survey of the Society's membership regarding psychosurgery, in which about a third of the membership responded to the following statements, as follows:

1. Psychosurgery should be made available to certain psychiatric patients if accompanied by proper safeguards and an adequate informed consent mechanism. (Seventy-three percent of the respondents agreed.)

2. Psychosurgery should never be used to solve social problems except when certain recognized incapacitating mental disorders are present. (Eighty-nine percent of the respondents agreed.)

3. More research is required to understand, improve or eliminate the need for psychosurgical procedures in conjunction with appropriate safeguards. Research should be conducted only in settings which permit careful evaluation of the results by multidisciplinary teams of specialists both pre- and postoperatively. (Eighty-two percent of the respondents agreed.)

4. An interdisciplinary commission should be established to promulgate guidelines for selecting and evaluating patients, for certifying that there is a recognized incapacitating functional disorder, for determining that psychosurgery is an appropriate last resort, for obtaining informed consent, and for following up and keeping records on the patients. (Seventy-six percent of the respondents agreed.)

In general, the Society for Neuroscience urges that psychosurgery be made available as a procedure of last resort for the desparately afflicted patient, but only in a context where careful evaluation is possible over a long period of time. Dr. Doty noted that while animal research in this area is helpful, the therapeutic outcome of psychosurgery can be assessed only with human patients. Requirements for informed consent for psychosurgery should not be so stringent as to be obstructive, but all of the potential risks and benefits must be carefully weighed. If some prisoners, particularly violent offenders, have a recognized mental disorder which may be properly treated by psychosurgery, they should not be denied access to this treatment. The belief of some groups that psychosurgery will be used to suppress political dissent, said Dr. Doty, is unfounded. He concluded that there is no substitute for the compassionate regard physicians feel for the welfare of their patients.

*Gabe Kaimowitz, Esq.* (Michigan Legal Services) stated that in his opinion the

Commission has insufficient data on which to base any valid conclusions regarding the acceptability of psychosurgery to control, modify or alter human behavior. He feared that surgeons would not reveal their experiments with psychosurgery until they were successful; alternatively, they would hide them under the guise of treatment. Further, if psychosurgery is permitted for the amelioration of pain or relief of epilepsy, these labels will be distorted to apply to studies on the experimental application of psychosurgery for the treatment of behavioral problems. Mr. Kaimowitz urged the Commission not to make any recommendations regarding psychosurgery on the grounds that it was in no position to do so.

WRITTEN TESTIMONY SUBMITTED IN LIEU  
OF PERSONAL PRESENTATION

*Robert J. Grimm, M.D.* (Assistant Director of Neurology, Good Samaritan Hospital and Medical Center, Portland, Oregon) believes that the new stereotactic techniques together with improved knowledge of brain function, better pre- and post-operative evaluations, and procedural reviews for protecting patient's rights now make it scientifically and legally possible to conduct psychosurgical programs for properly selected, otherwise hopeless cases. He suggested that composite experience, if assembled, would support the proposition that technical improvements have resulted in safe psychosurgery. There are only a few institutions in the United States with the facilities and expertise, however, to demonstrate the validity of such an assertion, and problems may arise in demonstrating clinical improvement independent of placebo effects, or in measuring subtle changes in personality and intellect. Nevertheless, he supported the use of psychosurgery in cases where the only alternative is hopeless consignment to institutional life, where there is good reason to believe psychosurgery would improve the patient's condition, and where problems surrounding informed consent have been overcome.

Dr. Grimm rejected the argument that interference with the decision of a psychiatrist or neurosurgeon regarding psychosurgery jeopardizes the physician-patient relationship. Rather, he believes that as in other complex medical situations where uncertainty prevails, input from many sources acts to clarify the benefits and risks of the procedure and serves as a source of strength for the responsible physician. Thus, interdisciplinary review of proposed psychosurgery should be welcomed, especially because psychosurgery involves the more general, social concern of behavior control.

Dr. Grimm recommended that psychosurgical practice be limited to those institutions in which competent clinical research evaluations and followup management can be conducted, and that a small number of special research centers be established where complex neurosurgical procedures may be studied with multidisciplinary techniques. In addition, he suggested establishment of a federal

insurance program to protect participating physicians from malpractice suits. Dr. Grimm does not personally favor psychosurgery but believes his recommendations provide a rational approach to resolving the issues under debate.

*M. Hunter Brown, M.D.* (Santa Monica, California) agreed with the working definition of the Commission that manipulations of the central nervous system for intractable pain which alter feeling and mood constitute "psychosurgery." He reported that in 1974, he and Dr. Ballentine reviewed 600 cases of psychosurgery and identified among those only six Hispanic patients and one black patient. The fact that so few patients from minority groups have undergone psychosurgery, he said, is due not to discrimination on the part of surgeons but to the economic realities and public policy. He is particularly concerned that involuntarily confined mental patients are being deprived of possible benefits from psychosurgery due to semantic issues regarding informed consent which could be solved by a neutral ombudsman. In his opinion, stereotactic single target and multitarget treatments have the the highest benefit to risk ratio of any procedure in neurological surgery. In competent hands, these procedures are not experimental but are subject, as in all branches of surgery, to continual refinement and progress.

*Ernest A. Bates, M.D.* (San Francisco, California) stated that although the theoretical aspects of psychosurgery are poorly understood, such surgery often seems to succeed in alleviating certain mental disorders. Therefore, he does not advocate its prohibition, but rather suggests that all aspects of its use, from patient selection through extensive follow-up studies, be subject to rigid controls. Dr. Bates questioned the use of psychosurgery for the purpose of modifying or controlling violence, since no cerebral focus for aggression has been identified. He urged extreme caution about its use in children because their behavior disorders (1) are poorly defined, (2) may result from environmental factors, and (3) may be outgrown. He also expressed concern about accepting consent from patients who may be incapable of anticipating the psychological consequences of the operation. Finally, he stressed that neurosurgeons should always bear in mind that the brain is unique to every individual, and that their work is irreversible. In Dr. Bates' opinion, it is unethical to perform any psychosurgery without adequate procedures to provide scientific information about its effects on brain function, although tests for psychological deficits in humans need further development. Neurosurgeons alone, he said, are never qualified to select patients for psychosurgery; they need input from other professions. Each case should be reviewed by various review committees to ensure that all alternatives have been exhausted and to define the complex issue of informed consent. In addition, carefully documented behavioral analyses of the results of all operations should be conducted and

made available through the literature. Dr. Bates urged that psychosurgery not be performed on prisoners, and that it be permitted for children, the mentally ill and the retarded only when absolutely necessary, as a last resort and under careful scrutiny. Although there is no evidence that blacks, or other minorities, predominate in any of the studies made thus far on patients receiving psychosurgery, he said, neurosurgeons must always guard against becoming the tools of social and political oppression or of those who seek easy medical solutions to social and political problems.

The National Association for Mental Health, Inc. suggested that until more research has been conducted concerning the cause of various mental and emotional disorders, and until there has been more animal research on brain function, psychosurgery should be performed only:

1. As a treatment of last resort, when the potential benefits outweigh the risks;
2. If the proposed procedure has been reviewed and approved by at least two other neurosurgeons not associated with the surgeon selected to perform the surgery; and
3. If the patient is represented by legal counsel when any final decision is to be made regarding the operation.

The Association defines psychosurgery as a surgical procedure on the structurally intact brain to produce behavioral change, not to correct or eradicate known or definite organic pathology, and suggests that it should still be classified as experimental. The Association believes that only a small number of physicians treating mental disorders engage in psychosurgery, and that most of them take a conservative approach to these procedures. The Association urges sensitivity to the difficult dilemmas posed by psychosurgery with respect to obtaining informed consent, particularly from individuals who are involuntarily confined.

#### CHAPTER 6—RECOMMENDATIONS

The term "psychosurgery," as used in this report, means (except as stated below); brain surgery, implantation of electrodes, destruction or direct stimulation of brain tissue by any means (e.g., ultra-sound, laser beams), or the direct application of substances to the brain when any of these procedures is performed either (1) on normal brain tissue of a person, for the purpose of changing or controlling the behavior or emotions of such person, or (2) on diseased brain tissue of a person, if the primary purpose of performing the procedure is to control, change, or affect any behavioral or emotional disturbance of such person. Such term does not include (a) electric shock treatments, (b) surgery or other invasions of the brain designed to cure or ameliorate the effects of movement disorders (e.g., epilepsy, parkinsonism), and (c) excision of brain tumors. With respect to relief of pain, surgical or other invasions of the brain which interrupt the transmission of pain along sensory pathways are not within the definition of psychosurgery; however, when such procedures are designed to relieve the emotional response to pain (without affecting the sensation of pain) they fall within the definition of psychosurgery. [A fuller explanation of this definition appears in the preface to this report.]

*Recommendation (1) Until the safety and efficacy of any psychosurgical pro-*

*cedure have been demonstrated, such procedure should be performed only at an institution with an institutional review board (IRB) approved by DHEW specifically for reviewing proposed psychosurgery, and only after such IRB has determined that: (A) The surgeon has the competence to perform the procedure; (B) It is appropriate, based upon sufficient assessment of the patient, to perform the procedure on that patient; (C) Adequate pre- and postoperative evaluations will be performed; and (D) The patient has given informed consent. If the IRB has good reason to believe that the patient is incapable of giving informed consent, recommendation (3) shall apply in lieu of recommendation (1) (D). (Adopted unanimously.)*

*Comment.* Some individuals and groups have urged the Commission to recommend a ban on psychosurgery—either on grounds that psychosurgery will be used as a political or social tool, or on grounds that psychosurgical procedures are unsafe and ineffective.

*The Commission affirms that the use of psychosurgery for any purpose other than to provide treatment to individual patients would be inappropriate and should be prohibited.* Accordingly, the Commission is recommending safeguards that should prevent the performance of psychosurgery for purposes of social or institutional control or other such misuse.

With respect to questions of safety and efficacy, two independent teams of scientists and clinicians have conducted pilot studies for the Commission to evaluate the outcomes of four different psychosurgical procedures (cingulotomy, orbital undercutting, multitarget limbic lesions, and prefrontal ultrasonic lesions). Sixty-one adult patients who received operations during the period 1965 to 1975 were examined. Both studies, drawing upon interviews and objective tests, provided evidence that (1) more than half of the patients improved significantly following psychosurgery, although a few were worse and some unchanged, and (2) none of the patients experienced significant neurological or psychological impairment attributable to the surgery. The investigators in one study suggested that the risks of the psychosurgical procedures that were performed may be less than the risks of continuing electroconvulsive treatments over long periods of time.

These studies appear to rebut any presumption that all forms of psychosurgery are unsafe and ineffective. The Commission finds that there is at least tentative evidence that some forms of psychosurgery can be of significant therapeutic value in the treatment of certain disorders or in the relief of certain symptoms. Because of this finding and the belief that the misuse of psychosurgery can be prevented by appropriate safeguards, the Commission has not recommended a ban on psychosurgery.

The safety and efficacy of specific psychosurgical procedures for the treatment of particular disorders, however, have not been demonstrated to the degree that would permit such procedures to be considered "accepted practice." For this

reason, and because of the possibility that psychosurgery might be misused, the Commission recommends for the present that psychosurgical procedures be performed only after review (such as generally precedes the conduct of research) by an IRB whose composition and procedures for review of psychosurgery have been approved by the Department of Health, Education, and Welfare. This review should assure a high degree of competence on the part of the surgeon performing the operation, appropriate scientific evaluation, diagnosis and reasons for recommending each patient, and protection of the patient's rights.

Determinations regarding the safety and efficacy of psychosurgical operations in the treatment of specific symptoms and disorders may be made by the national Psychosurgery Advisory Board required under the following recommendations.

*IRB Review Procedures.* A subcommittee of IRB members or consultants, approved by DHEW and including a neurosurgeon, a psychiatrist, a neurologist and a psychologist, should review technical aspects of the proposed psychosurgery, such as the competence of the operating surgeon to perform the proposed procedure and the plans for pre- and postoperative evaluation of patients. These elements may apply to more than one proposed operation; as such, they may be given a continuing approval by the subcommittee if it is satisfied that the surgeon is competent and the proposed examinations will provide a valid assessment of the outcome of each operation performed.

The subcommittee should also review the diagnostic evaluation of each surgical candidate to assure that the patient is a proper subject for the procedure in question. If the subcommittee finds the evaluation inadequate, it should request further information or examination of the patient. Here it must be emphasized again that the purpose for the performance of a psychosurgical procedure must be to provide appropriate treatment for a patient with a specific psychiatric symptom or disorder. The subcommittee should also be satisfied that appropriate nonsurgical treatments have been given sufficient trials, but this should not be construed to require trials of any therapy beyond the point at which potential benefits become unlikely or are outweighed by the risks of continuing that course of treatment.

The consent of each patient should be reviewed by the IRB as a whole to assure that the patient's rights are protected. This review should focus on procedures or forms employed in the consent process, as well as the circumstances of the actual consent given by each patient. The IRB may require that a third person, unaffiliated with the surgical team or the patient's referring physician, observe or participate in the consent process. The IRB may also require that an examination by appropriate consultants or a hearing before the IRB be conducted to determine the patient's ability to give informed consent to psychosurgery. If the IRB believes that the patient is incapable

of giving informed consent, the provisions of Recommendation (3) should apply.

The patient's privacy should be protected in the review proceedings. To this end, the identity of the patient should not be made known to the IRB as a whole or to the subcommittee unless (1) the IRB or Subcommittee requests that the patient be present at a hearing or examination, or (2) the patient requests a hearing with the subcommittee or IRB. If such a hearing or examination is held, it should be closed and the members of the subcommittee or IRB should maintain confidentiality, unless the patient waives this privilege. It is the responsibility of the IRB to inform the patient that he or she has the right to a hearing and may demand or waive confidentiality.

Psychosurgery review procedures that have been adopted by statute in certain states should be deemed to satisfy the requirements of this recommendation, provided that such statutory review is comparable to or more stringent than the IRB review required herein.

*Recommendation (2) A psychosurgical procedure may be performed on an adult patient who is voluntarily residing in a mental institution. Provided that: (A) A national psychosurgery advisory board has determined that the specific psychosurgical procedure has demonstrable benefit for the treatment of an individual with the psychiatric symptom or disorder of the patient; (B) If the operation is to be performed as part of a research project, the conditions set forth in the Commission's report on research involving the institutionalized mentally infirm are fulfilled; and (C) The conditions of recommendation (1) are fulfilled at the institution where the operation is to be performed. If the IRB has good reason to believe that the patient is incapable of giving informed consent, recommendation (3) shall apply in lieu of recommendation (1) (D). (One Commission member dissented.)*

*Comment.* In Recommendations (2), (3) and (4), the Commission incorporates the requirements of Recommendation (1) and imposes further conditions for the performance of psychosurgery on specific populations of patients whose capacity for self-determination may be limited by institutionalization, mental disability, involuntary confinement or immaturity. The Commission recommends that a psychosurgical procedure may be performed on a patient voluntarily residing in a mental institution and believed to be capable of giving informed consent: *Provided*, The determinations by the IRB required under Recommendation (1) have been made and, in addition, a national Psychosurgery Advisory Board has determined that such procedure has demonstrable benefit in the treatment of the patient's disorder (Recommendation (2)). This condition and some additional requirements are recommended with respect to adult patients who are incapable of giving informed consent or involuntarily confined (Recommendation (3)) and patients

who are minors (Recommendation (4)). The Commission also recommends that the conditions set forth in its various reports on research involving specific populations be imposed (where applicable) on the performance of psychosurgery as part of a research project.

It is the Commission's intent that, to the extent possible, a psychosurgical procedure not be used to treat a patient who is institutionalized until the potential benefit of the procedure has been demonstrated in the treatment of patients with the same disorder who are not so situated. The required determination of demonstrable benefit should be made by the Psychosurgery Advisory Board on the basis of (1) treatment of the same disorder in patients who are not institutionalized, (2) treatment of institutionalized patients who underwent the procedure for the same disorder prior to 1977 or outside the United States, or (3) when neither of the above approaches is feasible, persuasive scientific evidence or rationale to support a belief that the procedure is likely to alleviate the same disorder. A determination of demonstrable benefit should require less certainty than would be necessary to support a determination of safety and efficacy.

Because institutionalized persons may be vulnerable as a consequence of their disability or the dependence and depersonalization which often result from confinement, the IRB should scrutinize with care the consent of such persons to determine whether it is adequate. If the IRB has good reason to believe a patient is unable to give informed consent to psychosurgery, the provisions of Recommendation (3) will apply.

*Recommendation (3). A psychosurgical procedure should not be performed on an adult patient who: (i) Is a prisoner, (ii) is involuntarily committed to a mental institution, (iii) has a legal guardian of the person, or (iv) is believed by the Institutional Review Board (IRB) to be incapable of giving informed consent to such procedure, unless all of the following conditions are satisfied; (A) A national psychosurgery advisory board has determined that the specific psychosurgical procedure has demonstrable benefit for the treatment of an individual with the psychiatric symptom or disorder of the patient; (B) if the operation is to be performed as part of a research project, the conditions set forth in the Commission's report on research involving prisoners or report on research involving the institutionalized mentally infirm, as applicable, are fulfilled; (C) the conditions of recommendation (1) are fulfilled at the institution where the operation is to be performed, and such institution is separate from any prison or institution where the patient is regularly confined; (D) the patient has given informed consent or, if the patient is believed by the IRB to be incapable of giving informed consent, the patient's guardian of the person has given informed consent and the patient does not object; and (E) a court in which the patient had legal representation has*

*approved the performance of the operation. (One Commission member dissented.)*

*Comment.* Fairness requires that individuals should not be denied access to potentially beneficial therapy simply because they are involuntarily confined or unable to give informed consent. The Commission recognizes, however, that such individuals are vulnerable to coercion and that psychosurgery may be proposed in attempts to modify behavior for social or institutional purposes not coinciding with the patients' own interests or desires. Accordingly, the Commission recommends court review and, in some instances, appointment of a legal guardian in addition to the required determinations by an IRB and the national Psychosurgery Advisory Board. The Commission also recommends that the IRB review and the surgery itself be performed at a facility that is administratively independent of any facility in which the patient is regularly confined.

The process of national review should be initiated at the request of the surgeon wishing to perform the psychosurgery. Following approval by the Psychosurgery Advisory Board, the surgeon may initiate review by the appropriate IRB. Following IRB approval, court review should be initiated by a representative of the patient for whom surgery is proposed.

As indicated in the preceding comment, the determination of demonstrable benefit by the Psychosurgery Advisory Board should be made on the basis of (1) the use of the specific psychosurgical procedure to treat the particular disorder in patients who are not prisoners, institutionalized, under guardianship, or believed incapable of giving informed consent, (2) treatment of such persons who underwent the procedure prior to 1977 or outside the United States, or (3) when neither of the above approaches is feasible, persuasive scientific evidence or rationale to support a belief that the procedure is likely to alleviate the specific disorder.

The IRB and court should ascertain that a prisoner or other person involuntarily confined is never compelled to undergo psychosurgery or unduly influenced to consent to psychosurgery by the promise of probation, parole, reduction of sentence, release or otherwise.

Consent given on behalf of mental patients who are unable to give legally valid consent themselves should be reviewed with an awareness of the potential for conflict of interest inherent in such third-party consent. The consenting guardian should not be affiliated with the institution where the patient is confined or where the psychosurgery is to be performed. Consent given by the legal guardian of a patient who is not institutionalized should also be scrutinized to take into account the potential conflicts of interest that may be associated with the responsibility of providing care for such persons.

If the IRB has good reason to believe that a patient, lacking a legal guardian,

is incapable of giving informed consent for psychosurgery, the IRB should withhold approval of the operation pending authorization by a court and consent of a legal guardian, if one is appointed. If no court accepts jurisdiction, however, the operation should not be performed on such a patient. Similarly, in states that do not accept third-party consent for psychosurgery, a psychosurgical procedure should not be performed on a patient believed by the IRB to be unable to give informed consent for such an operation. In no case should a psychosurgical procedure be performed over the objection of an adult patient, ever following adjudication of incompetence and with the consent of a legal guardian.

The Commission recognizes that portions of this recommendation are at variance with the opinion of the Michigan court in *Kaimowitz v. Department of Mental Health* (1973). The Commission agrees with the "Kaimowitz" opinion that institutionalization may diminish the ability of prisoners and mental patients to make free choices by removing opportunities for asserting or exercising self-determination. On the other hand, it seems unfair to exclude prisoners or involuntarily confined patients from the opportunity to seek benefit from new therapies on the basis of an un-rebuttable presumption of diminished capacity or by prohibiting third-party consent. Therefore, the Commission recommends that such persons be permitted to obtain psychosurgery, subject to the extensive review requirements described above, and the expressed willingness of the patient to undergo the surgery.

With respect to the questions of safety and efficacy, it is clear that the information presented to the Michigan court in 1973 regarding amygdalotomy differs significantly from that which has been presented to the Commission regarding four other psychosurgical procedures. The Commission believes that the information presented on its record justifies its recommendation, for at least some psychosurgical procedures have been shown to present a potential for significant benefit, and the risks of such surgery do not appear to be nearly as great as previously supposed.

*Recommendation (4).* A psychosurgical procedure should not be performed on a patient under the legal age of consent to medical care unless and until: (A) a national psychosurgery advisory board has determined that there is good reason to believe that the specific psychosurgical procedure will benefit children with the psychiatric symptom or disorder of the patient; (B) the informed consent of both parents (if available) or a guardian has been given and, if the patient is a mature minor, the patient has not objected; (C) the conditions of recommendation (1) are fulfilled; (D) if the operation is to be performed as part of a research project, the conditions stipulated in the Commission's report on research involving children are fulfilled; and (E) a court in which the patient had

*legal representation has approved the performance of the operation. (Adopted unanimously.)*

*Comment.* The pilot studies conducted for the Commission did not examine the effects of psychosurgery on children, and the Commission has not reviewed data that would support the performance of any such operation on children at this time. However, the Commission does not wish categorically to deny children the possible advantages of a new therapy that might be safer and more effective than long-term use of other therapies. Therefore, as in the previous recommendation, the Commission incorporates the requirements of Recommendation (1) and, in addition, requires that the approval of both a national Psychosurgery Advisory Board and a court of competent jurisdiction be necessary conditions for the performance of psychosurgery on children.

The process of national review should be initiated at the request of the surgeon wishing to perform the psychosurgery. Following approval by the Psychosurgery Advisory Board, the surgeon may initiate review by the appropriate IRB. Following IRB approval, court review should be initiated by a representative of the patient for whom surgery is proposed.

An important prerequisite is a determination by the Psychosurgery Advisory Board that there is sufficient evidence from animal and adult human studies to support a belief that the specific psychosurgical procedure will benefit, children with the psychiatric symptom or disorder of the patient, based upon a consideration of the risk of alternative therapies or not conducting any therapy at all.

The Commission intends that the IRB take into consideration the reported feelings that a child may have expressed with respect to psychosurgery, and that such feelings of a "mature minor," i.e., child with a certain capacity for rational judgment, should be controlling. Implementation of this recommendation will require appointment of a third person to participate in the consent process.

Recognizing the limited capacity of children to consent to psychosurgery, the Commission also recommends court review to protect the rights of individual patients. The child should be represented in court by legal counsel.

The Commission emphasizes that the purpose for the performance of psychosurgery must always be to provide appropriate treatment for the specific psychiatric symptom or disorder of the individual patient. The required reviews should assure that social, institutional, or basic research purposes are not accepted as justification for psychosurgery on children.

*Recommendation (5).* The Secretary, DHEW, should establish a mechanism to compile and assess information regarding the nature, extent and outcomes of psychosurgical procedures performed in this country, the indications for the procedures, and the population on which they are performed. This ongoing mechanism should include stringent provisions

*to safeguard the privacy of individual patients. (Adopted unanimously.)*

*Comment.* The Commission recognizes that the pilot studies performed for it are not sufficient in themselves to establish the safety and efficacy of specific psychosurgical procedures. Evidence from the extant literature is also insufficient to establish the safety and efficacy of particular procedures in response to particular symptoms or disorders. It is important, therefore, to clarify further the effects of specific surgical interventions in the brain with respect to gains or losses in function and with respect to alleviation of specific symptoms or disorders. In Recommendation (1) the Commission has suggested that wherever psychosurgery is performed, it should be conducted in such a manner that good data will be collected to further the evaluative process. In this Recommendation (5), the Commission further proposes that a mechanism be set up on the national level to collect data on psychosurgery. Such data will assist the national Psychosurgery Advisory Board in making its evaluations regarding the safety and efficacy of specific psychosurgical procedures.

To the extent that it is compatible with the protection of privacy, the Secretary should include in this mechanism a provision for collecting data regarding the presenting symptoms and pre-operative diagnosis, past medical and social history of the patients, and outcome. In effect, psychosurgery should become a "reportable operation" in the sense that the Secretary should require that every case be reported, as is now required by states for certain communicable diseases. In addition, when the patients are children, prisoners, or institutionalized individuals, that fact should be reported. The data compiled by the Secretary should be analyzed, and summary reports should be issued and sent to Congress, on a yearly basis. The Commission is concerned, however, that the Secretary give serious attention to two considerations in designing such a mechanism: The desirability of public access to census information, and the preeminent need to safeguard the privacy of individual patients.

*Recommendation (6).* The Secretary, DHEW, is encouraged to conduct and support studies to evaluate the safety of specific psychosurgical procedures and the efficacy of such procedures in relieving specific psychiatric symptoms and disorders, provided that the psychosurgery is performed in accordance with these recommendations. (One Commission member abstained.)

*Comment.* The pilot studies performed for the Commission, while very informative, should be supplemented by more extensive studies in order to determine, with a higher degree of certitude, the safety and efficacy of the procedures under evaluation. Additional studies should be undertaken to evaluate other psychosurgical procedures. The importance of such research is sufficient to warrant the support of DHEW. Therefore, not only should the Secretary establish a mechanism for the collection of data, as de-

scribed in Recommendation (5), but the Secretary should support research that would utilize and extend those data to determine whether specific psychosurgical procedures are safe and effective.

*Recommendation (7). The Secretary, DHEW, should impose strict sanctions, up to and including the withholding of Federal funds, to assure compliance with regulations implementing these recommendations. (Adopted unanimously.)*

*Recommendation (8). Congress should take such action as it deems appropriate to assure that (A) psychosurgery is performed under conditions that are in compliance with DHEW regulations implementing these recommendations, and (B) psychosurgery is not conducted or supported by Federal agencies or components thereof unless such agencies or components are primarily concerned with health care or the conduct of biomedical and behavioral research. (Adopted unanimously.)*

CHAPTER 7.—DISSENTING STATEMENT OF  
COMMISSIONER PATRICIA A. KING

It is with much regret that I find it necessary to abstain from Recommendation (6), and dissent from Recommendations (2) and (3) of the Commission's Report on Psychosurgery. The Commission struggled long and hard to reach conclusions with respect to an extremely difficult and perplexing problem. It had to decide whether to recommend a ban on all psychosurgical procedures; and, should a ban be unjustified, to further decide on whom and under what circumstances such procedures could be performed. The result of these lengthy deliberations is, I believe, a basically thoughtful and responsible report.

I agree with the Commission's conclusion that a ban on the performance of all psychosurgical procedures is not an appropriate response to the perplexing problem. As long as there is reasonable promise that some patients will be benefited (and I believe our data, although limited, supports such promise), then some limited psychosurgical procedures should be permitted. The report, recognizes that the performance of psychosurgical procedures must be subject to rigid limitations in view of the risks of harm and abuse; I strongly concur with this sentiment. I accept, however, the

criticism of some that the Commission's report might be viewed as a more enthusiastic endorsement of psychosurgery than we intended. It was with this criticism in mind that I abstained on Recommendation (6) which states that "The Secretary, DHEW, is encouraged to conduct and support studies to evaluate the safety of specific psychosurgical procedures and the efficacy of such procedures in relieving specific psychiatric symptoms and disorders, provided that the psychosurgery is performed in accordance with these recommendations." (Emphasis added.) Perhaps, it would have been wiser to have omitted the Recommendation altogether. Since it is basically hortatory it adds little to the report and is subject to misinterpretation.

My basic disagreement with the Commission's Report however is with its conclusions about what protections should be afforded voluntarily committed patients residing in institutions. In my view, such patients should be accorded the same protections as all institutionalized persons and be required to undergo court review of their cases prior to the performance of psychosurgical procedures. I, therefore, dissented from Recommendation (2) because it omits any requirement of court review, and from Recommendation (3) because it does not include all voluntarily committed persons.

The Commission did not have before it either data which indicated who comprised the group referred to as the voluntarily committed, or data which indicated whether the voluntarily committed differed from the involuntarily committed in any significant manner that would warrant separate consideration. The Commission assumed that involuntarily committed persons were institutionalized through some judicial process and that voluntarily committed persons were institutionalized through "voluntary" admissions processes. It assumed that the distinction referred to above was significant, although it did not have any data to support such an assumption or any data about how the commitment process might differ from state to state. It is conceivable, for example, that as a part of the "plea bargaining" process in our criminal justice

system that some persons "agree" to voluntarily commit themselves to mental institutions in exchange for reduced or dropped charges. I do not mean to suggest that this happens, or, if it does, that it occurs in any significant degree. My point is that the Commission did not have before it sufficient data on which to justify distinctions between the two groups of patients.

Some would argue that the method of admission is a significant consideration, because the Commission's restrictions are too burdensome and are an undue infringement on the rights of patients to have access to therapeutic procedures. There is undoubtedly some merit to the suggestion. However, in view of (1) general public concern about psychosurgery (noted in the Report itself), (2) concern about whether an appropriate candidate for psychosurgery is ever able to give valid consent, (3) the limited available data about the safety and efficacy of specific psychosurgical procedures, and (4) the paucity of data before the Commission on commitment procedures, I believe caution was warranted.

The Commission did recognize that some of the voluntarily committed would be incapable of giving valid consent, but it chose to deal with that concern by making the IRB responsible for making the determination about whether a particular patient was so capable. It is questionable in view of the current concerns about psychosurgical procedures whether we should have ever saddled IRBs with such responsibilities. It is outrageous in my opinion to ask them to make that determination with respect to those residing in institutions. The impact of institutionalization alone, as discussed for example in "Kaimowitz," is significant enough to warrant treating those inside institutions different from those outside. Were I a member of an IRB operating under the Commission's recommendations, I would always vote for court review of the IRB determination at least until such time as we know more about the safety and efficacy of specific psychosurgical procedures, and the law regarding informed consent is more settled.

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