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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Determination of Secretary Regarding Recommendation on Psychosurgery of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

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DETERMINATION OF THE SECRETARY REGARDING THE RECOMMENDATION ON PSYCHOSURGERY OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

AGENCY: Public Health Service, HEW.

ACTION: Notice of the Secretary's determination.

SUMMARY: The Notice announces the Secretary's determination that (1) the Department will assist leading professional organizations to form a Joint Committee on Psychosurgery to establish mechanisms for the voluntary regulation and reporting of psychosurgical procedures; (2) the Department will promulgate regulations covering any procedures supported by DHEW programs. These regulations will generally follow the Commission's recommendations but would ban use of the procedures with prisoners, children, involuntarily confined mental patients, legally incompetent patients, and any patient who, in the judgment of the attending physician, is not competent to give informed consent.

FOR FURTHER INFORMATION CONTACT:

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DETERMINATION

BACKGROUND: The legislative requirement for the study of psychosurgery by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was incorporated in Pub. L. 93–348 after widespread expression of public and Congressional concern about such surgery, including allegations that these procedures were (1) being carried out without adequate evidence of safety, (2) carried out without adequate procedural safeguards for protection of the rights of the patients, (3) were being used for "social control" of dissidents and violence-prone individuals, and (4) were performed disproportionately on members of minority populations. Pub. L. 93–348 defines psychosurgery as: (1) surgery on the normal brain tissue of an individual not suffering from physical disease for the purpose of changing or controlling behavior or (2) surgery on diseased brain tissue of an individual if the sole object of the surgery is to control, change, or affect behavioral disturbances.

The Commission, in addition to taking public testimony, sponsored a literature review, a survey of psychosurgical procedures conducted in the United States and other countries, and the independent evaluation of the patients of four psychosurgeons.

The Commission's survey found that there are about 400 procedures meeting the definition of psychosurgery being performed annually in the United States. These operations are performed by approximately 60 surgeons (48 percent of the procedures performed in 1973 were performed by four surgeons). The findings indicate that no significant psychological deficits are attributable to the psychosurgery in the patients evaluated and that psychosurgery was efficacious in more than half of the cases studied. The data presented did not indicate that the procedure had been used for social control or that, the procedure had been applied disproportionately to minority or disadvantaged populations. Specifically, it was reported from correspondence with the most active psychosurgeons in the United States that out of a combined total of 600 patients, 1 was Black, 2 were Oriental Americans, and 6 were Hispanic Americans. Seven operations were reported to have been performed on children since 1970, and three prisoners underwent psychosurgery in Vacaville in 1972. Most psychosurgery patients were middle class individuals referred to neurosurgeons by psychiatrists and were about equally divided between male and female.

The Commission concluded (1) that the procedure did not constitute "accepted practice;" (2) that although the procedure was not actually used for "social control," it had the potential for such use; and (3) that it posed obvious problems with regard to the ability of individuals who were thought to be in need of psychosurgery to provide informed consent. It therefore made a number of recommendations to regulate psychosurgery in the United States.

Its recommendations would: (1) Set up stringent, procedural safeguards and criteria under which the procedure would be performed on adults; (2) provide additional special conditions for consent or authorization to perform the surgery on institutionalized adults and children; (3) establish a National Psychosurgery Board to determine if a specific psychosurgical procedure has demonstrable benefits for the treatment of a particular mental illness or behavior disorder; (4) establish a national registry of psychosurgery procedures; (5) encourage the Department to conduct research on psychosurgery; and (6) impose sanctions (including withholding of Federal funds) for failure to comply. In addition, the Commission recommended that the Congress take any necessary action to assure that psychosurgery is performed in compliance with these recommendations and that psychosurgery not be conducted by Federal agencies unless they are primarily concerned with health care or the conduct of biomedical or behavioral research.

DISCUSSION

It is clear that the Commission conducted a judicious study aimed at determining the risks and benefits of surgical treatment for psychiatric disorders. The recommendations of the Commission are a laudable attempt to ensure the rights and welfare of all classes of potential psychosurgery patients, with special safeguards for patients having limited capacity for informed consent, without unduly limit ing access of patients with severe psychiatric disorders to this potentially therapeutic treatment modality.

The Commission's recommendations must be viewed in the perspective of a basic complexity of the psychosurgery issue: Virtually all psychosurgery performed in this country takes place in private medical practice. However, most of the technical and substantive questions about psychosurgery, such as its safety and efficacy, can be answered adequately only in a research context. This overlapping of the clinical practice and research environments poses a difficult problem for a Federal agency; on the one hand the DHEW, operating through the National Institute of Mental Health (NIMH) and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), has a primary responsibility to study the efficacy and safety of therapeutic interventions including psychosurgery; on the other hand, these Federal agencies have no regulatory authority or process and therefore must avoid assuming such a role in the practice of psychosurgery.

It should be emphasized that the Commission found that psychosurgical treatment constitutes a miniscule proportion (estimated to be less than .001 percent) of psychiatric treatment in general. One survey conducted for the Commission suggests that only a little over 400 psychosurgical operations are performed in this country each year. In this survey, no evidence was found that any minority group, women, or members of any disadvantaged socioeconomic class were singled out for psychosurgery.

Not only did the studies supported by the Commission fail to find any widespread inappropriate use of psy-

chosurgery, but they contained evidence suggestive that psychosurgical treatment can be relatively safe and effective for certain forms of long term and intractable severe psychiatric disorders. In some cases, use of these procedures is the only way to alleviate the suffering of patients who have exhausted other treatments. It is therefore incumbent upon the Department to attempt to further define and assess the potential role of psychosurgery as a therapeutic strategy in psychiatry. The recommendations of the Commission can provide a framework for the conduct of such an effort in which the combined requirements of high scientific quality and adequate protection of human subjects can be met.

APPROACH

In order to receive the widest range of advice concerning the Department's reply to the Commission's recommendations, members of my staff reviewed the public comment received as a result of the FEDERAL REGISTER publication of those recommendations and met with a diverse cross-section of public interest groups and professional organizations. Representatives of public interest groups expressed varying opinions concerning the beneficial effects of psychosurgery with the majority voicing clear disfavor toward the use of psychosurgery either as a treatment or in research involving human subjects. Their comments reflected grave concern that the consequences of psychosurgical procedures are irreversible and produce damaging side effects of a permanent debilitating nature. In addition to challenging the meaningfulness of the informed consent criterion for acceptance, these public advocates urged that psychosurgery be banned for minors or institutionalized persons involuntarily committed to State or private long term care facilities. No respondent submitted evidence contradicting the Commission's findings about the composition of the population of psychosurgery patients.

Representatives of the leading professional organizations proposed that a voluntary group be established through a cooperative effort of concerned professional organizations and specialty societies, in conjunction with and supported by DHEW. The basic function of such a group would be to Oversee the voluntary implementation of the Commission's substantive recommendations.

SPECIFIC FUNCTIONS OF THE GROUP WOULD BE

To specify criteria for the composition of multidisciplinary local psychosurgery review panels, and develop guidelines for the review and evaluation of proposed psycho-surgical procedures. The criteria would include designation of experience or training requisite to assessment of psychosurgical procedures. Such local panels would review each proposed psychosurgical procedure at its institution to insure the competence of the surgeon, appropriateness of the procedure for that patient, and adequacy of informed consent. Where an existing Institutional Review Board has the requisite expertise, the institution may designate that Board to serve as the institution's psychosurgery review panel.

To collect data, with due protection of patient confidentiality, regarding the diagnosis, preoperative and postoperative conditions of patients, the type of operation and such further information as the group may deem appropriate and necessary to make determinations concerning the safety and efficacy of specific procedures.

To study the special informed consent issues in patients with limited capacity for such consent.

Concerning the need for further research, such a group would collaborate with DHEW staff in identifying psychosurgery research problems and opportunities. We would expect these experts to look at the evidence of safety and efficacy of psychosurgical procedures and advise us as to what research is required to establish such evidence for specific procedures.

CONCLUSIONS OF THE SECRETARY

Under present law, DHEW has no clear authority to regulate directly psychosurgical procedures currently being performed in this country. To the extent permitted by law, we can and will regulate any procedures supported by DHEW health programs. However, in view of the Commission's findings that the procedure is not in wide use, that it has positive results and rarely has negative side effects. that it is often treatment of the last resort and that it is not used disproportionately on minorities or for social control, we do not believe an effort to secure regulatory legislation would be warranted.

In lieu of regulatory legislation, we believe the Department should assist the leading professional organizations in forming a Joint Committee on Psychosurgery (JCP) to regulate voluntarily, the procedures through the issuance of guidelines and the formation of local psychosurgical review panels as discussed above. While compliance with the guidelines would be voluntary, professional standards, peer pressure, and malpractice considerations should result in compliance.

In establishing the JCP, I have adopted the recommendations of the professional organizations for the following reasons:

There are serious questions concerning our authority under existing legislation for imposing requirements on the use of psychosurgery. Also, there are no existing Federal mechanisms for implementing the recommendations.

Unlike drugs and devices, there are no established procedures for determining the safety and efficacy of surgery. Though voluntary cooperation of the concerned professional associations with the Department, no additional legislative base need be sought, and no new Federal effort need be started.

We believe that, because of the specialized facilities required, only a limited number of psychosurgery review panels would be established at local institutions. Through the cooperation of the Joint Committee, the Department would have better knowledge of the nature and extent and psychosurgery and improved control over its use.

This course of action would implement most of the basic substantive recommendations made by the Commission and will represent a significant partnership between the private sector and the Federal Government. Psychosurgery will remain a last resort treatment available to patients who need it.

No psychosurgical procedures are being performed by PHS or with PHS support and few, if any, are being paid for by Medicaid or Medicare funds. Nevertheless, we will publish regulations covering procedures that might be so supported in the future by these programs. This will serve as a twofold purpose: (1) The regulations will provide a mechanism for assuring that these procedures are performed with appropriate safeguards, and (2) they will provide a model for State and local governments and for other concerned organizations (e.g., the JCP) to consider adopting.

The regulations will, in general follow the Commission's recommendations, but be more restrictive in the case of patients unable to provide informed consent. The Commission's own findings show that the procedure is very rarely performed on prisoners and children. In fact, the Commission indicated it did not review any data which would support performance of psychosurgery on children at this time. Hence, in view of the public concern, performance of the procedure on prisoners and children in PHS hospitals or with DHEW funds will be banned absolutely for the time being.

The question of how to deal with mentally incompetent adults is more complex. Some are confined to mental institutions (either voluntarily or involuntarily), some have been adjudi-

cated legally incompetent, and others are not legally incompetent but lack the capacity, in fact, to make an informed judgment about psychosurgery. Informed voluntary consent in these situations is questionable, and yet, in a medical sense, these may be the persons who could most benefit by some type of psychosurgery.

Performance of the procedure on patients who are involuntarily confined or legally incompetent raises many of the same, issues as are presented by prisoners and children. Accordingly, we will include these patients within the ban already discussed. In view of the fact that the procedures have given rise to so much public concern, the regulation will also bar performance of the procedure on any patient who, in the judgment of the attending physician, is not, in fact, competent, although he or she may not have been so adjudicated. The regulations will provide a mechanism through which the physician could obtain advice when he or she is uncertain as to the competency of an individual patient.

The regulations can be amended to lift the ban, if and when the safety and efficacy of the procedure is more clearly demonstrated and/or when the consent studies conducted by the JCP establish effective procedures for the protection of patients with presumed limited capacity for truly informed consent.

Regulations implementing this decision will appear in a future FEDERAL REGISTER as a Notice of Proposing Rulemaking.

SUMMARY

We believe that this course of action implements fully the spirit of the Commission's recommendations. Controls recommended by the Commission will be effected through organizations which are traditionally involved in governing medical practice. Regulations will be published covering psychosurgical procedures conducted or supported by DHEW programs. These regulations will also serve as a model for control of psychosurgery generally and will include a ban against use of the procedures on vulnerable groups. Legislation may be sought if this voluntary approach does not prove to be effective.

Dated: November 2, 1978.

CHARLES MILLER,
Acting Assistant Secretary for Health.

Approved: November 6, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

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