EDITORIAL

The Attempted Revival of Psychosurgery

by George J. Annas, J.D., M.P.H.*

Recommendations concerning psychosurgery (the selective destruction of brain tissue to alter behavior) of the National Commission for the Protection of Human Subjects of Behavioral and Biomedical Research were published in the *Federal Register* on May 23, 1977.[1] The recommendations are remarkable primarily because of their source. One must be surprised when an organization set up for the protection of human subjects decides that its proper role is the promotion of a highly experimental and controversial procedure. While the stature that this Commission has gained from its past work may be sufficient to have these recommendations accepted, it was only a redefinition of the term psychosurgery to include neurosurgical operations for pain (a generally uncontroversial indication) that permitted this result. Since this definition is the basis of their report and since the definition is inaccurate, the report and its recommendations should be rejected and remanded by the Secretary of H.E.W. to the Commission for further consideration.

Briefly, the Commission found that psychosurgery should be performed only when it is both medically indicated and when the subject has given informed consent. The Commission's primary recommendation is:

> (1) Until the safety and efficacy of any psychosurgical procedure 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 there is any reason to call the patient's consent into question, more elaborate procedural safeguards—including a court hearing for prisoners, involuntarily committed mental patients, and children—are also required.

A system of elaborate procedural safeguards is the only viable alternative to a complete prohibition of psychosurgery. Like any such safeguards, however, their implementation will demand both a philosophical and an economic commitment if they are to be carried out in a manner which will protect the rights of potential subjects. What are the implementation problems as they relate to the protection of subjects?

Potential Future Abuses

Since the recommendations deal only with experimental surgery, they apply mainly until the "safety and efficacy" of a particular psychosurgical procedure are demonstrated. This leads to at least two major problems. The first is one that was arguably not within the Commission's mandate to consider: the potential danger that once safety and efficacy have been demonstrated, psychosurgery may be used to modify the behavior of prisoners, dissidents, minorities, and other deviant groups. An "approved" procedure is likely to take on a technological imperative of its own, with unpredictable results. I would submit that psychosurgery that "works" poses a greater danger to society than psychosurgery that does not, and that this issue demands attention to such things as deviance and violence *before* "safety and efficacy" are demonstrated. Upon full consideration of the potential dangers involved, a decision to either prohibit psychosurgery for certain "indications" (like violence) or to require court review for certain populations (like prisoners and children) may well be in order, even after safety and efficacy have been established.

Inadequate Data

The second danger is illustrated by the Commission's own report—the possibility that "safety and efficacy" may be determined on grossly inadequate data. On the basis of two "pilot" studies conducted by researchers at Boston University and MIT of four different psychosurgical procedures on 61 adults, the Commission concluded 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." (Comment to Recommendation 1). While this statement is not an overly enthusiastic endorsement, it cannot be supported by the Commission's evidence. First, the Commission neglects to identify which forms of psychosurgery it finds might be of value and for what symptoms. This omission is especially troubling since the Commission expanded the term "psychosurgery" as contained in its legislative mandate to include operations to relieve the emotional responses to pain, and if the pain patients were excluded from the 61 studied (15 such patients with 11 "successes"), the overall success rate would drop from a majority to about 43 percent. Moreover, of the remaining 46 patients, 20, or almost half, had more than one psychosurgical procedure. If the first operation (and the second in those cases that had three procedures) had been counted as a failure by the Commision, as it reasonably could have, the overall success rate in the nonpain group would have dropped to under 30 percent—less than the surgical placebo success rate identified by Beecher.[2]

Since the placebo effect may be especially high in a behavior-altering procedure done by a surgeon who is a true believer and has a strong rapport with his patient, the Commission could just as logically have concluded from these studies that the only evidence it had was that psychosurgery "worked" only for pain patients, but that for any other indication it was less effective than a placebo. The Commission's own statistics indicated that during the years 1971-73, about 500 psychosurgical procedures were performed annually in the United States by about 140 neurosurgeons. The Commission looked only at 61 cases of four surgeons who volunteered their cases for study. Most forms of psychosurgery were not seen at all; and since, in the present malpractice climate, surgeons cannot be expected to volunteer their failures or worst cases for study, one is skeptical of those that were seen. In fact, given the built-in bias in the selection process, the very limited sampling, and problems in testing and comparability, *no* conclusions about psychosurgery in general can be drawn from the Commission's data. The point is not who is right in interpreting the data; the data can be interpreted in many different ways. The critical issue is *who decides what is "safe and effective," and on what basis.* On this basis, therefore, it would seem essential that, in addition to adequate public representation, at least one highly respected biostatistician or epidemiologist be made a member of the Commission's proposed "National Psychosurgery Advisory Board" to help prevent any overly enthusiastic reading of reported results.

Informed Consent

Another danger is that the IRB review process might act simply as a rubber stamp, legitimizing an otherwise questionable procedure. A change in the regulations to require a personal appearance by the potential subject before the review committee on the issue of informed consent would be both appropriate and enforceable.

Adult prisoners and mental patients are rightfully given the absolute right to refuse psychosurgery. Proxy consent is, however, permissible under the regulations for children. I would submit that this is unjustified in

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CONFERENCE - STRESS, STRAIN, HEART DISEASE AND THE LAW
January 26-28, 1978
Copley Plaza Hotel, Boston, Mass
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Workshop 4 - The employer's and labor union's viewpoint

Friday - Jan. 27, 1978

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The physician's approach
The trial attorney's approach
The adjudicator's approach
Intermission and coffee break - 10:30 - 11:00 A.M.
Session 4. *Physical Stress and Heart Disease 11:00 - 12:00 A.M.*
Definitions
Current medical knowledge update
Luncheon and luncheon speaker - 12:00 - 2:00 P.M.
Session 5. *Psychologic Stress and Heart Disease* - 2:00 - 3:15 P.M.
Definitions
Current medical knowledge update
The role of occupational stress in coronary heart disease
Intermission and cofee break - 3:15 - 3:45 P.M.
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Saturday - Jan 28, 1978

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Workshop 2 - The trial attorney
Workshop 3 - The insurer
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that the Commision found *no* evidence of psychosurgery ever being beneficial for children.

The Commission's dismissal of the holding of *Kaimowitz v. Michigan Department of Mental Health*-the Detroit psychosurgery case—regarding informed consent is highly superficial and cavalier. The case is attacked on its constitutional arguments, after which its much stronger arguments on informed consent are simply dismissed by a comment that to exclude proxy consent for involuntarily committed mental patients and prisoners "seems unfair."

This conclusion was made possible only by transforming psychosurgery from a dangerous experiment into an "opportunity to seek benefit from a new therapy." Such a characterization simply cannot be justified, and the Commission itself admits to having studied *no* actual cases involving either involuntarily committed mental patients or amygdalotomies for violence—the facts at issue in *Kaimowitz*.

Finally, the Commision's recommendation that the Secretary of HEW "conduct and support studies to evaluate the safety of specific psychosurgical procedures and efficacy of such procedures in relieving specific psychiatric symptoms and disorders" is inappropriate. It is outside the Commission's Congressional mandate and unsupported by the evidence available to the Commission. Nothing in the Commission's report supports the concept that psychosurgery research should be on HEW's priority list, or that studies of the multiple types of procedures being used and the multiple "indications" for surgery employed by the more than 140 surgeons in this field would be fruitful. The Commision was set up to protect subjects and not to promote research. While these two activities are certainly compatible, emphasis on the latter tends to detract from the former.

While I have previously concluded that the recommendations could stand with certain modifications, this was probably an overly optimistic views.[3] A report that is based on an erroneous definition of the problem it seeks to solve is fatally flawed. The only rational solution is to begin again with a proper definition of psychosurgery and a more sophisticated view of the potential problems involved in the application of the procedure once it ceases to be experimental and becomes "therapeutic." If the Commission's life is continued by Congress, the Secretary of H.E.W. should remand this report and recommendations to it with specific instructions on how to proceed consistent with the above discussion. If the Commission's life is terminated, on the other hand, these recommendations should simply be allowed to die with it.

References

1. "Protection of Human Subjects: Use of Psychosurgery in Practice and Research: Report and Recommendations for Public Comment", *Fed. Reg.*, May 23, 1977, at pages 26318-26332. Approximately 100 responses were received by early August.
2. Beecher, Surgery as Placebo, 176 JAMA 1102 (1961).
3. Annas, Psychosurgery: Procedural Safeguards, *Hastings Center Report*, April, 1977 at 11.

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