approval except where necessary to eliminate apparent immediate hazards." Any "modification of the experimental design on the basis of experience gained" must also be made with the approval of the review committee. Yet just what all of this reviewing will mean is not clear.

The central concern of the FDA proposal seems to be to assure the safety and welfare of human subjects of new drug tests. As stated in the preamble to the proposed regulation, the committees are to assure appropriate supervision and "adequate safeguards for the health of human [test] subjects." This is an appropriate function for an independent peer group committee and closely resembles the purposes of the Public Health Service committees.

Commissioner Ley suggested in his testimony before Senator Nelson's Subcommittee on Monopoly of the Select Committee on Small Business on August 12 that the review committees would also provide a check on a test's scientific adequacy and necessity. This aspect of the review committee's role is totaly ambiguous in the FDA proposal. The scientific quality of new drug testing badly needs to be improved,[4] and some consideration of the scientific adequacy and necessity of a new drug test is essential to a consideration of the rights and welfare of test subjects.

(*b*) *The Council's Proposal.*—The regulations should set forth in some detail the legitimate concerns and method of operation of the review committees.

The review committee should, at the least, explicitly be given powers analogous to those of the committees established under the NIH grants. The NIH–PHS regulations require that its committees shall assure that—

(*a*) the rights and welfare of the individuals involved are adequately protected,

(*b*) the methods used to obtain informed consent are adequate and appropriate, and

(*c*) the risks to the individual are outweighed by the potential benefit to him or by the importance of the knowledge to be gained." *Protection of the Individual as a Research Subject*, Public Health Service, May 1, 1969, p. 1.

All of these considerations deal with the welfare and rights of the patient population. The assessment of the relative benefits against risks also calls for some scientific expertise and understanding of the particular area of medicine in which the experimentation is taking place.[5]

The review committees will have to be especially vigilant to insure that, in the words of the NIH–PHS regulation, "adequate and appropriate" methods are "used to obtain informed consent." Major problems were left unresolved by the FDA regulations adopted in 1967 (section 130.37) concerning consent by test subjects. For example, obtaining the consent of children in orphanages and the senile in homes for the elderly is a delicate matter at best. Often their legal guardian is the state. Members of such groups would benefit from a review committee acting in their interest to make sure that the state safeguards their rights.[6] The committee should also consider whether the information to be given to a test subject is adequate for him to make an informed judgment, in light of all the circumstances.

There are other areas in which the review committee's responsibilities will be especially great. It ought to develop enough information to allow it to be satisfied that the investigation provides maximum assurance of patient safety and that members of the test population receive adequate supervision and medical attention.

*3. The authority of the Review Committee*

(*a*) *Criticism of FDA proposal.*—No enforcement power is specified in the FDA's proposal. While the review committees are made "responsible for initial and continuing review and approval of the experimental project," the proposal does not describe what happens if a committee disapproves of a project. The

---

[4] The FDA can impose new testing standards by devices specifically designed for that purpose. The new regulations providing "Hearing Procedure for Refusal or Withdrawal of Approval of New Drug Applications and for Issuance, Amendment, or Repeal of Antibiotic Drug Regulations; Interpretive Description of Adequate and Well Controlled Clinical Investigations" which the FDA published in the Federal Register on September 19 are a useful step in this direction. (21 CFR § 130.12, § 130.14, and § 146.1).

[5] The Council believes that it can never be ethical to ask a person to take the risks associated with new drug testing if the tests themselves are unnecessary or will not, because of their design, yield significant results. Hence, any committee charged with protecting the rights and safety of test subjects must have the capacity to review the scientific aspects of the tests.

[6] Indeed, it is arguable that such groups should never be used in new drug testing where there is no expected benefit to the subject.