

Chronic Disease Hospital in Brooklyn who were injected with live cancer cells as a part of a research project. In 1966, Dr. Henry K. Beecher published under the title "Ethics and Clinical Research" in the *New England Journal of Medicine*, 274:1354-1360, a study of 22 cases of questionable testing practices.

Those of us in the health professions know that the pressure on a new drug investigator to produce results are often so intense that it is all too easy to treat subjects in an assembly line fashion. Moreover, the investigator, by virtue of his role, does not have sufficient detachment to weigh objectively the sensitive questions involving the rights and welfare of the human subjects of his tests.

These problems are most acute in tests involving the poor, the dispossessed, and the helpless. Since few people are anxious to participate in medical experiments, drug investigators understandably make heavy use of those people least able to resist the investigator's request. Such people are especially valuable to the investigator when they can be tested and observed in institutionalized settings such as orphanages, prisons, mental hospitals, and homes for the elderly. Experiments in hospitals also tend to utilize the poor since they are, in effect, wards of the state and have no private physician to protect their interests.

The FDA's 1967 regulations requiring informed patient consent (21 CFR §130.37) address this problem—but they do little to protect society's outcasts. What does it mean to require the informed consent of orphans, the senile, the mentally ill, or their respective guardians? How much information must they be provided? What kind of independent decision can a prisoner make when he believes that his consent will secure favorable treatment and better prospects for parole?

Some outside group, independent of the investigator and the new drug sponsor, is needed to protect the rights and safety of human test populations. The FDA has proposed that "peer group committees" be established to function as an independent reviewing body. We agree that much good could be accomplished by an experienced, independent review committee operating under a clear mandate to safeguard the test subjects' rights, safety, and welfare. Yet the FDA proposal would not establish such groups.

The National Institutes of Health have led the way in the development of peer group committees to review experimentation with human subjects. In a well-thought-out pamphlet entitled "Protection of the Individual as a Research Subject," Public Health Service, May 1, 1969, the responsibilities and characteristics of the peer group committee are set out in considerable detail.

The peer group review committees proposed by the FDA are loosely patterned after the PHS-NIH peer groups, but the detailed provisions of the PHS-NIH scheme—which assure the effectiveness and independence of the PHS-NIH peer groups—are omitted from the FDA proposal. What is more, while it may make sense to establish a peer review committee in a hospital or university setting, the FDA proposal does not address itself to the difficult problems of adapting the peer group concept to such institutions as prisons or orphanages.

It is arguable that the peer group review concept is inapplicable as a real solution to the problems of testing in institutions in which medical research is not normally carried on in a professional setting. Perhaps it will prove to be too cumbersome and expensive in practice. However, for the present, the review committee approach, if constituted along the lines proposed by these comments, holds sufficient promise so that it should be established.

The Council recognizes the complexity of the issues involved in policing new drug testing. The Council proposes that the Food and Drug Administration, perhaps with the cooperation of the NAS-NRC, establish a procedure—which might include FDA hearings—for developing information and soliciting opinions which will enable the FDA to formulate a long-range strategy to assure the welfare of test subjects—including appropriate guarantee of the scientific necessity and adequacy of new drug testing. In conducting the study, the Food and Drug Administration should solicit the participation of public groups—consumer, patient, para-professional, and health care groups—as well as drug manufacturers and new drug investigators.

Detailed information should be accumulated on new drug testing: which kinds of institutions are most frequently used; which classes of the population normally are used for new drug experimentation; what percentage of new drug tests are conducted in scientific and professional settings as opposed to other institutional settings; what percentage of new drugs are tested by individual practitioners not operating in any institution. The inquiry should explore the way that the peer group review system has operated under the NIH-PHS system.