a "peer" of the investigator. In our view, to speak of a "peer group" in a prison is a non sequitur.

For the review committee concept to work, the committees will have to be genuinely independent. The proposal pays lip service to the concept of independence in requiring "assurance that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee)." But independence requires something more. It requires that the committee be selected in some objective manner and it requires that its members have a degree of experience and expertise which staff members at institutions like prisons and orphanages may not have or recognize.

(*b*) *The Council's proposal.*—Some institutions in which new drugs are tested have preexisting peer group committees, established to meet the Public Health Service requirements. At present, most and perhaps all of those committees review all research done by their institutions, including tests of new drugs. If those committees are functioning adequately,[2] they presumably could continue to oversee research on new drugs undertaken within the institution. This would avoid administrative duplication and help assure supervision by a group with some experience and sophistication. The names and qualifications of persons on such committees should be submitted to the FDA on Form FD 1571.

For institutions which do not already have peer group committees, the FDA's regulation should establish guidelines for instituting review committees. A description of the selection process and the requisite qualifications for committee memberships should be included. In prisons, orphanages, and homes for the aged, the institution staff would probably not include enough appropriately trained personnel to compose a competent review committee, nor would they have the expertise or resources necessary to select a review committee which could, in the language of the proposed rule, "assure complete and adequate review of research."[3]

Participation by the investigator or the sponsor of the research in the nomination or selection of peer group members should be explicitly prohibited in the regulation. The regulation should require among the members of the commitee at least the following: experts adequately qualified to assess the potential medical benefits of the research and consider potential benefits against risks; an attorney selected, perhaps, by the local bar association; an independent physician having no connection with the institution or the investigator, selected, perhaps, by the local medical association; qualified representatives of appropriate universities; and representatives of the community. The names and qualifications of all members of the review committee should be submitted to the FDA on Form FD 1571 for its approval. The mode of selection of the committee should also be explicitly stated. The FDA staff should be available to assist institutions which lack the necessary competence in constituting a review committee.

In some cases a single review committee might review the new drug testing in a number of institutions in the same area. Several institutions might jointly establish a single review committee, or one institution might accept a committee established by another institution.

2. Responsibilities of the review committee

(*a*) *Criticism of FDA proposal.*—Like the Public Health Service peer group committees on which they were modeled, the FDA committees ought to have their purposes and functions carefully outlined in agency regulations. Unfortunately, the FDA proposal leaves the responsibilities of the review committees unspecified. There is, indeed, much confusion about the appropriate subject matter for the committees. In one sense their power seems very broad: they are "responsible for initial and continuing review and approval of the experimental project;" the investigator must "report to the commitee for review any emergent problems or proposed procedural changes which may affect the status of the investigation;" and "no change will be made without committee

[2] The adequacy of the functioning of existing peer group committees is a matter which the FDA should consider.

[3] The Public Health Service states in a similar context:

"The membership [of a review committee] should possess not only broad specific competence to comprehend the nature of the research, but also other competencies necessary in the judgments as to the acceptability of the research in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. The committee's maturity and experience should be such as to justify respect for its advice and counsel." *Protection of the Individual as a Research Subject,* Public Health Service, May 1, 1969, p. 6.