proposal provides no mechanism by which the committees could prevent the investigators from taking what they regard as unwise action. Nor does it effectively give such power to the FDA itself, since the proposal provides no method for even informing the FDA of committee findings or concerns.

When Senator Nelson asked how the FDA would know "whether the peer group was just perfunctory," Dr. Ley answered:

"There would have to be as part of the submission of the investigational institution to the sponsor and from the sponsor to us a statement that such a peer group existed, that such a peer group had reviewed the material, and that the minutes of the group were available and where. This is the minimum."

Actually, this "minimum" is not included in the FDA proposal. The proposal does not require the investigator or the sponsor to insure that minutes either be kept or be made available.

(*b*) *The Council's proposal.*—The regulations should state that no new drugs can be tested without the approval of the review committee. When it does not approve of a particular aspect of a new drug test, the review committee should report its findings to the institution as well as the investigator. In appropriate cases the review committee should immediately reports its conclusions to the FDA.

The review committee should analyze the testing program for research at the outset, before any work has begun. If the review committee concludes that any aspect of the program shows insufficient concern for the interests and welfare of the test subjects, it should be empowered to disapprove the program or require modification. In addition, the review committee should in a systematic way periodically review the testing procedures. The FDA proposal requires that the investigator return to the review committee for review when he is changing his protocol. But it is equally important that the review commitee from time to time review the progress of the tests on the basis of reports from the investigator and other data. For example, other developments in the scientific community might obviate the necessity for the particular experiment being undertaken; or preliminary test results might reveal unanticipated danger to test subjects.

The regulation should state that review committees should review the reports submitted by investigators to the new drug sponsors to make certain that such reports are complete. The review committee should also make a report detailing all of its findings and conclusions, copies of which should be sent both to the institution involved and the FDA. Minutes of review committee meetings should be kept and made available to the FDA on request.

4. Coverage of the review committees

The most glaring omission of the proposed regulation is the failure of the FDA to deal with phase 3 testing problems or to provide a review mechanism for noninstitutional tests of new drugs. Any comprehensive scheme adopted by the FDA to safeguard the rights of human subjects on whom new drugs are tested must deal with phase 3 problems as well as phase 1 and phase 2. In addition, the FDA should devise a method of bringing noninstitutional investigators under the surveillance of a review committee, perhaps through regional review committees.

III. CONCLUSION

For the reasons stated in these comments, the Council urges substantial revision of the proposed amendments regarding peer group committee review. As presently drafted, the proposal gives the delusive appearance of dealing in a meaningful way with a major problem. See *New York Times*, August 13, 1969, page 1.

The Council and its members are prepared to assist the FDA staff in the drafting of a meaningful review committee proposal and in undertaking an analysis of other approaches to this problem.

(Whereupon, at 12 noon, the subcommittee adjourned, subject to the call of the Chair.)