There may be some misunderstanding that the Food and Drug Administration approves clinical investigators and clinical research projects conducted by pharmaceutical firms. FDA neither approves investigators nor do we approve the firms' clinical research projects.

The pharmaceutical firms are expected to choose qualified investigators. The FDA may disqualify, however, an investigator from participating in clinical studies if he does not abide by the Investigational New Drug Regulations.

Further, pharmaceutical firms are required to conduct clinical investigations in accordance with the Investigational New Drug Regulations. We do provide comment and suggestions on their plan of investigational study if requested or if our review indicates it is needed. An IND Notice is terminated if the requirements of the regulations are not met.

(*b*) On page 11, the opening statement reads "It should be noted, however, that neither (i.e. the FDA nor the manufacturer) is primarily concerned with the rights and welfare of the institutionalized research subject."

The Federal Food, Drug, and Cosmetic Act under Section 505(i) and Section 130.3 of the New Drug Regulations place a definite and primary responsibility on both the FDA and the sponsor of an investigational study to assure that the health of the participants in such a study is protected. The sponsor must be sure that he selects capable investigators who can safeguard the subjects of the study, that adequate preclinical tests demonstrate that administration of the drug to man is justified, that there is a sound plan of testing (protocol) which minimizes risks to the subjects, that unexpected effects are promptly investigated and the study is stopped if they raise significant safety questions, and that each investigator agrees to obtain the consent of the subjects of the experiment (with certain exceptions specified in the law). The FDA in reviewing the submissions sponsors must make before initiating clinical trials, is required to assure itself that sponsors have met the above-mentioned requirements, as well as others, and to require cessation of the trials where appropriate safeguards are not observed.

6. Provide for the record the number of IND's (Notice of Claimed Investigational Exemption for a New Drug) in which Dr. A. R. Stough and his firm have been listed by the sponsor as clinical investigators for the last three years. The number of people involved in Dr. Stough's studies.

See Attachment A.

7. Provide same information as (6) for four other active clinical investigators.

See Attachment A.

If we can be of further assistance, please let us know.

Sincerely yours,

HERBERT E. LEY, Jr., M.D.,
Commissioner of Food and Drugs.

ATTACHMENT A

NUMBER OF "NOTICES OF CLAIMED INVESTIGATIONAL EXEMPTIONS FOR A NEW DRUG" (IND'S) IN WHICH DR. A. R. STOUGH AND 4 OTHER ACTIVE CLINICAL INVESTIGATORS HAVE BEEN LISTED BY THE SPONSOR AS INVESTIGATORS SINCE AUGUST 1966, WITH ESTIMATED NUMBER OF SUBJECTS

Investigator	IND notices	Subjects (estimate)[1]
A. R. Stough, M.D	72	2,681
Physician A	102	3,347
Physician B	41	1,707
Physician C	31	1,333
Physician D	19	861

[1] A large number of the IND notices are still active. The estimated number of subjects is based upon the annual reports which have been received, from preliminary reports submitted by clinical investigators, or from the number of patients planned for the protocol of investigational study.

Senator NELSON. On the question opened by Senator Dole, you had stated you were going to put in the record the memorandum of July 29 on Dr. Austin Stough?