that it was reasonably safe to initiate clinical investigations with the drug.

Two basic principles are designed to protect the subject of clinical trials:

First. That the animal tests provide enough information to show that experiment in man is justified.

Second. That those testing drugs in humans are competent, concerned physicians qualified to determine whether the desired effects are being achieved and who can undertake prompt measures against adverse reactions.

In his testimony, Dr. Goddard also announced that actions were underway to reorganize the Bureau of Medicine; to expand the FDA field investigative force; to formulate internal policy and procedure guidelines for surveillance over investigational new drugs; and to move quickly against violators of the IND requirements.

Since that time, the number of field inspectors who have been trained to perform this specialized task has increased from 67 to 140. And we established a scientific investigation unit within the Bureau of Medicine, headed by Dr. Frances O. Kelsey, who has accompanied us here today.

The planned clinical investigation is required to proceed in specified phases in the interest of safety.

Phase 1 starts when the new drug is first introduced into man—only animal and in vitro data are available—with the purpose of determining human toxicity, metabolism, absorption, elimination, and other pharmacological action, preferred route of administration, and safe dosage range; phase 2 covers the initial trials on a limited number of patients for specific disease control or prophylaxis purposes.

Phase 3 provides the assessment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment, or prophylaxis of groups of subjects involving a given disease or condition.

The Federal Food, Drug, and Cosmetic Act permits shipment of investigational drugs only if they are intended solely for investigational use by experts in the investigational field. The regulations issued pursuant to the act require the investigational drug notice to include a description of the scientific training and experience which the sponsor considers appropriate for the investigators of the drug and a summary of the training and experience of each investigator.

Ideally, phase 1 studies should be undertaken primarily by an individual qualified to observe subtle pharmacological effffects during initial trials. He should have adequate facilities for investigation with respect to patients, clinical laboratory services, and time to devote adequate attention to such studies.

The investigational drug notice also must include the name and a summary of the training and experience of the person who monitors and evaluates the investigators' findings. This is a person on the staff of the sponsor manufacturer. The drug sponsor may not distribute promotional material stating that the investigational drug under study is safe or effective for the conditions under investigation.

The sponsor must obtain statements from each investigator to assure that the investigator is qualified, maintains proper records and that he agrees to comply with the patient consent provisions of the law.