costeroids, for example, were considered as potentially susceptible of this approach. This legislation was not acted on last year. It is something that is currently under study by the Food and Drug Administration along with other methods of helping to assure the quality of drugs in the marketplace.

Senator NELSON. Thank you.

Dr. GODDARD. Before 1938, drug research and investigation was predominately empirical; the law did not require conclusive establishment of either the safety or the efficacy of a drug before marketing. Many discoveries were fortuitous. In many instances serious side effects were discovered only after the receipt of complaints as the drug was distributed widely.

One of the most important provisions in the 1938 Food, Drug, and Cosmetic Act was a requirement that all new drugs be studied and evidence of their safety be submitted to this agency for approval before the products were shipped. Here we see a major step toward rational therapeutic science. This was a substantial improvement in scientific method as well as in the law. After 1938, the accumulation of at least some clinical data was necessary before a drug could be marketed. The Food and Drug Administration, in administering the law, could require the accumulation of preclinical and clinical data according to a reasonable protocol before allowing the drugs to be marketed. But again let me emphasize that approval of drugs under this 1938 act was only contingent upon a showing of safety—not a showing that the drug would be effective for all of the conditions for which it was to be offered. The 1962 amendments correct this deficiency by requiring a showing of effectiveness, as well as safety.

At present, no drug may be shipped across State lines for experimental use in man until certain requirements, which are set forth in our investigational new drug regulations, are met. Some of the key provisions of these regulations are:

The sponsor of an investigation shall prepare and present an acceptable plan for the investigation. The plan describes the drub, outlines the experimental procedure, and identifies the qualified person who will conduct the studies. It establishes mechanisms for monitoring the studies, reporting on their progress, keeping all investigators as well as the agency informed of any hazards that are discovered, and taking the needed steps to carry the investigations out in a way that would minimize the risks to subjects of the experiment. The subjects, incidentally, must consent to participate, except in certain well defined situations where obtaining consent is not feasible or is not in the interest of the patient.

Senator NELSON. Has this provision of the law been complied with consistently by those doing the testing?

Dr. GODDARD. This particular provision was implemented under the regulations that we issued last September, as I recall, and took effect July 1 of this year. This was debated rather extensively in the scientific community. We had a number of meetings with clinical investigators about the provisions of these regulations and modified them slightly in accord with and following these discussions. But we think we have followed the lines that Congress intended us to in the 1962 amendments.

Senator NELSON. Did the 1962 amendments require that patients