If I may just make one additional—I should say this chart is one of the best graphic presentations I have seen of the flow of activity in research, development, and preparation for manufacture of a new drug and the preparation of a New Drug Application for submission to the Food and Drug Administration. It was prepared by Eli Lilly's research staff and presented at a hearing of a House of Representatives subcommittee studying drug safety, chaired by Congressman Fountain in June 1964. The chart shows the great complexities faced in the creation of a new drug and the assembly of material submitted as a New Drug Application.[1]

I might point out here that the steps are complex, and they are variable. This chart is not the exact course of every drug. These things flow back and forth. A certain finding in one instance may make it go back to something else and flow around. Nevertheless, it is a very complex process.

Strange as it may seem, few new drug products that our industry makes are ever "finished" as far as laboratory and clinical research are concerned. New analytical techniques are continually developed and applied and other efforts to improve absorption, stability, and clinical effectiveness of many old drugs represent a way of life in research-oriented and quality-conscious companies. These usually include more elaborate testing and specifications than appear in the U.S. Pharmacopeia and National Formulary, which are chemical descriptive documents. Clinical research continues to be sponsored by research-oriented companies on many old drugs even though the products have been on the markets for years.

The 1962 amendments to the Federal Food, Drug, and Cosmetic Act have had the effect of increasing greatly the testing required before a new pharmaceutical can be marketed, increasing substantially the risk connected with administrative decisions concerning the continued investigation and marketing of products, and enlarging greatly the period between investments made in research and the beginning of any monetary return—to keep the cycle of research trial going with its many failures and only occasional successes.

If we are to make additional progress, industry must be allowed to continue to fulfill the role it has succesfully performed up to now—namely, synthesizing and experimenting, conducting the long and costly process of screening, the preclinical testing, development of production and quality control procedures, and finally the long clinical trials leading to accumulation of data showing the safety and effectiveness of drug products.

I hope that we will always keep our academic-Government-industry science teams working together, because doing so will lead to major new health benefits.

Dr. Van Riper will follow me and discuss clinical testing. This is his area of specialty.

Senator NELSON. Thank you for your fine statement. I have some notes on questions to be asked. I think what we had better do is get all the testimony in the record and if we have some time we will go back.

(The attachments to Dr. Scheele's statement follow:)

[1] See chart, p. 2352, infra.