In other words, Meticorten tablets amount to only about 2½ percent of the total corticosteroid tablet market. The relative importance of Meticorten volume, both in terms of the consumer's drug bill and with respect to Schering, is certainly not large.

Nevertheless, those who require this medication have every reason to ask why Meticorten tablets should cost more than products which contain the same active substance available from other companies at much lower prices.

The answer lies in the basic difference in the nature of the functions and services performed by Schering Corporation in our economy, as contrasted with those performed by distributors of generic prednisone. Schering Corporation and the generic distributor operate in such different ways as to be engaged in totally different businesses.

I am not, however, going to discuss the merits of the so-called generic products and the so-called brand-name products and the question of therapeutic equivalence. There is a considerable difference of opinion in the scientific community on that subject. The study now going on under Government auspices hopefully will throw light on this question.

Let me explain what I mean by "different kinds of businesses."

Schering Corporation is fully equipped and fully staffed with highly skilled research scientists to discover and to develop new drugs, to produce them under the most rigid standards of good manufacturing procedures and quality control, to disseminate promptly throughout the scientific and professional world full and complete information about such new drug discoveries, to make available a wide range of dosage forms to meet all physician needs, to market them widely in all parts of the free world, and to continue to service its discoveries for the medical profession.

These are the characteristics of our company; it is research-oriented, it manufactures products of the highest quality, it markets its products worldwide, and it is devoted to total service to the medical profession for the benefit of its patients. Implicit, however, this succinct statement is a host of detail, activity, and responsibility.

What follows is an oversimplified and only a partial list of what Schering does, and must do, to fulfill its role in today's complex and highly competitive world of medicinal products. Moreover, it is what Schering actually did for prednisone.

In the first place, we must search constantly and continuously for new and better compounds which may be formulated into new and better medicines. The industry's average, as you know, is one success for every 6,000 probes. We must investigate each promising new compound in a series of costly, time-consuming steps: first in the laboratories and then in animal testing, to determine the usefulness, and more importantly, to insure the safety, of any such compounds for testing in human beings. We must then develop pharmaceutical formulations so that the useful compound can be made available as a medicine in a variety of dosage forms. Additionally, we must develop manufacturing procedures, often novel and frequently complex; we must learn how to make, initially, limited quantities for release to a limited numbr of doctors for clinical investigation of the compound's effectiveness and safety in human patients; and later, if successful, larger quantities for marketing throughout the world. These investigations on the part of clinical investigators must be carefully supervised and monitored, the results meticulously correlated and analyzed, and a host of detailed information accumulated, which would take much too long here to catalogue.

Suffice it to say that the research work that has to be done in conneciton with the investigation of a new and promising medicine, in view of the elaborate and strict rules and regulations of the Food and Drug Administration in our country—and similar requirements abroad—is costly, time-consuming, and involves a myriad of details. All this takes a number of years—nowadays usually from 5 to 8 years. In the meantime, considerable additional investigation proceeds, more data are developed, more reports prepared and filed with the FDA.

Other areas of our company's operations are involved:

Our engineers must learn how to make the new drug in large quantities for commercial use—both economically and accurately.

Quality control scientists must develop standards, design tests to validate them, so that up to 24 different factors contributing to the safety and effectiveness of a single tablet or capsule or vial of injectable liquid can be guaranteed.

A marketing organization must be established and continually maintained