to assure that the product will be speedily available throughout the United States and the free world.

Scientific and clinical documentation about all aspects of the new drug must be carefully created and produced by us and then cleared by the FDA in Washington.

Our representatives—or detail men—receive a thorough, in-depth course of training so that they are fully knowledgeable concerning every aspect of the new drug—its usefulness, its limitations, its advantages, its "problem points"—in short, they must be thoroughly briefed to be able to provide full information and to answer the questions about the new drug which the physician might ask.

Our detail men must then call on those doctors who might possibly use the new drug in their practice, brief them fully on the drug's properties and recommended uses, and provide them with samples so that they can become acquainted with the drug. These personal calls on physicians, hospitals and pharmacies must be supplemented with further information in medical journals, in direct-mail literature, in brochures and the like—all of which must be consistent with FDA requirements.

I could easily devote more time to explain to you the wide scope of the activities that actually did go into our discovery, development and marketing of prednisone. I could, for example, refer to the symposia on prednisone which we sponsored for the scientific and medical community, the brochures we prepared, the films we created and distributed, the host of things we did to make this new and dramatically useful product known to the physician and available to his patients throughout the world.

How completely different is the business carried on by the large majority of the distributors of generic prednisone. For the most part, they are essentially distribution operations; in fact, many of them have the finished product manufactured for them. These companies do not develop new drugs. They do not have the scientific staffs nor the facilities to develop them. They do no animal testing or clinical investigation. Usually generic distributors do not work for years to gain government approval.

They do not introduce new drugs. They lack the personnel and skill necessary to communicate to doctors all that needs to be communicated to them about the indications for the drug, the dosage regimen, the methods of application, the side effects and precautions, and so on. They cannot answer questions about the drug's use in individual cases or provide other services to the doctor. They do not supply samples liberally to provide the doctor free trial and experience with the drug and free materials to use on indigent patients.

They do not provide special formulations of the drug to use in treatment of eyes, ears or other organs, or special strengths for treatment of children, the elderly or other groups. These markets are usually too small and specialized. They limit quality control activities to legal requirements. They do not, in short, encounter the major burden of costs necessary to develop and launch a new drug successfully and prove its worth.

Without these activities, generic distributors contribute little to medical progress.

On the other hand, after someone else has developed a drug and after someone else has incurred the costs of introducing it properly, so that it gains widespread usage, they are able to copy it as soon as copying is legal. When the active ingredient is well known and highly regarded, they take advantage of this to sell it cheaply, in quantity, and frequently on a mail order basis. They concentrate on the one or two forms in widest use and on types of users easiest to reach. Sometimes such companies concentrate on Government bids only and operate in such a way as to minimize investment in facilities and personnel. Their entire business is built upon the pioneering work of others. Their appeal is based solely on their contention that their cheaper versions have the same active ingredient.

In fact, this is what happened in the marketing of prednisone.

When all is said and done, it was Schering's research which discovered prednisone, Schering's development which gave that product to the world and to the medical community, Schering's marketing and distribution which made it known and used throughout the world, Schering's activities which broadened its usefulness, and Schering's licensing which made it available from so many distributors. Without all this, there would not be today any generic prednisone at all.

We at Schering are proud of our discovery of prednisone; it represented a real breakthrough. Indeed, every corticosteroid tablet preparation introduced since