

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 number 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 catalog.

Suffice it to say that the research work that has to be done in connection 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 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, in 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.