Mr. STETLER. Our following witnesses are going to discuss the testing that has been done, the quality control, the research and development, the medical aspects of manufacturing, and production and engineering.

The discovery of a new potentially useful product moreover is merely the beginning. It must then be developed, another long and costly procedure which often requires more pople, more processes and more time than the original discovery. This stage requires years of animal and clinical testing, and the submission of a New Drug Application, plus exhaustive supporting data to the Food and Drug Administration.

Because the innovator discovers new compounds and health-saving uses for them that have never before existed, he must be particularly sensitive to, and capable of, assuring purity, potency, and safety through the uncompromising high quality of his product. Quality control and quality manufacture are the sine quo non of the research-oriented pharmaceutical industry. These precise disciplines are inextricably linked with the operation of the innovator firm.

Briefly, they consist of indispensable specifications and tests for each ingredient in the formula, proper design and formulation of the product, multiple inspections and test during processing and packaging, final product checks, and the preparation of detailed and meticulous records to show the complete manufacturing and control history of each batch, and to enable the manufacturer to trace his products after shipment. Quality firms are well organized to recall with precision from all commercial channels any particular lot of a suspected drug product at any time, or to provide emergency advice as to where a particular drug product can be obtained when needed.

Beyond the production process, the drug product, in all its forms and dosages, must be available when it is needed, where it is needed. Through his system of distribution points, the innovator reaches the entire Nation.

Furthermore, through the same system, he can cover an emergency within hours in virtually any village, city or county in the United States. No matter what the market situation, his product—in its full line—is there whenever and wherever the physician needs it.

Senator, on page 6, where we describe the PMA, I could skip that.

I would like to start over on the top of page 8.

The pharmaceutical industry as we know it today is very young—less than 30 years old. Within these three decades, we have seen the emergence of a variety of new drugs that have all but revolutionized the practice of medicine—sulfonamides and antibiotics, cardiovascular preparations and antidepressants, vitamins, hormones, and tranquilizers—an impressive array of drug products that have virtually wiped out some killing diseases, have shortened the length of the average stay in hospitals, have reduced the space requirements of mental institutions, and have been a boon to doctors everywhere in the practice of their calling.

From 1940 to 1966, an amazing total of 823 new single chemical entity drugs were introduced as prescription drugs in the United States. That is the listing that was attached as a supplement that you referred to a moment ago.