Another key factor in our standard procedures is the maintenance of records covering all manufacturing, packaging, and control operations concerned with a product. These records must be prepared with such care as to provide a history of each batch of every drug product.

One of the most important parts of our system of in-process controls is the testing required to assure the identity, strength, quality, and purity of all raw materials and finished products. Periodic checks are made even after it has reached the pharmacist's shelf to make certain it measures up to the company's high standards. The quality-conscious manufacturer continues his testing as long as a product is on the market.

As a final step in this system of controls, the manufacturer must provide for the proper disposition of returned goods.

As an illustration of the importance of checks and balances exercised during pharmaceutical manufacturing by some firms, I think it's interesting to note that in one of our own company's routine manufacturing operations we conduct some 687 inspections and tests during the course of making a finished product. Among these are 215 different inspections and tests on raw materials, 395 checkpoints and tests during the actual manufacturing, and 75 inspections and counts during the packaging operations.

The manufacturing principles I have discussed have been followed by the leading prescription drug companies of this country for many years. It is generally agreed by those who have first-hand knowledge of these research-minded pharmaceutical manufacturers that their plants stand out in their communities as models of modern industrial facilities. Control of air pollution and maintenance of waste treatment facilities are among the important contributions such companies make toward their environment.

In 1965, the Pharmaceutical Manufacturers Association joined with the Food and Drug Administration and the University of Wisconsin in providing training in the principles and procedures of modern drug manufacture. In his opening address, the Dean of the University's School of Pharmacy stated:

"Today, this 'know-how' (of drug making) exists and is constantly expanding as new, more complex and sophisticated drugs and dosage forms are introduced. Unfortunately, at the present time this know-how is confined to a relatively small segment of the total pharmaceutical industry."

In concluding, Mr. Chairman, I should like to emphasize that the manufacture of quality drug products is a time-consuming and exacting process, requiring the best personnel and facilities. The reputable and responsible drug manufacturers of this country go as far as present-day technology permits in order to provide the highest-quality prescription drugs for the medical profession and the public.

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Education:

Hobart College, 1936, AB—Biology and Chemistry.
Ohio State University, 1941, M. Sc.—Chemical Engineering.
Graduate Studies, University of Rochester, Administration; Princeton University Extension, Chemical Engineering.

Experience:

Vice Principal and Instructor: Shortsville High School, 4 years.
Merck & Co., Inc.—Positions from 1941–1958 in order, 17 years Supervisor in Pilot Plant and Chemical Engineering Division; Chemical Design Engineer; Manager Production Standards; Manager Industrial Engineering: Manager Design and Construction.
Merck Sharp & Dohme, Pharmaceutical Division: Chief Industrial Engineer.
Merck & Co., Inc., Chemical Division: Assistant Director of Engineering.
McNeil Laboratories, Inc. (1958 to present, 9 years): Director of Engineering, Vice President of Manufacturing and Engineering.

Professional Organizations:

American Institute of Chemical Engineers.
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