STATEMENT OF LELAND W. BLAZEY, VICE PRESIDENT, MANUFACTURING, ENGINEERING, AND PURCHASING, McNEIL LABORATORIES, INC., FORT WASHINGTON, PA.

Mr. BLAZEY. Mr. Chairman, I would like to have my statement which was submitted for presentation on November 16 made a part of the record.

Senator NELSON. Your statement will be printed in full in the record. You may read from it or extemporize, or present it in any way you wish.

Mr. BLAZEY. I would prefer, Mr. Chairman, to abstract some paragraphs from it, and I will let you know what pages I have deleted as I proceed through it.[1]

Senator NELSON. All right.

Mr. BLAZEY. My name is Leland W. Blazey. I am vice president in charge of manufacturing, engineering, and purchasing for McNeil Laboratories, Inc. I am appearing today on behalf of the Pharmaceutical Manufacturers Association.

Senator NELSON. Where is McNeil Laboratories' home office?

Mr. BLAZEY. Fort Washington, Pa., just outside of Philadelphia.

Senator NELSON. Is this where your manufacturing is done?

Mr. BLAZEY. Yes.

Senator NELSON. All of it?

Mr. BLAZEY. Yes.

Mr. GORDON. That is a subsidiary of what company?

Mr. BLAZEY. Wholly owned subsidiary of Johnson & Johnson.

Senator NELSON. There is another rollcall. I have to answer it.

(Whereupon, there was a short recess.)

Senator NELSON. Go ahead. Sorry about the interruption.

Mr. BLAZEY. Since the early forties, I have worked with several pharmaceutical companies and have participated in some of our industry's pioneering efforts in design and process procedures relating to antibiotics, medicinal chemicals and pharmaceutical products.

As one who has been trained in the techniques of pharmaceutical manufacturing and engineering, I shall attempt to explain the great care which goes into the manufacturing operations of the research-oriented, quality-conscious companies in our industry.

In particular, I shall try to point up how this dedication to quality is a distinguishing characteristic of the most respected prescription drug manufacturers in this country.

To begin with, manufacturing facilities and equipment must be adequate for the highly technological science of making safe and effective drug products. But more than that, it is essential that we have top-caliber personnel in sufficient numbers to do this highly complex job.

Although the FDA's good manufacturing practice (GMP) regulations outline the general conditions under which prescription drugs are to be produced, there are wide differences in the actual operations of quality manufacturers and those of less responsible companies. The quality-conscious companies go well beyond basic FDA requirements.

[1] The complete prepared statement and attachment submitted by Mr. Blazey for presentation on Nov. 16, 1967, begins at p. 2377, infra.