Control of air pollution and maintenance of waste treatment facilities are among the important contributions such companies make toward their environment.

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.

After all, it is not just the wood that makes the Stradivarius violin; it is the skill of the craftsman. It is not just the fabric that makes the fine suit; it is the skill of the tailor. So it is with prescription drugs. In the final analysis, differences in manufacturing process and controls can make the difference between good health and bad, between comfort and pain, and even between life and death.

Thank you.

Senator NELSON. I thank you.

(The complete prepared statement and attachment submitted by Mr. Blazey for presentation on November 16, 1967, follows:)

STATEMENT OF LELAND W. BLAZEY, VICE PRESIDENT, MANUFACTURING, ENGINEERING, AND PURCHASING, MCNEIL LABORATORIES, INC.

MANUFACTURING CONSIDERATIONS IN QUALITY DRUG PRODUCTION

Mr. Chairman and members of the committee, 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.

Since the early 40's I have worked with several pharmaceutical companies on technical assignments in development, engineering and production. Together with other technical personnel, I participated in some of our industry's pioneering efforts in design and process procedures relating to antibiotics, medicinal chemicals and pharmaceutical products.

I have also been responsible for directing the planning, engineering and construction on many projects dealing with chemical, pharmaceutical and research facilities in the United States and in foreign countries.

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 F.D.A.'s Good Manufacturing Practice (GMP) Regulations outline the general conditions under which prescription drugs are to be produced, there are wide differences between actual operations of quality manufacturers and those of less responsible companies. The quality-conscious companies go well beyond basic F.D.A. requirements. As a matter of fact, many of these firms did not find it necessary to make significant changes as a result of the 1962 Amendments to the Food and Drug Act and the subsequent promulgation of GMP regulations. Because of the high standards they had set for themselves over a period of many years, they were already in compliance with most of these new regulations.

As new medicinal agents have been discovered, our industry has recognized the need for constantly improving manufacturing methods and equipment.