of Compliance in the Bureau of Drugs. To my left is Mr. Bob Wetherell, who is in charge of our Office of Legislative Services. Mr. Peter Barton Hutt, our General Counsel, who usually accompanies me on these occasions, could not be here. He will try to get here later, but is now attending another Senate activity.

My statement is a little long. As I go through, I will try to summarize some areas, if that is acceptable to the committee.

Senator NELSON. You go ahead and present it in any way you wish. We have the time if you desire to read it, and we shall have some questions to ask as you proceed.

Dr. SCHMIDT. All right.

We are pleased to discuss our drug quality assurance programs and the effect these programs may have on other Government agencies involved in drug procurement and reimbursement.

Let me begin by stating that the pharmaceutical industry must bear the primary responsibility for assuring the production of high quality drugs. The Food and Drug Administration's role is to assure that manufacturers meet their responsibility. We do so by setting appropriate standards for the manufacture of drugs and by carrying out surveillance activities such as factory inspections and analyses of selected products. When firms do not meet their responsibilities, the Federal Food, Drug, and Cosmetic Act provides us with authority to take certain measures to bring about correction and/or to remove offending products from the market.

Our quality assurance programs for drugs are aimed at providing optimal assurance of drug quality to all physicians and consumers. These programs employ a major portion of our field manpower available for drug work and range in approach from continuing surveys of the manufacturing practices of selected drug firms to intensified targeted programs such as certification of specific products or plant inspection and analyses involving a certain product with identified problems.

The Federal Food, Drug, and Cosmetic Act requires inspection of every drug firm at least once every 2 years. In fiscal year 1973, we inspected 2,700 registered human drug establishments and made some 7,000 inspections of registered and related drug establishments.

Senator NELSON. Doctor, you mentioned 2,700 establishments. How many are there in the United States that manufacture drugs?

Dr. SCHMIDT. Well, counting all registered establishments of all kinds for all drug products, about 14,000 have registered during the biennium of 1971 to 1973. This is a very inclusive number, however.

Senator NELSON. Are these both prescription and nonprescription establishments?

Dr. SCHMIDT. Yes, sir. These include companies of all sizes that make prescription drugs, nonprescription drugs, food and bulk drugs, animal drugs, and so forth.

Senator NELSON. Do you inspect only those that manufacture prescription drugs, or do you inspect those that manufacture both prescription and nonprescription?

Dr. SCHMIDT. Well, as I just said, the requirement is, as you know from various speeches and remarks that have been made, the requirement is that we inspect all firms at least once every 2 years.