

would tend to cast doubt on the quality and vigor of FDA's quality assurance program. The Pharmaceutical Manufacturers Association has widely quoted Mr. Feinberg's statements and relied heavily on them in opposing Secretary Weinberger's proposals for drug reimbursement costs.

Mr. Feinberg has testified before State legislative bodies in opposition to the repeal of the ant substitution laws. This subcommittee has asked the DOD for material to support Mr. Feinberg's charges. This material will be placed into the record of these hearings at the appropriate place. A copy of this material was also given to the FDA and others for comment and analysis.¹

In addition, members of the office of compliance of the Bureau of Drugs visited the DPSC in Philadelphia to ascertain precisely what kind of data could have been the basis of Mr. Feinberg's many speeches and articles.

We would like to have you discuss this matter and these data in detail. For example, Mr. Feinberg stated that: "We develop definitive product specifications which often exceed official or commercial standards."

On the basis of the material submitted to you, would you please tell us the significance of these so-called extra requirements and the kind of drugs to which they are applied. Have any complaints about drugs or their manufacturing plants been submitted to the FDA by the Defense Department in the past 5 years?

Have they ever resulted in FDA action? In other words, has DPSC ever given you information sufficient to bring about an action on your part?

Given the information you have about DOD from the data they submitted to us and your examination of data in Philadelphia, how would you compare DOD's quality assurance program in size as well as quality with the FDA's? How significant really are DOD's activities in this field?

Would you mind commenting on that?

Dr. SCHMIDT. Mr. Chairman, I might make first just some general comments, and then if there are areas that you wish to explore in a more detailed fashion we can double back on it.

I myself became aware of these particular speeches by reading them, and it may be that my scientific background helped me in evaluating them as I read them. But I was not particularly alarmed or upset by the speeches myself, because they were general. There were no specific figures or times or any solid evidence contained in the speeches.

Mr. GORDON. Excuse me, Dr. Schmidt. There were some specific figures with respect to rejection of drugs and manufacturing plants.

Dr. SCHMIDT. Well, again, I guess I began by saying that perhaps my having read scientific literature for 20 years or more kind of helped me with this, because if I see a figure that says 43 percent, and it does not say 43 percent of what, I generally skip to the next article.

¹ See page 9978.