

Mr. GORDON. Were there cases of the companies refusing to tell who actually manufactured the product, or did they disclose everything?

Dr. APPLE. Mr. Gordon, I cannot say that they refused. But as of the compilations in November and December—October and November, rather—there were a number of firms that had not responded to the request for the information. In the article, the tables here show the actual date replied. In a number of instances there are blanks—actually it states “no reply.”

Mr. GORDON. What about these statements that Mr. Feinberg has been making about the rejection rate on DOD plant inspection is 45 percent, and the rejection rate on precontract award sample inspections is 42 percent?

The FDA explained what that meant yesterday.

Do you have any comments on that?

Dr. APPLE. Well, Dr. Feldmann may later on. He has studied the tables, and I have not. I can make this general observation. My concern when I hear a statement that 45 percent of the manufacturers have been rejected—I am interested in what the universe is, because it would be like my going up to Walter Reed Hospital or Bethesda Naval Hospital and going into the VD ward and then walking out of there and saying that 90 percent of the patients have venereal disease. Well, sure they do in the VD ward. But this does not characterize the total universe of patients in that hospital. So I think these statements that you cited are grossly misleading, and they are intended to be inflammatory and cast suspicion on the Nation's drug supply.

This is not to say that every firm meets the criteria. But I am saying that these are generalizations that we have been trying to find some documentation for.

Mr. GORDON. Well, you have the documentation. We gave it to you.

Dr. APPLE. Well, Dr. Feldmann will comment on that. He has studied that material. I have not, Mr. Gordon.

Mr. GORDON. All right.

Senator NELSON. Our next witness will be Dr. Feldmann, Associate Executive Director for Scientific Affairs of the American Pharmaceutical Association.

Go ahead, Dr. Feldmann.

Dr. FELDMANN. Thank you, Mr. Chairman. I am Edward G. Feldmann of the American Pharmaceutical Association.

You have requested that we discuss the views of the APhA on the potential value and usefulness to pharmacy practitioners of data and information secured by the Defense Personnel Support Center—DPSC—of the Department of Defense.

In order to provide a frame of reference for our response, as well as our interest in obtaining such data and information from DPSC relative to drug products and pharmaceutical manufacturers, permit me to describe briefly our ongoing involvement and activities in the area of drug product quality.