

a team from the FDA to visit that Agency, which they did. And I made sure that there will be effective communication henceforth, at least out of our Agency.

Senator NELSON. All right.

Go ahead, Doctor.

Dr. SCHMIDT. Well, if I might, I would like to just make one point about digoxin. You have heard much about bioavailability problems, and the digoxin story is such a nice example of an important drug in which problems arose. The first problem turned out to be content; the second problem turned out to be a dissolution problem.

We have instituted a program to handle the problem. In recent months and years much has been learned about bioavailability problems, even though it is a young field. And we can now say that these problems are manageable, and I think that the digoxin story is a kind of case history that demonstrates the bioavailability problems very well.

Mr. GORDON. Dr. Schmidt, I just want to go back to another problem that the Chairman was talking about just a few minutes ago, that is, about your contacts with the DOD.

The DOD stated in material given to us that there is a close working relationship between Defense Personnel Supply Center (DPSC) and the personnel of the FDA. As far as I can see, there is no such thing as of now, anyhow.

Would that be correct?

Dr. SCHMIDT. Well, I do not believe we had a close working relationship in the last few years with the DPSC. At least it does not meet my definition of close.

Senator NELSON. But you do now?

Dr. SCHMIDT. Well, very recently, we do, because I sent a team up there. I was intrigued by Mr. Feinberg's speeches, and it stimulated me to get a closer relationship.

Senator NELSON. Please proceed.

Dr. SCHMIDT. Thank you.

In my prepared statement I use another example of this problem, the large volume parenteral problem which I mentioned, and I would skip over that since we have talked about them.

Another program we have for monitoring drug quality is a joint effort involving the various pharmaceutical associations, the USP and FDA. Under this program, pharmacists across the Nation report apparent product defects or problems to the USP. Copies of these reports are furnished to the manufacturer or other distributor of the product in question and to the FDA. Based on the evaluation of these reports, we issue investigatory assignments to the field when indicated, or in some cases institute special programs or surveys.

During fiscal year 1973, we received 2,750 program reports. The program, while still young, is expanding at a very rapid rate as demonstrated by the fact that we have already received 2,350 reports for the first half of this fiscal year. We find in looking very recently that our reports now are coming in at the rate of about 1,000 a month, so that we believe this will be an extremely productive information gathering source.

I include an example on page 7 of the problem that came up with