

which digoxin is one. Both the FDA and USP responded at that time to DPSC's inquiries about its concern over tablet uniformity. With the laboratory assistance of FDA, DPSC recalled another batch of digoxin in 1970. Lack of content uniformity was the reason for this recall.

With the advent of the radio immune assay technique for measuring serum digoxin in 1970-71 there came about the laboratory capability to compare the bioavailability of various batches of digoxin. Prior to this time the testing of digoxin tablet content uniformity had to be done by in vitro methods.

Now, that is one reason for the apparent confusion between the statement regarding digoxin on page 5 of your statement. We are really talking about two different things. The DPSC was alerted by the clinicians that something was wrong with the digoxin. Actually, clinical impression was the thing that led to suspecting the drug. It was not until later that a laboratory test of bioavailability of this substance became available.

Mr. GORDON. General Hayes, the material submitted to us states that FDA was not informed of the problem.

General HAYES. Well, further investigation of that leads to some suggestive but incomplete evidence that there was correspondence between us and the FDA. It is not conclusive, but I think it is very suggestive. Unfortunately, it was not followed up to any extent.

Senator NELSON. Do you have a standard routine policy now of notifying the FDA of any problems that you may come across in terms of the quality of drugs that the DOD uses or any other aspect of good manufacturing procedures?

General HAYES. At this time, yes.

Senator NELSON. When was that program instituted?

General HAYES. It was really implemented properly, I would say, only in about the last year and a half.

Senator NELSON. But it is now a part of the routine procedure?

General HAYES. It is routine now.

Senator NELSON. Go ahead.

Mr. GORDON. You were saying something, General, before I interrupted you.

General HAYES. No, that is all right.

Mr. GORDON. General, Mr. Feinberg secured permission to make the statements and write the articles we referred to, did he not?

General HAYES. That is correct.

Mr. GORDON. Now, the person who gave permission, the person with whom he cleared these statements, did he know what was being said and its significance?

General HAYES. I can't answer that, I just can't answer that question.

Let's put it this way: Mr. Feinberg followed the proper procedure. He obtained clearance.

Senator NELSON. Go ahead, General.

Where are you in your statement, General?

General HAYES. I am not in my statement. I am still responding.

Senator NELSON. All right. Go ahead.