

revision announcement. And again, the FDA has been implementing that, as was testified to by Commissioner Schmidt.

Now, in the DPSC material that DOD supplied to you, they indicate in answer to your question—about when did they become aware of this, question 15(d)—they indicate that they learned of the problem in 1965. But they do not say what the problem was. They do not identify it in any way.

You also asked them about whether they supplied information about this to the FDA, and they responded there is no record on this. Their explanation is that this was before the so-called Intergovernment Professional Advisory Council, or IPAD, was fully operational.

I find this a little puzzling, because further on in their same response under 15(d), they say that they were regularly supplying such information—for at least several other products that are listed—going back to May of 1961; they supplied information in 1961, 1962, 1963 and so forth. So I do not quite understand that as an explanation.

Senator NELSON. Well, there is another contradiction, it seems to me, and that is, the Intergovernmental Professional Advisory Council on Drugs was established in July 1963, 2 years before the Department of Defense said they discovered problems with digoxin.

The other question is, why do you need an intergovernmental advisory council anyway; if you found some serious defect in a drug you would think that the agency would feel the responsibility forthwith, if it were a matter of any consequence, to notify the Food and Drug Administration.

Would you not?

Dr. FELDMANN. Well, I would think that it is desirable by whatever mechanism you choose to use to have exchange of information, whether it is this intergovernmental council or some other mechanism.

I would be more apt to question how effectively this particular operation has worked to achieve that intended purpose. The indications I have gotten are that for the most part information has been irregularly exchanged, and where it has, it has been largely provided to the DPSC, rather than the reverse being the case.

Senator NELSON. Well, since the DOD does not recite what the problem was, we do not know whether it involved a question of bioavailability or a question of product uniformity or neither.

Dr. FELDMANN. Correct.

I would also expand on my earlier statement to indicate to you that whether or not they informed FDA—and they apparently have no record—certainly they did not inform the professions. They did not inform the APhA, who, as I have indicated just in my immediate preceding testimony, has over the years made an effort to disseminate such information to the professions—to alert the professions, particularly pharmacy, but also the health professions in general, when to be alert to a potential problem or to take note of it.

And I think it is most unfortunate that they have not seen fit to make such information available, if indeed they have had it.