

Dr. SCHMIDT. Acetazolamide, acetylsalicylic acid in two forms. This list is 13 drugs, and 2 of them are acetylsalicylic acid in 2 different forms.

Ampicillin, chloramphenicol, both of which, of course are antibiotics; digoxin, which we have mentioned; diphenylhydantoin pediatric suspension form; nitrofurantoin; oxytetracycline, which is another antibiotic—these, of course, are batch-tested; phenylbutazone.

Senator NELSON. Not tetracycline itself, but oxytetracycline?

Dr. SCHMIDT. I am sorry. Would you say that again?

Senator NELSON. You mentioned oxytetracycline. You did not include the parent drug, tetracycline.

Dr. SCHMIDT. The antibiotics we are batch testing, as you know.

Senator NELSON. You mean this one tetracycline—

Dr. CROUT. No. Tetracycline is also on the list. We are coming to it.

Dr. SCHMIDT. I mentioned oxytetracycline, then phenylbutazone; riboflavin sugar coated tablets; then tetracycline hydrochloride, which is a plain tetrachloride; and then finally, trisulfapyrimidine, another pediatric suspension.

Now, I would again hasten to add that digoxin and the antibiotics and so on are batch tested, so that while there have been substantiated bioequivalency problems, we feel these problems are being managed.

When I said in my testimony that I felt that the bioequivalency area is being overdrawn, what I mean by this is that a lot of enthusiastic people are in the field hunting up names of drugs that have been suggested that might have bioavailability problems or whatever.

I think that one must be precise, and logical, and scientific in his thinking about such problems. And I have been unsuccessful in finding any large mysterious problem area that people hint at in their testimony about drugs.

Mr. GORDON. Well this has become a WPA project for many people. It puts them to work to try to dig up these drugs.

Excuse me, Commissioner. Did you say that these drugs that are on the market—say tetracycline—may present a bioavailability problem. Those that are on the market, however, are bioequivalent, are they not?

Dr. SCHMIDT. Well, this list is a list of drugs which we feel meet our requirements for having had a genuine bioequivalency problem. This is not a list of current problems.

Mr. GORDON. Oh, not a list of current problems.

Senator NELSON. Is it feasible for chemists, pharmacologists, scientists, to make an educated guess in advance, about what kind of a compound and what kind of a form might likely present the bioavailability problem?

Dr. SCHMIDT. Yes. And I think very importantly we have in our regulations—and again, I mentioned that we will deal with this problem—dealt with this issue—perhaps I could ask Dr. Crout very briefly to—

Dr. CROUT. Yes. I think the answer is yes. And there is increasing data in that area. It is a little easier, I think, to specify the kinds