

versity community. I think it is something that the drug industry itself and the FDA could work out with some consultations from the university community.

Senator NELSON. Well, as you proceed to clinically test the most frequently used drugs, will you be doing some contracting?

Dr. GODDARD. Oh, yes. I may have misunderstood the chairman's question, but I thought you were talking about the technical aspects of manufacture. If you are talking about the determination of therapeutic equivalency we will be working with the Public Health Service, hopefully the Veterans' Administration. We have opened discussions with them. We have a contract with the Georgetown University facility, defining certain drug classes that they are going to examine. Hopefully other parts of the university community will become involved.

Senator NELSON. I talked to Mr. Barrows just very briefly at one of the hearings. My interpretation of our brief conversation was that he was hoping that some of the distinguished universities could take over some of the testing job that needs to be done. Let me ask you this. Do you intend, in the clinical testing of these drugs, to follow a procedure in which you might contract with teaching hospitals to do double blind clinical testing?

Dr. GODDARD. We will be involved with contracts with teaching hospitals. As I indicated, we are negotiating with Veterans' Administration now. Many of these are teaching hospitals, research centers. We will also be working with the Public Health Service and also hopefully other parts of the academic world.

Senator NELSON. How many drugs are you selecting for such testing?

Dr. GODDARD. Probably no more than 50 classes, in other words, 50 different products where the drugs are made by more than one manufacturer, and the number of drugs then will be a function of how many are available in the class. For example, with rauwolfia, there are 42 different products in the market in place of straight rauwolfia. Obviously, I think it would be unwise to test all 42 of these. So, we will select some and test them and try to identify critical benchmarks to be tested with respect to the others, either in a laboratory or in animal testing.

Senator NELSON. So, you will be doing both chemical testing in the lab and, with a certain number of the drugs that you select, clinical testing as well?

Dr. GODDARD. Yes.

Senator NELSON. Then, if you can establish some kind of benchmarks, you may require that the other companies meet those benchmarks?

Dr. GODDARD. Or we may just simply carry out the test on the other products in that particular class and check those benchmarks in animals, let us say, as an example. If we find those acceptable, then we can publish the results and say, look, doctor, as far as drugs in this category are concerned, at this time of testing there were no differences.

Now, it could be made as part of the quality control procedure in the GMP's to require that certain animal tests, if these benchmarks are established, be carried out by the manufacturer. That is possible. So, we still have a way to go on this.