

that these drugs which are already in solution will be absorbed very rapidly.

Among those which are in solid form, we have given top priority to those which are of relative low solubility, with relative insoluble active ingredients. Those which are highly soluble, those which it has been demonstrated by some of the FDA and Public Health hospitals, are quickly dissolved.

Of the drugs which we feel demand top priority, there are only two or three dozen drugs which will require testing at the outset. This is not an inhuman job by any means, and we are on our way to doing it.

But this job, Senator, will never be completed. Because as soon as a drug comes out from under patent, and it becomes legally possible to make new generics, these will probably have to be looked at in the same way.

I recognize that there is one school of thought which says that we cannot make any statement about generic equivalency or lack of equivalency until we have tested all generics. In a way, this is true. Thus, we cannot say that all the tablets of a particular product meeting USP requirements will meet those requirements, because we have tested only a certain sample—and the only way we could test them all would be to destroy them all—but I think this kind of sampling although it is not 100 percent sure, gives us the practical protection that we require.

Senator NELSON. As I remember it, Dr. Goddard was intending to select a number and complete some kind of a study within the limits of some particular period of time; isn't that correct?

Dr. SILVERMAN. It is our expectation, sir, that the top priority drugs will be completely assayed by 1970.

Senator NELSON. 1970?

Dr. SILVERMAN. Yes, sir.

Dr. LEE. There is one other aspect of this, Mr. Chairman. One is this continuing study which Dr. Silverman has described. And the other is the sampling of drugs in the marketplace to make sure that they do in fact meet the standards, as an additional protection for the consumer of the drugs. The drugs tested will be taken out of pharmacies, drug-stores, and sampled and tested in the FDA laboratory in St. Louis. This will be a continuing surveillance operation to make sure that even with the good manufacturing practices and even with meeting the official standards, that, in fact, in the marketplace the drugs continue to meet the requirement standards.

Mr. GORDON. I have one nitpicking question. You say there are only two or three which demonstrate an initial lack of equivalency and one of them has no practical clinical importance. Are there two or three? Which is it?

Dr. LEE. Dr. Silverman.

Dr. SILVERMAN. There are two. One of them, as you have probably surmised, is chloramphenicol.

Mr. GORDON. There are two, but one has no practical—

Dr. SILVERMAN. The second one is tetracycline. And in the article cited in this publication, the scientists who wrote the article pointed out quite clearly that although differences were detected these were not of any clinical importance.