Senator NELSON. I suppose that in order to be scientific about it, you have to check some other batches to find out whether this is a shelf problem or accident.

Dr. GODDARD. Surely. Exactly; yes, sir.

Dr. BANES. These products are used, of course, in huge volume and these instances that I have cited are isolated instances. Nevertheless, we do wish to investigate them to see if there is any substance to these complaints.

Mr. GORDON. Do you know from the FDA's own experience that, even in these limited cases, there was a lack of clinical equivalence?

Dr. GODDARD. Do you mean our own direct experience? No; for example, the Defense Supply Administration has asked us upon occasion to check a particular drug they have purchased for potency and all other aspects that can be measured in the laboratory—particle size, dissolution rate, all the other characteristics. This we have done. They have told us there are problems with therapeutic equivalency, that their physicians have complained. And in at least one instance that I can recall, we checked it and chemically it was identical. But it subsequently developed on that one that too much of the crystalline form was present, not enough of the amorphous form, so there was a rationale for the physician's complaint.

Mr. GORDON. Did it meet USP standards?

Dr. GODDARD. At that time.

Mr. GORDON. How about at the present time?

Dr. GODDARD. USP standards are in the process of being changed.

Mr. GORDON. So if it meets USP standards, today's USP standards, it might have been violative?

Dr. GODDARD. I do not want to leave the committee with the impression that I am convinced that simple adherence to USP standards alone or NF standards will guarantee therapeutic equivalency. This is a complicated business. I think it is our job, however, to make certain that if manufacturers adhere to those standards, there is a very slight probability that there will not be therapeutic equivalency. That is going to require some clinical testing and that is what we are engaged in.

Senator NELSON. Would it be fair to extend your remark further to say that there is very little clinical evidence to show that if USP standards are met, drugs are not clinically equivalent either?

Dr. GODDARD. That is correct. They are only isolated instances.

Senator NELSON. And the FDA intends presently to begin selecting frequently used drugs and to test them to settle this issue?

Dr. GODDARD. Yes, sir.

Senator NELSON. I think that this testing program will be a great contribution to the public, the medical profession, and even the manufacturers if we can settle the question of equivalency.

Dr. GODDARD. Even at this time I would challenge the claim that you always have to buy a brand-named product in order to be sure that a drug is good. Poor manufacture and control will produce a bad brand-named drug just as surely as it will produce a bad generic-named drug. Manufacturers of brand-named drugs have yet to show that their products are, in fact, produced in all cases to meet subtle refinements over and above basic standards of therapeutic excellence that in any significant way affects the health and well-being of our people. I hope