up some of the work being done through the surveillance program. This is a system of reporting in by pharmacists and others, through the USP, when they find defective products. This eventually results in investigation of that product and possibly recall from the market, but this also tells FDA is attempting to provide part of this assurance through a surveillance program.

Now, had all of the other activities been thorough and adequate, these very defective products, dangerously defective, some of them, would not have been on the market, would not have gotten out into pharmacies and hospitals to be detected by the private sector and to be reported into FDA.

Senator ABOUREZK. In the absence of the specific evidence I have asked for, then I assume—I have got to interpret your position—correct me if I am wrong—your position is unless there is a 100 percent foolproof method of assuring that no product will ever get on the market that will have a different standard from what should be required, that would be against the MAC program, Now, that is my interpretation, am I wrong?

Mr. TRYGSTAD. Well, I think 100 percent assurance would be pretty hard for anyone to give, and possibly impossible.

Senator ABOUREZK. Well, that is what you are asking for, is it not?

Mr. TRYGSTAD. The assurance is not there today, and the plans——

Senator ABOUREZK. Is there any percentage of the assurance there today? Any part of it?

Mr. TRYGSTAD. Well, of course, we are better off today with the inspection procedures and requirements than with nothing, but we are not far enough along the way to just let any product be substituted by the government or anyone else for a product that a physician has confidence in and has been using on his patient.

Senator ABOUREZK. How far along are we, in your opinion, in being able to provide that assurance?

Mr. TRYGSTAD. I do not know.

Mr. GORDON. Mr. Chairman, may I interrupt for a second?

Senator ABOUREZK. Sure.

Mr. GORDON. Dr. Novitch of the Food and Drug Administration who accompanied the Secretary of HEW yesterday is here in this room, and perhaps he could enlighten us.

Dr. Novitch, could you step forward, please?

These programs that the Secretary referred to yesterday, will they be adopted before the MAC regulations go into effect?

Dr. NOVITCH. Yes. The bioequivalence regulations will be proposed before the MAC regulations become a final regulation.

Mr. GORDON. And the inspection programs and all of the other programs?

Dr. NOVITCH. Well, all of the other programs are in place and are constantly being improved. As Mr. Trygstad said, you cannot get 100 percent assurance, but the programs that are in place now, we feel, give a high degree of assurance for all drugs in interstate commerce, and they are constantly being improved.

Beyond that, the MAC regulations are intended to begin with drugs where there is no evidence of a bioavailability problem. In other words, we'll begin with those where there is reason to believe