He went on to describe FDA's drug quality program, plant inspection program, drug product surveillance program, and other programs, as well as bioequivalence regulations which will be published soon.

Now if you believe that the program that he described is not adequate, what specific evidence do you have that you can present to this committee that it is not?

Mr. TRYGSTAD. I think he has given his own evidence of the inadequacy of their present and past performance.

Senator ABOUREZK. What is that evidence?

Mr. TRYGSTAD. By enumerating the improvements they intend to make. Now the key word in that statement is "will." The steps that FDA has taken and will take to insure the safety a quality and so forth. These are unimplemented programs.

Senator ABOUREZK. May I ask you again what evidence do you have or can you produce for this committee to show that the Department of HEW cannot assure that drug products covered by the program all meet the same high standards of quality, using his words? Do you have evidence you can produce for the committee?

Mr. TRYGSTAD. I do not have evidence with me. I can give you a couple of references. In 1973 there was a General Accounting Office report made on inadequate inspections in a number of drug plants, and inadequate followup on them.

Senator ABOUREZK. How long ago was that?

Mr. TRYGSTAD. 1973.

Senator ABOUREZK. Was that the study? Do you think that is still valid 2 years later?

Mr. TRYGSTAD. I have no reaon to believe it is not. I would assume, of course, that——

Senator ABOUREZK. Well, what we are interested in is today, March 1975. At the time this proposed MAC program is to go into effect, what evidence can you provide that they are not ready to assure that standard of quality?

Mr. TRYGSTAD. I will have to go back to the Secretary's own statement that they are making plans to carry out these additional safeguards, improving the Good Manufacturing Practices, improving the inspections, improving the testing techniques that would be required. I cannot enumerate them all. You probably have them in front of you. But these are things that obviously are not adequate today or he would not have said we will improve them in the future. These are new programs he is talking about.

Senator ABOUREZK. And if he does them in the next month or so, will that be sufficient to meet your standards?

Mr. TRYGSTAD. It cannot be done in the next month or so.

Senator ABOUREZK. It cannot be done in the next month or so? Why not?

Mr. TRYGSTAD. Well, of course, I cannot say what the timetable is on these, but government programs do not work that way. I would like to point out to you one other interesting bit of FDA information.

In 1974 about mid-year, July, there was an article in the FDA "Consumer." It was on their surveillance program. Now, this pointed