tions, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved on the basis of which it could fairly and responsibly be concluded by such experts that the drug would have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof."

So, that definition of the standard was published in 1962. Counsel advises me that this was part of the Kefauver Act of 1962. So it has been 10 years since they knew what the standard would be. And it seems peculiar to me that they are still fussing around about producing evidence of effectiveness of the drug when they have had 10 years notice that that is what they had to do.

Dr. FINKEL. Well, the definition of "substantial evidence" really was not defined until May of 1970. What I meant was that there is a difference of opinion as to the definition of what constitutes substantial evidence and how it is to be obtained.

Senator NELSON. And how clear a notice can you have that you have to produce scientific evidence of effectiveness? The law says it in considerably more detail. The point is that the drug companies know what that means, and they know that they have got a drug in the marketplace, and they have to prove that it does what it claims it does, and if they can't prove that this does what they claim it does, then it is not to be permitted to be marketed under the Kefauver amendment.

Do you think there is any misunderstanding by the drug company that they had to prove that the drug effectively attacks the target organism that they claim it attacks, or the physical situation that they claim that it relieves? There isn't any doubt about that, is there?

Dr. FINKEL. I don't think so. But I think in some cases there has been a difference of opinion as to what constitutes substantial evidence.

Senator NELSON. I can only conclude that they have filibustered for 10 years, and the Government has been far too lenient in permitting them to continue to maintain less than effective drugs in the marketplace.

Ten years is an awfully long time. And the drug should not have been on the market in the first place if they couldn't prove that they do what they claim they do. And if 10 years later you are still arguing about "possibly effective" and "ineffective" and "probably effective" drugs, it is disgraceful, I think.

Mr. SEGGEL. Mr. Chairman, may I make a comment on that?

Senator NELSON. Yes.

Mr. SEGGEL. I am not familiar with all the past history you mentioned, but I will say this, that the Department is moving in aggressively now. The Food and Drug Administration is being greatly strengthened to carry out its regulatory function and has received a large increase in its budget. For a long time FDA didn't have the resources to do all that was necessary. What we are now doing is moving into the specific processes by which the requirement of that act can be carried forward effectively.

Mr. GORDON. The chairman previously referred to the memo that was sent out by the Surgeon General on December 11, 1970, to all agencies of the Department of Health, Education, and Welfare.