supposed to be effective. In fact, there is supposed to be substantial evidence of efficacy in addition to safety. How do we get to this "possibly effective" and "probably effective" business anyhow at this point?

Dr. FINKEL. Well, we feel, and the National Academy of Sciences felt, that there was some evidence of efficacy, and that is why they have used that classification of "possibly" and "probably". And we want to give the patients the benefit of the doubt and see whether efficacy can in fact be established. When those drugs came on the market the methods for studying them were unsophisticated. And some of them may indeed be effective. In fact, we have raised some, "possibly effectives" to "effective." And we feel that the drug should be studied according to present day methods before we make the final decision.

Mr. GORDON. How long are you going to study them? You gave the "possibly effectives" 6 months. It is many years for some of them and they are still on the market.

Dr. FINKEL. We recognize that 6 months—or even a year, for the "probably" effectives—is insufficient to develop and perform clinical trials and analyze them. So that we have allowed extensions for a good number of drugs where the firms have been interested in doing the studies. For many of the "possibly effectives" drugs—a number of firms have simply decided that there was no commercial interest, and have removed the drugs from the market.

Senator NELSON. Let me ask some questions just to refresh my memory.

We have had some testimony on this in the past, and it is vague in my mind.

The Kefauver amendment, which was passed in 1962, provided that, in addition to safety, substantial proof of efficacy had to be presented to maintain the drug in the marketplace. Was it, then, in 1966 when the implementation began under Dr. Goddard?

Dr. FINKEL. Yes.

Senator NELSON. And when did the drug companies get notice that the National Academy of Sciences was following the procedure of classifying drugs as effective, ineffective, possibly effective, and probably effective? How long had they had notice that these classifications were going to be used, and that they would have a certain amount of time to produce adequately controlled studies to qualify their drug as an effective drug to remain in the marketplace, do you recall?

Dr. FINKEL. I don't recall exactly when those, actually five, different classifications were announced. But the first publications of the Federal Register began to appear about 1969.

Senator NELSON. The first classifications by the NAS/NRC?

Dr. FINKEL. Right.

And it was then that it was announced in public, in print, anyway, that the firms would be given that amount of time to perform studies.

Senator NELSON. Let me see. If the drug is described as ineffective, it must be removed from the marketplace in what period?

Dr. FINKEL. Well, the firms are given 30 days to respond to the announcement of inefficiency and produce some evidence.

Now, some of them have, and it had to be reviewed. There were a few, though, that were given some extensions of time to perform clinical trials while the drug remained on the market.