Senator NELSON. Give me the time span allowed by the FDA for each one of these classifications, I have forgotten what they were. The ineffectives were given 30 days, as I recall.

And possibly effective is the next category.

Dr. FINKEL. Possibly effective was given 6 months, and probably effective was given 1 year.

Senator NELSON. And what was the description of the standards they had to meet to satisfy the requirements for adequately and scientifically controlled studies to support the claim of efficacy? What was the language used?

Dr. FINKEL. In May of 1970 we published a policy statement which defined adequately and well controlled studies. And those were the principles that the firms were to follow.

Senator NELSON. You don't recall when the NAS/NRC first proposed the categories of ineffective, possibly effective and probably effective?

Dr. FINKEL. I believe it was the FDA that devised that, the then Commissioner at that time.

Senator NELSON. Was it the FDA that suggested these classifications to be followed by the NAS/NRC?

Dr. FINKEL. Yes, sir.

Senator NELSON. When was that, do you know?

Dr. FINKEL. I am afraid I don't know.

Senator NELSON. What I am trying to get at is, how many years, how much time, have the drug companies had notice that adequate and well-controlled studies would have to be submitted to support claims of efficacy? Is it 3, 4, or 5 years since they knew?

Dr. FINKEL. Well, they knew in 1962 that all drugs on the market would have to be shown to be effective. However, they didn't know the ratings for their particular drugs until the publications, or shortly before each publication appeared in the Federal Register.

Senator NELSON. Did they know they would have to prove by some standard that the drug was efficacious?

Dr. FINKEL. Yes.

Senator NELSON. And now it has been 10 years since the drug companies have had notice that they were going to have to come forward with adequate and well-controlled scientific studies to prove the efficacy of their drug, isn't that correct?

Dr. FINKEL. Yes.

Mr. BRANDS. May I add a statement, Mr. Chairman.

Senator NELSON. Yes.

Mr. BRANDS. In the publication "Drug Efficacy Study," on July 9, 1966, the Commissioner of Food and Drug published an order in the Federal Register requiring each holder of an NDA approved between 1938 and 1962 to submit to FDA specified information on each drug that the manufacturer wished to retain on the market. So, you might say that in July 1966 was the first official notice they had that the study was going to take place.

Senator NELSON. I am looking at a publication, "Federal Food, Drug and Cosmetic Act as Amended May 1966," in which it says: "As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investiga-