NDA's for new combination products; four for duplicates of combinations already marketed. Counting the latter four, 62 NDA's were approved for drugs which were, in effect, "me too" drugs.

Senator NELSON. We have a situation here where 69 out of 83 New Drug Applications last year were for drugs that added nothing for all practical purposes to the improvement of the health of the public?

Dr. GODDARD. I would be careful on that, Senator, because it is a little early to tell. You know, the time a drug is marketed——

Senator NELSON. There is nothing that you do know about it that would prove that it has different functions from any other drug. Otherwise, it would be patentable as something else.

Dr. GODDARD. Yes. We know the drugs we have approved are safe and effective for the conditions that they are intended to be used. Then we keep them under surveillance for the next couple of years—in fact from then on in the marketplace—to see if changes have to be made in labeling and if new problems develop. So I am hard pressed to be really responsive and say there is not anything really good in these drugs. One of those "me too's" may be a better drug in terms of having fewer side effects in the long run.

Senator NELSON. Do you think your clinical tests would not have demonstrated that?

Dr. GODDARD. In the number of people involved, side effects might not have shown up.

Senator NELSON. But anyway, the 69 had nothing new about them?

Dr. GODDARD. Nothing to jump up and down about.

Senator NELSON. So what we have really done with the process of New Drug Applications is to take products that are not patentable or whose patents have expired and then, by keeping secret the results of clinical testing, have guaranteed a monopoly or an extension of it. This has been done with no statute on the book that Congress very affirmatively passed. Is that correct?

Dr. GODDARD. (Nods affirmatively.)

Senator NELSON. You said that a third of these were fixed combinations.

Dr. GODDARD. I am guessing at that. I would have to get an accurate count.

Senator NELSON. We have had testimony from pharmacologists, professors, physicians, including Dr. Calvin Kunin on Tuesday, to the effect that there was no reason for using fixed combinations at all. I asked Dr. Kunin if doctors prescribe them because they did not know any better. He was not prepared to say that. He did say, however, that it meant a lack of education in the use of drugs. What's your judgment about fixed combinations?

Dr. GODDARD. Senator Nelson, I am in favor of a limited number of fixed combinations. I think they serve a useful purpose in the marketplace and they ought to be available for those physicians who view them as offering an advantage to their patients.

In the practice of medicine I did use fixed combinations myself. As a patient, there have been times I have enjoyed the advantages of fixed combinations, being able to take one drug instead of two. I think there is a rational place for combinations. I am not a distinguished pharmacologist and I do not pretend to be. But as a former practicing physician, I would have to say that I see a very real place for fixed com-