refers to all the evidence upon which the manufacturer bases his belief that the product is safe, and effective, and also contains copies of the labeling which he proposed to use in promoting and selling the product—the submission of this labeling and our approval of it have an important bearing on truthful advertising of prescription drugs as will be discussed shortly.

Senator NELSON. The New Drug Application does not involve the question of patent?

Dr. GODDARD. No, sir.

Senator NELSON. So this is a nonpatentable drug?

Dr. GODDARD. The drug itself may be in addition patented by the manufacturer. I believe the patent period is 17 years, which gives him commercial exclusivity.

Senator NELSON. Are most of the New Drug Applications drugs that are nonpatentable?

Dr. GODDARD. Of the NDA drugs in the past decade, as a rough estimate, 50 percent of them, I am told, would be drugs that are not patented. However, I must point out that the members of the industry have said to me in discussions that holding a valid NDA is as good or better than having a patent.

Senator NELSON. Why?

Dr. GODDARD. Because of the policy of the Food and Drug Administration. We do not make public the information submitted by a manufacturer with respect to the clinical studies, the preclinical animal studies, the toxicity data——

Senator NELSON. What is that now?

Dr. GODDARD. We do not make public any of the data submitted by the manufacturer in his NDA.

Senator NELSON. So if a nonpatentable drug goes on the market, and another company desires to manufacture it, it would have to make a chemical analysis of the drug, perform the animal and clinical testing that the law requires, and then present the New Drug Application to FDA for exactly the same drug that has been adequately tested before, is that correct?

Dr. GODDARD. That is correct.

Now, the timespan covered from the discovery of a chemical entity until its ultimate marketing, on the average, through the NDA procedure is about 7 years.

Senator NELSON. The timespan for what?

Dr. GODDARD. The discovery of the chemical entity, its testing in the laboratory and all the steps it has to go through right up to marketing with a valid NDA, is approximately 7 years. So you see if a company can get an NDA approved and get into the marketplace with a drug, their leadtime may be sufficiently great that they can capture a significant share of the market and hold it for a long period of time.

Senator NELSON. Well, the same applies if a drug is patented. Then for 17 years, if it is a good, valid patent, the manufacturer has exclusive control in this country over the sale and distribution of that drug; is that right?

Dr. GODDARD. That is correct, sir.

Senator NELSON. I assume that the circumstances are different between a New Drug Application and the requirement that any competitor go through the experimental process when a patent expires.