discussion by the scientific community as well as the drug firms involved.

Senator NELSON. Well, speaking for a moment of a patented drug. The company that has the patent has gotten from the Congress 17 years of exclusive use, which is a good long time. Then, as the Commissioner is well aware, once a drug has occupied the market for 17 years, the habit of prescription is such that the original product most often dominates the market thereafter. They may reduce the price, but they have the advantage of having dominated the market, and of having had 17 years of experience with producing the drug. Is there any reason at all why, once a patent runs out, that the FDA should not then open up its files to reveal all of the information and background testing, instead of preserving an unfair competitive situation at great expense to the public? The Congress did not intend a patent to run beyond 17 years, but in effect, this kind of secrecy keeps small competitors who could not afford the testing out of the market. It just hampers competition unnecessarily.

What is the justification?

Dr. GODDARD. Mr. Goodrich, do you want to supplement my earlier remarks on this?

Mr. GOODRICH. Our concern, Senator, is not with the patent, but with the drug being safe and effective for the purposes for which it is offered. Now, through the drug procedures, there are fundamentals that the labeling be controlled and that there be established a system to keep us up to date on those drugs. It is a gross oversimplification to say that simply because the two drugs are the same by clinical test, they will have the same chance or you will get the same experience from them. Now, it is important to us——

Senator NELSON. That you get the same experience?

Mr. GOODRICH. You may get a report of an adverse effect from one drug that you do not get from another. It is very important to us, we think, that we get complete reporting of clinical experience with the drugs and the only way to do that is through the new drug procedures. Now, even with an unpatented drug, before the 17 years runs out, if the date is made available in the scientific literature, it is possible for other manufacturers to use that to obtain an effective approved New Drug Application.

Senator NELSON. You can't get a New Drug Application when there is an existing patent.

Mr. GOODRICH. No, I am speaking of the unpatented drug. With an existing patent, he might get an approved New Drug Application, but would not be allowed to market it because of the patent laws.

Senator NELSON. I do not think you have responded to me. Maybe I did not state the question very clearly. The question is what is the policy reason, at the expiration of 17 years of the patent, for the FDA not immediately making public all the information it has about the drug, including the experiments on the animals, experiments on human beings, and so forth. Why should that not become public information forthwith?

Dr. GODDARD. There is no reason why it should not be, but when the Congress passed the Freedom of Information Act, which provided that commercial and business information be exempted from public disclosure. There is a provision in the Criminal Code that prohibits