

However, when the patent runs out you have a situation as I understand it, where neither the FDA nor the manufacturer discloses everything they know about that drug. So a company that then wanted to go on to the market would not be able to get the benefit of all the information that was accumulated by the company that had the legal protection for 17 years, and this second firm could not come onto the market competitively and have the benefit of all the experience and knowledge that is accumulated by the original manufacturer.

This system is defended by industry on the grounds that, "Well, these are our trade production secrets and there is no reason why we should give them to anybody else." On the other hand, the only reason they got the 17 years' protection is that the people of this country gave them the protection. Do you have a viewpoint about what the requirements ought to be in terms of disclosures to the public of all information a company accumulates about the manufacture of a drug?

Mr. SQUIBB. You mean the New Drug Application file on such a drug after the patent has run out?

Senator NELSON. After the patent has run out and a New Drug Application is filed.

Mr. SQUIBB. I think there are some very interesting experiences being accumulated along these lines right now as these major patents run out in the tetracycline and chloramphenicol area. You see these things going on right now. I think you should not take the NDA bundle of material in any separate consideration from the patent itself. You have got to require, if you want to soften the length of the patent by making the drug patents say for only 5 years, that the NDA situation should be tied into that.

I do not think, having gone through the patent in 17 years that now you should ride for the next 17 years in effect on your NDA. Here you are adding something again from the Government to the patent law. In other words, it is not a valid patent any more but has the same effect. You have got this vast expensive bundle of NDA which the Government will not disclose to your competitors, so you can ride along on this.

Senator NELSON. Just so that the record will be understandable to those who read it, would you explain in a little more detail? At the end of 17 years the New Drug Application is then filed by the company?

Mr. SQUIBB. It has been filed, the New Drug Application, and you have been running on your patent.

Senator NELSON. Excuse me, filed at the time they got the patent?

Mr. SQUIBB. Perhaps, but not necessarily at the time you got the patent.

Senator NELSON. And that New Drug Application contains all the material, research results, and everything else that was required?

Mr. SQUIBB. At great expense.

Senator NELSON. To be supplied to the Government?

Mr. SQUIBB. Of course, the Food and Drug can call this a new drug or an old drug. This has been covered in your testimony, particularly I think with Mr. Stetler at some length. But I think we ought to consider how long a drug product covered by a patent or a New Drug Application in the public interest should be kept exclusively to one com-