Dr. JENNINGS. Scanty. That is, the numbers were not large, but there were, I believe, some 300 women who had completed the 2 years for which the product was originally approved.

Now, the quality of the data, I am not prepared to comment on at this time, but I think that is something that also enters into the picture. Since approval, of course, there have been considerable data required and submitted to the Food and Drug Administration, regarding both the safety and efficacy of these products.

Senator MCINTYRE. In your answer, you have indicated as far as quantity was concerned it was rather skimpy.

Dr. JENNINGS. That is right, sir.

Senator MCINTYRE. And you have also asked for an opportunity, and I will request it, that you comment on the quality of that information at that time. Would you provide that for the record?

Dr. JENNINGS. Yes, sir.[1]

Senator MCINTYRE. How soon after the approval of the original New Drug Application did the first report of thromboembolic side effects come to the agency's attention?

Dr. JENNINGS. I cannot answer that with any degree of exactitude, but I believe that it was within a matter of months.

Senator MCINTYRE. Pardon me?

Dr. JENNINGS. A matter of months.

Senator MCINTYRE. Somewhere between one and 12 months?

Dr. JENNINGS. Probably within our first—well, I am not sure, I would rather not give you an exact answer until I have had a chance to check it.

Senator MCINTYRE. Will you furnish the exact answer for the record, please.[1]

You quoted the September 12, 1963, report of the Wright Committee to the effect that "No significant increases in the risk of thromboembolic disease had been demonstrated."

Did FDA not, in fact, issue two different versions of the Wright Committee report?

Dr. JENNINGS. I am unaware of that, sir. Mr. Goodrich may be able to answer.

Mr. GOODRICH. There was a first report which was found by Dr. Wright to have some statistical errors in it and those errors were corrected.

Senator MCINTYRE. How did the finding of the August 4, 1963, version differ from the one you quoted, from the September 12, 1963, version?

Mr. GOODRICH. The first report of the Wright Committee indicated that on the basis of the statistical figures, the statistical calculations made, that there was an increased risk of thromboembolic disorder in ladies, as I remember, age 35 or older. I would have to go back to the record, but the problem there was that statisticians that looked at the information concluded that the incidence of thromboembolic disorders in nonusers, the data on which the comparison had been made, were inadequate and therefore there was no basis on which

[1] See p. 6821.