Senator McIntyre. Because of these deficiencies in the available information, the Wright Committee recommended:

> That a carefully planned and controlled prospective study be initiated with the objective of obtaining more conclusive data regarding the incidence of thromboembolism and death from such conditions in both untreated females and those under treatment of this type among the pertinent age groups.

What actions were taken by FDA to implement this recommendation in the 3-year period between the issuance of the Wright Committee report and the first report of the Advisory Committee on Obstetrics and Gynecology in August of 1966?

Mr. Goodrich. Dr. Wright did make that recommendation in the report. He also sent a letter to the Commissioner with it, in which he recognized that the preparation and execution of a prospective study would be difficult, if not impossible. We would be glad to supply that letter to the Senator, if he would like to have it.

Nonetheless, the problem there was that in order to do a meaningful prospective study involved thousands of ladies, under carefully controlled circumstances, by that I mean having number of patients in the order of 10,000 examined at intervals of about 6 months, which was simply beyond our capability of financing, and the conclusion was reached about the time of the first Hellman report that the quickest and most effective way of obtaining information—reliable information about thromboembolic episodes—was to do a controlled retrospective study. That retrospective study was financed and completed.

We, in the meantime, got the retrospective experience from England. Even today, it is not possible for us within the resources Dr. Edwards has explained here, to mount a prospective study with the numbers of patients that would be necessary. We think a prospective study is no longer necessary with respect to thromboembolic episodes, but a prospective study may very well be meaningful in some other parameters.

Senator McIntyre. On pages 3 and 4 of the Commissioner's statement, you list eight recommendations contained in the 1966 report of the Hellman Committee, and describe efforts made by FDA to implement six of them. However, you make no mention of efforts to implement the other two. One of these was the restatement of the Wright Committee recommendation to support prospective studies utilizing groups of subjects especially amenable to long-term follow-ups.

Now, your answer, I suppose, covers it, but I want to ask it for the record: has FDA as yet undertaken or caused to be undertaken studies such as these, and if so, when?

Mr. Goodrich. Again, the prospective study recommended by the Hellman Committee in 1966 was not undertaken. Instead, the retrospective study was planned and executed. We have recently, as outlined on Dr. Edwards' statement, beginning on pages 8 through 9, summarized the research that is underway and given the dates.

No. 6, on page 9, describes a prospective study at the University of Miami. I believe there is also one underway at Temple University, and the Walnut Hill Study.

Senator McIntyre. That is a carbohydrate metabolism study?