had received on thromboembolic disease and deaths associated with the pill, and I just want to make sure the answer you gave includes all reports which have been received by FDA from all sources since these drugs came on the market. And if your answer was not inclusive as far as that is concerned, would you please supply it for the record? Do I make myself clear?

Dr. EDWARDS. Yes, I believe they were, were they not?

Dr. JENNINGS. No, they were not, and that is what I pointed out to the Senator and said we would compile the figures I think he wants.

Dr. EDWARDS. I was thinking of something else.

Senator MCINTYRE. We had a feeling the figures you gave in response to the chairman's questions were only partial and I wanted to make sure.

Dr. EDWARDS. The period was from July to December, 1969. We will give you the total compilation of the figures.

Senator MCINTYRE. Thank you very much.

Dr. EDWARDS. Again, referring to the letter that the Food and Drug Administration sent to all physicians in 1968, the letter expressed the Food and Drug Admistration's conclusion that a definite association had been established—this is between the oral contraceptive and thromboembolic disease, and called their attention to the revised labeling, and asked for their assistance in monitoring adverse reactions.

In 1969, FDA's OB-GYN committee made another comprehensive review of the oral contraceptive problem.

The second report was published on August 1, 1969. In addition to a comprehensive review of the problem, the report contained the results of a well-defined retrospective study on thromboembolic phenomena by Dr. Philip E. Sartwell of Johns Hopkins. The Sartwell study established the association of increased risk of some thromboembolic disorders, confirming the earlier British studies.

Although the committee had also studied the problems relating to carcinogenesis and metabolic effects, they could not point to conclusive evidence associating these conditions with the use of oral contraceptives.

The committee concluded that "When these potential hazards and the value of the drugs are balanced, the ratio of benefit to risk is sufficiently high to justify the designation safe within the intent of the legislation."

As in their first report, the committee made a number of recommendations.

First of all, they recommended we investigate the carcinogenic and metabolic effect of oral contraceptives in humans.

They recommended we support development of new methods of contraception.

They recommended we support the National Fertility Survey in 1970 by the National Institute of Health.

They recommended that we improve the present system of reporting adverse reaction by financially supporting the use of centers to report reactions on oral contraceptives and by strengthening the present surveillance system of the Food and Drug Administration.