Lastly, they recommended that we sponsor an annual conference of scientific writers on contraceptive knowledge and accomplishments.

The FDA's review of the committee report and the Sartwell study led to a decision that a change in the uniform labeling was necessary. Accordingly, on November 14, 1969, we met with industry representatives to discuss the revised uniform labeling which has been required since January 1 of this year.

In December when I became Commissioner, the decision was made to issue a letter to all U.S. physicians, hospital pharmacists, and hospital administrators. In it, I warned that "carefully designed retrospective studies show that users of oral contraceptives are more likely to have thrombophlebitis and pulmonary embolism than nonusers" and I strongly urged physicians to familiarize themselves with the revised labeling.

I suggested that "a full disclosure of the potential adverse effects" to patients is advisable, and I also again requested their assistance in reporting adverse reactions to the Food and Drug Administration.

In addition, in December of 1969, reports came to our attention of the British announcement advising practitioners to prescribe only products containing .05 milligrams or less of estrogen. I indicated then that the Food and Drug Administration would await full data from England and evaluate this and our own data before making a decision on whether any action should be taken with regard to the oral contraceptives containing high doses of estrogen.

I would like to say in this regard, we just yesterday or the day before received a message from the British, inviting us to come to London on March 18 with appropriate individuals from the Food and Drug Administration and the National Institute of Health, to review their data.

So this month we will have the British information.

Senator NELSON. You will be sending a delegation shortly, did I understand you to say?

Dr. EDWARDS. That is right. We are to be there on March 18.

Senator NELSON. Are you, as Commissioner, going with the delegation?

Dr. EDWARDS. Yes, sir, I am. Three people from the Food and Drug Administration, in addition to two from the National Institute of Health.

Senator NELSON. If their data satisfies you and the group with you that oral contraceptives with more than 50 micrograms of estrogen do in fact induce a higher incidence of thromboembolism, will it be the decision of the FDA to order from the market all of those in this country that exceed 50 micrograms?

Dr. EDWARDS. Obviously, I think it would depend to a certain degree on the quality, or at least our interpretation of the quality of their data.

I think we have to continually bear in mind the formulation of these products, and this is certainly one of the alternatives that we have to think about if the data warrant it such a decision.

Senator NELSON. That is what I am getting at. If you and your scientists are satisfied with the quality of the research and conclude that they are correct, that over 50 micrograms increases the incid-