But we are worried about the patient who visits the physician once every 2 or 3 years or not at all. This is the patient we are trying to direct our attention to.

Senator DOLE. I know it is difficult to cover all situations in a memo, I can understand it is directed primarily to those who do not have a regular checkup and maybe have not seen the doctor in the first instance, may have some other way acquired the pill, but it will be published in the Federal Register and there will be comments, unquestionably.

Dr. EDWARDS. This is a long way from being the final document, but at least it is a start, in our judgment, in the right direction.

In conclusion, Mr. Chairman, there is no question about the effectiveness of oral contraceptives. Some questions of safety have arisen during this first decade of widespread use. We have examined the evidence of risk and we have resolved the safety issue for the present, as I have testified. I have indicated our need to continue and expand research projects for the discovery of vital safety information, and I have emphasized our lack of a comprehensive surveillance system. These are, to be sure, future needs.

The action we must take now, immediately, in my opinion, is to help inform the 8.5 million American women now taking oral contraceptives of the risk involved.

This action is commensurate with our mandate for assuring the public of safe and effective new drugs. In this and all matters, we will continue to exercise scientifically sound, legally correct, and administratively mature judgment on behalf of the public health.

Thank you.

Senator MCINTYRE. Referring to page 2 of your statement, you noted that the first oral contraceptive was approved for sale in this country on June 23, 1960. Would you please comment on the quantity and quality of the data submitted in support of this New Drug Application?

Dr. EDWARDS. If I may, I would like to have Dr. Jennings answer that question.

Dr. JENNINGS. I cannot at this moment, Mr. Senator, give you the exact number of cases that were included. The data probably by today's standard would seem somewhat scanty. There were field trials conducted in large numbers of women, and in relatively smaller amounts for fairly long periods of time, so that at the time the drug was approved for marketing in this country, the people concerned with the approval felt that they could approve it for a period of time of 2 years.

The first products were limited in duration of use for 2 years.

Senator MCINTYRE. I take it from your answer and from previous testimony, that the data that was available at that time, prior to the approval of these drugs would not be adequate in terms of the rules that we have today?

Dr. JENNINGS. I am not sure of that, Senator. I say that by today's standard, I am sure it would be considered somewhat skimpy.

Senator MCINTYRE. Somewhat what?