In essence, the reports of these three agencies in 1965 were virtually the same. Based on case reports they recognized that there might be trouble, but when they looked into the scientific base for information, they were unable to get sufficient data on the subject to come to any conclusion. The reasons for this are several: One, the base data; the incidence or prevalence of thromboembolic disease in the population was not known with accuracy, either in Great Britain or in the United States.

Second, the method of reporting or methods of reporting adverse reaction to drugs, both in Britain and the United States, were not very good, not very sophisticated, and they are still not very good.

In 1965, the Commissioner of the U.S. Food and Drug Administration decided that this problem was of sufficient seriousness so that an ad hoc committee was appointed, of which I was chairman, to look into the problem of the modern contraceptives with specific emphasis on the oral contraceptive. I had nothing to do with the choosing of the members of the committee, but, if I had, I could not have chosen better. In the first place, and importantly, there were some female members of the committee. Women use these drugs and it is important that they be presented in any decisionmaking body. Among the committee members were obstetricians and gynecologists of prominence, endocrinologists, and epidemiologists.

The committee was hard working and it worked continually against deadlines. Its first meeting was held in November of 1965 and it was told in the spring of 1966 by the new Commissioner, Dr. James Goddard, that the deadline for the first report was the 1st of August 1966. We met that deadline, and I think the first report is in your hands, Senator. If it is not, we certainly can make it available to you.

This report reflected the same general lack of basic knowledge that confronted the previous committee. Particularly there was no knowledge, no fundamental knowledge, on the thromboembolic disease. There was suspicion about malignancy. Compared to what we know today, there was very little known about the metabolic changes.

The Committee made 10 recommendations and a conclusion. Its recommendations were acted on quite promptly by the Food and Drug Administration, and the Public Health Service, with the exception of one recommendation, namely, that a large population be obtained that could be followed carefully. We made many attempts to find such a population that took the oral contraceptives over a long period of time that was susceptible to medical followup. We tried what you all might think was a good lead, the armed services, only to find that the data from the armed services and the movement of people in and out of the armed services made this source of information not very secure.

Our only large study, with long-term followup that merits consideration was the followup study of the Kaiser Permanente group, a captive population that can be looked at over time. One of the serious problems in this whole investigation is to get a population that you can observe over a long period of time.

The Committee made trips to each of the seven pharmaceutical houses that made oral contraceptives at that time to investigate reporting of adverse reactions. The committee actually appointed a consultant, Dr. Kohl, who happened to work in my department, to make these visits. I made one with him. I must say the pharmaceutical in-