

his report, he did so by taking excerpts from each of the task force reports, by talking to the Chairman of the task force during the writing, by mailing a rough copy of his draft to each member of the Committee, then by having a final meeting of the Committee to discuss the summary. They corrected the Chairman's summary as their own were corrected and the final draft was approved by a vote of the Committee as the report of the whole.

Following that, these drafts were meticulously edited and every reference in the second report on oral contraceptives was checked by me personally or my own staff in New York.

Now, there are significant differences between the second report on the oral contraceptives and the first report. The first and most outstanding is that the information about thromboembolic disease was available so that the Committee would say without equivocation—

Senator NELSON. May I interrupt? What was the date of the first report?

Dr. HELLMAN. The date of the first report was August 1, 1966.

Senator NELSON. And the second one?

Dr. HELLMAN. The second one was August 1, 1969. The Committee can say without equivocation that there is a relation between the oral contraceptives and thromboembolic disease. This relation had been established by three studies in Great Britain, first by the general practitioners study, second by a retrospective study conducted by Dr. Doll and Vessey, and third by a study of deaths in Great Britain due to thromboembolism. It was reinforced by the Sartwell study, which was conducted by Dr. Sartwell, who is a member of our committee and who is professor of epidemiology at the School of Public Health at Johns Hopkins.

It is interesting, I think, that without any communication between us and the British group, the design of the two retrospective studies was exactly the same. In essence, what we both did—both groups did—was to select patients of childbearing age, between the ages of 15 and 44, who were in hospitals for thromboembolic disease that was idiopathic. By idiopathic, we meant strictly defined thromboembolic disease without any known cause—such as an operation, an accident, obesity, pregnancy, and so forth. These patients were matched with controls. Our matching was a little bit different, but the controls were selected roughly within the same age group, married women, the same race and the same number of children. In the United States, we endeavored to get the same economic classification; namely, were they ward patients in hospitals or were they paying patients?

These four reports together enabled an estimation of the risk of death; namely, about 3 per 100,000 users. They also estimated the risk of hospitalization, of getting thromboembolic disease. The British reports said 1 in 2,000. They said excess risk, and by that we mean risk over normally occurring disease. They estimated the excess risk between 7 and 9 times. Our estimation of the excess risk of thromboembolic disease was about 4½ times. There is no significant difference between these estimates. They may sound a little different, but they are in the same ball park. It is quite possible that thromboembolic disease itself not related to oral contraceptives has a different incidence in different countries. For instance as far as we can tell, it is extremely rare in tropical countries, almost unheard of in India. So these differences are minor and need not concern us.