they should have been held suspect in a research series as pill connected.

I would like to make a few comments about the Wright committee study of 1963. This study also restricted data to continental U.S. deaths. It concluded the available evidence for the year 1962 did not reveal a death risk. All agreed the data the committee was working with was not as complete as desired.

Dr. Sheen Kassouf and myself objected to the statistical method used by the committee. Using women years instead of women users, we calculated the death rate to be increased approximately in the ratio of 3 to 1. Dr. Louis Lasagna makes reference in his book, "Life, Death and Doctor" to the problem of the woman user. He stated no one on the committee seemed to worry how long the user took Enovid. N.I.H. was asked to review the statistical debate. In conclusion, they replied there was little to be gained by prolonging the debate and that it would be better to go on monitoring.

The only conclusion I would like to make now is that the 1962 data was more suggestive of risk than safety and that majority opinion resolved doubts in favor of the pill instead of the public for the second time.

On September 30, 1968, the lead article in the J.A.M.A. was "Oral contraceptives and thromboembolic disease." It was written by Dr. Victor Drill and Davil Calhoun of the G. D. Searle Co. They concluded that U.S. data did not reveal a clotting or death risk. This paper is unique, being in effect, a major policy statement by the manufacturer on the safety of their own drug, which is in contention. At the time it was the only major negative report to the British studies. Of course, its conclusions are now opposed in the 1969 FDA report.

The Puerto Rican study I have spoken of now appears under the heading of large scale studies. There is still no mention of death. Drill and Calhoun list several other smaller Puerto Rican studies. They list one possible thrombophlebitis in those studies and they carry it in quotes. I mention this to show the authors do recognize some events as uncertainties in Puerto Rico.

But the Drill and Calhoun report grows in complexity. The 1969 FDA report analyzes the Drill-Calhoun paper. FDA states that the largest study used by Drill and Calhoun and the only one with numbers adequate to test the hypothesis is not in the medical literature. The only reference to it that could be found was a release issued by a voluntary agency. The FDA report continued that the authors of the unpublished reports stated:

> This study was not designed to provide a comparative incidence of thrombophlebitis. Such an investigation would require more detailed follow-up examinations than were feasible in order to establish (1) a positive diagnosis of the condition, (2) the existence of recognized contributing causes, and (3) whether the patient was hospitalized. Satisfying these criteria is necessary to provide any meaningful comparison with the only reliable base-line incidence data for this disorder which is limited to idiopathic, hospitalized cases.

The FDA report concludes:

> The evidence presented by Drill and Calhoun which constitutes the main negative evidence published to date is inadequate to show that the incidence of thromboembolism is either unaffected or reduced by oral contraceptives.