evidence and to provide the Food and Drug Administration with the best possible advice.

This committee of experts issued their first report in August of 1966. They found no adequate scientific evidence at the time to say that these compounds were unsafe for human use. However, the committee noted their concern for better data and made several recommendations which were subsequently acted upon by the Food and Drug Administration.

Included among these were the following:

First of all, the funding of a retrospective study to determine the possible relationship of oral contraceptives to thromboembolic disease.

Second, to support prospective studies utilizing groups of subjects especially amenable to long-term follow-up.

Third, the continuation and strengthening of FDA surveillance system.

Fourth, review of the mechanism for storage, retrieval and analysis of oral contraceptive surveillance data.

Fifth, to support laboratory investigation on carbohydrate metabolism, lipid metabolism, renal function, blood coagulation mechanisms, and potential carcinogenic effects in animals and man.

Sixth, to establish uniform labeling of contraceptive drugs.

Seventh, discontinuation of time limitation for administration of contraceptive drugs.

Lastly, to expedite approval of low dosage oral contraceptives.

The retrospective study was initiated; uniform labeling was achieved; the 2-year limitation was dropped; computer improvements were made in the storage, retrieval, and analysis of surveillance data; better reporting was discussed with the manufacturers; and effects were made to obtain better reporting from hospitals and from prescribers.

By 1966 competition in the oral contraceptive market had resulted in exaggerated and misleading claims. Advertising to physicians and some promotion materials attempted to establish ideas of product superiority which in our judgment had no scientific basis.

As a result, the Food and Drug Administration's efforts to correct this situation led us to the uniform label approach for oral contraceptives.

By early 1968, the improved surveillance system was reporting increasing numbers of thromboembolic diseases associated with women taking the oral contraceptive. At about the same time results of epidemeological studies in Great Britain became available. For the first time these studies demonstrated an increased incidence of thromboembolic disease in users of oral contraceptives. The British data, compiled by Dr. Inman, Dr. Vessey, and Dr. Doll, were reviewed by our experts who also considered the available U.S. data. These experts concluded that there was "a definite association between the use of oral contraceptives and the incidence of thromboembolic disorders."

Based on this conclusion, in June of 1968, FDA sent a letter to all physicians advising them of the British findings.

Senator NELSON. How many cases of thromboembolic disorders