direct response to this need." (p. 21) It is recognized that such studies cannot be accomplished overnight, four years nevertheless is a long time.

The risk of thromboembolism is stated as 4.4 times that of the non-user. This does not tell the whole story. The statistical studies by Sartwell and the British relate to women who are essentially perfect specimens. Women who had so-called predisposing conditions were excluded from the study. We do not know what the risk of thromboembolism is in women who are in good health when starting The Pill, and who subsequently encounter infection, become traumatized, or are beset with other problems. The general susceptibility of the woman taking The Pill has not been measured, nor, apparently, has any attempt been made to do so. Nothing has been done to try to identify the particularly vulnerable woman. We still do not know how many women are being affected by thromboembolism due to The Pill.

One of the major urgent needs, expressed by the various groups in the past, was for "prospective studies." The Advisory Committee, in its First Report on the Oral Contraceptives, August 1, 1966, recommended:

> III. Support of additional controlled population-based prospective studies utilizing groups of subjects that are especially amendable [sic] to long-term followup, such as married female employees of certain large industries, and graduate nurses.
>
> Although such prospective studies are difficult and require large populations, they may provide the only feasible method to answer the question of a relationship between the oral contraceptives and carcinoma, as well as the effect of these compounds on the growth and development of subsequent offspring.

The Second Report contains the following statement in respect of that recommendation (p. 2):

> Result: A prospective study of the effects of the oral contraceptives on cervical epithelium has been underway since 1967. Other prospective studies of effects of contraceptives on cervical cytology have been initiated *recently*. Corollary studies of possible effects on the breast *will also be* implemented. (italics added)

What happened to the large population studies that were deemed so important in 1966? Why are the corollary studies related to cancer of the breast yet to be started? Proposals for long range prospective studies on large population groups (one of 100,000 women, the other of 50,000), submitted to the F.D.A. pursuant to its request of two research organizations, were rejected by the Committee in early 1967. Apparently nothing is being done in terms of large population studies, yet the need is the same as it has been for 10 years.

The various Task Force Reports which, presumably, comprise the basis for the Chairman's Summary present some conclusions that are difficult, if not impossible, to reconcile with the conclusions of the chairman. Most of the deleterious effects, both established and feared but not *proven*, cannot yet be assigned a risk estimate.

On stroke:

> It is not possible with the existing data to estimate with assurance the magnitude of the increased morbidity and mortality risk of stroke among women using these compounds but it may be in the neighborhood of six-fold judging by findings of Inman and Vessey (18) and Vessey and Doll (30). (p. 58)

What does this mean in terms of numerical risk? One in 300, one in 500, or one in 1000 per year among Pill takers? Does the Chairman suggest that the benefit of pregnancy prevention outweighs this unknown quantity, which concededly is probably a sixfold risk?

As to biologic effects, generally:

> It is clear, however, that oral contraceptives have many varied effects on many organ systems. Indeed, there appears to be no organ system tested that is not affected in some way (p. 69).

With such comprehensive involvement, who knows, or can intelligently estimate, what the risks are?

As to post-Pill infertility:

> While clinical observers agree that most women conceive "promptly" after the discontinuation of oral contraception, valid statistical information is scanty. (p. 71).

How does that fit into the formula? Are women to be reassured by guesswork?