Appendix 1

Report of the Task Force on Thromboembolic Disease

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The activities of the Task Force on Thromboembolic Disease have been as follows:

1. To ascertain the effect, if any, of oral contraceptives on the factors responsible for blood coagulation.

2. To ascertain the incidence of fatal thromboembolic disease in the total female population of the United States of reproductive age, exclusive of cases associated with pregnancy or a surgical operation.

3. To ascertain the approximate number of women in the United States who have taken oral contraceptives, year by year, from 1961 through 1965.

4. To ascertain the incidence of fatal thromboembolic disease in women who had been users of oral contraceptives prior to death.

5. To specify and recommend for immediate development certain epidemiological studies which promise to establish the risks associated with the use of oral contraceptives, or the absence of such risks, much more effectively than is possible on the basis of the data now available.

1. Blood coagulation in women taking oral contraceptives has been the subject of many studies by competent investigators. Although the data on the behavior of individual coagulation factors are somewhat conflicting, no clear evidence has been advanced that these preparations significantly alter the coagulation behavior of the blood. Thus, in a recent and most meticulous investigation, Beller and Porges summarize their findings as follows: "Two different commercially available agents and a placebo were taken by a group of volunteers in a double blind study. There was no statistical difference in blood coagulation factors among the different groups." (In press, Am. J. Obstet. & Gynec.) But even if some of the blood coagulation factors had shown differences between users and nonusers, no blood-coagulation assay at the present time is considered a test for prediction or confirmation of the clinical diagnosis of thromboembolic disease. (Alexander, B.: Blood coagulation and thrombotic disease; Circulation, 25: 872, 1962. Wessler, S.: Stasis, hypercoagulability and thrombosis; Federation Proceedings, 22: 1366–1370, 1963.)

2. Estimates of the incidence of fatal pulmonary embolism among women, 15–44 years of age, not pregnant nor in the puerperal state, in the United States in 1963 are shown below:

Age (years)	*Deaths per million*
15–19	2
20–24	6
25–29	10
30–34	12
35–39	18
40–44	22
15–44	12

These estimates were obtained by including in the numerator deaths attributed to pulmonary embolism and infarction (ICD 465) plus the deaths assigned to antecedent causes which rarely lead to death except by pulmonary embolism (ICD 463, 464, 466) and including in the denominator only women who are neither pregnant nor in the puerperium.

The estimates shown above are necessarily rough because the total number of pregnancies is not known.[1] It is believed, however, that they represent the level and trend of mortality with sufficient accuracy for the purpose at hand.

Age-specific death rates from cerebral embolism and thrombosis (ICD 332) among women, 15–44

[1] It was assumed that one-sixth of all pregnancies in the United States or approximately 1 million were terminated by spontaneous fetal wastage, and the same number by illegal abortion.