The often neglected facts are that the Wright committee, sharply aware of the limitations imposed by the information it had to work with:

Concluded only that the available data showed no significant increase in the risk of fatal lung clots in Enovid users.

Cautioned that "any firm reliance on the risks as calculated is tempered by the assumptions made."

Made one, and only one, recommendation: that carefully planned, controlled studies be started.

Although the potential consequences may be immense, FDA has not acted to implement this recommendation in the 27 months since the Wright committee made it. Until the recommendation is carried out, the uncertainties about hazards will not be stilled.

Nor will the uncertainties be dispelled by what Dr. Irwin C. Winter, Searle's vice president for medical affairs, said a year ago was "undoubtedly . . . the most comprehensive large-scale study in the oral contraceptive field."

He referred to a study undertaken by Searle in cooperation with 38 Planned Parenthood Federation clinics. An initial check of a group of 5000 women, he reported, showed an incidence of inflammatory clots among pill users comparable to the minimum rate known in the normal female population.

But the usefulness of the study was frankly conceded to be limited even by Dr. Winter when he said that there was not "an adequate control group" and that "adequate statistics" on the normal incidence of thrombophlebitis "were not available."

A SIGNIFICANT YEAR

A further criticism was made by Dr. Herbert Ratner of the Stritch School of Medicine of Loyola University in Chicago, who dealt in an interview with acknowledgements by Dr. Winter that the 5000 women were limited to those who, before entering the study, had been on the pills for at least two years.

This means that the study excluded those women who had started on the pills but dropped out because of side effects—serious or otherwise—or for other reasons in the first 12 months of use.

And this initial period, Dr. Ratner said, is the one in which most side effects occur. Therefore, he said, any conclusions drawn from data on the selected group that was able to enter the study are open to question.

Today's concern is most intense not about nausea and other such effects associated with pill-induced pseudo-pregnancy, but about afflictions involving the circulatory system: fatal clots, disabling clots, eye damage. There are, however, other concerns, including a feared possible relation between pill use over several years and cancer.

Although his warnings about such a possible relation have been hotly and widely challenged, Dr. Roy Hertz, former chief endocrinologist of the National Cancer Institute, said in an interview that the estrogenic substances used in the pills are known to induce a wide variety of tumors in numerous species of animals.

"It is, therefore, imperative that their generalized distribution to women of child-bearing age for protracted perids of time be preceded by appropriately comprehensive epidemiologic studies to ascertain whether such effects are to be anticipated in man," he said.

"To date, no statistically adequate studies sustained for a sufficiently long period of time have been reported," Dr. Hertz said, but some are being organized at the National Institute of Child Health and Human Development, of which he is now scientific director.

He said that these studies will get follow-up data for prolonged periods of time on users of various methods of contraception so as to ascertain the comparative effects.

These studies are recognized as appropriate for dealing with the questions about a possible serious adverse reaction that, if it would appear at all, would not be expected to manifest itself until after many years of pill use. But such studies will not be directed primarily to answering questions about possible adverse circulatory effects that most commonly would appear in the initial months of use.