FINAL REPORT ON ENOVID BY THE AD HOC COMMITTEE FOR THE EVALUATION OF A POSSIBLE ETIOLOGIC RELATION WITH THROMBOEMBOLIC CONDITIONS

SUBMITTED TO THE COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, SEPTEMBER 12, 1963

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(Pages 1 through 13 of the Final Report on Enovid were identical to the Report on Enovid and, therefore, have been omitted. The balance of the Final Report on Enovid follows.)

DISCUSSION

Inasmuch as the population number for Enovid users estimated from available data is not an exact figure, but based on drug distribution figures, some attempts were made to determine the effects of a 50% decrease and a 10% decrease in the estimated population of white users to see what effect this might have on the mortality rates among Enovid users and the significance of any difference from those in the general population.

Any increase in this estimate of users would obviously reduce the user death rates and these rates would approach those in the general population. This would be particularly true if we deducted too many as Negro users, a possibility which remains. A 50% decrease in the estimate of users would double the Enovid rates. This would make the overall rate as well as the rates in the 20–24 and 40–44 year age groups very significantly greater. A 50% decrease in the population estimate represents an extreme possibility rather than a probable estimate and is deemed highly unlikely. A 10% decrease in our user-population estimate (which might represent a reasonable error) would, however, *not* yield Enovid-user death rates significantly different from the general population rates (total and individual 5-year age groups) at the level of $P=0.05$.

In summary, on the basis of the available data and if the above outlined assumptions are reasonably correct, no significant increase in the risk of thromboembolic death from the use of Enovid in this population group has been demonstrated.

There is a need for comprehensive and critical studies regarding the possible effects of Enovid on the coagulation balance and related production of thromboembolic conditions. Pending the development of such conclusive data and on the basis of present experience this latter relationship should be regarded as neither established nor excluded.

Although a detailed study is not within the scope of this report it it is recognized that in judging the over-all risk from and the values of the use of Enovid, data concerning the risks of pregnancy and induced abortion in each age group would be extremely important.

Any firm reliance on the risks as calculated is tempered by the assumptions made. This committee recommends that a carefully planned and controlled prospective study be initiated with the objective of obtaining more concusive data regarding the incidence of thromboembolism and death from such conditions in both untreated females and those under treatment of this type among the pertinent age groups.

References

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