death certificates and included 18 of the deaths of patients known to have taken Enovid. The assumption was then made that the mortality from thromboembolic conditions in the general population for 1962 was at least at the same rate as in 1961.

2. *Characteristics of the numerator counts*

Only deaths occurring among residents of the United States in 1962 were accepted. Furthermore, patients known to be pregnant at the time of their demise and postoperative thromboembolism cases, were excluded by virtue of the fact that the general population numerator would not include these groups in the codings listed above for thromboembolism.

The Enovid numerator had no negro deaths. Inasmuch as it was uncertain whether this lack of deaths among negroes using Enovid, in the data available to us, represented an inadequate population at the risk or not (since total use of the Enovid among negroes was not great and even at "normal" risks of thromboembolic death one would require a very large population at risk to obtain a single death), it was decided to omit negro females from both denominators and the general population numerator.

a. Every death reported in patients exposed to Enovid was again reviewed in detail to determine its suitability for inclusion on the basis of any thromboembolic phenomena irrespective of the underlying cause. These were distributed among the five year age groups into which they fell from 15 to 44 years of age. (For other purposes these were further subdivided into idiopathic and non-idiopathic cases).

b. The general population numerator similarly included all deaths from thromboembolic phenomena exclusive of those occurring among pregnant women or shortly after surgery regardless of other antecedent causes. These deaths were also subdivided into their 5 year age groups from 15 to 44 years of age.

3. *Validity of the denominator counts*

a. Inspection of some available data and the experience of members of the Committee relative to the use of Enovid for conception control indicated that the age distribution of the population of Enovid users would be drastically different from the age distribution of non-pregnant females in the general population. Thus, data were sought from a geographically diversified sampling of Planned Parenthood clinics and private practitioners for a cross-section of the age distribution of Enovid users. There were obtained for both white and negro patients. Although for reasons above noted negro patients were excluded from the final analysis of users, their distribution was not remarkably different from that of the white patients. Further assumptions were herein made: That the sample derived by solicitation was representative of all Enovid users in the United States at least with respect to age; that geographic differences might be accounted for by representation in the sample of data from all parts of the country; and that the blending or private and clinic patients occurred in the same proportion as might exist in the general population. Actually, the age distribution of private patients was not significantly different from that of the clinic patients.

The most unreliable data to be utilized in the calculation of relative risks resided in the denominator for the Enovid user group. The only data available were furnished by the manufacturer on the basis of prescriptions filled and renewed during each of the quarters of the year of 1962. The maximum estimated number of users of Enovid was 1,300,000, but this value contained an unknown proportion of negroes and a lesser but still unknown proportion of duplicate prescriptions. On the basis of the best preliminary estimate the committee could formulate, 300,000 were subtracted, leaving 1,000,000 white users of Enovid. These were then categorized according to the age distribution of the white Enovid user sample. This distribution provided the individual age group denominators which were subsequently used to calculate the thromboembolic mortality rates among such users.

b. The corresponding denominators for the 1962 general population included the distribution of white females for the same individual age groups. NVSD provided these data and also estimates of the age distribution of white non-pregnant women. For each age-interval denominator the estimated number of