sons, inertia, and lack of interest or awareness of the value of such data.

(*b*) Selective or biased reporting of incidents which may reflect fashions in medical interest rather than the magnitude of a possible hazard.

(*c*) The lack of a denominator population to evaluate the incidence of a possible adverse reaction.

(*d*) The lack of control populations not exposed to the oral contraceptives to permit comparison of the incidence of possible complications in users and nonusers, to see if, in fact, any excess risk occurs in users.

(*e*) The inability to detect potential long-term effects which might first appear after discontinuation of the oral contraceptives or even in the progeny of users.

Of the more formal and reliable epidemiologic methods, the one selected should depend upon the type of suspected complication and its temporal relation to the use of the drugs. Prospective studies of users and nonusers are capable of testing for each type of complication; however, they are extremely difficult and costly to perform if the suspected complication is thought to be of rare occurrence or if it is expected to occur after a latent period of many years. The prospective method has the advantages that it permits simultaneous study of all possible complications, including those which are initially unsuspected, and that certain biases are avoided. However, it does not reduce the problem that the inferences must be based on observation rather than experiment; i.e., that differences in disease frequency between the groups of users and nonusers may result from differences in their initial composition dependent on whatever determines the employment of contraceptive methods.

Efficient approaches to the principal possible types of complications are as follows:

(*a*) *Thromboembolic disease.* Here the supposed complication is serious, readily recognized in at least some of its forms, and quite rare. It may presumably occur at any time while the drug is being used, but not after termination of use. A case-control (retrospective) approach is the most efficient; a series of cases, and of suitable controls, are chosen and the number of drug users in each group is determined in order to demonstrate association or independence between drug and disease.

(*b*) *Cancer.* Here the suspected complication is again serious and readily recognizable. The situation differs from (*a*) in two respects: The disease is common and only a small proportion of cases could be expected to be attributable to the drug; and more important, the latent period would be expected to be very long, frequently extending until after the termination of drug use. A prospective study would be best but would be rendered exceedingly difficult by the length of latency and variations in contraceptive methods employed by a woman over her reproductive lifetime. The case-control approach employed at serial intervals of calendar time would also give promise, but no method is really efficient.

(*c*) *Diabetes or minor physiologic alterations* such as have been discussed in this report. Serial observations on adequate-sized groups of users and nonusers, incorporating whatever laboratory methods are required, will be needed.

Many different compounds administered in slightly different fashions, constitute the available oral contraceptives. The basic mode of action of currently marketed compounds is similar, however, namely, the inhibition of ovulation and the initiation of periodic bleeding through withdrawal. The committee has therefore chosen to approach broadly the potential problems raised by the massive use of the whole group of effective estrogen-progestogen formulations. For this purpose, the committee has been divided into four task forces with specific assignments, each headed by a chairman, as follows:

Task Forces

1. Thromboembolic Disease
   N. J. EASTMAN, M.D., *Chairman*
   C. TIETZE, M.D.
   P. E. SARTWELL, M.D.
   A. MASI, M.D.
2. Carcinogenic Potential
   R. SCOTT, M.D., *Chairman*
   R. HERTZ, M.D.
3. Endocrine and Metabolic Effects
   E. DELFS, M.D., *Chairman*
   E. CARRINGTON, M.D.
4. Efficacy
   K. ADAMSONS, M.D., *Chairman*
   H. FULLER, M.D.