established 11 years ago by the American Cancer Society, when its science writers seminars were created.

The risk of thromboembolism associated with the oral contraceptives has been compared with that from pregnancy, cigarette smoking, and automobile accidents. Such comparisons are probably irrelevant, contributing little to evaluation of the relative risk. The task of balancing the risk against the benefit to the individual and to society must eventually be met. As contraceptive practices spread to all segments of our society, it becomes virtually essential that the requirements of effectiveness and safety, and the desirability of inexpensiveness and lack of association with coitus be satisfied. Oral contraceptives have proved to be highly acceptable to many couples who had found other methods inconvenient or impractical.

(a) Action on recommendations of the 1966 report on the oral contraceptives

The Committee is gratified by the prompt response of the Food and Drug Administration to the majority of its previous recommendations as follows:

Recommendation I.—A large case-control (retrospective) study of the possible relation of oral contraceptives to thromboembolism.

Result.—A study was developed at Johns Hopkins University School of Hygiene and Public Health with Food and Drug Administration support. Results document an increased risk in the drug users, roughly comparable to that observed in the epidemiological studies in Great Britain.

Recommendation II.—Continuation and support of studies such as the ones being carried out by the Kaiser Permanente group in California and the University of Pittsburgh group in Lawrence County, Pa.

Result.—The Kaiser study is operating under support from the National Institute of Child Health and Human Development. Food and Drug Administration support to the project in Lawrence County, Pa. was discontinued for administrative reasons, but a locally sponsored central audit of prescriptions is operating.

Recommendation III.—Support of additional controlled population prospective studies utilizing groups of subjects that are especially amenable to long-term followup, such as married female employees of certain large industries and graduate nurses.

Result.—A prospective study of the effects of oral contraceptives on cervical epithelium has been underway since 1967. Other prospective studies of effects of contraceptives on cervical cytology have been initiated recently. Corollary studies of possible effects on the breast will also be implemented.

Recommendation IV.—Continuation and strengthening of the present surveillance system of the Food and Drug Administration.

Result.—At the present time, all adverse reactions to the oral contraceptives reported to the Food and Drug Administration from the Hospital Reporting Program, manufacturers, consumers and physicians are collected and reviewed by the Division of Drug Experience, Bureau of Medicine, where they are coded and stored in a computerized facility. Reports are then transmitted to the Division of Metabolic and Endocrine Drug Surveillance, Office of Marketed Drugs where serious reactions are collected separately in a card file. This Division is responsible for preparation of a yearly tabulation of these serious adverse effects which is submitted to the Commissioner. A separate listing is also made by staff in the Office of Marketed Drugs.

Recommendation V.—Review of the mechanism of storage, retrieval, and analysis of surveillance data.

Result.—The data are stored by both computer and hand-tabulated forms. The data still cannot be retrieved easily or quickly. In addition, there is a serious difficulty with followup of individual cases because there is no uniform indexing or coding method between source and recipient. Thus, reduplication of reports or difficulties may result. Data are analyzed according to simple criteria of drug used, age of patient, severity, and nature of adverse reactions, etc. But further statistical analysis is not useful since the total population providing the date is not known.

Recommendation VI.—A conference be held between the Food and Drug Administration and the respective drug firms concerning uniformity and increased efficiency of reporting.

Result.—Not held.

Recommendation VII.—Priority be given to support laboratory investigations concerning all aspects of the hormonal contraceptive compounds.