CHAIRMAN'S SUMMARY

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Since the publication of the last Report on the Oral Contraceptives in 1966,* scientific as well as public interest in this method of family planning has remained high. The reservations of the first report appear to have been justified. Concern about the immediate and long-range side effects of the hormonal contraceptives has increased as scientific investigations have uncovered a host of diverse biologic effects, and as the drugs have become available to increasingly large segments of the world's population.

Adverse reactions are continually reported in the scientific literature and the lay press. Since the vast majority of the reported adverse experiences are conditions which occur spontaneously in women of reproductive age, identification of an etiologic relation has been difficult and slow.

An increased risk of thromboembolic disease attributable to the use of hormonal contraceptives has now been defined in both Great Britain and the United States. Other risks, such as those of hypertension, liver disease and reduced tolerance to carbohydrates, have not been quantitated with the same precision. Some of the risks have been recognized by isolated clinical observations, whereas others have been predicted on the basis of experiments with animals or merely on theoretical grounds.

Controversy has centered about two areas: the scientific data required to establish an etiologic relation and the balance between acceptable risk and potential benefit. The voluntary submission of reports by individual doctors to scientific journals, to the pharmaceutical industry, or directly to the Food and Drug Administration is fregmentary at best. Since the data on the natural incidence of the disorders in question are not available, it is impossible to ascertain whether the haphazard voluntary reporting of an adverse reaction in fact represents an increase in the suspected complication. The limitations as well as the value of a voluntary reporting system for providing an initial warning of serious complication have been noted frequently. There is no easy escape from this dilemma. The current aggregate pharmacological experience with the oral contraceptives is unique, however, in that large numbers of healthy young women are using potent drugs for a purpose other than the control of disease. An improvement in national reporting of some of the alleged complications is therefore merited. If the annual national rates of incidence of the various complications thought to be associated with hormonal contraceptives were known, trends presently unsuspected might be quickly uncovered.

This pharmacological experience is unique also in the attention it has received by the press throughout the world. Particularly in Great Britain and the United States the Press has attempted to keep the public informed of each discovery and each reported difficulty. Such reporting is the quickest way to satisfy the public's right to know.

The task of conveying complicated scientific information to the public is a responsibility requiring well-informed and accurate reporting, based on a judicious appraisal of data. Neither the public nor the press is well served if information is exaggerated, mitigated, or suppressed. In the final analysis, both the physician and the layman must evaluate the risks of the hormonal contraceptives in comparison with other methods of contraception or no contraception at all. They can do so wisely only when they have access to all available information, accurately and dispassionately presented.

It is difficult to separate fact from fiction at the forefront of scientific discovery. Evaluation in the area of hormonal contraception has proved formidable to the best informed scientists. The epidemiological problems are unique, requiring refinements in technique not yet fully realized. Case reporting, particularly isolated experiences, may be inconclusive. Thromboembolic disease is but one example. Eight years were required from the time of the first reported death to establish the relative risk and an etiologic relation to the hormonal contraceptives. By reviewing a welter of scientific studies of varied value, the press has acquired an increasing awareness of the problems through hard work and study. So too have physicians and the public. This difficult course could have been shortened and made more efficient by periodic, well structured, and responsibly led impartial conferences of scientific writers. The pattern was

* Report on the Oral Contraceptives, Advisory Committee on Obstetrics and Gynecology, Food and Drug Administration, August 1, 1966.