

the natural occurrence of the disorder 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 limits, as well as the value, of the system of voluntary reporting of adverse reactions have been frequently noted. There is no easy escape from this dilemma, although innovative techniques in reporting of the suspected complication, as for example, cancer, might be very helpful.

It is difficult to separate fact from friction at the forefront of scientific discovery. Evaluation in the area of hormonal contraception has proved formidable to the best informed scientists. The epidemiologic problems are unique requiring refinements in technique not yet fully realized. Case reporting, particularly isolated experiences, is 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. Through perusal of a welter of scientific studies of varied value, the physician is expected to evolve a judgement that will be beneficial and informative to his patient. This difficult course could be shortened and made more efficient by periodic well structured, and responsibly led conferences. The Food and Drug Administration has a similar objective in publication of its Committee Reports. In the meantime, the physician has at least acquired awareness that there are problems, some of which may be serious, associated with the oral contraceptives.

If these problems are so difficult of solution, and if some of the adverse reactions are potentially hazardous, why use the oral contraceptive at all? The answer lies in their effectiveness. The theoretical effectiveness of the combined hormonal contraceptives is reflected in a pregnancy rate of approximately 0.1 per 100 women per year. The theoretical effectiveness of the sequential oral contraceptives appears to be somewhat lower, as indicated in a pregnancy rate of 0.5 per 100 women per year. The usually given pregnancy rates reflecting "use-effectiveness" reach 0.7 per 100 women per year for the combined regimen, and 1.4 per 100 women per year for the sequential regimen.

Effectiveness judged by the total number of pregnancies is significantly better with the oral contraceptives, combined or sequential, than with the intrauterine devices, or any of the traditional methods. The pregnancy rates among users of diaphragms with contraceptive paste thus appear to be 10 to 30 times higher than those among users of oral contraceptives. Similarly, those among users of intrauterine devices are 2 to 4 times higher. Knowledge of the relative effectiveness of the different contraceptive methods helps in the task of balancing the risk against the benefit to the individual and to society. As contraceptive practices spread to all segments of our society, it becomes virtually essential that the requisites of safety, effectiveness, inexpensiveness, and lack of association with coitus be satisfied. The economically advantaged and well educated members of society may be willing to accept a method of contraception that does not entirely satisfy all of these attributes, but the less favored members of society cannot realistically be expected to employ a method, the efficacy of which is in doubt, or use of a technique that requires privacy and special preparation.

Another factor helpful in evaluating benefit to risk is the continuation rate of the selected contraceptive practice. The continuation rates of oral contraceptives are higher than those of traditional methods of contraception such as the diaphragm, and lower than those of the intrauterine devices.

Known risks of oral contraceptives have often been compared with those of pregnancy, cigarette smoking, and automobile accidents. Such comparisons are probably irrelevant and contribute little to the evaluation of relative risks. This evaluation must be made from a knowledge of the relative advantages of the oral contraceptives in comparison with other contraceptive methods or no contraception at all.

Minor adverse reactions to the oral contraceptives, such as irregular bleeding, weight gain, headache, chloasma are well known. Their incidence may not be precisely documented, but their etiology is not in doubt because it has been relatively simple to establish a cause and effect relation and to observe a diminution in the symptoms with discontinuance of the drugs. Visual and emotional disturbances are documented with far less precision. Most of these minor reactions, however, are cared for by simple medical advice. Discontinuance of this method of contraception provides in the most part a satisfactory solution. This type of medical decision involves a few patients and does not require a policy decision necessitated by the potentially more serious adverse reactions such as