Result.—The Food and Drug Administration and the National Institutes of Health are supporting several studies on carbohydrate metabolism, lipid metabolism, renal function, blood coagulation mechanisms, potential carcinogenic effects and other studies in animals and man.

Recommendation VIII.—Uniformity in labeling contraceptive drugs.

Result.—Accomplished.

Recommendation IX.—Discontinuance of time limitation of administration of contraceptive drugs.

Result.—Accomplished.

Recommendation X.—Simplification of Administrative procedures to allow reduction in dosage of already approved compounds.

Result.—Although no formal policy has been enunciated, the sponsors of new products that represent either reductions in dosage or changes in dosage schedule have been permitted to submit reduced quantities of preclinical and clinical information. It has been suggested, however, in view of these reduced requirements that the quality of the studies submitted in support of efficacy be improved; that is, the majority of studies should include patients beginning therapy rather than those being switched over from another hormonal contraceptive and should not generally include postpartum patients or those who are breast feeding.

(*b*) *Utilization*

American women are sufficiently interested in oral contraception to continue its use despite some alarming reports in the national press. By early 1969 twenty preparations of oral contraceptives, combined and sequential, were being distributed in the United States at the rate of approximately 8.5 million cycles per month. Combined progestin-estrogen products prescribed in 20- or 21-day cycles account for 80 per cent of this total. As a result of the gradual trend toward the use of lower dosages, over 90 per cent of the combination tablets now prescribed contain 2.5 mg. or less of the synthetic progestin. The estimates of use for 1969 are twice as high as those listed in the national fertility survey of 1965. This apparent doubling of the numbers suggests a much wider use among older women and those of limited education. Such a trend could be forecast from the increased availability of contraceptive services in many of the poorer areas of our big cities.

The use of oral contraceptives has spread in foreign countries as well. Among the countries without laws prohibiting the distribution of contraceptives, only Japan and the U.S.S.R. now prescribe the general distribution or sale of these drugs. The estimate of world-wide distribution of oral contraceptives is now approximately 18.5 million cycles per month.

All available evidence indicates that the continuation rates of oral contraceptives are higher than those of traditional methods of contraception, such as the diaphragm, and lower than those of intrauterine devices. In its previous report the Committee indicated an anticipated use of 6 million cycles monthly in the United States in 1970. If the present estimate of 8.5 million cycles is correct, the Committee's projections were conservative.

(*c*) *Efficacy*

The theoretical effectiveness of the combined hormonal contraceptives is reflected in a pregnancy rate of approximately 0.1 per hundred women per year. The theoretical effectiveness of the sequential oral contraceptives appears to be somewhat lower as indicated by a pregnancy rate of 0.5 per hundred women per year. The usually given pregnancy rates, reflecting "use-effectiveness," average 0.7 per hundred women per year for the combined regimen and 1.4 per hundred women per year for the sequential regimen.

Effectiveness, judged by the total number of pregnancies, is significantly higher with oral contraceptives, combined or sequential, than with 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; those among users of intrauterine devices are 2 to 4 times higher.

(*d*) *Methods under evaluation*

Since the Committee's last report, pharmaceutical firms have continued to investigate synthetic progestins and estrogens in an effort to reduce side effects while maintaining maximal efficacy. For example, the most recently