

Obstetrics and Gynecology at Johns Hopkins University is the new chairman of our advisory committee, replacing Dr. Hellman.

Dr. Barnes will chair our meeting next Wednesday when we will review some of our present research projects.

I would like at this time to review some of our studies which are now under way. There are several general areas on which the total scope of the Food and Drug Administration's present program is based.

Information is being sought on the degree and mechanism of changes brought about by the oral contraceptive and the indications of these changes.

Also, we are trying to determine whether certain of these drugs, or their ingredients, have unique pharmacological properties; whether high risk subpopulations can be identified; and to what degree can findings observed in animals be extrapolated to the human population.

Clinical and animal studies presently under way and supported by the Food and Drug Administration include:

A retrospective study of a cost of \$175,000 on the relationship between thromboembolic phenomena and oral contraceptive use conducted by Dr. Philip Sartwell at the Johns Hopkins University School of Hygiene and Public Health. Here we are planning to extend this for another year, beginning next month, at a cost of approximately \$75,000.

We have an investigation going on of the carcinogenic potential, hematologic, and endocrine effects of two experimental oral contraceptive formulations using dogs and monkeys treated over a prolonged period of time. This continuing study by the International Research and Development Corp., was begun late in 1968 at a cost of \$372,000.

We have an intensive study of changes in blood coagulation and fibrinolysis in women using oral contraceptives, which was initiated at the New York University School of Medicine in May 1969, at an annual cost of \$27,000. Results are expected early in 1971.

We have the study of the University of Rochester on the possible effects in women of oral contraceptives on renal, bladder and ureteral function and the incidence of infection which was initiated in May 1969, at an annual cost of \$77,000.

We have the study at Temple University on the effects of oral contraceptives on lipid metabolism in subhuman primates and women of reproductive age, which was initiated in May of 1968 at an annual cost of \$118,000.

We have a prospective study on the effects of prolonged use of oral contraceptives on carbohydrate metabolism in a large group of women, and this has been underway at the University of Miami since June 1967, at annual cost of \$63,000.

Lastly, we have a study at Temple University on the effects of oral contraceptives on cervical cytology which was initiated in July of 1969 at a cost of \$95,000.

All of these studies are currently costing the Food and Drug Administration \$380,000 annually.

Senator DOLE. Dr. Edwards, there has been some testimony that additional funds are needed to research oral contraceptive research.