

4. Specially Designed Prospective Studies

Prospective studies are needed to verify findings from the case-controlled retrospective studies and to identify which women may be subject to increased risks from serious effects. There is only one such study now underway in the United States. It is supported by the National Institutes of Health and is conducted at the Kaiser Permanente Hospital in Walnut Creek, California. This is a long-term study designed to follow women on oral contraceptives through time and to monitor the effects of these agents on their health. It provides a flexible system of surveillance and permits the study design to be changed as understanding of the problem changes. FDA is presently developing a national multi-clinic study of correlates of abnormal cervical cytology including socioeconomic status and history of contraceptive use.

RELATION TO CONTRACEPTIVE DEVELOPMENT

It is impossible to consider studies of the medical effects of oral contraceptives without also considering the closely related subject of contraceptive development. The search for new methods of contraception has received increasing attention in recent years because of their importance in helping reduce dangerously high rates of population growth throughout the world.

The Federal Government has become engaged in this search. The Center for Population Research was established at the National Institutes of Health in August 1968 to conduct research on "birth control methods of all types and the sociology of population growth" as described by President Nixon in his Population Message of 1969.

The Center's research program comprises three major areas: 1) contraceptive development and related fields of reproductive biology; 2) the medical effects of contraceptives in use; and 3) population research in the behavioral sciences. The population research budget for FY 69 was \$10.8 million; the budget expected for FY 70 is \$28.4 million. Most of these funds will be used for contraceptive development because of the immediate importance of this topic.

Contraceptive development and the studies of the medical effects of contraceptives in use are closely related since the latter field of investigation may lead to technological improvements in the agents or better dosage regimes. Research on oral contraceptives may also develop leads which will contribute to the development of methods based on different principles. Many scientists are dissatisfied with the contraceptives now in use, partly because of an increasing recognition of the multitude of effects produced and there is a consensus on the need for other methods which produce their effect through different mechanisms. In addition, many of the scientific procedures and systems used for studies of medical effects are also used for contraceptive development, so the coordination of these two activities is conducive to efficiencies in time and funds.

RECOMMENDED RESEARCH PLANS

A plan for research on the medical effects of oral contraceptives is described below. It requires expansion of current programs and the initiation of four new categories of studies.

EXPANSION OF CURRENT PROGRAMS

1. Clinical Studies

The studies on topics already underway should be continued and expanded. They will explore in depth the metabolic and tissue changes which have been observed and also to investigate new areas for which we have as yet no information. Department scientists and consultants should prepare a detailed research plan for the scientific community in order to generate studies in the several major scientific areas previously described. Protocols should be generated through proper notification in the scientific literature, the use of Requests for Proposals, and through individual negotiation by Departmental scientists.

2. Animal Research

Animal research now underway should also be expanded for reasons already described and it will be useful to develop a Request for Proposals similar in principle to the ones proposed for clinical studies.