

8. Ancillary Surveys

A variety of surveys are required to describe the clinical and prescription practices now employed for oral contraceptives. These surveys would delineate what types of physical examinations and laboratory tests are conducted before oral contraceptives are prescribed, the frequency of physician visits, what information patients are given on potential drug hazard, the differences which may exist in diagnostic and hospitalization practice for oral contraceptive users and other women, and the ability of patients to give valid histories of contraceptive practice. Such information is of great importance to interpretation of other studies underway and have a bearing upon important decisions made by industry and government agencies concerning drug marketing.

RECOMMENDATIONS

Current research on oral contraceptives should be expanded and new studies initiated in the coming years. Such work is the responsibility of the Department. Both N.I.H. and the F.D.A. devoted \$1.9 million to this field in FY 1969. The Center for Population Research at N.I.H. alone will allocate approximately \$1.5 million to these studies in FY 1970 and presently expects to spend about \$2.5 million in FY 1971.

TABLE 1.—CURRENT RESEARCH ON MEDICAL EFFECTS OF ORAL CONTRACEPTIVES BY AMERICAN FEDERAL AND NONPROFIT AGENCIES WITH MAJOR PROGRAMS

Category	CPR ¹ (fiscal year 1969)	Other NIH ¹ (fiscal year 1969)	FDA ¹ (fiscal year 1969)	Ford Foun- dation ¹ (year end- ing Sep- tember 30, 1969)	Population council ¹ (year end- ing Dec- ember 31, 1969)	Total
Clinical studies.....	\$148,955	\$73,771	\$321,206	\$258,100	\$284,300	\$1,086,332
Animal research.....	44,623	70,983	245,064	10,000	65,100	435,770
Case-control surveillance.....	138,860		176,543			315,403
Specially designed prospective studies.....	645,390					645,390
Total.....	977,828	144,754	742,813	268,100	349,400	2,482,895

¹ Most recent 12-month period for which data are available.

TABLE 2.—SUPPORT OF RESEARCH PROJECTS ON THE MEDICAL EFFECTS OF ORAL CONTRACEPTIVES
CENTER FOR POPULATION RESEARCH, NICHD (FISCAL YEAR 1969)

Category	Project No.	Investigator, institution, project title	Annual funds
1.....	PH-43-67-1344	Victor Wynn, University of London, metabolic effects of oral contraceptives.	\$42,704
1.....	PH-43-67-1389	Elizabeth Stern, University of California, Los Angeles, steroid contraception and cervical dysplasia.	106,251
2.....	HD-3159.....	Burton L. Baker, University of Michigan, hypophyseal response to estrogens and progestins.	32,283
2.....	HD-2537	Elizabeth Stern, University of California, Los Angeles, effects of steroid contraception in the ovary.	12,340
3.....	NIH-69-2250	Albert Heyman, Duke University, a collaborative study of oral contraception and cerebrovascular disease.	138,860
4.....	PH-43-67-1346	Frederick A. Pellegrin, Kaiser Foundation Hospitals, contraceptive drug study.	645,390
Total.....			977,828
Plans for fiscal year 1970: Continuation of the above projects. In addition, the following projects have been approved but are not yet funded. Negotiations are also underway on several other projects, 1 on the possible effect of oral contraceptives on progeny (category 3):			
2.....	HD-4106	Mary Jane Gray, University of Vermont, effect of oral contraceptives on aldosterone secretion.	¹ 19,854
3.....		Colin White, Yale University, a retrospective study of the risks for cancer of the breast, body of the uterus, ovary, and cervix among users of oral contraceptives.	
3.....		Ralph Paffenbarger, University of California, Berkeley, oral contraceptives and tumors of the breast.	
5.....	HD-4835	Arlene P. Martin, University of Missouri, biochemical studies of 19-nor progestin metabolism.	¹ 24,208

Footnotes at end of table.