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## ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

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Gaithersburg

Hilton

620 Perry Parkway Gaithersburg, Maryland 20877 Telephone 301-977-8900

FDA

DHHS/FDA/COMMERICAL ACCTS 5600 FISHER LANE, HFA-122 ROCKVILLE, MD 20857

Statement Date	Page	Account Number
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Payment Due Upon Receipt

To insure proper credit please return the upper portion of this statement in the envelope provided with the return address appearing in the window.

AMOUNT PAID \$0.00

Please Return This Portion With Your Remittance

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GAITHERSBURG HILTON 620 Perry Parkway

Gaithersburg, Maryland 20879

Advisory Committee for Reproductive Health Drugs July 19, 1996

Approval for Payment: MIF 002904

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#### DEPARTMENT OF

#### **HEALTH AND HUMAN SERVICES** PURCHASE/SERVICE/STOCK REQUISITION

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| STOCK | SSUE | STOCK REQUESTING ORGANIZATION CUSTODIAL AREA DATE OBJECT CLASS Food and Drug Administration CDER 25.92 FOR REFERENCE CALL EXTENSION APPROPRIATION 7560600 22320Q 20 DELIVER TO FDA/Center for Drug Evaluation and Research 6-6992862-D-51784 ACS, Meeting Management Branch DATE REQUIRED Chapman Building, Room 200 July 8, 1996 1901 Chapman Avenue, Rockville, Maryland 20852 COST UNIT DESCRIPTION QUANTITY ITEM NO. OF (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.) REQUIRED ISSUE UNIT TOTAL Request is made for use of conference room for an advisory committee meeting. Conference room rental \$52,885.10 for one day Title of Meeting: Advisory Committee for Reproductive Health Drugs Location: The Hilton 620 Perry Parkway Gaithersburg, Maryland 20877 Contact: Frank Kohler (301) 977-8900 Date: July 19, 1996 Time: 8 a.m. to 6 p.m. Handicap Facilities are Available. (see attached statement) No Appropriate Government Facility Available. Conf. Rms. AB4C FUNDS AVAILABLE I certify that the property/services requested are required TOTAL \$2,885.10 for Government business, and are not available from excess or current assets,\* SGE Programs Øffic RECEIVING OFFICIAL - I certify that the quantities indicated in the "Quantity REQUESTED BY /Si Required" column above have been received in total or as annotated. Committee Momt. Ass RECEIVING OFFICIAL (Signature/Title) RECOMMEND APPROVAL (Signature/Title)\* ORDER DATE ORDER NO. (PO, DO, FEDSTRIP, ETC.) PPROVED BY (S.

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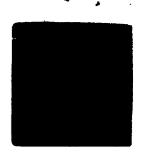
#### **JUSTIFICATION**

A meeting of the Advisory Committee for Reproductive Health Drugs was scheduled for July 19, 1996. Unfortunately, there were no available conference rooms in the Parklawn Building. No appropriate auditoriums are available to accommodate 200-250 persons. It is necessary to hold the meeting in the immediate vicinity because of the large number of government officials from NIH and FDA who will attend the meeting. Holding the meeting at a point distant from this area would not be cost effective because of the time and travel costs involved. Local hotel called: The Hilton. The Hilton in Gaithersburg was the only space available in this area. A hold was placed with the Hilton, Gaithersburg, until a purchase order could be approved.

Meeting schedule cannot be changed because participants and speakers have already been notified and this is the only compatible two days available on their calendars.

APPEARS THIS WAY
ON ORIGINAL







he Population Council, a nonprofit, nongovernmental research organization established in 1952, seeks to improve the wellbeing and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources.

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The Council analyzes population issues and trends; conducts research in the reproductive sciences; develops new contraceptives; works with public and private agencies to improve the quality and outreach of family planning and reproductive health services; helps governments design and implement effective population policies; communicates the results of research in the population field to diverse audiences; and helps strengthen professional resources in developing countries through collaborative research and programs, technical exchange, awards, and fellowships.

Research and programs are carried out by three divisions—the Center for Biomedical Research, the Research Division, and the Programs Division—and two Distinguished Colleagues. Council headquarters and the Center for Biomedical Research are located in New York City; the Council also has four regional and 14 country offices overseas. About 365 women and men from 62 countries work for the Council, more than a third of whom hold advanced degrees. Roughly 40 percent are based in developing countries. Council staff collaborate with developing country colleagues to conduct research and programs in some 50 countries in South and East Asia, West Asia and North Africa, sub-Saharan Africa, and Latin America and the Caribbean.

The Council is governed by a board of trustees composed of men and women from 12 countries. This group includes leaders in international family planning, development activists, business people, physicians, and social scientists.

The organization's funds come from governments, foundations and other nongovernmental organizations, internal sources, multilateral organizations, corporations, and individuals. The Council's current budget is US\$49 million.

# THE POPULATION COUNCIL

The Center for Biomedical Research undertakes basic research in the reproductive sciences and develops technologies that enable individuals to have safe, planned pregnancies and that promote their reproductive health. The Center is one of the world's leading institutions in the fields of contraceptive development and male reproductive physiology.

Staff in the Contraceptive Development Program conduct applied research and develop new methods of contraception to meet the needs of women and men. Clinical trials of drug formulations and devices developed at the Center are conducted by the Council's International Committee for Contraception Research (ICCR), a group of investigators from several countries who serve as consultants in the clinical evaluation of experimental contraceptive methods. The Contraceptive Development Program collaborates with the Council's Programs Division in contraceptive introduction and postmarketing activities.

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Staff in the Reproductive Physiology Program conduct basic research on reproductive processes in women and men. Investigations focus on male reproductive physiology, with the goal of understanding the coordinated sequence of events associated with male hormonal action, sperm maturation, and fertilization. This research, results of which are published in respected scientific journals, complements the Contraceptive Development Program by increasing the prospects for developing safe and effective contraceptives.

Through its postdoctoral training program in reproductive biomedicine, the Center sustains and enlarges the community of scientists whose research leads to advances in reproductive health care and new and improved contraception. This program helps train the next generation of reproductive scientists from developing countries, enhancing the capacity of those countries to address reproductive health issues.

C. Wayne Bardin, Vice President, heads the Center for Biomedical Research; James Catterall is Director of Reproductive Physiology, and Rosemarie Thau is Director of Contraceptive Research. The staff of 85 includes 25 principal investigators; in addition to staff, 26 postdoctoral fellows work at the Center, which is located on the campus of the Rockefeller University.

#### AREAS OF RESEARCH IN 1994

\*\*EONTRACEPTIVE DEVELOPMENT vaginal rings • spermicides and microbicides • abortifacients • subdermal implants for women and men • intrauterine devices • antifertility vaccines • probing studies in female and male contraception REPRODUCTIVE PRESIDENCE receptors and transcription • genetic mechanisms of androgen action • steroid metabolism • physiology of Sertoli cells • development and physiology of Leydig cells • testicular proteins • biology of gametes • transmission of HIV

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The Research Division's broad aims are to marshal social science expertise toward a better understanding of population issues and to promote applications of that knowledge to the design and implementation of policies and programs responsive to individual and societal needs in developing countries. The division undertakes analyses of population policy, demographic behavior, and interrelationships between population and socioeconomic change, often in collaboration with colleagues in developing countries. It administers the Population Council Fellowships in the Social Sciences, a program that plays a major role in strengthening developing countries' professional resources in the population field.

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Population policy is defined broadly as the full range of government actions with a potential population impact. In addition to analyzing policy, division staff study critical inputs into policy formation, such as consequences of population change at the individual and societal level.

The largest share of the division's research is on fertility and family planning, which includes analysis of fertility determinants and the factors underlying the unmet need for contraception, as well as experimental research to improve program design and performance. Work in these areas goes beyond narrow demographic issues, reflecting a deep concern for individual rights, health, and wellbeing.

The division's research on gender and family examines how family structure and function and men's and women's roles affect fertility outcomes and parental investment in children. Particular attention is given to adolescence as a critical social, economic, and reproductive phase in the life cycle.

John Bongaarts, Vice President, heads the Research Division; Cynthia B. Lloyd is Director of Social Science Research. The division's staff of 19 includes demographers, economists, sociologists, and anthropologists with expertise in the population issues of developing countries.

#### AREAS OF RESEARCH 1994

POPULATION POLICY redefining population policy • family, development, and population policy • population and environment • population and economic development • population policy in China and India • consequences of rural-urban migration Family Planning experimental studies in family planning • monitoring and analysis of family planning programs • determinants of reproductive behavior • unmet need for contraception • evaluation of program impact Gender, Family, and development investing in children • child mortality in China • adolescence and the transition to adulthood • women's roles

MIF 0029095

The Programs Division collaborates with governments, nongovernmental organizations, and scientific institutions in developing countries to design and implement population policies, improve delivery of family planning and related health services, enhance understanding of the determinants of reproductive behavior, and improve the conditions of women. This collaboration includes professional exchanges and research, training, awards, technical assistance, and dissemination of information.

The division's activities are divided into four programs: Population Policy, Reproductive Health, Family Planning, and Gender, Family, and Development. Work in these areas is developed, implemented, and evaluated by an interregional office in New York; regional offices in Cairo (West Asia and North Africa), Mexico City (Latin America and the Caribbean), Nairobi (sub-Saharan Africa), and New Delhi (South and East Asia); and 14 country offices.

Strengthening professional resources in developing countries is an objective of all programmatic activities. The division sponsors special programs to further this aim in the Middle East, Bangladesh, Mali, and Vietnam through awards, training, and institutional development.

George Brown, Vice President, heads the Programs Division; Anrudh Jain is Director, Programs, and Louise Kantrow is Director, Operations. Program Directors are: Judith Bruce (Gender, Family, and Development), Andrew Fisher (Family Planning), and Beverly Winikoff (Reproductive Health). Regional Directors are: Ayorinde Ajayi (sub-Saharan Africa), Barbara Ibrahim (West Asia and North Africa), Ana Langer (Latin America and the Caribbean), and Saroj Pachauri (South and East Asia). The division's staff of 183 includes 68 health and social scientists and other professionals.

#### AREAS OF RESEARCH AND PROGRAMS IN 1994

POPULATION POLICY population policies in Egypt, India, Kenya, and Mexico • population policy issues in the Middle East—REPRODUCTIVE HEALTH quality of services in reproductive health programs • managing unwanted pregnancy and preventing the consequences of unsafe abortion • new approaches to postpartum care • programs that address sexually transmitted diseases, including AIDS, within the context of improving women's reproductive health • safe motherhood • acceptability of reproductive health technologies—FAMILY PLANNING operations research and technical assistance (OR/TA) regional programs in Africa, Asia, and Latin

America • family planning research and technical assistance in Bangladesh, Mali, Pakistan, and Vietnam • improving quality of care in Indonesia, Peru, and Vietnam • expanding contraceptive choice in Africa, Asia, and Latin America—GENDER, FAMILY, AND DEVELOPMENT family structure and women's economic contributions to families • fathers' roles and responsibilities • family policy • gender training

#### DISTINGUISHED COLLEAGUES

The Population Council staff includes two Distinguished Colleagues, who provide an additional source of expertise in areas of relevance to the Council and represent the organization in their fields internationally.

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Paul Demeny, Distinguished Scholar, investigates the consequences of population change and analyzes public policy debates on population issues. He also serves as Editor of the Council's quarterly journal, *Population and Development Review*.

Sheldon Segal, Distinguished Scientist, conducts and coordinates biomedical research bearing on fertility regulation and reproductive health. He is also a scientific advisor to other organizations on matters related to family planning, reproductive rights, and ethical issues in population.

#### CORPORATE AFFAIRS

Corporate Affairs encompasses the office of Finance, Computer Services, Information Systems, Personnel and Office Services, and the External Relations Group, which includes Development, Public Information, Publications, the Library, and Grants and Contracts.

The division provides supporting services to the Council and, through its Publications and Public Information offices, communicates work by Council staff, consultants, and colleagues to an international community of policymakers, government planners, activists, teachers, media professionals, and the general public. Council publications include two scholarly journals, *Population and Development Review* and *Studies in Family Planning*, as well as newsletters, working papers, pamphlets, and books.

Sandra Arnold, Vice President, heads Corporate Affairs, overseeing a staff of 74. Donald Abrams is Treasurer and Director of Finance, and Monica Knorr is Corporate Secretary and Senior Director of the External Relations Group.

MCGEORGE BUNDY

Chair
Scholar-in-Residence
Carnegie Corporation of New York
New York, New York

ROBERT H. EBERT

Chair Emeritus
Caroline Shields Walker Professor
of Medicine Emeritus
Harvard University;
Consultant to the President and to
the Chairman
Wilhenk Memorial Fund

Milbank Memorial Fund New York, New York

MARGARET CATLEY-CARLSON

The Population Council
New York, New York

JORGE BALÁN Senior Researcher Centro de Estudios de Estado y Sociedad

y Sociedad Buenos Aires, Argentina

GEORGE BENNEM Vice Chancellor University of Ghana Legon, Ghana

Canberra, Australia

JOHN C. CALDWELL Coordinator Health Transition Centre Australian National University LAURA CHASIN<sup>1</sup>
Faculty
Family Institute of Cambridge
Watertown, Massachusetts

EDDAH GACHUKIA
Executive Director
Forum for African Women
Educationalists
Nairobi, Kenya

WERNER HOLZER Washington, DC

AZIZA HUSSKIN<sup>2</sup>
Chair of the Board
Cairo Family Planning Association
Cairo, Egypt

LUCILLE MATHURIN MAIR<sup>1</sup>
Ambassador-Permanent
Representative of Jamaica to the
United Nations
New York. New York

ELIZABETH J. MCCORMACK<sup>2</sup>
Associate
Rockefeller Family and Associates
New York, New York

ROBERT B. MILLARD Managing Director Lehman Brothers Inc. New York, New York

FREDERICK T. SAI<sup>2</sup>
President
International Planned Parenthood
Federation
London, England

SHOICHI SAKAMOTO<sup>2</sup>
Professor and Director
Aiiku Maternal and Child Health
and Welfare Center
Tokyo, Japan

GUILLERMO SOBERÓN ACEVEDO Executive President Fundación Mexicana para la Salud Mexico City, D.F. Mexico

KRISTER STENDARL.
Professor and Dean Emeritus
Harvard Divinity School
Cambridge, Massachusetts;
Former Bishop of Stockholm,
Sweden

HALDOR TOPSOE<sup>2</sup>
Chair
Haldor Topsoe A/S
Copenhagen, Denmark

AMINATA TRAORE
Regional Coordinator
PROWNESS/AFRICA, United Nations
Development Programme
Abidjan, Ivory Coast

MECHAI VIRAVAIDYA Chair Population and Community Development Association Bangkok, Thailand Executive Committee McGeorge Bundy, Chair Margaret Catley-Carlson Robert H. Ebert Werner Holzers Robert B. Millards Guillermo Soberón Acevedos

Finance Committee Robert B. Millard, Chair Margaret Catley-Carlson James D. Wolfensohn<sup>4</sup>

•;•

Audit Committee George Benneh.<sup>3</sup> Chair Eddah Gachukia Krister Stendahl<sup>3</sup>

Nominating Committee
McGeorge Bundy, Chair
Jorge Balán³
John C. Caldwell³
Margaret Catley-Carlson
Laura Chasin¹³
Robert H. Ebert
Aminata Traore
Mechai Viravaidya³

Salary Committee McGeorge Bundy, Chair Margaret Catley-Carlson Robert H. Ebert

1 Until December 1, 1994 2 Until June 30, 1994 3 As of July 1, 1994

4 As a non-trustee memi

#### OFFICERS

MCGEORGE BUNDY Chair of the Board

MARGARET CATLEY-CARLSON President

SANDRA ARNOLD! Vice President. Corporate Affairs

C. WAYNE BARDIN
Vice President, Center for Biomedical Research

JOHN BONGAARTS Vice President, Research Division

GEORGE F. BROWN Vice President. Programs Division SHIRLEY ALEXANDERS

MONICA KNORR Corporate Secretary<sup>3</sup>/Senior Director, External Relations Group

DONALD J. ABRAMS
Treasurer and Director of Finance

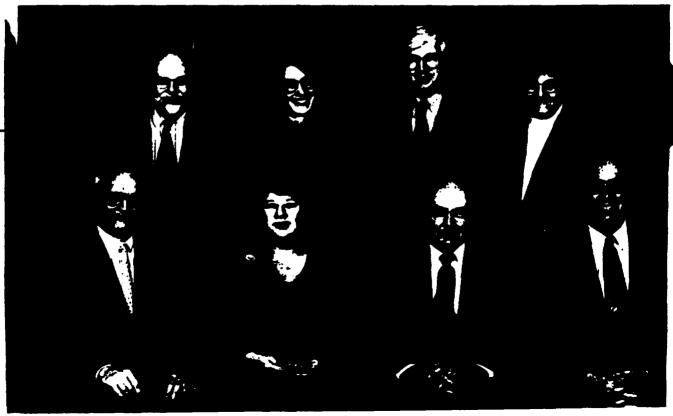
<sup>1</sup> As of July 5, 1994

<sup>2</sup> Until October 26, 1994

<sup>3</sup> As of December 8, 1994



Seated (Lior): Benneh, Catley-Carlson, Bundy, Millard, Gachukia Standing (Lior): Holser, Caldwell, Stendahl, Balán, Viravaidya



Seated (l to r): Bardin, Catley-Carlson, Bundy, Abrams Standing (l to r): Brown, Knorr, Bongaarts, Arnold

dare to think that a new global realization was attained at the International Conference on Population and Development in Cairo in September 1994. It is this: Demographic and development objectives will not be reached without improving people's—particularly women's—lives. Population policy must concern itself with more than family planning services.

This is precisely the agenda that the Population Council has been exploring, expanding, and implementing for many years.

For several decades policymakers have emphasized numbers—slowing the rate of population growth to accelerate economic development and alleviate poverty. At Cairo, the need to stabilize world population sooner rather than later was ever present, but the accent was on improving people's lives and future prospects. Issues related to the quality of men's and women's lives permeate the conference's Programme of Action: the value of education for all, but especially for young girls (who now comprise 70 percent of children not in school), of women's access to income and credit, and of men's involvement in caring for children. Improvement in these areas is a worthy end in itself, but it would also have a substantial, positive impact on our global demographic situation by changing people's childbearing decisions and reproductive behavior.

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While several issues at Cairo were highly contentious, family planning was so widely accepted that its value was hardly questioned. In this area the Cairo conference focused on improving quality of care and responding to individual needs, in part by recommending that appropriate reproductive health measures be integrated into family planning programs. Although the subject of abortion generated controversy that grabbed worldwide media attention, unsafe abortion was, for the first time, quietly acknowledged as a global public health problem

PRESIDENT'S MESSACE

# CHARTING A POST-CAIRO COURSE

responsible for hundreds of thousands of maternal deaths, disabilities, and illnesses every year.

Reflecting these concerns, Council programs stress safe contraception for women and men and improved quality and evaluation of family planning services. Council researchers continue to investigate ways to meet the vast unmet need for contraception and safe abortion around the world. The Council has been instrumental in testing the safety and acceptability of medical abortion using mifepristone (formerly RU 486). Medical abortion can save women's lives by providing a more private, noninvasive alternative to surgical abortion.

The Council also addresses several issues that were somewhat sidestepped at Cairo. These include the special needs of adolescents—the subject of a new Council initiative investigating ways to improve girls' prospects by increasing their educational and employment opportunities and fostering conditions that promote later, voluntary sexual and marital relationships and childbearing. On another front, the Council is pursuing research on preventing the spread of AIDS and other even more prevalent sexually transmitted diseases. Council scientists are developing a woman-controlled microbicide that would protect the user against a range of sexually transmitted diseases, including AIDS.

With global population quickly approaching 6 billion, we must not forget the impact of rapid population growth on development and the environment. Population is projected to increase until it stabilizes at less than 8 billion or reaches about 12 billion—depending on what we do in the next decade—by the year 2050, with most of the growth occurring in the developing world. Our research on the determinants and consequences of high fertility and rapid population growth, and our policy recommendations based on this research, have never been more needed.

There is now both exceptional promise and peril in the population field. On one side, we have global agreement on so many policies relevant to women. The Programme of Action sets quantitative goals for reducing infant, child, and maternal mortality rates by the year 2015. It also sets a price for a package of services in maternal health care, family planning, prevention of sexually transmitted diseases, and data collection: \$17 billion annually by the year 2000, \$21.7 billion by 2015. The world spertds a good deal more than this every year playing golf or preparing for war. As a global civilization, we have choices to make.

Post-Cafro, the horizon of the population field is nebulous. The Council is confronted with deep budget cutbacks in institutional and government spending—and even more proposed cuts—which threaten continuation of current programs and development of new initiatives. We need to reach out to a wider audience to make the case for continued progress in population-related work. The next few years will test our programming and fundraising abilities to build on and surpass the spirit of Cairo.

There is now both exceptional promise and peril in the population field.

As a global civilization, we have choices to make.

MARGARET CATLEY-CARLSON

March 1995

he Population Council is dedicated to two broad, closely linked goals: 1) improve the wellbeing and reproductive health of current and future generations and 2) achieve a humane, equitable, and sustainable balance between people and resources. This dual mission guides Council staff in pursuing five practical, overlapping objectives: broaden the population agenda, improve reproductive health, reduce unplanned and unwanted pregnancies safely, create conditions favorable for smaller families, and alleviate pressures for early sexual activity and marriage.

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The wide scope of Council activities in these areas—ranging from molecular biology to demography, from contraceptive development to on-site analyses of family planning programs and clinical trials—distinguishes the Council in the population field. The work described in the following pages represents a cross-section of the diverse projects underway at the Population Council.

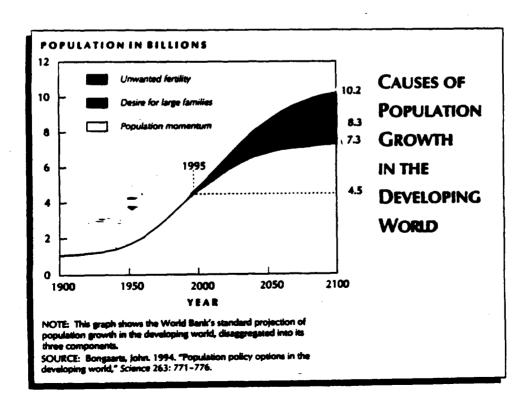
RESEARCH AND PROGRAM

# HIGHLIGHTS

The population field, once focused largely on family planning programs, has expanded to embrace a wide range of social and economic issues now understood to have a significant impact on reproductive behavior and demographic change. This broadened perspective was reflected in the agenda of the 1994 International Conference on Population and Development in Cairo—an agenda the Population Council played an important role in shaping. Indeed, the Council has for many years led the movement toward a broad-based approach to population issues.

The Council has also taken the lead in advocating a shift in focus from numbers to people—another tenet now widely held in the population field. The Council believes that family planning programs ought to help individuals meet their own reproductive goals in a healthful manner by focusing on reducing unwanted fertility safely. This rationale for family planning programs suggests that the population agenda must address issues related to individual wellbeing—notably reproductive health and freedom of choice—that may be minimized or excluded when family planning programs are designed to meet demographic targets.

In Cairo, the Council had many opportunities to communicate these views to the large international community of government leaders, policymakers, scholars, activists, and representatives of other nongovernmental organizations (NGOs) attending the population conference. Preparing for this event was a major institutional priority for the Council: Much work in 1994 was undertaken with an eye to







Cairo. The Council's activities at the conference included two official presentations by Council President Margaret Catley-Carlson; three panels at the NGO Forum addressing aspects of reproductive health, population policy, and quality of family planning services; a media briefing on women's lives in Islamic countries and related policy issues; and staff participation in several events sponsored by other organizations, including the Distinguished Lecture Series on Population and Development presented by the International Union for the Scientific Study of Population. Results of Council research and programs were widely disseminated through these channels and through publications distributed at the Council's information booth at the NGO Forum.

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#### Population policy

One of the Council publications that circulated at the Cairo conference was a 1994 "issues paper" titled *Population Growth and Our Caring Capacity*, which articulates the Council's argument for broadening the population agenda. The paper presents an approach to population policy developed by John Bongaarts (Vice President, Research Division) and Judith Bruce (Program Director, Gender, Family, and Development, Programs Division) that builds on Bongaarts's analysis of population policy options in "Population Policy Options in the Developing World," a 1994 article in the journal *Science*.

The issues paper explains that, while unwanted fertility remains a key cause of rapid population growth, a desire for large families and population momentum (a consequence of previously high fertility and a young population age structure) also contribute substantially to this growth. Thus, reducing overall fertility requires more than reducing unwanted fertility through family planning programs, vital as these programs are. Efforts are also needed to analyze and ameliorate the conditions that promote the other two components of population growth—efforts such as those underway at the Council to create conditions favorable for smaller families and to alleviate pressures for early sexual activity and marriage. This work aims to improve individual lives, but it will also contribute to stabilizing population—a goal the Council believes ought to be pursued in ways that do not jeopardize the health and wellbeing of individuals.

Effective implementation of population policy requires analysis of the evolution and performance of existing policies in various countries. Such analyses were presented at "Voices from the South—Population Policy Challenges: Case Studies from Africa, Asia, and Latin America," a panel at the Cairo conference NGO Forum, organized by Anrudh Jain (Director, Programs, Programs Division). The panel of social scientists discussed an ongoing comparative study of national policy evolution and performance in Egypt. India, Kenya, and Mexico. Country-specific studies were also undertaken in 1994 by staff in the Research Division, who investigated population policy in India and China.





#### Gender and family

One of the fundamental conditions fostering all three components of population growth is gender inequality. This phenomenon contributes to unplanned and unwanted pregnancies, compromises women's reproductive health, promotes the desire for large families, and encourages early and closely spaced childbearing. It does so by curtailing women's freedom of reproductive choice and access to family planning services, undermining their economic security, and denying them social roles apart from motherhood. The Council has long played a leading role in persuading the population field that women's lower status in society affects every aspect of the population issue. This view is now reflected in the Cairo conference's Programme of Action, which broadcasts an international consensus that equality for women must be a top priority on today's population agenda.

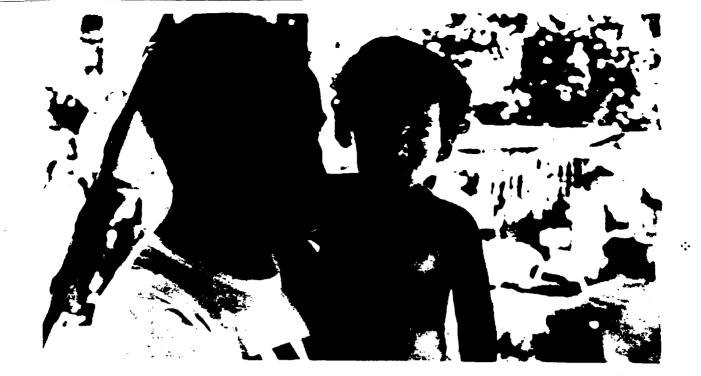
Because Council research on gender issues furthers all five institutional objectives and promotes the overarching goal of improving individual wellbeing, Council work in this area, and in the related area of family structure and function, is described in this first section. Clearly, this work has profound implications for the other four objectives discussed below.

Inequality undermines the wellbeing and health of women throughout the world. It also has direct demographic consequences in diverse societies, reports Gender Inequalities and Demographic Behavior, a series of papers published by the Council in 1994. The reports, written by Council staff and consultants, analyze how gender inequality manifests itself in different ways in Egypt, India, Ghana, and Kenya—four countries that have large populations but differ markedly in their cultures and rates of fertility decline. The studies reveal some commonalities—notably a high incidence of widowhood and a link between women's economic insecurity and high fertility—and some distinct differences among the countries in the nature and extent of gender inequality. These differences may underlie the varying effectiveness of the countries' population policies and family planning programs, the studies report. This series was one component of a project titled "The Family and Population Policy: Towards the Realization of Full Reproductive Choice," directed by Cynthia B. Lloyd (Director, Social Science Research, Research Division).

Gender and family issues in the Middle East were the focus of several Council events and publications in 1994. In addition to the report on gender inequalities in Egypt, these included a symposium on "Family, Gender, and Population Policy: International Debates and Middle Eastern Realities," organized by Barbara Ibrahim (Regional Director, West Asia and North Africa, Programs Division), Cynthia B. Lloyd, and Carla Makhlouf Obermeyer (Council consultant), and held in Cairo seven months before the International Conference on Population and Development. Findings from this symposium were presented in the report Family, Gender, & Population Policy: Views from the Middle East, prepared by Jodi Jacobson (Council consultant) and published by the Council's West Asia and







North Africa regional office. This office also published Arab Women: A Profile of Diversity & Change, a report by Nahid Toubia (Council consultant) on women's health, education, work, and rights in Arab countries.

Gender and family issues are addressed in the "Family Structure, Female Headship, and Intergenerational Poverty Program," a joint project of the Council and the International Center for Research on Women. In 1994 seven papers were added to the program's working papers series, ranging in subject from family law in Mexico to fathers' responsibility for children. The program also sponsored a meeting titled "Neglected Subjects in the Family: A Policy Dialogue."

The role of fathers in children's lives is gaining increasing attention in the population field, thanks in part to efforts by Programs Division staff. Following a workshop in Mexico in late 1993 titled "Bringing the Fathers Back In: Fathers' Responsibilities for Children" (co-sponsored by the Council, the Ford Foundation, and the Universitation Nacional Autónomo de México), social scientists in Latin America, the Caribbean, and North America formed a network to pursue research and programs related to this issue. In 1994 the Council began work on Men and Families, a newsletter for members of this network. The Council also co-sponsored with UNICEF a consultation titled "Men in Families," which explored ways to incorporate the issue of male involvement with children into the UNICEF agenda.

Family issues were also addressed in a study by Cynthia B. Lloyd, "Investing in the Next Generation: The Implications of High Fertility at the Level of the Family," published as a chapter in the 1994 volume *Population and Development: Old Debates, New Conclusions*. Her study provides an original analysis of the mechanisms underlying the fact that child welfare is most likely to be compromised in large families. Lloyd reports that girls and unwanted children are most vulnerable to the detrimental effects of living with many siblings.

#### IMPROVE REPRODUCTIVE HEALTH

The Council is-committed to improving the reproductive health of individuals as an end in itself and as a goal directly linked to the objective of reducing unplanned and unwanted pregnancies safely. Council efforts to meet this goal focus on improving the health of women and men in areas related to sexual activity; fertility and fertility regulation; wanted and unwanted pregnancy; and prenatal, labor/delivery, and postpartum health care. Because reproductive health has biological and social dimensions, improving it requires work in the laboratory and the field.

#### Reproductive physiology

Research in reproductive physiology at the Center for Biomedical Research is advancing our understanding of how the reproductive system functions at a basic biological level. The better our scientific understanding in this area, the better we can equip ourselves medically to fight the reproductive health problems that plague individuals and populations. This research also lays the foundation for developing new contraceptive technology, including methods that meet specific reproductive health needs, and provides means to investigate the reproductive health effects of methods under development.

The Reproductive Physiology Program, under the direction of James Catterall, focuses on the male reproductive system, which has received far less research attention over the years than the female system. Council work in this area includes studies in Catterall's and Milan Bagchi's laboratories on the mechanism of action of various steroid hormones. Catterall's laboratory, for example, uses advanced techniques of molecular biology to investigate how the steroid androgen carries out its function of orchestrating the masculinization of tissues. Understanding androgen action is essential for finding ways to inhibit or modify this activity—thereby opening a door to the development of new forms of reversible male contraception and, possibly, to therapies for hormone-linked reproductive health problems in men. This line of research also yields molecular tools that are useful for toxicological studies undertaken to identify the reproductive health effects of contraceptives based on androgens or anti-androgens.

The steroid hormones cortisol and corticosterone play critical roles in male and female fetal development in mammals. Two forms of an enzyme that facilitates the function of these steroids (118-hydroxysteroid dehydrogenase) are under investigation in the late Carl Monder's laboratory. Research in this lab has shown that one form of the enzyme plays an important role in testicular function and that a lack of the other form at birth results in a form of hypertension—a good example of how research on reproductive physiology may yield biomedical insights not limited to reproductive health.



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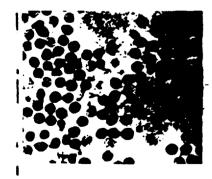
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Understanding how the testis develops and functions is vital for elucidating how sperm develop and mature (spermatogenesis), and, in turn, how this process can be manipulated to interfere with or promote fertility. The laboratories of Ching-Ling Chen, Yan Cheng, Glen Gunsalus, Matthew Hardy, and Patricia Morris study various aspects of the development and physiology of two key cellular components of the testis: Leydig cells (which secrete testosterone, a hormone required for spermatogenesis) and Sertoli cells (which maintain the environment in which spermatogenesis occurs). The identification of molecular signals that control the interactions between these cells and developing sperm was a recent, important finding in Morris's laboratory.

#### Sexually transmitted diseases

In the laboratory of David Phillips, scientists are studying how the human immunodeficiency virus (HIV), the pathogen that causes AIDS, is transmitted—an area of basic research with obvious reproductive health implications. Relatively little attention has been paid to the sexual transmission of HIV at this basic biological level; most research has focused on epidemiology, pathogenesis, immunology, and treatment of AIDS. Understanding fundamental aspects of HIV transmission holds the key to successful strategies for AIDS prevention. Work in Phillips's laboratory focuses on how HIV crosses the outer layer of cells (epithelium) in the genital tract and infects underlying cells.

In a direct application of this basic research in 1994, Phillips and colleagues at the Center for Biomedical Research developed a vaginally applied microbicide that inhibits infection by a range of sexually transmitted pathogens, including HIV. An Investigational New Drug application (IND) has been ap-



proved by the United States Food and Drug Administration (FDA) for this product. Work on the microbicide was carried out in collaboration with Christopher Elias (Senior Associate, Programs Division), who took the lead in establishing a dialogue about this product with women's health advocates. Participants in a series of meetings organized by Elias explored issues related to the development, testing, introduction, and acceptability of the microbicide. This process established an important precedent for the Council in engaging women's health advocates at an early stage in the development of reproductive health and contraceptive technology.

Moving from lab to field, the Council continued work on the Mexico Bisexual Men and AIDS project, a risk-reduction program for men and their male and female partners. Kathryn Tolbert (Associate, Programs Division) worked with project staff to produce a film on safe sex and bisexual behavior that was distributed in Mexico and the United States.

Also in Mexico, the Programs Division began work in two states, Guerrero and Oaxaca, to replicate a study of STD prevalence previously undertaken in Chiapas. The study explores issues of gender power and sexual behavior and their relationship to sexually transmitted diseases.

In the Council's West Asia and North Africa regional office in Cairo, the Reproductive Health Working Group, under the direction of Huda Zurayk (Senior Associate, Programs Division) continued analyzing its unprecedented study of gynecological and obstetric morbidity in Giza, Egypt. The Giza Morbidity Study, which reports a high prevalence of reproductive morbidity in this community, is being published in several formats in English and Arabic.

#### Safe abortion

Unsafe abortion causes unacceptably high levels of maternal deaths, disabilities, and illnesses every year. The Council's commitment to reducing these mortality and morbidity levels is reflected in work underway in the Center for Biomedical Research and the Programs Division, including studies of medical abortion using the antiprogestin mifepsistone (formerly RU 486) as an alternative to surgical abortion.

In 1994 the Council received US patent rights to misepristone as a donation from the drug's French manufacturer, Roussel Uclas. After submitting an IND application, the Council launched a Phase 3 clinical trial in the United States to test the safety and efficacy of misepristone as a medical abortifacient, under the direction of C. Wayne Bardin (Vice President, Center for Biomedical Research). Scientists at the Center are also investigating the long-term medical effects of misepristone and other antiprogestins and additional agents that could be used for medical abortion. An interdivisional management group is overseeing every aspect of the misepristone project, including fundraising, negotiations with potential



manufacturers and distributors, drug application filing, clinical trials, and media and public relations.

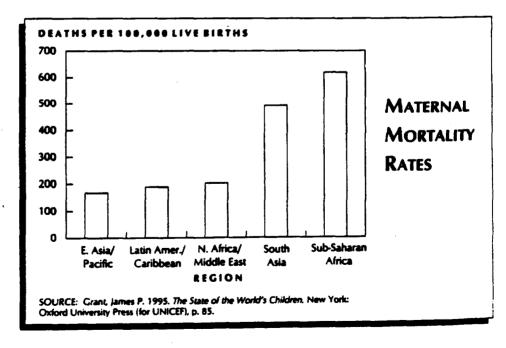
Beverly Winikoff (Program Director, Reproductive Health, Programs Division) developed and is overseeing acceptability and feasibility studies of medical abortion using mifepristone in developing countries. Research began in Vietnam in 1994, following up on studies conducted previously in China, Cuba, and India. The Reproductive Health Program produced a comprehensive review of the acceptability of medical abortion for a 1994 meeting of the Scientific Group on Medical Methods for Termination of Pregnancy, sponsored by the World Health Organization.

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Prevention and treatment of unsafe abortion is also promoted by the Programs Division through work in Latin America and the Caribbean. Efforts in Mexico centered on the public debate over decriminalizing abortion and on the quality of postabortion services offered in hospitals and clinics. Essays on these subjects were collected in the volume Razones y Pasiones en Torno al Aborto (Reasons and Passions Surrounding Abortion), edited by Adrianna Ortiz Ortega (Council consultant) and published in 1994 by the Council's regional office in Mexico City.

#### Safe motherhood

The Council continues its research on ways to reduce maternal morbidity and mortality from all gynecological and obstetric causes at the global and country level. For the past two years the Council has chaired the Interagency Group for Safe Motherhood, which works to keep safe motherhood high on the agendas of





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national and international institutions. In 1994 Safe Motherhood demonstration projects were initiated in Ecuador, Ghana, and Vietnam under the supervision of Nancy Sloan (Associate, Programs Division). These projects aim to determine the kind of prenatal and obstetric care that is most likely to improve women's health and reduce maternal mortality in these countries.

#### Postpartum care

The postpartum period is an often neglected phase in women's reproductive lives. Council staff are working to focus more attention on this period and to expand postpartum health care beyond traditional family planning concerns. Within the Programs Division, the Robert H. Ebert Program on Critical Issues in Reproductive Health and Population has undertaken investigations of postpartum service provision and of women's needs and preferences for care during this period; it is also testing alternative models of postpartum care. At the Center for Biomedical Research, scientists in the Contraceptive Development Program are seeking to develop contraceptives that will meet the reproductive health needs of breastfeeding women.



The safe reduction of unplanned and unwanted pregnancies is a goal shared by many organizations, but the Council plays a unique role in the collective pursuit of this objective. Rather than provide front-line services to individuals, the Council works behind-the-scenes, conducting biomedical, social science, and operations research, and assisting program managers and policymakers in designing services that help individuals meet their own reproductive goals in a healthful manner.

#### Family planning programs

The Council's perspective on the design and evaluation of family planning programs was articulated in a 1994 issues paper, Reconsidering the Rationale, Scope, and Quality of Family Planning Programs. This paper was based on a prior publication by Annudh Jain and Judith Bruce, "A Reproductive Health Approach to the Objectives and Assessment of Family Planning Programs," which appeared as a chapter in the 1994 volume Population Policies Reconsidered: Health, Empowerment, and Rights. The issues paper argues that helping individuals meet their own reproductive goals in a healthful manner ought to be adopted universally as the guiding rationale in designing family planning programs and as the main criterion for evaluating their success. It also stresses the need for a commitment to quality of care and for a new alliance between contraceptive and reproductive health services in family planning programs.



# FAMILY PLANNING PROGRAM SUCCESS

HARI index value

100

80

40

20

Sri Lanka U.S. Taiwan Philipi
1982-85 1970-75 1967-74 1978

Country

SOURCE: Jain, Anrudh and Judith Bruce. 5 accompanying main 1892. 1

This index measures family planning programs' success in helping individuals achieve their own reproductive intentions (HARI).

The Council helps family planning programs put these principles into action through work in its Research and Programs Divisions. Activities related to family planning are undertaken in the Programs Division through two interregional mechanisms: operations research and technical assistance (OR/TA) contracts and the Expanding Contraceptive Choice Program.

Operations research and technical assistance (OR/TA) remains a cornerstone of Council work. Operations research is a process of identifying and proposing practical solutions to problems in family planning/reproductive health programs with the goal of providing managers, administrators, and policymakers with the information they need to improve existing services and plan future ones. Technical assistance consists of transferring policies and procedures that have worked successfully in one family planning setting to other service providers and institutions. The Council's Programs Division administers all three regional OR/ TA contracts awarded by the United States Agency for International Development (USAID): Africa, Asia and Near East, and Latin America and the Caribbean. The Africa OR/TA II project, under the direction of Andrew Fisher (replaced by Ian Askew in 1995), completed its first year in 1994. The Asia and Near East project, under the direction of John Townsend, completed its fourth year. INOPAL II, the second phase of the OR/TA project in Latin America and the Caribbean, under the direction of James Foreit, was also completed. The Council was awarded a contract for this project's third phase, INOPAL III, which will operationalize the reproductive health approach to family planning programs.

The goal of the Expanding Contraceptive Choice Program is to facilitate the availability and appropriate use of contraceptive technologies within family planning programs by meeting users' needs. In sub-Saharan Africa, this program shifted its focus in 1994 from technology-dependent introductory activities to a broader assessment of the range of methods offered and of service delivery in family planning programs. Preintroductory studies of NORPLANT®\* implants were completed in Tanzania, Zambia, and Zimbabwe, and collaborative activities were begun in Botswana, Ethiopia, and Mauritius.

At the country level, the Programs Division worked to improve family planning services in Bangladesh, Mali, Pakistan, and Vietnam. In Mali, for example, a five-year community-based distribution project was initiated to increase access to and availability of voluntary family planning services in rural areas. This project is directed by Hervé Ludovic de Lys (Associate, Programs Division).

In another region of sub-Saharan Africa—a district of northern Ghana—the Navrongo Community Health and Family Planning Project is underway, modeled on an experimental study previously conducted by the Council in Matlab, Bangladesh. This joint project of the Research and Programs Divisions, and related research on determinants of reproductive behavior, were coordinated in 1994 by James Phillips (Senior Associate, Research Division) and carried out at the Navrongo Health Research Centre under the overall supervision of Ayorinde





<sup>\*</sup>NORPLANT® is the registered trademark of the Population Council for subdermal levonorgestrel implants.



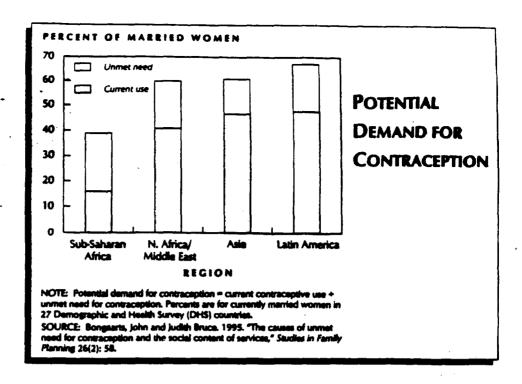
Ajayi (Regional Director, sub-Saharan Africa, Programs Division). Baseline research was completed and a pilot trial of the experiment was begun. Operations research was initiated to gauge community reaction to the pilot study, assess constraints on progress, and modify operations in response to lessons learned. The first goal of the Navrongo experiment is to develop a prototype family planning program compatible with the local social, cultural, economic, and institutional setting, with an eye to applying this program to other regions of sub-Saharan Africa.

Staff in the Research and Programs Divisions also joined forces to study the link between quality of care in family planning programs and contraceptive use. Barbara Mensch (Associate, Research Division) and Anrudh Jain, in collaboration with Maria Rosa Garate (Dissemination and Research Specialist, Programs Division) and Mary Arends-Kuenning (Council consultant), investigated this link in Peru. They found that quality of care significantly influences women's contraceptive use, whereas the mere presence of family planning services in a community has no such influence.

Integrating reproductive health services into family planning programs is the subject of Reproductive Health Approach to Family Planning, a report in the Ebert Program publications series. The paper is a compilation of presentations given by members of a panel organized by Programs Division staff at the 1994 USAID Cooperating Agencies meeting.

#### Unmet contraceptive need

At least 120 million women in the developing world have an unmet need for contraception. While researchers have traditionally attributed unmet need to inad-



equate access to contraceptive services and supplies, a 1994 working paper by John Bongaarts and Judith Bruce challenges this assumption. The paper, "The Causes of Unmet Need for Contraception and the Social Content of Services," argues that lack of knowledge, fear of side effects, and social and familial disapproval are primarily responsible for unmet contraceptive need, though access remains a problem for a significant proportion of people. This finding underscores the necessity of expanding investment in services that not only provide contraceptives, but also attend to clients' closely related health and social needs. It also suggests that family planning programs must reach beyond conventional boundaries of service provision to influence and alter the cultural and familial factors limiting voluntary contraceptive use.

#### Contraceptive research and development

The goal of reducing unwanted pregnancies is promoted through research in the Reproductive Physiology and Contraceptive Development Programs at the Center for Biomedical Research. The latter program, under the direction of Rosemarie Thau, aims to provide new technologies to meet the various contraceptive needs of women and men, especially in developing countries. Priority is given to methods that can address urgent requirements, such as the need for contraceptive methods that protect against sexually transmitted diseases, including AIDS, and more woman-controlled methods. Research also continues on methods that reduce user failures, side effects, discontinuation rates, and cost.

Work is progressing on subdermal implants for women. These deliver a steroid (a progestin), which diffuses slowly from capsules or rods placed beneath the skin, providing contraceptive effectiveness for one to several years. Studies continue on the Council's levonorgestrel-releasing implant, Norplant, and on a new version, Norplant II, which releases the same dose of progestin from two rods that Norplant releases from six capsules. In 1994 comparative Phase 3 clinical trials of the final formulation of Norplant II entered their fourth year. A New Drug Application (NDA) for this product is being prepared.

Studies also continue on a single implant for women that has some advantages over Norplant® and Norplant® II and may be more appropriate for lactating women. This implant, expected to be effective for two years, contains the progestin Nestorone™. In 1994 a Phase 2 dose-finding study of the prototype Nestorone™ implant was initiated in four countries, including the United States.

Progress was also made in research on intrauterine devices. A seven-year comparative study of two IUDs developed at the Council—the levonorgestrel-releasing IUD (LNg IUD) and the Copper T 380Ag IUD—has shown that these two devices are the most effective contraceptive methods ever investigated in long-term, multi-center, randomized clinical trials. Studies were initiated to determine whether the LNg IUD can be used to treat severe anemia, hypermenorrhea, and uterine myoma, following an unexpected finding several years ago that using the LNg IUD for more than five years protected women against uterine myoma and consequent hysterectomy. Another IUD developed at the Council—the Copper T 380A—was approved by the Food and Drug Administration as a device that can be used for ten years.

A new woman-controlled contraceptive under development at the Council is the vaginal ring, now in clinical trials. The ring slowly releases a steroid (progestin) or steroids (progestin and estrogen), which are then absorbed into the blood. One type of ring works for four months; another shows promise of being effective for one year—a more practical alternative for women in developing countries. Studies have shown that use of the ring does not increase the incidence of vaginal irritation.

Council scientists are also investigating a transdermal delivery system for steroids that could yield a convenient method of reversible, woman-controlled contraception. Six transdermal Nestorone<sup>th</sup> formulations were tested and evaluated in two clinics with promising results.

Several male contraceptive methods are being developed and tested at the Council. These include peptide-releasing subdermal implants and antifertility vaccines (immunocontraceptives). A strong argument in favor of continued development of immunocontraceptives is that a reversible, long-acting antifertility vaccine would be a valuable addition to the limited range of male contraceptive methods. A small-scale clinical trial of a male vaccine developed at the Council is underway in the United States. When used as a contraceptive, this vaccine would be combined with an androgen (MENT)-releasing implant designed to pro-



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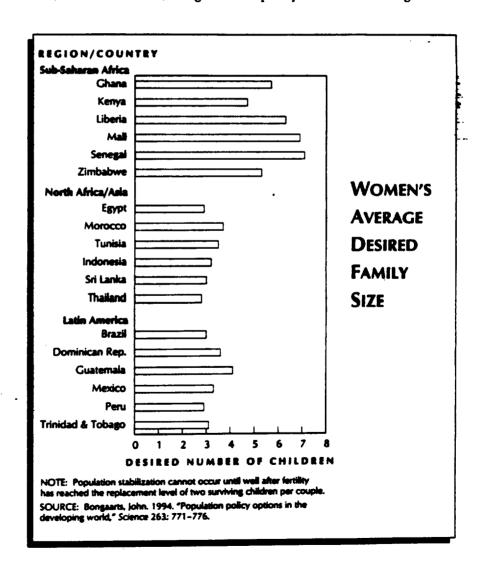


tect against loss of potency, libido, and secondary sex characteristics. The first clinical trial conducted with MENT, which would also be used in conjunction with the peptide implant for men, yielded encouraging results and will be expanded.

### CREATE CONDITIONS FAVORABLE FOR SMALLER FAMILIES

Population will continue to grow as long as people desire large families. In many parts of the developing world, desired fertility still exceeds two surviving children per couple—the replacement rate required for eventually stabilizing population. While fertility preferences are slowly declining in developing countries, efforts are needed to analyze and foster societal conditions that would hasten this decline.

Council research has shown that large average family size can be traced to a variety of sources, including poverty, limited education, high infant mortality rates, cultural tradition, and gender inequality. Discrimination against women



and girls operates on several levels to maintain high fertility preferences. Women in many developing countries choose to have large families because motherhood is the only valued social role for them, and because children serve as women's insurance against poverty, providing them with a source of economic support when they grow older and are likely to be widowed. Discrimination against girls inflates family size in regions where sons are valued more than daughters (parts of India, for example) and couples continue childbearing until they have achieved a desired number of sons, rather than children.

To create conditions favorable for smaller families, the Council's 1994 publication Population Growth and Our Caring Capacity recommends that societies make the following social and economic investments: increase education levels, especially among girls; increase child survival; improve the economic, social, and legal status of women; equalize women's and men's rights in marriage and responsibility for children; and support the right of children to be wanted, planned, and maintained. These measures are valuable in their own right, apart from their effect on fertility levels. Nevertheless, there is evidence that promoting equality and opportunities for women—by, for example, educating more girls, increasing women's access to income-earning work and financial credit, eliminating gender bias in inheritance laws, and promoting valued roles for women apart from motherhood—will not only improve the quality of women's lives but will also allow them to have fewer children without risk to their wellbeing.

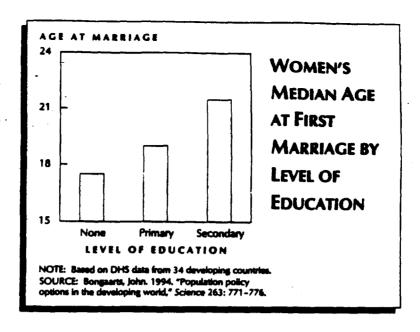


Nearly one-third of the population of the developing world is between the ages of 10 and 24. In many societies early sexual activity and marriage are widespread and often involuntary. This phenomenon has damaging social, economic, and health consequences for many young people, particularly women. Early childbearing within and outside of marriage also contributes substantially to population growth.

While the age structure of a population cannot be altered in the short run, the onset and pacing of childbearing can be modified through socially desirable means. To this end, *Population Growth and Our Caring Capacity* recommends that societies promote equality and opportunities for young women; provide young people with information about reproductive health and rights, sexuality, and marital rights; and increase young people's access to appropriate services.

Unfortunately, the special needs of married and unmarried adolescents are typically neglected in family planning programs. Adolescent reproductive behavior has also received inadequate research attention. Few systematic data exist on the social, cultural, and economic context in which early sexual activity and childbearing occur.





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Staff in the Council's Research and Programs Divisions are working to fill this gap: Sajeda Amin (Associate, Research Division), Judith Bruce, Cynthia B. Lloyd, and Barbara Mensch, in collaboration with Ayorinde Ajayi, Barbara Ibrahim, and Saroj Pachauri (Regional Director, South and East Asia, Programa Division), have developed a new research agenda on adolescence. The first site-identified to begin this investigation is Kenya, where officials readily acknowledge that adolescent sexual activity and childbearing are critical social problems. Despite this awareness, Kenyan policymakers and service providers have been minimally informed by evaluations of adolescent programs and facilities and have failed to assess the match between adolescent needs and the program and policy content of youth-serving organizations. Council staff have designed activities to expand the knowledge base that can be drawn upon to design effective programs and policies for young people.

Initiatives are also underway to raise awareness about adolescents' special needs and to promote strategies that will foster their health and wellbeing. Work undertaken in Latin America and the Caribbean in 1994 by Ana Langer (Regional Director, Latin America and the Caribbean, Programs Division) and Kathryn Tolbert focused on such issues as adolescent sexuality, consequences of pregnancy and childbearing for young women, adolescent fatherhood, factors associated with adolescents' decisions to induce abortion, and models of family planning service delivery for adolescents.

Early sexual activity and marriage were also the subject of research in the Middle East. Early Marriage & Reproduction in Two Egyptian Villages, a 1994 publication written by Laila El Hamamsy (Council consultant) and published by the Council's West Asia and North Africa regional office in Cairo, discusses so-ciocultural factors contributing to the high prevalence of early teenage marriage



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among girls in rural Egypt—a phenomenon that has negative social and health consequences for women as well as demographic repercussions.

#### LOOKING TO 1995

The Council's commitment to achieving the objectives discussed above will continue and expand in the future. Several Council projects initiated in 1994 will come to fruition in 1995 and can be anticipated as important contributions to the population field. These include:

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- completion of the mifepristone clinical trials in the United States and a report of findings from this study;
- initiation of phase two of the study of acceptability and feasibility of medical abortion using mifepristone in India;
- testing of the Council's microbicide in a Phase 1 clinical trial;
- launching of the third phase of the operations research and technical assistance (OR/TA) project in Latin America and the Caribbean (INOPAL III), and the second phase of the Asia and Near East OR/TA project;
- full-scale implementation of the Navrongo research experiment in family planning and community health;
- expansion of research and technical assistance activities in Vietnam through establishment of a country office;
- implementation of in-depth surveys on causes of unmet contraceptive need in four developing countries;
- initiation of a four-country study on interrelationships between fertility and investments in children;
- establishment of a Population Policy Research Fellowship Program in sub-Saharan Africa, administered by the Council's regional office in Nairobi;
- publication of Families in Focus: New Perspectives on Mothers, Fathers, and Children, a book written by Research and Programs Division staff and published by the Gouncil, which discusses family formation, structure, function, and policy, with an emphasis on the parent-child relationship;
- release of Learning About Sexuality: A Practical Beginning, a book published by the Council and the International Women's Health Coalition, which presents essays on aspects of sexuality ranging from its role in family planning programs to relevant biomedical research:
- introduction of *Population Briefs: Reports on Population Council Research*, a quarterly newsletter featuring short reports on work in the Research and Programs Divisions and Center for Biomedical Research.

The Council is committed to communicating its work, and that of others in the population field, to those concerned with population issues, including the public-at-large. To this end, the Council publishes and disseminates a wide range of written materials to varied audiences through its Publications and Public Information offices and its regional offices. The Council provides publications at no cost to professionals in developing countries who have limited funds or face considerable currency exchange barriers.

The Council publishes two scholarly, peer-reviewed journals, the quarterly Population and Development Review and the bi-monthly Studies in Family Planning, both of which have a dedicated readership worldwide. Supplements to the Review, each surveying in depth a major subject of policy relevance, are issued every other year. Paul Demeny is Editor of Population and Development Review; Ethel Churchill is Managing Editor. Julie Reich is Managing Editor of Studies in Family Planning.

Newsletters, working papers, conference proceedings, guidelines for research, pamphlets, and project summaries are among the other publications issued by the Council. Staff also publish their work in a wide range of external outlets, including peer-reviewed journals in their respective fields. Taken together, the nearly 400 publications listed in the following pages represent a substantial contribution to the knowledge base in the population field.

#### JOURNALS

Population and Development Review 20(1-4)

Population and Development Review supplement: Jason L. Finkle and C. Alison McIntosh (eds), The New Politics of Population: Conflict and Consensus in Family Planning.

Studies in Family Planning 25(1-6).

#### CENTER FOR BIOMEDICAL RESEARCH

Agarwal, A.K., T. Mune, C. MONDER, and P.C. White.
"NAD-dependent isoform of 118-hydroxysteroid dehydrogenase: Cloning and characterization of cDNA from sheep kidney," Journal of Biological Chemistry 269:25959–25962.

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# FAMILY STRUCTURE, FEMALE HEADSHIP, AND INTERGENERATIONAL POVERTY PROGRAM WORKING PAPERS

Family Structure, Female Headship, and Intergenerational Poverty is a joint program of the Population Council and the International Center for Research on Women.

- Brachet, Vivianne. "Absentee fathers: A case-based study of family law and child welfare in Mexico."
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#### DISTINGUISHED COLLEAGUES

#### DISTINGUISHED SCHOLAR

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#### OTHER CO-UNCIL PUBLICATIONS

Day of Dialogue on Women's Reproductive Health.

Population Growth and Our Caring Capacity. Issues Paper.

Reconsidering the Rationale, Scope, and Quality of Family Planning Programs. Issues Paper.

The Population Council 1993 Annual Report.

Well-qualified professionals are needed throughout the world to address population and development issues. Strengthening this professional base is an integral part of the Council's mission. Through its longstanding fellowship programs, the Council has helped advance the careers of nearly 2,000 social and biomedical scientists, many of whom have gone on to hold leadership positions in the population field. Through their work, the Council has played a key role in shaping population policy and programs and fostering research in the reproductive sciences.

The Population Council Fellowships in the Social Sciences, administered by the Research Division, support one year of work leading to a doctoral degree, postdoctoral research, or midcareer training in the population field. Candidates of all nationalities can apply for these fellowships, though preference is given to applicants from developing countries who are committed to returning home upon completion of their training. Fellowship recipients can pursue their studies at qualified institutions anywhere in the world. In 1994, fellowships were awarded to 21 out of 179 applicants.

The Middle East Research Awards Program in Population and Development (MEAwards), administered by the Programs Division, provides fellowships to Middle Eastern scholars pursuing advanced degrees in the social sciences. The Programs Division also administers a fellowship program in Vietnam and supports fellows in other developing countries who are linked to specific projects within the division. These fellows are selected on a competitive basis within particular regions, countries, or institutions.

The Council's biomedical fellowships program, administered by the Center for Biomedical Research, brings postdoctoral fellows to the Center to conduct research in reproductive physiology and contraceptive development. An effort is made to provide scientific experience that will be useful to the fellows upon their return home. In 1994, fellowships were awarded to 29 out of approximately 250 applicants.

#### BIOMEDICAL FELLOWS

Fellowship source, type, and/or title appear in parentheses.

#### AFRICA

#### BURKINA FASO

Blami Dao. Research associate, Obstetrics and Gynecology Clinic, CHU Aristide le Dantec, Dakar, Senegal. Development of contragestational medication using a combination of antiprogestins and antiestrogens (renewal).

#### THE AMERICAS

#### CANADA

Armand Zini. Urologist, McGill
University. Regulation and localization of
scavengers of reactive oxygen species in the
male reproductive tract (Ferdinand C.
Valentine Fellowship, New York Academy
of Medicine).

#### UNITED STATES

Lauri Benton. Graduate, Albert Einstein College of Medicine. Mechanisms controlling the proliferation of Leydig cell progenitors and their differentiation into mature Leydig cells (National Institutes of Health).

Kathleen Cullinan-Bove. Postdoctoral fellow, University of Maryland School of Medicine. Regulation of calcitonin gene expression by progesterone and estrogen in the uterus during pregnancy (National Institutes of Health).

Dianne Daniel. Postdoctoral associate. Rockefeller University. Cell-free analysis of the regulation of transcription by the androgen receptor (Surdna Foundation, renewal).

Dianne Hardy. Postdoctoral fellow, James Buchanan Brady Urologic Institute Research Laboratories, The Johns Hopkins Hospital. Structure, regulation, and mechanism of action of androgenresponsive genes (renewal).

Gerald J. Matthews. Urologist, Lenoù Hill Hospital. Programmed cell death and its relationship to spermatogenesis (American Foundation for Urologic Diseases).

#### ASIA

#### CHINA

Gao Hui-Bao. Associate professor, Shanghai Research and Training Center for Reproductive Medicine, Shanghai Second Medical University. Corticoateroidmediated control of testosterone production by the rat Leydig cell (The Rockefeller Foundation).

Liu Qiang-Yuan. Research associate, Department of Biochemistry and Molecular Biology, Institute of Basic Medical Sciences, Beijing. Characterization of human sperm proteins.

Tan Xin. Assistant professor, Beijing Medical University. Molecular structure of the cumulus oophorus and the interaction of the fertilizing spermatozoon with this material.

Tong Guo-Xia. Assistant professor, Harbin Medical University. Gene regulation by steroid and thyroid hormone receptors (renewal).

Yang Liang-Sheng. Researcher, Guangzhou Medical College. Identification and characterization of a novel progesterone inhibitor found in follicular fluid (The Rockefeller Foundation, renewal).

Yu He-ming. Assistant professor, National Research Institute for Family Planning, Beijing. Structure and genetics of an 80-kD human sperm protein (The Rockefeller Foundation, renewal).

Zhang Xun. Graduate student, Künming Institute of Zoology, Chingse Academy of Sciences. Role of growth factors in estrogen- and progreterone-induced gene expression (National Institutes of Health).

Zhu Li-Ji. Research associate, Beijing Union Medical College. Sertoli cell secreted proteins localized in the testis and epididymis (renewal).

#### INDIA

Rolands Aravindan. Research officer, Indian Institute of Science, Bangalore. Purification of proteins from germ cell-conditioned media that affect Sertoli cell secretory functions (renewal).

Muthukaeuppa Jeyakumar, Research student, t.enter for Reproductive Biology and Molecular Eridocrinology Primate Research Laborators, Indian Institute of Science, Bangalore, Interactions between thyroid hormone receptors and the transcription initiation machiners in cell-free systems.

Pradeep Kumar, Lecturer, Devi Ahilya Vishwavidyala: a. Lahore, Properties, function, and mot-cular hiology of estrus stage-specific protein of the rat uterus (The Rockefeller Four distion).

Malini Laloraya, Herearch associate, Devi Ahilya Vishwasidyaraya, Lahore, Factors regulating implantation of blastocysts in the rat uterus (The Rockefeller Foundation).

Promendu Mathur. 6 eader, Pondicherry University. Structure an 1 function of the testicular protein testin. The Rockefeller Foundation, renewal).

A. Jagannadha Rao. :	ır.
Department of Biochem	ian
Institute of Science. Effe	านกจ-
neutralization of luteiniz:	ne <b>00</b>
Leydig cell differentiation	kefeller
Foundation renewal)	4010000

Chidananda Sharma, Gr	ient.
Department of Biochemist:	
Institute of Science. Produc	icle-
stimulating hormone (FSH)	nd
FSH receptor peptides by re-	
DNA techniques for vaccine	)n
(renewal).	

#### JAPAN

Hiroaki Negishi. Instructor, Hokka io University School of Medicine. Mechanism of action of antiestrogens and antiprogratins in implantation.

#### EUROPE

#### ENGLAND

Rachel Pearce-Pratt. Postdoctoral fellov', Cambridge Research Laboratories. Cell biology and transference of the AIDS virus (Aaron Diamond Foundation, renewal).

#### FINLAND

Maarit Angerve. Physician, Helsinki University Central Hospital, Finland. Mechanism of action of antiprogestine and antiestrogens (renewal).

#### GERMANY

Joeanne Spiteri-Greeh. Postdoctoral fellow, Institute of Reproductive Medicine, University of Muenster. Effects of sexhormone-binding globulin/androgen-binding protein interaction with cell surface receptors (renewal).

#### ITALY

Claudio Panzironi. Researcher, Angelini Research Institute. Rome. Relationship between protein glycosylation and autoimmune disorders.

#### SERBIA

Radmila Runié. Postdoctoral fellow, University of Belgrade. Mechanism of transplacental transmission of HIV (renewal).

#### OCEANIA

#### AUSTRALIA

Moira O'Bryan. Graduate student, St. Vincent's Hospital, Department of Clinical Immunology, Fitzroy. Physiological significance of gonadotropin surge-inhibiting factor in male and female reproductive function (renewal).

## SOCIAL SCIENCE FELLOWS

Fellowship type or title appears in parentheses.

#### AFRICA

#### ALGERIA

Boy Benhamedi. Study toward Ph.D. in demography, University of Montreal.

#### Congo

Prosper Poukouta. Study toward Ph.D. in demography. Pennsylvania State University.

#### ECYPT

Mawaheb El-Mouelhy. Study toward M.P.H., Harvard University (MEAwards fellowship).

Montasser M. Kamal. Study toward Ph.D. in medical anthropology, McGill University (MEAwards fellowship).

Ossama Messallam. Study toward M.P.H., Boston University (MEAwards fellowship).

#### GHANA

Cherub Antwi-Nsiah. Postdoctoral research in social sciences, Nayrongo Health Research Centre (Mellon/Ghana fellowship).

Cornelius Debpuur. Study toward Ph.D. in demography, Brown University.

Joseph DeGraft-Johnson. Study toward Ph.D. in public health, University of North Carolina at Chapel Hill.

Eva D. Tagoe. Study toward Ph.D. in sociology, Brown University.

#### KENYA

Mabel Nyarango. Fieldwork in Kenya toward Ph.D. in demography, University of North Carolina at Chapel Hill.

#### MALAWI

Eliya Zulu. Study toward Ph.D. in demography, University of Pennsylvania.

#### NIGERIA

Jacob A. Adetunji. Postdoctoral research and training in infant and child mortality, Harvard University.

#### SENEGAL

Pierre Ngom. Study toward Ph.D. in demography, University of Pennsylvania and Mellon/Chana fellowship for postdoctoral research in demography. Navrongo Health Research Centre.

#### SLDAN

Mohi Eldin Magsoub. Study toward Ph.D. in health education, University of Limburg (MEAwards fellowship).

Maha El Tayeb El Obeid. Study toward M.A. in nutritional anthropology. Iowa State University (MEAwards fellowship).

Afaf Omer. Postdoctoral research in sociology. Brown University.

#### THE AMERICAS

#### BOLIVIA

Guido Pinto-Aguirre. Study toward Ph.D. in demography, University of Wisconsin-Madison.

#### Mexico

Alejandro Cervanteo-Carson. Study toward Ph.D. in sociology, University of Texas at Austin.

#### UNITED STATES

Karen Andes. Study toward Ph.D. in demography, Northwestern University.

Philip Chu. Study toward Ph.D. in demography, University of California at Berkeley.

Robert Davis. Fieldwork in Mauritania toward Ph.D. in risk management strategy, Johns Hopkins University.

Anita Garey. Postdoctoral research in sociology, Brown University.

Steven Green. Fieldwork in Kenya toward Ph.D. in demography, University of Pennsylvania.

Margaret Greene. Postdoctoral research in demography, The Population Council (1994–95 Bernard Berelson Fellow).

Darryl Holman. Study toward Ph.D. in demography. Pennsylvania State University.

David P. Lindstrom. Study toward Ph.D. in demography, University of Chicago.

Ivy Pike. Fieldwork in Kenya toward Ph.D. in anthropology, Binghamton University.

Jennifer Zeitlin. Study toward Ph.D. in international health economics, Harvard University.

#### ASIA

#### BANGLADESH

Mahidul Maision. Study toward M.P.H., Boston University (MEAwards fellowship).

#### BAHRAIN

Nadia Sayed Ali Jaafar. Study toward Ph.D. in population and development.

University of Oxford (MEAwards fellowship).

#### CHINA

Jiali Li. Postdoctoral research and training in population, The Population Council (1993–94 Bernard Berelson Fellow).

Duoleo Wang. Study toward Ph.D. in population, Southampton University.

#### INDIA

Alaka Basu. Midcareer study in demography, Cornell University.

Leila E. Caleb. Study toward Ph.D. in maternal and child health, Johns Hopkins University.

Arpita Chattopadhyay. Study toward Ph.D. in demography, Brown University.

Susmita Gheeh. Study toward Ph.D. in economic development, University of Southern California (1993–94 Ritchie Reed Fellow).

#### JORDAN

Farha Nasif Ghannam. Study toward — Ph.D. in social anthropology, University of Texas at Austin (MEAwards fellowship).

Assel Sawalha. Study toward Ph.D. in cultural anthropology, City University of New York (MEAwards fellowship).

#### Korea

Woojin Chung, Postdoctoral research in demography, University of North Carolina at Chapel Hill.

Shin-wha Lee. Study toward Ph.D. in international relations, University of Maryland.

#### LEBANON

Abla M. Sthat. Study toward Ph.D. in epidemiology, London School of Hygiene and Tropical Medicine.

#### PAKISTAN

Schail Agha. Study toward Ph.D. in child mortality, Johns Hopkins University.

#### PHILIPPINES

Rommel Silverie. Study toward Ph.D. in sociology. University of Hawaii at Manoa.

#### SRI LANKA

Lakshman Dissanayake. Study toward Ph.D. in population, University of Adelaide.

#### TURKEY

Aydam Gulerce. Postdoctoral research in developmental psychology, University of North Carolina at Chapel Hill (MEAwards fellowship). Ayea Kurdoglu. Visiting research in sociology, University of Warwick (MEAwards fellowship).

Esra Culsum Osyurek, Study toward M.A. and Ph.D. in anthropology, University of Michigan (MEAwards fellowship).

#### VIETNAM

Quynh Uyen Bul. Study toward M.P.H., Tulane University (Buffet fellowship).

Lan Ngoe Nguyen. Study toward M.P.H., Columbia University (Buffet fellowship).

Huan Nguyen-Dinh. Study toward Ph.D. in population economics, McMaster University (1994–95 Ritchie Reed Fellow).

#### EUROPE

#### BULGARIA

Dimiter N. Philipov. Midcareer study in demography, Princeton University (1993– 94 Frank W. Notestein Fellow).

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#### RUSSIA

Victor Agadjanian. Fieldwork and study toward Ph.D. in sociology, University of Southern California. Awards and contracts are the primary means through which the Council conducts research, transfers technology, and strengthens institutional capacity within the population field. Over four decades, the Council has collaborated with universities, hospitals, research centers, family planning agencies, and individuals in most countries of the developing world. Most of the Council's work is carried out through such collaboration. In 1994, awards and grants went to some 180 institutions and individuals in 49 countries, most of them in Africa, the Americas, and Asia.

The Programs Division administers the largest proportion of the Council's awards and contracts. These grants flow to agencies and individuals collaborating in the work described in the "Research and Program Highlights" section of this report. This listing includes the MEAwards (offered through the Middle East Research Awards Program in Population and Development), which support studies of women's health and social issues in the Middle East by scholars in that region.

The Center for Biomedical Research administers most of the Council's awards and contracts in the biomedical field, including clinical studies conducted by members of the Council's International Committee for Contraception Research.

#### AFRICA

#### Cameroon

#### University of Yaoundé, Yaoundé

Contraceptive technology update session on NORPLANT® capsules during the Third International Congress of the African Society of Obstetricians and Gynecologists.

#### Egypt

#### Ms. Amira Bahieddin, Cairo

Comparative study of the legislative status of Arab women (MEAward).

#### Cairo Demographic Center

Study of continuation/discontinuation of contraceptive use by method and reasons for dropout in the Clinical Services Improvement project.

## Egyptian Fertility Care Society, Cairo Study of IUD use in Egypt.

Improving the counseling and medical care of postabortion patients in Egypt.

#### El-Minia University

Comparative use-effectiveness study of Normant® and Normant® II implants.

#### Iba Khaldoun Center, Cairo

Evaluation of Egypt's population policy.

#### Drs. Beverly Jensen, Donald Heisel, Sahar El Tawila, and Sonia Dabbous, Cairo

Study of the images of women, the family, and family planning in popular television melodramas in Egypt (MEAward).

#### Dr. Mostasser Kamal, Cairo

Study of the impact of privatization of Egyptian health services on urban women's health (MEAward).

#### National NGO Steering Committee for the International Conference on Population and Development, Cairo

Research, workshops, and NGO report preparation for ICPD.

#### Social Planning, Analysis, and Administration Consultants, Cairo

Profile of clients of different providers of family planning services.

Study of provider training and long-term client outcome.

#### University of Alexandria, Faculty of Nursing, Alexandria

Developing approaches to community-based family planning outreach in Egypt: An assessment of Raidat Riflat programs.

#### Ghana

#### Family and Development Program, University of Ghana, Legon

Media activities related to the International\_ Year of the Family. ÷

## Health Research Unit, Ministry of Health, Accra

Situation analysis to evaluate the content of care.

Validation study of pregnancy complications.

#### Navrongo Health Research Centre, Navrongo

Support for Phase 1 of the Navrongo Health and Community Family Planning Project.

#### Kenya

## African Medical and Research Foundation, Nairobi

Dissemination workshop on the project "Female adolescent sexuality in Kenyan secondary schools."

#### Centre for the Study of Adelescence, Nairebi

Study of knowledge, attitudes, and behavior relating to sexual and contraceptive

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practice, at the Egerton University Health Centre.

Review of research on adolescents and of youth-serving organizations in Kenya.

#### Kenya Medical Women's Association, Nairobi

Congress on the health of women and safe motherhood.

#### Mali

#### Centre d'Etudes et de Recherches sur la Population pour le Développement, Bamako

Strengthening family planning programs in the Sahel region through improved evaluation, management information systems, and research.

#### Morocco

#### Dr. Aicha Belarbi, Rabat

Study of status, ways of life, and aspirations of unmarried youth in Morocco (MEAward).

#### Dre. Mokhtar El Harras and Drise Bensaid, Rabat

Study titled "Islam: The sociocultural system and fertility in Morocco" (MEAward).

#### Mozambique

#### Hospital Central de Maputo, Maputo

Study of the characteristics of patients admitted for induced abortion, and evaluation of health and economic costs of abortion complications and pregnancy interruptions at the Maputo Central Hospital.

#### Nigeria

Obafemi Awolowe University, Bo-Ife Support for operations research undertaken by the OR unit and network.

#### Women's Health and Action Research Unit, Obalemi Awelawo University, Healto

Assessment of abortion prevalence and services and the contribution of abortion to maternal mortality and morbidity in Nigeria.

#### Senegal

#### Ministry of Public Health and Social Affairs, Dakar

Situation analysis of Senegal's family planning service delivery system.

#### Réseau de Recherche en Santé de la Reproduction en Afrique, Dakar

Support for the Reproductive Health Network.

#### Sudan

#### Dr. Amna Badri, Omdurman

Study of the critical aspects of women's status that are predictive of fertility rates in Sudan (MEAward).

#### Drs. Isam Taba Osman and Paul Wani Gore, Khartoum

Study of population displacement in the -Sudan: Toward a policy on involuntary resettlement based on the New Halfa experience (MEAward).

#### Tanzania

#### Family Planning Association of Tanzania, Dar es Salaam

Comparative study of NorPLANT<sup>®</sup> implant services delivered by physicians and paramedics.

#### Tunisia

#### Dr. Lilia Labidi, Tunis

Study titled "Death: Popular culture and modern medicine in the contemporary Arab world" (MEAward).

#### Office National de la Femille et de la Population, Tunis

National workshop on operations research.

#### Zambia

#### Department of Post-Basic Nursing, University Teaching Hospital, University of Zambia, Lusaka

Study of women seeking termination of pregnancy or treatment of incomplete abortion at the University Teaching Hospital.

University Teaching Hospital, University of Zambia, Lusaka

Study of removals of NonPlant® capsules after five years among Zambian women.

#### Zimbabwe

## University of Zimbabwe, Department of Obstetrics and Gynecology, Harare

Preintroduction clinical trial of NORPLANT® capsules in Zimbahwe.

Study of formulation preferences of overthe-counter vaginal preparations.

#### THE AMERICAS

#### Argentina

#### Fundación Instituto de Biología y Medicina Experimental, Buenos Aires

Research on a method for assessing the fertilization capacity of sperm samples in humans.

#### Hospital Provincial, Rosario

Preintroduction clinical trial of NORPLANT® capsules.

#### Bolivia

#### CARE/Bolivia, La Paz

Overcoming barriers to rural family planning service delivery in the public sector.

#### Centro de Investigación, Educación y Servicios, La Pas

Comparative study of three strategies to improve the sustainability of a Bolivian family planning provider.

#### Community and Child Health Project, Project Management Unit, Ministry of Health, La Pas

Pilot project to increase access to family planning services in rural campesino communities.

## Servicio de Información para el Deserrollo. La Paz

Study of unwanted pregnancy and unsafe abortion in Bolivia.

#### Tailor de Estudios Sociales, La Paz

Study of the characteristics and quality of abortion services conducted in the private medical sector in Bolivia.

#### Brazil

#### Centro de Estudos e Comunicação en Sexualidad e Reprodução Humana, São Paulo

Production of a videotape on legal abortion in São Paulo.

#### Centro de Pesquiase e Controle das Doeugas Materno-Infantis de Campinas, São Paulo

Elaboration of prototype informationeducation-communication materials on the diaphragm, to be used in introductory trials.

Evaluating the effectiveness and acceptance of a new method of disphragm use.

#### Centro lategrado de Saúde Amaury de Medeiros, Recile

Assessment of quality of care for incomplete abortion in Recife.

#### Colectivo Feminista Sexualidade e Saúde, São Paulo

Evaluation of the effectiveness and acceptance of a new method of diaphragm use.

#### Escola Paulista de Medicina, São Paulo

Study of the binding of sex-hormonebinding globulin to cell membranes and of the mechanism of action of this protein.

#### Fundação Assistencial Educacional e Médico-Social, Goiania

Study of the effects of the availability of misoprostol on the incidence of complications for induced abortion.

#### Fundação Instituto Miguel Calmon de Estudos Sociais e Económicos, Salvador

Situation analysis of reproductive health in Bahia.

#### Instituto Materno Infantil de Pernambuco, Recife

A new strategy for counseling on the use of lactational amenorrhea to prolong natural postpartum infertility.

#### Protecas Médica A. Empresas Ltda., Salvador, Bahia

Acceptability and cost-effectiveness of postpartum and postabortion family planning in a health maintenance organization in Bahia.

#### Sociedade Cearense de Pediatria, Fortaleza

Situation analysis of reproductive health in Ceara, in collaboration with the State Secretariat of Health.

#### Chile

## Asociación Chilena de Protección de la Familia, Santiago

Comparative use-effectiveness study of NORPLANT® and NORPLANT® II implants.

#### Centro de Desarrollo y Estudios Jurídicos, Santiago

Media activities related to the International Year of the Family.

#### Instituto Chileno de Medicina Reproductiva, Santiago

Comparative use-effectiveness study of Normant® and Normant® II implants.

Study of the correlation of *in vivo* and *in vitro* release rates of Nestorone<sup>TM</sup> progestin from subdermal implants.

Assessment of the effects of MENT on steroid hormones following intramuscular administration in normal men.

Purchase of laboratory equipment for use in ICCR-sponsored clinical studies.

Study of the bioavailability of Nestorone<sup>TM</sup> progestin administered transdermally.

Clinical dose-finding study of Nestorone™ progestin subdermal implants.

Phase 2 clinical study of Nestorone™ progestin in lactating women.

Bone metabolism study of nursing women who use NORPLANT® capsules.

Assessment of the effects of multiple intramuscular injections of MENT in normal and hypogonadal men.

Study of the correlation of in vivo and in vitro release rates of Nestorone<sup>TM</sup> progestin from contraceptive vaginal rings.

Bone metabolism study of nursing women who use progesterone vaginal rings or the Copper T 380A IUD.

## Pontifica Universidad Católica de Chile, Santiago

Study of the effects of anordiol on ovulation in the cebus monkey.

#### Colombia

## Asociación Pro-Bienestar de la Familia Colombiana, Bogotá

Posimarketing surveillance of Normant® capsules.

Testing of pricing and payment systems to improve access to and cost recovery from Normant capsules.

#### Dominican Republic

#### Asociación Dominicana Pro-Bienestar de la Familia, Santo Domingo

Safety and efficacy study of reformulated Normant® II rods.

Clinical study of vaginal inspection via colposcopy in women not using a contraceptive vaginal ring.

Phase 1 pharmacodynamic study of Nestorone<sup>TM</sup> progestin.

Clinical studies of contraceptive vaginal rings of different formulations.

Study of Nestorone<sup>TM</sup> progestin implants.

Clinical study of contraceptive vaginal rings releasing norethindrone acetate/ ethynylestradiol.

Comparative blood-concentration study of levonorgestrel released from NORPLANT<sup>●</sup> II rods.

Clinical study of the efficacy of NORPLANT® capsules.

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Study of estradiol blood levels associated with the use of estradiol vaginal rings.

#### Ecuador

#### Centro Médico de Orientación y Planificación Familiar, Quito

Operations research to introduce Depo-Provers to family planning programs in Ecuador.

Institutionalizing operations research and program evaluation capabilities in an Ecuadoran family planning organization.

#### Guatemala

# Asociación de Ginecología y Obstetricia de Guatemala, Guatemala... City

Study of reproductive health problems and the role played by unwanted pregnancies in Guatemala.

Symposium titled "New alternatives in hormonal contraception" at the IX International Congress of the Society for the Advancement of Contraception.

#### Asociación Pro-Bienestar de la Familia de Guatemala, Guatemala City

Project to improve acceptance of longacting contraception through the introduction of NonPLANT® capsules and the reduction of medical barriers in Guatemala.

Baseline study of reproductive health beliefs and attitudes of males in four health districts in the Department of El Quiche.

Support for injectable contraceptive service delivery provided by volunteer community family planning promoters.

#### Centro de Población de la Universidad del Valle de Guatemala, Guatemala City

Study of reproductive health cognition and speech patterns of urban and rural indigenous community residents in the Department of Quetzaltenango.

#### Project Concern Internacional— Guatemala, Atitlán

Project to increase knowledge and skills of reproductive service providers in two conservative indigenous communities on Lake Atitlán.

#### Haiti

#### Comité de Bienfaisance de Pignon, Port-au-Prince

Support for a model postpartum program for rural populations in Haiti.

#### L'Institut Haïtien de Santé Communautaire, Port-au-Prince

Improvement of promoters' performance through supervision.

#### Honduras

#### Asociación Hondureña de Lactancia Materna, Tegucigalpa

Improvement of reproductive health through nongovernmental organizations promoting social development.

#### CARE Internacional en Honduras, Tegucigalpa

Incorporation of family planning into CARE programs in Western Honduras.

#### Mexico

#### Academia Mexicana de Investigación en Demografía Médica, A.C., Mexico City

Study of the relationships between contraceptive method choices, method characteristics, and breastfeeding practices, in collaboration with the Instituto Mexicano de Seguridad Social.

Strategy to increase the acceptance of noscalpel vasectomy in outpatient clinics of the IMSS.

## Analysis of a large survey of adolescent sexual behavior.

Study of the prevalence and sociocultural context of reproductive tract infections in the IMSS Guerrero Delegation.

#### Casa de la Mujer "Rosario Castellanos," A.C., Oaxaca

Study of the prevalence and sociocultural context of reproductive tract infections in the Valley of Oaxaca.

## Centro de Investigaciones en Salud de Comitán, A.C., Chiapas

Technical assistance and meetings on sexually transmitted diseases in three states of Mexico.

#### Centro para los Adolescentes de San Miguel de Allende, A.C., San Miguel de Allende

Study of the prevalence and significance of sexual violence and aggression in San Miguel de Allende and design of prevention programs.

#### Consejo Nacional de Prevención y Control del SIDA, Mexico City

Project to influence risk behaviors of bisexual males in Mexico

#### Desarrollo e Investigación de la Planificación Familiar, A.C., Mexica City

Strengthening the coverage extension strategy of Mexico's Ministry of Health.

Project to expand activities related to NORPLANT® capsules in Mexico.

#### Dirección General de Atención Materno Infantil, Mexico City

Support for an international conference on breastfeeding and production of a training manual on breastfeeding.

## Ediciones Técnico Científicas, S.A. de C.V., Mexico City

Production of the INOPAL fourth- and fifthyear workplan; seventh, eighth, and ninth semiannual reports; and ALTERNATIVAS.

#### El Colegio de México, A.C., Mexico City

Media coverage of output of the Interdisciplinary Group of Women, Work, and Poverty.

#### Federación Mexicana de Asociaciones Privadas de Salud y Desarrollo Comunitario, A.C., Ciudad Juáres

Cost analysis of three services in private family planning programs.

#### Fundación Mexicana para la Planeación Familiar, Mexico City

Use of quality management systems to institutionalize operations research in family planning organizations.

#### Fundación Mexicana para la Salud, A.C., Mexico City

Study on breastfeeding and work in rural Mexico from an anthropological and gender perspective, in collaboration with the Instituto Nacional de la Nutrición Salvador Zubirán.

Study on intrapartum social support and its effects on breastfeeding, in collaboration with the Instituto Nacional de Salud Pública. Case, tudies of family planning, AIDS, immunicization, and cholera policies in Mexico. Unking research to decisio, making.

#### Institut Nacional de la Nutrición Salvado Zubirán, Mexico City

Study of the genetic polymorphism of testosterio restradiol hinding globulin.

#### Instituto <sup>e</sup> ccional de Salud Pública. Cuernavac - Morelos

Strengthenin the Institute's operations research cape offities.

#### La Liga de la Leche de México, A.C., Mexico City

Targeted educa—mal intervention to increase the pre-dence and duration of exclusive breasting.

#### Nicaragua

Asociación ProNicaraguense, Y
Use of managemoperations reseat

#### Paraguay

Centro Paragua ilos de
Población, Asun

Development of los inprove the quality of care or munity-based distribution in

#### Peru

Associación Benéfica l' IA
(Proyectos en Informatic Salud,
Modicina y Agricultura), ma
Project to expand activities re ited to
NORPLANT® capsules in Peru.

#### Centro de Investigaciones Socialógicas, Económicas, I diticas y Antropológicas de la Pontífica Universidad Católica del Perc. Lima

Technical assistance for creating database on domestic violence in Peru.

#### Instituto Andino de Estudios en Población y Desarrollo, Lima

Development of organizational mode. and means of family planning service deli ery to rural and semirural populations in two regions of Peru.

Development of a sustainable model to disseminate "The ABC of Primary Care 1 Family Planning" in the Libertadores-W ri region.

Assessing the impact of the availability and quality of service on contraceptive use and fertility in Peru.

#### Promoción de Labor<del>es</del> Educativas y Asistenciales en Favor de la Salud, Lima

Technical assistance for postpartum family planning training.

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#### United States

## American College of Nurse-Midwives, Washington, DC

Organization and initiation of a situation analysis for the Safe Motherhood Demonstration Project in Vietnam.

#### AVSC International, New York City

Situation analysis of Turkey's family planning and pregnancy termination services.

#### Columbia University, New York City

Study of formulation preferences of overthe-counter vaginal preparations.

#### Family Health International, Research Triangle Park

Institutionalizing operations research and program evaluation capabilities in an Ecuadoran family planning organization.

#### The Feminist Press, New York City

Publication of a hook under the Council's SEEDS project.

#### Ms. Farha Nasif Ghannam, Austin

Study of displacement and resettlement: The social reconstruction of space in Zawiya Al-Hamra, Cairo (MEAward).

## Health Research Association of the LAC/USC Medical Center, Los Angeles

Evaluation of Nestorone<sup>TM</sup> progestin implants of various steroid formulations.

Evaluation of vaginal rings releasing norethindrone acetate and ethynylestradiol.

Study of lipoprotein levels associated with the use of NORPLANT® capsules.

Three- to five-year safety and efficacy study of Normania II rods.

Clinical study of estradiol-containing vaginal rings for estrogen replacement.

Comparative blood-concentration study of levonorgestrel released from Normant® II rods.

## International Center for Research on Women, Washington, DC

Analysis of data on the care of children, in connection with the Population Council's International Year of the Family publication, Families in Focus.

Technical assistance to the Population Council's program on family structure.

#### Ms. Rhoda Kanaaneh, New York City

Study of the impact of Israeli population policy and family planning services on Palestinian perceptions of motherhood and family (MEAward).

#### National Patent Development Corporation, New Brunswick

Research on hydrogel-type polymers as vehicles for controlled release of LHRH analogs.

#### New York Hospital-Cornell University Medical College, New York City

Comparative blood-concentration study of levonorgestrel released from Normant II rods.

Research on corticosteroid metabolism in juvenile hypertension.

#### New York University Medical Center, New York City

Comparative blood-concentration study of levonorgestrel released from Norplant® II rods.

Comparative use-effectiveness study of NORPLANT® and NORPLANT® II implants.

Safety and efficacy study of reformulated Norplant® II rods.

Study of contraceptive vaginal rings containing norethindrone acetate and ethynylestradiol.

## President and Fellows of Harvard College, Cambridge

Support for gender, family, and population policy debates.

## Regents of the University of California, San Francisco

Comparative use-effectiveness study of NORPLANT® and NORPLANT® II implants.

Comparative blood-concentration study of levonorgestrel released from NORPLANT® II rolls.

Safety and efficacy study of contraceptive rings containing norethindrone acetate and ethynylestradiol.

Clinical study of the efficacy of NORPLANT® II rods.

## Reproductive Health Services, St. Louis

Study of the abortifacient effects of misoprostol administered intravaginally in the first trimester of pregnancy.

#### Tufts University, Boston

Study of male contraceptive development, targeting an RNA/DNA protein.

#### University of Medicine and Dentistry, Robert Wood Johnson Medical School, New Brunswick

Comparative use-effectiveness study of Norplant® and Norplant® II implants.

## University of Michigan, Ann Arbor Proposal for analysis of focus group data on

Proposal for analysis of focus group data on women's status and family planning in Bangladesh.

#### ASIA

#### Bangladesh

#### Ain O Salish Kendra, Dhaka

Editing and publishing the papers presented in the symposium series "Comparative analysis of feminist perspectives."

#### Dr. Zaman Ara, Dhaka

Development and testing of a practical community-based health delivery system for rural and periurban women with reproductive tract problems.

## Bangladesh Association for Prevention of Septic Abortion, Dhaka

Assessment of reasons for having traditional abortion by women hospitalized for postabortion complications.

#### Dr. Abdel Latif Bhuiya, Dhaka

Study of high-risk obstetric patients attending the antenatal clinic at Dhaka Medical College !lospital.

#### Ms. Ismat Ara Bhuiya, Dhaka

Sociodemographic and behavioral profile of professional blood donors in relation to STDs and HIV/AIDS in major cities of Bangladesh.

## Center for Population and Development, Dhaka

Assessment of alternative approaches to contraceptive logistics management at the peripheral level.

#### Environmental Survey and Research Unit, Department of Geography, University of Dhaka, Dhaka

Assessment of problems faced by womenheaded households in Embankment settlements.

#### Prof. Musharraf Hussain, Dhaka

Study of the prevalence of hepatitis B and hepatitis C markers and hepatitis risk factors among pregnant women.

#### Dr. Md. Shah Jalal, Dhaka

Collection and analysis of data on the cultural and social context of antenatal behavior among rural pregnant women.

#### Dr. M. Kabir, Dhaka

Estimation of the maternal mortality rate for Bangladesh using the sisterhood method with 1991 Contraceptive Prevalence Survey data.

#### Program for the Introduction and Adaptation of Contraceptive Technology, Bangladesh, Dhaka

Assessment of alternative approaches to contraceptive logistics management at the peripheral level.

#### China

#### State Family Planning Commission, Xizhimen

Postmarketing surveillance of NonPLANT® capsules.

#### India

#### Centre for Operations Research and Training, Vadodara

Evaluation of the impact of training private doctors to promote oral contraceptive pills: Second phase of an Indian Medical Association project.

Case studies on quality of care in India.

## Council for Social Development, New Delhi

Seminars on India's new population policy.

Population information dissemination.

Situation analysis of the family welfare project in Uttar Pradesh.

#### Gujarat Institute of Development Research, Ahmedabad

Study of decisionmaking related to population and family planning in India.

#### Indian Association for the Study of Population, Jawaharlal Nehru University

Underwriting the support of the Population Council-IASP Scholarships in Population Sciences.

#### Indian Institute of Health Management Research, Jaipur

Evaluation of the impact of Mobile Educational Service Units in increasing accessibility and acceptability of contraception in India.

#### Indian Institute of Management, Bangalore

Qualitative study of providers of family planning services at the primary health center level.

Institute of Psychological Research and Services, Patna University, Patna Case studies on quality of care in India.

#### Ms. Shari Kessler, Chiarescure Studios, New Delhi

Production of a photo bank for the Asia and Near East OR/TA project.

#### King Edward Memorial Hospital, Pune

Study of the abortifacient effects of misoprostol administered intravaginally in the first trimester of pregnancy,

## National Institute of Immunology, New Delhi

Immunological studies of the sperm membrane protein SMP-2.

Population Centre, Bangalore
Case studies on quality of care in India.

Population Research Centre, Baroda Case studies on quality of care in India.

#### Population Research Centre, Patna University, Patna

Promotion of family planning and maternal/ child health care through dairy cooperatives in rural Bihar.

#### Rural Women's Social Education Centre, Tamil Nadu

Evaluation of user perspectives on the diaphragm in an urban Indian setting.

#### URMUL Rural Health Research and Development Trust, Rajasthan

Study of ethnomedical models of vaginal discharge in rural Rajasthani women and how they relate to a biomedical model:

Implications for developing interventions for reproductive tract infections.

#### Indonesia

#### Center for Health Research, University of Indonesia, Depok

Analytical review of quality of care research in Indonesia.

#### Indonesian Society for Perinatology, Jakarta

Critical review of Indonesian research and programs on reproductive tract infections.

## Indonesian Society of Obstetrics and Cynecology, Depok

Intervention research on improving information and contraceptive method choice among clients in an urban area.

## National Family Planning Coordinating Board, Jakarta

Study to improve knowledge of and services for acceptors of Normanto capsules.

Situation analysis of service delivery points in the NFPCB's long-term method priority program provinces.

Follow-up study among IUD acceptors on Java Island.

#### University of Indonesia, Faculty of Medicine, Community Medicine Division, Depok

Intervention research on improving information and contraceptive method choice among clients in a rural area.

## Women's Studies Center, University of Indonesia, Jakarta

Study of women's perspectives on reproductive tract infections in Indonesia.

#### Israel

#### University of Tel Aviv

Study of the effect of milepristone combined with RU 39411 or tamoxifen on fertilization and early development in rats.

#### Japan

#### University of Kobe

Study of contraceptive rings releasing estradiol and progesterone for use by postmenopausal women.

Clinical study of the contraceptive effectiveness and safety of levonorgestrel IUDs.

#### Jordan

#### Ms. Mary Kawar, Amman

Study of the determinants of female labor force participation among single women in Amman (MEAward).

#### Drs. Saleh Mawajdeh and Raoda Al-Outob, Irbid

Assessment of the quality of prenatal care (MEAward).

#### Laor

#### Ministry of Health, Vientiane

Support for an operations research workshop on reproductive health.

#### Lehanon

#### Ms. Abla Sebai, Beirut

Study of predictors of mortality among the aged in Lebanon (MEAward).

#### Nepal

#### New ERA, Kathmandu

Strengthening systems for institutionalizing family planning services in Nepal.

#### Pakistan

#### Behbud Association of Pakistan, Rawalpindi

Evaluation of contraceptive service delivery through mobile service units.

## Family Planning Association of Pakistan, Lahore

Evaluation of contraceptive service delivery through mobile service units.

#### **Philippines**

#### Ateneo de Davao University, Davao City

Diagnostic study on implementing the Health Volunteer Workers Program.

## Demographic Research and Development Foundation, Queson City

Evaluation of factors leading to continued company support for an industry-based family planning program.

#### Research Institute for Mindanao Culture, Cagayan de Oro City

Evaluation of factors affecting family planning program dropout rates in Region X.

Support for DMPA monitoring and follow-up studies.

#### Social Research Office, Ateneo de Davas University, Davas City

Support for DMPA monitoring and follow-up studies.

#### Social Science Research Institute, Iloile City

Evaluation of factors that contribute to the performance of the Barangay Service Point Officers and the Barangay Health Workers in the delivery of family planning services in Iloilo City.

#### UPCB Educational Foundation, Baguio City

Diagnostic study of the implementation of the Department of Health training course for family planning providers in the Cordillera Autonomous Region and the Cagayan Valley.

#### Singapore

#### National University of Singapore

Comparative blood-concentration study of levonorgestrel released from NORPLANT® II rods.

#### Thailand

#### Khon Kaen University

Support for an operations research workshop on reproductive health in collaboration with the Laos Ministry of Health, to be held in Vientians, Laos.

Study of formulation preferences of overthe-counter vaginal preparations.

#### Siriraj Family Planning Research Center, Bangkok

Comparative use-effectiveness study of Normant® and Normant® II implants.

Comparative blood-concentration study of levonorgestrel released from NORPLANT® II rods.

Study of formulation preferences of overthe-counter vaginal preparations.

#### Thai Population Association, Bangkok

Support for the Eighth Thai National Symposium on Population Studies.

#### Turkey

#### Dr. Cem Behar, Istanbul

Study of migration, mobility, and fertility decline in a traditional community in Istanbul, Kasab Llyas Mahalle, 1860-1920 (MEAward).

#### Dr. Guler Flock, Istanbul

Study of child health and family process in urban Turkey (MEAward).

#### Dr. Akile Gursey, Istanbul

Study of social and cultural dimensions of low birthweight in Turkey (MEAward).

#### Dr. Nuran Hortaesu, Ankara

Longitudinal study of the relationship between spouses and between married couples and kinship networks in the first year of marriage (MEAward).

#### Institute of Child Health, Istanbul University, Istanbul

Project to involve fathers in postpartum family planning and health in Istanbul.

#### Janet Melsan, Dr. Aysen Bulut, and Dr. Gulbin Gokeny, Istanbul

Project to involve fathers in postpartum family planning and health in Istanbul (MEAward).

#### University of Istanbul

Study of the abortifacient effects of misoprostol administered intravaginally in the first trimester of pregnancy.

Comparative clinical study of immediate postabortion use of the levonorgestrel IUD and NORPLANT® capsules.

#### Vietnam

## Centre for Family and Women Studies,

Study of production, reproduction, and family wellbeing.

#### Hanoi Obstetrie and Gynecological Hospital, MCH/FP Center, Hanoi

Evaluation of the acceptability and feasibility of mifepristone as a method of pregnancy termination.

#### Hung Vuong Hospital, Ho Chi Minh City

Organization and initiation of a situation analysis for the Safe Motherhood Demonstration Project in Vietnam.

Evaluation of the acceptability and feasibility of milepristone as a method of pregnancy termination.

#### Institute of Sociology, Hanoi

Support for a demographic training workshop.

Translation, editing, publication, and distribution of a reader on social demography.

#### Ministry of Health, Hanoi

Study of contraceptive use-dynamics in Vietnam.

Organization and initiation of a situation analysis for the Safe Motherhood Demonstration Project in Vietnam.

Evaluation of the acceptability and feasibility of mifepristone as a method of pregnancy termination.

#### Research Centre for Gender, Family, and Environment in Development, Hanni

Study of production, reproduction, and family wellbeing.

#### Vietnam Women's Union, Hanel

Study of production, reproduction, and family wellbeing.

Evaluation of the impact of a training program on knowledge and practice of family planning for commune-based health workers.

#### EUROPE

#### Austria

#### Urologischen Abteilung Lendeskrankenanstalten, Salsburg

Dose-finding study of continuous administration of an LHRH agonist by hydrogel implants for prostate cancer.

#### Belgium

## Institute of Tropical Medicine,

Study of formulation preferences of overthe-counter vaginal preparations in Abidjan, Côte d'Ivoire.

#### England

## London School of Hygiene and Tropical Medicine

Support to an intern for collaborative research in Pakistan.

#### Panes, London

Communication of the population debates in the Middle East.

#### Finland

#### The Family Federation of Finland, Helainki

Clinical studies of contraceptive vaginal rings releasing Nestorone™ and ethynylestradiol.

Clinical study of the effects of multiple intramuscular injections of MENT in normal and hypogonadal men.

Study of the pharmacokinetic and pharmacodynamic effects of Nestorone<sup>TM</sup> progestin implants in women with endometriosis.

Dose-finding study of contraceptive rings containing Nestorone™ progestin.

Retrospective analysis of patient selection and performance of levonorgestrel-releasing IUDs and Copper IUDs.

Purchase of laboratory equipment for use in ICCR-sponsored clinical studies.

#### University of Helninki

Radioimmunoassays on serum samples submitted by laboratories conducting research on potential contraceptives.

#### University of Jyväskylä

Study of a Nestorone<sup>TM</sup>-releasing vaginal ring.

#### University of Kuopie

Study of a Nestorone<sup>TM</sup>-releasing vaginal ring.

#### France

#### Hôpital Saint-Antoine, Paris

Evaluation of vaginal rings of Nestorone<sup>TM</sup> progestin and ethynylestradiol formulation.

Comparative study of the effects of vaginal administration of Nestorone™ progestin on the maturation of the endometrium during hormonal menopausal treatment.

Clinical study of the effects of multiple intramuscular injections of MENT in normal and hypogonadal men.

Pilot study with the GnRH antagonist
Azaline B as a potential male contraceptive.

Study of the hormonal and clinical efficacy of a GnRH agonist implant (Histrelin) as a potential male contraceptive.

#### University of Rennes

Study of the purification of rat germ cell proteins responsible for the paracrine regulation of Sertoli cells.

#### OCEANIA

#### Australia

#### Centre for Reproductive Health Research, Sydney

Clinical study of bone mineral density and the mechanisms of bleeding in users of Normant® capsules.

Study of the abortifacient effects of misoprostol administered intravaginally in the first trimester of pregnancy.

Study of contraceptive rings containing norethindrone acetate and ethynylestradiol.

Glinical study of vaginal inspection via colposcopy in women not using a contraceptive vaginal ring.

Clinical study of estradiol blood levels associated with estradiol Silastic® vaginal rings. Consultants listed are primarily those who work for the Council on an ongoing basis.

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Michael P. Todaro

#### **IAdjunct Associate**

2Transferred from Programs Division, Bangladesh, to Research Division, New York, January 1995

#### Transferred from Programs Division to Research Division February 1994

4Visiting Associate

#### Consultante

Jacqueline Adair-Jones, Mary Arenda-Kuenning, Fred N. Binka, Cornelius Debpuur, Mian Bazle Hossain, Frank Indome, Elise Jones, Bruce MacLood, Moni Nag, Alex Nazzar

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<sup>\*</sup>Asterisk indicates that individual left the Council during 1994.

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Project Director, Asia and Near East OR/TA

John Townsend

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J. Elias, Valerie Hull

<sup>6</sup>Effective January 1995. Peter Donaldson was Regional Director through mid-January 1994; John Townsend was acting Regional Director from mid-January through December 1994.

Transferred from New York to Bangkok July 1994

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Fatou Sow

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\*Associate, Programs Division. through May 1994

9As of February 1995, replacing Andrew Fisher as Project Director, Africa OR/TA

10Transferred from Belivia to Kenya August 1994 LATIN AMERICA AND THE CARIBBEAN

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Project Director, INOPAL James R. Foreit

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Distinguished Scientist Sheldon J. Segal

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Consultant

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HSenior Associate, Research Division, through June 1994

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Chilean Institute of Reproductive Medicine

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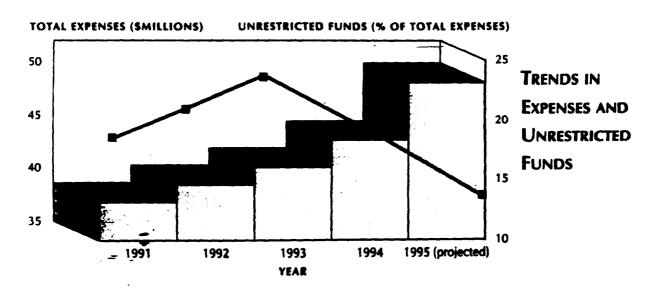
Samia El Hadi El Nagar Institute of Economic and Sociological Research, Sudan

Ayse Oncu Bogazici University, Turkey opulation Council expenditures in 1994 were US\$44 million, representing a 6 percent increase over 1993 and a five-year compound growth rate of 8 percent. (The costs of Council work on mifepristone are not included in 1994 financial reports, but will be recorded in future years, along with the offsetting income.) This level of expenditure, our highest ever, is a result of continued growth in donor support for the Council's research and programs. There was nevertheless a deficit of \$0.9 million in the Council's unrestricted General, Operating, and Leasehold Fund in 1994. This shortfall in unrestricted funds results largely from two circumstances: first, although donors' contributions to programmatic work have increased, some donors have reduced their contribution to indirect administrative costs; second, royalty income from licensed products fell by 45 percent from its 1993 level. The growth in overall expenses and the dramatic changes in unrestricted funds, which are used to sponsor innovative work and to support the administration of the Council, are illustrated in the chart below.

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Unrestricted funding is expected to decline further in 1995. To balance the 1995 budget, the Board of Trustees approved both expense reductions and an increase in the percentage withdrawal from the John D. Rockefeller 3rd Memorial Fund.

The following pages present summary financial statements and a list of the generous donors whose funds supported Council activities in 1994.



# FINANCIAL REPORT

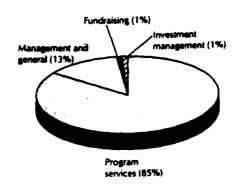
# SUMMARY STATEMENT OF SUPPORT, REVENUE, EXPENSES, AND FUND BALANCES

Year ending December 31, 1994

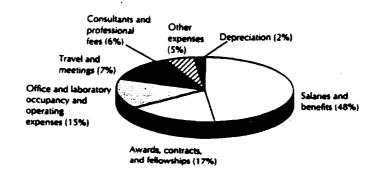
Support and revenue	General, perating, and lessehold  920 3,120	John D. Rockefeller 3rd Memorial Fund	Restricted	Total #	Il funds
Support and revenue	920		Restricted	1994	1993
Support and revenue		1	<del>_</del>		
		1			
Grants and gifts designated for current use	3.120	4	34.076	34,997	32,243
Payments received under license agreements	-,			3,120	5,655
Other revenue	173	3,164	990	4,327	7,722
. Total support and revenue-	4,213	3,165	35,066	42,444	45,620
Expenses					
Program services					
Center for Biomedical Research	2,394		11,678	14,072	13,925
Research Division	759		2,327	3,086	3,015
Programs Division	1,869		16,820	18,689	17,154
Distinguished Colleagues	459		- 151	610	653
Publications .	914		388	1.302	1,231
Total program services	6,395		31,364	37,759	35,978
Supporting services					
Management and general	2,608	435	3,281	6,324	5,533
Fundraising	325		29	354	312
Total supporting services	2,933	435	3,310	6,678	5,845
Total expenses	9,328	435	34,674	44,437	41,823
Excess (deficiency) of support and					
revenue over expenses	(5,115)	2,730	392		
Other changes in fund balances					
Funds transferred to support current operations	4,238	(4,238)			
Increase (decrease) in fund balances					
for the year	(877)	(1,508)	392		
Fund balances at beginning of year	3,599	44,400	3,542		
Fund balances at end of year	2,722	42,892	3,934		

A complete set of financial statements audited by KPMG Peat Marwick LLP can be obtained by writing to the Council Treasurer.

#### **Uses of Funds**



## **EXPENSES BY TYPE**



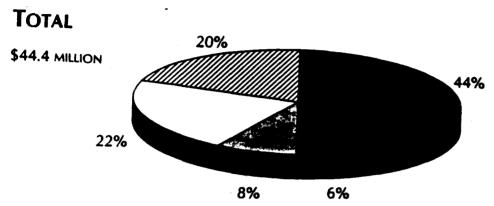
## **SUMMARY BALANCE SHEET**

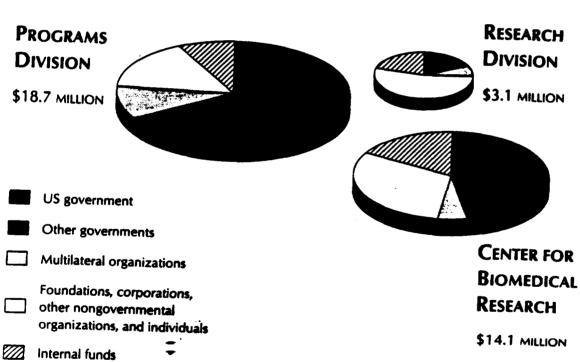
December 31, 1994 (in thousands of dollars)

(in thousands of dollars)	Unrestricted			V	
	General,	John D.		Tarak	.m 4
		Rockefeller 3rd		Total all funds	
	leasehold	Memorial Fund	Restricted	1994	1993
Assets					
Cash and investments*	1,693	39,553	12.826	54.072	59,577
Grants and gifts receivable	7		42,554	42.561	37,102
Other current assets	3,155	171	3,406	6,732	3.266
Leasehold improvements and equipment	5,7 <b>63</b>		-,	5,763	5,761
Total assets	10,618	39,724	58,786	109,128	105,706
Liabilities and fund balances					
Liabilities					
Accounts payable	1,405	884		2,289	3,406
Awards and fellowships payable	852		4,987	5,839	5,280
Grants for future periods			46,938	46,938	44,478
Other liabilities	968		3,546	4,514	1,000
Interfund due to/(due from)	4,671	(4,052)	(619)		
Total liabilities	7,896	(3,168)	54,852	59,580	54,164
Fund balances (deficit)					
General and operating	(3,041)	·		(3,041)	(2,161)
Leasehold improvements and equipment	5,763			5,763	5,760
Other funds		42,892	3,934	46,826	47,943
Trial fund balances	2,722	42,892	3,934	49,548	51,542
Total liabilities and fund balances	10,618	39,724	58,786	109,128	105,706

<sup>\*</sup>On December 31, 1994, stock investments were 66 percent and bonds and cash were 34 percent.

# SOURCES OF SUPPORT FOR COUNCIL ACTIVITIES





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#### **SOURCES OF SUPPORT FOR 1994 ACTIVITIES**

The Population Council gratefully acknowledges the donors listed below for supporting our 1994 activities, including those whose multi-year funding was received in prior years.

The Council is especially grateful to donors of unrestricted funds, which are essential for leveraging restricted grants and contracts. These funds also support the Council's innovative research in its earliest stages.

The Council welcomes gifts in any amount, which are tax-deductible in the United States. Please also consider making a gift to the Council in your will. Contributions or requests for further information may be addressed to the Director of Development.

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<sup>\*</sup>Asteriak denotes matching gift.

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#### POPULATION COUNCIL OFFICES

#### HEADQUARTERS --

The Population Council ... One Dag Hammarskjold Plaza New York, New York 10017 USA telephone: (212) 339-0500 facsimile: (212) 755-6052 e-mail: pubinfo@popcouncil.org

#### Center for Biomedical Research

Tower Building 1230 York Avenue New York, New York 10021 USA telephone: (212) 327-8731 facsimile: (212) 327-7678

#### SOUTH AND EAST ASIA

Regional Office The Population Council 42 A Golf Links New Delhi, India 110 003 mail address: The Population Council Sangha Rachana 53, Lodi Estate, 3rd floor New Delhi, 110 003, India telephone: (91)(11) 461-0912, 3, 4 facsimile: (91)(11) 461-0912

#### Bangladooh

The Population Council P.O. Box 6016 Gulshan, Dhaka, Bangladesh telephone: (880)(2) 881227, 886657 facsimile: (880)(2) 883132

The Population Council TIFA Building, Suite 404 Jl. Kuningan Barat No. 26 Jakarta, Indonesia 12710 telephone: (62)(21) 5200094, 5200494 facsimile: (62)(21) 5200232

#### **Pakistan**

The Population Council House Na. 55, Street Na. T Sector F 6/3 Islamabed, Pakiegen telephone: (92)(51) 217439, 217536 faceimile: (92)(51) 214553, 822401

#### **Philippines**

The Population Council Monteverde Mansions Unit 2A3 **85 Xavier Street** Greenhills, San Juan Metro Manila, Philippines telephone: (63(2) 722-6886 facsimile: (63)(2) 721-2786

The Population Council P.O. Box 11-1213 Nana Post Office Bangkok 10112, Thailand telephone: (66)(2) 251-4766, 251-7066 facsimile: (66)(2) 255-5513

#### WEST ASIA AND NORTH AFRICA

Regional Office The Population Council P.O. Box 115 Dokki, Cairo, Egypt telephone: (20)(2) 5738277 facsimile: (20)(2) 5701804

#### SUB-SAHARAN AFRICA

Regional Office The Population Council P.O. Box 17643 Nairobi, Kenya telephone: (254)(2) 713480, 713481 faceimile: (254)(2) 713479

#### Burkine Face

The Population Council 01 BP 6250 Ouagadougou 01, Burkina Faso telephone: (226) 33-57-95 facsimile: (226) 36-16-25

#### Mali

The Population Council **BP E666** Immouble SOGEFI, 3ème étage **Quartier du Fleuve** Berneko, Mali telephone: (223) 22-80-86, 22-30-43 facsimile: (223) 22-21-78

Senegal
The Population Council **BP 21027** Dakaz, Sonogal telephone: (221) 24-19-93, 24-19-94 facsimile: (221) 24-19-98

The Population Council

2 Regent Estate **Bagamoyo Road** P.O. Box 62121 Der on Saleem, Tanzenia telephone & facsimile: (255)(51) 75197

#### LATIN AMERICA AND THE CARIBBEAN

#### Regional Office

The Population Council Apartado Postal 105-152 11560 Mexico, D.F., Mexico telephone: (52)(5) 280-1725, 280-1475, 280-1600 facsimile: (52)(5) 281-0702

...

The Population Council Caixa Postal 6181 13061 Campines São Paulo, Brazil telephone: (55)(192) 392856 facsimile: (55)(192) 392440

#### Guetemale

The Population Council Boulevard Liberación 15-86, Zona 13 Edificio Obelisco, Oficina 305 Guatemala City, Guatemala telephone: (502)(2) 32-28-80 facsimile: (502)(2) 34-55-86 mail address: The Population Council Gua 107 P.O. Box 02-5368 Miami, FL 33102-5368 USA

#### Haiti

The Population Council 28 Rue Metellus Petion-Ville, Haiti telepnone & facsimile: (509) 57-4591

The Population Council Residencial Casavola No. 37 Area Bancatlán, Miraflores Tegucigalpe, Honduras telephone & facsimile: (504) 32-60-21

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#### STAFF

EDITOR/WRITER

Judith Anderson Masslo

ART DIRECTOR/DESIGNER

Diana Hrisinko

COPYEDITOR

Robert Heidel

DESKTOP PRODUCTION

Sue Rosenthal, Suzanne Antonelli

EDITORIAL ASSISTANT

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EDITORIAL BOARD

James Catterall, Ethel Churchill, Anrudh Jain, Monica Knorr,

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# Non-U.S. Clinical Studies

Ridgely C. Bennett, M.D., M.P.H.

Medical Officer, DRUDP

# **Proposed Regimen**

- ◆ Single oral dose of three 200 mg tablets of mifepristone
- ♦ In two days, two 200 ug tablets of misoprostol, unless confirmed termination

# Studies 14 and 24: Design

	Study 14	Study 24
No. patients	1286	1194
<b>Duration of gestation</b>	<u>≤ 49 d</u>	≤ 63 d
Day 1: Mifepristone	600 mg	600 mg
Day 3: Misoprostol	<b>400</b> μg	400 μg; if no abortion in 3 hours, additional 200 μg
Follow-up	Day 8-15	Day 10-18

#### **Exclusion Criteria**

- ◆ Smoke ≥ 10 cigarettes/day
- ◆ Cardiovascular disease
- ◆ Asthma
- ◆ Glaucoma or high intraocular pressure
- ◆ Diabetes
- ♦ Hyperlipidemia
- ◆ Renal, adrenal, or hepatic insufficiency
- ◆ Anemia

#### **Treatment Outcome: Definition**

◆ Successful: complete expulsion without need for surgery

#### **♦** Failure:

- incomplete expulsion
- pregnancy continued
- surgery required for hemostasis

### **Efficacy Evaluable Population**

#### ♦ Pregnancy confirmed

	n/N	%
Study 14	1205/1286	93.7
Study 24	1104/1194	92.5

#### Study 14: Treatment Outcome

#### **Efficacy Evaluable Population**

	N	Rate (%)
Complete expulsion	1149	95.4
Incomplete expulsion	34	2.8
Ongoing Pregnancy	18	1.5
Surgery to stop bleeding	4	0.3
Total	1205	

#### Study 14

### Complete Expulsion Rate for Efficacy Evaluable Population by Gestational Age

Gestational Age (days)	Events/N	Rate (%)
< 36	117/119	98.3
36-42	447/463	96.5
43-49	570/607	93.9
50-56	12/13	92.3
57-63	3/3	100.0
<b>≤ 49</b>	1134/1189	95.4

8

Study 24

### Complete Expulsion Rate for Efficacy Evaluable Population by Gestational Age

Gestational Age (days)	Events/N	Rate (%)
< 36	15/15	100.00
36-42	163/171	95.3
43-49	293/306	95.7
50-56	358/389	92.0
57-63	196/223	87.9
<b>≤ 49</b>	471/492	95.7

9

#### **Study 24: Treatment Outcome**

#### Evaluable Patients with Gestational Age $\leq$ 49 Days

	n	Rate (%)
Total	210	
Misoprostol not ac	lministered	
Complete expulsion	19	100.0
Single dose mis	oprostol	<del></del>
Complete expulsion	189	99.0
Incomplete expulsion	1	0.5
Surgery to stop bleeding	1	0.5
Complete expulsion rate	208/210	99.0

## **Analysis of Success Rates for Subgroups:**Studies 14 and 24

Subgroup	Study 14	Study 24
	n/N (%)	n/N (%)
If GA≤ 49 days	1134/1189 (95.4)	471/492 (95.7)
and took $\leq 1$ misoprostol dose	1134/1189 (95.4)	208/210 (99.0)
and known outcome	1160/1216 (95.4)	227/230 (98.7)
and if unknown outcome = failure	1160/1264 (91.8)	227/239 (95.0)

+t

# **Success Rates:** Studies 14 and 24

	Study 14 (N=1286)	Study 24 (N=1194)
Evaluable (N)	1205	1104
No. of Patients with Success	1149	1025
Rate (%)	95.4	92.8

# Adverse Events with Incidence > 2%: Studies 14 and 24

Adverse Event	Incidence (%)	
	Study 14	Study 24
Painful contraction of uterus	78.5	85.6
Nausea	40.7	49.9
Vomiting	16.8	29.1
Diarrhea	12.3	15.4
Headache	2.6	3.1
Dizziness	1.2	2.6
Metrorrhagia	N/A	3.4
Anemia	10 mm N/A	2.9

#### Cardiovascular Adverse Events

- ♦ Mild to moderate
  - tachycardia and palpitations
  - hypotension
  - hypertension
  - syncope
- **♦** Severe
  - 1 case hypotension

+3

### Serious Adverse Events: Studies 14 and 24

◆ Enrolled	2480
<b>♦</b> Hospitalizations	21 (1%)
<b>♦</b> Heavy bleeding	52 (2%)
<ul> <li>surgical intervention</li> </ul>	15 (1%)
<ul> <li>blood transfusion</li> </ul>	4 (<1%)

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San Dela Mare	CASET
Joan Truy	Pront a m
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Jodi Mage	Physic. for Reprochair (HIT
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Mexader C. Sager Sandra Croak-Brossman	Planned Maenthord NYC Pfeyer, Anoton, CT
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Carolyn Morcharse  Pamela Straits  Man Ramsey	Than Univ. Met St.
Margaret Commany	PPFA PDA.

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Susan Ital	National Whole Cac
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Lise Mirail	Acc/2
Janus Sunglika	A(CG
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NAME	AFFILIATION
`	1
GWEN MIZGERAUD	NAT'L APORTION & REPREDUCTUTE  NAT'L APORTION & PROBLETS ACTON L.
Adrian Frah-Bernan	NICHONITI
Bridget N. Ehart	Votors for Choice.
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#### Speakers PLEASE SIGN IN

• • • •	
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Donny Harrisa M.O.	Southwester Madriel Chini
Char Pearson	LIWHO
Lebucca Livestet	American marker life leage
Nin 1 dellims	Amer- Medical Women's 15 sm.
Lisa Kreser	AGI
JAN RZICKOM)	Not Ora De Women
Rendall K. O'Bennon	Hefrie A blik told Trust fired
S.L. ROMNEY MD	Society of his School and Charge
Gracie Hou	Family Research Council
1 MESTHOFF	A606-6
View Jaluell	Manuarts for Sefe
Wandy Simonds	private citizen
Man Segal	Fernat Worang Cealth te
Lynn Borath	PP Westchester Rockland
MARK Louviere mo	NE Form Family Parter
Elean Smal	Feminist Majority Foundate
	LIFE BSUES INSTITUTE
Che Kalker	National Women's hund Center
Joanne Hysterd	Women's legal pepense Fin
Marie Bass	Rep Health Tech. Projec
	. 0

NAME	AFFILIATION
Dlove Fild	Playing farething Federat
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Marcy Wilder	NARAL
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#### Memorandum

Date

·10 July 1996 (Wednesday)

From

Executive Secretary

Subject

CONFIDENTIAL MATERIAL FOR JULY MEETING

To

Members of the Advisory Committee for Reproductive Health Drugs

Attached, for your information, are four CONFIDENTIAL reviews of the New Drug Application to be discussed at the meeting on 19 July. This material is not to be shared with anyone except FDA staff and other Committee members.

We look forward to seeing many of you at the dinner next Thursday evening. Those of you who haven't yet told me of their availability for dinner should do so as soon as possible.

/\$/

Food and Drug Administration

APPEARS THIS WAY

#### MEMORANDUM

### DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION Center for Drug Evaluation and Research

Date:	Jüly 15, 1996
From:	<u> </u>
	Advisory domittee/for Kephoductive Health Drugs 18/18/18/18
	Voting by Consultants at July 19, 1996
Re:	Voting by Consultants at July 19, 1996 Reproductive Health Drugs Advisory Committee Meeting
To:	CDER
Through:	/ <b>\$</b> /
_	Advisors and Consultants Staff

#### Issuet

This memo seeks your concurrence to name three consultants as temporary voting members at the next Reproductive Health Drugs Advisory Committee Meeting.

#### Background:

At the July 19, 1996, Advisory Committee for Reproductive Health Drugs meeting, the committee will be reviewing mifepristone for interruption of early pregnancy. The charter allows for consultants to be named as temporary voting members for their expertise and to assure the presence of a quorum for voting. Because paperwork for new members scheduled to rotate onto the committee has not yet been completed, I am asking-that three consultants (Dr. Janet Daling, Dr. Cassandra Henderson, and Dr. Jane Zones) who are scheduled to participate in the meeting, and who have just completed terms as members on the committee, be named as temporary voting members for this meeting both for their expertise and experience, and to assure a voting quorum for this meeting.

I agree that it is appropriate to name Dr. Janet Daling, Dr. Cassandra Henderson and Dr. Jane Zones as temporary voting members for the meeting of the Advisory Committee on Reproductive Health Drugs on July 19, 1996.

	I concur
	I do not concur
	<u></u>
Date	CDER

APPEARS THIS WAY
ON ORIGINAL

#### FDA FOOD AND DRUG ADMINISTRATION U.S. Department of Health and Human Services Public Health Service 5600 Fishers Lane Rockyi

Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

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T96-51 July 19, 1996 Susan Cruzan (301) 443-3285

FDA Advisory Committee Reviews Mifepristone

An FDA advisory committee today concluded in a 6 to 0 vote (with 2 abstentions) that clinical data show that the benefits of a mifepristone and misoprostol regimen for terminating early pregnancies outweighs its risks. The studies presented to the Committee involved women treated within 49 days of the beginning of their last menstrual period. The following may be used to respond to questions.

During the advisory committee meeting, FDA's Reproductive Health Drugs Advisory committee discussed data and presentations by the Population Council, sponsor of the application, and FDA. Approximately 35 individuals also made comments during the open public hearing portion of the meeting. The Population Council, a non-profit research organization, presented data from two French trials in 2,480 women that showed the combination of mifepristone and an oral prostaglandin (misoprostol) to be about 95 percent effective. -

Safety data from U.S. trials in more than 2000 women were also presented to compare how the U.S. experience relates to the French data. Trials were conducted in the U.S. to complement the European data, and to confirm whether the drug regimen could be

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Page 2, T96-51, FDA Advisory Committee - Mifepristone safely used in the American medical system.

The regimen used in the clinical trials consisted of 3 tablets (600 milligrams) of oral mifepristone followed two days later by 2 tablets (400 micrograms) of oral misoprostol.

The advisory committee also agreed in concept with, but expressed reservations about, the sponsor's proposal for a restricted distribution system under controlled conditions, with mifepristone available to patients only in registered or approved facilities. In European and U.S. clinical trials, the procedure required several visits to a medical facility, counseling, a precise dosing scheme, and close monitoring.

Patients participating in those trials were given detailed information about the treatment and asked to sign a formal decision document giving their informed consent. This document included information that if the treatment fails, a patient must be prepared to have pregnancy terminated by surgery.

Adverse events seen in clinical trials included painful contractions of the uterus, nausea, vomiting, diarrhea, pelvic pain and spasm, and headache. A very small percentage of patients in the clinical trials required hospitalizations, surgical treatment or transfusions.

The Committee recommended post-marketing studies to gather further information about the actual application of this regimen in the U.S.

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Page 3, T96-51, FDA Advisory Committee - Mifepristone
Mifepristone was developed by the French firm Roussel Uclaf,
which transferred the U.S. patent rights to this drug to the

The combination of mifepristone and an oral prostaglandin has been marketed in Europe since 1989 for medical termination of early pregnancy.

Population Council in May 1994.

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