Chapter 1

Summary, Issues, and Options

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Chapter 1

Summary, Issues, and Options

Overview

This assessment considers the probable impacts of specific fertility planning technologies on population grotvth. The influence of direct factors such as age at marriage and contraceptive use on population growth is relatively well understood. Less well understood are the indirect influences–the economic, sociocultural, religious, and political forces—that modify attitudes toward family size. Detailed examination of these indirect factors is beyond the scope of this study. Nevertheless, recognition of their importance in determining the use of fertility planning technologies underlies everything that follows.

The following pages examine the contribution of fertility planning technologies to reducing birth rates, improving maternal and child health, and enabling couples to choose the number and spacing of their children. They also explore future changes in contraceptive use and birth rates that might be possible. The strengths and weaknesses of present technologies and techniques are summarized, and the probable availability of new or improved technologies within the next 10 to 20 years is estimated. Also examined are how the U.S. Government supports international population assistance, both through its international aid programs and through contraceptive research and development (R&. D), and how the Food and Drug Administration's (FDA) regulatory role in assuring the safety and efficacy of drugs and medical devices affects U.S. international population assistance efforts. Finally, this report enumerates options that Congress might consider in the areas of reproductive research and contraceptive R&D and in furthering the aims of its international assistance programs, and highlights issues that could benefit from oversight hearings,

Introduction

Following World War II, the world experienced a sudden sustained drop in death rates which, combined with little change in birth rates, procluced unprecedented growth in the world)s population. Today, about 80 million people, the equivalent of an additional Mexico or Nigeria, afre added to the **planet every** Year.

More than 90 percent of this growth is in the developing world. In the United States and other more developed countries (MDCs), infant mortality is low and life expectancy exceeds 70 years, yet populations are stable or increasing only moderately because birth rates are low. In the less developed countries (LDCs), where infant mortality, although declining, is high, and life expectancy has not yet reached 5.5 years, birth rates remain high and populations are increasing, often at dramatic rates.

Rapid population growth in LDCs is a key factor in limiting the ability of these countries to raise their standards of living. Important obstacles to their socioeconomic development include limited resources, food distribution problems, high rates of debilitating disease and infant mortality, lack of proper sanitation, scarcity of investment capital, and shortages of educational facilities and work opportunities. But each of these barriers to a better quality of life in LDCs is intensified by the rapid pace of their population growth.

Because LDC governments that once dismissed rapid population growth as incidental to their well-being now actively seek help with their population problems, the United States and other MDCs provide population planning assistance as part of general developmental aid

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to countries who need and want help in reducing their birth rates. Such assistance has enabled many of these countries to achieve significant decreases in their population growth rates during the past decade, and there is now an international consensus that access to contraceptive services is a basic human right.

The issues examined here are not new to Congress. The United States has been a leader in world population issues since the early 1960's, when the Draper Commission recommended that the U.S. Government provide assistance for population planning, and the governments of a number of countries began to deal openly with what they saw as dangers in the sudden disparities between their birth and death rates. In its 1978 review, the House of Representatives through its Select Committee on Population issued a series of reports on population and developmental assistance, and identified areas requiring additional study. Foremost among these was the area of fertility planning technology.

Findings and conclusions

Fertility is declining in most LDCs, but population growth is continuing at high levels because of the momentum for future growth initiated by the high birth rates and rapidly falling infant mortality rates of the recent past. More than 1 billion people will be in their peak reproductive years (ages 15 to 29) during the next two decades.

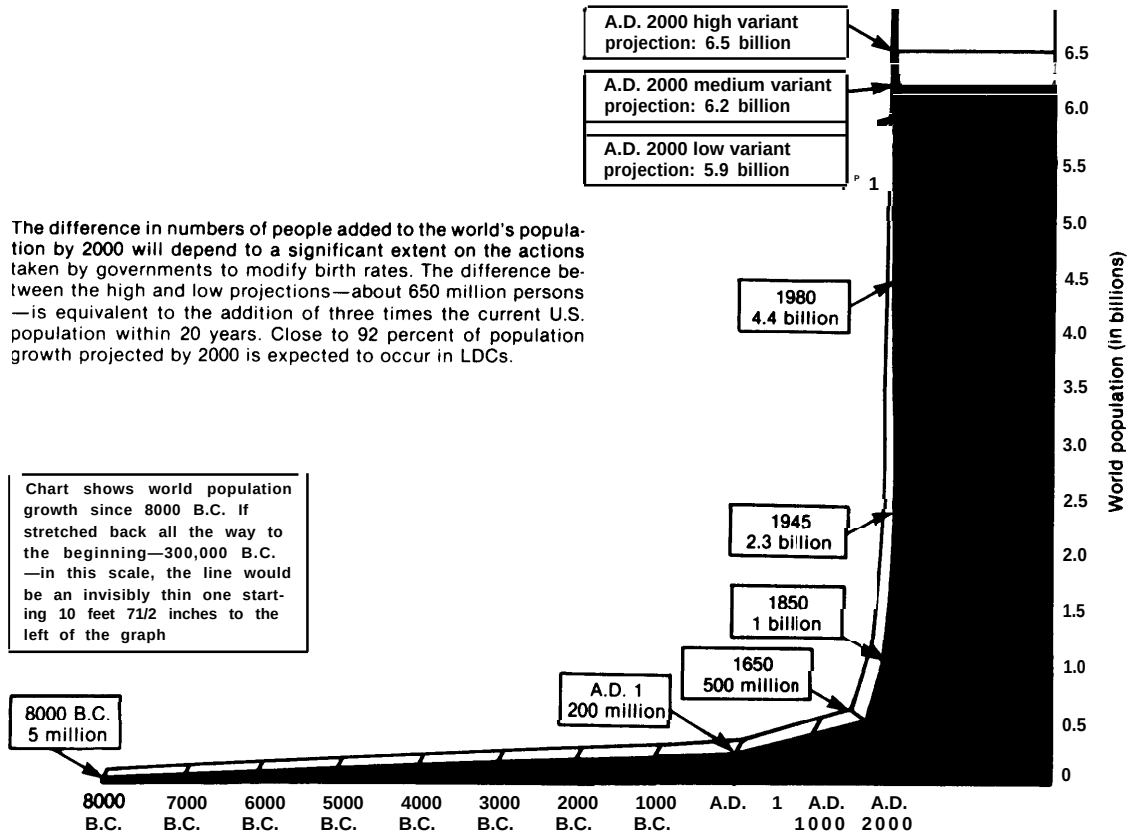
Even if growth rates continue their current decline, the world's population is expected to increase from 4.5 billion in 1981 to between 5.9 billion and 6.5 billion in the year 2000 (see fig. 1). Almost 92 percent of this growth will occur in LDCs. Growth will be greatest, according to current projections, in Africa (76 percent of the 1980 population added in 20 years), followed by Latin America (65 percent), and Asia (43 percent). But more of the increase in absolute numbers will occur in Asia (63 percent) than in Africa (22 percent) or in Latin America (15 percent), simply because many more people already live in Asia. Three-quarters of all LDC growth is expected to occur in just **18** countries: India, China, Brazil, Nigeria, Indonesia, Bangladesh, Pakistan, Mexico, Philippines, Thailand, Vietnam, Turkey, Iran, Egypt, Ethiopia, Burma, South Korea, and Zaire, listed here in the approximate order of the magnitude of their projected growth.

The striking momentum of world population growth means that the number of births expected each year will increase despite falling fertility rates, because the number of people in the reproductive ages (15 to 44) is increasing. The pyramid in figure 2A depicts the age structure that is typical of most LDCS, where populations are predominantly youthful because of high fertility and declining infant mortality during the past 20 years. If fertility rates were to fall rapidly, the lower groups of the pyramid (ages O to 4, 5 to 9, etc.,) would begin to contain fewer individuals. The older ages (10 to 14, 15 to 19, etc.,) would then form a "bulge," which would contribute a disproportionate number of people of reproductive age some 5 to 10 years later. This bulge is illustrated in figure 2B by the U.S. "Baby Boom:" members of this group are now of reproductive age and, although their fertility is thus far lower than that of their parents, the absolute size of this group is already resulting in an increase in the numbers of births per year in the United States.

The same cycle will take place in LDCs during the next 20 years, but on a more massive scale. Stationary population growth—the stabilization of deaths and births at near equal levels—would not be achieved until members of the largest age group (those now between O and 4 yeas) reach old age some 60 years from now. The age structure of a stationary population illustrated in figure 2A describes a typical MDC today.

Current declines in fertility are unevenly distributed among LDCs but many of those with the largest populations have achieved the greatest declines. China's birth rate has declined dramatically. Estimates of fertility decline between

Figure 1.—World Population Growth From 8000 B.C. to 2000 A.D.

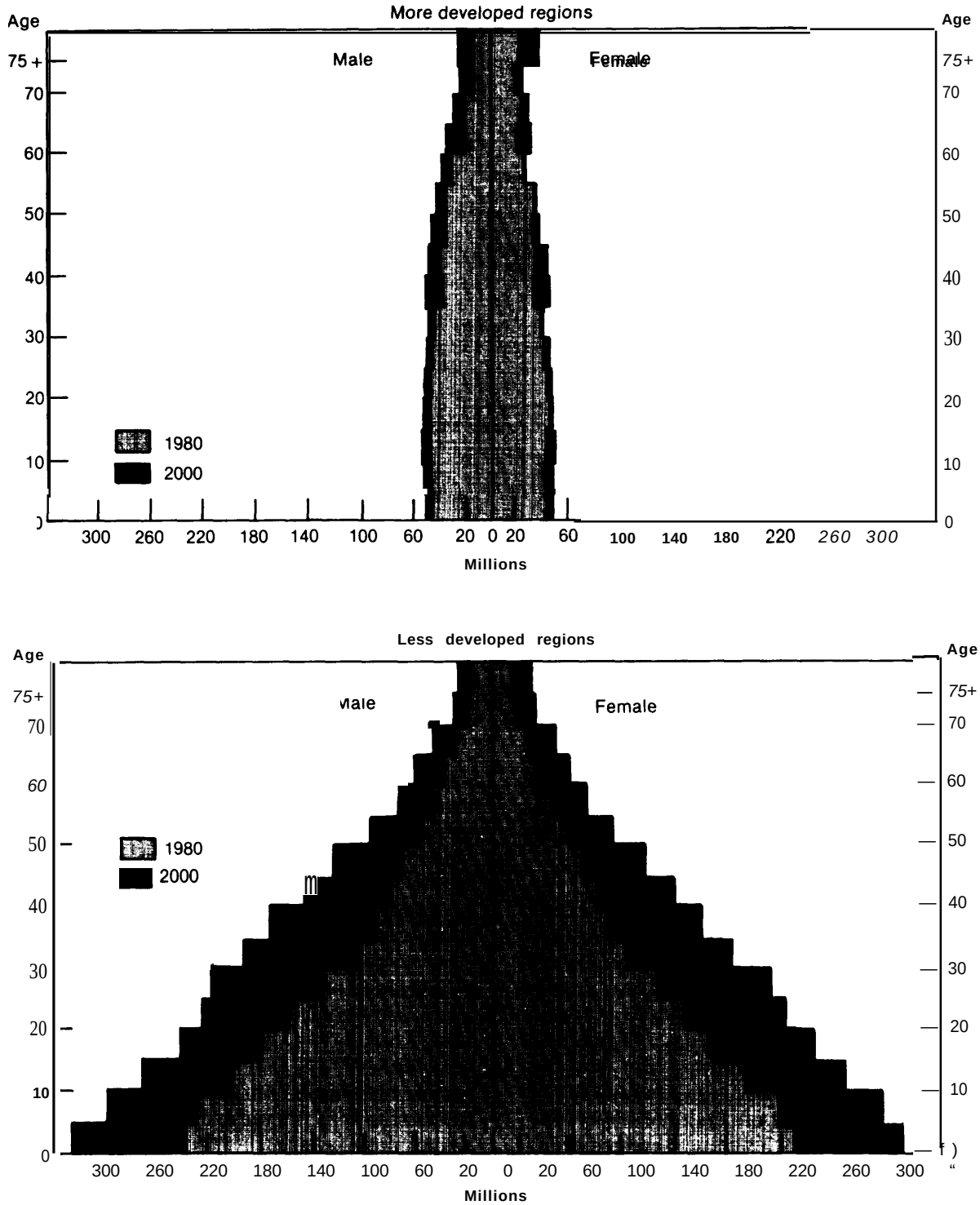


SOURCE: United Nations, *World Population Trends and Prospects by Country, 1950-2000: Summary Report of the 1978 Assessment,* New York, 1979, projections 1980-2000; Arthur H. Westing, "A Note on How Many Humans Have Ever Lived," *Bioscience,* vol. 31, 1981; graph adapted from "Population Growth from 8000 B.C. to the Present," Oct. 6, 1981, © 1981 by the New York Times Co. Reprinted by permission.

1965 and 1981 range from 17 to 58 percent. South Korea's fertility has fallen by 34 percent, Colombia's by 34 percent, and Thailand's by 36 percent during the same period (table 1).

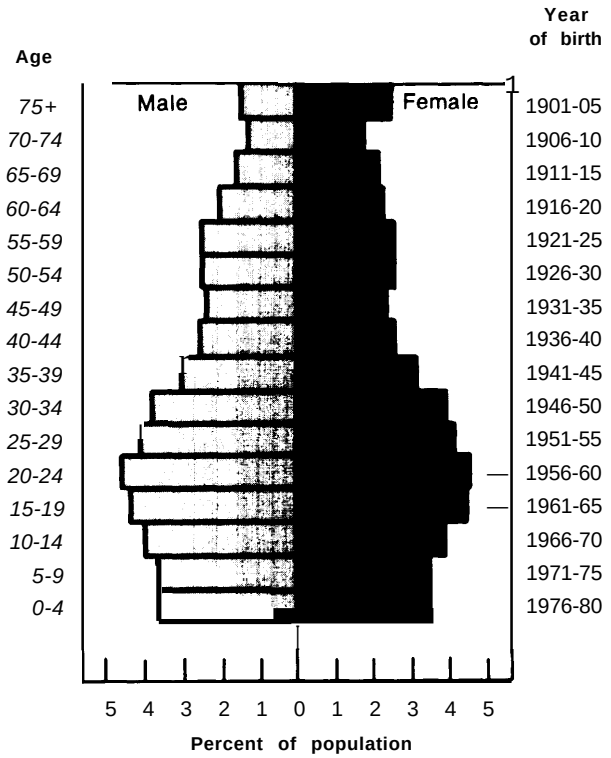
Significant fertility declines are usually associated with some or all of the following conditions that involve government policy and action with regard to population programs (ordering does not imply relative importance): 1) governmental policies that encourage and promote equal status and opportunities for women, higher age at marriage, and more equitable distribution of wealth and educational opportunities, all of which lead to a higher standard of living; 2) programs designed to bring about a decline in infant mortality; 3) a government policy with explicit goals for reduction of birth or population growth rates; 4) a strong commitment to population planning by the country's leaders; 5) a family planning organizational structure with executive power to mobilize more than one government sector and to coordinate with the private sector; 6) population program funding (usually both external and internal sources); 7) provision of a broad range of contraceptive methods; 8) sufficient numbers of well-trained and motivated family planning program personnel; 9) population and family planning information, education, and communication (IEC) efforts that effectively reach all sectors of the population; and 10) direct or indirect incentives that encourage couples to limit the size of their families. The relative importance of these components is not known because country settings differ, and the nature of the country's developmental process and the level of certain key indicators (life expectancy, gross na-

Figure 2.—Age-Sex Composition of More Developed and Less Developed Regions, 1980 and 2000: Medium Series Projections



SOURCE: U.S. Bureau of the Census, Illustrative projections of World Populations to the 21st Century. Special Study Series, table 2, pt. B, p. 23, No. 79, January 1979.

Figure 2B.—Popuiation Pyramid of the United States illustrating the Effects of the Baby Boom



SOURCE: U.S. Bureau of the Census, Illustrative Projections of World Populations to the 21st Century, Special Study Series, p. 23, No. 79, table 2, pt. V, January 1979.

tional product (GNP), nonagricultural labor force participation, literacy rates, etc.) affect the extent to which a program can succeed in lowering fertility. But the degree of political will and commitment and the extent of administrative capacity play major roles in determining the magnitude of fertility decline.

Most people in the developing world live in countries that now consider their rates of population growth higher than desirable and want help in achieving lower rates. Recent experience has shown that growth rates can be slowed, often with startling success, despite the momentum inherent in LDC age structures. Although other development factors influence fertility, both stronger family planning programs and more effective, safer, and easier-to-use contraceptive methods can make important contributions to slowing population growth in the next two decades.

If governments decide to take actions to reduce population growth in addition to those actions currently planned, the world's population in 2000 will be closer to the lower estimate of 5.9 billion than to the upper estimate of 6.5 billion. Even the low projection, however, means that today's 4.5 billion world population will increase by 1.5 billion in just 20 years. For the longer term, additional efforts undertaken now can be still more decisive in terms of the number of people added to the world's population. The difference between the high and low projections for 2050 is 4 million people—a number nearly equal to today's global total.

Countries that wish to reduce their population growth rates have three options: raise mortality rates, encourage emigration (or discourage immigration), or reduce fertility rates. The first is morally untenable, and the second is not feasible over the long term because there are no countries left to accept vast numbers of immigrants. The only viable solution is to lower fertility rates. Many LDC governments have already decided to encourage this latter option; in the last 20 years, the proportion of the world's people who live in countries that provide support for family planning services has risen from about 10 percent to 90 percent.

Most LDCs face similar environmental and economic problems. In a number of these countries, the need to increase food and fuel production to keep pace with population growth has led to significant environmental degradation through denuding of forests, transformation of productive land into desert, and waterlogging and salinization of irrigated land, The large balance-of-payments deficits and increased debts confronting most oil-importing LDCs in recent years have depressed their rates of economic growth, lowering prospects for meeting basic health care needs, and making the provision of jobs a formidable task.

The collective effects of these continuing environmental and social problems, exacerbated by rapid population growth, have led 10 increased international migration and political instability. U.S. interests are directly involved, for example, in present immigration pressures

Table 1.—Percent Reductions in Crude Birth Rates From 1965 to 1981 for Selected Countries

	UN medium variant	Crude birth rates		
	Population (millions) 1981	(births per 1,000 population) 1965	1981 (projected)	Percent reduction
Asia				
China[a]	969	30-40[b]	17-25[b]	17-58
India[a]	710	43	36	16
Indonesia[a]	155	46	35	24
Bangladesh[a]	91	50	46	—
Pakistan	85	48	44	—
Philippines[a]	53	44	34	23
Thailand[a]	49	44	28	36
South Korea[a]	39	35	23	34
Sri Lanka[a]	15	33	29	12
Malaysia[a]	14	42	31	26
Latin America				
Brazil	130	42	32	24
Mexico[a]	72	44	33	25
Colombia[a]	28	44	29	34
Venezuela	15	42	36	14
Chile[a]	11	33	22	33
Middie East				
Turkey	46	41	32	22
Egypt	43	42	41	—
Tunisia[a]	7	45	33	27
Africa				
Nigeria	80	50	50	—
Zaire	29	47	46	—
Tanzania	19	51	46	10
Kenya	17	50	53	—
MDCs				
United States	224	19	16	16
Japan	117	19	14	26
United Kingdom	56	18	13	28
France	54	18	14	22

— Slight fertility reduction, but data for trend measurement are not precise enough to warrant attaching a number.
[a]Signifies strong to moderate family planning program effort. Not all countries with strong to moderate programs included.
[b]China crude birth rate figures represent a range of estimates provided by National Academy of Sciences and U.S. Census Bureau. Official Chinese estimates of current birth rates are lower; see Chen report on China, app. A.

SOURCES: U.N., 1979-*World Population Trends and Prospects by Country, 1950-2000: Summary Report of the 1978 Assessment* for 1981 and 2000 population figures; Population Reference Bureau *1981 World Population Data Sheet.*

from Mexico, the Caribbean, South America, and Southeast Asia.

Rapid population growth is an intensifier of current environmental, food, energy, and resource pressures in LDCs, and its interaction with these problems is generating a new category of national security concerns. The implications of this interaction for national security, a term that is itself changing, remain largely unexplored.

Direct fertility determinants

Aside from indirect influences such as levels of socioeconomic development, education, and family size preferences, four factors have a direct and important impact on the number of births that will occur in the next 20 years: age at marriage, prevalence of breastfeeding, prevalence of induced abortion, and–the most significant—use of contraception.

Young age at marriage and near universality of marriage in the absence of widespread contraceptive use are important causes of high birth rates in many countries. In Europe and the United States, reductions in the proportion married and increases in age at marriage have historically helped reduce growth rates. In many LDCs, high infant, child, and adult mortality in association with the social stigma attached to illegitimate births has necessitated very young age at marriage and maximum reproduction to ensure survivral of the family lineage. Increases in age at marriage have contributed to fertility decline in many LDCs in recent years and may continue to do so in such areas as the Asian subcontinent, where age at marriage remains low.

Breastfeeding delays the return of ovulation after childbirth, sometimes for as long as a year or more. If large numbers of women breastfeed for long periods, a natural form of birth-spacing occurs that can cause a modest reduction in overall fertility rates. But breastfeeding is an important influence on fertility only in societies with high fertility rates. Breastfeeding is an imperfect individual contraceptive because the amount of protection against pregnancy that it confers is extremely variable. In LDCs, fewer women are now choosing to breastfeed, and many women are breastfeeding for shorter lengths of time.

The limitations of current contraceptive technologies and lack of access to their use cause many women in all parts of the world to seek induced abortion to terminate unwanted pregnancies. Induced abortion is a medically safe procedure when performed early in pregnancy by skilled personnel. But the risk of maternal death or serious complications increases greatly when it is performed by less skilled personnel in marginal facilities and when it is performed later in pregnancy. Rates of induced abortion are high in LDCs, even though its legal use is constrained in some countries by religious beliefs. It is rarely a preferred method of fertility planning, but is resorted to when other means are not available, or fail.

Of all the means available, contraceptive use is by far the most important in lowering fertility. On average, women are fecund (capable of bearing children) from age IS to 45, about 30 years. In the absence of contraception and allowing for time spent pregnant and infertile (due to infertility following birth or to breastfeeding), and time not spent in union because of divorce or widowhood, a woman could expect to have an average of about 10 children. If reduction of fertility rates to those associated with population stabilization (about 2.2 births to each woman) is desired, it is necessary that some method of contraception be used for up to 25 years.

The major methods of contraception currently in use are:

- Sterilization—vasectomy in the male, and tubal ligation/occlusion in the female.
- Steroid hormones—combined (estrogen and progestin) or low dose progestin oral pills, or intramuscular, long-acting progestin injections. These synthetic steroids are given in different combinations and different doses, depending on the commercial product, but they act primarily by inhibiting ovulation through suppression of the hypothalamic hormones that stimulate the release of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the anterior pituitary. The synthetic steroids also cause endometrial changes that make the uterus inappropriate for implantation should breakthrough ovulation and fertilization occur. other changes that contribute to the contraceptive effect include scant and thick cervical mucus, reduced sperm transport and penetration into the uterus, and altered sperm and ovum transport within the fallopian tubes.
- Intrauterine devices (IUDs)—the insertion of a foreign body, made either of an inert substance or impregnated with other materials (copper, progesterone). Although the IUD prevents implantation in some mammals, its mode of action is unknown in the human being. There are several possible modes of action, from interference with sperm transport, to interference with ovum transport, to interference with implantation in the uterus. There is also some evidence that IUDs lead to increased sperm

damage and affect the motility of the ovum in the fallopian tube.

- Barrier devices—the condom for the male and the diaphragm and cervical cap for the female.
- Vaginal spermicides—high viscosity fluids that both kill sperm and block them from entering the cervical canal.
- Coitus interruptus-male withdrawal prior to ejaculation.
- Periodic abstinence (rhythm, natural family planning)—timed to avoid coitus near the day of ovulation.
- Postcoital douches-water or spermicidal solutions that flush out anci kill sperm in the vagina,

The effectiveness and order Of effectiveness of these methods in MDCs are listed in table 2.

Between now and the end of the century, more than 20 new or significantly improved technologies for contraception are expected to become available. The most likely candidates are identified in table 3. Highly likely to be available by 1990 are:

- Steroid hormones: safer oral contraceptives, improved long-acting steroid injections, and two new methods of administration—steroid implants (e.g., capsules in the forearm) and steroid vaginal rings.
- IUDs: three improved types are anticipated. Improved versions of the copper-releasing IUD will be effective longer than current IUDs. Advanced versions of the progestin-releasing IUD may be as effective as the pill and require replacement only every 5 to 10 years. Postpartum IUDs, which can be safely inserted immediately following delivery without excessively high expulsion rates, will make IUDs available to large numbers

Table 2.—Theoretical and Use Effectiveness of Various Means of Contraception
(by pregnancies per 100 woman-years In MDCs)

Method	Theoretical effectiveness	Use effectiveness Rantae	Use effectiveness Average
Sterilization:			
Tubal	—	—	0.06
Vasectomy	—	—	0.15
Steroidal contraceptives:			
Injectable progestins (3-month regimen of medroxyprogesterone acetate)	0.24	–	0.24
Orals	0.1	0.2-4.5	0.7
IUDs:			
Lippes loop	1.9	—	2.7
Copper T	—	—	2.2
Diaphragm and jelly	3	3.3-33.6	12
Condom	3	6-30	12
Aerosol foam	3	3.0-35	14
Jelly or cream		2.0-45	20
Coitus Interrupts	8	10-38	18
Periodic abstinence	2.5	5-40	20
Suppositories	14	17-27	22
Douche	16	21-40.6	35

SOURCES: R. G. Wheeler, G. W. Duncan, and J. Speidel, *Intrauterine Devices — Development, Evaluation, and Program Implementation*, Academic Press, 1974.
L. Liskin, "Periodic Abstinence: How Well Do New Approaches Work?" Population Information Program, The Johns Hopkins University, Baltimore, Md., September 1981.

Table 3.—Future Fertility Planning Technologies

Highly likely before 1990
1. Safer oral contraceptives
2. Improved IUDs
3. Improved barrier contraceptives for women
4. Improved long-acting steroid injections
5. Improved ovulation-detection methods for use with periodic abstinence
6. Steroid implants
7. Steroid vaginal rings
8. LRF-analog contraceptives for women
9. Prostaglandin analogs for self-administered induction of menses
Possible by 1990 but prospects doubtful
1. Monthly steroid-based contraceptive pill
2. Improved monthly steroid injection
3. New types of drug releasing IUDs
4. Mini-dose vaginal rings
5. Antipregnancy vaccine for women
6. Improved barrier contraceptives for men
7. Sperm suppression contraceptives for men
8. Reversible female sterilization
9. Simplified female sterilization techniques
10. Simplified male sterilization techniques
11. LRF analogs for self-administered induction of menses
Uniikely by 1990 but possible by 2000
1. Antifertility vaccine for men
2. Antisperm drugs for men
3. Antisperm maturation drugs for men
4. Lactation-linked oral contraceptives for women
5. Ovulation prediction methods for use with periodic abstinence
6. New types of antiovulation contraceptive drugs for women
7. Contraceptive drugs for women that disrupt ovum transport
8. Reversible male sterilization
9. Pharmacologic or immunologic sterilization for women
10. Pharmacologic or immunologic sterilization for men
11. Agents other than LRF analogs for self-administered induction of menses

SOURCE: Office of Technology Assessment Survey; S. B. Schearer and M. K. Harper, 1980.

of women in LDCs who otherwise might lack access to the medical personnel needed for insertion of other types of IUDs.

- Barrier devices for women: one-size-fits-all diaphragms, disposable diaphragms, spermicide-impregnated diaphragms, vaginal films, vaginal sponges, vaginal rings that release spermicides, and cervical caps that can be left in place for weeks or months.
- Improved ovulation-detection procedures for use with periodic abstinence methods: a wide varietv of biological and biochemical parameters-are altered when a woman ovulates, and researchers are endeavoring to improve or simplify the physical tests that a woman can use herself to determine when she ovulates. Improved methods of evacuating changes in cervical mucus, hormones in urine or saliva, and basal body temperature would enable greater numbers of users of periodic abstinence to know with certainty when they could safely engage in sexual intercourse during the second half of the menstrual cycle without risk of pregnancy, although the prediction of ovulation is likely to remain problematic. *
- New hormonal methods: methods that would reversibly inhibit ovulation using synthesized agonists or antagonists to one of the hormones that controls ovulation, luteinizing-releasing factor (LRF).
- Drugs that induce menstruation: prostaglandin analogs that depend on uterine muscle contraction for their action. Administered as vagina] suppositories, these drugs can also induce abortion during the first 8 weeks of pregnancy in about 90 percent of cases.

Most R&D on contraceptives has been conducted by MDC governments and the pharmaceutical industry. Prior to 1967, contraceptive R&D was financed largely through the private sector. In the 1970's, however, of funds spent worldwide on reproductive research and contraceptive development, private industry provided about 10 percent, and governments and philanthropic and nonprofit organizations pro-

Vialed $10 percent. The U.S. Government is the major current funder of research on improved contraception, providing nearly 60 percent of worldwide expenditures. Approximately 70 percent of worldwide funds go to basic research, 20 to 25 percent to contraceptive development, and less than 10 percent to safety evaluation.

The market approval process of the FDA affects population planning assistance, because the U.S. Food, Drug, and Cosmetic Act prohibits pharmaceutical manufacturers from exporting drugs for uses not approved for marketing in the United States. This policy is based primarily on the premise that one standard of drug approval is necessary, and under this premise, the United States would be promoting a double standard if it exported drugs not approved for use in the United States.

The FDA approval process for all drugs averages 7.5 years. FDA requirements for the specific types of tests and test animals to be used in providing safety and efficacy data for contraceptives usually make the average length of the approval process for contraceptive drugs longer than for other drugs by about a year. The reason for these more stringent testing requirements for contraceptive drugs over other classes of drugs is that contraceptives are given to young, healthy individuals and can potentially be administered over a period of 30 years, whereas other drugs are usually used to treat diseases and/or are often administered only for a few weeks at most.

Drug patents run for 17 years, but effective patent life is shortened by the regulatory process. For oral contraceptives, however, short. ened patent life has not affected the original manufacturers' abilities to retain a large share of the market even when prices were increased after the patent period had expired.

But expanding product liability has escalated costs and made the prediction of future costs uncertain for both the pharmaceutical industry and its insurers. As in the case of patent life, these difficulties are being experienced by all drugs (and products in general), but the contraceptive market has been especially affected by product liability problems.

•Such methods would also benefit couples with infertility)' problems l)j pinpointing the fertile period.

Rising product liability costs and the ability of manufacturers to retain their market share even after patents expire signify higher prices for contraceptives and reduced purchasing power for family planning programs.

International population assistance

International population assistance evolved in response to growing awareness of the problems that accompany rapid population growth and to requests from LDC governments for technical assistance in addressing these problems. The purposes for which population assistance funds are expended include: 1) development of population planning policies appropriate to the recipient country; 2) contraceptive commodities; 3) systems for contraceptive distribution and use; 4) information, education, and communication activities; 5) research on the delivery of family planning services, on the development and application of improved or new contraceptive methods, on the social, economic, and cultural conditions that affect their acceptance and use, and on those social conditions that directly affect birth rates (e.g., age at marriage); and 6) the gathering, evaluation, analysis, and dissemination of demographic and other information.

Less than 2 percent of official development assistance from all MDC donors is currently allocated to population activities, a proportion that represents a small decline since 1970. The United States provides just under 4 percent of its total development assistance for international population activities.

In 1980, total resources (excluding China) committed to population and family planning programs in LDCs amounted to about $1.0 billion. Of this total, LDC contributions accounted for about $450 million, private sources about $100 million, and MDC sources about $450 million. ” Donor governments (including the United States) are the principal source of MDC assistance; funds are channeled: 1) through nongovernmental organizations (NGOs) such as the International Planned Parenthood Federation (IPPF) and Family Planning International Assistance (FPIA); 2) directly to LDC governments (bilateral assistance); and 3) through multilateral organizations such as the United Nations Fund for Population Activities (UNFPA). Private sector donors channel money primarily through NGOs such as IPPF. MDC and private contributions arrive in LDCs as money, contraceptives, information, and technical assistance in developing and administering family planning programs and in collecting and analyzing population data. Agencies administering the largest amounts of population assistance are the U.S. Agency for International Development (AID), UNFPA, and IPPF (fig. 3).

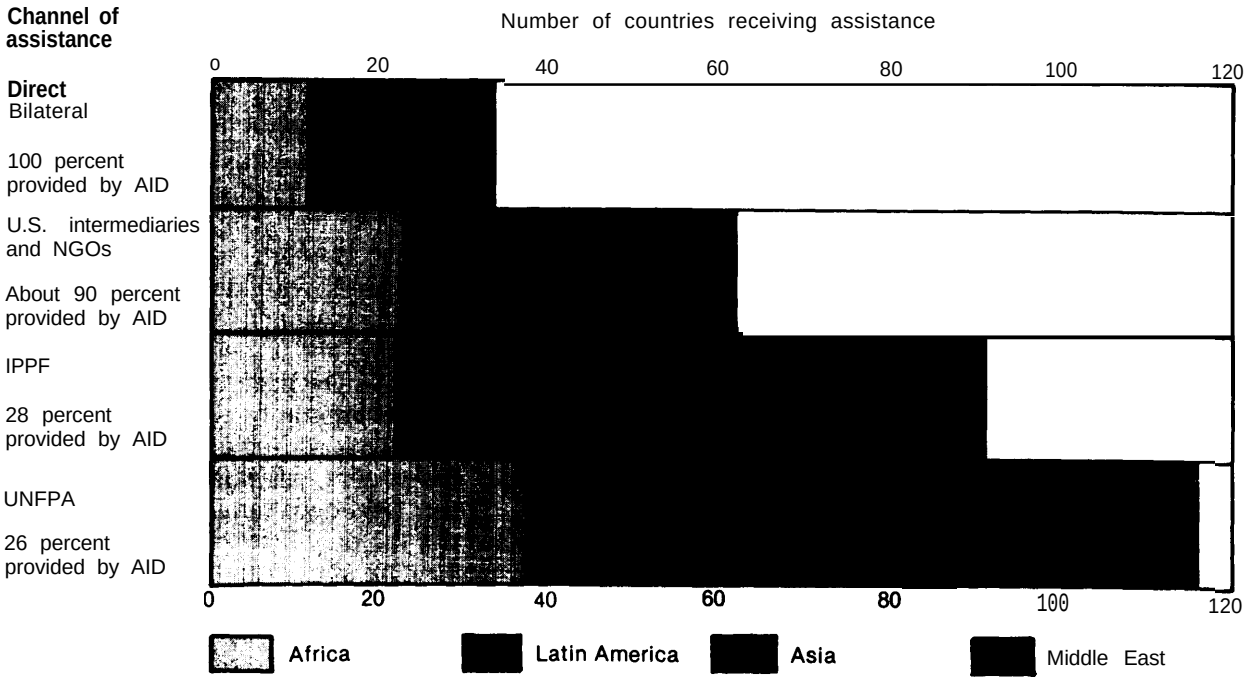
The United States supports population assistance through two main channels, AID (Office of Population) and the World Bank. The World Bank receives moneys in the form of general development appropriations, about 1 percent of which are directed toward population projects. AID, in turn, channels funds bilaterally to LDC governments, multilaterally to UNFPA, and through private intermediary organizations, such as IPPF, FPIA, etc. World Bank support is exclusively loan assistance; AID programs are largely grant assistance but include some loans as well.

The Foreign Assistance Act states that the population planning component is “to increase the opportunities and motivation for family planning and to reduce the rate of population growth.” It authorizes the President “to furnish assistance . . . for voluntary population planning. In addition to the provision of family planning information and service and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families.”

In recent years this has been translated by AID into program expenditures of about 50 percent for family planning services, 15 percent for institutional development and training, 10 percent for information and education, 10 percent for biomedical and operations research, 10 percent for demographic analysis, and 5 percent for policy development and research into factors that increase the use and acceptance of family planning services.

● China's expenditures in 1980 for its intensive birth planning campaign are estimated to have approached $1.0 billion; see app. A.

Figure 3.–Channels Through Which AID Population Assistance Arrives in LDCS, 1979



[a]Some countries receive population assistance from more than one source.

SOURCE: UNFPA, Report on Population Assistance, 1979

In fiscal year 1979, AID bilateral assistance totaling $48 million went to 33 LDC governments. NGOs such as FPIA, Association for Voluntary Sterilization (AVS), International Statistical Institute (World Fertility Survey), Population Council, International Fertility Research Program (IFRP), etc., channeled an additional $90 million from AID into technical assistance to 64 LDCs. Multilateral assistance totaling $30 million from AID went to UNFPA (26 percent of UNFPA's budget), which UNFPA in turn granted to 116 LDCs. IPPF channeled $22 million of AID funds (28 percent of its budget) to private IPPF affiliates in 88 LDCs. (The usual funding level is about $12 million; this $22 million included forward funding to alleviate IPPF cash flow problems and the fiscal year 1980 appropriation was reduced accordingly. Thus the United States, in population assistance as in other developmental programs, provides both special assistance to nations with whom it has a close relationships and a share of the multilateral international support that goes in some measure to virtually every LDC (fig. 3).

The amount of U.S. population assistance channeled through AID rose from $5 million in 1965 to $185 million in fiscal year 1979. This figure remained constant in 1980 and increased to $190 million in 1981 through continuing resolutions. The 1982 appropriation has been increased to $211 million; the authorization for fiscal year 1983 is $230 million.

Although the United States continues to provide the most population assistance to LDCs, its proportion of the total amount has decreased over the last 14 years. The United States provided 50 percent or more of all primary source assistance until 1974, when this proportion leveled off to about 40 percent, where it has remained. This decrease is largely due to increased contributions from other MDC donors, including the Scandinavian countries, Japan, and West Germany. In addition, the impact of inflation cut the 1981 funding level, in constant dollars, to $41 million below that of the peak year of 1972 ($121 million). The 1982 appropri-

ation is $28 million below the amount required to maintain the 1972 level.

International population programs

Population assistance has had diverse impacts, including a heightened awareness of the problems associated with rapid growth. Government officials, scientists, and informed lay people in LDCs and MDCs are working together to develop, test, and disseminate new contraceptive methods. Many women of reproductive age in LDCs have at least heard of family planning even though some may not fully understand what it means or may not yet have convenient access to contraceptive methods. More data of better quality are available to enable governments to formulate policy, set demographic goals, and monitor program effectiveness. Each of three decennial census rounds from the 1960's to the present has been characterized by substantial improvements in data collection techniques and data processing and analysis capabilities in LDCs. The World Fertility Survey and Contraceptive Prevalence Surveys are providing important data on fertility trends and differentials, levels of contraceptive knowledge and use, and program evaluation. Operations research projects are testing innovative approaches to the delivery of fertility planning information and methods. Social marketing programs have put contraceptives, on the road to being self-financing in some LDCs. And the mass media campaigns associated with social marketing programs have played a major role in enhancing public awareness and acceptability of family planning.

The need for greater sensitivity to and knowledge of the role of the sociocultural factors that motivate people to adopt family planning is clear. Social settings that allow women few options beyond raising large numbers of children, and negative attitudes of peer groups, relatives, and spouses can be important constraints to contraceptive use, Thus population and development programs that are multifaceted and address relevant social, economic, and health needs along with delivery of family planning services are most likely to be successful.

Family planning programs contribute significantly to improved health of women and children and have made a substantial difference in accelerating the rate at which fertility declines, as shown in table 1. (The countries noted with asterisks in table 1 are those that have strong-to-moderate family planning programs efforts.) In countries with strong family planning efforts for which data are available, fertility declined an average of 30 percent between 1965 and 1975. This compares with declines of about 4 percent in similar countries with weak family planning programs and 2 percent in countries with no programs. On balance, about 15 to 20 percent of the declines in fertility between 1965 and 1975 in 94 LDCs is attributable to the family planning component of population program effort. Thus, although family planning programs are not the only factors at work in countries experiencing substantial fertility declines, such programs clearly make a difference.

The use of contraceptive technologies can substantially lower birth rates, but their availability and acceptability vary. Delivery systems may be inadequate or culturally inappropriate so that family planning services are in fact not effectively available. The contraceptive methods used in a particular country may not be the ones preferred but the ones available. People may become dissatisfied and discontinue the methods used because of side effects, the need for repeated application, costs, medical contraindications, contraceptive failure, and concerns about long-term safety, A realistic goal is for each country to have enough technologies appropriate for local conditions so that each individual has access to at least one method that meets his or her current needs. Improved and new technologies could enhance family planning effectiveness and efficiency by reducing side effects, permitting easier administration, and simplifying delivery system requirements.

At present, of 374 million couples of reproductive age in LDCs (excluding China), some one-fifth, or about 74 million, are using contraception. By 2000, there will be at least 638 million couples of reproductive age (889 million couples if China is included). Because about 80 percent of these couples would need to use some form of contraception if fertility were to

approach replacement levels, the number of couples practicing family planning regularly and consistently would have to increase about sevenfold in the next 20 to 30 years.

Program costs per user currently range from $6 to $100 annually in LDCs, for an average of about $15 per user for an efficient family planning program (one that combines public and private sectors, provides access to voluntary sterilization, includes IEC activities, demographic data collection and analysis, and adequate infrastructure support). In order to increase current contraceptive use to the 80 percent of all couples of reproductive age necessary to approach replacement fertility levels, 300 million LDC couples (excluding China) would now have to be practicing contraception. Although contraceptive use is not expected to exceed 50 percent by 2000, if it were to reach the 80-percent level it would require, using the $15 cost per user per year, a minimum total international population support budget of $4.5 billion annually, including the contributions of LDCs. (This figure excludes China; PRC expenditure data are estimated in app. A.) Using the same assumptions of cost per use, and using 1980 dollars, the rise in numbers of couples in the reproductive ages would increase this cost to about $7.4 billion in the year 2000. (Under this formula, the amount rises to $10.7 billion when China's childbearing-age population is added.)

Program emphasis will shift in coming years as LDC needs change. More emphasis will be given to innovative approaches to the delivery of services to rural populations. Programs will need to rely more heavily on private sector delivery system development in order to become self-supporting. Family planning programs will be integrated with other components of development. Decentralized approaches that identify and meet community-level needs and that focus on primary health care and capitalize on local institutions will be more prevalent. The need for well-trained and highly skilled managers will be crucial as the demand for services grows. More emphasis will have to be placed on increasing work opportunities for women in all sectors of development, including family planning programs.

Effective use of present and new technologies will be a high priority. Program managers will have to allocate resources to ensure adequate distribution, storage, and back-up medical services. The effective communication of information on fertility planning technologies will be of central importance in allowing couples to choose family planning methods appropriate to their current needs. As countries move to self-financing, more will establish their own facilities for contraceptive manufacture. Since new or improved fertility planning technologies are more likely to be developed in MDCs, efforts to enable LDCs to readily import these new technologies will need to be expanded. LDCs may also want to enter into special import-export arrangements that will permit sale of fertility planning technologies among themselves.

Because LDCs consider the slowing of their population growth an urgent need and the lead time required to make new contraceptive methods available is relatively long, the methods that should be emphasized in the next decade are those already in hand and those that will become available in the next few years. Experience with family planning programs in LDCs indicates that if commitment is strong, if delivery systems are adequate and culturally acceptable, and if a broad range of methods is made available, the pace of fertility reduction can be enhanced. Although imperfect, currently available contraceptive methods can provide the basis for fertility reduction, but further biomedical research is critical to improving the safety, efficacy, and acceptance of contraceptives.

For policymakers concerned with modifying population growth, the most meaningful population information is the difference in numbers of people added to the world's population if governments do or do not take feasible actions to reduce birth rates in addition to those already under way. The actual amount attributable to additional governmental actions that reduce birth rates is neither accurately known nor explicitly stated by most demographic experts who make projections. There is general agreement, however, that if governments intensify current actions to reduce growth rates, the

low variant projection is more likely to be achieved. The total difference between the high and low variants is sizable—650 million persons—and is equivalent to the addition of three times the current United States population in just 20 years.

Issues and options —-.

The breadth of purpose of international population assistance, the range of its activities, and the variety of U.S. governmental involvement in these activities result in many issues of congressional interest. Not all of these issues require legislative action, and many can be examined through the congressional oversight process. In this section, the principal issues and related legislative options for: 1) Federal involvement in contraceptive R&D, and 2) international population assistance support are addressed.

In the biomedical research area, the issues center on the U.S. Government's key role in support of reproductive and contraceptive R&D and on reconciling how the United States regulates the drugs and medical devices industries with the need to diffuse these technologies to countries that may have different risks or perceptions of risks.

Contraceptive technologies

The U.S. Government's role in the development and dissemination of contraceptive technologies is mediated through two avenues: 1) the R&.D activities of the National Institutes of Health and AID; and 2) the regulatory policies of FDA. Peripheral to contraceptive technologies, but possibly affecting them, are U.S. patent laws and their interrelationships with FDA's regulatory process and the direction that product liability legal doctrines have taken in the United States.

THE ROLE OF THE U.S. GOVERNMENT IN CONTRACEPTIVE R&D

The Federal Government not only supports contraceptive R&D, but also regulates the drug and medical devices industries through FDA's market approval process in which efficacy and safety requirements must be met. The development and dissemination of contraceptive technologies thus can be influenced through Federal funding of contraceptive R&D, and through governmental actions that could stimulate or restrain expanded or renewed interest in contraceptive products by private industry.

ISSUE: Federal support of contraceptive R&D

In 1979, governmental agencies throughout the world provided approximately 80 percent of funding for reproductive research and contraceptive development. The United States provided nearly 60 percent of all funds, or about $89 million. Approximately 70 percent of worldwide expenditures were devoted to basic research, training, and institutional support; about 23 percent to contraceptive development; and approximately 7 percent to evaluation of current methods.

Federal support is provided by the Contraceptive Development Branch of the National Institutes of Child Health and Human Development's (NICHD) Center for Population Research and, to a lesser extent, by AID. AID is a major funder of the Program for Applied Research on Fertility Regulation (PARFR) and the International Fertility Research Program (IFRP). Federal funds are also provided indirectly through AID's contribution to the International Committee for Contraceptive Research (ICCR), to the UNFPA, and the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT).

OPTIONS:

A. Sustain financial support of R&D at current levels.

If Congress continues to judge that governmental action is warranted to continue the development of improved contraceptives for use at home and abroad, the minimum action would be to sustain support of existing programs at

current levels. Although the dollar amount for reproductive research and contraceptive development increased from $80 million in 1972 to $112 million in 1979, inflation has meant, in terms of constant dollars, a cut of about 20 percent from the 1972 funding level.

With limited research dollars, individual investigator-initiated research that may not be part of a larger program might have higher priority and be more likely to be funded than large, goal-oriented, contract research of the type needed for stimulating contraceptive development.

B. Substantially increase financial support.

Arguments for increases in contraceptive research include the following: Present contraceptive development programs may develop many useful new and improved contraceptives over the course of the next two decades if additional money is available. Because many LDCs are actively pursuing policies to reduce population growth and there is increasing concern in MDCs about the side effects of current fertility planning methods, there is a strong need for improved contraceptive methods both in the United States and abroad. The potential impact is enormous in terms of improved family planning effectiveness, reductions in numbers of unwanted pregnancies and induced abortions, improved maternal and family health, alleviation of human suffering, and opportunities for economic progress. Without such added investments, emergence of many new contraceptive products is likely to be either prevented or very substantially delayed.

Congress can authorize and appropriate more funds for the entire field of reproductive research, using the presently available funding channels, NICHD and AID. This action could strengthen this field in a balanced, comprehensive fashion and thereby increase scientific prospects for discovery and development of improved contraceptives in the future.

Alternatively, Congress may wish to increase funding only for contraceptive development. Added investments in this specific area are highly likely to produce payoffs in the form of useful new technologies. As total public funding for such development is currently less than $20 million annually, present funding levels could be significantly increased at relatively low cost. An additional $20 million annually in this specific field could have a substantial impact.

The budget of AID's Office of Population also could be augmented and earmarked or recommended for contraceptive development, which would enable AID to increase funding for both the three U.S.-based international contraceptive development programs and other groups that could contribute to this endeavor,

Increases in NICHD's budget would need to be earmarked for the Contraceptive Development Branch. Such action would greatly increase the volume of goal-oriented R&D being conducted under contract by NICHD. This action would contribute directly to the development of new contraceptives for U.S. use and indirectly to the work of international programs seeking to develop and introduce new contraceptives in LDCs.

C. *Reduce financial support.*

Although it could be argued that industry invests little in contraceptive R&D because government funds are available, and that one impact of this option would thus be increased industry participation, such factors as product liability are major deterrents to greater industrial participation in contraceptive R&D. For basic reproductive research, the additional factors of longer time for return on investment and greater risk further deter industrial participation in fundamental research.

For government research, reduction or elimination of Federal funding for basic research and contraceptive R&D would produce different effects depending on how the reductions were carried out.

A reduction exclusively in NICHD's budget would rapidly result in a discontinuation of research by many U.S. research centers now working in this field under NICHD support. Much of the Nation's safety research on contraceptive methods currently in use would also be eliminated. At least initially, the direct effect on the U.S.-based contraceptive development programs to which AID contributes (IFRP,

PARFR, and ICCR) would be minimal, as they are not funded by NICHD. But because these other programs utilize basic research and goal-oriented research findings that emerge from NICHD-funded projects, over the long term their prospects for successful development of new methods could be reduced significantly.

A reduction exclusively in AID's contraceptive development program likely would be detrimental for at least three of the four nongovernmental contraceptive development and dissemination programs, Three programs—IFRP, PARFR, and ICCR—are highly dependent on AID funding, and any substantial reductions in their budgets would essentially put them out of business. While PIACT might continue its work independently if its budget were maintained under such circumstances, it could not replace the clinical research and applied R&D work of the other three organizations as PIACT concentrates largely on providing product information to LDCs.

STIMULATE THE INTEREST OF PRIVATE INDUSTRY IN CONTRACEPTIVE R&D

Most of the numerous factors that might stimulate more private industry interest in contraceptive R&D concern removing apparent disincentives against developing and marketing of contraceptive products. But as these factors also involve major issues in their own right, trying to change these factors to promote contraceptive R&D quickly impinges on other substantial interests. Hence, although options for some factors are discussed here, it should be kept in mind that the effects of these changes would reach beyond contraceptives to other drugs and other products.

ISSUE 1: product Liability and the Contraceptive Industry

According to representatives of companies actively researching new contraceptive products, product liability is as great a negative factor in making a business decision regarding new contraceptives as meeting the FDA requirements for safety and efficacy.

The primary effect on a manufacturer from product liability is financial; i.e., compensation for claimants and defense of claims. A secondary effect is the adverse publicity accruing to the product and its manufacturer. Because of increasing frequency of claims and escalating size of successful judgments against contraceptive manufacturers, pricing of liability insurance has become so uncertain that insurers are either withdrawing from the field, mandating that manufacturers self-insure larger and larger amounts of first-dollar costs, or placing contraceptive drugs and devices in special categories of risk separate from product liability insurance for the manufacturer's other products.

As liability costs are business expenses that are incorporated into the price of the affected product, manufacturers may be increasingly reluctant to devote research and development efforts to products such as IUDS. Once the sale is made, there is less opportunity to recoup liability costs, as sales are not as frequent and continuous as they would be for oral contraceptives. With the latter, liability costs can be passed on, which may explain in part the large price increases of oral contraceptives (discussed next) in comparison with other drugs. Thus, product liability may be affecting not only the propensity of private industry to develop new contraceptives but also the kinds of contraceptives to be developed in the future.

Because the product liability problem is of concern for products in general, the contraceptive field may well be an inappropriate forum for congressional consideration of this larger liability issue. But recognition by the Congress of liability problems with contraceptives might encourage the congressional committees that have jurisdiction over laws governing commercial products to consider changes in these laws,

ISSUE 2: Effective Patent Life

The current process through which drugs and medical devices are cleared for commercial distribution and sales takes a number of years. However, in order to protect its interest in the potential new product, a company must apply for and be granted a patent long before the product has been approved by FDA. Drug patents run for 17 years, but it takes an average of 8.5 years for a contraceptive drug to clear the regulatory process, cutting its effective patent life to less than 9 years. Whether this situation

inhibits the development of new drugs and medical devices is not clear.

Wyeth Laboratories and Ortho Pharmaceutical share approximately 70 to 80 percent of the U.S. market for oral contraceptives. Wyeth's patent on norgestrel is still in effect, but the patent on norethindrone expired in 1973. Since the patent expiration, only Mead-Johnson and Lederle have entered the market, and Lederle no longer markets its oral contraceptive. No generics (nonbrand name drugs) have entered the market. The Pharmaceutical Manufacturers Association also reported in August 1980 that oral contraceptives had the greatest price increases of all classes of pharmaceuticals in the periods 1969 to 1979 (187 percent) and 1978 to 1979 (23.7 percent), as compared to only a 37.4 percent increase in price during 1969 to 1979 and a 6.5 percent increase in 1978 to 1979 for a sample of over 1,000 drugs. Although other factors (e.g., product liability) may be at work, shortened patent life has not had a significant effect on the oral contraceptive market. After patents have expired, prices have remained high and new firms have not been able to enter the market on a competitive basis.

ISSUE 3: Export of Non-FDA Approved Drugs

The market for U.S. manufacturers of contraceptives could be expanded if the law on the export of non-FDA approved drugs were changed.

Current law prohibits the export of drugs for uses that are prohibited in the United States. Two categories of drugs are at issue: 1) drugs unevaluated for use; and 2) drugs evaluated but not approved for use. There are some exceptions to the drug exportation ban; e.g., investigational drugs can be exported for investigational purposes, provided that the importing country's government has approved such imports. In addition, medical devices not approved for marketing in the United States can be exported if: 1) they conform to the laws and specifications of the importing country; and 2) their export is not considered by the Secretary of Health and Human Services to be contrary to the public health and safety of the importing country.

Changes in the export provision of non-FDA approved drugs have been considered by Congress. In the 96th Congress a bill adopting the medical devices export law for drugs was passed by the Senate but died in the House of Representatives.

OPTIONS

A. Keep the status quo, where drugs not approved for marketing in the United States cannot be exported to other countries but medical devices can be exported under certain conditions.

By keeping the status quo, Congress prevents the foreign marketing of drugs that have not been adequately tested or whose safety has not been established by U.S. standards.

Current law does not affect the foreign production and use of contraceptives that are not approved for use in the United States. For example, medroxyprogesterone acetate (Depo-Provera) is manufactured and used as a contraceptive abroad, although approved only for the treatment of endometrial and renal cancer in the United States.

Keeping the status quo helps to avoid the danger of "unsafe" drugs being manufactured in the United States and then "dumped" on other countries as some critics have charged. Existing law protects the United States from being criticized for subjecting other people to risks to which it does not allow U.S. citizens to be exposed.

However, the relative risks and benefits of a drug are not the same for people in LDCs, where health conditions, including the risks of pregnancy and childbearing, are quite different from those in the United States. Further, the wide range of contraceptives available to U.S. women may not be available to women in LDCs, a factor that affects the risldbenefit assessment of a particular contraceptive. Thus, the United States may be depriving women in LDCs of drugs that would have a greater benefit than risk for them.

B. Adopt the medical devices export law for drugs.

As in the case of medical devices, non-FDA approved drugs could be exported, provided that

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the specifications and laws of the importing country were met, and the Secretary of HHS determined that the importing country's public health and safety were not compromised.

C. *Adopt the medical devices export law for drugs, and add one or more of the following provisions:*

1, Require that the risk/benefit analysis for an unapproved drug take into consideration conditions of the drug's use (and other health risks) to individuals ***in the importing country***

This provision is based on the assumption that the risks and benefits of a given drug can change from country to country. Some advocates of this provision believe that a risk/benefit analysis of a drug should be based on data actually obtained in the importing country and in response to requests from that country, Determination of a drug's benefits would be based on the prevalence and severity of the target medical condition, and safety assessments could consider such items as the extent to which the drug user could be monitored for adverse reactions. Other user conditions—e.g., nutritional status—that could affect a drug's safety and efficacy could also be studied,

Instead of actually collecting data from clinical trials conducted in the importing country, it may be more feasible to adjust data collected from other countries to reflect user conditions and disease prevalence in the importing country. It is very difficult to collect data from a sufficient number of women within any given country when low-incidence, but very important, medical events are to be assessed. Many importing countries would lack the capacity to conduct such assessments.

z. *Establish industrial standards of conduct.*

Procedures could be developed in which officials–and perhaps the public–in importing countries could be informed of the risks, benefits, and costs of the drugs they wish to import. Written verification of such an informed consent process, signed jointly by company executives and importing country officials, could be filed with the Secretary of Health and Human Services (HHS). Violation of that document could serve as a basis for withdrawal of approval.

D. Develop international standard-setting mechanisms on the use, safety, and effectiveness of contraceptive drugs and devices.

If modifications of existing export laws on drugs along the lines of the current medical devices export law (options 2 and 3) are adopted, such international standards would be helpful to the Secretary of HHS in determining whether or not the importing country's public health and safety are compromised.

WHO could be encouraged to develop international standards for safety and efficacy and/or for labeling and promotion standards for contraceptive drugs and devices. These standards —in conjunction with safety data specific to the importing country—could provide the basis for the Secretary's decision.

INTERNATIONAL POPULATION ASSISTANCE

Because the momentum for large increases in the world's population is clearly present and recognized, many LDCs now actively seek population assistance. They recognize the implications of their high growth rates, and their requests for population assistance have risen to the point that donor agencies can meet only a fraction of current requests for such aid. Further, the people who will contribute to the anticipated surge in world population gorwth in the next few decades have already been born (see fig. 2A), and a very substantial increase in the use of fertility planning methods is required in LDCs in order to slow population growth.

There are two issues to be addressed in U.S. international population assistance efforts—level of funding, and the distribution channels through which U.S. funds are dispensed.

ISSUE 1: Level of Funding

Because there are many competing demands on Federal funds, careful examination of the impact of various funding levels is essential.

OPTIONS:

A. Reduce financial support.

Reduced support from the United States for population programs would force LDCs to reduce their programs, cut back on supplies that require foreign exchange, eliminate training

programs, and probably decrease program outreach to rural and other hard-to-reach areas, Because the momentum for population growth already exists, spending for population programs deferred now would still be necessary at higher funding levels because of inflation, loss of trained personnel, and duplication of start-up costs. The capability of LDCs to finance their own family planning programs through such promising avenues as commercial retail sales (CRS) programs would be postponed. (CRS programs provide oral contraceptives, condoms, and spermicides at low cost and can effectively extend to hard-to-reach areas. However, they require substantial initial funding for bulk procurement of contraceptives, subsidizing of retail prices, and technical assistance in the establishment of backup medical services,) Also, if the U.S. level of support were to be decreased now, self-sufficiency of LDCs in population planning and progress in economic development might be further delayed, resulting in: 1) deteriorating social and economic conditions including increased death rates in LDCs; 2) need for significant future increases in general economic developmental assistance from MDCs to LDCs; or 3) if the United States were to abstain from future increases in economic developmental assistance, widening of the economic chasm between MDCs and LDCs, with all of the political implications that are associated with these differences.

Overall, U.S. cuts would disrupt the current working balance among private organizations, intergovernmental agencies, and government donors, with particularly adverse effect on the private agencies that are likely to suffer major reductions yet are often the most cost effective. Under current budgets, AID and the multilateral donors cannot meet current commitments. With further cuts, many countries and agencies would have to reconsider their ability to implement effective programs.

The U.S. Government, as the largest single donor to international population assistance, has been able, to some degree, to coordinate population assistance efforts and influence the direction of funding. A reduction in population assistance funds would reduce U.S. influence on program strategies and design.

B. Increase financial support,

population and family planning programs have been a key factor in recent fertility declines. The needs of many LDCs for population assistance and the current shortfall of funds for these purposes are well-documented.

Congress has in fact increased its appropriation from $190 million in fiscal year 1981 to $211 million in 1982; $230 million has been authorized for 1983. These current and potential increases represent a significant step and underscore the importance of population assistance at a time when many high priority social programs are being cut. However, inflation has reduced the purchasing power of these funds to below that of the total amount provided for population funding in the peak year of 1972 ($121 million, or about $239 million in 1982 dollars). At a time of rising requests for assistance, the AID population commitment is decreasing in purchasing power.

AID's fiscal 1982 budget is about $200 million below levels of documented need and insufficient to the point that: 1) most AID-supported projects and programs will receive less than the funds needed to satisfy demand for family planning services or otherwise function optimally (this includes inability to meet shortfalls at UNFPA, IPPF, and other major private voluntary organizations); 2) there will be few new initiatives in Africa (where governments are now beginning to ask for assistance) and the Near East; and 3) projects are being terminated prematurely, before recipient countries become self-sufficient.

UNFPA's 1982 calendar year budget of $135 million represents a shortfall of $40 million to $100 million. " The $40 million represents the

*On the basis of its 1979-80 projections of 15 percent per year growth in contributions from MDC donors, UNFPA set up multi-year commitments for various LDC and international programs, both new and ongoing. As 1980-81 unfolded, a plateau in the U.S. contribution occurred, and the U. S. dollar strengthened in foreign markets, making other currencies relatively weaker. These events combined with inflation to give MDC donations less actual value

(Footnote continued on p. 22)

gap between available funds and established needs for ongoing programs and commitments previously made. The $100 million includes new programs that have been requested and merit funding, but for which funds are not available. However, a much larger number of countries now wish populaiton assistance, and there has been a 20 percent increase in couples of childbearing age in LDCs since 1972. This argues for an even greater increase in assistance commitments in the coming years.

Excluding China, only 20 percent of couples of reproductive age are currently using contraception in LDCs. Efficient programs cost an average of $15 per user annually (new programs can cost as much as $100 per user). Many countries are only beginning to implement family planning programs so start-up costs are very high. If fertility is to fall to replacement levels, contraceptives must be used by about 80 percent of couples in the childbearing ages. The growth in the population, the need for increased use of fertility planning methods, and higher costs of programs that cannot be fully implemented until LDCs themselves can contribute more support all argue for major incremental increases in population assistance in the coming years.

One approach to steady incremental increases in funding would be to meet the recommendation of the International Conference of Parliamentarians on Population and Development held in Colombo, Sri Lanka in 1979. Delegates representing 58 countries unanimously called for a total annual allocation of $1 billion in international population assistance (exclusive of LDC commitments) by 1984.

More recently, at the International Conference on Family Planning in the 1980's held in April 1981 in Jakarta, Indonesia, participants from 76 African, Asian (including China), Latin American, and Middle Eastern countries joined representatives of major international agencies in calling for a rapid increase in overall national and international expenditures for population and family planning programs to $3 billion annually. LDC representatives stressed the urgency of reducing high fertility rates, slowing the momentum for further growth, raising women's status and economic opportunities, and providing family planning services as a basic human right.

Assuming that the United States wishes to maintain its 40 percent share of the total assistance budget and that other MDCs and private sources increase their contributions, the goals set by these international representatives might be attained, although the timing is likely to be delayed. If the United States were to increase its contributions by 30 percent per year (assuming an annual inflation rate of 15 percent), its contributions could keep pace with inflation and incremental funding would be available for increasing needs. The United States would thereby maintain its leadership position in population assistance and would contribute significantly to meeting requests from LDCs for assistance with a problem most of these countries now view as high priority.

ISSUE 2: Distribution of Population Assistance Funds.

Present channels and content of population assistance programs reflect both the priorities of the assistance agencies and the needs of

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than numerical value. An approximate shortfall of $10 million to $15 million resulted from exchange rate fluctuations due to the increasing value of the dollar. Current program commitments to between 55 and 60 programs, when added to reasonable extensions of existing programs, yield, at a minimal estimate, a shortfall of some $40 million per year for the next several years. (This shortfall could be as high as $100 million in total value in requests for both 1-year and multiyear projects that merit funding but which UNFPA cannot meet.) As a result, UNFPA's governing council has asked the organization to assess and evaluate each of its programs in order to see where cuts can be made, but has used the assumption that there will be a 10 percent increase in contributions in the next few years. If contributions do rise at this rate, if programs are reviewed and realigned, and costs can be reduced by extending multiyear programs to cover additional years, UNFPA could meet its commitments. The total annual UNFPA budget required to meet commitments after realigning and reassessing would rise from the 1980-81 total of $132 million to at least $146 million in 1981-82.

LDCs. A change in the present distribution system would affect the type of aid available and hence would have different impacts on different regions,

Because of differences among regions, varying approaches are required. In general, Asia's primary needs are for efficient and effective services delivery to very large rural populations, a large volume of supplies, and additional training in health care and program management.

In Latin America, some governments are reluctant in the face of religious and conservative opposition to give rigorous support to family planning programs, but public demand for family planning services is growing rapidly. As a consequence, support for private agencies and expansion of family planning within health care systems are increasing.

In the Middle East, the limitation of opportunities beyond childbearing for women is a major barrier to fertility change. Expansion of government and private services, and of broad social programs, is needed. The continuation of innovative efforts by private population and family planning agencies to change perceptions of the role of women is crucial.

Birth rates in some countries in Africa are the highest in the world, but few African countries have formulated policies that make a direct connection between their serious economic and social problems and rapid population growth. As most of these countries do, however, favor the provision of family planning services in the context of maternal and child health activities, emphasis should be on support for family planning as a component of health programs. Improved collection and analysis of demographic and other data would make an important contribution to increased understanding of the magnitude of population growth and its impact on economic development and the environment. Expansion of the role of existing private voluntary agencies would facilitate delivery of family planning services and improvements in maternal and child health.

There is thus a major difference between Asia, for example, where governmental programs are established but where support is needed to make them comprehensive and effective, and Africa, where there is much less appreciation of the implications of rapid population growth and less governmental commitment to extend family planning services widely.

However, these broad generalizations mask the variability that exists among countries, which is at least as great as that among regions. Different countries have different cultural values and development goals and thus require different forms of assistance. Different forms of government and different political alliances also make some forms of assistance more appropriate to one country than another.

Technical assistance and commodities for population planning and family planning programs are currently channeled through several major international agencies and many private nongovernmental agencies. The largest agencies, AID, UNFPA, IPPF, and the World Bank provide technical assistance in varying degrees in the areas of family planning services (including commodities); information, education, and communication; institutions and training; research and evaluation; policy development; and data collection.

Each agency tends to have different emphases and priorities within a broad range of support activities. For example, UNFPA provides technical assistance for basic population data collection, and channels assistance for family planning services primarily through health ministries incorporated into maternal and child health programs. AID is the largest supplier of commodities and places strong emphasis on family planning services delivery. IPPF emphasizes family planning services delivery in private sector clinic settings. Because each agency has different emphases and countries have differ-

ent priorities, the agencies can cooperatively tailor their support to individual country needs.

About 28 percent of AID funds are currently dispensed to the multilateral agencies (UNFPA and IPPF), 26 percent are dispensed bilaterally, and 46 percent dispensed to and through private intermediaries and organizations, Changes in present proportions of assistance would have uncertain effects on the balance that has been achieved among these agencies and there are no compelling reasons for considering changes at this time. Given current shortfalls, duplication of efforts is not an issue, but if funds are increased, efforts to promote greater coordination among agencies at administrative and country levels would need to be examined more closely.

Additional issues for congressional oversight

Several additional issues that Congress may wish to consider for oversight are as follows:

- Although population issues are the jurisdiction of several congressional committees, there is no single congressional mechanism for continued oversight of international population assistance. A prime issue, therefore, is whether population growth in LDCs and its implications for their progress toward economic self-sufficiency should continue to be addressed within the general subject of international economic developmental assistance, or whether a committee or subcommittee should be formed to focus directly on issues related to national, regional, and world population growth.
- Present criteria for determining which countries receive population assistance are established by AID, except for-the following provisions: limitation of assistance to the poorest countries (currently interpreted as yearly income below approximately $300 per capita), prohibition of aid to Communist bloc countries, and prohibition of funding of abortion services. A review of Congress's legislative guidelines and the ways in which AID has interpreted them would be a necessary corollary of changing the current levels of funding and of the current apportioning of aid between multilateral and other channels through which assistance is funneled.
- As summarized earlier in looking at the differences among Asia, Latin America, the Middle East, and Africa, the pace of population change in different regions of the world varies greatly. Each region requires different types of assistance and runs on different timetables, and in some settings immediate results cannot be expected. Priorities and restrictions in addressing these various aspects of global population growth require clarification. For example, current restrictions prohibit aid to China. The result of this action toward the country which contributes the largest proportion of global growth may be that U.S. population assistance is oriented less toward having the greatest impact on total world population growth than to slowing population growth in those regions of the world and in those countries where the United States has a strong interest. Congress may want more extensive reviews of these priorities and the reasons behind them.
- If governmental support for social programs, including economic aid to LDCs, is reduced, there will be a need to accelerate the pace of self-sufficiency of LDCs, and for additional support from the private sector in both LDCs and MDCs. Congress may therefore wish to explore the extent to which this support can be encouraged, and how governmental actions can facilitate greater activity by the private sector in LDCs.
- Factors that may be inhibiting the development, manufacturing, and marketing of medical products—e.g., product liability suits, shortened patent life, and FDA's export provisions on drugs–are not unique to the contraceptive market, but are representative of problems that have arisen generally for all types of consumer products. Addressing these generic consumer product problems through the issue of fertility planning technology may be inappropriate, but

some resolution of these generic problems will eventually have to be made. Thus, Congress might want to address these general issues through those committees tht have jurisdiction over product liability, patent laws, and the FDA's regulatory processes.