Production and Distribution Capabilities for New Fertility Planning Technologies Over the Next Two Decades*

Introduction and conclusions

This section reviews the interrelationships between changes in the manufacture and distribution* * of current and new fertility planning technologies and their availability in less developed countries (LDCs), and looks at the ways in which production and distribution will influence the development of new technologies.

These impacts ultimately influence the cost, formulation, design, and ease of supply and resupply of the contraceptive technologies to be distributed by government programs in LDCs. Many agencies and organizations in addition to the government agencies directly responsible for distributing the relevant technologies significantly affect and are affected by manufacturing and distribution decisions. These include ministries of trade, labor, industry, and finance in LDC governments, as well as international donor agencies, technical assistance agencies, and manufacturers. Other agencies are peripherally involved: these include those responsible for setting manufacturing and quality control standards, for regulating drugs and devices, and for supplying manufacturing equipment.

The following pages provide a qualitative consideration of the likely courses of events over the next 20 years in the production and distribution of fertility planning technologies. More extensive research would be necessary to accumulate quantitative information.

"This summary is drawn from a report prepared for OTA by Richard T. klahoney of the Program for the Introduction and Adaptation of Contraceptive Technology. The development of new fertility planning technologies and increased demand for contraceptives will require extensive changes in systems of manufacturing and distribution. The effects of these changes will be significant in both LDCS, where governments will need to examine their capability to provide commodities in the context of moving toward self-sufficiency in their family planning programs, and MOCS, whose roles in

Several conclusions have been reached about the evolution of family planning programs and the development of new technologies over the next two decades:

- 1. Many of the prospective fertility planning technologies (silastic implants that release steroid hormones, biodegradable implants, injections that utilize hormone-carrying polymers, silastic vaginal rings) will require the creation of new manufacturing capacities for their widespread distribution. No similar technologies, either for fertility planning or for other purposes, are currently being marketed in large scale. This requirement for new manufacturing technologies may:
 - a) increase the time required for new products to become widely available;
 - b) increase the dependency of the public sector on the private commercial sector (located mainly in more developed countries (MDCS)) for establishing the capability to manufacture the new technologies;
 - c) make it increasingly difficult for most LDCS to establish local production of new technologies: and
 - d) enlarge the role of international donor agencies and MDC manufacturing companies in determining the kinds of technologies that will be available to LDCs.
- 2. Other constraints to the introduction of products may be of more importance for the availability of new or improved methods than possible limitations in manufacturing. Because introduction of a new product into a family planning program is expensive, time consuming, and can lead to disruptions in the program, program managers need substantial justification for its introduction. The most important justification is that the new product will result in a significant new increase in contraceptive use.
- 3. There is a trend in a number of the most populous LDCs toward government sponsorship of local production of fertility planning technologies. The impetus for this trend often comes from

providing future population assistance are likely to be substantially altered.

"Distribution here refers to the processes and routes whereby contraceptives arrive in the hands of users from their initial point of manufacture While this includes distribution from receiving points for supplies at the commodities headquarters of LDC family planning programs to clients of such programs, the major focus of this paper is on distributing mechanisms and channels that precede this point in the supply chain.

- high government levels—the president, prime minister, or cabinet—rather than from donors or officials of the family planning program itself.
- 4. Those LDCS that do establish local production may be limiting their access to future improved versions of the technology. This is true not only because of the difficulties in "retooling" a manufacturing facility (to switch from an "older" to a "newer" version of an IUD, for example) but also because access to the new technology may be constrained by patents and licenses. An LDC may find it prohibitively expensive to acquire the production know-how and licensing necessary to manufacture the improved technology, and thus opt to stay with the "older" version of the method.
- 5. As a corollary to conclusion 4, LDCS that do not establish local production of a particular method may be enhancing their future access to modifications and improvements of that method. Further, the levels of product use they can achieve will permit them to request, for very little additional cost to the donor or themselves (depending on whether the commodities are donations or purchases), '(customized" products* to fit their particular needs. These LDCS will, however, continue either to be dependent on donors for their commodity supplies or will have to use hard currency to purchase products on the international market. These considerations, and others, could lead some countries to the conclusion that local production is the more desirable course to pursue.
- 6. The eight large multinational firms that manufacture most of the world's contraceptives will continue to play an important role through the year 2000. These firms will probably be responsible for manufacturing products for use by nearly one-half of the population of the developing world, Local production in the LDCS with the largest populations (such as India, China, and Indonesia) may meet the needs of the other half.
- 7. For economic reasons, if family planning programs are to have adequate supplies of commodities, the large bilateral and multilateral donors (the U.S. Agency for International Development (AID) and the United Nations Fund for Population Activities (UNFPA)) will need to remain active in commodity procurement through 2000. However, they will be likely to diversify the commodities they provide in response to re~llests from LDCS for products
- Products utilizing special packaging or presentations to meet local needs.

- more suited to their individual social and cultural needs.
- 8. The two major international aid agencies have taken similar policy stances on procurement of commodities and local production although UNFPA has given slightly greater emphasis to the latter. UNFPA has been directed by its Governing Council to provide logistic support, including contraceptive commodities, if required and to encourage, where appropriate, the local production of contraceptives. AID's program is under continual review but currently gives preference to the supply of commodities. AID takes the view that the development of local production facilities must be considered in the context of the total aid commitment to the particular country and to the needs of the country. If the total aid package and the need for local production are compatible, AID will support local production.
- It seems unlikely that many LDCs will Procure products produced by government-ov&ed or private locally-owned factories in other LDCs.

Manufacturing constraints to the development and supply of future technologies

Because few radically new* * fertility planning technologies are expected to be made available in the next 20 years, most manufacturing and distribution efforts will focus on existing technologies and the modifications of these technologies likely to be introduced within the next decade (see ch. 5).

Radically new technologies are likely to reach only the stage of prototype manufacture and large-scale field testing by 2000. If the major clinical and laboratory studies of these contraceptive technologies now under way demonstrate their safety, efficacy, and acceptability, they would be ready for introduction to national family planning programs. Preparations for the introduction of subdermal silastic implants are already being launched by the Population Council and the Rockefeller Foundation in several LDCS.

But before any of these methods can be introduced on a large scale, mass production facilities to provide adequate supplies must be established. Because each of these technologies, as a technology per se, is rela-

[&]quot;• "Radically new" is used here to designate those contraceptives under development or that will be discovered that would represent a fundamem tally different biological means of contraception than those technologies currently available. For instance, a hormonal injectable contraceptive for men would be radically new, whereas a new hormonal injectable for women would not.

tively novel, the startup time for its large-scale manufacture would be considerably longer than that required for a new pill, for example.

Thus, the early large-scale manufacture of these contraceptives is likely to be carried out by large multinational pharmaceutical firms in MDCs, which have the expertise, facilities, and resources to launch the production of a new product in a comparatively short period.

Public sector family planning programs already rely heavily on large contraceptive manufacturers in MDCs, and the advent of improved methods appears likely to continue this dependence. This analysis examines some of the consequences of this dependence, but an in-depth evaluation of its costs and benefits would clearly be useful.

Richard Buckles (2) contends that the public sector has paid insufficient attention to the production component of making new contraceptive technologies available. He believes that research and development organizations should work out full-scale plans for how, where, at what cost, and with what personnel new technologies are to be produced. Public sector development assistance agencies are generally not prepared to undertake such production, he points out, and are doing little to become more effective partners with industry in making new methods available to national programs.

Distribution system constraints to the availability of new technologies

The introduction of a new technology can have great impact on a government family planning program. Although it is possible for a national program to introduce and distribute new technologies in a fairly short period, experience indicates that to do so is likely to lead to severe damage to the program, and there is growing recognition of the need for careful planning prior to the introduction of a new technology.

The sheer inertia of large bureaucracies can lengthen the interval needed for introduction of a new technology. For example, even though the Copper T IUD was developed in the mid-1970's, very few family planning programs have yet introduced it for widespread use.

The introduction of a new "improved" technology, such as an oral contraceptive or IUD, into a national program can take from 2 to 5 years. In most cases, the introduction process can be expected to take even longer.

The systematic introduction of a new technology involves a number of major steps:

- 1. Obtaining the approval of the body responsible for distribution, such as the ministry of health.
- 2. Obtaining the approval of the local drug regulatory agency.
- 3. Identifying a donor agency willing to provide continuous supplies, or establishing local manufacturing capabilities.
- 4. Conducting and analyzing studies on product acceptability among the target populations.
- 5. Determining the qualifications of personnel approved to distribute the product and implementing training programs,
- 6. Developing training materials for service providers
- 7. Designing and implementing motivational and promotional campaigns.
- 8. Establishing physical distribution, storage, and warehousing procedures.
- 9. Designing and implementing monitoring programs to evaluate product performance.

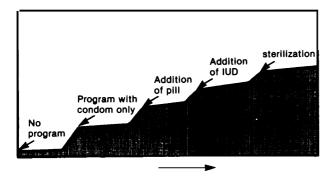
In order to carry out these steps, numerous institutional, financial, and individual resources need to be marshaled. They include those of the relevant offices in the ministry of health, the local drug regulatory body, donor agencies, university or private research groups skilled in market research, the medical community, university or private groups skilled in the development of information, education, and communication materials, and university or private research groups skilled in program evaluation. Completion of these steps is obviously time consuming and can inhibit the introduction of new technologies.

Program managers in LDCs are likely to want substantial justification for the addition of a new technology or the replacement of an old technology. The likelihood that an IUD will reduce bleeding among users may be insufficient reason for its introduction if it offers no other advantages or has concomitant disadvantages such as short lifetime or high price. Although a new sterilization procedure may be faster and easier to perform, it may not be introduced if it requires retraining of the entire medical staff providing the program's sterilization services.

An oft-stated reason for introducing a new technology is that it will provide an alternative for users of currently available methods. This argument is based on the net increase in contraceptive use commonly observed when a program introduces a new method, The incremental increases in contraceptive use experienced by a typical family planning program can be seen in figure D-1.

Program managers realize that the introduction of a new or modified method with clinical advantages over currently used methods can result in increased contraceptive use, but express concern about wheth-

Figure D-1 .—Prevalence of Contraceptive Use



SOURCE: G. Perkin and L. Saunders, "Extending Contraceptive Use," PIACT

er the new method can attract sufficient additional users to justify the costs, in both financial and institutional terms, of adding the product to the distribution program.

An example is the use of the injectable contraceptive Depo-Provera in Thailand, the country most often associated with program use of this method. The government has not moved aggressively to expand distribution of Depo-Provera, which has never been used by more than a few percent of all users, for several reasons, including the international controversy that surrounds this product because of the Food and Drug Adminstration's (FDA) lack of approval for its use as a contraceptive by women in the United States. A major factor is the relatively more complicated and expensive logistical cost of Depo-Provera distribution compared with that of pills and condoms. Depo-Provera is roughly equal in purchase price to the pill in terms of duration of protection but requires either that mobile teams of doctors, nurses, or midwives visit users on a regular basis, or that the user herself return to the distribution center for a new injection. Oral contraceptives have their own logistical problems, but the additional problems of Depo-Provera have inhibited its broader distribution in a country where its safety and acceptability are widely recognized.

The development of new or improved fertility planning technologies is clearly a matter of high priority. It should be recognized, however, that the development of a method that has statistically better efficacy rates than presently used products will not naturally lead to the introduction of that product to family planning programs. The new or modified product could well remain a little-used product. Thus, in setting priorities for fertility planning technology research, giving priority to those that promise to reach significant new groups of potential users-

—such as men—is extremely cost effective as such products are likely to have the greatest comparative appeal to program managers.

To produce locally or not to produce locally

There is a definite trend toward the establishment of government-sponsored fertility planning technology production facilities in LDCS. Among the countries that have developed major capacities to meet their own needs in the past 10 years are Indonesia (pills), India (condoms, IUDS, and pills), Egypt (pills and IUDs), and the People's Republic of China (condoms, pills, IUDS, injectable, barrier methods, and abortion and sterilization methods).

When an LDC government takes an active role in facilitating the establishment of local production of fertility planning technologies, policymakers at the highest levels, often the president or prime minister, are apt to be involved in the decision. In several Asian countries, the push for local production has come not from the relevant program bureaucracies, but from top government officials. The Office of the President in Indonesia and the Office of the Minister of Economic Planning in the Philippines were highly influential in the decision to consider establishing local production of contraceptive technologies in those countries.

Unlike many other new developments in family planning programs, this trend toward establishing local production has been instigated by decision-makers within the country, often in the face of lack of support or opposition from donor agencies. The reasons for this trend toward local production are as yet unclear, but several observations can be made.

First, the decade of the seventies saw the formalization and implementation of government commitments to family planning, and most governments are now committed to either directly providing or permitting others to provide contraceptive technologies to their people. As these programs grew, it became apparent that the potential market for contraceptive products is very large compared to the markets for almost all other health products for whose distribution the government takes primary responsibility. Contraceptives are provided to healthy couples during a potential three decades of their lives. In most LDCs healthy, fecund couples constitute some 15 percent of the total population. In a moderate-sized LDC of 50 million, the number of eligible couples would thus be about 7.5 million. If family planning programs were to reach their goal of up to 70 percent use of contraceptive products, the likely totals

of product units are impressive. If in this hypothetical population of 7.5 million eligible couples an average of 5 million were to be continuing users, and of these users, 25 percent each were to use the pill and IUD, 15 percent to use the condom, 30 percent to be sterilized, and 5 percent to use other methods (with moderate continuation rates), the demand for contraceptive products would be as follows:

	Users	Product use	Total
Method	(million)	per user/yr	product use/yr
Pill	1.25	13 cycles	16.25 million
Condom	0.75	100 condoms	521,000 gross
IUD	1.25	0.5	625,000 IUDs

At current world market prices for these products the approximate value of this use would be:

	Unit price		Total value of product used (millions)	
Method	Public sector	Private sector	Public sector	Private sector
Pill	\$4/gross ^a	\$14/gross ^b	\$3.09 2.08 0.32	\$56.88 72.94 4.38
Total			\$5.49	\$134.20

These amounts are impressive when compared with the total health procurement budgets (exclusive of fertility planning technologies) of most LDCs. For example, the health procurement budget for the Philippines for 1980 was set at \$20.5 million. Its population of approximately 45 million implies (by the above calculations) contraceptive technology procurement of approximately \$4.9 million at public sector prices. (At current levels of use the actual supply plans of AID to the Philippines average \$4.5 million per year for the next 4 years.)

On a worldwide basis, these costs constitute an important limitation to the introduction of new technologies. As S. Bruce Schearer of the Population Council

Cost will be a significant obstacle to uptake and use of the new technologies . . . Will foreign assistance agencies be able to keep footing the bill for establishing new manufacturing (capacities) and paying for an increasing variety of technologies, some of which will probably be more expensive, for an ever-increasing number of acceptors for the next 20 years? Hundreds of millions of dollars are likely to be required for all these commodities, one way or the other. Where will this come from . . .?

These calculations, when carried out by decisionmakers in LDCs, are likely to lead them to several conclusions: maximum control over the allocation of resources of these magnitudes is desirable, as is the avoidance, wherever possible, of paying commercial prices for products. Even though public sector prices can be obtained by relying on commodities assistance from international agencies, LDC decisionmakers would not like to find themselves in a permanent position of having a program of major importance to their country's well-being totally dependent on foreign donors for supplies of the commodities necessary for continued program operation.

Donor agencies have carried out similar calculations. Recognizing the valuable role they play by procuring contraceptives at low public sector prices to LDCS, AID, the International Planned Parenthood Federation (IPPF), UNFPA (via UNICEF), and other donors make commodity procurement and supply important components of their assistance programs. In order to obtain the lowest possible prices, some donor agencies procure uniformly packaged products with little product variation (dosage, design, etc.). Another factor favoring low prices is that manufacturers need incur no marketing costs, or costs of negotiations with regulatory agencies in the recipient countries, which are handled by the donor.

Private manufacturers have also examined these market trends and have concluded that confessional supply of contraceptives to public agencies is an economically attractive alternative to direct privatesector marketing for the huge low-income, littledeveloped markets of potential users in LDCS. They have determined that if they subtract all costs related to product merchandising and concentrate solely on manufacturing costs, they can sell products to public programs at low prices and still make a reasonable profit. They have thus been willing to become full participants in the current three-party arrangement for supply of contraceptives to public programs that prevails in most LDCS.

This three-way partnership is not, however, fully stable because of the differing views and needs of different participants. For example, the two public sector donor agencies most involved in commodities procurement, UNFPA and AID, have somewhat dissimilar views on meeting the need for public sector support of commodities. Aid, through Joseph J. Speidel (4), Acting Director, Office of Population, has stated:

... Since AID's ability to provide support for contraceptive commodities is dependent on annual appropriations for this purpose, a long-range policy must be subject to continuous review. However, AID does not at this time intend to alter previous policy regarding contraceptive supply and our planning includes provisions for the continuation of these efforts.

At present, AID provides grant-funded orals and condoms to all bilateral and grant programs except 1ndo-

^aCurrent AID price including freight. ^bThese are approximate averages of private sector wholesale prices. Substantial varia

nesia, the Philippines, and Thailand. The Office of Population has discouraged use of loan funds for family planning commodity programs, but there is no firm AID policy on this issue. Because a part of population funds must now be used for loans, there is a tendency for some AID missions to urge a switch to loan funding for contraceptive purchases. However, most countries resist this change and it is anticipated that the current practice of grant funding will be continued in most countries.

The following amounts were spent by the Office of Population for contraceptive commodities during the years 1975-81 (4).

Year	Amount (rounded) in millions of dollars
1975	\$24
1976	36
1977	27
1978 :	23
1979	43
1980	34
1981	39

These amounts average approximately 20 percent of the total budget of the Office of Population.

AID appears, in the absence of new policy determinations to the contrary or a lack of funds, to intend to continue the provision of commodities to family planning programs into the foreseeable future. However, along with other donors, it will continue to review its policy in order to ensure adequate supplies of contraceptive commodities to LDC programs.

The UNFPA governing council at its meeting on June 23, 1981 (6) confirmed that support of family planning will be its first priority. Family planning efforts oriented towards the individual and the family will include programs integrated with maternal and child health services in the primary health care context and in other programs as appropriate to social and cultural conditions as well as:

- delivery of services at the community level, including improvements in the logistical systems through which such services can be provided;
- training of personnel;
- strengthening of management;
- logistics support including provision of contraceptives, if required;
- encouragement, where appropriate, of local production of contraceptives; and
- research into traditional and new contraceptive methods and development of improved means including natural family planning methods.

UNFPA will thus support both commodity procurement and local production of contraceptives where appropriate. In commenting on local production, Speidel noted that:

While AID has no "policy" so far as local production is concerned, such efforts must be undertaken with caution since the Agency's experience with such ventures is not encouraging. The rate of population growth is important to development. As an agency, it is our policy to assist in the reduction of the rate of population growth by providing cooperating governments with contraceptive supplies. Local production of contraceptive commodities puts one into another area of economic development, and that is the development of local industry, the provision of jobs, and the transfer of technology. These elements of economic development should be reviewed in the context of other possibilities for the expansion of industry, as well as in the context of family planning programs.

In order to make high quality contraceptive products available in developing countries at little or no cost to the user, AID's purchases of large quantities of these products have made a significant contribution. In the case of some products, however, most notably oral contraceptives, the price obtained by the AID program makes the economics of local production of this product questionable at best without consideration of other factors. The price paid by AID has increased approximately \$0.04 per cycle since 1974 and is currently less than \$0.18. When one considers the retail price in the United States has risen from around \$3 to \$8 per cycle during this same period of time these savings to program costs are even more striking. The lack of profitability this price differential provides for local production will tend to discourage these developments at this time. In addition, local production of oral contraceptives is only possible for packaging and tableting. Synthesis of raw materials is not practical. Dependence on local production is likely to create problems relating to locked-in technology, protectionist import policies, low quality, and uncertainty of supplies.

In this context, it should be noted that AID has assisted the Government of Indonesia in establishing local production of oral contraceptives by supplying raw materials and providing technical assistance. However, Indonesia represents a very large market and was the first country to accept, in principle, commodities on a loan basis.

Very little rigorous research has been conducted to assess the economic feasibility of local contraceptive technology production in LDCS. Although it is widely believed that it costs substantially more to produce contraceptive products in LDCS than in such MDC factories as those of Akwell and Syntex, two major AID suppliers, a recent Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) study tends to cast doubt on this assumption (6). Car-

ried out at the request of the Government of the Philippines, the study extensively detailed the economic feasibility of condom production in the Philippines. It gathered information from equipment suppliers in Japan, the United Kingdom, and the Netherlands, and calculated the costs of latex, packaging materials, chemicals, miscellaneous supplies, electricity, space, labor, taxes, import duties, etc. The study made a thorough analysis of the potential demand in appropriate relationship to both the government family planning program and the private sector market.

A summary of the study provides a useful comparison of the cost to the U.S. Treasury of placing one condom in the hands of a Filipino man through 1) a grant by AID; and 2) through AID supporting all the costs of building and running a condom factory in the Philippines. Using 1980 costs, these two figures are \$0.039 and \$0.036, respectively, or a savings of \$0.003 per condom following the local production route using accepted practices of amortization of capital costs. The local production cost includes the value of the customs duties and/or taxes that the Philippine Government would normally levy on machinery and materials for condom production. If the Philippine Government were to waive these duties and taxes, the net cost per condom would be reduced to \$0.027 or a reduction of 33 percent over grantprovided commodities.

PIACT has also carried out a preliminary assessment of the feasibility of local production of oral contraceptives in the Philippines, which is to be followed by an in-depth evaluation comparable to that carried out for condoms. The preliminary study provides approximate figures from which conclusions can be drawn about the feasibility of local production. Using the comparison analogy of the previous paragraph, the AID procurement route would cost \$0.188 per cycle of oral contraceptives including freight and insurance in 1981, and the local production route would cost approximately \$0.20.

The economic feasibility of local production of oral contraceptives has been recognized by many of the larger LDCS and by multinational pharmaceutical firms. As is detailed later, most larger LDCS have local production of oral contraceptives either in government plants or factories of multinational pharmaceutical firms.

The PIACT calculations for condom and oral contraceptive production were designed to be readily adapted to the situation in other LDCS; it would appear that in countries similar in population size to the Philippines the costs would be comparable.

The question of UNFPA and AID support for the establishment of local production is really one of alloca-

tion of scarce resources for population assistance to LDCS. In order for family planning programs to operate, they must have access to contraceptive technologies that couples can use. These technologies can be provided by donors in two ways: through donations or through support of local production. It seems logical that if outlays of financial resources for these two options are comparable, local production deserves serious consideration and, in some situations, implementation, particularly in consideration of the adage that it is better to teach a man to fish now than to give him free fish forever.

Although the major donors may intend to continue indefinitely to provide commodities where needed, LDCS cannot consider these intentions a guarantee. In some LDCS, local production may fill the need for the reliable, continuing sources of commodities necessary for a successful national program.

Local production may never be economically feasible in some LDCS. These countries, especially the smaller ones, will either have to rely on external assistance or will have to identify other means to procure the commodities they need.

At the present time, virtually all contraceptives used in national family planning programs, with a few exceptions (China, India, Egypt), are manufactured by MDC-based multinational drug firms in factories located in both MDCS and LDCS. Virtually all of these contraceptive products are supplied by AID, UNFPA, or, on a smaller scale, the Swedish International Development Authority (SIDA) and IPPF at the request of LDC governments. The major manufacturers providing these products at confessional prices to these agencies are:

These eight manufacturers account for almost all of the products used by public programs in countries that do not now manufacture their own supplies. Thus both donors and these major manufacturers have important stakes in the evolution of contraceptive production in LDCS.

The manufacturers are concerned about local production because several of them have developed local private-sector markets in LDCS. Prominent among these are Schering, Organon, and Dong Kuk, Moreover, Syntex and Schering provide raw materials to plants in Indonesia and Egypt, respectively, as two examples, for the production of oral contraceptives. Local production in LDCS would cut into the quantities that donors procure for those same countries, but local production might also stimulate the private sector by enhancing government efforts to

encourage the adoption of family planning. On the other hand, production by local governments might cut into private-sector production because the government-produced contraceptives would be cheaper than those produced for the private sector.

Finally, not all manufacturers supplying LDCS also have developed private-sector markets in those same countries, and vice versa. For example, Wyeth does not supply the public sector but sells to the private sector in several LDCS; Syntex sells to the public sector but has almost no private-sector sales in LDCS.

In summary, the influence of the private-sector market in decisionmaking with regard to public-sector production and distribution of fertility planning technologies is difficult to evaluate and varies from country to country. The factor that will most heavily affect the private sector is the strength and nature of the government family program.

The role of the private-sector market in LDCS

Public information about the size and rates of growth of private-sector markets for contraceptives in LDCS is sparse. Studies several years ago showed that most contraceptive use in LDCS was the result of purchase through the private sector (l). Although the relative proportion of contraceptive users supplied through the private sector may have decreased as the reach of family planning programs has extended, their absolute number has probably grown. Many would argue that the growth of family planning programs has been a major contributor to the growth of private-sector sales in LDCS by introducing added numbers of individuals to the use and practice of contraception. As contraception becomes a normal part of their lives, some will move from free or subsidized supplies from government outlets to purchased supplies from the private sector. Others would argue, and quite convincingly, that when family planning programs become significant in coverage, they can cut deeply into the expansion of private-sector markets.

The international manufacturers that have been supplying fertility planning technologies to LDCS thus find themselves facing a complex series of calculations.

The role of locally owned private sector manufacturers in LDCS

Although the production of fertility planning technologies is largely the province of governments and international manufacturers, privately owned factories in LDCS, whose owners are businessmen in these countries, also play a significant role. In Thailand, a locally owned rubber products company manufactures condoms, in the Philippines a locally owned pharmaceutical corporation has been tableting and packaging pills for the local market for several years, a locally owned company in Mexico manufactures IUDS, and a Korean company also manufactures condoms. These companies have, almost without exception, been established to sell products to the private sector, but sometimes supply products to the public sector in their own countries.

It would appear that more serious consideration needs to be given to the role of these companies. In many countries these local resources have not been used because Congress requires AID to purchase U.S.-made products with its funds for commodities. Thus U.S.-made oral contraceptives are imported for use in the Philippines even though a private, locally owned firm manufactures tablets of similar composition.

Current status of local production and implications for donors

The following table lists the 20 most populous LDCS and indicates which of these countries had production capacities (G = government controlled, P = private ownership, (L) = local, (M) = multinational) for oral contraceptives, IUDS, or condoms as of 1980, and which are examining plans (pi) for establishing production of these technologies.

	Method		
Country	Ocs	IUDS	Condoms
China	\boldsymbol{G}	\boldsymbol{G}	\boldsymbol{G}
India	<i>G</i> , P (M)	G	G, P(M)
Indonesia	G, P(M)	pl	p]
Brazil	P(M)	_	_
Bangladesh	P(M)	_	_
Pakistan	P(M)	G	pl
Nigeria	_	_	<u>-</u>
Mexico	P(M)	P(L)	P(L)
Vietnam	<u> </u>		pl
Philippines	P(L)	_	pl
Thailand	P(M)	_	_
Turkey	P(M)	_	_
Egypt	Ġ	G	_
Iran	P(M)	_	_
Republic of Korea.	P(M)	_	P(L)
Ethiopia		_	
Burma	_	_	_
Zaire	_	_	_
Argentina	P(M)	_	_
Colombia	P(M)	_	_

The local companies are owned by business people in the LDC; some minor amounts of foreign capital may be involved. The multinational companies either export their products to LDC factories for local packaging, or carry out partial or complete manufacture in LDCs using, in both instances, subsidiary or joint venture companies.

The table demonstrates that multinational private pharmaceutical firms have found it economically feasible to establish oral contraceptive tableting and packaging facilities in these countries. (In many of these LDCs the companies have established local production because of national restrictions on the import of finished pharmaceutical products. These firms nevertheless concluded that they could produce locally and profitably-that in fact the local production of oral contraceptives in an LDC can be economically justified.) In four countries-China, India, Indonesia, and Egypt-the government has established an oral contraceptive facility of its own. If international donors were to terminate the supply of oral contraceptives to the largest LDCs, these countries would be able to turn to local production facilities to meet their needs, but product selection would

The situation is somewhat different for IUDs and condoms. Here, the governments or local industries have been more active than multinational firms in establishing production, but only in a few countries. By and large, the world's largest LDCs depend on foreign supply of condoms and IUDs. Plans to establish IUD production in Indonesia are well under way and locally made IUDs should be ready for use in the national program by mid-1981. Several countries—lndonesia, Pakistan, Philippines, and Vietnam—are exploring the possibility of condom production. It is not yet clear whether these countries will actually establish a facility in the immediate future, but strong government interest will most likely result in the establishment of production facilities within the next two decades. Because reliance on outside donors is greater for these products than for oral contraceptives, if international donors were to cease supplying condoms and IUDS to the largest LDCs, these countries would not be able to meet their requirements from facilities within their borders. The situation is better for condoms than for IUDs.

Very few of the less populous LDCs have production facilities for contraceptive technologies. None appear to have facilities for IUDa or condoms, although condoms are made in a Japanese-owned factory in Malaysia. Several multinational pharmaceutical firms have set up production facilities for oral contraceptives in smaller LDCs, but these facilities are primarily to supply regional markets and provide only small quantities to the local private sector.

In summary, the situation is approximately as follows:

- Oral Contraceptives: The largest LDCs could rely on domestic sources of supply. The smaller countries have to rely on sources of supply from outside their borders.
- IUDs: A few larger LDCs could rely on domestic sources of supply. The smaller countries have to rely on external sources.
- Condoms: Several larger LDCs if current plans come to fruition, will have domestic production facilities. Almost all other larger, and all small LDCs have to rely on external sources.

Almost all LDCs will be dependent upon external sources of supply for the technologies used in their national family planning programs during the next 20 years. How they meet these needs will be determined by an interactive process of review and discussion among the countries, manufacturers, and donors.

Should donors decide not to provide commodities support to countries in need, the decision on how to procure those commodities would clearly rest with the governments of the LDCs themselves, who would be free to procure either from multinational manufacturers primarily located in MDCa, or from manufacturing facilities located in other LDCs. If donors continue commodities assistance to LDCs, decisions on how and what to procure will have to be reached jointly between country and donor.

Most bilateral donors will require that commodity assistance be in the form of products manufactured within their own countries, as is the case with most current commodities assistance, which is provided directly in the form of finished products rather than as financial resources that can be used to purchase such products. Only multilateral and nongovernmental donors will be free to procure from any available MDC or LDC manufacturer.

From the LDC point of view there is something to be said for obtaining commodities support from multilateral or nongovernmental organizations, as this process allows a much wider selection of products to be obtained. But because bilateral donors—the funders of multilateral and (either directly or indirectly through multilateral donors) nongovernmental organizations—most often work under strong political pressure to procure from companies in their own countries, it is to be expected that most bilateral donors will remain directly involved in commodities procurement.

There are fewer pressures operating on multilateral donors to remain involved in procurement. One that does exist is from those bilateral donors funding

the multilateral organizations who want to spread the financial burden of procurement and to have commodities appear as a small proportion of the bilateral's overail budget. Some bilateral donors, however, do not have contraceptive manufacturers in their own countries and are therefore more willing to have the multilateral assume the substantial logistical tasks of commodities supply to many LDCS.

The continued involvement of large bilateral and multilateral donors in commodities procurement is supported, however, by the economies to be realized by large-scale procurement of identical products, not only in purchase price, but also in distribution and storage systems. Yet it seems likely that more and more LDCS, even some of the smaller ones, will be willing to forego marginal economies of these kinds in order to have contraceptive technologies more appropriate to the particular needs of the country. The marginal economies referred to here are those gained by obtaining uniform bulk quantities of commodities rather than nonuniform commodities, an element that permits the confessional prices offered to public agencies by companies.

Commodity trade between LDCS

If LDCS exercise control over the procurement of commodities, one of the options available to them is to procure from manufacturers located in other LDCS; this option is receiving increasing attention. A recent review of population-planning activities carried out by the Association of South East Asian Nations (ASEAN) concluded that a high-priority future activity was the coordination of contraceptive production among ASEAN countries. In Mexico, an IUD manufacturer has recently granted the public-sector rights for sale of his product to other LDCS to the private, nonprofit PIACT de Mexico.

It appears that no LDC has directly purchased contraceptives manufactured in another LDC. UNFPA has procured condoms manufactured in Korea and shipped these to other LDCS, and there are probably other instances of multilateral or bilateral aid agencies procuring contraceptives manufactured in one LDC and shipping them to another. But LDCS do not generally procure fertility planning technologies manufactured in other LDCS. One reason for this is that program managers believe it is in the interest of the program to provide a product to users that is considered to be of international first quality. LDC consumers, as do MDC consumers, tend to believerightly or wrongly—that products manufactured in LDCS are unlikely to be of the same quality as products manufactured in MDCS.

A distinction needs to be made here. In several LDCs₃MDC-based, multinational contraceptive manufacturers have established production facilities. If LDCS do begin to procure their own commodities, it is likely that they will purchase from these multinational companies, who in turn will manufacture the product in one of their LDC factories. In such situations it is conceivable that the product label will not show the country of manufacture or will show only the country in which the manufacturer is headquartered.

There is little indication at present that LDCS are prepared to purchase contraceptives from production facilities located in and controlled by either the government or local private businessmen in other LDCs, but a thorough survey of this matter is needed.

Additional conclusions

Multinational contraceptive manufacturers in MDCS will continue to be, to 2000, the predominant suppliers to most LDCS. They will not, however, supply most of the LDC population because the world's two most populous countries—China and India—will meet virtually all of their needs through local manufacture in government-controlled factories. But multinationals will have access to huge markets totaling several billion individuals and more than 100 million users of contraceptive methods. For the most part, these companies will supply their products to the public-sector portions of their markets (nonprofit family planning programs) under special low-cost confessional terms negotiated with public agencies and local governments. Supplies are likely to be made available to the private-sector portions of these markets under normal commercial terms at prices similar to those prevailing in MDCS.

A problem may arise in the interaction between the development of new contraceptive technologies and their production in LDCS. It is possible that LDCS that directly negotiate confessional purchases from the multinational manufacturers will have more ready access to new technologies than those LDCS relying on manufacture in government-controlled plants or in local factories controlled by local private individuals, or by multinational manufacturers. The specialized manufacturing know-how needed to produce the technologies likely to be developed and the complexities of patent regulations are likely to make access to these new technologies virtually impossible for LDCS that rely on local manufacturing operations. LDCS that establish domestic production capacity may thus be substantially limiting access to both

new technologies and to future modifications of the technologies currently in production.

LDCS that procure from the international market will need to have capacities that permit them to effectively exercise their relative flexibility. They will need systems to help them identify new technologies, to decide whether a new technology will be useful to them, and to determine what options they have in its design, packaging, labeling, etc. These LDCS will also need the capacity to secure and trans-

for production know-how. Thus, LDCS that import a substantial portion of their commodities will not be able to fully rely upon the procurement mechanisms and logistics and supply systems set up by commercial manufacturers or donor agencies in obtaining the best products for their needs in a timely fashion. They will need to set up experienced, capable staff units within their national family planning programs to carry out these functions.

Appendix D references

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