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Private Sector Local Production of Contraceptives: Current Options for A.I.D.

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Executive Summary

As the global demand for contraceptives is growing rapidly, A.I.D. is interested in finding alternatives to donating contraceptives to developing country family planning programs. This study was requested to update A.I.D. on the alternative of providing assistance for the production of contraceptives by the private sector in developing nations. PATH (Program for Appropriate Technology in Health) was asked to prepare this paper because of its experience with local manufacturing projects for contraceptives and other health related products in developing countries.

Objectives of the Study

This study has four main objectives: (1) to provide A.I.D. with alternative strategies for meeting contraceptive demands in developing countries in the 1990s; (2) to suggest possible A.I.D. activities to facilitate local private sector contraceptive production; (3) to provide A.I.D. with an update on selected examples of experience since 1980 with the private sector production of contraceptives in Bangladesh, Egypt, India, and Mexico; and (4) to outline how developing countries can access technical assistance for private sector production from private and U.S. government agencies.

Key Findings from Country Case Studies

- Relative to estimated A.I.D. procurement costs during the period 1985 through 1991, the estimated capital investments required for local production are modest. In Bangladesh A.I.D. will have spent more than US$51 million on 1.2 billion condoms during this period. The total foreign exchange investment for establishing a condom manufacturing facility is significantly less, around US$5-8 million.

- There are major projects currently under way in Bangladesh, Egypt, and India to initiate large-scale local production of contraceptives by both private sector and government-owned manufacturing firms.

- In all of the countries reviewed, a significant portion of capital investment and annual operating costs for the local production of contraceptives can be paid in local currency.

Conclusions

- Currently, other than Bangladesh and Egypt, opportunities for A.I.D. to assist in establishing entirely new full-scale private sector contraceptive production ventures in developing nations are limited.

- Compared with setting up new full-scale facilities, there is much wider scope for A.I.D. to provide assistance for intermediate production or to upgrade and expand existing facilities of private sector and, in selected cases, parastatal producers of contraceptives.

- Technical services provided by private and U.S. government agencies can assist developing country private sector firms with the local production of contraceptives.

- Substantial opportunities exist for A.I.D. to facilitate private sector local production in a manner consistent with a "Buy American" policy.

Recommendations

PATH recommends that A.I.D.:

1. **Provide assistance to initiate, upgrade, and/or expand local contraceptive production facilities in selected developing countries.**

   - *Facilitate the transition from imported donor-supplied contraceptives to locally-produced contraceptives.*
     A.I.D. assistance to developing countries could include: developing a long-term national contraceptive supply strategy; conducting feasibility studies; donating "know-how," equipment and/or technical training; conducting factory audits; arranging creative financing support; donating raw materials; purchasing locally made goods; and facilitating duty-free arrangements for imported equipment, raw materials, and spare parts. Possible candidates for these types of assistance include: Bangladesh (condoms and OCs), Brazil (condoms and IUDs), Egypt (IUDs and OCs), India (IUDs), Mexico (OCs), and Pakistan (condoms and IUDs).

   - *Facilitate intermediate production (packaging and screening).*
     In cases where the economic feasibility of full-scale production is marginal, A.I.D. might assist the final processing and packaging of imported components or bulk goods. Prospective countries for local electronic screening and packaging of condoms include Egypt, Nigeria, Pakistan, and Turkey.

   - *Ensure long-term involvement by technology suppliers.*
     A.I.D. should support projects involving suppliers experienced with the transfer of technology to developing countries and provide some form of extended supervision.

   - *Include parastatals or public/private partnerships.*
     Where private sector opportunities are not available, A.I.D. should assist parastatals, especially if they are operating competitively in the market economy.

2. **Provide assistance to upgrade national contraceptive quality oversight capabilities.**

   A.I.D. should marshall the resources of private sector as well as other U.S. government agencies and act as a "general contractor" for transfer of equipment, know-how, and training for regulatory review agencies, systems, and test laboratories.

3. **Establish a clearinghouse for requests.**

   A.I.D. should set up a clearinghouse to track and facilitate developing country requests for A.I.D. assistance in local manufacture of contraceptives.

4. **Coordinate with other agencies.**

   A.I.D. should coordinate with other agencies to help ensure the best use of available global resources for assisting local contraceptive production.

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List of Abbreviations

AIDAB	Australian International Development Assistance Bureau
A.I.D.	United States Agency for International Development (Washington, D.C.)
CID	Chemical Industries Development Company
CIDA	Canadian International Development Agency
CDRH	Center for Devices and Radiologic Health
CPS	Contraceptive Prevalence Survey
CPSD	Commodities and Program Support Division, Office of Population, A.I.D.
CYP	Couple Years of Protection
DHHS	Department of Health and Human Services
EDHS	Egypt Demographic and Health Survey
EPA	Environmental Protection Agency
EPTC	Egyptian Pharmaceutical Trading Company
FDA	Food and Drug Administration
FINIDA	Finish International Development Agency
FP	Family Planning
FPHSP	Family Planning Health Services Project, USAID, Bangladesh
FPLM	Family Planning Logistics Management Project
GMP	Good Manufacturing Practices
GTZ	German Technical Assistance Agency
IIT	Indian Institute of Technology
IPDC	Industrial Promotion and Development Company of Bangladesh
IPPF	International Planned Parenthood Federation
ISTI	International Science and Technology Institute, Inc.
IUD	Intrauterine Device
JSI	John Snow, Incorporated
LRCI	London Rubber Company (India)
MOH	Ministry of Health
MOHFP	Ministry of Health and Family Planning
MWRA	Married Women of Reproductive Age
NIOSH	National Institute for Occupational Safety and Health
NODCAR	National Organization for Drug Control and Research
OC	Oral Contraceptive
OIH	Office of International Health
ORS	Oral Rehydration Salts
OSHA	Occupational Safety and Health Administration
PAHO	Pan American Health Organization
PASA	Participating Agency Services Agreement
PATH	Program for Appropriate Technology in Health
PHS	Public Health Service
PIACT	Program for the Introduction and Adaptation of Contraceptive Technology
RSSA	Resource Support Service Agreement
SMP	Social Marketing Project (Dhaka, Bangladesh)
UNDP	United Nations Development Program
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development (Missions)
VFT	Vaginal Foaming Tablets
WHO	World Health Organization

I. Study Objectives and Rationale

Objectives and Underlying Assumptions of the Study

This study is addressed to a wide spectrum of A.I.D. program managers and does not assume a great deal of experience on the part of the reader in either family planning or private enterprise development. This study assumes that local production of contraceptives in developing countries, whether by private sector or government-owned firms, is only one of many approaches to ensure adequate availability of contraceptives.

The study has four main objectives:

1. to provide A.I.D. with alternative strategies for meeting contraceptive demands in developing countries in the 1990s;
2. to suggest possible A.I.D. activities to facilitate local private sector contraceptive production;
3. to provide A.I.D. with an update on selected examples[1] of experience with the private sector production of contraceptives since 1980. These examples are drawn from some of the countries where PATH has had involvement with local production: India, Bangladesh, Egypt, and Mexico. In addition, a recent example of oral rehydration salts production in the private sector in Ghana is presented in Section IX;
4. to outline how developing countries can access technical assistance for private sector production from private and U.S. government agencies.

Rationale for Local Production and for Focus on Private Sector

Facilitating the production of contraceptives in developing countries is not a new concept. During the last 15 years, USAID Missions have supported a variety of local production initiatives (described in Section III below). The United Nations International Contraceptive Study Project (ICOSP) concluded in 1975 that to meet increases in contraceptive requirements it was "becoming increasingly important to take local production facilities into account." This 1975 study also observed that the private sector had shown considerable leadership in producing contraceptives in developing countries.

While A.I.D.'s population assistance program was established to increase access to voluntary family planning, recent projections indicate that international donors and national governments may be unable to meet the increasing

demands for family planning (Gillespie et al., 1988; Kocher and Buckner, 1989). For example, as pointed out by Gillespie et al. (1988), the combination of an increasing contraceptive prevalence with an increasing population of married women of reproductive age (MWRA) implies dramatically higher requirements for contraceptives in the coming decades (see Figure 1). Excluding the People's Republic of China, it is conservatively estimated that by the year 2000 there will be more than 670 million MWRA in developing nations, of whom more than 340 million will be practicing contraception. This translates into an annual procurement cost of over $450 million from all sources. (With the exception of medical supplies for sterilization procedures, these estimates are based on 1988 A.I.D. unit costs for contraceptives. See Appendix C in Gillespie et al., 1988.)

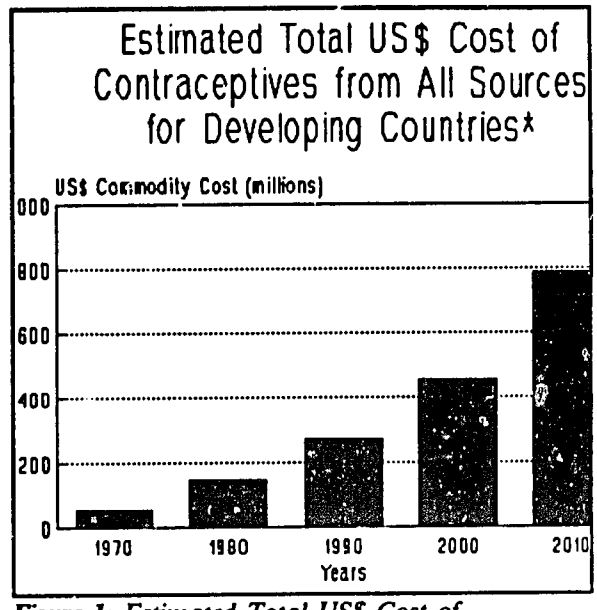

*Figure 1: Estimated Total US$ Cost of Contraceptives from All Sources for Developing Countries, 1970-2010 *(Excluding People's Republic of China). Data from Gillespie et al., 1988.* PATH 1/90

Approximately three quarters of all contraceptives donated to the developing world come from A.I.D.[2] Funds obligated for A.I.D. contraceptive procurement have increased by more than 30 percent between FY 1983 and FY 1989, with over $58 million obligated in FY 1989. Funds obligated for A.I.D. contraceptive shipments accounted for more than 20 percent of A.I.D. population assistance in 1989. This was an all time high for A.I.D. contraceptive commodity expenditures (A.I.D., CPSD, April 1990). While A.I.D. has supported a variety of local production projects over the years, these dramatically higher procurement costs give new urgency to the assessment of local production as an alternative to donating contraceptives to developing nations.

Private sector solutions to development problems have become a priority for A.I.D. in recent years. Modest percentages of development assistance budgets

for family planning, health care, and other social services have been directed to encouraging the private provision of social services in an effort to better sustain U.S. investments in development.[3] Given the reality that a diversity of ownership patterns exists throughout developing countries, however, this study cannot focus exclusively on private sector facilities. To do so would rule out a large portion of feasible options to A.I.D., many of which might eventually evolve into private sector ventures.

II. Basic Components of Private Sector Local Production of Contraceptives

Definitions of Key Elements

Private Sector Local Production of Contraceptives: the manufacture of contraceptives within developing nations by firms that are privately owned. There are a wide variety of ownership patterns in developing nations which blur the distinction between private and government-owned ventures. In many developing nations truly private firms may not be permitted to exist; therefore, parastatal production may be the only feasible option for donor agencies to pursue.

Minimum Volumes of Commodities from Local Production: the minimum annual output generally required to justify production--approximately 15 million cycles of oral contraceptives, 70 million condoms, or one million IUDs (see Table 1). This assumes a manufacturing plant is devoted entirely to one product. Some innovation has occurred in the efficient production of smaller quantities of condoms per year, but this technology is not yet generally available for developing countries. It may be feasible to produce smaller volumes annually through the following two approaches.

Diversity of Production: lower production volumes may be feasible through the manufacture of a variety of goods by one plant. Examples include the manufacture of surgical gloves in a condom factory.

Regional Production: the full-scale manufacture of a contraceptive in one facility for nations in a given region. In practice there are no known examples of this strategy being implemented for contraceptives, although there are examples for other pharmaceutical products. While it should be considered as an option, it appears that it is not likely to arise in the near future. This is chiefly due to difficulties in arranging a regional consortium of buyers who will make long-term commitments to purchase contraceptives from one source.

Required Inputs for Local Production:

Initial Capital Investment: funds required to initiate a full-scale local contraceptive production project. As shown in Table 1, the cost of setting up

Table 1: Basic Components of Typical Full-Scale Local Contraceptive Production Facilities for Selected Methods

	Oral Contraceptive	Condom	IUD
Minimum Annual Production Volume	15 million cycles	70 million condoms	1 million IUDs
Approximate Capital Cost	US$2.5 to 6 million	US$5 to 8 million	US$2 to 3 million
Percent of Capital Cost Requiring Foreign Exchange	60% to 80%	60% to 80%	60% to 80%
Approximate Annual Operating Cost	US$1 to 2 million	US$2 to 3 million	US$0.35 to 0.75 million
Percent of Operating Cost Requiring Foreign Exchange	20% to 40%	20% to 40%	20% to 40%
Level of Technology	Very high	Moderately high	High
Technology Suppliers	Multinationals, consulting engineers	Reputable manufacturers only	Reputable manufacturers, consulting engineers
Imported Inputs	Equipment, steroids, inert ingredients, packaging material	Equipment, raw latex, chemicals, packaging, lubricant (silicone)	Equipment, high purity copper (wire, tubing), specialty plastic, sterilant gas (EtO)
Potential Locally Available Inputs	Structural engineering, labor, packaging	Raw latex, structural engineering, labor, packaging	Structural engineering, labor, packaging
Possible Intermediate Production	Secondary packaging	Electronic screening, primary packaging	Sterilization, assembly, packaging
Unique Occupational Hazards	Exposure to airborne steroid particles	None	Exposure to EtO gas, EtO emissions into environment

production facilities for the manufacture of contraceptives may range from US$2.5-6 million for OCs, US$5-8 million for condoms, and US$2-3 million for sterilized copper T IUDs in individual packages. These are gross estimates which depend on a variety of factors, such as land, building costs, fees for technology transfer, etc. In some cases, depending on the products currently being manufactured, the estimated project costs for expanding an existing production facility within an existing plant tend to be less expensive than building a plant from scratch. This may make expansion a more attractive option than instituting an entirely new facility. Typically, the proportion of the above capital costs that must be covered in hard currency ranges from 60 to 80 percent.

Annual Operating costs: the total manufacturing costs for labor, raw materials, utilities, depreciation, interest payments, etc. Annual operating costs for local production facilities are of course closely tied to the type of contraceptive and volume of production. The range of annual production costs at the minimum volumes indicated above is from a low of some US$350,000 to US$750,000 for 1 million IUDs, to a high of US$3 million for the annual production of over 70 million condoms (see Table 1). Due to the use of local labor, energy, and materials, much lower percentages of annual operating costs have to be paid in hard currency than capital investment costs, from as little as 18 to 20 percent to a more typical 40 percent.

Specific Product Considerations

For the local production of each of the three contraceptives considered in this study, there are unique requirements for technical personnel, technology sources, facility construction, raw materials, and worker protection. These special requirements must be understood to appreciate the constraints for implementing local production.

Oral Contraceptive Production:

Technology Sources: The essential ingredients in OCs, steroids, are manufactured either by large multinational companies or by companies in a handful of the larger, developing countries. Virtually all local production of OCs in non-socialist countries is undertaken by firms that are either subsidiaries of, or otherwise related to, large multinational pharmaceutical companies. There have been successful technology transfers for OC production, however, using consulting engineers who were not affiliated with multinationals.

Level of Technology: Maintaining the exacting standards for content uniformity for low-dosage OCs requires very sophisticated manufacturing equipment as well as advanced pharmaceutical manufacturing expertise to supervise and validate the production of this contraceptive.

Potential Occupational Hazards: The potent steroids used in the manufacture of OCs require expensive dust collection, air handling, and air-fed suits to avoid worker exposure to steroids. Implementing these systems requires rigorous training for both workers and factory management.

Condom Production:

Technology Sources: Because the fine details of condom manufacture are proprietary and linked to equipment modification of individual technology suppliers, it is not feasible to introduce condom production by simply purchasing machinery from various manufacturers. Condom production technology must be obtained as a complete system from a reputable manufacturer willing to supervise production for an extended period of time. Abrupt, turnkey transfer of condom production is not recommended for most developing country situations. (In this paper, "turnkey" is used to refer to the transfer of production capability from one agency to another with no long-term obligations for follow-up to ensure successful technology transfer.)

Level of Technology: A variety of condom technologies have evolved in the United States, England, India, and Japan. These can be accessed through licensing, joint ventures, and subsidiary as well as turnkey arrangements. Certain technology suppliers have extensive experience with setting up and adapting condom technology in tropical and/or developing-country conditions. Of importance is the quality of latex available, either locally or for import. Some manufacturing technologies have stricter latex quality requirements than others. (While condom quality assurance has received attention in the past, current concern regarding AIDS has heightened interest in quality assurance procedures and condom quality assurance management [PATH, 1990].)

Potential Occupational Hazards: Minimal

IUD Production:

Technology Sources: At present, clinically proven IUD designs are available from both public and private institutions through licensing agreements. Some licensing arrangements are designed to ensure a prolonged period of supervised production and confirmation of meeting quality control standards before conferring full license rights. Past experience with IUD production in developing countries provides examples of insufficient institutional oversight for quality control, which, combined with diminished interest in the specific device, ended production efforts.

Level of Technology: As medical devices, U.S.-manufactured IUDs are subject to the Class III[4] medical devices regulations of the U.S. Food and Drug Administration (FDA). IUDs utilizing chemical activity to enhance efficacy, i.e., progesterone or copper, are regulated as drugs under U.S. law. Hence, while the technology involved in manufacturing IUDs is fairly typical of the plastic injection-molding industry (with the exception that small injection-molded parts for IUDs require great precision), product assembly and packaging are done under strict clean room conditions. The entire manufacturing process is subject to stringent good manufacturing practices and must be able to meet local regulatory agency review. Potential manufacturers of IUDs should already have experience with the manufacture of sterile medical devices.

Potential Occupational Hazards: The requirements for sterilizing IUDs often involve the use of ethylene oxide (EtO) gas, the use of which requires safeguards to minimize the potential for worker exposure, as well as high standards for microbiological procedures to validate sterilization.

Phases of Production: Local Packaging to Full Production

For each type of contraceptive being considered for local production there are intermediate stages of production, ranging from final packaging of imported products to complete production, testing, and packaging (see Table 1 and Figure 2). For any given type of contraceptive, various stages of production may be in progress simultaneously within one country. These intermediate stages should not be overlooked and may provide some of A.I.D.'s most feasible alternatives in local production. The advantages of phasing in production include facilitating the gradual scale-up of production to allow more time for training and development of quality control measures, increasing the range of options for local contraceptive production, and providing an opportunity to

Quality Assurance Testing	->	Secondary Packaging of Imports	->	Primary Packaging & Screening	->	Full-scale Production

Figure 2: Spectrum of Local Production from Quality Assurance to Full Production

develop culturally appropriate packaging and patient inserts. The disadvantages of phased production may include higher costs, due to duties on imported finished products, and longer total implementation time and cost to achieve complete local production.

OCs - Since only a few developing countries have the capability to produce their own steroids (such as Brazil, China, India, and Mexico), most facilities import the steroids to manufacture OCs (see discussion of current practice at Organon, Bangladesh, and at CID, Egypt, in Sections VI and VII below). Some firms import OCs sealed in blister packs and package them in boxes suitable for local marketing.

Condoms - Electronic screening[5] and packaging of condoms are relatively labor-intensive activities and may be economically feasible in certain developing countries. Electronic screening and packaging of condoms bought untested in bulk quantities have been shown to be economical at levels of output well below that required for full-scale manufacture (see example of current experience of PROFAM-Mexico, discussed in Section VIII below).

IUDs - The production of IUDs can be introduced into a developing country in a phased process whereby initially the manufactured components are imported, assembled, packaged, and sterilized locally (see current plans for IUD introduction in India, discussed below in Section V).

Framework for Assessing Options for Local Production

In order to make effective decisions concerning the local production of contraceptives, it is important to have an overall framework that guides the collection of data, assists in weighing the alternatives, and helps to avoid problems experienced in previous transfers of contraceptive manufacturing technology. The essentials of such a framework are presented in Appendix A. This appendix illustrates the sequence of decisions that should be followed in virtually any country where the option of local production is being considered.

III. Status of Local Contraceptive Production in Developing Countries

Update on Current Status in Developing Countries

Opportunities for New Full-scale Facilities: In general, most developing countries that have sufficient population size and rates of method-specific contraception use to justify production already have implemented local production of one or more methods (see Table 2). The only developing countries with use prevalence for specific contraceptives sufficient to support full-scale contraceptive production currently without this capability are as follows:

For IUDs: India, Vietnam, and Egypt (all have either concrete plans set in motion or have completed studies indicating feasibility).

For condoms: Bangladesh (plans under discussion).

For OCs: Algeria (plans under discussion).

An examination of condom shipments to Africa in 1988 found that no country on the African continent received more than 40 million condoms from all donor sources. Only one country (Egypt) received more than 30 million condoms, while only one other (Zimbabwe) received more than 10 million (PATH, 1989). Given that all countries on the African continent combined received donations of over 130 million condoms in 1988, an African regional production facility (possibly in Nigeria) could be justified (PATH, 1989). Despite existing regional trade agreements within Africa, cooperation for this type of project may be hard to achieve.

Opportunities to Upgrade and/or Expand Existing Facilities: If there are so few candidate countries for new full-scale local production operations, why is local production an option worth further consideration? While there is a fairly limited scope for introducing new full-scale production facilities, there is a wide range of interventions needed to upgrade and expand existing production facilities. For example, assistance might be provided to Pakistan to upgrade from Lippes Loops to Copper T production; or to Brazil and Mexico to upgrade condom and IUD production; or to Bangladesh, Egypt, and Indonesia to upgrade and/or expand OC production of modern low-dose formulations.

Table 2: Current Status of Contraceptive Production in Selected Countries by Method and Donor Involvement Since 1970

	Contraceptive Method			Donor and/or Executing Agency Involvement (Past and/or Current)		
Country	OC	IUD	Condom	A.I.D.	UNFPA	Other
Algeria	Goverment (under development)				OC production	UNIDO/PATH
Argentina	Private multinational		Private multinational			
Bangladesh	Private multinational		Private (under consideration), Government (under consideration)		OC and condom feasibility	PATH/PIACT
Bolivia	Private multinational					
Brazil	Private multinational	Private local	Private local, Private multinational	Preliminary condom feasibility		The Population Council
Chile	Private multinational					
China	Government	Government	Government		Production: All methods	The Population Council PATH/PIACT
Colombia	Private multinational					
Cuba	Government	Government (under consideration)			OC production, IUD feasibility	PATH/PIACT
Ecuador	Private multinational		Private local, Private multinational			
Egypt	Government	Government (under consideration), Private (under consideration)		Lippes Loop,* OC feasibility	IUD feasibility	The Population Council, GTZ - raw materials PATH/PIACT
India	Government, Private multinational	Government (under development), Private (under development)	Government, Private multinational	Lippes Loop,* OC feasibility	IUD and condom feasibility, IUD and condom production	The Population Council PATH/PIACT
Indonesia	Government, Private multinational	Government	Government	Lippes Loop,* OC production	IUD feasibility, IUD production	Netherlands, The Population Council PATH/PIACT
Mexico	Private multinational, Private local	Private local	Private local (manual dipping), local screening and packaging	Condom packaging		
Nigeria		(Under consideration)	(Under consideration)	Preliminary		
Pakistan	Private multinational	Private local	Government (under consideration)	Lippes Loop*		The Population Council
Thailand	Private multinational		Private (under development)			
Turkey	Private multinational		Private (under consideration)			UNIDO condom feasibility
Venezuela	Private multinational					
Vietnam		Government (under development)	Government		IUD and condom feasibility, Condom production	FINIDA/AIDAB PATH/PIACT
Zimbabwe				Preliminary OC feasibility		

Government = Government controlled.
Private = Private ownership.
Local = Owned by business people from the developing country (some minor amounts of foreign capital may be involved).
Multinational = Generally either export their products to developing countries for local packaging or carry out partial or complete manufacture in developing countries; in both instances, operations are carried out by subsidiaries or in joint ventures.
* Late 1960s, early 1970s

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Opportunities for New Facilities for Intermediate Production: There is also scope for establishing new ventures to initiate intermediate stages of production, such as the electronic screening and primary packaging of condoms. Prospective countries for these types of ventures in sub-Saharan Africa include Cameroon, Ghana, Nigeria, Zaire, and Zimbabwe, and in Asia and the Near East include Bangladesh, Egypt, Pakistan, the Philippines, and Turkey.

Opportunities for Quality Assurance: The promotion of quality assurance capability, such as condom quality assurance testing labs in selected countries in Africa, represents an important first step toward local production capability. When local quality assurance institutions have sufficient credibility to validate locally made contraceptives, local consumers may be more willing to buy locally made products. Regardless of whether contraceptive products are destined for local or export markets, the highest possible quality control standards will be required before locally made products may qualify for purchase by foreign (or donor) buyers. Assistance, at minimum for condom quality assurance, is indicated for the sub-Saharan African nations of Cameroon, Ethiopia, Ghana, Kenya, Nigeria, Zaire, and Zimbabwe. Assistance for contraceptive quality assurance also may be indicated in the Asia/Near Eastern countries of Bangladesh, Egypt, India, Indonesia, Pakistan, the Philippines, Thailand, and Turkey. In Latin America, Brazil, Haiti, Mexico, and Trinidad may have quality assurance needs, principally related to condoms. The above is not meant to be an exhaustive listing, but illustrates the wide scope for technical assistance in this area.

Volume of A.I.D. Commodities Donated: In order to identify prospective countries for private sector local production of contraceptives, it is appropriate to consider the volume of A.I.D. donated commodities. As shown in Table 3, based on cumulative expenditures for the three-year period from October 1986 through September 1989, the major recipients of A.I.D. contraceptive commodities are Zimbabwe, Nigeria, and Ghana for Africa; Bangladesh, Pakistan, and Egypt for Asia and the Near East; and Mexico, Peru, and Colombia for Latin America. With the exception of Ghana, all of these countries have ongoing local contraceptive production or have been considered as potential locations for this type of manufacture. As will be discussed later in this paper, there are opportunities to assist local production in the majority of these countries.

Table 3: Summary of A.I.D. Family Planning Commodity Costs from 10/86 thru 9/89 for Selected Major Recipient Countries by Region
(Data from A.I.D./C.P.S.D. NEWVERN Information System: Quantity Summary for the World, Run date 4/6/90, Courtesy of FPLM)

Region	Country	IUD	Condom	VFT	Orals	Total	Rank Order
Africa	Botswana	$32,930	$353,030	$0	$158,304	$544,264	
	Ghana	36,628	551,374	523,854	670,964	1,782,820	(3)
	Kenya	181,480	1,081,577	421,781	0	1,684,838	
	Nigeria	600,621	543,508	328,661	466,530	1,939,320	(2)
	Tanzania	0	692,836	0	0	692,836	
	Zaire	9,258	560,464	122,691	73,596	766,009	
	Zimbabwe	505,404	1,336,007	47,832	2,878,490	4,767,733	(1)
	Total	$1,366,321	$5,118,796	$1,444,819	$4,247,884	$12,177,820	
Asia and the Near East	Bangladesh	826,580	$18,400,237	$0	$4,131,783	$23,358,600	(1)
	Egypt	2,576,084	5,079,136	76,152	574,133	8,305,505	(3)
	India	4,363,406	0	0	0	4,363,406	
	Morroco	138,221	302,904	0	2,776,440	3,217,565	
	Pakistan	497,854	13,812,357	1,397	868,113	15,179,721	(2)
	Philippines	84,010	369,504	0	2,254,716	2,708,230	
	Thailand	7,710	1,319,483	456	1,278,541	2,606,190	
	Turkey	843,824	1,250,277	0	145,440	2,239,541	
	Total	$9,337,689	$40,533,898	$78,005	$12,029,166	$61,978,758	
Latin America	Brazil	$0	$1,038,924	$250,493	$288	$1,289,705	
	Chile	714,230	196,530	27,278	508,896	1,446,934	
	Colombia	307,375	782,542	0	416,954	1,506,871	(3)
	Costa Rica	205,198	768,918	0	305,452	1,279,568	
	Guatemala	40,640	433,009	378,258	389,054	1,240,961	
	Jamaica	0	881,156	0	545,503	1,426,659	
	Mexico	1,289,325	2,370,361	0	2,548,162	6,207,848	(1)
	Peru	425,130	1,069,077	240,907	480,948	2,216,062	(2)
	Total	$2,981,898	$7,540,517	$896,936	$5,195,257	$16,614,608	

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A.I.D. Experience with Local Production of Contraceptives and ORS

Contraceptive Production: As shown in the fifth column of Table 2, A.I.D. has supported activities related to local contraceptive production in at least eight countries. Due in part to the lack of detailed documentation, it is beyond the scope of this paper to give a comprehensive summary of A.I.D.'s experience in this field during the last 15 years. Some earlier A.I.D. activities (in the 1970s) were in cooperation with The Population Council to transfer Lippes Loop IUD manufacture to India, Egypt, and Pakistan. These early projects were initially successful, but in some instances suffered from inadequate follow-up. Other A.I.D. experience includes the provision of raw materials and training to the Indonesian government pharmaceuticals group, Kimia Farma, to manufacture OCs. Although the Indonesian project encountered problems, today this manufacturer is successfully producing contraceptives. Other A.I.D. activities have included feasibility studies for OC and IUD production in India and for OC production in Zimbabwe (Lach et al., 1982; Chafetz and Parrott, 1987). The former study had a very favorable impact in subsequent Indian local production efforts. The latter concluded that the prospects for local OC production were quite limited, citing a negligible private sector OC sales market, high local production costs, and less than adequate demand from the national family planning program.

Production of Oral Rehydration Salts (ORS): Contraceptives and ORS are both considered essential drugs by WHO and related agencies. Experience with the manufacture of ORS is highly relevant to the production of contraceptives. Many aspects of facilitating ORS production are similar to the requirements for assisting the manufacture of contraceptives: assessing technical and financial feasibility, transferring technology, and ensuring compliance with good manufacturing practices. Through Project SUPPORT, managed by PATH, the A.I.D. Office of Health has articulated a strategy to increase the availability of reasonably priced ORS in developing countries by mobilizing private sector resources. Project SUPPORT has successfully assisted in the initiation of private sector production and marketing of ORS by firms in Ghana, Guatemala, and Turkey. An update on the development of private sector production of ORS in Ghana is provided in Section IX. This case study provides a useful example of financial innovations to overcome a lack of foreign exchange.

A.I.D. Access to Technical Assistance for Local Production

Most aspects of local production of contraceptives, such as feasibility assessment, technical assistance, and regulatory mechanisms to ensure compliance with accepted standards for good manufacturing practice and quality assurance, can be assisted by a variety of U.S. private sector firms and agencies as well as by agencies of the U.S. government (see Appendix B).

Private Sector Assistance: A number of private sector agencies have had experience providing technical assistance to non-U.S. pharmaceutical manufacturers. These agencies can provide information, training, and on-site audits pertaining to regulatory, quality assurance, and good manufacturing practices issues for pharmaceutical and medical devices. Part 1 of Appendix B provides information on a variety of for-profit and non-profit agencies that have expertise related to local production of contraceptives. A brief contact list is included.

U.S. Government Agency Assistance: Instituting local production of contraceptives requires effective regulatory mechanisms to ensure compliance with accepted standards for good manufacturing practices and quality assurance. Assistance for these components of local production, as well as assistance in providing for safe working conditions and environmental safeguards for the areas surrounding a production facility, can be accessed from U.S. government agencies. There is the important proviso, however, that the mandates of these organizations (to protect the American consumer, worker, and environment) may substantially limit the extent to which assistance is available internationally. It is stressed that U.S. government agencies with expertise bearing on local contraceptive production are not mandated to provide international assistance to developing nations. Federal budget reductions throughout the past several years have decreased Public Health Service technical staff and at times it is not possible for agencies to provide the needed expertise. The extent to which they do provide assistance is often a reflection of professional courtesy and diplomacy. Part 2 of Appendix B provides detailed information on how A.I.D. can involve U.S. government agencies in the local production of contraceptives.

Mechanisms for Obtaining U.S. Government Agency Assistance: A variety of administrative mechanisms permit A.I.D. to gain access to services related to local production from U.S. government agencies. A promising approach for obtaining assistance from FDA, NIOSH, and other agencies under the aegis of

the Public Health Service is through the Office of International Health, Office of the Assistant Secretary for Health, Public Health Service, Department of Health and Human Services, (OIH, OASH, PHS, DHHS). In some cases, OIH/OASH serves as the access point for A.I.D. to obtain services of several agencies of the Public Health Service under a single agreement. OIH/OASH has indicated a willingness to play such a role in this case, subject to the willingness of CDC and FDA, and possibly NIH, to participate in the effort. The OIH has numerous administrative linkages to A.I.D., principally with the A.I.D. Office of Health. It should be possible to initiate activities to facilitate local production through existing Resource Support Services Agreements (RSSAs) and Participating Agency Services Agreements (PASAs). Long-term assistance would require the establishment of new administrative mechanisms.

IV. Key Issues

Advantages and Disadvantages of Local Production

As summarized in Figure 3, there are as many arguments against local production as in support of it. On the plus side are such potential advantages as ensuring a continuity of contraceptive supply independent of donor agencies; the use of otherwise idle manufacturing inputs and in some cases excess pharmaceutical production capacity; the development of additional skills, infrastructure and jobs; and the facilitation of culturally appropriate packaging. On the negative side are such potential drawbacks as a lower volume of central A.I.D. purchases possibly leading to increased costs per unit, the risk of failing to achieve the technical and quality requirements for local production within developing countries, higher costs per unit due to higher costs for energy and packaging, and the long-term nature of the technical assistance required to establish and sustain high quality local production. The central conclusion from assessing the pros and cons of local production is that there is no single across-the-board recommendation concerning its desirability or feasibility. It must be evaluated on a case-by-case basis for a given country, based on current and projected demographic, political, and economic conditions. See Appendix A for a practical framework to assess the feasibility for local production in a given country.

Financial and Cost Implications of Local Production for Donors

Cost Per Unit: Local production of contraceptives should not be pursued in hopes of achieving a lower cost per unit for A.I.D. procured commodities. As shown in Table 4, results from three separate feasibility studies provided estimated costs per unit for contraceptives: for OCs a cost per cycle of about 11 cents; for condoms approximately 3 cents each; and for IUDs a range from 44 to 56 cents each. Although all three of these estimates are lower than A.I.D. commodity prices, in practice, the actual cost per unit will probably tend to be comparable to, if not slightly more costly than, bulk-purchased A.I.D. contraceptives. Savings in lower labor costs may be more than offset by higher costs for energy, raw materials, and packaging. Until a final price is negotiated between the technology supplier and a potential manufacturer, there is no certainty as to the exact cost per unit. The final cost per unit will vary with a host of factors, such as the price of raw materials, duties, technology fees, etc.

Figure 3: Advantages and Disadvantages of Local Contraceptive Production*

I. Advantages

1. Contraceptives may be viewed as strategic commodities by developing countries; local production can help ensure continuity of supply and facilitate long-term planning for a national population strategy.

2. Significant manufacturing inputs are available in many developing countries. The value added from these inputs can reduce foreign exchange expenditures.

3. Excess pharmaceutical production capacity exists in some developing countries. The use of this capacity can increase the productivity of prior capital investments.

4. Local production allows for effective donor assistance while reducing donor dependency.

5. Local production develops skills and infrastructure, and creates jobs.

6. Local packaging of contraceptives facilitates development of culturally appropriate packages.

7. By remaining constant over time, locally produced goods and packages can retain brand familiarity.

8. Local production can engender national pride.

9. Private sector local production may help create an indigenous market for contraceptives through the self-interest of local manufacturers.

II. Disadvantages

1. By lowering the volume of A.I.D.'s centrally procured stocks, local production could increase the cost of contraceptive commodities to the remainder of the A.I.D.-supplied countries.

2. A.I.D. and other donor supply of contraceptives to qualified host countries can be expected to continue as long as needed and therefore investment in local production is not justified.

3. Technology and quality requirements for contraceptive production may not be readily achieved in developing country settings.

4. The cost of locally produced products may compare unfavorably with centrally procured goods.

5. Publicly operated contraceptive or drug industries may not have a good track record.

6. Local contraceptive production may not be deemed to be the most effective use of development capital.

7. Long-term technical assistance may be required, both to establish and sustain high-quality production.

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* Adapted from Free et al., March 1984.

Table 4: Estimated Cost per Unit, Capital Costs, and One-Year Operating Costs for Three Methods of Contraception (estimates from three separate feasibility studies)

	OC Production Plant Expansion (1982)	Condom Production Complete Factory (1987)	IUD Production Complete Factory (1988)
Annual Production	15 million cycles	70 million condoms	1 million IUDs
Total Factory Cost (in U.S. millions)	$ 1.925	$ 7.4	$ 1.7 - 2.95
Operating Cost (for one year, in U.S. millions)	$ 1.664	$ 2.45	$ 0.442 - 0.561
Estimated Cost per Unit	$ 0.11 per cycle	$ 0.03 per condom	$ 0.44 - 0.56 per IUD
A.I.D. Commodity Cost as of CY 1990	$ 0.13	$ 0.0423	$ 0.964

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N.B. These costs are highly dependent on the date the estimate was made, as well as local conditions and circumstances. These costs are presented as very rough indicators of the range of investment required for local production and should not be generalized to include methods produced in other countries in the future. Please note that, although all three of the above estimates are lower than recent A.I.D. commodity prices, in practice the actual cost per unit will probably tend to be comparable to, if not slightly more costly than, bulk-purchased A.I.D. contraceptives. Savings in lower labor costs may be more than offset by higher costs for energy, raw materials, and packaging.

Reduced Foreign Exchange Requirements: Although a lower cost per unit may not be achieved by producing contraceptives locally, it is of key importance that roughly 20 to 40 percent of the capital cost and even higher proportions of operating costs (40 to 80 percent) can be covered in local currency. This has the potential to permit foreign exchange (convertible currency such as U.S. dollars), currently allocated by donor agencies to purchase contraceptives, to be used for other purposes. Assuming that local currency requirements can be covered either by the local government or by some form of cost recovery (such as charging for contraceptives in public sector clinics as practiced in Egypt), from the donors' perspective reducing foreign exchange requirements is equivalent to reducing the total cost of commodities (Free et al., February 1984). Even when assuming the maximum annual operating costs and foreign exchange requirements per year (as shown in Table 1), in situations where local governments can support all local currency requirements, there is potential for substantial donor savings in foreign exchange.[6]

Potential Leverage from One-Time Investments: Under certain circumstances local production can provide a high degree of financial leverage. In countries that have committed the local resources to pay for essential labor, raw materials, and overhead costs, such as the People's Republic of China, the <u>one-time donor cost</u> of providing the technical assistance necessary to establish local manufacturing projects has been dramatically lower than the <u>annual cost</u> of providing amounts of commodities equivalent to those locally produced. See Figure 4. For example, in the current United Nations Population Fund (UNFPA) China Phase II projects for 1985-1989, the <u>one-time UNFPA cost</u> for projects to locally manufacture IUDs, OCs, vaginal suppositories and tablets,

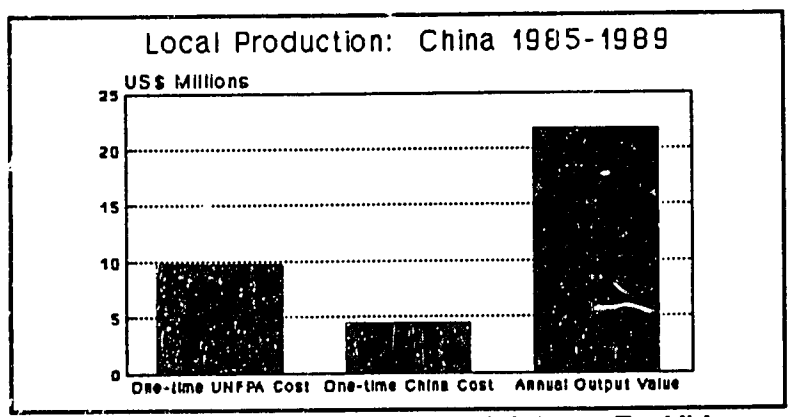

Figure 4: One-Time Cost to UNFPA and China to Establish Local Production vs. Value of Annual Output if Procured on the International Market: China 1985-1989 *PATH 1/90*

condoms, and steroids was US$9.7 million. Assuming that their production capacity is fully utilized, the estimated annual cost of procurement for the equivalent of the total output of these local production facilities is US$21.8 million (see 1989 UNFPA China Phase II Impact Statements, Appendix C). While these costs do not include the local annual cost to the People's Republic of China for raw materials, maintenance, and salaries, it is of interest that the total reported one-time contribution by China for start-up costs for construction and equipment for these facilities was the equivalent of less than US$4.5 million in local currency. With a one-time investment of approximately US$10 million, UNFPA has provided the equipment, training, and technical assistance to enable China to manufacture over a five-year period the equivalent of some US$100 million in contraceptives procured on the international market.

Need for Assured Purchase of Locally Produced Commodities

Donor agencies hoping to lower commodity expenditures through local production must be certain that locally produced contraceptives will be purchased by the government and/or by family planning clients. When examining the local need for contraceptives in a developing nation, a clear distinction must be made between public sector need, which usually involves the ministry of health providing free contraceptives, and the private sector needs of a relatively small middle and upper class. In some instances, such as oral contraceptive production in Bangladesh, local production facilities in developing nations only provide for the relatively small, private sector market and operate to varying degrees in competition with free or heavily subsidized donor-agency imports. Unless there is a carefully planned, phased transition by the local government from a system of distributing free, donated contraceptives to a system of government-purchased, locally produced contraceptives, there can be no assurance that the local production effort will be economically viable. The output of expanded local production must be purchased either by the government (as in India and Indonesia) or by the individual clients of public sector family planning programs (as in Egypt).

The call for feasibility studies for local production may come from the private sector, developing country governments, or from donor agencies that provide large quantities of free contraceptives.[7] The challenge in assisting private sector local production is not simply one of setting up new factories or upgrading existing ones. The challenge is also to convert a system where the public sector market is supplied by donor agencies, and may be in competition with the

private sector, into a system where both the public and the private sector markets utilize local private sector production.

V. Private Sector Contraceptive Production in India

Background and Demand for Contraceptives

Demand for contraceptives: After remaining almost unchanged for about five years, the effective contraceptive prevalence rate for India increased from 24 percent in 1982 to 35 percent in 1987 (Brown et al., 1987). The Indian Ministry of Health and Family Welfare (MOHFW) has provisionally estimated that as of March 1988, 40 percent of eligible MWRA (age 15-44) were using MOHFW-approved methods of contraception. The present strategy for India's family planning program strongly emphasizes the expansion of reversible methods. The Government of India goal set for the year 1990 is for an effective contraceptive prevalence rate of 42 percent. This goal translates into a 1989-1990 target of the following numbers of required acceptors annually: 6.8 million sterilizations, 5.2 million IUD insertions, and 14.5 million acceptors of other methods (Table 1 in Brown et al., 1987).

India: Selected Data

Population Projections
1989: 835.7 million
2000: 1,042.5 million

Number of Acceptors (1987-1988)*
(MOHFW Annual Report, 1987-1988)
Condoms: NA
IUDs: 4.36 million
OCs: NA

Estimated Commodity Needs (1987-1988)*
(MOHFW Annual Report, 1987-1988)
Condoms: 828.9 million
IUDs: 4.4 million
OCs: 26.8 million cycles

A.I.D. Commodity Costs (1985-1991)
Condoms: US$0
IUDs: US$5.1 million
OCs: US$0

Local Production Status
Condoms: Private and Government
IUDs: (Plans advanced)
OCs: Private and Government

*Provisional figures

OC production: India has extensive OC production capability. In addition to the government-owned Indian Drugs and Pharmaceuticals Ltd., as of 1988 there were seven private sector companies manufacturing OCs: Ethnor, German Remedies, Hindustan, Infar, Parke-Davis, Searle, and Wyeth (PIACT, 1988). In 1982 the USAID/Delhi Mission supported a consultant to review the potential for both private and public sector manufacturers of oral contraceptives to expand to reach a target production of 150 million cycles annually by 1988. This assessment involved an examination of both private and public facilities, "with respect to good manufacturing practices as required in the U.S.: quality control procedures for raw materials, safety materials, safety procedures employed for personnel exposed to steroids, personnel qualification, and drug

storage facilities." The study found a current government sector capacity of 11 million cycles annually and concluded that the target could only be reached by either constructing new Indian government-owned facilities or cooperating with several facilities in the private sector (see Lach, Bronnenkant, and Bronnenkant, 1982, page 83).

As part of the Government of India's effort to increase the number of couples using "spacing methods," the manufacture and distribution of oral contraceptives is being dramatically expanded in a new social marketing effort to make OCs available from pharmacies at a subsidized price, with the proviso that women see a doctor within three months after beginning the use of OCs (Brown et al., 1987). (In this paper the term "social marketing" refers to the use of commercial marketing techniques to distribute contraceptives through grass roots retail sales at subsidized prices. India's program for the sale of Nirodh condoms is one of the oldest social marketing programs, implemented in 1968 by the Indian Ministry of Health.) The OCs for the program are produced by Indian government-owned manufacturers, using imported steroids. The current variety of 21-pill cycle "Mala" OCs will be augmented in the near future by a new social marketing product called "Ecroz," an upscaled 28-day pill cycle with seven supplemental iron pills (Population Services International, 1989).

IUD Production: Despite an earlier attempt to manufacture IUDs in a government-owned venture begun in the late 1960s, India does not currently mass-produce IUDs. As discussed below, two separate IUD technology transfer projects have been recently negotiated and should be in production within one or two years.

Condom Production: While the Government of India gives away some 500 million condoms annually from all family planning and related clinics, India's condom social marketing program, Nirodh, reported sales of 266 million from April 1987 to March 1988 (Kuppuswamy, personal communication, 1989; Population Services International, 1989). With support of some $8 million in grants from UNFPA and Japan, the Government of India has expanded the condom production capability of the parastatal Hindustan Latex Ltd. (HLL) from 288 to 608 million condoms annually. This, combined with recent expansion from a capacity of 480 to 640 million condoms annually by the private sector condom manufacturer, London Rubber Company (India), gives

India an output of one billion a year and an excess capacity of some 200 to 300 million condoms annually. India currently exports to a variety of nations, including England and the USSR.

Pharmaceutical Technology and Regulation: It is important to acknowledge the highly developed technical expertise of India's pharmaceutical production and biomedical research (PIACT, 1988). The Indian Council of Medical Research has some 22 collaborating institutions throughout India and is in the process of field-testing existing and new contraceptive methods, some of which are entirely indigenous in origin (Brown et al., 1987). The Indian government has a long history of drug regulation and has recently promulgated a detailed set of regulations requiring good manufacturing practices for drugs and medical devices (SCRIP No. 1378, 1989).

There is currently considerable dispute between U.S. pharmaceutical manufacturers and India's pharmaceutical industry concerning patent laws and the protection of intellectual property rights (SCRIP Nos. 1296, 1338, and 1371, 1988; SCRIP Nos. 1400 and 1416, 1989). In India there is no patent protection for finished products, only for manufacturing processes. This makes it somewhat controversial to enter into arrangements with Indian firms involving new technologies that have patent protection in the United States. Under Indian patent law, the most flagrant imitation of U.S. patented drug or medical devices is entirely legal as long as the process used to manufacture it is not identical to that used to make the original. A 1986 PIACT study found that considerable effort had been made by a private sector Indian firm to duplicate and even patent a copper T IUD that was protected under a U.S. patent (Free/PIACT, 1986).

Flow of Commodities into the Country

According to the UNFPA mission for India in 1985, "In order to ensure a steady availability of required contraceptives, India should become self-reliant in the production of these commodities." The extent to which India is not currently self-sufficient in contraceptives is indicated by Table 5. Since 1985 India has received a total of 8.4 million IUDs from A.I.D., valued at an estimated US$5.1 million. Over the same period, India has received 9.2 million IUDs from UNFPA, 1.3 million cycles of OCs, and almost 200 million condoms (data not shown).[8] Given the current and projected demand, the capacity for

Table 5: Estimated Quantity and Cost* for Contraceptives Shipped or Planned for Shipment by A.I.D. to Bangladesh, Egypt, and India: 1/1/1985-12/30/1991

	Condoms	TCu 200	TCu 380	VFT	OCs	Row Totals
Bangladesh						
Total Number of Units	1,195,728,000	600,000	1,922,400		53,439,200	
Average Unit Cost	$0.043	$0.610	$1.005		$0.258	
Estimated Purchase Cost	$51,676,122	$366,000	$1,932,073		$13,792,894	$67,767,089
Egypt						
Total Number of Units	220,248,000	385,000	4,286,400	10,112,000	10,831,200	
Average Unit Cost	$0.043	$0.610	$1.002	$0.084	$0.248	
Estimated Purchase Cost	$9,545,681	$234,850	$4,294,698	$850,782	$2,690,457	$17,616,468
India						
Total		8,424,000	1,000			
Estimated Unit Cost		$0.610	$0.950			
Estimated Purchase Cost		$5,138,640	$950			$5,139,590
Summary for the Three Countries Combined						
Total Number of Units	1,415,976,000	9,409,000	6,209,800	10,112,000	64,270,400	
Average Unit Cost	$0.043	$0.610	$1.003	$0.084	$0.256	
Total Estimated Purchase Cost	$61,221,803	$5,739,490	$6,227,721	$850,782	$16,483,351	$90,523,147

Source: NEWVERN Database courtesy of FPLM, 4/90. PATH 4/90

*Both quantity and cost data are estimates. Quantities include shipments that are planned as far in advance as 12/30/91. Shipping costs are not included. Pre-1986 NEWVERN data for shipment quantities are being verified. Given that planned shipments may change, and validation has not been completed for the data for 1985, the above data must be treated with some caution. Discrepancies between estimated purchase costs and average unit costs are due to rounding error.

OC production and condoms appears adequate; however, IUD production is clearly a high priority for India.

Case Studies of IUD Manufacture in India

The following is an update on issues relating to private sector production of IUDs in India. This update is in two parts: (1) The case of a government-owned IUD manufacturing project that failed; and (2) an update on current progress with the local manufacture of IUDs in India by both government-owned and private sector firms. The latter update will cover what promises to be two parallel, large-scale technology transfers of IUD manufacture facilities: one to an Indian government parastatal; the other to a private firm. These two projects combined will have an annual capacity of over 5 million IUDs. Especially important in this discussion are developments for medical device regulation that will help ensure the success of this technology transfer through long-term monitoring of quality control.

An Early IUD Manufacturing Project at Kanpur, Uttar Pradesh, India

Production of Lippes Loops was initiated in India in 1965 as result of interaction between the Ministry of Health and The Population Council. The site was located in Kanpur, Uttar Pradesh, under the Directorate of Industries. The initial devices (Lippes Loops) were tested by The Population Council and found to be of suitable quality. This facility was subsequently placed under the authority of the Uttar Pradesh Small Industries Cooperation (UPSIC) in 1971. A Government of India report indicated that the quality of the IUDs was maintained at a high level during the first two years. In 1975, Finishing Enterprises, Inc., of North Tonawanda, New York, supplied a Copper T 200 mold to the Kanpur facility at the direction of The Population Council. No additional training, validation, or follow-up occurred at that time, and it is not clear whether Copper T 200s were ever routinely produced by the Kanpur site. In 1981-1982 samples of IUDs provided to the Indian Council of Medical Research were rejected due to inadequate quality.

In 1982 the USAID Mission in India and the Government of India sponsored a consultancy by representatives of Finishing Enterprises, Inc., to conduct an analysis of Indian IUD production. These consultants inspected the Kanpur facility and recommended that the IUD production operation be stopped, since the Kanpur facility was no longer qualified to manufacture these devices (Lach, Bronnenkant, and Bronnenkant, 1982).

The Kanpur case suggests that serious problems arose due to a change in leadership at the local factory, a lack of continuing technical assistance by the technology supplier, and lack of monitoring by the Government of India and related agencies. Of importance in this case example was the finding that the locally available quality control agencies were well-equipped, with knowledgeable personnel fully qualified to conduct tests on IUDs. There was no adequate administrative mechanism, however, to empower the quality control laboratory to periodically review the IUDs made at the Kanpur plant (L. Bronnenkant, personal communication, 1989).

Post-Kanpur Progress Toward IUD Manufacturing

The lessons learned from the problems experienced with IUD manufacture at Kanpur have provided some of the impetus for significant improvements in the conditions for technology transfer, follow-up, licensing, and regulation in India's current plans for IUD production. In 1984, the Indian government-sponsored Expert Committee on Indigenous Manufacture of Copper T 200s was convened. This committee, showing remarkable foresight, recommended the following:

- Population Council specifications should be used for both manufacture and regulation for quality assurance.
- Indigenous manufacturing should be done by at least one firm but should not be entrusted to more than two or three firms.
- These firms should represent both the public and private sector.
- The Indian Institute of Technology (IIT), New Delhi, should constitute an independent testing agency for any IUDs produced in India.
- The copper T device should be regulated under the auspices of the Drugs and Cosmetics Act (this law corresponds to the laws that established the United States FDA).
- Technical assistance should be provided to both the India Institute of Technology, New Delhi, and the Central India Pharmacopoeia Laboratory to perform quality assurance functions.
- Firms should obtain foreign collaboration for know-how, training, and certain essential equipment.
- Critical raw materials should be imported (for example, the plastic, Dupont "Alathon 20-2005 low-density polyethylene," and the 99.99 percent pure copper, with specified trace elements, used in the manufacture of IUDs).

Based on the above recommendations, the Indian Ministry of Health selected the Department of Biomedical Engineering at the India Institute of Technology, New Delhi, as the independent testing authority for IUDs and other contraceptive devices in India. The Ministry of Health concluded that the public sector would require up to five million units of Copper T 200 per year, to be met primarily by a public sector manufacturer. It was decided that private sector manufacturing sources for the public sector would be phased in as needed. In view of this, private firms were advised to develop their plans initially on the basis of the private sector market. For the public sector producer, the Ministry of Health selected Hindustan Latex Ltd. (HLL) to set up a Copper T 200B manufacturing plant in Trivandrum, India. HLL was asked to secure their own financing for this venture. They have since requested and received commitments for financial assistance from UNFPA.

The Ministry canvassed the private sector for statements of interest and intent and met with five companies in September 1986. This canvassing involved a survey of the prospective firms concerning: (1) involvement with foreign IUD manufacturers; (2) capability for clean room assembly operation, ethylene oxide use, plastic medical device production and strict adherence to international standards; (3) plans for ensuring continued high quality; and (4) whether they had carried out a technical feasibility study, market study, and a study of export potential.

At the Indian Ministry of Health request, UNFPA funded PIACT to review IUD manufacturing possibilities in India and to make recommendations that would ensure viability and long-term quality. The PIACT study found ample capability for the manufacture of IUDs in India. In addition to finding the parastatal, HLL, potentially capable of carrying out this project in accordance with international good manufacturing practice (GMP) standards, several private sector firms appeared to have good prospects for producing IUDs. The PIACT report stressed the need for a third-party validation system for the IUDs based on The Population Council standards for Copper T 200B IUDs. This would provide the Government of India with exact criteria for accepting or rejecting output from the public sector facility.

The PIACT study also recommended that the Government of India establish a National Quality Control Laboratory for IUDs and possibly other contraceptive

devices. This type of laboratory is seen as a *sine qua non* for setting up local IUD production, regardless of whether it is in the public or private sector. This recommendation was accepted by the Government of India. In 1989, PIACT arranged technical training for two senior IIT-New Delhi staff with FDA and other medical device experts in the U.S.

Current status of IUD technology transfer

The USAID Mission in New Delhi has considered providing financial assistance to facilitate IUD manufacturing projects. A private sector project by the firm Famy Care Ltd. ultimately did not require any USAID financial support. The public sector project involving HLL was not assisted, in part because HLL is not a private sector firm.

The public sector: In the public sector, HLL of Trivandrum has negotiated to purchase know-how and a license for production of the Copper T 200B from Finishing Enterprises, Inc., of North Tonawanda, New York. Financial support is being provided by UNFPA. The manufacturing agreement involves a very strict phase-in process whereby during the first year IUDs are assembled from components made by Finishing Enterprises. The formal issuance of a license to HLL is contingent upon completion of a second year of supervised production and validation to demonstrate that locally produced IUDs meet quality standards both of the technology supplier and of the IIT-New Delhi, Medical Devices Testing Laboratory. The Government of India is a third party to the agreement between HLL and Finishing Enterprises. The government will arbitrate any disagreement between HLL and Finishing Enterprises over the interpretation of results from IUD quality control tests. As stated by the president of Finishing Enterprises, very high quality control standards will be maintained, for it is in no one's interest to allow sub-standard IUDs to be produced and distributed in India (L. Bronnenkant, personal communication, 1989). This philosophy is shared by the technology supplier for the parallel, private sector Indian IUD production venture as well.

The total requirements for the project for HLL are estimated to be approximately US$5 million, of which some US$2.5 million is for capital, training, and technology transfer costs and US$2.5 million is for procurement of IUD components for intermediate production while the factory is being constructed. The annual production of the factory is to reach four million

IUDs by the end of the project. The agreement between HLL and Finishing Enterprises includes a provision for retooling of Copper T 200 machinery for Copper T 380A manufacture, should the Government of India decide to purchase Copper T 380A in addition to, or instead of, the Copper T 200.

The private sector: The private sector firm undertaking IUD manufacture is Famy Care Ltd., a subsidiary of Permanent Magnets Ltd. of Bombay, India. The parent firm is an established company involved in the manufacture of cast and ceramic magnets. Famy Care concluded a licensing agreement with Leiras, a Finnish company that holds a Population Council license to produce copper T IUDs. The Famy Care agreement is very similar to the HLL agreement, in that there is provision for phased-in production to ensure gradual acquisition of technology: (1) importation and sales of finished products; (2) importation and assembly of parts; to be followed by (3) complete manufacture. Famy Care obtained all the bank financing required for the project, including the required foreign exchange, without any donor agency assistance.

Conclusions Regarding IUD Production in India

General

India's experience provides an example of two extremes in local production. Although for two years production may have been of high quality, the Kanpur project was ultimately a failure. At the other extreme, it presently appears that India's second generation IUD manufacturing projects with Finishing and Leiras have had an auspicious beginning. Excellent safeguards are in place with: (1) phased production; (2) strict licensing arrangements; (3) standardized Population Council guidelines for GMPs; and (4) an emerging Indian government administrative mechanism and expertise to ensure that high quality is maintained over the long term. In addition to the above safeguards, a key ingredient to the success of the second generation IUD manufacture lies in the Indian government's ability to assure both private and public sector manufacturers that it will purchase the devices produced by new ventures.

A.I.D.'s Role

While the current progress with local production of IUDs is taking place without direct A.I.D. assistance, there are opportunities for A.I.D. to facilitate local production in India, such as the area of quality assurance. For example, the USAID/Delhi Mission is currently involved in the initial stages of developing a Government of India/USAID/Delhi Mission/Government of

Japan-supported project called "Quality Control of Health Technologies." This may involve some US$40 million over a five-year period for four sub-projects: creation of a National Institute for the Standardization and Quality Control of Vaccines and Biologics; quality control of contraceptives; quality control of pharmaceuticals; and quality control of vaccine and contraceptive delivery systems.

VI. Private Sector Contraceptive Production in Bangladesh

Background and Demand for Contraceptives

Based on the sheer volume of commodity requirements, by 1992 Bangladesh is clearly a candidate for local production for both OCs and condoms. USAID/Dhaka has estimated the following 1992 annual contraceptive commodity requirements for Bangladesh at the point it is projected to achieve a 40 percent prevalence rate: IUDs - 616,000; oral contraceptives - 26.2 million cycles; condoms - 250.6 million.[9]

Bangladesh: Selected Data

Population Projections
1989: 110 million
2001: 147-154 million

Contraceptive Prevalence (1989)
Total: 32.8 percent
Condoms: 3.1 percent
IUDs: 1.7 percent
OCs: 9.1 percent

Number of Users (1989)
Condoms: 634,000
IUDs: 348,000
OCs: 1,061,000

Estimated Commodity Needs (1989)
(USAID/JSI/FPLM, November 1988)
Condoms: 191.2 million
IUDs: 0.49 million
OCs: 22.2 million cycles

A.I.D. Commodity Costs (1985-1991)
Condoms: US$51.7 million
IUDs: US$2.3 million
OCs: US$13.8 million

Local Production Status
Condoms: none
IUDs: none
OCs: Organon/Bangladesh Ltd
(Sales 1988: 2.9 million cycles)

Flow of Contraceptive Commodities into the Country

It is useful to review A.I.D. procurement for Bangladesh for the period from January 1985 through December 1991. These amounts are not projections, but fairly accurate estimates of actual or scheduled contraceptive shipments, which reaffirm that the above projections are valid. As shown in Table 5 in Section V, over the seven-year period 1985-1991 (1990-1991 data include planned shipments that have been scheduled, but not yet sent) A.I.D. will have spent an estimated total of $68 million for contraceptives shipped to Bangladesh. This breaks out to $51.7 million for 1.2 billion condoms, $2.3 million for 2.5 million IUDs, and $13.8 million for 53.4 million cycles of oral contraceptives.

Local Production of Condoms

Early 1980s: A.I.D. has been the sole source of condoms for the Bangladesh National Population Program, supplying condoms for the program since 1974. The condoms imported into Bangladesh are used for free distribution in various government programs, free distribution by non-governmental organizations, and for subsidized sale in the USAID/Dhaka-funded social marketing program called the Social Marketing Project. In 1982 a PIACT study, funded by UNFPA,

reviewed the options for local production of condoms in Bangladesh. The 1982 PIACT study provided a cost analysis for local production of condoms for four phases of introduction, each of which assumed an annual production of 100 million condoms.

Phase I	Packaging of imported bulk tested condoms
Phase II	Packaging and testing (electronic screening) of imported bulk untested condoms
Phase III	Full-scale production of condoms
Phase IV	Expansion of full-scale production from 100 to 200 million condoms per year

The estimated project costs in 1982 U.S. dollars for these phases, which include the cost of all tangible assets and working cash reserves, were $2.3 million for Phase I, $2.7 million for Phase II and, depending on the technology supplier, from $5.1 to $7.9 million for Phase III. Phase IV, a complete facility expanded to 200 million condoms annually, had a project cost estimated between $7.1 and $13.9 million, depending on the technology supplier. The cost per unit for these options varied from 3.61 to 3.89 cents as compared with the 1982-83 A.I.D. commodity price of 4.4 cents, not including shipping.

All of the above 1982 estimates were based on the assumption that a private sector firm would pay 15 percent interest in local currency as well as pay import duties. If a donor agency were to provide the capital without interest and duties were waived, the cost per unit would range from 3.58 cents in Phase I to 2.76 cents in Phase III and 2.52 cents in Phase IV. Given the national interest involved in promoting this type of project, it seems reasonable to assume that these latter arrangements would be considered by the Bangladesh government.

The 1982 PIACT study concluded that:

- the annual rate of condom distribution (then around 87 million per year) was sufficient to engage a local production plant at above minimum scale;
- actual usage, probably in the range of 50-80 million condoms per year, was more than adequate to justify local packaging of bulk imported condoms;
- condom use of not more than 200 million pieces per year might reasonably be expected by the year 1990;

- condom production was technically feasible in Bangladesh; significant inputs existed for condom production in Bangladesh in the form of raw materials, energy, technical expertise, and unskilled manpower. This conclusion was based partly on the assumption that local production of liquid latex of sufficiently high quality for condom production would become available from Malaysian stocked rubber plantations in the Chittagong Hill Tract area under an Asian Development Bank financed program.
- locally produced condoms could be comparable in price to centrally procured international goods;
- foreign exchange expenditures for condoms could be reduced by local production to less than 25 percent of the total cost if interest on loans was paid in local currency; less than 50 percent if the interest was paid in dollars.

The 1982 PIACT study recommended that:

- planning for condom production should focus on a joint venture with an internationally experienced condom manufacturer capable of adapting the technology to a developing country and tropical conditions.
- local condom production should be phased in, starting with electronic screening and packaging of bulk, imported condoms;
- International Organization for Standardization standards for condoms should be adopted, performance standards should be included in purchase agreements, and receipt checks should be carried out on a routine basis.

Current Status of Condom Production: Partly as a result of the 1982 UNFPA feasibility study, there have been two parallel developments toward local production of condoms in Bangladesh: a private and a public sector venture.

Private Sector venture

This venture has been under consideration for at least three years. It has been initiated by two well-established Bangladeshi businessmen who have set up a consortium in cooperation with two Bangladesh government corporations (the Industrial Promotion and Development Company of Bangladesh (IPDC) and the Bangladesh Chemical Industrial Corporation (BCIC), as well as the Asian Development Bank (ADB), the Commonwealth Development Company (CDC) and London Rubber Company Overseas, United Kingdom. The India affiliate of London Rubber Company Overseas, United Kingdom, London Rubber

Company India (LRCI) of Madras, will provide technical support. In a strict sense this is not a fully private venture, since it involves an international development bank and two Bangladesh government parastatal equity holders. The total production capacity for the proposed factory is 160 million condoms per year, operating three shifts year-round. The total venture is expected to cost some $7.93 million, which includes $4.46 million for equipment costs with the balance for building improvements, "know-how" fee, and other expenses.

Loans for this venture are anticipated from IPDC for $355,000, CDC for $1.65 million, and ADB for $2.76 million. The ADB loan will be handled through the Government of Bangladesh. The Government of Bangladesh would be charged about one percent interest and would lend the money to the project at about seven percent interest. The ADB approval for this loan is dependent on the consortium's receiving firm commitments from buyers for the factory's output.

The consortium has requested that raw materials be given duty-free entry and that the factory receive preferential energy tariffs. While imported latex would be used during the initial operation, local latex would eventually be used. A feasibility study done by one of the parastatal investors estimated a production cost of about $.024 per unit ($3.50 per gross). The Government of Bangladesh approved this project in October 1988 subject to the availability of purchase guarantees. The factory would need an income of some $2 million a year (i.e., to sell at least 50 million condoms annually at a price of $.04 each) in order to break even. The developers have requested purchase guarantees for 60 percent of the factory's output for at least four years. To date the Bangladesh government has not made a commitment to buy the required quantity of condoms to allow the venture to proceed.

The public sector option

The Bangladesh government requested Japanese government assistance for a plant in 1985, but was turned down in 1986 due to Japan's concerns over lack of local funding to keep the plant running. The lack of high quality local latex was also viewed as a reason not to support the venture. The Bangladesh government has continued to express interest in Japanese assistance, in part due to estimates of current and future condom requirements, which exceed the capacity of the proposed private sector plant. Furthermore, there is interest on

the part of the Government of Bangladesh in further expanding condom use as part of a shift in contraceptive method mix away from sterilization.

While considerable interest has been expressed by the Bangladesh government, UNFPA has recommended to the government that this public-sector initiative not be considered until the private sector venture option has been given ample opportunity to proceed. This position was taken on the grounds that the Bangladesh government has indicated that it favors private industry in the local production of contraceptives, and the private sector consortium is in line with both UNDP and UNFPA private sector initiatives and strategies.

Pros and cons of the two ventures

In 1988 UNFPA requested PIACT assistance for a brief update on the local production of condoms. This update found advantages for the private sector proposal including the technology supplier's equity involvement, the suitability of the proposed technology for lower quality latex, and the technology supplier's prior developing country experience. For the public sector venture, there is concern that it would have inadequate follow-up and the dependency of Japanese technology on high-quality Malaysian latex might eliminate the option of eventually using local Bangladesh latex.

Local Production of Oral Contraceptives

Early 1980s: In 1982 PIACT assessed the potential for local production of OCs in Bangladesh in a UNFPA-funded study. The 1982 demand for OCs was estimated to be 9.5 million cycles per year, not sufficient to fully utilize a dedicated OC production facility. At that time, one existing private sector multinational firm, Organon/Bangladesh, was making approximately 1.5 to 2 million cycles per year as part of a multi-product pharmaceutical enterprise and selling them through private distributors. Organon/Bangladesh has been importing steroids and processing them into OCs for at least 10 years. While the commercial markets in Bangladesh contained small quantities of imported OCs from Schering and Wyeth, the principal items marketed were Organon/Bangladesh's locally manufactured Ovostat and a low-dose formulation, Restovar.

The 1982 PIACT study found that Bangladesh had a strong pharmaceutical industry, including six firms that were involved in the manufacture of hormonal preparations. Both Organon/Bangladesh and two additional multinational OC

producers had expressed interest in developing local production capacity to meet the public-sector need for OCs at international public-sector prices.

The PIACT study estimated the project and production costs for expanding an existing facility to produce 15 million cycles annually. The study assumed that the existing facility was already equipped to produce steroid-containing products, but that state-of-the-art air-handling and filtration systems, as well as equipment for worker safety for handling estrogens, would be installed. The estimated project costs were $1.64 to $1.93 million, depending on the type of formulation and form of the final product. The estimated direct manufacturing costs per cycle varied from $0.112 per cycle to $0.132 per cycle, depending on the packaging. This compared to the 1982 price of $0.21 per cycle paid by A.I.D.

The 1982 PIACT study concluded that:

- expenditure of funds for a new facility was not warranted. If made at all, investment should be made into financing the expansion of existing, private sector production capabilities.
- public funds should be invested into expanding the capabilities of the existing drug regulatory authorities to ensure the highest standards for quality in the pharmaceutical industry.
- cost estimates of OC production in an expanded facility demonstrated that OCs could be sold to the Bangladesh government for a price competitive with centrally procured international goods.
- foreign exchange expenditures for OCs could be reduced by local production to less than one-half of the total cost, assuming that the project was financed in local currency.

The UNFPA comments on the PIACT report included a recommendation that local production, if agreed upon, should be undertaken in the private sector, that prevailing constraints would make it next to impossible to consider a public sector venture, and that a beginning should be made with the purchase by the Bangladesh government of locally produced OCs before undertaking local manufacture of condoms.

Current Status of OC Production: The situation in Bangladesh remains quite similar to what was observed in 1982. Organon/Bangladesh continues to manufacture a variety of OCs for the private sector market, including Ovostat,

Marvelon, and Lyndiol with total sales of 2.9 million cycles in 1988 (USAID/JSI, 1989). The combined private sector sales of Wyeth and Schering products were less than 110,000 cycles in 1988.

While Organon/Bangladesh is concerned with maintaining and expanding its private sector market, it appears to have considerable interest in expanding production for the public sector. A recent USAID/JSI study reported that Organon/Bangladesh is in the process of expanding its production capacity despite the fact that it already has a surplus production capacity for the private sector (USAID/JSI, 1989). This study concluded that there is a strong potential for the private sector to expand production of high quality OCs and cited the preference of Bangladeshi wholesalers and retailers for promotion of OC production for private sector sales. Apart from self-interest, this preference was based on a desire for assured supplies of a variety of OCs as well as the impression that commercial brands of contraceptives were perceived by consumers to be of higher quality than free government varieties.

Conclusions

General

- While the Bangladesh government has the option of continuing to encourage the simultaneous development of two condom production projects, it seems likely that the private, consortium effort will be implemented first.
- Despite the seeming disadvantages of the Japanese public sector condom proposal, a plan for an alternative supply should be encouraged. Demand for condoms will in all likelihood continue to expand. The production of the proposed private-consortium factory, even running three shifts year-round, is not sufficient to meet current government and SMP commodity needs. The presence of an alternate source of condoms would provide competition to ensure that the highest standards are met by the private consortium. Japanese condom manufacturers should be encouraged to assume an equity involvement in the project in order to ensure that a long-term presence by the technology supplier will be maintained.
- Private sector OC production capacity is being expanded without any direct assistance from donor agencies. There may be opportunities for donors to facilitate this expansion, such as assistance for capital investment and/or willingness to consider local purchases.

A.I.D.'s Role

- Studies are needed to assess the ability of Social Marketing Project condom and OC users to pay more toward the production and distribution costs of contraceptives and to determine what the implications of this increase in price are for demand. This offers some opportunity to help expand the private sector OC market and eventually market condoms for a profit. At present there is no private sector market in Bangladesh for condoms; they are either given away or sold at a heavy subsidy.
- A.I.D. has options to assist local OC and condom production efforts, including the donation of technical expertise, machinery, and materials from the United States, such as packaging foils.
- As recommended by the above-cited 1982 PIACT study, A.I.D. could also provide assistance to technical and regulatory systems for quality assurance. This is extremely important in order that the Bangladesh government can have a mechanism to seek redress and alternate supplies should quality of locally made condoms or OCs be inadequate. It is also an essential prerequisite for donor purchase of locally made condoms and OCs for public sector programs.

Role of Multilateral Donors

The World Bank and/or other funding agencies are encouraged to make long-term commitments to purchase the output of the proposed consortium factory. If this commitment can be made, a condom factory could begin production in the early 1990s.

VII. Private Sector Contraceptive Production in Egypt

Background and Demand for Contraceptives

Demand for Contraceptives: Recent data from the Egypt Demographic and Health Survey (EDHS) of 1988 indicate major changes in contraceptive use have occurred in the last eight years (Egypt National Population Council, 1989). Current contraceptive prevalence in 1988 was 37.6 percent, an absolute increase of 14 percentage points and a relative increase of 60 percent since 1980. The IUD and the pill are the most popular methods and together account for 82 percent of all users. A dramatic increase in IUD use has occurred over the last four years, with the IUD now equaling the pill in importance.

Egypt: Selected Data

Population Projections
1989: 54.8 million
2000: 71.2 million

Contraceptive Prevalence (1988)
Total: 37.6 percent
Condoms: 2.4 percent
IUDs: 15.6 percent
OCs: 15.3 percent

Number of Users (1988)
Condoms: 190,400
IUDs: 1.2 million
OCs: 1.2 million

Estimated Commodity Needs (1988)
(JSI/FPLM, 1989)
Condoms: 19.1 million
IUDs: 0.4 million
OCs: 15.7 million cycles

A.I.D. Commodity Costs (1985-1991)
Condoms: US$9.5 million
IUDs: US$4.5 million
OCs: US$2.6 million

Local Production Status
Condoms: None
IUDs: (Plans in progress)
OCs: Parastatal

Importance of Private Sector: In Egypt the private sector is the predominant source of contraceptive methods. In 1988 over 85 percent of women relying on supply methods (oral contraceptives, condoms, vaginal foaming tablets, etc.) obtained them from pharmacists (Egypt National Population Council, 1989). More than half (52 percent) of contraceptors relying on clinic methods, such as the IUD, obtained them from a private doctor. While most of the private sector commodities are subsidized by donors, this high reliance on the private sector has important implications for local production in that it presents an opportunity for cost recovery to pay for local production.

Government programs coexist with effective private sector and social marketing institutions. While family planning services are provided without charge at government clinics, contraceptives must be purchased at these clinics at prices controlled by the government. Socially marketed contraceptives are sold at the

same government prices as other commercial products. As a result, the private sector market exists for all methods. Again, this has the potential to generate income to support the costs of producing and distributing contraceptives locally. In 1988, A.I.D. signed a cooperative agreement with the Egyptian Pharmaceutical Trading Co. (EPTC) and the Egyptian Ministry of Health that allows the EPTC to retain 30 percent of the revenue from the sale of A.I.D.-donated contraceptives to pharmacies and other institutions. This revenue will cover warehousing and distribution costs for A.I.D. contraceptive commodities (Springsteen/FPLM, 1989, page 4).

An important Egyptian social marketing institution for family planning is Family of the Future (FOF). Receiving support from A.I.D. for both commodities and administrative costs, FOF currently markets condoms, OCs, Depo-Provera, and IUDs. The prices of FOF products are regulated by the Egyptian government in the same manner as other private sector contraceptive products. This means that FOF products offer no price advantage to the consumer. Family of the Future distributes contraceptives on a commercial basis to over 7000 pharmacy outlets and has a unique role in the promotion of IUDs. Unlike other contraceptive social marketing programs, FOF has promoted IUD sales through a marketing campaign oriented towards doctors. The FOF approach provides training to doctors for IUD insertion and also permits IUDs to be purchased from pharmacies by prospective users for insertion by their doctor. Family of the Future repackages A.I.D.-donated IUDs in a consumer-oriented manner to enhance sales. The success of this approach is indicated by the EDHS finding that 17 percent of current IUD users purchased their IUDs at a pharmacy before having them inserted, usually by private doctors (Egypt National Population Council, 1989, page 26).

Pharmaceutical Regulation: Egypt has a highly developed commercial pharmaceutical industry as well as an institutional framework for drug regulation. Pharmaceutical production is monitored and regulated by a Council for Pharmaceuticals, Chemicals, and Medical Equipment. The National Organization for Drug Control and Research (NODCAR) examines samples of drugs and medical devices as requested by the Ministry of Health's department for pharmaceutical administration. NODCAR has received assistance from the FDA on regulation of medical devices and standards for the regulation of

medical devices, such as IUDs, are under development (see Appendix B for additional information regarding FDA assistance to Egypt).

Flow of A.I.D.-Donated Contraceptive Commodities into the Country

As shown in Table 5 in Section V, for the seven-year period 1985 through 1991, A.I.D. will have shipped a total of 220 million condoms, 4.7 million IUDs, 10.1 million vaginal foaming tablets, and 10.8 million cycles of OCs to Egypt, at an estimated cost of $17.6 million, not including shipping. Projected A.I.D. supported contraceptive distribution for 1991 is 870,000 IUDs, 49 million condoms, and 3.6 million cycles of OCs. The total cost of commodities requested for fiscal years 1989 and 1990 is $3.8 million. Based on this volume of IUD procurement, local production of IUDs, which requires a minimum lead time of two to three years, is an option for A.I.D. worth considering. UNFPA has been discussing possible support for IUD production, as will be reviewed below.

Potential Expansion and Upgrading of OC Manufacture

There is also an opportunity for A.I.D. to upgrade and expand local OC production in Egypt. As pointed out by Washchuck (1981), about half of the public sector pharmaceutical capital equipment in Egypt was installed before the mid 1960s. In the late 1970s and early 1980s, the Egyptian government spent over $50 million for capital improvements and plant renovation (Washchuck, 1981, page 5). Despite this expenditure, the manufacture of OCs in government facilities has been subject to problems of outdated manufacturing techniques and equipment.

Beginning in the late 1960s an Egyptian parastatal importing firm provided steroids and other raw materials to three government pharmaceutical companies that would granulate, mix, tablet, package, and distribute oral contraceptives to both the private and public sectors. These three government pharmaceutical companies were set up as joint ventures with multinational pharmaceutical companies under licensed investment agreements with the Government of Egypt, under which the government owns 51 percent and the foreign firms own the remainder (Loudis and Rochat, 1977). The Chemical Industries Development Company (CID) was established prior to 1970 and was authorized by Schering AG (Germany) to tablet Schering oral contraceptives in three formulations: Anovlar, Primlovar, and Ginlovar. In 1970-71 the Wyeth Company (U.S.) entered into a partnership with the Nile Company to produce Ovral, and in 1974 Searle (U.S.) entered into a partnership with the Kahiro Pharmaceutical

Company to manufacture Ovulen-50 and Ovulen-1/50. These parastatal firms are allowed to distribute up to 75 percent of their production to commercial pharmacies (Fox et al., 1986).

The Chemical Industries Development Company is currently manufacturing Anovlar-1 and Anovlar-2 under its agreements with Schering. CID receives steroids and technical assistance from Schering as part of West German technical assistance to Egypt. While Schering does not have an agreement with CID to provide quality assurance checks, they do provide training and other support as requested by the Egyptian or German government.

CID has made requests to USAID/Cairo for assistance to increase its OC production capacity since 1981. The USAID/Cairo Mission is moving away from physical plant-type projects, however, as part of an emphasis on increasing the proportion of A.I.D. family planning funds that are going for direct service delivery. In addition to increasing production capacity, CID may need assistance to upgrade its OC packaging. USAID/Cairo Mission staff recently reported that there may be problems with the CID blister packages for Anovlar, which are 21-day rather than 28. This packaging format is viewed as causing problems with compliance and it is hoped that the format can be changed. At the time of this report, it was unclear how CID was going to proceed in seeking assistance for its OC production.

While the Government of Egypt has relied exclusively on local production of OCs for its needs, the Family of the Future program has been relying on A.I.D.-donated OCs, which include the low-dose pill, Norminest Fe. FOF is interested in expanding further and, according to Family Planning Logistics Management (FPLM), there is strong interest in introducing an additional OC, Norquest, through FOF. According to Egypt Mission staff, Norquest is viewed as an important alternative to Norminest Fe, which has been found to have a high rate of breakthrough bleeding.

If USAID/Cairo were to consider providing technical assistance to upgrade and expand CID's OC production, it should also confer with representatives of FOF to assess the feasibility of purchasing locally manufactured OCs for use in the FOF program. Assuming that locally produced OCs could meet the quality, formulation, and packaging requirements to be marketed by FOF, long-term

savings could result for A.I.D. in reduced foreign exchange requirements for OC procurement.

Local Production of IUDs in Egypt

Early Production of Lippes Loops IUDs: As of 1977, Lippes Loops were being manufactured at an estimated annual rate of 100,000 units using molds supplied by the Ford Foundation. At that time there were allegations that these IUDs were of poor quality. The estimated cost of these IUDs to the Government of Egypt was only US$0.021. The government provided the Loops without charge to physicians and paid them a fee for each Lippes Loop inserted (Loudis and Rochat, 1977). Since 1985 local Lippes Loop production has ceased and a study conducted by PIACT in 1987 found that Egypt currently has no indigenous local production of IUDs.

Current IUD Production Efforts: The Government of Egypt has expressed interest in producing all contraceptives locally (UNFPA, 1985, page 44). As the use of Copper T devices was expanding, in 1987 the government requested UNFPA assistance to assess the feasibility of IUD production in Egypt. A prefeasibility fact-finding mission was conducted by PIACT in fall 1987. During this mission, discussions were held with the Egyptian Ministry of Health, donors, service delivery agencies, warehousing and distribution groups, current manufacturers of pharmaceutical and medical devices, and potential providers of raw materials.

The mission assessed current and projected demand estimates and established the presence of a generic capability, not limited to specific companies, for the manufacture of individually packaged, sterile IUDs according to internationally accepted standards for good manufacturing practices. In addition, the mission established which raw materials were locally available in order that preliminary budgeting could include materials needed for importation. The mission concluded that local production was very likely to be feasible despite the fact that initial Government of Egypt estimates of demand for IUDs had proven to be somewhat inflated.

In 1988 the Government of Egypt and UNFPA requested that PIACT conduct a feasibility study to provide an in-depth technical and financial review of issues related to local IUD production. This review involved an assessment of both public and private sector manufacturers. Three companies were identified for

detailed review of technical and management resources. Using information supplied by these companies, the cost of manufacturing the Copper T 380A IUD was estimated, with the proviso that these estimates were not to be interpreted as bids by the potential suppliers. Of the three companies interviewed, two were private sector and one was state owned.

Financial analysis of data provided by the three firms showed per unit costs for Copper T 380A IUDs, assuming production of one million a year, ranging from US$0.44 to US$0.56.[10] As explained in the discussion of cost per unit in Section IV, it is important not to assume that these estimated per unit costs, which are approximately half of the current A.I.D. price, would be this low when a final agreement is signed. The total fixed investments ranged from a high of US$2.95 million for the government-owned facility (which had to include the cost of building a new structure) to a low of US$1.78 million. Annual estimated production costs ranged from US$488,236 to a low of US$365,255. These results suggest that, compared to imported IUDs, the local production of IUDs would be no more expensive, and of similar quality, but would require dramatically less foreign exchange.

The feasibility study concluded that local production of the Copper T 380A was technically and financially feasible. The Government of Egypt requested that the Copper T 380A be produced in order to maintain continuity with the current program method. The study recommended implementation of local production of IUDs in Egypt with the following stipulations:

1. that one of the prime candidate manufacturers identified during the feasibility study be chosen by the Ministry of Health and given a letter of intent from the Ministry for the purchase of IUDs for a period of not less than five years;
2. that duty-free importation of raw materials be allowed;
3. that regulatory approvals and quality assurance monitoring be arranged and coordinated by the National Organization for Drug Control and Research (NODCAR).

Because the current policy of Egypt allows the import of contraceptives duty free, it was deemed reasonable to assume that supplies for contraceptive production could also be imported without duty. In order to assure the highest quality for IUDs manufactured in Egypt, it was agreed that the Ministry of

Health would enter into a licensing agreement with the developer of the IUD to manufacture the device.

If A.I.D. were able to purchase IUDs manufactured in Egypt, significant savings in foreign exchange might result. The total cost of imported materials is a relatively small proportion of the projected annual production cost for IUDs. Assuming that cost recovery in Egypt's predominantly private sector IUD distribution system can cover local currency costs, the foreign exchange required for an annual production of one million IUDs is only US$80,000 for essential imported raw materials. Hence, local currency can cover virtually all of the costs for the locally made IUDs. Ignoring capital investment costs and assuming the current A.I.D. central procurement and shipping cost of approximately US$1 each, the annual savings in foreign exchange for one million IUDs would be over US$900,000 annually.

Despite a formal decision by the Ministry of Health to proceed with the local production of the Copper T 380A, there have been delays resulting from internal discussions between various government ministries. It is uncertain as to whether a final commitment will be made to manufacture IUDs in the near future.

Conclusions Regarding Local Production in Egypt

General

- The Government of Egypt has a long tradition of and interest in local contraceptive production that should be assisted wherever feasible. Egypt has already established OC production and may soon acquire IUD production capability. In view of the current levels of condom sales and distribution, which do not warrant full-scale production, consideration should be given to providing assistance to develop local condom screening and primary packaging capability.
- Egypt's strong private sector market for contraceptives provides long-term potential for income generation to sustain local production. While the precedent of using income from A.I.D.-donated commodities to pay for distribution costs is valuable, it should be viewed as a first step toward eventually recovering the full cost of contraceptive production. This will require efforts both to increase revenues from sales and possibly to reduce foreign exchange costs of contraceptives through local production.

Oral contraceptives

- Attempts should be made to reassess the current status of OC production in Egypt and the desirability of USAID/Cairo support for upgrading and expanding this production.

IUDs

- Continued assistance should be provided to the medical devices regulatory system. See Appendix B for further information on current A.I.D./FDA assistance.[11]
- Assuming current UNFPA efforts toward local production of IUDs are successful, A.I.D. should consult with the FOF program to assess a willingness for these locally produced IUDs to be substituted for A.I.D.-donated IUDs.

VIII. Private Sector Electronic Screening[12] and Packaging of Condoms In Mexico: The Experience of PROFAM-Mexico

Local Electronic Screening & Packaging of Condoms: Technical and Cost Issues

Intermediate levels of production, which can have the advantages of requiring less capital expense and/or technical expertise, should be considered for countries without adequate volume of demand to warrant full-scale manufacturing. With condoms, for example, the main capital investment in full-scale condom manufacture is for latex dipping equipment and supporting factory infrastructure. Where capital is not available or where local demand is too low to warrant full-scale manufacture, intermediate production involving packaging and/or electronic screening to ensure condom quality may be considered. As electronic screening and packaging of condoms are the labor intensive elements of the total condom production cycle, the importation of bulk, untested condoms can be a feasible option in countries with low labor costs.

Mexico: Selected Data

Population Projections
1989: 86.7 million
2000: 107.2 million

Contraceptive Prevalence (1987)
Total: 52.7 percent
Condoms: 1.9 percent
IUDs: 10.2 percent
OCs: 9.7 percent

Number of Users (1987)
Condoms: 219,000
IUDs: 1,177,000
OCs: 1,120,000

A.I.D. Commodity Costs (FY 1986-1989)
Condoms: US$2.4 million
IUDs: US$1.3 million
OCs: US$2.5 million

Local Production Status
Condoms: Private/Intermediate
IUDs: Private Local
OCs: Multinational

At least two options for local condom packaging and/or electronic screening can be considered by local private sector or parastatal firms:

Option 1. Boxing of imported, tested, lubricated, primary packaged condoms. This operation involves minimal capital investment and can be conducted on leased premises using staff seated at tables filling boxes manually. It is essential that such an operation have a quality assurance laboratory to confirm that imported condoms meet all required standards. A variety of arrangements can be made for packaging, ranging from an entirely manual operation for folding,

gluing, and filling boxes with a staff of some thirty people, to full automation where boxes are machine assembled and filled.

This local boxing arrangement involves relatively low risks in that it is not a specialized installation, and the only major financial risk would be the purchase of furniture and fittings. Options for reducing or increasing capacity could be accommodated easily by increasing the number of shifts.

Option 2. Electronic screening, lubrication, primary packaging, and consumer boxing of bulk unscreened condoms.

The packaging and boxing of unscreened, bulk products would have higher value added than boxing screened, packaged products. There is added risk, however, due to the transport of bulk condoms before or after screening. Unpackaged condoms may be vulnerable to deterioration during shipment (Free, Hutchings, Lubis et al., 1986). While the total investment in the first year is higher with Option 2, the annual operating costs are almost exactly the same. The decrease in condom costs is compensated for by increased labor costs and the cost of foil and lubricant. This means that, although the overall cost per unit is about the same,[13] the amount of foreign exchange required is significantly reduced.

Local packaging permits local private sector entrepreneurs to minimize their investment and foreign exchange requirements while developing a market for their products. As the market expands, they can increase the complexity of the packaging operation in stages. However, relying on imported, bulk-shipped condoms has disadvantages, in that this type of local packaging operation is vulnerable should it receive condom shipments with high reject rates from electronic screening. Also, some condom manufacturers may be reluctant to supply bulk condoms so as to avoid disclosure of their products' reject rates. Other condom manufacturers may wish to retain ultimate control over their product quality, and therefore may refuse to allow other firms to test and package their products. The success of any local condom packaging operation will depend on the local company's ability to enter into an agreement with a major condom manufacturer for the long-term supply of the bulk product.

The Experience of PROFAM-Mexico

Mexico has had various types of private sector production of condoms, IUDs, and OCs for well over ten years. Private local and multinational firms manufacture OCs, two firms are involved in condom manufacture (one via

manual dipping, the other via electronic screening and packaging of imported condoms), and one firm is manufacturing an IUD, the Copper T 220C. The option of local electronic screening and primary packaging of condoms has been carried out successfully for ten years in Mexico by the private sector social marketing firm, PROFAM-Mexico. This firm began as an A.I.D.-funded Population Services International contraceptive social marketing venture in 1979 and received A.I.D. assistance for three and a half years, ending in 1982. Currently PROFAM-Mexico sells contraceptives, including a variety of condoms, to wholesalers who in turn sell these products to virtually all of Mexico's pharmacies. The following history of PROFAM-Mexico is an instructive example of how intermediate production can succeed.

1979: PROFAM-Mexico began packaging in 1979 with the purchase of bulk, prepackaged, electronically tested condoms from the United States. Upon arrival in Mexico these condoms were removed from their packaging and then repacked into PROFAM-Mexico's packaging.

1980: In 1980 PROFAM-Mexico acquired electronic screening machines which permitted the purchase of bulk, unscreened condoms.[14] At the time PROFAM-Mexico began local electronic screening, there was a 40 percent difference in the cost of screened condoms versus unscreened. Today the difference is only 25 percent.

1985: In 1985 the Mexican government stopped the importation of foreign condoms, due to the supposed availability of Mexican-made condoms. Unfortunately, these locally made condoms were substandard: in some cases a 50 percent reject rate was found. Later that year, the Mexican government responded to petitions that the local supply was not adequate and permitted importation with a 45 percent ad valorem to the invoice price. At this time PROFAM-Mexico imported bulk, unscreened condoms from the United States.[15]

1987: With the advent of AIDS awareness, between late 1987 and early 1988 an acute demand for condoms made access to high-quality, low-priced condoms quite difficult for PROFAM-Mexico. PROFAM-Mexico found it necessary to seek condoms from a variety of sources, including China, Korea, and the United States. Depending on the supplier, electronic screening reject rates varied from a low of 4 to 5 percent to a high of 18 percent.

Late 1988 to present: The Mexican government's ad valorem duty on condoms was lowered in 1988 from 45 percent to 25 percent and in 1989 from 25 percent to 15 percent. As the condom market has responded to the demand stemming from concerns regarding AIDS, PROFAM-Mexico has been able to secure contracts from U.S. manufacturers for both screened and unscreened bulk condoms.

Conclusions

Bulk Shipping

The bulk shipment of both screened and unscreened condoms is feasible. PROFAM-Mexico has not had any difficulty with bulk shipments of condoms, with the exception of an initial consignment of condoms shipped with inadequate talcum powder and hence, an excessive rate of adhesions. It is important to stress that PROFAM-Mexico has fairly close physical proximity to its main sources of condoms in the U.S. Other countries, which require long shipping times through tropical regions, should be able to avoid problems if they address the technical issues surrounding the shipment of bulk, unpackaged condoms.[16]

Financial Implications

The inexpensive labor costs in Mexico have meant that it is financially advantageous to carry out local testing and packaging. This has been true despite substantial duties imposed on imported condoms by the Mexican government, formerly 45 percent and currently 15 percent. The only exception to this is, in very rare instances, some manufacturers have given PROFAM-Mexico low prices for bulk, screened condoms that were only 10 percent more expensive than unscreened condoms. When the price difference is this narrow it makes economic sense to buy condoms that have already been screened.

A.I.D.'s Role

Local packaging can be an effective way to make condoms available for developing nations that do not have the volume of demand to warrant full-scale condom manufacture. For nations with low labor costs and limited foreign exchange, this is an option that A.I.D. may find worth pursuing.

IX. A.I.D. Office Of Health Case Study for ORS in Ghana

Background and Need for Oral Rehydration Salts

Recently progress has been made in the development of private sector production of oral rehydration salts (ORS) in Ghana. This program, part of the work of Project SUPPORT, funded by Science and Technology/Health/A.I.D., provides examples of useful innovations in financing arrangements and interagency cooperation that may have practical implications for the local production of contraceptives.

Ghana has an estimated infant mortality rate of 95 per 1000, of which a significant proportion is attributed to diarrheal diseases. While estimates of the need for ORS sachets ranged as high as 10 million sachets a year, it was estimated that less than 1 million sachets were consumed annually (Project SUPPORT, April 1988; Green 1987). Despite large donations of one-liter ORS sachets by UNICEF, distribution was quite restricted. Given the limited availability of ORS sachets through the Ghana Ministry of Health and given the low proportion of children at risk who had access to Ministry services, it was concluded that the private sector could play a useful role in manufacturing and marketing ORS.

Selection of a Local Manufacturer

An assessment of prospective manufacturers focused on those with the ability to:
(1) manufacture ORS according to WHO Good Manufacturing Practices;
(2) promote and distribute products widely through the private sector; and
(3) were financially solvent and able to undertake the costs of ORS production without impairing their financial condition. Based on these three main criteria, a company was selected that not only had the required technical expertise, but was also responsible for a USAID Mission-funded project for contraceptive social marketing and had great potential to distribute ORS. The company had both an unused production capacity and a network of experienced sales people working through pharmacists, chemical sellers, private medical clinics, midwives, supermarkets, and shops. The linkage of the ORS manufacturer with a USAID-funded social marketing program promises to improve the impact of the Ghana USAID Mission investment in social marketing.

Financial and Organizational Arrangements

Ghana has very limited access to foreign exchange. In order to pay for the costs for production and packaging equipment, a quality control laboratory, and improvements in the factory to comply with WHO Good Practices in the Manufacture and Quality Control of Drugs requirements, a direct loan of approximately $100,000 was made in U.S. dollars. This is being paid back in local currency with a 10 percent annual interest rate. The repayment is being used to pay for ORS promotional activities within the social marketing program. In addition to the direct loan, a one-time grant was made to the manufacturer to cover the costs of launching and advertising the new ORS product.

The success of this project is the result of agreements among several organizations: the Ghana Ministry of Health, UNICEF, A.I.D., Project SUPPORT, and the manufacturer, Danafco. To ensure a long-term supply of raw materials, a creative agreement was developed wherein UNICEF (using funds provided by the Ghana USAID Mission) will supply raw materials for the manufacture of ORS to the Government of Ghana Ministry of Health, which will, in turn, supply them to the manufacturer for use in producing the ORS. The local manufacturing firm will pay for these raw materials by supplying the Ministry of Health of Ghana with an amount of finished product equal to the value of the raw materials it received. The production in excess of the government's requirement will be sold in the private sector through the Ghana Social Marketing Program (GSMP). UNICEF has special expertise with respect to obtaining the raw materials for ORS manufacture; this ensures very low costs through global procurement arrangements.

Prospects for Sustainability

The long-term success of Project SUPPORT's Ghana program hinges on access to raw materials and an assurance of an adequate private sector demand. The current arrangements are sufficient for the manufacturer to produce enough high-quality ORS to meet the needs of both the Ministry of Health and the private sector. While UNICEF has agreed to provide the raw materials through 1990, eventually pricing within the private sector must increase to a level that will cover raw materials costs, costs of production, and debt repayment, as well as manufacturer profit. Since the fall of 1988 the manufacturer has implemented production under careful quality assurance review. Given the effective marketing infrastructure of the GSMP and indications of an improving economy, the prospects for sustaining the production of ORS appear favorable.

In Uganda, a program modeled after the Ghana Project SUPPORT experience is now under way, with production anticipated to begin in mid-1990. This project also involves the Ministry of Health, UNICEF, A.I.D., Project SUPPORT, and a local pharmaceutical company. As in the Ghana project, UNICEF will provide the raw materials for the ORS sachets and the local manufacturer will pay for these raw materials with an amount of sachets equal to the cost of the raw materials.

Quality Assurance and Good Manufacturing Practices

An important component of the Uganda project is a provision for accountability on the part of the local manufacturer to comply with WHO GMPs. This includes a stipulation that the local manufacturer will submit to an annual quality assurance audit, to be conducted by the executing agency, PATH, to document compliance. This type of auditing requirement can be highly sensitive and must be negotiated at the beginning of a project rather than after production has started. While this type of audit arrangement may work short term, it must be handled carefully to avoid eliminating incentive and motivation to manufacture in accordance with GMPs after the project ends. Ideally the local national agency responsible for regulating essential drugs should have responsibility for similar audit activity without any need for outside review. Quality assurance audits can be costly and, if international audits are to be continued after the project ends, funding mechanisms must be identified.

X. Findings, Conclusions, and Recommendations

Findings from Country Case Studies

The case studies presented in this paper illustrate a wide variety of approaches to assist the implementation of local production of contraceptives by both private and public sectors.

1. Between 1985 and 1991, Bangladesh, Egypt, and India will have received an estimated combined total of $90.5 million in A.I.D.-procured contraceptives: 1.4 billion condoms, over 15 million IUDs, and over 64 million cycles of OCs (See Table 5, Section V).

2. In these three countries there are major new projects currently under way for large-scale local production of contraceptives. Both private sector and government-owned manufacturing firms are planning for production of contraceptives. In Bangladesh, plans for the production of condoms have been strongly promoted by a private/public sector consortium while a parallel, all government sector condom facility has also been considered. In Egypt, a sequence of feasibility studies has recently found the local production of IUDs to be technically and financially feasible. Three qualified firms have been identified as potential manufacturers, one of which is government owned. Two parallel IUD production ventures are under way in India, one by a parastatal and the other by a private sector firm.

3. In all of the countries reviewed, a significant portion of capital investment and annual operating costs for the local production of contraceptives can be paid in local currency. To the extent that local currency requirements can be paid by the local government or by cost recovery programs, these reductions offer potential to reduce donor agency expenditures for contraceptive commodities. For example, A.I.D. will purchase 4.7 million IUDs for Egypt for the 1985-1991 period at a cost of over US$4.5 million. If purchased in the U.S. and donated to Egypt, the raw materials required to manufacture the same quantity of IUDs in Egypt would cost less than US$400,000.

4. Relative to estimated A.I.D. procurement costs for the period from 1985 through 1991, the capital investments required for local production are modest. An extreme example is Bangladesh. While over $51 million will have been spent by A.I.D. to provide 1.2 billion condoms for Bangladesh during this period, the total foreign exchange investment for establishing a condom manufacturing facility is significantly less, around US$5-8 million. The estimated costs for imported raw materials to manufacture 200 million condoms annually would be less than US$2.5 million dollars.

5. A.I.D. has received requests for assistance to develop local production capacity in Bangladesh, Egypt, and India and has been able to respond to some of these requests. Although not based on a defined policy, A.I.D. does have prior experience in supporting local production ventures.

6. In these three countries, large social marketing programs coexist with local production ventures. To varying degrees, all three countries rely on supplies of imported contraceptives donated at no cost to their family planning or social marketing programs. Some means are required to ensure that locally produced contraceptives are available to the social marketing programs at a cost that consumers can absorb, while at the same time making sure that local manufacture remains financially viable.

7. The local, electronic screening and primary packaging of condoms by PROFAM-Mexico is a practical example of an intermediate level of production in a country that has insufficient demand to warrant full-scale production. This approach significantly reduces the need for foreign exchange for importation of condoms and permits appropriate packaging for local marketing.

8. The use of innovative financial methods by Project SUPPORT to help private sector ORS production in Ghana is a model for how contraceptive production might be assisted. The barter of raw materials for finished products helps overcome the problem of limited foreign exchange in developing nations.

Conclusions

1. Currently, other than Bangladesh and Egypt, opportunities for A.I.D. to assist in establishing entirely new, full-scale private sector contraceptive production ventures in developing nations are limited. Most nations with adequate population size and contraceptive prevalence rates have local production facilities in place. See Table 6.

2. Compared to setting up new, full-scale facilities, there is wider scope for A.I.D.'s assistance to institute intermediate production or to upgrade and expand existing facilities of private sector and parastatal producers of contraceptives. Many of these facilities do not have sufficient capacity to serve national needs and some are deficient in quality. For example, local electronic screening and packaging of condoms may be feasible in Nigeria and Turkey, while opportunities for upgrading and/or expanding production may exist for OCs in Egypt and Indonesia, for IUDs in Pakistan, and for condoms and IUDs in Brazil. See Table 6.

3. Technical services provided by private organizations and U.S. government agencies (e.g., for training, feasibility assessment, management consultation, and regulatory systems) are a valuable resource that A.I.D. can use to assist private sector firms to initiate, upgrade, or expand local production of contraceptives. The review of the services available from a variety of U.S. government agencies demonstrates that there is ample precedent for technical assistance from these agencies to further the local production of contraceptives in developing countries (see Appendix B).

4. Substantial opportunities exist for A.I.D. to facilitate private sector local production consistent with a "Buy American" policy. These include the donation of U.S.-made manufacturing and quality assurance equipment, as well as the donation of raw materials or partially manufactured goods: e.g., unpackaged, untested condoms for local electronic screening and packaging operations.

Table 6: Selected Countries with Potential for A.I.D. Local Contraceptive Production Assistance Projects by Level of Assistance and Region

Level of Assistance	Region: Africa	Asia/NE	Latin America
Quality Assurance	Cameroon[a] Ethiopia[a] Ghana[a] Kenya[a] Nigeria[a] Zaire[a] Zimbabwe[a]	Bangladesh Egypt India Indonesia Pakistan Philippines Thailand Turkey	Brazil Haiti[a] Mexico Trinidad[a]
Intermediate Production	Cameroon Ghana Nigeria Zaire Zimbabwe	Bangladesh Egypt Pakistan Philippines Turkey	Mexico
Upgrade and Expansion		Bangladesh Egypt Indonesia Pakistan	Brazil Mexico
Full-Scale Initiative	Nigeria[b]	Bangladesh Egypt India[c]	

[a] Principally condom quality assurance
[b] Assumes regional market
[c] New projects well under way

Recommendations The following proposed A.I.D. options for facilitating private sector production of contraceptives in developing countries are arranged under four major headings: (1) Provide assistance to initiate, upgrade and/or expand local production facilities; (2) Provide assistance to upgrade national contraceptive quality oversight; (3) Establish a clearinghouse to handle requests for A.I.D. assistance with local contraceptive production; and (4) Coordinate with other agencies. In the recommendations made here, it is assumed that the required technical assistance can be accessed from private and U.S. government agencies through the mechanisms described in Appendix B.

1. <u>Provide assistance to initiate, upgrade and/or expand local contraceptive production facilities.</u>

   a. *Facilitate the transition from imported, donor-supplied contraceptives to locally produced contraceptives.*

   In countries where most or all contraceptives are distributed at subsidized or no cost to the user, the major obstacle to development of local production has been obtaining assurances that the locally produced product will be purchased for national programs (see Section VI regarding condom production in Bangladesh). Government authorities have been reluctant to commit to these purchases while donated commodities remain available. Mechanisms are required to effect a smooth and phased transition from imported donor supplies to locally made contraceptives, without an immediate drop (and in some cases a temporary increase) in the dollar value of foreign assistance to the implementing division of the host government. Accordingly, it is recommended that a transitional arrangement be negotiated with host governments in countries where local contraceptive manufacturing opportunities exist.

   Of the three main A.I.D. recipient case study countries for this paper, both Bangladesh (condoms and OCs) and Egypt (OCs) have private sector or private/public consortium plans for local manufacture. They may be candidates for this transition. India may also be receptive to some aspects of this approach for IUD production, although the projects are already well advanced. Additional countries with potential for this approach are Brazil (IUDs, condoms); Mexico (OCs); and Pakistan (IUDs, condoms). Other opportunities may arise when NORPLANT® (NORPLANT is a registered trademark of The Population Council) is approved by the U.S. Food and Drug Administration and can be

included in A.I.D. program scope. The suggested activities for A.I.D. to carry out to accomplish this transition are described below:

(1) **Assist government and private sector agencies in assessing alternative or supplementary contraceptive supply strategies.**

- *Review long- and short-term supply availability of donor-supplied and locally-produced contraceptives.*
- *Conduct marketing surveys of both public sector and private sector markets to provide updated information pertinent to an increased reliance on locally produced contraceptive methods.* These marketing surveys should identify opportunities for new method introduction and should include studies to examine appropriate pricing for both government and private sector contraceptives (Lewis and Kenney 1987; Schwartz et al. 1989). This should also include qualitative assessment of locally produced contraceptive products for consumer satisfaction. This would establish the requirements for changes in characteristics of specific brands of contraceptives, as well as improvements in packaging for improved compliance and/or marketing potential.
- *Develop a long-term supply strategy.* In addition to technical assistance from logistics experts from programs such as FPLM, the development of a long-term supply strategy should be coordinated with marketing and engineering representatives of parastatal and private sector contraceptive manufacturers as well as ministry of health and family planning officials and social marketing specialists. The supply strategy should specify priorities for the development of supplementary or alternative supplies for the future. Specific attention should be given to compatibility of existing private sector and parastatal contraceptive products with the program objectives of health, family planning, and social marketing programs.
- *Support prefeasibility studies.* Based on the recommendations of the above long-term supply strategy, the following types of prefeasibility studies by qualified short-term consultants may be required: review of local packaging options, review of options for expanding production of existing facilities, and a review of options for a new production facility. An example of this type of assistance is the 1982 India USAID Mission, which requested a review of OC and IUD manufacture in anticipation of expanded production (Lach, Bronnenkant, and Bronnenkant, 1982).

(2) **Provide technical assistance for local contraceptive production.** (This type of assistance should stem from a prefeasibility study based on a thorough review of supply options.)

- *Investigate locally available materials.* Support technical assistance to investigate local manufacturers and assess the quality of their materials; where appropriate, provide funds to establish or improve production, or reduce manufacturing costs of local materials. An example is the long-term technical assistance to improve the quality of latex production, such as by ADB in Chittagong, Bangladesh (Free/PIACT, 1982).
- *Support the upgrade of local packaging.* Support technology transfer to upgrade aspects of local packaging, from improving packaging designs and improving the quality and capacity of existing packaging facilities, to improving capabilities in carrying out product stability and shelf life studies.
- *Upgrade method presentations and formulations.* The persistent use of 21- and 22-day cycle pill packs in local production may be leading to problems in user compliance and demand. Based on a review of local conditions, efforts should be made to upgrade 21-pill cycle packaging to 28-day cycle formulations, regardless of whether they are produced by parastatal or private sector firms. India is in the process of introducing an upgraded OC packaging in its social marketing; the Egyptian parastatal, CID, may need assistance in upgrading their OC packaging.
- *Assist existing local contraceptive production facilities.* This includes renovations to ensure compliance with good manufacturing practices, occupational health and safety, and environmental protection. Technical assistance for assessment of current status of existing local production requires expert short-term consultants to conduct reviews of production facilities for good manufacturing practices, quality assurance systems, and quality control expertise, as well as reviews of occupational health and safety and environmental protection. Indonesia's parastatal OC production firm may be in need of this type of assistance.
- *Expand existing production facilities.* Assuming that high quality standards have been confirmed at a given facility, expansion of its existing capacity may be an option. The time and effort involved depends on the technologies existing in the factory and the extent to which they are utilized. While expansion could involve a straightforward doubling of production by using existing equipment for an additional shift, it can also

be a very long-term process that requires expert technical assistance through a sequence of prefeasibility and feasibility studies. In either case it has potential for considerable leverage from a one-time loan or grant. Examples of donor agency-supported expansions include India's parastatal, Hindustan Latex Ltd., which received one-time UNFPA and Japanese financial assistance of some US$8 million to increase production by 320 million condoms annually. Potential expansions of OC manufacturing have received varying degrees of attention in Egypt, where a request was made for A.I.D. assistance to Chemical Industries Development Co.; and in Bangladesh, where a recent request for assistance was made to the Canadian International Development Agency by Organon/Bangladesh (D. Vermette, personal communication, 1989).

- *Initiate new production facilities.* The prospects for this type of assistance are limited to only a few countries, such as condom production in Bangladesh and IUD production in India and Egypt (see Table 6). If regional cooperation can be achieved, local production of condoms should be considered in Africa, with Nigeria as a leading prospect. The arrangements for full-scale production are similar to those required for the expansion of an existing facility, only they would require much more time and resources.

(3) **Facilitate financial assistance.** There is a need for innovative financial arrangements to provide incentives for local private sector firms to undertake contraceptive production. Apart from direct grants, types of financial assistance may include:

- *reduced interest rates on loans from local banks to local producers;*
- *guarantees on loans from local banks to local producers;*
- *provision of direct loans to local producers.*

Alternative financial arrangements might include:

- *innovative exchanges of raw materials* supplied by the donor or by a third party, such as UNFPA or UNICEF, in return for a specified proportion of the local producer's output (see Project SUPPORT in Ghana described in Section IX);
- *agreements by a donor to purchase locally made contraceptives;* these arrangements might link the purchase price to the value of essential imported components. By making this type of purchase agreement contingent upon contraceptives meeting international standards, the donor agency has some control over the quality of locally made products.

Where the essential raw materials can be imported from the United States this type of arrangement would be consistent with a "Buy American" policy;

- *use of PL-480 grain funds to cover local currency costs* of upgrading or expanding local production (FDA assistance to the Egyptian government was initially funded in this manner);
- *sale of a developing country's debt* to a multinational pharmaceutical company at a discount; in return the multinational company has the opportunity to expand an existing joint venture to produce low-cost contraceptives at a lower-than-market investment cost (Bergsman and Edisis, 1988);
- *use, by a U.S. private voluntary agency, of the A.I.D. Debt for Development mechanism* to fund local costs of starting up a new project or expanding an existing firm (A.I.D., February 1989).

Financial assistance in the form of grants or loans may be needed for spare parts, new equipment, materials, building renovations, royalty payments for licensed technology, and other production costs. Often there is an acute shortage of foreign exchange for the importation of spare parts. Funding of spare parts provides practical assistance at relatively low cost in an area of major need.

(4) **Promote national policy.** The following are areas concerning national policy that could have significant impact on the feasibility of private sector local production.

- *Patent laws.* Greater protection of product patents in a country like India might improve chances of joint ventures with foreign firms. Multinational firms are reluctant to transfer patented technology to countries where patent protection is perceived to be weak. Current negotiations on proposed cooperative assistance by the India USAID Mission and Federal Drug Administration are being delayed over just these types of concerns.
- *Regulations for joint ventures involving contraceptives.* National regulations on such issues as the proportion of local equity in the venture may deter multinational investment from contraceptive manufacture. As an example, London Rubber Company Overseas formerly promoted licensing arrangements. This policy has been changed, in part due to requirements in many nations for levels of local ownership that make licensing arrangements undesirable.

- *Within-country tax laws.* Tax deductions should be considered for all private firms that manufacture contraceptives, regardless of whether this is all or part of what they produce. While India permits a 100 percent deduction of taxes on family planning donations made out of company profits, there is no tax relief in India for a company's manufacturing costs based on the fact that it manufactures contraceptives.
- *Tariffs and duties on imported finished contraceptives.* It is usually desirable to eliminate tariffs and duties in order to keep local prices as low as possible. This forces local producers to compete with the international market, which is essential in order to maintain lowest prices at the highest quality.
- *Import duties on raw materials and components used to manufacture contraceptives and on technical equipment used in manufacture of contraceptives.* This policy can have a dramatic impact on the local cost of contraceptives. In the case of a feasibility study in the Philippines, waiving of duties was estimated to reduce the unit cost of condoms by 33 percent (Mahoney, 1982). The Government of India has recently waived tariffs on machinery used to make contraceptives (Kuppuswamy, personal communication, 1989).

b. *Facilitate intermediate production (packaging and screening).*

In cases where economic feasibility for full-scale production is marginal or where the scale of need is insufficient to justify manufacturing, a local, value-added activity may be warranted. These local activities involve final processing and packaging of imported components or bulk goods. Capital costs and risks are much smaller than for full-scale production. Donor costs for commodities can be reduced and quality is more readily assured when compared to full-scale production projects. Most of the arrangements outlined above under Section 1.a. may be applied to this activity. At a later date, these activities can be expanded to full-scale production if the need changes, or economical, smaller-scale technologies become available. See Figure 5.

Local packaging permits and facilitates development of local package design. It is recommended that A.I.D. offer technical assistance in design and testing techniques for local promotional designs and instructional messages. Expertise is available through several A.I.D. contractors.

Figure 5: Current Status of Local Production for Bangladesh, Egypt, India, and Mexico by Contraceptive Method, 1990

Spectrum of Production:	A.I.D. Supplied Methods →	Quality Assurance Testing Capability →	Secondary Packaging of Imports →	Primary Packaging & Screening of Imports →	Full-scale Production
IUDs:	Bangladesh Egypt India Mexico	India Mexico	Egypt		Mexico
OCs:	Bangladesh Egypt Mexico	Bangladesh Egypt India Mexico	Bangladesh Egypt Mexico		Bangladesh Egypt India Mexico
Condoms:	Bangladesh Egypt Mexico	Bangladesh Egypt India Mexico	Bangladesh Egypt Mexico	Mexico	India

PATH 1/90

The option of local electronic screening and packaging of condoms should be given serious attention. As long as appropriate measures are taken to ensure the quality of bulk, unpackaged condoms is maintained during shipment, this is appropriate for countries that lack the market size to warrant full-scale condom production. A.I.D. should fund efforts to introduce this type of intermediate production and in this way create markets for the export of U.S. packaging and screening technology as well as large quantities of bulk, untested condoms. Prospective countries for local, electronic screening and primary packaging of condoms include Egypt, Nigeria, Pakistan, and Turkey. See Table 6.

c. *Ensure long-term involvement by technology suppliers.*

Turnkey projects for production of contraceptives have not been generally successful in the developing world. Projects involving experienced joint venture partners and providing some form of extended supervision should be favored. Arrangements should be encouraged in which the technology supplier agrees to buy back a percentage of surplus output. These buy-back arrangements have considerable advantage in ensuring quality.

A.I.D. could periodically offer consultants to assess local contraceptive manufacturing capabilities and make recommendations that will ensure economic viability and continued or expanded local supply of high quality products.

d. *Include parastatal or public/private partnerships.*

In some countries parastatal or public/private partnerships may represent the only available opportunity for local production. It is recommended that requests for assistance in upgrading and expanding contraceptive production be considered for these institutions, especially if they are licensed by a validated technology supplier, are operating competitively in the market economy, and if existing private manufacturers will not be disadvantaged.

2. <u>Provide assistance to upgrade national contraceptive quality oversight capabilities.</u>

Driven by the profit motive, commercial manufacturers can be efficient engines of productivity and are without equal in the large-scale production of uniform quality, low-cost consumer goods. However, they must operate within a regulatory oversight environment so that standards of quality remain immune from the continuing effort

to cut costs. Developing country governments are becoming more aware of the need for quality oversight.

U.S. leadership in drug and medical device regulatory oversight is well appreciated throughout the world. As described in Appendix B, private sector agencies as well as FDA, OSHA, NIOSH, and the Environmental Protection Agency (EPA) have established mechanisms or are open to providing international assistance. A.I.D. has an outstanding opportunity to address this need by marshalling the resources of private sector as well as other U.S. government agencies and acting as the "general contractor" for transfer of equipment, know-how, and training for regulatory review agencies, systems, and test laboratories. With appropriate overtures it seems likely that host governments will be very receptive to this form of assistance.

This type of assistance should be considered regardless of the prospects for local production of contraceptives. The following items may require short-term technical assistance from representatives of the Food and Drug Administration or other competent agencies involved with standards and regulation of contraceptive quality.

a. *Assist local authorities in reviewing and improving mechanisms for monitoring the quality of imported and locally made contraceptives.*
   Two good models for practical USAID Mission activity to strengthen the regulatory framework for quality control are (1) the UNFPA-funded project for the development of an Indian National Center for Technological Evaluation of IUDs and Tubal Rings; and (2) the proposed Government of India/USAID/Delhi Mission/Government of Japan-supported project for quality control of health technologies.

b. *Assist local regulatory groups in reviewing local standards for contraceptive quality for consistency with internationally accepted standards.*

c. *Assess existing protocols and equipment for in-process and final testing of contraceptives.*

d. *In cooperation with local regulatory authorities, provide for training and assistance to:*
   (1) update analytical laboratories with trained personnel equipped to carry out nationwide quality assurance activities; (2) ensure adequate quality assurance training, guidance, and oversight is available to all private and public firms

producing contraceptives and provide analytical instruments to individual factories.

3. **Establish a clearinghouse for requests for A.I.D. assistance.**

Over the last 15 years A.I.D. has accumulated a substantial amount of experience in the support of local contraceptive production ventures. Should an overall strategy to support local production activities be articulated by A.I.D., a great deal more assistance might be provided. As part of a strategy to facilitate private sector and parastatal activities for local contraceptive production, it is recommended that A.I.D. set up a clearinghouse for requests for A.I.D. assistance relating to this area. This clearinghouse function could include initial screening of requests and project formulation where appropriate. An A.I.D.-supported clearinghouse would have to be up-to-date on local production ventures supported by other donor agencies.

4. **Coordinate with other agencies.**

Other international agencies involved in or considering assistance for quality assurance and/or local production of contraceptives include the United Nations Population Fund, the United Nations Development Program, the WHO Global Programme on AIDS, the WHO Special Programme of Research Development and Research Training in Human Reproduction, and the World Bank. Other bilateral agencies are also involved in this form of assistance (Japan International Co-operation Agency. Australian International Development Assistance Bureau, Canadian International Development Agency, Danish International Development Agency, Finnish International Development Agency). Some form of surveillance or coordination is essential in order to make the best use of available global resources. It is recommended that A.I.D. support the development of communication networks with other agencies operating in A.I.D. host countries with a view to project review, joint (multi- or bilateral) project development, mutual project facilitation, and optimum allocation of resources. In view of the diversity of interests and experience in this area, consideration should be given to the eventual establishment of a donor-wide international clearinghouse for local production activities. An A.I.D.-supported clearinghouse could be viewed as a first step in this direction.

XI. Endnotes and References

Endnotes

1. In this study, only the major reversible methods of contraception are assessed. Vaginal foaming tablets, injectables (DMPA, NET EN) and NORPLANT® are not discussed, as they are either not currently FDA-approved or have relatively little impact on contraceptive prevalence.

2. USAID *Highlights* Vol. 6, No. 4, Fall 1989.

3. Policy Determination N14, June 1986, in PDPR/PPC/USAID, September 1987; and USAID, April 1989.

4. A Class III medical device is one that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user. According to FDA regulations, a production facility for these types of devices requires a pre-approval inspection to assure compliance with Good Manufacturing Practices for Medical Devices.

5. While the term, "electronic testing" is common, "electronic screening" is used here to emphasize the quality control and quality assurance systems required for modern condom manufacture.

6. This is illustrated by a hypothetical comparison of annual A.I.D. purchase costs vs. potential annual savings through local production. This comparison assumes that the donor agency pays for all annual production costs that require foreign exchange, that 60 percent of annual production costs are paid in local currency, and that this local currency is paid either by the local government or through cost recovery from family planning clients. It also assumes that annual production costs are at the top of the ranges indicated in Table 1; that production is at minimum annual volumes, as shown in Table 1, of 1 million IUDs, 15 million cycles of OCs, and 70 million condoms, and the A.I.D. commodity purchase cost for the equivalent of one year's production volume is based, conservatively, on a price of $0.95 per IUD, $0.10 per cycle of OCs, and $0.03 per condom. The minimum annual savings arrived at in this comparison are $0.65 million for IUDs, $0.7 million for OCs, and $1.6 million for condoms. These estimates are minimum estimates in that local currency is likely to cover more than 60 percent of total annual production costs, annual production costs are likely to be lower than assumed for this figure, and procurement costs to A.I.D. may be higher.

7. See Chafetz and Parrott/ISTI (January 1987), a USAID-sponsored OC feasibility study in Zimbabwe.

8. Data sources: Family Planning Logistics Management Project.

9. For reasons beyond the scope of this paper, this projection assumed the number of condoms required for one couple year of protection (CYP) in Bangladesh was 180. This has since been revised downward (USAID, FPLM/JSI, November 1988, page 59).

10. In this analysis, fixed investment refers to land and site preparation, buildings and civil works, plant and equipment technology, and working capital. It is assumed that a lump sum fee will be paid to the technology supplier and that the fee would be incorporated into the

manufacturer's fixed capital assets according to prevailing law. This accounting practice is considered standard according to the United Nations Industrial Development Organization. If a royalty payment were part of the agreement, the royalties would not be capitalized but would be included as a cost of production. The projection in this study assumed a royalty-free license (PIACT, 1988).

11. A related quality assurance effort supported by the Egypt USAID Mission is currently under way with PIACT providing technical assistance and equipment to establish a condom quality assurance laboratory for the Family of the Future program.

12. See endnote 5.

13. A feasibility assessment for condom production in Turkey estimated the cost per unit with Option 1 to be $0.0262, of which 92 percent would have to be paid in foreign exchange. With Option 2 the cost per unit was estimated at $0.0267, of which 62.2 percent would have to be paid in foreign exchange. These estimates were made under the assumptions of purchasing land and a building, and an annual production of 50 million units per year. These estimates are highly dependent on the date the estimate was made, as well as local conditions and circumstances.

14. The testing machines were purchased used from the bulk supplier, which assured that the testing machines were compatible with the variety of condoms imported. The funds used to purchase these machines were from PROFAM.

15. At that time there were two local manufacturers of condoms in Mexico, who both relied on very low technology processes that were not obtained from internationally reputed condom manufacturers, and could not meet international quality standards (de la Macorra, personal communication, June 1989; Free and Sebastian, March 1986.)

16. For example, requiring the supplier to package the bulk condoms in reasonably small quantities in opaque plastic bags with sufficient talcum powder to minimize adhesions.

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Framework for Assessing Options for Local Production

Assessing technical and economic feasibility

As outlined by Sherris and Perkin (1988), the decision to undertake local production requires a careful review of the following areas:

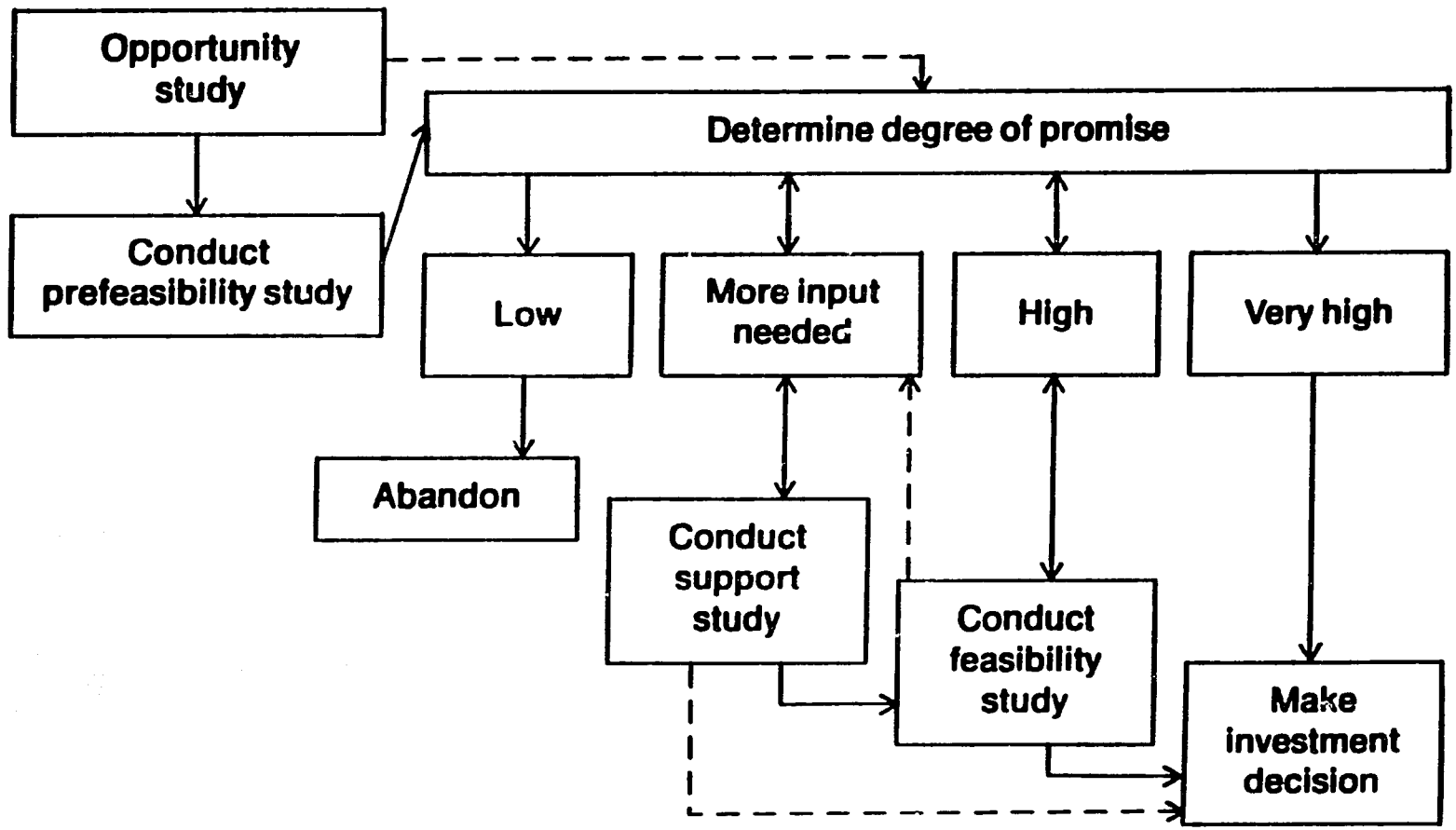
- Assessment of long-term demand for a given method.
- Assessment of in-country technical capability specific to the product under consideration.
- Assessment of financial feasibility.
- Review of the degree of success of similar in-country projects.
- Assessment of the institutional capability to continually monitor product quality.

The experience of PATH and other agencies (e.g., UNIDO, 1978) supports the concept of a sequence of progressively more detailed studies leading up to the final determination as to the feasibility of local production. Some of the steps shown in Figure 6, Decision Pathways for Investment in Industrial Projects, are discussed below. These steps are not meant to be a rigid model: in practice they may be combined or certain aspects completed in a different sequence.

1. **Opportunity study**

   The process should be initiated with a brief fact-finding study to sound out as many related agencies as possible: local government development planners, health and family planning officials, private sector firms and entrepreneurs, multinational pharmaceutical companies interested in joint ventures, and multilateral and bilateral donors. This initial study should strive to include all concerned parties as soon as possible in the evaluation of the proposal. The assessment of long-term demand requires accurate demographic indices of contraceptive use for specific methods and a sober appraisal of institutions for contraceptive distribution and promotion. There should be a consensus regarding the minimum projected demand for the contraceptive among all parties consulted. Often this initial study suffices to rule out the option of local production and, in turn, minimizes time and expense invested.

Figure 6: Decision Pathways for Investment in Industrial Projects



2. **Prefeasibility study**

This type of study assumes a high degree of promise and requires a substantial budget. Financial, manufacturing, and family planning program experts should review existing and future demand for the specific method in question. They should also review existing support systems, essential materials and chemicals, survey existing manufacturers of related products, and review potential financial arrangements. The financial review should include local, private capital, and local government, as well as international private and governmental sector loan and grant sources. At this stage it is critical that there be: (1) a consensus among all leading organizations concerning the desirability of local production of a specific type of method; (2) a clearly feasible mechanism for required foreign exchange and local currency funding, both for the capital cost and for the annual production costs of the output of the proposed facility; and (3) clear commitments for long-term purchase of the contraceptive product. This is especially important if the local government is the main prospective buyer for the product.

3. **Feasibility study**

Technical and financial assessment: This study must make detailed assessments of potential manufacturers and obtain refined technical and financial information from these manufacturers concerning estimated capital and manufacturing costs. The study must reconfirm the accuracy of demand assessments, which can fluctuate rapidly with changes in government policy and program objectives regarding the national profile of contraceptive use. It must also make a detailed assessment of local technical expertise specific to the product considered. The technical assessment is an essential precursor to the financial assessment. In addition, the study must confirm the prospects for sufficient political stability for the long-term success of the project. The study must establish the feasibility of all required licensing and importation of essential materials not available locally, as well as confirm arrangements for institutional review of quality assurance. Consideration should be made of the potential for exports to offset an inadequate domestic market. Government offers to impose tariff protection for local production should not be considered, as this may inflate local costs of contraceptives above those currently available. In summary, the study should provide key agencies all the required information to make a decision

to proceed with the production and to make a final choice as to the manufacturer of the contraceptive method and the supplier of technology.

Impact on existing programs: There must be a determination of the impact local production will have on donor-supported programs. For example a social marketing or community based distribution program may be unwilling to accept locally made products to replace donor-supplied items. The cultural norms of given countries may work for or against locally made products. National leaders may want locally made products, while consumers may prefer imports. Locally made products of comparable quality to centrally procured imports may be much more difficult to market simply because the primary packaging is less appealing to local consumers. In some cases the rationale for expanding local production is the hope of providing an alternative supply of contraceptives for a social marketing program currently supported by donated commodities. In such a situation the feasibility assessment should have the full involvement and support of ongoing social marketing program managers.

Private sector contraceptive technology transfer

Based on PATH's experience in a variety of developing nations (see Appendix B, Part 1), certain steps (which may occur in this order or in varying sequences) have been identified in introducing local contraceptive production within the private sector.

1. **Identifying local proponents**

   Local proponent businesses should have a record of innovation and access to financing at high quality banks. These businesses should be sound financially and able to provide pro formas to show how they will be able to absorb this new project and remain solvent. Ideally these companies should make products that local residents like and trust. These companies should also have a good relationship with the government and with the Ministry of Health.

   It is less important for the companies to have experience in the manufacture of a given contraceptive than it is for the companies to have a successful track record in establishing manufacture of products using technologies that are relevant to the product under consideration and/or new to the manufacturer. The choice of which companies to visit should be as objective as possible. Local politics may exclude visits to the most

promising manufacturers. Competing local interests may make it difficult to readily identify the most likely manufacturers. Where possible, independent sources of information should be used (such as a local chamber of commerce) instead of sole reliance on recommendations by local officials.

An essential criterion for evaluating a local proponent is that, once the idea is presented, the company develops an enthusiasm for the project greater than that of the donor agency. If a company has to be repeatedly convinced of the attractiveness of the project, alternative companies should be contacted.

2. **Identifying sources of technology**

Depending on the country and the specific method of contraception, a variety of technology suppliers must be considered. If this identification of sources is being made by a private company without help from an executing agency experienced in local production, this may involve a lengthy set of tours of supplier production facilities to confirm their institutional and technical capability.

3. **Bringing local proponents together with the sources of technology**

The proponents and technology suppliers should be mutually convinced of each other's capability to meet the requirements asked of them. While the private company usually has the ultimate say as to the source of technology to select, in certain situations the donor agency or local government agency may be making the determination as to which private-sector firm will undertake production. In these situations, the technology suppliers may have important insights as to which firm is most appropriate.

4. **Arranging for financing**

Capital for local production is available in many developing countries. There are often, however, constraints on how this capital can be made available: interest rates may be too high; the maximum term may be too short; collateral requirements may be unavailable; loans in U.S. currency may not be available. The donor agency must be able to provide assistance to overcome these obstacles through a variety of approaches, including lending at below-market terms, providing loan guarantees, or making outright grants for the purchase of technology.

Access to Technical Assistance for Local Production

Part 1 of this appendix provides information on services available from private nonprofit and for-profit agencies. Part 2 provides detailed information on what services are available from U.S. government agencies and how these services can be accessed by A.I.D.

Part 1. How A.I.D. Can Involve Nongovernmental Agencies in the Local Production of Contraceptives

There are a variety of agencies that have expertise related to local production of contraceptives. All of the agencies mentioned in this appendix have had experience providing technical assistance to non-U.S. pharmaceutical manufacturers.

I. For-Profit Agencies

The following organizations are examples of for-profit agencies that provide information, training, and on-site audits pertaining to regulatory, quality assurance, and good manufacturing practices issues for pharmaceuticals and medical devices. A private sector contacts list follows.

Pharmaceutical and Medical Device Manufacturers

Major pharmaceutical and medical device manufacturers have provided the services of senior experts to assist developing country projects for local production. This assistance may occasionally be provided on a case by case basis, often as a professional courtesy at below prevailing private sector consulting fee rates. This avenue should not be overlooked as a source of short term assistance for local production for both private and parastatal manufacturers.

The Center for Professional Advancement's Institute for Applied Pharmaceutical Sciences

The Institute is a division of the Center that provides continuing technical education, short (two to three day) courses, and advanced seminars for professionals in the pharmaceutical, medical device, cosmetic, and allied industries. The Institute's courses, available for U.S. and international participants, are held in New Jersey. Fluent English is required of all course participants. The Center also offers its courses on an "In-Plant" (on-site) basis.

The GMP Institute

The GMP Institute provides GMP compliance training and consulting services to the food, drug, medical device, and cosmetic industries. The Institute focuses on GMP auditing and training and has worked

extensively with U.S. pharmaceutical manufacturers; the Institute also has provided several training courses for non-U.S. manufacturers.

Interpharm

Interpharm Group publishes and distributes books and booklets on health-related topics and makes available other government source documentation. It can perform health-care manufacturing facility planning, validation activities, and quality/GMP audits worldwide.

II. Nonprofit Agencies

Philadelphia College of Pharmacy and Science

This is one of several U.S. academic institutions that have highly qualified experts who can occasionally provide technical assistance or assist in short-term training programs for visiting foreign technical staff (see private sector contacts lists).

Program for Appropriate Technology in Health (PATH) and
Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

PATH and its implementation arm for contraceptive-related projects, PIACT, have over ten years of experience in providing assistance to countries considering new contraceptive products and supply options. PATH projects have been carried out or are in progress in numerous countries, including Bangladesh, China, Cuba, Egypt, Indonesia, Mexico, the Philippines, Thailand, Turkey, and Vietnam. PATH has set up quality assurance procedures for condoms and IUDs. To assess the availability of resources to locally produce one or more contraceptive products, PATH has recently carried out local production fact-finding, prefeasibility, and feasibility studies in Bangladesh, Egypt, India, and Turkey. PATH has provided loan guarantees and loans to both private and government agencies planning or implementing local production projects. PATH has helped to build factories to produce OCs, condoms, IUDs, and injectables and currently is involved in assistance to over 12 different factory sites.

University of Iowa, College of Pharmacy

Members of the faculty of this institution have provided technical assistance to USAID Missions to review local production facilities. The college has an FDA-approved production facility for the small-scale manufacture of drugs for clinical trials.

Nongovernmental Contacts List

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General Information
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East Brunswick, NJ 08816-0257
(201) 613-4535

GMP Institute, Inc.
Customer Service Center
7063 Production Court
Florence, KY 41042
(606) 342-9900

The Interpharm Group of Companies
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Philadelphia College of Pharmacy and Science
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Part 2. How A.I.D. Can Involve U.S. Government Agencies[1] in Local Production of Contraceptives

I. Food and Drug Administration:[2] Safety and Efficacy of Medical Devices and Drugs

As a consumer protection agency for U.S. citizens, the U.S. Food and Drug Administration (FDA) oversees a wide range of regulatory, technical assistance, and research activities to ensure the safety and efficacy of foods, drugs, and medical devices (USDHHS 1984, September 1987; Simmons, 1985; GMP Inst. 1985). The expertise the FDA has accumulated in this arena can be effectively accessed and utilized by A.I.D. in its efforts to establish local production of contraceptives such as IUDs, condoms, and oral contraceptives in developing countries. It must be stressed, however, that FDA activity outside the U.S. is primarily directed toward protecting the U.S. public by ensuring the quality of imported food and drugs. The FDA can provide only limited assistance for products and materials not imported into the United States. With regard to contraceptive production, the FDA's assistance can go beyond technical expertise in ensuring high quality manufacture of drugs and devices; it may also include assistance in efforts to build effective counterpart regulatory institutions to ensure quality in the long term.

Examples of Available Assistance

Medical Devices:[3] As defined by FDA regulations, condoms and IUDs made of inert materials represent Class II and III medical devices, respectively. (IUDs utilizing chemical activity to enhance efficacy, i.e., progesterone or copper, are regulated as drugs under U.S. law.) The principal branch of the FDA for regulation of the manufacture of these types of contraceptives is the Center for Devices and Radiological Health, which was created in 1976 partly in response to concerns raised by complications arising from the Dalkon Shield IUD. The International Affairs Department within the Center is oriented toward small manufacturers. This department has on occasion participated in a variety of activities to assist developing countries, including: the 1986 WHO/PAHO/FDA-sponsored conference on regulatory issues regarding medical devices; 3-day counterpart visits involving the FDA and China, Greece, Egypt, Israel, the Philippines, and the USSR; and a GMP workshop in Egypt (WHO/PAHO/USFDA, 1986).

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[1] While the following summary of available resources focuses on U.S. government agencies, it should be emphasized that there is wide diversity internationally in manufacturing practices, regulatory institutions, and codes for good manufacturing practices. Persons interested in promoting local production of contraceptives should be aware that there are well over 12 different national codes of GMP as well as GMP codes set by the European Free Trade Area and the World Health Organization. International Device GMPs, Interpharm Press, Inc., Prairie View, Illinois, USA, 1981.

[2] An FDA contacts list is provided at the end of this appendix.

[3] For more information about FDA medical device good manufacturing practices and quality assurance activities in other countries, contact the International Affairs Coordinator (see FDA Contacts List following this appendix and USDHHS, March 1984).

The FDA does not finance these activities. FDA assistance must be paid for by the requesting country government, international organization, or USAID Mission. Mechanisms for USAID Missions seeking FDA assistance are described in the next section.

Also within the Center for Devices and Radiologic Health (CDRH) is the Division of Small Manufacturer Assistance, Office of Training and Assistance. This division has provided consultation services for foreign manufacturers of latex products such as surgical gloves and condoms in Thailand, Malaysia, and Indonesia (CDRH 1988). The Division of Small Manufacturer Assistance recently worked with the FDA's Technical Assistance Branch to make recommendations to the Egyptian government regarding the regulation of sterile medical devices such as syringes.

Up until six or seven years ago this office had worked exclusively in the United States. Various U.S. importers then requested this office's assistance to ensure that their product materials from developing countries were meeting FDA requirements for quality assurance. Rising AIDS prevalence has increased the demand for surgical gloves, which in turn has increased requests by U.S. importers to have compliance reviews of their foreign manufacturers.

The most common basis for Division of Small Manufacturer Assistance services stems from U.S. importers who have approached foreign governments to request FDA assistance on behalf of manufacturers who export to the U.S. In special instances, however, if a foreign government is willing to pay for all expenses, FDA assistance may be provided even to foreign manufacturers who are <u>not</u> exporting to the U.S. Assistance in this case is usually limited to situations where foreign policy objectives are furthered or to support WHO programs. For technical assistance, a request from a foreign government must first be cleared with the FDA internally. Such requests should be submitted to the International Affairs Staff, Office of Health Affairs, as discussed below. For example, subject to internal approval of FDA, a one- to two-day symposium might be arranged for latex glove and condom manufacturers to attend. This symposium would be devoted to a presentation of U.S. regulatory requirements and FDA principles of quality assurance. Preceding the symposium, FDA experts may tour local plants for a few days, critiquing quality assurance practices.

Drugs: An approximate counterpart to the Division of Small Manufacturer Assistance, which is involved with medical device quality assurance issues, is the Center for Drug Evaluation and Research, Office of Compliance, Division of Manufacturing and Product Quality, which has an oversight role for the production of pharmaceuticals, including oral contraceptives. It must be emphasized that in virtually all cases this Division can only conduct GMP audits if the product under consideration is for import into the United States. In most cases this is done in the context of a drug application. This office, however, may be able to review and comment on layouts of manufacturing plans of pharmaceutical manufacturing companies that

request FDA input. In most instances this office is involved in the review of bulk ingredients that are used for U.S. manufacturing purposes.

FDA International Affairs Staff, Office of Health Affairs

The main gatekeeping office for foreign assistance by the FDA is the International Affairs Staff, under the Associate Commissioner for Health Affairs, Office of Health Affairs (see FDA Contacts List). It is best to seek the early approval by the Associate Commissioner for Health Affairs' office for virtually any type of assistance. The Associate Commissioner then coordinates with the appropriate FDA component through the International Affairs Staff. This is especially true for a project that may entail a series of short-term requests or one long-term stint of technical assistance. In general, the International Affairs Staff does not provide long-term technical assistance.

The International Affairs Staff includes Desk Officers for various regions. For example, the FDA has worked collaboratively with the Pan American Health Organization (PAHO) to establish a three-year GMP training program for industry and government inspectors in Latin America.[4] It also has arranged technical assistance to UN agencies to train inspectors and laboratory staff.[5] The Africa and Eastern Mediterranean Desk is currently working with A.I.D. in Egypt on five projects,[6] in the areas of drug control regulations, blood products and vaccines, food control, flour fortification with iron, and technical assistance with the development of a pharmacopeia center. Again, the FDA role vis-à-vis A.I.D. is essentially one of short-term consultation. All funds must be provided by the party requesting assistance or some third party.

International Programs and Technical Support Branch

The majority of this branch's work relates to handling requests for FDA inspection for GMPs. These inspections must be updated every two years in order for drug applications and drug exportation to the U.S. to be FDA-approved. The burden of requesting the inspection is on the developing country production agency. These GMP inspections are handled by the International Programs and Technical Support Branch of the FDA. All inspections follow FDA specifications for good manufacturing practices for drugs and medical devices and are conducted by about 75 field personnel representing all FDA field offices. These

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[4] *Scrip*, No. 1413, May 19, 1989, page 20.

[5] Contact Americas Desk Officer in the FDA's International Affairs Office, for more information. The contact for PAHO training is Regional Advisor for Pharmaceuticals, PAHO, Washington, D.C., Telephone: (202) 861-3238 (see FDA Contacts List).

[6] Under U.S. public law 480, funds from the sale of surplus agricultural commodities grain shipped to Egypt (local Egyptian currency) paid for projects in development. These activities are now being supported with USAID Mission funds.

inspections take place in some 40 countries and are conducted by the same staff who conduct inspections of U.S.-based firms.

Mechanisms for A.I.D.-FDA Collaboration

A promising mechanism for obtaining assistance from the FDA, NIOSH, or OSHA is for USAID Mission staff to contact an appropriate project officer at A.I.D. in Washington, D.C., who will then, in turn, contact the Office of International Health, Office of the Assistant Secretary for Health, Public Health Service (PHS), Department of Health and Human Services (DHHS) (see FDA Contacts List for address and contact information).

The Office of International Health is frequently cited as a very helpful resource for facilitating A.I.D. and USAID Mission access to the FDA, the Centers for Disease Control, and related public health service agencies. The OIH has devised a variety of arrangements for long- and short-term assistance from public health service agencies to A.I.D. It has been involved in preparations for long-term arrangements for interagency cooperation between the India USAID Mission and Public Health Service agencies. According to the Acting Director of the FDA International Affairs Staff, discussion is under way concerning the possibility of developing a Participating Agency Services Agreement between the A.I.D. Office of Health and FDA, for the provision of technical assistance for development of a vaccine quality control facility in India. It is also possible for this office to obtain assistance for A.I.D. from OSHA, which is in the Department of Labor, under similar agreements. Further, FDA is working with A.I.D. to develop an interagency agreement for the provision of quality assurance assistance in the purchase of ORS.

In this way, A.I.D. Washington and USAID Missions can deal with one office, the OIH, and get access to all the above agencies at once. The chief difficulty for USAID Mission staff is to identify the appropriate project manager at A.I.D. who can respond to a Mission request. Government Accounting Office regulations generally require an overhead of at least 10 percent be charged for interagency services such as those provided through OIH.[7] Typically, Public Health Service staff salary is not charged to USAID Missions for consultations of less than two weeks. Longer terms of assistance often require paying for PHS agency staff salary in addition to travel and per diem.

Potential Administrative and Funding Mechanisms

In the absence of an administrative mechanism specifically designed to provide services of PHS personnel and PHS expertise in the area of contraceptive production, we have attempted to identify existing agreements which might be used to initiate work in this area. While none of the existing arrangements

[7] The rate for CDC, FDA, and NIH, all of which have major infrastructure costs, is 20 percent. These rates are low when compared to nongovernmental organizations.

appear to be ideally suited for this need, there appear to be four agreements between PHS and A.I.D. which might be used, subject to the willingness of the responsible offices within A.I.D. and the availability of funds in the agreements.

A. Health Resource Support RSSA According to the Deputy Director of OIH, one potential mechanism is the S&T/Health Project titled Health Resource Support, Project # 936-5929.01, Agreement # BST-0067-R-HI-2238-00.[8] This Resource Support Service Agreement between A.I.D. and the Office of International Health provides for the conduct of studies and related work that will assist the Office of Health with developing its health programs and policies. The Public Health Services provide assistance to developing countries in project development, implementation, and/or evaluation of health programs and workshops. While this agreement has been mainly used to support evaluations, it has a scope for use for a wide variety of activities. Unfortunately, this RSSA does not permit USAID Mission buy-ins, which may preclude any substantial assistance.

B. Nutrition/Health/Family Planning/International Projects An alternate option is an arrangement with the Asia Bureau of A.I.D. The agreement is called Nutrition/Health/Family Planning/International Projects # BAS-0249-R-HI-4208. The above agreement has a significant amount set aside for Vitamin A related assistance, but may present opportunities for other activity as well, so long as it is presented in the context of a health initiative. Unfortunately, this agreement is limited to the Asia Near East region, does not permit Mission buy-ins, and the funds available may be limited.

C. Service in Support of Technical Assistance to Selected Developing Countries In addition to the above options, there is an OIH arrangement for assistance from currently active and recently retired experts in the private sector under a subsidiary arrangement termed "Service in Support of Technical Assistance to Selected Developing Countries." This PHS contract was established to facilitate rapid response if technical assistance outside the government is needed. This arrangement involves funds obligated from several A.I.D. agreements and has the advantage of being highly flexible and permitting fairly rapid processing of requests for non-government assistance. This arrangement involves a work order approach, unlike an indefinite quantity contract which requires the time-consuming submission of a scope of work through the A.I.D. Contracts Office.

The above are promising examples of arrangements that permit initiation of assistance from FDA and other related agencies in the short term. It is clear that the above mechanisms would usually apply to initial or

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[8] For a description of this Resources Support Service Agreement, see the Directory for the Office of Health, Bureau for Science and Technology, U.S. Agency for International Development, Washington, D.C. 20523; November 1988, page 12.

infrequent, ad hoc types of assistance. For longer-term projects, interagency agreements must be worked out.

II. Occupational Safety and Health Administration: Reducing Hazards in the Workplace

Created within the Department of Labor to identify and reduce workplace hazards affecting American workers, the Occupational Safety and Health Administration develops safety standards in four major areas: general industry, maritime, construction, and agriculture (OSHA 1979, 1985). Health and safety standards development for USAID-sponsored local contraceptive production efforts would fall under the rubric of general industry. The manufacture of contraceptives involves significant potential occupational hazards in at least two areas: potential exposure to airborne particles of steroids during OC tablet manufacture and potential exposure to ethylene oxide gas, often used to sterilize IUDs. In both instances, OSHA has mandatory training requirements for workers.[9]

OSHA services available to employers include consultation assistance and education through OSHA's Training Institute in Des Plaines, Illinois. OSHA welcomes international participants in its training courses. Foreign government employees can attend OSHA training programs without paying tuition. Other foreign nationals, many of whom are funded by the International Labor Organization, are welcome to enroll in OSHA classes if there is still room available in them.[10]

While OSHA has not conducted training programs outside of its United States training facility for non-U.S. groups in the past, it could be arranged for groups of 25 or more if funded by outside agencies. Although OSHA rarely makes international site visits, labor officials from other countries concerned about occupational health issues can call OSHA to get advice and technical assistance.

OSHA has an ongoing working relationship with A.I.D. to provide a U.S.-based, three-week program on occupational safety and health training for developing country personnel. This A.I.D.-sponsored training generally consists of a one-week introduction to U.S. institutions such as OSHA, combined with various site visits, followed by up to two weeks of academic training at institutions such as Cornell University and the University of California at Berkeley.

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[9] See under General Industry Training Requirements; 29 CFR parts 1910. See Subpart I, "Personal Protective Equipment: Respiratory Protection," page 21 and Subpart Z, "Toxic and Hazardous Substances: Ethylene Oxide," page 40 in OSHA 1988.

[10] For more information, contact the OSHA Training Institute (See OSHA Contacts List). In addition, the Washington, D.C., liaison person for the OSHA Training Institute is the Program Officer, Bureau of International Labor Affairs (see OSHA Contacts List).

Mechanisms for USAID-OSHA Collaboration

As described above in the section on access to FDA assistance, the OIH of the Public Health Service can assist USAID Missions in getting short-term assistance from OSHA if OSHA wishes to use this route rather than having its own agreement directly with A.I.D. OIH could make the necessary contacts and arrange travel. Alternatively, according to the Director of Communications and Consumer Affairs, requests for OSHA training and technical assistance should go directly to the Secretary of Labor, U.S. Department of Labor, Washington, D.C. 20210, with a copy of the letter sent to the Under Secretary of Labor for International Affairs at the same address. The Secretary of Labor will then require that this USAID Mission letter be answered within ten working days. Even if this first reply represents only an intermediate response, the Secretary's office will ensure a follow-up final reply.

III. National Institute for Occupational Safety and Health: Investigating Potential Hazards

Recommendations for OSHA safety and health standards may also come from the National Institute for Occupational Safety and Health, an agency of the Department of Health and Human Services. NIOSH is placed within the U.S. Public Health Service in the Centers for Disease Control. NIOSH conducts research on various safety and health problems, provides technical assistance to OSHA, and recommends standards for OSHA's adoption. By law, NIOSH is required to respond to requests for assistance from employers, employees, and their representatives where imminent workplace hazards are suspected. In addition, NIOSH provides medical, nursing, and industrial hygiene technical and consultive assistance to federal agencies to control occupational health hazards and to prevent related trauma and disease. Especially important is NIOSH's investigation of toxic substances and its development of criteria for the utilization of these substances in the workplace. For example, NIOSH has extensively researched and documented the occupational health hazards associated with exposure to ethylene oxide, often used to sterilize IUDs, and steroids, used in the production of oral contraceptives (Austin and Silken, 1986; NIOSH, May 1981; Schoenborn, 1988; Harrington et al., 1978; USDHHS 1988).

NIOSH assistance pertinent to contraceptive production has been provided by specialists (see CDC/NIOSH Contacts List) in three branches: (1) the Industry Wide Studies Branch, which has done industry surveys on OC production in the U.S. from 1978 to 1983 and has recently completed a series of industry-wide studies on ethylene oxide production; (2) the Hazard Evaluation and Technical Assistance Branch, which conducts short-term evaluations to assess occupational health safety conditions, etc., on request; and (3) the Engineering Control Technology Branch, which conducts studies on topics such as health hazard control in OC tablet-making operations (Anastas, 1984).[11]

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[11] In addition, NIOSH has an information clearinghouse and information retrieval specialists. NIOSH's reports are available either from their clearinghouse or through the quasi-governmental National Technical Information Service (NTIS).

While NIOSH's mandate is to focus on occupational safety issues in the United States, some international assistance has been provided, including: (1) a review of an OC production facility in Puerto Rico; (2) an assessment of ethylene oxide exposure in Mexico; (3) a project examining exposure to lead in battery manufacturing in Jamaica; (4) a project examining asbestos exposure in Barbados; and (5) a review of occupational exposure to excessive noise in the West Indies (Harrington et al., 1978; Matte, 1988; NIOSH, 1989; NIOSH, 1988). Some of these projects were done at PAHO's request. NIOSH has also been involved in long-term projects to set up institutions with occupational safety and health capabilities in Trinidad and Taipei. There is clearly considerable interest in international occupational health and safety issues within NIOSH.

Mechanisms for A.I.D.-NIOSH Collaboration

As long as funding is available from an outside source for NIOSH technical assistance, USAID Mission requests can be honored on an occasional basis. While there appears to be no formal mechanism for fielding international requests concerning occupational health per se, given NIOSH's status as a Public Health Service agency within the Centers for Disease Control, it is possible to access assistance through the same channels as outlined above for the FDA. The Centers for Disease Control's International Health Program Office (see CDC/NIOSH Contacts List) can help determine which branch of NIOSH would be most appropriate to approach. According to the Acting Deputy Assistant Director for Operations, International Health Program, Centers for Disease Control, it is best to contact the Assistant Director for International Health CDC to access NIOSH assistance from the CDC. There is also an International Liaison Division within the International Health Program Office that can assist in making referrals to the appropriate center within the CDC. This office has expertise in responding to emergency situations that require a quick response. Contact the Director of the International Liaison Division (see CDC/NIOSH Contacts List). According to the Chief of the Research Division, A.I.D, S&T/POP, USAID Missions can cable this office if they would like to access NIOSH assistance.

IV. Environmental Protection Agency: Minimizing Impact of Local Production on the Environment

The Environmental Protection Agency (EPA) has been involved with international activities pertinent to contraceptive manufacture on a limited basis. Waste management issues associated with production of contraceptives represent an area where EPA technical assistance could be valuable. According to the Chief of the Waste Treatment Branch, developing nations are often in a position of emulating the U.S. in adopting tough standards on waste management, but have not instituted mechanisms to ensure compliance (see EPA Contacts List). Hence, assistance is needed both for technical and regulatory issues. An example of EPA assistance in this area is an educational visit by a group of Chinese technical staff concerned with pharmaceutical manufacture, which came to the U.S. in April 1988 and met with the EPA experts (along with the FDA, OSHA, and NIOSH) to discuss steroid waste treatment and management. As with the other

agencies discussed above, the EPA will provide short-term assistance without charging for the salaries of its employees, so long as all travel costs and living expenses are covered by the requesting agency.

Mechanisms for A.I.D.-EPA Collaboration

According to the Deputy Director, Developing Country Staff, Office of International Activities, there is a memorandum of understanding between A.I.D. and EPA that permits assistance to respond to any form of environmental hazard. A USAID Mission has only to contact the EPA at the following address to get assistance: U.S. Environmental Protection Agency, 01A-A106, Washington, D.C. 20460. The EPA International Affairs Office can make arrangements for EPA staff to go outside of the U.S. to provide technical assistance on an occasional basis. EPA expenses must be covered by an outside agency and, ideally, requests should come from the State Department. A.I.D. project managers should contact either the Deputy Director of Developing Country Staff, Office of International Activities, or the Deputy Director, International Visitors and Travel Coordinator (see EPA Contacts List).

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NIOSH

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1989 UNFPA China Phase II Impact Statements

IMPACT STATEMENT
1989 Tripartite Review
People's Republic of China

Project:	CPR/85/P22
Project Name:	IUD Production
Implementing Agency:	State Pharmaceutical Administration of China
Executing Agency:	Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

UNFPA Project CPR/85/P22 will enable the Wuxi Medical Instrument Factory to produce 1.5 million Copper T 220C intrauterine devices annually by bringing to the factory essential new equipment and technology, thereby improving manufacturing conditions and enabling them to begin producing plastic and copper IUDs. This project follows UNFPA Project CPR/80/P1O which established Copper T 220C manufacturing at the Tianjin Medical Instrument Factory and responds to an increasing demand in China for copper and plastic IUDs. As the demand for contraceptives increases, it is hoped that annual production at the Wuxi Factory will increase to 2 to 3 million devices within five years.

This project will directly support the Chinese Government's objective of increasing domestic availability of plastic and copper IUDs which clinical trials have shown to be superior to the stainless steel ring device with respect to pregnancy, expulsion, and continuation rates. This, in turn, will further the Government's long-term objective of decreasing population growth and will respond to the Chinese medical community's request for an increased supply of individually packaged and sterilized IUDs.

The total <u>one-time donor cost</u> of this production project is approximately US$0.8 million compared to an <u>annual</u> cost of US$1.2 million to an international donor if these same devices were supplied directly to the State Family Planning Commission. The per unit cost shown in the following equation is based on bulk procurement donor costs, rather than commercial prices which would be much higher.

1.5 million devices x US$0.80 per device = US$1,200,000

The Chinese Government's contribution is approximately Renminbi (RMB) 800,000 for building and equipment in addition to the on-going costs of raw materials and salaries, thereby extending the impact of UNFPA funds.

IMPACT STATEMENT
1989 Tripartite Review
People's Republic of China

Project:	CPR/85/P23
Project Name:	Oral Contraceptive Production
Implementing Agency:	State Pharmaceutical Administration of China
Executing Agency:	Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

UNFPA Project CPR/85/P23 will make possible the expansion and improvement of oral contraceptive production at the Nanjing No. 2 Pharmaceutical Works. The factory will double its current output, resulting in the production of enough short-acting oral contraceptives to protect 3.5 million couples each year.

Modified manufacturing processes and modern equipment will improve the product quality. Advanced analytical instruments and procedures will make possible the monitoring of in-process quality and provide finished-product quality assurance. The introduction of modern foil and plastic packaging technology will provide individual cycle blister packages resulting in improved stability, greater product acceptability, and extended shelf life.

A serious concern in oral contraceptive manufacturing is worker exposure to steroids. Technical assistance in factory design provided by this project will reduce exposure and will result in improved control of environmental waste pollution.

This project continues the expansion of oral contraceptive production begun with UNFPA Project CPR/80/P13 which resulted in the Beijing Pharmaceutical Works having the capacity to produce oral contraceptives for more than 9 million couples per year.

The total <u>one-time donor cost</u> of this production project is approximately US$2 million, compared to an <u>annual</u> cost of US$5.46 million to an international donor if these same supplies were provided directly to the State Family Planning Commission. The per cycle cost shown in the following equation is based on bulk procurement donor costs, rather than commercial prices which would be much higher.

3.5 million users x 13 cycles = 45.5 million cycles
45.5 million cycles x US$0.12 per cycle = US$5,460,000

The Chinese Government's contribution is approximately RMB 6 million for building and equipment in addition to the on-going costs of raw materials and salaries, thereby extending the impact of UNFPA funds.

IMPACT STATEMENT
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People's Republic of China

Project:	CPR/85/P24
Project Name:	Vaginal Suppositories and Tablet Production
Implementing Agency:	State Pharmaceutical Administration of China
Executing Agency:	Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

UNFPA Project CPR/85/P24 will provide advanced technology, production equipment, and laboratory instrumentation to expand and upgrade the production of vaginal contraceptives at factories in Guangzhou and Tianjin. The project will establish capacity for annual production of 100 million vaginal tablets and 10 million vaginal suppositories.

The State Pharmaceutical Administration has stated that current production technology and equipment for vaginal contraceptives are obsolete, resulting in inefficient production, poor product quality, and unsuitable packaging, at a time when the demand exceeds the available supply. This project will allow the factories to meet the growing demand, increase the variety of contraceptives available in China, and with new packaging techniques facilitate the distribution of these products to rural areas. The two factories assisted by this project will serve as model plants for efficient vaginal contraceptive production in the People's Republic of China.

A new formulation will increase product stability and safety. The active ingredient will change from the toxic phenyl mercuric acetate to non-toxic nonoxynol-9, the spermicide most frequently used worldwide. A change in the base ingredient will improve the stability and performance.

The total <u>one-time donor cost</u> of this production project is approximately US$1.271 million, compared to an <u>annual</u> cost of US$5.9 million to an international donor if these same products were supplied directly to the State Family Planning Commission. The per unit costs shown in the following equations are based on bulk procurement donor costs rather than commercial prices which would be much higher.

Tablets: 100 million x US$0.04 per tablet	=	US$4,000,000
Suppositories: 10 million x US$0.19 per suppository	=	US$1,900,000
TOTAL		US$5,900,000

The Chinese Government's contribution is approximately RMB 2.5 million for building and equipment in addition to the on-going costs of raw materials and salaries, thereby extending the impact of UNFPA funds.

IMPACT STATEMENT
1989 Tripartite Review
People's Republic of China

Project:	CPR/85/P25
Project Name:	Condom Production, Testing, and Packaging
Implementing Agency:	Ministry of Chemical Industry
Executing Agency:	Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

UNFPA Project CPR/85/P25 will enable the Qingdao Latex Factory and the Guangzhou No. 11 Rubber Factory to improve the production quality, testing, and packaging for 350 million condoms annually, an amount equal to approximately 36 percent of the number of condoms produced in China. This project also will strengthen the research and development capability of the Research Institute of the Latex Industry located in Zhuzhou.

For the Guangzhou and Qingdao factories, modern compounding equipment will enable the factories to improve product batch-to-batch consistency, reduce condom thickness, and improve strength and stability, all of which will enhance consumer confidence and acceptance. The Ministry of Chemical Industry has stated that present condom testing apparatus is outdated, and most condoms are still being checked manually. The introduction of electronic testing apparatus will substantially increase the final quality of the product. New automatic packaging machines will produce individually sealed packages which will extend shelf life and make transport to remote areas possible. Automatic, individual packaging will also allow the condoms to be lubricated, thereby increasing consumer acceptance.

Basic latex research and development is carried out by the Research Institute in Zhuzhou for the entire latex industry. Modern analytical instruments provided by this project will enable the Institute personnel to better evaluate raw materials for homogeneity and other properties and thus improve overall formulation. Observing latex processing at various industry and research facilities followed by long-term advanced technical training will help Institute personnel address specific formulation issues and improve the overall condom manufacturing process.

The total <u>one-time donor cost</u> of this production project is approximately US$2.661 million, compared to an <u>annual</u> cost of US$7.29 million to an international donor if these same products were supplied directly to the State Family Planning Commission.

350 million @ 144/gross = 2,430,555 gross x US$3.00 per gross = US$7,291,665

The Chinese Government's contribution is approximately RMB 1.2 million for building and equipment in addition to the on-going costs of raw materials and salaries, thereby extending the impact of UNFPA funds.

IMPACT STATEMENT
1989 Tripartite Review
People's Republic of China

Project:	CPR/85/P26
Project Name:	Steroid Production
Implementing Agency:	State Pharmaceutical Administration of China
Executing Agency:	Program for the Introduction and Adaptation of Contraceptive Technology (PIACT)

UNFPA Project CPR/85/P26 will expand and improve bulk steroid production at factories in Hubei and Yangzhou. Sufficient steroid will be produced by these factories to manufacture oral contraceptives for 20 million women annually. The project will also modify manufacturing processes, enhance worker protection, minimize pollution from wastes, strengthen product quality, and institute the use of international good manufacturing practices.

The introduction of new technology, analytical and monitoring instrumentation, and advanced safeguards will upgrade the foundation for steroid production that already exists in China, and will address the current difficulties with labor protection, waste disposal, and inadequate facilities.

After the completion of the project, the annual production of norgestrel will be 400 kg in Yangzhou and 300 kg in Hubei; production of norethindrone in Hubei will be 500 to 600 kg. UNFPA Projects CPR/80/P13 in Beijing and CPR/85/P23 in Nanjing will be supplied with steroid from this project.

The total <u>one-time donor cost</u> of this production project is approximately US$3.015 million compared to an <u>annual</u> cost of US$1.8 to US$1.95 million to an international donor if these same products were supplied directly. The per kilo cost shown in the following equation is based on a conservative estimate of bulk prices available to an international donor.

1200 to 1300 kg x US$1500 per kilo = US$1.8 to US$1.95 million

The Chinese Government's contribution is approximately RMB 5.5 million for building and equipment in addition to the on-going costs of raw materials and salaries, thereby extending the impact of UNFPA funds.

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