

AID CONTRACEPTIVE SUPPLY PROGRAM OF THE OFFICE OF POPULATION

by

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WHEN AID FIRST DEVELOPED a policy to assist LDC family planning programs in 1965, contraceptives or the machinery for their manufacture were specifically excluded from AID assistance. Until contraceptive assistance was permitted it 1967 it was difficult for AID population Officers in LDCs to be taken seriously in their efforts to promote social and economic development. With the lifting of the contraceptive ban in FY 1967, and the earmarking of Population Funds under Title X of the Foreign Assistance Act in FY 68, AID assistance to Family Planning Programs took a great leap forward from a total of \$10.5 million in three years, to \$34.8 million in FY 1968, to \$125.6 million in FY 73. Through FY 1978, out of a cumulative total of 1,168.6 million in Population Program Assistance, AID provided \$183.8 million worth of commodities, including \$108.7 million for 638 million cycles of oral contraceptives and \$51.8 million for 13.8 million gross of condoms. It seems reasonable to have spent approximately 16 percent of AID's total population program funds for contraceptives when one considers three facts:

1. Contraceptives are essential to the prevention of births, which is the point of the whole program.
2. Contraceptives practically always require hard currency foreign exchange, which is the most difficult part of the family planning program budget in LDCs.
3. The United States has both the technical and industrial capacity to provide safe and effective contraceptives economically while preserving the balance of payments.

FDA APPROVAL

In 1967 when AID agreed to supply contraceptives to LDCs the Agency decided at the level of the Administrator that only contraceptives approved by FDA would be supplied with AID funds. This decision was made to ensure the safety and effectiveness of the contraceptives provided and to avoid any possible allegation that AID would provide contraceptives to an LDC that were not good enough for the American public. Thus AID had a good bureaucratic stance when Senate hearings and other publicity questioned the safety and effectiveness of oral contraceptives. On the other hand, this AID regulation has made it mandatory to put inappropriate medical warnings on the packages of oral contraceptives.

TERM CONTRACTS

Procurement of contraceptives has been done by GSA without charge to AID based on specifications developed in the Office of Population. Between 1967 and 1972 about 30 million cycles of oral contraceptives and less than 11 million gross of condoms were purchased. Relatively small amounts were purchased from time to time on the basis of Mission-funded PIO/Cs against term contracts made by GSA with the manufacturers. This was a fairly satisfactory arrangement when small quantities were involved and the manufacturers could produce them easily in a short time with their own shelf package design bearing their trade names.

PACKAGING

However, term contracts for relatively small amounts resulted in several different manufacturers supplying oral contraceptives to the program. Field visits plus Mission Communications made us aware of several problems. For example, when brands were changed, family planning acceptors were upset at subsequent visits to clinics by the obvious differences in the oral contraceptives being dispensed. On the supply side, many of the clinics visited did not have adequate quantities of oral contraceptives and therefore would not liberalize their distribution; as a result, clients were obliged to return every month, often from long distances,, only to wait for long periods to acquire one cycle of pills. Likewise, Missions all too frequently cabled requests for immediate delivery of pills which could only be met by emergency juggling of supplies and by expensive air shipments. In light of these problems it became obvious that an in-country pipeline of oral contraceptives was required, as well as a standard package with good protection for storage. The Blue Lady Pack was developed to standardize the packaging, to include three months supply in one package, and to offer adequate protection for storage under tropical conditions. The Blue Lady Package has become quite popular and has been adapted by Schering-Berlin, UNICEF, IPPF, UNFPA and others. The Blue Lady Package permits IE&C tie-in programs and assures to LDC clients an unchanging oral contraceptive package.

HORMONE INGREDIENTS

Although we solved the psychological problems created by changing packaging styles and brand names, we soon ran into a problem caused by a change in the oral contraceptives. After study of the problem, with the advice of the most expert consultants available and using only recently available knowledge concerning the effects of various types of progestogens and estrogens on such factors as water retention and endometrial activity, we were able to understand why a shift from one oral contraceptive approved by FDA to another oral contraceptive approved by FDA could cause serious program problems in the LDCs. Specification were then changed in view of this information in order to retain competition in bidding and insure that there would be no serious change in the physiological affect of new oral contraceptives on the LDC patients. Thus we learned the hard way by field experience that the packaging, for psychological reasons, and the chemical content for physiological reasons for continuity of use, must be kept as constant as possible. This has important implications both in procurement and local production of contraceptives.

CONSOLIDATION CENTRAL PROCUREMENT WITH GUARANTEED QUANTITY CONTRACTS

In 1972, just as the demand for oral contraceptives was rapidly increasing, GSK solicitation of bids brought no Offers from the manufacturers. Representatives of the Office of Population and GSA then visited the manufacturers to determine why no offers were made. The manufacturers claimed to

have lost money on AID business because under the term contract arrangement the monthly demand for production varied enormously and therefore production became very expensive as production lines were enlarged or cut back frequently. As a stopgap measure proprietary procurement was made of contraceptives at approximately double the price obtained by competitive bidding.

All of the above experience led to the Office of population spending many months convincing the Agency to shift oral contraceptive procurement to a system of bulk central procurement -- the system under which we are still operating. Under this system we are able to take advantage of economy of scale, that is, that is contracts are made for 50 to 100 million cycles of oral contraceptives at one time. Contracts are for guaranteed quantities such as 5 or 6 million oral contraceptive cycles per month to be manufactured during a period of one year. Such an arrangement permits the manufacturer to establish an efficient and constant level of manufacture. This enabled AID to buy oral contraceptives at 13.2 cents a monthly cycle when other government agencies and government-sponsored clinics were paying about 40 cents and 75 cents, respectively, and private commercial wholesalers were paying approximately \$1.50. By consolidating worldwide demand, we were able to purchase such huge quantities that the probability of having a standard project over a period of time was greatly enhanced. Financial management by the Office of Population was simplified in that Title X funds for contraceptive purchases were retained in Washington rather than dispersed throughout the world to many Missions, to be later returned to Washington piecemeal until a large enough amount of funds had been accumulated to warrant a new contract.

LEAD TIME

The purchase of large quantities of contraceptives at a favorable price under guaranteed quantity contracts requires a long lead time to insure that there is no lack of contraceptives at any point worldwide even under unfavorable circumstances. The Office of Population has concluded that to avoid any discontinuity in the supply lines, each country program should have one year's supply of contraceptives on hand and one year's supply on order. The time periods involved from reservation of funds to shipment of supply from the manufacturer are as follows:

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| 4 Months | Time for PIO/C to progress AID Procurement to GSA, request for offers, preparation of offers, and contract negotiation. |
| 12 Months | Contracts call for the first production of oral contraceptives twelve months from the signing of the contract. This is necessary to obtain favorable prices and to enable manufacturers to gear up AID production. Contracts for condoms should be executed about four months in advance of delivery. |
| 12 Months | Large consolidated contracts for 60 or 80 million monthly cycles of oral contraceptives require one year's manufacturing time. A shorter manufacturing time would require more machinery or overtime work and higher prices. Annual contracts also assure a continuing flow of supply. |
| 28 Months | Total Time
The process outlined above delineates time after the OYB levels should have been established. This process should be orderly and continuous with a new MO/C for procurement every twelve months to keep the supply process going. At the present time we have |

the opportunity to exercise an option for up to a 50% increase in quantities based on revised Mission requirements. This option would normally be exercised about six months after a contract is executed.

CENTRAL SYSTEMS

The office of Population purchases contraceptives with funds provided in a central PIO/C,, combined with funds provided by a funded PIO/C from SA countries and from countries where oral contraceptives are purchased with loan funds. The amount of funds in the PIO/C is based upon country program requirements which are forwarded by the Missions in Table 8 of the Annual Budget Submissions. These submissions represent the best judgment of the country program officials and the AID Missions as to the contraceptives needed during the next two years based upon program experience. When there is insufficient program experience to make a judgment programs are requested to order enough contraceptives so that a pipeline will be established sufficient to service 10 percent of the fertile population with oral contraceptives and 5 percent with condoms. This is considered a modest pipeline in view of the fact that some 60 or 70 percent of the fertile population must practice family planning if we are to have successful programs and in view of the fact that the cost of contraceptives has been approximately 16 percent of the total cost of programs which cannot be successful without adequate contraceptives. Some months after the Annual Budget Submission, each Mission submits a non-funded PIO/C to Washington; although contracts are made on the basis of the ABS, shipments are made only against these PIO/Cs. Thus there is another opportunity for Missions to correct inaccurate estimates made previously.

Experience has demonstrated that projection of future requirements two years in advance is not always accurate as attested by many requests from Missions to change their previous orders. In order to systematize the required corrections and to keep AID/W better informed of field inventories and requirements on a continuing basis the Office of Population instituted a quarterly reporting system in 1974. The Quarterly Report requires a statement of the inventory of contraceptives, the number of users, the number of new acceptors, and the quantities distributed during the past three months. With accurate information of that kind at hand. it would be possible for AID/W to avoid either shortages or excessive inventories.

The Office of Population believes that we have instituted a rational and reasonable system for procuring and shipping contraceptives but for many years we have recognized the deficiencies in field logistics programs. Since at least 1972 we have attempted to obtain staff to give technical assistance to LDCs in order to improve end-use accountability of commodities provided. Because we could not satisfy this need with direct hire employees, we developed a resources agreement with the Center for Disease Control and IQC contracts with two firms, Experience Inc. and Medical Service Consultants, Inc. to supply contract personnel for this effort. Contractors continue to make field visits to countries to assist the Missions and LDC program officials to improve their record and reporting system" their warehousing and inventory systems and their methods of distributing contraceptives.

Note by Ravenholt (June 27, 2001):

The above excellent analysis of our contraceptive supply system demonstrates the superb management skills of Dr Bill Boynton, my deputy, and Dr Harald Pedersen, Chief, Family Planning Services Division - vital strengths of the population program until removed by Assistant Administrator Sander Levin - zealot "Gun for Hire" of the Roman Catholic political machination to destroy AID's powerful assistance program for improved birth control in the less developed world. Defeated candidate for Governor of Michigan, Sander Levin decapitated, dispersed and degraded USAID's world-leading population program during the Jimmy Carter Administration.