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**Legal and Regulatory Environment  
Affecting Family Planning in Egypt**

by

**Betty Butler Ravenholt  
Susan Russell**

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**LEGAL AND REGULATORY ENVIRONMENT  
AFFECTING FAMILY PLANNING IN EGYPT**

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Under the OPTIONS II Project**

**by**

**Betty Butler Ravenholt  
Susan Russell**

## PREFACE

**O**PTIONS for Population Policy II is a five-year project funded by the Office of Population of the U.S. Agency for International Development. The goal of the project is to help A.I.D.-assisted countries formulate and implement policies that address the need to mobilize and effectively allocate resources for expanding family planning services. The project provides technical assistance to:

- improve the analytic capacity of developing country institutions to design, manage, and monitor family planning programs;
- assess legal and regulatory policies affecting the delivery of family planning services;
- promote efficient use of public sector resources in family planning programs; and
- increase private sector participation in service delivery.

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## TABLE OF CONTENTS

|     |  |      |
|-----|--|------|
|     | LIST OF FIGURES AND TABLES .....   | viii |
|     | ACRONYMS .....   | ix   |
|     | EXECUTIVE SUMMARY .....  | xi   |
| I.  | <b>BACKGROUND ON FAMILY PLANNING IN EGYPT</b> .....                                | 1    |
|     | <b>A. Achievements</b> .....   | 1    |
|     | <b>B. Remaining Challenges</b> .....   | 3    |
| II. | <b>ACCESSING SERVICES AND SUPPLIES</b> .....                                       | 4    |
|     | <b>A. Specific Regulations Governing Provision and Use</b> .....                   | 4    |
|     | 1. Issues Affecting All Methods .....  | 4    |
|     | 2. Oral Contraceptives .....   | 5    |
|     | a. Oral Contraceptives in General .....  | 5    |
|     | b. Mini-pills .....  | 6    |
|     | 3. IUDs .....  | 7    |
|     | 4. Injectables .....   | 8    |
|     | 5. Norplant® .....   | 10   |
|     | 6. Voluntary Sterilization .....   | 11   |
|     | 7. Other Methods .....   | 12   |
|     | <b>B. Technical Competence of Providers: Physicians, Nurses, Pharmacists</b> ..... | 13   |
|     | 1. Level of Knowledge About Specific Methods .....                                 | 13   |
|     | a. Oral Contraceptives .....   | 13   |
|     | b. Injectables .....   | 14   |
|     | c. IUDs .....  | 14   |
|     | d. Norplant® .....   | 14   |
|     | 2. Preservice Training and Continuing Education .....                              | 15   |
|     | <b>C. General Regulation of Practice of Medicine and Pharmacy</b> .....            | 16   |
|     | 1. Professional Certification .....  | 16   |
|     | 2. Limitations on Private Practice .....   | 17   |
|     | 3. Prescription Requirement .....  | 18   |
|     | <b>D. Economic Interests in Choice of Methods</b> .....                            | 18   |
|     | 1. IUDs .....  | 18   |
|     | 2. Triphasics .....  | 19   |
|     | <b>E. Other Access Issues in the Public Health Delivery System</b> .....           | 20   |
|     | 1. Quality of Family Planning Clinic Services .....                                | 20   |
|     | 2. Government Administrative Procedures .....                                      | 21   |

|      |  |    |
|------|--|----|
| III. | AVAILABILITY OF CONTRACEPTIVES ON THE MARKET .....                 | 22 |
| A.   | Introduction of Products into the Market .....                     | 23 |
| 1.   | Import Policies and Relationship to Local Production .....         | 23 |
| 2.   | Process for Registration and Pricing .....                         | 24 |
| B.   | Costs of Import and Local Production .....                         | 26 |
| 1.   | Tariffs on Products and Raw Materials .....                        | 26 |
| 2.   | Sales and Value-added Taxes .....                                  | 27 |
| 3.   | Exchange Controls .....  | 28 |
| C.   | Statutory Price Controls .....                                     | 29 |
| 1.   | Approval and Appeal Process .....                                  | 29 |
| 2.   | Impact on Operation of Marketplace .....                           | 30 |
| D.   | Investment Climate .....   | 34 |
| 1.   | Foreign Investment .....   | 34 |
| a.   | Regulations Concerning Control of Ownership .....                  | 34 |
| b.   | Joint Ventures .....   | 35 |
| c.   | Repatriation of Profits .....                                      | 35 |
| d.   | Free Zones and New Cities .....                                    | 36 |
| e.   | Hiring Foreign Personnel .....                                     | 37 |
| f.   | Impact of Protection for Parastatals .....                         | 37 |
| 2.   | Local Investors .....  | 38 |
| a.   | Regulation of Production .....                                     | 38 |
| b.   | Import of Raw Materials .....                                      | 39 |
| c.   | Patent and Trademark Laws .....                                    | 39 |
| IV.  | ADVERTISING AND PROMOTION REGULATIONS .....                        | 40 |
| A.   | Mass Media .....   | 40 |
| B.   | Point of Sale .....  | 42 |
| V.   | RESTRICTIONS AFFECTING NONPROFIT ORGANIZATIONS .....               | 42 |
| A.   | Registration with and Supervision by MOSA .....                    | 42 |
| B.   | Sale of Donated Commodities and Fees Charged for Services .....    | 43 |
| VI.  | COMMITMENT TO NATIONAL PROGRAM GOALS .....                         | 44 |
| VII. | NEXT STEPS .....   | 45 |
| A.   | Summary .....  | 45 |
| B.   | Proposed Activities .....  | 49 |
| 1.   | Expand the Availability of Injectables .....                       | 49 |
| 2.   | Expand the Availability of Mini-pills .....                        | 50 |
| 3.   | Selectively Reduce General Constraints on Access .....             | 50 |
| 4.   | Reduce Negative Impact of Price Controls and Import Policies ..... | 51 |
| 5.   | Secure Commitment and Support of Mid-level Officials .....         | 52 |

|                                |           |
|--------------------------------|-----------|
| <b>BIBLIOGRAPHY</b> .....      | <b>53</b> |
| <b>PERSONS CONTACTED</b> ..... | <b>56</b> |

## LIST OF FIGURES AND TABLES

|           |   |    |
|-----------|---|----|
| Figure 1. | Contraceptive Prevalence Rate by Source . . . . .   | 2  |
| Figure 2. | Contraceptive Method Mix by IUD Source . . . . .  | 2  |
| Table 1.  | Contraceptive Method Mix, EDHS 1992 . . . . .   | 3  |
| Table 2.  | MOH Rationale for Determination of Retail Prices<br>for Pharmaceutical Products . . . . . | 29 |
| Table 3.  | Illustrative Prices of Selected Contraceptive Products . . . . .                          | 32 |
| Table 4.  | Matrix of Most Important Policy Constraints . . . . .                                     | 46 |

## ACRONYMS

|       |   |
|-------|---|
| CSI   | Clinical Services Improvement Project       |
| CSMP  | Contraceptive Social Marketing Project      |
| EDHS  | Egyptian Demographic and Health Survey      |
| EDO   | Egyptian Drug Organization                  |
| EFCS  | Egyptian Fertility Care Society             |
| EFPA  | Egyptian Family Planning Association        |
| EJMDA | Egyptian Junior Medical Doctors Association |
| EMA   | Egyptian Medical Association                |
| EPTC  | Egyptian Pharmaceutical Trading Company     |
| FHI   | Family Health International                 |
| FOB   | Free On Board                               |
| FOF   | Family of the Future                        |
| GOE   | Government of Egypt                         |
| HIO   | Hospital Insurance Organization             |
| IMF   | International Monetary Fund                 |
| IUD   | Intrauterine device                         |
| L/C   | Letter of credit                            |
| LE    | Egyptian Pound                              |
| MD    | Medical Doctor                              |
| MOH   | Ministry of Health                          |
| MOSA  | Ministry of Social Affairs                  |

|              |  |
|--------------|--|
| <b>MWRA</b>  | <b>Married women of reproductive age</b>             |
| <b>NPC</b>   | <b>National Population Council</b>                   |
| <b>OC</b>    | <b>Oral contraceptive</b>                            |
| <b>OTC</b>   | <b>Over-the-counter</b>                              |
| <b>PPFPP</b> | <b>Private Practitioners Family Planning Project</b> |
| <b>PVO</b>   | <b>Private voluntary organization</b>                |
| <b>RCT</b>   | <b>Regional Center for Training</b>                  |
| <b>RN</b>    | <b>Registered Nurse</b>                              |
| <b>SDP</b>   | <b>Systems Development Subproject</b>                |
| <b>SIS</b>   | <b>State Information Service</b>                     |
| <b>STD</b>   | <b>Sexually transmitted disease</b>                  |
| <b>TFR</b>   | <b>Total fertility rate</b>                          |
| <b>THO</b>   | <b>Teaching Hospitals Organization</b>               |
| <b>UNFPA</b> | <b>United Nations Population Fund</b>                |
| <b>VS</b>    | <b>Voluntary sterilization</b>                       |

## EXECUTIVE SUMMARY

There are many positive elements in the overall environment for family planning in Egypt, as evidenced by the 45% contraceptive prevalence rate for modern methods. The private sector in general provides nearly two-thirds of all services and supplies, of which the commercial segment of this sector is the predominant provider. To move substantially beyond current levels of contraceptive prevalence, constraints to the delivery and use of family planning services in both the public and private sectors will have to be reduced.

This report identifies and assesses the broadly defined legal and regulatory issues which impede progress toward increased contraceptive prevalence. The methodology and the analysis of findings reflect the particular characteristics of Egypt's family planning effort, especially its relatively high modern contraceptive prevalence and the history of participation by the private sector (particularly the commercial sector), which produces as well as imports contraceptive products.

The most important constraint to increased contraceptive use in Egypt is the limited choice of methods, which is due to multiple factors that have their greatest negative impact on the private sector. The analysis shows that injectables and progestin-only (mini-pill) oral contraceptives have the greatest potential for expanded use, yet they are not accessible to most Egyptian women: regulations restricting the provision of injectables have only recently been removed, and government policies are undermining the viability of the oral contraceptive market in the private sector, where 83% of users obtain their supplies. Norplant® and voluntary sterilization, which have less potential for expanded use in the Egyptian context, are inaccessible in part because of regulations and standards of practice related to provision and client eligibility. Because of the limited choice of methods, family planning is not practiced by as many women as it might be. In addition, the restrictions on the private sector mean that the Ministry of Health will bear an increasingly large share of the cost of delivering services to a growing number of contraceptive users.

There is no question that a segment of the population must receive free or subsidized services in order to have access to contraceptive methods. However, there is equally no question that public resources are inadequate to provide the amount of services needed to achieve the country's family planning goals. The private sector must continue to play an active role in meeting the growing demand of those who can afford to pay. Yet the current system of contraceptive price controls as exercised by the Ministry of Health is creating an environment in which even products that have already been approved are disappearing from the marketplace. Not only are pharmaceutical companies declining to introduce new technologies in Egypt, but also parastatal manufacturers are refusing to keep a consistent supply of locally produced low-dose oral contraceptives on retail shelves because of financial losses.

Availability of all contraceptive methods through private practice physicians is essential. Active involvement of pharmacists in family planning activities can also greatly

enhance contraceptive consumers' use of the private sector, since these providers are already sought out by lower-income health care consumers for advice and sometimes treatment. Specifically, university curricula for pharmacists should include well-developed sections on family planning, contraceptives, and client counseling. Continuing education in family planning for pharmacists should be regularly provided. Referral networks between neighborhood pharmacists and nearby physicians should be encouraged. Approval of pharmacists to provide contraceptive injections should be strongly considered.

Correct and consistent contraceptive use plays a very important role in maintaining and expanding levels of contraceptive prevalence. Informed, well-trained service providers are essential to this process. Considerable effort should continue to be made to disseminate national standards of practice for family planning and to enforce their adoption. This enforcement should use appropriate channels, such as regular monitoring processes within the public sector and continuing education requirements for relicensing in the private sector.

The "glue" that can hold together and strengthen all efforts at expanding family planning service delivery and contraceptive prevalence in Egypt is the political will or commitment to ensure that legal and regulatory systems operate effectively and efficiently.

Tremendous emphasis should be given to activities which can develop deep within the GOE bureaucracy a clear understanding of the following: 1) the ramifications of administrative/regulatory decisions on service delivery effectiveness; 2) the importance of family planning activities to the national population policy; and 3) President Mubarak's commitment to this area.

Such activities are especially important in settings where regulatory and legal systems, while rationally stated, are vulnerable to political and personal intervention. Motivated, knowledgeable bureaucrats can facilitate in hundreds of ways the processes necessary for successful family planning service delivery. Unmotivated, uninformed bureaucrats can equally well constrain effective service delivery and restrict optimum contraceptive availability and use.

In light of the goals and constraints discussed above, important next steps include the following:

1) expand the availability of injectables by

- expanding the range of authorized providers and increasing their level of knowledge; and
- identifying users and targeting IEC and recruitment efforts to specific market segments.

**2) expand the availability of mini-pills by**

- **targeting IEC and recruitment efforts toward breastfeeding women;**
- **widely advertising the availability of private sector sources; and**
- **increasing the level of provider knowledge to overcome existing misinformation problems.**

**3) selectively reduce general constraints to access by**

- **projecting alternative timetables for reaching contraceptive prevalence targets under different scenarios of authorized providers;**
- **conducting further research on potential barriers where information to date is inconclusive;**
- **developing policies to accelerate introduction of contraceptive products;**
- **proposing policies to expand use of mass media to the private sector;**
- **preparing implementation plans for expansion of Norplant® that ensure maximum access and safe conditions; and**
- **continuing education of family planning service providers on the health risks of repeated pregnancy and childbirth may be the most effective way to expand the availability of voluntary sterilization.**

**4) reduce negative impact of price controls and import policies by**

- **developing strategies for ensuring a stable flow of supplies in the private sector.**

**5) secure commitment and support of mid-level officials by**

- **developing and delivering presentations to target groups to demonstrate the importance of family planning and their role in its success; and**
- **identifying and proposing changes in procedures administered by mid-level officials to facilitate their role in supporting family planning.**

## **I. BACKGROUND ON FAMILY PLANNING IN EGYPT**

### **A. Achievements**

Family planning enjoys considerable support in Egypt. Results of this support can be seen in the 45% contraceptive prevalence rate for modern methods among married women of reproductive age (MWRA) reported by the 1992 Egyptian Demographic and Health Survey (EDHS). There is virtually universal (99.4%) knowledge of at least one modern contraceptive method among MWRA, and 81.5% of respondents want to limit or postpone childbearing for at least two years.

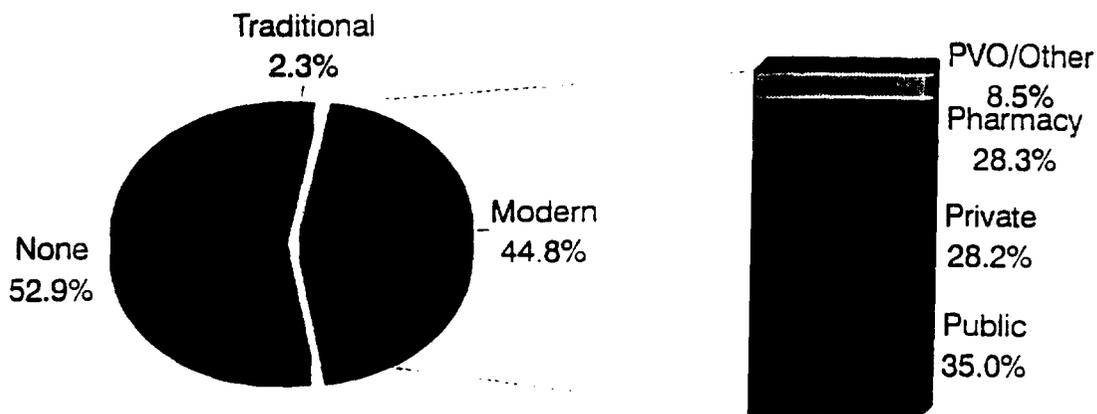
A national population policy was adopted in the 1960s, and President Hosni Mubarak has made repeated references to its importance. The National Population Council (NPC) was established in 1985 as a coordinating agency for the national population and family planning program. At the governorate level, the NPC is active and successful in coordinating and supporting family planning activities. A number of governors and their wives have become personally involved in supporting these programs.

In the public sector, during the past several years the Ministry of Health (MOH) has placed significant emphasis on expanding family planning service delivery and increasing contraceptive prevalence. More than 7,000 nurses and 6,000 doctors have been trained in counseling, service delivery, and infection control through the MOH Systems Development Subproject (SDP). Considerable efforts have been made to provide adequate client counseling and information on correct usage to Egyptian women.

The private sector provides a very significant proportion of contraceptive methods: the EDHS reports that 65% of users receive services through the private sector: 6.7% from private voluntary organizations (PVOs), 56.5% from private practice and commercial outlets, and 1.8% from other sources. See Figure 1. The price of private sector services is kept low for some contraceptive methods as a result of government pricing policies, support of parastatals (which produce contraceptives), and donated products. The Government of Egypt's (GOE) general move toward privatization in many industries is having some impact on commercial participation in contraceptive manufacturing and distribution. However, the GOE plans to continue to ensure that contraceptives remain "affordable" to everyone.

Figure 1.

# CONTRACEPTIVE PREVALENCE RATE BY SOURCE

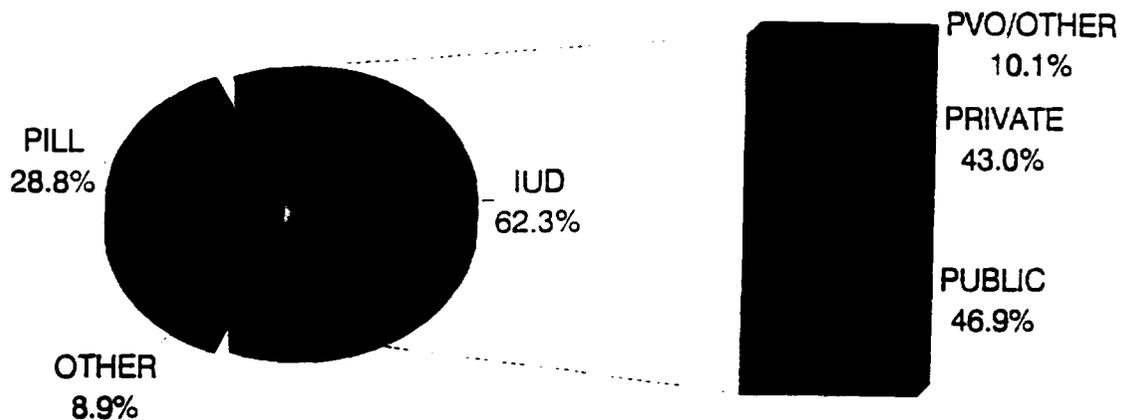


EGYPT 1992 DHS

Figure 2.

# CONTRACEPTIVE METHOD MIX BY IUD SOURCE

MODERN METHODS ONLY



## B. Remaining Challenges

The commitment of high-level officials and the policy environment in Egypt have contributed to the positive trend toward increased contraceptive use, and the GOE has established an ambitious target of 53% contraceptive prevalence by 1997 and a decrease in the total fertility rate (TFR) to 2.9 by 2005. The availability of and access to a wide range of contraceptives are critically important to the program's success: the method mix of contraceptive users will determine how high the contraceptive prevalence rate will have to be to achieve the TFR goal.

There is a wide range of contraceptive methods that are legal in Egypt. The most recent draft of standards of practice for family planning outlines the recommended procedures for providing oral contraceptives, injectable contraceptives, intrauterine devices, condoms, diaphragms, spermicides, surgical contraception, and traditional methods of contraception. However, in practice not all of these methods are available. In fact, most married women of reproductive age who are using a modern contraceptive rely on IUDs (62.3%) or oral contraceptives (28.8%), with a very small percentage relying on condoms and other methods [1992 EDHS]. See Figure 2.

Table 1 demonstrates the current (EDHS 1992) reliance on oral contraceptives and IUDs in Egypt, making its family planning program essentially a "two method program":

Table 1. Contraceptive Method Mix, EDHS 1992

| METHOD                  | CONTRACEPTIVE METHOD MIX<br>AMONG MWRA, 1992 DHS (modern<br>methods only) |
|-------------------------|---|
| Oral contraceptives     | 28.8  |
| IUD                     | 62.3  |
| Injectables             | 1.1   |
| Voluntary sterilization | 2.4   |
| Condoms                 | 4.5   |
| Other barrier methods   | 0.9   |
| <b>TOTAL</b>            | <b>100.0</b>  |

Thus, remaining constraints to family planning service delivery and acceptance must be identified and resolved. This report examines the legal and regulatory issues that have an effect on family planning, assesses their potential impact, and proposes possible means for resolving those which act as constraints.

## **II. ACCESSING SERVICES AND SUPPLIES**

A wide range of methods are available in Egypt, to varying degrees, with the exception of the mini-pill, which is currently in the final stages of approval and pricing for entry into the market. Among the reasons for the "two-method" program, is that access to a range of methods is restricted by policies on who may provide them under what circumstances, and who may use them under what circumstances; weaknesses in the ability of providers to furnish accurate information and effective services; and other constraints to access.

### **A. Specific Regulations Governing Provision and Use**

#### **I. Issues Affecting All Methods**

The National Family Planning Service Guidelines for Egypt, a standards of practice manual, were first published in 1990. The guidelines are a very important step in improving and standardizing family planning services in Egypt, because before 1990 there was no standard. A new standards of practice manual, "Performance Principles for Family Planning Clinical Services Delivery: A Resource Manual," was drafted in 1992.

The 1990 guidelines were developed by the Regional Center for Training (RCT) and the Family Planning Systems Development Project through the Ministry of Health. Family planning experts from outside and inside Egypt gathered the most recent information on provision of services and compiled it in the form of a manual. Local physicians reviewed the guidelines to make sure that they were culturally appropriate for Egypt.

Copies of the guidelines have been placed in many MOH clinics providing family planning services. They are also supposed to be given to each provider who receives training through the MOH and RCT programs. Dissemination of the National Family Planning Service Guidelines to private practice physicians is limited to those who participate in the RCT family planning training program. Theoretically, copies are available for any physician who wishes to go to the Ministry of Health or the National Population Council to take one.

The provision of contraceptives other than barrier methods is restricted to physicians, although oral contraceptives are widely available from pharmacies without prescription, and nurses are reported to provide some clinical methods. There are currently 65,000 physicians practicing in the country, and a policy decision has apparently been made

to reduce the annual number of MD graduates in an effort to ameliorate what is considered to be an over-supply. Cultural and financial constraints appear to limit the number and location of female physicians available. There are 12,000 pharmacies throughout the country, and they are considered to be widely accessible.

There is a great shortage of well-trained nurses; but this is caused by cultural and social prejudices against nursing, poor nursing training programs at most levels, and the fact that entrance to nursing school does not require high scores on the *Thanawiyya Amma*, the universal high school exam.

With respect to client eligibility and use of family planning services, the national standards of practice require that family planning methods be provided only to married women between the ages of 16 and 49. According to the guidelines, physicians should give medical exams, including skin, eye, mouth and teeth, thyroid, breast, heart, weight, blood pressure, abdominal, and pelvic exams to new clients; to all clients annually; and to all clients with side effects or complications. These are the practices that are followed in MOH clinics, but it is likely that most of these tests are performed in private sector clinics as well.

## **Conclusions and Recommendations**

The impact of restrictions on who may provide clinical contraceptives varies from one method to another. With respect to standards governing access to family planning services generally, there is anecdotal evidence on both sides of the issue as to whether requirements for physical tests constitute a barrier because of time, cost, and/or embarrassment involved. Limited access to female physicians could make requirements of physical tests an even greater barrier; and the cost of nonessential tests could constrain access for those who purchase services in the private sector. There is a need to gather more quantitative information upon which to base a conclusion, and to determine price elasticity of demand for contraceptives.

### **2. Oral Contraceptives**

#### **a. Oral Contraceptives in General**

Oral contraceptives (OCs) can be purchased easily without a prescription, and are principally obtained from pharmacies (83.6%). However, OCs can also be purchased in public (11.6%), PVO (1%), and private clinics (.7%). The price of OCs is generally low as a result of government policies described in the section III.

According to the national standards of practice, oral contraceptive users should return to the clinic every three months for the first year after beginning the method. While the follow-up visits do not include a complete physical examination, they could still pose a constraint for women who want to accept the method but are deterred because of the

inconvenience and/or cost of time and travel. At Clinical Services Improvement Project (CSI) clinics, oral contraceptive acceptors often do return after the first three-month period, but they are not required to come back again before the end of the first year of use. MOH clinics presumably follow the standards of practice. If a woman accepts the method, however, she can choose to purchase oral contraceptives from a pharmacy without returning to the clinic. Thus, even if the three-month follow-up is implemented at clinics, women need not comply.

The standards of practice manual lists the following as absolute contraindications to use: known or suspected pregnancy, impaired liver function, known or suspected breast cancer, and coronary artery disease. Relative contraindications include: breastfeeding, severe headaches, diabetes, and being over the age of 40 and a heavy smoker or having a family history of heart attack or stroke. As described in section II.B., there are reports of provider misinformation about contraindications.

### **Conclusions and Recommendations**

Oral contraceptives are easy to obtain, and there are no significant regulatory barriers with respect to their sale and distribution or to delivery of related services.

The suggestion in the national standards of practice manual that OC users should return to the MOH clinic every three months for a follow-up visit seems medically unnecessary and, if followed, could present a barrier to use because of the cost in time and inconvenience. This guidance should be reconsidered. Relative contraindications noted in the manual differ from those recommended in guidelines of INTRAH and merit further review.

#### **b. Mini-pills**

Progestin-only mini-pills are not currently available in Egypt; however, they are in the process of being registered. The relevant pharmaceutical companies had not applied for registration of the mini-pill until recently, and the registration process can take up to three years. Organon and Schering will both introduce progestin-only pills once they have been approved.

### **Conclusions and Recommendations**

Progestin-only pills, which are safe and effective during breastfeeding, could play an important role in encouraging contraceptive continuation rates and extending birth intervals because there is a high rate of breastfeeding (80% of Egyptian newborns are still breastfed at 12 months of age according to the 1992 EDHS). Approximately 20% of women of reproductive age in Egypt may be breastfeeding at any given time. Many of these women may already be using some other form of contraception such as the postpartum IUD. Some may choose not to adopt a contraceptive method at all during breastfeeding. One quarter (25%) of breastfeeding women not using another contraceptive method, however, might use the mini-pill if it were available to them. If this threshold of acceptance were reached by 2005, overall contraceptive prevalence would increase by 5 percentage points as a result of the mini-pill alone. This illustrates the importance of the prompt completion of the registration process for this type of oral contraceptive.

### **3. IUDs**

Any MD may insert an IUD. It is reported that occasionally nurses go to patients' homes and insert IUDs, or nurses insert them in the clinic when the doctor is not there. Most women in Egypt have access to a clinic or a doctor, but there are fewer doctors per capita in rural areas and in Upper Egypt. It is said that in Upper Egypt clients prefer women physicians to insert IUDs and to provide other family planning services; however, female physicians are more difficult to find in Upper Egypt than male physicians.

The standards of practice manual gives no age or parity restrictions on IUD use. Known or suspected pregnancy, pelvic infection, history of ectopic pregnancy and menstrual disorders, and anemia are the primary contraindications for use of IUDs given in the manual.

IUDs are sold in pharmacies; while they can be purchased without a written prescription, most women do follow their doctor's verbal recommendation concerning brand and size, where applicable, when they purchase an IUD at a pharmacy [CSMP Influencer Study]. The price of the CuT 380 is kept low as a result of government policies described in the section III.C.

### **Conclusions and Recommendations**

The policy stating that only physicians can insert IUDs does not pose a serious barrier with respect to availability of providers, since there are many physicians. Insertion of IUDs by nurses does not seem to be a viable alternative in Egypt because of the shortage of trained nurses and the cultural/social limitations on nursing as a career. To change these constraints would require enormous costs in time and effort. With the large number of underemployed doctors in Egypt, allowing IUD insertion by nurses would not necessarily expand availability or affordability of the method. However, in areas where the

only MD may be male and where clients may prefer a female practitioner, such as in rural areas and in Upper Egypt, the policy may reduce access to IUDs and should be further examined.

IUDs are easy to obtain; there are no significant regulatory barriers with respect to their sale and distribution, or to delivery of related services.

#### 4. Injectables

A Ministry of Health Advisory Committee has approved injectables for use in all MOH family planning centers, and more recently the Minister announced that injectables would be available in commercial pharmacies to MDs in the private sector as well. Under the new decree, injectables may be provided by any MD, not necessarily by a specialist.

While changes are expected soon, the history of injectables in Egypt sheds light on why its current use is so low. Use of the injectable contraceptives Depo-Provera and Noristerat has been allowed only at a Teaching Hospital Organization (THO), Health Insurance Organization (HIO), or other public or university hospitals by an OB/GYN specialist [Ezz El Din Osman]. Use of injectables has been further constrained by their limited availability at these approved sites. Only 1.1 % of MWRA use injectables [1992 EDHS]. Anecdotal reports suggest that in current practice, in some very busy family planning clinics, nurses--under a physician's supervision--provide the injection.

Depo-Provera is not yet available in pharmacies, but is usually purchased at the site where the user receives the injection. Some private physicians provide Depo-Provera, but they have obtained their supplies primarily through Family of the Future (FOF) distribution channels. FOF, a USAID-supported contraceptive social marketing project, ceased to operate at the end of 1992. While informal channels for Depo-Provera exist, they do not represent a large market, because total availability of Depo-Provera in Egypt is not large.

When Depo-Provera was first introduced to the Egyptian market in 1983, it was primarily provided in the form of in-kind grants from the UNFPA. Shipments of Depo-Provera were irregular, and injectables were often unavailable. Commercial sales of Depo-Provera were limited to FOF/EPTC (Family of the Future/Egyptian Pharmaceutical Trading Company) promotion and distribution to OB/GYN specialists. These limitations made the method inconvenient for many users, because they could not receive the injections every three months as required and had to use other methods as well. In addition, rumors that injectables cause cancer were widespread; and the U.S. Food and Drug Administration's refusal to approve Depo-Provera for use in the U.S. further fueled negative reactions. Side effects, perhaps exacerbated by irregular availability, were reported. Some sources report that it was because of these rumors, others said that it was because of a struggle to control distribution, that Depo-Provera and, by proxy, other injectables were removed from the market, to be re-introduced later only in a limited way through OB/GYN specialists in teaching hospitals and in MOH and CSI clinics.

Depo-Provera is given every 12 weeks and Noristerat is given every eight weeks on days 1-5 of menses. The injection is generally given in the hip and, less frequently, in the arm. The new standards of practice manual will include a statement about the effectiveness and safety of Depo-Provera injected in the arm. This may make the method more accessible to women who must see a male physician and do not want to receive the injection in the hip. The standards of practice recommend annual follow-up visits for women who use this method. The manual does not give a user profile, but it does give the following contraindications to use: known or suspected pregnancy, breast cancer, unexplained uterine bleeding, and diabetes. The Ministerial Decree of 1983, which authorized distribution and use of injectable contraceptives, also listed breastfeeding as a contraindication to use [Schmidt]. In fact, breastfeeding is a prime indication for use, since injectables are progestin-only contraceptives.

Physicians who participated in the 1992 Contraceptive Social Marketing Project (CSMP) survey cited the following reasons for prescription of injectables: patient cannot use OCs (68.8%); no side effects (22.6%); patient preference (22.6%); and effectiveness (16.1%). As described in section II.B., physician knowledge of injectables is very low, and many are unaware of any side effects.

### **Conclusions and Recommendations**

While injectables will soon become more accessible, steps can be taken to increase their use. The reference in the Ministerial Decree to breastfeeding as a contraindication should be reconciled with standards of practice. Because of the popularity and effectiveness of the injection method, increased knowledge of injectables by private practice physicians, and provision by pharmacists could further increase the acceptance rate for this method and, therefore, contraceptive prevalence.

Priority should be given to efforts that ensure the timely expansion of availability of injectables. Because widespread availability of even one additional contraceptive method has been associated in cross-country studies with an increase in national contraceptive prevalence of up to 12 percentage points [Jain, cited in Kenney, 1993], the urgency of these actions is obvious. However, factors which may temper the maximum positive impact of injectables on contraceptive prevalence in Egypt include the following:

- an existing contraceptive prevalence rate of 45% for modern methods;
- present limitation of the injection site to the hip, which is a barrier for women who do not want to see a male physician;
- exclusion of nurses and pharmacists as providers of injectables; and
- no existing regular source of supply of injectables (either commercial or donated).

If the anecdotal evidence is correct, and nurses are administering injections of Depo-Provera and Noristerat under the supervision of doctors, this practice could be legitimized in the standards of practice manual, perhaps making the method less expensive to offer. Given the shortage of nurses and availability of physicians, such a change might not result in significant increases in prevalence.

The delivery of injectables by pharmacists, however, might increase the acceptability of this method. This is because of the potentially greater ease of access to pharmacies (when compared with waiting periods in clinics and private practice offices), and the absence of an office visit fee (in contrast to private practice physicians). There is a great deal of resistance within the MOH and the medical community to an expanded health care role for pharmacists, especially regarding the provision of injections of any kind. Considerable effort would be required to overcome this resistance, and to strengthen considerably training for pharmacists in family planning, both in their university curriculum and in continuing education. The widespread availability of pharmacies and access to pharmacies, especially by lower-income consumers, would appear to make this a policy area worth future exploration.

Expanded use of injectables throughout a broader spectrum of the MWRA population must be supported by increased information and training/counseling for both physician providers and users. Any potential side effects, such as breakthrough bleeding, must be correctly understood so that they do not become reasons for mass discontinuation of method use, and method disrepute.

#### 5. Norplant®

Approved in many other countries, Norplant® only recently received approval from Egypt's Technical Committee of the Medical Services Committee/MOH. (The Medical Services Committee was known as the Supreme Council for Pharmaceuticals prior to April 1, 1993.) While Norplant® has received technical approval and a registration number, the registration process is not yet complete, because the pricing part of the procedure is not yet resolved.

There was concern among Ministry of Health officials that the method had never been tested on Middle Eastern/Egyptian women, so clinical trials for Norplant® were required and set up in university hospitals. The trials, which occurred over five years, have shown to the satisfaction of the Technical Committee that Norplant® is safe for use by Egyptian women.

Norplant® may be well-received in Egypt because clients and doctors alike prefer a method that requires little compliance. After the registration process is completed with the assignment of a retail price, Norplant® will be introduced according to the current strategy approved by the Advisory Committee and the implementation plan which is being prepared by a MOH Task Force with USAID cooperating agency assistance. In any case,

Norplant® will be provided by OB/GYN specialists only. Guidelines for delivery of implants do not appear in the 1992 draft of the Standards of Practice Manual, probably because implants are not yet in general use. (In the 1990 Family Planning Services Guidelines for Egypt, contraindications for use of Norplant® are stated as the same as for injectables.)

### **Conclusions and Recommendations**

Attention should be given to completing the implementation plan for the introduction of Norplant®. However, since IUDs are a widely used long-term method, expansion of the comparatively expensive Norplant® has to be viewed in that context. Furthermore, factors which may temper the impact of Norplant® on contraceptive prevalence include the following:

- cost;
- limited availability; and
- limited number of physicians trained in Norplant® insertion.

### **6. Voluntary Sterilization**

Voluntary sterilization (VS) is not against the law in Egypt, but there are religious and political reasons why it is not endorsed as a contraceptive method. According to the 1992 EDHS, voluntary sterilization has been made available to only 2.4% of MWRA using modern contraceptives. Some family planning providers in Egypt say that women choosing voluntary sterilization are under-represented in the statistics. Influential religious leaders say that nonreversible methods of contraception are not acceptable in Islam. Consequently female voluntary sterilization in Egypt is usually provided only if pregnancy poses a serious medical risk to the mother and if the mother already has many children.

In the National Standards of Practice, grand multiparity (five or more births) is included as a medical risk for the women. OB/GYN specialists can perform voluntary sterilizations in the hospital or in their offices/clinics. The national standards of practice recommend that sterilization be used only if another pregnancy would pose a serious medical threat to the mother. Criteria for medical indications for VS are identified as follows: cardiac/lung disease, history of breast cancer, AIDS, severe kidney disease, diabetes, grand multiparity (>5), two or more caesarian sections, or other life-threatening diseases.

It is universally believed, however, that a doctor must receive the written consent of the woman's husband before he can perform a sterilization for her. This "requirement" does not appear in the national standards of practice for family planning, and it is not clear

that it appears in any ministerial decree. Sometimes doctors perform elective tubal ligations while performing a caesarian section for the second or third birth. It is still required in practice (see above) that the physician obtain written permission from the woman's husband before performing a tubal ligation, and physicians uniformly meet this requirement.

There are a few physicians, however, who believe voluntary sterilization is an acceptable method for self-selected clients, even though these women do not demonstrate medical-related indications. These physicians are primarily found in urban areas and serve better educated, more affluent women. It is becoming somewhat more common for physicians to regard grand multiparity as a medical-related indication for voluntary sterilization.

Male voluntary sterilization, while legal, is rarely ever performed. Egyptian men are not likely to request vasectomy as a method of contraception. The 1992 EDHS showed no respondents whose husbands had had vasectomies.

Worldwide experience indicates that many countries that move into the highest levels of contraceptive prevalence have done so only when voluntary sterilization has become widely available. VS accounts for 35%, 23%, and 66% of contraceptive prevalence in Mexico, Tunisia, and the Dominican Republic, respectively. Many developing countries with contraceptive prevalence of 60% or more have at least 33% of prevalence accounted for by VS. Even Catholic Latin American countries follow this trend.

### **Conclusions and Recommendations**

In the cultural and religious context of Egypt, VS is a particularly sensitive method. Continuing education of family planning service providers on the health risks of repeated pregnancy and childbirth may be the most effective way to expand the availability of voluntary sterilization to women within this religious and political environment.

The issue of whether a husband's written consent is legally required to perform VS should be clarified, and information should be quickly and clearly disseminated to practitioners if it is not.

Cultural and religious constraints are such that it does not appear that a major effort to change the climate for male voluntary sterilization would be worth its cost in time or resources.

### **7. Other Methods**

Spermicides are available in Egypt only in the form of foaming tablets. Diaphragms are basically unavailable. While these products have been accepted as family planning methods in Egypt, their prices are very high compared with other available methods.

Pharmaceutical companies are reluctant to import them because they believe there is not a sufficient market for profitability. Physicians may choose not to prescribe spermicides and diaphragms because they are less effective than other methods and require strict compliance by the patient. There are no legal restrictions, however, regarding spermicides and diaphragms.

Condoms can be purchased in pharmacies or in MOH and PVO clinics. The FOF used to provide condoms through its *raeda rafaya* outreach program. Distribution of condoms through other outlets is not considered appropriate in Egypt for cultural reasons. There appear to be a sufficient number of pharmacies to ensure that private sector distribution of condoms through these outlets alone does not pose a barrier for acceptance of the method.

### **Conclusions and Recommendations**

Condoms are easy to obtain; and there are no significant regulatory barriers with respect to their sale and distribution, or to delivery of related services.

#### **B. Technical Competence of Providers: Physicians, Nurses, Pharmacists**

##### **1. Level of Knowledge About Specific Methods**

###### **a. Oral Contraceptives**

The benefits of oral contraceptives are known by a growing number of physicians, since 7,300 MOH, 80 CSI, 9 THO, and 1,100 Egyptian Junior Medical Doctors' Association (EJMDA) physicians have now received training in family planning methods [RCT report and MOH SDP document n.d.]. There are some physicians who continue to prescribe high-dose oral contraceptives because they believe the older formulations are more appropriate for obese women, and many of their clients are obese. Some physicians tell patients that they must "rest" from the pill after two years, although this is not included in the national standards of practice. Many physicians use out-dated contraindications or over-apply contraindications to oral contraceptive use. For example, varicose veins, diabetes, and headaches, all relative contraindications, are treated by some as absolute contraindications; and many physicians will not prescribe oral contraceptives for women over 40. In addition, a pharmacist survey fielded by the Contraceptive Social Marketing Project in 1992 showed that pharmacists rated the truth of the statement "oral contraceptive use does not cause cancer" as 5.7 on a scale of one to ten. Only half of the physicians surveyed by CSMP reported that they discuss with patients how to use oral contraceptives or the possible side effects of this method.

## **b.     Injectables**

A CSMP study of physicians in 1992 showed that only 2.2% of physicians were "very familiar" with injectable contraceptives, while 69.2% and 28.2% were not at all familiar and somewhat familiar, respectively. Of the 69.6% who do not recommend use of injectables, 85.5% cited negative side effects as one reason, and 24.6% cited unavailability. Of those who do not recommend injectables, 25% stated that they would if they were available, and 28.8% said they would recommend them if they had more information.

## **c.     IUDs**

A consumer intercept study conducted by the CSMP in 1992 indicates that physicians replace IUDs an average of every two to three years; but in a study of family planning influencers also conducted by the CSMP, doctors said they replaced IUDs every three to four years. There are indications that the interval between insertion and removal is increasing as doctors become more aware of the benefits of the newer IUDs. They are also beginning to insert an IUD directly after removing an old one rather than instructing the patient to wait one month.

## **d.     Norplant®**

Because Norplant® is not well known, rumors about side effects are growing. These rumors include the following: Norplant® causes cancer; it is only experimental; it "eats" bones and skin; it causes diabetes; it causes infertility, paralysis, and heart problems; and it moves around inside the body. These rumors can be heard not only from clients in clinics and their relatives, but also from physicians who do not work in the facilities providing Norplant®.

## **Conclusions and Recommendations**

Considerable priority should be given to continuing dissemination of the national standards of practice to service providers. Distribution of the guidelines themselves as well as family planning training programs should be continued within the MOH system. Monitoring of quality assurance should be strengthened within the Ministry system to ensure adherence to the standards of practice. In the private sector, adherence to standards of practice should be monitored by professional associations such as EJMDA and the physicians' syndicate. Development of requirements for initial licensing, for continuing education/training, and for periodic relicensing of physicians could provide a system for promulgation and acceptance of the national standards of practice. Increased method continuation rates--effected by better informed service providers--can reasonably be expected to enhance contraceptive prevalence.

## 2. Preservice Training and Continuing Education

MDs usually graduate from medical school with four months of academic training in obstetrics and gynecology, of which approximately one week focuses on family planning. In addition, they have had a one-year internship, which includes an obstetrics and gynecology section. Consequently, graduating physicians may have had some (one week) clinical practice in family planning, but may not have actually provided services on their own. OB/GYN specialists have more academic concentration in family planning: they have approximately two weeks of clinical practice, during which they insert an average of 10 IUDs.

Ain Shams University offers a new Family Planning Specialization that consists of a 13-month program for general practitioners who have at least one year of experience or who plan to work in family planning. More emphasis is placed on teaching the uses of contraceptive methods and introducing new technologies than in the regular OB/GYN specialization. Some obstetrics is studied, mainly diagnosing high-risk cases and infertility; and some endocrinology and demography are also included. There is less emphasis on gynecology than in the OB/GYN specialty. A large academic section is devoted to counseling and provision of each method. Clinical practice takes place every day for a minimum of two hours [Dr. Omniyya].

Little or no instruction on family planning topics is included in the regular curriculum for pharmacy students.

Most nurses have attended a nursing secondary school, and some have attended a two-year technical program; a few have attended university. Nurses with a diploma from the nursing secondary school or a two-year technical program have had little or no instruction in family planning topics. Clinical practice is not emphasized. There is a High Institute for Nursing, which provides a five-year program including a one-year internship. In this program nurse candidates are exposed to topics including family planning, sex, and reproductive health during their obstetrics courses; but these areas are not well developed. They are exposed to some contraceptive methods: oral contraceptives, IUDs, condoms, and injectables. However, nurses who are graduated from the High Institute usually become instructors or administrators and rarely work in patient care [M. Elliott, Dr. Ali Abdel Azeim].

Continuing education is not required for any health professional/ worker to continue practicing. Continuing education usually occurs in the form of MOH or USAID project-based or self-paid programs. The MOH, Family Health International (FHI), and other organizations sponsor seminars and talks by distinguished lecturers for physicians working in family planning. Many physicians have received basic training in family planning through the MOH, THO, RCT, CSI, the Private Practitioners Family Planning Project (PPFPP), or university training programs. Some nurses receive family planning training through the RCT and its satellites (7,500 in the past three years).

Training in family planning for pharmacists, however, is virtually nonexistent. The CSMP used to provide some seminars for pharmacists, and the Egyptian Fertility Care Society (EFCS) publishes a pharmacist's journal. However, physicians in general do not approve of a role for pharmacists in family planning. They believe that only doctors should be allowed to provide contraceptive methods. Since most MOH officials are doctors rather than pharmacists, it may be difficult to gain support for pharmacist training to increase their involvement in service provision.

The 1992 CSMP Influencer study revealed that 52% of the private practice physicians interviewed in Cairo and Alexandria received their IUD insertion training ten or more years ago, and 30% received training within the past five years. The doctors in the sample received their training as follows: 24% during university courses, 17.7% from the Egyptian Family Planning Association (EFPA), 10.4% from other university courses, 9.5% from CSI, 9.4% abroad, 5.2% from PPFPP through EJMDA, and 5.2% from the Society of OB/GYNs. These percentages have likely changed during the last year because of increased training through the MOH/SDP and RCT projects. Physicians surveyed at an FHI lecture series in 1992 said that they would like more clinical training in family planning methods.

### **Conclusions and Recommendations**

Increased emphasis should be placed on family planning in the regular curricula in medical, nursing, and pharmacy schools. Active involvement of knowledgeable, appropriately trained pharmacists in family planning service delivery could increase the use effectiveness of contraceptives among Egyptian women by providing them with a convenient source of correct information.

#### **C. General Regulation of Practice of Medicine and Pharmacy**

##### **I. Professional Certification**

There appear to be no regulatory restrictions on the number and, therefore, availability of health care service providers in Egypt. In fact, so many MDs have been graduated annually from the state-funded medical schools over time (approximately 5,000 per year) that it has been difficult for many MDs to earn enough money through practice to maintain or to purchase the equipment necessary for adequate infection control.

Neither physicians nor pharmacists must meet any special requirements to provide family planning services or supplies, although both groups must be registered with the appropriate professional syndicate upon graduation from university in order to enter into practice in general. A graduate fills out a form including his/her scores on the medical or pharmacy school final exams and is presented with a card that identifies him/her as a physician or pharmacist. The first card is free of charge, but the physician must renew each year for a fee of approximately LE 15.

To open a private clinic or practice, a physician is supposed to register with the physicians' syndicate. However, many physicians do not register due to tax reasons or simply because it is easier not to register [Dr. Ali Abdel Azeim, Dr. Nabil Nassar]. As part of the registration process, the doctor must apply for a tax card; and the clinic must be inspected by officials from the syndicate. It is estimated that of the 65,000 practicing physicians in Egypt, only 40,000 have registered their practices.

Pharmacists must register with the pharmacists' syndicate in order to open a pharmacy. The pharmacist must prove that s/he is qualified, and the premises must be inspected by the syndicate.

Physicians', pharmacists' and nurses' syndicates are nongovernmental agencies registered under the Professional Syndicates Law. While these organizations are nongovernmental (their officers and board members are elected from among the membership), they have been given authority by the GOE to license and monitor, at least in theory, members of their respective professions. Syndicates also represent the political and economic interests of their memberships. To practice medicine or pharmacy legally, an individual must join, or register with, the relevant syndicate.

It is reported that the nurses' syndicate acts mainly as a union for nurses. Nurses are not required to register with their syndicate before beginning employment [Project Hope].

The Egyptian Medical Association (EMA), the Egyptian Junior Medical Doctors' Association (EJMDA), and the associations of other medical specialties are also nongovernmental organizations but are registered under the Ministry of Social Affairs. These associations operate in the areas of scientific research and social work and have no GOE-authorized regulatory control over their membership. While it is a requirement that all practicing physicians join the physicians' syndicate, it is not a requirement that physicians join the EMA, EJMDA, or any other professional association.

## 2. Limitations on Private Practice

There are no regulations barring health professionals, except nurses, from private practice. Nurses cannot provide independent services. MDs can easily open private clinics if they can afford to. MDs working at MOH clinics often have their own clinics as well. There are two restrictions for these MOH doctors: 1) they cannot operate their private clinics during MOH hours; and 2) residents cannot operate clinics. The MOH, however, allows doctors to use MOH facilities after hours for their private clients. Some residents have their own clinics despite the regulation.

Pharmacists are also free to open pharmacies if they have enough money. The only restriction for pharmacies is that a new pharmacy cannot be established within 100 meters of an existing pharmacy.

The majority of women have access to private clinics. The preliminary findings of the 1992 EDHS indicate that 65% of the MWRA currently using modern contraceptives obtained them through private sources. A smaller percentage of IUDs were inserted at private clinics in 1992 (53%) than in 1988 (57%). This decrease may be due to the success of the MOH in mobilizing its clientele and the improved quality of service delivery in MOH family planning clinics, including the increased number of trained physicians in these public clinics. The percentage of women using private voluntary organizations as a source for contraceptives increased from .5% in 1988 to 6.7% in 1992, which is mainly attributable to CSI clinic operations.

### 3. Prescription Requirement

Officially, all pharmaceuticals in Egypt, including aspirin and cold medicines that are over-the-counter (OTC) drugs in many countries, require a prescription. In practice, however, prescriptions are required only for narcotics and medicines for treating serious illnesses such as cancer.

### **Conclusions and Recommendations**

The registration process for service providers neither poses a barrier to provision of contraceptive methods nor promotes the provision of family planning services.

There are no professional regulations that prohibit private practice provision of family planning services, as demonstrated by the large number of women obtaining contraceptives (principally oral contraceptives and IUDs) through the commercial/private practice sector. However, the limitations imposed by the government family planning program as described above, do constrain contraceptive availability in the commercial/private sector and should be removed wherever possible.

General prescription requirements do not appear to present any obstacle to contraceptive use.

#### **D. Economic Interests in Choice of Methods**

##### I. IUDs

Dramatic, recent increases in IUD prevalence have created noticeable sensitivity within the service delivery sector concerning the reasons for these increases. The fact that physicians receive a higher fee for inserting IUDs than for prescribing other methods, and that training grants are available for IUD insertion have caused some to postulate that there is a physician bias toward IUDs. While IUDs are a safe, effective, long-term contraceptive appropriate for many Egyptian women, it seems possible that economic incentives to practitioners have had at least some impact on increased IUD use. However,

such economic incentives are not objectionable unless women for whom IUD use is inappropriate are being given these devices.

An internal CSI study revealed that requests for IUDs at CSI clinics outnumber insertions, indicating that IUDs are not inserted if the woman prefers another method or if there are contraindications. MOH clinics are just beginning to implement a monitoring system, but research on clients in MOH clinics revealed that most came to the clinic seeking an IUD. (There is considerable promotion of IUDs in the nationwide State Information Service--SIS--family planning mass media program; this promotion undoubtedly contributes to the acceptance of IUDs among contraceptive consumers.)

Many family planning professionals report that client and physician satisfaction with IUDs is due in large part to the effectiveness of the method and to the fact that only minimal user compliance is required [Rebecca Copeland, Amani Selim, Dr. Ali Abdel Azeim, Dr. Laila Kafafi]. Also, the fact that there are fewer instances of STDs in Egypt than in many other countries may make the IUD more satisfactory for more women.

## 2. Triphasics

Only one triphasic oral contraceptive is currently on the market in Egypt. The local manufacturer makes a higher margin on this pill because it has a higher price than the low-dose or high-dose pills. (The foreign licensor actually makes less on the triphasic, because it includes a smaller amount of the active ingredient/hormone which the licensor supplies.) While pharmacists carry the triphasic formulation, they report that they do not sell it unless the customer asks for it by name and that they want to provide the formulation that the woman is used to. To the extent that this is true, an economic bias toward promotion of triphasics by the pharmaceutical manufacturer or even the distributors does not necessarily affect what the pharmacist sells to his or her client [Dr. Aly Zewar, Schering and Latin America St. Pharmacy]. Other family planning service providers report, however, that there is a push by pharmacists to sell the more expensive oral contraceptive formulations.

Physicians receive promotional visits from the medical representatives of various local and international contraceptive pill manufacturers. Representatives of the available triphasic certainly promote to physicians its advantages over other oral contraceptive formulations. Triphasics, in general, have the additional attraction to physicians of being a newer, more sophisticated technology. But since physicians in Egypt do not dispense drugs, their prescriptions for triphasic orals do not gain them any direct financial advantage.

## **Conclusions and Recommendations**

Economic interests of providers currently do not appear to have a noticeable adverse effect on contraceptive method acceptability, but it may be an issue that merits monitoring as efforts are made to expand use of other methods.

## **E. Other Access Issues in the Public Health Delivery System**

### **I. Quality of Family Planning Clinic Services**

In the past, quality assurance/improvement and infection control have been problematic in Egypt. However, with the growing emphasis on quality improvement at the national level through the SDP training program, MOH clinics have greatly improved during the last few years. There are additional projects implemented through the Regional Centers for Training, the Teaching Hospitals Organization, the Clinical Services Improvement Project, and the Egyptian Junior Medical Doctors' Association, which emphasize the quality of family planning services. It is difficult to tell whether the training programs are successful, because monitoring of service improvement is just beginning. By all reports, however, there has been improvement in quality of family planning services at all delivery points [SDP and CSI draft evaluation reports]. Pilot studies in Qalubiya and Fayoum governorates are currently under way.

While services in clinics have been improving, there are indications that quality assurance has not been a clearly understood issue for clients at MOH clinics. A 1992 CAPMAS survey "Assessment of Family Planning Services in Egypt," revealed that lack of cleanliness of the clinics was mentioned by only 17% of clients when asked what they did not like about the MOH clinics. (In qualitative focus group research undertaken on behalf of CSI clinics, cleanliness of clinic sites was always mentioned by participants as one of their concerns.) However, 32.7% complained of long waiting times. The MOH clients did not seem to know about the possibility of infection. It seems reasonable to assume, however, that the experience of infections or side effects caused by low quality of service delivery does create barriers to expanded contraceptive prevalence, whether or not women's perception of cleanliness meets developed-country expectations.

### **Conclusions and Recommendations**

Without further data it is difficult to conclude that quality of services constrains access. However, some concern is currently voiced in Egypt that quality assurance/improvement efforts have led to tests and follow-up visits which create a constraint to contraceptive acceptance. There have been some reports of physicians requiring five to six pelvic exams in the first year after IUD insertion [e.g., "Next Step for Egypt -- Access to More Methods"], or requiring ultrasound examinations before insertion.<sup>1</sup> Many physicians cannot afford ultrasound equipment and would not exclude themselves from providing IUDs because they cannot provide ultrasound examinations. A recent study by Pathfinder International indicates that use of ultrasound in family planning service

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<sup>1</sup> It should be noted that a recent Population Council study on quality assurance revealed that women who were interviewed found that it was reassuring to have three to four follow-up visits in the first year of IUD use.

delivery does not increase contraceptive acceptance or the financial sustainability of the service-providing organization.

## 2. Government Administrative Procedures

Agreement on a bilateral family planning project involves USAID and the GOE, including the Ministry of International Cooperation and the relevant implementing agencies. After an agreement has been reached, the Minister of Planning reviews the proposed budget of the submitting implementing ministry. These budgets include donor contributions as well as GOE contributions to the subprojects. Additionally, the GOE contribution to this budget--especially in the case of employee salary and incentive payments--is, as of the beginning of the new Population/Family Planning III Project, a condition of the agreement between the two governments for the disbursement of local cost financing.

During implementation of the project, however, MOH managers are required to seek annual approval of the Egyptian contribution (for example, for personnel and salary line items) from mid-level bureaucrats in the Office of Administration and Regulation who have no project-specific knowledge or experience. These mid-level bureaucrats can and do decide to withhold full funding for particular line items, even when the project budget has already been approved by the Ministry of Planning, and when the amount of the GOE contribution is a condition of the bilateral agreement. It is still unclear in the minds of many experienced government employees how the budget process functions.

Considerable management time is required to negotiate these budget approvals annually. Substantial confusion and disruption within the service delivery system are also caused by the uncertainties over employee compensation.

Both the Government of Egypt and donor agencies of other governments have financial accountability requirements for their contributions to family planning service delivery activities. Periodic reporting is supplemented by large-scale annual or multi-year audits. To date, each government or donor agency has implemented its own independent audits. This has meant, for example, that in 1992-93 the MOH/SDP, among other projects and organizations, has had auditors in its central and/or governorate offices almost without interruption.

## **Conclusions and Recommendations**

Family planning service providers must devote time both to service delivery and to administration. To the extent that administrative regulations and procedures divert undue time and effort from service delivery related tasks, they are constraints to the provision of family planning services and to the expansion of contraceptive prevalence.

Wherever possible, necessary systems for budget and other approvals should be streamlined. Particularly, systems should allow for multiyear approvals of budgets and activities as described in project documents. Interim or annual approvals should be required only in the case of changes in project design, cost, or implementation. Where approval of budgets and activities has been given at the ministerial level, it should not be necessary to seek subsequent lower-level approvals.

Every effort should be made by the GOE and donor agencies to share reporting systems and audit procedures/results. Such sharing could ensure that program implementers are not being asked constantly to respond to the varied demands of multiple agencies for similar information, which reduces the amount of time and attention available for service delivery. In the case of financial audits, which require considerable time to execute and are generally quite costly, it would appear to be to the advantage of all concerned if the GOE would make the results of its audits of USAID-funded projects available to USAID. Under USAID regulations, the presentation of GOE-sponsored audit results for relevant projects could take the place of part of the required USAID-funded financial audits. (USAID would still have to monitor the soundness of internal controls and compliance with USAID regulations in the use of agency funds.)

Tremendous emphasis should be given to activities which can develop deep within the GOE bureaucracy a clear understanding of the ramifications of administrative decisions on service delivery effectiveness, the importance of family planning activities to the national population policy, and of President Mubarak's commitment to this area. Such activities are especially important in settings where regulatory and legal systems, while rationally stated, are vulnerable to political and individual intervention. Motivated, knowledgeable bureaucrats can facilitate in hundreds of ways the processes necessary for successful family planning service delivery. Unmotivated, unknowledgeable bureaucrats can equally well constrain effective service delivery and restrict optimum contraceptive availability.

### **III. AVAILABILITY OF CONTRACEPTIVES ON THE MARKET**

Laws and policies governing approval of products, importation, local production, and pricing (curbing free and continuous availability of a full range of methods) are other reasons for the "two-method" family planning program in Egypt. Currently, OCs are both imported and locally produced by parastatals; other products are imported. The impact of laws and policies varies depending on the type of product. However, the major problem is pricing.

## **A. Introduction of Products into the Market**

### **I. Import Policies and Relationship to Local Production**

If a drug can be produced locally, companies are encouraged to produce under license in Egypt. This may be more profitable to the parent companies than importing finished drugs--depending on the retail price allowed--as the cost of production is lower in Egypt. Once a particular pharmaceutical formulation is locally produced, importation of similar formulations is prohibited.

For pharmaceutical products, only three or four presentations of the same general drug have been allowed into the market. For example, only three roughly similar low-dose oral contraceptives (Microviar, Nordette and Norminest) are currently registered for sale in Egypt. Unless the producer can prove that a brand is significantly different in composition from already approved brands, the product is generally not allowed into the market.

Once a pharmaceutical product is approved and registered, importation appears to be fairly easy. The importer must set up a regular letter of credit, and this process takes approximately one month. The importer must also have a license to import, but this is not difficult to obtain.

If a product is locally produced, however, its import is restricted. While this restriction protects local manufacturers from competition, the rationale often given is that it protects the consumer from higher-priced imported products. The Minister of Health<sup>2</sup> has been quoted as saying "that he would never approve the legal import of such (high-priced) medicines. 'You know, these medicines are extremely costly, and once we approve their import, the country's doctors, encouraged by their strong effect in treating serious disease, will have an easy time to widen their use in the country. Result: the patient will shoulder unbearable burdens to buy them.'" The Minister is also quoted as saying that the country should cautiously import some of these drugs [Pharmaceutical Industry Goes Astray].

Importers of pharmaceuticals must submit an annual plan stating how much of each drug will be imported during the following year. Although companies can get an increase if they go over the planned amount, most companies choose to overestimate how much they will require so that they do not have to repeat the approval process. Another regulation that affects imports is Ministerial Decision 58/1976, which states that the importer must provide a regular supply of a drug for at least three years.

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<sup>2</sup> A new Minister of Health was appointed in November, 1993. His position on these issues has not yet been fully articulated.

## **Conclusions and Recommendations**

Aside from limiting imports of types of pharmaceutical products that are locally produced, import quotas do not pose a barrier to importing contraceptives. The import substitution policy adopted by the GOE for pharmaceuticals does not significantly limit the availability of oral contraceptives, since there is more than one locally produced brand - as long as these locally produced brands are consistently available. **There are indications, however, that price controls on locally produced products are leading to shortfalls in manufacturing output and, therefore, retail stock outages.** Price control policies and quota restrictions on importation of drugs should be re-examined in light of their potential joint impact on contraceptive availability.

The GOE is not constraining the number of methods currently available by limiting pharmaceutical preparations to only four presentations of the same type of drug. If, however, prices for pharmaceuticals are freed from controls, this restriction could block manufacturers of less expensive, price-competitive brands from entering the market and, therefore, could limit the price accessibility of contraceptives to lower-income consumers. A long-term strategy for free market operation within the pharmaceutical sector should be developed and initiated.

The Ministry of Health should consider making a distinction between the public and commercial sectors in its limitation of presentations of each drug type. For example, it may be financially advantageous to the Government of Egypt to limit the types and quantities of pharmaceutical products that it supplies through the MOH system. This could be achieved by limiting the public sector to supplying generic products. It does not appear necessary, however, for the government to control the commercial availability of drugs in the same way, since consumers pay the price of the commercial pharmaceutical products that they wish to have.

### **2. Process for Registration and Pricing**

The registration process does not appear to be longer for imported pharmaceuticals than for locally produced drugs. Some categories of pharmaceutical products are considered essential by the government and are completely controlled. These include: cancer medicines, insulin, baby milk, and contraceptives. Because of their special status, essential drugs are regulated more closely than other pharmaceuticals [Organon, Schering].

IUDs and condoms do not require the same registration or approval process as OCs, injectables, and spermicides. OCs, injectables, and spermicides are classified as medicaments according to tariff schedule 30.03 (contraceptives, insulin, tumor and cancer medicaments, cardiovascular medicaments, bilharziasis, and artificial plasma substitutes) [Organon, Schering]. Registration of oral contraceptives must be renewed every ten years. The initial registration often takes three years, and the renewal can take one year [Syntex].

To register a medicament, or drug, in Egypt, the following information must be provided:

- a certificate showing that the product is for use as a pharmaceutical drug;
- Ministry of Health Form #17 from the MOH in the country of origin;
- a certificate from the country of origin stating that the drug is authorized for use there;
- four copies of the product formula;
- the insert leaflet;
- FOB (free on board) price;
- a list of countries in which the drug has already been approved;
- description of product pharmacology;
- stability data or studies;
- four copies of the outer packaging;
- certificate of analysis;
- certificate of analysis for raw materials;
- description of the method of analysis (four copies);
- specifications -- criteria used in analysis;
- Egyptian Drug Information Center worksheet for the drug authority; and
- computer sheet for the Pharmacy Department.

The above information must be provided to the Medical Services Committee/MOH. There, the documents are examined to make sure the information is complete and they are then sent to a Technical Committee. The Technical Committee may send the information to a specialized subcommittee or request clinical trials. The Technical Committee also sends the product file to the laboratory at the National Organization for Pharmaceutical Control, where samples of the drug produced at the local factory (or produced abroad, in the case of imported finished products) are tested to be sure they meet the specifications

laid out by the parent company in the certificate of analysis. After certification by the laboratory, the file returns to the Technical Committee, which then either approves the product for registration or rejects the application. The Technical Committee's approval includes a statement of any restrictions on product distribution that it deems appropriate (e.g., only through specialists, only through the public sector, etc.).

At this point the product, if approved, receives its registration number; and the issue goes before the MOH pricing committee. Once a price is set, the drug can be introduced into the Egyptian market. However, the price set by the pricing committee is often not satisfactory to the manufacturer, and the drug may not be introduced after all. The entire process often takes two to three years. Even if all documentation is in order, companies feel they need support within the MOH in order to move their products through this process. They also hope that the product does not become a political issue, because additional trials/time may be required for approval.

According to industry sources [Organon], IUDs (classified as "other appliances" in tariff schedule 90.19) and condoms (classified as "hygienic and pharmaceutical articles of unhardened vulcanized rubber, with or without fittings of hard rubber" in tariff schedule 40.12) do not require price approval by the MOH as part of their registration procedure except for the CuT 380 because it is a donated product (see section on pricing). To market IUDs in Egypt, a firm need only give two samples of the product to the MOH for confirmation of product sterility [Organon].

### **Conclusions and Recommendations**

A registration system for pharmaceuticals is necessary and is not in itself an undue barrier to provision of contraceptives. The registration process as described in Ministerial Decree No. 297/1976, "Relating to Documents Demanded and Proceeding Adopted in Case of Registration of Local or Foreign Pharmaceutical Preparations," is rational. The implementation of that process, however, is vulnerable to individual and political interventions in ways that do constitute constraints. For example, the Technical Committee does not meet at regular intervals. Clinical trials seem to be required on an ad hoc basis, and decisions about how many test cases are needed seem to depend on the personal preference of relevant Technical Committee members. Though not extensive, laboratory tests required to confirm product composition take several months, when the same tests could be conducted in one week. Efforts should be made to regularize the implementation process for drug registration.

#### **B. Costs of Import and Local Production**

##### **I. Tariffs on Products and Raw Materials**

According to the tariff schedule, OCs are classified under schedule 30.03 and have a tariff rate of 1%. Other medicaments fall under schedule 30.05 with a rate of 10%.

Condoms are classified under schedule 40.12, section a, "methods of contraception," with a rate of 5%. Raw materials are taxed at the time of import. (For OCs, the rate for raw materials appears to be the same as for finished OCs, or they are classified under schedule 29.39, which includes "hormones and other," and have a tariff of 5%.) According to local representatives of Schering AG, the raw materials required for local production of OCs have a tariff of 1%. Representatives from Organon say the rates are 10% and 5% for finished pharmaceuticals and raw materials, respectively.

IUDs fall under heading 90.19, "other appliances worn, carried, or implanted in the body, a) contraceptive loops" and have a 5% tariff rate. One industry source has said that finished IUDs have no official tariff and that the tariff differs by consignment.

### **Conclusions and Recommendations**

Contraceptive products have import tariffs that are the same as or lower than other pharmaceutical products and medical devices. These duties do not pose a significant barrier to importation of contraceptives at present. Nonetheless, it should be noted that many countries with strong population policies, such as Indonesia, have eliminated tariffs and duties on contraceptives.

### **2. Sales and Value-added Taxes**

The MELES Tariff and Sales Tax schedule says that imported medicaments receive a sales tax of 1.625%, while locally produced medicaments are taxed at 5%, except those that have been exempted by decree of the Minister of Health. (N.B., although imported products have a lower sales tax rate, they are subject to import duty.)

Local representatives of Schering AG report that oral contraceptives are exempt from sales tax. It seems that exceptions or variations are frequently the rule. Sedico, for example, receives a reduced sales tax on its products because it is affiliated with ACDIMA, an Arab company that receives a tax break. OTC contraceptives, such as condoms, receive a sales tax rate of 5%, as do medical devices such as IUDs.

Sales taxes are included in the retail price and are collected from the pharmacist by the distributor, who then transfers them to the Tax Authority.

## **Conclusions and Recommendations**

Sales taxes are absorbed by service providers and retailers. Although the cost is passed on indirectly to consumers, it does not appear that retail prices are reduced for products which are exempt from sales tax. Providers are more affected by the tax, as they may have to reduce their profit margins to maintain competitive prices. Overall, contraceptives are taxed at the same or a lower rate than other pharmaceutical products. (While price elasticity of demand for contraceptives in Egypt is unknown, it is doubtful that a 5% sales tax on the 75 piastre--US\$0.22--retail price of a box of six condoms, for example, is a constraint to prevalence of use.)

### **3. Exchange Controls**

Exchange controls in Egypt are under the jurisdiction of the Committee for Foreign Exchange, a department of the Ministry of Economy, and are subject to change [All About Business in Egypt]. Since 1991, obtaining the foreign exchange required for business transactions has been a simple process. It usually only takes one day to exchange LE for dollars.

Anyone can hold a foreign exchange account. Funding of these accounts must be through interbank transactions, check, wire transfer, and more recently, cash. The cost of foreign exchange has been high in the past. Importers were hurt in the late 1980s when the pound was devalued. The exchange rate now is a floating rate, and is very stable against the dollar.

Local currency accounts can only be kept at banks that are at least 51% Egyptian-owned. According to some industry sources, the government is currently more concerned with domestic currency accounts than with foreign currency.

## **Conclusions and Recommendations**

Exchange controls do not currently pose a barrier to importing contraceptive products or raw materials.

## C. Statutory Price Controls

### I. Approval and Appeal Process

All manufacturers, distributors, and foreign licensors are affected by the price controls placed on contraceptive products in Egypt. According to the CSMP Influencer Study, however, significant percentages of pharmacists are selling IUDs, OCs, and Tops condoms at prices other than the regulated prices. Table 2 shows how the MOH determines the retail price for pharmaceutical products.

Table 2. MOH Rationale for Determination of Retail Prices for Pharmaceutical Products

|                                  |   |
|----------------------------------|---|
| Cost of Raw Material             |   |
| +/- Cost of Packaging            |   |
| = Subtotal #1                    |   |
| +20% of Subtotal 1 for           | indirect costs of manufacture   |
| +30%                             | admin / financial costs   |
| +15%                             | marketing costs   |
| +3%                              | research costs  |
| +11.6%                           | scientific office (detailing) costs   |
| = Subtotal #2                    |   |
| +25% of Subtotal 2 for           | profit  |
| = Price to distributor           |   |
| +7.8%                            | distributor mark-up   |
| +5%                              | sales tax   |
| +1%                              | stamp tax   |
| +4.5%                            | cost of credit accounts with retailers<br>(this amount is discounted if retailer pays cash) |
| = Price to retailer (pharmacist) |   |
| +/- 20% pharmacy mark-up         |   |
| = Price to consumer              |   |

As described earlier, the initial price for pharmaceutical products classified as medicaments are set by an MOH committee as part of the registration process. This committee includes the head of the pharmacists' syndicate, the presidents of three public sector firms, and presidents of two local private companies. "Our prices are being set by our competitors' says one [pharmaceuticals] managing director" [Pharmaceutical Industry Goes Astray].

Companies are allowed to make their case to the committee regarding the need for a certain price. If the committee decides on a lower price, however, the company must decide whether or not to distribute the product at all at the approved low price. Pricing is the last and often longest step in the registration process. The committee may deliberate over the price of a drug for one or two years.

The Egyptian Drug Organization (EDO) is a GOE entity which controls public sector pharmaceutical companies, including the Egyptian Pharmaceutical Trading Company, also known as EPTC or EgyDrug, and has representatives on the MOH drug pricing committee. The EDO has been placed under a holding company to initiate the process of privatization, as directed by the International Monetary Fund (IMF). The public sector is still being restructured and the number of holding companies may be reduced, but the Minister of Health is expected to try to maintain control over pharmaceutical prices in order to keep them low.

Under the current IMF standby agreement, pharmaceutical products fall within the fifth category: "sensitive commodities and subsidized imports to be sold at cost to reflect the national importance of the products." However, the majority of pharmaceutical products are sold below cost [Pharmaceutical Industry Goes Astray]. Pharmaceutical prices in Egypt were supposed to reach world levels by June 1993, but there is no evidence that this will happen even within the next year. While letters to the editor in daily newspapers indicate that raising pharmaceutical prices is not politically expedient at this time, industry representatives believe that there will be some movement on the pricing issue soon.

While all drugs are subject to review by the pricing committee, some "nonessential" drugs may be allowed higher margins. Essential drugs, including OCs and injectables, are sensitive products and thus are kept at very low prices. Condoms and IUDs are not controlled, except for the CuT 380 donated by USAID.

Contraceptive products donated by international agencies create another pricing constraint within the commercial marketplace. The government assigns a price to each donated product. Thus if a particular brand of contraceptive is donated, even if it is also imported or produced in the private sector, it cannot be sold at any other than the assigned prices.

## 2. Impact on Operation of Marketplace

Multiple industry sources report that prices for many pharmaceutical products in Egypt are so low that there is significant smuggling of these pharmaceuticals to other countries in the Middle East, Africa, and Europe, where the products can be sold at a substantial profit and still undercut local brands (See Table 3). With a new law in Egypt requiring that all new drugs use the same brand name in Egypt as in other countries, smuggling drugs for resale in other countries will become even easier. Some foreign companies are reluctant to introduce new products in Egypt if their prices are to be

controlled, because goods smuggled out of Egypt may compete with the same brand in other countries' markets. Consequently, some mini-pills, for example, may not be introduced in Egypt if they do not reach the manufacturer's desired price because the companies fear it will be smuggled out of Egypt and compete with its product in other countries.

The black market for pharmaceuticals in Egypt consists mainly of non-approved drugs smuggled into the country and sold for high prices, and of locally produced drugs purchased at controlled (low) prices smuggled out of Egypt for resale elsewhere. This is a result of MOH reluctance to approve expensive drugs and of price distortions in the local market.

The availability of the donated CuT 380 IUD creates a "dumping" effect in the market, as private manufacturers or importers cannot compete with its assigned price. If the donation were phased out, the commercial sector would likely import it for sale since it is one of the least expensive in the international market.

There also have been some reports of doctors purchasing the low-cost (LE 2) CuT 380 IUD at public sector (MOH) clinic sites for use at higher prices in their private practices. This practice would create "leakage" in the future if price controls were eased and the commercial sector offered the CuT 380 at a higher price.

Another distortion caused by price ceilings is that high-dose pills are kept at a lower price than the newer low-dose pills, which produce fewer side effects. Some service providers fear this price discrepancy may cause women to purchase the high-dose pills initially, experience side effects, and discontinue the method. Other service providers cite multicountry experience where even lower-income contraceptive users prefer higher-priced contraceptives because of perceived quality differences.

Table 3. Illustrative Prices of Selected Contraceptive Products

| PRODUCT                             | PRICE (LE)             |
|-------------------------------------|------------------------|
| <b>ORAL CONTRACEPTIVES</b>          |                        |
| Triovlar (Triphasic; low dose)      | 1.20                   |
| Nordette (low dose)                 | .45                    |
| Microvlar (low dose)                | .35                    |
| Norminest (USAID-donated; low dose) | .35                    |
| Anovlar (high dose)                 | .13 (1)<br>.10 (2)     |
| Primovlar (high dose)               | .18 (1)<br>.10 (2)     |
| <b>IUDs</b>                         |                        |
| Multiload 250                       | 40.00                  |
| Multiload 375                       | 45.00                  |
| Nova T                              | 60.00 (1)<br>50.00 (3) |
| CuT 380                             | 2.00                   |

- (1) observed price
- (2) official price
- (3) distributor's suggested price

New drugs are priced on a cost-plus basis, and many commercial distributors are satisfied with the prices approved on newly registered drugs. While a new drug may be approved at a price acceptable to manufacturers, price increases are rarely granted for specific existing brands. There is an application process for obtaining a price increase for a particular drug, but pharmaceutical companies rarely attempt this. They reportedly believe the attempt is futile. (One manufacturer's representative says, however, that increases are approved about 90% of the time, but that oral contraceptive prices are not allowed to increase, since OCs are essential products.) To receive a price increase, a manufacturer must fill out an application form and prove that the costs of production have increased or that the exchange rate has become less favorable. Theoretically, prices are allowed to increase once a year, and there is no limit on the percent of increase allowed. In practice, pricing is a give-and-take process between the pricing committee and the manufacturers.

The pricing committee may allow an increase on a nonessential drug because it is maintaining a very low price on an essential one. Usually, price increases are provided by the Ministry as blanket increases every year or two. These blanket increases may provide enough profit to sustain the newer products, but they are not adequate to allow for profits on drugs that were introduced several years ago at an exceptionally low price. Manufacturers received price increases of 20% in 1988 and 35% in 1991, but this has not matched the rate of inflation, which for years was 20% and is now 15%. Interest rates have been approximately 17% per year and the Egyptian Pound has been devalued. The price increases granted have not allowed manufacturers' sales to keep up with their costs.

The price ceilings in the pharmaceuticals industry have hit every level of the distribution chain, but local manufacturers are beginning to fight back. The manufacturers must use foreign exchange to buy raw materials and then sell the finished product for a price so low that even the state-owned companies are threatening to stop producing certain drugs, including oral contraceptives [Pharmaceutical Industry Goes Astray, and Schering]. Some pharmaceutical technologies are not being introduced because foreign parent companies are concerned that they will not be profitable. Manufacturers cannot cut expenses by laying off redundant employees because the labor laws do not allow it. Cid, a state-owned company losing LE 18 million/year on sales of LE 120 million, is threatening to stop production of its Schering-licensed oral contraceptives. If injectables are allowed to become widely available in the private sector, they, too, will be affected by pricing policies.

### **Conclusions and Recommendations**

The pricing of pharmaceutical products is a delicate issue for any country. In Egypt, the problem is even more complicated because the prices have been held at such low levels for such a long time that large percentage increases would be required to bring prices close to market levels. (One package of regular dose oral contraceptives costs the same as two pieces of subsidized bread.) Manufacturers and importers clearly cannot continue to supply oral contraceptives at current prices, but politically, the Ministry of Health may not be able to raise the prices to market levels all at once. Raising prices in the private sector may cause more people to rely on the public sector for services, while keeping prices too low in the private sector may cause stock outages and discontinuation of methods.

A plan should be developed to open up the market for the commercial sector while assuring continued consumer affordability, based on market segmentation. Strategies might include the sale of similar products at different prices, leaving the decision to the consumer as to which one to purchase; or permitting sales of some products at market price in exchange for a guarantee of a low price for certain other products. New products should be priced at levels that allow manufacturers and importers a significant profit so they will be willing to provide a steady supply, and price increases for these products should be granted yearly as allowed by the law. Existing products should receive substantial price increases each year until they are close to market levels. Since data on price elasticity of

demand for contraceptives are not available for Egypt, changes in acceptance of methods should be monitored. If acceptance of methods is negatively affected by price increases in the private sector, the GOE may need to provide more free or subsidized contraceptives through public sector outlets.

Underlying all concerns about pricing of pharmaceuticals in Egypt is the need for the GOE to consider limiting its price regulatory activity to the price of goods and services offered by public sector outlets, and to allow the commercial/private sector to operate within the principles of a free market economy. As suggested above, this might be achieved by using generic products in the public sector.

The black market for contraceptives can affect prevalence because it discourages manufacturers from introducing new contraceptive products in Egypt. Changes in the pricing regulations mentioned above can limit black market activity in contraceptives.

"Leakage" of low-cost products from the public sector to the private sector, however, can continue to affect adversely foreign investments in the pharmaceutical sector. Commercially produced and distributed products cannot usually be price competitive with such "leaked" brands. Effective systems for control of product flow from the public to the private sector will be needed to supplement changes in price controls.

#### **D. Investment Climate**

##### **L. Foreign Investment**

###### **a. Regulations Concerning Control of Ownership**

Most foreign investment in Egypt takes the form of joint ventures. One hundred percent Egyptian-owned and 100% foreign-owned companies may, however, benefit from Law 230 of 1989, which attempts to stimulate foreign investment.

In general, Law 230 simplified the investment process by making the Investment Authority the only agency a foreign investor must deal with in order to get a project approved. The process has been streamlined, so that applications can be ready for approval within 20 days. Under the new law, price controls by the GOE and price ceilings are generally not allowed on products produced by these foreign firms, but pharmaceutical products are among the exceptions to this law.

Most foreign business investments must be approved by the government. The government encourages investment in the pharmaceuticals industry, especially if the investment includes imported high-tech equipment. Squibb was recently allowed to open a 100% U.S.-owned plant under Law 43, which was an exceptional decision. Generally the government gives priority to plants that will offer the potential to generate foreign exchange, offer an opportunity for import substitution, or provide advanced technology.

A Japanese pharmaceutical company, Otuska Pharmaceuticals, has begun production in Nasr City for the export market.

### **Conclusions and Recommendations**

While it is difficult for foreign investors to obtain permission for a 100% foreign-owned company in Egypt, it is possible. There are many other investment opportunities as well, and the GOE is rapidly making improvements in all areas to facilitate private investment. Regulations concerning foreign ownership are not a significant barrier to local production of contraceptives. However, GOE control of prices of any pharmaceuticals, including contraceptives, produced by these investment projects is a significant potential barrier to local production.

#### **b. Joint Ventures**

Law 43 of 1974 and Law 230 of 1989 were established to encourage transfer of technology and foreign investment through joint ventures, but Law 230 allows full foreign ownership. Forms of joint ventures include joint stock companies, limited liability companies, partnerships limited by shares, and limited or simple partnerships. Investment can take many forms, and some industries are subject to additional rules. Unless the venture is a joint stock company with 51% Egyptian-held stock, banks cannot participate in local currency transactions with the business. The pharmaceutical industry in Egypt includes both joint venture manufacturers and local manufacturers producing under license from foreign companies.

### **Conclusions and Recommendations**

Regulations concerning joint ventures neither impede nor provide preferential status for foreign investment in the pharmaceuticals industry nor do they affect the proliferation of contraceptive methods.

#### **c. Repatriation of Profits**

Repatriation of profits is allowed within the limits of the credit balance in a project's foreign exchange account. Repatriation of capital is allowed only after five years of the date of importation. If the capital is sold for foreign currency, it can be repatriated in a lump sum. For Law 230 companies producing under license, 5% of the ex-factory price of finished products goes to the local scientific office (medical representatives and product managers hired by the international manufacturer) for their services, and 5% is paid through the scientific office to the parent company in royalties. For other companies producing under license, the royalty is waived in return for equity. Royalties are taxable and can be repatriated. Licensing fees are not subject to regulation.

## **Conclusions and Recommendations**

Limits on repatriation of profits do not impede foreign investment in the pharmaceuticals industry.

### **d. Free Zones and New Cities**

Free zones exist in Cairo, Alexandria, Port Said, and Suez. The Free Zones Authority was established under Law 43. Types of businesses in free trade zones include storage and warehousing, mixing and repacking, assembling and manufacturing for the export market, and services supplying other businesses in the zone. Goods are not taxed when entering or leaving free zones, but goods coming from within Egypt are subject to export formalities when brought into the zones.

If goods manufactured in the free zone are taken out of the zone and brought into the rest of Egypt, they are subject to duty as imports, but allowances are made for Egyptian content. Free-zone projects are free of Egyptian taxes, except for an annual payment of not greater than 1% of the value of the goods entering and leaving the zone. Compensation of foreign employees working in the zone is free of income tax, and projects are protected by the Law 230 guarantee against nationalization. Free trade zone transactions are exempt from Egyptian foreign exchange controls.

In Egypt "new cities" are designed to shift some of the productive capability out of the established cities and avoid use of scarce agricultural land for non-agricultural activities. Established under Law 59 of 1979 for New Urban Communities, "new cities" provide investors with 10-year tax holidays extendable to 15 years, customs duty exemptions on imports, and other benefits to Egyptians and foreigners involved in industrial and import substitution projects.

## **Conclusions and Recommendations**

While free zones may encourage investment in manufacturing and stimulate activities in some industries, they tend to encourage manufacture for export rather than for local consumption. Thus, while they provide incentives for investment in general, the existence of free zones does not influence the local production of contraceptive products for local consumption.

New cities provide an opportunity for investors involved in production for the local market as well as those involved in export production. The benefits available for investments in the new cities may encourage investment in pharmaceutical manufacture.

#### **e. Hiring Foreign Personnel**

Egyptian companies law stipulates that Egyptian workers must make up 90% of the labor force in a limited liability company and receive not less than 80% of the total wages paid. In addition, 75% of the professional and administrative employees must be Egyptian and their salaries must not be less than 70% of the total wages for the category [Egyptian Companies Law, MELES, Article 174 and 175, and All About Business in Egypt]. For a shareholding or joint-venture company, 75% of the employees must be Egyptian, and their salaries must make up at least 70% of total salaries. However, for advisor and specialist positions, foreign personnel can be hired if there is no Egyptian who fulfills the qualifications. This can be done by applying for an exception from a special committee formed by the Minister of Manpower and Training. Exceptions will be made within two weeks of application, and if no reply is issued, the exception is considered approved for one year or the requested amount of time, whichever is shorter. [Companies Law, Article 176 and Decision No.62/1982].

#### **Conclusions and Recommendations**

Laws on hiring foreign personnel do not act as a barrier to investment by foreign pharmaceutical companies.

#### **f. Impact of Protection for Parastatals**

The Egyptian government spends LE 250 million to assist companies in the manufacture of subsidized drugs and LE 70 million to finance certain medicines. [Pharmaceutical Industry Goes Astray] Many public sector pharmaceutical products are losing money, and many of those that are not losing money owe their success to government subsidies and bail-outs. In addition, some manufacturers of oral contraceptives receive all of their raw materials free through soft loans or grants from donors [B. Ravenholt].

While state-owned companies suffer from price controls, the government does provide them with some relief. Generally the pharmaceuticals produced by the state-owned enterprises are priced lower than those produced in the private sector. Such pricing makes it difficult for the private companies to compete successfully with parastatals. Private companies attempt to produce products that are different from those produced by government-owned manufacturers. With 12 parastatals, however, it is difficult to find original products. In addition, for some government tenders, only state-owned manufacturers are eligible.

In terms of investment, however, the main changes brought about by Law 43 and Law 230 included rationalizing investment laws to encourage both local and foreign investment. Foreign firms receive most of the same benefits and are subject to most of the same regulations as local firms.

## **Conclusions and Recommendations**

While some preferential treatment is offered to parastatal manufacturers of pharmaceuticals, the GOE is making efforts to privatize many industries. Elimination of subsidies on production of contraceptives for the commercial market should be a goal for the GOE to achieve government cost savings as well as a more efficient market for provision of family planning services. Subsidies for contraceptives destined for low-income users of MOH outlets, however, may continue to be necessary.

GOE efforts to rationalize investment regulations for both foreign and local investors are well under way. Progress in this area should be continued to encourage investment in all areas of the economy.

### **2. Local Investors**

Some issues, such as free zones and price controls, affect local investors in the same way that foreign investors are affected. However, the following factors have a particular impact on local investors.

#### **a. Regulation of Production**

In addition to receiving approval from the Investment Authority to initiate an investment project, pharmaceutical manufacturers are required by law to be inspected by MOH officials at every step of the construction of the plant. Representatives of local manufacturers report that such inspections have indeed been carried out.

The plant must have air-tight production areas and an adequate system for sterilizing equipment and ensuring quality. After the plant begins production, regulations require that local formulations of international brands be tested to make sure they meet the licensor's specifications. Every third batch is supposed to be tested to maintain quality.

## **Conclusions and Recommendations**

Regulations on local manufacture of pharmaceuticals do not impede the production of contraceptives in Egypt.

### **b. Import of Raw Materials**

Al-Goumhouriya Company for drugs, chemicals, and medical requisites (GomCom) is the sole importer of pharmaceutical raw materials. GomCom takes part in all import transactions, and requests tenders for raw materials needed by local producers. The manufacturers must fill out a form stating the exact chemical required, and GomCom orders it from the lowest bidder. Although companies must import indirectly through GomCom, they are required to get import licenses or import through agents, and they may import according to demand.

All imported pharmaceuticals must be registered, and importers must obtain regular supplies of drugs for at least three years from introduction. The Egyptian Pharmaceutical Trading Company may distribute pharmaceuticals, if it has an agreement with the importer, but if the EPTC distributes the same product as another distributor, the imports designated for EPTC must be clearly marked and packaged differently than those destined for the private distributor.

Importers must be registered agents with import cards. To import any product, a letter of credit (L/C) must be opened at one of the four public sector banks or through an accredited commercial bank. The application for the L/C must be submitted by the importer or his agent or by an accredited bank. The required documents include: a proforma invoice (original and four copies) and the import card. The commodity imported must fall under the types of activities included in the commercial register of the importer.

## **Conclusions and Recommendations**

While it may be easier for companies to import their own raw materials directly, importation of raw materials exclusively by GomCom does not seem to affect negatively the production of contraceptives in Egypt. In fact, it may offer raw materials at lower prices than could be obtained if manufacturers imported raw materials individually.

### **c. Patent and Trademark Laws**

Egypt is a party to the Paris Convention, but the patent law excludes "substances prepared or produced by chemical processes if such products are intended to be used for food or medicine." A formula will receive exclusive privileges for 10 years and then others can copy it [Schering, Organon]. Processes are not covered by the patent law, under which the regular patent term is 15 years. GOE officials have stated that new patent laws will be developed as soon as amendments to the copyright law are approved. (Egypt is on the U.S.

Trade Representative Special 301 watch list because copyright laws are not adequate.) Although the existing patent laws are not strong, they are enforced.

### **Conclusions and Recommendations**

Patent laws in Egypt afford patent owners with shorter patent life than those in many other countries. However, with 10-year patents, manufacturers and importers are afforded some protection. Lack of stronger patent laws has caused some manufacturers to withhold new pharmaceutical products from the Egyptian market, but most contraceptive formulations are not new. Because development of additional contraceptive methods does not always require technology as expensive as that required for development of many other drugs, the shorter patent life in Egypt does not seem to have a great effect on the contraceptive market.

## **IV. ADVERTISING AND PROMOTION REGULATIONS**

### **A. Mass Media**

There is no official distinction between ethical and OTC drugs in Egypt. As discussed above, all drugs require a prescription. In practice, however, only narcotics and medicines for serious illnesses actually require a prescription.

In theory, no drugs can be advertised through the mass media unless the advertisements are directed at doctors through special journals or programs. Advertisements for very common drugs, such as aspirin and vitamins, have recently, however, appeared in the mass media.

Because contraceptives are part of the national program for family planning, an exception has been made for them. This exception has been granted to the State Information Service (SIS) and various nonprofit organizations. Family of the Future, for example, promoted its oral contraceptive brand Norminest through educational advertisements on television and radio. Branded advertisements are usually directed to physicians, while educational or method-specific advertisements are geared toward the public.

IUDs cannot be advertised directly, but organizations can sponsor programs about family planning where all methods, including their brand of IUD, are discussed. Condoms can be advertised, but advertisements may use only the brand name--not the word condom--in referring to the method. Condoms are usually not advertised through the electronic media. This practice is based on perceived cultural rather than legal constraints and is self-enforced by organizations distributing condoms.

While advertisements for oral contraceptives have been allowed for nonprofit organizations, commercial manufacturers and distributors have not attempted to advertise for orals, because doing so would only add to the costs of an already unprofitable product. It is not clear whether the same exception would be made for the commercial sector to advertise contraceptives as has been made for the nonprofit and public sectors.

To date, the scientific offices representing manufacturers have not been allowed to advertise through the mass media, but instead have used medical journals or specialized magazines and conferences.

The SIS often advertises family planning topics and sponsors programs about family planning for television and radio. Other nonprofit organizations receive a substantial discount on the cost of airing promotional television spots. They pay approximately LE 500 per 30-second spot, while a private for-profit company would pay LE 5,000 for the same amount of time.

Nonprofit organizations also advertise their family planning clinics, since they receive a substantial media discount as part of the national family planning program. Some nonprofit organizations have been recipients of donor funds that can be used to pay the costs of advertising and promotion. Local advertising also is done by nonprofit agencies. CSI clinics have often used a car with a megaphone, local meetings, and stickers to promote their clinics in villages.

Private practice physicians and clinics may advertise through any media. The cost is very high for them, and many cannot afford it. Most advertising for physicians in Egypt is done through word of mouth.

Pharmacies may advertise in any media. However, they usually choose print or outdoor signs rather than the electronic media, because they serve a limited area and do not require national coverage. Print advertising is considerably less expensive than air time.

Advertisements for radio and television must be approved by the communications censor, who usually does not ban an advertisement but may make suggestions for changes.

### **Conclusions and Recommendations**

The State Information Service makes an enormous annual investment in family planning and method-specific information/advertising and promotion on television and radio. In GOE FY 1991/92, for example, the SIS contributions in cash and in kind totaled LE 16,632,142. This investment was further increased by the GOE's significant discounts on the price of air time for family planning advertising. Near universal knowledge of at least one modern contraceptive method and growing demand for contraceptives, especially IUDs, are due at least in part to the success of this mass media effort.

An exception should be sought to allow advertising of commercially distributed contraceptives. It is generally regarded as true that the more sources from which information is received by consumers, the more likely the information is to be accepted and acted upon. Advertising of contraceptives by the commercial sector also ensures that consumers are constantly aware of the private sector as a source of family planning services. Unless the MOH is financially and logistically able to provide a growing population of contraceptive users with goods and services, it will be increasingly important to the GOE that as many contraceptive consumers as are able seek products and care from the private sector.

It must be remembered that profitability of sales--dependent on retail price allowed by the GOE--largely determines whether or not distributors/manufacturers feel financially able to invest in contraceptive advertising.

#### **B. Point of Sale**

Advertisements for all pharmaceuticals are allowed at the point of sale. Stickers, posters, calendars, samples for physicians, and other promotional efforts are used frequently. Point-of-sale materials can be seen in pharmacies, clinics, and hospitals.

#### **Conclusions and Recommendations**

There are no regulations restricting the use of point-of-sale advertising or promotional materials in Egypt.

### **V. RESTRICTIONS AFFECTING NONPROFIT ORGANIZATIONS**

#### **A. Registration with and Supervision by MOSA**

Nonprofit organizations are formed under Law 32 for voluntary organizations. In order to form an organization, the founders must register with the Ministry of Social Affairs (MOSA). This involves submission by the founders of the organization of an application form including their names and personal information, the name of the organization, and its purpose. There must be at least 15 founders.

Depending on the geographical scope of the association's intended operations, the application is submitted to the central (national), governorate, or other appropriate level department of MOSA. A receipt for this submission is given to the applicant. If there is no reply from the department within 60 days of the date on the receipt, then the association is approved.

For most organizations, registration is the last contact they have with MOSA. MOSA does, however, retain the right to send auditors to the organization; and the

organization is required to send reports of general and executive board meetings to MOSA. In practice, most do not send reports. For associations linked with big projects or foreign donors, however, the link with MOSA is more pronounced. While foreign funds may be transmitted directly to the nonprofit association, the agreement for such donations is made under the aegis of MOSA.

MOSA is allowed to request any planning, monitoring, reporting, or budget documents from registered associations. MOSA usually enforces compliance in reporting only if it perceives problems with the administration of the association. In cases of suspected malfeasance, the Minister of Social Affairs has the right to remove the association's board of directors and appoint a new board.

In practice, many nonprofit organizations are staffed with MOSA employees who have been seconded to them. The chairman of the Board of Directors of the Egypt Family Planning Association (EFPA)--the largest family planning PVO in Egypt--is herself the Minister of Social Affairs. Such staffing practices virtually eliminate the distinction between the private nonprofit and the public sectors in Egypt.

### **Conclusions and Recommendations**

Registration of private voluntary organizations is required by law in most developed countries. If a PVO in these countries violates a law, the responsible parties can be brought to account in court, or the organization's registration as a tax-exempt or charitable institution can be withdrawn.

In Egypt, however, the Ministry that grants registration to PVOs is able to intervene directly in their organizational structure and personnel in the case of perceived malfeasance. This makes PVOs--especially those which may be operating in politically unpopular areas or with enviable resources--particularly vulnerable to government intervention. Significant investments in PVOs by donor agencies should be reconsidered because of these organizations' inherent insecurity.

#### **B. Sale of Donated Commodities and Fees Charged for Services**

MOSA does not regulate the sale of donated commodities by nonprofit organizations, but they must follow the same rules as for-profit organizations distributing the same commodities. For example, a nonprofit organization that distributes contraceptives is expected to follow the same laws as any other distributor of pharmaceutical products.

Fees charged for commodities and services provided through a nonprofit organization are not subject to any additional regulations. These organizations are considered part of the private sector. The only price controls that apply are those that apply to the pharmaceutical industry as a whole, such as the price ceiling for oral

contraceptives, injectables, and the CuT 380 IUD. Service fees can be set according to the needs of the organization.

### **Conclusions and Recommendations**

Regulations affecting nonprofit organizations' sale of commodities and fees charged for services do not seem to have a negative effect on the provision of family planning services in Egypt.

## **VI. COMMITMENT TO NATIONAL PROGRAM GOALS**

The success of the national program to date is an indication of the commitment at the highest levels of government decision making to the achievement of Egypt's family planning goals. However, commitment is also required from mid-level officials within the MOH and other ministries who have responsibility and authority over regulations and procedures that impact family planning. Actions at this level have enormous influence over the pace of activity of family planning services delivery.

The evidence shows that this high-level commitment has not been effectively transmitted to mid-level government operations in areas where support is crucial for timely implementation of plans. As detailed in section II.E.2. on administrative procedures, MOH managers must devote an inordinate amount of energy to securing resources that have already been allocated in an approved budget, and to meeting multiple government and donor reporting requirements related to financial accountability. Among mid-level officials, there appears to be no use of independent judgment or exercise of discretion to give priority to family planning by expediting requests, facilitating operations, or streamlining cumbersome procedures.

Similarly, the actions of the wide range of officials responsible for the process of introducing products into the marketplace are not reflective of a commitment to national family planning goals. This is evident in the slowness with which some products have been brought into the market. As described in section II.A.2. on registration of products, the process may be rational; however, the amount of time required and the level of scrutiny applied are highly discretionary.

### **Conclusions and Recommendations**

Evidence suggests that officials responsible for day-to-day operations of government have not been provided with direction and support for according priority treatment to the family planning program.

An organized, systematic education program about the nation's family planning program needs to be conducted to instill deep within the GOE bureaucracy a clear

understanding of the relationship between administrative decisions and success of national program goals. Furthermore, mid-level officials must have the support of high-level policy-makers in two ways: streamlined rules and regulations; and authority and flexibility permitting them to accord priority attention to family planning-related issues when they arise. At the same time, high-level officials have a responsibility to supervise and evaluate the performance of subordinates and to hold them accountable for their performance in promoting national family planning goals.

## **VII. NEXT STEPS**

### **A. Summary**

The major constraint to increased contraceptive prevalence in Egypt is the limited range of methods that are available and accessible. This constraint is reflected in the reliance of family planning clients on IUDs and pills (62% and 29% of modern methods, respectively). The reasons for the limited range of methods vary from one method to another. The matrix shown in Table 4 shows, in schematic form, the most important policy constraints for each method.

Progestin-only pills (mini-pills) may soon be introduced on the market. However, a serious potential barrier to making them widely available is the government's price control policy, which is beginning to undermine the flow of pill supplies in the market.

The most problematic issue for access to injectables has been its restriction to certain facilities. They will now be available from public sector physicians, and the Minister recently announced their availability from private sector physicians and in pharmacies. However, price control policies would have the same negative impact on injectables as they currently have on the pill market.

Norplant® is just being made available on the basis of an approved strategy for which implementation plans are being prepared. Norplant® is expensive, and it remains to be seen how the government's pricing decision will affect consumer affordability and profitability in the market. Voluntary sterilization is primarily used for medically high-risk women, and is not very accessible.

These major factors, as well as others described in this report, can be overcome with the continuing support of high-level policy makers. However, it is essential to have the commitment and vigorous cooperation of mid-level officials, who control the day-to-day decisions affecting service delivery and operation of the contraceptives market. The evidence suggests that a great deal needs to be done to secure their support.

Table 4. Matrix of Most Important Policy Constraints

Seriousness of Constraint: 1=minimal 2=problematic 3=significant

| Constraint                              | Orals<br>(28.8%)   | IUDs<br>(62.3%)                 | Injectables<br>(11%)  | Norplant®          | VS<br>(2.3%) | General   |
|---|--|---------------------------------|---|--------------------|--------------|---|
| <b>PROVIDERS AND USERS:</b>             |  |                                 |   |                    |              |   |
| Professions which may provide/re-supply | 2<br>(MDs only; but pharmacists supply with no prescription) | 1<br>(MDs - but few female MDs) | 2<br>new decree says injectables will be available in pharmacies - but none to date because companies such as UpJohn haven't completed paperwork plus pricing issue looms | 2<br>(OB/GYN only) |              |   |
| Availability of authorized professions  |  |                                 | 1<br>fewer MDs in rural areas and Upper Egypt, particularly female MDs  |                    |              |   |
| Where may be provided/re-supplied       |  |                                 |   | 2                  |              |   |
| Client eligibility/contraindications    |  |                                 | 1<br>review breastfeeding contraindications   |                    | 3            |   |
| Exams/tests/procedures                  | 1<br>(3-month re-supply visits)                              |                                 |   |                    |              | 1<br>exams by male MDs; price in private sector   |
| Provider knowledge                      | 2  |                                 | 3   | 2                  | 2            |   |
| <b>MARKET</b>                           |  |                                 |   |                    |              |   |
| Registration process                    | 2<br>(especially mini-pill)                                  |                                 | could slow expansion to private sector  |                    |              |   |
| Consumer affordability                  | (could be problematic, if price controls eased)              |                                 | could become problematic, if price controls eased   | 3                  |              |   |
| Profitability/price controls            | 3  | 2                               | could become problematic, if price controls apply   |                    |              | 3<br>price controls may be undermining the market |
| <b>ADVERTISING</b>                      |  |                                 |   |                    |              |   |

| Constraint                | Orals<br>(28.8%) | IUDs<br>(62.3%) | Injectables<br>(1.1%)                  | Norplant® | VS<br>(2.3%) | General   |
|---------------------------|------------------|-----------------|--|-----------|--------------|---|
| PVO/government mass media |                  |                 |  |           |              |   |
| Commercial mass media     | 2                |                 | could slow expansion in private sector |           |              |   |
| OTHER                     |                  |                 |  |           |              | 2<br>awareness &<br>commitment<br>at mid-level of<br>government |

Recent events present opportunities for injectables and mini-pills to be made widely available. Timely policy development and strategic planning can capitalize on these and other opportunities for achieving the following objectives:

**Objective 1: Expand Availability of Injectables**

- systematically expand the range and knowledge level of authorized providers; and
- identify likely users and target IEC and recruitment to specific market segments.

**Objective 2: Expand Availability of Mini-pills**

- target IEC and recruitment toward breastfeeding women;
- widely advertise availability of private sector sources; and
- increase the level of provider knowledge to overcome existing misinformation problems.

**Objective 3: Selectively Reduce General Constraints to Access**

- project alternative timetables for reaching contraceptive prevalence targets under different scenarios of authorized providers;
- conduct further research on potential barriers where information to date is inconclusive;
- develop policies to accelerate introduction of contraceptive products;
- propose policies to expand use of mass media to the private sector;
- prepare implementation plans for expansion of Norplant® that ensure maximum access and safe conditions; and
- continue education of family planning service providers on the health risks of repeated pregnancy and childbirth may be the most effective way to expand the availability of voluntary sterilization.

**Objective 4: Reduce Negative Impact of Price and Import Policies**

- develop strategies for ensuring a stable flow of supplies in the private sector.

**Objective 5: Secure Commitment and Support of Mid-level Officials**

- develop and deliver presentations to target groups to demonstrate the importance of family planning and their role in its success;
- identify and propose changes in procedures administered by mid-level officials to facilitate their role in supporting family planning.

## **B. Proposed Activities**

### **1. Expand the Availability of Injectables**

Many women will find injectables to be particularly suited to their needs because of their progestin-only content and mode of operation. The Minister of Health was expected to approve in the near future the provision of injectables by all physicians in the public and private sectors (currently limited to OB/GYNs in certain locations). However, successful expansion requires a supportive environment, mobilization of providers, and widespread awareness of the benefits of injectables. Price controls and import laws will also affect injectables, and are discussed in section VII.B.4. below.

a. Propose policies for the gradual extension and increased level of knowledge of authorized providers, to include RNs and pharmacists. First, determine what criteria are used to distinguish MDs from RNs and pharmacists in granting authorization, and then use training and other mechanisms to improve physician skills, and help other providers in meeting the criteria. Second, develop the case for a policy to expand the type of personnel who may provide injectables, including nurses and pharmacists, based in part on the premise that these personnel are already qualified to give injections and immunizations. Analyze and present multiyear plans showing how long it will take to expand injectables using different types of providers in different regions of the country (public and private sector MDs; non-MD clinic personnel; pharmacists; regional variations regarding gender of MDs and access to clinics and pharmacies). Propose limited experiments with training and provision by other providers, to test the effectiveness of a modified policy.

b. Include a training segment in the strategic plan: provider knowledge of injectables is extremely low, although many indicated they would recommend injectables if they had more information. Draw up a strategic plan for rapid, short-term, on-site training and accompanying technical materials for MDs and those who are in key positions to refer clients. This will help ensure professional readiness to provide injectables once they are available.

c. Ensure that standards of care are accurate and provide for their widespread dissemination (e.g., injectables may be given in the arm as well as the hip, a fact that may prove enormously important to women who are reluctant to be served by male physicians). The original ministerial decree authorizing injectables and listing breastfeeding as a contraindication should be reconciled with standards of practice.

d. A strategic plan should ensure that IEC efforts are consistent with availability and policies governing injectables, and are targeted at those most likely to seek this type of method.

## 2. Expand the Availability of Mini-pills

If the mini-pill is finally approved at a price that manufacturers are satisfied with, Schering and Organon are planning to introduce it into the market. A strategic action plan should be implemented to ensure its successful expansion. Success will partially depend on factors which affect oral contraceptives generally, but it will also depend on the extent to which the mini-pill is made accessible to women who are breastfeeding. Limitations on availability and access to OCs include restrictive or incorrect interpretation of standards of care, and uncertainty about whether the commercial sector can use the mass media to advertise.

a. A strategic action plan should include timely and appropriate IEC efforts aimed at women who are breastfeeding; and the mass media should be used extensively to advertise the general availability of mini-pills in the private sector while seeking a policy to allow more direct advertising by the commercial sector.

b. Ensure widespread dissemination of standards of care to overcome the problem of misinformation about OCs in general, through short-term training and technical materials.

## 3. Selectively Reduce General Constraints on Access

Many general and method-specific issues act as constraints in varying degrees on access to services and availability in the market. Some of these constraints merit attention now because they are most likely to have a positive impact on the program in the long term.

a. Increase types of personnel authorized to provide services: analyze policies on who may currently provide each type of method, and present results through a projection of timetables for increased contraceptive prevalence with and without changes in policies, showing regional differences with respect to gender of providers and availability of private sector sources. This activity would generate the data required to expand the accessibility of injectables (as described above), and other methods.

b. Identify and reduce medical barriers: seek additional information on potential service barriers regarding issues on which data is inconclusive, such as the added cost of medical exams and tests in the private sector, and the scarcity of female physicians for pelvic exams and IUD insertion in Upper Egypt.

c. Facilitate future introduction of contraceptives: identify family planning products which are likely to be introduced in the future, and assess the degree to which product registration and other procedures may slow these efforts. Propose policies that can specifically accelerate the introduction of these products.

d. **Expand use of the mass media:** for those contraceptive methods that are already being advertised in the mass media by PVOs and the State Information Service, include additional information on types of places where these methods can be found in the private sector (presumably, pharmacies and private physician offices). Develop and propose policies to grant permission for contraceptive advertising to the private sector; or for maximizing the use of mass media to refer clients to private sector sources.

e. **Review plans for expansion of Norplant®:** Norplant® is a new and relatively costly product, thereby presenting challenges which will take time to address. An immediate issue for Norplant® is where it will be made available in its next phase of expansion. Current implementation plans being prepared for expansion of Norplant® should ensure maximum access and safe conditions.

f. **Expand availability of VS** through continuing education of service providers. Low use of VS is in very large part due to cultural and religious attitudes that will be shaped only over a long period of time. Continuing education of family planning service providers on the health risks of repeated pregnancy and childbirth may be the most effective way to expand the availability of voluntary sterilization to women within this religious and political environment.

#### 4. Reduce Negative Impact of Price Controls and Import Policies

Retail prices of contraceptive methods are kept artificially low through price controls, intended to benefit consumers. However, there are very disturbing indications that availability of oral contraceptives and possibly other methods are becoming increasingly less available in the private commercial sector as a result of these price controls. One parastatal may stop producing an oral contraceptive on the market despite government support for parastatals; stock outages in the private sector have occurred and are increasing; manufacturers are discouraged from introducing certain products (e.g., Shering and Organon could decide not to introduce the mini-pill); women may be using high-dose pills solely because they are less expensive; and a black market in contraceptives is further undermining manufacturers' decisions to expand their contraceptive business. Even if price controls are eased, other policies would have to be modified to ensure a healthy market. Furthermore, existing import policies could foster monopolies of high-priced products already in the market.

Lastly, elimination of price controls will likely result in price increases to the consumer. The policy of price controls has also created an opportunity similar to that provided by social marketing projects which initially market products at artificially low prices. The challenge in both situations is to ease prices to levels closer to what the market can eventually bear, in an environment where the public and private sectors are collaborating in a sustainable family planning program with satisfactory levels of contraceptive prevalence.

a. **Develop a market segmentation strategy: analyze current private and public sector service use, analyze DHS and other data sources for information on income, household consumption, and indicators of price elasticity.**

b. **Develop a multi-stage plan for easing price controls and modifying import policies, based on the market segmentation strategy. Include approaches that will ensure a healthy market as well as consumer affordability, including: sale of similar products at different prices, letting consumers make the decision; permitting higher prices on some products in exchange for guarantees of lower prices on others; use of generic formulations in the public sector which are lower cost and less likely to result in leakage to the private sector.**

c. **Develop a mechanism to monitor impact on consumer patterns.**

#### **5. Secure Commitment and Support of Mid-level Officials**

**It is essential to have the collaboration and support of personnel who are responsible for day-to-day administration of rules and regulations that govern the delivery of family planning services in both the public and private sectors. Yet it is difficult for personnel at this level to relate their performance to the overall efficiency and effectiveness of the country's population goals. Information, support, and supervision from high-level policy makers can increase their contribution to the family planning program.**

a. **Identify personnel within government who are responsible for the various administrative and financial procedures affecting the operation of family planning services and affecting entry into the contraceptive market. In collaboration with policy makers, develop and deliver presentations to target groups to demonstrate the importance of family planning, and to identify their role in its success.**

b. **Examine current regulations and administrative procedures affecting family planning, and propose modifications for streamlining them. Review the job descriptions and supervisory practices affecting key personnel to identify ways to strengthen their ability to support family planning.**

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