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# OPTIONS

## Assessing Legal and Regulatory Reform in Family Planning

MANUAL ON LEGAL AND REGULATORY REFORM

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**OPTIONS**

for Population Policy

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## ASSESSING LEGAL AND REGULATORY REFORM IN FAMILY PLANNING: MANUAL ON LEGAL AND REGULATORY REFORM

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# 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.

The OPTIONS II Project has developed special policy approaches to promote expanded support for family planning. Technical experts have prepared working papers aimed at codifying project experience and analytic approaches. The papers are intended to provide uniform guidance to OPTIONS current and future staff, furnish A.I.D./W and Mission staff with analytic tools to improve program and strategic planning, and help developing country policy makers and analysts to conceptualize and critically analyze policy aspects of the population sector.

The papers are being published as part of an ongoing Policy Paper Series focusing on various aspects of operational policy in family planning. Titles in the Policy Paper Series include:

- (1) Assessing Legal and Regulatory Reform in Family Planning
- (2) Strategic Planning for the Expansion of Family Planning
- (3) Policy Issues in Expanding Private Sector Family Planning
- (4) Communicating Population and Family Planning Information: Targeting Policy Makers
- (5) Cost Recovery and User Fees in Family Planning

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# OPTIONS MANUAL ON LEGAL AND REGULATORY REFORM

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One of the mandates of the OPTIONS for Population Policy II project is to work with governments to reform laws and regulations that inhibit family planning users and providers. This manual seeks to provide background material on these regulatory issues, give guidance on how these issues can be analyzed, and suggest ways that reform can be achieved. The central recommendation for setting priorities in this area is to weigh the likely benefits or payoffs resulting from policy or legal reform against the anticipated costs or difficulties of achieving it.

Payoffs can be conceived of as savings that accrue to the government when clients switch from the public sector to the private sector, or as increases in contraceptive prevalence. Improvements can also be cast in terms of intermediate outcomes, such as increases in the number of outlets or providers of family planning services or number of methods available. Costs relate to all that is involved with achieving the policy reform, such as required resources and time, etc. When payoffs can be quantified in financial terms, such as with savings to the government, this approach can be thought of in a cost-benefit framework. When they are defined as increases in contraceptive prevalence or in number of service outlets, this approach represents a cost-effectiveness analysis.

## BACKGROUND

The macroeconomic, regulatory and policy setting in which family planning services are provided is likely to influence contraceptive prevalence levels, method mix, and the distribution of contraceptive services among public, commercial, and private non-profit sources. The focus here will be on the impacts of policies on contraceptive prevalence and on the source distribution, specifically on the share and number of users obtaining services from private sources.

Some of the policy and regulatory issues that are discussed here primarily affect the private sector, while others have effects on both the public and private sectors. The policy and regulatory issues that are likely to have the greatest impacts on contraceptive prevalence are those that affect both the public and private provision of services. Among these are restrictions that limit the number of family planning methods and providers and sources of family planning services. Empirical evidence from different countries indicates that contraceptive prevalence increases with the number of methods that are widely available and with the number of sources from which family planning services can be obtained (Jain 1989; Ross et al. 1989).

Restrictions on methods, providers and users, which will be described in more detail shortly, can be the result of bureaucratic delays and problems or they can result from specific codes or regulations (i.e., prohibitions on sterilization or requirements of husband's consent, restrictions of pill, injectable, IUD, etc. provision to physicians, requirement of prescription for obtaining oral contraceptives, etc.). These types of restrictions can severely limit the choices that are available to potential users, in terms of both methods and sources, which, in

turn, lowers contraceptive prevalence. Regulatory issues that are of cross-cutting importance for both the public and private sectors should be evaluated in terms of whether and how they affect contraceptive prevalence. While in most cases primary emphasis should be placed on tracking changes in contraceptive prevalence, other outcomes that should be considered are changes in method mix, access and quality of services, and non-pecuniary costs.

Other regulatory and policy issues primarily affect the private sector. Many governments have grown increasingly interested in stimulating greater private provision of family planning services, partly in the hope of shifting some of the service and financing burden away from the public sector. Another reason for interest in the private sector is the concern that free public services are often going to middle- and upper-middle-income households that could afford to pay for services. Finally, low service quality (i.e., long waiting times, etc.) in some public systems has been cited as a possible deterrent to contraceptive use, and it is hoped that an expansion of private sector services, which are of higher quality, could induce increases in contraceptive prevalence.

The starting point for analyzing constraints on private provision of family planning services is the standard microeconomic supply and demand framework. In this framework, reliance on private services is viewed as a result of the interaction of the supply of and demand for private services. Private supply depends on the returns from delivering family planning services and the returns associated with alternative investments. The demand for private services depends on household income and on the convenience, price, and quality of private

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and alternative sources of family planning services. The public policies that are described here generally lower either the demand or supply of private services, which in turn reduces the services provided by the private sector to levels that are lower than they would otherwise be. Regulations and policies that primarily affect the private sector should be evaluated in terms of whether and how they raise government spending levels by lowering private sector service provision, and the extent to which they lower contraceptive prevalence.

This document describes how regulatory issues can be conceptualized and assessed with the ultimate objective of achieving policy and regulatory reform. However, the overall approach and analysis proposed here may prove useful even in contexts where adoption of a formal process for undertaking reform is not feasible. First, it may help policy makers better understand how structural adjustment programs will affect the family planning sector. Second, it may provide insights about the sector that are helpful when formulating strategic plans, even where regulatory reform is not envisioned.

# INITIAL ANALYSIS

One of the challenges will be to recognize when and where regulatory and policy reform alone can bring about significant increases in contraceptive prevalence and private sector service use. Other factors may be playing such an important role that accomplishing policy reform can have only a small effect on contraceptive prevalence or private sector use. In such cases, policy reform may be necessary but not sufficient to bring about the desired changes, and one should identify what other changes would be required.

Analysis of the unmet need for family planning services should shed light on the magnitude of increases in contraceptive prevalence that would result from the loosening of restrictions governing method availability and service provision. For example, if analysis of recent Demographic Health Surveys (DHS) data suggests that desired fertility is very close to actual fertility and that those who wish to space or limit their childbearing are contracepting, then changing the types of policies outlined here may have little impact on overall contraceptive prevalence, whether provided publicly or privately. On the other hand, if sterilization is illegal and a large proportion of women indicate that they do not want any more children but are either non-contracepting or using less effective methods, then working toward the legalization and diffusion of sterilization services could have a significant payoff in terms of increases in contraceptive prevalence and births averted. Analysis of the source distribution and characteristics of private sector users may also indicate the potential for shifting to private sources. For example, if many higher-income, educated residents use public sources, it may indicate a wide scope for private sector growth.

## OTHER INFLUENCES ON THE PRIVATE SECTOR

While analysis of the determinants of private sector use is in its infancy, several factors that are outside the scope of these regulatory issues have been argued to have major effects on private sector use. First, the widespread availability of free public services may deter contraceptors from switching to private sources, even if private prices fall or if private services become more readily available. In these cases, it may be essential to introduce some type of cost recovery scheme, or screening/testing into the public system if these reforms are to induce a shift from public to private sources. Second, household income levels may be so low that even if private prices drop slightly, they may still be so high that they discourage private sector use. Third, private delivery networks may be poorly developed and private providers may lack the training and equipment to provide family planning services because of inadequate access to capital markets, so that these reforms may do little on their own to increase use of private services. In such cases, a complementary package of service delivery assistance may be necessary to stimulate private sector expansion.

These non-regulatory influences should be considered before embarking on an assessment of regulatory issues. They constitute an important part of the context of family planning service provision and are likely to play a major role in influencing how effective policy and regulatory reform will be at generating higher contraceptive prevalence or stimulating greater private sector use. In general, greater emphasis should be placed on legal and regulatory reform in environments where there is a large unmet demand for family planning and/or where

there is greater potential for users to switch from the public to the private sector.

### ASSESSMENT OF REGULATORY ISSUES

When taking stock of the regulatory environment in a particular country, first, it should be determined whether any prior assessment of some or all of these issues has been undertaken. Many of these issues have been examined as a part of SOMARC country assessments and The World Bank sector reports. For example, assessments have been done for Indonesia (The World Bank 1990; Kenney 1989; and SOMARC 1987), Ghana (SOMARC 1990a), the Philippines (Kenney 1990 and SOMARC 1990b), as well as many other countries in the world. Moreover, since family planning services are provided within a larger health context, previous studies from health projects/sources should be also sought out. Two other potentially useful references are the checklist devised for the OPTIONS I Project and a review paper by Lewis and Kenney on the private sector (Issacs 1988; Lewis and Kenney 1988).

Second, through structured interviews with government and private sector representatives (from manufacturing, retailers, distributors, service providers, NGOs, professional associations, etc.), it may be possible to narrow down the issues to those that are likely to be relevant for a particular country. Many private sector organizations are knowledgeable about their markets and are likely to have a very good understanding of which legal and regulatory barriers constitute major constraints. They may also be willing to share analysis from market research studies that provides insight into other market factors that are important considerations.

### CAVEATS

Before discussing specific regulatory issues in more detail, several general points should be made. The first point is that the importance of any one of these factors is likely to vary significantly across countries. The second point is that these factors may have different effects on the private and public sectors. For example, high tariffs on imported commercial contraceptives raise the retail price of commercial products, which can lower the demand for services from private sources. This may then lead to higher demand for services from public sources, which could increase the financing burden on the public sector.

The third point is that specific policies or regulations may be of importance for one method or set of providers, and have little bearing or even positive effects on other methods or providers. For example, the prescription drug requirement for oral contraceptives may have adverse impacts on the commercial pill market with no adverse effect on the commercial market for condoms (in fact a prescription drug requirement could actually boost sales of condoms as potential pill users substitute condoms instead). Likewise, physicians may support the prescription drug requirement while midwives and pharmacists may advocate its removal.

The fourth point is that it is important to understand the rationale for a policy or regulation. Many of the regulations that are discussed here (such as the registration of pharmaceutical products) were intended to protect the general public from fraudulent or unsafe practices. Others are the result of pressure exerted by special interest groups with vested interests in the regulation (such as prohibitively high tariffs on imported

products that are designed to protect domestic production). Other policies may be in place to satisfy macroeconomic objectives (as with taxes and tariffs designed to raise revenues and balance federal budgets). Understanding the background and supporters of a particular policy or regulation provides a basis for determining how difficult it will be to change the policy. It can also provide a guide for anticipating which groups will be opposed to reform and which groups will be supportive.

The fifth point is that the macroeconomic context may play an important role in influencing which reforms are feasible or even desirable. In many countries, governments have been implementing uniform tax and import policies across all sectors as a part of overall economic reform packages. One of the rationales for this policy is that it makes the system less cumbersome. If the government has adopted this type of approach, it may be very difficult to gain exception for family planning products.

more background information on each of the major regulatory issues and also contains suggestions for some simple analysis that could be undertaken in the field to provide evidence about whether the policy is actually acting as a constraint on use, and what the likely magnitude of the impact is. It also provides an indication of who is likely to gain and who is likely to lose from reform.

## CHECKLIST

Table 1 gives a list of regulations and laws that may be deterring family planning service use. These factors have been grouped into five different categories: Regulations that Constrain Contraceptive Options; Tax and Import Policies; Advertising and Promotion Regulations; Other Regulations Affecting the Commercial Sector; and Regulations Affecting Non-Profit Organizations. Table 2 summarizes the mechanisms through which a given government regulation or policy can lower contraceptive prevalence or deter private family planning service provision and the government authorities that are likely to be in charge of the policy. The text provides

**TABLE I**  
**LEGAL AND REGULATORY CHECKLIST**

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**Regulations that Constrain Contraceptive Options**

Restrictions on Specific Methods

- Prohibitions on provision of certain methods
- Restrictions on who may receive a method and under what circumstances

Restrictions on Service Delivery and Distribution

- Prescription requirement
- Regulations on sale, distribution, or delivery of services

Registration, Licensing, and Certification Policies

- Approval and registration of contraceptive products, formulations, packaging
- Certification of family planning providers and clinics

Limitations on Private Practice

- Barring private practice
- Who can practice and where

**Tax and Import Policies**

Tax Policies

- Sales taxes/value added taxes

Import Policies

- Import tariffs
- Import quotas
- Exchange controls

**Advertising and Promotion Regulations**

- On prescription drugs
- On family planning products
- On use of point of purchase materials or mass media
- On generic and brand advertising

**Other Regulations Affecting the Commercial Sector**

- Patent and trademark laws
- Discouragement of foreign investment
- Statutory price controls

**Restrictions Affecting Non-Profit Organizations**

- On sale of donated commodities
- On use of fieldworkers
- On fees charged for services

**TABLE 2**  
**SUMMARY OF REGULATIONS AND POLICY ISSUES**

REGULATORY OR POLICY AREA	AUTHORITY RESPONSIBLE	ISSUE/PROBLEM	CONSEQUENCES
Specific methods	Health Regulations (MOH) Other Studies	Prohibition of sterilization or other methods; restrictions on who can receive methods and under what conditions	Reduces choices available to potential contraceptors which is likely to reduce contraceptive prevalence. Could either stimulate or reduce private sector service provision. May stimulate private sector if private sector is able to circumvent restrictions.
Delivery/Distribution of Services	Health Regulations (MOH)	Restricting IUD insertion, injectable, or implant provision to physicians	Lowers access to services by reducing supply points and raising travel times and raises costs of service provision; may reduce supply and demand; no quality loss has been found from loosening these restrictions in many studies, but they may enhance safety/quality.
Prescription and Dispensing	Health Code; Medical/Nursing Practice Acts (MOH)	Requirement of prescription for pills	Raises the costs to consumers of obtaining commercial products; likely to result in lower demand; may increase safety/quality of pill use.
Product Approval; Licensing; Registration	Local FDA Equivalent	Paperwork/Delays/Higher costs	Raises costs of bringing commercial products to the market; may reduce availability and diversity of commercial products; may raise quality of commercial products. Can limit availability of methods in the public program.

REGULATORY OR POLICY AREA	AUTHORITY RESPONSIBLE	ISSUE/PROBLEM	CONSEQUENCES
Certification of Private Providers/Clinics	MOH/Family Planning Service	Paperwork/Delays/Strict requirements	Raises costs of gaining certification as a family planning provider; may reduce availability/number of private providers; may raise quality of private services.
Private Practice	Health Regulations (MOH)	Restrictions on private practice	By restricting or banning private practice, may lower supply of private services, and hence raise prices.
Sales/Value Added Taxes	Finance Ministry/Treasury	Raise retail prices of commercial products	With higher prices, demand may be reduced.
Import Tariffs	Customs/Trade Ministry	Raise retail prices of commercial products	With higher prices, private demand may be reduced.
Advertising and Promotion	Health Regulations (MOH); Other Laws	Prohibition or limitation on advertisement of prescription drugs or all family planning products	May lower awareness of commercial products/providers, reducing demand for commercial products and services.
Patent or Trademark Laws	Legislative or Judicial System	Absence of protection or enforcement	Can reduce R&D and lower quality in an unregulated environment; can lower supply costs; may lead to highly competitive conditions with many products and low prices.
Statutory Price Controls	National Price Board; Finance or Health Ministry	May lower commercial prices	If commercial prices are constrained at artificially low levels.
Non-Profit Organizations	Justice, Finance, Commerce Ministries; MOH or Family Planning Service	Restrictions on fee schedules, charges for commodities, scope of service	May constrain NGO providers from expanding service levels or make it difficult for them to cover costs.

Note: MOH denotes Ministry of Health; FDA denotes Food and Drug Administration; R&D denotes Research and Development; NGO denotes Non-Governmental organization.

# REGULATIONS THAT CONSTRAIN CONTRACEPTIVE OPTIONS

**R**egulations and policies in this area can affect both the public and private sectors and relate to:

- a. prohibition on provision of certain methods;
- b. restrictions on who may receive a method and under what circumstances;
- c. prescription requirements;
- d. restrictions on what types of health personnel may offer different family planning services and where services can be provided;
- e. registration of contraceptive products; and
- f. certification of new family planning providers and clinics.

These regulations constrain the options available to potential contraceptors, either by reducing the number of methods that are available and the number of outlets where services can be provided, or by limiting contraceptive choices for some groups.

## RESTRICTIONS ON SPECIFIC METHODS

Some governments prohibit the use of certain family planning methods, such as sterilization, or place limits or conditions on who can receive a method, such as requiring the husband's consent, a certain parity level, or that a woman's health be endangered in order for her to receive a sterilization. Other regulations include requirements of laboratory tests or physical exams or completion of lengthy forms that request personal information as a condition of service provision or resupply. These regulations are sometimes referred to as "punitive quality" (Bruce 1990) because they may actually lead to worse outcomes in the name of improving quality. If these policies are enforced, they may serve to effectively narrow the range of

available methods to the point that they do not meet contraceptors' needs or desires. They may also increase the psychic costs of contracepting, lengthen waiting times, and increase the costs of providing services.

These policies can affect both public and private providers—but not always in the same direction. For example, if sterilization is officially prohibited, it may be completely unavailable through the public health system, but it may be obtainable through the private sector, for those who are able to pay. In that case, the sterilization restriction may actually stimulate private sector provision. Likewise for restrictive medical practices, such as requirements of physical exams every six months for pill resupply in the public sector. In other circumstances, the regulations may deter both public and private provision of services. These types of policies are often contained in health regulations or in other public statutes.

These regulations can have many different types of supporters. For example, religious groups may support prohibitions on sterilization services while medical societies may back the regulations that govern method provision. If the private sector actually benefits from restrictive practices in the public system, it may be resistant to change.

With all the policies and regulations described here, the first step is to make certain that the regulations and statutes on the books are implemented in practice. If they are not implemented, it may not be worth devoting any time to trying to change them, unless they are of symbolic importance. In fact, drawing attention to their lack of enforcement could do more harm than good if it leads opposition groups to call for their enforcement. Second, it is

important to ascertain whether there are unwritten rules that are actually used in practice but which are not reflected in official regulations or statutes. In some countries, practices may have developed over time that serve as constraints while at the same time not representing an official written policy. Furthermore, statutes or policies may have been officially changed in some countries, without attendant dissemination about the policy change to providers or clients, so that the system may continue to function as if the policy were on the books. Therefore, if providers and clients are unaware of an official policy change, it might be best to recommend that the government implement an education and training program to inform providers and clients of the new policy.

Targeted unmet need analysis, indicating perhaps that a significant share of the respondents want to use a method but are not contracepting, can also reveal whether these regulations are acting as constraints. If it does appear that these policies are limiting the availability of modern methods, a rough estimate can then be made of the effects on contraceptive prevalence. Jain (1989) did a simple analysis in which he used cross-national data to estimate the relationship between contraceptive prevalence and the "availability" of modern methods. He found that the widespread availability of one additional modern method is associated with an increase of

12 percentage points in contraceptive prevalence. The availability index was constructed using male sterilization, female sterilization, the IUD, the pill, the condom, and abortion, based on judgements made by persons knowledgeable about a particular country. Availability does not pertain solely to whether a given method is approved; it takes into account availability from public and private sources.\*

When assessing effects on contraceptive prevalence, it should be considered how widely the additional method will be made available. For example, if the regulatory change will result in IUDs being provided in most rural and urban areas, then it may be appropriate to assume that a 12 percentage point increase in prevalence will result because of the addition of a method. On the other hand, if the regulatory change would result in the addition of IUDs on the commercial market in a country where only physicians can insert IUDs and where there are very few private physicians who offer family planning services, the impact on contraceptive prevalence is likely to be very small or nonexistent. Furthermore, the introduction of a new method is likely to induce shifts from other methods to the new method. While this may be desirable because it may mean that contraceptive needs are more closely matched with the prevailing method mix, it may accomplish little in the way of increasing prevalence or raising the number of births averted.

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\* While this study showed a fairly close relationship between contraceptive prevalence and method availability, care should be used when using the point estimate. First, it seems likely that the effect of adding an additional method will depend on the contraceptive prevalence level in a given country and on the degree of unmet demand for family planning services. Neither of these factors is taken into account in Jain's analysis. Furthermore, the availability index is based on "expert judgements" which may be hard to replicate and which are likely to be inconsistent across countries. Finally, it would be helpful if the analysis could be redone without abortion being counted as a modern method of contraception.

## RESTRICTIONS ON SERVICE DELIVERY AND DISTRIBUTION

Restrictions in this area include requirements that: (1) oral contraceptives be obtained only with a prescription; (2) IUDs, injectables, and sterilizations be provided only by physicians; and (3) sale of condoms be limited only to pharmacies. These regulations are in place for many reasons: because of medical practice patterns held over from colonial times or imported from developed countries; because of interest in maintaining high service quality; or because they reflect the interests of powerful interest groups such as physicians. These restrictions reduce the number of outlets and providers where potential users can obtain commercial services and thus raise the costs to consumers (both in terms of travel time and service fees) of obtaining commercial services. They are likely to greatly reduce service provision through both the public and private sectors. For example, if physicians are the only providers who are permitted to offer most methods, it may be necessary to offer family planning services at a public clinic only one day a week or on some other restricted basis which reduces the convenience of obtaining services. Moreover, households will tend to face higher out-of-pocket expenditures for private services, since private physicians generally have higher fees than private midwives.

In most countries, the number of physicians is much lower than the number of paramedics, nurses, midwives, or pharmacies and the number of pharmacies is lower than the number of chemical sellers or other retail outlets. It should be pointed out that there is considerable literature on how these restrictions and their removal affect service quality (much of it from operations research projects) that demonstrates that

quality does not suffer when trained nurse midwives or paramedics are permitted to insert IUDs or when trained pharmacists are allowed to sell pills without prescription (Bruce 1990; Einhorn and Trias 1978; Eren, Ramos, and Gray 1983).

Because these regulations are not enforced or honored in practice in many countries, the first step is to understand whether they are really serving to reduce supply and access. A successful strategy for quickly assessing the extent of enforcement may involve direct observation in pharmacies and informal questioning of practitioners and clients. In addition, survey data on source of service can indicate whether these constraints are binding. For example, if DHS data show that only a small fraction of rural pill users obtain supplies from pharmacies or that very few condom users obtain condoms from retail outlets, this would indicate that these restrictions constitute a barrier to use.

If these regulations do seem to be enforced, estimates of the ratios of physicians, midwives, pharmacies, etc. should be obtained from the government or the relevant professional association. If possible, separate estimates should be made for rural and urban areas, or by province or region, to pinpoint whether these policies create particular difficulties in certain areas. For example, the availability of physicians and pharmacies is often much higher in urban than in rural areas, so that these restrictions may have a greater impact on rural contraceptive use. In general, the greater the divergence between the number of outlets where family planning services can be obtained under current policies and the projected number of outlets after the policy change, the greater will be the likely impact on contraceptive prevalence. As a related

exercise, projections of desired contraceptive prevalence could be used to estimate the number of providers that would be required to meet future need levels and then determine the magnitude of the likely shortfall.

In addition, analyzing DIIS or other survey data on perceived access to family planning services and to particular methods may be useful. If respondents report long distances to service outlets, problems with clinic hours or waiting times, or if they know of no or only a few sources of family planning services, and if these respondents tend to have an unmet need for contraception, this would provide additional evidence that contraceptive use is being constrained because of these policies and regulations.

While we lack solid evidence on the magnitude of changes in contraceptive prevalence that would prevail under different scenarios, some results presented in Ross et al. (1989) may provide a guide as to what could happen if a policy change led to an increase in the number of outlets where contraceptives can be obtained. Evidence from Thailand suggests that contraceptive prevalence was higher in villages in which there were more outlets for family planning services. Contraceptive prevalence was compared for villages with one, two to three, and four sources of services. On average, it appeared that having one additional source is associated with a five percentage point increase in contraceptive prevalence. This should be used only as a rough guide to what may happen, particularly since the data came from only one country. Again, actual increases in contraceptive prevalence are likely to be systematically related to the level of unmet demand for family planning services and to current levels of service availability. Furthermore, if regulatory

reform leads particularly to relatively greater access to private services, some public sector users may switch to private sources, which would then lessen the financing burden on the public sector.

### REGISTRATION, LICENSING, AND CERTIFICATION POLICIES

These policies encompass registration of contraceptive products, formulations, brand names, trademarks, packaging, obtaining import or distribution licenses, and certification of family planning providers and clinics. Problems generally center around bureaucratic procedures that result in a significant amount of paperwork and delays when seeking approval for new products or clinics. While they may affect both the public and private sectors, they may have greater bearing on private sector activities.

Bureaucratic delays and paperwork can lead to long delays in the introduction of contraceptive products because of difficulty in obtaining approval for new products or licenses for distribution. A significant amount of paperwork may also be required just to maintain existing products on the market. Certification of private providers or clinics may also involve long delays or require special training in family planning or equipment which is difficult or costly to obtain. The time and resources devoted to obtaining licenses or certification raise the costs of carrying out family planning activities, which can in turn reduce private investments in family planning. They may also result in consumers having a narrower choice of methods or providers, which has been shown to be associated with lower contraceptive prevalence. At the same time, these procedures, while cumbersome, may serve to protect the public from unsafe products or providers.

Registration and licensing policies are generally handled by government units equivalent to the U.S. Food and Drug Administration (FDA) within Health Ministries. The reasons for the delays are manifold, stemming from inefficiencies and inadequate staffing levels in local FDAs, or cautiousness related to the past dumping of outdated or unsafe pharmaceutical products in developing countries. Certification of private clinics and providers is also governed by Ministries of Health. Thus, government officials within these different parts of the Ministry of Health, private manufacturers, and private providers may be able to provide some insight about the process for registration, licensing, and certification.

To gauge the impacts of registration policies, one should first assess whether a full range of family planning methods/brands and relatively new products such as the implant have been approved and are available in the country—if they are, that's a sign that registration and licensing problems are not overriding. If only a few products are available, the extent to which regulatory barriers constitute the root problem should be addressed. An alternative explanation relating the narrow method mix to perceived low levels of demand should also be considered. If it does appear that a narrow method mix is a consequence of bureaucratic problems, the likely impact should be analyzed following what was suggested in the section on "Restrictions on Specific Methods."

To assess whether certification constitutes a real problem, the following should be examined: the share of contraceptors, who obtains services from private doctors, midwives, clinics, or hospitals; how many private doctors, midwives, clinics and hospitals provide general health care services and how many provide family planning services;

and whether there are waiting lists of providers or clinics seeking certification. If only a small share of contraceptors obtain services from these private sources, a large number of private providers do not offer family planning services, and there are waiting lists and long delays in the certification process, improving certification procedures would likely increase the provision of private sector services. However, the absence of waiting lists should not necessarily be taken as a sign that there is no problem. Potential providers may be so discouraged about the process that they do not even bother to apply for certification.

#### LIMITATIONS ON PRIVATE PRACTICE

Many governments constrain physicians and midwives from freely entering private practice. Some governments bar private practice altogether or limit the extent of private practice. These regulations often arise because of attempts to fully staff the public health system at low cost. These restrictions could reduce the number of private providers or the hours devoted to private practice, which decreases the supply of private family planning services.

When assessing the effects of these restrictions, it is important to take into account the extent to which public sector practitioners also conduct private practice. In many countries, public sector physicians have thriving private practices at public sector clinics or hospitals or in another setting. Furthermore, because of low pay and the high returns from private practice, many public sector physicians do not work complete days at their public sector posts. Thus, these government restrictions may not have a very severe effect on the supply of private services. Observation of staffing patterns at public clinics and informal

discussions with public sector physicians and midwives and representatives from associations for midwives and physicians can provide a general sense of how this is occurring in a given country. If permitting private practice leads to increases in the number of outlets at which family planning services can be obtained, this could lead to greater private provision of services and to increases in contraceptive prevalence.

There should also be awareness of possible innovation in this area regarding private/public partnerships. For example, in some countries, lack of access to needed equipment may be a real constraint to provision of sterilizations by private physicians. To the extent that public hospitals are outfitted with this equipment and it is not being used to its full capacity level, arrangements could be made for private physicians to provide services to their clients in public operating theaters, while paying a fee to the public sector. Other hybrid arrangements may be feasible, such as contracting out for private physician or midwife services for use in mobile delivery teams or on a part-time basis in public health clinics, combined with fee collection to pay for the physician's or midwife's time. Given the current and projected health care financing crisis facing many developing countries and the large share of health budgets devoted to physician salaries, these types of partnerships may prove especially important in expanding service availability.

# TAX AND IMPORT POLICIES

## TAX POLICIES

Many governments impose value added taxes (VAT) on products that flow through commercial channels as a major source of revenue generation. Value added taxes can raise retail prices of commercial products significantly, depending on the stages during the distribution chain at which they are applied and the value of the VAT. If the VAT is expressed in percentage terms, and if it is applied at two stages in the distribution chain, say retail and wholesale, then the retail price with the VAT will be  $(1 + \text{VAT})(1 + \text{VAT})$  as large as it would be otherwise. If it is applied only at one stage, the retail price with the VAT will be  $(1 + \text{VAT})$  higher than otherwise. If the VAT is 7 percent, and it is applied at two stages in the distribution chain, then the retail price will be 1.149 higher, or 14.49 percent higher; while if it is applied at only one stage, the price will be 1.07 higher, or 7 percent higher.

Higher prices could in turn reduce demand for commercial services. In general, these taxes are applied to all products that flow through commercial channels, often making it difficult to gain an exception for family planning products. Before doing any further analysis, the first step is to make certain that the taxes are actually collected—practice may differ from the written policy. If it appears that the government is collecting the taxes, the negative effect on demand of the higher prices should then be assessed.

First, the cumulative effects of the value added tax, that is, how much it adds to the retail price, should be determined. To develop an idea of how much private demand may be lowered by the VAT, an estimate is needed for the price elasticity of demand (i.e., the percent change in de-

mand that results from a one percent change in the price). Unfortunately, we do not have much solid evidence about this, and it is likely to vary from country to country and, within countries, across income groups. However, studies from Jamaica and Thailand do provide estimates of the price elasticities for specific methods (Akin and Schwartz 1988). Estimated price elasticities varied from method to method and across the two countries. Elasticity estimates for the condom were  $-.70$  in Thailand and  $-1.51$  in Jamaica, while for the pill, they were  $-.07$  in Jamaica and  $-.11$  in Thailand. In the above example with a VAT of 7 percent applied at two stages in the distribution chain, as already noted, the effect on the retail price is an increase of 14.49 percent. If we use the estimates from Thailand and Jamaica to form a range, the effect of the VAT would be to lower demand for condoms by 10.14 to 21.88 percent, and to lower demand for pills by 1.01 to 1.59 percent (this is obtained by multiplying the elasticity estimate by the percent increase in the price due to the VAT).

After calculating the likely increase in pill use, the next step is to consider possible savings to the government in terms of lower service delivery costs. If all of the additional commercial pill users had not been previously contracepting, the increases in pill use increase prevalence without lowering public service delivery costs. At the other extreme is the case in which all of the additional commercial pill users had been previously receiving services from the public sector. In that case, no additional increase in prevalence occurs, but the government does experience savings on service delivery costs. Some middle ground is also possible, with a fraction of the additional pill users constituting new contraceptors and the remainder

having switched from the public sector. Finally, it is also possible that some of the additional pill users switched from other privately provided methods, in which case they do not add to contraceptive prevalence nor do they generate a savings to the government.

It may also be helpful to assess the implications for contraceptive prevalence and government savings of the two extreme cases to set bounds on the likely magnitude of the change. When trying to calculate savings to the government, an estimate of the decline in public sector users (i.e., the number of switchers) should first be made. This must then be combined with an estimate of the marginal costs of serving family planning clients in the public sector. In the past, many analysts have used the average cost (total costs divided by total users) as an estimate of marginal cost. However, in many countries, average cost is likely to exceed marginal cost, because of fixed costs that do not vary with the number of contraceptors. Therefore, a more conservative approach, and one that is easier to implement, is to calculate what the government saves in terms of commodities from not serving that additional group of users. This can be done with a simple calculation equal to the product of the decrease in users and the cost per pill cycle.

#### CAVEATS

Several things should be kept in mind here. First, these estimates come from two lower-middle-income developing countries, so it is difficult to know how generalizable they are to countries in other income categories. Second, responsiveness to changes in commercial prices is likely to depend on the availability of public services—in countries with readily available public services,

responsiveness to commercial prices may be higher (i.e., elastic), while in countries with smaller public roles, responsiveness may be lower (i.e., inelastic). Third, to the extent that contraceptors switch from one method to another in response to price changes, increases in commercial pill prices may be associated with decreases in pill use and increases in use of other methods. Therefore, these estimates may provide poor indicators of the effects on overall contraceptive prevalence.

Fourth, when calculating the effect of taxes (and tariffs) on prices to consumers, it is important to consider how most private sector clients receive their services. If they receive their oral contraceptives primarily through pharmacies, the above calculation is suggested. However, if they obtain them from private physicians or midwives, the price paid by the client also includes a service fee which should be taken into account when calculating the effect on price. For example if the service fee is  $F$ , on average, and the price for a cycle of oral contraceptives is  $C$ , then the percent change in the price will depend on both  $F$ ,  $C$ , and the VAT, and it will be considerably smaller than if no service fee were involved.

It may also be useful to consider what share of monthly (or yearly) income or expenditures is required to provide a month's (or year's) worth of protection, both with and without the VAT for households in different income categories. SOMARC staff consider prices that constitute less than 2 percent of monthly income affordable for clients in the lower-middle and upper-lower income groups (the so-called C and D income groups). For many developing countries, information on household income and expenditure levels is available from published World Bank docu-

ments or from income, employment, and expenditure surveys that are regularly conducted by central statistics bureaus. This simple analysis may shed some light on whether the VAT pushes prices out of the reach of buyers in certain income groups. Since income information can be problematic, especially in rural areas, it may be best to calculate the share of household expenditures that would be required for different contraceptive methods. Another piece of information that may be instructive is the share of household expenditures devoted to all health services and products for different income groups. Finally, it should be kept in mind that, if the share and number of pill users in different economic strata getting services from commercial outlets is high, then this is evidence that the VAT may not be an important constraint on demand.

### IMPORT POLICIES

The import of family planning products and equipment may be limited by governments through the imposition of tariffs or quotas on imported products or control of foreign exchange movements. Tariffs raise prices on imported products, which may translate into lower demand. In most countries, tariffs are applied in percentage terms. With an across-the-board tariff of 20 percent imposed on all imported products, the ultimate effect is to raise the retail price by 20 percent (calculation of the effect on demand follows the steps outlined above for analysis of the VAT that use elasticity estimates). Exchange controls generally reduce imports, resulting in a lower supply and possibly higher prices. To assess whether exchange controls are limiting the development of the commercial market, one should examine whether commercial family planning products are readily available. Two factors are likely to be

important here: the extent of domestic manufacturing of commercial family planning products and how tightly access to foreign exchange is controlled.

To determine whether removing tariffs will have an effect on private sector service use or contraceptive prevalence, again it should be first determined whether duties on imported contraceptives are actually collected (in some countries, only a share of the tariff may be collected through kick-backs and corruption and therefore, the revenue may not reach the government). Then, the total import picture should be considered. If the government also places limits on movements of foreign exchange, then even with the removal of the tariff, there may be little or no change in supply or price because importers cannot raise their import levels that much. Furthermore, if almost all of the commercial product is domestically produced, then removing the tariff may have little effect on the commercial price. (Note that tariffs on raw materials for production of contraceptives may discourage domestic manufacturing or raise prices of domestically produced products.) The domestic manufacturing of family planning products varies widely across countries: domestic production of multiple brands which constitute the majority of the commercial market is prevalent in many of the Latin American countries, while most African countries rely exclusively on imported contraceptive products. Therefore, in Latin America, removing tariffs on imported family planning products may stimulate more imports but may not lead to lower commercial prices, while in Africa, it may have a larger effect on use. If it appears that removing the tariff would lower commercial prices, then the same types of analysis suggested above for analyzing the effects of taxes should be used.

When tariffs (or duties) are imposed on family planning products, it is important to look at the overall tariff structure. If all imported products are treated similarly, there may be little hope of gaining exception for family planning products. It may require that the Health Ministry argue for an exemption of a whole list of essential drugs that includes family planning products, which may have severe budgetary implications for the Finance Ministry in terms of lost revenues. If, however, family planning products are singled out and have tariffs that are much higher than other imported goods, or if essential drugs are exempted from tariffs and family planning products are not on the essential drug list, there may be much greater scope for action. In cases where family planning products are assessed much higher duties than other imports, the family planning ministry may be able to argue for equal treatment for family planning products. Where family planning products are not placed on essential drug lists whose products are duty free, it would be appropriate to concentrate on changing the essential drug list.

Support for high tariffs may be found in the finance ministry which is trying to keep government revenues high, or among domestic manufacturers who seek protection from imports. The losers are foreign manufacturers, importers, and potentially consumers who have to pay higher prices.

# ADVERTISING AND PROMOTION REGULATIONS

In many countries, commercial promotion of prescription drugs and non-prescription family planning products is illegal. In other countries, general message promotion is permitted, while name-brand advertisement is illegal. These restrictions often pertain to oral contraceptives and other ethical pharmaceutical products in an effort to protect the public. Special restrictions specifically on the promotion of family planning products are in place in other countries due to the sensitive and private nature of contraception and because of pressure from religious authorities. These restrictions serve to either totally eliminate advertisement or to reduce commercial firms' willingness to promote products. When name-brand advertisement is illegal, individual firms do not have an incentive to develop campaigns to promote generic contraceptive use because while they will bear the full costs, other firms and possibly the public program will benefit from the campaign. These restrictions reduce awareness of commercial products and services, which in turn leads to lower commercial demand and reduced earnings for commercial firms.

One potential limitation cited in Lewis and Kenney (1988), based on interviews with commercial manufacturers, is that many firms believe that direct brand-name advertising and marketing through the mass media may not be profitable. They believe that such a campaign may raise consumer loyalty to their brand, but at the same time the benefits would be spread across other commercial firms and the public sector. This would imply the need for subsidies to induce individual firms to undertake promotional campaigns. In fact, most of the cases in which large-scale private promotional campaigns have been undertaken have been

part of a contraceptive social marketing program, where there is an initial subsidy to finance start-up costs and promotion and where ongoing operations are sometimes also subsidized. Therefore, it is not clear *a priori* what would be accomplished from reducing advertising and promotion restrictions alone, without providing subsidies or other support for advertising and promotional activities.

Unfortunately, no studies have been published that assess how these restrictions affect knowledge and use of contraceptives. Outside of the context of social marketing programs, no analysis has been done that documents the impact of brand-name advertising on the demand for other brands and for public services, or that assesses the effects of easing advertising restrictions. However, some simple analysis of DHS or other survey data may be instructive. These surveys typically include a series of questions that relate to the respondent's knowledge of individual methods and of different sources where services can be obtained. Low levels of knowledge of methods and sources could point to a need for dissemination of information on the issues. Furthermore, survey responses may also provide an indication of the likely reach of radio, television or newspapers through information provided on whether the respondent has or watches/listens to television or radio, and how often, and whether the respondent is literate.

# OTHER REGULATIONS AFFECTING THE COMMERCIAL SECTOR

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## PATENT PROTECTION

In many countries of Asia and Latin America, patent laws are weak and often are not enforced. This reduces potential profits from commercial sales of patented products and lowers incentives for firms to market their products and invest in research and development, but it can stimulate domestic production of imitation products. For example, in one country, the absence of patent protection reportedly led to a highly competitive market with nearly 30 different brands of oral contraceptives and low prices. Quality may not be uniform in an unregulated market, which could reduce demand. The major multinational manufacturers and developers of pharmaceutical products are strong advocates for patent protection, arguing that its absence undercuts their market shares and reduces returns to research and development.

When all facets of the issue are considered, the net effect of weak patent protection on the size of the commercial sector is not clear *a priori*. Competition and low prices may attract consumers while variable quality may deter use. To analyze whether patent laws are constraining the size of the commercial sector in a country, the following should be addressed: the size of the commercial market, how many brands are available and their prices, and whether product quality is an issue. To the extent that the commercial sector has a large market share and has prices that are low by international standards, the absence of patent protection may stimulate the commercial sector, even while cutting into the profits of the multinational firms.

## DISCOURAGEMENT OF FOREIGN INVESTMENT

In addition to weak patent protection laws, other government regulations concerning control of ownership, repatriation of earnings, and hiring of foreign personnel can reduce incentives for foreign commercial firms to make investments in family planning and other areas. Finance, Trade, and Employment Ministries may control regulations in these areas. As with import policies, it may be necessary for health ministries to gain exception for family planning products. These types of regulations have different purposes and intent. Controls on foreign ownership and hiring of foreign personnel often arise because of a desire to promote indigenous capital formation, investment, and employment. Controls on repatriation of earnings are often in place to encourage or force reinvestment in the country or to reduce movements of foreign exchange out of the country.

These regulations can greatly reduce private involvement in family planning, in both the local production and import of family planning products, especially in countries that lack a thriving private market domestically. By protecting domestic firms from the full force of international competition, they may stimulate development or growth of a domestic industry. However, if family planning products are not produced by local firms, these types of regulations may greatly reduce the supply of private services by discouraging foreign production and import of family planning products.

## STATUTORY PRICE CONTROLS

In some countries, commercial prices are regulated by the government (i.e., by national price boards or the Finance or Health Ministries), resulting in price ceilings. The use of price ceilings is generally part of an administrative strategy designed to control prices in the economy and keep inflation down. Another objective may be to keep certain products affordable to the poor. One major problem is that the administrative board that sets prices may apply very rigid rules for setting prices that have little or nothing to do with underlying costs. Furthermore, updating of prices to reflect increases in costs is often slow. One constituent group for price controls are the consumers, who are able to obtain services or products at the artificially low prices (which is one reason that riots have occurred among urban middle-income households in some African countries when price ceilings are raised on bread or other staples).

Price ceilings constitute the maximum retail price that can be charged for a product or service. When price ceilings are set at a very low value, they may not be high enough to cover costs. Physician visits may also be subject to price ceilings. Commercial manufacturers and providers will only stay in the market as long as they can cover costs from revenues. Thus, price ceilings, if they are binding constraints, can significantly lower private supply. They can also lead to black markets.

To determine whether price ceilings constitute a significant constraint on private suppliers, it should first be determined whether the price ceiling is binding, that is, if prevailing prices fall short of ceiling levels, then it is safe to conclude that the price

ceiling does not constitute a problem. Alternatively, if private manufacturers withdraw their products from the market and the commercial availability of the product is very limited or has fallen, these are strong signs that the ceiling is a problem. For example, price ceilings reportedly contributed to the pull-out of commercial manufacturers from the Peruvian market and are the central constraint on local manufacture of pharmaceuticals in Egypt.

If the price is at the ceiling level and it pertains to oral contraceptives, the share of pill users obtaining services from commercial outlets (this can be easily estimated using DHS data) should then be estimated. For example, in some Latin American countries in which prices are controlled with ceilings, commercial sources provide the majority of pills. In such cases, ceilings do not seem to be a problem, and may possibly have stimulated demand for commercial products by keeping prices low.

To quantify the effect of the price ceiling, what is needed is information on the shape of the supply curve. To the extent that the supply curve is upward sloping and the price ceiling is binding, the quantity supplied would go up if the price ceiling were removed (the extent of increase would depend on the supply elasticity), leading to increases in contraceptive prevalence.

# REGULATIONS AFFECTING NON-PROFIT ORGANIZATIONS

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In some countries, non-profit organizations are formally or informally constrained in their outreach and fee setting policies. Regulated areas include ability to charge for donated commodities and fees charged for services. To the extent that non-governmental organizations (NGOs) are limited in the fees they can charge, this may constrain their supply of services. These types of issues may gain even more importance as NGOs face tighter funding levels from external sources. In some cases, there is no official policy and all that would be needed is clarification of the policy; this was true in the Philippines, where many NGO providers believed that they were prohibited from charging any fees for services when they received free government supplies, when in fact there was no government policy to that effect.

The most straightforward way to obtain information on regulatory issues of concern to NGOs is through interviews with NGO associations and providers. After taking into account the problems they see, an assessment should be made of how much the NGO contribution to family planning services could change. In many countries, DHS can provide baseline information on what share of contraceptors are obtaining services from NGOs (unfortunately the source data are of uneven quality and usefulness across countries). In some cases, these surveys also include questions regarding knowledge of the existence of NGO providers in neighborhoods, villages, and cities, which can indicate something about the perceived availability of NGO services. In addition, it is important to keep in mind other constraints on NGO expansion. Many NGOs depend heavily on outside donors just to meet basic operating costs, lack incentives to adopt efficient management and operat-

ing practices, are not focused or consistent in their targeting of services, and have not adopted cost recovery strategies for a variety of reasons. Therefore, when assessing the potential for NGO expansion, one should consider how an expansion would be financed and whether there is excess service capacity.

# ASSESSING HOW TO ACHIEVE REFORM AND ITS COSTS

In most of the areas discussed above, suggestions are made about how to assess whether specific legal and regulatory constraints are binding, and for those that are binding, how to determine the magnitude of the effects on contraceptive prevalence and/or on switching from public to private sources. After conducting this appraisal, it should be possible to rule out several issues as not relevant for a particular environment. These should not be considered further. For the remaining issues, one should then undertake an analysis of what it would take to achieve the reform and how much it would cost.

To assess what it would take to achieve reform, an understanding of which individuals or organizations would be responsible for changing the policy, which individuals or organizations would carry it out, and what it would take to get decision makers to change the policy should be developed. It is also important to identify influential supporters of the status quo and key individuals or groups who would like to see the policy change or who could be persuaded to that view. A plan must be developed that outlines the concrete steps that would be taken both by the analysts and by the government and other parties. A detailed description of how to make these assessments is contained in the OPTIONS guide: "Assessing How to Achieve Policy Reform and Its Costs" (1991).

The leverage that USAID has for achieving policy reform should also be considered. In negotiating bilateral agreements, A.I.D. missions have sometimes included clauses that explicitly address legal and regulatory issues. For example, in Uganda, a bilateral agreement contained a clause by which all contraceptive methods that were imported under the bilateral project would be duty free.

A more recent development is the use of non-project assistance as a mechanism for compelling governments to adopt reform. For example in Ghana, the current USAID bilateral project contains a schedule by which the government must implement a series of legal and regulatory changes as conditions for disbursement of three different tranches, amounting to \$13 million in total. These conditions include the establishment of a national population authority, which has, as one of its objectives, "to maximize the role of the private sector in achieving national population goals," the expansion of the essential drug list to include oral contraceptives, the elimination of duties on commercial import of contraceptive products, and the elimination of price controls on contraceptive commodities over a three-year period. The experience in Ghana with this approach may be very instructive for future applications. Since the use of non-project assistance is very recent, it is premature to draw any conclusions about its efficacy for achieving legal and regulatory reform and for attaining ultimate objectives. One difficulty with this approach is that family planning assistance may be "held hostage" to the non-project assistance reforms, which could have serious consequences. Hopefully, the impacts will be carefully studied, so that one can gauge its potential usefulness in future applications.

In addition, one should be aware of the possibilities for collaborating with other projects. For example, if the most serious reservation to allowing other groups, such as chemical sellers, to sell oral contraceptives is that these groups lack adequate training which could lead to misuse of the pill, then special training could be undertaken (as it was in Ghana) and point of purchase materials could also be developed. Activities like these must be evaluated within the mandate

of ongoing USAID or government training and communications projects.

After mapping out a strategy for achieving reform, it is then necessary to estimate what it would cost to carry out the plan. Costs should include staff time, travel and expenses, and the cost of any workshops or observational travel that are integral parts of the strategy. Standard budgeting and costing techniques should be used. At this point, it is also important to consider other costs, such as those borne by the government. These could include foregone tax or tariff revenues (i.e., government losses in tax revenue) on each commercial sale, or required government staff time. They may also include the cost of operating the new system that meets some of the objectives of the previous system. For example, if price ceilings were in place partly to protect the poor, then the deregulation may have to include some sort of targeted subsidy or exemption system for the poor, which entails new administrative costs.

# CHOOSING PRIORITIES FOR POLICY REFORM

The figure below shows a simple four-way categorization according to the expected payoff from removing the regulation and the costs of successfully achieving reform. By combining the foregoing analysis of the benefits, effectiveness, and costs associated with each type of reform, what should emerge are crude estimates of cost-effectiveness ratios or net savings to the government. Benefit-cost or cost-effectiveness ratios should also reflect the estimated probability of success associated with each reform effort. These should form the basis for developing rankings of priorities for regulatory and legal reform.

		EXPECTED BENEFITS/PAYOFF FROM REMOVING REGULATION	
		LOW	HIGH
COST/ DIFFICULTY IN ACHIEVING REFORM	LOW	Cost and benefits of these activities should be weighed	These activities should be given highest priority
	HIGH	These activities should not be undertaken	Cost and benefits of these activities should be weighed

# EVALUATING PROJECT ACTIVITIES

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Project activities that are undertaken in this area should be judged in terms of whether they lead to or contribute to legal and regulatory reform *and* whether they subsequently generate improvements in ultimate objectives such as increases in contraceptive prevalence or in private sector users. As is clear from the proposed approach, we lack solid evidence on the impacts of legal and regulatory constraints. Therefore, it will be especially important for project activities to be designed in such a way that changes in contraceptive prevalence or other indicators can be tracked. As more experience is gained in this area, it may be fruitful to revise this manual to reflect insights gained through project activities.

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