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Contraceptives and common sense: Conventional methods reconsidered

Judith Bruce
*Population Council*

S. Bruce Schearer

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Contraceptives and Common Sense: Conventional Methods Reconsidered

The Population Council

Judith Bruce

S. Bruce Schearer
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Charles B. Keely

**Contraceptives and Common Sense: Conventional Methods Reconsidered**
Judith Bruce and S. Bruce Schearer
Contraceptives and Common Sense: Conventional Methods Reconsidered
Contraceptives and Common Sense: Conventional Methods Reconsidered

a Public Issues paper of The Population Council

Judith Bruce
S. Bruce Schearer
The Population Council
One Dag Hammarskjold Plaza
New York, N.Y. 10017 U.S.A.

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My colleagues and I at the Population Council ask: What can be done in the coming decade to bring the interests of individuals who use (or want to use) contraceptives closer to the center of attention in the development and improvement of methods to prevent pregnancy? In considering this question, we accept two compelling arguments: that the perspective of the user—his or her perceived needs, wants, concerns, and aspirations—is a point of view that those who work in contraceptive development must take increasingly into account; and that the safety and health risks of using contraceptives, including the risk-to-benefit ratios of using one type over another and of contracepting rather than conception, need greater and more continuous attention.

This is not intended to criticize any of the presently available contraceptive methods. Every one of them is important and, because people’s needs vary so greatly, their variety is desirable. In fact, it can be argued that the range of available contraceptives needs to be expanded to include substantially more rather than fewer varieties for men and for women.

There is no doubt, however, that increasing knowledge of the risks and side effects of some contraceptives is, as an earlier Public Issues paper by Stephen L. Salyer and James J. Bausch pointed out in 1978, “encouraging a rising level of dissatisfaction with current contraceptive technology. Signs of concern and disenchantment are found . . . in indications that a shift away from pill use may be under way . . . . The sexually active person is faced with an uncomfortable choice between highly effective methods involving varying degrees of risk.
and safe methods that may detract from sexual enjoyment. . . .” It seems evident that a considerable expansion of effort to produce the widest range of safe, convenient, and effective contraceptives must be undertaken, and that the perceived needs and concerns of the user must be kept centrally in mind throughout every phase of this work.

Barrier, or conventional, methods of contraception—those that physically block the passage of sperm into the uterus or chemically inactivate the sperm in the vagina—are an important group of methods in need of further development. Most have been around for decades. Some, like the condom and the diaphragm, are familiar to many; others, including cervical caps and spermicidal suppositories, tablets, and foams, are becoming more widely known. Often, however, these methods are perceived as clumsy or inconvenient to use, are believed to be ineffective, and are considered too plain and old-fashioned for this era. Yet, as Judith Bruce and S. Bruce Schearer point out in this paper, research shows that most of these methods are capable of providing high use-effectiveness, contrary to common views. The authors’ examination of social trends and the special needs of many groups of current contraceptive uses, including adolescents, women over 30, and those worried about the health risks of the pill and the intrauterine device (IUD), indicates that barrier methods are increasingly perceived as a modern, safe, and common sense way to prevent pregnancy. They are, in this increasingly health-conscious age, the only group of contraceptives offering high effectiveness with the absence of any known health hazards, and the option of complete and instant freedom to try to conceive if and when the users wish. For these reasons, nearly 20 percent of contraception in the United States today is based on the use of conventional methods.
In such a climate, one might expect developers of contraceptives to be giving some priority to better and more barrier methods, but one would be surprised and disappointed: in 1977, while public agencies spent some $9 million to test the safety and effectiveness of oral contraceptives and $1 million to test IUDs, no funds were allocated to test currently available barrier methods. And while these same agencies concurrently spent $5.7 million to improve and develop new hormonal contraceptives for women, $1.8 million on new approaches based on immunology, $1.5 million on new hormonal contraceptives for men, and $1.3 million on new techniques of abortion, they spent only $143,000 on the development of better barrier contraceptives. This would appear to be out of tune with the times and somewhat unheeding of the message consumers are sending with increasing clarity.

The authors persuasively argue that this important area of contraception has been too long ignored, that a large and sustained effort to develop new and better barrier contraceptives is sensible and required, and that now is the time to begin. We need to listen more attentively to the common sense of the contraceptive user in this important field of health technology.

George Zeidenstein
New York City
Here begin the medicines to be made whereby a woman might cease to conceive for one, two, or three years: (mix a concoction of certain drugs and honey), moisten lint therewith, and place it at her uterus.

*Papyrus Ebers*, Pl. 93, 6–8
(c. 1550 B.C.)
The ancient Egyptians had a simple, if not always effective way of preventing conception—crocodile dung was put into the vagina to separate the sperm from the egg. There are examples dating back almost half a million years of female-applied contraceptive barriers using a full range of animal, vegetable, and even mineral products: chopped grass, spider webs, leaves, honey combined with sodium carbonate. In ancient Greece, women used tаниc acid on their homemade tampons as a spermicide. A bush tribe in northern South America has traditionally employed okralike seed pods with one end snipped off as a kind of female-controlled vegetable condom held in place by the vagina.

The earliest condoms for men were made of animal skin formed into sheaths; they were used initially as protection against venereal disease and later as a means of contraception. Both ancient and modern preliterate peoples, as well as most of the early literate civilizations, found the simplicity and logic of placing a barrier between the sperm and the opening of the uterus easy to comprehend. The principle was handed down from generation to generation and society to society until the latter part of the nineteenth century, when the first modern barrier contraceptives were developed—condoms made of vulcanized rubber, diaphragms, cervical caps, and vaginal spermicides. Until the 1960s these methods—updates on the ancient modes—were the most reliable and most widely used means of birth control in the modern world.¹

Since the 1960s the solution to the problems of contraception have been based increasingly on complexity, not simplicity. This is not surprising in
an age of computers, lasers, zero-based budgeting, and high-technology medical treatment. The oral contraceptive (the "pill") was developed in the late 1950s using newly discovered synthetic hormones that act in intricate ways on glands at the base of the human brain. Intrauterine devices (IUDs) were widely introduced in the 1960s in a host of scientifically engineered configurations that act inside a woman's uterus in ways that are still too complex to be fully understood. Nearly half of all married couples in the United States who use some method of contraception—and most do during the course of their marriage—now use either the pill or IUD.

Both of these methods introduced new concepts in contraception. They seemed significant breakthroughs at the time of their introduction. Our hindsight permits us to see the limitations of both methods, but the concept behind hormonal contraceptives in particular dominates our vision of future technology. We continue to invest almost exclusively in research on hormonal methods of contraception. Of the nearly $70 million spent by public institutions on contraception research during 1976, only around $50,000 was devoted to improving barrier methods of contraception. The low priority given to research on barrier methods reflects a bias of reproductive scientists and health professionals in favor of high technology, sophistication, and a belief that "science" will solve our health problems. Barrier methods have simply become too simple to capture our imaginations.

Yet, if we examine emerging social trends and consider the special needs of some large groups for better contraceptives—adolescents, women over 30, individuals concerned with health and safety—in many respects barrier methods appear to offer both a modern and a commonsense solution to an age-old problem. They are, even with their present
disadvantages, the only methods that offer potentially high contraceptive effectiveness combined with freedom from any known short- or long-term side effects and the freedom to be fertile in the future if the user so desires.

Thus, we believe that the time is at hand for a comprehensive reexamination of barrier techniques for contraception. In this Public Issues paper we examine in some detail how good or bad are today's barrier contraceptives, how acceptable they are, and how they can be used to make them as close to the ideal concepts of modern contraception as possible. We document new patterns of use and demand for barrier contraceptives in this country, and we consider the potential utility of these methods for couples living in developing countries. In view of the shortcomings of present-day barrier methods, we review the opportunities for using science and technology to develop new and improved barrier contraceptives. Finally, we believe that our assessments of current social trends in contraception hold implications for public policy, and we briefly state these in the last part of this paper.
Contraception
That Meet
Modern Needs

1
The introduction of highly effective contraceptives in the 1960s encouraged new social demands by women. During the 1960s four highly effective contraceptive techniques—oral contraceptives, intrauterine devices, and male and female sterilization—became widely available in the United States for the first time. Their advent accelerated changes in the basic nature of family life and in the roles of women, changes that are still under way today. By providing individuals with the capability to control their fertility with nearly complete effectiveness, these methods opened up a new range of opportunities for couples and for women in particular. During the decade following their introduction, the amount of childbearing by American women was sharply reduced, and the time at which women elected to bear their children shifted significantly to older ages. These shifts were accompanied by the entry of women into the labor force in large numbers and by their increasing sense of entitlement, at all ages, to a broader role in national life beyond the domain of the family alone.

In retrospect, it now seems clear that the wide availability of effective new means of contraception encouraged a wave of new social demands by women. These demands—for personal growth and fulfillment, for control over one's body and future, for individual autonomy and expression within family life, for equity and sharing between men and women, for personal health and safety, and for sexual equality and fulfillment—have gained wide acceptance in contemporary social life. They are altering relationships between men and women, between parents and children, and between health professionals and consumers. Individuals, particularly women, are making increasingly independent decisions about health technologies and health care systems; their discontent is feeding a growing "alternative" health care movement. A growing number of men want to participate more equally in decisions about contraception, including sharing the risks of contraception, but they have few acceptable
choices. More women over 30 are still building or just starting their families. There is a striking increase in the number of adolescents who are sexually active, and most wish both to delay childbearing and to safeguard their future fertility. Among all age groups there is an increasing emphasis on preventive and curative self-health care, a growing discomfort with the ingestion of synthetic substances and systemic drugs, and an enlarging definition of health that stresses physical and sexual well-being.

Within the last five years, as these changes have been taking place, an ironic development has occurred. The very contraceptives that facilitated the emergence of new social demands are beginning to be perceived as hindering their realization. Sophisticated health technologies that entail the risk of long-term effects—particularly health effects and, for the young, impaired fertility—are increasingly perceived as closing off future options. Both the pill and the IUD are coming to be viewed as examples of technologies that exceed our grasp, that interfere too powerfully with basic life processes in ways we do not fully comprehend, and that consequently have a capacity to cause us harm in ways that we can only partially predict and rarely prevent.

This shift in attitude shows little sign of reversing, since its foundations are based on increasing knowledge from medical studies about the health hazards of modern contraceptive methods. Consider these developments:

- In 1975, over one-third of all contraceptive users in the United States employed oral contraceptives as their method. Beginning in the same year, new research findings began to show that oral contraceptives can cause serious health problems. In 1976, it was shown that these
problems are serious enough to require hospitalization in over 0.5 percent of pill users each year. Overall, these findings indicate that if a woman takes oral contraceptives throughout her reproductive years, interrupting use only for childbearing, she has better than a 1-out-of-10 chance of experiencing a stroke, heart attack, other type of circulatory system disease, gall bladder surgery, ulcerations of the cervix serious enough to require hospitalization, or a liver tumor caused by her use of the pill. According to more recent findings, the risk of those side effects that are related to the circulatory system is much higher among women who smoke and take oral contraceptives, but much lower among contraceptive users who do not smoke.

- The popularity of intrauterine devices in the United States declined between 1973 and 1975, despite the fact that overall use of contraception showed a substantial increase. Research on IUD safety over the past five years has demonstrated that long-term use of this method may cause pelvic infections, which, in turn, can lead to permanent sterility in some women.

- Recent studies have found that vasectomized rabbits and monkeys develop debilitating, often fatal autoimmune diseases. Millions of American men have been vasectomized, with no signs to date of any adverse health effects; it therefore seems unlikely that the findings from these animal studies are directly applicable to humans. Nonetheless, the National Institute of Health is now conducting extensive follow-up studies of vasectomized men to determine whether any long-term side effects do occur in humans.
Female sterilization fortunately remains free from such clouds of potential long-term health risks, but in spite of its dramatic increase in popularity over the past decade, its irreversibility is perceived by many women as a major drawback that undermines control over their future.

Paradoxically, the impressive documentation of the known risks of the pill and the IUD has increased the anxiety of many people about the unknowns. It is no longer enough for contraceptive methods to be highly effective. Consumers want contraceptives that are effective, safe in the short and long term, self-administered, and fully reversible. This is the modern concept of contraception.

This concept is not fully met by any of the presently available contraceptives. However, one class of contraceptives comes the closest: barrier methods. What is most modern about present-day barrier techniques is the concept they embody: simple, direct, and reversible contraception. It is a concept in easy harmony with demands for personal control and freedom from domination by formal social institutions. It sidesteps reliance on high technology and ingested chemicals, as well as overdependence on science to solve health problems. To the best of our knowledge, barrier methods are safe and reversible.

What is least modern about barrier methods is their still insufficient and variable effectiveness and the feeling by many users that their application interferes too significantly with sexual fulfillment. We now examine these issues in greater detail.
How Good—or Bad—are Barrier Contraceptives?
No other class of contraceptives provokes such a wide range of opinion about their value and effectiveness as barrier methods. The diversity of views about barrier techniques reflects contradictory findings about their contraceptive performance in different clinical studies, as well as strongly opposing emotional reactions to the coitus-related nature of these methods.

Effectiveness of Barrier Contraceptives

At first glance, the clinical data on the performance of barrier methods are so contradictory as to offer support for almost any point of view. For instance, in studies carried out between 1938 and 1976 the diaphragm has exhibited a failure rate in preventing pregnancies varying from over 30 to as low as 2 pregnancies per year per 100 users. At a pregnancy rate of 30, the diaphragm would be classified as one of the least effective of all contraceptive methods, comparable to reliance on postcoital douching or on calendar rhythm. At a pregnancy rate of 2, on the other hand, the diaphragm would be classed as a highly effective method, slightly more effective than most IUDs and only slightly less effective than oral contraceptives. The situation regarding the use of spermicides and condoms is virtually identical: pregnancy rates range from a low of 2–3 failures per 100 users per year to a high of 20–30, depending on the study consulted.

Part of the answer to these apparent discrepancies in findings lies in the way the studies have been conducted. But the same broad range in pregnancy rates has been exhibited among those studies that have employed the most rigorous scientific methodology. Thus it appears that the good or bad performance measured in the various studies of barrier methods actually occurs among the differ-
ent populations studied. The fundamental conclusion from the 100 or more clinical studies to date is not that the studies have been improperly conducted, nor that barrier methods perform well or poorly. The inescapable conclusion is that some populations can and do use barrier contraceptives—the condom, the diaphragm, vaginal spermicides—with extremely high effectiveness, while other populations are able to obtain only low effectiveness.

Put somewhat differently, the available research shows that barrier contraceptives of all types are technologically capable of providing very high effectiveness. At best, if they are used with correct technique at each coitus, barrier methods fail to prevent pregnancy in about 2–3 out of every 100 users during each year of use. This protection is about equivalent to that offered by an IUD. Interpreting these statistics into individual terms, a woman who obtains the best level of performance from barrier contraceptives over the course of her reproductive years has about a 50 percent chance, on the average, of experiencing one unplanned pregnancy due to contraceptive failure. Among present-day contraceptives, only oral contraceptives and sterilization can offer better protection. (A lifetime oral contraceptive user has a 5–10 percent chance of experiencing one unplanned pregnancy, on the average.)

Unfortunately, according to many studies carried out in this country, many, probably even most users of barrier contraceptives do not obtain this high level of performance from barrier methods. In fact, among the overall population of married contraceptive users in the United States, barrier method users experience about three times as many contraceptive failures as IUD users. Again in average statistical terms, if a woman were to use

Research on the condom, diaphragm, and vaginal spermicides shows that all of these methods are technologically capable of providing very high effectiveness, equivalent to that provided by IUDs.

Some groups, however, achieve only low effectiveness because they fail to use barrier methods consistently and correctly.
barrier methods at this low level of effectiveness over the course of her fertile years, she would be likely to have roughly two to three unplanned contraceptive failures. When barrier methods are used with such poor effectiveness, they are similar in performance to such traditional contraceptives as postcoital douching, withdrawal, rhythm, or prolonged lactation.15

**Factors That Determine Effectiveness**

New users obtain high effectiveness when they are given full information about the advantages and disadvantages of barrier methods, competent instruction on how to use them, and follow-up support.

What factors determine whether a couple—or a population—will use barrier contraceptives with low or high effectiveness? The research studies show that confirmed, experienced users generally use all types of barrier methods with high effectiveness.16 New users have also been shown to obtain high effectiveness if they are given full information, competent instruction, and follow-up support in their use of these methods.17 Poor effectiveness, on the other hand, has usually been observed in studies in which new users are given only limited information and instructions on use and little or no follow-up support.18 To some extent increasing levels of educational and socioeconomic status of the user appear to compensate for a lack of instruction and support, but not completely.

Instruction, information, and support for new users are so important for effective use of barrier methods because of the central role that sexual attitudes and behavior play in the performance of these methods.19 Barrier methods, like oral contraceptives, are self-administered. Unlike oral contraceptives, however, their use is related to the sex act. The condom and spermicides must be used just before coitus. The diaphragm can be inserted for as long as four hours before sexual activity, but it too must be inserted immediately before coitus when unplanned sexual activity takes place. All of
these methods therefore necessitate interruption of ongoing sexual behavior, as well as touching of sexual organs by either the man or woman.

Not all couples can accept these requirements. To use barrier methods successfully, a couple must be able to accept them psychologically and integrate their use into their sexual behavior. Without achieving this, they will use the method incorrectly or will occasionally take chances in order to avoid the emotional burden that use of the method causes them. Under such circumstances, some couples will then blame the method for any unplanned pregnancies. Hence, a precondition for the effective use of barrier methods is an acceptance by the user of how the method mechanically relates to his or her sexual practices, and an understanding of how and when to employ it.

This explains the key role played by instruction, information, and support. Full information allows couples who cannot meet the psychological and behavioral demands of barrier methods to appreciate this in advance and to select some other method of contraception better suited to their needs. Additionally, for couples who are motivated to try barrier methods, they offer both practical help and psychological support for successfully and efficaciously incorporating barrier methods in their sexual practice.

Numerous studies have documented the importance of information and support in determining how effectively any particular population will use barrier contraceptives. One of the most convincing is a study conducted in the early 1970s among young, unmarried, childless white women from predominantly lower socioeconomic groups in New York City. These women selected the diaphragm for contraception after participating in a half-hour discussion of the different contraceptives.
being offered by a low-cost family planning clinic on Manhattan’s Lower East Side. Although they were new to diaphragm use, these young women employed the method with very high effectiveness—the overall contraceptive failure rate for the population was 2.2 pregnancies per 100 users per year. This effective use was combined with strong acceptance of the method: 83 percent continued to use the diaphragm after one year. The authors of the study attributed this success to two factors:

- “the objectivity with which the [alternative] methods were offered and the thoroughness with which they were described [which] allowed the full exercise of patient self-selection”;
- “the level of instruction, which bolstered the patient’s self-confidence, and a mechanism for continuing supervision. The participation of personnel who believed in the method and who possessed the skill and patience to teach it was crucial.”

The high effectiveness obtained by established users—most of whom did not receive this kind of information and instruction—presumably reflects their having learned through trial and error how to use these methods. Their continued use of a barrier method reflects their successful adjustment to the coitus-related demands of these methods. It also reflects their motivation to avoid pregnancy, a third key factor in determining how regularly and effectively a couple will use barrier contraceptives.

In sum, three human factors exert paramount influence in determining how effectively—or ineffectively—a couple will use barrier contraceptives:

- the capacity of both partners to adjust emotionally and behaviorally to the coitus-related demands of these methods;
- the level of motivation of both partners to avoid pregnancy;
- the quality of instruction and information the new users receive about these methods.

These factors explain the key role played by the attitudes and practices of service providers, health specialists, and pharmacy personnel in the performance of barrier methods. Some health professionals often see the coitus-related demands of barrier methods as a major drawback, and they are biased both against barrier methods and against the potential ability of users to employ them reliably. In contrast, other professionals regard the users' participation as a positive feature that reaffirms its voluntary nature. In their discussions with prospective users of barrier methods, service providers communicate their attitudes—negative or positive—and thus either undermine or enhance the users' success in employing these contraceptives. When the service provider is the family doctor or a woman's gynecologist, these conveyed attitudes can exert substantial authority and influence. When the service provider is a pharmacist or clerk expressing a negative or mocking attitude, the effect can be discouraging to the would-be user of over-the-counter methods.

Technological factors also influence the effectiveness of barrier methods, although to a lesser extent. The quality of barrier contraceptives varies, and not all products of the same type are equally effective. At the extreme, it is evident that condoms manufactured with inferior latex or made too thinly can rupture during coitus, and that spermicides containing insufficient active ingredients or a type of jelly, cream, or foam that fails to adequately cover the interior of the vagina will not provide high contraceptive efficacy. Since drug control laws in most countries are lax in their regulation
of over-the-counter products, such instances of grossly inferior quality do sometimes occur.

Even among well-manufactured barrier contraceptive products marketed by major pharmaceutical manufacturers, differences in inherent effectiveness may exist between different types of products. Among spermicides, the prospective user can choose among vaginal jellies, creams, liquifying vaginal suppositories, foaming vaginal tablets, and aerosol foams. Based on very incomplete data from clinical studies of effectiveness, which show that jellies or creams used alone are less effective than the other varieties of vaginal barrier methods, it is generally recommended that the creams and jellies be used only in conjunction with a diaphragm.

Each of the other types of spermicides, along with the condom or the diaphragm used with jelly or cream, has demonstrated low pregnancy rates in selected individual studies—as well as very high pregnancy rates in many other studies. Unfortunately, the comparative effectiveness of the suppositories, tablets, and foams—or of these spermicides compared to the diaphragm used with either jelly or cream—is virtually unknown because few comparative studies have ever been undertaken to answer this basic question. The limited data we have suggest that inherent differences in effectiveness between these methods are slight. One study conducted in the early 1960s concluded that, among new users, the diaphragm used with jelly or cream was slightly more effective than foaming vaginal tablets. A later study by the same investigators showed that the diaphragm was appreciably more effective among new users than aerosol vaginal foam. In both studies, however, the differences in effectiveness either between the diaphragm (with jelly or cream) and foaming tablets

Limited data suggest that inherent differences in effectiveness between the various types of barrier methods are slight.
or between the diaphragm and aerosol foam were insignificant among long-term users of these three methods, suggesting little inherent difference in efficacy between them.

Unfortunately, many of the spermicide products on the market today remain untested under rigorous scientific conditions, let alone in comparison with alternative products. It is possible, therefore, that some of these products may not be capable of providing very high effectiveness. Until researchers conduct carefully designed comparative studies, the user has little guidance beyond the findings reported here in selecting among the half-dozen or more varieties of vaginal spermicides currently on the market.

Thus far, this examination of the utility of barrier methods has focused exclusively on their contraceptive performance. What about their side effects? How safe are they in comparison with other types of contraceptives?

To varying extents, oral contraceptives, IUDs, and surgical sterilization of women all infrequently cause illnesses or injury sufficiently serious to require hospitalization. More rarely, they give rise to fatal side effects. In contrast, barrier methods cause no known illness, disease, or mortality. Indeed, there is recent evidence that the diaphragm may even offer the health benefit of a reduced risk of cervical cancer.

The only adverse health effects known to be associated with barrier methods are rare instances of allergic reactions to the rubber or dusting powder used in condoms and diaphragms or to the chemi-
To varying extents oral contraceptives, IUDs, and female sterilization infrequently cause illness, injury, or more rarely, death. In contrast, barrier methods cause no known illness, disease, or mortality.

cals present in spermicides. Some types of spermicides cause a sensation of warmth in the vagina as they are dissolving, but this is not associated with any adverse effect on vaginal tissues. Recently, it has been realized that some of the chemicals in spermicides are likely to be absorbed through penile or vaginal tissues into the bloodstream. If this happens—and it is not yet established to what degree it does—these chemicals might exert toxic effects on the body. Based on the little we know about the toxicity of these chemicals and on the fact that they are used only intermittently, significant health hazards do not seem highly likely. In the case of spermicidal jellies and creams used in conjunction with the diaphragm, actual clinical data over seven years of observation have revealed no illness or disease caused by this method. Further studies of these and other types of spermicides are now being considered by various research groups to provide more complete information about their potential absorption and toxicity.

In comparing the relative safety of different contraceptives, the US Food and Drug Administration and most physicians feel it is necessary to consider one additional factor: the risk of illness or death associated with any unplanned pregnancies that may occur because of failures in the contraceptive effectiveness of different methods. It should be stressed that this factor is not always a relevant concern to a woman using contraceptives. During certain times in their reproductive years, most women are prepared to accept an unplanned pregnancy as a wanted (albeit earlier than intended) pregnancy. Under these circumstances, she is prepared to accept the health risks of pregnancy and childbirth. During such periods in a woman's life, she would not give much weight to the health risks of pregnancy in evaluating the relative safety of different contraceptive methods. For such a woman, barrier
methods offer contraception free from known health risks.

However, for women who are fully committed to not becoming pregnant, health risks arising from pregnancies due to inadequacies in their contraceptive method are of concern. Figure 1 presents a comparison of the relative safety of different reversible methods of contraception that takes into account such risks of unwanted pregnancies. Barrier methods are included in the figure with two different levels of effectiveness—low (equivalent to using these methods with an annual contraceptive failure rate of 21.5 pregnancies per 100 users) and high (equivalent to an annual failure rate of 2.5 pregnancies per 100 users). The figure also includes barrier methods used with low effectiveness coupled with abortion of all contraceptive failures that would occur under such circumstances. The comparison is based on risks of death; no other risks to health are taken into account. The data in the figure are specific to Western women, and would yield very different results if calculated for women in developing countries.37

Figure 1 shows that even when the mortality risks of unplanned pregnancies are taken into account, all barrier methods are extremely safe contraceptives. Indeed, for women willing to use abortion to terminate any unwanted pregnancies, or for couples who can use barrier methods with enough consistency to obtain high contraceptive efficacy, barrier contraceptives offer by far the greatest safety of any reversible means available today.

A very important footnote to the safety of barrier contraception—even when used with low effectiveness—is the safety of abortion. Mortality risks associated with abortion are extremely low.38 In addition, a series of recent international studies organized by the World Health Organization and
Figure 1
Mortality Associated with Use of Reversible Contraceptives (No Use of Abortion Unless Noted)

- Barrier Methods, Low Effectiveness, with Abortion of Accidental Pregnancies
- Barrier Methods, High Effectiveness
- Intrauterine Devices
- Barrier Methods, Low Effectiveness
- Oral Contraception among Nonsmokers
- Oral Contraception among Smokers

Deaths per 100,000 Nonsterile Women per Year of Use of Method

Deaths Resulting from Pregnancy and Childbirth if No Contraception or Abortion Is Used

Age of Women

15-24
25-29
30-34
35-39
40-44
the US Center for Disease Control show that modern suction abortion has no effect on subsequent fertility or pregnancies. There is evidence from one of these studies (in Singapore) that abortion by D&C (dilatation and curettage) may sometimes cause an increase in subsequent miscarriages, but this finding was not observed in a parallel study in New York City. At any rate, the vast majority of all legal abortions are now performed using the suction technique.

In addition to their intrinsic safety, barrier methods are the only contraceptives to offer some degree of protection against sexually transmitted diseases. While there is some uncertainty and, indeed, scientific dispute about the extent of this protection, condoms clearly can prevent the transmission of gonorrhea and some other less common venereal diseases if they are used with vigorous care to avoid all skin contact between sexual partners. The diaphragm used with jelly or cream and spermicidal foams and suppositories used alone appear to offer partial protection against some types of venereal disease. In view of the virtual epidemic of venereal disease that has occurred during the past decade in the United States, even such incomplete protection can have considerable importance for teenagers and others having varied sexual partners.

While the preceding discussion on the utility of barrier contraceptives is pertinent to couples in both industrialized and developing countries, those living in developing countries face special problems. The reader is referred to Part 6 of this paper for a more complete discussion of the utility of barrier contraceptives for such couples.
Current Acceptability and Emerging Demand for Barrier Contraceptives

3
According to national statistics, the popularity of barrier contraceptives in the United States has declined substantially over the past decade. Among contraceptive developers, manufacturers, and service providers there now exists a widespread conviction that these methods are no longer acceptable to most couples.

Current Acceptability and Use

Examination of the statistics shows clearly that this conviction is incorrect. In spite of the sharp drop in the use of barrier methods between 1965 and 1976, very substantial numbers of couples continue to use these methods. In 1976, 18–19 percent of all couples practicing contraception used a barrier method. Among those couples using reversible contraceptives (i.e., excluding those who were sterilized), between 27 and 33 percent were using a barrier method in 1976. It is interesting to note that the levels of barrier method use are similarly high throughout most of Europe. Statistics also show that most of the loss in popularity of barrier methods in the United States took place among older couples who were firmly committed to no further births and adopted sterilization. Among younger married couples there was a slight overall increase in popularity of these methods, mainly due to an increased use of the diaphragm. (For more on this see pp. 31ff.)

The Role of Service Providers in Determining Acceptability

Service providers exert a major influence on the acceptability of barrier contraceptives. Simply put, motivation and knowledge being equal, a person who visits a clinic that supports barrier methods is more likely to use them. The current level of bar-
rier method use in the United States—nearly one-third of all married couples who use some form of reversible contraception—is probably a minimum indication of the acceptability of these methods. With appropriate support by service providers, acceptance would very likely be increased. 49

Table 1 summarizes the percentage of patients using the diaphragm, drawn from three different service provision settings: (1) publicly supported organized family planning service providers, such as Planned Parenthood and state health depart-

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Approximate Annual Case Load</th>
<th>Percent of New Patients Selecting Diaphragm</th>
<th>Percent of New Patients 19 and under Selecting Diaphragm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A public clinic in the South</td>
<td>over 15,000</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>2. A clinic operated by a voluntary organization in the Midwest</td>
<td>over 10,000</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>3. A public clinic in the East</td>
<td>over 20,000</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>4. A clinic operated by a voluntary organization in the West</td>
<td>over 10,000</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>5. Three clinics operated by a voluntary organization in the East</td>
<td>over 30,000</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>6. Combined data from three women-run clinics</td>
<td>1,500</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>7. A privately and publicly supported adolescent health center</td>
<td>over 3,500</td>
<td>NA</td>
<td>30</td>
</tr>
</tbody>
</table>

Sources: Planned Parenthood of New York City, three women's health services, and Aida Torres of the Alan Guttmacher Institute. Project 7 is within "The Door—A Center of Alternatives," in New York City.
Attitudes and practices of service providers exert a major influence on the acceptability of barrier contraceptives; (2) women-run health centers, which are all private; and (3) a special teenage clinic. Within the network of organized family planning services there is wide variation in the proportion of women using the diaphragm. In some of these clinics, as many as 20 percent of all clients use barrier methods, while as few as 2 percent use them in others. Within the network of privately operated women's health services (there are approximately 200 such health collectives in the United States), the proportion of women selecting the diaphragm or other barrier methods is extremely high; typical clinics report that as many as 80 percent of their clients select these methods.

As the preceding suggests, a significant number of small and some large service providers do not find the provision of barrier methods unusually difficult. However, some providers still argue that the time required for an effective discussion of barrier methods with a prospective user prevents them from offering better services in this area. The instruction must deal with sensitive sexual topics and requires 10 to 15 minutes of competently guided discussion. Diaphragm users need fitting to determine the correct size of the device they should use. They also need a demonstration on how to actually insert and remove the device, following which the new user may either disappear behind a curtain, insert the diaphragm, and be assured that she has put it in place properly, or return within a week with the diaphragm in place to demonstrate her competence. The time consumed in this initial visit of the barrier method user is generally less than that required to insert an IUD and only slightly longer than required for a thorough discussion of the oral contraceptive.

The time and the quality and nature of the required discussions are often viewed as excessively costly burdens in a busy clinic or private office
practice. If this perception is indeed correct (and it may not be), the initial outlay of professional time will be compensated for by fewer subsequent consultations. Oral contraceptive and IUD patients require regular follow-up visits. IUD users should be seen within six weeks of insertion and at least annually thereafter. Oral contraceptive users are usually seen within three months of their first visit and in many services are asked to return twice a year for resupply and "discussion," if not examination. Once a woman has obtained a diaphragm or spermicide and has learned how to use the method, her need for further follow-up support or medical review is minimal. A woman's diaphragm size might change if she gains or loses 15 pounds or gives birth. Otherwise, a diaphragm (and a diaphragm prescription) should last about three years. In effect, the professional input required by barrier method users is slightly higher at the beginning, but over time the user is less physician-dependent than the IUD or oral contraceptive user.

Less time and involvement by physicians in the provision of barrier contraceptives might improve the quality of services and lower the costs. Some services use nurse/midwives or other trained health care paraprofessionals to supplement physicians' services, a practice often preferred by women. Some services strive to reduce the distance between "professional" and "user" by emphasizing that the user's perceptions and motivations are the critical factors in making health technologies work. They encourage greater participation by the user through open-ended discussion, self-examination, and the like. Both measures appear to improve information levels and foster the self-awareness that makes effective use of barrier methods possible. A recent study compared the knowledge levels of women receiving contraceptive services from medical, paramedical, and self-help facilities (the third
type is generally run by women who are specially knowledgeable and committed, though not formally trained as professionals or paraprofessionals). As shown in Table 2, women receiving services from conventional medical sources had the lowest knowledge levels, while those receiving services from self-help facilities had the highest.

A number of legal and practical obstacles also block greater use of these methods. Some states, for example, impose age restrictions on the purchase of over-the-counter contraceptives. In some states, a diaphragm prescription cannot be refilled without a physician’s review. Although it might make sense to remind a woman to see a doctor at yearly intervals, forbidding a reorder of a diaphragm without physician participation inconveniences and costs

<table>
<thead>
<tr>
<th>Knowledge Tested</th>
<th>Medical Facilities</th>
<th>Paramedical Facilities</th>
<th>Women-run Self-help Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy identification (clitoris, uterus, vagina, os, Fallopian tube, urethra, ovary, labia, cervix, hymen)</td>
<td>46.2%</td>
<td>54.6%</td>
<td>72.2%</td>
</tr>
<tr>
<td>Definitions of gynecological procedures (breast exam, Pap smear, speculum, pelvic exam, D&amp;C, biopsy)</td>
<td>82.0</td>
<td>85.6</td>
<td>98.0</td>
</tr>
<tr>
<td>Knowledge of appropriate frequency of performing these procedures</td>
<td>60.0</td>
<td>67.6</td>
<td>73.2</td>
</tr>
<tr>
<td>Contraceptive contraindications, if any (for the pill, IUD, diaphragm, foam, condom)</td>
<td>22.0</td>
<td>39.2</td>
<td>39.2</td>
</tr>
</tbody>
</table>

the user senselessly. Because barrier methods have traditionally been given a low marketing priority by manufacturers, not only has the packaging and labeling suffered but in some cases products have ceased to be available. The cervical cap, a small, flexible cap that fits over the cervix and was used in the 1930s and 1940s, is virtually impossible either to have fitted or to find in a drugstore. The few physicians who fit caps get their supplies from England and other European countries.

Despite a low interest in barrier contraceptives that has prevailed among service delivery personnel and pharmaceutical companies, there are indications, as the next section documents, that a resurgence in the popularity of such methods is under way. If service providers respond positively to this demand, it seems likely that the acceptability and use of barrier methods will increase substantially in the years ahead.

Information from a number of sources—national surveys, family planning service statistics, and commercial data—demonstrate an increased demand for barrier contraceptives:

- Data compiled by the National Center for Health Statistics on the practice of contraception by white, never-divorced, married couples in the United States indicate a small increase in the number and proportion of persons using the diaphragm between 1973 and 1976. This increase reverses a downward trend in diaphragm use that had been under way since 1965. These same statistics show that the increase has occurred mainly among younger couples married fewer than ten years.
• These statistics also show that condom and, to a lesser extent, spermicide use has begun to increase among younger black couples, while condom use continued to decline among older black couples.

• Many family planning clinics have noted steady increases since 1975 in the demand for diaphragms and in the use of condoms and foams. The Center for Family Planning Service Statistics, which collects information from clinical services such as those operated by Planned Parenthood, public hospitals, and public health departments, has documented this trend (see Table 3).

• Indirect evidence suggests a resurgence in the use of barrier contraception by couples who obtain their contraceptives from drugstores and private physicians. Suppliers of the latex used in the diaphragm are reporting a demand they cannot meet, and at least one major diaphragm manufacturer reports difficulty in producing sufficient quantities to meet the growing new demand. Pharmacists are experiencing a shortage of diaphragms and are sometimes out of supply. At the same time, pill manufacturers are seeing a decline in sales—according to one company, by as much as 15 percent each year—that appears to indicate a shift to other forms of contraception. A number of pharmaceutical companies are introducing new spermicidal products to the over-the-counter market.

Among the reasons cited for this emerging new demand are increased awareness of and concern about the side effects of oral contraceptives; this concern has been closely accompanied by a persistent decline in the use of the pill and IUD. It has also been assumed that the "return" to barrier methods in the United States after 1971 was related to the liberalization of abortion laws in several
### Table 3
Percent Distribution of Clinic Patients by Age and Contraceptive Method at Last Clinic Visit, 1972 and 1976

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diaphragm</td>
<td>2.3%</td>
<td>5.3%</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.2%</td>
<td>6.3%</td>
<td>4.8%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Foam</td>
<td>4.0%</td>
<td>5.6%</td>
<td>3.3%</td>
<td>4.6%</td>
<td>3.6%</td>
<td>5.1%</td>
<td>6.6%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Condom</td>
<td>0.7%</td>
<td>2.0%</td>
<td>0.4%</td>
<td>1.5%</td>
<td>0.6%</td>
<td>1.7%</td>
<td>1.6%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Orals</td>
<td>70.3%</td>
<td>67.2%</td>
<td>81.3%</td>
<td>78.1%</td>
<td>70.3%</td>
<td>67.0%</td>
<td>53.1%</td>
<td>47.2%</td>
</tr>
<tr>
<td>IUD</td>
<td>15.5%</td>
<td>9.6%</td>
<td>7.9%</td>
<td>4.1%</td>
<td>16.5%</td>
<td>10.1%</td>
<td>23.5%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Sterilization</td>
<td>1.0%</td>
<td>1.7%</td>
<td>0.1%</td>
<td>0.4%</td>
<td>0.9%</td>
<td>1.4%</td>
<td>2.5%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Rhythm</td>
<td>0.2%</td>
<td>0.3%</td>
<td>0.1%</td>
<td>0.3%</td>
<td>0.2%</td>
<td>0.3%</td>
<td>0.4%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Other</td>
<td>1.0%</td>
<td>1.2%</td>
<td>0.6%</td>
<td>1.0%</td>
<td>0.9%</td>
<td>1.1%</td>
<td>2.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>None</td>
<td>5.0%</td>
<td>7.1%</td>
<td>5.3%</td>
<td>7.3%</td>
<td>4.8%</td>
<td>7.0%</td>
<td>5.5%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Total</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Use of barrier methods is increasing among young married couples in the United States.

trend away from the use of oral contraceptives began in the late 1960s.56

Who are the new users of barrier methods? National data indicate that younger couples are showing a new and distinct preference for the diaphragm and, among some groups, spermicides and the condom, while the popularity of all of these methods has declined among couples married for 10 to 20 years.57 In short, it appears that the new users of barrier methods are clustered primarily in the younger age groups.

Data from England, Australia, and the United States reveal that better-educated women and women married to professionals on the whole have been more likely to use barrier methods than other groups.58 Recently, however, use of these methods appears to be diffusing to groups with lower levels of educational attainment. For example, the data gathered by the National Center for Health Statistics show that the trend toward increased use of condoms and spermicides may be much more pronounced among married black women than married white women.59 Other data show that, in communities where the proportion of women using the diaphragm has been several times higher than the national average, diaphragm use is becoming prevalent among all types of women.60

This last point bears importantly on how the new patterns of use and demand for barrier contraceptives are developing in the United States. The observed differences in patterns of contraceptive use between various groups of people are not due simply to educational or age differences. They also reflect important differences in social attitudes and in access to information and services. Highly educated women are generally the first to adopt superior health technologies, in part because their relative privilege permits them to make informed choices earlier than other women. There are other
elites among women whose health care practices have not been systematically studied. For example, women health care professionals and women married to such professionals constitute a type of elite group that may well have a different pattern of contraceptive use than women more isolated from full information. Indeed, evidence (surveys of physicians' wives and family planning professionals) suggests a considerable difference between what health professionals recommend to patients and the methods they themselves use; a disproportionate number of physicians' wives use barrier methods.\(^6\) A recent addition to the sociology of contraceptive use among professionals is the remark by the commissioner of the US Food and Drug Administration that he would rather his wife and daughter use some method other than the oral contraceptive.\(^6\) In the long run the contraceptive choices of professionals are likely to have a persuasive influence on their clients.
Groups for Whom Barrier Methods Have Special Appeal
Increasing use of and demand for barrier contraceptives seems to be a fact. Just how far this emerging demand will extend in the years ahead is uncertain, but substantial increases in barrier method use seem very likely. It is not likely, however, that this new demand will extend equally to all social groups. Rather, the specific characteristics of barrier contraceptives are likely to make them especially suitable for and appealing to certain social groups.

As documented in Part 3, the only group for which a definite statistical increase in the use of barrier methods has been demonstrated up until 1976 (the last year for which national statistics are available) is young married couples. This is not surprising in view of the obvious advantages of barrier contraceptives for this group. Most young married couples are planning to have children in the future, and for many of them a slightly higher risk of pregnancy is more acceptable than unwanted risks to health or fertility that may be associated with more effective contraceptive methods. This is especially so since legal abortion is both available and acceptable to the majority of these couples. Also, sexual communication between these young people is generally more open and easy than it was for earlier generations, and barrier contraceptives are therefore more easily and successfully accommodated as part of their sexual practices. The fact that barrier method use is on the increase among both white and black and upper- and lower-income young couples (although with different types of barrier methods being preferred by these different subgroups) suggests that this is only the beginning of an extended social trend.

Four additional groups stand out as important and interested future “markets” for these types of contraceptives: adolescents, women over 30, men who wish to share the health risks of contraception, and
women for whom self-care and feminist health care is important. Taken together, these groups now represent a large share of all contraceptive users. Because of the postwar baby boom and present social trends in sex, marriage, and childbearing, the overall size of these four groups will increase significantly during the coming decade.

To some extent, growth in use of barrier methods among these four groups seems inevitable, and in the following discussion we document the evidence that such growth is already taking place. But to some degree, the amount of growth in barrier method use will also depend upon policies and actions adopted by health authorities and pharmaceutical companies over the next several years. In what follows, therefore, we assess the utility of barrier contraceptives for these four groups and comment on some of the policy implications of these assessments.

The most rapidly growing group of contraceptive users in the United States is women under the age of 20. This "audience" for contraception has been expanding in two ways: (1) numbers—more and more young women, perhaps as many as 4 million teenage girls, are sexually active and in need of contraception, and (2) age—almost half the teenagers seeking contraception today are under 17. Consider the following statistics:

- Between 1971 and 1976, the percentage of never-married women aged 15–19 who had had intercourse increased from 27 to 35 percent. Among the youngest—the 15-year-olds—18 percent had had intercourse, up from 14 percent in 1971. The median age at first intercourse was 16.2 years.
The most rapidly growing group of contraceptive users is unmarried teenagers.

Use of contraception among these teenagers dropped from 83 to 75 percent between 1971 and 1976. However, among those who are using some type of contraceptive, use is much more frequent. Yet only 30 percent of the users (22 percent of all sexually active teenagers) use a contraceptive at each intercourse.67

In 1976, half of all sexually active teenagers had more than one sexual partner. But when surveyed, almost 50 percent of unmarried, sexually active women aged 15–19 reported no intercourse in the four weeks preceding the interview. In other words, sexual activity among adolescents is very irregular.68

The most dramatic changes in the types of contraceptives used by teenagers between 1971 and 1976 were large shifts toward oral contraceptives (from 24 to 47 percent) and large shifts away from withdrawal (from 31 down to 17 percent) and the condom (from 32 to 21 percent). Fewer than 10 percent of adolescent contraceptors use spermicides or the diaphragm, and there was a slight decline in use of these methods between 1971 and 1976.69

Teenagers tend to try several different contraceptive methods, and the youngest favor such nonmedical methods as the condom, spermicides, douching, and withdrawal.70

Despite the increased popularity of the pill among teenagers, use of over-the-counter barrier contraceptives is significant and is likely to increase.

Thus, it is clear that despite increasing popularity of the pill among teenagers, barrier contraceptives, especially the over-the-counter methods, hold an important place in adolescent contraceptive practice. As the number of sexually active adolescents grows and as adolescent sex becomes more typical, the use of over-the-counter barrier contraceptives by this group is likely to increase.
But beyond the inherent demand among teenagers for a wide variety of methods and, specifically, for barrier contraceptives under some circumstances, a number of important social and health policy issues suggest that increased barrier method use by this group should be encouraged. One of the most positive findings from a recent national survey of teenagers is that they are becoming more effective contraceptors and more of them are seeking to use contraception earlier. However, there are costs associated with the use of more effective contraception when this is achieved primarily through use of oral contraceptives or IUDs. The irregularity of sexual activity among teenagers and their vulnerability to adverse health effects that may take years to become manifest argue against the use of these methods by teenagers. Continuous use of oral contraceptives or an IUD among this age group can be seen as overmedication that exposes users not only to the inherent risks of these methods, but also to additional unnecessary risks because the method is being used for long periods with no purpose. This concern is now being expressed by many physicians, who note the following:

- Women who begin using oral contraceptives at a young age will frequently go on using them for many years continuously. This will expose them to a substantial cumulative health risk, particularly if they smoke, as many teenagers do.

- Young women whose menstrual and ovulatory cycles are not yet fully established are not a suitable population for oral contraceptives, since these contraceptives contain powerful hormones that could potentially disrupt the natural biological establishment of their cycles.

- Venereal disease rates have sharply increased among sexually active young people; oral con-
traceptives and IUDs provide no protection against sexually transmitted diseases and may even promote certain types of infections.76

- Most configurations of the IUD are not well tolerated by women who have never had a child. Those few that are should be made more available, but even these are often expelled or cause distressing bleeding and pain, leading to their removal, especially in young, never-pregnant women. Further, all IUDs increase the risk of pelvic inflammatory disease, especially among young women who have a variety of sexual partners (as is common among teenagers), thus creating a risk of subsequent infertility.77

For these reasons, some members of the medical community have apprehensions about the increasing reliance of adolescents on the pill and IUD. This apprehension, however, has not yet been translated into enthusiasm for barrier methods.

The key issue here is whether adolescents can employ these methods with sufficient consistency to obtain high effectiveness. Young men carry condoms. Young women could carry spermicides or the diaphragm (and some do), although it would help if the diaphragm were more portable and if various spermicidal jellies, creams, and suppositories were packaged in single applications. But, clearly, many adolescents cannot always plan ahead for sexual activity. And even with the best intentions and advance planning, the application of spermicides or a condom so close to the sex act can be socially and emotionally difficult for adolescents. To use them effectively, they must find a way to incorporate barrier methods into their sexual practices and—more important—their partnerships.

In spite of these problems, large providers in different parts of the country have begun to prescribe...
diaphragms for as many as one-fifth of their teenage clients (see Table 1). Recent studies show that with adequate instruction and support, these young users are obtaining very high effectiveness. Marketing of condoms and spermicides is being increasingly directed to young people, and drugstores in many states are selling these methods off-the-shelf in supermarket style.

These trends suggest that a positive shift in basic policy regarding the provision of contraceptive services to teenagers is under way. In the past there has been a tendency for many private physicians and organized family planning services concerned with the "social" risks of teenage pregnancy to make judgments on behalf of their adolescent clients and thus to promote the use of oral contraceptives and IUDs.

Slowly it is being recognized that adolescents are a heterogeneous group and that they will—and should—seek individual solutions compatible with their personal habits, preferences, and concerns for safety and effectiveness. For some, oral contraceptives or the IUD will be the right choice. For those who can adapt their behavior to meet the requirements of barrier methods, these techniques can offer full safety, high effectiveness, full reversibility, ease of purchase, and freedom from medical (and therefore very often parental) authorities.

Informed choice implies more than a review of medical facts. Both organized family planning programs and private physicians should encourage discussion of social issues with teenagers making contraceptive choices. Drawing teenage males into discussion of health and safety risks in coeducational and clinic settings may help raise the explicit issues of male and female risk and responsibility in a constructive way. For example, in wishing to take increased responsibility for contraception, young
women may be expressing something positive about the desire to control their own lives and their intense motivation to avoid pregnancy. But they may also be expressing a helpless acceptance of unwanted health risks associated with contraception because they are afraid to ask the man to use the condom. The attitudes of adolescents to abortion and their access to it vary widely throughout the United States and will likely be an important element in the selection of a method. Unwanted pregnancy is a possible outcome of use of barrier methods, and for adolescents either unwilling or unable to obtain abortions, it is a life-altering event.

These and other health and social issues need full discussion with young people faced with a complex and difficult decision. Service providers should seek to create an environment that permits an informed and individual choice. If they do, it is likely that the use of barrier contraceptives by adolescents—with high effectiveness—will become more widespread.

American women over 30 are not what they used to be. Marriage and family building patterns are changing dramatically. Compared with previous decades, many more women over 30 in this country are now just beginning or still building their families. Childbearing is shifting to older ages: among married couples in the United States, over half of all births in 1975 were to women aged 25 or over. Much of this childbearing entailed the births of first children among women over 30. In 1964 only 7 percent of all births to women aged 30–34 were first births; by 1976, this percentage had more than doubled to 16 percent. A comparable increase in first births occurred among women 35–39 years of age.
Although women over 30 are not the only ones participating in these shifts in childbearing and family formation, the postwar generation is exceptionally large. By 1980, there will be an estimated 15.7 million women in the United States between the ages of 30 and 39. This group of women possesses a number of unique social characteristics:

- Since 1970 the percentage of single men and women among those aged 25–29 has increased, indicating not only that later marriage has gained general acceptance, but also that high proportions of adults may never marry. Demographers estimate that 7–9 percent of all adults now in their late 20s will never marry.

- In 1960 there were 35 divorced persons per thousand married persons. By 1976, this figure had more than doubled to 75 per thousand. Moreover, the increase in the divorce rate rose more between 1970 and 1976 than between 1960 and 1970. Four out of every ten first marriages now end in divorce.

- Between 1970 and 1976 the number of households with males 25–44 living with women to whom they were unrelated doubled.

- Families headed by women who have no husband present represent a growing proportion of all families. Many more women are passing through this increasingly common life-cycle stage than in the past.

Given the personal uncertainties that these changes imply and the increasing need for flexibility in partnership, marriage, and childbearing, irreversible methods of birth control are not an option for a growing number of women over age 30. A great many of these women have selected the oral contraceptive as their technique, and they now face a serious dilemma: the risks of adverse health effects
of the pill for women over 30 are significant. Worse still, these risks increase with age, and the longer a woman over 30 remains on the pill, the higher her risk of experiencing a serious health problem. These risks are particularly large for women over 30 who smoke, as about half of all oral contraceptive users do. In view of these risks, the US Food and Drug Administration has recently stipulated that women receive a written warning each time they purchase oral contraceptives. The following statements are excerpted directly from the insert that the FDA now requires be included in every package of oral contraceptives:  

- "Blood clots are the most common of the serious side effects of oral contraceptives.... For women aged 20 to 44, it is estimated that about 1 in 2,000 using oral contraceptives each year will be hospitalized because of abnormal clotting. The risk increases with age."
- "The risk of having a heart attack increases with age and is also increased by such heart attack risk factors as high blood pressure, high cholesterol, obesity, diabetes, and cigarette smoking."
- "Studies have found that when certain animals are given estrogen, cancers may develop. These findings suggest that oral contraceptives may cause cancer in humans."
- "Women who use oral contraceptives have a greater risk than nonusers of having gall bladder disease requiring surgery."
- "Although it is your decision, since many risks increase with age, birth control pills are not recommended for women past the age of 40."

Confronted with this information each time they open a package of oral contraceptives, women over 30 will inevitably experience anxiety about their
use of this method. Among these women are a large number who have used the pill for many years. Some of these were among the initial users of this method when it was introduced in the 1960s, and, as a group, they have experienced the earliest and longest exposure to these hormones. Anxiety among these long-term users will be especially high, since many are aware that sometime between 1980 and 1990 sufficient time will have elapsed to determine whether their use of oral contraceptives has increased their risk of breast cancer or other cancers. In the meantime, these women must live with the uncertainty that their long-term use of oral contraceptives could be carcinogenic, an action that biologically may take between 10 and 25 years to become manifest.93

In response, many of these women over 30 are now switching from the pill to alternative methods of contraception, a trend that is likely to increase as the impact of the new package inserts begins to take effect. In the past five years, much of this switching has been to sterilization: in 1975 roughly half of all married women over age 30 who had completed their childbearing were relying on surgical sterilization (of either the husband or the wife) to avoid further pregnancies.94

But, as noted above, for increasing numbers of these women, sterilization is not an acceptable alternative. Many such women are reevaluating barrier contraceptives. The safety of these methods, the availability of abortion backup for any contraceptive failures, and, for older couples whose sexual activity may be decreasing, the suitability of barrier methods for occasional or intermittent use are attractive features.

Another reason for predicting an appreciable shift toward barrier contraceptives by women over 30 during the next decade has to do with the very
large increase in the numbers of such women that will occur during this period, and with some of the social characteristics of these women. Between now and 1990, the number of women aged 30–39 will grow by about 5 million to a total of nearly 20 million, as women born in the postwar baby boom pass into their 30s. The attitudes of this group of young women—sometimes called the “revolutionary class of 1968”—have been shaking habit and custom ever since they began to enter college in the mid-1960s. The oldest members of this group, now in their early 30s, were at the forefront of changing sexual attitudes and practices, and many of them came of age sexually as adolescents and young adults just as the oral contraceptive (in a much higher dosage than its current form) was being made widely available. Their numbers, their values, and their prior long-term use of hormonal methods are likely to lead to a substantial shift to barrier methods among this age group during the first half of the 1980s.

Women alone bear the health risks of conception—that is, the risks of pregnancy and childbirth. To some extent, however, the health risks of contraception can be shared between men and women. This can be done in the following ways:

- The man can accept all of the health risks of contraception by having a vasectomy.
- The man can free the woman from health risks associated with contraception by using the condom.
- The man can support, assist, and encourage his partner in the use of spermicides or the diaphragm, which may entail drawbacks and in-
conveniences for the man in comparison with use of the pill or IUD, but which will reduce the woman's contraceptive health risks.

- Couples who wish to share risks can also alternate the method they use. For example, the man may use a condom for a period, after which the woman could use the diaphragm.

Many American men appear to be highly motivated to share risks but are not ready to have a vasectomy and are not disposed to use the condom. Although advances in condom sensitivity have been made over the last ten years, they are still unsatisfactory to some men. How does such a man share in the risks of contraception with his partner? Alan Guttmacher recounted that he once asked a woman to describe how she inserted a diaphragm so that he could describe this to his patients. She responded that in fact it was her husband who regularly inserted the diaphragm for her. As this anecdote illustrates, a fundamental way for the man to share contraceptive responsibilities with his partner is to be appreciative and supportive of the responsibility and demands the woman carries. Especially for the diaphragm and spermicides, this includes a full understanding by the man of how the method must be used to be effective, along with his full adaptation to and acceptance of this in the sex life he shares with the woman. As we stressed in Part 2, a couple's motivation and ability to integrate the coitus-related requirements of barrier methods into their sexual activity is crucial to their acceptance and effective use of this type of contraceptive. Consequently, a man's emotional support and participation in the use of female-controlled barrier contraceptives is essential if his partner is to be able to use these methods continuously and effectively, and thus to gain freedom from the health risks associated with other methods of contraception.
There are strong indications that men do wish to share in the responsibilities and risks of contraception. In 1976, among all couples practicing contraception, one-quarter employed vasectomy or the condom. Older men involved in partnership with older women are more likely to use the condom than any other group, as reported by national surveys and organized family planning services. Among married couples over age 35, 24 percent of those using reversible contraception employ the condom. Couples having a relationship of some duration and depth are generally better able to communicate about sex and contraception and have more experience in sharing responsibilities in other parts of their lives than young people just beginning their sex lives. Younger couples who wish to conceive together some time in the future are often especially motivated to safeguard their fertility, and they may select the condom particularly for this reason. In fact condom use is increasing among young black couples in the United States, and its use has remained constant over the past five years among young, unmarried, middle-class white couples.

But in spite of these trends, more direct sharing of contraceptive responsibility by men on a large scale will probably await the development of new, safe, and acceptable male methods, such as male-applied spermicides, more sensitive condoms, reversible vasectomy, and, perhaps, male oral contraceptives. A male oral contraceptive is now being tested, but this hormone-based method unfortunately appears to have some side effects and troubling unknowns that may limit its eventual acceptability. Research on male methods has lagged far behind female methods, in part because scientists have developed a fuller understanding of the female reproductive system and therefore are aware of a greater number of points for intervention in that
system. The original emphasis by scientists on understanding female anatomy and on systemic intervention in the female reproductive system reflects a deeply held and continuing bias that reproduction and all related tasks are "women's work." So ingrained is this bias that the analysis of risks and benefits of oral contraceptives conventionally centers solely on the woman, emphasizing the risk of childbearing. ¹⁰¹ No attempt has yet been made to take into account the fact that whereas the health risks of childbearing are unavoidably sex-specific, the health risks of contraception can be assumed by either partner.

Men wishing to minimize women's risks and expand their own options thus have a very important political and public way of sharing. They can be more vocal with their elected officials, with the health professions, and with the pharmaceutical industry about the need for more contraceptive research on male methods and improved barrier methods for both males and females.

There are about 200 women's health collectives in the United States, serving approximately 10,000 women. ¹⁰² The women organizing and receiving these services have been dissatisfied with the established health care system, which they consider economically predatory and, more importantly, the source of inferior medicine. The publication of Our Bodies, Ourselves in 1971 heralded a new activist approach by women to their bodies and their health. ¹⁰³ This book, authored by the Boston Women's Health Book Collective, has sold over 2 million copies and has been translated into 13 languages. Its central ideas, which have helped to fuel the growing alternative-care movement, have been
Women's health collectives emphasize barrier methods and rhythm techniques because these methods are safe, voluntary, and self-administered.

the emphasis on self-care, learning more about one's body, communicating with other women about health problems and their solutions, and looking beyond and challenging professional advice that perpetuates negative or false concepts about women and their bodies. One curious response to this indigenous health care movement is that of some family planning and health care professionals who recognize the benefits of traditional healing and health systems in developing countries but exhibit far less certainty about these benefits when offered on their own doorsteps. In several instances professional associations have pressured women's health care centers almost out of operation by challenging their licensing or discouraging doctors from working with them. The history of these alternative-care systems and the professional responses to them deserves more detail than can be given here. The central fact is simply that these new providers of information and service are filling a deeply felt and growing need for women's health care not now available from conventional providers.

In many ways, these services are the contemporary equivalent of the first “birth control” clinics organized by women 40 years ago. The marvelous paradox is that both movements began by emphasizing the same technology—the diaphragm and other types of barrier and so-called natural methods—which were more generally understood and of greater variety 40 years ago. The women's health collectives emphasize barrier and natural methods because they are safe, entirely voluntary, and self-administered techniques. These collectives are developing new and redeveloping old nonhormonal contraceptive methods. Among the old “new” methods are the cervical cap and the contraceptive sponge. Testing the cervical mucus as an indication of ovulation is also receiving renewed popularity as a means of contraception.
Use of modern contraceptives does not necessarily increase a woman's knowledge of her body. In contrast, barrier contraceptives and methods that rely on observation of bodily changes give women an active role in health and contraception that an increasing number consider desirable. This suggests that the ideal contraceptive is not necessarily one that requires minimal participation. The contraceptive implant, various types of contraceptive injections, and the IUD—all of which rely on professional administration and removal (with the exception of the injection, which cannot be "removed" once it has been administered)—are not advances when viewed in the light of the contemporary women's health movement. Self-care is seen as more liberating and reliable.

Women's health care groups emphasize full education of the prospective user. Group sessions are held frequently so that women may share information; many of the groups report that women already have a great deal of evidence and theory about the interaction of different types of contraceptives with their bodies (often passed from woman to woman or mother to daughter). Women in the past generally have not shared their thoughts outside very tightly knit groups of friends, largely because they have been made to believe that these views and observations are inferior to professional advice and information. In addition to providing the published scientific information that is available about the risks and benefits of different methods, women's health care groups encourage bodily and fertility awareness. Each woman is encouraged to examine herself, locate and see her cervix, and note the physical changes that identify the onset of ovulation. Many alternative-care groups do not recommend a particular method of contraception. Most provide all legal methods, including oral contraceptives under prescription and insertion of IUDs for women who want them.
The concepts advanced by women's health care groups are likely to increase demands for more sensitive treatment from health professionals and for a more active management by women of their own fertility.

The women's groups document and publish their work in a number of ways. *Our Bodies, Ourselves* has been revised and continues to serve as a key resource. A number of providers publish newsletters, such as *Health Right* (New York City), *WomenWise* (New Hampshire), and the *Tallahassee Examiner* (Florida). Networks of women concerned with health issues put out such publications as the *National Women's Health Network News* and *Women's Health Roundtable* (both in Washington, D.C.), and an international bulletin called *ISIS* has devoted two issues to women's health care. In addition, most women-run health services have developed excellent educational materials for their members and those who use their services.

One area in which this movement could be particularly valuable is health care instruction. With increased financial support, these groups could document for wider dissemination their observations and findings on women's health issues, including their approaches to educating women about their bodies. Perhaps ways could be developed in the next few years to allow the systems and information developed by women's health collectives to be shared with those out of their direct reach. For example, the bulletins of health professionals could carry reprints of their articles. Medical schools and other training facilities for health professionals could incorporate materials from the self-care movement into their textbooks and manuals.

With or without additional support and attention from established professionals and providers, it is likely that the concepts on which these women's health care groups are based will attract a growing number of women concerned with understanding their bodies and actively managing their fertility. The concepts advanced by women's health care groups often strike very responsive chords in
women outside the network, and they are likely to be an important stimulant during the coming decade in increasing demands for more knowledgeable and sensitive treatment from health professionals, for emphasizing the prevention of disease in "well women" rather than curing sick women, and for a wider use of barrier contraceptives.
Using Science and Technology To Improve Barrier Contraceptives
If the concept of barrier contraception is a modern one, the available techniques unfortunately are not. For the most part, they are the products of decades-old research and development that have been handed down with only minor changes through several generations of consumers. Barrier methods have not benefited from the kind of broad-scale application of modern science and technology that other types of contraceptives have received during the last several decades, and many of the drawbacks of existing techniques reflect an unnecessary obsolescence that could be overcome through the application of sophisticated pharmaceutical research efforts.

**How Barrier Methods Can Be Improved**

Diaphragms, for example, need to be fitted by a physician, a drawback that could be overcome through the design of “one-size-fits-all” devices. Use of the diaphragm requires obtrusive paraphernalia—a large, fragile plastic box for storage and toothpaste-size tubes of spermicide—drawbacks that it should be possible to change. Another major drawback is the requirement that the diaphragm be used along with a spermicidal jelly or cream. The existing jellies and creams are widely felt to be esthetically objectionable, and they are not fully effective. Also, they have the serious inconveniences of needing to be left in the vagina (with the diaphragm in place) for six hours after coitus, to be applied only a short time before coitus, and to be replenished before each subsequent ejaculation during coitus.

A number of approaches could be explored for eliminating these drawbacks. The simplest would be to test whether a spermicidal jelly or cream is required for full effectiveness of the diaphragm.
On the basis of experience with their own clients, some physicians believe that the diaphragm is just as effective when used alone as when it is used with jelly or cream, but this proposition has never been scientifically tested. If some type of spermicidal agent is in fact required, it might be possible to develop a spermicide-impregnated diaphragm. Another solution might be a universal-size diaphragm with a thick, compressible rim that would adhere firmly to the sides of the vagina during coitus, thus totally blocking the passage of sperm and eliminating the need for spermicides. Also, spermicides themselves could be improved, as discussed in more detail below.

In general, such improvements would appear to be well within the technical competency of modern pharmaceutical research—if sufficient research monies were invested. With such effort, diaphragm-like barriers could be developed that could be more easily fitted, carried, stored, and inserted by women under a variety of conditions and circumstances.

Condoms, especially, have suffered from the neglect of pharmaceutical research efforts. As a contraceptive technique, the condom has one principal, perhaps even sole, drawback: by reducing tactile sensations, it detracts from the sexual enjoyment of the man (and sometimes the woman) during coitus. If this drawback could be overcome, the method would undoubtedly gain a much wider acceptance, since it offers virtually perfect protection against pregnancy, significant protection against venereal disease, and convenience and ease of use. For women, the condom offers tangible, visible protection against both pregnancy and venereal disease with no accompanying risk of health, along with the advantage that the method is employed by the man.
To improve condoms, a tough, elastic membrane capable of transmitting heat and tactile stimulation is needed. To overcome the basic problem of a deadening of physical sensation, what is needed is the development of a tough, elastic membrane capable of transmitting heat and tactile stimulation and physically and economically suitable for manufacturing into condoms. Some very limited research toward this objective has been carried out using new types of materials that absorb moisture within their physical structure, thus allowing increased transmission of heat. With adequate investments in basic materials research and development, radically new types of condoms that would transmit sensation to a far greater degree could probably be developed.

Spermicides have benefited from greater product development activity than either condoms or diaphragms over the past two decades, but they have important limitations. The greatest drawback is their imperfect effectiveness as contraceptives. Notwithstanding some limited research efforts to develop more potent spermicidal chemicals and carrier substances that effectively spread the spermicide throughout the vagina so that it can come into contact with sperm, users of current products must accept a small but real risk that they will become pregnant—even if they faithfully use the products as instructed. Other limitations are the messiness and smell of most spermicidal products, the physical difficulty of placing them in the vagina, the requirement that they be placed shortly before coitus, the need to replenish the application of the spermicide after each coitus, and the need to avoid washing or douching for at least six hours after coitus. The excessive lubrication and the leakage of fluids from the vagina that accompany the use of most spermicides are distasteful to many users and often detract from sexual pleasure. Itching, irritation, and the local sensation of heat have been encountered with some formulations of spermicides. A number of practical problems asso-
related with the packaging and informational components of spermicides also need attention. For example, many products on the market today employ cumbersome vaginal inserters. Most are available only in bulky containers too large for easy carrying. The instructions for use of these over-the-counter products are often vague and confusing and sometimes misleading.

All of these problems are susceptible to applied research, some of it very simple and direct, some of it highly complex and costly. Aside from straightforward improvements in packaging and labeling, perhaps the greatest need is for more research to develop better carrier substances for the spermicides—that is, the jellies, creams, or foams that are used to disperse the spermicidal chemical within the vagina. These chemical vehicles need to be improved so that they cover the cervical os more thoroughly and uniformly, stay in place during coitus, and remain in place for longer periods. More potent spermicidal chemical agents also might help to improve effectiveness, although the potency of present agents would be sufficient if they were dispersed adequately by the carrier substances. Using modern know-how in plastics and other synthetics, it might even be possible to develop a totally physical barrier to sperm that would be applied in the form of a paste or cream to the opening of the cervix at the rear of the vagina. When first applied, the substance would have to adhere to local tissues, thus effectively sealing off the entrance to the uterus. Shortly after application, it would have to rapidly lose its capacity to adhere, except where bonding to the local tissues has already occurred, and it would need to be elastic, so that it would stretch during coitus. It would also need to be either biodegradable or in some other way unstable, so that it would dissolve and be released from the local tissues after the sperm...
Research and development work is needed to adapt barrier contraceptives to the special needs and conditions of developing countries. Technologically, it seems feasible to incorporate highly effective bactericidal agents into spermicides so that they can protect users against venereal disease.

had been inactivated or removed. Various synthetic materials individually possess some of these properties, and they could be taken as the starting point for such research. The main point is that, as for condoms, sufficiently intensive applied materials research offers considerable promise for the development of new, superior types of spermicidal products.

Another needed improvement is the adaptation of all types of barrier contraceptives to the special needs and conditions that prevail in developing countries. Couples in these countries often live under conditions where piped water and electricity are not available and where coitus takes place either surreptitiously at night in a room crowded with sleeping children and in-laws or during the daytime in isolated spots outdoors. Under such conditions, spermicides are needed that can be used quickly, unobtrusively, and without the need for running water. Most developing countries are located in tropical zones, and present spermicides often melt or spoil at high temperatures. The high humidity that often prevails in these countries causes problems for foaming vaginal tablets, which lose their capacity to effervesce when exposed to moisture.\textsuperscript{108} With proper pharmaceutical formulation work, more stable products could be developed.

A final area for improvement of barrier contraceptives particularly stands out because of its importance for public health. This is the need to enhance the prophylactic properties of barrier contraceptives against venereal disease. Technologically, it seems feasible to incorporate highly effective bactericidal agents into spermicides in a manner that would provide virtually complete protection against the organisms that are responsible for causing most genitally transmitted venereal diseases. New antibacterial agents may be needed for this
purpose, as well as new chemical substances that can serve as vehicles to disperse both the bactericide and the spermicide. Basic laboratory research and applied behavioral studies are likely to be needed, along with costly and very complex epidemiological investigations to ascertain the actual efficacy of any new agents that are developed and the behavioral conditions required for such effectiveness. Although an adequate research program to meet these needs would undoubtedly be sophisticated and costly, successful efforts would achieve major social benefits.

This brief outline demonstrates some of the ways in which modern science and technology can be applied to improve barrier contraceptives. To what extent are such efforts being undertaken?

Until very recently, the answer was to almost no extent. The current latex condom was developed in the early 1930s, the latex diaphragm at about the same time. Few improvements have been made in these products since then. Apart from ongoing research by condom manufacturers to modernize production processes for condoms and to develop the thinnest latex membranes that can be used to manufacture devices that will not rupture, little has been done to create new types of condoms that would provide greater tactile sensitivity for users. After a brief, unsuccessful period of experimentation with various types of plastic condoms in the early 1970s, condom manufacturers focused their development efforts mainly on cosmetic changes—such as variations in color and shape—that would enhance the product’s appeal to users without changing its basic characteristics. Spermicides have received somewhat more attention from pharmaceutical company research and development labs.
In view of the low cost of much of the research needed to improve barrier methods and the many possibilities that have been identified, it is hard to understand the near absence of work in this area.

But while there has been some improvement in their effectiveness, on the whole the basic technique has changed little in its convenience and ease of use since spermicides were first widely marketed in the 1940s and 1950s. The one exception is the introduction of pressurized spermicidal foam in the early 1960s, which brought the advantages of increased product shelf-life, better distribution of spermicide within the vagina, and immediate effectiveness following application.

Yet, during these same decades, well over $100 million was spent to develop and introduce new types of oral contraceptives and intrauterine devices. As a result of this large effort, around 70 different types of oral contraceptive products and nearly 20 different types of IUDs are now being sold worldwide (under some 250 brand names), while only five basic types of condoms, three types of diaphragms, and roughly 20 different spermicidal products are available. The reasons for this disparity are complex, but the outcome is clear: the development of improved techniques for barrier contraception has lagged behind the development of other new forms.

To complement private-sector efforts and to meet the special needs of couples in developing countries for better contraceptives, public agencies in the early 1970s decided to establish a number of publicly funded and operated contraceptive programs. Currently these programs are operated by the World Health Organization, the National Institute for Child Health and Human Development of the Department of Health, Education, and Welfare, the Population Council, the International Fertility Research Program, the Program for Applied Research on Fertility Regulation, and the Program for the Introduction and Adaptation of Contraceptive Technology. Unfortunately, the extent of research on barrier contraceptives by
these public-sector programs has been minimal. According to questionnaires completed by these groups and the principal agencies that fund them, expenditures on all types of barrier contraceptive research totaled only $50,000 in 1976 and $143,000 in 1977, out of total applied contraceptive testing and development expenditures of $30.2 million and $33.7 million for these years, respectively.\textsuperscript{111}

In view of the comparatively low cost of much of the research needed to improve barrier methods and the numerous avenues for improvement that have been identified, the near absence of work in this area by both private- and public-sector organizations is difficult to understand.

In the past year there have been some encouraging signs that this situation may be changing, at least with respect to private pharmaceutical company research. Scientists working in pharmaceutical companies are reporting a dramatic upsurge in research and development work on barrier contraceptive products. For example, at least one large pharmaceutical company is conducting research to improve the diaphragm and to introduce a new spermicide product in the United States. Another large company with extensive experience in packaging and marketing toiletries is considering applying its know-how and marketing research techniques to improving the ease of use and acceptability of spermicides.

Although there is no way of estimating the extent of commitment by private companies, the nature of the work reported suggests that it is focused primarily on developing improved versions of present barrier methods. At least some of the work entails the use of commercial marketing research techniques to identify consumer preferences and acceptance and to study behavioral aspects of the improved methods.
Within the last year or two there has also been a small increase in research on barrier contraceptives by public-sector contraceptive development programs. These programs have focused on such applied research approaches as the development of spermicide-impregnated contraceptive sponges, heat-stable vaginal suppositories for use in the tropics, intracervical devices, spermicide-releasing vaginal rings made of synthetic rubber, and flexible, dissolvable films placed in the vagina or over the penis. Work on these ideas is going forward very slowly because of the limited resources being made available.

Unfortunately, most of the new activity in barrier contraceptive research appears to be limited to approaches aimed at short-term payoffs, usually through improvements in existing products. It is important to recognize that none of these types of research is likely to result in fundamentally new techniques. The technological drawbacks of existing barrier products place inherent restrictions on the extent to which they can be improved. For truly innovative and superior barrier contraceptives to be developed, there is a need for more basic research on the biological and medical aspects of barrier contraception, as well as in the area of materials technology. Pharmaceutical companies appear to be unwilling or unable to invest the large sums of research monies and the corresponding long-term commitment of research personnel to carry out the kind of basic research that would be needed to develop radically new types of barrier contraceptives. Nor is the public sector filling this need, despite the fact that it constitutes by far the greatest source of
support for such basic research in the world today.\textsuperscript{113}

Nor is most of the new activity being accompanied by a thorough program of behavioral research to determine the acceptability of these approaches and to incorporate users’ preferences and needs into the design of the methods. Barrier contraceptives, by their very nature, are directly linked to sexual behavior, and many of the drawbacks of barrier methods result from unwanted interference in the sexual practices of the user. Consequently, many, perhaps even most of the ideas for improvements in these contraceptives deal specifically with the manner in which they influence (or are influenced by) sexual behavior. In order to design and test such “behavioral improvements,” some type of applied social science research must be used in conjunction with the biomedical and technological research. Public-sector contraceptive development programs are conducting some very limited social science research in this area, most of it academic in nature.\textsuperscript{114} The pharmaceutical industry is employing marketing research during some of the later stages of product development and presentation.

But for the most part, biomedically trained professionals guide the contraceptive development work in both the public and private sectors. As a rule, they are not well equipped to intimately involve the necessary behavioral research elements in all phases of the development effort. There is a pressing need to bring into this research flexible and creative user-oriented approaches—such as the group-session marketing research techniques used by private industry—if the early phases of clinical research and field evaluations are to result in useful new barrier contraceptive products.
Consumer Participation in Future Research

The almost total lack of interest in barrier methods by professional contraceptive developers during the past decade and the strong behavioral components of these methods suggest that significant improvements are likely to depend on some form of consumer participation in determining research priorities and in the research process itself.

Various types of participation are possible—through formal social science research, through marketing research techniques, through the lobbying activities of organized consumer groups—and all can play a constructive role. One relatively untried approach deserves special mention. The women's health care collectives described in Part 4 could constitute an important resource for clinical investigations on nonhormonal methods of contraception, as well as on the sources and cures of vaginal infection. The investigations conducted by these groups operate on very different principles from those of conventional clinical research. In a conventional research design, the population of women or men using health services (often a public clinic) are asked to give their informed consent to participate in tests of effectiveness and safety of various—sometimes experimental—contraceptive methods. These experimental users are monitored through interviews and examinations. Their relationship to the study ideally excludes contact with other participants, while maintaining a highly structured, formalized contact with the professionals conducting the study. Individuals participating in this type of research are contributing to the "knowledge base of medical science," which is objectified and is generally at some distance from their personal goals.115

Women-run research begins with the purpose of helping the participants find out more about their bodies and health. Work and investigation on the ovulation method of contraception illustrates how
their “research” operates. Women in health care collectives begin by monitoring their own cervical mucus, taking their temperatures, and keeping records of both objective and subjective information. With personal experience gained, a study group is organized of 10 to 30 women, who conduct the same rigorous monitoring on themselves. This group meets every week over several months. In the first month all members of the group abstain from intercourse and contraception in order to be able to monitor bodily changes, which are often masked by use of contraceptives. Once the women have developed greater sensitivity to their monthly “rhythm,” some begin to use different types of contraceptives as “insurance” while they continue to educate themselves about bodily changes.

Exchange of information among members of the study group is a basic principle of this research, in marked contrast to conventional research. In the latter, great care is often taken to ensure that study subjects are not told what the investigators are looking for, lest suggestible subjects experience psychologically induced side effects. Women-run research encourages exchange in an environment in which there is no obvious investment in either identifying or denying responses and observations. While personal subjectivity clearly influences the outcomes of such research, this is a strong advantage as well as a potential drawback of such an approach. These efforts often provide more rapid collection of information because women are highly motivated to contribute and develop useful information for other women.

These groups could contribute to the development of better contraceptives through first-hand, small-scale investigations to test new ideas. With appropriate technical as well as financial assistance from professional contraceptive developers, these groups might become a constructive new resource.
for the development efforts being undertaken by public agencies and the pharmaceutical industry. Women's groups would clearly welcome legitimization and support. For example, the National Women's Health Network, an organization of women's health collectives, health consumers, and health workers, has begun to ask for recognition of the important role women, both lay and professional, can play in contraceptive and other health research. Testimony on behalf of the Network in the 1978 hearings of the House Select Committee on Population requested that women's health groups be given funds to support their research on contraceptive methods and informational materials.116
Barrier Methods in Developing Countries
In a recent study carried out by the World Fertility Survey in India, Panama, and Turkey, over 800 randomly sampled married women who had some knowledge of contraceptive methods were interviewed to learn which contraceptives they used. Twenty-four of the women reported their husbands were currently using condoms. Only eight, all living in urban areas, had ever used a diaphragm, but none was using the method at the time of the study. The study did not inquire about spermicide use. By way of comparison with these figures, however, the study found that 316 of the group were either sterilized (husband or wife) or were currently using the pill or the IUD.

This profile of contraceptive use is typical for the majority of developing countries. It illustrates the minor role played by condoms and the negligible role played by the diaphragm and spermicides in most of these countries. For the most part, modern barrier methods have been given very little emphasis by health and family planning personnel. Most of the hundreds of millions of dollars spent each year to provide contraceptives to people in developing countries has been devoted to supplying oral contraceptives, IUDs, and sterilization. Condoms, spermicides, and diaphragms are imported into many developing countries and, in some cases, are manufactured locally. The availability of diaphragms, for example, is illustrated by Table 4. However, these methods—the diaphragm and spermicides in particular—are not readily available except to members of elite social groups, who obtain them through private physicians or purchase them from a very restricted number of outlets located in well-to-do urban areas.

What accounts for this apparent lack of popularity of barrier contraceptives in developing countries? Is the emerging new demand for and use of barrier
<table>
<thead>
<tr>
<th>Brand of Diaphragm</th>
<th>Countries Where Available</th>
</tr>
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<tbody>
<tr>
<td><strong>Durex</strong></td>
<td>India, Lebanon, Sri Lanka</td>
</tr>
<tr>
<td><strong>Koromex</strong></td>
<td>Afghanistan, Argentina, Bangladesh, Barbados, Bolivia, Chile, Colombia, Egypt, El Salvador, Ghana, Guatemala, Honduras, Hong Kong, Iran, Iraq, Jamaica, Jordan, Kenya, Lebanon, Liberia, Malaysia, Mauritius, Mexico, Nicaragua, Nigeria, Panama, Paraguay, Peru, Philippines, Puerto Rico, Sierra Leone, Sri Lanka, Surinam, Tanzania, Trinidad and Tobago, Uganda, Uruguay, Venezuela</td>
</tr>
<tr>
<td><strong>Nakayama</strong></td>
<td>Taiwan</td>
</tr>
<tr>
<td><strong>Ortho</strong></td>
<td>Bahrain, Barbados, Belize, Botswana, Cyprus, Dominican Republic, El Salvador, Ethiopia, French Polynesia, Guatemala, Guyana, Haiti, Hong Kong, India, Iran, Iraq, Jamaica, Jordan, Kenya, Kuwait, Lesotho, Libyan Arab Republic, Malaysia, Mauritius, Netherlands Antilles, Nigeria, Pakistan, Panama, Philippines, Puerto Rico, Rhodesia, Saudi Arabia, Singapore, Surinam, Taiwan, Thailand, Trinidad and Tobago, United Arab Emirates, Venezuela, Zambia</td>
</tr>
<tr>
<td><strong>Ortho-White</strong></td>
<td>Barbados, Ghana, Guyana, Mexico, Netherlands Antilles, Paraguay, Puerto Rico, Singapore, Surinam, Trinidad and Tobago</td>
</tr>
<tr>
<td><strong>Ramses</strong></td>
<td>Brazil, Chile, Hong Kong, India, Jamaica, Kenya, Liberia, Malaysia, Mexico, Netherlands Antilles, Paraguay, St. Lucia, Tanzania, Trinidad and Tobago, Uruguay, Venezuela</td>
</tr>
<tr>
<td><strong>Ortho All-Flex</strong></td>
<td>Barbados, Dominican Republic, Guyana, Netherlands Antilles, Puerto Rico, Trinidad and Tobago</td>
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Methods strictly a developed-country phenomenon, generated by the special social demands and conditions that exist in these materially wealthy cultures, or does it have international significance? A brief look at condom use is instructive.
Although overall use of condoms in developing countries is very low, a handful of countries have experienced high acceptability and use of this barrier method. India, for example, has undertaken a vigorous and imaginative effort to distribute condoms commercially through such outlets as groceries, tea shops, shops selling cigarettes and chewing tobacco, soap and edible oil shops, and even stands selling match boxes or battery cells. Sales of the condom, called Nirodh (prevention), have increased from 7 million pieces annually before the program was initiated in 1968 to 280 million pieces in 1976-77. Sales for 1978 were anticipated to reach 350 million pieces. These sales have continued to increase despite sharp declines in the last eighteen months in IUD insertions and sterilization operations. Both the IUD and the sterilization programs met with popular dissatisfaction arising from reports of insufficient attention to aftercare and a sense of coercion on the part of some acceptors. This latter point is important because commercial sales are a very good indicator of people’s voluntary acceptance of family planning. A recent study of the Nirodh program estimated that a regular user consumes 72 Nirodh pieces a year and that, on this basis, the program’s impact on the birth rate may exceed that of all of India’s sterilizations and IUD insertions combined. In India, commercial sales of condoms are meeting a need and providing a product that people are willing to spend money for.

In Sri Lanka, a condom called “Preethi” was introduced over a two-year period, beginning with a nationwide distribution and mass media advertising campaign. This program included alterations in the appearance of condoms to make them more appealing: they now come in colors—blue, red, black—and even in different textures. In about a dozen developing countries, including India and Sri Lanka, the embarrassment associated
with condoms and their notoriety (associated with their use in extramarital sex) have been deliberately diminished through greater openness in their advertisement, through marketing efforts aimed at associating them with masculinity and responsibility, and through the willingness of prominent people to identify themselves with the method. In Thailand a well-known family planning figure goes from village to village distributing condoms in a carnival-like atmosphere.¹²¹ In these villages, condoms are called by his name, “Mechais.” In all of the countries where an open marketing approach has been taken and sufficient time has elapsed to evaluate the results—Bangladesh, Colombia, India, Indonesia, Jamaica, Kenya, Korea, and Thailand—the level of condom usage has increased significantly.¹²²

This phenomenon is particularly interesting because the increase in condom use has not appreciably reduced usage levels of other available contraceptive methods. Rather, it has often gone hand in hand with the increased use of other methods.¹²³ This is not surprising, however, in view of the low continuation rates for oral contraceptives and IUDs in most developing countries. On the average in developing countries, out of every 100 women who receive an IUD, 34 stop using it within one year and another 10 during the second year. Among every 100 pill users, 55 abandon the method during the first year, and another 16 during the second.¹²⁴ With dropout rates this high, couples need other contraceptive options to turn to, and if they are available and socially acceptable, a barrier method such as the condom provides this option.

The experience with condoms summarized here demonstrates their high potential acceptability in Africa, Asia, and Latin America. In the absence of intensive public education campaigns, a variety of...
social taboos block this acceptance and use. While these social barriers of course differ somewhat from culture to culture, in many respects they are quite similar to the taboos against condoms that prevailed in Europe, Japan, and North America several decades ago. In all of these regions, as well as in the developing countries mentioned above, campaigns directed at publicly legitimizing condoms and making them widely available through commercial outlets have proven successful. At least two dozen other developing countries are now initiating such programs, and others are likely to follow suit in years ahead. As these efforts move forward, large increases in condom use in developing countries will occur.

Acceptability of Other Barrier Methods

The developing-country experience with condoms suggests that other barrier methods might also be well accepted if they were promoted and made widely available. Certain inherent features of these methods would also seem to favor their acceptability. As with condoms, the way in which diaphragms work is readily comprehensible and quite similar to the indigenous barrier methods traditional societies have been using for centuries. By comparison, the mode of action of the oral contraceptive is much more mysterious, even to highly educated people.

Also, from a policy standpoint it is known that the greater the range of contraceptive methods available in a country, the greater the use of contraception. This has been shown in several studies, most recently in an analysis of data from 33 developing countries. Three factors are responsible for this effect: (1) various subgroups in any population hold differing preferences for contraceptive
methods; (2) a variety of methods permits dissatisfied users to seek out and switch to another method; and (3) the more methods there are, the greater the chance that couples will have access to at least some methods. This third point is especially important with respect to condoms and spermicides, which can be made widely available without participation by physicians, who are in extremely short supply in many developing countries.

Finally, actual experience with spermicides in several developing countries has demonstrated their acceptability. In one of these countries, the Dominican Republic, two types of spermicides—vaginal foam and vaginal tablets—have been introduced as standard methods offered countrywide by the government-sponsored family planning program. Acceptance has been high, and use of the tablets in particular (often referred to as vaginal foaming suppositories) is increasing rapidly. High acceptance has also been found in a large-scale program in Colombia and in pilot studies in the Philippines.

But despite all of these indications of potential acceptability of spermicides and, possibly, of diaphragms in developing countries, very few family planning programs offer these methods and use is very low. Strong professional opposition blocks wider availability and promotion in most such countries. There seems to be little doubt that many of the reasons for this strong bias against barrier contraceptives are similar to those at work in the United States (see Part 2). Some health care policymakers in developing countries perceive barrier methods as outmoded, second-class technology, and they are highly skeptical about the capacity of impoverished and poorly educated couples to use barrier methods reliably. They believe these methods are inefficacious and have low appeal for potential users. Many of these officials and health...
workers also believe that dispensing barrier methods takes too much time and consumes too much of their clinical resources. They often feel that extensive promotion of these methods will detract from their efforts to create efficient new health systems utilizing the same kind of "modern" contraceptive technologies employed in more highly industrialized developed countries. Also, the open discussion of sexuality is generally restricted in most developing countries. Personnel at all levels of policymaking and service delivery tend to be more comfortable in discussing, promoting, and providing such comparatively asexual methods as the pill, the IUD, and sterilization, rather than the coitus-related methods. That condoms have escaped some of the negative attitudes associated with female-controlled barrier methods and have been given more attention by family planning programs in a number of countries may reflect the fact that male sexuality is more openly a topic of discussion than female sexuality in most developing-country cultures.

A key obstacle to wider acceptance and use of barrier contraceptives in developing countries is the belief that barrier methods, especially the female-controlled methods, cannot be used effectively by poor women because of their lack of motivation and their particular lifestyles. As happens in regard to adolescents in the United States, many policymakers and professionals in developing countries regard traditional women as unable to make informed choices and to use contraceptive methods properly.

These convictions are in part self-fulfilling. The policymakers' prophecies of the incompetence of poor women are confirmed by the results that oc-
cur when barrier methods are introduced with little or no understanding of rural women's culture, and without thorough education and follow-up. Not surprisingly, therefore, much of the limited data on the effectiveness of condoms, spermicides, and the diaphragm in developing countries indicates that moderate to high contraceptive failure rates are observed. A study in India, for example, shows that some segments of populations use the diaphragm with moderate effectiveness. The India study was conducted in ten family planning clinics in Bombay, which provided almost exclusively the diaphragm with jelly to low-income women. The women's return to the clinic was well correlated with the extent of use and satisfaction with the method. This return rate showed no relationship to the woman's income level, education, mother tongue, or the availability of tap, latrine, or bathroom facilities. This last finding suggests that women motivated to use the diaphragm find ways to insert it and clean it that do not require modern sanitary facilities. Of those who maintained contact with the clinic (generally those who lived closer to it), the cumulative pregnancy rate was 10 percent (excluding loss to follow-up) over a 12-month period.

There has been some experience indicating that high effectiveness can be achieved with barrier contraceptives in developing countries. In general, however, effective use of barrier methods by women in developing countries can be expected only if adequate training and psychological support are provided to new users, along the lines described in Part 2. Until these methods have been tested in developing countries under conditions in which thorough, supportive instruction, information, and counseling have been given to new users by appropriately trained service providers, their effectiveness in these settings must remain a matter of debate and conjecture.
Barrier Method
Safety in Developing Countries

Barrier contraceptives offer the greatest safety of all reversible methods for women who can use them with high effectiveness and are willing to obtain a legal abortion for any accidental pregnancies.

Tests of how effectively barrier methods can be used by developing-country couples are especially important because effectiveness of use bears directly on the health and welfare of women who practice contraception in these settings. Maternal deaths associated with pregnancy and childbearing among low-income groups in developing countries are extremely high. Despite these high risks, most low-income women want several or sometimes even many children. But for those who do not want another child or who fear the health risks of pregnancy, ineffective contraception poses a serious problem—especially since legal, high-quality abortion is rarely available in developing countries. A woman in this circumstance who experiences a contraceptive failure because she is unable to use a barrier method effectively will generally have little choice but to obtain an illegal (often dangerous) abortion or to bear the child, thus running the high risk of pregnancy-related maternal mortality. For this reason, if a woman who wants no more children finds the pill, the IUD, or sterilization (for herself or her spouse) acceptable, she would be taking an unreasonable health risk if she chose a barrier method and used it with poor effectiveness. On the other hand, for a woman who can use barrier methods with high effectiveness—or, if she uses them with low effectiveness, is willing and able to obtain a legal abortion for any accidental pregnancies—barrier methods offer greater safety than any other type of reversible contraceptive.

Barrier methods are also a safe alternative for certain groups of women in developing countries who may be able to use them with only moderate effectiveness and who cannot rely on abortion for contraceptive failures. One such group is women who are spacing births. Such women want more children in the future and are prepared to accept the health risks associated with pregnancy. While only
partially effective use of barrier methods by such women might result in childbirth earlier than they intended, they would still achieve a substantial delay between births and at the same time avoid the side effects of other types of contraceptives during the intervals between pregnancies.

Another such group is women who have no access to sterilization, oral contraceptives, or the IUD or who find these methods unacceptable and have discontinued their use. For such women, barrier methods, even if used only with low effectiveness, are far more effective than no method at all. A family planning project in the Sialkot District of Pakistan offered barrier methods to women on the same terms as the IUD or the oral contraceptive. This was done because the project staff observed the high concern of users for health and safety and believed that all users should be properly introduced to barrier contraceptives as either a fallback choice or, for many, the most acceptable first choice.135

Whether barrier contraceptives can be effective, acceptable contraceptives for a large number of couples in developing countries is unknown because these methods have been virtually untried. The positive response by low-income couples in several developing countries is no guarantee that wide acceptance and effective use will occur everywhere, but it is a signal that much wider promotion and delivery of these methods should be attempted, at least on a pilot basis. Pilot studies need to be carried out locally to find out which barrier contraceptives and service delivery techniques work in different settings.
Pilot studies should be carried out to determine which barrier methods and service delivery techniques work in various settings.

These pilot studies should use trained and committed paramedical workers wherever possible, since these personnel are the most readily available and, for barrier contraceptives, probably the most effective. A great number of programs around the world are training traditional birth attendants, organizing group meetings of rural traditional women, and setting up “mothers’ clubs” and other local women’s organizations. Tests of effective use of barrier methods could be developed within these group settings. For example, it might be worthwhile to solicit the views of traditional birth attendants on these methods. They would be likely to understand how the diaphragm, condom, and spermicides work, since these are often similar to traditional methods. In fact, traditional birth attendants may be more favorably disposed to providing barrier methods than oral contraceptives because of the tangibility of their mode of action, the fact that these methods add to their “equipment,” and the likelihood that fitting the diaphragm or providing instruction on the use of other barrier methods would reinforce their personal relationship to the women being served.

Some types of traditional birth attendants could undoubtedly be trained to fit the diaphragm, just as paraprofessionals in the United States now do. There is some experience from developing countries in doing this. Under the Sialkot Project of Pakistan, lady family planning visitors (who were matriculate level and drawn from the community) were trained to fit diaphragms successfully. A project now in the planning stage in Egypt may include traditional birth attendants, along with paramedical staff, among those whose skill in diaphragm fitting is developed and tested. Unlike IUD insertion, there is no mortality risk from the diaphragm-fitting procedure, and the familiarity with anatomy required for diaphragm fitting is likely to be part of the traditional birth attendant’s competence.
In conducting field studies it is important to select communities that have a history of using traditional barrier methods and a tradition of involvement of local indigenous female health workers who are able to openly discuss sexual topics with women. Women's comfort with their bodies varies tremendously from society to society. In many traditional societies (e.g., in parts of West Africa), women focus sharply on their sexual attributes and derive a sense of power from their sexuality. In other societies women regard their menstruation and sexuality negatively. Women's body images (how they regard and understand their bodies) and their willingness to put foreign objects into their bodies also vary from society to society. Suitable anthropological tools are available to determine how women perceive their bodies and to anticipate some of their basic responses to different methods.¹⁴⁰

Field studies should also examine the proposition that the mode of use of the diaphragm or spermicides requires that the woman be comfortable handling herself and have some privacy. While the Bombay study cited above suggested that availability of hygiene facilities may not influence the diaphragm's acceptability, these are real concerns. For some women, the visibility of barrier methods could be a problem. Packages containing spermicides or a diaphragm are often more conspicuous than packages of oral contraceptives; thus women may be better able to use the latter with greater privacy. Use of a diaphragm or a spermicide is visible. The insertion and removal procedures may be noticed in a small household, and the sexual partner is often aware during coitus that the method is being used. Most women will probably desire privacy, at least from children and in-laws. All barrier methods also require a degree of positive communication between a woman and her sexual partner, a requirement that will rarely be met in a number of developing countries.
Finally, where these methods have been shown to be acceptable to rural, traditional people, they must be made available through local community outlets at low cost and without embarrassment. Condoms are being introduced into village pharmacies; however, the spermicides used either alone or with the diaphragm are rarely available. Cost and packaging are also issues needing further consideration in field tests. Condoms cost only several cents each; each application of a spermicide should be of comparably low cost. Condoms often come individually packaged, and it has been suggested that spermicidal tablets could be similarly packaged in single applications.

Pilot tests of the acceptability of spermicidal tablets in developing countries are about to be carried out with funding from the US Agency for International Development, which is purchasing a supply of 10 million vaginal foaming tablets for this purpose.\(^{141}\) Other international agencies and governmental bodies concerned with family planning need to give similar priority to pilot studies of different types of barrier contraceptives. It has not been simple to develop clinical procedures, user education, and follow-up to maximize the acceptability and safety of hormonal contraceptives in developing countries, but governments and international agencies have successfully accomplished these steps. Such action should now be extended to barrier methods.
Recommendations for Policy and Action
The trends and opportunities that we have identified in the foregoing sections of this paper point to the desirability of increased use of barrier methods in the years ahead. The past experience and problems we have discussed point to a downgrading of barrier contraceptives by some health policymakers and family planning service providers and to profound neglect of these methods by contraceptive developers in both the public and private sectors.

This leads us in this section to a call for new policies and action to remove existing biases and other practical obstacles that still prevent a wider use of barrier contraceptives in the United States and in developing countries.

Providing Supportive Family Planning Services

The ability of all types of contraceptive providers and counselors to introduce prospective users to barrier methods should be enhanced. Organized family planning services should take steps to eliminate biases against barrier contraceptives.

As we discussed in detail in Part 2, no other single practical step is likely to do more to increase the contraceptive effectiveness of barrier methods than establishment of supportive, fully informative counseling services for prospective users of these methods.

A concerted effort should be made to develop special in-service training programs for the staff of organized health and family planning services. These staff badly need more complete and accurate information about barrier methods. They should be encouraged to adopt a more positive attitude toward these methods and to develop the capacity to discuss them fully, empathetically, and
frankly with prospective users. Their in-service training should include an open discussion of providers' attitudes about users' sexuality and of the relationship of barrier techniques to sexuality. It should include training in discussion techniques that staff can use to achieve more effective communication with prospective users. Finally, such training should include information about emerging trends in the use of barrier methods and identification of groups (as in Parts 3 and 4 above) to whom they might be particularly attractive.

The development of visual aids would assist health workers to communicate more effectively with potential users. These aids should include pictorial representations of male and female anatomy that show how (and when) barrier methods are used. Public agencies that now operate contraceptive service delivery programs could test the effectiveness and acceptability of different visual materials through their own programs and by funding private groups, such as the Planned Parenthood associations. Manufacturers of barrier contraceptives should be encouraged to apply their considerable expertise in communications and marketing to creating materials for use in commercial displays and in clinics. Properly done, these could include such basic facts about human reproduction as when ovulation occurs and the risk of pregnancy is the highest, as well as more specific information about the range of available barrier methods and what makes them effective.

If such training programs and visual aids are to be developed, federal agencies and private, nonprofit organizations must make substantial new funding available. Congress, the Department of Health, Education, and Welfare, and, for military health services, the Department of Defense should be encouraged to do this. The assistance of private foundations concerned with health care should be solici-
ted, as well as the support and assistance of such professional health care associations as the American Medical Association, the American Public Health Association, and the various nursing associations. Both private and public hospitals and clinics that offer family planning services should be encouraged to seek funding from all these sources to devise and implement suitable training programs.

Funds are also needed to organize local and regional workshops to provide this training. Such workshops could be held in conjunction with family planning conferences and meetings of medical and nursing associations. These conferences and meetings already take place on a regular basis for the purpose of discussing medical and service-delivery concerns, and special workshops related to barrier methods could be easily appended. The participants should include staff of federally and privately funded family planning services, state-supported health services, women's health collectives, and private physicians.

It is also essential to incorporate scientific and service-delivery presentations on barrier contraceptives directly into the programs of professional meetings held by obstetrician-gynecologists, general practitioners, nurses, nurse-midwives, and other groups involved in the first line of health care. Many of those attending such conferences will be highly influential in spreading more objective and positive views about barrier methods among the private health care community.

These information-dissemination efforts could be supplemented through existing newsletters and bulletins that reach particular constituencies, such as professional journals for physicians, nurse-midwifery journals, and the like. These journals and newsletters could feature the proceedings of conferences, document in-service experiences, and present the findings of studies on barrier methods.
Since women's health collectives have had more extensive experience in providing barrier methods than many other services, their knowledge should be shared with other programs. In many of their publications they are providing practical and useful information about the way in which barrier and rhythm methods of birth planning are employed, as well as users' responses to these methods and the kind of communication that leads to proper use. Specific grants might be made to some of the women's collectives and other services with experience in providing barrier methods to prepare resource books for prospective users and for health care providers.

Special educational, service-delivery, and outreach programs are needed to give adolescents greater access to a full range of contraceptive choices, including barrier contraceptives. Current national survey statistics on contraceptive practice should be extended to include use of contraception by unmarried teenagers. Research and policy analysis on the health effects of the different types of contraceptives used by teenagers is urgently needed.

Adolescents need greater access to choice in the contraceptives they use. Not all teenagers will want to use barrier contraceptives, but many who would are not offered the choice. Full access to information about these methods and encouragement to try them are being denied many adolescents because of the pervasive biases against barrier methods in the medical community and the resulting poor image of such techniques among teenagers.

Public information and education programs directed at teenagers are necessary to counter these
biases and to let young people know that barrier methods exist and are potentially useful. This information should be incorporated into sex education and human biology courses being given by high schools and teen centers. Publications that reach teenagers should present a comprehensive and balanced review of contraceptive options, including barrier contraceptives. What is most needed is open dialogue with and among teenagers about the variety of contraceptive methods available and how, specifically, each of these methods matches or fails to match individual needs. Such dialogues should be included as part of every social service and counseling program for teenagers. Finally, the Department of Health, Education, and Welfare should continue to fund the updating and distribution of informational booklets for teenagers that describe all existing contraceptive methods, including—in unbiased terms—barrier contraceptives. These booklets should discuss, in simple language easily understood by any teenager, the comparative risks and benefits of each method for this special age group so that they can make their own informed choices.

Health and family planning services and adolescent centers that have extensive experience in providing barrier methods to teenagers should receive special grants from federal agencies to document their approaches and to evaluate which educational programs work and which do not. Staff from these services could provide technical assistance to the members of other services where changes in attitudes and practices are desired. Providers who have had special success in working with teenagers should be engaged to produce one or more resource books offering practical guidelines on the delivery of contraceptive services to teenagers.

More basic statistical data about the contraceptive practices of unmarried teenagers are badly needed
to clarify policies and develop better programs to meet this group’s reproductive needs. The National Center for Family Planning Statistics or another of the federally mandated bodies that collect health statistics based on periodic national surveys should give special attention to monitoring adolescent use of contraception. Data are particularly needed on the numbers of new users under 20, their ages, and the methods they currently use. It would also be valuable to know the methods they initially selected, their continuation rates for various methods, and their reasons for switching or discontinuation. From a health policy standpoint, the apparent decline in condom use by unmarried teenagers and the implications of a possible resulting increase in oral contraceptive use by very young women need to be studied.

If teenagers are to have a full and informed choice about contraception, service providers and health professionals need to know more about the health tradeoffs that different methods offer to this age group. Since most research on contraceptive safety and side effects has been directed toward adults, very little is presently known about the health risks of different types of contraceptives for teenagers. National research and regulatory bodies, such as the National Institute of Child Health and Human Development, the Food and Drug Administration, and the Center for Disease Control, should provide funding and carry out their own studies to determine the risks and benefits to adolescents of different hormonal contraceptives, the IUD (including the varieties specifically designed for nulliparous women), and barrier methods. Data for very young women should be especially analyzed for any long-term health implications. Costly, large-scale prospective epidemiological studies will be needed to answer many of the pertinent health questions, and these
Major improvements should be made by pharmaceutical companies in the packaging and labeling of barrier contraceptive products in order to enhance the ability of users to employ these products with high effectiveness.

To some extent the use-effectiveness of barrier methods is influenced by the package design, which can affect the mechanical ease with which the product is applied. This factor is especially important for vaginal spermicides and condoms, which are applied during periods of sexual excitation. Also, the convenience of the packaging—how it can be carried, concealed, used unobtrusively, how resistant it is to physical damage—influences both the product’s acceptability and, to some extent, its effective use. Some pharmaceutical companies are now applying marketing research and package design skills to improving the containers for spermicides and the diaphragm. Much more effort is needed, especially with regard to the inserter used to place spermicides into the vagina.

Current labeling of barrier contraceptive products is so poor in quality that it stands in the way of informed, intelligent, and effective use of these products by consumers. At an April 1978 meeting of users of barrier contraceptives, consumer advocates, and researchers convened by the FDA, there was broad agreement that the directions on most...
packages of spermicides are not effective in guiding users as to mode of use and relative efficacy. This is illustrated by the following labeling on effectiveness taken from spermicides currently on the market:

- "X contains one of the most effective sperm-killing agents you can obtain ... it cannot provide an absolute guarantee against becoming pregnant."

- "Y [contains] one of the most powerful spermicides available ... no contraceptive can guarantee 100% protection."

- "Z contains a premeasured dose of the most widely used spermicide, nonoxynol 9. This highly effective, potent spermicide prevents pregnancy by killing sperm on contact ... no contraceptive provides an absolute guarantee against becoming pregnant."

Users are not seeking guarantees; they want to know their risk of becoming pregnant if they use the product as directed. If studies have found different rates of use-effectiveness among different populations, users want to know this and the reasons for it.

As we discussed in Part 2, a couple is likely to use a barrier method effectively only if they have a full understanding of the coitus-related requirements of these methods. Labeling claiming that spermicides are "pleasant, simple to use," or offer "a new level of convenience" misrepresent the method and give false encouragement to couples who may be unable to accept these methods. The manufacturers of these products should be encouraged to provide a brief, realistic description of the nature of the product as part of its outside and inside labeling. The labeling should prominently stress the
need to use the product precisely as instructed and consistently at each intercourse in order to obtain high effectiveness.

While instructions for use of spermicides and the diaphragm are generally complete, for some products they are difficult to understand. Consumers at the FDA-sponsored meeting called for clear, graphic illustrations and representations of how to use each method, along with clear and accurate instructions in large print.

All of these labeling recommendations can be condensed to one idea: what is needed is information, educational material, and instructions—not one-sided promotion. Pharmaceutical companies should design the labeling of these products to serve the needs of consumers as thoroughly as this means of communication will allow, rather than seek to convince or falsely reassure a potential customer. In the long run, improved, informative labeling and advertising will not only serve the public interest, but will also create more successful, effective, and satisfied users of these products and, thereby, a greater demand for them.

Improvements in packaging, labeling, and advertising must originate with private pharmaceutical manufacturers. They can be encouraged to make these improvements through the requests and advocacy of medical and pharmacy groups, particularly the American Medical Association, the American Public Health Association, the American Pharmaceutical Association, and the American College of Pharmacy. Organized consumer groups can educate private industry about consumer needs in this area, and large government procurers of these products, such as the armed forces and the Department of Health, Education, and Welfare, can both influence and assist pharmaceutical manufacturers in improving their products. Finally, the Food and Drug Administration holds regulatory
powers to require labeling changes, and this agency is currently requesting consumers to participate in identifying labeling needs for these products by writing directly to the FDA and joining in special meetings for this purpose.

A minimum of $2 million annually should be devoted by public agencies to funding applied research on barrier contraceptives. An additional $5 million should be devoted to mission-oriented research on reproductive physiology, especially of the vagina and cervix, and on synthetic materials. This more basic research should be guided to contribute new knowledge and new materials needed for the eventual development of completely new forms of barrier contraceptives.

As documented in Part 5, public agencies in the United States and abroad are now spending negligible amounts on research to improve barrier contraceptives. Some comparative figures on specific research topics are of interest. In 1977 public agencies spent about $9 million to test the safety and effectiveness of existing oral contraceptives and roughly $1 million to test the safety and effectiveness of IUDs. No allocations of funds were made for studies of barrier contraceptive safety and effectiveness that year, although a small amount of research funded in other years was underway.

In the area of applied research to improve and develop new contraceptives, public agencies spent $5.7 million on various types of new hormonal contraceptives for women, $1.8 million on new immunologic approaches, $1.3 million on new abortion techniques, and $1.5 million on new hormonal contraceptives for men. Only $143,000 was spent to develop better barrier contraceptives.
Thus, out of a total of $33.7 million spent on all types of applied contraceptive research by public agencies in 1977, less than 0.5 percent went to barrier methods. In view of the fact that 19 percent of the entire practice of contraception in the United States (including sterilization) is comprised of barrier methods, it is difficult to understand why such a minuscule percentage of public research monies was devoted to these methods.

We therefore recommend that steps be taken to bring funding levels for applied research on barrier methods up to at least $2 million annually. This would give applied barrier method research about the same priority as most other contraceptive development leads (although still considerably less than hormonal approaches for women). These funds should be devoted to three clearly identifiable applied research needs:

- **field studies of the effectiveness of different types of barrier methods** Around two dozen products for barrier contraception are on the market today, but almost no field studies to compare the effectiveness of different types of barrier contraceptives or to compare these with oral contraceptives and IUDs have been carried out. There is little doubt that inherent differences in effectiveness and acceptability exist between different types of spermicides and possibly between brands of the same type. Similarly, inherent differences very likely exist between the diaphragm used alone and used with one or another type of spermicide. Also, the effectiveness of all barrier methods varies widely with different conditions of service delivery and among different populations of users, but little is known of the underlying factors that cause these differences. If well-designed and carefully executed epidemiological studies were con-
ducted, many of these questions could be answered.

- **toxicology and pharmacology studies of the safety of spermicides** There is a pressing need to conduct animal and clinical pharmacology studies of barrier methods that employ chemical agents, in order to address safety concerns related to the possible absorption of these chemicals into vaginal or penile tissues. The first goal of such studies should be to determine whether absorption of the different chemical constituents indeed occurs and, if so, its extent. If any appreciable amount of absorption is found, then animal toxicology and, possibly, human epidemiological studies would be required.

- **applied contraceptive development work on barrier methods** The potential applied research agenda to develop improved and new barrier contraceptives is vast, as illustrated in Part 5. Priority in this research should be given to technological advances that reduce the behavioral demands of barrier methods. Particular emphasis should be placed on the development of barrier contraceptives tailored to the special needs and problems of adolescents and of low-income women in developing countries. This research and development should be closely tied to mission-oriented research on synthetic materials.

Presently, public agencies in the United States spend approximately $42 million annually for all types of basic and mission-oriented research in reproduction. Little of this is being devoted to areas of research likely to lead to better barrier contraceptives. We therefore recommend that public agencies take steps to identify particular areas of research—such as research on the physiology of the vagina and cervix and research on new syn-
thetic materials—that would be likely to contribute to the development of new forms of barrier contraceptives. We recommend that increased funding be made available specifically for such types of research, ultimately to an annual level of at least $5 million.

These recommendations imply a shift in research priorities. To some extent, the need to actually shift funds from existing areas of study in order to support barrier method research could be avoided by earmarking a significant portion of any new monies strictly for barrier method research. Also, a period of organizational planning and mobilization would undoubtedly be required to effectively absorb such large funding increases, both in applied research and development and in the more basic research areas. Although the professional and institutional capacities to undertake such research exist today, donor agencies will need to generate greater interest among these professionals in barrier research problems. Conferences, workshops, and professional dialogue will be required; and even with an intense groundbreaking effort, actual research expenditure at the levels recommended here would probably not be achieved in less than several years.

The major agency that funds this type of research in the United States is the Center for Population Research of the National Institute for Child Health and Human Development, which is part of the Department of Health, Education, and Welfare. Unfortunately, despite overall political support, Congress has given low priority to increases in this agency's research budget, and consumers will have to exert additional public pressure if new authorizations are to be passed. The research budgets of other public-sector agencies active in this area are much smaller than that of the NICHD, but their work is highly complementary and should be a part
of increased activity on barrier methods research. A number of these agencies are mentioned in Part 5; others engaged principally as donors are the Office of Population of the US Agency for International Development, the Ford Foundation, and the Rockefeller Foundation.

Pilot tests of the acceptability and effectiveness of spermicides and the diaphragm among rural and traditional women in developing countries should be initiated. Condom promotion and distribution through commercial channels should be greatly expanded.

Only after a variety of applied service delivery research projects have been undertaken will we know the utility of female-controlled barrier methods for low-income women in developing countries. Great differences in regional outcomes are likely, but in places where pilot projects demonstrate that barrier methods meet the needs of specific groups of users and can be used successfully, expanded service delivery programs should be initiated.

Ways in which these pilot studies might be designed and undertaken were detailed in Part 6. Acceptability studies need to be conducted through existing clinical outlets that are part of large-scale, nationally funded programs; through smaller, privately operated experimental projects; and through traditional health networks. The United Nations Fund for Population Activities, the Population Projects Section of the World Bank, the Division of Family Health of the World Health Organization, the Office of Population of USAID, and the International Planned Parenthood Federation are the major funding agencies through which such work should be supported. These agencies, in col-
laboration with various international research and technical assistance organizations in the population field, should sponsor and assist developing-country researchers to conduct such field tests.

At the same time, these organizations should support and encourage expanded promotion and distribution of condoms through commercial channels. The successful experiments for doing this that were described in Part 6 can serve as models for expanded efforts.

Consumers and professionals who agree with these recommendations need to exert their influence—as consumers, as constituents, as taxpayers, and, for professionals, as participants in health services and research—to convince policymakers to carry out these actions.

In the ideal, users' priorities in service delivery and contraceptive research would determine decision makers' priorities. In practice this is rarely the case, not because decision makers are unwilling to listen but because users are not organized, their views are not fully articulated in the form of pragmatic recommendations, and their voice is admitted late—usually too late—into the policymaking process. Users as a group, therefore, generally have little influence in shaping or determining the health care they receive and the technology with which they are served.

Unfortunately, because of the strong professional biases against barrier methods that continue to exist, it seems unlikely that the five recommendations listed above will be acted upon—unless the users of fertility regulation services press scientific and government policymakers to act on them. For these
changes or related ones to be made in the systems that deliver contraceptive services and allocate research monies, users must act as a group to exert collective pressure as consumers, constituents, and taxpayers on the political levers available to them. If these changes are to take place, users of contraceptives, consumer action groups, and like-minded health providers need to express their concerns and desires for action to their congressmen, to senior health officials in the federal government, and to the pharmaceutical industry. If this is done, we believe that a major improvement in contraceptive practice will occur in the years ahead.

2. Each year the World Health Organization's Special Programme of Research, Development and Research Training in Human Reproduction hosts a meeting of the principal agencies that support or directly conduct contraceptive research. Agencies that have participated in these meetings, in addition to WHO, are the National Institute of Child Health and Human Development (of HEW), the US Agency for International Development, the International Fertility Research Program, the Program for Applied Research on Fertility Regulation, the Population Council, the Pathfinder Fund, the Ford Foundation, the Rockefeller Foundation, the International Committee for Applied Research on Population, the Medical Research Council of Great Britain, the Indian Council of Medical Research, the International Development Research Centre, the International Planned Parenthood Federation, and the Program for the Introduction and Adaptation of Contraceptive Technology. For the 1977 and 1978 meetings, at the request of WHO, the participating agencies completed questionnaires documenting their funding of various types of research. The statistics on funding noted in this report are based on detailed analyses of these questionnaires. These statistics have been closely compared for accuracy with funding data recently collected by the Ford Foundation as part of a follow-up survey to its earlier comprehensive funding study by Roy O. Greep, Marjorie A. Koblinsky, and Frederick S. Jaffe, *Reproduction and Human Welfare: A Challenge to Research* (Cambridge, Mass.: MIT Press, 1976). They have also been checked for accuracy with 1977 funding data for US federal institutions provided in the *Inventory and Analysis of Federal Population Research* (Washington, D.C.: DHEW Publication No. [NIH] 78–133, 1978). Allowing for some differences in definitions, the three sources of funding statistics are in general agreement.

5. Vessey et al., cited in note 4. This statistic refers solely to hospital admission for strokes, heart attacks, other thromboembolic disease, gall bladder disease, and cervical ulcerations, all of which have been confirmed in other studies as being associated with oral contraceptive use. The rate of hospitalization cited is the excess that occurred for oral contraceptive users in comparison with diaphragm and IUD users. Since the incidence of these side effects increases with age (see Figure 1 in text), the rate would be lower for younger women and higher for older women. Also, the rate depends to some extent on smoking (see note 7 below). The findings of Vessey et al. are based on an eight-year study of 17,000 women in Great Britain and were confirmed by the Royal College of General Practitioners' study (cited in note 4) of an additional 46,000 women. See S. Bruce Schearer, "Safety and effectiveness of oral contraceptives and intrauterine devices," in Advances in Obstetrics and Gynecology, ed. Ronald M. Caplan and William J. Sweeney (Baltimore: The William and Wilkins Company, 1978), pp. 475–484, for detailed discussion of the Royal College findings.

6. At an average annual rate of hospitalization for these side effects of 0.5 women out of every 100 users, over a 25-year period of use an estimated 12.5 women would be hospitalized among every 100 users. The rate would be less among non-smokers and greater among smokers (see note 7).

7. Anrudh K. Jain, "Cigarette smoking, use of oral contraceptives, and myocardial infarction," American Journal of Obstetrics and Gynecology 126, no. 3 (1 October 1976): 301–307; Shapiro et al., cited in note 4; Christopher Tietze and Sarah Lewit, "Life risks associated with reversible methods of fertility regulation," paper presented at the International Symposium on a Reappraisal of Fertility Control: Benefits versus Risks, Montreal, September 1978; Christopher Tietze, "The pill and mortality from cardiovascular disease: Another look," Family Planning Perspectives 11, no. 2 (March/April 1979): 84. About one-third of the hospitalizations due to oral contraceptive side effects are related to circulatory diseases, and these in particular have been linked to smoking. It is therefore likely that the annual average rate of hospitalization caused by side effects among nonsmoking pill users is lower than 0.5 percent, in the range of 0.3 to 0.4 percent annually. Among young women who do not smoke, it would be still lower. Among smokers the overall average rate would range from 0.6 to 0.7 percent annually. Among older smokers it would be considerably higher.


12. See Vessey et al., cited in note 4; Bernstein; Hatcher et al.; Hall; Menken et al.; Peel; Tietze; Dingle and Tietze; Tietze and Lewit; Trussell (all cited in note 11); also Christopher Tietze, The Condom as a Contraceptive (New York: National Committee on Maternal Health, 1960); Raymond Belsky, "Vaginal contraceptives: A time for reappraisal?" Population Reports, Series H, no. 3, George Washington University Medical

13. Vessey et al., cited in note 4; Bernstein; Vessey and Wiggins; Hall; Lane, Arceo, and Sobrero; Menken et al.; Dingle and Tietze; Tietze and Lewit; and Trussell (all cited in note 11); Tietze; Bernstein; Carpenter and Martin; and Glass, Vessey, and Wiggins (all cited in note 12).

14. Use-effectiveness rates of between 2 and 3 pregnancies per 100 users per year have been demonstrated for the condom, diaphragm, and at least one type of spermicide in studies employing vigorous scientific methodology: Vessey et al., cited in note 4; Vessey and Wiggins; and Lane, Arceo, and Sobrero (both cited in note 11); Carpenter and Martin; Peel; Glass, Vessey, and Wiggins (all cited in note 12). In addition, in other well-designed studies a pregnancy rate of 4.3 for an aerosol foam spermicide was reported by Bernstein, cited in note 11, and Bernstein, cited in note 12, and similar pregnancy rates for some populations of condom users were reported by Peel, cited in note 11, and Tietze, cited in note 12. Also, Tietze and Lewit, cited in note 11, reported pregnancy rates of 5 to 7 for some populations of diaphragm users. A number of studies of various types of spermicides employing less rigorous scientific
methodology have also found pregnancy rates between 2 and
4, but the reliability of these findings is less certain. Use-
effectiveness rates for most IUDs vary from about 2 to 5 preg­
nancies per 100 users per year and for oral contraceptives
used in developed countries from 0.2 to 0.5 (Hatcher et al.;
Vessey et al.; and Menken et al., all cited in note 11).

15. Menken et al.; and Trussel (both cited in note 11). See Hatcher
et al., cited in note 11, for pregnancy rates of traditional
contraceptives.

16. Vessey et al., cited in note 4; Hall; and Vessey and Wiggins
(both cited in note 11); Glass, Vessey, and Wiggins; and Tietze
(both cited in note 12).

17. Mary E. Lane, “Contraception for adolescents,” Family Plan­
ing Perspectives 5, no. 1 (Winter 1973): 19–20; Mary Lane,
“Benefits and risks of diaphragm and condom use,” in Risks,
Benefits, and Controversies in Fertility Control, cited in note 8,
pp. 547–555; Bernstein; and Lane, Arceo, and Sobrero (both
cited in note 11); Bernstein; and Carpenter and Martin (both
cited in note 12).

18. Hall; Bernstein; Menken et al.; Dingle and Tietze; Tietze and
Lewit; Trussell; Hatcher et al.; Wortman; Chandrasekaran and
Kuder (all cited in note 11); Belsky; Bernstein; Tietze; Dumm,
Piotrow, and Dalsimer; and Flavier, Eduarte, and Lopez (all
cited in note 12).

19. Warren B. Miller, “Psychosocial aspects of contraception,” in
Proceedings of the Symposium on Contraceptive Technology, 16–17


21. Bernstein; and Lane, Arceo, and Sobrero (both cited in note
11); Lane, both articles cited in note 17; Bernstein; and Car­
penter and Martin (both cited in note 12).

22. Lane, Arceo, and Sobrero, cited in note 11.

23. The instructions given to new users in Lane, Arceo, and So­
brero, cited in note 11, were as follows:

—“The type of diaphragm selected depended upon the ana­
tomic characteristics of the woman's vagina, specifically the
degree of muscle tone in the retropubic vault and the length,
rigidity and direction of the cervix. An important consider­
ation was the woman's ability to manipulate a given type of
rim.
—The largest diaphragm was chosen that could rest with its
posterior rim behind the cervix and its anterior rim in the
groove behind the symphysis pubis. It was important that the
woman have no sensation of its being in place.
—The patient was taught to recognize these anatomic land­
marks with the aid of a three-dimensional pelvic model and
through her own exploration of her vagina.
—She was required to demonstrate, immediately following
fitting, that she was able to place the diaphragm properly and
to remove it.
—It was emphasized that the diaphragm and spermicidal jelly
or cream had to be used at the time of each coital exposure.
—The patient was encouraged to insert the diaphragm and
jelly or cream as long as six hours in advance of anticipated
need in order to minimize its coital dependence, and to leave it
undisturbed for a minimum of six hours postcoitally.
Douching was discouraged. Much of this instruction, together
with advice on care and inspection of the diaphragm, was
given during the group session or the 5–10 minute routine
nurse counseling session that followed the prescription of any
method, leaving to the clinician the actual fitting and observa­
tion of the patient. The time devoted to the latter, beyond that
required for the examination, was also 5–10 minutes (the same
for IUD insertion), depending on the difficulty of fitting and
response of the patient. The patient was asked to return after
one week (during which time she was advised to use another
method of contraception concurrently), in order to check on
the fit of the diaphragm and on the woman’s technique of
insertion. She was then scheduled to return annually.”

family planning clinic,” *Journal of Biosocial Science* 10, no. 2
(April 1978): 159–167; Malcolm Potts, “The importance of
vaginal contraception,” paper presented at the International
Workshop on New Developments in Vaginal Contraception,
25–27 April 1979, Guatemala City, Guatemala; Lane, both ar­
ticles cited in note 17; Hall, cited in note 11.

25. Lane, Arceo, and Sobrero; Hall (both cited in note 11); Lane,
both articles cited in note 17; Miller, cited in note 19.


27. Dingle and Tietze; Tietze and Lewit (both cited in note 11).


29. See notes 11 and 12.

31. Tietze and Lewit, cited in note 11. In the first study, by Dingle and Tietze (cited in note 11), pregnancy rates during the first six months were 18.8 per 100 users for the diaphragm used with jelly or cream and 33.6 for the foaming tablets. However, rates for later months were 11.4 and 14.5, respectively. In the second study (Tietze and Lewit) pregnancy rates for the first six months were 10.3 for the diaphragm and 16.2 for the vaginal foam; during the second year of use, the rates dropped to 7.6 for the diaphragm and 10.4 for the vaginal foam.


34. See note 33.


37. Figure 1 in the text is based on the data in the following table showing annual number of births and deaths associated with the use of reversible contraceptive methods per 100,000 non-sterile women. These data are derived, with additional calculations for barrier methods, from Christopher Tietze, John Bongaarts, and Bruce Schearer, “Mortality associated with the control of fertility,” Family Planning Perspectives 8, no. 1

<table>
<thead>
<tr>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No contraception, no abortion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of live births</td>
<td>56,085</td>
<td>59,290</td>
<td>55,780</td>
<td>47,170</td>
<td>31,680</td>
</tr>
<tr>
<td>Birth-associated deaths</td>
<td>5.6</td>
<td>7.2</td>
<td>12.7</td>
<td>20.8</td>
<td>21.6</td>
</tr>
</tbody>
</table>

Barrier contraception used with low effectiveness ³ and abortion of accidental pregnancies

| Number of induced abortions | 17,150 | 20,360 | 19,630 | 15,610 | 8,400 |
| Abortion-associated deaths | 0.2 | 0.4 | 0.4 | 0.4 | 0.2 |
| Method-associated deaths | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total deaths | 0.2 | 0.4 | 0.4 | 0.4 | 0.2 |

Barrier contraception used with high effectiveness ³, no abortion

| Number of live births | 2,412 | 2,820 | 2,620 | 2,000 | 965 |
| Birth-associated deaths | 0.2 | 0.3 | 0.6 | 0.9 | 0.7 |
| Method-associated deaths | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total deaths | 0.2 | 0.3 | 0.6 | 0.9 | 0.7 |

IUD, no abortion

| Number of live births | 1,545 | 1,910 | 1,770 | 1,350 | 650 |
| Birth-associated deaths | 0.15 | 0.2 | 0.4 | 0.6 | 0.4 |
| Method-associated deaths | 0.80 | 1.0 | 1.0 | 1.4 | 1.4 |
| Total deaths | 0.95 | 1.2 | 1.4 | 2.0 | 1.8 |

Barrier contraception used with low effectiveness ³, no abortion

| Number of live births | 13,155 | 15,710 | 14,630 | 11,430 | 5,860 |
| Birth-associated deaths | 1.3 | 1.9 | 3.3 | 5.0 | 4.0 |
| Method-associated deaths | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total deaths | 1.3 | 1.9 | 3.3 | 5.0 | 4.0 |

Oral contraception, no abortion — women who do not smoke

| Number of live births | 1,545 | 1,910 | 1,770 | 1,350 | 650 |
| Birth-associated deaths | 0.15 | 0.2 | 0.4 | 0.6 | 0.4 |
| Method-associated deaths | 0.85 | 1.6 | 3.0 | 9.1 | 17.7 |
| Total deaths | 1.00 | 1.8 | 3.4 | 9.7 | 18.1 |

Oral contraception, no abortion — women who smoke

| Number of live births | 1,545 | 1,910 | 1,770 | 1,350 | 650 |
| Birth-associated deaths | 0.15 | 0.2 | 0.4 | 0.6 | 0.4 |
| Method-associated deaths | 3.15 | 6.1 | 11.8 | 31.3 | 60.9 |
| Total deaths | 3.30 | 6.3 | 12.2 | 31.9 | 61.3 |

¹The various rhythm techniques of contraception have not been included in this table because available scientific data do not permit reliable estimates of their effectiveness.

²Since there are only small differences in overall mortality for the various methods between women aged 15–19 and those aged 20–24, these two age groups are considered together.

³Low refers to 90 percent effectiveness, which is equivalent to an annual contraceptive failure rate of 21.5 pregnancies per 100 users. High refers to 98.5 percent effectiveness, which is equivalent to an annual contraceptive failure rate of 2.5 pregnancies per 100 users.


41. See note 40.

42. See note 40; also, John J. Cutler et al., "Vaginal contraceptives as prophylaxis against gonorrhea and other sexually transmissible diseases," *Advances in Planned Parenthood* 12, no. 1 (1977): 45–56.


45. See note 44.

46. Menken et al., cited in note 11.

47. Ford, both articles cited in note 44.

48. Ford, both articles cited in note 44. Use of the diaphragm, condom, and foam increased from 14.7 percent to 16.0 percent between 1973 and 1976 among married couples aged 15–24 who used some form of reversible contraception.
49. Elizabeth B. Connell et al., “A new look at barrier contraceptives,” *Contemporary Ob/Gyn* 10 (August 1977): 76–91. In this panel discussion it was noted that prominent obstetrician/gynecologists often thought of barrier methods as “that greasy kid stuff” and discouraged their use.

50. See note 23 and Lane, both articles cited in note 17.

51. See note 49; Lane, Arceo, and Sobrero, cited in note 11; and Lane, both articles cited in note 17.

52. Personal communication from Dr. Hans Lehfeldt, Clinical Professor of Obstetrics and Gynecology, New York Medical Center.


54. See note 44. There has also been a small increase in the proportion of married black women using this method; almost the entire increase is among women over age 35 (Ford, both articles cited in note 44). It is interesting to note that the proportion of young couples using withdrawal and rhythm—both safe, “natural” methods—also increased, in fact doubled, during this period, while the proportion using the pill and IUD declined.


57. See notes 44, 48, and 54. An exception to this general trend of declining use by older couples is the increased use of the diaphragm by older black couples (described in note 54).

58. Vessey et al., cited in note 4; McEwan, cited in note 24; Caldwell and Ware, cited in note 56; Sylvia Wassertheil-Smoller et al., “Contraceptive practices of wives of obstetri-
cians," *American Journal of Obstetrics and Gynecology* 117, no. 5 (1 November 1973): 709-715. None of the physicians surveyed recommended the diaphragm or the condom for postabortion patients, yet 25 percent of these physicians used barrier methods themselves; 64 percent recommended the pill to their patients, but only 28 percent of physicians' wives were using it. Informal surveys of organizations conducting family planning or population-related work turn up low use of the pill, high use of the diaphragm. Survey conducted by S. B. Schearer and Deborah Harrison at the Population Council, 1976; survey conducted by Geraldine Oliva and Jan Cobble, "Contraceptive behavior of family planning clinic staff," Planned Parenthood/Alameda–San Francisco, 22 October 1978, mimeo.

59. See note 44.


61. See note 58.


63. Torres, cited in note 53. In 1976, teenagers comprised 40 percent of all new patients of organized family planning services in the United States.


66. See note 65.

67. See note 65.

68. See note 65.

69. See note 65.
70. See note 65.


72. Dr. Louise B. Tyrer, Medical Director of the Planned Parenthood Federation of America, called provision of contraception to teenage women who have infrequent sexual intercourse a “disservice.” Discussion cited in note 49.

73. See notes 4-7.


75. See note 43.

76. See notes 40 and 42.

77. See note 8.

78. See Lane, Arceo, and Sobrero, cited in note 11; Lane, both articles cited in note 17.


80. See Lane, Arceo, and Sobrero, cited in note 11; Lane, both articles cited in note 17; Klein, cited in note 74; Tyrer, cited in note 72; Connell et al., cited in note 49.

81. See “Women at work”; “Marital status . . .”; “U.S. family . . .”; Glick and Norton; and Rindfuss and Bumpass (all cited in note 3).

82. In 1976, there were 3,168,000 live births in the United States, as compared with 4,027,000 in 1964; 47 percent of these 1976 births were to women aged 25 and over.


84. See note 83.

86. See "Marital status . . .," cited in note 3.
87. See Glick and Norton, cited in note 3.
88. See "Marital status . . .," cited in note 3.
89. See "Marital status . . .," cited in note 3, pp. 4–5. It is difficult to interpret changes in household patterns. When unrelated males and females are living together, the tendency is to report on the males as "head of household"; thus, in looking for information on "living together," data on household patterns of males (as reported) may be more indicative than data on females. In 1970, the percentage of two-person primary individual households headed by males aged 25–44 living with someone of the opposite sex was 26.4 percent. In 1976, this had increased to 52.2 percent.
90. See "Marital status . . .," cited in note 3.
94. See note 44.
95. See note 85.
96. See note 44.
97. See notes 44 and 53.
98. Ford, first reference cited in note 44, Table 1, p. 265.
101. Malcolm Potts, J. Joseph Speidel, and Elton Kessel, "Relative risks of various means of fertility control when used in less-developed countries, in Risks, Benefits, and Controversies in Fertility Control, cited in note 8, pp. 28–51; C. Tietze, J. Bongaarts, and S. B. Scheerer, "Mortality associated with the control of fertility," Perspectives in Family Planning 8 (1976): 6–14; Tietze
and Lewit, cited in note 7; A. K. Jain, "Mortality risk associated
with the use of oral contraceptives," Studies in Family Planning
8, no. 3 (1977): 50–54.

102. Personal communication from Judy Norsigian, National
Women's Health Network, 332 Charles River Road, Watertown, Mass., 02172. The figure of 10,000 is an estimate based
on the knowledge that about 100 (of the 200) health collectives
offer services and that the case load of each varies from 500 to
several thousand.

103. Our Bodies, Ourselves has sold over 2 million copies in 13 lan-
guages and has recently been revised. A second book, Our
Children, Ourselves, is also a bestseller. Copies can be obtained
from the Boston Women's Health Book Collective, Box 192,
West Somerville, Mass., 02144.

104. Examples of harassment by professional groups have been
noted by the Tallahassee Feminist Health Center, the Los
Angeles Feminist Women's Health Center, and the Women's
Community Health Center in Boston. Documentation can be
obtained by writing the Feminist Women's Health Center,
1017 Thomasville Road, Tallahassee, Fla., 32303.

105. J. Billings and E. L. Billings, "Determination of the fertile and
infertile days by the mucus pattern: Development of the ovula-
tion method," in Natural Family Planning, ed. W. A. Uricchio
and M. K. Williams (Washington, D. C.: The Human Life
Foundation, 1973), pp. 149–163. Dr. Hanna Klaus reports that
Bantu women around Mwanza, Tanzania, have used examina-
tion of changes in cervical mucus to detect periods of fertility.
Similar reports have come from Ghana, northern India, and
from Cherokee tribes in the United States. For fuller informa-
tion on this method as currently employed, write the Boston
Women's Health Book Collective, Box 192, West Somerville,
Mass., 02144.

106. Personal communication from Dr. Christopher Tietze, New
York City.

107. M. H. Redford, G. W. Duncan, and D. J. Prager (eds.), The
Condom: Increasing Utilization in the United States (San Francisco:

108. S. M. Keeny, C. Rhodes, and S. B. Scheerer, "The purchase,
shipment, storage, and distribution of contraceptives in devel-
oping countries: A manual on how family planning programs
can minimize spoilage and damage of their contraceptives"


111. See note 2.


113. See reports cited in note 110; also, Greep, Koblinsky, and Jaffe, cited in note 2.

114. See reports cited in note 110, especially for WHO's Special Programme and NICHD's Center for Population Research.

tion of Human Fertility (Copenhagen: Scriptor, 1977); also see Vessey et al. and Royal College of General Practitioners, both cited in note 4.

116. Testimony by Judy Norsigian presented on behalf of the National Women's Health Network at the hearings on contraceptive research before the House Select Committee on Population, Washington, D.C., 8 March 1978.


119. V. P. Kumar, "A contraceptive of the future," Centre Calling 13, no. 2 (Delhi: Department of Family Planning, Government of India, 1978).


122. Kumar, cited in note 119; Davies and Louis, cited in note 120; Mechai, cited in note 121; James R. Foreit, Martin E. Gorosh, and Duff G. Gillespie, "Community-based and commercial contraceptive distribution: An inventory and appraisal," Population Reports, Series J, no. 19, George Washington University Medical Center, March 1978; Jack Thomas, "Marketing family planning," Front Lines (1 June 1978): 4-5; personal communication from Dr. Henry Elkins, the Population Council. The Bangladesh program was initiated in 1976 by the Bangladesh Contraceptive Social Marketing Program (PSI). Sales grew to 2 million pieces in 24 months. A research and evaluation project is now under way under the auspices of Dacca University and the International Committee on Applied Research in Population and will be completed in 1979.


125. See note 122.

126. See note 1; also Paula H. Hass, “Contraceptive choices for Latin American women,” *Populi* 3, no. 4 (1976): 14–24; Michele G. Shedlin and Paula E. Hollerbach, “Modern and traditional fertility regulation in a Mexican community: Factors in the process of decision making,” Working Paper of the Population Council, Center for Policy Studies, September 1978; Michele G. Shedlin, “Cultural indicators in the acceptability of fertility regulation,” Columbia University, Center for Population and Family Health, 1974, mimeo; and Michele G. Shedlin, “Cultural factors relevant to the design and implementation of a community-based family planning program,” Columbia University, Center for Population and Family Health, 1975, mimeo. Dr. Hollerbach, in a personal communication, observes that “when body concept drawings, a tool developed by Dr. Shedlin, were completed by women in a community study in Mexico, they demonstrated that women are not totally uninformed about reproductive and sexual functioning, but are often considerably misinformed. Women’s images of their bodies will influence their acceptability of different contraceptive methods. For instance, in Jamaica, women often fear using the condom or IUD because they fear that the device will become lost inside them or will ‘fly’ up into their head. However, in Mexico the operation of barrier methods and intrauterine devices is easily understandable. In developing countries, especially in those areas servicing the urban and rural poor, consultation should be made with indigenous medical personnel, such as midwives or herbalists, to see if folk methods involving insertion (leaves, sticky substances, abortifacients, etc.) are familiar to these women and what side ef-
fects, if any, pertain to them. This information would indicate whether clinic clients have experience with insertion methods.” Dr. Hollerbach stresses the need for consultation with indigenous personnel, rather than with physicians, because knowledge of folk methods is typically transmitted through female networks of friends and kin and may be unknown to medically trained males.


128. Personal communication from Dr. Fernando Gomez, Population Council advisor in research and evaluation to the national family planning program of the Dominican Republic.


130. Chandrasekaran and Kuder; Chandrasekaran and Karkal (both cited in note 11).

131. See note 130.


135. Wajihuddin Ahmad, “Field structures in family planning,” *Studies in Family Planning* 2, no. 1 (January 1971): 6–13; and personal communication from Dr. Wajihuddin Ahmad, currently codirector of Al Azhar University’s program in population studies in Cairo. He was Joint Secretary and Commissioner for Family Planning of the government of Pakistan while the Sialkot project was being undertaken.

136. The training of traditional birth attendants in family planning is an important part of Indonesia’s national program. Similar work has been carried out on a smaller scale at several sites in Egypt, including one under the auspices of the Alexandria Family Planning Association; in the Philippines, under the Bohol Maternal and Child Health–based Family Planning Project; and in Nigeria, under the Rural Maternal and Child
Health/Family Planning Project and the Cross River State Ministry of Health in Calabar. The role of women's organizations and women's groups is described in Judith Bruce, "Women's organizations: A resource for family planning and development," *Family Planning Perspectives* 8, no. 6 (November/December 1976): 291–297.

137. See notes 1 and 126.

138. See note 135.

139. A two-year pilot project to introduce barrier contraceptives in Egypt was undertaken in March 1979 by the Egyptian Family Planning and Population Board, with support from the United Nations Fund for Population Activities. Dr. Mary Taylor Hassouna is the principal investigator.

140. See note 135.

141. Personal communication from Dr. James Shelton, Office of Population, USAID.


143. The sources for this section are cited in notes 2 and 110.

144. See note 2. The total refers to the amount spent by all public-sector agencies indicated in note 2. Two US federal agencies, NICHD and AID, spent $18.1 and $4.6 million, respectively. (In the US Department of Health, Education, and Welfare analysis cited in note 2, slightly higher totals are given for these two agencies—$19.1 million and $7.3 million, respectively—because a broader definition for applied research is used.)

145. In 1977, US agencies spent $36.3 million on "research on reproductive processes" and an additional $5.7 million on grants to university centers working on such research (see US Department of Health, Education, and Welfare, cited in note 2). It should be noted that the term "mission-oriented" research is operationally difficult to define and, depending on the criteria used, such research might be classified under either "contraceptive development" or "research on reproductive processes." The intent of our recommendation is not to specify definitions but to increase barrier method research funding to about $7 million annually, with distribution of the funds determined by the substantive research needs described in this section and in Part 5 of this paper.
Judith Bruce has been an Associate of the Population Council's International Programs division since 1977. Her work is focused on the roles and status of women, a priority Council concern. In 1975, Ms. Bruce was one of the organizers of the program “Third World Craftswomen and Development,” of the International Women's Year Tribune. She has been active in the United States since 1969, when she was a plaintiff in a class action case that challenged New York's restrictive abortion law. She has testified before the US Congress on women's priorities in contraceptive services research and has served as an adviser to the US State Department on women's roles in developing countries. A term member of the Council on Foreign Relations, she holds a B.A. degree in biological anthropology from Harvard University.

S. Bruce Schearer is an Associate, International Programs division, the Population Council. In collaboration with other international organizations and with relevant bodies in developing countries, he is seeking to identify new policies and institutional mechanisms that can serve to advance the international transfer and diffusion of contraceptive technologies. Dr. Schearer, who holds a doctorate in biochemistry from Columbia University and has done graduate work in international affairs, has testified before the US Congress on issues of contraceptive research and safety and publishes regularly in this field. He serves on the boards of Planned Parenthood of New York City, the Population Resource Center, and the Western Hemisphere Region of the International Planned Parenthood Federation.
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