



Saving Lives **NOW**

Female Condoms
and the Role of U.S. Foreign Aid

Prevention Now! Campaign

An initiative of the Center for Health and Gender Equity

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About The Report

Although the female condom is an effective tool for HIV prevention that is available today, this method is not readily accessible throughout the world due to cost, stigma and a lack of political will. As a leading provider of funding for HIV/AIDS prevention, treatment and care, and reproductive health supplies worldwide, the United States has an important role to play in procurement, distribution and programming of female condoms. However, there is little knowledge among policy makers and advocates about what the current U.S. role is and, thus, a lack of understanding of what more the U.S. should do.

This report presents an overview of the female condom, explains its relevance to a global response to HIV prevention and identifies key challenges to making it accessible to women and men worldwide. The report also provides policy makers, donors and sexual and reproductive health and rights advocates with an understanding of current U.S. support for procurement, distribution and programming of female condoms.

The report is based on a review of all peer reviewed published literature from January 2000 until December 2007, in addition to well designed transparent grey literature (see References). Interviews were conducted with key experts from organizations with expertise on female condoms, including the U.S. Agency for International Development, United Nations Population Fund, Office of the Global AIDS Coordinator, Population Services International, John Snow Inc., Female Health Company, PATH, the Bill and Melinda Gates Foundation and others. For a list of experts interviewed, please refer to Annex B. Peer reviewed published literature prior to 2000 has been included only when more recent literature could not be found on a particular topic.

Based on evidence gathered through these reviews of published literature and extensive interviews, the report concludes with concrete recommendations to remove barriers that have denied women and men access to female condoms and to ensure stronger U.S. support for female condoms in the future.

While our long-term goal is to ensure that female condoms are available and accessible to every woman, we know it will take years of committed actions by donors, activists and service providers to reach this goal. With increased and steady support from donors like the U.S., and a phased approach to improve and expand programming and training to reach all target groups, geographic areas and life situations, female condoms will gradually become available to all, improving health and saving lives.

SERRA SIPPEL

Executive Director

Center for Health and Gender Equity

Executive Summary

In 2007, women represented half of all HIV infections worldwide, and 61% of HIV infections in sub-Saharan Africa. Eighty percent of all HIV infections are sexually transmitted. In spite of this reality, two and a half decades into the HIV and AIDS pandemic, the disease continues to outpace the global response. For every person who goes on antiretroviral therapy for treatment, six people are newly HIV infected. As international donors and country governments move forward with plans to make male circumcision more accessible and invest millions of dollars into developing microbicides and vaccines, they cannot afford to overlook the only available HIV prevention intervention that was designed to allow women to initiate protection: female condoms.

While the unique nature of female condoms in providing women with their own source of protection should be reason enough for donors and governments to promote the method, female condoms hold other advantages as well. They fill their own niche, as consumers often alternate their use with that of male condoms, thus increasing the total number of protected sex acts. They can be used by women living with HIV who do not wish to become pregnant, to protect against superinfection and to reduce the chance of HIV transmission to seronegative partners. Female condoms offer dual protection against both unwanted pregnancy and HIV, and some women and men report more sexual pleasure with female condoms than with male condoms. Female condoms also provide an additional option for protection during anal intercourse for men who have sex with men and heterosexuals. Moreover, female condoms can prepare for future microbicide use because they present similar programming and marketing requirements.

Certainly, female condoms are not the perfect method for everyone, and they bring unique challenges. Female condoms are prohibitively expensive in many parts of the world, and users can find them noisy, physically unappealing, or difficult to use. However, female condoms are a cost-effective mechanism for HIV prevention when measured against the costs of potential HIV infections or other HIV prevention mechanisms. Also, as more and more female condoms are produced and purchased, their cost will drop. Well designed and executed programs have overcome challenges such as noise and physical appearance, resulting in successful uptake and usage.

However, if current low investment levels in female condoms persist, these obstacles will remain significant. Female condoms are not readily accessible in most countries. In the countries where they are accessible, there is a growing demand for them. But because the vast majority of potential consumers are unaware that female condoms exist, there are no meaningful estimates of global demand. It is clear, however, that insufficient numbers of female condoms are available to those who need them globally for HIV prevention.

High quality female condom programming is critical to increasing female condom demand and uptake. Providers should ensure access to the product in a comfortable environment to promote acceptability and continued use of female condoms. Programmers also need to approach their distribution creatively, using engaging and appropriate marketing for different populations. To increase accurate and consistent use, training for providers and consumers is essential. Another consideration for programmers is that female condoms should be provided to those groups that are most in need of alternative options to male condoms without stigmatizing condom use. Civil society groups can be extremely valuable

in developing effective programming because of their access to populations vulnerable to HIV infection and their experience working with these groups.

The U.S. has an important role in female condom procurement, distribution, and programming and is one of the largest procurers of female condoms for international distribution. Compared to other donors, the U.S. excels at female condom procurement and logistics. Recipients of U.S. female condoms experience fewer stock-outs and supply chain challenges than the recipients of non-U.S. procured female condoms.

However, bureaucratic obstacles, funding restrictions, and a lack of high level commitment to female condoms have significantly hindered the expansion of U.S.-funded female condom distribution efforts. The U.S. government has no policy guidance encouraging missions or contractors to promote female condoms, which has meant that female condom procurement is dependent on a few field-level champions who are committed to the method. The cost differential between male and female condoms also discourages the latter's procurement, as providers who do not understand the benefits of female condoms see little reason to choose a higher priced method.

Perhaps the most significant deterrent for both male and female condom use lies within U.S. global policy for preventing the sexual transmission of HIV. The policy guidance adopted by the U.S. Office of the Global AIDS Coordinator prioritizes condom promotion programs under the President's Emergency Plan for AIDS Relief (PEPFAR) for "high-risk persons," stigmatizing condom use and leaving married women and youth at particular risk of HIV infection. In addition, the congressionally mandated requirement that PEPFAR spend 33% of all HIV prevention funds on abstinence-until-marriage programs directs a disproportionate amount of money toward programs that promote only abstinence and fidelity as means of preventing HIV. The Government Accountability Office (GAO) and Institute of Medicine, National Academy of Sciences (IOM or Institute of Medicine) have both found that the abstinence-until-marriage requirement is an obstacle to effective prevention efforts and should be removed.

Based on interviews with key experts and an extensive review of current literature on female condoms, the findings and recommendations of this inquiry are as follows:

FINDING: U.S. agencies responsible for female condom programming and procurement do not have policies that promote the integration of female condoms into HIV prevention and family planning programs. Whether the U.S. procures female condoms in a given country is highly dependent on the personal biases of USAID mission staff.

RECOMMENDATION: USAID and OGAC should issue policy guidance promoting female condom procurement and programming within U.S.-funded development programs, including PEPFAR. As a signatory of ICPD, the U.S. should promote female condoms as a vital tool to prevent both pregnancy and HIV infection.

FINDING: The U.S. excels at assisting countries in female condom logistics and procurement.

RECOMMENDATION: The U.S. should expand technical assistance for female condom logistics and procurement to additional countries to increase HIV prevention efforts.

FINDING: Sustained product availability and effective programming is limited to a few countries. Accurate estimates for female condom needs do not exist.

RECOMMENDATION: The U.S. should apply intensive programming efforts to an additional three countries for scale-up and replication. These efforts could be used to create a more realistic assessment of global female condom needs for scale-up.

FINDING: PEPFAR currently promotes both male and female condoms by population to “high risk” groups instead of targeting promotion at the level of the general population. This results in stigmatization of condom use.

RECOMMENDATION: The U.S. should increase HIV prevention efforts by expanding the scope of female and male condom promotion to encompass the general public. Programming for female condoms will depend on each area’s epidemiological profile, and should be free of messages and attitudes that stigmatize condom use. (See Annex D: Populations that Benefit from Female Condoms.)

FINDING: More efforts by the U.S. are needed in female condom promotion and programming. Requiring PEPFAR focus countries to pay for male and female condoms out of their prevention budgets negatively impacts promotion of female condoms, as male condoms are cheaper and missions will purchase the cheaper product.

RECOMMENDATION: The U.S. should invest more funds in female condom promotion and programming. The U.S. should subsidize female condoms for PEPFAR-funded programs.

FINDING: Coordination between U.S. government cooperating agencies working on female condom availability and programming could be improved. Coordination around programming and procurement among international donors exists at the headquarters level but is not always replicated at the country level. At the country level, no mechanism exists to involve civil society.

RECOMMENDATION: At the country level, the U.S. should include civil society, especially women’s health and rights groups, in stakeholder meetings and encourage financing mechanisms that increase government-civil society collaboration in female condom programming.

FINDING: The requirement in the 2003 Global AIDS Act that 33% of PEPFAR prevention funds be spent on abstinence-until-marriage programs undermines the ability of countries to determine how best to prevent HIV transmission among their own populations and stigmatizes male and female condom use.

RECOMMENDATION: Congress should remove all earmarks and funding directives for abstinence-only, abstinence-until-marriage and fidelity prevention programs and fund comprehensive, integrated, and evidence-based HIV prevention programs that include female condoms and that promote and protect women’s health.

Introduction

HIV/AIDS is becoming a women's pandemic, and women need prevention now. They need the only tool for HIV prevention that women can initiate. They need access to the female condom and education on its use.

BEATRICE WERE, UGANDA HIV/AIDS ADVOCATE AND
2005 RECIPIENT OF THE HUMAN RIGHTS WATCH AWARD

Since 1965, the United States government has supported international voluntary family planning programs, increasing the availability and use of modern contraceptives among women and men in developing countries. Additionally, since 1974, the United States has played a major role in international agreements that recognize the basic rights of all couples and individuals to make responsible decisions about family size and birth spacing free from discrimination, coercion and violence and to have access to the information and means necessary to do so.

In 1994, at the International Conference on Population and Development (ICPD) in Cairo, the U.S. joined the global community to recognize the rights of individuals to attain the highest standard of sexual and reproductive health. Given the AIDS epidemic, the fundamental principles of the 1994 ICPD Programme of Action — *comprehensive, good quality reproductive and sexual health services that foster women's rights and empowerment* — are now more relevant than ever. The female condom has an important role in achieving the goals of ICPD, and moreover, the Millennium Development Goals set in 2000 by world leaders.

Access to female condoms and education about their use are critical means to preventing the spread of HIV, reducing unintended pregnancy and advancing the sexual and reproductive health and rights of all people worldwide. Increased support from donor governments like the United States is necessary in order to provide the funds needed to dramatically increase access to female condoms. However, when it comes to female condoms, there remains a lack of knowledge and understanding about the product among government officials, HIV/AIDS and sexual and reproductive health advocacy groups and service providers. The negative perceptions of female condoms within these different sectors obscure their many advantages and make it difficult to gain political will for increasing government investment in the method.

Part one of this report presents an overview of the female condom—the product and its relevance to U.S. HIV prevention strategies. The report highlights benefits of the female condom for both women and men. It also identifies key challenges to making the product widely accessible to women and men in developing countries. Part two of the report gives an overview of current U.S. support for procurement, distribution and programming of female condoms. It explains the respective roles of USAID and the Office of the Global AIDS Coordinator (OGAC) in female condom procurement and provides an analysis of factors that limit availability and effective implementation of female condom programming in the field.

Finally, the report offers recommendations for how the U.S. can and should increase its support for female condoms, working toward realizing its international commitment to promote the highest standards of sexual and reproductive health for all.

Part I: About Female Condoms

I. Why Female Condoms

The Female Condom: An Essential Tool for Women

The female condom is the first HIV-prevention technology developed since the onset of the AIDS epidemic.

“PLANNING FOR MICROBICIDE ACCESS IN DEVELOPING COUNTRIES: LESSONS FROM THE INTRODUCTION OF CONTRACEPTIVE TECHNOLOGIES,” G. BROWN ET AL., 2007

Expanded HIV prevention efforts that include all available methods and services are needed now more than ever. In 2007, UNAIDS estimated that 33.2 million people are living with HIV (UNAIDS 2007a). At this time, for every person who goes on treatment, there are six people who have just acquired HIV (Global HIV Prevention Working Group 2007).

The HIV/AIDS epidemic has evolved from an epidemic in the 1980s that mostly affected men who have sex with men to one where women represent 50% of those living with HIV worldwide (UNAIDS 2007a). In fact, the proportion of women among adults living with HIV/AIDS has grown in all regions of the Global South. Three quarters of all women living with HIV live in sub-Saharan Africa, where in 2007, women made up 61% of all adults living with HIV/AIDS, an increase from 59% in 2005. In the Caribbean, the proportion of people living with HIV who are women grew from 37% in 2001 to 43% in 2007 (UNAIDS 2007a, 8-9).

Given the epidemic’s increasing impact on women, access to a full range of approved prevention methods — especially those that women can initiate — is critical. “Increasingly, it is being realized that we cannot stand by, applauding progress in vaccine and microbicide development, without attending to women’s immediate needs... As a currently available device that women might use to protect themselves against HIV, the female condom stands alone” (Barbosa et al. 2007, 261).

Scientists are currently working to develop an effective HIV vaccine and an effective microbicide to prevent HIV acquisition. However, experts now estimate that it will be at least ten years until an HIV vaccine that is less than 100% effective is invented, approved and made available for use. The impact of any vaccine on slowing HIV transmission rates depends on the efficacy of the vaccine, the vaccine coverage level and supplemental HIV prevention behavior, including condom use (Andersson et al. 2007). Experts also estimate that the most optimistic prognosis for a microbicide that is at least 33% effective is, at a minimum, five years away (Black 2007). Since scientific experts predict that the first generation of vaccines and microbicides will not be 100% effective, there will still be a need to use both male and female condoms for years to come.

While male circumcision is newly proven to prevent HIV transmission in men, it is unclear to what extent and when women will be protected by it. Three randomized clinical trials showed male circumcision’s effectiveness in reducing the risk of HIV acquisition for men (Auvert et al. 2005; Bailey et al. 2007; and Gray et al. 2007). However, a new study

Access to a full range of approved prevention methods — especially those that women can initiate — is critical.

suggests that the protective effect of male circumcision may not transfer to reduced risk for female partners (Miller and Holmes 2007). Since HIV-negative circumcised men are less likely to acquire HIV, their partners will also be less likely to be exposed to the virus (Turner et al. 2007). However, men who are HIV-positive prior to circumcision and who do not wait for the wound to heal (approximately six weeks) may put their partners at higher risk of HIV acquisition (Wawer 2007). At any rate, male circumcision campaigns would need to be sustained in high HIV-prevalence settings over many years before having a substantial impact among women (Matovu et al. 2007).

Female Condoms: The Product

Several different female condom products are available for consumer use, and others are in development. The Female Health Company (FHC) manufactures the FC1 and FC2. The FC1 is a polyurethane sheath with flexible rings located at either end to aid insertion and hold the condom in place. More recently the Female Health Company introduced its second generation product, the FC2. The FC2 retains the design of the FC1 but is made of nitrile which allows FHC to decrease manufacturing costs. Medtech Products Ltd. manufactures the VA-Feminine Condom, also called the Reddy Female Condom. This product is made of latex and uses a sponge to secure the condom in a woman's vagina. The PATH Woman's Condom is still in development. Like the FC1, the Woman's Condom is a polyurethane sheath but relies on foam pads on the sides of the condom to hold the product in place.

The only female condom that has received regulatory approval from the U.S. Food and Drug Administration (FDA) is the FC1. In 2006, the World Health Organization (WHO) concluded that the FC2, under present manufacturing conditions, is acceptable for bulk purchase by UN agencies. UNFPA is now procuring the FC2 for programs worldwide. The FC2 is currently undergoing review by the FDA, and USAID plans to phase out procurement of the FC1 if this review results in approval (Spieler 2007). Though neither the Reddy Female Condom nor the PATH Woman's Condom have received regulatory approval from the FDA or been deemed acceptable for bulk purchase for UN agencies, the Reddy Female Condom is available for purchase in several countries, including India and Brazil.

Female Condoms vs. Male Condoms: A False Dichotomy

Both male and female condoms are needed to combat the AIDS pandemic. More than twenty years into the epidemic, efforts on HIV prevention are still drastically behind what is needed: In 2007, "only 9% of risky sex acts worldwide were undertaken using a condom, and the global supply of condoms is millions short of what is needed" (Global HIV Prevention Working Group 2007). The current supply of both male and female condoms is highly inadequate. "The supply of female condoms....is significantly below levels that would have an impact on the HIV epidemic. Large-scale production, distribution and promotion programmes, including cost reduction, are greatly needed" (Delvaux and Nostlinger 2007, 51-52).

While male condoms are more widely used and are currently less costly to produce, distribute and program, female condoms are a distinct product that is vital for HIV preven-

tion and offers several specific advantages for certain individuals. HIV prevention is radically different for men and women: men can initiate and control male condom use; however, women must either persuade men to use a male condom, refuse unsafe sex and risk violence, or try a female condom as a point of negotiation (Amaro 1995). A benefit of female condoms is that people with latex allergies can use the polyurethane and nitrile products (Welbourn 2006). The female condom can also provide some protection against herpes infection or re-infection by covering the outer parts of the labia, as well as the clitoris (Welbourn 2006). Female condoms can be used regardless of penis size. They can be inserted up to eight hours prior to sexual intercourse; thus, initiating protection does not require the interruption of sexual activity. As one woman from a study in Brazil put it: “When I am going to date and know I am going to drink, then I put the female condom before, because I think it is more safe, because I know that if I drink I can forget to put it on” (Dias et al. 2006, 73).

Some studies have shown that women, when provided with the additional option of female condoms, tend to use both male and female condoms, depending on the sexual partner and circumstances (Artz et al. 2000; Macaluso et al. 2000). Other studies have shown that female condoms were most likely to be used by those who did not want to use male condoms (Agha 2001). While more male condoms are sold than female condoms, it is important to give people a whole range of options (Stallworthy 2007). As was learned in the contraceptive field, a wide range of contraceptive options increases overall contraceptive use (Hatzell et al. 2003; Bruce 1990).

Numerous studies have found a wide range of acceptability among different groups of women, heterosexual men and men who have sex with men (Hoffman et al. 2004; Francis-Chizororo et al. 2003). However, female condom acceptability has by no means been universal (Hart et al. 1999), showing that female condoms must be introduced strategically, and education, training and support must be on-going. More operations research needs to be done for both male and female condoms to make their use more acceptable in all sexual relationships and to achieve consistent use (Feldblum 2007).

Female Condoms as HIV prevention

Studies of female condoms show that their ...ability to prevent disease transmission [is] similar to those of male condoms.

ROXANNE NELSON, LANCET INFECTIOUS DISEASES, 2007

The female condom is currently the only available and effective method to prevent HIV, as well as STIs, that is designed for female control and initiation. Correct use of the female condom has been estimated to reduce the per-act probability of HIV transmission by 97% (Trussell et al. 1994 cited in Fernandez et al. 2006). In addition, laboratory studies have shown that the female condom is impermeable to various STI organisms, including HIV (PATH and UNFPA 2006; Drew et al. 1990 cited in Hoke et al. 2007). Modeling exercises have estimated that perfect use of the female condom for one year by a woman having sexual intercourse twice per week with an HIV-positive partner can reduce her risk of acquiring HIV by more than 90% (PATH and UNFPA 2006). Male and female condoms, when used consistently and correctly, are comparable in effectiveness (Chen et al. 2007,

The female condom is currently the only available and effective method to prevent HIV, as well as STIs, that is designed for female control and initiation.

557-562; Macaluso et al. 2007, 88-96). Moreover, the female condom has “virtually no side effects” (Brown et al. 2007).

The female condom has only been approved by the U.S. FDA for pregnancy prevention and not for HIV prevention. But it would be ethically impossible to test female condoms for HIV prevention: one cannot conduct a trial and give participants only female condoms, and female and male condoms cannot be combined during the same sexual act. “There is no possibility of doing a true gold standard randomized controlled clinical trial for female condoms” (Gabelnick 2007). At a major consultation convened by PATH in 2005, a consensus was forged that it would be a poor use of funds to conduct a clinical trial to prove the effectiveness of female condoms; instead funds should be spent on programming (PATH 2005).

The Impact of Female Condoms on the Total Number of Protected Sex Acts

Numerous recent studies have demonstrated that female condom promotion and use increases the total number of protected sex acts, reducing sexually transmitted infections (STIs) and the risk of HIV transmission and acquisition.

Many women alternate between male and female condoms, thereby increasing the number of protected sex acts. A 2007 study of 818 female sex workers in Madagascar over 18 months found that short and medium term promotion of both male and female condoms increased the total number of protected sex acts and reduced STI prevalence. Participants were tested for chlamydia, gonorrhea and trichomoniasis every six months. They received condom promotion and risk reduction counseling and were counseled to use female condoms only when the male condom could not be used. Both male and female condoms were available for the same price. Following six months of male condom distribution, participants used protection in 78% of sex acts. With the addition of the female condom, protected sex acts increased to 83% at twelve months and 88% at 18 months. STI prevalence declined from a baseline of 52% to 50% with male condoms only at 6 months. With the female condom added, STI prevalence dropped to 41% at month 12 and 40% at month 18. “This trial provides moderate but promising evidence of public health benefits gained from adding the female condom to male condom distribution,” finding that female condom provision allows women to “substantially reduce risk of STI acquisition” (Hoke et al. 2007, 465).

Other studies from around the world have yielded similar results. In Mombasa, Kenya, adding female condoms to a male condom program for sex workers produced small but significant increases in consistent condom use with all sexual partners (Thomsen et al. 2006). In India, 65% of participating sex workers reported use of the female condom when their partner or client did not use a male condom (HLFPPT and TNS 2007). A systematic review of 237 articles found that ten studies revealed long-term use of the female condom, suggesting that the female condom reaches women less likely to use other dual protection methods (Vijayakumar et al. 2006).

A large study in Brazil highlights the effectiveness of the female condom in increasing the number of protected sex acts and provides an important model for female condom introduction (Barbosa et al. 2007). A 1998 to 1999 preparatory study at 20 sites in six cities in Brazil preceded a national effort to introduce the female condom into public health services. The State and Municipal Health Departments in each city committed to ensuring female condom availability at the end of the study. The twenty sites represented a range of different HIV epidemics within Brazil. Professional teams generated educational and training materials to use in the clinics, with availability publicized in the media. The health workers received a standardized 48-hour training program three times at each clinic. Following an educational session, 2,382 women volunteered to use the female condom and report their experiences. Of those seen fifteen days later, 1,782 had used the female condom at least once. Among those seen at the 90 day follow-up, 1,453 women had used female condoms at least once, with 1,296 stating that they liked the female condom and wanted to continue to use it, an acceptability rate of 54% (1,296 out of the original 2,382). Among these 1,296 women, barrier use at last intercourse, either with a male or female condom, increased from 33% at baseline to 70%. “The advent of the female condom substantially raised the proportion of sexual intercourse acts that were protected... The reasons are...not well understood, but may be due to the dialogue between partners stimulated by introduction of the female condom...or couples may prefer to alternate the method of protection they use” (Barbosa et al. 2007, 265). On the basis of the results of this study, the Ministry of Health in Brazil decided in 2000 to purchase two million female condoms to distribute in twenty states.

Female Condoms as Pregnancy Prevention

In addition to preventing transmission of HIV and other STIs, female condoms can also be used to prevent pregnancy. When used correctly with every act of sex, there will be an estimated five unintended pregnancies in one year for every 100 women using female condoms.¹ As commonly used, of 100 women using female condoms during the first year, there will be an estimated 21 unintended pregnancies (JHBSPPH et al. 2007).

Although few married heterosexual couples use condoms as their primary method of contraception, unmarried people and youth use condoms in greater proportions to prevent unwanted pregnancy. Use of condoms as the primary method of contraception for these groups is around 20% (UNFPA 2007). Given that female condoms offer effective pregnancy prevention, it is plausible that some young couples would want to use female condoms as one of their contraceptive options.

For many women of reproductive age living with HIV, pregnancy prevention is a serious concern. Numerous studies have shown that many people living with HIV continue to be sexually active, with findings ranging from 45% to 77% (Pearson et al. 2007; Gaede et al. 2006). As for all women, having the ability to choose whether and when to have children is a fundamental right of women living with HIV. Many seek to conceive children, and their right to do so should be fully supported with relevant services and counseling. At the same time, female condom accessibility, affordability and availability are critical for women living with HIV who do not wish to become pregnant: “For HIV positive women and girls, using a condom is...a matter of life and death. Female condoms could make a critically important contribution to protecting HIV positive women’s sexuality and continued sexual

¹ Of 100 women using the male condom, users experience two unintended pregnancies in the first year with perfect use, and 15 with typical use (JHBSPPH et al. 2007).

activity, as a fundamental part of our sexual and reproductive rights...” (Welbourn 2006: 32). As one woman living with HIV who uses female condoms put it: “My prime motivation for using this protection [female condom] has been to be able to continue to have a pleasurable and fulfilling sex life, safe in the knowledge that he [husband] and I are also practicing safer sex” (Welbourn 2006: 36). As part of prenatal and postnatal care, pregnant women living with HIV, as well as all pregnant women, should be counseled on male and female condom use so that they can freely and responsibly plan or prevent future pregnancies according to their fertility desires (See Annex D: Populations that benefit from female condoms).

Female Condoms as a Tool for Negotiation

Although female controlled HIV prevention methods cannot address the root causes of women’s vulnerabilities, they will provide women with more alternatives to protect themselves from infection. No one method will be right for every woman or girl, but reproductive health and rights are advanced by putting the tools of prevention in women’s hands.

“PREVENTION: AN UPDATE ON FEMALE-CONTROLLED METHODS FOR HIV PREVENTION,” J. MATHEWS AND T. HARRISON, 2006

Right now, the female condom is the only biomedical HIV-prevention tool that women can opt to use themselves.

“FEMALE INITIATED HIV PREVENTION: WHAT WILL WE LEARN FROM UPCOMING TRIALS?,” AIDS VACCINE ADVOCACY COALITION, AFRICAN MICROBICIDES ADVOCACY GROUP, AND GLOBAL CAMPAIGN ON MICROBICIDES, 2007

Qualitative studies over the last decade have shown that women view female condom use as a means of enhancing safe sex bargaining power within the relationship, particularly when women obtain female condoms in the context of an intervention focused on women’s sexuality and empowerment (Hoffman et al. 2004; Green et al. 2001; Okunlola et al. 2006; Rivers et al. 1998).

While some sex workers report that they have had good experiences using the female condom without the knowledge or consent of their clients, most women report needing to negotiate either male or female condom use (Welbourn 2006). Indeed, negotiation skills are critical for both male and female condom programs (Oyeyipo and Nyamukapa 2007). While some women argue that they want their male partners to use male condoms so that women do not have sole responsibility for preventing transmission or acquisition of HIV, other women say “with the female condom I can take control and I feel more confident” (Welbourn 2006, 35).

In this way, female condoms provide a needed alternative to male condoms. A recent study in Brazil found that “access to an alternative to the male condom makes it possible to increase women’s capacity to negotiate their protection from HIV and other STIs” (Barbosa et al. 2007, 265). An evaluation of the introduction of the female condom to South Africa found that a third of the women stated that they could use the female condom in situations where men refused to use male condoms (Mqhayi et al. 2003 cited in Mantell et al. 2005). As one partner of an intravenous drug user put it from a study in

Access to an alternative to the male condom makes it possible to increase women’s capacity to negotiate their protection from HIV and other STIs.

Brazil: “For me the female condom is better, at least I don’t have to keep asking him, insisting that he uses it [the male condom]. Because all the times that I insist, there is a fight...Then I use the female condom...” (Dias et al. 2006, 72).

While it is critical to have systems in place to assist women facing gender-based violence (Stewart 2007), the option to use the female condom was especially important for women in one study who reported partners who were violent and refused to use male condoms (Dias et al. 2006). A number of experts interviewed for this brief stated that there should be research on whether female condoms can be used in situations of gender-based and partner violence, both for heterosexual couples and for men who have sex with men (Harrison 2007; Campbell 2007; Frost 2007).

Female Condoms as a Source for Pleasure

Some women find sexual pleasure with the female condom superior to that of the male condom, or as one woman who participated in a Brazilian study of female condom users put it: “You feel more sensation with the female condom” (Dias et al 2006, 71). Some women reported that the external ring produced increased stimulation of the clitoris, facilitating orgasm. Some sex workers also reported that the female condom helped men to maintain their erection and ejaculate: “I had found clients who uses [sic] the male condoms and had difficulties to come. With the female condom, they come with no trouble” (Dias et al. 2006, 71).

Unlike the male condom, female condoms do not have to be removed shortly after ejaculation, and the non-latex versions can be used with any kind of lubricant (JHBSPH et al. 2007). Female condoms can be used in any sexual position and can be used with massage oils, which can bring added pleasure (Welbourn 2006). As a result, female condoms can be promoted as a way of enhancing sexual pleasure for both men and women. There is growing evidence that promoting pleasure alongside safe sex messaging can increase the consistent use of condoms and other forms of safe sex (Philpott et al. 2006).

Female Condoms as Protection during Anal Intercourse

Unprotected anal intercourse is the sexual behavior with the highest probability of HIV transmission (Royce et al. 1997 cited in Mantell et al. 2005). A recent meta-analysis found very high levels of HIV among men who have sex with men in low and middle income countries. Researchers found that these men had odds of HIV-seropositivity 19.3 times higher than background populations, with an urgent need for increased prevention strategies (Baral et al. 2007). After removing the inner ring, female condoms can be used during anal sex, thereby expanding choices available to heterosexuals, men who have sex with men, bisexual and transgender people seeking to engage in safe sex (Sippel 2007a). Studies have documented men who have sex with men using female condoms since 1998, with some studies showing a preference for female condoms over male condoms (Gibson et al. 1998). An early study of female condoms found that among 27 women living with HIV in the U.S. who used the female condom, 8 (or 30%) had also used the female condom for anal intercourse (Kalichman 2000). However, the female condom has not been specifically approved for anal use and clinical studies to do so would be prohibitively expensive at

this time (Gabelnick 2007). Only a handful of groups of men who have sex with men in Asia have access to female condoms (Frost 2007).

Female Condoms: Preparing the Way for Microbicides

The female condom, while a critical method to prevent HIV transmission and acquisition now, can also be a way to prepare for future microbicide use. “Several positive features of the female condom, such as enhanced sexual sensation for women and partners, greater coverage of the genital surface, insertion prior to sexual intercourse, greater control of prevention for women, augmentation of women’s and men’s choices of protection methods, design and packaging, and provider bias are likely to apply to microbicides as well” (Mantell et al. 2005, 4). Providers need to be trained to talk to women about anatomy and options for protection for both female condoms and microbicides.

Moreover, programming lessons learned from the introduction of the female condom promise to inform and ease microbicide uptake in the future. Civil society groups and social marketers that have made headway in educating communities about female condoms can play a similar role with microbicides. Groups like the Society for Women Against AIDS in Africa are “exceptionally skilled in getting people interested in and excited about [female] condoms...Such knowledge and skills will be invaluable as we develop more and more prevention technologies” (Germain 2007).

II. Female Condoms are an Imperfect Method with Unique Challenges

No currently available method is perfect for everyone – which is why in 2006, US\$222 million was allocated to inventing and developing a partially effective microbicide (HIV Vaccines and Microbicides Resource Tracking and Working Group 2007). Numerous challenges exist to promoting and distributing female condoms, such as stigma, cost, noise and physical attributes of the device.

Cultural and Societal Attitudes and Behaviors

The use of both female and male condoms has been stigmatized, often due to cultural, social, religious and political attitudes about sex and condoms. For example, condoms are often seen as appropriate only for use with “high-risk” groups such as sex workers or occasional partners rather than in marriage or long-term relationships, even though in some countries, married women are at high risk of acquiring HIV (UNAIDS 2006, 22; Hirsch et al. 2007; Ugonnet et al. 2002 cited in Matovu et al. 2007). Additionally, sex with a condom generally is deemed as less enjoyable and associated with the fear of something negative (disease or unwanted pregnancy). Overcoming such stigmatization and societal attitudes toward sex in order to normalize condom use regardless of a person’s marital or social status will take commitment from donors like the United States, as well as service providers and trainers.

Furthermore, in order for female condoms to gain increased acceptance by communities, gender roles that undermine or oppose women's empowerment and agency must be overcome. Studies have found that some women who have attempted to raise the issue of male or female condom use have been met with gender-based violence (Campbell et al. 2007; Maman et al. 2001; van der Straten et al. 1998). Gender-based violence and coerced sex pose a serious challenge to female condom use and acceptance. Such cultural and social norms and behaviors must be changed in order to create an environment that welcomes women-initiated protection, such as female condoms.

Cost

Purchased in bulk by USAID in 2007, the FC1 female condom cost US\$0.59 each, while male condoms cost only US\$0.0385 each.² This cost differential exists because the polyurethane material of female condoms costs more than the latex used to make male condoms and because far fewer female condoms are produced. The new nitrile female condom, FC2, can cost as little as US\$0.22 purchased in bulk (JHBSPPH et al. 2007). However, the U.S. government has not begun procuring FC2s because they do not yet have FDA approval.

UNFPA estimates that programming for reproductive health commodities requires four times the amount of investment as the commodities themselves (UNFPA 2007). PSI reports that in 2005, net unit costs for female condoms in countries where more than 3,500 units were sold ranged from US\$0.08 per unit sold in South Africa to US\$6.41 per unit sold in Mali. These costs included programming. The average global net cost per unit sold in 2005 was US\$1.28 (Greene 2008). Costs for implementing a new female condom project may start off high, but they generally decrease as the program matures and product sales and volumes increase. When PSI first started female condom promotion in Zimbabwe, the cost per unit was US\$4.50. However, as the program expanded and began increasing sales, the product plus programming cost dropped to less than US\$1 per unit (Madan 2007).

The additional cost of manufacturing and programming female condoms can result in increased costs for users, those who are least able to afford female condoms. In many countries, male condoms are available at no cost, but female condoms are prohibitively expensive (Welbourn 2006). Although reuse could lower the cost of female condoms, it would reduce the cost only marginally. The World Health Organization does not currently recommend reusing female condoms. However, due to the high cost and inaccessibility of female condoms in many regions, instances of reuse have been reported. Studies have shown that the structural qualities of the FC1 female condom are such that they can endure up to seven rounds of disinfection and reuse (WHO 2002). As a result, the WHO has developed guidelines for disinfection and reuse of the FC1 only. These guidelines are being tested for safety and efficacy. The WHO cautions that program managers must ultimately decide the feasibility and suitability of recommending reuse in their local settings (JHBSPPH et al. 2007; WHO 2002).

While female condoms are more expensive than male condoms, female condom use that averts HIV acquisition or transmission is highly cost effective compared to the costs of

² The price at which the U.S. procures male and female condoms fluctuates based on contract cycles. From 2003 to March 2007, the U.S. procured female condoms for US\$0.59 per unit. In 2008, the USAID | DELIVER Project will purchase female condoms from the Female Health Company at a unit cost of US\$0.80. In 2007, the price of male condoms was US\$0.0385, which will drop to US\$0.0357 in 2008 (Anderson 2007b). For the purposes of this document, the authors will use the 2007 U.S. procurement prices.

Female condoms should be assessed in terms of marginal cost effectiveness.

antiretroviral therapy (ART) for life (Dowdy et al. 2006). In fact, female condoms should be assessed in terms of marginal cost effectiveness, i.e. when all the factors of programming and unit price are taken into account, what is the marginal cost for the female condom for every additional risky sex act protected? There are likely some circumstances where no additional sex acts will be protected by male condoms. The female condom becomes cost effective in this situation because it is protecting risky sex acts that would otherwise not be protected no matter how many male condoms were available in a particular setting (Stallworthy 2007). In addition to saving the financial costs of ART, averted HIV infections provide huge benefits to the individual, community and the country. Compared to other HIV prevention interventions, such as voluntary counseling and testing, which can cost up to \$300 per client at the beginning of program implementation, female condom promotion and programming is highly cost-effective (Madan 2007).

Noise, Appearance and Ease of Use

The FC1 has been reported to be noisy, or as one woman put it: “a wrinkling noise, like a supermarket bag.” However, as another woman put it, “once you have the female condom warmed up to body temperature the noise seems to stop – but then again maybe I just stop listening at that stage?” (Welbourn 2006, 33). FC2s are reported to be less noisy.

Many find that female condoms are not sexually appealing in appearance and difficulties with insertion and use during sex are common for first time users, but these barriers and perceptions have been effectively altered with on-going education, training and practice. In the words of one woman: “The sight of it is a serious turn-off” (Welbourn 2006, 34); however, a recent study of sex workers in India funded by the British Department for International Development (DFID) found that promotion efforts successfully combated negative impressions of female condoms. On first seeing the female condom, over 75% felt it was too big, over half felt it was too clumsy and almost half found it difficult to use. After a one-year intensive effort to promote female condoms, 45% of respondents found female condoms easy to use (HLFPPT and TNS 2007).

III. Access and Availability of Female Condoms

We haven't tried hard enough with the female condom yet.

PAUL FELDBLUM, SENIOR EPIDEMIOLOGIST, FAMILY HEALTH INTERNATIONAL, 2007

The female condom is currently available in 108 countries (Oxfam Novib et al. 2007). However, female condoms are not readily accessible in most countries, and accurate global estimates for female condom needs do not exist. As noted above, studies have shown that female condoms are often used in situations where one or both partners find the male condom unacceptable, therefore demonstrating a unique need for the product (Francis-Chizaroro and Natshalaga 2003; Dias 2006). However, current UNFPA estimates of global female condom need are based on the number that must be purchased in order to bring their per unit cost closer to that of male condoms. While sales data for female condoms can be generated, there is currently no accurate way to assess unmet need.

Insufficient male and female condoms are available to those who need them globally for HIV prevention. In 2007, almost 26 million female condoms were distributed worldwide (Female Health Company 2007). This is compared to roughly 11 billion male condoms (UNFPA 2007, 17). UNFPA estimates that condom use in 80% of non-marital and 30% of marital risky sexual encounters is needed to significantly reduce HIV infection rates. UNFPA defines risky sex as: sex between casual partners, sex between men, sex with a person living with HIV, sex with a sex worker and marital sex when one partner has multiple partners (UNFPA 2005). To meet these targets, UNFPA estimates that 13.5 billion male and female condoms would have been needed for HIV prevention in 2006 (UNFPA 2007).

Compared to the estimated 11 billion male condoms that are produced every year, female condoms still account for only about 0.2% of the total condom supply in the world. For every U.S. dollar spent on procuring male condoms, donors spend about five cents on procuring female condoms (Brown et al. 2007).

Female Condom Programming

Female condoms have had only half-baked programming – so when the program fails, the blame is often put on the product rather than the programming, or lack of it.

YASMIN MADAN, COUNTRY DIRECTOR, PSI VIETNAM, 2007

Programming is critical to creating demand for the female condom and promoting continued use (Madan 2007; Warren 2007). “Most disease prevention and contraceptive methods take years after development to achieve widespread acceptance” (Mantell 2005, 13) – and the female condom has been no exception to this rule. Experiences in Brazil, Ghana, Zimbabwe and South Africa, where the female condom has been actively promoted, indicate that effective programs can generate demand (Warren and Philpott 2003).

Female condoms need sustained support for introduction, marketing and programming. In the few countries that have seen sustained uptake, governments have made long-term commitments to providing female condoms and donors have provided sustained support (Brown et al. 2007).

“In other countries, lack of sustained program support and funding has resulted in very poor access and low levels of use. Donor support has been uneven and rarely sustained over several years” (Brown et al. 2007, 12). Moreover, supply must be consistent. Even in Zimbabwe, which has one of the most successful female condom programs, an assessment of the Ministry of Health found that “the ultimate demand for the female condom to date has not been measured, principally because there has never been a time when supplies were available on a consistent basis” (Zimbabwe Ministry of Health and Child Welfare 2006, 10).

Having adequate supplies is necessary but not sufficient to generate demand: programs are needed as well. A study of 255 female condom users in Brazil found that the following issues were critical to acceptance and use of female condoms:

- Rehearsal with the female condom, including practicing with a female pelvic model.
- Counseling about anticipating a period of adjustment during which difficulties in using the female condom are considered normal and should be expected;

- Sufficient encouragement, noting the advantages and pleasure;
- Testimonials from others who liked and adopted the female condom;
- Learning strategies to negotiate condom use with sexual partners;
- Information on female genital anatomy;
- Information on STIs.

Follow-up sessions in the Brazil study to track the number of female condoms distributed and frequency of use unintentionally contributed to the success of female condom adoption, as it enabled health workers to assess and address client problems with female condoms (Dias et al. 2006). A review of 135 studies found that initial negative reactions to female condoms become more positive over time (Vijaakumar et al. 2006), indicating that follow-up with female condom users is critical.

An ideal situation in each country would include procurement of female condoms by the government, normalization of female condom use by social marketers, and affordability of female condoms managed by suppliers and providers. Strong links among communities, civil society, social marketers and the public sector would facilitate the creation of demand and the management of supply. This ideal has yet to be reached, as linkages have not yet developed and communities do not have enough awareness of female condoms to generate demand (Nelson 2007a).

Female Condoms Should be Programmed and Distributed Creatively

We need to reach the woman on the street, in the village, where she lives – how does she get a female condom?

MARY ANN LEEPER, SENIOR STRATEGIC ADVISOR, FEMALE HEALTH COMPANY, 2007

While female condoms can be distributed through health centers by nurses or other health personnel, given the shortage of health personnel exacerbated by the HIV/AIDS crisis, other venues have been used successfully. Peer education and distribution by youth, sex workers, pharmacies, hairdressers, and HIV/AIDS support groups have all been successful approaches. For example, Colectiva Mujer y Salud, an NGO in the Dominican Republic, conducts training with rural women with low literacy skills using pictures of female condoms and other information on low risk and high risk sexual practices, as well as information on how HIV is not transmitted (Gay et al. forthcoming). Given the challenges of the impact of the HIV/AIDS crises on health providers (PHR 2004; IOM 2005), it would be most strategic to provide programming on female condoms in communities, while not ignoring obvious linkages within health services.

The Population Council is currently undertaking a mapping experience of female condom programming in Kenya and is implementing a three-pronged intervention to incorporate the female condom into VCT services, private sector workplace HIV prevention programs and as part of a service integration strategy in selected family planning sites (Brady 2007).

Female Condoms Require Training for Providers and Consumers

Provider training programs are critical (Hoffman et al. 2004). Provider norms should require counseling on the female condom option, and information on female condoms should be given in pre-service training in nursing schools, medical schools and any community provider training program. If providers are inadequately prepared to counsel women about the challenges of female condom initiation, or believe that female condoms are a method only for high risk groups, they can contribute substantially to slow uptake of female condom use (Hoffman et al. 2004). A study of 1,740 sexually active consumers of female and male condoms surveyed in 1998 found that women who had obtained information about the female condom from physicians or clinics were more likely to have used the method consistently (Meekers and Richter 2005).

Providers also must be made aware that adequate follow-up and ongoing support programs are essential to clients' acceptability and continued use of the product. "Introducing the female condom to clinic staff...(and) in turn to women clients, takes effort and commitment on the part of staff, not only at the outset, but continuously after training" (Barbosa et al. 2007, 265). A study in Brazil found that clinics with only incipient health education programs retained only 54% (114 women out of the 235) of those who returned for female condom follow-up; whereas clinics with a strong health education program and a community outreach program retained 78% (511 of 669) of those who returned for female condom follow-up (Barbosa et al. 2007).

It is important to program female condoms for a range of groups so that female condom use is not stigmatized.

Female Condom Distribution Priorities

Male or female condoms should be used in all sexual acts, unless both partners are known to be free of HIV and STIs and consistently sexually monogamous over the course of their sexual relationship. However, both female and male condoms have been stigmatized. As noted, condoms are often seen as only for use with sex workers or occasional partners rather than in marriage or long-term relationships. While sex workers are at high risk of HIV acquisition and therefore should have access to female condom programming, it is important to program female condoms for a range of groups so that female condom use is not stigmatized (Oxfam Novib et al. 2007).

Because HIV is still so highly stigmatized, female condoms should be marketed not just as a method for HIV and STI prevention, but also as a contraceptive. Studies have shown that women find that their negotiation skills for safe sex are increased when they assert that female condoms are being used for contraception – an important programming consideration (Dias et al. 2006).

Female condoms should also be promoted for heterosexual men as well as men who have sex with men so that men can suggest female condom use with their partners. A study in Brazil of 255 women and 29 men whose partners used female condoms found that it is sometimes the male partner who introduces female condom use (Dias et al. 2006). Yet despite studies showing the importance of involving male partners (Witte et al. 2006), few female condom programs have targeted men or couples directly (Mantell et al. 2005).

Based on an area's epidemiological profile, female condom programming should target different sectors of the population. For example, pregnant women are at increased risk for HIV infection during pregnancy (Mataka 2007). Antenatal care providers should alert

pregnant women to this risk and to their prevention options, including female condoms. Also, adolescents should learn about female and male condoms prior to becoming sexually active, making it more likely that they will consistently use condoms in the future (Siegel et al. 2001; Hawkins et al. 1999). A list of populations who can most benefit from female condom programming is included in Annex D.

Civil Society and Women's Groups as Advocates for Female Condoms

In Zimbabwe and Ghana, women's rights and reproductive health organizations played important roles in bringing female condoms to their countries (Ebin et al. 2006). In both countries, women's groups saw a need for the product and advocated for their governments' support in procurement. In Zimbabwe, the Women and AIDS Support Network (WASN) worked in coalition with the government to develop a strategy for introducing female condoms into the country. WASN also organized a nationwide petition drive in support of female condoms that coincided with the government's efforts (Ebin et al. 2006). Whereas the Zimbabwean government ultimately worked with PSI to conduct mass media campaigns and coordinate public and private sector distribution, civil society took responsibility for these activities in Ghana (Ebin et al. 2006). In some countries, such as Nigeria, civil society groups are the most important distributor of female condoms (Oyeyipo and Nyamukapa 2007). Civil society's close relationships with populations at risk for transmitting or contracting HIV and the significant role that civil society plays in championing the rights and needs of these individuals should qualify civil society for a role in negotiations around female condom procurement and programming.

PART II: Female Condoms: U.S. Foreign Policy and Assistance

In many ways, the U.S. government has led the global community in terms of the female condom and its use in HIV prevention efforts around the world. However, bureaucratic obstacles, funding restrictions, and a lack of high level commitment to the method have significantly hindered the expansion of U.S.-funded female condom distribution efforts, including in populations with high HIV prevalence.

I. U.S. Role in Female Condom Procurement, Programming and Distribution

U.S. Global HIV Prevention Strategy and Female Condoms: PEPFAR and USAID

The U.S. Government has supplied nearly 1.9 billion condoms worldwide from 2004 through 2007 — procuring both female and male condoms. In fact, Dr. Peter Piot of UNAIDS has said that the U.S. Government is the largest supplier of condoms, more than all other developed countries combined.

THOMAS KENYON, MD, MPH, PRINCIPAL DEPUTY GLOBAL AIDS COORDINATOR AND CHIEF MEDICAL OFFICER, OFFICE OF THE GLOBAL AIDS COORDINATOR, 2007

In the January 2003 State of the Union Address, President George W. Bush announced a new U.S. initiative to address the global AIDS pandemic. Several months later, the U.S. Congress passed the *United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003* (Global AIDS Act), which authorized US\$15 billion over five years (2004 – 2008) for the President’s Emergency Plan for AIDS Relief (PEPFAR).³ The initiative’s original goal was to prevent 7 million new HIV infections, treat 2 million people living with AIDS related illnesses, and provide care and support for 10 million persons affected by AIDS.

The Global AIDS Act created the Office of the Global AIDS Coordinator (OGAC) within the Department of State to oversee PEPFAR. OGAC is responsible for the oversight and coordination of all resources and international activities of the United States government to combat the HIV/AIDS pandemic.

Prior to PEPFAR, the U.S. Agency for International Development (USAID) was the government agency primarily responsible for coordinating U.S. efforts to combat global HIV/AIDS. In addition to supporting programming, USAID allocated its global health funding to procure male and female condoms for family planning and HIV prevention. Although OGAC is now responsible for coordinating U.S. international HIV/AIDS assistance, male and female condom procurement under PEPFAR is coordinated through USAID.

³The U.S. Congress is expected to reauthorize PEPFAR for another five years in 2008.

Female condoms were just 1.6% of total U.S. condom procurement in 2007.

The U.S. and Female Condom Procurement

The United States government plays an important role in shaping global trends in reproductive and sexual health supplies. U.S. funding for international family planning and HIV prevention commodities represented 42% of global donor support in 2006 (UNFPA 2007). This leadership has extended to the female condom.

The U.S. had an important role in bringing the female condom to market by supporting early acceptability studies (Gabelnick 2007). USAID funded the CONRAD Program and FHI to organize the Phase III clinical trial of the FC1 for pregnancy prevention and to analyze and report the findings. USAID supported this work because proof of FC1's safety and effectiveness would lay the groundwork for FDA product approval in the U.S., which in turn would facilitate product approval and registration in developing countries. USAID also prioritized and supported research, including program/operations and acceptability research, partnering with FHI and the Population Council's Horizons Project, among others (Spieler 2007).

After the UNFPA and the German government, the U.S. is the third largest supporter of female condom programs globally (Deperthes 2007). Of the 108 countries where female condoms are distributed, the U.S. has supplied female condoms to 30 countries over the last decade and to 16 countries in 2007 (NEWVERN 2008).²

The U.S. has dramatically increased distribution of female condoms in recent years, with shipments growing from 1,109,000 in 2003 to 8,743,000 in 2007. However, even considering these increasing numbers, female condoms were still just 1.6% of total U.S. condom procurement in 2007 (NEWVERN 2008). By this measure, and in comparison to the substantial unmet need, U.S. investment in female condom procurement falls short.

The Commodity Fund

In 2002, USAID established the Commodity Fund to help overseas missions address the global need for HIV prevention. The Commodity Fund is a central procurement mechanism that provides USAID missions with male and female condoms for HIV prevention programs free of charge (DELIVER 2006). Since condoms from the Commodity Fund are solely for HIV prevention or dual protection within HIV prevention programs, missions that want to procure female condoms for family planning programs that lack an HIV component are not eligible to receive free female condoms through the Commodity Fund and must pay for the method out of their mission budgets. Also, beginning in 2006, the U.S. government decided that because HIV/AIDS funding levels for the fifteen PEPFAR focus countries were significantly higher than those for non-focus countries, the focus countries must pay for male and female condoms from their own budgets (Rilling 2008).

The U.S. and Female Condom Logistics

Commodities security, including effective logistics management and distribution systems, is essential to ensuring the success of the female condom as a prevention method (Sarley 2007). Through a USAID-funded contract implemented by John Snow Inc. (JSI)

²Other bilateral donors for female condom procurement include the German, Canadian, British, and Dutch development agencies.

and subcontractors, the USAID | DELIVER PROJECT works to ensure that supplies of contraceptive and HIV commodities, including the female condom, align with the quantity, quality, and distribution needs of each country covered by the project. JSI assists host governments and USAID missions in forecasting future need and facilitates discussions between USAID mission staff, country governments, social marketers and other recipients to determine the demand for contraceptives, including female condoms. The project also provides partners with software to help calculate need. In some countries, the project manages the actual distribution of commodities (Sarley 2007). According to Robert Nelson, program and sales director for the Female Health Company, “USAID is the best to work with in terms of procurement. USAID has the fewest pipeline and logistical problems and are able to meet requests in a timely manner” (Nelson 2007b).

However, the USAID | DELIVER PROJECT only operates in countries where USAID missions have requested, and can pay for, such support (Sarley 2007b). As a result, the project is not currently involved in female condom logistics management in every country that receives U.S.-procured female condoms.

The U.S. also excels at providing multiyear procurement commitments and flexible partnerships, which ensure the steady supplies vital to program success. USAID first began shipping the Female Health Company’s FC1 in 1998 (NEWVERN 2008). USAID’s three-year contract with the Female Health Company (FHC) to procure female condoms between 2003 and 2006 was extended through March of 2007 (Anderson 2007b). For the remainder of 2007, USAID procured female condoms from FHC through the USAID | DELIVER PROJECT. In 2008, USAID plans to continue procuring female condoms through USAID | DELIVER. The agency anticipates a smooth transition from FC1 to FC2, should the FDA approve the newer product (Rilling 2008).

The U.S. also surpasses others at anticipating procurement intentions and communicating these to FHC (Nelson 2007c). As a result, female condom recipients in the countries to which the U.S. is shipping rarely experience stock-outs. Unfortunately, as happened in Tanzania in 2006, stock-outs can occur when USAID missions do not submit their orders for female condoms in a timely manner (Pipeline 4.0 2007), because missions must allow three to six months lead time for additional shipments (Blackburn 2007). The fault does not always lie with the missions, however, since they must receive accurate information from programmers and marketers. While stock-outs are an obstacle to sustaining interest in female condoms, they can be avoided through coordination and communication between suppliers and groups working directly with consumers.

The U.S. and Female Condom Programming

In Zimbabwe, PSI’s U.S.-funded programs used mass media to position female condoms as a contraceptive for urban women so that female condom use for HIV prevention was not stigmatized. Due to PSI’s work, 65% to 85 % of Zimbabwean women surveyed at hair salons remembered *care* branded female condoms without prompting (Madan 2007). Because approximately 97% of Zimbabwean women visit a hair salon at least once a month, PSI also promoted female condoms for women in Zimbabwe using hair salons in low-income, urban areas. With funding from the U.S. and British governments, PSI trained female hair stylists from 500 salons in low-income neighborhoods to demonstrate correct use, discuss common misperceptions and answer questions on female condoms.

Salons sold female condoms at subsidized prices. Between 2002 and 2004, the percentage of Zimbabwean women who reported ever using the female condom increased from 15% to 28%. Women who had observed a female condom demonstration at a hair salon were 2.5 times more likely to have tried the female condom than were women who had not seen a female condom demonstration. Between 1997 and 2007, PSI's annual sales of female condoms increased from 120,720 to over 2.2 million (Greene 2008). In 2006, 53% of female condoms were sold through hair salons (AIDSMark 2007, 27). In addition to promoting female condoms in hair salons, pharmacies, and retail outlets, female condoms were integrated into HIV/AIDS and reproductive health programs, such as HIV/AIDS home based care, VCT, PMTCT, family planning and support groups for people living with HIV (Zimbabwe Ministry of Health and Child Welfare 2006; Madan 2007; AIDSMark 2007, 29).

Through the HIV/AIDS social marketing project AIDSMark, USAID also supported PSI in promoting female condoms in Myanmar and Thailand to female sex workers and men who have sex with men under the brand name *feel* (AIDSMark 2007; PSI 2007b).

Another USAID-funded project, Men as Partners (MAP) of Engenderhealth, is doing innovative work in providing workshops and training for men to discuss gender norms and learn about reproductive health. In a U.S.-funded MAP program in Kenya, health education workshops provided participants with information on female condoms (The Acquire Project and The National Youth Service 2004; Levack 2007). However, at the time of the MAP project, only limited supplies of female condoms were available (The Acquire Project and The National Youth Service 2004). The U.S. has not supplied female condoms in Kenya since 1999 (NEWVERN 2008), while UNFPA and IPPF have donated just 489,400 female condoms to Kenya since 2000 (RHInterchange 2007). If female condom supplies are increased, MAP trainings could offer an important opportunity to test whether educating men about female condoms can significantly increase product demand.

II. Limits on U.S. Procurement and Programming of Female Condoms

In U.S. foreign assistance policy, female condoms have been successful only where they have had individual champions within USAID missions, cooperating agencies, or governments and civil society overseas. Although female condom procurement and programming has increased, it is clear that their potential impact is much, much greater. For example, since the implementation of PEPFAR in 2004, only five PEPFAR focus countries (Haiti, South Africa, Tanzania, Vietnam and Zambia), have ever received U.S. procured female condoms. Despite the need for female condoms, between 2001 and 2007, USAID shipped eighteen *million* female condoms as compared to almost three *billion* male condoms (RHInterchange 2007). Furthermore, while USAID has supported female condom programming in over twenty countries through AIDSMark, many of these projects were pilots and funding was not sustained for more than three or four years (Mahdi 2007).

Lack of Policy Guidance on Female Condoms

One of the reasons that more female condoms are not being distributed is that high-level officials are not encouraging U.S. government field staff to do it. While USAID headquarters have queried missions globally on country needs for female condoms on an annual basis, USAID has had no specific guidance to promote female condoms. At the country level, therefore, female condom promotion can depend on the personal beliefs of the USAID Health, Nutrition and Population (HNP) officer, mission director, or U.S. ambassador rather than on the evidence regarding the product's acceptability and efficacy. For example, despite a number of studies with evidence to the contrary, one USAID Resident Advisor in South Africa stated: "No hard evidence exists to date that female condoms provide greater empowerment for women over male condoms to take control of their sexual health" (Wilson 2007).

The U.S. Global AIDS Act of 2003 that authorized PEPFAR funding does not explicitly mention female condoms, only "condoms" (Sippel 2007b). The 2007 PEPFAR Report to Congress, while only explicitly mentioning female condoms a few times, does express support for expanding social marketing of female condoms and promoting female condoms for people living with HIV (OGAC 2007a). However, female condoms are not cited in any OGAC program guidance, nor does OGAC have policies encouraging the inclusion of female condoms in HIV prevention efforts. Even in calling for "prevention services that empower them [women and girls] to prevent HIV infection," the *Program Self-Assessment Tool for Mainstreaming Gender into PEPFAR Programs* fails to cite female condoms as an intervention (PEPFAR Gender Technical Working Group 2007).

Lacking the incentive of specific policy guidance on female condoms, U.S.-funded agencies such as PSI have not prioritized female condoms. "PSI is one of the largest distributors of female condoms; however, even within the PSI network, female condoms remain a marginal product, with programming dependant on the presence of female condom 'champions' in individual offices" (Westfall et al. 2005).

Procurement Policies and Cost Differential

While it is the role and duty of USAID missions to pay attention to cost effectiveness when making procurement decisions, U.S. government procurement policies complicate female condom provision because they set up a cost-benefit analysis that works against the product. As noted above, in 2002, USAID established the Commodity Fund to provide missions with free male and female condoms to address the need for HIV prevention (DELIVER 2006).

Beginning in 2006, PEPFAR focus countries were no longer eligible to receive male and female condoms at no cost from the Commodity Fund (see Commodity Fund text box). As a result, focus countries must use their PEPFAR prevention funds to purchase condoms. A number of experts interviewed noted that this presents a major obstacle to female condom procurement because of the significant cost differential between male and female condoms. PEPFAR focus countries are allotted a finite sum of money for condom procurement, and country coordinators must divide this sum between male and female condoms. Given the high cost of female condoms (US\$0.59) compared to male condoms (US\$0.04), barring any incentive or policy directive encouraging female condoms, there is

Female Condom promotion can depend on personal beliefs of the USAID officer rather than on evidence of acceptability and efficacy.

little reason for coordinators to request the higher-priced product. In fact, given the significant pressure on country coordinators to show high numbers of program beneficiaries, there is a substantial *disincentive* to female condom programming in PEPFAR focus countries.

Ironically, integrating female condoms into HIV prevention programs is actually cheaper for USAID missions in non-PEPFAR focus countries, as they can access supplies through the Commodity Fund at no direct cost to the missions. According to several persons interviewed, there are strong indications that this has had a positive impact on female condom programming in these countries.

The Commodity Fund also does not provide female condoms at no cost to missions for contraceptive use. Mission-funded family planning programs that lack an HIV component are not eligible, and missions must pay for the method out of their budgets. According to a USAID procurement specialist, missions rarely purchase female condoms for family planning (Blackburn 2007). By providing free female condoms for HIV/AIDS programs but forcing family planning programs to pay for them, USAID deters missions from incorporating female condoms into their family planning activities, risks stigmatizing the method as a product used only for disease prevention, and ignores the vital role that family planning centers play in providing women with a range of pregnancy prevention options.

U.S. government procurement policies in turn affect government contractors and their programming choices. Program managers worldwide recognize the potential for female condoms in their prevention activities, but lament the lack of funding to support programming. According to a former deputy country director for PSI Zimbabwe, female condoms have not lived up to their potential as a mainstream prevention method because they have only ever received “half-baked programming.” In other words, female condom programs rarely fully consider crucial aspects of programming for creating informed and sustained demand, such as integration with other services, opportunities for private distribution such as hair salons, and training at the provider and user levels (Madan 2007). Other program managers must struggle with whether to incorporate information about female condoms into their prevention portfolios for fear of promoting a product that might be popular, but inaccessible or unaffordable (Lungo 2007).

PEPFAR Funding Restrictions

Within the Global AIDS Act of 2003, the U.S. Congress mandated that 33% of PEPFAR prevention funds be allocated for abstinence-until-marriage programs starting in 2006. From its inception, OGAC adopted the “ABC” (Abstain, Be faithful, use Condoms) approach to HIV prevention and interprets the abstinence-until-marriage earmark to apply to programs that exclusively teach abstinence and/or being faithful (A or AB only).

A set of studies in Mexico, Nigeria, Uganda, Vietnam and Papua New Guinea, funded by the National Institutes of Health and published by the *American Journal of Public Health* found that for most women around the world *marital sex represents their greatest risk for HIV infection*. Responding to the well-documented epidemiological evidence that men’s extra-marital sex is a major element of HIV risk for married women, researchers found that prevention messages that associate infidelity with immorality simply are not compatible with different cultural views on marriage (Hirsch et al. 2007).

The studies also found that “ABC” programs may actually be fueling the spread of AIDS

because the approach stigmatizes those who use condoms or those who ask their marriage partners to use condoms. In “ABC” programs, abstaining or being faithful in marriage are presented as the most moral choices, with condoms as a last resort—only to be used if you are sexually immoral because you failed to choose “A” or “B,” or are part of an “at-risk” population. As a result, women are discouraged from asking their husbands to use condoms, because asking them to do so is tantamount to accusing them of infidelity and implicates them as being immoral. Stigmatizing condoms also discourages men from using condoms in extramarital sex, because their use demeans those extramarital relations.

Adolescents and youth are also poorly served by PEPFAR prevention programs. While PEPFAR funds can support programs that provide adolescents aged 15 or older with information about condoms, programs cannot access PEPFAR funds to promote or provide condoms to youth in most situations, and programs that target adolescents under the age of 15 cannot receive funding to promote the most basic information about condoms (Boonstra 2007). There is scant evidence that any PEPFAR programs explicitly mention female condoms for adolescents. However, FHI/YouthNet, supported by USAID, produced materials for working with adolescents that included detailed information about female condoms (FHI 2007).

The U.S. policy focus on abstinence and marriage is based on the presumption that discussion of condom use encourages adolescent sexual activity. In fact, a review of 83 studies measuring the impact of curriculum-based sex and HIV education for heterosexual partners, including studies in Brazil, Kenya, Mexico, South Africa and other countries of the Global South, found that many of the sexuality education programs that also discussed or promoted the use of condoms and/or other forms of contraception if young people choose to be sexually active, delayed the initiation of sex or decreased the number of sexual partners, improved efficacy in refusing unwanted sex, and increased condom or contraceptive use. None of the programs in developing countries hastened or increased sexual behavior (Kirby et al. 2007).

Promoting abstinence as a sole option for adolescents and young adults raises serious human rights concerns, as it involves withholding life-saving information (Dworkin 2007). All adolescents should receive age-appropriate sexuality education, along with age appropriate information on female and male condoms, as well as life skills planning (FHI/YouthNet 2005). In fact, young women and men need to learn about female condoms before they become sexually active, as sexuality education prior to initiation of sexual activity is most effective in preventing transmission of HIV (Gay et al. 2005; Hawkins et al. 1999; Stanton et al. 1998).

Moreover, two congressionally mandated studies have been conducted on PEPFAR; one by the Government Accountability Office (GAO) and the other by the Institute of Medicine. Both studies found that the earmark requiring that one-third of all U.S. global HIV prevention funding be spent on abstinence-until-marriage programs is undermining global efforts to prevent seven million new HIV infections by 2008.

The IOM noted: “it [PEPFAR] needs to urgently put the accent on preventive measures of proven efficacy on a much larger scale” (Sepulveda 2007). PEPFAR guidance contributes to stigmatizing condom use by promoting condoms for “high risk” situations (OGAC 2006). PEPFAR stresses “the importance of marriage and mutual faithfulness in reducing the transmission of HIV among individuals in long-term relationships” (OGAC 2006, 8). Yet, marriage and marital fidelity of sero-discordant couples places the sero-

Young women and men need to learn about female condoms before they become sexually active, as sexuality education prior to initiation of sexual activity is most effective in preventing transmission of HIV.

Nearly everyone is a high risk person in a generalized epidemic with high prevalence; thus most people need information about and access to all preventive methods, including condoms.

negative partner at high risk of HIV acquisition unless there is correct and consistent male or female condom use. The recent IOM study noted, “It is critical that prevention succeed, and thus PEPFAR needs to have strong mechanisms for ensuring that all proven prevention interventions are available when needed. Even as defined by PEPFAR, nearly everyone is a high risk person in a generalized epidemic with high prevalence; thus most people need information about and access to all preventive methods, including condoms” (IOM 2007, 261).

Under PEPFAR, organizations with a religious or moral objection are exempt from having to promote and provide condoms, even when doing so is necessary to address the needs of the population for which they are working (IOM 2007, 261). Others interviewed for this brief stated that PEPFAR was enormously effective in bringing attention and resources directly to the AIDS pandemic but that the focus on abstinence had weakened prevention efforts. As a USAID memo of 1998 noted, and it is still true now, “There is a serious concern that introduction of the female condom in high risk settings alone could stigmatize the female condom” (de Zalduondo et al. 1998).

IOM notes that PEPFAR does “not fully capitaliz[e] on opportunities to integrate prevention activities optimally with each other and into treatment and care programs.” IOM also recommends that PEPFAR will need to “emphasize effective, evidence-based prevention with the same urgency and intensity it has focused on treatment” (IOM 2007, 7). In the short-term, U.S. funds should support the obvious linkages which will have the most impact on the AIDS pandemic. Universal access to treatment under PEPFAR should be linked to comprehensive condom programming. Therefore, the U.S. government and PEPFAR should actively program and promote female condom use, particularly among sectors of societies where use will have a major impact on the AIDS pandemic, keeping in mind that these categories can overlap. (Appendix D contains a list of populations that would benefit from female condom promotion.)

Female Condom Supplies and Programming Coordination

USAID funded female condom social marketing and programming through AIDSMark, a cooperative agreement with PSI and six other partners. This agreement ended in December 2007, and was replaced by AIDSTAR (AIDS Support, Technical Assistance Resources), which still includes PSI, among others. Under AIDSTAR, USAID will fund partner organizations to provide technical assistance and implementation support to global HIV care, treatment and prevention programs (USAID 2007; PSI 2007c). It will be up to USAID missions to determine whether or how these programs will incorporate female condom components.

While in some countries the coordination between PSI and JSI is extremely effective, in other countries the coordination could be improved. Coordination can depend on personal factors, such as the interest of the JSI and/or PSI country representative, their working relationship, and their personal commitment to the female condom, rather than a particular policy of USAID, PSI or JSI. USAID should devise a mechanism that would encourage institutional collaboration among its implementing partners.

In Zimbabwe, a national program has been carefully designed under the leadership of the Zimbabwe National Family Planning Council with support from a technical support group on condom programming. Demand for female condoms has skyrocketed, and a

combined effort of public sector and social marketing has resulted in the highest per capita utilization of female condoms in the world (Campbell 2007). A key element of the Zimbabwe success has been the participatory nature of the strategy design and national scale-up efforts, with ownership shared between government, multilateral and bilateral partners. In collaboration with DFID, UNFPA, PSI and JSI, USAID has played a key role in ensuring consistent supplies of female condoms in Zimbabwe and providing support for social marketing and distribution networks (Zimbabwe Ministry of Health and Child Welfare 2006). To improve coordination elsewhere, U.S. policies could provide incentives to U.S.-funded projects to actively collaborate with stakeholder negotiations around female condoms in each country.

Collaboration with Civil Society on Female Condom Needs and Programs

We support ministries and civil society leadership to ensure the availability of both male and female condoms, recognizing that gender dynamics also must be addressed for prevention programs to be effective.

THOMAS KENYON, MD, MPH, PRINCIPAL DEPUTY GLOBAL AIDS COORDINATOR, CHIEF MEDICAL OFFICER, US PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR)

Numerous experts interviewed from the U.S. government and cooperating agencies receiving U.S. funds reported that civil society is not routinely given access to U.S. decisions on female condoms. U.S. field staff have not consistently consulted with civil society groups to assess whether and how female condom programming should be pursued, and thus are not employing fully informed, cost-effective analyses when making decisions about whether or not to procure female condoms.

Without consistent access to U.S. government staff in the field, civil society and women's groups can only advocate for female condom procurement and programming by appealing to their own ministries of health or U.S. partnering organizations such as PSI. However, the impact of their advocacy may be limited by a lack of knowledge, awareness, or support for female condom programming within health ministries and U.S. partner organizations (Brady 2007). By providing incentives for ministries of health and U.S. partners to collaborate with civil society, especially women's health and rights groups, a whole range of HIV prevention activities, including female condom programming, can be encouraged. USAID could employ a similar mechanism to that of the Global Fund, which ensures a seat at the table for civil society in countries that wish to acquire Global Fund grants for HIV/AIDS work. In other words, USAID funds could be awarded or increased based on ministry of health partnerships with civil society and women's groups.

Part III: Findings and Recommendations

FINDING: U.S. agencies responsible for female condom programming and procurement do not have policies that promote the integration of female condoms into HIV prevention and family planning programs. Whether the U.S. procures female condoms in a given country is highly dependent on the personal biases of USAID mission staff.

RECOMMENDATION: USAID and OGAC should issue policy guidance promoting female condom procurement and programming within U.S.-funded development programs, including PEPFAR. As a signatory of ICPD, the U.S. should promote female condoms as a vital tool to prevent both pregnancy and HIV infection.

FINDING: The U.S. excels at assisting countries in female condom logistics and procurement.

RECOMMENDATION: The U.S. should expand technical assistance for female condom logistics and procurement to additional countries to increase HIV prevention efforts.

FINDING: Sustained product availability and effective programming is limited to a few countries. Accurate estimates for female condom needs do not exist.

RECOMMENDATION: The U.S. should apply intensive programming efforts to an additional three countries for scale-up and replication. These efforts could be used to create a more realistic assessment of global female condom needs for scale-up.

FINDING: PEPFAR currently promotes both male and female condoms by population to “high risk” groups instead of targeting promotion at the level of the general population. This results in stigmatization of condom use.

RECOMMENDATION: The U.S. should increase HIV prevention efforts by expanding the scope of female and male condom promotion to encompass the general public. Programming for female condoms will depend on each area’s epidemiological profile, and should be free of messages and attitudes that stigmatize condom use. (See Annex D: Populations that Benefit from Female Condoms.)

FINDING: More efforts by the U.S. are needed in female condom promotion and programming. Requiring PEPFAR focus countries to pay for male and female condoms out of their prevention budgets negatively impacts promotion of female condoms, as male condoms are cheaper and missions will purchase the cheaper product.

RECOMMENDATION: The U.S. should invest more funds in female condom promotion and programming. The U.S. should subsidize female condoms for PEPFAR-funded programs.

FINDING: Coordination between U.S. government cooperating agencies working on female condom availability and programming could be improved. Coordination around programming and procurement among international donors exists at the headquarters level but is not always replicated at the country level. At the country level, no mechanism exists to involve civil society.

RECOMMENDATION: At the country level, the U.S. should include civil society, especially women's health and rights groups, in stakeholder meetings and encourage financing mechanisms that increase government-civil society collaboration in female condom programming.

FINDING: The requirement in the 2003 Global AIDS Act that 33% of PEPFAR prevention funds be spent on abstinence-until-marriage programs undermines the ability of countries to determine how best to prevent HIV transmission among their own populations and stigmatizes male and female condom use.

RECOMMENDATION: Congress should remove all earmarks and funding directives for abstinence-only, abstinence-until-marriage and fidelity prevention programs and fund comprehensive, integrated, and evidence-based HIV prevention programs that include female condoms and that promote and protect women's health.

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Annex A: Acronyms

ABC	Abstain, Be faithful, use Condoms
AIDS.	Acquired Immunodeficiency Syndrome
AIDSTAR.	AIDS Support, Technical Assistance Resources
ART	Antiretroviral Therapy
CHANGE	Center for Health and Gender Equity
DFID	Department for International Development, United Kingdom
FDA	U.S. Food and Drug Administration
FHC	Female Health Company
GAO.	Government Accountability Office
GBV	Gender-based Violence
HIV.	Human Immunodeficiency Virus
HNP	Health Nutrition and Population
ICPD	International Conference on Population and Development
IOM	National Institute of Medicine, National Academies of Science
JSI	John Snow, Inc.
MAP.	Men as Partners
NGO.	Non-Governmental Organization
OGAC	Office of the Global AIDS Coordinator
PEPFAR.	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother to Child Transmission
PMTCT-Plus	Prevention of Mother to Child Transmission with AIDS treatment for the mother, her partner, and her family
PPT.	Prevention of Perinatal Transmission
PSI	Population Services International
STI	Sexually Transmitted Infection
UNAIDS.	Joint United Nations Programme on HIV/AIDS
UNFPA.	United Nations Population Fund
U.S.	United States
USAID	U.S. Agency for International Development
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

Annex B: Experts Interviewed

Doris Anderson, *Program Analyst*

Office of Population and Reproductive Health
Bureau of Global Health
U.S. Agency for International Development
Washington, DC

Roberta Black, Ph.D., *Team Leader*

Topical Microbicide Team
National Institute of Allergy and Infectious
Diseases
National Institutes of Health
Bethesda, MD

Martha Brady, *Associate*

Population Council
New York, NY

Bruce Campbell, *Country Representative*

UNFPA Zambia
Zambia

Patricia Coffey, Ph.D., *Program Officer*

PATH
Seattle, WA

Bidia Deperthes, *HIV/AIDS Technical Adviser*

Comprehensive Condom Programming
United Nations Population Fund
New York, NY

Maxine Eber

Reproductive Health Technical Advisor
Population Services International
Washington, DC

Jane C. Feinberg, *Program Officer*

JSI Research and Training Institute, Inc.
Arlington, VA

Paul Feldblum, Ph.D., *Senior Epidemiologist*

Family Health International
Research Triangle Park, NC

Bill Finger

Information Dissemination Coordinator
YouthNet
Family Health International
Research Triangle Park, NC

Lester Freeman, *Senior Program Analyst*

Henry M. Jackson Foundation for the
Advancement of Military Medicine
Division of AIDS
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Bethesda, MD

Kevin Frost, *CEO*

Americans for AIDS Research
New York, NY

Nomi Fuchs-Montgomery, *Technical Advisor*

The President's Emergency Plan
for AIDS Relief
Office of the Global AIDS Coordinator
Washington, DC

Henry Gabelnick, Ph.D., *Executive Director*

CONRAD
Arlington, VA

Richard Harrison, *Country Manager*

PSI/Zambia
Lusaka, Zambia

Teresa Harrison, *Former Senior Project Manager*

Ibis Reproductive Health
Boston, MA

Phil Harvey, *President*

DKT International
Washington, DC

Theresa Hatzell Hoke, Ph.D.

Senior Research Associate
Family Health International
Research Triangle Park, NC

Lori Heise, *Executive Director*

Global Campaign for Microbicides
Washington, DC

Thomas Kenyon, MD

*Principal Deputy Coordinator and
Chief Medical Officer*
The President's Emergency Plan for
AIDS Relief
Office of the Global AIDS Coordinator
Washington, DC

Maggie Kilbourne-Brook, Program Officer

PATH
Seattle, WA

Alain Kouda, MD

*DAIDS Clinical Operations
Clinical Study Manager*
National Institute of Allergy and
Infectious Diseases
Division of AIDS
National Institutes of Medicine
Bethesda, MD

Mary Ann Leeper

Senior Strategic Advisor
Female Health Company
Richmond, VA

Andrew Levack, Director, Men as Partners

EngenderHealth
New York, NY

Trisha Long, CPT/Pipeline Program Officer

John Show, Inc.
Arlington, VA

Nancy Lowenthal, Ph.D.

Senior Technical Advisor, HIV/AIDS
U.S. Agency for International Development
Washington, DC

Susana Lungo

*Regional Marketing and
Technical Services Director*
Pan American Social Marketing Organization
Guatemala, Guatemala

Yasmin Madan, PSI/Vietnam Country Director

Population Services International
Hanoi, Vietnam

Inas Mahdi

*Former AIDSMARK Evaluation and Dissemination
Specialist*
Population Services International
Washington, DC

Judy Manning, Ph.D.

Health Development Officer
Research, Technology and Utilization Division
Office of Population and Reproductive Health
U.S. Agency for International Development
Washington, DC

Robert Nelson

Director, Program and Sales
Female Health Company
London, England

Charity Ngaruro

Deputy Director
Procurement and Logistics
Population Services International
Washington, DC

Katy Pepper

Africa Region Programme Manager
Female Health Foundation
Capetown, South Africa

Jeanna Piper, MD

DAIDS Medical Officer
Topical Microbicide Team
Division of AIDS
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Bethesda, MD

Michael Pope, Director

Female Health Company (UK)
London, England

Maria Cristina Ramirez

Senior Program Advisor/Logistics
International Planned Parenthood Federation
Western Hemisphere Region
New York, NY

Mark Rilling

Division Chief Population and Reproductive
Health Commodities Security and
Logistics Division
U.S. Agency for International Development
Washington, DC

Ilka Rondinelli, *Senior Quality of Care Advisor*

International Planned Parenthood Federation
Western Hemisphere Region
New York, NY

Monica Ruiz, Ph.D.

Acting Director, Public Policy
Americans for AIDS Research
Washington, DC

David Sarley, *Deputy IQC Manager*

John Snow, Inc.
Arlington, VA

Laura Skolnik, *Senior Technical Advisor*

Office of HIV/AIDS
Bureau of Global Health
U.S. Agency for International Development
Washington, DC

Jeff Spieler, Ph.D., *Senior Science Advisor*

Office of Population and Reproductive Health
Bureau for Global Health
U.S. Agency for International Development
Washington, DC

Guy Stallworthy, *Senior Program Officer*

Strategic Business Planning
Delivery Team in Global Health
Bill and Melinda Gates Foundation
Seattle, WA

Kiersten Stewart, *Director of Public Policy*

Family Violence Prevention Fund
Washington, DC

Jim Turpin, Ph.D., *Microbiologist*

Prevention Sciences Branch Division of AIDS
National Institute of Allergy and Infectious
Diseases
Bethesda, MD

Fulvia Veronese, Ph.D.

Office of AIDS Research
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Bethesda, MD

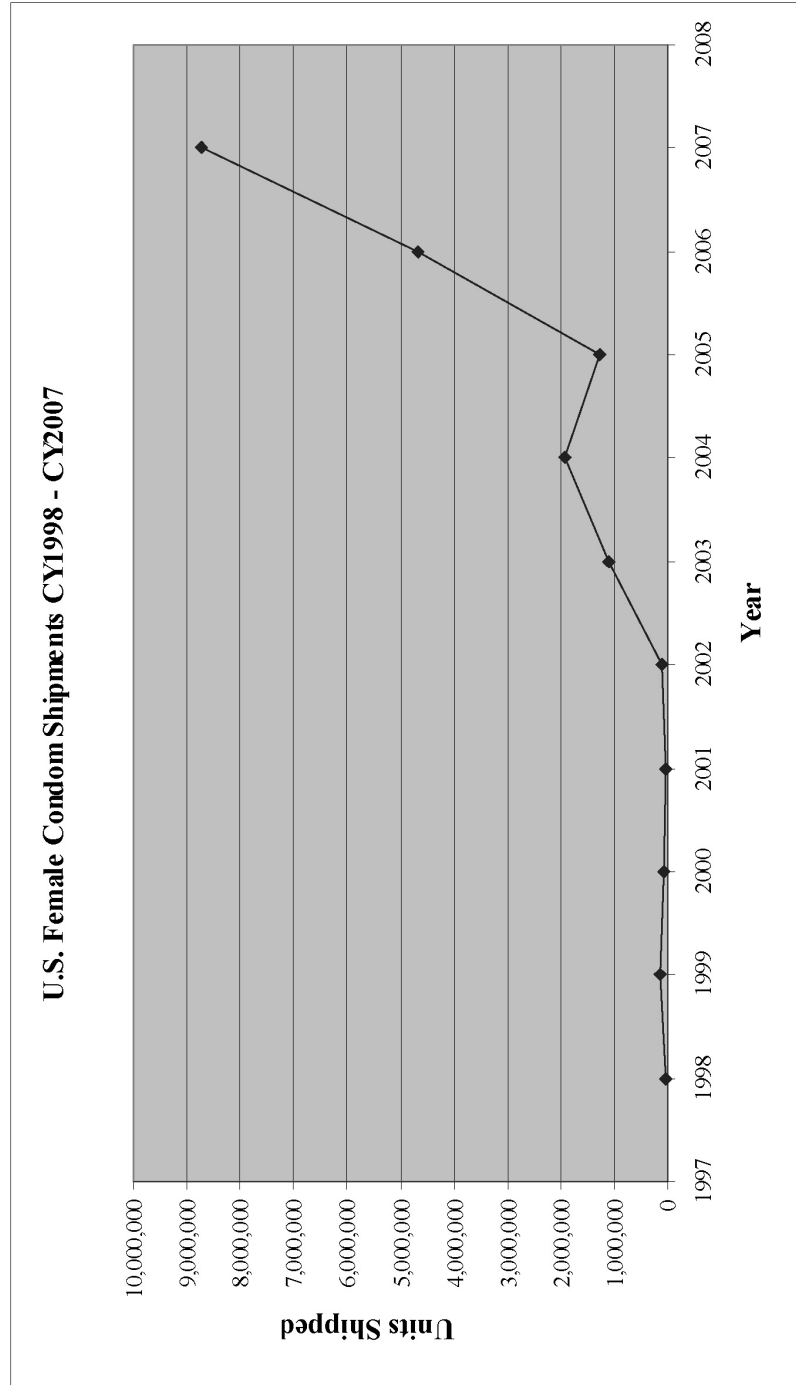
Mitchell Warren, *Executive Director*

AIDS Vaccine Advocacy Coalition
New York, NY

Mimi Whitehouse, *Manager, RHInterchange*

Information Systems Specialist
JSI Research and Training Institute, Inc.
Arlington, VA

Annex C: U.S. Female Condom Procurement



Source: NEWVERN. 2008. NEWVERN is the information system for the Central Contraceptive Procurement (CCP) team of the GH/PRH/CSL Division of USAID. Arlington, VA: John Snow, Inc. <http://portalprd1.jsi.com/portal/page/portal/DELIVERWEBSITE>. Accessed 18 January 2008.

Annex C: U.S. Female Condom Procurement

Country	2003		2004		2005		2006		2007	
	FC	MC	FC	MC	FC	MC	FC	MC	FC	MC
Angola	0	24,492,000	41,000	29,034,000	0	7,221,000	0	768,000	0	15,000,000
Benin	0	0	0	0	0	0	5,000	30,000	2,000	0
Bolivia	0	7,959,000	60,000	7,002,000	0	5,001,000	45,000	5,001,000	68,000	4,008,000
Burkina Faso	70,000	16,989,000	0	294,000	0	0	0	0	0	0
Cameroon	60,000	4,002,000	138,000	3,738,000	60,000	9,642,000	46,000	2,499,000	1,000	6,177,000
Congo, DR	455,000	0	300,000	70,110,000	400,000	29,001,000	24,000	0	24,000	4,062,000
Cote d'Ivoire	20,000	1,002,000	0	0	0	528,000	0	1,320,000	0	3,000,000
Guatemala	25,000	0	50,000	12,000	0	120,000	50,000	0	50,000	12,000
Haiti*	45,000	20,133,000	0	5,712,000	35,000	12,105,000	85,000	6,045,000	235,000	17,700,000
Laos	0	6,966,000	0	5,814,000	0	9,003,000	0	15,147,000	40,000	2,193,000
Lesotho	55,000	3,000,000	0	7,041,000	0	0	0	1,476,000	999,000	5,502,000
Madagascar	0	15,360,000	0	13,251,000	0	24,540,000	0	10,860,000	80,000	12,402,000
Mali	0	9,888,000	75,000	3,351,000	50,000	8,877,000	0	9,594,000	0	888,000
Senegal	240,000	5,058,000	57,000	10,761,000	183,000	14,259,000	0	12,219,000	232,000	11,487,000
South Africa*	10,000	0	0	30,000	0	0	300,000	0	0	0
Swaziland	5,000	0	0	5,595,000	180,000	0	0	1,479,000	28,000	900,000
Tanzania*	100,000	0	190,000	0	0	18,582,000	1,056,000	36,780,000	549,000	0
Thailand	0	0	0	0	71,000	0	0	0	15,000	579,000
Togo	24,000	17,418,000	30,000	5,418,000	5,000	8,307,000	62,000	0	0	0
Vietnam*	0	26,745,000	0	5,001,000	0	10,344,000	20,000	7,683,000	20,000	0
Zambia*	0	0	0	0	0	10,803,000	495,000	0	275,000	48,135,000
Zimbabwe	0	47,748,000	1,000,000	47,151,000	300,000	36,441,000	2,475,000	101,106,000	6,125,000	97,848,000
Total:	1,109,000	206,760,000	1,941,000	219,315,000	1,284,000	204,774,000	4,663,000	212,007,000	8,743,000	229,893,000

* PEPFAR Focus Country

Source: NEWVERN. 2008. NEWVERN is the information system for the Central Contraceptive Procurement (CCP) team of the GH/PRH/CSL Division of USAID. Arlington, VA: John Snow, Inc. <http://portalprd1.jisi.com/portal/page/portal/DELIVERWEBSITE>. Accessed 18 January 2008.

Annex C: U.S. Female Condom Procurement

Country	Recipient	U.S. Female Condom Recipients CY2003-CY2007				
		2003	2004	2005	2006	2007
Angola	USAID Angola	0	41,000	0	0	0
Benin	Ministry of Health	0	0	0	5,000	2,000
Bolivia	PROSALUD	0	60,000	0	45,000	68,000
Burkina Faso	PSI	70,000	0	0	0	0
Cameroon	Ministry of Health and Bansa Baptist Hospital	60,000	138,000	60,000	46,000	1,000
Congo, DR	AIDSMARK, PSI and Various Partners	455,000	300,000	400,000	24,000	24,000
Cote d'Ivoire	PSI/AIMAS	20,000	0	0	0	0
Guatemala	PASMO (PSI Affiliate)	25,000	50,000	0	50,000	50,000
Haiti*	PSI	45,000	0	35,000	85,000	235,000
Laos	Family Health International	0	0	0	0	40,000
Lesotho	PSI	55,000	0	0	0	999,000
Madagascar	AIDSMARK	0	0	0	0	80,000
Mali	Central D'achat des Génériques (PSI Affiliate)	0	75,000	50,000	0	0
Myanmar	PSI	0	0	0	0	0
Senegal	Ministry of Health	240,000	57,000	183,000	0	232,000
South Africa*	Society for Family Health (PSI Affiliate)	10,000	0	0	300,000	0
Swaziland	PSI	5,000	0	180,000	0	28,000
Tanzania*	AED/T-MARC	100,000	190,000	0	1,056,000	549,000
Thailand	PSI	0	0	71,000	0	15,000
Togo	PSI	24,000	30,000	5,000	62,000	0
Vietnam*	PSI	0	0	0	20,000	20,000
Zambia*	Society for Family Health (PSI Affiliate)	0	0	0	495,000	275,000
Zimbabwe	Ministry of Health and PSI	0	1,000,000	300,000	2,475,000	6,125,000
Total:		1,109,000	1,941,000	1,284,000	4,663,000	8,743,000

* PEPFAR Focus Country

Source: NEWVERN. 2008. NEWVERN is the information system for the Central Contraceptive Procurement (CCP) team of the GH/PRH/CSL Division of USAID. Arlington, VA: John Snow, Inc. <http://portalprd1.jsi.com/portal/page/portal/DELIVERWEBSITE>. Accessed 18 January 2008.

Annex D: Populations that Benefit from Female Condoms

While female condom use is appropriate for the general population, the following are specific groups that can benefit the most from targeted marketing, programming and distribution efforts, depending on each country's epidemiological context.

Women who seek services for prevention of perinatal transmission (PPT) and PMTCT-Plus. According to the Office of the Global AIDS Coordinator's guidance, the minimum package of services for preventing mother-to-child transmission must include family planning counseling or referral. However, the guidance does not include a provision for counseling on the use of female condoms (OGAC 2007c).

Women who attend antenatal care. HIV-negative women are at greater risk of HIV infection during pregnancy (Mataka 2007) and therefore, women who attend antenatal care should be informed of female condoms as well as other prevention options.

Couples in long-term relationships, including marriage. In some countries, married women are at high risk of acquiring HIV (UNAIDS 2006, 22; Hirsch et al. 2007; Ugonnet et al. 2002 cited in Matovu et al. 2007). And yet, "[t]he needs of the married and cohabitating population have been neglected ... despite the fact that more than half of HIV infections in the severe epidemics of Southern and East Africa are occurring in this group. And barriers to condom adoption by married couples may not be as severe as is often assumed" (Delvaux and Nostlinger 2007, 56). In some instances, making female condoms available to women and men can lead to increased negotiation of condom use.

Women facing gender-based violence. Women who face gender-based violence should have access to the option of female condoms, along with other essential services, even though the female condom is often impossible to use without detection by male partners.

Women needing abortion and postabortion care services. Postabortion care programs, which are supported by U.S. government funds (POLICY et al. 2007), "provide an excellent entry point for introducing the female condom as a contraceptive method for the prevention of both repeated unwanted pregnancies and STI/HIV infection (Rasch et al. 2007, 67).

HIV sero-discordant couples. The female condom allows HIV positive men and women to continue engaging in fulfilling sexual experiences with sero-discordant partners while providing highly effective prevention against pregnancy and HIV transmission or infection. One HIV positive woman stated, "Using the female condoms has been a way of enjoying sexual pleasure, whilst feeling confident that I won't infect him [husband] and won't get pregnant" (Welbourn 2006).

Women living with HIV. Globally there are 15.4 million women living with HIV (UNAIDS 2007a, 15). Besides using female condoms to prevent HIV transmission, it is important to use male or female condoms to decrease the possibility of HIV reinfection, STI acquisition, and pregnancy prevention for those wishing to avoid unintended pregnancy (Viera et al. 2004). While women living with HIV have reported problems with female condom availability (Welbourn 2006), PSI/Zimbabwe has been highly successful in distributing female condoms through support groups for women who are HIV positive (Eber 2007a).

People served by PEPFAR-funded care and treatment programs. By September 2007, 1,358,500 people were receiving PEPFAR-supported antiretroviral treatment (ART) in focus countries, and more than 3.9 million people were receiving support services, not including orphans and other vulnerable children (OGAC 2008b). Moreover, since PEPFAR's inception, the program has supported over 30 million counseling and testing sessions throughout the world (OGAC 2008a). Female condoms should be promoted within PEPFAR care and treatment programs to reduce superinfection and STIs among those living with HIV and reduce the likelihood of HIV transmission to others.

Men who have sex with men. U.S. supported programs should promote HIV prevention methods that will protect from HIV acquisition or transmission during anal sex. In Myanmar, men who have sex with men sex workers “began to request that they be supplied with female condoms because they desired an HIV prevention method that was less stigmatized, easier to use if a partner is inebriated and as effective as male condoms” (AIDSMark 2007).

Female and male sex workers; their clients and their husbands/partners. In southern Africa, USAID and other donors support PSI programs that promote female condoms among sex workers (PSI 2007). Also, sex workers in India have responded positively to a recent program launched by the National AIDS Control Organization of India to supply sex workers with female condoms (Nanda 2007). As a population that is at high risk of HIV infection and transmission, female and male sex workers, their clients and their partners should have unhindered access to female condoms.

Clients of voluntary counseling and testing for HIV (VCT). A review of VCT centers in Kenya found that female condoms represented a “missed opportunity.” (Mung’ala et al. 2006: 100). In-depth interviews of VCT counselors and employees found that male clients all reported a willingness to try female condoms, but supplies were irregular, and counselors believed that female condoms were not as good as male condoms (Mung’ala et al. 2006, 102).

People who will not use male condoms. Though male condoms are a highly effective prevention tool, stigma, cultural norms and product discomfort act as deterrents to consistent and continued use of the product. While similar factors may affect female condom use, female condoms are an alternative prevention option that has been proven to appeal to individuals who are not willing to use male condoms (Francis-Chizororo and Natshalaga 2003; Dias 2006).

Adolescents prior to sexual activity. Globally, young people aged 15 to 24 accounted for 40% of new HIV infections during the last year (Piot 2007). Young women and men need to learn about female condoms before they become sexually active, as sexuality education prior to initiation of sexual activity is the most effective in preventing transmission of HIV (Gay et al. 2005; Hawkins et al. 1999; Stanton et al. 1998).

Adolescents who are sexually active. Almost all women and men over the age of 20 are sexually experienced (Singh et al. 2003). In most sub-Saharan countries, one third or more of women have had premarital sex by age 18 (Boonstra 2007). Adolescents living with HIV also need access to female condoms and effective programming on the product’s use.

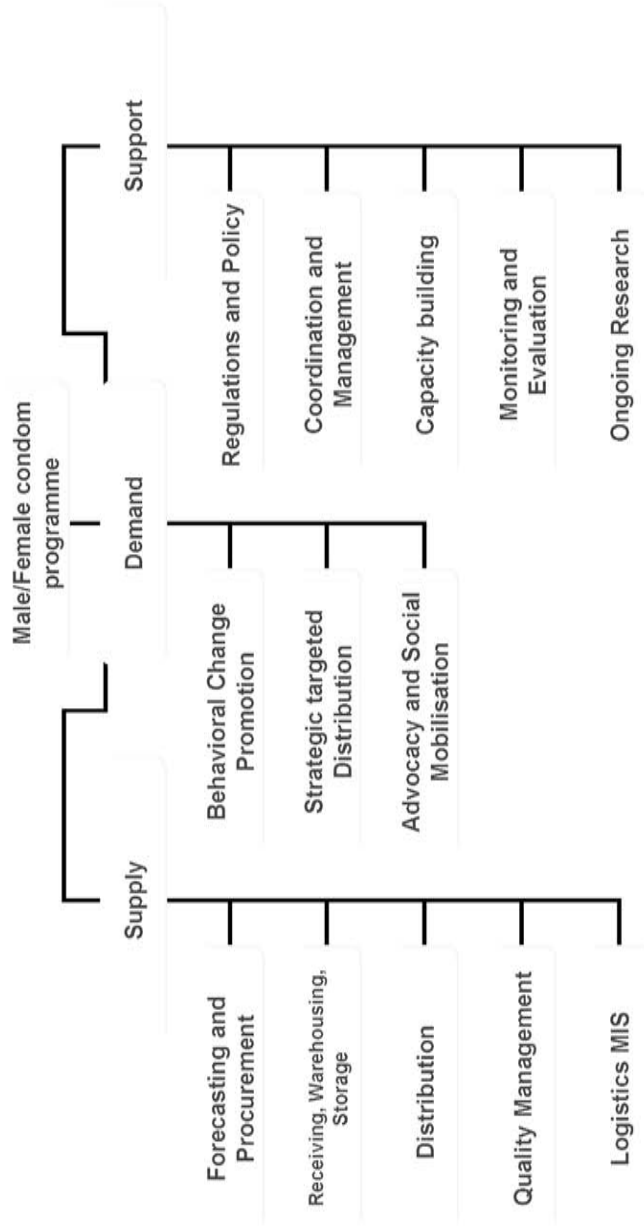
Orphans and vulnerable children (OVC). The Office of the Global AIDS Coordinator has defined orphans as a child aged 0 to 17, who has lost one or both parents to HIV/AIDS (IOM 2007). These orphans, especially as they enter adolescence, are at high risk of HIV acquisition (Sippel 2007c). In Zimbabwe, one study found female orphans aged 15 to 18 had a greater number of HIV infections than their non-orphan peers (Gregson et al. 2005).

Partners of Intravenous Drug Users (IDUs). IDUs are often at high risk of HIV acquisition, as are their sexual partners (2007; Gay et al. 2005). IDUs or partners of IDUs may be able to use female condoms at times when drug use makes male condom use less likely (Stallworthy 2007).

Refugees. “Approximately 80% of refugees are women and children” (Women’s Commission for Refugee Women and Children 2008). Women and girls in refugee settings are particularly vulnerable to HIV infection because they often must engage in transactional sex to meet their most basic needs (UNAIDS and UNHCR 2007). Host countries are frequently unable or unwilling to provide assistance to refugees under their national AIDS programs, and refugees rarely have access to HIV prevention commodities (UNAIDS and UNHCR 2007). In an effort to address the specific vulnerabilities of women and girls in refugee settings, programs should include female condoms in their prevention packages.

Annex E: Female Condom Programming: What it Takes

Operationalizing the Male/Female Condom Strategy, Within the Context of the National AIDS Strategy and RH Programme



Source: Oyeyipo, C. and D. Nyamukapa. 2007. *Implementing Male and Female Condom Programmes at the Community Level: Experiences from Nigeria and Zimbabwe*. PowerPoint presentation for the International Women's Summit. World YWCA and International Community of Women Living with HIV/AIDS. Nairobi, Kenya. 6 July 2007.

Annex F: The Female Condom

What are Female Condoms?

PATHWoman's Condom



- A polyurethane sheath partially enclosed in a rounded polyvinyl alcohol capsule that is designed for ease of insertion and dissolves quickly after insertion.
- Pads of foam on the outside of the condom are designed to adhere lightly to the inside of the vaginal wall, holding the condom in place, and allow for easy release after intercourse.
- Flexible polyurethane ring sits on outside of vagina. If lubrication is desired, it must be applied to the condom.¹
- **Not approved for use or purchase by the WHO or FDA.**

1. Aulin, G. 2005. Presentation to the Global Consultation on the Female Condom. PATH, Baltimore, MD. 16 October 2005.

Female Health Company FC1 and FC2



- FC1: Polyurethane sheath with a large flexible ring at the external end and smaller, internal ring used for insertion at closed end. FC1 is lubricated with a silicone-based lubricant.²
- **FC1 is the only FDA approved female condom.**
- FC2: Same design as the FC1 but made of nitrile, a synthetic rubber. FC2 is cheaper to manufacture than FC1 and does not create the noise associated with FC1.³
- **WHO has determined that FC2 is acceptable for bulk procurement by UN agencies, and FC2 is under FDA review.**

2. Female Health Company (FHC). What is FC Female Condom? Chicago: Female Health Company. <http://www.femalehealth.com/FC1.html>.

3. Female Health Company (FHC). What is FC2 Female Condom? Chicago: Female Health Company. <http://www.femalehealth.com/FC2.html>.

VA-Feminine Condom aka Reddy Female Condom



- A latex pouch with a V frame at the open end and a sponge at the closed end.
- The pouch is inserted into the vagina and the sponge acts to hold the condom in place. The V frame fits snugly on the outside of the vagina.
- VA-Feminine Condom is manufactured by Medtech Products Ltd.⁴
- **Not approved for use or purchase by the WHO or FDA.**

4. Medtech Products Ltd. Products: Female Condom. Chennai, India: Medtech Products, Ltd. www.medtechproducts.org/female_condom.html.

About the Center For Health and Gender Equity

The Center for Health and Gender Equity (CHANGE) is a U.S.-based nongovernmental organization that seeks to ensure that U.S. international funding, policies and programs promote sexual and reproductive health and rights and gender equality by advocating for effective, evidence-based policies and increased funding for critical programs; and by holding the U.S. government accountable when policies and funding fail to uphold human rights or promote public health.

CHANGE believes that every individual has the right to basic information, technologies, and services necessary to enjoy a healthy and safe sexual and reproductive life free from coercion and preventable illness.

About the Prevention Now! Campaign

Prevention Now! is a global campaign working to prevent the spread of HIV, reduce unintended pregnancy, and advance the sexual and reproductive health and rights of all people worldwide. Through education and advocacy, the Prevention Now! Campaign seeks to ensure that governments and donor agencies provide the funds needed to dramatically increase access to female condoms and other existing HIV prevention options for women and men now. The campaign seeks to build partnerships among national efforts and link those to international efforts. To join the campaign, visit www.preventionnow.net.

Center for Health and Gender Equity (CHANGE)

6930 Carroll Avenue, Suite 910
Takoma Park, MD 20912 USA
tel +1 (301) 270-1182
fax +1 (301) 270-2052
Email: change@genderhealth.org

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