
CHAPTER 8

FEMALE CONDOMS:

Access to Dual Protection Technologies



With Beth Anne Pratt

IN 2006, AN ESTIMATED 39.5 MILLION ADULTS WERE LIVING WITH HIV INFECTION worldwide, almost half of whom were women. The percentage of women with HIV has increased steadily over the years, from 35% in 1985 to 48% in 2006.¹ In 2006, two thirds of all adults and children with HIV lived in sub-Saharan Africa, of whom 59% were women.² These numbers reflect women's higher biological vulnerability to HIV infection relative to men, as well as gender inequalities in many societies that limit women's ability to protect themselves from HIV.

These vulnerabilities have prompted the search for female-initiated HIV prevention methods. The main female-initiated methods under consideration include female condoms, diaphragms, and microbicides. Studies on the diaphragm's efficacy in preventing HIV and other sexually transmitted infections (STIs) are still ongoing, as are efforts to develop microbicide products.³ As of mid-2006, the only method available on the market with proven efficacy in preventing both pregnancy and STIs was the female condom.⁴ Because of its ability to protect against both pregnancy and STIs, the female condom is known as a "dual protection" technology.

Introduced in 1992, the female condom has been launched in almost 100 countries worldwide. While the technology generated high levels of initial enthusiasm, adoption by end-users, providers, national governments, and donors has remained low. This chapter examines the low uptake and limited access for the female condom from its development in the mid-1980s through its introduction in the 1990s to efforts in the mid-2000s to address the multiple barriers to access. The female condom story highlights the challenges of creating access to a technology when barriers are encountered at many different levels—global, national, local—and when advocates are unable to create an access architecture and strategic plan for addressing these barriers. In this chapter, we describe current attempts to build architecture and access strategies to address persistent problems of product availability and affordability, as well as its adoption by many actors: end-users, providers, national governments, and global agencies. Whether advocates can create successful access for the female condom remains to be seen.

Product Development (Phase 1)

Lasse Hessel, a Danish physician, developed the female condom in 1984. Mary Ann Leeper, senior vice president of Wisconsin Pharmacal Co., Inc. (a company that primarily manufactured chemical products such as home cleaners and institutional health care products), heard about Hessel and his invention. In October

1987, Leeper and Hessel discussed the female condom and agreed that Wisconsin Pharmacial would develop the product to meet U.S. Food and Drug Administration (FDA) requirements in exchange for marketing rights in the United States, Canada, and Mexico. Hessel agreed to develop the manufacturing technology for the female condom. He sought a U.S. patent for the female condom, which he acquired in 1988. Wisconsin Pharmacial created a new division, the Female Health Company, to take responsibility for the female condom work. The company embarked on the studies required to gain FDA approval for the technology, with Leeper leading the effort. By the end of 1988, Leeper was ready to submit a clearance application for FDA approval, believing that the product met approval criteria.⁵ At this same time, the FDA made a decision to use stricter criteria to evaluate all new condoms—based on a Citizen’s Petition filed by the National Women’s Health Network. The Network, though advocating for the development of new methods for HIV protection, believed that the developers of new male and female condoms needed to provide more effectiveness data than originally required by the FDA.⁶ Based on the Network’s petition and subsequent discussion within the FDA, the regulatory agency classified the female condom as a Class III medical device, requiring more extensive safety and efficacy studies for Wisconsin Pharmacial’s product than Leeper originally thought necessary.⁷ These studies would require more time and investment from Wisconsin Pharmacial. To raise capital for female condom development, the company went public in 1991.

Meanwhile, Hessel was experiencing financial and technical problems in his efforts to develop the manufacturing technology for the female condom. To solve these problems, he sold the female condom’s world rights (outside the United States) to a Dutch investor. In 1989, this investor established Chartex Resources, Ltd., a London-based company, to manufacture the female condom and market it outside of North America. With resources from the investor (millions of dollars) and also a nonprofit Danish foundation, Chartex developed state of the art production processes for the technology and received permission to market the device in a number of countries outside the United States.

The FDA approved Wisconsin Pharmacial’s application to market and distribute the female condom in the United States in 1993, and one year later, it approved the Chartex manufacturing facility. The FDA stated that it accelerated the approval process for the female condom because the device was the only existing female-initiated barrier method. But the agency also expressed concerns about the device’s effectiveness in the field at preventing pregnancy and protecting against STIs. Because of these unresolved questions, the agency required

product labeling stating that male latex condoms appeared to offer better protection against pregnancy and disease.⁸ As FDA Commissioner David A. Kessler said at the time of approval, “The female condom is not all we would wish for, but it is better than no protection at all. . . . I have to stress that the male latex condom remains the best shield against AIDS and other sexually transmitted diseases.”⁹ FDA approval allowed Wisconsin Pharmacal to begin importing large quantities of the female condom for sale in the United States.

The product approved by the FDA in 1993 is a transparent polyurethane sheath the same length as a male condom with a flexible ring at each end. Polyurethane, invented in the 1940s, is a polymer whose molecules consist of a long repeating chain of smaller units called monomers. The polyurethane material used in female condoms is produced by combining two monomers (a diisocyanate and a polyol), creating a thin and odorless material that transfers heat better than the latex used in male condoms. The inner ring of the female condom is used to insert the device and secure it in place during intercourse, while the softer outer ring remains outside the vagina. The female condom can be inserted several hours prior to intercourse. It is prelubricated with a silicone-based, nonspermicidal lubricant. The FDA initially approved a shelf life of three years for the device but later revised this to five years.

Laboratory-based studies of efficacy show that the female condom provides protection against both pregnancy and sexually transmitted infections with no known side effects.¹⁰ Early field research of contraceptive effectiveness under conditions of typical use shows an estimated 79% effectiveness for female condoms, compared to 85% for male condoms.¹¹ More recently, preliminary results from the first multisite study to compare contraceptive effectiveness of female and male condoms, supported by the World Health Organization (WHO), show effectiveness rates in Panama, China, and Nigeria as 94–98% for the female condom and 92–96% for the male condom.¹² Studies in Kenya, Thailand, and the United States also indicate that female condoms provide as much protection from STIs as male condoms.¹³ Moreover, while they note that there is an absence of clinical trial data on the female condom’s efficacy and effectiveness in preventing HIV infection,¹⁴ the American Foundation for AIDS Research states that “the female condom is 94–97% effective in reducing the risk of HIV infection if used correctly and consistently.”¹⁵

In its early years, the female condom generated great excitement in the United States and around the world. The product’s approval received prominent attention in the media. Both specialists and the general public had high expectations.

One advocate describes her excitement about the new technology:

I had . . . high hopes for this new technology—it was effective, easy to learn to use, had no side effects, and wasn't tied to the existence of sophisticated medical facilities, unlike other technologies such as the pill or diaphragm. Most exciting, to me at least, the female condom could be used by a woman acting alone, a great advance over its male equivalent. This feature struck me as an unambiguously good thing—now women could take charge of their own reproductive health; now they could be freed from their dependence on their male partner's willingness to use the male condom in order to protect them from disease.¹⁶

But sales of the female condom did not take off right away. By 1995, Wisconsin Pharnacal had limited funds to market the product, and the company decided to restructure its business. First, in 1995 it purchased Chartex, and the next year it split into two companies, with the Female Health Company relocating to Chicago and remaining public. O. B. Parrish remained chief executive officer of the Female Health Company, and Leeper took over as president and chief operating officer in 1996. These changes gave the Female Health Company full ownership of all intellectual property related to the female condom. Its subsidiary, Chartex, continued as the sole manufacturer of the technology.

The Female Health Company refers to its product as the FC Female Condom. The product is known as Reality in North America and elsewhere as the Female Condom, Femidom, Femy, Preservativo Feminino, El Condon Femenino, and MyFemy. As of early 2008, the FC is the only female condom with FDA approval. It has been the primary female condom manufactured, marketed, and used in studies worldwide from 1992 until 2005, when the Female Health Company released a second-generation product, the FC2.

Introducing the Female Condom (Phase 2)

By the early 1990s, the Female Health Company was poised to introduce its innovative dual protection technology around the world. The company first launched its product in Switzerland in 1992. The device subsequently was registered by the U.S. FDA, the European Patent Convention, and by regulatory agencies in 11 additional countries. During the 1990s, the Female Health Company supplied female condoms to public agencies in over 80 countries (for public distribution and social marketing campaigns) and sold them commercially in 17 others. The product's main advocate since its introduction has been the manufacturer, the

Female Health Company, whose only product is the female condom. The company established the Female Health Foundation in 1996 to promote global women's health projects related to female condom use, including economic empowerment projects, sexual negotiation skills training, and reproductive health education. The foundation's partners include UN agencies (UNAIDS, UNFPA, WHO), national governments, non-governmental organizations, and community-based organizations.

Efforts to introduce the female condom showed some success in a number of countries where the product was actively promoted to try to achieve high levels of adoption, such as South Africa, Zimbabwe, Brazil, and India. For example, in Zimbabwe in the mid-1990s, more than 30,000 women petitioned the government to make female condoms accessible so women could protect themselves against HIV infection and STIs.¹⁷ Population Services International (PSI) began a social marketing project in 1997 (funded by USAID and the United Kingdom Department for International Development) and marketed the device under the brand name Care as a "contraceptive sheath" rather than a condom in order to avoid stigmatizing associations with STI prevention.¹⁸ Sales of female condoms were higher than PSI and its partners expected. In its first year (1997), the program sold 120,720 condoms. Sales figures rose steadily, and in 2002, the program sold 683,700 female condoms.

Despite successes in these few countries, most efforts to introduce the female condom between 1992 and 2005 showed only low levels of uptake. The high expectations of enthusiasts for the female condom were not easily realized. Many supporters believed "that if women were offered a method over which they had greater control, they would adopt it readily."¹⁹ That simply never happened. Attempts to introduce the female condom worldwide encountered five access barriers at the global, national, and local levels: (1) limited affordability, (2) low end-user adoption, (3) lack of provider adoption, (4) insufficient global consensus, and (5) inadequate architecture.

Limited Affordability

The high price of the female condom is often cited as the primary obstacle to access. Family Health International's AIDS Control and Prevention Project (AID-SCAP) organized a meeting in October 1993 on the potential role of the female condom in international AIDS prevention.²⁰ Participants at the meeting discussed the problems of price as a barrier to access. Product price has remained a topic at all subsequent meetings on the female condom.

The commercial price to end-users in developing countries of the Female Health Company's product at introduction was approximately \$2.00–\$3.00 per condom. To make the product more affordable for governments and end-users, UNAIDS and the Female Health Company in 1996 negotiated a public-sector pricing agreement, reducing the price for developing country governments to approximately \$0.58 per condom for bulk purchases. This public-sector price was reportedly only 10% above the cost of production.²¹ Governments that purchase the female condom at this price provide the product free to end-users in public clinics or make the product available at low prices to end-users through social marketing programs. Despite this much lower public-sector price, the female condom is still much less affordable for governments than a male condom (the price of which, by contrast, is about \$0.02 per condom for bulk purchases on the world market). Whether the product is affordable for the end-user depends on whether she is able to obtain the product through a public sector program where it is either free or available at subsidized prices.

One strategy used by some advocates of the female condom to address affordability issues was to seek global consensus for allowing end-users to use the product multiple times. When the U.S. FDA approved the female condom, it did so for one-time use. But advocates argued that since the polyurethane material used to make the female condom is stronger than latex, it could retain its structural integrity for repeated use. If end-users could utilize the product multiple times, this would reduce product cost per use. A number of studies were conducted on this issue, some of these supported by USAID. These studies found that indeed the female condom can be washed and reused multiple times without causing serious damage to its structural and microbiological integrity.²²

The issue of reuse was debated at the global level during the female condom's introduction phase. WHO held consultations in 2000 and 2002 to review the evidence on reuse and make recommendations. Subsequently WHO issued a statement that did not recommend or promote the reuse of female condoms based on existing evidence.²³ The agency stated that unresolved safety questions about reuse remained and called for additional clinical and laboratory testing. The agency however recognized the diversity of contexts and personal circumstances and stated that the final decision on reuse should be made by each national government. WHO prepared a protocol for handling and preparing female condoms for reuse to be used by program managers who decided to evaluate the feasibility of reuse in local settings. This compromise suggests that advocates did not adequately address the affordability problems of female condoms through the

reuse strategy. But interest in the reuse issue has persisted. A recent review of the research on female condom effectiveness, for example, called for more reuse studies because the possibility of reuse makes the female condom a much more affordable option.²⁴

Affordability problems have depressed end-user adoption in settings where the product is only available through individual purchase.²⁵ In many countries, however, governments or non-governmental organizations make the product free to women at health facilities through donor-funded programs or provide it at subsidized prices in outlets such as pharmacies, clinics, supermarkets, and convenience stores. In these settings, the female condom's high price from the manufacturer is less problematic for end-users, but it continues to pose a barrier to governments, non-governmental organizations, and donors who purchase the product in bulk.

The high price of the female condom has affected adoption by global and national actors in other ways as well. Some analysts argue that high prices have distorted demand for the product and undermined donor and national government support. As Friel states, "One cannot miss the play of a familiar vicious cycle: because of perceived low demand, donors are unwilling to invest in female condom programming and procurement, women do not find the product accessible and the apparent low demand is perpetuated."²⁶

Low Adoption by End-Users

Certain technical characteristics of the female condom can give negative first impressions to some users and pose continuing barriers to end-user adoption.²⁷ Some women consider the female condom to be large and bulky, aesthetically unappealing, prone to slippage and twisting during sexual intercourse, stiff in its internal rings, and difficult to insert, as well as unpleasantly noisy and smelly.²⁸ Studies have shown a high frequency of misuse and low levels of acceptability on the first attempt at use. Following repeated attempts, user confidence and satisfaction increase, as do users' skill at correct insertion and removal.²⁹ Without adequate training and counseling, women may lose interest after initial failed attempts or may expose themselves to risks of STIs and unplanned conception through mishandling of the female condom.³⁰

Cultural attitudes also affect end-user adoption of the female condom. Women may feel shame and inadequacy if the female condom causes awkward problems during intercourse.³¹ In some countries, female condom adoption is held back by negative cultural perceptions about touching or placing something within a

woman's vagina.³² A study conducted among refugees in Kenya noted a major gap in respondents' knowledge of reproductive anatomy to the extent that some refugees questioned advocates' assurances that condoms (both male and female) would not disappear permanently into an individual's body cavity resulting in illness or death.³³ Another acceptability study in Burundi noted users' beliefs that the female condom was "incompatible" with a special sexual technique ("ruganga"), prevalent among many communities around the Lake Victoria basin, involving clitoral stimulation with a man's penis.³⁴

The politics of sexual relations can also create barriers for women who seek to use the female condom. Some studies show that men are far more willing to use either male condoms or female condoms with casual sex partners, particularly commercial sex workers, than they are with regular partners. For example, a study conducted among commercial sex workers in Mombasa, Kenya, demonstrated an increase in the number of protected sex acts with clients but no change in unprotected sex with boyfriends—regardless of female condom availability.³⁵ Men may interpret a woman's request to use a female condom as a symbol of a woman's infidelity or that a woman is suffering from an STI. In a study from South India, 56% of women reported that requesting the use of a condom resulted in violence from their husbands.³⁶ The association of the female condom with commercial sex workers in some settings, as opposed to a regular family planning measure for married couples, further compounds the problem of women's efforts to use the device.

Finally, female condoms have sometimes been used for other purposes by end-users. In Zimbabwe, where the government makes female condoms available for free in clinics and hospitals, there are reports of traders removing the rubber rings from the female condom, painting them, and selling them as bangles in the marketplace.³⁷ Though this practice is not widespread, the example illustrates how health technologies can be used in unexpected ways and can appear in unexpected places.

Lack of Provider Adoption

Efforts to introduce the female condom at the local level encountered a number of barriers to provider adoption. Some providers found themselves without the capacity, support, and training to implement female condom programs and therefore could not provide instruction, counseling, and follow-up to their clients.³⁸ Some providers lacked sufficient health infrastructure to promote the method. For example, many clinics had no female pelvic models on which to demonstrate female condom use.³⁹ An absence of provider support led to high discontinuation

rates among clients in female condom programs.⁴⁰ This discontinuation, in turn, led circularly to the perception among providers of a lack of end-user demand for the female condom. Providers were therefore reluctant to promote the female condom, especially when provider-preferred substitutes existed for contraception and STI prevention, notably the more cost-effective, easy-to-use, and often publicly subsidized male condom.⁴¹

Cultural attitudes and patterns also affected provider adoption. Provider training and counseling efforts often focused on female clients, with little information directed toward male partners and little effort made at encouraging open communication between partners about protection methods. Without male cooperation and support or training for women in sexual negotiation skills, female end-users may be unable to assert their right to an independent choice of contraception.⁴² Moreover, the provision and promotion of female condoms, even with male cooperation and involvement, do not necessarily translate into increased use if existing cultural, educational, or political inequalities prohibit female control over reproductive health decisions.⁴³ Providers are often unwilling or unable to intervene in these gender-based patterns of decision-making among couples. In addition, cultural stereotypes have affected provider preferences; the female condom has been viewed as a “method of last resort” for commercial sex workers when male condoms are unavailable.⁴⁴

Provider adoption has also been affected by problems in availability—especially inconsistency of supply—at the local level. In some areas, oversupply has been reported for public service agencies and nongovernmental organizations (NGOs), resulting in wastage and expired stock.⁴⁵ Other NGOs and private pharmacies have found themselves stocked out of the female condom or anticipate female condom shortages when funding stops from pilot projects.⁴⁶ These problems with supply undermine provider adoption. Some providers believe that government or donor agencies are not serious about their long-term commitment to the female condom. As a result, some providers view female condom programs as an externally driven, unsustainable experiment for which government, donor, and consumer interest will inevitably wane over time.⁴⁷

Insufficient Global Consensus

Efforts to introduce female condoms have also suffered from a lack of global consensus about the need for the technology and its relationship to other family planning and HIV prevention technologies. Several international agencies—especially WHO, UNFPA, and UNAIDS—all have signaled their support for

female condoms through financial and administrative investments in research, programs, and advocacy activities. But individuals and organizations in the broader global health community have expressed sharply diverging views of the technology.

As the female condom is a dual protection technology, decisions about its promotion have required the collaboration of different global health policy communities—especially those dedicated to family planning and those focused on HIV prevention. These groups have tended not to communicate well with each other,⁴⁸ and their views of the female condom have differed because their work seeks distinctly different global health goals. Family planning groups, which seek to promote the most effective contraceptive, have been reluctant to promote the female condom because it is less effective than hormonal contraceptive methods. HIV prevention activists, by contrast, advocate a harm-reduction model that emphasizes the minimization of risk through a combination of strategies with varying degrees of effectiveness. Bringing these different groups together in global health requires concerted communication and hard work, and this did not occur for these policy communities in the introduction phase of the female condom.⁴⁹

Splits also arose between women's health advocates and other health researchers. In his review of a 1997 AIDSCAP meeting on "The Female Condom: From Research to the Marketplace," Friel notes,

*'Women's advocates' were said to be pushing for the female condom now; 'researchers and donors,' on the other hand, said it was too expensive until more research shows it to be effective in slowing the AIDS epidemic. The dilemma was and is real: if we don't invest in it, how can the female condom show success?'*⁵⁰

The strongest advocates for the technology came from the international women's health community. Their support for the female condom resulted in part from evidence showing that heterosexual intercourse, rather than women's intravenous drug use, put women at greater risk of HIV infection than men. They concluded that women needed methods under their own control to protect themselves against HIV infection.⁵¹ Some analysts have argued recently that international women's health advocates' efforts to promote the technology diminished after a period of initial excitement, once the technical and design problems became apparent in the introduction phase.⁵² These advocates did not give up on the female condom, but some began focusing on other technologies such as microbicides.⁵³ Microbicides are seen as a preferable female-initiated HIV prevention

method compared to female condoms because microbicide gels are supposedly “invisible.” Women therefore would not have to obtain their partners’ cooperation in order to use the technology.⁵⁴ Recent microbicide studies, however, have questioned whether gels will indeed be invisible to male partners. Other research points out that in many cultures, women will always seek male partners’ consent and cooperation about the use of reproductive health technologies, even if the technology’s design allows for “invisible” application.⁵⁵ Furthermore, optimistic estimates suggest it will be 2010 before an acceptable microbicide will be on the market.⁵⁶ As a result, the female condom is the only technology currently available (other than the male condom) that can protect against both pregnancy and STIs.

Significant gaps in the evidence base about the female condom also hampered global adoption. Female condom research has focused on acceptability studies and pilot studies conducted in different countries. These studies have been important for assessing both end-user perceptions of the new technology and field experiences in using the technology in small-scale interventions. But large-scale epidemiological studies on the female condom that could provide good evidence for moving the technology from introduction to scale-up have not yet been carried out.⁵⁷

Large-scale epidemiological studies could encourage global adoption in several respects. First, large studies of actual female condom use, with outcome data such as pregnancy, STIs, or HIV infection, could help convince implementing organizations, donors, and other reluctant groups that they should invest in the technology.⁵⁸ The potential for the female condom to affect HIV incidence, for example, can only be shown in large-scale national programs. Data from large-scale studies could also help demonstrate whether scaling up female condom availability would result in significant and continued uptake. The focus on acceptability research and pilot studies has helped perpetuate the view of the female condom as still “in trial.” Because doubts—both real and imagined—exist about effectiveness, many implementing agencies and national governments are unwilling to integrate the female condom into STI, HIV/AIDS, or family planning programs beyond a pilot project.⁵⁹ Similarly, many donors are reluctant to provide substantial funding for female condom programming and procurement.

Inadequate Architecture

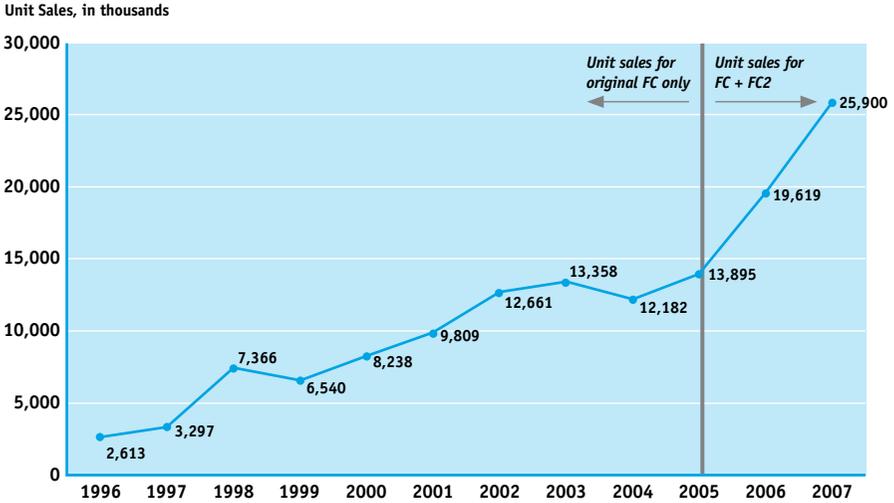
Any new technology needs an effective champion to expand access. The female condom has its advocates, including international women’s health groups, the

Female Health Company, and the Female Health Foundation. While the Female Health Foundation has promoted the product, the Foundation's efforts have focused mostly on local and national issues, rather than at the global level. Furthermore, the foundation is almost entirely funded by the Female Health Company, making some national and global actors uncomfortable and distrustful.⁶⁰ No other nonprofit organization has taken primary responsibility to promote access for the female condom at the global level. Nor has there been a global campaign for the female condom like the one for microbicides.

In its introduction phase, the female condom lacked an important component of architecture: an access plan to mobilize individuals and organizations behind the technology. At global meetings, experts discussed and identified important activities for scaling up. For example, the 1997 AIDSCAP meeting concluded with more than 40 "next steps to the marketplace." Six of these next steps emerged as consensus recommendations: (1) begin large-scale introduction in two to three countries in order to answer operational research questions, (2) promote the female condom for men as well as women, (3) market the female condom simultaneously through interpersonal and mass media strategies, (4) expedite research on whether the female condom can be used more than once, (5) provide incentives for alternative, less expensive product designs, and (6) disseminate information broadly, including to the media.⁶¹ But none of these "next steps" or "consensus recommendations" became prioritized or written into a plan.⁶² With no access plan, no global champion beyond the manufacturer and its foundation, and no strong architecture for partnership, the numerous problems discussed in this section persisted as barriers to access.

Rethinking Strategy for Scaling Up (Phase 3)

By early 2005, access to the female condom seemed to be leveling off worldwide (see Figure 8.1). In the nine years following the female condom's introduction, only 90 million units were sold.⁶³ Sales increased nine-fold between 1997 and 2003, but from a relatively low starting point.⁶⁴ Between 1996 and 2005, the Female Health Company operated at an annual net loss. According to the company's annual report in 2002, members of the board of directors needed to make substantial loans to help keep the company afloat.⁶⁵ By 2004, approximately 12.2 million units were sold per year, representing only 0.1–0.2% of the number of male condoms sold worldwide.⁶⁶ The company received a USAID contract in 2003 to provide female condoms to AIDS prevention initiatives in developing countries. But worldwide orders for female condoms did not change significantly

Figure 8.1 | Unit sales of the Female Health Company products (FC and FC2)

Note. All unit sales prior to 2005 refer to sales of the original female condom product (FC). In 2005, the company introduced a second product, known as the FC2. All unit sales in 2005 and the following years are of both the FC and FC2 products. Data from *Female Health Company Annual Reports*, available at <http://www.femalehealth.com> (retrieved March 22, 2008).

between 2002 and 2005, and neither did the proportion of female to male condoms sold.⁶⁷

To remain viable, both the company and the technology required strategic change. Various product advocates and donors who sought to promote the female condom technology pursued three strategies: (1) new product development, (2) training and promotion, and (3) building architecture. These strategies represent efforts by the product champions and key stakeholders to improve consultation, cooperation, and consensus in order to reduce the barriers to access. The strategies seek to address continuing problems in affordability, provider and end-user adoption, and global architecture.

New Product Development

One way to reduce the high price of the female condom is to develop cheaper designs than the original polyurethane-based condom. As PATH vice president Michael Free remarked in a 1997 AIDSCAP meeting, “The only way to get the production price down is to break the technology barrier to create a much less expensive material.”⁶⁸ New product designs could also allow new manufacturers

to enter the female condom market. This could create competition in what was a monopoly market. In addition, new product designs could raise end-user adoption by improving the original product's lack of appeal to women.

The ideal female condom product, according to PATH, should have the following features: (1) be highly protective, (2) be stable and secure, (3) cost less than \$0.10, (4) be extremely easy to use, (5) provide great sensation, and (6) allow for environmentally safe disposal.⁶⁹ To narrow the gap between the existing female condom and this ideal product, several alternative designs to the FC Female Condom are now under development (see Table 8.1 for a list of these products). The new designs differ according to their material (synthetic latex or polyurethane) and design features (for example, length, shape of outer ring, lubricated/nonlubricated, with/without anchoring sponge, separate from/built into underpants), and can be manufactured with or without a spermicide.

The first new product is the Female Health Company's FC2, which uses a nitrile polymer synthetic latex alternative to the FC Female Condom. Nitrile polymer (the material used in manufacturing surgical gloves) is cheaper than polyurethane and involves an improved, more efficient production process whereby condoms are dipped onto a mold, as opposed to welded together down a seam as was the case with the original polyurethane model. In 2005, the Female Health Company further cut costs for the FC2 by switching manufacturing operations from the Chartex facility in London to a factory in Kuala Lumpur, Malaysia. Initially, operations in Malaysia consisted of a borrowed line in a surgical glove factory, but by 2007, public-sector FC2 sales were doing well enough for the Female Health Company to increase its manufacturing capacity by opening its own factory.⁷⁰ Recently, the Female Health Company established a partnership with its FC distributor in India, the government parastatal Hindustan Latex Limited (HLL). HLL previously collaborated in social marketing for the original FC to high risk populations in six states across India, as well as private-sector distribution to the general population in two additional states. In 2008, HLL will begin production of the FC2 in India for the Indian governments' National AIDS Control Organization. The government, in partnership with NGOs, will sell the FC2 through social marketing in selected Indian states at heavily subsidized prices to end-users (approximately \$0.13 per female condom compared with \$1.00 per unit cost of production).⁷¹

In 2007, WHO gave the FC2 a positive technical review prior to the 2006 Toronto AIDS meeting. The Female Health Company and UNAIDS then negotiated a reduced price agreement that enabled the sale of the FC2 to the global

Table 8.1 | Manufacturers of female condom products, as of 2008

Manufacturer	Country	Product	Registration	Brand Names
Female Health Company	United Kingdom	FC Female Condom®	U.S. FDA CE plus 11 other countries	FC FC Female Condom Reality Femidom Dominique Femy MyFemy Protectiv' Care FC2
Mediteam	Belgium	The Belgian Female Condom		
Silk Parasol Corporation	United States	Silk Parasol		Panty Condom
PATH	United States	Women's Condom		WC Woman's Condom
Natural Sensation Company (Acme Condoms)	Colombia	Panty Condom Female Condom	CE INVIMA (Bolivia) undergoing review in Brazil, Argentina, Australia, USA	Panty Condom
Medtech	India	VA Female Condom	CE Indian MOH undergoing review in China, Brazil, South Africa, Russia	VA Female Condom Reddy Female Condom V-Amour

public sector via UN agencies at a price of \$0.74–0.87 per unit.⁷² The FC2 also received a CE (European Conformity) mark from the European Economic Area for use by European public-sector agencies.⁷³ However, as of March 2008, the FC2 was still under review by the U.S. FDA. This means that while UN agencies and European donors have integrated the FC2 into their AIDS prevention programs, U.S. purchasers—including USAID (with whom the Female Health Company has one of its largest contracts), the City of New York, and Planned Parenthood—can only purchase the original FC. Consequently, though the

Female Health Company would prefer to discontinue the original FC and transfer all of its manufacturing operations to Malaysia, the London Chartex plant has to stay open to produce the original FC for U.S. purchasers.⁷⁴ The inability to discontinue production of the original FC also means that in countries in which both the UN and USAID supply female condoms to the public sector, whether a woman obtains either the original FC or the FC2 is determined entirely by which donor funds the supplier to her particular clinic, program, or region and not by consumer choice or market mechanisms.

The next two products, the VA Female Condom (also known as the Reddy Female Condom or V-Amour) and the Natural Sensation Panty Condom, are marketed in limited quantities outside the United States, but do not have U.S. FDA approval and are not currently purchased by major donors.⁷⁵ Three other new products are also in development. The furthest in development is a polyurethane prototype developed by PATH in partnership with CONRAD, the Andrew W. Mellon Foundation, the Bill & Melinda Gates Foundation, and a number of private donors. This product, called the PATH Woman's Condom, seeks to be more user-friendly and cost-effective than both the FC and the FC2. PATH's innovations include the addition of a dissolving insertion capsule, made of polyvinyl alcohol, which allows easy proper placement, a soft outer ring that sits snugly against a woman's body, and four small dots of foam on the condom's surface to ensure that the condom lines the vagina without twists, bunches, or movement.⁷⁶ In 2008, the PATH Woman's Condom was ready to begin the combined Phase II/III effectiveness trials required by the U.S. FDA pending funding.⁷⁷ PATH currently expects a public-sector price for the product of \$0.30–0.40, but with scale-up and material and process innovations, the organization hopes to reduce this amount by half.⁷⁸ Early acceptability studies conducted in South Africa, Thailand, and Mexico have indicated a positive response from users, most notably ease of insertion and correct use from the first attempt.⁷⁹ Two additional products, the Silk Parasol and the Belgian Female Condom, are also in development. Regulatory approval is contingent on the companies' ability to find funding for clinical trials and regulatory applications.⁸⁰ Some female condom advocates argue for amending the clinical trial requirements and streamlining the regulatory approval process for female condoms in the United States in order to bring these new products to market more quickly.⁸¹

Even with new product designs and more competitive markets, the female condom will probably always cost more than a male condom because it is larger, more complex, and has increased performance demands.⁸² The manufacturing process

is simply more costly for female condoms, even at large numbers. Additional manufacturers and more competition will help lower prices, ensure steady product supply, and offer more choice to women, but it will take some time before the new products complete development and enter the market to compete with Female Health Company products. Until this occurs, affordability of the female condom for donors and national governments will depend on (1) the negotiation of reduced price agreements with the Female Health Company as a monopoly supplier and (2) a significant increase in demand for the FC2 to give the company economies of scale. A recent PATH and UNFPA document presents the Female Health Company's FC2 pricing strategy and challenges:

FHC hopes to develop a coalition of regional buyers to enable cost savings through bulk regional procurement. Nonetheless, to achieve even a 50 percent price reduction (\$0.31), global sales and bulk purchasing will have to increase to 200 million units—more than 14 times the total 2005 sales of the FC Female Condom (14 million units). This will require a substantial increase in global demand.⁸³

Increasing demand for the product around the world remains a persistent challenge for female condom advocates.

Training and Promotion

By the mid-2000s, acceptability studies among women showed that the design of the female condom—most notably its bulkiness, difficulty of insertion, and noise—constituted major barriers to ongoing use, as was the perception that male partners do not like the technology. Similarly, providers had serious doubts about donors' ability to maintain a consistent supply of female condoms. Providers also questioned the technology's usefulness when a cheap, effective, and available alternative existed—the male condom. Providers perceived a lack of demand for the product among women and their male partners. They also wondered about the effectiveness of the female condom in the absence of counseling and monitoring. Without training in sexual negotiation skills and lacking power in sexual relations, women seem as unlikely to propose a female condom to their male partner as they would a male condom.⁸⁴ To address these barriers to end-user and provider adoption, female condom advocates developed a number of training and promotion strategies. These include counseling and support for women and their male partners, provider training, the creation of user-friendly instructional materials, and the identification of nontraditional channels (such as taxi stations) through which to promote and distribute the condom.

Well-designed and implemented training programs and materials can significantly increase adoption. For instance, prior to the launch of its public-sector female condom program, the South African government organized a Training of Trainers program to prepare providers for the new technology.⁸⁵ The program created a network of trained health care workers to promote the method, train other providers, and give support to end-users. The training shifted providers' family planning and STI counseling from a "provider-centered" approach to a "client-centered" one in which clients choose technologies most appropriate to their personal needs and desires.⁸⁶ The training also encouraged providers to use the female condom themselves in order to gain firsthand experience and greater understanding of potential problems. A recent study in Brazil showed that extended provider counseling can overcome negative first impressions and can raise adoption and long-term use by some women.⁸⁷

Some recent reports suggest that the involvement of male partners in female condom promotion can be effective in cultures where women have limited power and status.⁸⁸ In South Africa, for example, the Female Health Foundation has targeted male police officers in special workshops, and in Zambia, the Society for Family Health (the local PSI affiliate) distributes the product to men in barber-shops. Program staff in both countries report high levels of interest by men who enjoyed the feeling of sex without a male condom and appreciated sharing the responsibility of protection and contraception with their partners.⁸⁹

Building Architecture

A major barrier to female condom access has been the absence of an effective global architecture and champion. Beginning in the mid-2000s, a new architecture of female condom access began to emerge. Global agencies, particularly UNFPA, began to take a stronger advocacy role. In 2005, UNFPA launched the Global Female Condom Initiative to promote the device as a dual protection method. UNFPA thus became one of the Female Health Foundation's most enthusiastic partners. The UN agency aims to scale up female condoms in 22 countries through its global campaign for the technology.⁹⁰

Female condom advocates also began to collaborate to expand access to the technology. In September 2005, a partnership among PATH, UNFPA, the Bill & Melinda Gates Foundation, USAID, the U.K. Department for International Development, and other advocates sponsored the Global Consultation on the Female Condom in Baltimore, Maryland. Experts from around the world attended this meeting to review evidence about the female condom's effectiveness and program experiences. To avoid repeating past mistakes, organizers set up a working group to

ensure that commitments would be implemented. Participants also decided to identify and prioritize the next steps for scaling up into a strategic access plan.

The meeting agreed on four steps for action: (1) develop greater political and social support for the female condom at local, national, and international levels, (2) increase public and private-sector investment in female condoms, (3) move beyond the pilot stage to scale up the use of female condoms and to monitor and evaluate impact, and (4) conduct research to improve programming, including operational research to identify behavior change strategies and evaluations of long-term impacts.⁹¹ UNFPA's female condom initiative and the Global Consultation, together with the launch of the FC2, marked a turning point in efforts to expand access to the female condom and produced a measurable rise in sales, although total sales are tiny compared to global sales of male condoms. One important result of this meeting was the abandonment of pilot projects in favor of national distribution strategies. UNFPA now only introduces female condoms within the context of national scale-up, and the Female Health Foundation actively distances itself from pilot projects.

Strategies for adoption of the female condom have also shifted to stress HIV/AIDS prevention and control. The Female Health Company rarely mentions contraception or family planning in its current literature, instead marketing the FC and FC2 as integral to the battle against HIV/AIDS. The disagreements between the AIDS and family planning policy communities are thus disappearing, as the AIDS context comes to dominate advocacy of the female condom.

Activists recently launched a new global campaign called Prevention Now! to push for universal access to female condoms (led by the nonprofit Center for Health and Gender Equity in Takoma Park, Maryland). While the campaign's advocacy literature briefly mentions the goal of reducing unintended pregnancies, its dominant message calls for accelerated prevention of HIV and other STIs through expanded use of female condoms. It remains to be seen what impact Prevention Now! will have on global adoption of the female condom, but the campaign does represent a large and diverse coalition of private and public partners and operates without a specific link to the Female Health Company. This independence may lend its efforts a credibility that the Female Health Foundation has lacked due to its ties to the main manufacturer.⁹²

Advocates of different female-initiated methods are also moving toward more collaboration.⁹³ In late 2004, the Global Campaign for Microbicides organized a meeting in London to address barriers and opportunities for increasing access to the female condom. This meeting represented a major change from prior positions

promoting microbicides as the better female-initiated barrier method.⁹⁴ PATH and UNFPA have come to believe that “strong introduction programs [for the female condom] can also help pave the way for the introduction of other new protection methods, such as cervical barriers and microbicides, which will become available in the next decade.”⁹⁵

Conclusions

In 1993, the report for an AIDSCAP meeting on the female condom came to the following conclusion:

*Without concrete steps by the public sector and sustained interest on the part of both family planning and AIDS professionals, it is safe to predict that the female condom will not be available to women in low income countries, and one potential weapon in the fight against STDs/HIV in developing countries will be lost.*⁹⁶

This statement proved to be prescient. The story of female condom access has been one of disappointingly low uptake. Many advocates continue to hope that the product will eventually be more widely used, and they continue to work to make the female condom more available, affordable, and acceptable to women and their partners, as well as to national governments and donor agencies. As Latka notes, the female condom faces similar challenges to those of the tampon when first introduced in the United States in the early 1930s.⁹⁷ The example of the tampon shows that controversial products can become mainstream. Over time, the female condom may become more widely adopted throughout the world, but only if concerted efforts are made to overcome major barriers. In this review of female condom access, we have shown that such efforts are presently seeking to address blockages at multiple levels, including technology design, global architecture, product price, distribution, and adoption at all levels (see Table 8.2 for a summary of access barriers).

This chapter has emphasized that new technologies like the female condom face many access barriers at the local level. Providers have lacked capacity, training, and support to promote the female condom and counsel end-users. Many providers remain unconvinced about the acceptability of the female condom for their clients. Design problems and product price, as well as the necessity of having to practice the technology in order to use it effectively, have discouraged end-users, providers, and governments from adopting the female condom. Sociocultural

issues have also played a role, such as a woman's inability to negotiate with male partners for contraceptive choice and the strong association of the female condom with commercial sex workers. As of March 2008, a few implementation studies have begun to emerge (for example, among sex workers in Madagascar).⁹⁸ These studies provide guidance on ways to address provider and end-user factors to enhance female condom access.

This chapter shows the importance of building global consensus and coordination for technology access. The failure to develop an effective global architecture and access plan to promote the female condom between 1992 and 2005 slowed progress on many fronts. Differences in donor requirements for product approval have meant that donors are providing two different Female Health Company products, sometimes within the same national context.

The lack of information and research—particularly field trials—has hampered efforts to guide scale-up. The absence of information and research on supply, demand, acceptability, and cost-effective implementation methods has proven to be a major problem for national governments and donors seeking to integrate the female condom into existing reproductive health policy. Governments also lack the assurance from large-scale epidemiological studies that the female condom is an effective and appropriate national-level intervention against HIV/AIDS and other STIs. This dearth of large-scale research represents a major barrier to national and global adoption of the female condom and is a direct result of long-term weaknesses in female condom architecture.

Recently, however, advocates for the female condom have begun to guide access forward. The Female Health Foundation, UNFPA, and other partners are working with national governments to move the female condom beyond pilot projects. Through new production processes and negotiated pricing agreements, public-sector prices have been reduced to make the technology more affordable to governments and donors. A variety of new designs are awaiting approval, with the innovative PATH Women's Condom likely to enter the marketplace in the next three to five years. The new products and manufacturers will introduce competition into what essentially has been a monopoly market. Program successes in countries such as South Africa, Zimbabwe, India, and Brazil have provided a positive blueprint for integrating the female condom into reproductive health initiatives. Governments, donors, and providers are learning from these experiences to manage the main national and local level challenges of the female condom: public-sector stock-outs, poor demand forecasting, lack of consumer choice, and advocacy for the product directed to male partners.

The access barriers for the female condom are numerous and exist at multiple levels. Presently, the most challenging problem for advocates is that many people do not believe that the female condom is an effective and cost-effective strategy for the control of STIs and the prevention of pregnancy. Expanding access to this technology may require substantial donor subsidies, intensive counseling and support mechanisms, new product designs, and a consistent supply of female condoms. A dedicated partnership of advocates for the female condom may be able to reshape this perception and the logistical realities that underpin it. But only a deep commitment to the female condom is likely to create wider access to this technology in the near future.

Table 8.2 | Female condoms access table

	BARRIER	STRATEGY	SPECIFIC ACTION
ARCHITECTURE	Lack of global architecture and global champion for female condoms	Identify effective leadership and design partnerships for the technology	<p>UNFPA has taken on a global advocacy and promotion role for the female condom and launched a comprehensive initiative in 22 countries</p> <p>Advocates established the Prevention Now! campaign to promote universal access to female condoms within an integrated STI and pregnancy control program</p>
	No strategic plan for female condom access	Create strategy for technology access	<p>1997 AIDSCAP meeting identified 40 steps for scaling up the female condom, but these steps were never prioritized or written into a strategic plan</p> <p>UNFPA, PATH, the Bill & Melinda Gates Foundation, USAID, DFID, and other advocates sponsored the 2005 Global Consultation on the Female Condom and identified steps to boost support, increase investment, generate data, and scale up</p>
ADOPTION	Lack of global consensus and global/national adoption	Produce acceptance of the technology at the global and national levels	Increasing numbers of field trials conducted on acceptability and effectiveness though large-scale epidemiological studies have yet to be carried out
	Lack of adoption by providers due to limited training and infrastructure, as well as provider preferences	Develop and implement provider training programs	<p>Some countries launched provider training programs (such as Training of Trainers) to create networks for promotion, training, and counseling of providers</p> <p>The Female Health Foundation updated training manuals for providers so that infrastructure such as female pelvic models are no longer necessary</p>
	Low adoption by end-users due to technical, cultural, and gender factors	Develop counseling services for end-users, programs that address stigma, and new product designs; identify nontraditional channels for distribution	Some programs developed extended counseling services to train and support end-users to use female condoms and build sexual negotiation skills

Table 8.2 | Female condoms access table (continued)

	BARRIER	STRATEGY	SPECIFIC ACTION
ADOPTION			<p>Some programs identified nontraditional channels for female condom promotion and distribution including police officers, taxi stations, and barbershops</p> <p>Some programs implemented social marketing projects aimed at destigmatizing female condoms</p> <p>NGOs, companies, and donors formed partnerships to develop new products that address design problems</p>
AFFORDABILITY	High product price (affecting government, donor, and end-user affordability)	Find ways to lower prices through subsidy programs, public-sector pricing, promotion of reuse, and competition.	<p>Donors provided subsidies to distribute female condoms free of charge or at low prices; high product prices limit the scope of these programs</p> <p>UNAIDS negotiated a public-sector pricing agreement with the Female Health Company for the FC and FC2</p> <p>Advocates sought global consensus for female condom reuse but these efforts were unsuccessful</p> <p>NGOs, companies, and donors formed partnerships to develop new products with cheaper materials; once approved, these products will provide competition in the marketplace</p> <p>The Female Health Company, UNFPA, and other donors have begun negotiations for FC2 bulk purchasing to take advantage of economies of scale; success of this strategy depends on a major increase in global product demand</p>
AVAILABILITY	Inconsistent supply of female condoms	Assure adequate quality and quantity of production; seek to develop multiple producers	Partnerships were formed to develop, bring to trial, and eventually scale up the new FC2 latex condom and PATH female condom

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