

**Obstetrics and Gynecology Devices Panel of  
the Medical Devices Advisory Committee**

Open Public Hearing Comments from the  
December 11, 2008, panel meeting for the  
Female Health Company FC2 Female Condom  
(P080002)





November 24, 2008

Obstetrics and Gynecology Devices Advisory Committee  
Food and Drug Administration  
c/o Center for Devices and Radiological Health (HFZ-470)  
9200 Corporate Boulevard  
Rockville, MD 20850

Dear Members of the Advisory Committee:

Thank you for the opportunity to submit comments for the Food and Drug Administration's (FDA's) review of the FC2 Female Condom, sponsored by the Female Health Company. Through our work as an independent, not-for-profit organization focusing on reproductive health research, policy analysis and public education in the United States and internationally, the Guttmacher Institute has developed and analyzed a great deal of information on unintended pregnancy and sexually transmitted infections (STIs) and their implications for the health of women and men.

The female condom is an especially significant tool for women as being the only method, along with the male condom, that provides dual protection against both unintended pregnancies and STIs, including HIV/AIDS. Its importance is heightened in developing countries, where women have less social and economic autonomy but comprise more than half of the 33 million people currently living with HIV around the world. While FC1 faces barriers to distribution, particularly in developing countries, because of its higher price, the FC2 could overcome some of these obstacles due to its lower material and manufacturing costs. We also note that research shows that FC2 performs comparably to FC1 in clinical trials and has been approved for use by the UN.

The female condom is also a critical addition to the choices available for women to control their fertility. Research indicates that nearly half of all pregnancies in the U.S. are unintended, and that many factors can influence contraceptive use patterns, including method switching, over women's lifetimes. Increasing the array of contraceptive methods available to women is important to helping women choose contraception that is appropriate for them at different phases of their lives and to practicing contraception consistently and correctly over several decades.

We urge the FDA to consider the most current and accurate data available in making an evidence-based decision on the safety and effectiveness of the FC2 during its review process. We again thank the FDA for the opportunity to provide these comments.

Sincerely,

A handwritten signature in cursive script that reads "Cory L. Richards".

Cory L. Richards  
Executive Vice President  
Vice President for Public Policy

Advancing sexual and reproductive health worldwide through research, policy analysis and public education

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Tuesday, November 18, 2008

Dr. Marcelle Cedars, Chairperson  
Obstetrics and Gynecology Devices Advisory Committee  
United States Food and Drug Administration  
C/O Michael T. Bailey, Ph.D., Executive Secretary  
Center for Devices and Radiological Health  
Office of Device Evaluation/DRARD  
9200 Corporate Blvd. HFZ-470  
Rockville, MD 20850

Dear Dr. Cedars and Members of the Advisory Committee:

We are pleased to learn that the FDA's Obstetrics and Gynecology Devices Advisory Committee is planning to move forward with its review of the Female Health Company's FC2 Female Condom. Once you have completed your scientific review of the FC2 Female Condom, we are hopeful that you will conclude that it is safe and effective because your decision will quickly result in expanded access to woman-initiated HIV prevention in the United States.

As health care providers and women's health advocates, we are deeply concerned about the growing impact of HIV/AIDS among women in the United States and around the globe. Over the past two decades the proportion of women among people living with HIV/AIDS (PLHIV) has more than tripled – from 8 percent of PLHIV in 1985 to 26 percent in 2007. HIV infection has emerged as the leading cause of death for African American women aged 25-34, high-risk heterosexual contact is responsible for 80 percent of new HIV infections among American women, and one in four young adults aged 15-20 years contract a sexually transmitted infection each year. In this context, expanded access to the female condom—the only safe, effective, and available woman-initiated prevention method—is essential to provide women and men with more options to practice safer sex.

The evidence of the female condom's value in the fight against HIV is compelling. Both the FDA and the WHO consider the FC1 Female Condom safe and effective. More than 200 peer-reviewed studies have demonstrated that when women have access to the FC1 Female Condom and education on its use, it becomes a product that they demand. Research in Madagascar has shown that when the FC1 Female Condom is distributed along with male condoms, the rate of protected sex acts increases significantly and the prevalence of STIs declines. New York City has expanded its purchase and distribution of the FC1 Female Condom as part of a broad HIV/AIDS prevention campaign, and a recent study of this campaign has shown a decline in the number of newly reported AIDS cases. Additionally, survey data have shown a 37 percent increase in female condom usage over the course of the campaign to date.

The high unit cost of the female condom relative to the male condom has limited its availability to HIV prevention programs over the past 15 years. In 2006, for example, just 20 million female condoms were distributed worldwide—roughly the equivalent of one female condom per year for every 100 women aged 15 to 49 in Africa, Asia, and Latin America. By comparison, 6 to 9 billion male condoms were distributed.

The Female Health Company's second-generation FC2 Female Condom is made with a new material that allows it to be manufactured with cost efficiencies that will drive down its unit price significantly if it is procured and distributed in bulk. The WHO has already paved the way to expanded access by recognizing the FC2 Female Condom as equivalent to the FC1 Female Condom in regard to safety, effectiveness, and acceptability. This decision has opened the door to increased uptake and distribution by UN agencies. The FDA can take action by determining that the FC2 Female Condom is safe and effective. This decision will enable state and local governments in the United States and USAID-funded international prevention programs to provide women with the only HIV-prevention tool that they can initiate and negotiate with their husbands and partners.

The evidence is clear and compelling: women need expanded access to woman-initiated HIV prevention. We look forward to FDA's scientific review of safety and effectiveness data related to the FC2 Female Condom, and we are optimistic that your review will produce a positive determination.

Sincerely,

National Association of Nurse Practitioners in Women's Health  
Advocates for Youth  
American Medical Women's Association  
Association of Reproductive Health Professionals  
Black Women's Health Imperative  
Catholics for Choice  
Clearinghouse on Women's Issues  
Feminist Majority  
Hadassah, The Women's Zionist Organization of America, Inc.  
Mid-Suffolk National Organization for Women  
National Capital Area Union Retirees  
National Council of Women's Organizations  
National Family Planning and Reproductive Health Association  
National Latina Institute for Reproductive Health  
Reproductive Health Technologies Project  
San Diego State University – Department of Women's Studies  
Society for Women's Health Research  
United Methodist Church, General Board of Church & Society  
Women's Research & Education Institute  
YWCA USA



November 26, 2008

Obstetrics and Gynecology Advisory Panel  
Center for Devices and Radiological Health (HFZ-470)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: Premarket Approval amendment for the FC2 Female Condom

Dear Members:

I am pleased to submit these comments on behalf of the Global Campaign for Microbicides, regarding the proposed premarket approval (PMA) amendment for the FC2 Female Condom sponsored by the Female Health Company.

The Global Campaign for Microbicides is a broad-based, international coalition of organizations working to accelerate access to new HIV prevention options, especially for women. We work to mobilize support among policymakers, opinion leaders, and the general public for increased investment in microbicides and other female-controlled methods of HIV prevention. We do not fund or develop products, nor do we receive any corporate funding. We are simply advocates, working in collaboration with hundreds of nongovernmental organizations (NGOs) worldwide, to build a sustained political base for access to female-initiated HIV prevention methods

As you know, worldwide, women bear the burden of HIV infection. Physiologically, women are two to eight times more likely than men to contract HIV from a single exposure.<sup>1</sup> Here in the United States, nearly half (43%) of all teenagers living with AIDS are girls. The brutal fact is millions of women of all ages lack the social and economic power necessary either to insist upon male condom use or to leave relationships that put them at risk of HIV. And the poorer, the less educated, and the more marginalized a woman is, the less power she has to protect herself from HIV.

In a press briefing last September, the Centers for Disease Control and Prevention reported that African American women are one of the three sub-populations in the United States experiencing the highest rates of new HIV infection<sup>2</sup> and make up the majority of women living with AIDS in our country. At a hearing of the House Committee on Government Oversight and Reform on September 16, 2008, Dr. Anthony Fauci

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<sup>1</sup> Cummins JE, Dezzutti CS, "Sexual HIV-1 Transmission and Mucosal Defense Mechanisms," *AIDS Review* 2000; 2: 144-154, cited by amfAR, The Foundation for AIDS Research, "Fact Sheet: Woman and HIV/AIDS," March 2008.

<sup>2</sup> CDC Fact Sheet, "MMWR Analysis Provides New Details on HIV Incidence in U.S. Populations" 11 September, 2008, available on-line at [http://www.cdc.gov/nchhstp/newsroom/docs/CDC\\_Incidence\\_MMWR.pdf](http://www.cdc.gov/nchhstp/newsroom/docs/CDC_Incidence_MMWR.pdf).

underscored that expanding the range of prevention options specifically with regard to woman-initiated prevention methods is an essential part of any comprehensive approach to the United States HIV epidemic.<sup>3</sup> Right now, there is only one method that a woman can initiate without her partner's active cooperation and that is the female condom. Thus, the role this method could play in HIV prevention is hard to overstate.

You may have heard that women do not like female condoms and will not use them. But I submit to you that this perception may have more to do with their cost and shortcomings in how they have been introduced and promoted than anything else. Consider this evidence:

A 2003 survey of 198 young women (15-25 years old) living in inner city Denver found that African American women and younger women were the two groups most interested in potentially using female condoms, if such a method were readily available to them. These are exactly the populations most at risk of HIV right now. This suggests that if a female condom were readily accessible—that is, available at low or no cost as the male condom is in most communities—they might well use it.<sup>4</sup>

Also consider this: A growing body of evidence indicates that the more women have access to, and education about, the female condom, the lower their overall percentage of unprotected sex acts.<sup>5</sup> Fonatanet et al showed this dynamic among sex workers in Thailand,<sup>6</sup> as did Choi among women in northern California, just to give two examples.<sup>7</sup> These studies and others further show that female condom use does not replace the use of male condoms, but instead is complementary and contributes to increased use of condoms overall. As one Rwandan woman I know said, “just tell him, ‘If you do not put on yours, I will put on mine.’”

Unfortunately, the FC1 condom has not been as widely adopted, either in the US or internationally, as one would hope. This has to do with a number of factors that have already been mentioned here today. But I want to tell you about evidence I have seen of passionate demand for them.

I had the good fortune to travel through four countries in eastern Africa earlier this year and meet with staff in 27 NGOs in the region. One message we heard over and over is that, while there were some acceptability issues around the female condom, these were

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<sup>3</sup> CDC Domestic HIV Incidence Hearing, Testimony of Dr. Anthony Fauci, 16 September, 2008, available on-line at <http://oversight.house.gov/documents/20080916102733.pdf>.

<sup>4</sup> Bull SS, Posner SF, Ortiz C, Evans T, “Knowledge of, Attitudes toward, and Stage of Change for Female and Male Condoms Among Denver Inner-City Women,” *Journal of Urban Health* 2003.

<sup>5</sup> USAID, PATH, UNFPA Factsheet, “The female condom: significant potential for STI and pregnancy prevention,” *Outlook*, May 2006, 22 (2).

<sup>6</sup> Fonatanet A, Saba J, Chandelying V, et al, “Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial,” *AIDS*, 1998, 12 (14): 1851-1859.

<sup>7</sup> Choi K, Gregorich S, Grinstead O, et al, “The Efficacy of Female Condom Skills Training in HIV Risk Reduction Among Women: A Randomized, Controlled Trial.” *American Journal of Public Health*, 2008, 98(10): 1803-1813.

far outweighed by the unmet demand for them in the region. People had some limited exposure to this prevention tool when the first acceptability trials were going on in the 1990s but since then, they have been consistently either unavailable or unaffordable to women in this region. The NGO staff we met with told us that many of the women they serve want to use a female condom, but either cannot find it on the shelves or cannot afford it when they do find it.

Research among women in South Africa has further shown that many women believe it is easier to convince their partners to use a female condom than a male condom, and that a female condom is more effective in preventing pregnancy and sexually transmitted infections.<sup>8</sup>

In 2007, only 25.9 million female condoms were available for distribution worldwide, while 11 billion male condoms were distributed.<sup>9</sup> This is, in part, due to the current FC1's high production costs. Fortunately, this challenge will be somewhat addressed by the FC2. Made from polyurethane, the FC1 generally cost around US \$0.68 to produce, or 27 times the cost of a male condom. The synthetic latex used to produce the FC2, however, makes significantly lower production costs possible.<sup>10</sup>

The reduced price for production, as well as the more user-friendly format of the FC2, should help to increase both access and acceptability of the female condom globally.

While a reduction in price is important, however, I am sure we all agree that the most important factor is product safety and reliability. A 2005 study comparing the FC1 to the FC2 is reassuring on this score. A randomized crossover trial, it compared the two condoms with regard to breakage, slippage, outer ring displacement, and incorrect penetration rates. The study concluded that the FC2 was functionally equivalent to the FC1 and that the breakage rate for both FC1 and FC2 condoms was significantly lower than that for male condoms (0.73% and 0.85%, respectively). Additionally, the study found that the FC2 synthetic latex condom was functionally equivalent to the FC1 Reality condom with regard to total clinical failure, or the sum total of any event that could result in pregnancy or transmission of sexually transmitted infections. In short, we have evidence that the FC2 condom is equivalent to the FC1 condom—but less expensive.

Your decision to approve the FC2 condom would offer women one additional important advantage. There is general consensus in the field that insufficient introductory work, combined with provider bias, substantially inhibited uptake of the FC1 when it first appeared in the 1990s. The advent of FC2 provides an opportunity to reintroduce the female condom as a method of contraception and HIV prevention, and to promote it as a

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<sup>8</sup> Delany S, Nutley T, Mqhayi M, Hatzell T, Rees H, "Female condom: increasing access to female controlled HIV prevention in South Africa." Int. Conf. AIDS, Abstract D11317, 2002, July 7-12.

<sup>9</sup> GCM Factsheet, "Expanding Access to Female Condoms in Africa," available online at <http://www.global-campaign.org/clientfiles/EastAfricaFemaleCondom-action.doc>

<sup>10</sup> Leeper MA. FC2 female condom. Presented at: Global Consultation on the Female Condom, September 26-29, 2005; Baltimore, Maryland.

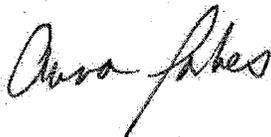
“next generation” version that corrects some of the original acceptability problems experienced with FC1.

I will close with the words of Lucas Mkwizu, director of an NGO in Tanzania. The national prevalence of HIV infection is about 8% among women of reproductive age in Tanzania, and 6% among men.<sup>11</sup> In the hardest hit areas, the rate goes as high as 24%.<sup>12</sup> We asked Mr. Mkwizu, among other things, how he thought the men he worked with would feel about increased access to female condoms in Tanzania. He said, “most families have been affected by HIV. People want to avoid death so there is a possibility for change of attitude but there must be education and access going together.”

Mr. Mkwizu’s organization very much wants to have female, as well as male, condoms to distribute in the communities they serve. They are ready and willing to do the education and promotion. But they need you to take a step to get those female condoms into their hands. I urge you to support this PMA amendment for approval of the FC2—to make it an accessible, affordable option for women and men here in the US and around the globe.

On behalf of the Global Campaign for Microbicides and our many partners, I would like to thank the Panel for the opportunity to submit this testimony and urge their approval of the FC2. Please do not hesitate to contact me at (202) 822-0033 with any questions about this testimony.

Sincerely,



Anna Forbes  
Global Campaign for Microbicides  
PATH  
1800 K Street NW, Suite 800  
Washington, DC 20006

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<sup>11</sup> Tanzania Commission on AIDS, “HIV and AIDS Information: Current Status of HIV/AIDS”, 2008, available on-line at <http://www.tacaids.go.tz/index.php/hiv-and-aids-information/about-hiv-and-aids.html>.

<sup>12</sup> BBC News, “Outcry at Tanzanian HIV Beating”, published online on November 28, 2007, available on line at <http://news.bbc.co.uk/2/hi/africa/7117184.stm>





November 24, 2008

Obstetrics and Gynecology Devices Advisory Panel  
Center for Devices and Radiological Health (HFZ-470)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: Pre-market approval amendment for the FC2 Female Condom

Dear Members:

I am pleased to submit this comment regarding the proposed pre-market approval (PMA) amendment for the FC2 Female Condom sponsored by the Female Health Company. I submit this comment on behalf of PATH—an international, nonprofit, nongovernmental organization with offices in 19 countries. PATH works to improve health by advancing technologies, strengthening health systems, and encouraging healthy behaviors. Our work focuses in five areas: health technologies, maternal and child health, reproductive health, vaccines and immunization, and emerging and epidemic diseases.

For the past 20 years, PATH has been developing technologies that help health care workers and individuals in developing countries to overcome obstacles to good health and health care through a program called HealthTech, which is funded by the US Agency for International Development and others. Through this program we have advanced over 30 technologies, including new, lower-cost versions of the diaphragm and the female condom to help women protect themselves against HIV and AIDS, other sexually transmitted infections, and unintended pregnancy. The reproductive health issues confronting women in developing countries are similar to the concerns of women in the United States as well—the feminization of the HIV epidemic and women's unmet need for barrier protection from both sexually transmitted infections (STIs) and unintended pregnancy. Therefore, we urge your support for this PMA amendment and for approval of the FC2 Female Condom.

In 2005, PATH convened the Global Consultation on the Female Condom with funding from the United Nations Population Fund (UNFPA), the Bill & Melinda Gates Foundation, the US Agency for International Development (USAID), the William and Flora Hewlett Foundation, and the United Kingdom's Department for International Development (DFID), to discuss the status of the class of female condoms worldwide and to develop a plan of action to build support for the method. At this meeting, more than 100 experts from 15 countries concluded that expanding the range of female condom products approved and available on the global market would be

consistent with the stated need to expand access to women's HIV protection methods. In addition, a priority action item was to explore reclassification of female condom devices from Class III to Class II in an effort to facilitate access to this important prevention technology.

We urge your support for this PMA amendment and for approval of the FC2 Female Condom for the following reasons:

- Since the Reality® female condom was approved by the United States Food and Drug Administration (USFDA) in 1993, millions of women in more than 100 countries have used the female condom. It has a long record of safety and use. The FC1 (Reality®) female condom protects from STIs as well as unwanted pregnancy, and provides the only female-initiated alternative to male condom use. Several studies show that having the FC1 available results in an increase in protected sex acts and a decrease in STIs, including HIV/AIDS.<sup>1,2,3,4</sup> Clearly, having a woman-initiated protection option has the potential to improve women's health—especially in circumstances where male condom use is not an alternative.
- Sixteen years of experience with the FC1 female condom has shown that a wide range of women find female barrier protection an acceptable option.<sup>5</sup> However, the high cost of the FC1 limits the availability of and women's access to this prevention technology. In response to the call for a lower-cost product, the Female Health Company initiated production of the FC2 female condom in Malaysia. The FC2 offers the same product design as the FC1 but is made from synthetic nitrile, which allows for lower material and production cost.
- Data from a randomized crossover performance study in South Africa comparing the FC2 to the FC1 female condom found comparable performance between the two products.<sup>6</sup> With over 200 women completing the study and a total of 1,910 FC1 and 1,881 FC2 condoms used, the total clinical failure rates (i.e., the sum of any event that could result in pregnancy or transmission of STIs) were very similar and low (FC1 5.24% compared to FC2 4.3%). Thus this study suggests the two products are functionally

<sup>1</sup> Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases*. 1993;20(3):137–139.

<sup>2</sup> Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: Results from a randomized controlled trial. *AIDS*. 1998;(14):1851–1859.

<sup>3</sup> French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. *Sexually Transmitted Diseases*. 2003;30(5):433–439.

<sup>4</sup> Hoke TH, Feldblum PJ; Van Damme K, et al. Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex worker. *International Journal of STD and AIDS*. 2007;18(7):461-466.

<sup>5</sup> Mantell JE, Stein ZA, Susser I. Women in the time of AIDS: barriers, bargains, and benefits. *AIDS Education and Prevention*. 2008, April;20(2):91-106.

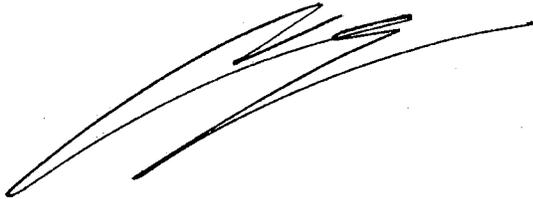
<sup>6</sup> Beksinska M, Smit J, Mabude Z, Vijayakumar G, Joanis C. Performance of the Reality® polyurethane female condom and a synthetic latex prototype: a randomized crossover trial among South African women. *Contraception*. 2006;73:386–393.

equivalent. Safety and acceptability data from the study suggest that the incidence of adverse reaction was no greater with the FC2 than with the FC1. In performance and acceptability, the two products are similar.

Other agencies have approved the FC2 based on these data. The FC2 has received the CE marking for European marketing. The CE marking is a mandatory European process for certain product groups to indicate conformity with the essential health and safety requirements set out in the European Directives. In addition, the Female Condom Technical Review Committee—which was convened by the WHO/Reproductive Health and Research and was composed of technical experts in condom research, design, manufacture, and testing, as well as public-sector procurement, the regulation of female condoms, and clinical trials—reviewed the FC2 in 2006 and determined the FC2 was acceptable for procurement by United Nations agencies.

Your support of this PMA amendment for approval of FC2 will give women in the United States access to a product that currently is available to women in other countries and also improve American women's options for barrier protection. Given the epidemic of sexually transmitted infections in our country and the few choices available for dual protection, we urge your support of this amendment for market approval. Thank you for your attention in this matter.

Sincerely,

A handwritten signature in black ink, consisting of several overlapping, sweeping strokes that form a cursive name.

Christopher J. Elias, MD, MPH  
President and CEO



November 17, 2008

Dr. Michael Bailey  
FDA

Dear Dr. Bailey:

Thank you for the information. I enclose the statement I wish to make on your hearing on the female condom. I am Professor of Epidemiology and Psychiatry Emerita in Columbia University and I have worked on reproductive health for the last twenty five years. I am an author of multiple publications and a co-author in the following publication:

French PP, Latka M, Gollub EL, Rogers C, Hoover DR, Stein ZA. Use-effectiveness of the female versus male condom in preventing sexually transmitted diseases in women. Sex Trans Dis 2003;30:433-439.

Our joint response on this has been as follows:

French PP, Latka M, Gollub EL, Rogers C, Hoover DR, Stein ZA. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. Sex Transm Dis. 2003 May; 30(5):433-9.

#### Reviewers Comment

*In this study, 1442 women attending a sexually transmitted disease clinic were randomly assigned to receive either female or male condoms. The groups were then followed-up to assess their rates of acquiring gonorrhea, chlamydia, early syphilis, or trichomoniasis. It is not explained why HIV was excluded from this group.*

#### Authors Response

Outcomes for this study were derived from the Philadelphia's public health database of STIs that were reportable at that time; HIV was not a reportable disease. Further, the clinic offered VCT for HIV anonymously, and therefore it was not possible to follow women over time who for incident HIV when they came to the clinic for HIV testing.

#### Reviewers Comment

*The authors found that the incidence rates for the first new post-intervention STD per 100 women-months of observation were 6.8 in the female condom group and 8.5 in the male condom group (rate ratio = 0.79, CI: 0.59-1.06). The authors conclude that women counseled on, and provided with, female condoms fared no worse and experienced a non-significant reduction in STDs compared to the male condom group. A limitation found in the previous study holds true here as well. Women were counseled on female condom use. The results of this study may not be reflective of STD rates following use by the general population.*

### Authors Response

This issue pertains to one of generalizability. It should be noted that the design of this trial, more so than other clinical trials, allows for the results to be more generalizable to an important high-risk population, namely, women seeking free health care services. This study was based in Philadelphia's largest (by volume) STI clinic and this study engaged all women who attended that clinic during a specific time period. Unlike a typical clinical trial, women did not have to attend multiple "run in" sessions before they were randomized, which leads to a highly select group of participants in the trial. Rather, in this study, the cohort was defined by all women who simply attended the public health clinic during our specified intervention period, with randomization being done by week of clinic service. Women's outcomes were then followed through the public record databases. Thus, this study did not involve the typical 'select' group of highly-motivated persons, and rather took all women seeking care a busy public health clinic, thereby making it more, rather than less generalizable.

### Reviewers Comment

*However, this is a much more serious limitation of this study. A subgroup analysis by the authors found that women in the male condom arm had little access to female condoms and rarely used the female condoms. However, women in the female condom arm had continued access to male condoms from sources outside of the clinic, and findings from the substudy revealed that male condoms accounted for 1/3 of condom protected sex acts in this study arm.*

*The authors suggest that women in the female condom arm may have improved negotiating power to use any type of condom when the female condom is given as an option. Even if this is true, it fails to separate the effect of the female condom from the male condom, and therefore cannot provide any evidence of equivalence between the two. If 1/3 of the women in the female condom arm are using male condoms, however almost none of the male condom arm women are using female condoms, the benefit of the female condom may be overestimated while actually be attributable to male condom use.*

### Authors Response

This logic is faulty. The two arms being compared were as follows:

- 1) women who were counseled about male condoms, and had access to male condoms only
- 2) women who were counseled about female condoms, but had access to, and used, male condoms obtained through other sources outside the study. This was determined by the stub-study mentioned above.

The following table outlines the main comparisons being made with this design

	<b>Trial Arm 1</b>	<b>Trial Arm 2</b>
	Male condoms	Female condoms + Male condoms
What is different between the 2 arms  Or  What any observed difference between the 2 arms would be attributable to		Female condom*
Proportion	15.8%	12.4%
Odd Ratio & (95 CI)	0.75 (0.56-1.01)	

\*Here the common factor across the 2 arms is male condom use, therefore, male condom use must be factored out of the comparison. The unique difference between the 2 arms, it is the female condom, and therefore, the lower STI proportion and lower incidence must be attributable to the female condom –the unique factor in the comparison.

If it is assumed that in both arms, that protection is conferred only by the male condom, then one would have to assume that 1/3 use of male condoms in Arm 2, is equal to 100% use in Arm 1. That logic is patently flawed.

I would like to make an oral presentation, including one slide, within the time that has been allotted to me in the afternoon.

Thank you.

Sincerely,

Zena Stein, M.A., M.B., B.Ch.  
Professor of Epidemiology and Psychiatry Emerita





# STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.  
Commissioner

November 12, 2008

Dr. Michael Bailey  
Center for Devices and Radiological Health (HFZ-470)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Re: Request to Make an Oral Presentation at the Meeting of the Obstetrics and Gynecology Devices  
Panel of the Medical Advisory Committee (Docket No. FDA-2008-N-0038)

Dear Dr. Bailey:

I am writing to request a time slot to make an oral presentation at the meeting of the Obstetrics and Gynecology Devices Panel of the Medical Advisory Committee (Docket No. FDA-2008-N-0038) to be held on December 11, 2008.

For over three years, the New York State Department of Health AIDS Institute has partnered with Columbia University's HIV Center for Clinical and Behavioral Studies to promote female condom use among heterosexually active women in New York State. This National Institute of Mental Health funded project (Grant #MH074370-01A1) is a four year research study to test the impact of a state-wide female condom promotional intervention targeted at the level of agency directors and risk reduction counselors.

I would like to present to the December 11 panel a brief overview of this project and its role in promoting the female condom in New York State. I would also like to review some of the research that supported funding of this project including data that demonstrates (1) the female condom is an effective prevention method with demonstrated efficacy in preventing pregnancy, HIV, and other sexually transmitted infections and (2) when female condoms are integrated into prevention programs alongside of male condoms the rate of protected sex increases.

My work on this project has convinced me that the female condom has a key role to play in HIV prevention and that access and cost are critical issues that limit female condom use. FDA approval of the FC2 will help remedy these barriers to widespread female condom acceptance. As the World Health Organization has already supported FC2 procurement by UN agencies, I hope the FDA will follow suit and approve immediate market distribution of the FC2.

I propose to present alone; my contact information is listed below. I am available for both the morning and afternoon time slots. Thank you for your consideration of my request.

Sincerely,

Dara Shapiro, MPH  
Assistant Director, HIV Education & Training Programs  
AIDS Institute  
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Patricia S. Coffey, Program Officer, PATH

Patricia S. Coffey is a program officer for field research and evaluation and leader of the newborn/maternal cluster in the Health Innovation Portfolio within the Technology Solutions Global Program. She is responsible for the implementation of social science and operations research of newborn maternal and reproductive health technologies. Specifically, Dr. Coffey designs, implements, conducts monitoring and evaluation, and interprets research results relating to novel product designs/approaches. She coordinates activities of multiple partners in field studies evaluating and introducing innovative maternal child health-related uses of the Uniject™ prefill injection device, chlorhexidine products for umbilical cord care, neonatal resuscitators, and rapid screening tests, among others. In addition, she is responsible for implementing field research that incorporates the user perspective into the development of new barrier contraceptive methods. She also leads intervention research focusing on behavior change communication, particularly related to increasing access to dual protection methods. She has extensive experience in the design, implementation, and evaluation of applied public health programs in both international and domestic settings. Dr. Coffey holds a PhD in applied population research from the Institute for Population Studies at the University of Exeter in the United Kingdom, and an MPH in population and family health and behavioral sciences and health education from the University of California, Los Angeles.

Dr. Coffey is speaking on behalf of PATH, an international, non profit, nongovernmental organization whose mission is to improve health. PATH has worked for more than a decade to improve women's options for barrier protection. As part of this effort, PATH has developed a second-generation female condom. While at PATH, Dr. Coffey worked on the development and testing of two female barrier methods—the SILCS diaphragm and the Woman's Condom. She convened the Global Consultation on the Female Condom in 2005, in conjunction with other international agencies, to assess opportunities to expand access to female condoms. In 2006-2007, she led a stakeholder survey to assess opportunities for expanding access to female condoms through HIV/AIDS prevention and treatment programs in low-resource settings.

Key points:

PATH works broadly to support products in the class of female condoms as a way to improve women's options for both pregnancy and STI protection.

Outcomes from the Global Consultation on the Female Condom, a meeting of more than 100 experts from 15 countries, concluded that expanding the range of female condom products that are approved and available on the global market would be consistent with the stated need to expand access to women's HIV protection methods. In addition, a priority action item was to explore reclassification of female condom devices from Class III to Class II in an effort to facilitate access to this important prevention technology.

The FC2 offers the same product design as the FC1 but is made from synthetic nitrile which allows for lower material and production cost.

Data from a randomized cross-over performance study in South Africa comparing the FC2 to the FC1 female condom found comparable performance between the two products. Other international agencies have approved the FC2 based on these data.

We urge your support of this amendment for market approval.





# FIU

FLORIDA INTERNATIONAL UNIVERSITY  
*Miami's public research university*

OB GYN Devices Panel  
Medical devices Advisory Committee  
Food and Drug Administration  
Center for Devices and Radiological health  
9200 Corporate Blvd  
Rockville, MD 20850

7 December 2008

Re: FC2 Female Condom

To the Panel,

You will today review evidence on the FC2, a barrier method at least partially under the control of women, to reduce risk of both pregnancy and disease. Approval of this device would provide women with only the 2<sup>nd</sup> option available to them for this purpose.

The FDA is charged with guaranteeing the safety and efficacy of a product before approving it.

Notwithstanding the necessity of such a review to ensure the public health is not compromised, the Panel's approach must be tempered by the well-recognized, and continuing 'mis-fit' of a Class III - or "significant risk" rating for simple, vaginal barrier devices. These devices do not carry significant inherent risks to their wear. Their risk is related to women's exposure to semen, for which *effectiveness* is the key criterion for judgment. The original intent of the device regulations was to protect women from inherent risks attending device use - such as those with the Dalkon Shield. It is clear that by any scientific or public health standard (as opposed to a bureaucratic one), this device, as many others, should be subject only to Class II standards - ie. the filing of a premarket notification, or "510k".

Furthermore, the Panel must maintain a keen consciousness about the continued emergency of women's need for HIV prevention methods that are at least somewhat in their control rather than *wholly* controlled by men, which is the case for male condoms, male fidelity, and abstinence: many women of all backgrounds in this country and elsewhere, continue to be victims of unprotected and forced sex.

Finally, in addition to delays imposed by the Medical Device Amendments, which had the ultimate effect of depriving women of barrier protection options that might

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reduce risk of pregnancy and disease (cervical cap, female condom), women globally have suffered at least a 10-year delay in HIV prevention work due to their "invisibility" in the early years of this epidemic.

These observations taken together call for an exceedingly sober approach *vis a vis* approval of FC2. Every decision to postpone approval carries with it a cost. We know all too well the cost of delays. Epidemiologists just recently estimated that 365,000 premature deaths in South Africa would have been averted had HIV treatment that the country was capable of providing, been made available to those who needed it (*NY Times* Nov 26, 2008; page 1).

The case for ensuring device effectiveness is clear. The failure modes of this product - those which subject a woman to exposure to semen - must be evaluated. Data on these failure modes are amply provided for in the carefully-conducted South African study submitted (RHRU study). Failure modes include: invagination of the device; penile "misrouting" (ie. insertion next to, but not inside, the sheath); and rips or tears.

"Slippage" of the female condom does not constitute an event that puts women at risk. Indeed, one can even define some slippage as normal and inherent to proper device use. One of the greatest advantages to the female condom is large protective surface area - the vulva being covered as well as the vagina - making slippage of no consequence as long as the outer ring stays outside the woman's body, and the penis stays within the outer ring and the sheath.

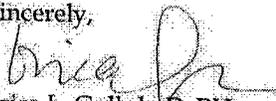
Indeed, in the numerous studies I have conducted with the female condom (see references, below), women - American, French, African; STI clients, drug-using women, HIV positive women, young immigrant women, postmenopausal women - have cited the large, protective sheath as a key advantage this method has over the male condom. It has made women more comfortable, confident and likely to re-use this method of protection. Most of these women were completely unprotected in sex acts before trying the female condom; their attempts at convincing a male partner fell on deaf ears, leaving them with little else besides prayer to avoid infection or re-infection by sexually transmitted agents.

This wholly undue emphasis on slippage seems to be an unfortunate carryover from male condom use; yet the female condom is completely different in the way it protects.

Instead of imposing further costs to women through additional roadblocks to protection with an alternative and less expensive female condom, the advisory panel should be seeking all possible ways to compensate women for the multiplicative delays in science and policy they have already suffered over the past nearly 20 years since the emergence of HIV. The utterly lacking sense of urgency on the part of the US public regulatory and health agencies has contributed significantly to the current emergency.

The Panel today must have the courage to use the careful evidence presented today, as well as reason, compassion and insight to recommend immediate approval of FC2 and its wholehearted support and promotion by US public health agencies to ensure its rapid diffusion here and worldwide.

Sincerely,



Erica L. Gollub, DrPH

#### References

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Advancing  
gender equity  
and social justice  
in international  
population and  
health policy

December 3, 2008

Michael Bailey  
Center for Devices and Radiological Health (HFZ-470)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Dear Michael Bailey:

In light of next week's FDA hearing to consider approval of the FC2 female condom, I am enclosing a copy of *Saving Lives Now: Female Condoms and the Role of U.S. Foreign Aid* by the Center for Health and Gender Equity (CHANGE).

While CHANGE is not seeking the report's submission as official material for the hearing and takes no official position on approval of the FC2, we believe the report might be useful to you as a potential resource for panel members. The report includes an extensive review of peer-reviewed literature from the past eight years about the female condom, its effectiveness in preventing HIV transmission and pregnancy, and the challenges it has faced in terms of cost, cultural barriers, and programmatic weaknesses.

If you have any questions about the report's findings, please do not hesitate to contact me at 202-393-5930 or [ssippel@genderhealth.org](mailto:ssippel@genderhealth.org).

Sincerely,



Serra Sippel  
Executive Director

Redaction – 59 page copyright protected report titled  
“Saving Lives Now: Female Condoms and the Role  
of U.S. Foreign Aid”

This document can be found online at:

<http://www.preventionnow.net/images/savinglivesnowfinal.pdf>



CHICAGO WOMEN'S AIDS PROJECT

6249 N. Kenmore • Chicago, IL 60640 • Ph: (773) 271-2242 Fax: (773) 271-2618

October 25<sup>th</sup>, 2008

Dear the United States Federal Drug Administration (FDA),

We, the Chicago Women's AIDS Project (CWAP) and the undersigned persons below, are writing to demand the **rapid approval** of the female condom 2 (FC2) in late 2008 or early 2009. The availability and access to FC2 is vital to millions of women in the United States and worldwide. It is especially important for those at risk of contracting HIV and other sexually transmitted infections. It is also essential to the countless women who are unable to negotiate use of the male condom with their partners or who are at risk of forced sexual relations.

Any delay of access to FC2 will *continue to cost the lives of millions of women in EVERY nation*. Additionally, studies have shown that FC2 has high efficacy and acceptability rate among women and men, yet continues to remain off the market. We, advocates of women's health, can no longer accept this!

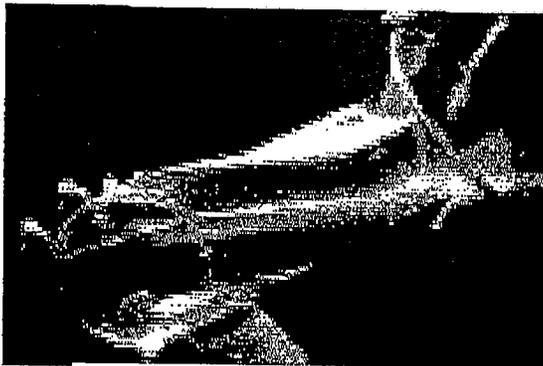
Thus, we ask you, the FDA, to quickly approve FC2 in late 2008 or early 2009. It is time for this most necessary HIV prevention and contraception tool to be in the hands of women across the globe.

Sincerely,

The Chicago Women's AIDS Project  
(CWAP) and the following persons:

Prevention Education ■ Support Services ■ Client Advocacy

Redaction – 7 pages containing personal information from 97 individuals signing the Chicago Women's AIDS Project written comment.



# The Female Condom

1. Female Condoms are the ONLY safe and effective woman-initiated HIV and STD prevention tool available.
2. Female condoms are at least as effective as the male condom in preventing STDs.
3. Studies show that when female condoms are made available through effective programs, along with male condoms, MORE people have protected sex.
4. FC2 is the new version of the Female Condom. It is made of a softer, more durable material and has no seam, but is just as effective and safe (and even more comfortable) than FC1.
5. The FC2 is composed of a latex alternative, so it's less costly than the original polyurethane version.
6. Despite rising rates of HIV infection among women around the world, only 26 million female condoms were distributed worldwide compared with 11 billion male condoms. Female condoms only account for 0.2% of the world's condom supply.
7. Female condoms can be used as a tool for pleasure, as some women and men find increased pleasure with the female condom as compared to the male condom.

On December 11, 2008 the Food and Drug Administration (FDA) advisory committee will decide whether to recommend the approval of FC2, the second generation of the Female Health Company's female condom. The World Health Organization (WHO) and the United Nations Population Fund have already approved the FC2 for distribution by HIV/AIDS and family planning organizations. **Tell the FDA to approve FC2 so we can get more female condoms out to the world NOW. Sign a letter TODAY to show your support!**



**Statement by Eleanor Hinton Hoytt  
President and CEO  
Black Women's Health Imperative**

**Before the Food and Drug Administration  
Obstetrics and Gynecology Devices Panel**

**on Approval of the Second Generation Female Condom (FC2)  
December 11, 2008**

Good Morning, Chairwoman Cedars and members of the Obstetrics and Gynecology Devices Panel. My name is Eleanor Hinton Hoytt, president and CEO of the *Black Women's Health Imperative (Imperative)*, the only national organization devoted solely to advancing the health and well-being of the nation's 19.5 million Black women and girls. On behalf of the *Imperative*, I wish to thank you for the opportunity to address the importance of and need for safe and effective HIV, STD and pregnancy prevention methods for Black women.

Increasing access to acceptable and affordable contraceptive and risk reduction options remains a critical need for Black women. In 2006 Black women accounted for more than 61 percent of new HIV infections and 66 percent of the majority of new AIDS cases among women. Even more tragically, AIDS is the #1 killer of young Black women, ages 25 to 34. Black women also have the highest rates of STDs, and 50 percent of our Black girls, ages 14 to 19, have at least one STD. The most recent report on unintended pregnancies states that among Black women and girls, nearly 70 percent are unintended.

These facts underscore the sense of urgency for a new and improved woman-controlled method that has the potential for transforming and empowering lives, if it is accessible and available.

Because of issues of dependency, economic instability, intimate partner violence and other social factors, Black women are often placed in vulnerable situations where they are unable to negotiate male condom use. The opportunity and freedom for women to make decisions about safe sex practices moves us closer to addressing some of the historical, social and contextual factors that play a role in Black women's high risk for HIV. Without an available woman-controlled barrier method, Black women's lives will continue to be dramatically and disproportionately impacted.

While there is no perfect method for everyone, the female condom is the only device that provides women with a safe option and a point of negotiation with their partners. With this option, the general dynamics of choice and self-protection change—giving women more control.

In conclusion, the Black Women's Health Imperative and our 100,000-plus members are pleased to offer support for the approval of the second generation of the female condom. We look forward to being a partner in promoting the female condom as an option for preventing HIV and STD infections and reducing the numbers of unintended pregnancies for all women—nationally and globally.

Thank you for your time and efforts.



## FDA: Female Condoms

1. USAID's relationship with the female condom pre-dates my own involvement, going back to the periods of product development, clinical trials, and regulatory review and approval. My own involvement began with shipments of the approved female condom to developing country family planning and HIV/AIDS prevention programs. These shipments will be the focus of my comments. We appreciate that Mary Ann and FHC invited us to provide this historical background.
2. USAID has purchased and provided female condoms to developing countries since 1998, shipping 42k that year. We shipped 134k in 1999, 73k in 2000 and 20k in 2001 – the fluctuations being due to a range of administrative issues; and 119k in 2002. After these pilot and introductory efforts, programmatic interest began to grow. Five years ago we shipped female condoms to about 10 countries; today we are shipping female condoms to 17 countries (with several additional countries planned already for next year). We have shipped female condoms to 29 countries to date.
3. While USAID is the primary donor providing female condoms to developing countries, USAID is not alone. Donations of female condoms, as captured in a database of donors who report their data, are increasing. Several donors have become increasingly involved in funding the purchase of female condoms, as well as increasing investments in programmatic activities related to expanding correct and consistent use.
4. DFID, IPPF, UNFPA, World Bank, KFW, PSI and others share an interest in switching provision of female condoms from FC1 to FC2, primarily due to price, but also increased client acceptability. It is my impression, though I don't have the data to prove it, that USAID is the only donor still providing FC1 to developing countries. I believe that all other donations have already switched to FC2. It is not helpful programmatically or logistically to maintain these two products in programs. USAID also would like to switch and is prepared to do as quickly as possible upon FDA's approval.
5. In recent years, all female condoms provided by USAID have been funded with HIV/AIDS prevention funding. And the vast majority of these female condoms have gone to support HIV/AIDS prevention programs in Africa. While there is dual protection marketing, the over-riding emphasis is on disease prevention.
6. With most of the USG's HIV/AIDS funding available for programs in Africa, this distribution across regions is not surprising. This year we are shipping female condoms to 8 countries in Africa, 7 countries in Asia and 2 countries in this hemisphere. What those numbers mask is the relative size of our donations across the regions – 87% of our female condom shipments this year go to African countries, 12% to Asian countries and just 1% to LAC.
7. What might be surprising is the scale of female condom programming in select countries. As an example, Zimbabwe. This country requests on the order of 5 million female condoms a year; they are distributed through kiosks and drugs sellers, through pharmacies, and increasingly hair salons for women and barbers for men – drawing on the lessons learned that women and men benefit from

repeated exposure to new ideas and products in familiar, safe environments, where they can ask their questions, see demonstrations, and take time to become familiar with the product and its benefits from their various perspectives. As a result of this effort, reported "ever use" of female condoms among all sexually active adults ages 15 to 49 is 20.2%, and "current use" is 9.2% (up from 8.1% in 2005). Data from PSI TRaC survey 2007. This in a country where 21% of Zimbabwean women and 14.5% of men ages 15-49 are HIV positive. Each correct use is important; each consistent use is important too.

The prospect of buying a comparable product at a 25% cost savings, being able to serve that many more people for the same level of investment, is very attractive and not trivial. Thanks for your attention and careful consideration of these important issues.



**Mark A. Rilling**

Division Chief, Office of Population and Reproductive Health  
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Good Morning Members of the FDA Obstetrics and Gynecology Devices Panel. My name is Donna Crews; I am Director of Government Affairs at AIDS Action Council, Washington, DC. AIDS Action is one of the oldest national HIV/AIDS organizations. Since its founding in 1984, AIDS Action has been in the forefront of HIV and AIDS policy debates and discussions. Our vision is a world without AIDS. We will work Until It's Over—until no one acquires HIV, until those living with HIV have the care and services they need, and until a cure is found.

The United States epidemic today is very diverse touching nearly all population groups. There are severe disparities in the impact that HIV and AIDS is having on communities of color, women, and men who have sex with men. According to the 2006 report by the Centers for Disease Control and Prevention women comprise 27% of the new HIV infections in the United States. Today I will focus my attention on women. We must remember that HIV is a 100% preventable disease. If one is aware of their HIV status precautions can be utilized to ensure that HIV is not transmitted to another individual. In the case of heterosexual sex male condoms have been found to aid in the prevention of HIV, but that is a form of prevention that is only controlled by men not by women.

If a woman asks her male sexual partner to utilize a condom and he refuses she has no other option to protect herself from possibly being exposed to HIV, other sexually transmitted infections, or an unintended pregnancy. If the second generation female condom is approved today it will give women another option to protect themselves from HIV, unintended pregnancies, and other STIs.

I would like to take this opportunity to read to you a letter signed by over 170 organizations 115 throughout the United States as well as 55 international organizations -

Dear Obstetrics and Gynecology Devices Advisory Committee Members,

We, the undersigned organizations committed to women's sexual and reproductive health and human rights, strongly urge you to consider the importance of female condoms while you deliberate over FDA pre-market approval of the FC2--the second generation of the Female Health Company's female condom--that enables a woman to initiate protection against HIV and other sexually transmitted infections (STIs), as well as unintended pregnancy.

HIV/AIDS is rapidly becoming a women and girls' pandemic. According to UNAIDS, women comprised half of the 33.2 million people living with HIV/AIDS in 2007. The realities of many women's lives, coupled with a lack of access to sexual and reproductive health information and services including HIV prevention tools, make it difficult for women to take the steps necessary to protect themselves against STIs and HIV infection and unintended pregnancy. Poverty, intimate partner violence, restrictive gender and cultural norms, and limited access to education are just a few of the factors that contribute toward increasing a woman's risk of HIV.

AIDS Alliance for Faith and Health  
Atlanta, GA

AIDGwinnett  
Duluth, GA

AIDS Foundation of Chicago  
Chicago, IL

AIDS Funding Collaborative  
Cleveland, OH

AIDS Institute  
Washington, DC

AIDS Partnership Michigan  
Detroit, MI

AIDS Project Los Angeles  
Los Angeles, CA

AIDS Taskforce of Greater Cleveland  
Cleveland, OH

AIDS Treatment Activists Coalition  
Boston, MA

AIDS Vaccine Advocacy Coalition  
New York, NY

Allies Linked for the Prevention of HIV and AIDS  
Boise, ID

AltCare Health Center  
Oak Park, IL

American Jewish World Service  
Washington, DC

American Medical Student Association  
Washington, DC

American Medical Student Association, Brown University Chapter  
Providence, RI

CitiWide Harm Reduction  
Bronx, NY

Common Ground–Westside HIV Community Center  
Santa Monica, CA

Community AIDS Resource and Education Services  
Kalamazoo, MI

Community Hepatitis/HIV Advocates of Iowa Network  
Des Moines, IA

Connecticut Microbicides NOW  
New Haven, CT

EngenderHealth  
New York, NY

Family Care International  
New York, NY

Family Planning Council  
Philadelphia, PA

Flora Stone Mather Center for Women, Case Western Reserve University  
Cleveland, OH

Foundation for Integrative AIDS Research  
Brooklyn, NY

Gay Men's Health Crisis  
New York, NY

Global AIDS Alliance  
Washington, DC

Global Business Coalition on HIV/AIDS, Tuberculosis, and Malaria  
New York, NY

Global Campaign for Microbicides  
Washington, DC

Harlem United Community AIDS Center  
New York, NY

Harm Reduction Coalition

National Association of People with AIDS  
Silver Spring, MD

National Coalition of American Nuns

National Coalition of STD Directors  
Washington, DC

National Council of Jewish Women  
Washington, DC

National Latina Health Network  
Washington, DC

National Organization for Women, Monterey Peninsula Chapter  
Greenfield, California

National Women's Health Network  
Washington, DC

Nebraska AIDS Project  
Omaha, NE

Ohio AIDS Coalition  
Columbus, OH

Open Door Clinic  
Elgin, IL

Origami Female Condom  
Beverly Hills, CA

Our Bodies, Ourselves  
Boston, MA

PATH  
Washington, DC

Pediatric AIDS Chicago Prevention Initiative  
Chicago, IL

Pennsylvania Campaign for Microbicides  
Philadelphia, PA

SisterLove  
Atlanta, GA

Social Sectors Development Strategies  
Boston, MA

Southside Help Center  
Chicago, IL

STOP AIDS Project  
San Francisco, CA

SW IA Latino Resource Center  
Red Oak, IA

Title II Community AIDS National Network  
Washington, DC

Treatment Action Group  
New York, NY

TruthAIDS  
Philadelphia, PA

United Church of Christ Wider Church Ministries  
Cleveland, OH

United Church of Christ Justice and Witness Ministries  
Cleveland, OH

United Church of Christ HIV & AIDS Network  
Cleveland, OH

University of Illinois Project WISH  
Chicago, IL

Vermont Committee on AIDS, Resources, and Education  
Burlington, VT

The Women's Collective  
Washington, DC

Women's Global Health Imperative  
San Francisco, CA

Nigeria

Busia Widows and Orphans Association  
Busia, Uganda

The Canadian Treatment Action Council  
Toronto, Canada

Christian Health Association of Nigeria  
Nigeria

Coalition for Sexual and Bodily Rights  
Istanbul, Turkey

Czech AIDS Help Society  
Prague, Czech Republic

Egyptian Initiative for Personal Rights  
Cairo, Egypt

European AIDS Treatment Group  
Antwerp, Belgium

Founder God's House International.org

Fundacion Oriéntame  
Bogota, Columbia

Global Youth Coalition on HIV/AIDS

Health Hope & HIV Network  
St. John's Antigua, West Indies

Intimate Friends International  
Cameroon

Instituto Patricia Galvao  
Sao Paulo, Brazil

Interact Worldwide  
London, UK

The International Community of Women Living with HIV/AIDS  
Namibia

Witbank, South Africa

Society For Women's Action and Training Initiatives  
India

STI/HIV Epidemiology and Control Unit  
Institute of Tropical Medicine  
Antwerp, Belgium

TB Action Kenya  
Kenya

Thohoyandou Victim Empowerment Programme  
Sibasa, Thohoyandou

Uganda AIDS Commission  
Uganda

Uganda Young Positives  
Uganda

Universal Access to Female Condom Joint Programme  
The Netherlands

Vikalp  
Baroda, India

Women and Children First  
London, UK

Women's Health Advocacy Foundation  
Thailand

Women for Women's Human Rights  
Istanbul, Turkey

Youth Coalition for Sexual and Reproductive Rights  
Ontario, Canada

Youth Empowerment Foundation of Grenada  
Grenada

ZETA-12 Research Group  
Enugu, Nigeria



Dázon Dixon Diallo, MPH

Founder/President

SisterLove, Incorporated

Atlanta, Georgia AND Witbank, Mpumalanga, South Africa

I Have  
Conflicts  
of Interest

#### Notes/Outline of Statement

Good morning. Thank you to the Chair and the Advisory Committee, the distinguished panel of speakers and presenters, fellow brothers and sisters. I am Dazon Dixon Diallo, founder and president of SisterLove Inc., a 19 year old women's HIV/AIDS organization located in Atlanta GA and in the Mpumalanga Province in South Africa.

I have been involved in HIV/AIDS prevention and support for women at risk and affected by HIV for over 23 years. There is one clear directive that has always, and continues to play itself over and over in every HIV scenario regarding women and girls: Change Women's Lives, Change the Epidemic. Address the key factors, mostly rooted in gender inequality and oppression, that drive the vulnerability of women and girls, and we would see a dramatic reduction in the transmission, infection and shortened lifespan of women and girls worldwide.

SisterLove is on a mission to eradicate the negative impacts of HIV/AIDS and other reproductive health challenges upon women, girls and their families. We carry out our mission primarily through health education, reproductive justice advocacy and leadership, HIV/STD prevention intervention services and research. In South Africa, we also work to create economic solutions to the prevention and healthcare needs of women affected by HIV/AIDS. Among our advocacy work, is a focus on increasing prevention options that are women-centered and women-controlled. Increasing women's options increases the likelihood that they will have the power and motivation to protect themselves and their families.

I am here to motivate you to support the approval of the FC2 Female Condom, effective, more affordable prevention option for women for the following key reasons:

- The disproportionate burden of HIV/AIDS globally and domestically is shouldered by women who are poor, abused and most often of African descent – least protected and most unheard/unrepresented in the decision-making arenas;
- the tripartite epidemics of HIV/AIDS, poverty and violence and the sense of powerlessness that is exploited by these crises, increase vulnerability and decrease quality of life for women and their families; and
- the current inequality in the accessibility, availability, affordability and acceptability of the female condom contributes to the gross health disparities that exacerbate life threatening diseases and conditions, especially HIV/AIDS.

I am a 43 year old African American woman who is divorced and sexually active. That makes me seem a likely woman at risk for HIV/AIDS, as Black women are more than 60% of HIV among women in the U.S. Typical, except that I do not live at or below the poverty line, I am not a substance abuser or in recovery from substance abuse, I am not a survivor or sufferer of intimate partner violence, nor am I economically dependent. I know more than the average woman does about HIV AIDS risks and consequences – and I use female condoms because I have really good access to them, and because I need variety in my safer sex activities.

Much of today's testimonies will focus on women who experience the true brunt of the pandemic – women in the poorest regions of the world including Africa, Asia and Latin America. What often gets overlooked, is the parallel track that exists for African American women and African women, 60% of the epidemic in the SubSaharan Africa versus 60% of the epidemic in women in the U.S. And in the Southern U.S., economic, educational, political, social and cultural issues are common threads that impede the access and progress that women at risk need. I want you to remember the hundreds of thousands of HIV+ women and women at risk in the U.S. as well as in the poorest regions of the world.

Slide #1 – U.S. HIV/AIDS case rates by regions – The South is the most disproportionate

Slide #2 – another slide depicting the South in a Bar Graph

Slide #3-6 – Zip Code Slide

Slide #7 – Picture of folks at SisterSong – Chicago – Let's Talk About Sex Photo of Group

Though we may not experience comparable rates of commercial sex work, the sex trade is alive and flourishing – for drugs, money, housing, food, companionship, etc.

For many of the reasons that have been articulated in documents that are available to us all, such as the report from Center for Health and Gender Equity, "Saving Lives Now" and other research publications, we need the FC2 approval from the U.S. FDA sooner, not later, as more women and girls are infected with HIV or facing unwanted and possibly dangerous pregnancies with each passing day.

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

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.

Though the cost differential between female and male condoms is disparaging, the female condom can still be assessed in terms of some cost effectiveness when compared to other HIV prevention interventions, such as the proposed antiretroviral therapy for high risk individuals or voluntary counseling and testing for general populations.

Expensive- Unequal and Unfair in prevention budgets

Cost of payout for purchasing condoms made available in communities where economic, social and cultural prohibit accessibility, availability and affordability –

SisterLove interventions are accompanied by both male and female condoms.

In 4 months of purchases, SisterLove's expenditure rate is as follows:

10,000 male condoms purchased for \$535 total, while 2,000 female condoms for \$2,536. This means that the women's product is purchased at 20% the amount of male condoms and the price of female condoms is nearly 5x's more.

In the reproductive justice community and in communities of women fighting HIV/AIDS and other STIs, the female condom is just one tool in a much needed toolbox for people at risk to choose from. There will not be a magic bullet or single source solution to preventing HIV transmission. Women and girls around the world need affordable, accessible, available and acceptable prevention options that they control and initiate. The FC2, while still not perfect, is a key tool to help shift the trajectory of women's risks for HIV/AIDS, and another weapon in a weak arsenal of real firepower to defeat the pandemic.

A decision to approve the FC2 and give the green light to US aid agencies to provide more resources and funding for the purchase and effective distribution of the female condom, is a step in the direction of helping change how women activate their power to protect themselves. With every measure of these changes, we improve the probability of eradicating the threat of HIV/AIDS and other STIs. Change women's lives and you change the epidemic.

Read the Chicago Women's AIDS Project letter and submit with signatures.

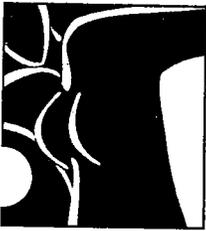
Thank you for your time and attention to this critical issue for women and girls in need of a break – a sign that says their lives matter, and a signal that the U.S. can advance its own positions with regard to respecting and protecting women's sexual health by ensuring women's options are made fully available, accessible and affordable as part of good public health practice and upholding our human rights.

Dazon Dixon Diallo, MPH

Presented on 12.11.08

Gaithersburg, MD





**NATIONAL  
WOMEN'S  
HEALTH  
NETWORK**

A VOICE FOR WOMEN, A NETWORK FOR CHANGE

**FC2 Female Condom  
ObGyn Devices Advisory Panel Meeting  
December 11, 2008**

**Remarks by Cindy Pearson, Executive Director  
National Women's Health Network**

Thank you for the opportunity to testify. I represent the National Women's Health Network (NWHN), a grassroots, member-supported national advocacy organization. NWHN does not accept any financial support from pharmaceutical companies or medical device manufactures. We drove here this morning, paying our own way, and have no financial ties to report with any company involved in the manufacture or promotion of condoms or other contraceptives.

Founded by activists in the early 1970s who wanted women's questions about their health to be taken seriously, NWHN values the FDA for the many important roles it plays in safeguarding the health of consumers, including using the regulatory process to ensure that new products have enough evidence to justify approval. We understand that FDA has to carefully weigh exactly how much evidence is enough – and competing pressures such as urgent need for a new product versus legitimate scientific questions that aren't fully answered can make the decision about how much evidence is “enough” a tough one.

However, even though it is a tough assignment, the FDA often gets it right, and in the case of the original female condom the FDA did get it right. Today, as we meet to discuss and advise the FDA about the new female condom, NWHN is optimistic that the FDA will get it right once again and approve the new condom for women.

Approval of the original female condom was a long process, with several points at which the entire reproductive health community joined FDA in a discussion about how much evidence is needed to be reasonably sure that female condoms are safe and effective. NWHN was happy to play a key role at various times in that process, including prodding FDA to require clinical trials in the first place, educating FDA about the usefulness of a barrier device with less than perfect effectiveness and coming to consensus with the contraceptive development community about a new FDA guidance for clinical trials of barrier contraceptives. In each case, we think the FDA made the right decision that the evidence available was enough to assure women that the female condom is reasonably safe and effective.

Today, the Advisory Panel is being asked to give input to the FDA on whether or not the amount of evidence that is available is enough to assure women that this new female condom, FC2, is also reasonably safe and effective.

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real-world examples: women track multiple symptoms more than once each day on fertility awareness charts; Weight Watchers encourages its members to use a journal that requires tracking many different types and amounts of foods multiple times a day; and, I imagine that all of you on the advisory panel were given a travel reimbursement form that asks to you record the cost of multiple types of expenses, multiple times for each day. Certainly we all appreciate a well designed form, but we can make do very well with what we're given.

To sum up our reaction to these FDA's concerns about data collection, we do not believe that any of these concerns are sufficient to cast doubt on the validity of the data.

NWHN does have one concern to raise at this point, and would appreciate advisory panel discussion of this issue. Given that many women use a spermicide along with a condom, it seems to us to be reasonable to ask the company to conduct lab tests to examine what happens when the new female condom is exposed to spermicide. We will be interested in your discussion of this question.

In summary, NWHN believes that there are enough data to assure women that we are reasonably certain that the new female condom is safe and effective. We urge the Advisory Panel to recommend that the FDA approve the new female condom. Thank you for your time.