

Breaking Regulatory Barriers for Greater Female Condom Access

June 3, 2015



Special thanks to our sponsoring partners



About the National Female Condom Coalition



- ▶ Partnership of U.S. and U.S.-based advocates, researchers, health departments, community-based & national organizations
- ▶ Mission: increase awareness, acceptance, access, and use of female condoms
- ▶ Advance mission through education, advocacy, and collaboration
- ▶ Learn more and connect with us at
 - ▶ www.nationalFCcoalition.org
 - ▶ www.facebook.com/NationalFCCoalition



About the National Female Condom Coalition



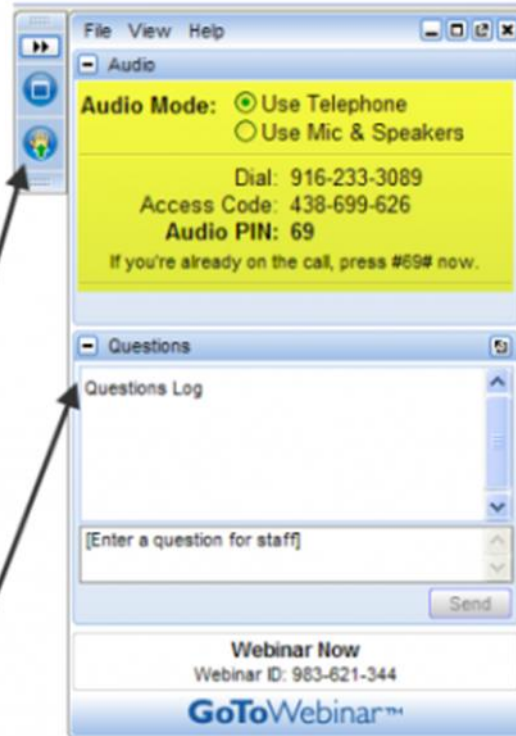
- ▶ Our coordinated national advocacy agenda includes:
 - ▶ Full integration of female condoms into sexual health, HIV prevention, and family planning programs
 - ▶ Programming and policies to scale up female condom awareness, acceptance, access, and use throughout the country
 - ▶ Supporting research, development, and introduction of safe and effective receptive-partner initiated condoms for people of all genders who engage in receptive vaginal and anal sex

Some tech tips for today

- ▶ Use the Question feature to ask questions during the webinar

During the session, you can use this button to "Raise Your Hand" if you have a question.

If there are more questions than can be answered during a session, the Organizer may ask that you type in questions in the Question Log so that they may be addressed later, via email.



- ▶ All attendees are in listen-only mode
- ▶ Everyone can ask questions at any time using the questions feature
- ▶ We will take short Q & A breaks throughout, and the moderators will read submitted questions
- ▶ Send a question if you are having trouble hearing or seeing the webinar

Some tech tips for today

- ▶ Options for listening to the webinar
 - ▶ Use your computer's speakers or plug your headphones into your computer to hear the presentation
 - ▶ Use the telephone to dial in using the webinar system's access code



- ▶ Click on the “audio” tab
- ▶ Dial the telephone number, access code, and PIN you see on your computer



Some tech tips for today

- ▶ Download the slides from the NFCC website so you can follow along on your own if you choose or are having problems viewing the webinar online.

www.nationalfcccoalition.org/webinar



Today's speakers

- ▶ **Mags Beksinka, *MatCH Research***
 - ▶ Female Condoms - A Review of Products Currently Available and in Development
- ▶ **Saskia Husken, *Universal Access for Female Condoms Joint Programme***
 - ▶ The impact of the regulatory improvements for the on-the-ground programming of multiple female condom products
- ▶ **Coco Jervis, *National Women's Health Network***
 - ▶ FDA Approval of Female Condoms: A Long Road
- ▶ **Jessica Terlikowski, *AIDS Foundation of Chicago***
 - ▶ Paving the Way for More Female Condom Options



Female Condoms - A Review of Products Currently Available and in Development

Mags Beksinska, Jenni Smit

Maternal Adolescent and Child Health Research, Dept of O&G, University of the Witwatersrand, South Africa.

www.matchresearch.co.za

Why are new fc products being developed?

- ▶ Acceptability issues such as appearance, size, and insertion are being addressed in new designs.
- ▶ Sensitivity and improved experience (pleasure).
- ▶ Latex and synthetic latex designs can keep material costs down.
- ▶ New designs are adopting large scale manufacturing to keep down costs.
- ▶ We all want variety, just like different male condoms!

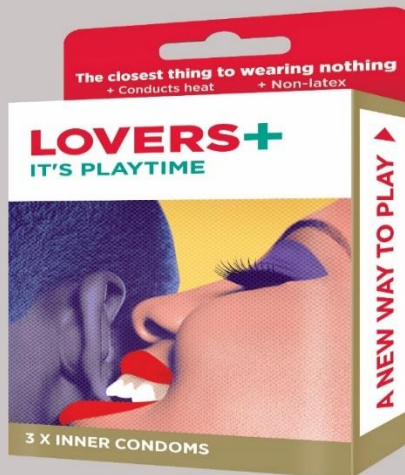
FEMALE CONDOM DESIGNS



FC2 Female Condom



- ▶ Synthetic nitrile latex, flexible polyurethane internal ring used for insertion.
- ▶ Made by the Female Health Company and manufactured in Malaysia.
- ▶ FDA and WHO/UNFPA approved and available globally to public and private sector markets- most widely available FC.



Woman's Condom/V Condom



- ▶ Polyurethane material with cap made of PVA (polyvinyl alcohol) used for insertion, which dissolves after insertion.
- ▶ Not pre-lubricated.
- ▶ Made of polyurethane.
- ▶ Transferred to Chinese manufacturer (Dahua) in 2008 & SFDA approved in 2011. Not yet pre-qualified by WHO/UNFPA. Available in pilot projects in South Africa.

Cupid & Cupid2 Female Condom



- ▶ Natural rubber latex with insertion sponge and octagonal outer frame.
- ▶ Available in pink or natural latex color.
- ▶ Two sizes available.
- ▶ Made in India by Cupid Ltd, available globally.
- ▶ EU approved in 2010; WHO pre-qualified in July 2012 (standard size).

Phoenurse Female Condom



- ▶ Produced and distributed in China (SFDA approved).
- ▶ Made of polyurethane.
- ▶ Distinctive Insertion tool but can be inserted using inner ring.
- ▶ Dumbbell shaped body with inner ring.
- ▶ Not yet pre-qualified by WHO/UNFPA, available in China.

Innova Panty And Air Condom

- ▶ Made by Innova, Columbia
- ▶ Both made of polyethylene
 - ▶ **Panty:** -Re-usable thong panty with replaceable FCs - this means it has no outer ring as panty holds condom in place.
 - ▶ **Air FC:** -inserted by small bubble of air in polyethylene capsule. Outer “frill” opens to lie outside body
 - ▶ Not yet pre-qualified by WHO/UNFPA. Available in Columbia.



PleasureMore Female Condom



- ▶ Natural rubber latex with flexible polyurethane internal ring used for insertion.
- ▶ Two sizes available.
- ▶ Made in China by HBM Ltd, available in South Africa.
- ▶ Not yet pre-qualified by WHO/UNFPA.

Reddy Female Condom V-amour/VA w.o.w

- ▶ Natural rubber latex pouch attached to a V-shaped outer frame.
- ▶ Sponge retention mechanism used for insertion.
- ▶ 90cm body length.
- ▶ Was made by MedTech Health Products, India, and was sold in India and some African countries. Now under licence to a company in the US and sold as the vibrating female condom
- ▶ Not yet pre-qualified by WHO/UNFPA.



Origami Female Condom

- ▶ Origami Healthcare Products have been developing a new FC in the US- The ORIGAMI FC. A phase 1 feasibility and acceptability trial funded by NIH was awarded in 2010.
- ▶ Made of biocompatible non-allergenic silicone.
- ▶ Concertina design that opens on insertion.
- ▶ Not yet available in the market.

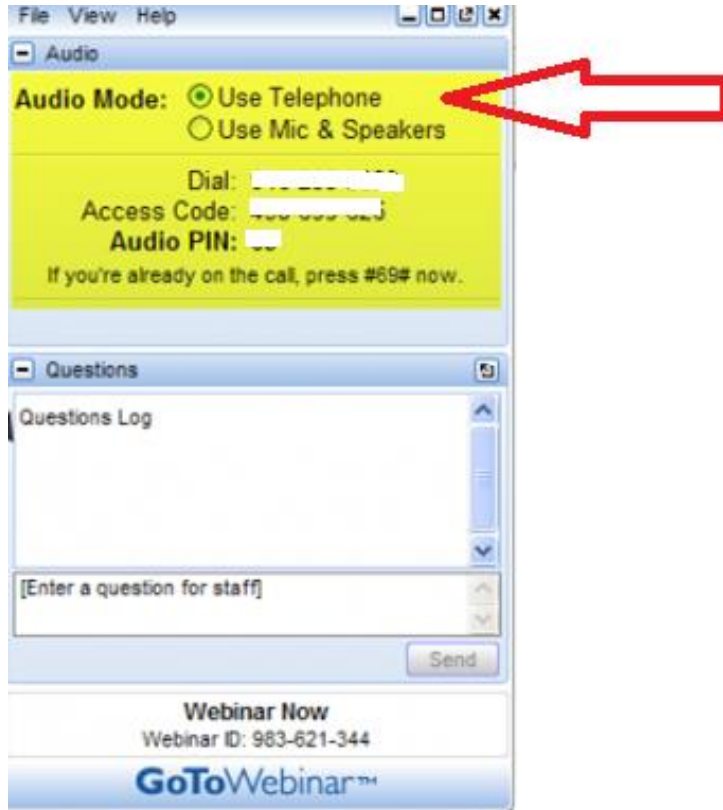


Velvet Female Condom

- ▶ Made by HLL Lifecare, India who have experience in FC1 & VA w.o.w manufacture have designed a latex FC that looks very similar to FC2.
- ▶ The cost of this condom will be much lower than existing prices.
- ▶ Not yet pre-qualified by WHO/UNFPA.



Questions?



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Performance and Functionality of Existing Products: Recent Studies

Clinical Testing of New Female Condoms:
Progress with New Designs

A Randomized Controlled Trial of the Functional Performance of the Woman's Condom (WC), FC2, VA w.o.w and Cupid

- ▶ Randomized cross-over clinical trial to evaluate device function, safety and acceptability of three new and control FC2.
- ▶ Study population: 300 women in south Africa and 300 women in China (2011-2012).
- ▶ Women used all four condom types (5 of each type).
- ▶ Non-inferiority was demonstrated for all condom functions for the three test condoms.
- ▶ Data used for Cupid WHO/UNFPA prequalification*.



Beksinska, M.E., Piaggio, G., Smit, J.A., Wu, J., Zhang, Y., Pienaar, J.; Greener, R., Zhou, Y. & Joanis, C. (2013). Performance and safety of the second-generation female condom (FC2) versus the Woman's, the VA worn-of-women, and the Cupid female condoms: a randomized controlled non-inferiority crossover trial. *Lancet Global Health*, 1 (e), 146-152.

A Randomized Controlled Trial of the Functional Performance of Velvet, Cupid2 and FC2 Female Condoms

- ▶ Randomized cross-over clinical trial to evaluate device function, safety and acceptability of two new and control FC2.
- ▶ Study population: 300 women in south Africa (2013-2014).
- ▶ Women used all 3 condom types (5 of each type).
- ▶ Non-inferiority was demonstrated for all condom functions for the two test condoms.
- ▶ Data will be used for WHO/UNFPA prequalification



Non-Gender Specific Internal Condom; ORIGAMI Healthcare Products, Inc.

- ▶ Condom designed for vaginal or anal use.
- ▶ 24 couples will use 5 of the IC study condoms, and 5 FC2s during vaginal intercourse (12 heterosexual couples) or anal intercourse (12 homosexual couples).
- ▶ Funded by the Bill and Melinda Gates Foundation, study will be conducted in Durban, SA by MatCH Research.

Origami Female Condom

- ▶ Randomized crossover study evaluating acceptability and performance of the OFC compared with the FC2 among 20 couples recruited in US.
- ▶ Participants used three OFC and three FC2 as their primary contraceptive methods for 2 weeks
- ▶ Implemented by the Women's Global Health Imperative at RTI International, funded by NICHD. Completed in 2013.

Woman's Condom Safety and Pregnancy Efficacy Study

- ▶ Multi-centre, open label, non-comparative study testing the safety and efficacy of the WC among 450 women from 10 centres in the US.
- ▶ Regulatory sponsor CONRAD, implemented by NICHD.
- ▶ 6-month study completed in 2012, results due shortly.



Performance and failure mode study comparing the Woman's Condom and the FC2 female condom, and using prostate-specific antigen as a biomarker of semen exposure

- ▶ Randomized Crossover Study comparing self-reports of clinical failure rates among 330 couples using WC and FC2.
- ▶ Regulatory sponsor CONRAD, implemented by California Family Health Council.
- ▶ Completed in 2011, analysis continued into 2013.

Performance and failure mode study comparing the Woman's Condom and the FC2 female condom, and using prostate-specific antigen as a biomarker of semen exposure

- ▶ Secondary objectives to compare the ability of the WC and the FC2 to prevent vaginal exposure to semen, as indicated by detection of PSA within the vagina & to calculate the sensitivity and specificity of reported failures for the presence of semen, using PSA as the indicator of semen presence.
- ▶ If results from this study and from the NICHD study show that PSA is an accurate measure of condom failure, CONRAD and NICHD will encourage the US FDA to consider a shift in the type of data required for product approval based on this more accurate, less costly method of determining product failure.

Bill and Melinda Gates Foundation: Grand Challenges - Develop the Next Generation of Condoms

- ▶ The recent Grand Challenges funding awards have included several FC designs.
- ▶ The winners of the FC awards include existing condom manufactures (e.g HLL), Origami and new inventors (Univ of Indiana).
- ▶ FC award winners are looking at improved pleasure and sensation
- ▶ These New FCs will undergo larger trials when prototypes are finalised.

Female and Male Condoms as Medical Devices

How Class of Medical Device Affects
Regulatory Controls: An Overview

Condoms as Medical Devices

- ▶ Condoms are classified by FDA as “medical devices”
- ▶ Medical Devices are classified as I, II or III, with Class I deemed to be the lowest risk and III the highest.
- ▶ The Class affects the regulatory controls which ensure that Medical Devices are safe and effective and provide a means whereby unsafe/ineffective devices may be reported to FDA and removed from the market.

Class I and Class II Devices

- ▶ **Class I** E.g. dental floss/ elastic bandages and some sexual lubricants*. 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.
- ▶ **Class II** E.g. Nebulizer/cardiac monitor/ **male condoms (MCs)**/ some sexual lubricants. 43% of medical devices fall under this category.

*Personal lubricants are classified as either a Class I or a Class II Medical Device, depending on the use or what the formula contains. Since lubricant is absorbed by the body and can enter the bloodstream, the FDA ensures the product and ingredients are tested by FDA approved laboratories.

Class III devices

- ▶ **Class III** - These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury! Examples of Class III devices include implantable pacemakers, breast implants and **Female condoms (FCs)**. Only 10% of medical devices fall under this category.

Device Class Controls

- ▶ **Class I** - general controls - most, if not all, Class I devices are exempt from 510k *
- ▶ **Class II** - general controls, special controls & 510(k) - Pre-Market Notification required, unless “Grandfathered” (marketed prior to 1976)
- ▶ **Class III** - general controls and Pre-Market Approval (PMA)

*A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)⁶) that is not subject to premarket approval.

How did MCs get into Class II ?

- ▶ MCs were marketed and sold before the Medical Device Amendments of 1976 and were therefore grandfathered into newly created Class II as part of the initial classification of all existing devices.
- ▶ However MCs are not exempt from 510(k) requirements, and 510(k) premarket notification must be submitted to the FDA before a new MC, or an existing MC that has been substantially changed or modified, is introduced.

MC Class II Continued...

- ▶ Most new latex condoms meet the “substantially equivalent” requirement with respect to condoms that were on the market before the 1976 Amendment. Consequently, most new latex condoms are approved through the “substantially equivalent” requirements contained in Section 513(i).

SO why is a Female Condom Classified as Class III by US FDA?

- ▶ As the FC was a completely new product, the FDA decided to regulate it as a class III medical device, (although FCs are Class II in the EU) a category that is generally reserved for high-risk medical equipment such as pacemakers and certain lasers that requires the highest level of regulatory scrutiny.
- ▶ Limited clinical data were available to reassure safety concerns

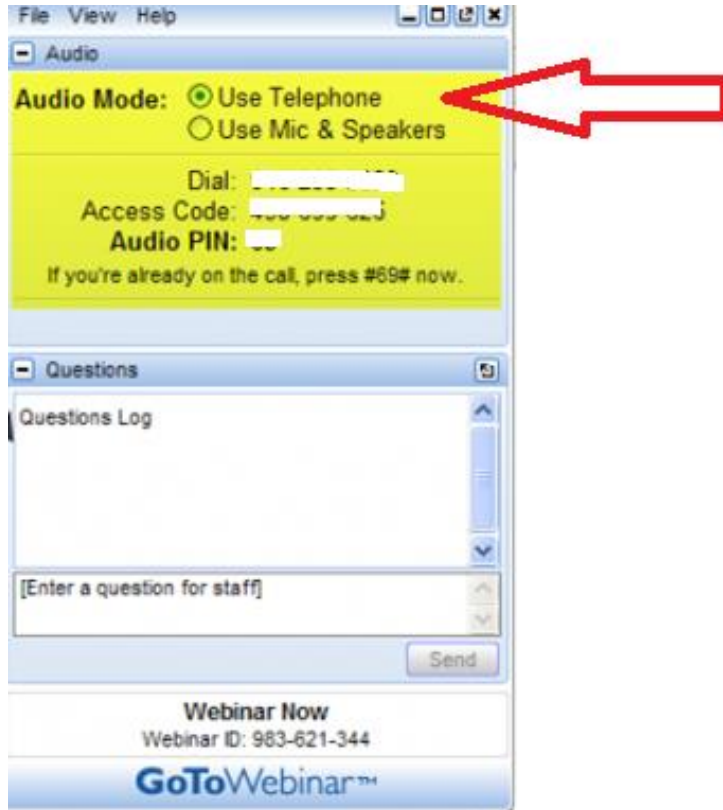
What has changed for FCs since 1993?

- ▶ A body of clinical data is now available for acceptability, functionality, some pregnancy and STI efficacy.
 - ▶ History of safety (absence of safety concerns reported e.g. no reports of toxic shock syndrome, low reporting of material allergies)
 - ▶ Shift from use of MC standards and specifications to FC standards and generic specifications.
- ✓ ISO 25841:2014. Female condoms – Requirements and test methods.
 - ✓ Beksinska M, Joanis C, Manning J, Smit J, Callahan M, Deperthes B, et al. Standardized definitions of failure modes for female condoms. Contraception 2007; 75(4):251-5.
 - ✓ Condoms – Guidance on clinical studies –Part 2: ISO/DIS 29943-2, Female condoms, clinical function studies based on self reports.
 - ✓ WHO/UNFPA Female Condom Generic Specification, Prequalification and guidelines for procurement, 2012.

What would change if FCs moved into Class II

- ▶ Would be treated in a similar way to Male condoms.
- ▶ Would possibly require less clinical work if a design was considered similar to a currently approved design.
- ▶ Would still have to adhere to existing specifications and standards.

Questions?



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FDA Approval of Female Condoms: A Long Road

Coco Jervis

The National Women's Health Network

A brief timeline of the first female condom regulatory approval process

- ▶ 1987 - Wisconsin Pharmacal submits an FDA application for approval to market and sell female condoms in the U.S.
 - ▶ The National Women's Health Group submits a citizen's petition to the FDA asking the FDA to withdraw marketing clearance for the female condom because it had not been tested for effectiveness in preventing pregnancy, HIV or other STI's.
 - ▶ The FDA agrees and determines that female condoms are a new kind of product and decides to regulate it as a class III medical device.

A brief timeline of the first female condom regulatory approval process

- ▶ 1993 - The first female condom gains FDA approval and finally enters the U.S. market.
 - ▶ Public health experts hailed it as a game-changer, however journalists mocked it, clinicians ignored it, and many women shunned it, claiming that the condom was aesthetically unappealing and technically difficult to use.



Class III designation

- ▶ Class III medical devices require the most stringent regulatory controls as there is insufficient information to assure safety and effectiveness.
- ▶ Class III devices usually support or sustain human life, are of substantial importance in sustaining or supporting life, implanted devices, or those that presents potential unreasonable risk of illness or injury
- ▶ Other examples of Class III devices: replacement heart valves, silicone gel-filled breast implants and implantable pacemakers.

Obstacles posed by the Class III designation

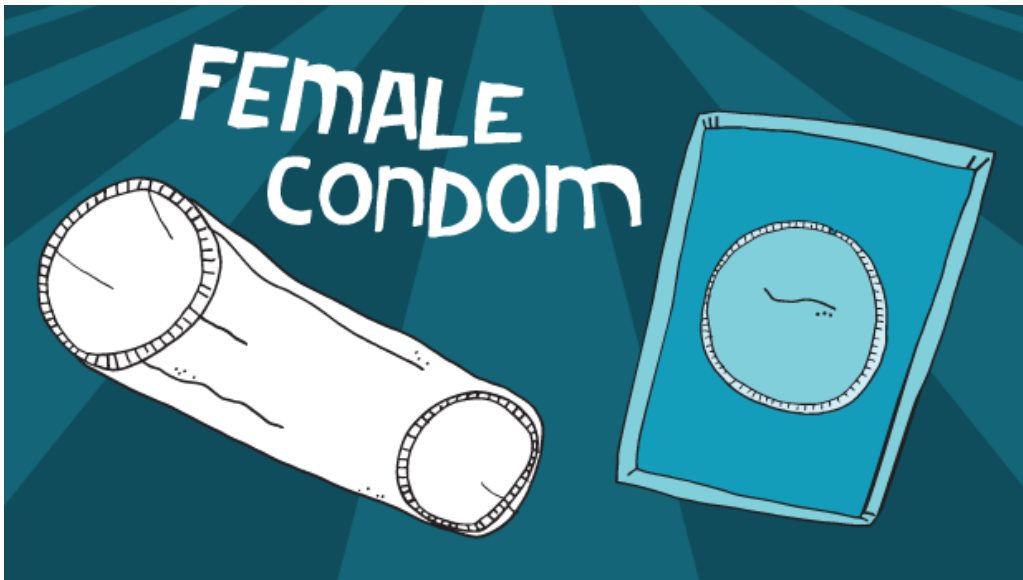
- ▶ Affordability and accessibility barrier in launching the first female condom due to the high costs of extensive safety and efficacy trials.
- ▶ Curtails product innovation.
- ▶ Significant costs and delay associated with reclassification process.
- ▶ May inaccurately categorize safety and efficacy profile of the product discouraging consumer uptake.

Paving the Way for More Female Condom Options

Jessica Terlikowski

AIDS Foundation of Chicago

National Female Condom Coalition



The case for down-classification

- ▶ Class III designation is unnecessary due to already existing controls that ensure FC safety
- ▶ Class II special controls (applied to male condoms) are also sufficient for FCs
- ▶ Device reclassification can be initiated internally by FDA or external petition by industry, advocates, researchers, etc. when/if “new information” arises
- ▶ The “New Information”
 - ▶ Ample data demonstrate FCs are safe, effective, perform well
 - ▶ Existence of and adherence to standardized product definitions, testing procedures, and industry guidance by product developers and manufacturers enable quality safeguards



The case for down-classification

Class II designation would:

- ▶ Accurately reflect the latest scientific evidence regarding safety, performance, and efficacy
- ▶ Align USFDA FC regulation with that of other regulatory agencies
- ▶ Increase feasibility of manufacturers submitting FCs for USFDA review



The case for down-classification

- ▶ Expanding the number of USFDA-approved FCs would:
 - ▶ Expand consumer choice
 - ▶ Only one product is available in the US, the FC2
 - ▶ Enable US-funded foreign aid programs to purchase and distribute wider array of FCs



Female and male condom dispensers in France.

Making down-classification a reality

- ▶ NFCC began conversations with FDA in 2014
- ▶ Lead advocacy partners include NWHN, PATH, MatCH and others
- ▶ USFDA pre-market approval retrospective offers unique opportunity
- ▶ The Center for Devices and Radiological Health at the FDA currently reviewing Class III products to determine if reclassification is warranted
- ▶ Announced in April that female condoms are candidates for reclassification
- ▶ Issued request for public comment on reclassification
 - ▶ Comments due June 29



Taking action for down-classification

- ▶ Organizations can endorse NFCC comments to FDA
 - ▶ Form will be available on NFCC website
 - ▶ Webinar recipients will receive email with request to endorse
 - ▶ Sign on and encourage your networks to do the same
- ▶ Submit your own comments **by June 29**
 - ▶ Modify the NFCC-created template to tailor the comments to reflect your constituents' needs and perspectives
- ▶ Stay tuned for grassroots opportunities to engage in this effort starting in July
 - ▶ Petition campaign
 - ▶ NFCC will deliver messages on Global Female Condom Day, September 16



Global Female Condom Day



- ▶ International day of action
- ▶ Organizing tools & resources available
- ▶ Visit www.FemaleCondomDay.org
- ▶ More information about action opportunities coming soon!



Upcoming Female Condom Conference

UAFC, in collaboration with PSI, CHANGE and MatCH Research, is very pleased to invite you to the third Global Female Condom Conference to discuss the latest developments in the field of female condoms.

SAVE THE DATE

INITIATE, INNOVATE AND INTEGRATE
— Global Female Condom Conference 2015 —

Date **1-3 December 2015** • Location **Durban, South Africa**

The conference will be an opportunity to exchange knowledge, best practices, new ideas, and information on the latest research, programming, advocacy, communications, procurement and social marketing. Together we can increase acceptability, availability and affordability of female condoms worldwide.

Up to date information on the conference will be shortly available on our websites.

psi **MatCH Research** **female condoms 4All** **UAFC** **CHANGE**
Healthy lives. Measurable results. Maternal, Adolescent and Child Health Research Department of Obstetrics and Gynaecology Faculty of Health Sciences University of the Witwatersrand joint programme CENTER FOR HEALTH AND GENDER EQUITY

- ▶ Global Female Condom Conference
- ▶ December 1-3, 2015
- ▶ Durban, South Africa

Upcoming Female Condom Conference



The poster for the Global Female Condom Conference 2015 features a vertical bar on the left with segments of pink, purple, orange, green, and blue. The main text is in pink and black, with a large pink condom graphic on the right. The conference dates are highlighted in a pink box.

Global
Female Condom
Conference 2015
Initiate • Innovate • Integrate

1-3 December 2015
Coastlands Umhlanga Hotel & Convention Centre, Durban, South Africa

Dear colleagues and friends,
Let's take female condoms to the next level!

Major steps have been made towards universal access to the only dual protection method that women can initiate themselves. However, the goal is not yet realized. More work is needed to initiate, innovate and integrate this contraceptive life-saver. The Global Female Condom Conference 2015 will be a vital opportunity to contribute to this mission. We are very pleased to invite you to this exciting event.

Programme
The conference offers a varied programme with scientific presentations, discussion panels, interactive workshops and much more. A diverse audience, from policy makers to programmers and researchers, will participate. The governments of South Africa and Brazil will share their experience with globally the largest female condom programmes. Influential advocates, representatives of manufacturers and high level speakers including Karl Hofmann (PSI) and Jagdish Upadhyay (UNFPA) will give keynote talks.

Enroll in workshops on female condom availability, demand creation and support in getting female condoms prominently on the agenda of governments, donors, implementing organizations and procurement agencies. Discuss all the latest developments and lessons learned, to see how these can benefit new female condom programmes and other upcoming women-initiated products.

Registration
Registration is open as of 20 May. Please use our online registration form.

Fees

Early bird, 20 May - 31 July	Regular rate, 1 August - 15 November	As of 16 November or on-site registration
170 US dollar (ZAR 2000)	270 US dollar (ZAR 3200)	300 US dollar (ZAR 3570)

We will offer the opportunity to submit abstracts for oral or poster presentations and/or to book an information stand. A small and limited scholarship programme for financial support to attend the conference is available. More information on both the abstract submission and the scholarship programme can be found on our website from mid June.

Register now

Also on behalf of our co-organizers Population Services International (PSI), the Center for Health and Gender Equity (CHANGE) and MatCH Research University of Witwatersrand, we are looking forward to welcome you in Durban!

Mrs Greetje Lubbi (incl elektronische handtekening)
Chair International Steering Group
Universal Access to Female Condoms Joint Programme (UAFC)

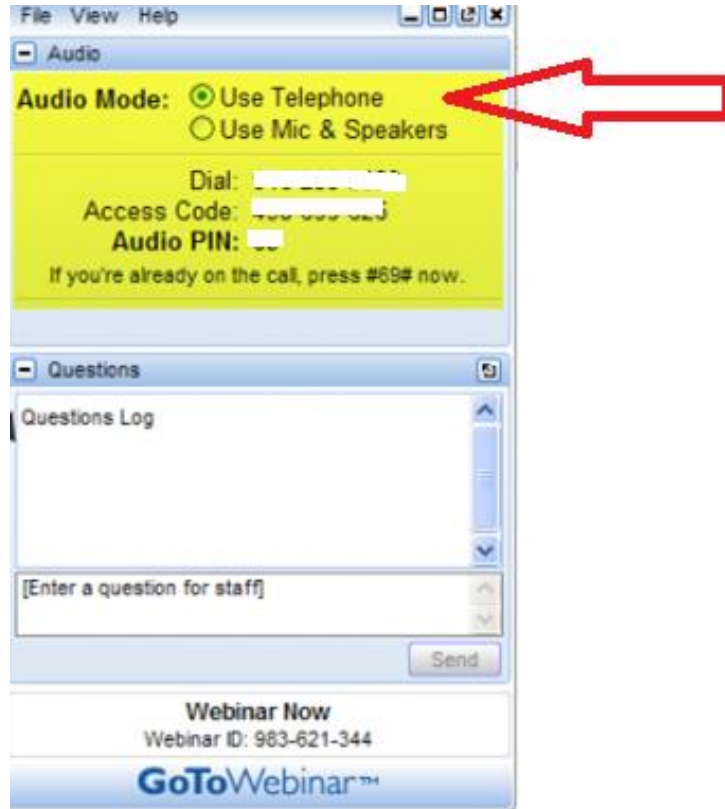
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For up-to-date information on the conference, please visit: www.femalecondoms4all.org/conference2015

UAFC **MatCH Research** **psi** **CHANGE**

- ▶ Scientific presentations
- ▶ Discussion panels
- ▶ Interactive workshops on
 - ▶ FC availability
 - ▶ Demand creation
 - ▶ Placing FCs on the agenda of governments and policy makers

Questions?



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Thank you for joining us!

- ▶ Learn more about the National Female Condom Coalition at www.nationalfccoalition.org or contact us at contact@nationalfccoalition.org.
- ▶ Look for an email this week with the video of this webinar, the downloadable slides, resources and ways you and your organization can help move down-classification of the female condom forward.