UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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OBSTETRICS AND GYNECOLOGY DEVICES PANEL

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December 11, 2008
8:00 a.m.

Holiday Inn
Two Montgomery Village Ave.
Gaithersburg, Maryland

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SUSAN RAMIN, M.D.	Voting Member
HOWARD SHARP, M.D.	Voting Member
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INDEX

	PAGE
CALL TO ORDER - Marcelle Cedars, M.D.	5
FDA Conflict of Interest Disclosure Statement - Michael T. Bailey, Ph.D.	6
Temporary Voting Status Statements - Michael T. Bailey, Ph.D.	8
Panel Introductions	11
Welcome and Update - Colin M. Pollard	13
Open Public Hearing Statement - Marcelle Cedars, M.D.	22
OPEN PUBLIC HEARING	
Allison Farrell	24
Eleanor Hinton Hoytt	31
Mark Rilling	36
Susan Wysocki	43
Dara Shapiro	48
Zena A. Stein	53
Deborah Arendale	60
Donna Cruz	65
Dazon Dixon Diallo	69
Patricia S. Coffey	75
Cynthia A. Pearson	83
INTRODUCTION - Colin M. Pollard	90
SPONSOR PRESENTATION	
Introduction/History - Mary Ann Leeper, Ph.D.	123
FC2 Development - Michael Pope, B.Sc.	132

RHRU Clinical Study –
Mags Beksinska, B.Sc., M.Sc., Ph.D. pending 142

FDA Points Raised – Mary Ann Leeper, Ph.D. 159

Statistical Data – Doug Taylor, Ph.D. 166

Summary – Mary Ann Leeper, Ph.D. 173

PANEL QUESTION AND ANSWER 174

FDA PRESENTATION

Preclinical Review – Elaine Blyskun 200

Clinical Review – Julia Carey-Corrado, M.D. 204

Statistical Review – Zhiwei Zhang, Ph.D. 222

Epidemiology Review –
Hesha Jani Duggirala, Ph.D., M.P.H. 228

PANEL QUESTION AND ANSWER 236

PANEL DISCUSSION AND FDA DISCUSSION QUESTIONS

Question 1 270

Question 2 284

Question 3 301

Question 4 315

Question 5 330

OPEN PUBLIC HEARING

Amy Allina 333

Jeff Spieler 335

Anna Forbes 342

Beth Jordan 346

SPONSOR SUMMATION – Mary Ann Leeper, Ph.D. 348

PANEL VOTE 352

ADJOURNMENT 371

M E E T I N G

(8:00 a.m.)

DR. BAILEY: Hello? I'd like everybody to take their seats. We're going to get started.

DR. CEDARS: I'd like to call the meeting to order if people could please take their seats. Do you want me to whistle? I can. I can. I'd like to call this meeting of the Obstetrics and Gynecology Devices Panel to order. I'm Dr. Marcelle Cedars, the Chair of this Panel. I am a reproductive endocrinologist from UCSF. If you haven't already done so, please sign the attendance sheets that are on the table by the doors, and if you're presenting in any of the open public sessions today and have not previously provided a copy of your presentation to the FDA, please arrange to do so with Ms. Toby Lowe, and if Ms. Lowe could identify herself? Thank you.

I note for the record that the voting members present constitute a quorum as required by 21 C.F.R. Part 14, and I'd also like to add that the Panel participating in the meeting today have received training in FDA device law and regulations. I'd also like to remind all attendees, if you've not already done so, to please silence your cell phones.

Dr. Bailey, the executive secretary for the

Obstetrics and Gynecology Devices Panel, will make some introductory remarks.

DR. BAILEY: Good morning. I will now read the FDA Conflict of Interest Disclosure Statement. The Food and Drug Administration is convening today's meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee under the authority of the Federal Advisory Committee Act of 1972. With the exception of the industry representative, all members and consultants of the Panel are special government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations.

The following information on the status of this Panel's compliance with federal ethics and conflict of interest law is covered by, but not limited to those found at 18 U.S.C. 208 and 712 of the federal Food, Drug and Cosmetic Act, are being provided to participants in today's meeting and to the public. FDA has determined that the members and consultants of this Panel are in compliance with federal ethics and conflict of interest laws.

Under 18 U.S.C. 208, Congress has authorized FDA to grant waivers to special government employees who have financial conflicts when it is

determined that the Agency's need for a particular individual's service outweighs his or her potential financial conflict of interest. Under Section 712 of the Food, Drug and Cosmetic Act, Congress has authorized FDA to grant waivers to special government employees and regular government employees with potential financial conflicts when necessary to afford the committee essential expertise.

Related to the discussion of today's meeting, members and consultants of this Panel who are special government employees have been screened for potential financial conflicts of interest of their own as well as those imputed to them, including those of their spouses or minor children and, for purposes of 18 U.S.C. 208, their employers. These interests may include investments, consulting, expert witness testimony, contracts, grants, Cooperative Research and Development Agreements, teaching, speaking, writing, patents and royalties, and primary employment.

Today's agenda involves the discussion of a premarket approval application for FC2 Female Condoms sponsored by the Female Health Company. This device is indicated to help prevent HIV/AIDS and unintended pregnancy. This is a particular matters meeting

during which specific matters related to the PMA will be discussed.

Based on the agenda for today's meeting and all financial interests reported by the Panel members and consultants, no conflict of interest waivers have been issued in accordance with 18 U.S.C. 208 and 712 of the FD&C Act. A copy of this statement will be available for review at the registration table during this meeting and will be included as part of the official transcript.

Ms. Elisabeth George is servicing as the industry representative acting on behalf of all related industry and is employed by Philips Medical Systems.

We would like to remind members and consultants that if the discussions involve any other products and firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participants need to exclude themselves from such involvement and their exclusion will be noted for the record. The FDA encourages all other participants to advise the Panel of any financial relationships that they may have with any firms at issue.

I am now going to read the first of two

appointment to temporary voting status statements. Pursuant to the authority granted under the Medical Devices Advisory Committee Charter, dated October 27th, 1990, and amended August 18th, 2006, I appoint the following as voting members to the Obstetrics and Gynecology Devices Panel for the duration of this meeting on December 11th, 2008: Ralph D'Agostino, Ann Davis, Paula Hillard, David Katz, Jeanne Marrazzo, Nancy Padian, Phillip Stubblefield, Michael Thomas, David Warner, and Jonathan Zenilman.

For the record, these people are special government employees and are consultants to this Panel or another Panel under the Medical Devices Advisory Committee. They have undergone the customary conflict of interest screening review, and they reviewed materials to be considered at this meeting. This was signed by Daniel Schultz, director, Center for Devices and Radiological Health, and signed on November 25th, 2008.

The second statement. Pursuant to the authority granted under the Medical Devices Advisory Committee Charter of the Center for Devices and Radiological Health, dated October 27th, 1990, and as amended August 18th, 2006, I appoint Melissa Gilliam as temporary voting member of the Obstetrics and

Gynecology Devices Panel for the duration of the meeting on December 11th, 2008. For the record, Dr. Gilliam serves as a consultant to the Advisory Committee for Reproductive Health Drugs of the Center for Drug Evaluation and Research.

She is a special government employee who has undergone the customary conflict of interest review and has reviewed the materials to be considered at this meeting. This was signed by Randall Lutter, deputy commissioner for policy, and dated November 26th, 2008.

Before I turn the meeting back over to Dr. Cedars, here are a few general comments. Transcripts of today's meeting will be available from Free State Court Reporting, and there's information about that outside the door. Information on purchasing videos for today's meeting can be found on the table outside the meeting room. Presenters to the Panel who have not already done so should provide FDA with a copy of their remarks.

I would like to remind everyone that members of the public and press are not permitted in the Panel area beyond the speaker's podium. The press contact for today's meeting is Siobhan Delancey. Would you like to stand, please? So

please talk to Siobhan if you have any press issues. And I request that reporters wait to speak to FDA officials until after the Panel meeting. I'd like to now pass it back to Dr. Cedars.

DR. CEDARS: Good morning. At this Panel, we will be making a recommendation to the Food and Drug Administration on the premarket approval application P080002 for the FC2 Female Condom from the Female Health Company. Before we begin, I'd like to ask our Panel members and FDA staff seated at the table to introduce themselves. Please state your name, your area of expertise, your position, and your affiliation, and if we could start with Ms. George, please?

MS. GEORGE: My name is Elisabeth George, and I'm the Vice President of Quality and Regulatory at Philips Healthcare.

DR. HILLARD: Paula Hillard, Professor of Gynecology and Obstetrics at Stanford University Medical School.

DR. WARNER: Lee Warner, senior scientist, Division of Reproductive Health at CDC.

DR. DAVIS: Ann Davis, Professor of OB/GYN, Tufts Medical School, Department of Peds and OB/GYN.

DR. KATZ: David Katz, Professor of

Biomedical Engineering and Professor of Obstetrics and Gynecology at Duke University.

DR. THOMAS: Michael Thomas, Professor of Obstetrics and Gynecology and director of the Division of Reproductive Endocrinology and Infertility at the University of Cincinnati.

DR. D'AGOSTINO: Ralph D'Agostino, Chair of the Mathematics and Statistics Department at Boston University, consultant to the Committee.

DR. PADIAN: Nancy Padian, reproductive epidemiologist, Distinguished Fellow at the Women's Global Health Imperative at RTI and a Professor in the Department of Epidemiology, School of Public Health, UC Berkeley.

DR. SHARP: Howard Sharp, Associate Professor of Obstetrics and Gynecology, University of Utah School of Medicine.

DR. RAMIN: Susan Ramin, Professor and Chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Texas in Houston.

DR. STUBBLEFIELD: Phillip Stubblefield, Professor of Obstetrics and Gynecology, Boston University.

DR. ZENILMAN: Jonathan Zenilman, Professor

of the Department of Medicine, Division of Infectious Diseases at Johns Hopkins School of Medicine and also the School of Public Health, and chief of the Infectious Disease Division at Johns Hopkins Bayview Medical Center.

DR. GILLIAM: Melissa Gilliam, Associate Professor of Obstetrics and Gynecology at the University of Chicago and Chief of Family Planning.

DR. MARRAZZO: Jeanne Marrazzo, Associate Professor of Infectious Diseases at the University of Washington in Seattle.

DR. PETERSON: Bert Peterson, Professor and Chair, Department of Maternal and Child Health and Professor of Obstetrics and Gynecology at the University of North Carolina Chapel Hill.

DR. WHANG: Joyce Whang, Acting Director of the Division of Reproductive, Abdominal and Radiological Devices here at FDA.

DR. BAILEY: Mike Bailey, Executive Secretary of the Advisory Panel.

DR. CEDARS: Next, Colin Pollard, Chief of the Obstetrics and Gynecology Devices Branch, would like to make some introductory remarks to the Panel. Mr. Pollard?

MR. POLLARD: Thank you, Dr. Cedars. What

I'd like to do very briefly this morning is to review for you a number of developments of the past year since the Panel last met. And I'd like to speak to three things of note, a public health notification that the Center issued, a workshop on fetal monitoring that we held about a month ago and some new labeling requirements for male condoms, which I think is particular relevant considering today's PMA topic.

The public health notification, which we issued October 20th of this year related to serious complications associated with transvaginal placement of surgical mesh in the repair of pelvic organ prolapse and treatment of stress urinary incontinence. The Center received since 2004 more than 1,000 MDRs, medical device reports, from nine separate manufacturers. And the essence of the notification, in terms of what we were looking at, the most frequent complaints, erosion through the vaginal epithelium, infection, pain, urinary tract symptoms, and recurrence of these problems. Also reported were perforation of bowel, bladder, and blood vessels and vaginal scarring.

And the recommendations in this notification started with obtaining training for mesh

placement technique, being vigilant for the adverse events, including infection and perforation, informing the patients, informing them that the mesh is permanent, that complications may occur, additional surgery may be needed, and the risks related to erosion, including impact on quality of life; and, finally, if patient labeling is available from the manufacturer to provide that to the patients.

Last month, FDA in concert with the perinatology branch at NICHD held a workshop to look at intrapartum fetal monitors and, in particular, computer-assisted diagnosis. Two purposes of the workshop: One, to gather ideas on how to identify and differentiate categories of CAD-type devices, computer-assisted device systems, and the corresponding levels of evidence that would be needed for validation. And, secondly, we wanted to look at whether currently available databases or ones that we knew would be available in the near future could be used to either wholly or in part verify or validate those intrapartum CAD algorithms.

And just a little bit about the attendance. We were really pleased with the kind of attendance we had. We had several top-notch maternal fetal

medicine experts, specifically in the area of labor management. We had members of the industry who are manufacturing these products or might manufacture them in the future, biostatisticians in this particular field and several other kinds of stakeholders.

And just sort of a short summary because we're still working on the summary, we had two breakout sessions specifically to do those two objectives, and we got a lot of good ideas. I think, in general, I think one of the fairly strong senses that we got from the maternal fetal medicine folks were for these CAD systems that were really going to be a jump-up from what's available today, that they wanted to see randomized trials looking at some kind of outcome measure, some kind of fetal outcome measure as a validation of CAD success. We had asked them to look at some interim type multi-case, multi-reader type studies, and it was fairly universal that they didn't think that that was going to really be sufficient for these kinds of new systems.

We've put together a pretty nice website on this topic, and we're going to be adding to it. The summary we've just started working on, and the next steps, depending on how we take this, could be to

look at the input we got here and possibly develop a guidance document for -- to provide some help to manufacturers and others developing these kinds of systems. So that could lead to a Panel meeting looking at a draft guidance document, but that would be some time in the future.

And, finally, I'd like to speak to male condoms made from natural rubber latex and the new labeling guidance that FDA just issued a final rule on. You have a copy in your -- in one of the two folders in front of you. That copy, I should point out, is considered for reference only. It hasn't achieved its complete release for -- as in final. But the final rule goes into effect in January, so we expect it will be considered final very shortly.

So I'm going to just briefly take you through about an eight-year history of this, where the initial history, what we did, our proposal, the nature of the public comments, and what we finally wound up with. So this dates back to December of 2000, when a new statute, public law 106554, was enacted and directed FDA to reexamine condom labeling for medical accuracy with respect to accuracy or lack of accuracy -- I'm sorry -- effectiveness or lack of effectiveness against sexually transmitted diseases,

especially HPV, and this was part of a larger HPV statute. And that same year, there was an inter-agency workshop headed by NIAID, the National Institute of Allergic and Infectious Diseases, that looked at what kind of evidence there is on condom effectiveness related to STIs.

And so, in 2001, we began our own review of the literature and including an implementation plan for the statute. We used the workshop report, which issued in June of 2001 as an initial building block. We limited our scope to male condoms made from natural rubber latex primarily because that was the vast market share of these products that are used in the U.S. and the vast preponderance of available evidence as well.

And we developed a two-tiered perspective for looking at condom effectiveness. And in the context of all the kinds of things we looked at, we looked at physical properties, we looked at condom slippage and breakage studies, we looked at issues related to plausibility for STI risk reduction, namely the transmission vectors for different STIs. We also looked at various evaluation statements and summaries about condom effectiveness from other federal agencies. And I should add that even as this

was an FDA initiative, it was very much a strong inter-relationship with CDC and NIH, and we got a lot of help from both of those organizations in developing our implementation plan and the details of it. And, obviously, we looked at quite a bit of clinical data on condom protection against STIs, probably several hundred studies, at least three to four hundred studies in various levels of quality.

And, in essence, it boils down to when we looked at the common STIs, the most common STIs, we looked at about eight or nine of them and broke them into two different groups based on what we considered to be the transmission vector and what we -- as we got into the data, saw a stronger evidence for risk reduction. And so we called it Group 1 STIs and Group 2.

And the Group 1 included HIV/AIDS, gonorrhea, chlamydia, trichomoniasis, and hepatitis B virus. And the Group 2 STIs were STIs like syphilis, genital herpes, genital HPV, and chancroid. And if you know a little bit about STIs, obviously, you can see that this Group 2 are sort of lesion-oriented type STIs, where if the lesion is on the penis and the condom is covering it, you're going to get some protection, but if it's not, you're not going to get

any protection. So you see a different level of risk reduction than you do for the Group 1 STIs, where the bug is actually contained in the semen.

And so this led to our 2005 proposal with a two-tiered concept of effectiveness. And it also included warnings about nonoxynol-9. We got quite a few public comments, probably more than 100 different commenters, and many of those comments had multiple comments within them. It took us quite a while to sift through them. One of the almost universal levels of comments from even people who didn't agree on the details was it was confusing, to sort of make it simple. And so what we wound up doing was a label comprehension study to try to drill into that a little bit. And we simplified our message quite a bit, and we also decided to defer the issue about warnings about nonoxynol-9 because that was found to be particularly confusing.

So last month, we issued a final rule. As I said, in your folder, you have the guidance document that resulted from that. As I mention, it defers response on nonoxynol-9. It also does not deal with synthetic male condoms or female condoms, and it's effective January 9th of next year. And I'm not going to read all of this, but you can see in the

guidance document there's one sort of labeling box called "important information" that's on the outside retail package that is sort of a very general cursory kind of statement of what we're getting at. And then on the package insert, a little bit more detailed message about degree of STI protection that you get from using condoms.

So the next steps on this one is going to be a letter to the industry, even though I think a lot of them are already aware of this. This is just to give them a little bit more help on that. We're planning an article in *FDA Consumer* to sort of go hand in hand with this because as this releases, we're concerned that people understand the message that we really do believe condoms are very effective products for STI protection, and we don't want people to misconstrue what we're trying to get across here. We'll probably partner with some other public health agencies, both at federal and state levels if we can, to sort of further this kind of education approach. And we will also need to address other condoms not covered.

I'd also like to point out that this is the last meeting for Dr. Cedars and Ms. George as regular members of our Panel, and I just want to let both of

them know that we truly appreciate all the work they've brought to the Panel and the service they've done for the federal government and for the public health in general. And we will miss your input very much so. And so this is just a very heartfelt thank you for all your help.

And, finally, I'd like to mention, regarding the open public hearing, we've got two open public hearings, one in the morning, and one in the afternoon, and we do believe this is an important part of the Panel meeting, and it brings an added perspective that sometimes we sort of in our own sort of FDA circle and elsewhere don't have quite the same ability to bring it to. So we're looking forward to that. And we would encourage, if you are interested, to ask questions of these speakers. So thank you very much, Dr. Cedars.

DR. CEDARS: Does the Panel have any questions for Mr. Pollard?

(No response.)

DR. CEDARS: If not, thank you. We'd now like to proceed with the open public hearing portion of the meeting. And I, too, would like to extend my gratitude to the open public hearing participants in attendance today. Public comments on devices or

issues before the Panel is a very important component of Panel meetings. We look forward to your presentation, and we'll be opening the floor after each speaker to allow Panel members to ask questions regarding the presentation.

Both the FDA and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the Advisory Committee meeting, the FDA believes it is important to understand the context of any individual's presentation. For this reason, FDA encourages you, the open public hearing or industry speaker, at the beginning of your written or open statement, to advise the committee of any financial relationship that you may have with the Sponsor, its products or, if known, its direct competitors.

For example, this financial information may include the Sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at this meeting. Likewise, the FDA encourages you at the beginning of the statement to advise the Committee if you do not have any financial relationship. If you choose not to address the issue of financial relationship at the beginning of your

statement, it will not preclude you from speaking.

Prior to the meeting, we received formal requests to speak for today's open public sessions. I would like to please ask that all speakers remember that we do have a time limit. We want to be able to allow all the public hearing session speakers to have their time to share their information with us. We will be setting a timer. It will go to yellow when you have one minute left, and we ask that you wrap up so that there will be time for questions.

Our first speaker is Ms. Allison Farrell. If you would, please come to the microphone. We ask that you speak clearly and directly into the microphone to allow the transcriptionist to provide an accurate record of the meeting. Yes, please.

MS. FARRELL: Okay. My name is Allison Farrell, and I'm here today to share with the Advisory Committee my experience with the female condom. I was first introduced to the female condom while a graduate student at New York University eight years ago. I graduated from NYU with a Master of Public Health and then went to work on a multi-city social marketing campaign designed to increase HIV testing among at-risk inner city youth. Working in the field of HIV/AIDS in New York City facilitated my

interest in minority health issues and, specifically the plight of women living with HIV.

I'm now living in Columbia, South Carolina and pursuing a post-graduate degree in social work. South Carolina's HIV rates are among the highest in the nation. While I might have been familiar with the female condom for years, it was only recently that I started focusing on what I could do to help women in South Carolina embrace it. I see the dual value of the female condom and appreciate two critical issues plaguing women in my state, and that's HIV and teen pregnancy rates.

What I see are real women with real needs who are ready for more options to be available to help protect them against the transmission of HIV. My colleagues are eager to do the same thing and endorse more options as well. But support for these options will remain limited as long as access is limited, and access is going to remain limited until we can lower the cost of it. Until we can address the access issues, it's hard for any of us to capitalize on what the female [sic] has to offer the women that are looking to us for help.

I'm really concerned about the women living in the more rural areas of South Carolina where the

budgets are over-stretched and program funding is cut back to the bare minimum. That's why it makes sense for us to spend less on the device itself and more on raising awareness and education efforts that we know can make an impact on behavior.

In the past, I focused my prevention efforts on the male condom, but my recent experience in South Carolina has reminded me that sexually active HIV positive people struggle with the monotony of male condoms just like everybody else does. Their complaints are no different than anyone else's. Despite its efficacy and the millions of units distributed each year in the U.S., the male condom is simply not doing a good enough job of preventing the spread of HIV in the United States. Sad, but true.

However, research seems to indicate that offering the male condom in conjunction with the female condom leads to an increase in protected sex acts, and that's really inspiring to me. Most women I encounter in South Carolina have never seen a female condom. Most women are eager to hear about it, and as with anything unfamiliar, I find that women are initially confused, a little bit unsure about its benefits, how to use it. They tell me that it's really no big deal once they start using and

once they get the hang of it. And my impression is while they may not totally replace the use of the male condom with the female condom, they do add it to the mix and actively use it.

From a direct practice standpoint, my experience with the female condom is short-term. So I can only really tell you what I've seen and that I believe that the future is promising for it.

During the course of my outreach and education efforts, the younger women that I've had the opportunity to educate really do respond to the novelty of it at first, which I think is a really positive thing and helps take some of the edge off of a very personal conversation that a lot of times people are not comfortable having.

I encourage every woman to practice with it before they have sex, and we talk about ways to discuss it with our partner and ideas to help make it exciting, encouraging them to build it into their sexual routine. It's an opportunity for women to be creative, to get to know their body, and to embrace their sexuality and take control of what's happening in their bedroom, and that's empowerment, and it's a very, very powerful thing for somebody like me in my position to have a woman that feels empowered that I

can work with.

The female condom is reliable, it's available, and something that women can take ownership of. It's scary to me how many women tell me that they rely on a man to come prepared with protection. They put their health, their life into the hands of a romantic partner that may or may not know his status, and even scarier, and this happens all the time, they may not disclose it.

It's been my experience that HIV positive women also express frustration and sadness about a loss of intimacy. Sexuality is a healthy and vital part of who we are, and to see that part of a person denied is really a difficult thing for somebody in my position to address.

For example, one HIV positive woman who I know is married and his husband is HIV negative, they have been using male condoms for over ten years. So each and every sexual act for a decade has been protected in this couple. That's awesome, and, I mean, it's great thing; it's rare, but it's awesome that they're doing that. But he's tired of condoms, he complains, and he's starting to actually question the risk of the occasional unprotected sex act. So she feels guilty, but she's very committed obviously

to protect her husband's -- his status, his negative status. The female condom fit their needs, and it took some of her shame away and allowed her to embrace her status in a way that was responsible but still protected the needs of her husband.

When embraced by a woman, the female condom neutralizes her alliance on her male partner for protection. I talk about women -- I talk with women about how they can navigate and address many of the issues and the barriers that they run up against with male condoms. For example, if he doesn't have a condom, what do you do? If he doesn't want to wear a condom, you will.

The female condom is something for women to call their own and that they can initiate the use of. It's made to fit a woman's body, it's hers, and that alone is powerful. It's reliable, it's easy to store, its packaging fits easily into a woman's wallet or purse, and it's easy to use. Most importantly, when it's used, it is effective.

That's a pretty good deal, and there's no doubt that we need more right now. We need a lot. But waiting on microbicides to halt the spread of HIV is ignoring what we're up against today. My experience tells me that the female condom has the

potential to play a critical role in how to help educators, social workers, and medical providers engage and educate communities and assist the people that are in need. Giving women another reliable choice of protection is an invaluable tool in combating what we know is a true epidemic in the United States. Thank you.

DR. CEDARS: Thank you. Are there any questions from the Panel?

DR. D'AGOSTINO: Yeah, there is a female condom already available?

MS. FARRELL: Right.

DR. D'AGOSTINO: Does that not fit the bill? Why the need for a new one?

MS. FARRELL: I mean, for me, it's the cost. It's hard for, you know, the -- if we can lower the cost of it and make it -- increase the access to it, by lowering the cost of, you know, for the organizations that are providing it and for women that would buy it directly, I think that's real important.

DR. D'AGOSTINO: Thank you.

DR. CEDARS: Dr. Stubblefield?

DR. STUBBLEFIELD: What problems have your patients that you've worked with experienced using

the female condoms? What sorts of things need to be fixed?

MS. FARRELL: Well, you know, I don't run up against -- and this, you know, like I said, I can't speak from a long-term, five or ten years out. I can speak from a relatively short-term. The biggest thing that we kind of come up against is women who -- they have to be fairly comfortable with their body, but even a discussion on the female condom, me having the opportunity to talk to them, I can work with them on that and talk to them, and that's where you get into kind of some of the sexuality issues and embracing -- you know, a woman feeling comfortable with her body.

I really encourage women to use it a couple of times beforehand and get used to it, and once they do that, it's like anything that you're not used to. I mean, I think we've kind of lost, you know, over time with the male condom -- I mean, it was new at one point, too.

DR. STUBBLEFIELD: Thank you.

DR. CEDARS: Thank you. The next speaker is Eleanor Hinton Hoytt.

MS. HINTON HOYTT: Good morning. My name is Eleanor Hinton Hoytt. I'm president and CEO of

the Black Women's Health Imperative. The Imperative is the only national black women's organization devoted solely to the health and well-being of the 19.5 million women and girls in this country. I wish to thank you, the Panel, for the opportunity to address the importance of a need for safe and effective HIV, STD, and pregnancy prevention methods for black women.

It's simple. Increasing access for 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 number one killer of young black women, ages 19 to 34. Black women also have the highest STD rates and is among black girls, 50 percent of our black girls, ages 14 to 19 have at least one STD. And the most recent report on unintended pregnancies states that among black women and girls, nearly 70 percent are unintended.

These facts only 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 available, accessible, and

affordable. 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 black women and all 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 and compromised.

While we understand there is no perfect method for everyone, the female condom is the only advice [sic] available 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, therefore giving women more control over that negotiation.

In conclusion, I'd like to say that the Black Women's Health Imperative and its 100,000 plus constituencies are pleased to offer support for the approval of this second generation of the female condom. Although we don't have data and we have not

done the health education on the female condom, we have done some anecdotal conversations with men and women, and what we find that the women are willing, the men are reluctant because it releases their power. And so we look forward to being a partner in promoting the female condom as an option for preventing HIV and STD infections and reducing the number of unintended pregnancies for all women, not only nationally, but also globally. Thank you for your time.

DR. CEDARS: Thank you. Are there any questions from the Panel for Ms. Hinton?

DR. STUBBLEFIELD: Yes.

DR. CEDARS: Yes, Dr. Stubblefield?

DR. STUBBLEFIELD: We certainly agree of the need for the female condom, but what about the new one that's being developed here that this is -- that we're here to discuss, the FC2?

MS. HINTON HOYTT: The new one, I guess I agree with the former speaker that the option for having it more accessible and available, if it lowers the cost in any way. If there is a way that -- and, in fact, one of our new faculty member -- new staff members, Dr. Nadra Tias, has had experience with the female condom, and she has been involved with our

staff in doing some of the research on the female condom. And so from her perspective, she felt that the first version of the female condom was more difficult but was more desirable, and we believe now that -- and the major factor is that the high cost. There is no way that we can support black women, particularly lower income black women, in figuring out how to do -- to negotiate with a device that is not accessible to them because of the high cost.

DR. STUBBLEFIELD: Thank you.

DR. CEDARS: Dr. D'Agostino?

DR. D'AGOSTINO: Even if there is no data that it will actually stop or prevent sexually transmitted diseases, it's still useful?

MS. HINTON HOYTT: Yeah, we think so, I think, and certainly, some of this is social and psychological. If we in any way can give some of the negotiation control and give options to black women so -- and all women so that we would be in a position to negotiate, we think that's an empower, and it certainly conveys a sense of freedom in being able to make some of the decisions. It's a decision-making process issue.

DR. CEDARS: Thank you. The next speaker is Mark Rilling.

MR. RILLING: Thank you. I'm going to show some slides, a little bit of background. My name is Mark Rilling. I'm the chief of the Commodities, Security, and Logistics Division in the Office of Population and Reproductive Health in the Bureau for Global Health at the U.S. Agency for International Development. I don't have a conflict of interest.

USAID's relationship with the female condom predates my -- let's see. Do I advance this through the down arrow key? Okay. My own involvement -- USAID's relationship with the female condom predates 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.

USAID has purchased and provided female condoms to developing countries since 1998, shipping 42,000 that year. We shipped 134,000 in 1999, 73,000 in 2000, and 2,000 items in the year 2001, these fluctuations being due mostly to a range of administrative issues.

After these pilot and introductory efforts, programmatic interest began to grow. Five years ago, we shipped female condoms to about ten 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.

While USAID is the primary donor providing female condoms to developing countries, USAID is not alone. Donations for 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 and programmatic activities related to expanding correct and consistent use.

The British Development Organization, the Global Fund, IPPF, UNFPA, the World Bank, the Germans, 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 would also like to switch and is prepared to do so as quickly as possible upon FDA's approval.

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 overriding emphasis is on disease prevention.

With most of the U.S. government's HIV/AIDS funding available for programs in Africa, this distribution across regions is not surprising. This year, we are shipping female condoms to eight countries in Africa, seven countries in Asia, and two countries in this hemisphere. What those numbers mask is the relative size of our donations across these regions. Eighty-seven percent of our female condom shipments this year go to African countries, 12 percent to Asian countries, and just 1 percent to Latin America.

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 drug sellers, through pharmacies, and increasingly hair salons for women and barbers for men, drawing on the lessons learned that women and men benefit from related 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 in Zimbabwe among all sexually active adults, ages 15 to 49, is 20.2 percent, and current use is 9.2, up from 8.1 percent in 2005. This is a country where 21 percent of Zimbabwean women and 14.5 percent of men, ages 15 to 49, are HIV positive. Each correct use is important. Each consistent use is important, too.

This prospect for USAID of buying a comparable product at a 25 percent cost savings, being able to serve that many more people in the developing world for the same level of investment, is very attractive and not at all trivial. Thanks for your attention and careful consideration of these

important issues.

DR. CEDARS: Thank you. Are there any questions from the Panel? Dr. --

DR. PADIAN: John first.

DR. ZENILMAN: I have two questions. One is have you folks done any studies on storage conditions and time -- from time of release to time of use and status of the condoms in those conditions? I assume that many of these places -- storage conditions can get quite hot?

MR. RILLING: We've done stability studies. I didn't bring any of the data with me. These studies have included female condoms. We have them in various storage conditions in ovens at I think 25 and 35 and 40 degrees, and I think at 65 percent humidity and 70 percent humidity. But I haven't --

DR. CEDARS: Perhaps that's --

MR. RILLING: -- look at that data for a while. We have --

DR. CEDARS: Perhaps that's a question we could pose to the company.

DR. ZENILMAN: Right, no, I'm saying there are some -- they did report some storage -- I'm wondering if they actually did any real field studies in storage --

MR. RILLING: We have not --

DR. ZENILMAN: Okay.

MR. RILLING: -- drawn samples from the field that have been there for prolonged periods of time and run studies on those. We don't get complaints on female condoms from the field as we do with male condoms. So we don't have reason to believe that there are storage issues. The actual time in country ranges from, like, 18 months to 36 months from the time we ship it in and it typically gets used, but that varies widely across countries and distribution programs.

DR. ZENILMAN: The other question I have is with increasing focus on the environment, how are these disposed of after use?

MR. RILLING: That varies, too, but the two primary means are burial and incineration.

DR. CEDARS: Dr. Padian?

DR. PADIAN: I also have two quick questions. One is you said that it would not be helpful to have both. I thought I heard you say that, both FC1 and FC2, and I was wondering why?

MR. RILLING: The systems that we're supporting and shipping these through in developing countries barely function. And duplicate products

are not helpful. It's much easier to forecast and distribute one product --

DR. PADIAN: Uh-huh.

MR. RILLING: But to manage them separately is an unnecessary hassle.

DR. PADIAN: Okay. My second question was insofar as you have sort of ecological rates of female condom use, for example, you said in Zimbabwe, I was wondering if you had similar rates of male condom use, and, specifically, what I'm interested in is when there is widespread promotion of female condoms, if you have any idea whether that has impact on uptake of male condoms.

MR. RILLING: There is data on that, but I haven't been a part of those studies. I think what the -- my impression is -- there are other people here who know the answer to that question based on actual studies.

DR. PADIAN: Okay.

MR. RILLING: My impression is that total condom use increases when women and men have a choice between male and female condom use.

DR. PADIAN: Thanks.

DR. CEDARS: Dr. Marrazzo?

DR. MARRAZZO: Thanks for your

presentation. It sounds like during your tenure of the transition, other countries' distribution perspectives have switched to FC2. I'm just wondering if you've observed any trends or patterns or sort of singled events in that transition that they've had to deal with, or has it been pretty much seamless and just the same as FC1?

MR. RILLING: Yeah, very easy.

DR. CEDARS: One more quick question. Dr. D'Agostino?

DR. D'AGOSTINO: Yeah, I have a similar question. Have there been any data collected on the rates of developing HIV and STIs and so forth as you shift more and more to the use of the FC2?

MR. RILLING: I don't know the answer to that question. My impression from the studies I've heard presented is that it's very difficult to tie incidence of disease to male or female condom use.

DR. D'AGOSTINO: It's a hard question.

MR. RILLING: Yeah, consistent and correct use in every sex act is difficult to achieve.

DR. CEDARS: Thank you. The next speaker is Susan Wysocki.

MS. WYSOCKI: Good morning. My name is Susan Wysocki, and I'm the president and CEO of the

National Association of Nurse Practitioners and Women's Health and am also a women's health nurse practitioner, and I have no conflicts of interest.

Prior to this meeting, a number of health providers and women's health advocacy groups sent a letter to the FDA expressing concern about the growing impact of HIV/AIDS and STIs among women in the United States and globally. And it's with hope that this Panel will provide a recommendation for the FC2 female condom to give women even more chance to protect themselves that I'm here today to emphasize that concern.

I think if I gave you my three-second presentation, it would come down to options for women to protect themselves, access, which really comes down to cost, a question that has been asked a couple of different times.

The statistics around these infections are well-known to many of the panelists. Over the past two decades, the proportion of women among people living with HIV/AIDS has more than tripled. HIV infection has emerged as a leading cause of death of African-American women, age 25 to 24. High-risk heterosexual contact is responsible for 80 percent of these new infections. And I think we were all wowed

with the information that one in four young adults, age 15 to 20, has contracted a sexually transmitted infection each year.

In this context, expanded access to the female condom that's not only safe and effective as a woman-initiated prevention method is essential for both men and women to be able to practice safer sex.

More than 200 peer review studies have demonstrated that when women have access to the female condom and education on its use, it becomes a product in demand. You've heard about the efforts by USAID. Certainly, the female condom distributed along with male condom, the rate of protected acts of sex increases significantly, not only in other countries, but in New York City, where they have expanded purchase and distribution of female condoms, has also shown a decline in the number of newly reported AIDS cases. Additionally, survey data have shown a 30 percent increase in female condom usage over the course of that campaign in New York City.

The issue here today is there is a high cost to the female condom relative to male condom, and that has limited its availability for distribution in the United States, as well as worldwide.

The second generation female condom is made from new material that allows it to be manufactured with cost efficiencies that will drive down the unit price significantly, if I understand correctly on what this hearing is about today. WHO has already paved the way for the condom to be provided, and the FDA today will hopefully take action by determining the FC2 as safe and effective. This decision will enable state and local governments in the U.S., as well as USAID-funded international.

The evidence is clear and compelling. Women do need expanded access to women-initiated STI prevention methods. And we look forward to FDA's scientific review of the safety and effectiveness data today and are optimistic that your review will produce a positive determination. Thank you.

DR. CEDARS: Thank you. Are there any questions? Yeah, Dr. Padian?

DR. PADIAN: I wondered in the promotion of female condom in New York, if that was presented in a hierarchal array of choices for people or how it was promoted?

MS. WYSOCKI: I don't know exactly what you mean by hierarchal. If it was given, you can have this or that kind of thing?

DR. PADIAN: Well, like, for example, you should use a male condom, and only if you can't get your male partner to use a condom, you should use a female condom, or they're equal or what?

MS. WYSOCKI: I don't know the answer to that question. I think as has been stated a couple of times here today, that the provision of both, giving both options gives some flexibility in terms of protection and allows the couple to, you know, when they tire of male condom, as was stated earlier, another option to go to and overall increases protection.

DR. CEDARS: And the next speaker is from the New York State Department of Health so --

DR. PADIAN: Oh, cool.

MS. WYSOCKI: Oh, well, that should help then.

DR. CEDARS: Perhaps you'll get those questions answered.

MS. WYSOCKI: Fill in my blanks.

DR. PADIAN: I did that intentionally.

DR. CEDARS: Okay. Dr. Stubblefield?

DR. STUBBLEFIELD: You mentioned World Health Organization. Have they taken a position on the FC2?

MS. WYSOCKI: Yes, I believe that they have. Let me see if I can get to this. The WHO has already paved the way to expanded access by recognizing the FC2 condom as equivalent to the FC1 female condom in regard to safety, effectiveness, and acceptability.

DR. STUBBLEFIELD: Thank you.

MS. WYSOCKI: You're welcome.

DR. CEDARS: Thank you.

MS. WYSOCKI: Thank you.

DR. CEDARS: And our next speaker is Dara Shapiro.

MS. SHAPIRO: Hello. My name is Dara Shapiro, and I'm the Assistant Director of Education and Training for the New York State AIDS Institute. I have no conflict of interest, and my travel and related expenses were paid by the New York State Department of Health.

I've been working in public health for over 12 years, so I've been familiar with the female condom for a long time. But like many health professionals, I had not really considered the importance of the female condom an effective method for preventing pregnancy and the spread of HIV and other sexually transmitted infections.

My awareness changed when I began working on the New York State female condom promotion in 2006. After reviewing much of the research and speaking to front-line healthcare workers, I am committed to making the female condom more available in New York State. When women and men do not have access to female condom, their choices for protection during sex are reduced by half.

I'm going to talk about New York State today and why we need the FC2 now. New York State has 7 percent of the nation's population, but 18 percent of all persons living with AIDS, most of whom reside in New York City. New York City's case rate is three times the U.S. average.

Twenty-five years into the HIV/AIDS epidemic, women and girls are increasingly affected. The proportion of AIDS cases among women has nearly tripled in New York State since 1986. At the start of the epidemic, 1 in 10 New Yorkers with HIV were women. Today, 1 in 3 are female.

Women used to be infected by injecting drugs. Today, most women are infected through heterosexual transmission. In New York City, heterosexual transmission accounts for 92 percent of new HIV cases among females. Yet, New York City data

are not unique. CDC data, as shown by the pink line in this graph, demonstrate that heterosexual transmission among women has increased in the U.S. since the beginning of the epidemic.

New York State is committed to expanding access to female condoms. Both the state and city departments of health distribute free female condoms to agencies. In addition, since 2006, the AIDS Institute has collaborated with Columbia University to address female condom promotion at the provider level. Preliminary results from this study were presented at the 2008 National HIV Prevention Conference, and there is widespread interest in the outcome of our work. The program provides a one-day training for counselors that is designed to address misconceptions about the female condom and provide skills practice around use and promotion.

Like other female condom research, the female condom program has found that access to and beliefs about female condoms are obstacles to widespread use. However, provider and client attitudes can change with education and effective programming. Research shows that both women and their partners like the female condom when they give it a chance, and our own study is finding that after

counselors attend the one-day training, their attitudes about the female condom are more positive and counselors are more willing and better able to promote female condom use with clients.

While attitudes can be changed, access still must be addressed. The cost of female condoms has always been an issue, and this directly affects availability. Our study has shown that almost half of agency directors surveyed found limited access to female condoms a barrier to programming and promotion of the product within their agency.

And, as one of our counselors has put it, "The only problem I have is with telling people where to find female condoms outside of agencies that hand them out. I feel as though this could be a major barrier to continued use for those people who try the five or six I give them but then don't know where or how to get more. It's kind of hard to say, hey, try these. They're great, but you can't get them anywhere local."

As the HIV/AIDS epidemic becomes increasingly feminized, the female condom is even more important. Right now, there are only two options available in the U.S. that protect against sexually transmitted infections and HIV, male condoms

and female condoms. Microbicides, vaccine, and pre-exposure prophylaxis as viable methods are still years away. In terms of cost, the FC2 can be manufactured and sold for less than the original version. Less expensive female condoms will mean more individuals and agencies can purchase them. The price of female condoms will become even more important as federal and state funding are cut, due to the current fiscal crisis the U.S. is facing.

New York State is working hard to promote the use of female condoms, and we are making progress. Additional efforts to improve the product and reduce cost, like the FC2, are needed now to support this public health effort. When the female condom is available, protected sex increases. Studies show that many couples with access and education alternate between male and female condoms. More choices does translate to safer sex.

I urge the Committee to recommend premarket approval of the FC2 and thank you for the opportunity to present.

DR. CEDARS: Thank you. Are there questions from the Panel? If not, thank you.

MS. SHAPIRO: Thank you.

DR. CEDARS: The next speaker is Zena

Stein.

DR. STEIN: Hello. I'm Zena Stein from Columbia University. I'm a Professor Emerita of Epidemiology and Psychiatry and co-director of the HIV Center. I suppose one of my claims is that I've been in this field of trying to develop methods that women can use to protect themselves from HIV and STIs probably as long as anybody here.

What I'm complaining about is that in the FDA record, a criticism, a major criticism of a paper which we published in the year 2003. It was a study we did in Philadelphia with CDC and with the support of the Philadelphia Health Department. And it's a study which was succeeded in randomization between a group of women who were given a short, small group intervention to describe how to use the male condom effectively and a control group, or another group intervention, or even a very similar intervention in using the female condom.

Now, the purpose of this study was because people were saying that if you provide the female condom, two things: One, women will stop using the male condom and use the female condom, for which there was less proof; and, secondly, if that happened, the rates of new cases of sexually

transmitted infections would increase. This was the purpose of the study.

So it's a very simple study. We randomized women according to which week they came into a large sexually transmitted infection clinic in Philadelphia. And if they came one week, they were intervened and given the instructions on the male condom, and if they came another week, they were given a very similar bit of instruction, 20 minutes, on the female condom.

So, after that, we gave out from the clinic male condoms, but, of course, people could get male condoms anywhere. And we gave out female condoms, which you couldn't get anywhere. So women were supplied with three months or six months amount of female condoms, told to come back any time and contact us.

A weakness of the study is that we would expect that it's more difficult to get the female condom. However, we were able to follow up through the record system, which covered the whole of Philadelphia and all their clinics, all new cases of the STIs, gonorrhea, chlamydia, tric, and syphilis for everybody who came back of the 1,500, who were randomized. Women were young, minority, and, of

course, an STI clinic concentrates on high-risk people.

This study, which I don't regard as the best in the world, but it did have randomization, it did have intention to treat, this study is criticized in the FDA record. So as an academic, I thought I would say I thought the criticism was inappropriate. It's on the FC1, not on the FC2, but remember they were publicly provided condoms. So FC2 would be a big advantage to the clinic.

The three points of criticism leveled at the study were, one, that it didn't include HIV. Well, that period, you couldn't include HIV. It wasn't notifiable, and it wasn't -- information wasn't easily available.

The second point of criticism was that the population wasn't generalizable. Now, generalizable, it applied to all women who used this particular clinic, which was very large and central in Philadelphia. Nobody opted out of treatment. So it's generalizable to young minority women on the whole who are at risk for STIs.

And the third point, which I tried to explain on this slide, which I couldn't understand, they said that clearly the results, which were

slightly better, that the bottom line there proportioned who in the end had STIs, 15.8 percent in those who were given counsel on the male condom only and 12.4 percent who were counseled on the female condom only. Our purpose was to show that female condom counseling was just as good. In practice, it's slightly better in the various statistical maneuvers you can do, but those are the numbers.

Now, the criticism said that because -- which we knew from a sub-study, that many women in the female condom group couldn't get a female condom and about a third of them probably used a male condom. And, as a matter of fact, in the sub-study, women alternated. Many women used either or both, and that's part of the theory. You give options to a couple.

So it was criticized. They say the reason why the female condom worked out just as good as the male condom was because a third of the women in the female condom used male condoms. Well, I leave you to think about that criticism. I thought the criticisms were biased against the study, which is why I'm taking the trouble to use it.

And I'd also like to say that the Philadelphia system accepted our intervention,

adopted it, and if you halve the price of the female condom, FC1 with FC2, I think it'll have a really beneficial effect on the work at the clinic.

DR. CEDARS: Thank you. Dr. D'Agostino?

DR. D'AGOSTINO: I assume the criticism is coming from the idea that we -- while I think the study design makes a lot of sense, it's a natural use type of study. This is what people presumably will do -- they can have the male and female available. It doesn't direct to what the female condom is actually capable of doing, and I think that might be what the criticism was about, as opposed to this is not what people will do in practice, but what do we get out of this study about the female condom directly?

DR. STEIN: You know, you try and do a randomized controlled trial.

DR. D'AGOSTINO: Well, you know, but --

DR. STEIN: I'm serious. I'm serious.

DR. D'AGOSTINO: But I think that's a very good comment to come back with, but it begs the question on what information can we get out of the study.

DR. STEIN: That if you provide -- if the clinic provides the female condom in a public clinic,

you will, as we've already noted, you will reduce the proportion of people who use unprotected sex, and you probably would reduce the incident infection rate.

DR. D'AGOSTINO: But that's not significantly different, though. How many -- I mean, those rates are not different --

DR. STEIN: They're not statistically significant. We analyzed it in several ways. The point is -- it's lower. It's certainly not higher.

DR. D'AGOSTINO: It's certainly not significant either.

DR. CEDARS: Dr. Warner?

DR. WARNER: Yes, Dr. Stein, over here.

DR. STEIN: Yeah?

DR. WARNER: I had a question about this, and I understand that your study or any other study would have the obligation to give male condoms. Do you have any data on how the male and female condoms were used? So in the -- give both. It's not random, or it may not be random. Would they have used a particular type with a particular type of risky partner?

DR. STEIN: Different type of --

DR. WARNER: Partner --

DR. STEIN: Partner?

DR. WARNER: So maybe was a certain condom used with higher risk partners, one-time partners?

DR. STEIN: All I can say is the overall population, which we know quite a lot about, a small proportion of them were actually sex workers, and it is a population with multiple partners -- sex workers, and there's a high incidence -- really expect about 20 percent of the population will come back with new infections.

DR. WARNER: Um-hum.

DR. STEIN: I can tell you that it's the kind of population we are aiming at really in this country.

DR. WARNER: Thank you.

DR. CEDARS: One quick question, Dr. Marrazzo?

DR. MARRAZZO: You mentioned that the proportion of unprotected sex acts decreased. Did you actually collect data on reported protection of sex acts in the study?

DR. STEIN: No, not in this study. On other studies and other studies elsewhere, and some have been imported here. Internationally, that's been done better, not -- there's a series of studies which have been summarized, so I shouldn't do that --

DR. MARRAZZO: Thank you.

DR. STEIN: -- which suggest exactly that, that the proportion of unprotected encounters is decreased.

DR. CEDARS: Thank you. The next speaker is Deborah Arendale.

MS. ARENDALE: Good morning. I'm Deborah Arendale, Vice President of Health Policy for the American Social Health Association, which is a non-profit, non-partisan organization that's been around since 1914.

Since that time, we've been seeking to eliminate sexually transmitted diseases and their harmful consequences for families and communities. We have no conflicts today, and I really appreciate the opportunity to talk to the Panel about this second generation condom.

We've been in the business for about 90 years, although I haven't personally been there for 90 years although it feels like it some days. And what we have learned are lessons that all of us know without 90 years of experience, and that is that no one actually wants to get a sexually transmitted infection and that there really aren't enough tools for people who do want to prevent sexually

transmitted infections to do so.

As a result, the United States has staggering rates. We have the highest rates of sexually transmitted infections of any industrialized nation, with about 19 million new cases every year. And STIs are a significant burden for women and teenagers in communities of color. And what we know about these infections, as with many other diseases, that they are fueled by poverty, lack of access to care, and as a result, they do pose a significant burden and take their greatest toll in communities of color. The racial disparities are staggering.

The rates of chlamydia and gonorrhea among African-Americans are 16 and 8 percent -- and eight times higher -- sorry -- respectively than for whites, and these infections are often asymptomatic. But the consequences of them are quite severe, as most of you know quite well. They have very serious sequelae, including infertility.

An STI such as chlamydia will also make women more susceptible to HIV infections. The percentage of women in the United States living with AIDS has grown exponentially in the last two decades so that now, four-fifths of women with HIV in the U.S. are from communities of color. And that really

is -- these are numbers that we really should all be very embarrassed by.

The scope of this epidemic is brought home for us by the fact that in 2002, as Susan Wysocki alluded to, HIV was the leading cause of death for African-American women between the ages of 25 and 34. And Latino women in the United States are also disproportionately affected. The rates of cases for those women are six times higher than for white women. And we know that these are not just statistics. These are mothers and daughters and sisters, and we are all diminished by this impact of this disease.

Women are at increased risk for a number of reasons. Many of them are biological. But there are also very important social factors that can make it difficult for women, especially young ones, to effectively negotiate safer sex and condom use. In a study done with young black women in Los Angeles, and I can't remember now if it's '97 or '98, but roughly ten years or so ago, fully 90 percent of participants indicated that there would be some level of conflict if they were to try to introduce discussions of safer sex and condom use with their partners.

As we know, female condoms are the only

woman-controlled method of safer sex. And we also know what the birth control pill did for women. It allowed women unprecedented control over their reproductive status. And we believe that female condoms, of course, offer that same kind of control and the possibility of effective protection against STIs.

Female condoms have the advantage, of course, as we know, that they can be inserted prior to having sex. But as we've heard from countless presenters this morning, they are actually really too expensive and that this is a significant barrier to women being able to use them.

We believe that this new generation female condom provides the same female-controlled method but at a more affordable rate. We don't as an organization work on direct science. I can't stand here and talk about the hard science issues of this. I really can only talk about the social issues, the impact on women of color. Being one, I'm particularly concerned about these issues and the need for women to have greater access.

So we do urge the Committee to move forward with continuing whatever needs to be done to get us to approval of this condom as soon as possible. We

really appreciate the opportunity to address you and would be happy to continue to work with you in any way that would be helpful. Thank you.

DR. CEDARS: Thank you. Dr. Padian?

DR. PADIAN: Insofar as it's a little bit challenging to use the female condom completely clandestinely, my question is that you said that women had a conflict bringing up safe sex in the context of their relationship. Is that conflict mitigated if they're introducing a female condom, which can't be used or is difficult to use clandestinely?

MS. ARENDALE: I can't speak from a research perspective.

DR. PADIAN: Um-hum.

MS. ARENDALE: I can always speak intuitively, which for a scientific panel probably sounds a little silly. But if you have the ability to insert a condom before sex and you're hot and heavy in the moment, you don't have to negotiate, my guess is. That certainly gives an advantage right there, that you can insert it prior to sex as opposed to with male condoms, where you're much more in the moment, so you're, you know, you're already protected before you enter the sex act.

DR. PADIAN: Thanks.

MS. ARENDALE: That's not science, though.

DR. PADIAN: No, that's a good answer.

DR. CEDARS: Thank you.

MS. ARENDALE: Thank you.

DR. CEDARS: The next speaker is Donna Cruz.

MS. CRUZ: Good morning, Dr. Cedars, and members of the FDA Obstetrics and Gynecological Panel. My name is Donna Cruz. I'm Director of Government Affairs at AIDS Action Council here in Washington, D.C. AIDS Action is one of the oldest national HIV/AIDS organizations in the country. Since its founding in '84, AIDS Action has been in the forefront on 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, and 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 CDC, women comprise 27 percent 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 percent 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. And the letter is available for you today.

"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 premarket 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 the UNAIDS, women comprise half of the 33.2 million people living with HIV and 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. The feminization of HIV and AIDS require a woman-centered response, and access to a range of safe, effective, and affordable prevention methods

for women, including female condoms and effective education on their use, can play a strong role in stemming the number of new HIV infections. Women need tools like the female condom to stay healthy, plan pregnancy, protect themselves and their partners from HIV.

"According to the Center for Health and Gender Equities' report, 'Saving Lives Now: Female Condoms and the Role of U.S. Foreign Aid,' several studies have demonstrated that effective promotion and programming of the female condom increased the total number of protected sex acts, thus reducing a couples risk of infection of HIV and STIs.

"Despite the urgent need for women-controlled HIV prevention methods, domestic and international HIV/AIDS organizations face many challenges in providing the female condom to women and communities in greatest need, including a lack of political will and donor investment as well as the relatively high cost of the product. The FC2 female condom can play a major role in increasing distribution and facilitating uptake of the female condom in the U.S. and internationally because it is composed of a less costly material than the first generation Female Health Company female condom, FC1.

"Coupled with sustainable procurement and distribution and effective programming, the FC2 has great promise for getting into the hands of women worldwide and ultimately saving lives. Though researchers are tirelessly working to develop a broad-spectrum of new prevention technologies, including microbicides, vaccines, and pre-exposure prophylaxis, such products will not be available for many years. Female condoms are tools women can use right now, today, to protect themselves against HIV and other STIs.

"With the HIV/AIDS crisis continuing across the globe, the need to step up prevention efforts is ever more critical. The approval of a safe and effective female condom that can be made available to more women is an important step in putting the power of prevention into women's hands."

I won't read the list of organizations, but it is attached. The letter itself is out front, and I don't have any conflicts of interest.

DR. CEDARS: Thank you. Thank you. Our next speaker is Dazon Dixon Diallo.

MS. DIXON DIALLO: Thank you. It helps to come down the line because so many things have already been said, and then sometimes it's not

helpful. So I'll try to do best. Good morning and greetings. Thank you for inviting me and having me here. I'm Dazon Dixon Diallo, founder and president of SisterLove Incorporated, which is a 19-year-old women's HIV/AIDS service organization located in Atlanta, Georgia, and also in the Mpumalanga Province in South Africa.

I've personally been involved in HIV/AIDS prevention and support for women at risk and affected by HIV and AIDS for over 23 years. And there is one clear directive that has always and continues to play itself over and over in every HIV scenario regarding women and girls that I've been in. And that is change women's lives and you change the epidemic.

Address the key factors mostly rooted in gender and equality and oppression that drive the vulnerability of women and girls, and we could see a dramatic reduction in the transmission, in the infection rates, and in the shortened lifespan of women and girls worldwide.

Now, my organization, SisterLove, is on a mission to eradicate the negative impacts of HIV and AIDS and other reproductive health challenges upon women, girls, and their families. And we carry out our mission primarily through health education,

prevention interventions, reproductive justice advocacy and leadership, and services, as well as prevention research. We provide the fullest array of services, including HIV voluntary counseling and testing, one-to-one individual prevention counseling and case management, as well as group and community-level interventions, which include teaching eroticizing, safer sex, particularly with the male/female condoms, and other risk reduction tools. You can fill in your own blanks.

Now, I'm here primarily, of course, to support the approval of the FC2 because of effective and more affordable prevention options for women, and that's for what you will see here on the slides; but also for these following key reasons. The disproportionate burden of HIV/AIDS globally and domestically is shouldered by women who are poor, often abused, and most often of African descent, least protected, most unheard, and most unrepresented in the decision-making arenas.

The triple 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 and 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.

I'm a 43-year-old black woman who is divorced and sexually active. So that makes me seem a likely woman at risk for HIV and AIDS, as, for example, in my state, black women are 23 times more likely than white women to be infected with HIV. Am I typical? Not so much because I do not live at or below the poverty line. I'm not a substance abuser or in recovery from substance abuse. I'm not a survivor or sufferer of intimate partner violence, and 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 a little variety in my safer sex life just like you all. And I still, despite all of that, have challenges with consistent use and negotiation with a potential or a new partner.

So I know that much of today's testimony actually has a focus on women who experience the true brunt of the pandemic, women in the poorest regions of the world, Africa, Asia, Latin America. And what

often gets overlooked is the parallel track that exists for African-American women and women of African descent in the U.S. For example, around 60 percent of the epidemic in sub-Saharan Africa is in women, and around 60 percent of the epidemic in women in the U.S. is in African-American women. And in the southern United States, the economic, educational, political, social, and cultural issues, as expressed here in this slide, are common threads that impede the access and progress that women at risk need.

I want you all in your deliberations to remember the hundreds of thousands of HIV positive women and women at risk right here in the United States, particularly in the southern region, as well as in the poorest regions of the world. We look at ourselves as living in developing communities, similar to our sisters in developing countries.

So if you just pay attention to that quick rate in my state right there as of 2005 -- we know these numbers have changed with the new incidence numbers. But in the State of Georgia, the overall rate is about 17. And if you look again at women across the south, here is another disproportionate representation with that high red bar representing women and girls in the southern region, including

Washington, D.C.

But if you bring it home, here are the top ten zip codes in the State of Georgia. The three that we focus on particularly are 30318, 30314, and 30310. Now, these zip codes are contiguous, they are common, and they are extremely transmigrated, in terms of in the city, in the sense that they occupy large academic institutions. They occupy one of the largest heroin access sites in the southern region of the U.S., and they also are home to a lot of commercial sex work. And though we may not experience comparable rates of sex work to other regions of the world, we certainly experience high rates of sex transaction. It's alive and flourishing for things like drugs, money, housing, food, companionship, and oftentimes, status.

And for many --

DR. CEDARS: I need to ask you to wrap up, please.

MS. DIXON DIALLO: Yes. So for many of the reasons that have already been expressed, I'm here to support the approval of FC2. Most importantly is the issue of cost and its unequal and unfair disadvantage to organizations and our prevention budgets. One quick example is in four months of purchase,

SisterLove's expenditure rate was for 10,000 male condoms in a four-month period, we spent about $535. For 2,000 female condoms in that same period, we spent over $2,500, which is a limitation to our budget and our opportunity.

I also have brought a letter in solidarity from the Chicago Women's AIDS Project, which is co-signed by about 70 individual women, including women living with HIV. I thank you for the opportunity. And that is my time, but I would also quote not only Martin Luther King but also our recently elected president-elect that when we are looking at issues of every day lives of women at risk, the "fierce urgency of now" is upon you to make the appropriate decision to increase access and to reduce the incidence of HIV in women and girls at home and around the world. Thank you.

DR. CEDARS: Thank you. Do we have any questions? Thank you.

MS. DIXON DIALLO: Thank you.

DR. CEDARS: Our next speaker is Patricia Coffey.

DR. COFFEY: Good morning. My name is Dr. Patricia Coffey, and I'm a social scientist at PATH Headquarters in Seattle. PATH is an

international non-profit, non-governmental organization that works to improve health by advancing technologies, strengthening health systems and encouraging healthy behaviors. The president and CEO of PATH, Dr. Chris Elias, submitted written testimony to the Advisory Panel, and I'm pleased to have this opportunity to present orally on behalf of PATH.

I've worked in the field of reproductive and women's health for over two decades. I began my work as a Peace Corps volunteer in West Africa. One of my main responsibilities was to teach family life education to young people and consult with married couples about their preferred family planning method.

Upon my return from West Africa, I worked as a family planning counselor in a bilingual clinic in the Los Angeles area. I heard from women and young people about their need for family planning methods that were free from systemic side effects, that were easily accessible, and that were protective of not only unintended pregnancy, but also sexually transmitted infection.

Early in the 1990s, while at USAID, I became acquainted with a new reproductive health technology, the FC1. In my role as research advisor,

I advocated with international organizations, including UNAIDS, for the usefulness of the female condom as a way to protect the -- as a way for women to protect themselves from both unintended pregnancy and STIs, including HIV. These experiences formed the foundation of my belief in a woman's right to choose her method of fertility regulation and of the need for an expanded range of woman-initiated barrier methods.

I am, like this FDA Advisory Panel, concerned about the safety and efficacy of female condom products. I'm also concerned about the more than 1 in 6 married and the 1 in 13 never married women, age 15 to 49, who have an unmet need for contraception, the more than 76 million women worldwide who experience unintended pregnancy every year, and the more than 19 million women worldwide who are living with HIV infections primarily as a result of heterosexual contact. Further, I'm concerned about the estimated 340 million women and men who experience treatable sexually transmitted infections annually, of which more than 100 million are among young people age 15 to 24. Expanding access to female condom products is one clear way to increase levels of protected sex and meet the needs

of these vulnerable women and men.

PATH has been actively investigating the needs of women for female condoms over the last ten years. In my role as social science research advisor at PATH, I led a team that conducted research in several developing countries and the United States to identify features and characteristics that make female condoms easier to use and more acceptable for both partners.

Our new female condom product, which we call the woman's condom, was evaluated in a comparative phase 1 slippage and breakage study with the FC1 and found to have good performance and to be comfortable and easy to use. To date, however, PATH has not found funding for the contraceptive effect -- study required by U.S. FDA for market clearance. So plans to bring this product to the United States market have been sidelined.

In addition to female condom product development work, I led a team that convened a global consultation on the female condom in 2005. At this meeting, international researchers, donors, policy makers, and reproductive health advocates met to review the health impact of female condoms, broaden our understanding of the opportunities and obstacles

to female condom programming, and identify strategies to advance access to female condoms worldwide.

PATH is committed to expanding the class of female condom products. We believe that expanding access to female condom products will result in greater use by women and couples who are at risk of unintended pregnancies and STIs, including HIV. Our investigations over the last ten years have led us to conclude that access to and use of female condom products will be increased by creating a product with improved user acceptability, lower cost, or both.

The FC2 female condom has the potential to meet these criteria. Approval of the PMA amendment for the FC2 female condom is especially critical in light of the probability that future access to FC1 will be limited. As the FC2 condom becomes more widely available and demand in other countries increases, it will probably not be cost-effective for the Female Health Company to keep two production facilities open, especially if one facility is designated solely to service one market. Hence, there is a real likelihood that if the PMA amendment for the FC2 female condom is not approved, women in the United States will be left without access to any female condom product.

We believe that approval of the PMA amendment for the FC2 female condom is the only ethical way forward, thereby allowing women and couples in the United States the option of choosing either male or female condoms as their protection method.

In summary, expanding access to female condom products is one clear way to meet the unmet needs of women for protection of unintended pregnancies and STIs, including HIV. The FC2 female condom represents a lower cost option for couples and women worldwide. A lower cost female condom product may ensure market viability in both the United States and international arenas. In the interest of women in the United States and their sisters worldwide, I urge you to support this premarket approval amendment for the FC2 female condom. Thank you.

DR. CEDARS: Thank you. Questions?

DR. ZENILMAN: Help me understand the logic of what you're saying. Our charge was to look at the efficacy and other characteristics, and what you're saying is that if we believe that it's not as good as the FC1, we should still approve it because otherwise there won't be anything available?

DR. COFFEY: Well, it's for you to decide

related to safety and efficacy that -- I think --

DR. ZENILMAN: Right, but you said -- basically, you said unless you do this, people won't have access to anything. You're saying --

DR. COFFEY: Well, they may --

DR. ZENILMAN: You're saying the logic of that would be people -- you would actually approve of people having access to an inferior product in your logic?

DR. COFFEY: Well, in fact, people worldwide have access to the FC2 now, so this is really --

DR. ZENILMAN: Well, I'm not saying what people outside have. I'm saying basically what our charge is and what you're saying.

DR. COFFEY: Well, I guess if I was in your position, I would want to weigh the relative risk and benefit of what the data are showing me related to the equivalency of FC1 and FC2 and also the clear need that we've heard today and which we all know based on data and probably our experiences of the need for further protection options for women and couples who are at risk of HIV and unintended pregnancy. So I think that that's in some ways an ethical issue that needs to be taken into these

deliberations. And I think that's what we're saying.

DR. ZENILMAN: Well, I disagree with you. I think you're proposing a moral hazard by -- we --

DR. CEDARS: But if I could interrupt this line of questioning, we're going to discuss the PMA later --

DR. ZENILMAN: Okay.

DR. CEDARS: Thank you. Oh, I'm sorry, Dr. Gilliam?

DR. GILLIAM: Could you clarify for me, PATH has developed a women's condom, and then what is the impetus for that? What improvements were you seeking with your product?

DR. COFFEY: The FC1 product has a variety of limitations that have been well documented in the literature. And so our belief was that if we improve the acceptability of another female condom design, it would lead to better use, it would lead to more consistent and correct use of the female condom product.

DR. GILLIAM: But could you be specific about what --

DR. COFFEY: Yeah, so the issues related to the FC1 have to do with problems with insertion, problems with instability and fit of the female

condom, especially during sex, and then some aesthetic issue, which are always there when we talk about condom products. And so our design has really attempted to address the fit and stability issue primarily. And then we have also had an interactive process where we have a variety of people around the world who act as co-designers. And so we've been able to get a variety of feedback from potential users about how we might be able to make the product more acceptable, and we've incorporated those incremental design changes into our final product design.

DR. GILLIAM: And do you think the FC2 meets any of those requirements, and do you have any information or thoughts about the slippage issue for FC2?

MS. COFFEY: Well, what I know is what you know, which is what the data are from the RHRU study.

DR. CEDARS: Thank you. And the next speaker is Cindy Pearson.

MS. PEARSON: Thanks. I represent the National Women's Health Network, which is a grassroots, member-supported, national advocacy organization. The Network does not accept any financial support from pharmaceutical companies or

medical device manufacturers. We have no financial ties with any company involved in the manufacture or promotion of condoms or other contraceptives.

The Network 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 the FDA has to carefully weigh exactly how much evidence is enough. And competing pressures, such as an urgent need for a new product versus legitimate scientific questions that aren't fully answered, can make decisions about how much evidence is enough a tough one.

However, even though it's 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, the Network 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 and a couple Panel members who are here today joined the FDA in a discussion about how much evidence is needed to be

reasonably sure that the female condom is safe and effective. The Network was happy to play a key role at various times in that process, and we're happy to be here again today.

But to prepare for this meeting, we reviewed all the information that the FDA made available on its website. This is some of it. And we're pleased to see that the Agency reviewer has clearly communicated to the Panel, at least in this written test material, some key points with which the Network agrees. Studying the likelihood that new condoms slip or break when used is an acceptable way to evaluate new versions of previously approved condoms. Longer, larger studies with pregnancy outcomes are not necessary to assure ourself that a new version of a previously approved condom is acceptable.

The likelihood that the new female condom would slip or break was studied using a well-established approach to compare new condoms to older condoms. And this study found that the new condom is not inferior to the original female condom, which finding reached the level of statistical significance.

However, after reading the FDA's executive

summary, it's clear that the Agency reviewer has asked the Panel to consider whether or not those data, which did reach statistical significance, are actually reliable. And the FDA review team seems not to be concerned about the design of the study, which is very standard, but about the day-to-day experience of the women who took part in the study.

Specifically, they've raised concerns about whether all the right questions were included on the log used by women to record the experience, whether the log had enough room on it for women to fully record their experience, whether the right women took part in the study, and whether actually talking to women rather than just reading their logs was a mistake.

The FDA's concerns about the strength of the data go right to the heart of the FDA's duty to determine how much evidence is enough. And, in some cases, we, the Network, completely disagrees with the reviewer's concerns, and we hope you will, too. For example, the question about whether the wrong women took part in the study has to do with inclusion of sex workers and whether sex workers are less accurately able to describe what happens when they have sex or whether information learned from sex

workers isn't relevant to American women.

We feel strongly, and we believe research bears this out, that information learned from sex workers is relevant to American women and that sex workers can and do accurately describe what happens when they try new condoms. We urge you on the Panel to tell the FDA that those data are worthy and should be included.

The FDA review team also expressed concerns that the right questions weren't included on the log women used to record their experience and that women were interviewed about their experience rather than the researchers relying solely upon log records. The Network believes, and this is a point of feminist pride backed up by science, that interviewing women is a legitimate way to obtain information about their experience. Women's voices are as reliable as women's check marks on a piece of paper. Granted, interviewing women about their experience takes place a few weeks after the actual experience, but that doesn't mean that women don't remember the intimate details of what happens to them.

Similarly, whether or not the right questions were included on the log seems to involve whether or not women can remember if a female condom

slipped out if the word slip isn't on the log. Now, I just want to remind the Panel that the FDA acknowledges that partial slippage doesn't have any bearing on effectiveness. So what we're talking about is whether a woman can recall if a condom slipped out completely during intercourse. I'll just say for myself, I may not remember every time the waistband of my skirt slipped a little bit, but I would certainly remember if my skirt slipped completely off.

(Laughter.)

MS. PEARSON: Finally, the FDA has raised a concern that the log used by women to keep track of their experience didn't have enough space for women to record what happened if they used more than one condom a day. Well, I'm here to tell you women are very good at keeping track of lots of things that all happen in the same day. Just to give a few 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 many of you on the Advisory Panel were given a travel reimbursement form for today's meeting

that asks you to record multiple types of expenses multiple times for each day.

Certainly --

DR. CEDARS: If you could, wrap up, please.

MS. PEARSON: We all appreciate a well-designed form, but we can make do very well with what we're given.

To sum up, our reactions to FDA's concerns about data collection, we do not believe that any of these concerns are sufficient to undermine the data that were collected in the pivotal study. And, in summary, the Network 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.

DR. CEDARS: Are there questions?

DR. MARRAZZO: Why do you think the slippage rate was so much lower in the study for the FC1?

MS. PEARSON: There's a lot of reasons why it might have been lower for -- are you asking whether it appeared to be lower for FC1 versus FC2 or --

DR. MARRAZZO: No -- the numbers --

MS. PEARSON: -- lower in this study compared to other studies?

DR. MARRAZZO: No, FC1 compared to all other studies. It was significantly lower, if it's not just the way the question was asked or not asked?

MS. PEARSON: You know, because there have been different uses of that word slippage over the 19 or 20 years in which there have been studies of different versions of the female condom, I think the important question is the internal comparison of FC1 to FC2, and if it appears to be lower in this study than in other studies, that might have something to do with the study design, but the real question of importance to women is whether the comparison between the two seem to be -- we can be reasonably assured that FC2 isn't worse, and that's what the data seemed to show.

DR. MARRAZZO: Okay.

DR. CEDARS: Thank you.

MS. PEARSON: You're welcome.

DR. CEDARS: Next, Colin Pollard, chief of Obstetrics and Gynecology Devices Branch, would like to make some introductory remarks regarding the remainder of the meeting today.

MR. POLLARD: Thank you, Dr. Cedars, and I

also just want to acknowledge all of the previous speakers from the open public hearing. I thought you heard a lot of very on-point comments that get to many of the key things that we're asking the Panel to address later in the day. And I'd also like to point out you have a folder -- I'm not sure if Mike mentioned this already, but you have a separate folder that has -- there's many of the written letters and comments that we've received, some of which were from the speakers and some of which were for people who could not be here today.

So what I'd like to do is, before you get into the Sponsor presentation and the FDA review presentation, is give a little bit of a backdrop, and I'm calling this a little intro, but it's actually going to take about 20 or 25 minutes because I thought it would be important to touch on three important aspects that affect why we're here today. One, I'd like to give a basic regulatory overview of how FDA reviews condoms; and, secondly, speak a little bit about some general comments about condom failure mode studies, which is the pivotal study in the PMA today; and, finally, a few specific comments about today's PMA.

So to review, and I know many of you

understand this very well, classification is a risk-based approach, again, defined by the statute. And any of this -- well, first of all, speaking of regulation of any medical device, it starts with FDA's three-tiered classification scheme for medical device that serves as a foundation for how we regulate a product. And I'd also like you to keep in mind a date, May 28, 1976, the enactment date of the Medical Device Amendments and the actual point in time defined in the statute when FDA looked back to see what was legally on the market in the U.S. And in the late '70s and early '80s, FDA initially classified thousands of medical devices that were on the market.

So how does FDA regulate condoms? And any discussion of that starts with an appreciation of FDA's three-tiered classification scheme that serves as our foundation. So Class I, classification starts with Class I general controls for devices posing the least risk, and by risk I mean the health consequences of device use and/or device failure.

Class II is assigned to devices whose design or intended use poses a more complex review picture, where the risk is higher, but FDA believes that performance standards or other special controls

would be sufficient to ensure its safety and effectiveness. One of the general controls for Class I and Class II devices is the 510(k) premarket notification, the regulatory pathway to market that I'll speak to in just a second, although most Class I devices have been exempted from this.

And Class III is assigned to devices with an even more complex picture, higher risk, and even less is known about their safe and effective. Class I and Class II controls are deemed insufficient to ensure safe and effective, and Class III devices follow a different pathway to market, the so-called premarket approval application, or the PMA.

So let's talk about male condoms first. When the Medical Device Amendments were enacted in 1976, FDA was aware that there were already many male condoms on the market at that time. The Panel, which helped FDA with the initial classification process, recommended that male condoms be placed in Class II. There was a long history of safe and effective use of condoms, and the Panel believed that general controls plus performance standards would ensure their safety and effectiveness. There were some clinical studies in the medical literature at the time, but the Panel's classification recommendation was based

primarily on the experience of many Panel members in their own clinical practice. And, so, in 1981, FDA classified male condoms into Class II.

And, by statute, the Class II designation defines the regulatory pathway to market; superficially, a manufacturer brings a Class II device to market by submitting a 510(k) premarket notification to FDA for review. And the regulatory essence of a 510(k) submission is showing that a new device is substantially equivalent to a predicate device, that is, a legally marketed pre-amendments device, in terms of both its intended use and its design. It's something of a "me, too" concept, and that's how new male condoms are brought to market by the manufacturer showing, just to repeat, that its new condom is substantially equivalent in terms of safety and effectiveness to another male condom that was legally marketed before 1976 or found substantially equivalent since then.

So what has happened with male condoms since they were classified in Class II many years ago? First, there have been many significant developments of test methodology and benchmarks to characterize a quality condom, and this effort has been characterized by numerous types of studies of

condom properties. And there has been significant substantial work in the clinical arena over the past 30 years studying how well condoms work and putting some definition and precision to what was already known.

On the pre-clinical side, over the past 30 years, there's been a concerted effort to develop performance standards addressing both methodology and condom quality benchmarks. Industry, independent test labs, and FDA, including its own field test labs, have worked extensively on this, and there is a national and an international standard for male condoms made from natural rubber latex.

FDA recognizes both of those standards. And, over time, these standards have evolved to keep up with the science, adding and subtracting, replacing various sections as appropriate. FDA has played a significant role in encouraging standards development, both by participating in standards meetings as well as by sponsoring key studies that serves as a basis for new requirements; for example, the shelf-life testing that now supports an expiration date.

When, back in the '90s, manufacturers began developing male condoms made from synthetic

materials, such as polyurethane and cobalt polymers, FDA responded by publishing a guidance document spelling out additional testing needed to support a new 510(k). Now the standards process is almost caught up, and a draft international standard for this condom type is nearly complete.

Turning to the clinical side, there's been significant work done here, too. Over the past 30 years, there have been hundreds of publications describing clinical studies of male condoms, mostly male condoms made from natural rubber latex. These studies have addressed many different aspects of condoms and their performance. But this morning, I'm going to focus briefly on what these studies can say about risk reduction with respect to the two purported uses for condoms; that is, prevention of sexually transmitted infection and prevention of unintended pregnancy. There have also been many studies of male condom failure modes, and I'll go into that more later.

So with respect to protection against STIs -- I hope I covered this adequately earlier this morning. I can't really truly devote the kind of time needed to get into it in detail. FDA's conclusion on this, now codified as a special control

and effective this coming January, is that condoms, male condoms made of natural rubber latex remain a very effective method. They're highly effective against HIV/AIDS when used correctly and consistently.

But as the new labeling control highlights, there is a wide range of common STIs, and condoms provide better protection against some STIs than others. Again, this conclusion applies to condoms made from natural rubber latex, and that's because these represent the large -- the very large share of condom use and the vast preponderance of clinical studies. FDA will now turn to other condom types to see whether these labeling recommendations should apply to them as well.

With respect to protection against unintended pregnancy, there are not as many studies here as there are with respect to STIs, but still a substantial body of evidence. Data available at the time of classification, there was some published studies, but not of today's caliber or quality.

And CDC, starting in 1973, had already begun its national survey of family growth, and data from this survey has served as a regular basis for estimates of pregnancy rates when relying on condoms.

And, at this point today, the survey has been conducted seven times, most recently in 2002, and that -- sorry, in 2008, and that data should be available some time next year. And there have been at least three high quality studies of contraceptive effectiveness of male condoms in the past ten years.

This slide summarizes the results of these three studies, the prospective randomized trials comparing male natural rubber latex condoms to new synthetic condoms with respect to contraceptive effectiveness. A couple of points. Effectiveness is presented inversely as contraceptive failure; that is, the percentage of women who became pregnant during the six-month duration when they were relying on the condom, and this data is presented both as a typical use rate and a perfect use rate.

You might remember I just spoke about the national survey of family growth conducted periodically by CDC. Condom effectiveness can be derived from that data, and the numbers in this slide are taken from a chapter by Trussell on contraceptive technology. These are one-year estimates, not six-month. And the perfect use rate pretty much matches up with what we saw in the clinical trials. The one-year rate derived here is the same as what we would

have gotten if we simply doubled the six-month rate from the randomized trials. The typical use rate here is more than what would have been estimated from the clinical trials, and I won't get into how that was derived.

So the current status of male condom regulation, to summarize, male condoms are Class II devices. The pathway to market is 510(k) premarket notification. These submissions are typically supported by a variety of bench studies, many whose underpinnings are based in performance standards that have been recognized for years. Male condoms made from synthetic materials also follow the 510(k) track, but they are supported by additional bench studies and a clinical failure mode study, which I will speak to in just a bit.

So let's turn to female condoms, and how does FDA regulate female condoms. It's worth noting that when FDA first classified pre-amendments devices back in the late '70s, we were not aware of any female condom. This was not brought to our attention until 1988 by the Sponsor, and we confirmed its pre-amendment status. We took this product before our Advisory Panel.

The product was called the Gee Bee Ring,

made from animal skin, but not much more than that was known. There was no data on its physical performance and no data on clinical performance; that is, whether it provided some measure of protection against STIs or unintended pregnancies. And because of this lack of safety and effectiveness data, the Panel recommended that the generic category of female condom be placed into Class III. FDA concurred and classified the female condom into Class III, and the primary regulatory consequence is that a manufacturer of a female condom needs to use the PMA pathway to market entry.

And just to review, and, again, I know virtually all of you know this very well, a PMA, that is, a premarket approval application, is submitted by a manufacturer to FDA and should show with reasonable assurance that the new device is safe and effective for its intended use. The PMA should be supported by valid scientific evidence. The data should show that the device when used properly results in an acceptable risk/benefit balance with respect to the target population as laid out in the labeling. And the folder you have in front of you provides additional details on what this means, including the definitions of safety, effectiveness, and valid