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Center for Devices and Radiological Health
Food and Drug Administration
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Silver Spring, MD 20993-0002

Ben Fisher, PhD.
Division Director
Division of Reproductive, Gastro-renal, Urological Devices
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Shuren and Dr. Fisher,

The undersigned organizations urge the U.S. Food and Drug Administration to expedite its efforts to down-classify female condoms from a Class III to a Class II medical device. As leading organizations in the HIV/STI prevention, and reproductive and public health sectors, we are deeply concerned that the public comment notice for down-classification has not yet run in the Federal Register. Down-classification of female condoms would significantly reduce the regulatory barriers to approval of new, safe and effective female condoms. This, in turn, would provide people with more options for protecting themselves and ultimately promote both individual and public health.

Advocates for HIV/STI prevention and sexual and reproductive health applauded the U.S. Food and Drug Administration's Center for Devices and Radiological Health's (CDRH) 2015 recommendation to consider down-classification of female condoms. It signaled the agency's recognition of the strong scientific literature indicating that a variety of female condom products are safe, perform well, and are effective prevention tools with a unique and important public health role to play. We need to know when we can expect to see this recommendation carried forward via publication in the Federal Register.

Recent events have escalated the need for this recommendation from important to urgent. Veru, now the manufacturer of the FC2, has recently chosen to drastically increase the price of the FC2 and to move to a prescription-based distribution model. This extreme price increase (from \$2-\$3 each to \$10 each) and change from over-the-counter (OTC) availability to prescription access puts the FC2 – the only dual-protection option available to women in this country -- further out of reach for many of the people who need it most.

Three other internal (“female”) condoms have completed the WHO/UNFPA prequalification process and have been approved by the WHO/RHR Technical Review Committee. These models (the Cupid, the Velvet and the Woman’s Condom) are now being sold and distributed in dozens of countries whose governments have given regulatory approval to their safety and effectiveness. Major public health entities including Populations Services International (www.psi.org) and DKT (www.dktinternational.org) are distributing these condoms using Total Marketing strategies to ensure that they are available at affordable prices and in accessible settings.

The impetus to move forward with down-classification rapidly has acquired a new urgency with Veru’s decision to put the FC2 out of the reach of people in the U.S. who are at highest risk of HIV and have the least ability to afford and access a \$10 condom that can only be obtained via a prescription. Down-classifying female condoms will ultimately motivate other female condom manufacturers to submit their products (with are already being sold at a fraction of the price in other countries) for U.S. regulatory review.

The ability of one company to restrict access to an essential public health tool underscores the urgent need to enable access to other safe and effective options. We urge the FDA to enable pathways for other female condom products to enter the U.S. market and move forward with down-classification of female condoms from a Class III to a Class II device. Clinical data and consumer experience with female condoms over the past several decades overwhelmingly demonstrate that female condoms are safe. These data reinforce the assertion that Class III special controls are no longer needed for this category of product—even in the United States.

Sincerely,

U.S. Organizational Endorsers

ACRIA, New York, NY

AIDS Alabama, Birmingham, AL

AIDS Action Committee of Massachusetts, Boston, MA

AIDS Foundation of Chicago, Chicago, IL

AIDS United, Washington, DC

American Sexual Health Association, Silver Spring, MD

APLA Health, Los Angeles, CA

ASPIRATIONS, Baton Rouge, LA

BOOM! Health, Bronx, NY

Brothers Health Collective, Chicago, IL

Cascade AIDS Project, Portland, OR

Center for Black Equity, Washington, DC

Cervical Barrier Advancement Society, Cambridge, MA

CDGPro, Washington, DC

Counter Narrative Project, Atlanta, GA

Desert AIDS Project, Palm Springs, CA
East Los Angeles Women's Center - HIV Promotoras en Accion Project, Los Angeles, CA
Equality California
Equitas Health, Dayton, OH
Essential Access Health (formerly California Family Health Council), Los Angeles, CA
EverThrive Illinois, Chicago, IL
G III Associates, Washington, DC
GLMA: Health Professionals Advancing LGBT Equality, Washington, DC
Presbyterian AIDS Network (PAN), Washington, DC
PHEWA, Presbyterian Church USA, Washington, DC
DC Fights Back, Washington, DC
Gay Men's Health Crisis, New York, NY
Harm Reduction Coalition, New York, NY
Health GAP, Washington, DC
Hispanic Health Network, New York, NY
HIVE, San Francisco, CA
HIV Medicine Association, Arlington, VA
House of Blahnik, Inc., Philadelphia, PA
Housing Works, New York, NY
Hyacinth AIDS Foundation, New Brunswick, NJ
HIPS, Washington, DC
Ibis Reproductive Health, Cambridge, MA
Illinois Caucus for Adolescent Health, Chicago, IL
Illinois Public Health Association, Springfield, IL
In Our Own Voice: National Black Women's Reproductive Justice Agenda, Washington, DC
IXu LLC Petoskey, MI
Latino Commission on AIDS, New York, NY
Lowcountry AIDS Services, North Charleston, SC
Minnesota AIDS Project, Minneapolis, MN
NASTAD, Washington, DC
Nashville Cares, Nashville, TN
National Coalition of STD Directors, Washington, DC
National Consumers League, Washington, DC
National Female Condom Coalition, Chicago, IL
National Women's Health Network, Washington, DC
NMAC, Washington, DC, US
NO AIDS Task Force, New Orleans, LA
Okaloosa AIDS Support & Informational Services, Inc. (OASIS), Ft. Walton Beach, FL
Pediatric AIDS Chicago Prevention Initiative, Chicago, IL
Positive Women's Network-USA, Oakland, CA
Prevention Access Campaign, Brooklyn, NY

Pride Action Tank, Chicago, IL
San Francisco AIDS Foundation, San Francisco, CA
Sexuality Information and Education Council of the United States (SIECUS), Washington, DC
Southern HIV/AIDS Strategy Initiative (SASI), Durham, NC
South Side Help Center, Chicago, IL
The AIDS Institute, Washington, DC
The Well Project, Brooklyn, NY
Test Positive Aware Network, Chicago, IL
Treatment Action Group, New York, NY
UCHAPS, Washington, DC
Woodhull Freedom Foundation, Washington, DC

Global Organizational Endorsers

Nalalne Associates for Reproductive Justice Sexual and Reproductive Justice Coalition Global
Doctors for Choice, Johannesburg, South Africa

Individual Endorsers

Debbie Allen, Chicago, IL
Mykalah Anderson, Columbus, OH
Jamie Boban Ndayishimiye, Chicago, IL
Jill Blumenthal, San Diego, CA
George Brown, New York, NY
Mary Dally-Muenzmaier, Milwaukee, WI
Isisah Duckworth, Lansing, IL
Jim Eigo, New York, NY
Karin Egge, St. Paul, MN
Anna Forbes, Kensington, MD
Susie Hoffman, Brooklyn, NY
Mark Ing, New York, NY
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Bruce Lang, Bloomington, IL
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Sarah Michienzi, Chicago, IL
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John Peller, Chicago, IL
Keith Peltason, Chicago, IL
Laura Ponchick, Los Angeles, CA
Carolynn Poulsen, Falls Church, VA
Stacey Ravanese, Oak Forest, IL
Bruce Richman, Brooklyn, NY
Peter Schuster, Chicago, IL
Heather Searfoss-Allaire, Columbus, OH
Charles Stephens, Atlanta, GA
Jessica Terlikowski, Portland, OR
Eb Troast, San Francisco, CA
Noel Twilbeck, New Orleans, LA
Joyce Turner Keller, Baton Rouge, LA
Stephaun Wallace, Philadelphia, PA
Caroline Watson, Pinole, CA
Adam Weaver, North Charleston, SC
Julene Weaver, Seattle, WA
Andrea Weddle, Arlington, VA
Takala Welch, Chicago, IL