

November 30, 2017

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Dear Drs. Fauci and Dieffenbach,

The undersigned 93 organizations and 175 individuals committed to women's sexual health and reproductive justice are deeply concerned that the National Institute of Allergy and Infectious Diseases (NIAID) intends to end its investment in microbicides research and development. We strongly urge NIAID to maintain its expressed commitment to developing technologies that help both cisgender and transgender women meet their HIV prevention needs, and continue to prioritize topical microbicide development alongside other prevention modalities. The advent of safe and effective microbicides, products that could be applied vaginally or rectally to reduce sexual acquisition of HIV, would enable women to better protect themselves against HIV. Despite the critical role microbicides could play in women's sexual health and autonomy, NIAID has indicated that it will direct its investment only to long-acting systemic prevention products such as implants, injectables, and vaccines.

Microbicides are particularly needed to reduce new HIV infections among women. UNAIDS data estimates that women comprised 47 percent of new HIV diagnoses among adults globally in 2015. Women represent more than half of all people living with HIV worldwide, and account for 60 percent of those with HIV in sub-Saharan Africa. Younger women are especially vulnerable. Nearly 1,000 young women ages 15-24 newly acquire HIV in Africa every day. These numbers are expected to increase. In the U.S., Black and Latina cisgender and transgender women continue to be disproportionately impacted by HIV. According to the Centers for Disease Control and Prevention, Black women make up 61 percent of all women diagnosed with HIV in the U.S., a rate that is 16 times higher than that of White women and nearly five times that of Latinas. Transgender women of color are hit particularly hard, with some of the highest HIV prevalence rates overall. In addition to the numerous social and structural factors that contribute to women's HIV vulnerability, such as inadequate access to health care, discriminatory policies,

poverty, unstable housing, violence, and trauma, too few women-controlled HIV prevention options exist.

The development of varied HIV prevention options is especially important for women. Women require prevention modalities that meet the diverse needs, contexts, and desires that occur across the lifespan. For example, the needs of sexually active young women who want to prevent pregnancy differ from women who want to bear children, are pregnant or breastfeeding, or who engage in anal intercourse. Women of all ages, and at all times within their lives, deserve the ability to protect themselves against HIV. Microbicide research and development is based on the notion that one size does not and cannot fit all, and thus it is critical that it continues.

The microbicide field has made substantial gains in the last decade, which may be for naught should the NIH divest from further development. The most significant of these achievements is the monthly dapivirine vaginal ring, now under regulatory review with additional submissions being planned. If approved, the dapivirine ring would be the first microbicide and first biomedical HIV prevention product specifically for women – and also the first long-acting product. This is only the beginning. The vaginal microbicide field currently boasts more than 10 candidate products in various stages of development, including multi-purpose technologies (MPTs) that in addition to protecting against HIV, could protect against other STIs, such as HSV-2, and/or prevent unintended pregnancy. Women across the globe state time and time again that they want and need products like these to reduce acquisition of HIV and STIs as well as to determine if and when to become pregnant.

Directing all resources to only vaccines and long-acting and systemic HIV prevention options such as long-acting injectables would ignore what women who are vulnerable to HIV have clearly articulated needing -- more, not fewer options to meet different times and contexts over the course of their lifespan, including contraception, conception, pregnancy, and breastfeeding. The family planning field has demonstrated time and time again that providing women with a variety of methods to meet their needs and preferences results in greater product use and satisfaction and fewer unintended pregnancies. This same principle is applicable to the field of HIV prevention. Now is not the time to stop. Microbicides research, including of MPTs, must continue to ensure research advancements made in the field are not lost.

Refocusing the prevention research agenda solely on vaccines and long-acting systemic products at the cost of further development of microbicides is also scientifically short-sighted, especially as injectable formulations under study have not yet proven effective. It will also require researchers to redirect their efforts, which could result in losing the scientific expertise that may not be easily regained. It could also result in serious public health consequences. The redirection contradicts NIAID's claims that developing tailored, safe, effective, and desirable prevention tools to meet people's diverse prevention needs and contexts is a top priority.

Early treatment, viral load suppression, and oral pre-exposure prophylaxis (PrEP) are exciting interventions to reduce HIV acquisition. In order to ensure that women who are vulnerable to HIV have options that suit their needs, all prevention avenues should be pursued—vaccines, long-

acting systemic products (such as injectables and implants), as well as microbicides—topical short-acting and long-acting (yet reversible) on-demand products. NIAID’s ongoing investment in developing safe, effective, acceptable, and accessible microbicides that fit all women’s lives is essential to achieving an end to the HIV epidemic.

Sincerely,

U.S. Organizations

AIDS Alabama, Birmingham, AL
AIDS Alliance for Women, Infants, Children, Youth & Families, Washington, DC
AIDS Foundation of Chicago, Chicago, IL
AVAC, New York, NY
Bailey House, Inc., New York, NY
Black Women’s Health Imperative, Washington, DC
Callen-Lorde Community Health Center, New York, NY
CAMI Health, Folsom, CA
Caribbean Women's Health Association, Inc., Brooklyn, NY
Cascade AIDS Project, Portland, OR
Center for Black Equity, Washington, DC
Cervical Barrier Advancement Society, Cambridge, MA
Chicago Recovery Alliance, Chicago, IL
Chicago Women’s AIDS Project, Chicago, IL
Colorado Organizations and Individuals Responding to HIV/AIDS, Boulder, CO
Church Ladies for Choice of New York City, New York, NY
Diaspora Community Services, Brooklyn, NY
Emerging Infectious Diseases Panel American Academy of Nursing, Chicago, IL
Global Network of People Living with HIV (GNP+), Sterling Heights, MI
HealthHIV, Washington, DC
HIV Prevention Justice Alliance, Chicago, IL
HIVE, San Francisco, CA
HMM, Fort Wayne, IN
HIV Modernization Movement-Indiana, Indianapolis, IN
Housing Works, New York, NY
Howard Brown Health, Chicago, IL
Ibis Reproductive Health, Cambridge, MA
IKnowAwareness, Atlanta, GA
Illinois Public Health Association, Springfield, IL
International Partnership for Microbicides, Silver Spring, MD
International Women's Health Coalition, New York, NY
IRMA, Chicago, IL
Jacobs Institute of Women's Health, Washington, DC
Joseph P. Addabbo Family Health Center, Inc., Arverne, NY
Legal Council for Health Justice, Oak Park, IL
MashUp! Nashville & Street Works Incorporated, Nashville, TN

National Coalition for LGBT Health, Washington, DC
National Council of Jewish Women, Washington, DC
National Female Condom Coalition, Chicago, IL
National Network of Abortion Funds, Washington, DC
National Women's Health Network, Washington, DC
NMAC, Washington, DC
PATH, Washington, DC
Pediatric AIDS Chicago Prevention Initiative, Chicago, IL
Planned Parenthood of Illinois, Chicago, IL
Planned Parenthood of New York City, New York, NY
Positive Women's Network-USA-Louisiana, Baton Rouge, LA
Positive Women's Network-USA-Colorado, Boulder, CO
Positive Women's Network-USA, Oakland, CA
PowerSource Tucson, Inc., Tucson, AZ
Poz Haven Foundation, Denver, CO
Project Inform, San Francisco, CA
Sexuality Information and Education Council of the United States (SIECUS), Washington, DC
Southern HIV/AIDS Strategy Initiative, Durham, NC
Silver Creek Strategies, Novelty, OH
SisterLove, Inc., Atlanta, GA
Test Positive Aware Network, Chicago, IL
The AIDS Institute, Washington, DC
The Center for HIV Law and Policy, New York, NY
The Global Forum on MSM & HIV (MSMGF), Oakland, CA
The Well Project, Brooklyn, NY
Treatment Action Group, New York, NY
UCHAPS, Washington, DC
Universal Condom Work Group, Los Angeles, CA
Women Organized to Respond to Life-threatening Diseases (WORLD), Oakland, CA

Non-U.S. Organizations

AIDS and Rights Alliance for Southern Africa (ARASA), Windhoek, Namibia
Asociación Bienestar y Desarrollo, Barcelona, Spain
Asociación Sare, Pamplona, Spain
Center for AIDS Policy Studies and Research Child Foundation of India, Visakhapatnam, India
Centre for Popular Education and Human Rights, Ghana (CEPEHRG), Accra, Ghana
Centre for the Development of People, Lilongwe, Malawi
Centre for HIV Prevention Advocacy, Kisii, Kenya
Centre Stage Media Arts Foundation Zimbabwe, Bulawayo, Zimbabwe
Grupo de Trabajo sobre Tratamientos del VIH (gTt-VIH), Barcelona, Spain
ICASO, Toronto, Canada
Interagency Coalition on AIDS and Development (ICAD), Niagra Falls, Canada
International Community of Women living with HIV Eastern Africa (ICWEA), Kampala, Uganda
Lambda, Valencia, Spain

Makerere University Johns Hopkins University (MU-JHU), Kampala, Uganda
Masaka KP HIV Prevention and Support Organization, Kampala, Uganda
Mouvement Français pour le Planning Familial, Paris, France
Ngo Hygie-Enwerem Foundation, Lagos, Nigeria
Nyanza Reproductive Health Society, Kisumu, Kenya
Pan African Positive Women's Coalition-Zimbabwe, Harare, Zimbabwe
Pangaea Zimbabwe AIDS Trust (PZAT), Harare, Zimbabwe
Peer to Peer Uganda, Kampala, Uganda
PINA, Kampala, Uganda
PositiveLite.com, Toronto, Ontario, Canada
Real Opportunities Network, Accra, Ghana
STOP SIDA Consell de Cent, Barcelona, Spain
Support On AIDS and Life Through Telephone Helpline (SALT), Kampala, Uganda
Thailand National CAB, Chiang Mai, Thailand
Tororo Forum for People Living with HIV Networks, Eastern Region, Uganda
Treatment Advocacy and Literacy Campaign, Lusaka, Zambia
Salamander Trust, Welbourn, Great Britain

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