Mitchell Steiner, M.D.
Chief Executive Officer

Brian Groch
Chief Commercial Officer

Suzanne Marinakos
Executive Director, Market Access

Veru Healthcare
4400 Biscayne Blvd, Suite 888
Miami, FL 33137-3212

October 4, 2017

Dear Dr. Steiner, Mr. Groch, and Ms. Marinakos,

The 212 undersigned HIV/STI prevention, reproductive health, public health, provider organizations, and advocates write to express our collective outrage with Veru Healthcare's new FC2 pricing, marketing, and distribution practices. Veru's decision to end over-the-counter (OTC) sales of the FC2, the only FDA approved receptive-partner initiated tool that protects against HIV, STIs, and unintended pregnancy exacerbates significant barriers such as lack of awareness and comfort[1] among consumers and providers, high product cost, and limited access points experienced by individuals who need the FC2 most.

Our extensive experience in prevention and pregnancy, along with substantial data, indicate that providing a full range of available contraceptive and HIV/STI prevention options, including internal (female) condoms, is crucial to enabling public health. Removing OTC status puts the FC2 further out of reach for people particularly vulnerable to HIV and STIs. It also contradicts Veru's claims that its new model will enable greater FC2 access. We are concerned that requiring a clinician gatekeeper will substantially *reduce* access for all, including individuals with low incomes and poor access to quality health coverage and care. [2][3][4] We are also skeptical that this approach will increase access for those with health insurance.

While we recognize and acknowledge that retail sales of the FC2 have been low, we assert that this is because the company has failed to employ the necessary tactics to effectively engage, educate, and market to consumers and providers. The onus has fallen on public health departments and nonprofit organizations to market the FC2 to consumers. Chicago's "Put a Ring on It," Washington D.C.'s "DC's Doin' It" and New York City's "Get Some" campaigns focused on social marketing while the FC2 manufacturer missed a critical opportunity to support and build off of these campaigns.

Currently, dozens of jurisdictions across the country are developing and implementing comprehensive Ending the Epidemic and Getting to Zero strategies to end the HIV/AIDS epidemic through expanding access to HIV prevention, treatment, and care. Veru contends it is committed to promoting public health and supporting

---

[1] Weeks, M. R., Coman, E., Hilario, H., Li, J., & Abbott, M. (2013). Initial and Sustained Female Condom Use among Low-Income Urban U.S. Women. *Journal of Women's Health*, *22*(1), 26–36. http://doi.org/10.1089/jwh.2011.3430

[2] Landau SC, Tapias MP, Taylor McGhee B. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. Contraception. 2006; 74: 463-70.

[3] Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health. 2016; 25(3): 249-54.

[4] Potter JE, McKinnon S, Hopkins K, Amastae J, Shedlin MG, Powers DA, Grossman D. Continuation of prescribed compared with over-the-counter oral contraceptives. Obstetrics and gynecology. 2011;117(3):551.

HIV/STI prevention in the U.S., but is again missing this opportunity to engage jurisdictions and communities committed to ending HIV/AIDS domestically. The FC2 plays an important role in ending the epidemic. Veru could seek ways to support jurisdictions' prevention efforts. Yet Veru erected new and unnecessary barriers that further limit consumer and provider awareness at a time when forward-thinking cities and states are looking to expand access to prevention tools.

To demonstrate that the company is committed to contributing to ending the HIV/AIDS epidemic as it contends is the case, we urge Veru take the following actions:

1. **Price the FC2 at a level that is accessible to people who are most vulnerable to HIV and STIs.** The FC2 was already out of reach for most people who need it due to its high cost. Male condoms range from approximately .40 to .65 per condom in the retail market. Veru's drastic price increase from (from $2-$3 each to $10 each) and new reliance on health insurance cements the inability of people who are low-income, uninsured, and under-insured to purchase it. Consequently, Veru turned the FC2 into an elite prevention tool beyond the reach of people who need it most. Additionally, Veru's patient assistance program is unrealistic and woefully insufficient to meet the FC2 needs of people who are under/uninsured. It adds significant and undue burden on the person seeking assistance as well as their provider. In addition to charging customers approximately $30 for 12 FC2s and shipping, the program requires individuals use the internet and a debit or credit card and have stable housing to receive the shipped package. If Veru is truly committed to expanding access to HIV-vulnerable people in the U.S. and prioritizing the public's health, it must recognize that selling more of a deeply discounted product is better than selling none of a higher-priced product.

2. **Invest in community engagement, consumer education, social service and clinical provider training, social marketing, and meaningful collaboration with diverse partners who support public health.** Without public education, training, and intensive outreach to potential prescription providers, Veru's "by prescription" decision will compound the existing barriers that already make it difficult for people to access and use the FC2. Public health departments and community-based organizations are key FC2 education and access points for people living with and vulnerable to HIV. For years, the HIV, STI, and reproductive health sectors have allocated their limited funds to facilitate successful implementation of the FC2 and fill the manufacturer's marketing and education gaps. In several cities with significant populations living with and vulnerable to HIV, these sectors play a vital role in increasing awareness of FC2 as a viable safer sex option through original social marketing campaigns, community education, provider training, and distribution. Failing to make such critical investment now will exacerbate FC2 access disparities for HIV and STI vulnerable people.

3. **Clearly communicate to the HIV, STI, reproductive health, and public health sectors Veru's implementation timeline for ensuring timely and affordable FC2 access among populations who are HIV/STI vulnerable, low-income, uninsured/under-insured, and lack access to a health care provider.** Veru should develop and disseminate a communication that clearly outlines its approaches to meet the prevention needs of key populations. Veru's website states that the global health sector is a focus of the company and includes no mention of efforts to meet the STI and HIV prevention needs of people in the U.S. The Centers for Disease Control and Prevention (CDC) data on HIV and STIs demonstrate the significant need in the U.S. for increased access to prevention methods. According to the CDC, there were more than 37,000 new HIV infections in 2014. HIV continues to disproportionately impact gay men of all races and ethnicities, and Black cisgender and transwomen. The CDC also reports that approximately 20 million new STIs occur each year. Despite this context, the FC2 is the least visible product on the Veru website, where it is frequently referred to as a "Disposable Contraceptive Device," an uncommon and unrecognizable term for the FC2.

4. **Make the FC2 available over the counter.** Research shows[5] that expanding visibility and access points for HIV/STI prevention and contraception options is critical to increasing acceptance and uptake. Pulling FC2s off the shelves and putting them behind a gatekeeper further hinders people's awareness and understanding of the product and creates an unnecessary waiting period for FC2. Twenty-nine percent of U.S. women at risk for unintended pregnancy who have ever tried to get a prescription for hormonal contraception report problems obtaining a prescription or refills.[6] This illustrates the extent to which "prescription-only" restrictions restrict access—restrictions that, in the case of the FC2, are unnecessary and not imposed in any other country. The barriers introduced include cost, lack of insurance, difficulty obtaining an appointment or getting to a clinic, not having a regular doctor, clinician requiring a clinic visit, and limited pharmacy access.[7] Additionally, since most pharmacies will not have FC2s in stock, people who present a prescription may be required to wait at least 24 hours before obtaining it. Such a system does not match how people access condoms. Like male condoms, female condoms should be available at a neighborhood convenience store or even in a public restroom to meet immediate safer sex needs.

5. **Use positive, affirming messaging and images to educate and increase FC2 uptake among populations disproportionately impacted by HIV and STIs.** Fear-based imagery and messaging depicting women as victims are ineffective approaches for increasing acceptance of an underutilized prevention modality. Additionally, such methods contribute to a deeply stigmatizing and ultimately dangerous narrative depicting people with HIV and other STIs as violent perpetrators. Consequently, we strongly oppose Veru's investment in and promotion of any marketing campaign and advocacy efforts that perpetuate this depiction that harms and further stigmatizes people living with HIV and STIs. We urge Veru to redirect those resources and collaborate with leading advocates and experts in HIV and STI prevention and public health to develop a social marketing campaign that promotes health, autonomy, and sexual pleasure.

6. **Outline Veru's plan to ensure FC2 access if the Affordable Care Act (ACA) and Medicaid are undercut.** Relying on prescription coverage for FC2 access assumes that insurance coverage enabled by the ACA and Medicaid will continue with current protections. Nineteen states have not yet expanded Medicaid, leaving access to health care out of reach for millions of low-income Americans. 27 million people remain uninsured.[8] States opting out of the Medicaid Expansion have exacerbated U.S. health disparities. For example, the CDC estimates that one-half of new HIV infections occur in the southern U.S., a region where health care access remains woefully limited because most states refused to expand Medicaid. Additionally, seven southern states do not reimburse for the FC2[9] making the prescription model ineffective for many low-income people in the region hardest hit by HIV.[10] While the most recent ACA repeal efforts failed, attempts to undermine critical protections, restructure Medicaid, slash family planning funding, and defund Planned Parenthood continue.

We look forward to a written response directed to the National Female Condom Coalition coordinator Jessica Terlikowski at jterlikowski@aidschicago.org outlining in detail the actions Veru will take to prioritize the health and lives of people living with and vulnerable to HIV and STIs over profits.

---

[5] Weeks, M. R., Coman, E., Hilario, H., Li, J., & Abbott, M. (2013). Initial and Sustained Female Condom Use among Low-Income Urban U.S. Women. *Journal of Women's Health*, *22*(1), 26–36. http://doi.org/10.1089/jwh.2011.3430.

[6] Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health. 2016; 25(3): 249-54.

[7] Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health. 2016; 25(3): 249-54.

[8] https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201609.pdf

[9] Witte, S., MacPhee C., Ginsburg, N., Deshmukh, N. Medicaid Reimbursement for the Female Condom, *American Journal of Public Health*: published online before print August 17, 2017.

Sincerely,

U.S. organizations:

ABCD Health Services

ACRIA

The Afiya Center

AIDS Alabama

AIDS Foundation Houston, Inc.

AIDS Foundation of Chicago

AIDS Research Consortium of Atlanta

AIDS United on behalf of Public Policy Committee

American Run To End AIDS (AREA)

APLA Health

Arkansas RAPPS

Aspirations

Association of Nurses in AIDS Care

Aunt Martha's Health and Wellness

AVAC

Being Alive LA

Cascade AIDS Project

Cervical Barrier Advancement Society

Chicago Women's AIDS Project

Children's Hospital Los Angeles-Division of Adolescent and Young Adult Medicine

Christie's Place

Connect To Protect Los Angeles Coalition (C2PLA Coalition)

East Los Angeles Women's Center - Promotoras en acción contra el SIDA

End AIDS Now and Let's Kick ASS (AIDS Survivor Syndrome)

Global Protection Corp.

Harm Reduction Coalition

Health Global Access Project

HealthHIV

HIV Medicine Association

HIVE

HIV Prevention Justice Alliance

House of Blahnik, Inc.

Howard Brown Health

Huskies for Reproductive Health: University of Southern Maine student group

Ibis Reproductive Health

iknowAwareness LLC

Illinois Public Health Association

International Rectal Microbicide Advocates

JWCH Institute Inc.

Los Angeles LGBT Center

Los Angeles Women's HIV/ AIDS Task Force

Lowcountry AIDS Services Consumer Advisory Board

NASTAD (National Alliance of State and Territorial AIDS Directors)

National Asian Pacific American Women's Forum (NAPAWF)

National Association of County and City Health Officials

National Coalition for LGBT Health

National Coalition of STD Directors

National Female Condom Coalition

National Women's Health Network

The New School Student Health Services

NO/AIDS Task Force (d.b.a. CrescentCare)

Pals for Health

PAWS at Springfield College

Pediatric AIDS Chicago Prevention Initiative

Planned Parenthood Northern California Eureka Site

The Pleasure Chest

Portland Public Health

Positive Women's Network - USA

Project Inform

Pueblo Y Salud, Inc.

Ryan White Planning Council of Dallas Homeward Bound

San Francisco AIDS Foundation

Sexuality Information and Education Council of the United States

Silver Creek Strategies Novelty, OH

SisterLove, Inc.

Southern AIDS Coalition

Southern HIV/AIDS Strategy Initiative

Treatment Action Group (TAG)

Universal Condom Work Group Los Angeles

URGE: Unite for Reproductive & Gender Equity

The Well Project

Whitman-Walker Health

International organizations:

Education as a Vaccine

The Eliezah Foundation Initiative

Faith Mulira Health Care Centre, Masooli

Femmes-Santé-Développement (FESADE)

New HIV Vaccine and Microbicide Advocacy Society

San Patten and Associates, Inc.

TEEBRI

Individuals:

Erika Aaron

Kelli Aarstad

Soraida Acosta

Hana Afra

Alejandra Aguilar

Amanda Ayers

Tia Baratelle

Lori Barrientos Sanchez

Lou Bigelow

George Brown

JP Cano

Megan Canon

Chelsey Castiglione, Planned Parenthood Northern California Eureka Site

Nate Cedilla

Jayden Colby

Jennifer Collins

Clare Collins

Christopher Culp

Mary Dally-Muenzmaier

Toni Donovan

Karin Egge

Jim Eigo

Xavier Erguera

Dawn Fadden

Erin Falvey, Christie's Place

Lauren Fifarek

Julie Fitch

Anna Forbes

Erica Gafford

Thelma Garcia, East Los Angeles Women's Center - Promotoras en acción contra el SIDA

Lisa Gary, Aunt Martha's Health and Wellness

Bryn Gay

Joseph Green

LaWanda Gresham

Krissie Guerard, MN Department of Health

Gwen Guillory

Laura Haave

Andria Hancock-Crear

Nanci Hanover

Becky Hardin, Being Alive LA

Michael Harney, Prevention Educator/Street Outreach Worker

Michelle Harris

Clara Hazlett-Norman

Tiffany Hendrix, Clinica Romero

Susie Hoffman

Nicole Holmes, Center on Halsted

Mark Hubbard

Saskia Husken, Rutgers

Alex Iling

Matleena ,Impola

Seyoung Jeon

Kelvin Johnson

Taneshia Johnson, Mercy Care

Christine Johnston

Shyronn Jones, iknowAwareness LLC

Marsha Jones, The Afiya Center

Anthony Jordan-Parnell, Aunt Martha's Health and Wellness

Kellen Kaiser

Rachel Knopf, The New School Student Health Services

Sara Komoroske

Skylar Lange, Dallas RWPC, Needs Assessment Committee Chair

Christina Lares

Samantha Leaf, ISA Associates

Marc-André LeBlanc

Richard Legault

Christina Lombardo

Michael Luciano, Lowcountry AIDS Services Consumer Advisory Board

Alan Timothy Lunceford – Stevens, End AIDS Now and Let's Kick ASS (AIDS Survivor Syndrome)

Surajkumar Madoori, Treatment Action Group

Jacqueline Matuza

Roslynn McAlister, Aunt Martha's Health & Wellness

Carolyn McAllaster, Southern HIV/AIDS Strategy Initiative

Julie McAvoy-Banerjea

Nicole McDermott

Robert McGee II, Ryan White Planning Council of Dallas Homeward Bound

Peter McLoyd

April McNally

Tucker Meijer

Kirsten Myhr

Scott Nelson

Brent Nicholson-Earle, American Run To End AIDS (AREA)

Ekene Onwuanum, TEEBRI

Susan Oser

San Patten, San Patten and Associates, Inc.

Julie Patterson, Silver Creek Strategies Novelty, OH

Michael Pease

Laura Pegram

John Peller, AIDS Foundation of Chicago

Shawn Peterson, Portland Public Health

William Phelps

Ashley Phillips

Stacy Ploskonka

Laura Ponchick

Carolynn Poulsen

Michael Pulido, CSUN Pride Center

Gary Robbins

Tracy Robin

Deneen Robinson, The Afiya Center

Traci Roy

Rachel Sager

Ollie Schwartz

Monica Serrano, AIDS Foundation of Chicago

Jane Sey

Naomie Shembo

Liz Simmons

Milton Smith, Connect To Protect Los Angeles Coalition (C2PLA Coalition)

Allyna Steinberg

Rebecca Stern

Tegra Straight

Pamela Tassin, AIDS Foundation of Chicago

Daria Taubin

Katie Taylor

Jessica Terlikowski, AIDS Foundation of Chicago

Sam Thompson

Carole Treston, Association of Nurses in AIDS Care

Bella Tsang

Evany Turk

Joyce Turner Keller, Aspirations

Noel Twilbeck, NO/AIDS Task Force (d.b.a. CrescentCare)

Jason Valdez

Ty Veno, PAWS at Springfield College

Brenda Villanueva, Pueblo Y Salud, Inc.

Joachim Voss

Amanda Wahnich, New York City Department of Health and Mental Hygiene

Stephaun Wallace, House of Blahnik, Inc.

Margret Watkins

Susan Watkins

Julene Weaver

Andrea Weddle, HIV Medicine Association

Joan Whitaker, ABCD

Rose Whitlock

Dace Zeps