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United States of America

October 30, 2018

To:

**RE: FC2 Internal Condom: Lower price, Easier purchasing and Complimentary training support packages**

Dear Sir/Madam,

We are happy to inform you of the many positive changes in our FC2 Internal Condom for US Public Sector programming, designed to provide additional benefits to your organization/department. The FC2 is now more *affordable*, more *available*, and *supported through complimentary training* with certain minimum order quantity purchases for the public sector, not in the least starting with the FDA's decision to change the category name from the "female condom" to the "internal condom":

***More affordable than ever***

We are happy to report that the FC2 internal condom is now offered to all public sector and 501(c)(3) entities at only \$0.95 per device until December 31<sup>st</sup> (based on a box of 1000 devices)! Starting January 1<sup>st</sup> this price will be \$1,10 per device, so make sure you still take advantage of a lower price in the year 2018. We have also added the option to purchase smaller quantities by offering a box containing 100 devices or a box that contains 1000 devices. This makes it even simpler to order the quantity you need.

***Easily available***

We have listened to your feedback, and made the product more available and more affordable with the decision to discontinue our relationships with all distributors – **we are now the only organization selling the FC2 internal condom directly to the US public sector.** We have also added the option to place your order directly on our website and it will be shipped to you immediately (<https://fc2.us.com/product/fc2-bulk-purchase-case/>). You can contact us directly, should you require an official Purchasing Order.

***Complimentary training support packages***

Through our 20 years of experience with the internal condom, we know how important it is to provide training and education on the FC2. For two decades, our master trainers have educated service providers and communities around the world; and it is our pleasure to inform you that we have now made support packages available to the US public sector free of charge, to accompany your procurement of the FC2! The FC2 support packages start at a procurement quantity of 5000 devices and include demonstration models, IEC materials and master trainings by our expert FC2



internal condom trainers. Please see the final page of this letter for an overview of the complimentary support packages offered to make your FC2 procurement count even more!

Why is it so important to include the FC2 internal condom in your public sector programming to prevent STDs such as HIV as well as unplanned pregnancies? And who are we exactly? Please indulge us while we elaborate further on the added value of the FC2 to your program!

The Female Health Company is the division of Veru that manufactures, markets, and sells the FC2 Internal Condom. FC2 is the only female condom approved by the U.S. Food and Drug Administration (FDA) and prequalified by the World Health Organization (WHO) that provides dual protection against unintended pregnancy and sexually transmitted diseases (STDs), including HIV.

**FC2 is part of the solution to a rapidly growing epidemic.** For those who are sexually active, male condoms and FC2 internal condoms are the only barrier methods approved or cleared by the FDA for preventing unintended pregnancy and sexually transmitted diseases, including HIV. The FC2 internal condom is safe and effective if used correctly and consistently, with high acceptability among women and men around the world. In a recent study in South America: 73% of women found the FC2 to be comfortable, adaptable and beautiful, with a soft and smooth texture – and they want to keep using it!<sup>1</sup>

The Kinsey Institute's Condom Use Research Team (KI-CURT), in collaboration with Clue, a Berlin based company that provides a cycle tracking app for women, recently released findings from a study of condom use from a female perspective.<sup>2</sup> The foremost highlighted finding was that females play a larger role than expected in deciding when to use a condom.

- About 1 out of 5 reported that they decide (rather than their partner deciding)
- About three-quarters reported that both partners usually make the decision
- Only 5% of respondents reported that their partner usually decides about condom use

FC2 gives women another choice for how they may protect themselves during sexual activity. A woman cannot necessarily guarantee that a male partner will be willing to wear a male condom; but she can be proactive about her own sexual health and insert an FC2 female condom.

### **The current epidemic:**

The US has the highest rates of STDs of any industrialized nation. The CDC estimates that there are 20 million new cases of STDs in the U.S. each year. In 2016 alone<sup>3</sup>

- Syphilis rates increased by 17.6 percent, including a 35.7% increase in women
- Gonorrhea increased 18.5%
- Chlamydia increased 4.7%
- An estimated 39,782 people in the US were diagnosed with HIV, the virus that causes AIDS. About 1 in 7 people living with HIV in the US do not know they are infected.<sup>4</sup>



The CDC also estimates that STDs cost the United States nearly \$16 billion annually in direct healthcare costs alone.<sup>3</sup> The direct medical costs of treating STDs are over \$8.4 billion a year, while the indirect costs are much higher – including lost wages and productivity, as well as quality-of-life costs such as physical pain, anxiety, shame, anger and depression.<sup>5</sup>

**Moreover, STDs take their heaviest toll on women, adolescents, and people of color:**

Women and STDs

- Women may be more easily infected, less likely to have symptoms, and more likely to suffer long-term consequences such as pelvic inflammatory disease, infertility, ectopic pregnancy, cervical cancer and increased risk for HIV<sup>3</sup>
- It is estimated that over 24,000 women each year in the U.S. lose the ability to conceive or carry a pregnancy to term due to undiagnosed or untreated STDs<sup>3</sup>

Youth and STDs

- The CDC reports that youth and young adults account for 50% of the new STD infections in the U.S. each year, yet they make up only 25% of the sexually active population<sup>3</sup>
- In a survey of 838 teenage females it was found that teenage girls are at increased risk because they are highly susceptible to cervical infections and often lack access to basic reproductive health information and care<sup>6</sup>
- That same survey showed based on its sampling size that 24% of female adolescents in the U.S. have at least one of the most common STDs<sup>6</sup>
- By race, non-Hispanic black teenage girls have the highest prevalence, with an overall prevalence of 48% compared to 20% among both whites and Mexican Americans<sup>6</sup>
- Overall, approximately half of all the teens in the study reported ever having sex. Among these girls, the STD prevalence was 40%<sup>6</sup>

People of color are disproportionately affected by STDs and associated consequences, due in part to increased likelihood of poverty and limited access to quality health care, STD screening, and treatment.<sup>7</sup>

**Condoms: successes and challenges**

To date, it is clear that condoms, male and internal, continue to play a key role in the prevention of STDs, including HIV/AIDS. Since the beginning of the HIV/AIDS epidemic, it is estimated that condoms have averted approximately 50 million new cases.<sup>8</sup> However, condom usage among sexually active U.S. youth has been on the decline. A 2014 study found that 50% of its respondents (479 men) refuse to use male condoms due to negative attributes they associate with it.<sup>9</sup>

**The solution:**

FC2, when used consistently and correctly, gives a woman control over her sexual health by providing dual protection against STDs, including HIV/AIDS, and unintended pregnancy. **FC2 can be used in tandem with LARC and PrEP in order to offer greater protection against HIV and unplanned pregnancy.**

### *FC2 – Benefits and Why users like it*

- Internal condoms may be a source of pleasure for both partners, and are experienced by some men as less constrictive versus male condoms. FC2 can also be inserted before sex without interrupting the natural flow of sexual activity. Additionally, there are many benefits to offering the non-latex material made from nitrile comprising the FC2 internal condom:
  - People with a latex allergy or sensitivity can still use the FC2 internal condom
  - Nitrile can hold both water and oil based lubricants, while latex (male) condoms tear when any oil substance is applied
  - Nitrile heats up to the body temperature, making sex with the FC2 feel warm and more natural. It is also odorless, gluten and paraben free.
  - The FC2 can be inserted in advance
  - Nitrile has less than 1% chance of tearing <sup>10</sup>
  - Acceptability: Studies show that in many cultures, the internal condom is found acceptable by women and their partners.
  - Natural rubber latex condoms for men are highly effective at preventing sexually transmitted infections, including HIV/AIDS, if used correctly. If you are not going to use a male natural rubber latex condom, you can use the FC2 Internal Condom to help protect yourself and your partner.

### *FC2 is Effective*

- **FC2 is comparable to male condoms** in effectiveness in preventing pregnancy.<sup>11–16</sup>
  - When used correctly, (FC2) “reduces access of semen to the vagina, and, thereby prevents or decreases the rate of pregnancy ... the (FC2) condom barrier prevents access to the vagina of pathogenic bacteria and viruses in secretions as well as contact between lesions on the shaft of the penis and the vagina.” <sup>17</sup>
  - FC2 female condoms offer highly effective protection against both HIV and other STIs when used correctly and consistently. <sup>17</sup>

### *FC2 – Good Business Sense*

- FC2 reduces the risk of HIV infection when properly used and is therefore a **cost-effective** public health intervention compared to the costs of treating all HIV infections.<sup>18–20</sup>
  - Economic benefits and FC2 as an effective HIV prevention intervention: The D.C. female condom program, evaluated by Holtgrave et al., prevented enough HIV infections in its first year to save over \$8 million in future medical care costs, over and above the cost of the program, based on mathematical modeling analysis and the costs of distributing condoms and treating HIV in 2012. “These results clearly



- indicate that delivery of and education about female condoms is an effective HIV prevention intervention and an outstanding public health investment.”<sup>20</sup>
- The same study found that for every \$1 dollar spent on internal condoms in a public health program, \$20 dollars is likely to have been *saved* in testing and treatment. <sup>20</sup>
  - Internal condoms are a catalyst for **increased levels of protected sex acts** when promoted and distributed alongside male condoms.<sup>21-23</sup>
    - Importantly, studies also show that when the internal condom is made available as an option along with male condoms there is a significant increase in protected sex acts with a concurrent decrease in STIs. The increase in protected sex acts varies by country and averages between 10 percent and 35 percent.
    - **This means that when internal condoms are offered alongside male condoms, overall protected sex acts increase:** Latest research from South Africa confirms these findings by showing that at baseline with only a male condom in the market, the number of unprotected sex acts was at 43.3%. When the Internal Condom was introduced to the market, after 1 year from baseline, the number of unprotected sex acts (no male or internal condom used) fell to only 8.4%. Protected sex acts went up to 92% when internal condoms were made available. <sup>24</sup>

We hope to have informed you of the new positive changes and opportunities in affordability, availability and support packages for the FC2 internal condom in the US public sector, and that we have highlighted some of the impact the internal condom can have on your constituencies and overall programming. We look forward to (continue) to work with you and are ready to answer any questions you might still have! In the meantime, please refer to the FDA’s approved labeling for more information about the FC2 internal condom and also feel free to take a look at our website [www.fc2femalecondom.com](http://www.fc2femalecondom.com) for the many training resources we have made available!

With warm regards,

Denise van Dijk  
President Female Health Company

Rachel Steiner  
Business Development Manager US Public Sector

*NOTE 1: You may find the FC2 Internal Condom for purchase at unauthorized vendors. We can’t guarantee the quality or safety of FC2 Internal Condoms purchased on other websites or via other vendors. Single condoms cannot be re-sold in any commercial/retail setting.*

*NOTE 2: Veru Inc. is the successor entity to The Female Health Company and as such, is the sole supplier of the FC2 Female Condom® in the United States. Furthermore, the FC2 Female Condom® is the only internal condom approved by the United States Food and Drug Administration for sale and use in the United States.*

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