



**RE: FDA Public Hearing on “Using Innovative Technologies and Other Conditions of Safe Use to Expand which Drug Products can be Considered Nonprescription” [Docket No. FDA-2012-N-0171]**

**Statement by Kirsten Moore, President & CEO  
Reproductive Health Technologies Project**

**March 23, 2012**

Thank you for convening this meeting and for the opportunity to share comments today. My name is Elizabeth Dawes and I am a Senior Associate at the Reproductive Health Technologies Project - a national nonprofit advocacy organization. I am giving comments on behalf of our President & CEO, Kirsten Moore. Our mission is to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, appropriate, and acceptable technologies for ensuring her health and controlling her fertility. RHTP does not receive any funding from pharmaceutical companies.

As implementation of the Patient Protection and Affordable Care Act continues, we think it is critical to explore creative strategies that will expand access to proven safe and effective medications used to treat reproductive health conditions and prevent unintended pregnancy. Approximately 32 million Americans will have health care coverage as a result of reform.<sup>i</sup> This means there could potentially be 32 million new patients in an already stressed system. Making certain medications available without a prescription, thus eliminating the need for a costly and time-consuming doctor’s visit, may be one way to increase access to needed medication and improve health outcomes while allowing clinics to operate as efficiently as possible.

The average American woman spends five years pregnant or trying to become pregnant and 30 years trying not to be pregnant. As a result, millions of American women rely on hormonal contraceptives to prevent unwanted pregnancy over an extended period of time. In addition, hormonal contraception is prescribed on a long-term basis to treat medical conditions such as endometriosis; premenstrual dysphoric disorder; iron-deficiency anemia; fibroid tumors; and ovarian cysts just to name a few.

Because hormonal contraception helps women protect their health and achieve their fertility goals and improves child health outcomes, we support innovative strategies to reduce barriers to access.<sup>ii</sup> Despite the fact that a variety of contraceptives are available by prescription, about half of all pregnancies in the United States are unintended.<sup>iii</sup> While pregnancy itself is not a disease, unintended pregnancy is a biomarker for poorer health outcomes for women and children. Cost, lack of awareness of different options, cultural norms, personal beliefs, and concern about side effects may dissuade women from seeking contraceptives. The current service delivery model – requiring a prescription and requiring women to refill that prescription on a monthly or three-month basis – also acts as a barrier to contraceptive use and continuation. To most successfully treat some reproductive health conditions and prevent unintended pregnancy, women need uninterrupted access to hormonal contraceptives.

Unfortunately, the way the FDA decided to treat Plan B One-Step (and other levonorgestrel-containing emergency contraceptive products) is an example of how not to reduce barriers to access. Even though the Agency recently recommended over-the-counter availability, earlier actions have put the product in a de facto ‘behind the counter’ category.<sup>iv</sup> Keeping Plan B One Step behind the counter does not enhance

individuals' ability to access Plan B One Step and, in fact, may deter them. Evidence shows that some pharmacists or pharmacy staff may impose their own beliefs on consumers and refuse to sell them a product they could use to protect their health and prevent unwanted pregnancy.<sup>v</sup> We hope the take-away from this disappointing episode will be that when a product has met the standard for safe and effective use as a nonprescription product it should be put on the shelf and not subjected to additional review or point of sale restrictions.

Similar to Plan B One Step, there is evidence that women can safely and effectively use daily hormonal contraceptive pills without the supervision of a so-called learned intermediary.<sup>vi</sup> Studies conducted in metropolitan areas across the United States show that clinician or pharmacist presence is not required for consumers to understand product necessity, appropriateness, contraindications, and product utilization.<sup>vii,viii,ix</sup> In fact, in the US, there is little scientific evidence that clinical counseling actually improves contraceptive use.<sup>x</sup>

RHTP, like other public health groups, is exploring the potential for bringing a daily levonorgestrel hormonal contraceptive over-the-counter. For the millions of American women who need or choose to use hormonal birth control, a daily OTC levonorgestrel pill would mean improved access, convenience, consistent use, and health outcomes.

For other hormonal contraceptives which don't yet have sufficient data to support nonprescription status, we strongly advise FDA to consider alternative models for dispensing these products and promoting their safe use in order to ensure that all women who need them can access them. Electronic kiosks, retail clinics, and self-dispensing machines are under development and in use across the United States and have been shown to be acceptable and appropriate for clients willing to forego an in-person consultation with a clinical provider. For those wishing to consult with a health care professional, expanded use of telephone or provider-to-patient video interface have similarly met with patient satisfaction, demonstrated acceptable outcomes, and helped to lower health care costs.<sup>xi</sup>

Using technology to enhance reproductive health service delivery aligns with recent United States Government investments. Billions of dollars were provided for health information technology programs through the Affordable Care Act and the Health Information Technology for Economic and Clinical Health (HITECH) Act.<sup>xii,xiii</sup> Telemedicine and health information technology allow health service providers to be more efficient, reduce costs, and meet the needs of their patients to improve health outcomes.

We urge you to consider all possible innovative tools and technology so that women who do not need a medical exam can access hormonal contraceptives and continue using them on the schedule necessary to prevent pregnancy and as prescribed for other treatment. We hope that the FDA will make expanded access to safe and effective medical treatment a reality.

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- <sup>i</sup> Health Reform by the Numbers, March 19, 2010, <http://www.whitehouse.gov/health-care-meeting/by-the-numbers>.
- <sup>ii</sup> Preventive Services for Women: Closing the Gaps, February 16, 2012. <http://www.iom.edu/~media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/PreventiveServices-Testimony.pdf>
- <sup>iii</sup> Facts on Unintended Pregnancy in the United States, January 2012, <http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html>.
- <sup>iv</sup> Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step, December 7, 2011, <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm>.
- <sup>v</sup> Davidson LA, et al. Religion and conscientious objection: A survey of pharmacists' willingness to dispense medications. *Social Science & Medicine*. 71(1):161-165.  
Laura A. Davidson, Clare T. Pettis, Amber J. Joiner, Daniel M. Cook, Craig M. Klugman
- <sup>vi</sup> Should the contraceptive pill be available without prescription? January 24, 2009, [http://ocsotc.org/wp-content/uploads/2010/12/Grossman\\_Jarvis\\_should-OCs-be-avail-without-a-prescription.pdf](http://ocsotc.org/wp-content/uploads/2010/12/Grossman_Jarvis_should-OCs-be-avail-without-a-prescription.pdf)
- <sup>vii</sup> Raymond EG, et al. Comprehension of a prototype emergency contraception package label by female adolescents. *Contraception*. 79(3):199-205.
- <sup>viii</sup> Birth Control Within Reach – A national survey on women's attitudes and interest in pharmacy access to hormonal contraception, June 2004, Pharmacy Access Partnership.
- <sup>ix</sup> Raine TR, et al. An over-the-counter simulation study of a single-tablet emergency contraceptive in young females. *Obstetrics and Gynecology*. 119(4):772-79.
- <sup>x</sup> Improving Contraceptive Use in the United States, 2008, <http://www.guttmacher.org/pubs/2008/05/09/ImprovingContraceptiveUse.pdf>.
- <sup>xi</sup> Grossman D, et al. Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine. *Obstetrics & Gynecology*. 118(2):296-303.
- <sup>xii</sup> Health Information Technology and Publicly Funded Family Planning Agencies: Readiness, Use and Challenges, March 2012, <http://www.guttmacher.org/pubs/Health-IT.pdf>.
- <sup>xiii</sup> The EHR: It's about our patients, not technology, March 19, 2012, <http://www.ama-assn.org/amednews/2012/03/19/edca0319.htm>.