

Working Group on Oral Contraceptives Over-the-Counter Statement of Purpose¹

The Working Group on Oral Contraceptives (OCs) Over-the-Counter (OTC) is a coalition of reproductive health rights and justice organizations, non-profit research and advocacy groups, university-based researchers, and prominent clinicians who share a commitment to providing all women of reproductive age easier access to safe, effective, acceptable, and affordable contraceptives.

The working group is exploring the potential of over-the-counter access to oral contraceptives to reduce disparities in reproductive health care access and outcomes among low-income, poor, and young women and to increase opportunities for every woman to access a safe, effective method of contraception, free of unnecessary control, as part of a healthy sexual and reproductive life.

The substantial literature available on oral contraceptive pills confirms they meet most of the FDA's criteria for OTC status. At a population level, the drug's benefits outweigh the risk for women of reproductive age; the potential for misuse or abuse is low; a consumer can easily self-diagnose the condition for which the pills are indicated; and directions for use are straightforward. Because progestin-only pills are very safe and have fewer contraindications, we are considering a strategy of pursuing an OTC switch for this type of pill first. Indeed, two progestin-only emergency contraceptive products are currently available without a prescription to those 17 and older.²

At the same time, members of the working group recognize that benefits and risks of an OTC product will accrue to individual women differently based on factors such as underlying health status, race, class, education and literacy, immigration status, and access to culturally competent reproductive and preventative health services. As such, the working group is committed to evaluating the risks and benefits of a switch from multiple perspectives.

There is evidence that the current prescription status for hormonal contraception may serve as a barrier to access for many women. The current health care delivery system for contraceptive care is stretched thin. Eighteen percent of non-elderly women lack access to private health insurance or Medicaid.³ In addition, young women and immigrant women report encountering cultural and linguistic barriers in accessing quality, comprehensive reproductive health services.⁴ An opinion survey from 2004 found that 68% of women said they would likely use hormonal contraception if it were available directly from a pharmacy, and Latinas and African American women were even more likely to say they would take advantage of pharmacy access than their non-Hispanic white counterparts.⁵ Uninsured women and women 18-25 years old were also more likely to support pharmacy access to these methods than insured women or women 36 years and older.⁵

In addition, research suggests that a learned intermediary prescribing hormonal contraception does not necessarily improve reproductive health outcomes and women themselves might be able to screen themselves for contraindications. For example, a recent study among Latinas in Texas found that women can accurately use a checklist to assess whether they are contraindicated to pill use.⁶ Still, health advocates are keenly aware of the limited age-appropriate, culturally relevant information and education available to women and men about the range of contraceptive options and the pros and cons of each, and more data more closely approximating a real-world OTC environment are needed to determine how well current or potential users of contraception in the US can accurately and adequately self-screen.

Giving women greater control over their birth control choices with easier access to safe, effective options may lead to higher rates of initiation and continuation and fewer gaps in use, thereby

potentially leading to an overall decrease in the rates of unintended pregnancy and abortion. However, some women might not benefit from a switch or may find access more difficult in an OTC environment. The experience with moving Plan B over the counter shows that cost, especially when there is limited competition in the marketplace, remains a barrier for some women.

Members of the working group are committed to analyzing the risks and benefits of OTC access for specific subgroups of women. While we recognize that an OTC switch of a progestin-only pill will not improve outcomes and access for every woman, we believe it may help reduce barriers for some women, including those who currently lack health care access.

To maximize the benefit and minimize the risk for every woman, the working group will carry out several activities, including conducting original research, engaging in public education and discussion, building consensus on key issues, particularly with those who will be affected by a switch, and where possible, influencing the drug development and regulatory process. We will initiate dialogue with professional medical organizations as well as organizations representing diverse groups of women and create informational materials appropriate for different audiences. If an OTC switch for an oral contraceptive does take place, we also plan to monitor the impact on women's health, access, and out-of-pocket expenditures.

We recognize our goal cannot be achieved without creating conditions that will promote good outcomes in an OTC environment, and will support policies that:

- Expand availability of comprehensive sexuality education in schools and for consumers no longer in school
- Promote investment in cost-effective, culturally appropriate preventive health care
- Train health educators, including pharmacy staff, to answer consumers' questions about OTC contraceptive methods
- Ensure that medical care is guided by scientifically-accurate, unbiased medical information and each patient's own religious or ethical beliefs
- Ensure Medicaid coverage of OTC birth control and STD prevention options.

While the focus of our work is domestic, we recognize that regulatory changes in the US could have ramifications in other countries. We plan to disseminate our results internationally and hope to adapt our materials for women outside of the US who could benefit from easier access to birth control pills. Additionally, we acknowledge that we can learn from the experiences of other countries where contraception is more demedicalized than in the US and will look to international experience to inform our efforts.

The working group is open to clinicians, researchers, and advocates with a direct interest in the issue. Employees of the pharmaceutical industry and FDA are welcome to join the group informally as individuals, although we will involve them in our activities at our discretion. The working group's activities are guided by a Steering Committee composed of individuals from the research, clinical, and advocacy communities. The working group is funded by private foundation and government research grants and in-kind contributions of group members. The working group does not accept any contributions from manufacturers of birth control methods to support its research, advocacy, and education efforts.

¹ This statement was approved by the Working Group Steering Committee on April 27, 2010, and may be revised and updated as data and real world experience on this topic accumulates.

² Commissioner von Eschenbach's decision to place an age restriction on OTC access was not supported by the FDA's own scientific review staff and advisors who argued the product was safe enough for OTC access by any one

at risk of an unintended pregnancy (see Tumino v von Eschenbach 2009). While the FDA recently lowered the OTC age cutoff from 18 to 17, public health professionals and public interest lawyers continue to seek appropriate, evidence-based labeling on all emergency contraceptive products.

³ “Fact Sheet: Women’s Health Insurance Coverage.” Kaiser Family Foundation, Oct 2009.

<http://www.kff.org/womenshealth/upload/6000-08.pdf>

⁴ “Abortion and Women of Color: The Bigger Picture.” *Guttmacher Policy Review*, Summer 2008, Volume 11, Number 3.

⁵ Landau SC, Parker MT, Taylor-McGhee B. Birth control with in reach: a national survey on women’s attitudes toward and interest in pharmacy access to hormonal contraception. *Contraception*, 2006, 74:463-470.

⁶ Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use. *Obstetrics and Gynecology* 2008; 112(3):572-578.