

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

The Working Group on Oral Contraceptives (OCs) Over-the-Counter (OTC) is an informal coalition of reproductive health and rights organizations, non-profit research and advocacy groups, university-based researchers and prominent clinicians who share an interest in women's health and access to contraception. Our goal is to evaluate objectively the risks and benefits of demedicalizing contraceptive care, with an eye toward improving access to OCs and potentially other hormonal contraceptive methods by making them available without a prescription.

The substantial literature available on oral contraceptives confirms they meet most of the FDA's criteria for OTC status – 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 the FDA also wants to know that health care practitioners are not needed for the safe and effective use of an OTC product, the outstanding safety question is whether women can appropriately self-screen for contraindications to OC use, including hypertension. Experience indicates that in countries where OCs are already *de facto* obtainable OTC, women use them safely without prior screening by a health care professional.

In addition to FDA criteria, there are other risks and benefits of an over-the-counter switch worthy of consideration. For example, there is evidence that the current prescription status for hormonal contraception may serve as a barrier to access – both logistical and financial – for some women and does not enhance women's health care or health outcomes. In addition to giving women greater control over their birth control choices, easier access may lead to higher rates of initiation, continuation and fewer gaps in use, thereby potentially leading to an overall decrease in the rates of unintended pregnancy and abortion.

On the other hand, some women might not benefit from a switch or may find access more difficult in an OTC environment; it is our goal to understand how any negative consequences can best be eliminated or minimized. We recognize that a switch will impact various populations of women and groups of health care providers differently and are committed to understanding these impacts, promoting the positive outcomes and working to resolve any negative consequences. We believe our efforts will help us reach a shared goal – providing all women of reproductive age easier access to safe, effective, acceptable and affordable contraceptives.

To this end, 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, host a meeting to gauge support for this issue among organizations representing diverse groups of women, and create informational materials on the safety of OCs. We will seek funding for future research and advocacy activities.

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 OCs. Additionally, we acknowledge that we can learn from the experiences of other countries where

¹ This statement was approved by the Working Group on August 4, 2006 and may be revised and updated as data and real world experience on this topic accumulates.

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.