

Advocating for Over-the-Counter Oral Contraceptives

Eleanor Bimla Schwarz, MD, MS; Amy S. Gottlieb, MD; Wendy L. Bennett, MD, MPH

Dr. Schwarz (ebschwarz@ucdavis.edu) is a professor of medicine in the Division of General Internal Medicine at the University of California-Davis. Dr. Gottlieb (Amy.GottliebMD@baystatehealth.org) is a professor of medicine and obstetrics & gynecology at University of Massachusetts Medical School-Baystate and associate dean for faculty affairs at University of Massachusetts Medical School-Baystate. Dr. Bennett (wendy.bennett@jhmi.edu) is an associate professor of medicine in the Division of General Internal Medicine at the Johns Hopkins University School of Medicine.

Oral contraceptives (OCs) are among the most commonly used medications in the United States. OCs offer women many non-contraceptive benefits including reductions in anemia, dysmenorrhea, acne, endometrial, and ovarian cancer.^{1,3} Although estrogen-containing OCs are associated with an increase in thromboembolic events, the risk of thromboembolism faced by pregnant and postpartum women is far greater.⁴ As a result, multiple studies have shown OCs to have beneficial effects on all-cause mortality.^{5,8} Nonetheless, access to OCs is limited in many communities, and one of every 20 US women of reproductive age experiences an unintended pregnancy each year.^{9,10}

There is growing interest in making OCs over-the-counter (OTC) in the United States. Worldwide, the majority of countries enable women to access OCs without a physician's prescription.^{11,12} Among U.S. women, surveys show widespread support for OTC access to OCs.¹³ Multiple medical organizations have now endorsed OTC access to OC, including the American Medical Association (AMA), the American College of Obstetrics and Gynecology (ACOG), and now also The Society of General Internal Medicine (SGIM).¹⁴ In 2012, SGIM's "Women and Medicine Task Force" (formerly the "Women's Health Task Force") signed on to the national OC OTC Working Group's Statement of Purpose. In 2016, the Task Force was asked to renew its support and, as part of that process, SGIM's Council approved listing both the "Women and Medicine Task

Force" and SGIM as signatories to the OCs OTC Working Group's Statement of Purpose (see <http://ocsotc.org/statement-of-purpose/>).

In making the decision to support OTC access to OC, SGIM reviewed the current evidence that strongly favors the benefits of OTC status for OCs over the potential for harm. The main concern about the safety of OTC access to OCs is whether women can self-screen for contraindications to use. Although OCs are safe for most women of reproductive age, some chronic conditions increase risk for medical complications or reduce the effectiveness of the pill. The U.S. Centers for Disease Control and Prevention's Medical Eligibility Criteria for Contraceptive Use provide an evidence-based list of conditions and medications that are considered relative and absolute contraindications to contraceptive methods.¹⁵ The only contraindication to use of estrogen-containing OC that cannot be identified without reviewing a woman's medical history is hypertension; progestin-only pills have even fewer contraindications and are safe for women with hypertension. Several studies have shown that women can accurately screen themselves for contraindications to OC using simple checklists, whether or not the pills contain estrogen.¹⁶

Finally, there is evidence indicating that OTC access to OC increases adherence without adversely affecting receipt of preventive health screenings.¹⁷ In focus groups, women have reported potential benefits of OTC access, including convenience and pri-

vacy.¹⁸ Many believed OTC availability of OCs would help to reduce unintended pregnancy and help to destigmatize birth control. However, some women worried that the cost of OTC OCs would be higher if insurance no longer covered them. If costs for an OTC OC remain low, or covered by insurance, public sector cost savings are predicted to be considerable.¹⁹

The OCs OTC Working Group's Statement of Purpose highlights the importance of conducting research on the implications of making OCs OTC and sharing study findings with regulatory specialists considering a switch to OTC status. The Statement supports policies that will "expand coverage of OTC birth control without a prescription in all public and private insurance plans; ensure adolescents have full access to OTC contraceptives; ensure pharmacies and retail outlets have proactive measures in place to guarantee an individual's religious or moral beliefs do not interfere with people's access to contraception; train health educators, including pharmacy staff, to answer consumers' questions about OTC OCs; and expand access to the full range of contraceptive methods, especially for people who have a harder time obtaining the contraception they want and need."

In keeping with SGIM's mission to "lead excellence, change, and innovation in clinical care, education, and research in general internal medicine to achieve health care delivery," our full support of efforts to bring OC OTC is warranted.

continued on page 2

References

1. Collaborative Group on Epidemiological Studies on Endometrial Cancer. Endometrial cancer and oral contraceptives: an individual participant meta-analysis of 27,276 women with endometrial cancer from 36 epidemiological studies. *Lancet*. 2015 Sep; 16(9):1061–1070.
2. Havrilesky L, Moorman P, Lowery W, et al. Oral contraceptive pills as primary prevention for ovarian cancer: a systematic review and meta-analysis. *Obstet Gynecol*. 2013;122(1):139-47.
3. ACOG Practice Bulletin No.10: noncontraceptive uses of hormonal contraceptives. *Obstet Gynecol*. 2010 Jan;115(1):206-18. doi: 10.1097/AOG.0b013e3181cb50b5.
4. Kamel H, Navi B, Sriram N, et al. Risk of a thrombotic event after the 6-week postpartum period. *N Engl J Med*. 2014 Apr 3;370(14):1307-15.
5. Charlton B, Rich-Edwards J, Colditz G, et al. Oral contraceptive use and mortality after 36 years of follow-up in the Nurses' Health Study: prospective cohort study. *BMJ*. 2014 Oct 31.
6. Hannaford P, Iversen L, Macfarlane T, et al. Mortality among contraceptive pill users: cohort evidence from Royal College of General Practitioners' oral contraception study. *BMJ*. 2010 Mar 11;340:c927.
7. Beral V, Hermon C, Kay C, et al. Mortality associated with oral contraceptive use: 25 year follow up of cohort of 46,000 women from Royal College of General Practitioners' oral contraception study. *BMJ*. 1999 Jan 9;318(7176):96-100.
8. Vessey M, Villard-Mackintosh L, McPherson K, et al. Mortality among oral contraceptive users: 20 year follow up of women in a cohort study. *BMJ*. 1989 Dec 16;299(6714):1487-91.
9. Frost J, Frohwirth L, Zolna M. Contraceptive needs and services, 2013 Update. <https://www.guttmacher.org/sites/default/files/pdfs/pubs/win/contraceptive-needs-2013.pdf>. Accessed March 31, 2017.
10. Unintended pregnancy in the United States, fact sheet Sep 2016. Guttmacher Institute. <https://www.guttmacher.org/sites/default/files/pdfs/pubs/FB-Unintended-Pregnancy-US.pdf>. Accessed March 31, 2017.
11. Upadhyia K, Santelli J, Raine-Bennett T, et al. Over-the-counter access to oral contraceptives for adolescents. *J Adolesc Health*. 2017 Mar 6.
12. Grindlay K, Burns B, Grossman D. Prescription requirements and over-the-counter access to oral contraceptives: a global review. *Contraception*. 2013 Jul;88(1):91-6.
13. Grossman D, Grindlay K, Li R, et al. Interest in over-the-counter access to oral contraceptives among women in the United States. *Contraception*. 2013;88(4):544-52.
14. OCs OTC working group. professional organization resolutions or policies related to OCs OTC. <http://ocsotc.org/resources/#professionalorgs>. Accessed March 31, 2017.
15. U.S. medical eligibility criteria for contraceptive use, 2016. *Morb Mortal Wkly Rep*. 2016 Jul 29; 65(3):1-103. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm>. Accessed March 31, 2017.
16. Grossman D, Fernandez L, Hopkins K, et al. Accuracy of self-screening for contraindications to combined oral contraceptive use. *Obstet Gynecol*. 2008 Sep;112(3):572-8.
17. Hopkins K, Grossman D, White K, et al. Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users. *Contraception*. 2012 Oct;86(4):376-82.
18. Baum S, Burns B, Davis L, et al. Perspectives among a diverse sample of women on the possibility of obtaining oral contraceptives over the counter: a qualitative study. *Women's Health Issues*. 2016 Mar-Apr;26(2):147-52.
19. Foster D, Biggs M, Phillips K, et al. Potential public sector cost-savings from over-the-counter access to oral contraceptives. *Contraception*. 2015 May;91(5):373-9.