

March 05, 2012

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Dear Working Group Member,

In this month's update from the OCs OTC working group, we highlight a recent op-ed in the *LA Times* that called for OTC access to the pill to overcome insurance and provider restrictions on access, as well as research documenting the low prevalence of contraindications to progestin-only pills (POPs). This new study adds to the large body of evidence that OTC access to POPs would be very safe. We also include information below about a recent legislative change in Australia that will allow women to access a refill for OCs without a prescription. Finally, we provide a brief summary of an upcoming FDA public hearing about the possibility of expanding the kinds of drugs that could be provided without a prescription and the ways in which patients could safely access them.

Please let me know if you have any questions or comments about the information in this update

Thanks,

A handwritten signature in black ink, appearing to read "Dan", is positioned below the text "Thanks,".

Daniel Grossman, MD
Senior Associate, Ibis Reproductive Health

Los Angeles Times op-ed highlights the non-contraceptive benefits of OCs and calls for OTC access

In response to the controversy surrounding the requirement that employers, including religiously affiliated employers, provide insurance coverage for contraception as part of the Affordable Care Act in the US, Malcolm Potts wrote in an [op-ed](#) about the many non-contraceptive benefits of the pill-- from regulating menstrual periods to reducing the risk of uterine and ovarian cancer. Dr. Potts argues that these additional benefits of oral

contraceptives are so compelling that the church should consider lifting restrictions on doctors at Catholic institutions and allow them to prescribe the drug for these non-contraceptive effects. But if the church still refuses to provide contraception, Potts suggests that making the pill available over the counter would improve access for women whose insurance does not cover or whose provider refuses to prescribe contraception. Dr. Potts also participated in a [radio call-in show](#) and debated Dr. Angela Lanfranchi on whether the pill should be available over the counter.

New research highlights the low prevalence of contraindications to progestin-only pills

In recent years the OCs OTC working group has focused on progestin-only pills (POPs) as the most likely candidate to be the first OTC oral contraceptive in the US. One reason for this is that the FDA has already approved levonorgestrel-containing emergency contraception products for OTC sale, and like POPs, these EC products do not contain estrogen. New research now documents the low prevalence of contraindications to POPs-- conditions that might make use of the pill risky to some women. White and colleagues found that only 1.6% of women from the general population and 0.6% of current users in El Paso, Texas, had at least one contraindication to POPs. This contrasts with the prevalence of contraindications to combined oral contraceptives, which has been [reported](#) to be as high as 39%. Below is the [abstract](#) for the new study, and please [email Kate](#) if you would like a copy of the article.

Abstract

Background: Progestin-only oral contraceptive pills (POPs) have fewer contraindications to use compared to combined pills. However, the overall prevalence of contraindications to POPs among reproductive-aged women has not been assessed.

Study Design: We collected information on contraindications to POPs in two studies: (1) the Self-Screening Study, a sample of 1267 reproductive-aged women in the general population in El Paso, TX, and (2) the Prospective Study of OC Users, a sample of current oral contraceptive (OC) users who obtained their pills in El Paso clinics (n=532) or over the counter (OTC) in Mexican pharmacies (n=514). In the Self-Screening Study, we also compared women's self-assessment of contraindications using a checklist to a clinician's evaluation.

Results: Only 1.6% of women in the Self-Screening Study were identified as having at least one contraindication to POPs. The sensitivity of the checklist for identifying women with at least one contraindication was 75.0% [95% confidence interval (CI): 50.6%-90.4%], and the specificity was 99.4% (95% CI: 98.8%-99.7%). In total, 0.6% of women in the Prospective Study of OC Users reported having any contraindication to POPs. There were no significant differences between clinic and OTC users.

Conclusion: The prevalence of contraindications to POPs was very low in these samples. POPs may be the best choice for the first OTC oral contraceptive in the United States.

Australian Parliament passes bill to allow dispensing of OCs by pharmacists to current users whose prescription has expired

On March 1, the Australian Senate passed the [National Health Amendment \(Fifth Community Pharmacy Agreement Initiatives\) Bill 2011](#), which will allow pharmacists to dispense one pack of oral contraceptives to women who previously had the medication prescribed by a doctor-- a practice referred to as "medication continuance." Pharmacists will also be allowed to dispense a standard pack of lipid-lowering statins without a prescription to previous users. The supply will be provided at the usual co-payment level under the national Pharmaceutical Benefits Scheme. The measure passed despite vocal opposition from the Australian Medical Association, which [argued](#) that only doctors are adequately trained to make clinical assessments and determine the need for treatment. The law is scheduled to go into effect on July 1, 2012. For more information, see this [article](#) in *The Daily Telegraph*.

If you're interested in learning more about the prescription requirements for OCs in other countries, please visit our [interactive map](#) of OTC availability.

US FDA to hold public hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription"

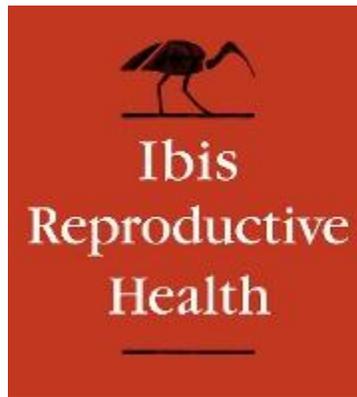
On March 22-23, the US Food and Drug Administration will hold a [public hearing](#) to receive comments on the possibility of a new paradigm for OTC drugs. Under this paradigm, the Agency would approve certain drugs that would otherwise require a prescription for OTC use under conditions of safe use. Some of the examples of "conditions of safe use" the FDA cites include making refills of certain medications available OTC if the person initiated use with a prescription, and using a computerized kiosk to help a person self-select for appropriate use. While we continue to believe that true OTC status should be the goal for OCs, these conditions of safe use might be relevant for combined oral contraceptives (COCs, which contain estrogen). For example, a woman could use an automated kiosk to get her blood pressure checked and review the list of contraindications before obtaining COCs over the counter.

We plan to attend this meeting and have requested to make an oral presentation. If you plan to attend the meeting or would like to give input on our presentation, please [email Dan](#). The deadline to submit a request for oral presentation is March 9, 2012, and the deadline to submit written comments is May 7, 2012.

About us

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is an informal coalition of reproductive health and rights organizations, nonprofit 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 working group is coordinated by Ibis Reproductive Health.



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Contact us

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