

January 24, 2012

In This Update

[Working group meetings](#)

[Interactive map on prescription requirements for OCS](#)

[APHA approves policy advocating for insurance coverage of OTC contraceptives without prescription](#)

[FDA meetings on drospirenone-containing OCS and the Ortho-Evra patch](#)

[Editorial on pharmacy access models for reproductive health care](#)

[About us](#)

[Contact us](#)

Dear Working Group Member,

We hope that 2012 is off to a good start for all of you. Advocates for contraceptive access finally received some good news last week when the US Department of Health and Human Services (HHS) announced that the exemption for religious employers to provide insurance coverage for contraception will remain narrow. Most religious-affiliated organizations will be required to cover birth control for their employees, but they will be given until August 2013 to comply. We applaud HHS for this move to make sure that as many women as possible will have access to contraceptive services without cost sharing as part of the Affordable Care Act. For more information, see these articles in the *New York Times* and the *Washington Post*.

We know many of you are actively involved in responding to and hopefully identifying a way to overcome Secretary Sebelius's rejection of the FDA approval of full OTC access for Plan B One-Step® without an age restriction. Our working group is obviously watching closely how our community, Teva, and the FDA move forward to inform our efforts to expand OTC access to contraceptives. The working group was highlighted in an article on the Plan B One-Step® decision in the *Tan Sheet*, an industry newsletter focused on nonprescription drugs. If you would like to become a member of the EC Coalition, coordinated by the Reproductive Health Technologies Project, and receive updates on the Plan B efforts, please contact [Morganne Rosenhaus](#).

Below are several updates related to the working group, including information about our meetings in October and the launch of our new interactive map on prescription requirements for oral contraceptives around the world.

Please let me know if you have any comments or questions about any of this information.

Thanks,



Daniel Grossman, MD
Senior Associate, Ibis Reproductive Health

OCs OTC Working Group meetings in October 2011

In October 2011 the working group held two meetings in Washington, DC. The first was a day-long general working group meeting with 44 participants, including clinicians, pharmacists, health researchers, advocates, and representatives of several pharmaceutical companies. The focus of this meeting was to provide an overview of the latest evidence on the safety of OCs and OTC use and women's and providers' perspectives on OTC access; review the decision to move forward with a progestin-only pill (POP) as the first OTC contraceptive; discuss cost and insurance coverage in an OTC environment; and identify strategies for moving forward with an OTC switch. The second meeting was a half-day summit with 26 participants to discuss a range of possible mechanisms for maintaining Medicaid coverage of OCs in an OTC environment. The goal of the meeting was to address concerns among some working group members that a non-prescription OC could be unaffordable for the women who would stand to benefit from it most. This session focused on outlining potential strategies for getting public insurance coverage of OTC contraception without a prescription in the wake of health reform, and identifying other ways to ensure that an OTC OC would be affordable for all women and low-income women in particular.

Please email [Kate Grindlay](#) if you would like the full minutes of the meetings.

Interactive global map on prescription requirements for oral contraceptives

We are thrilled to announce the launch of a new interactive map on the working group website that displays the oral contraception prescription requirements for countries around the world. Through published articles, country drug registers, an online survey (which many of you participated in!), and email correspondence with government officials and other in-country contacts, we have documented for over 120 countries where OCs are formally available OTC (with or without screening by pharmacy staff), informally available OTC, or by prescription-only. This interactive map will be updated as we continue to accumulate data. If you have corrections or comments related to any of these countries, please email [Kate Grindlay](#). Many thanks to you for your help collecting this information!

American Public Health Association approves policy advocating for insurance coverage of OTC contraceptives without a prescription

At its annual meeting in November 2011, the Governing Council of the American Public Health Association (APHA) adopted a policy entitled "Improving Access to Over-the-Counter

Contraception by Expanding Insurance Coverage." In the policy, APHA urges:

- Congress, state legislatures, and city councils to enact legislation and ordinances that will provide federal and state Medicaid coverage for all family planning drugs and supplies that are approved by the FDA for sale over the counter, to use their contracting power to encourage coverage of OTC contraceptives, and not to require a prescription for such coverage;
- Federal, state, city, and county government agencies to implement regulations and policies that will provide federal and state Medicaid coverage for all family planning drugs and supplies that are approved by the FDA for sale over the counter, and not to require a prescription for such coverage;
- Health insurers and managed care organizations participating in Medicaid and the private insurance market to include in their insurance products coverage for all family planning drugs and supplies that are approved by the FDA for sale over the counter, and not to require a prescription for such coverage.

The policy will soon be posted on the APHA [website](#) and will help guide the Association's future advocacy efforts.

FDA meetings on drospirenone-containing OCs and the Ortho-Evra patch and increased risk of blood clots

Last month the FDA advisory committee for Reproductive Health Drugs and Drug Safety and Risk Management convened to review the safety, benefits, and risks of drospirenone-containing oral contraceptive pills and the Ortho-Evra transdermal patch in light of emerging safety concerns regarding the risk of blood clots in the legs and lungs (arterial and venous thromboembolic events, or ATE and VTE). The body of evidence on whether drospirenone-containing birth control pills elevate women's risk of VTE is mixed and there are methodological shortfalls associated with a number of the studies. A recent large [FDA study](#) found that the absolute risk of developing blood clots with drospirenone-containing oral contraceptive pills is low, but appeared to be higher than for older oral contraceptives, with 10 in 10,000 women taking pills over a year estimated to develop blood clots with drospirenone-containing OCPs, compared with 6 in 10,000 women taking older oral contraceptives; the risks for both are lower than those associated with pregnancy, which is 20 in 10,000 women over a year.

After reviewing the evidence, the FDA panel voted 15-11 that the benefits of drospirenone-containing oral contraceptives for prevention of pregnancy outweigh their risks; however, in a second vote they recommended 21-5 that labeling on Yaz, Yasmin, and other drospirenone-containing oral contraceptive pills be revised to better highlight the risks of blood clots. In a separate meeting, the panel concluded 19-5 that the Ortho-Evra patch may be associated with a higher risk of blood clots than older drugs, but should remain available as an option for women.

[Click here](#) for coverage of the panel's decision on OCPs in *Time*.

[Click here](#) for coverage in the *New York Times* on the panel's decisions on OCPs and [here](#) for coverage on the transdermal patch.

Editorial on pharmacy access models for reproductive health care

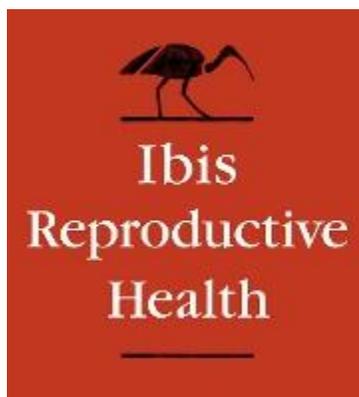
Downing D. Inviting the pharmacist: A model for improved reproductive care access. *Contraception*. 2012;85(1):2-4.

Click [here](#) to read this editorial by Don Downing on collaborative models of pharmacy practice and the role pharmacists can play in supporting access to reproductive health care.

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.



www.ibisreproductivehealth.org

Contact us

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