

April 30, 2012

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### Dear Working Group Member,

In this month's update from the OCs OTC Working Group, we provide information about last month's FDA public hearing on a possible change in how OTC drugs are approved, as well as data from the evaluation of a pharmacy access OC provision model in London. We also highlight new research on women's interest in OTC access in the US and on the barriers that 17 year olds still face trying to obtain OTC emergency contraception.

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

### FDA holds public hearing on "conditions of safe use" to expand drugs considered for OTC sale

On March 22 and 23, the FDA held a public hearing on using innovative technologies and other conditions of safe use to expand which drug products can be considered non-prescription. Much of the hearing focused on the potential for pharmacists to play a more active role in drug therapy, but there was also discussion about the use of computerized kiosks or other tools. Such technology could help users determine if an OTC drug is appropriate for them, and might also help with ongoing use.

While much of the discussion concentrated on medications for hypertension, asthma, and severe allergies, three of the presentations focused on oral contraceptives:

- Elizabeth Dawes of the Reproductive Health Technologies Project [explained](#) how the prescription requirement is a barrier to contraceptive access and highlighted how the recent decision surrounding Plan B One-Step is an example of how *not* to reduce these barriers.
- Dan Grossman gave an [overview](#) of the data supporting an OTC switch for OCs and how the conditions of safe use being considered by the FDA were particularly relevant for combined OCs.
- Bimla Schwarz from the University of Pittsburgh presented preliminary findings from her [research](#) on a kiosk that provides information about and screening for hormonal contraception in an acute care setting.

Our presentations were highlighted in this piece on *Bloomberg Businessweek*: [Doctors pressure FDA for nonprescription birth control pills](#).

The FDA is accepting written comments on this topic until May 7, 2012, and Dan plans to submit a written version of his presentation. If you are interested in submitting comments and would like to discuss your submission, please email [Dan](#). It seems likely that the FDA would have to proceed through a rule-making process to develop the framework for this new paradigm, which would likely take several years. For more information, please see the [hearing announcement](#) in the Federal Register.

Also, check out this article by Elizabeth Dawes that highlights how technology and other service-delivery innovations are improving access to contraception in Wisconsin: [Winning in Wisconsin: Changing the game with innovations in contraceptive service delivery](#).

### **UK National Health Service recommends expansion of pharmacy access program based on evaluation of London pilot**

In 2009, a pilot pharmacy access project was launched in several London pharmacies where trained pharmacists provided OCs without a prescription. The [evaluation](#) of the project was just released, and it has attracted a great deal of press attention in the UK. Over a period of 21 months, five pharmacies provided over 700 consultations, of which about 70% resulted in an initial supply of contraception. Almost half of the women receiving OCs were first-time users. The vast majority of women accessing the service were under 30 years old, and 23% were 19 or younger (the project had a minimum age requirement of 16; three clients seeking services were referred because they were younger than 16). Questionnaires with clients found that they were very satisfied with the pharmacies' services, and a mystery shopper evaluation was also quite positive. Based on the evaluation, the NHS recommends expanding the service nationally, as well as considering expanding it to women under age 16.

Here are links to some of the press coverage of the evaluation:

- *BBC News*: [Widen over-the-counter pill access, says NHS report](#)
- *Mail Online*: [Girls aged 13 'should be given the contraceptive Pill from pharmacies without a prescription' claims NHS report](#)

- *Marie Claire*: [Should the pill be available without a prescription?](#)

A similar pilot project is being launched in Aberdeen, Scotland, where women age 16 and older will be able to access the pill from trained pharmacists. For more information, see this article in *The Scotsman*: [Women to get the Pill direct from pharmacist](#).

### Study highlights women's interest in OTC access to oral contraceptives, as well as concerns about cost and safety

Dennis A, Grossman D. Barriers to Contraception and Interest in Over-the-Counter Access Among Low-Income Women: A Qualitative Study. *Perspectives on Sexual and Reproductive Health* 2012;44(2):84-91. Click [here](#) for the article, and below is the abstract:

**CONTEXT:** Barriers to contraceptive access encourage nonuse and gaps in use, which contribute to the high prevalence of unintended pregnancy in the United States. One strategy to improve access to oral contraceptives is to make them available without a prescription.

**METHODS:** From March 2007 to January 2009, focus group discussions and in-depth interviews were conducted with 45 low-income women in the Boston area to explore how they obtain contraceptives and their opinions about making oral contraceptives available over the counter. Transcripts of the discussions and interviews were deductively and inductively coded. Data were analyzed thematically, and illustrative quotes were extracted.

**RESULTS:** Overall, participants reported ease in obtaining contraceptives, which were available at multiple accessible locations throughout Boston. However, various barriers—unaffordable copays and clinic visits, the time required for clinic visits, restrictions on the number of packs of prescription contraceptives (e.g., the ring, the pill) purchased monthly and the limited time frame in which to purchase them—deterred consistent use of preferred methods. Most participants supported over-the-counter access to oral contraceptives; however, they raised concerns about cost, as well as the safety of such access for minors, first-time users and women with medical conditions.

**CONCLUSION:** Women's concerns about over-the-counter access to contraceptives must be addressed if this approach is to improve use and potentially help reduce the unintended pregnancy rate.

The article was highlighted in this blog posting: ['On Minimum Wage, It's a Lot of Money': Poor Women Talk About Birth Control](#).

### New research finds barriers to OTC access to EC for 17 year olds in the US

Wilkinson TA, Fahey N, Shields C, Suther E, Cabral HJ, Silverstein M. Pharmacy Communication to Adolescents and Their Physicians Regarding Access to Emergency Contraception. *Pediatrics* 2012; 129(4):624-9. Click [here](#) for the article.

In 2009, the US Food and Drug Administration (FDA) made Plan B emergency contraception available without a prescription to consumers age 17 years or older in the US (those younger than 17 require a prescription); however, a study recently published in the journal *Pediatrics* found that the age restrictions lead to misinformation regarding who can take EC, and at what

age it is available without a prescription. In the study, female callers telephoned 943 pharmacies in five US cities posing as 17-year-old adolescent patients or as physicians calling on behalf of their 17-year-old patient. The pharmacies selected were in locations representative of the 41 states without pharmacy access laws. While 80% of pharmacies reported that EC was available that day, one in five pharmacies incorrectly told the adolescent callers that it would be impossible to obtain EC under any circumstances, compared with 3% of physician callers; 36% and 33% of adolescents and physicians, respectively, were not offered additional suggestions for how to obtain EC. Roughly two-fifths of adolescent callers (43%) and physicians (39%) were given the incorrect age (usually higher) when they asked about the threshold for access to EC without a prescription. This study shows the significant access barriers that adolescents face in accessing EC under current federal regulations imposing an age limit--and it highlights how important it is to ensure that a future OTC daily oral contraceptive does not have an age restriction.

### **American Public Health Association releases policy statement supporting insurance coverage for OTC contraceptives**

As noted in a previous update, at its annual meeting in November 2011, APHA approved a policy statement entitled "Improving Access to Over-the-Counter Contraception by Expanding Insurance Coverage." The [policy statement](#) has been finalized by APHA and is available on its website. Below are the statement's final recommendations:

Recognizing the public health benefit of improved access to contraception, including barrier methods to prevent STIs, APHA urges-

1. 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;
2. Federal, state, and 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;
3. 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.

### **Get involved in the OCs OTC Working Group!**

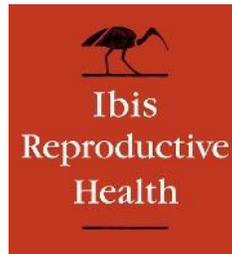
There are several ways you can get involved in the working group. If you haven't already, please sign on to our [statement of purpose](#). We welcome both institutional and individual endorsements. Another way is to write a blog post, op-ed, or piece in your organization's

newsletter or campus newspaper. If you are interested in this, we would be happy to help provide feedback and background articles, as well as help you think about ways to frame the piece. And finally, we're starting to plan a working group meeting for later this year. If you have ideas about what you'd like to see covered at that meeting, please let us know. You can email [Dan](#) or [Kate](#) with any questions, comments, or other ideas.

## 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](http://www.ibisreproductivehealth.org)

## Contact us

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