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In This Update

<u>The Atlantic magazine names</u> OCs OTC as one of the best new ideas for 2012

New and improved FAQs on the OCs OTC website

New research on progestinonly OC users in the US

Recent media coverage related to OCs OTC

Get involved in the working group!

About us

Contact us

Dear Working Group Member,

As summer winds down and we head into a busy fall, I wanted to let you know that the next OCs OTC Working Group meeting will take place on October 22, 2012, in Washington, DC. We will be sending out a preliminary agenda in the next few weeks, but if you are interested in attending, please let Kate or me know as soon as possible. We will be holding a small block of hotel rooms, and we will have a limited amount of travel support available.

In the update below, we provide information about new research and media coverage relevant to the working group. Perhaps most interesting is the piece from *The Atlantic* magazine, which named making the pill OTC one of the best new ideas for 2012.

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

Thanks,

Daniel Grossman, MD

Vice President for Research, Ibis Reproductive Health

The Atlantic magazine names OCs OTC as one of the best new ideas for 2011

The July-August issue of *The Atlantic* magazine included the Ideas List 2012, their "annual compendium of prescriptions, provocations, and modest proposals for making the world a better place." Featured prominently among the 23½ ideas was "sell the pill over the counter." Here's the great <u>idea</u>:

Oral contraceptives are some of the safest and most effective drugs on the market. Yet they remain irrationally difficult for many women to obtain, and not just those working at Catholic institutions. Most doctors prescribe the pill for one year, requiring women to receive full pelvic exams in order to re-up; on top of that, many health insurers dole out pills only one month at a time. These barriers can thwart consistent use, increasing the odds of unintended pregnancy--and abortion.

There's a simple solution here: sell the pill over the counter. Oral contraceptives have long met most of the FDA's over-the-counter criteria, and recent research has shown that annual Pap smears not only are superfluous, but often lead to false positives and expensive follow-up testing. Reserving the pill as a reward for a regular checkup with a gynecologist is no longer just condescending--it's also medically unsound.

Here's a link to the full Ideas List.

New and improved FAQs on the OCs OTC website

In our June 2012 update, we mentioned a new Frequently Asked Question (FAQ) that we added to the working group website discussing <u>pelvic exams</u> as an unnecessary barrier for contraceptive access. Since then, we have been busy revising and updating our other FAQs about moving OCs OTC to include information from recently published research related to an OTC switch. We have also created some new FAQs based on emerging contraceptive access issues such as health care reform, out-of-pocket expenses and cost sharing for contraception, and the feasibility of a "pharmacy access" model. Check out the full list of FAQs <u>here</u> and the new ones below:

- Why move OCs OTC?
- What is the likely impact of health care reform on women's contraceptive access?
- Will OTC contraception be available without cost sharing under the new health care law?
- Would women's out-of-pocket expenses for OCs increase if they were to go OTC?
- Given the new no-cost sharing benefit for contraception under health care reform, is there still a need to make OCs available OTC?
- Could pharmacy provision of OCs improve access to effective contraception?
- Is there anywhere in the world where OCs are already available OTC?

We hope you find the new and updated FAQs informative and relevant. If you have ideas for additional questions please <u>contact Kate</u>.

New research published on who uses progestin-only OCs in the US and their out-of-pocket expenditures

A new study using nationally representative data found that only about 4% of OC users took progestin-only pills (POPs) during the period 1996-2008. Compared to women who took combined OCs (COCs, or pills with estrogen), POP users were more likely to be older, in the postpartum period, or to have certain medical conditions like high blood pressure. No association between race/ethnicity and POP use was observed. POP users were more likely to

pay more than \$15 per pack and to receive only one pack of pills at a time.

Since it seems likely that the first OTC OC in the US would be a POP formulation, this study has important implications. First, it highlights how women may be unfamiliar with POPs, and it will be important to inform women about this type of pill as the OTC switch process moves forward. In addition, the study suggests that physicians may be biased against this formulation, thinking that POPs are only appropriate for a narrow segment of the population with certain conditions. In fact, the US Medical Eligibility Criteria cites fewer contraindications to POPs compared to COCs, meaning that the former should be appropriate for more women. In order to counter any physician opposition to an OTC switch, it will be important to understand their concerns and address them with relevant evidence.

Please see the abstract below, or email to request a copy of the article.

Liang S-Y, Grossman D, Phillips K. User characteristics and out-of-pocket expenditures for progestin-only versus combined oral contraceptives. *Contraception*. 2012 Jul 6. [Epub ahead of print].

Background: Little is known about the proportion of oral contraceptive pill (OCP) users that use progestin-only pills (POPs), factors associated with POP use, and whether out-of-pocket expenditures and dispensing patterns are similar to combined oral contraceptives (COCs).

Study Design: Observational cohort using 1996-2008 Medical Expenditure Panel Surveys.

Results: Among all OCP users, 4% used POPs and changed little between 1996 and 2008. Women were more likely to use POPs if they received postpartum care (p<0.001), had a diagnosis of hypertension (p<0.001), or resided in the West (p<0.01). POP users, compared to COC users, were more likely to pay \$15 and more (p<.01) and less likely to obtain more than one pack per purchase (p<0.001), controlling for age, race/ethnicity, and insurance coverage.

Conclusion: POP use is very low in the United States. POP users obtained fewer packs per purchase compared with COC users, suggesting that POP may be used as transitional OCPs, particularly during the postpartum period.

Recent media coverage related to OCs OTC

The May issue of *Contraceptive Technology Update* (CTU) featured an <u>article</u> entitled "Progestin-only pill eyed as OTC OC candidate" that highlighted the <u>recent paper</u> by White et al. documenting the low prevalence of contraindications to POPs. It also presented findings from a survey of CTU readers in 2011 that found that about 20% supported OTC availability of the pill, and 23% supported pharmacy access to OCs.

An <u>article</u> in *The Tan Sheet* entitled "Birth Control Primed for Switch" focused on Dan Grossman's testimony at the FDA public hearing on OTC conditions of safe use.

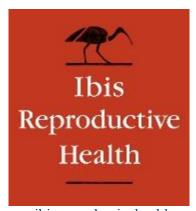
Get involved in the OCs OTC Working Group!

There are several ways you can get involved in the working group. If you haven't already, please sign on to our <u>statement of purpose</u>. 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 the October 22 working group meeting. If you have ideas about what you'd like to see covered at that meeting, please let us know. You can email <u>Dan</u> or <u>Kate</u> 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

Contact us

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