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Dear Working Group Member,

In this month's update, we highlight new research from the [Border Contraceptive Access Study](#) demonstrating that women using OTC OCs continue to get Pap smears and other preventive screening at high rates. On a related topic, we have added a new [Frequently Asked Question](#) about how pelvic exams should not be required in order to obtain OCs. We also summarize a recent session held by the working group at the [Civil Liberties and Public Policy 26th Annual Conference](#).

In addition to our [interactive map](#) documenting the prescription requirements for OCs around the world, we are hoping to highlight efforts in other countries to improve access to hormonal contraception. Below, Françoise Tourmen of the French Association for Contraception provides us with an update about efforts in France to make oral contraceptives available in pharmacies without a prescription.

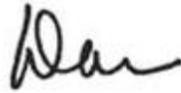
And while projects in several countries move forward to make OCs OTC, we were disappointed to learn that the South Korean FDA recently reversed its policy on OCs, which are currently available OTC but will require a prescription as early as next year. [Reactions](#) to this decision have been mixed, but the Korean Women's Association United criticized the decision, saying, "Classifying oral contraceptives as prescription medicine is tantamount to removing women of their right to make a decision on pregnancy." While this decision came in the context of good news about making emergency contraception available OTC, it is unclear why the KFDA made the decision to start requiring a prescription for OCs.

In our [last update](#), we included information about the FDA's recent public hearing on a possible new paradigm for approval of OTC drugs that would include "conditions

of safe use." I submitted written comments to the FDA based on my testimony at the hearing, which you can access [here](#).

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

Thanks,



Daniel Grossman, MD
Senior Associate, Ibis Reproductive Health

Women accessing OCs OTC continue to get Pap smears and other recommended screening

One concern about an OTC switch for OCs that has been voiced by physicians is that women won't get screening for cervical cancer or sexually transmitted infections if they are not forced to see a clinician to obtain a prescription for their birth control. Other [research](#) has found that women not using hormonal contraception continue to have high rates of screening for cervical cancer. But now research from the Border Contraceptive Access Study sheds new light on this issue. In this study, about 500 women living in El Paso, Texas, who obtained pills OTC in Mexico were compared to a similar number of women obtaining pills in El Paso clinics. The researchers found that 91% of OTC users had had a Pap smear within the prior three years. While this was lower than the almost universal screening among clinic users, it was above the US national average of 85%. The most common reason OTC users gave for not getting a recent Pap was because it was too expensive. The authors conclude by writing, "If barriers to access are an important reason why women fail to obtain recommended screening, it is likely that the prescription requirement for OCs only limits their access to contraception, rather than improving their access to screening."

Please see the abstract below, or [email us](#) to request a copy of the article. This research was highlighted in a recent online article in Mother Jones: [Holding Birth Control Hostage](#).

Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users.

Hopkins K, Grossman D, White K, Amastae J, Potter JE. *Contraception*. 2012 Apr 19. [Epub ahead of print]

Background: Interest is growing in moving oral contraceptives over-the-counter (OTC), although concerns exist about whether women would continue to get preventive health screening.

Study Design: We recruited cohorts of US-resident women who obtained oral contraceptives from US family planning clinics (n=532) and OTC from pharmacies in Mexico (n=514) and interviewed them four times over 9 months. Based on self-reports of having a Pap smear within 3 years or ever having had a pelvic exam, clinical breast exam, and testing for sexually transmitted infections (STIs), we assessed the prevalence of preventive screening using Poisson regression models.

Results: The prevalence of screening was high for both groups (>88% for Pap smear, pelvic exam, and clinical breast exam and >71% for STI screening), while the prevalence ratios for screening were higher for clinic users, even after multivariable adjustment.

Conclusions: Results suggest that most women would obtain reproductive health preventive screening if oral contraceptives were available OTC, and also highlight the need to improve access to preventive screening for all low-income women.

Improving access to hormonal contraception in France

By Dr. Françoise Tourmen, Association Française pour la Contraception

Hormonal contraception in France is provided by physicians and, for the past three years, midwives (only for women in good health). Fifty-seven percent of reproductive-aged women use pills and 27% use the IUD. However, the number of unintended pregnancies and the abortion rate have not decreased and have even slightly increased over the past ten years. This is the French dilemma. Since 2002, levonorgestrel emergency contraception (EC) has been very easy to obtain: it is available OTC in all pharmacies (23,000 pharmacies in France), refundable with prescription (it costs 6.5 €, or \$8.6 US Dollars), and it is free and anonymous for people under the age of 18 in pharmacies, schools (from school nurses), and family planning clinics. Yet this expanded EC access has not reduced the abortion rate. Furthermore, there are health worker shortages that limit access to prescription methods of contraception, and for these reasons we must offer a new means of access to hormonal contraception. Unfortunately, we have faced opposition from society and from many physicians.

In 2009, a new law authorized a pilot project that would have allowed direct access to OCs in pharmacies, where trained pharmacists would use a checklist based on the [Washington Direct Access Study](#) model. But the Conseil Constitutionnel (equivalent to Senate) refused to approve this project because of one detail: the duration of the pilot had been omitted. For three years, physicians and two pharmacist syndicates (unions) worked to correct this oversight, but they ran up against opponents in spite of the favorable recommendations from the IGAS (Inspection Générale des Affaires Sociales) and from the Pharmacists' Academy.

The availability of OTC progestin-only oral contraceptive pills (POPs), with very low contraindications, may be the best choice for France, but it has run up against the law: all the pills are registered on a list of poisonous substances. It is necessary to remove this barrier, which opponents will use even though many potentially harmful drugs in France are available OTC, including paracetamol (acetaminophen) and non-steroidal anti-inflammatory drugs. In addition, POPs are typically reserved for breastfeeding and in cases of absolute contraindications to combined oral contraceptives (COCs).

We are also working to transfer medical responsibility to other health professionals, such as nurses and pharmacists, and for new legal possibilities, such as using checklists. This project has generated interest in public hospitals and family planning clinics, but administrative procedures are long and complicated, and the first applications have only just been submitted. Time will tell if this scheme can be established in the private sector in France. We had hoped that a decree would be issued at the end of Nicolas Sarkozy's presidency that would have allowed a six-month renewal of pills in a pharmacy, but it was never issued. We have high expectations for François Hollande and his administration.

In conclusion, there are still many difficulties and oppositions in France to liberalizing access

to hormonal contraception from a political, administrative, and also professional point of view. In this difficult context, foreign experiences and new ideas are crucial.

OCs OTC at the Civil Liberties and Public Policy 26th Annual Conference

In April 2012, the working group convened a panel session at the Civil Liberties and Public Policy 26th Annual Conference entitled, "The Pill: Over-the-Counter and (Under Your Control??)." Kate Grindlay, a Senior Project Manager at Ibis Reproductive Health, Anjela Jenkins, a Policy Analyst, attorney, and Law Students for Reproductive Justice Legal fellow at the National Latina Institute for Reproductive Health, and Vanessa Cullins, the Vice President for External Medical Affairs at Planned Parenthood Federation of America, were on the panel. During this workshop, we discussed why, 50 years after the FDA's approval of the pill, advocates are pushing to move it over the counter now, and the potential impact this might have on women of color, low-income women, undocumented women, and young women. We then presented information based on research on a variety of key things we need to think about related to having a pill available over the counter, including: the safety and effectiveness of a pill that women could get without seeing a doctor, and why we have chosen a progestin-only pill as the first pill to move OTC; cost and insurance coverage of an OTC pill; women of color's access to preventive health services; and health care reform and how it impacts this discussion. We also went over the process of how an oral contraceptive pill might actually change to being available over the counter. Finally, we devoted the bulk of the session to an interactive discussion and question-and-answer period to allow participants to reflect on how their priorities and the priorities of their communities can be incorporated into and shape the advocacy and public dialogue around this issue.

Overall, OCs OTC received a positive response at the conference. There was an active discussion in the panel session, and participants seemed enthusiastic about the idea of an OTC product, although some expressed concerns about young teens and whether they would have the capacity to use the pills correctly and consistently. Some participants also expressed cynicism about the feasibility of a switch in light of the political climate and recent EC/FDA experience; however, at the same time many felt that the political climate was precisely the reason we need an OTC option now.

This session was recently highlighted in the blog, The Provider Project: [Birth Control On Demand, Without Apology, and Over-the-Counter!](#)

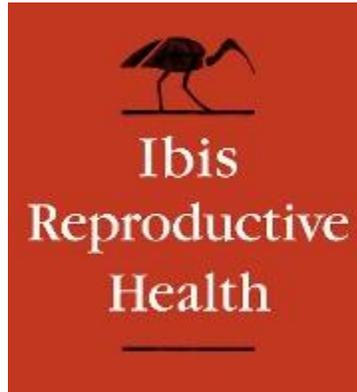
Get involved in the OCs OTC Working Group!

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

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