

April 12, 2013

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### Dear Working Group Member,

We wanted to share several developments related to the OCs OTC Working Group. As many of you know, last Friday a federal district court ruled that the FDA must lift the age restriction on over-the-counter emergency contraception within 30 days, which will give all women access to truly OTC EC and paves the way for a future OTC OC without an age restriction. Please click [here](#) to see our statement about the court's decision. There has been a great deal of media coverage of the EC ruling, and one article on TIME.com made the connection with a future OTC OC.

In addition, the Department of Health and Human Services (HHS) clarified in February that OTC contraceptives must be covered by new private health plans without cost sharing under the ACA, but the woman must have a prescription. This guidance clarifies that at least for plans governed by the ACA, there is no risk that women will lose insurance coverage for oral contraceptives if one or more formulations become available OTC--and in fact women could even use their insurance to obtain an OTC OC. Our goal remains insurance coverage without a prescription, a [policy](#) that was endorsed by the American Public Health Association in 2011, and we are exploring strategies to attain that objective. Please see [below](#) for more information about the recent HHS guidance.

Finally, several articles have been published in recent months related to an OTC switch for OCs. I authored an article in the current online edition of Annals of Internal Medicine entitled "[Moving Oral Contraceptives Over-the-Counter as a Strategy to Reduce Unintended Pregnancy](#)" that builds on the recent Committee Opinion issued by the American College of Obstetricians and Gynecologists (ACOG) in support of an OTC switch and highlights more recent evidence. Several other recent articles are summarized below, including a paper on the global prescription requirements for OCs, and a survey of resident physicians about their support for an OTC switch for OCs.

If you have any questions or comments about this update, please let me know.

Thanks,

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

Daniel Grossman, MD  
Vice President for Research, Ibis Reproductive Health

## **FDA-approved OTC contraceptives must be covered by new private insurance plans without cost sharing under the ACA, but the woman must have a prescription**

In February, the Department of Health and Human Services (HHS) released a set of [Frequently Asked Questions \(FAQ\)](#) that address implementation of the Affordable Care Act's preventive services requirement, including the requirement that insurers cover contraception and other women's preventive health services without cost sharing. We are pleased that the FAQ clarifies that insurers must cover FDA-approved over-the-counter contraceptive methods used by women--but unfortunately a woman must get a prescription from a health care provider to use her insurance for OTC contraception. The FAQ also emphasizes that insurers must cover the range of FDA-approved contraceptive methods, including IUDs and implants (male condoms are not covered because men are not included in the women's preventive services guidelines). While plans may use "reasonable medical management" to control costs (for example, covering a generic drug without cost sharing, but imposing cost sharing on the brand name), plans must have a waiver process so that a woman is able to obtain the method her health care provider determines is best for her. The National Women's Law Center developed an excellent [summary of the FAQ](#). The OCS OTC Working Group is pursuing several strategies to ensure that public and private insurance plans cover a future OTC OC, ideally without requiring a prescription. Please contact [Britt Wahlin](#) if you would like to get involved in this work.

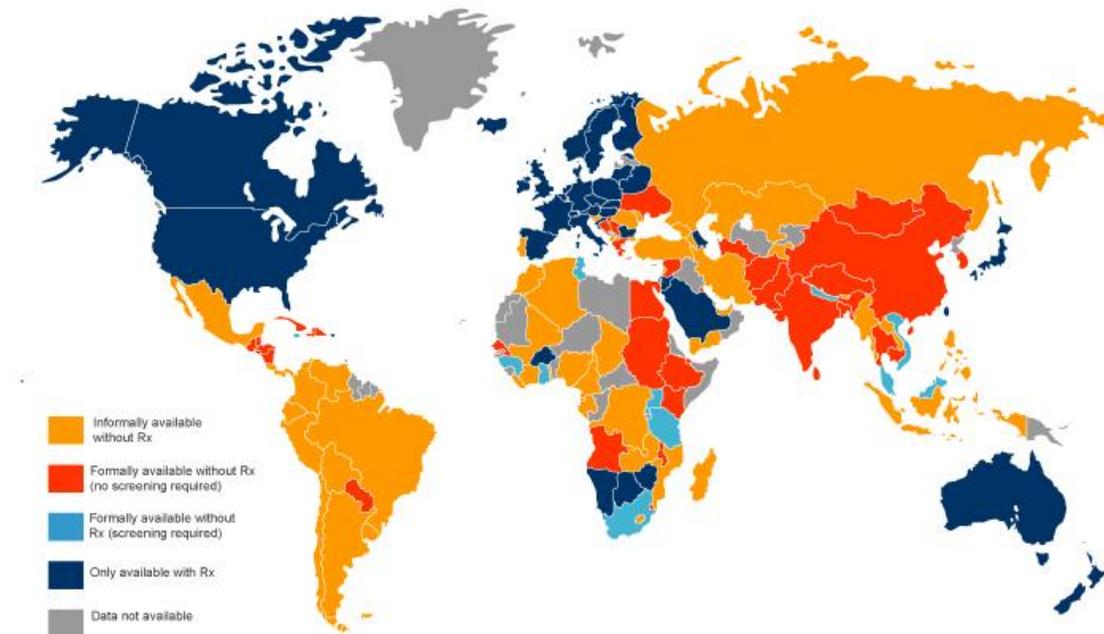
## **Prescription requirements and over-the-counter access to oral contraceptives: a global review**

From April 2011 to September 2012, we researched official documentation and conducted an online survey with government officials and pharmaceutical and reproductive health specialists to ascertain the prescription requirements and informal OTC availability of OCs in 147 countries worldwide.

We found that OCs are available without a prescription in nearly 70% of countries surveyed, and the majority of the world's population lives in countries with OTC access. OCs were informally available without prescription in 38% of countries (n= 56), legally available without prescription (no screening by a health professional required) in 24% of countries (n=35), legally available without prescription (but with required screening) in 8% of countries (n=11), and available only by prescription in 31% of countries (n=45).

Mapping these findings highlighted geographic and socioeconomic patterns of prescription requirements, with most OTC availability in low- and middle-income countries. The United States, Canada, and most of Western Europe require a prescription, while OCs are available OTC informally in much of Central and South America and legally in much of Southern Asia. Prescription and screening requirements in Africa are more varied. These data can be used by policymakers, reproductive health researchers and advocates, program planners, and women seeking information on OC prescription requirements and informal access in countries around the world. Country experiences with OTC provision may also provide evidence about the safety and effectiveness of this model and serve as an example for other countries considering removing the prescription barrier to OCs. Please visit our [interactive map](#) that displays the results of this research.

## Global Oral Contraception Availability



**Source:** Grindlay K, Burns B, Grossman D. Prescription requirements and over-the-counter access to oral contraceptives: a global review. *Contraception*. 2012. doi: 10.1016/j.contraception.2012.11.021.

### Study: Physician attitudes toward over the counter availability for oral contraceptives

This study surveyed primarily Ob/Gyn and Family Medicine residents about their opinions regarding an OTC switch for OCs. The majority of respondents were against an OTC switch for both combined OCs and progestin-only pills (POPs), although respondents had more favorable views about OTC POPs. The survey had a very low response rate (4%), but it gives some idea of the negative perceptions that at least physicians in training have about OTC OCs--and identifies areas of misinformation among physicians regarding the safety of OCs used without a prescription. The article is available [here](#), and the abstract is below:

To assess physician attitude towards making oral contraceptives available over the counter in the United States (US). We assessed physician attitudes towards a transition from prescription only to over-the-counter availability (rx-OTC) for oral contraceptive pills by disseminating an electronic survey directed primarily to residents training in Obstetrics and Gynecology (OBGYN) and Family Practice in the US. An overwhelming majority of 638 respondents (71%) were against an rx-OTC switch for combined oral contraceptives and among this subset of respondents the primary concern was safety (92.3%). Overall, respondents were evenly divided on the issue of an rx-OTC switch for progestin-only-pills but of those who opposed, 73.2% cited safety as their primary concern. For progestin-only-pills female respondents were more likely to support OTC availability. Most OBGYN and Family Practice residents opposed to OTC availability for oral contraceptives cite safety as their primary concern. Considering the abundant evidence as to the overall safety of oral contraceptives, especially progestin-only-pills, there appears to be a knowledge deficit among OBGYN and Family Practice residents regarding the safety of oral contraceptives.

**Source:** Howard D, Wall J, Strickland J. Physician attitudes toward over the counter availability for oral contraceptives. *Matern Child Health J*. 2012; doi:10.1007/s10995-012-1185-6.

## Get involved in the OCs OTC Working Group!

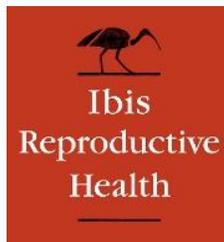
There are several ways you can get involved in the working group. If you haven't already, please sign on to our [statement of purpose](#). We are very pleased that over 50 organizations and individuals have signed on to the statement, including most recently ACOG, the Association of Reproductive Health Professionals, the Center for Reproductive Rights, Choice USA, NARAL Pro-Choice America, the National Health Law Program, the National Institute for Reproductive Health, the National Partnership for Women & Families, and Nursing Students for Choice, among many others.

Another way you can get involved in the working group 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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