

Moving the birth control pill over the counter in the United States

INTRODUCTION >>

The birth control pill, also called oral contraception or 'the pill,' is a popular contraceptive method that has been around for over 50 years. Over 80% of women who have been sexually active have used the pill at some point, but still half of all pregnancies in the United States are unintended, and many of these occur because women who weren't trying to get pregnant were not using birth control consistently or at all.

Requiring a prescription for the pill is a barrier for many women, including those without access to a health care provider, transportation, child care, or insurance. Research indicates that making the pill available over the counter (OTC) would lead to greater use of effective birth control and lower rates of unintended pregnancy. An OTC pill would remove the unnecessary burden of requiring a woman to visit a doctor to get the birth control she needs. The most likely process for an OTC switch is for a pharmaceutical company to submit an application to the Food and Drug Administration (FDA) to make a specific pill product available as a nonprescription drug.

SAFETY AND EFFECTIVENESS >>

The pill is safe for most women to use, meets all of the FDA's criteria for OTC sale (see table below), and has a strong safety profile, including compared to currently available OTC medications.

FDA criteria	Oral contraceptives
Drug has no significant toxicity if overdosed	True
Drug is not addictive	True
Users can self-diagnose conditions for appropriate use	Women are able to determine if they are at risk of unintended pregnancy
Users can safely take the medication without a clinician's screening	Research shows that women can self-screen for contraindications without involving a clinician
Users can take the medication as indicated without a clinician's explanation	Research shows that continuation is similar/higher among women obtaining pills OTC compared to in a clinic

Complications associated with the birth control pill are rare and the benefits outweigh the risks for most women. And while some women face risks associated with using the pill, research shows that with the help of a simple checklist, women can determine if the pill is safe for them to use or if they should consult with a health care provider to discuss other options.

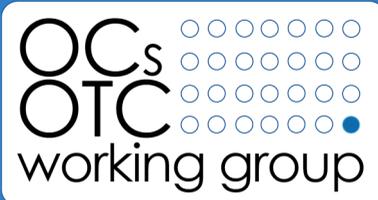
Progestin-only pills (POPs), which do not contain estrogen, have even fewer contraindications (conditions that make use inadvisable) than combined oral contraceptives (COCs), making them an excellent candidate for the first OTC birth control pill in the United States. A very small proportion of women have health conditions that would make use of a POP harmful.

A pelvic exam is neither medically necessary nor required in order to start taking birth control pills. Furthermore, research suggests that women still get recommended preventive screening like Pap smears even if they obtain contraception OTC.

Moreover, OTC access to the pill may help improve continuation. In a study of women living in Texas, those who obtained the pill OTC in Mexico were found to stay on the pill significantly longer compared to those who obtained pills by prescription in US clinics.

WOMEN'S INTEREST >>

In a 2011 national survey of 2,046 US women, 62% said they supported OTC access to the pill, and 37% said they were likely to use an OTC pill if one were available. About 30% of women using no contraceptive method or a less effective method (like condoms) said they were likely to start using the pill if it were available OTC. Women of all racial and ethnic groups and at every educational level had similar interest in using an OTC pill.



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COST AND INSURANCE >>

The Affordable Care Act (ACA) requires insurance companies to cover OTC contraceptives for women, but a prescription is needed. Some state Medicaid programs cover OTC contraception without a prescription, though most require a prescription for coverage of OTC methods, like emergency contraception (EC).

Requiring a prescription for insurance coverage undermines the benefits of OTC access. Public and private insurers should enable women to get OTC birth control on the spot at the pharmacy or drugstore without a prescription. State Medicaid programs currently covering OTC EC without a prescription may provide useful models. TRICARE, which provides health care for military personnel, also covers OTC EC without a prescription.

Even after the ACA, millions of women, including many low-income women, young women, women of color, and immigrant women, still do not have insurance coverage. Others have insurance plans that do not cover birth control due to religious exemptions. In the 2011 survey, the majority of respondents likely to use an OTC birth control pill (66%) were unwilling to pay more than \$20 per month. Therefore, in order to have the greatest impact, an OTC birth control pill must be affordable for all women.

CLINICAL PERSPECTIVES >>

Leading medical groups, including the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians, support making the pill available OTC. The American Medical Association passed a resolution in support of manufacturers applying to the FDA for an OTC switch for the pill. The American Public Health Association urges insurance providers, including Medicaid, to

cover OTC contraceptives without requiring a prescription. The American College of Clinical Pharmacy supports OTC sale of the pill if covered by Medicaid and sold with a pharmacist available for consultation.

INTERNATIONAL EXPERIENCE >>

The pill is already available OTC in over 100 countries. A 2012 study found that among 147 countries surveyed, the pill was informally available without prescription in 38% of countries, legally available without prescription (with no screening by a health professional required) in 24% of countries, legally available without prescription (screening required) in 8% of countries, and available only by prescription in 31% of countries.

IMPACT >>

Interest in OTC access to the pill is high. Removing the prescription barrier, particularly if pills are available at low or zero out-of-pocket cost, could increase the use of effective methods of contraception and reduce unintended pregnancy and costs for pregnancy care.

Planned pregnancies are more likely to lead to healthy outcomes for women and their children. An OTC option for the pill could improve women's access to contraception and help them plan their pregnancies.

Some women also use the pill to prevent or treat a number of medical conditions, including heavy bleeding during menstruation, acne, ectopic pregnancy, and iron-deficiency anemia, and for cancer prevention. OTC access would make it easier for these women to get the pill as well.

Moving a birth control pill OTC will reduce barriers to effective contraception and help women plan their families, and has the potential to significantly reduce unintended pregnancy in the United States.