Moving Oral Contraceptives Over the Counter as a Strategy to Reduce Unintended Pregnancy

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In December 2012, the American College of Obstetricians and Gynecologists (ACOG) released a Committee Opinion supporting over-the-counter (OTC) access to oral contraceptive pills (1). A growing body of evidence indicates that OTC provision of oral contraceptives is safe and effective and that women are interested in obtaining pills this way. With half of all U.S. pregnancies being unintended—a figure that has remained unchanged over the past decade—innovation is needed to improve uptake and ongoing use of effective contraceptive methods (2).

The principal question about the safety of an OTC pill is whether potential users could screen themselves for contraindications to use without the help of a clinician. Although oral contraceptives are safe for most women of reproductive age, some have contraindications that could put the user at risk for medical complications or reduce the effectiveness of the pill. In 2010, the U.S. Centers for Disease Control and Prevention issued the Medical Eligibility Criteria for Contraceptive Use, an evidence-based list of conditions and medications that are considered relative and absolute contraindications to contraceptive methods (3). For combined oral contraceptives, which contain estrogen and progesterin, all of the contraindications other than hypertension are identified by reviewing a woman’s medical history; progesterin-only pills have an even shorter list of contraindications that does not include hypertension. Several studies have shown that women can accurately identify these contraindications themselves using simple checklists (4).

Over-the-counter access also seems to be at least as effective as provision by prescription. A study from Kuwait, where oral contraceptives are available OTC, found that continuation of the pill was similar between women who did and those who did not consult with a physician (5). Another study in Texas found that women who lived near the border and obtained OTC pills in Mexico stayed on them substantially longer than those who obtained the pills by prescription in U.S. clinics (6).

At the recent North American Forum on Family Planning, we presented the results of a nationally representative survey of women at risk for unintended pregnancy about their interest in using OTC oral contraceptives. Thirty-seven percent of women reported that they were likely to use them, including 59% of current users and 30% of women using no method or a less-effective method (7). These findings suggest that OTC availability might reduce unintended pregnancy by increasing uptake of the pill among women not using an effective method and by reducing gaps in use among current users, but this remains to be proven.

Although an OTC contraceptive pill may sound revolutionary in the United States, OTC access is already a reality in many parts of the world—pills are available without a prescription in pharmacies in more than 100 countries. In some countries, such as India and China, the pills are officially available OTC, but in other countries, such as in most of Latin America, they are generally available without a prescription, although they technically are in a category of medication that should require one (8). In a few additional countries, innovative projects are under way that are aimed at improving access to contraceptive pills by relaxing the prescription requirement. In several London pharmacies, oral contraceptives are available directly from trained pharmacists, whereas in Australia, women whose prescriptions have expired are able to obtain a pack of pills directly from a pharmacy to tide them over until they can see their physician.

Some obstetrician-gynecologists have voiced concerns about OTC access to the pill, including whether women will appropriately self-screen for contraindications and whether they will continue to obtain recommended preventive screening for cervical cancer and sexually transmitted infections. A recent study from Texas found that a high proportion of women obtaining oral contraceptives from Mexico without a prescription obtained these screening tests at proportions that were higher than national averages (9). Moreover, the push toward delinking preventive screening from provision of prescription birth control has been growing. Both services are important, but there is no medical reason to make one contingent on the other. Rather than holding contraception hostage, physicians should emphasize the importance of evidence-based screening recommendations.

Even after ACOG’s statement of support, we will not be seeing an OTC oral contraceptive product on the shelf of a local pharmacy any time soon. The most likely way for this to occur would be for a pharmaceutical company to do a series of studies required by the U.S. Food and Drug Administration, which would review the data to determine whether the specific product is appropriate for OTC sale. The research would need to document that women can read and understand the product label, use that information to determine whether they are appropriate candidates for the product, and use the product correctly over time without the supervision of a physician. It remains to be seen whether any pharmaceutical company will move for-
ward with these studies, and with what product. The first OTC pills in the United States will probably be progestin-only pills because this formulation has fewer and rarer contraindications (10) and is similar to emergency contraceptive products that have already been approved by the U.S. Food and Drug Administration for OTC sale.

One area of concern is the price of OTC pills and whether insurance will cover them. If an oral contraceptive becomes available OTC at an inaccessible price, it is unlikely to have the desired effect of reducing unintended pregnancy. Although OTC medications have not traditionally been covered by insurance, there is some precedent for coverage of OTC products, such as antihistamines, nicotine replacement therapy, and OTC emergency contraception. Under the Patient Protection and Affordable Care Act, new private health insurance plans must cover all contraceptive methods approved by the U.S. Food and Drug Administration without copayments or deductibles. This coverage also applies to OTC contraceptives used by women, such as emergency contraception or spermicide, but the beneficiary must have a prescription.

The decision by ACOG to support OTC access to contraceptive pills was certainly bold, and it is likely that not all practicing obstetrician-gynecologists agree with it. But the evidence to date clearly indicates that oral contraception could be safely provided OTC and that women would use it effectively. Given the potential for opposition from various social and professional groups, the ACOG statement may help to motivate a pharmaceutical company or other sponsor to perform the required research for an oral contraceptive product to become available OTC. At the same time, advocacy will be needed to ensure insurance coverage of OTC contraceptives, ideally without a prescription, so that this effort has the greatest possible impact on unintended pregnancy. Making at least some formulations of the pill available without a prescription will increase the options available to women to help them better meet their contraceptive needs.

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