Editorials

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The Potential Impact of Over-the-Counter Access to Oral Contraceptives to Reduce Unintended Pregnancy

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Over the past five years, several advances have been made in the provision of contraceptive services that have markedly reduced barriers to access. Unquestionably, the most important development is the contraceptive coverage guarantee under the Affordable Care Act, which requires most health insurers to cover all methods approved by the U.S. Food and Drug Administration (FDA) without cost sharing such as copayments or deductibles. In some settings where the cost barrier has been removed and counseling has focused on method effectiveness, the uptake of long-acting reversible contraceptives—including intrauterine devices and implants—has increased significantly.[1]

However, the next big thing in birth control is already making news before it is even available: over-the-counter (OTC) access to oral contraceptives. Unlike the contentious debate over the availability of OTC emergency contraception, there has been little argument about the safety and effectiveness of OTC daily oral contraceptives. Although this could certainly change as the debate intensifies (particularly concerning adolescent use of OTC pills and insurance coverage), the clear support for OTC access by medical groups such as the American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG) has helped focus the discussion.[2,3]

Although there has been significant media coverage about the possibility of OTC oral contraceptives, it will likely be several years before birth control pills are sold on the pharmacy shelf. A company would need to conduct several studies with its specific product, including a label comprehension study showing that consumers understand a simple OTC label and can use the information to determine if the product is right for them, as well as an actual use study demonstrating that they use the product appropriately over time. These studies would then be submitted to the FDA to determine whether the specific pill used in the studies is appropriate for OTC sale. Once these studies begin, the quickest timeline for approval of an OTC product is approximately three years. No pharmaceutical company has publicly acknowledged that it is working toward this goal, but the support of medical groups could be instrumental in motivating a company to move forward.

The AAFP and ACOG policy statements supporting OTC oral contraceptives as a way to reduce unintended pregnancy are based on a thorough review of the evidence. Studies have shown that women can accurately use simple checklists to determine if they have contraindications to using hormonal contraception.[4] Data also indicate that women obtaining OTC oral contraceptives are significantly more likely to continue use than women obtaining prescriptions at clinics.[5] Surveys have found that U.S. women are very interested in using an OTC pill, and about one-third of women using no contraceptive or a method less effective than pills say they would be likely to start using an OTC oral contraceptive if one were available.[6] These study results and survey data suggest that making the pill available OTC would improve uptake and continuation of effective contraception, which could help to reduce unintended pregnancy.

However, future use of OTC oral contraceptives will be closely linked to price. In one survey, willingness to pay for an OTC pill dropped off precipitously beyond $20 per cycle.[6] In a recent cost modeling analysis, researchers found that full insurance coverage of an OTC pill without requiring any out-of-pocket expenditure from women would

result in the biggest reduction in unintended pregnancy.[7] The AAFP and ACOG statements include support for insurance coverage of OTC oral contraceptives without requiring a prescription to trigger such coverage.[2,3]

As efforts move forward to bring an OTC pill to market, there will certainly be areas of controversy. If the experience with levonorgestrel emergency contraception is any indication, the topic of an age restriction is likely to be raised. We learned with emergency contraception that increasing teenagers' access to contraceptives did not increase sexual risk-taking, and it might help improve use of more effective methods in this population.[8] However, it will be important to include adolescents in the studies required by the FDA (e.g., label comprehension study, actual use study) to determine whether OTC access is appropriate for this population. From a medical perspective, contraindications to oral contraceptives—especially combined oral contraceptives—are more prevalent among women 35 years and older compared with younger women.[4]

Despite our best hopes, OTC access to oral contraceptives will not be a universal remedy. In the cost modeling study previously mentioned, it is estimated that even with full insurance coverage, we would expect a reduction in unintended pregnancy of 7% to 25%.[7] This highlights how OTC access must be one component of a multipronged strategy aimed at improving access to all contraceptive methods, including long-acting reversible contraceptives, to help women better plan their pregnancies using the method best for them.

Professional societies such as AAFP and ACOG have played a pivotal role in articulating the safety and effectiveness of OTC oral contraceptives. These efforts will help ensure that OTC availability has the biggest possible impact on public health and on individual women's lives.

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