



Commentary

It's Time for Over-the-Counter Oral Contraceptive Pills

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In a historic first, the United States Food and Drug Administration (FDA) is considering an application for over-the-counter status for an oral contraceptive pill (OCP). In July 2022, this application from HRA Pharma proposed a prescription to over-the-counter switch for a progestin-only (norgestrel 0.075 mg) OCP. Over-the-counter OCPs offer unprecedented potential to dramatically increase access to a safe and effective form of contraception in the United States, particularly for adolescents, and it's time for the FDA to make them available.

OCPs are the most commonly used prescription contraceptive in the United States, and over 80% of sexually active women in the United States have used an OCP at some time [1]. OCPs are especially popular among adolescents [1]. Despite their popularity, OCPs can be difficult to obtain [2]. Adolescents are particularly impacted by barriers to contraceptive access, including those related to transportation, appointment availability and/or scheduling, confidentiality concerns, and cost. In a recent national survey [3], the overwhelming majority of respondents reported facing at least one barrier to obtaining contraception as a teen or young adult, and a large majority experienced more than one barrier. Over half of respondents

reported being unable to obtain a prescription for OCPs due to barriers. Adolescents of color, those living in poverty, adolescents with disabilities, and sexual orientation and gender identity minority youth are disproportionately affected by barriers to access to contraception [2]. Though not a panacea, over-the-counter access to OCPs would be an important step toward reducing inequities in contraceptive access and equipping adolescents to determine the course of their reproductive lives. Indeed, data indicate adolescents are likely to purchase and use over-the-counter OCPs: in a 2015 survey, 29% of teens reported they would likely use an over-the-counter progestin-only OCP, should one become available [4].

OCPs may contain a progestin only or a combination of estrogen and a progestin; all OCPs, including the norgestrel 0.075 mg OCP currently under consideration for over-the-counter status, are highly effective contraceptives [1,5–8]. Furthermore, recent data indicate an over-the-counter progestin-only OCP is associated with high user satisfaction and acceptable bleeding patterns, including among adolescents [9]. Importantly, OCPs are also safe—and have been used safely by hundreds of millions of people worldwide, including many who obtained them over the counter. There are very few conditions that make the use of progestin-only OCPs, in particular, unsafe; these are exceedingly rare in adolescents. Additionally, the list of potential side effects and risks associated with progestin-only OCPs is shorter and less worrisome than that of many other medications currently available over the counter. Estrogen-containing contraceptives are also safe for most adolescents. The most serious potential risk with the use of estrogen is that of venous thromboembolism (VTE); however, the risk of VTE associated with modern estrogen-containing contraceptives is

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low, particularly for adolescents, and lower than the risk of VTE associated with pregnancy or the postpartum period [10]. Notably, data indicate adolescents can understand the Drug Facts label information required for the safe and effective use of over-the-counter OCPs [11] and can use self-screening tools to identify conditions that may make the use of estrogen unsafe and should be discussed with a clinician or pharmacist before choosing a method of birth control [12]. No medical appointment, pelvic examination, or laboratory testing is required to start OCPs, making them appropriate for over-the-counter status.

Because of the potential benefits to adolescents associated with over-the-counter OCPs, and given adolescents' ability to use OCPs safely, it is imperative that any OCP approved for over-the-counter status be available without age restrictions or a requirement for parental consent. Clinicians with expertise in adolescent health have long recognized the importance of supporting adolescents to make decisions about their own sexual and reproductive health. Many adolescents choose to involve parents in decision-making around contraception, and parental involvement should be encouraged when possible; however, parental support is not feasible for all adolescents for a variety of reasons. Adolescents who are unable to involve parents in their decisions around contraception should not be restricted from using OCPs available over the counter to other teens. Moreover, adolescents should not be excluded from using over-the-counter OCPs as a strategy to entice contact with clinicians. It is our view that withholding over-the-counter OCPs from adolescents will only exacerbate inequities and not translate into healthcare visits. Rather, clinicians have an important role in educating, and addressing concerns from, adolescents using over-the-counter OCPs, just as they do for patients using other over-the-counter medications. For example, all OCPs must be taken consistently, and clinicians should continue to educate patients about the importance of taking OCPs, especially progestin-only OCPs, which have short half-lives, consistently and on time. Some adolescents who use over-the-counter OCPs may experience irregular bleeding or other side effects that require management, prompting contact with clinicians. While many people use OCPs, including progestin-only OCPs, successfully and happily, future research regarding continuation rates among over-the-counter OCP users will be important, as will evaluation of the accessibility, benefits, and potential risks of over-the-counter OCPs. Regardless of whether patients are using over-the-counter OCPs, clinicians should encourage health maintenance visits for all adolescents and take advantage of visits scheduled for other reasons as opportunities to provide sexual and reproductive health care, such as screening for sexually transmitted infections, when indicated. Pharmacists and other professionals, as well as online resources, can also be valuable sources of information for adolescents using over-the-counter OCPs. Given adolescents face numerous and unique barriers to contraceptive access, they may have the most to gain from over-the-counter access to OCPs—and they must not be prohibited from accessing any OCPs made available over the counter. Cost may be a barrier for some adolescents seeking over-the-counter OCPs; it will be critical that current federal regulations, which require insurance companies to cover contraceptives with no out-of-pocket cost, also apply to any OCPs made available over the counter.

All people, including adolescents, have a right to determine if and when they have children. For many adolescents, access to safe and effective contraception is essential to achieving this

right and to living happy, healthy lives. Over-the-counter OCPs are endorsed by the American College of Obstetricians and Gynecologists [13], American Academy of Family Physicians [14], and American Medical Association [15] and have the potential to expand contraceptive access for adolescents, including those underserved or excluded by the healthcare system. The United States should join over 100 other countries around the world and make OCPs available over the counter. FDA approval of the 0.075 mg norgestrel pill is an important first step; subsequent approval of additional OCPs, including those containing estrogen, must follow.

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