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Promising development for access to contraception: the pill over-the-counter moves into final FDA review stage

The Contraceptive Access Initiative applauds HRA Pharma and the supporters that have worked on this development for many years

WASHINGTON — In a major advance in contraceptive access, HRA Pharma, a Perrigo company, has filed an application to the U.S. Food and Drug Administration requesting approval for access to the company’s progestin-only oral contraceptive pill without a prescription, according to the New York Times.

The FDA now begins a time-limited, 10-month review process, during which the agency will review the data on safety and effectiveness of the pill and decide whether to approve the product for OTC status. Key steps of the process typically include a communication from the FDA to the applicant informing it of the agency’s planned timeline and a date for an FDA Advisory Committee meeting.

“The application for a birth control pill to be made available over-the-counter marks a significant advance in contraceptive access,” said Dr. Raegan McDonald-Mosley, chief executive officer of Power to Decide, chief medical advisor for the Contraceptive Access Initiative and a practicing OB-GYN. “For more than six decades the pill has been one of the most commonly used contraceptive methods to prevent pregnancy and improve reproductive health and wellbeing. Approving access to an over-the-counter pill is a health equity imperative and will eliminate long-standing barriers to accessing this safe and effective medication. We encourage the FDA to move swiftly to approve this application.”

May 2022 polling shows strong bipartisan support among voters for over-the-counter access to oral contraceptives, and members of Congress recently introduced legislation urging the FDA to swiftly consider this switch.

Major medical groups, including the American College of Obstetricians and Gynecologists and the American Medical Association, endorse OTC access to the pill for people of all ages without a prescription.
“Over-the-counter access to oral contraception is a critical health equity issue and we must continue to remove unnecessary barriers,” CAI Co-founder Dana Singiser said. “The Affordable Care Act requires insurance coverage of contraception with no copay, and we urge the administration to clarify that this includes over-the-counter contraceptives, which will soon include the oral contraception pill.”

**Background on the pill and over-the-counter applications**

Since 2016, the FDA has been working with two pharmaceutical companies on a prescription-to-OTC switch. The pill’s safety and efficacy are well established after 62 years on the market, so the FDA must only be satisfied that women can understand the label and be trusted to follow the label instructions.

HRA Pharma’s progestin-only pill, sometimes called the “minipill,” is preferred by 5% of pill users because it is more compatible for people who are breastfeeding or have certain health concerns. It is poised to be the first birth control pill allowed to be sold on pharmacy shelves without the need for a prescription.

The other pill OTC candidate, owned by Cadence Health, is the most commonly used birth control pill — preferred by 95% of pill users — and contains a combination of estrogen and progestin. Frequently called the “combined pill,” Cadence Health has been progressing toward filing an application for FDA approval for OTC status, but has been encountering “regulatory hurdles,” according to the New York Times.

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The nonprofit [Contraceptive Access Initiative](https://www.thepillotc.org) (CAI) advocates for increasing access to hormonal contraception over the counter, free from stigma, bias and coercion.