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FDA delays meeting, vote on the pill OTC
CAI urges FDA to prioritize a timely, evidence-based review of the data

WASHINGTON — In a disappointing development, the U.S. Food and Drug Administration has delayed the Nov. 18 expert meeting and vote on the application to make the progestin-only, daily oral contraceptive minipill available without a prescription. A new date for the meeting has not been announced. The nonprofit Contraceptive Access Initiative issued the following statement.

“We urge the FDA to prioritize the review of over-the-counter access to the pill and to proceed in a timely manner. Particularly amid the current reproductive health access crisis, accessing the pill on the pharmacy shelf is a public health imperative. With the pill’s well-established safety record we expect the FDA to proceed without further delay.”

The FDA follows a 10-month approval timeline for over-the-counter applications and has previously committed to that timeline for this application.

A second daily oral contraceptive pill is nearing the final stages of review for over-the-counter status approval.

The FDA Process
After a lengthy FDA process, two popular birth control pills are nearing the final stages of review for over-the-counter status approval:

● HRA Pharma’s progestin-only mini pill, preferred by many with certain health conditions, will next be reviewed by an FDA advisory committee that will vote on a recommendation; the FDA typically follows the recommendation of the advisory committee. The 10-month clock for FDA review and approval runs out in the spring of 2023. This is a progestin-only pill — the same type of medication as emergency contraception, which is already available over-the-counter for all ages.

● The most common birth control pill, chosen by 95% of pill users in the United States, is expected to finish the FDA review process within a few years. This pill contains estrogen and
progestin. The makers of this pill are developing a novel technology solution to help consumers screen for safety.

The Medical Community

In a major development, the American Medical Association announced in June that it supports making the birth control pill available over the counter (OTC) for all ages — joining the American College of Obstetricians and Gynecologists, American Academy of Family Physicians and many other medical groups.

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The nonprofit Contraceptive Access Initiative (CAI) advocates for increasing access to hormonal contraception over the counter, free from stigma, bias and coercion.