

# DAILY BEAST

## Hey FDA, Free the Birth Control Pill!

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After the U.S. Supreme Court overturned *Roe v. Wade* last summer, contraceptive manufacturer HRA Pharma asked the FDA to switch its birth control pills from prescription-only to over-the-counter.

While the Food and Drug Administration (FDA) recently postponed an advisory panel meeting to discuss granting women over-the-counter access to a birth control pill that has been available only by prescription since 1973, the drug maker still expects FDA approval sometime in mid-2023.

If that happens, women in the United States will join those in the majority of countries who can get birth control pills, formally or informally, without a prescription.

But there's a catch: they will only have access to one brand of one kind of birth control pill, a progestin-only pill. And while it may be safer to use than other birth control pills, the pill has drawbacks.

Regular birth control pills contain two female hormones, estrogen and progesterone. The progestin-only drug is nicknamed "the mini-pill" because it only contains progesterone. Unlike regular birth control pills, the mini-pill doesn't affect milk production in nursing mothers and has less tendency to cause traveling blood clots (venous thromboembolism or VTE) in women who smoke.

On the other hand, the mini-pill only works if women take it at the same hour every day. If they take it more than three hours later, women must use another form of contraception for the rest of the month and start the cycle again. The same is true if they miss a day. With regular birth control pills, if women miss a day in the cycle, they can take two pills the following day.

It is paternalistic for the FDA to restrict women's OTC options to progestin-only pills—and to limit them to one progestin-only product. The agency presumably doesn't trust women to compare the risks and benefits of the various birth control pills and decide which is best for them. Yet, a 2006 study of women in the Seattle area who were asked to self-assess for birth control pills found they matched the opinion of doctors 90 percent of the time—the other 10 percent said they were *more conservative* than the doctors.

The American College of Obstetrics and Gynecology has long supported all over-the-counter hormonal contraception—including estrogen/progesterone birth control pills—stating the risk of VTE “with combined oral contraceptive use is small compared with the increased risk of VTE during pregnancy and the postpartum period.”

The college also believes women do not generally need an annual exam to take birth control pills. Obstetrician-gynecologists make money performing yearly exams, which makes the college's position especially noteworthy—as it essentially argues against its own profession's financial interests.

The American Academy of Family Physicians also supports over-the-counter birth control pills, as does the American Medical Association. Most reproductive health care providers surveyed in 2016 favored OTC birth control pills.

Research suggests that OTC birth control pills lead to greater compliance. One study compared oral contraceptives, which are available over the counter in Mexico—just across the U.S.-Mexico border at El Paso/Ciudad Juarez. The researchers found that providing “users with more pill packs and removing the prescription requirement would both lead to increased continuation.”

Ironically, the FDA allows children to purchase lethal doses of acetaminophen (Tylenol) and aspirin without a prescription. Yet it blocks adult women from a safer product that medical experts think they should be able to buy—without requiring an unnecessary and expensive doctor’s visit.

In 2006, the FDA approved over-the-counter access to emergency contraception—the so-called “morning after pill”—for women 18 and older. In 2013, the FDA approved OTC emergency contraception for women of all ages. The most well-known emergency contraceptive is named “Plan B.”

The FDA must not make women wait until the middle of next year before letting women only begin to get control over Plan A. The agency should reclassify all birth control pills—not solely progestin-only pills—over-the-counter for women of all ages.

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