



May 8, 2023

Food and Drug Administration,  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Re: Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee on the approval of Opill as an over-the-counter oral contraceptive.**

Docket No. FDA-2022-N-1959

The fight for access to effective nonprescription woman-controlled contraception has been ongoing for more than half a century. Now the FDA has the opportunity to move the campaign further along. PharmedOut, an evidence-based prescribing project at Georgetown University Medical Center, urges the FDA to approve Opill as the first over-the-counter (OTC) oral contraceptive in the United States. Oral contraceptives are available OTC in [many other countries](#), and it's about time the U.S. caught up.

Since the approval of the first prescription birth control pill [in 1960](#), numerous studies have shown oral contraception to be both [safe and effective](#); it is time that the most popular form of birth control is made accessible to all. Opill has been on the market since it was granted FDA approval in 1973 and has an excellent safety record. Other medications available OTC, including [aspirin](#), [ibuprofen](#) and [acetaminophen](#) /paracetamol (Tylenol) are far more dangerous than birth control pills. OTC medications are supposed to be safe and effective when used as directed for self-diagnosed conditions. No condition is easier to diagnose than being at risk of pregnancy.

Today, the birth control pill is the [most commonly prescribed form of contraception](#) by women and adolescents in the United States. Although birth control pills are safe and effective, there is still the glaring issue of access. Adolescents and young women are an especially key demographic to consider. There are so many barriers — including lack of parental support, lack of access to health care, the costs associated with a doctor's visit, etc. In 2021, [one in ten](#) women in the U.S. reported having no personal doctor/health care provider. Women of color were least likely to have access. Approving over-the-counter contraception eliminates this hurdle for disadvantaged women. Of course, medication [costs will still be a barrier](#) for some, but granting approval for Opill would be a first step in the right direction.

Even after a prescription is acquired, in some states, women can still be denied birth control pills by a [pharmacist citing moral or religious obligations](#). Religious beliefs should not be an infringement on anyone's bodily autonomy. The FDA can straightforwardly fix this by making oral contraception available over-the-counter.

We have heard concerns that women who don't take Opill at the same time every day could experience unintended pregnancies. These concerns apply equally to progestin-only and low-dose combined estrogen-progestin oral contraceptives available by prescription. Women can



understand labels, including contraindications. In addition, birth control pills are so commonly used that information regarding the importance of not missing doses — or taking doses late — is common knowledge. In any case, these patronizing concerns are not grounds to take away a woman's choice from her.

At a time when abortion rights are being stripped away state by state, equitable access to effective birth control is critical to women's reproductive freedom. In light of [Roe v. Wade being overturned](#), and growing state restrictions on abortion, there has never been a greater need for increased access for woman-controlled, effective birth control.

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