

## FDA approves first over-the-counter birth control pill in US

Manas Mishra and Sriparna Roy July 13, 2023

July 13 (Reuters) - The U.S. Food and Drug Administration on Thursday approved the first over-the-counter contraceptive pill, paving the way for millions of women in the country to purchase birth control without prescription.

The approval comes as more states ban abortion following a ruling by the Supreme Court last year that overturned the Roe v. Wade decision to legalize the procedure nationwide.

The daily contraceptive Opill, sold by Perrigo (PRGO.N), was first approved for prescription use in 1973, and the over-the-counter approval allows people to obtain it without first seeing a healthcare provider.

Perrigo will next week share its pricing plan for the pill, which will be available in stores and online in the first quarter of next year.

"Today marks an important step in the drive toward meaningful access to essential healthcare for Americans," Health and Human Services Secretary Xavier Becerra said in a statement.

The approval will help women overcome barriers to obtaining contraceptives such as the cost and time of a healthcare provider visit, transportation and finding childcare during the appointment.

Opill, also known as a "minipill", uses progestin, a form of the progesterone hormone which plays a role in the menstrual cycle and pregnancy. It does not contain the hormone estrogen unlike combination contraceptive drugs.

Women should take a progestin-only pill within the same three hours every day to avoid pregnancy. Combination pills that contain both estrogen and progestin do not have such a limitation.

"I jokingly refer to it as a mini step in the right direction. It does have its drawbacks. If women don't take it at precisely the same time every day, they have to start all over again (from the next menstrual cycle)," said Dr. Jeffrey Singer, a senior fellow at libertarian think tank Cato Institute.

The most common side effects of the pill include irregular bleeding, headaches and dizziness. The FDA advises it should not be taken by those who have or have had breast cancer.

The National Catholic Bioethics Center and other groups have opposed making Opill available without prescription, saying physicians should be involved in health decisions, especially for teenagers, along with parental supervision, to avoid harm.

A panel of the FDA's advisers had in May <u>voted</u> unanimously in favor of Opill's OTC sale, with advisers saying that more women were likely to be harmed by an unplanned or unwanted pregnancy than the drug's side effects.

Perrigo gained the daily-use pill first through its \$2.13 billion acquisition of Paris-based HRA Pharma in 2021.

Shares of the company were up 2% in noon trading.