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The F.D.A. Now Says It Plainly: Morning-After Pills Are Not Abortion Pills

Labels of Plan B One-Step had previously said, without scientific evidence, that the pill might block fertilized eggs from implanting in the womb.

By Pam Belluck

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The Food and Drug Administration on Friday significantly changed the information that will be in every box of the most widely used emergency contraceptive pills to make clear that they do not prevent a fertilized egg from implanting in the womb. The agency explained in an accompanying document that the products cannot be described as abortion pills.

Up to now, packages of the brand-name pill, Plan B One-Step, as well as generic versions of it have said that the pill might work by preventing a fertilized egg from implanting in the womb — language that scientific evidence did not support. That wording led some abortion opponents and politicians who equate a fertilized egg with a person to say that taking the morning-after pill could be the equivalent of having an abortion or even committing murder.

The F.D.A. revised the leaflets inserted in packages of pills to say that the medication "works before release of an egg from the ovary," meaning that it acts before fertilization, not after. The package insert also says the pill "will not work if you're already pregnant, and will not affect an existing pregnancy."

In a question-and-answer document posted on the F.D.A.'s website, the agency explicitly addressed the abortion issue. In answer to the question, "Is Plan B One-Step able to cause an abortion?" the agency writes: "No." It added: "Plan B One-Step prevents pregnancy by acting on ovulation, which occurs well before implantation. Evidence does not support that the drug affects implantation or maintenance of pregnancy after implantation, therefore, it does not terminate a pregnancy."

Since the Supreme Court overturned the ruling that ensured the national right to abortion, advocates of abortion rights have warned that some conservative states may outlaw or restrict morning-after pills on the erroneous grounds that they might cause abortions. Advocates and reproductive health providers have also worried that people who are misinformed about how the pills work may decline to use an effective tool to prevent unwanted pregnancies.

For at least a decade, the pills have figured in political debates about abortion. During the 2012 presidential election, Mitt Romney called emergency contraceptives "abortive pills," and two other Republican presidential candidates, Newt Gingrich and Rick Santorum, made similar statements.

Some conservative states allow pharmacists or pharmacies to refuse to carry Plan B, which was approved in 1999 and is available without a prescription. And a recent study found that more than 60 percent of about 1,400 people surveyed believed that morning-after pills work by preventing the implantation of a fertilized egg.

But scientific evidence has never shown that Plan B affects a fertilized egg's ability to attach to the uterus. The F.D.A. acknowledged as much 10 years ago, after a 2012 investigation by The New York Times, when a spokeswoman for the agency said that "the emerging data on Plan B suggest that it does not inhibit implantation."

As a result of The Times's reporting, MedlinePlus, a website run by the National Institutes of Health, deleted passages suggesting emergency contraceptives could disrupt implantation. Other health and medical websites made similar changes. In 2013, European health authorities revised the label of Norlevo, a pill that is identical to Plan B, to say that it "cannot stop a fertilized egg from attaching to the womb."

The F.D.A. said it made the change now because it had completed a review of a 2018 application to alter the label that was submitted by Foundation Consumer Healthcare, a company that in 2017 bought the Plan B brand from Teva Pharmaceutical Industries. Agency officials said the pandemic delayed the review process and that the timing was not motivated by political considerations.

The company did not conduct any new studies for its application, submitting already existing research, a spokeswoman said.

"As the label was written previously, it was causing more confusion, and was incorrect according to the scientific research," the company's marketing director, Tara Evans, said. "Our goal was to clarify misinformation," she said, adding that "the events of 2022 reignited the urgency."

Students for Life of America, which earlier this year posted an Instagram video with a caption saying "Plan B can cause an abortion. It's right there on the box," said in an email on Friday that it rejected the F.D.A.'s new language on the science of the pills.

“For years we’ve been saying that the packaging indicated abortions could take place,” the organization said. “Their answer is to just change the box.”

Plan B One-Step and its generic versions — including brands like Take Action, My Way and Option 2 — contain levonorgestrel, one of a class of hormones called progestins that are also found at lower doses in birth control pills and intrauterine devices. The pills are most effective in preventing pregnancy if taken within 72 hours of sexual intercourse, although they can sometimes work if taken within five days.

Another type of morning-after pill, marketed as Ella and containing a compound called ulipristal acetate, is only available by prescription and is not affected by the F.D.A.’s label change. There has been less research on this type of pill, but studies suggest that it is highly unlikely to prevent implantation of a fertilized egg. In 2009, after months of scrutiny, Ella was approved for sale in overwhelmingly Catholic Italy, where laws would have barred it if it had been considered to induce abortions.

According to data published in 2021 by the Centers for Disease Control and Prevention, nearly one-quarter of women of reproductive age who have sex with men answered yes to the question: “Have you ever used emergency contraception, also known as ‘Plan B,’ ‘Preven,’ ‘Ella,’ ‘Next Choice,’ or ‘Morning after’ pills?” The agency did not break down the data by the type of pills taken.

Dr. Giovannina Anthony, an obstetrician-gynecologist at the Women’s Health and Family Care Clinic in Jackson, Wyo., said that because of claims by anti-abortion groups some patients have been confused about whether the pills can cause an abortion, and her staff will now be able to use the F.D.A.’s new interpretation of the scientific evidence to reassure them.

Dr. Anthony, whose state is among those trying to restrict access to abortion, said the F.D.A.’s new guidance “is critical for women who have had unprotected sex and live in geographic areas where abortion is either inaccessible, banned or impossible to obtain. It should encourage more women to use Plan B as an effort to decrease the unplanned pregnancy rate.”

As far back as the 1999 approval process, the maker of Plan B — Barr Pharmaceuticals, later acquired by Teva — asked the F.D.A. not to list an implantation effect on the label, The Times reported in 2012.

Experts said implantation was likely placed on the label partly because daily birth control pills, some of which contain Plan B’s active ingredient, appear to alter the endometrium, the lining of the uterus into which fertilized eggs implant. Altering the endometrium has not been proven to interfere with implantation. But in any case, scientists said that unlike the accumulating doses of daily birth control pills, morning-after pills do not have time to affect the uterine lining.

By 2007, evidence was accumulating that morning-after pills did not block implantation. In 2009 to 2010, during discussions about making Plan B available over the counter for all ages, Teva also asked that implantation be deleted from the label.

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