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FDA Approves New Generic Abortion Pill

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The U.S. Food and Drug Administration (FDA) has approved a new generic version of mifepristone, the 200 mg abortion pill used with misoprostol to terminate early pregnancies. The drug, produced by Virginia-based Evita Solutions LLC, is authorized for use through 70 days of gestation, making it the second generic version of mifepristone allowed on the U.S. market.

In its approval letter (pdf is available here), the agency stated that Evita's tablets are bioequivalent and therapeutically equivalent to Mifeprex, the brand-name product made by Danco Laboratories. According to the FDA:

> Adequate information has been presented to demonstrate that the drug meets the requirements for approval under the [Federal Food, Drug, and Cosmetic] Act.

Evita's product falls under mifepristone's Risk Evaluation and Mitigation Strategy (REMS), a federal safety program governing the prescription and dispensing of abortion drugs. The FDA required the REMS to be "fully operational before the drug enters interstate commerce." It limits distribution to certified prescribers and pharmacies, and requires patients to sign risk acknowledgments.

The decision has reignited the moral and political fight over abortion. Pro-life groups and some Republican lawmakers condemned the approval as a "betrayal." They warned that expanded chemical abortion access undermines both medical safety and human dignity.

Over two-thirds of all U.S. abortions now occur through medication, and the number continues to rise.

What the Drug Does

Evita Solutions, whose mission is to "normalize abortion," states on its website that its newly approved product "is used in combination with misoprostol for safe, effective medical abortion."

Mifepristone, sometimes called the "abortion pill," or RU-486, works by blocking progesterone, a hormone necessary to maintain pregnancy. Without progesterone, the uterine lining breaks down, ending the embryo's viability.

A second drug, misoprostol, is taken within 24 to 48 hours afterward. It causes uterine contractions that expel the pregnancy tissue — and a forming human life with it.

When used together in the recommended sequence, the regimen is about 97-percent effective in ending early intrauterine pregnancies.

The combination has been approved for medical use in the U.S. since 2000. However, the FDA's

approval has been repeatedly challenged in courts. Most recently, the *Alliance for Hippocratic Medicine v. FDA* case sought to revoke or restrict its approval. Yet, the Supreme Court in June 2024 unanimously upheld access, ruling that the plaintiffs lacked legal standing to sue.

Safety Warnings and Complications

The drug that is nearly 100-percent lethal for an unborn child is widely promoted as "safe" for mothers. Yet both Evita and the FDA acknowledge that mifepristone carries serious medical risks, some of which can be fatal.

The product labeling bears a boxed warning, the FDA's strongest alert, including the following:

> Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following Mifepristone tablets, 200 mg use.

The company urges patients to seek immediate medical attention for heavy bleeding, fever, severe abdominal pain, or signs of infection. Common complications include prolonged bleeding (with about one percent of women requiring surgical intervention), sepsis, and "rare" but deadly bacterial infections such as *Clostridium sordellii*. There are contraindications for women with ectopic pregnancy, adrenal failure, bleeding disorders, or allergies to mifepristone or misoprostol. Other reactions include nausea, weakness, chills, and vomiting.

Administration Reacts

Facing backlash from conservatives and pro-life groups, the White House defended the FDA's approval of a second generic mifepristone as a bureaucratic obligation.

Press Secretary Karoline Leavitt told reporters on Friday that the move was "not an endorsement of this drug." She stressed that the FDA and the Department of Health and Human Services (HHS) were "simply following the law":

> By law, the secretary of Health and Human Services must approve a generic drug application if the application demonstrates the generic drug is the "same" as the brand-name drug.

Indeed, under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, the FDA is required to approve a generic drug once it proves "bioequivalence" and therapeutic sameness to the reference product. In practice, the agency has almost no discretion to deny such approval. The only exceptions are technical. They include an incomplete application, unresolved patent or exclusivity barriers, or credible new safety data about the reference drug itself.

HHS Secretary Robert F. Kennedy Jr. said in a statement on X that the FDA's approval occurred because of procedural necessity. He added that Joe Biden's administration had earlier removed mifepristone's in-person dispensing rule "without studying the safety risks." He pledged to correct that.

Interestingly, the public record contradicts Kennedy's claim. The FDA's own materials show that the agency, for what it's worth, conducted a "comprehensive review of the published literature" and other "relevant safety and adverse-event data" before changing the dispensing rules.

In September, Kennedy and FDA Commissioner Marty Makary announced they'd launch a review to reexamine the drug's safety framework.

The administration's posture — technically correct, politically evasive — fits a familiar pattern. When the science is inconvenient, it becomes "procedural." When the politics are volatile, the process becomes the shield. Behind the language of regulation lies a deeper story that began in the last century, when population control became part of public policy.

Mifepristone and Population Control

The story of mifepristone in America is deeply tied to the population-control movement that emerged in the early 20th century and expanded globally by mid-century. Long before the drug reached the U.S. market, private foundations, international nonprofits, and public-health agencies were funding research aimed at limiting birth rates — especially in the developing world and among poor and minority populations in the United States.

Among the most influential players was the Rockefeller Foundation, whose funding and policy initiatives helped shape the modern framework for what became known as "reproductive medicine." In 1952, the foundation seeded the Population Council, a New York-based nonprofit dedicated to fertility regulation and contraceptive development. For decades, the council promoted "family-planning" programs across the globe, working with national governments and the United Nations (UN).

When the French pharmaceutical firm Roussel Uclaf developed RU-486 in the early 1980s, the Population Council became the key U.S. conduit for its testing and eventual approval. In 1994, Roussel Uclaf transferred the U.S. marketing rights for mifepristone to the council. Three years later, in 1997, the council granted those rights to Danco Laboratories. The company still manufactures and distributes the brand-name Mifeprex.

During the same period, media reports indicated that the Rockefeller Foundation assisted China's state-owned Hua Lian Pharmaceutical in meeting FDA standards to produce mifepristone for export, a move intended to expand availability of the drug.

Twenty-five years later, it remains to be seen whether the Kennedy-Makary review will challenge that agenda.