## ABORTION PILL EXPOSED



## **EXECUTIVE SUMMARY**

In 2020, Live Action is exposing the shocking history of the abortion pill and the abortion industry's radical plan to deregulate this lethal drug.<sup>1</sup> Since *Roe v. Wade*, the abortion industry has pushed for greater access to abortion, claiming that legalized abortion eliminates so-called "back-alley" abortions. Yet, the industry consistently opposes even modest regulations on the killing of preborn children, like parental notification laws or requiring abortionists to obtain hospital admitting privileges. They are now using the coronavirus threat as a ruse to challenge the Food and Drug Administration (FDA) in federal court, insisting that even minor safety regulations of the abortion pill violate a woman's right to due process.

That regulation is known as a "risk evaluation mitigation strategy" (REMS), and it requires the abortion pill to be prescribed and dispensed at a healthcare setting, clinic, or hospital by a qualified medical professional. According to the Association of Pro-Life Obstetricians and Gynecologists, the abortion pill poses a **fourtimes higher risk of complication than surgical abortion** *in the first trimester*. Yet, the abortion industry recklessly insists on the abortion pill's later-term use; its availability without a prescription, blood work, or ultrasound; and the total elimination of REMS.

Since the FDA first approved it, nearly **4 million preborn children** have been chemically destroyed by this pill. There have additionally been **24 reported maternal deaths**, and the FDA has received over **4,000 reports of adverse events** from women experiencing hemorrhage, excruciating abdominal pain, and severe life-threatening infections. Yet, abortion manufacturers have only been required to report adverse events as reported to them by abortion facilities like Planned Parenthood. Women who experience these side-effects are likely to seek care at emergency rooms (which are not required to report adverse events to the FDA) and not the abortion facilities that prescribed the pill. This means **the true number of adverse events far exceeds 4,000 cases**.

In 2016, under the Obama administration, REMS was relaxed to permit the abortion pill's dispensation to women in their 10th week of pregnancy, and manufacturers are now only required to report maternal deaths to the FDA.<sup>2</sup> REMS still requires the prescribing clinician to be capable of diagnosing **ectopic pregnancy**— a serious condition and leading cause of maternal death. If this condition goes undiagnosed, a woman may wrongly attribute her excruciating pain and heavy bleeding to the usual side-effects of the abortion pill.

Despite these dangers to women and children, the abortion industry seeks to "demedicalize" the abortion pill and even encourages illegal means to circumvent REMS. The abortion pill is now being illegally

<sup>&</sup>lt;sup>1</sup> The abortion pill was formerly referred to as RU-486 and is sold in the US by Danco Laboratories, Inc. as Mifeprex. In 2019, GenBioPro, Inc. was approved to sell a generic version of mifepristone. The abortion pill is also referred to as "chemical abortion" or "medication abortion."

<sup>&</sup>lt;sup>2</sup> Previously, the FDA only approved abortion pill prescriptions during the first seven weeks of pregnancy.

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trafficked into the US through foreign websites like AidAccess and Rablon, but also by numerous black market sellers who are endangering the lives of American citizens. A New York woman was recently charged for the illegal importation of misbranded abortion pills into US commerce after she sold the drugs to a Michigan man who attempted to slip the pills into his pregnant girlfriend's water bottle. Finally, the abortion industry, along with its billionaire allies and benefactors, is funding clinical trials in multiple states and around the globe to provide the abortion pill to **girls as young as ten years old**, and to **women who are well into in their second trimester**.

Live Action demands the removal of all legal protections for abortionists and any clinician that prescribes the abortion pill. Until that day comes, the FDA must not approve new abortion drugs, and must resist efforts by the abortion industry to lift REMS and allow dangerous, unsuprevised do-it-yourself abortions. Women also deserve to learn about abortion pill reversal (APR) before they are given a prescription for the abortion pill. The FDA could pull the abortion pill from the market today under its power to declare the drug an imminent hazard to public health. This report therefore argues:

The FDA commissioner should use his authority under 21 CFR § 2.5 to ban the abortion pill as an imminent hazard to public health that poses a significant threat of danger to women and preborn children.

The abortion pill, and its deregulation, is promoted by a network of billionaire philanthropists, foundations, universities, researchers, media figures, and politicians, with deep connections to the **American eugenics movement**.

The FDA, whose primary mission is to ensure drugs are safe and effective, was forced (under political pressure from the Clinton administration) to disregard normal drug approval protocols, opting for an accelerated process typically reserved for high-risk drugs to cure life-threatening illnesses. Yet, **pregnancy is not an illness, and the abortion pill does not cure or prevent a disease**.

Demedicalized, do-it-yourself abortion simply means women will be **exposed to the deadly risks of the abortion pill without informed consent**, and that minors, or even sexual predators will be able to obtain this lethal drug online and without a prescription. The FDA must **resist the abortion industry**, along with its allies in academia, news media, the medical community, the pharmaceutical industry, billionaire-philanthropic circles, and politics, who push for **dangerous do-it-yourself abortions**.

The FDA must **zealously defend the safety of women and preborn children** as it squares off against the abortion industry in multiple federal court cases.

The FDA must **crackdown on foreign websites illegally trafficking abortion pills into the US,** which put the lives of American women and children at risk.

The FDA must scrutinize **the ethical best practices and legal compliance of clinical trials** being conducted to expand access to the abortion pill for distribution via telemedicine, online, and at pharmacies.

A woman who regrets her decision to take the abortion pill must be told about **APR** as early as possible, as a safe and effective means of saving the life of her preborn child.