

July 28, 2020

The Honorable Stephen Hahn, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hahn,

We urge you to protect American women and preborn children by removing the abortion pill (mifepristone) from the US market.<sup>1</sup> While we are encouraged by the FDA's decision to shut down illegal websites trafficking unapproved abortion pills into the US, we further insist you exercise your authority under 21 CFR § 2.5 to classify the abortion pill as an "imminent hazard to the public health" that poses a "significant threat of danger."

This lethal drug that the FDA permits for killing innocent preborn children during the first 10 weeks of pregnancy is also highly dangerous for women. According to the FDA's adverse event reporting system, the abortion pill has resulted in over **4,000 reported adverse events** since 2000, including **24 maternal deaths**. Adverse events are notoriously underreported to the FDA, and as of 2016, the FDA only requires abortion pill manufacturers<sup>2</sup> to report maternal deaths. Manufacturers gather this information from the prescribers, such as Planned Parenthood facilities. Yet, women who experience side effects like heavy bleeding, abdominal pain, or severe infections are likely to seek care at emergency rooms, not the abortion facilities where they received the pills. Since emergency rooms are not required to report abortion pill adverse events to the FDA, **the true number of adverse events is impossible to assess**.

As you know, the FDA first approved "RU-486" in 2000 to be sold as Mifeprex. Your predecessors in the Clinton administration set aside normal FDA procedures, opting for an accelerated approval process. This process is typically reserved for high-risk drugs used to cure life-threatening illnesses, even though pregnancy is not an illness, and the abortion pill does not cure or prevent any disease.

The abortion pill is so dangerous the FDA placed it under a "risk evaluation mitigation strategy" (REMS)—requiring the pill to be prescribed and dispensed in a healthcare setting, hospital, or clinic. Under REMS, women receive written disclosures of the side effects, which include hemorrhage, excruciating abdominal pain, and severe, potentially life-threatening infections. REMS also requires the prescribing clinician to be capable of diagnosing ectopic pregnancy—a serious condition and leading

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<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>2</sup> Danco Laboratories, Inc. and GenBioPro, Inc.

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 Mifeprex.

According to the Association of Pro-Life Obstetricians and Gynecologists, the abortion pill poses a **four-times higher risk of complication than surgical abortion in the first trimester**. Yet, abortion industry advocates recklessly insist on the abortion pill's later-term use; its availability without a prescription, blood work, or ultrasound; and the total elimination of what little informed consent REMS currently provides. For instance, Gynuity Health Projects—a research group associated with Planned Parenthood—is now conducting clinical trials in multiple states and around the globe to provide the abortion pill to **girls as young as ten years old**.<sup>3</sup> Gynuity also conducts its dangerous clinical trials on women in Burkina Faso in their second trimester, despite the high risk of infection, and uterine rupture. This region also has limited access to blood products to aid these women when they require emergency intervention. It is difficult to believe that Gynuity complies with federal regulations, FDA standards, and ethical practices concerning the use of human subjects for its clinical trials.

Despite these risks, the abortion industry has, for years, sought the total removal of all safety protocols and has even encouraged illegal means to circumvent REMS. As you know, the abortion pill is now being illegally 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 under 21 USC § 330(a) 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. Thankfully that man was caught and charged with the attempted murder of a preborn child.

Now abortion industry advocates have challenged REMS in federal court, using the coronavirus pandemic as a ruse, and claiming that this lethal drug is part of a woman's right to choose under *Roe v Wade*. The constitutional merits of the right to abortion aside, the Supreme Court places no burden on the FDA to approve dangerous methods of abortion. Yet, on July 13, 2020, a lone federal district judge circumvented the FDA's considered judgement that this dangerous drug be dispensed in a healthcare setting, and enjoined the FDA from fully enforcing the REMS protocols. This rogue judicial activism is a gross breach of the separation of powers, undermining the FDA's statutory authority to regulate drug safety, while recklessly endangering American women and preborn children. The FDA must fight back.

For these reasons, we urge you to pull the abortion pill from the US market immediately and declare it an imminent hazard to the public health under 21 CFR § 2.5. We also encourage your continued efforts to stop the illegal trafficking of black market abortion pills into US commerce, and to fight back against the abortion industry's radical push to overturn REMS in the courts.

Sincerely,

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<sup>3</sup> <https://clinicaltrials.gov/ct2/show/NCT02513043>

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