

United States Senate

WASHINGTON, DC 20510

September 1, 2020

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

Dear Commissioner Hahn,

We wish to thank you for your steadfast leadership at the Food and Drug Administration (FDA) during this time of national uncertainty. We are especially proud of the FDA's defense of the safety of women and children as the abortion industry executes a multifront campaign to circumvent the FDA's statutory authority to regulate the highly dangerous abortion pill.¹ However, given the devastating impact this drug has had on American women and children, we must now urge the FDA to exercise its authority under 21 CFR § 2.5 and classify the abortion pill as an "imminent hazard to the public health" that poses a "significant threat of danger" and remove this pill from the U.S. market.

First, we were encouraged by your efforts to stop the illegal trafficking of mail-order abortion pills into U.S. commerce by foreign companies like Aid Access and Rablon.² Foreign pill traffickers have proliferated in recent years, defying FDA safety requirements, and placing the lives of women and children at serious risk. By openly violating FDA requirements, these foreign actors attempt to kick open the doors for sexual predators and men like Jeffrey Smith to obtain the pill for illegal purposes.³ You may be aware that Smith tried to slip abortion pills into his pregnant girlfriend's water bottle after illegally obtaining the pills from online seller named Ursula Wing.

¹ The abortion pill was formerly referred to as RU-486 and is sold in the United States by Danco Laboratories, Inc. as Mifeprex. In 2019, the FDA approved GenBioPro, Inc. to sell a generic version of mifepristone. The abortion pill is also referred to as "chemical abortion" or "medication abortion."

² Letter from U.S. Congressman Michael C. Burgess to Norman Sharpless, M.D., Acting Commissioner of the Food and Drug Administration (May 10, 2019), https://burgess.house.gov/uploadedfiles/burgess_and_robby_fda_letter_2019.pdf.

³ Kevin Murphy, [Abortion-Drug Dealer Pleads Guilty, Linked to Grand Rapids Man Accused of Poisoning Pregnant Woman's Drink](https://www.wisconsinrapidstribune.com/story/news/2020/03/05/abortion-pill-dealer-ursula-wing-guilty-case-tied-grand-rapids-man/4966488002/), Wisconsin Rapids Tribune (Mar. 5, 2020), <https://www.wisconsinrapidstribune.com/story/news/2020/03/05/abortion-pill-dealer-ursula-wing-guilty-case-tied-grand-rapids-man/4966488002/>; Chelsea Conaboy, [She Started Selling Abortion Pills Online. Then the Feds Showed Up](https://www.motherjones.com/politics/2019/02/she-started-selling-abortion-pills-online-then-the-feds-showed-up/), Mother Jones (Mar. 2019), <https://www.motherjones.com/politics/2019/02/she-started-selling-abortion-pills-online-then-the-feds-showed-up/>.

Wing, who has been charged with smuggling unbranded drugs into interstate commerce, has called for “copy cats” to follow in her footsteps. The FDA must continue to stand vigilant against this reckless illegal activity.

Second, we strongly support your zealous fight against the abortion industry’s scheme to bypass the FDA’s statutory authority to protect the health and safety of all Americans, by using the Coronavirus (COVID-19) threat as a ruse to eliminate the Risk Evaluation Mitigation Strategy (REMS).⁴ On July 13, 2020, a federal judge sided with these groups, and suspended the REMS in-person requirements during the COVID-19 pandemic. We believe that this rogue judicial activism is a gross breach of the separation of powers, undermining the FDA’s statutory authority to ensure drug safety, while recklessly endangering American women and children. The FDA must resist this opportunistic ploy to expand access to abortion under the fallacy that the REMS imposes an undue burden on women’s rights.

Third, to these same ends, we must insist on a serious examination of the ethical practices and FDA compliance of clinical trials like the TelAbortion project conducted by Gynuity—a research group associated with abortion giant Planned Parenthood. Gynuity’s direct-to-consumer abortion pill by mail experiment has been going on for nearly five years and has now expanded to 13 states. In addition to placing the lives of American women and children at risk by offering their clinical study to girls as young as ten years old,⁵ they use women in Burkina Faso in their second trimester as research subjects, despite the high risk of infection and uterine rupture—this is also a region where emergency services and blood products for transfusions are in short supply. We find these practices and uses of human subjects to be highly suspect, and we ask the FDA take immediate steps to review these activities.

As these examples prove, it is by now nakedly obvious that the abortion industry and its allies in the media, billionaire philanthropic circles, and special interest groups, have wanted an unregulated and demedicalized⁶ abortion pill since the moment the FDA first approved it in 2000. As you may further know, the Clinton administration approved this lethal drug under pressure from these same groups and under a highly politicized approval process.⁷ We believe this deadly

⁴ Letter from U.S. Senator Cindy Hyde-Smith to the Honorable Stephen Hahn, M.D., Commissioner of the Food and Drug Administration, (Apr. 14, 2020), <https://www.hydesmith.senate.gov/sites/default/files/2020-04/041420%20-%20MOC%20Letter%20to%20FCA%20on%20Chemical%20Abortion%20During%20Coronavirus%20-%20final.pdf>.

⁵ Feasibility of Medical Abortion by Direct-to-Consumer Telemedicine, U.S. National Library of Medicine, <https://clinicaltrials.gov/ct2/show/NCT02513043>.

⁶ Emily Bazelon, The Dawn of the Post-Clinic Abortion, *The New York Times* (Aug. 28, 2014), <https://www.nytimes.com/2014/08/31/magazine/the-dawn-of-the-post-clinic-abortion.html>.

⁷ A Judicial Watch Special Report: The Clinton RU-486 Files, Judicial Watch, <https://www.judicialwatch.org/archive/2006/jw-ru486-report.pdf>.

pill should never have been approved, yet the abortion industry was politically rewarded with an accelerated approval process normally reserved for high-risk drugs that address life-threatening illnesses like AIDS. As you are surely aware, pregnancy is not a life-threatening illness, and the abortion pill does not cure or prevent any disease. Nevertheless, this pill that is specifically designed and intended to kill preborn children was raced to the market, with devastating consequences.

It is telling that, under the REMS, an abortion pill prescriber must guarantee his competence to properly date a pregnancy, and to provide or arrange for “surgical intervention” in case the pill fails, or in case the woman needs emergency intervention.⁸ Women will sign a Patient Agreement which reads: “If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.”⁹ Prescribers also must be capable of diagnosing ectopic pregnancies—a serious condition if not properly diagnosed, and a leading cause of maternal death. According to FDA reports as of 2018, at least 97 American women with undiagnosed ectopic pregnancies received the abortion pill, and at least two bled to death.¹⁰

Yet based on the federal district court’s order eliminating the in-person requirements of the REMS, it is an open question as to whether women receiving the abortion pill via telemedicine will ever receive blood tests, ultrasounds, or the necessary screening to determine the actual date of her pregnancy, or the potential occurrence of a deadly ectopic pregnancy. Indeed, by demedicalizing and deregulating the abortion pill, women will be left to engage in a form of “DIY” chemical abortion, as the abortion industry collects payments, and as prescribers evade all legal risk and FDA oversight.¹¹ This is unconscionable.

According to FDA reporting, the abortion pill has taken more than 3.7 million preborn lives, caused 24 maternal deaths, and resulted in at least 4,195 adverse maternal reactions including hemorrhage, excruciating abdominal pain, and severe life-threatening infections. Of course, adverse events are notoriously underreported, which makes the true number impossible to assess.

⁸ Mifeprex Prescriber Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Prescriber_Agreement_Form.pdf.

⁹ Mifeprex Patient Agreement Form, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_Patient_Agreement_Form.pdf.

¹⁰ Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018, RCM #2007-525, U.S. Food and Drug Administration, <https://www.fda.gov/media/112118/download>.

¹¹ Some advocates are even encouraging dangerous misoprostol-only “DIY” abortions. See Erica Hellerstein, The Rise of the DIY Abortion in Texas, *The Atlantic* (June 27, 2014), <https://www.theatlantic.com/health/archive/2014/06/the-rise-of-the-diy-abortion-in-texas/373240/>.

Moreover, as of 2016, abortion pill manufacturers are only required to report maternal deaths. However, most women experiencing adverse reactions (such as hemorrhaging) are more likely to seek emergency care at hospitals and emergency rooms, rather than returning to the abortion facility where the pill was prescribed. This further casts into doubt even the 4,195 adverse events reported by manufacturers prior to the 2016 changes.

Therefore, while the REMS imposes minimal safety standards to protect women, and a minimal standard of care on prescribers, the fact is that the abortion pill poses a four-times higher risk of complication than surgical abortion in the first trimester.¹² Moreover, the pill will likely fail for between 5% and 7% of women, who often then seek follow-up surgical abortions.¹³ While we support the FDA's continued fight to defend the REMS, to monitor dangerous clinical studies, and to shut down illegal websites, these measures alone fail to protect the thousands of women harmed even by *compliant* usage of this drug – or the millions of children killed. To protect vulnerable women and children, we strongly urge the FDA to remove this deadly drug from the U.S. market and exercise its authority under 21 CFR § 2.5, declaring it an “imminent hazard to public health.”

Sincerely,



Ted Cruz
United States Senator



Kevin Cramer
United States Senator



Steve Daines
United States Senator



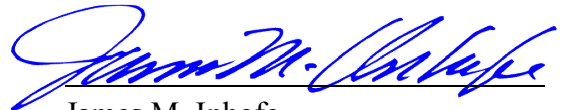
Joni K. Ernst
United States Senator

¹² Abortion Pill Exposed, Live Action, https://www.liveaction.org/wp-content/uploads/2020/07/abortion_pill_report_final.pdf.

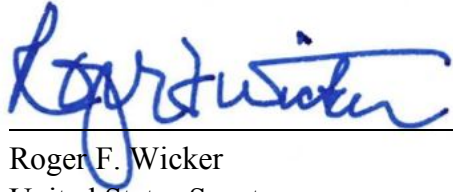
¹³ Maarit Niinimäki, et al., Immediate Complications after Medical Compared with Surgical Termination of Pregnancy, <https://pubmed.ncbi.nlm.nih.gov/19888037/>.




Mike Braun
United States Senator



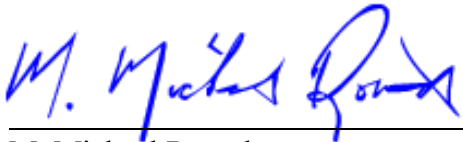
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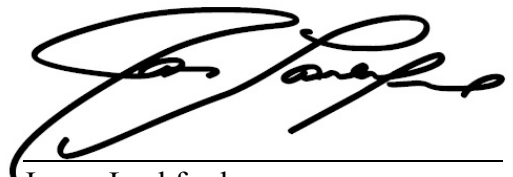
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United States Senator



Pat Roberts
United States Senator



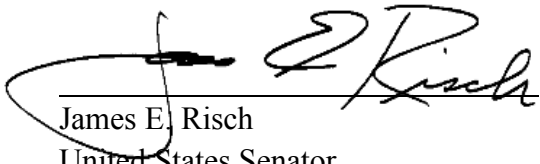
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