

United States Senate
WASHINGTON, DC 20510

October 9, 2025

Dear Secretary Kennedy and Commissioner Makary,

Under your leadership, we have seen a strong commitment to reevaluating the policies that affect the most vulnerable among us—the unborn. We applaud your acknowledgment of the concerns surrounding the FDA’s approval and regulation of the abortion pill regimen—mifepristone and misoprostol—and your commitment to following the science to ensure the safety and well-being of women and unborn children alike.

But the work is far from over. The “abortion-on-demand” culture enabled by the Biden-Harris administration’s removal of critical safeguards on the only FDA-approved abortion regimen¹ is currently the biggest threat to unborn life in America today. Under current FDA regulations, these drugs can be obtained via mail order without meaningful consultation with a medical professional and without any confirmation of who is purchasing them or for what purpose.² These policies have enabled abortion pills to be obtained by abusers, traffickers, and even minors.³

The aftermath has not only been deadly for preborn babies, but lethal to their mothers.⁴ Contrary to the narrative peddled by the media that taking abortion pills is “safer than taking Tylenol,”⁵ evidence shows that the risk of serious medical complications after taking mifepristone is at least twenty-two times higher than reported on the drug label.⁶ In fact, more than 1 in 10 women who take mifepristone will experience a serious adverse event.⁷

Unrestricted access to abortion pills is systematically undermining states’ rights and violating pro-life state laws.⁸ Every month, thousands of abortion drugs are shipped into states that have otherwise limited access to abortion after *Dobbs*, degrading pro-life laws at the state level across the country.⁹ Pro-life states have been forced to defend their citizens against radical abortion extremists. Louisiana and Texas are taking legal action against a New York doctor whose mail-order abortion business put at least two women in the hospital¹⁰ and a California doctor who allegedly sold abortion drugs to men.¹¹

¹ <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.

² <https://sbaprofite.org/newsroom/press-releases/brief-fda-failed-women-rubber-stamping-mail-order-abortion-drugs>.

³ <https://www.nytimes.com/2025/08/14/us/marine-abortion-pills-lawsuit-texas.html>; <https://www.nbcnews.com/news/us-news/texas-attorney-poisoned-pregnant-wife-abortion-medication-sentenced-18-rcna138065>.

⁴ <https://sbaprofite.org/latest-news/abortion-drug-stories-5-women-who-suffered-deadly-complications>.

⁵ <https://lozierinstitute.org/peer-reviewed-study-debunks-abortion-drugs-are-safer-than-tylenol-claim/>.

⁶ <https://eppc.org/publication/stop-harming-women/>.

⁷ <https://www.ffroa.com/wp-content/uploads/2025/09/ROA-Foundation-Chemical-Abortion-Data-Review-2.pdf>.

⁸ A recent report by the Charlotte Lozier Institute showed that there are *more* abortions occurring (or at least being sold) since *Dobbs* because of the proliferation of unethical, unlawful online sales that are nevertheless given cover by the current FDA regulations. <https://lozierinstitute.org/how-many-abortions-are-occurring-in-america-post-dobbs/>.

⁹ <https://societyfp.org/wp-content/uploads/2025/06/WeCount-Report-9-December-2024-data.pdf>.

¹⁰ <https://sbaprofite.org/newsroom/press-releases/la-grand-jury-indicts-ny-abortionist-for-harming-la-girl-baby-with-abortion-drugs>; <https://sbaprofite.org/newsroom/press-releases/ag-paxton-sues-ny-abortionist-for-harming-texas-women-babies-with-abortion-drugs>.

¹¹ Texas, Cease and Desist letter to Dr. Remy Coeytaux, <https://www.texasattorneygeneral.gov/sites/default/files/images/press/Coeytaux%20Cease%20and%20Desist.pdf>; Louisiana, Declaration of Rosalie Markezich, <https://storage.courtlistener.com/recap/gov.uscourts.txnd.370067/gov.uscourts.txnd.370067.264.6.pdf>.

The Biden-Harris administration enabled the deception of American women and the violation of states' constitutional rights by relying on faulty data to claim that there would be no increase in complications if abortion drugs were approved for mail-order. But the current data reveals the truth. This year, two groups of researchers reviewed the outcomes of 865,727 medically-induced abortions from 2017 to 2023,¹² all of which occurred *after* the FDA stopped collecting complication information other than death in 2016. Their research found “that chemical abortion *poses greater risks to women in real-world clinical use* than revealed in the clinical trials of mifepristone and that the rate of serious adverse events from the chemical abortion regimen continues to grow in recent years.”¹³ Despite this, President Biden used the COVID-19 pandemic as a pretext to remove these critical safeguards and fundamentally undermine women's reproductive health. But in November 2024, seventy-three million Americans¹⁴ voted to bring a stop to this radical abortion agenda.

We commend your recent statements acknowledging the data discrepancies surrounding abortion pill safety and your commitment to reviewing the science.¹⁵ We are also encouraged by HHS's recent announcement that it will review prior Risk Evaluation and Mitigation Strategies (REMS) approvals given the recent studies raising concerns about the drug's safety.¹⁶ Given this commitment, however, we are deeply concerned about the FDA's approval of a new generic version of mifepristone.¹⁷ While we recognize the FDA's statutory responsibility in evaluating drug applications, the timing of this approval appears inconsistent with the comprehensive safety reassessment your agencies have prioritized. Out of respect for this important review, and with full confidence in your dedication to protecting women's health, states' rights, and unborn life, we urge you to take decisive action to reevaluate whether this generic version of mifepristone is suitable to enter the market.

Today, your agencies have all the information they need to bring an end to previous Democrat-administrations' abortion drug regulations while a comprehensive review is conducted. As a starting point, we recommend the following:

1. Suspend the approval of any new generic versions of mifepristone pending the outcome of the REMS safety review;
2. Commit to ensuring that all generic versions of mifepristone are included in the ongoing reevaluation of prior REMS approvals;
3. Reinstate the in-person dispensing requirement for mifepristone and all its generic versions;
4. Suspend the distribution of mifepristone and all generic versions as an “imminent hazard” under Section 505(e) of the Federal Food, Drug, and Cosmetic Act (FDCA); and
5. Withdraw FDA guidance permitting pharmacy distribution of mifepristone and all its generic versions.

We are committed to continuing to work together to give a voice to the voiceless and protect women from the dangerous effects of unregulated access to chemical abortion drugs. The life, safety, freedom, and health of millions of Americans, born and unborn, depend on it.

¹²<https://www.ffroa.com/wp-content/uploads/2025/09/ROA-Foundation-Chemical-Abortion-Data-Review-2.pdf>;
<https://eppc.org/publication/stop-harming-women/>.

¹³ [emphasis added]; <https://www.ffroa.com/wp-content/uploads/2025/09/ROA-Foundation-Chemical-Abortion-Data-Review-2.pdf>.

¹⁴ <https://apnews.com/projects/election-results-2024/>.

¹⁵ <https://thehill.com/policy/healthcare/5267781-fda-commissioner-marty-makary-mifepristone/> (Commissioner Makary stating his commitment to review the science related to abortion pills and follow where it leads); <https://sbaprolife.org/newsroom/press-releases/breaking-hhs-sec-kennedy-reveals-biden-admin-twisted-abortion-drug-data> (Secretary Kennedy stating that the Biden FDA “twisted” abortion drug data.)

¹⁶ <https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/>.

¹⁷ https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2025/216616s000ltr.pdf.

Sincerely,



Senator Lindsey O. Graham



Senator John Barrasso, M.D.



Senator Shelley Moore Capito



Senator Tim Scott



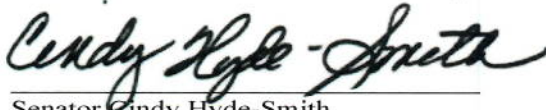
Senator James E. Risch



Senator Jim Justice



Senator Ted Budd



Senator Cindy Hyde-Smith



Senator Tim Sheehy



Senator Kevin Cramer



Senator Todd Young



Senator John Thune



Senator Tom Cotton



Senator James Lankford



Senator Jim Banks



Senator John Cornyn



Senator Pete Ricketts



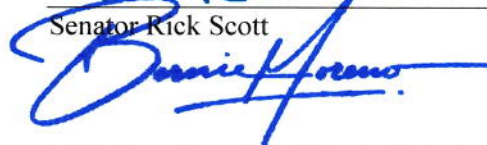
Senator Steve Daines



Senator Roger Marshall, M.D.



Senator Rick Scott



Senator Bernie Moreno



Senator Bill Hagerty



Senator Deb Fischer



Senator Mike Lee



Senator Roger F. Wicker



Senator Josh Hawley



Senator Joni K. Ernst



Senator Jon Husted



Senator Charles E. Grassley



Senator Rand Paul, M.D.



Senator Katie Boyd Britt



Senator Jerry Moran



Senator Ron Johnson



Senator Marsha Blackburn



Senator Ted Cruz



Senator Markwayne Mullin



Senator Mike Rounds




Senator John Boozman



Senator Ashley Moody



Senator John Hoeven



Senator Tommy Tuberville



Senator John Kennedy



Senator Cynthia M. Lummis



Senator Bill Cassidy, M.D.



Senator Mike Crapo



Senator Eric S. Schmitt



Senator Dan Sullivan



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Senator Thom Tillis



Senator John R. Curtis



Senator Mitch McConnell