**October 3, 2025**

**The Honorable Robert F. Kennedy Jr.**
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

**The Honorable Marty Makary**
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Kennedy and Commissioner Makary,

On behalf of the undersigned individuals, the organizations we lead, and the millions of Americans we represent, we write with **grave concern** over the Food and Drug Administration's **reckless decision** to approve a new generic version of mifepristone, the first drug in the chemical abortion regimen. This decision should be immediately reversed, and mifipristone should be pulled from the market altogether.

This approval directly contradicts Secretary Kennedy's recent public assurances that the safety of abortion drugs was in question and would receive thorough review.

Secretary Kennedy stated on September 4, 2025, during the Senate Finance Committee hearing, **"... during the Biden Administration, they actually twisted the data to bury one of the safety signals, a very high safety signal, around 11 percent. We're going to make sure that doesn't happen anymore."** Yet rather than pausing to examine the mounting evidence showing the harmful effects of mifepristone, the FDA has chosen to expand access to a drug that has already **killed millions of preborn children** and **harmed countless women**, undermining the very commitment that the Secretary publicly made to protect patients.

Chemical abortions now account for over 60% of all reported abortions in the United States, ending the lives of an estimated 7.5 million children since mifepristone's initial approval in 2000. A chemical abortion consists of a two-step process. First, a pregnant mother will take mifepristone to starve her preborn child to death. Next, she will take misoprostol to induce labor contractions and deliver the baby's dead body. At this stage in the first trimester, children developing in the womb already have a detectable heartbeat and brainwaves, and are beginning to move their arms and legs.

A new study of insurance claims data conducted by the Ethics and Public Policy Center analyzed 865,727 chemical abortions between 2017 and 2023 and found that more than one in ten women experienced serious, sometimes life-threatening complications, including hemorrhage, infection, and sepsis. This complication rate is **twenty-two times higher** than the Food and Drug Administration's own outdated claims.

In response to the new data, attorneys general from 22 states have cited this EPPC study and called on the FDA to reinstate safety safeguards for mifepristone. They warn that removing these protections puts

women at serious risk and ignores the clear evidence of harm writing in part, "in light of the serious risks to women who are presently being prescribed this drug without crucial safeguards, and in the event the FDA is unable to reinstate the 2011 safety protocols for mifepristone, the FDA should consider withdrawing mifepristone from the market until it completes its review and can decide on a course of action based on objective safety and efficacy criteria."

In contrast to the depth and rigor of the newly available data, the FDA-approved labeling for mifepristone is based on only ten clinical trials involving fewer than 31,000 women, some of which date back more than forty years. This creates a **dangerous disconnect**: women today are told these drugs are "safe," when the best available evidence shows the opposite.

Meanwhile, the Biden administration stripped away even minimal safeguards, allowing these drugs to be dispensed through telehealth and mail-order pharmacies. This reckless policy creates an **alarming number of opportunities for coercion and abuse**.

Just recently, a woman in Texas filed suit after her partner allegedly slipped abortion pills into her drink, resulting in the death of their preborn child against her will. These drugs were obtained from Aid Access, a criminal organization that illegally ships abortion pills into Texas and other states where abortion has been outlawed. This case shows the need for stronger safeguards and enforcement to protect innocent lives from these dangerous drugs and unlawful practices.

Mifepristone is not medicine. It is a **lethal drug** designed to end the lives of preborn children, and in doing so, it places women at **serious risk**. The FDA's mission is to **protect public health.** We ask that the FDA conduct a thorough and proper review of mifepristone, as promised by Secretary Kennedy. The American people expect decisive action, not delay, when lives are at stake.

We urge you, in the strongest possible terms, to **reverse this dangerous approval immediately**. Rather than expanding the license for these drugs, the FDA should acknowledge the clear evidence of harm and **withdraw mifepristone from the market**.

Every abortion is a **violation of human rights**, and every life lost is an **irreplaceable son or daughter**. The federal government must stop enabling this violence under the false banner of "healthcare."

For Life,

***Lila Rose***
Founder and President
Live Action

***Kristan Hawkins***
President
Students for Life and Students for Life Action

***Ryan T. Anderson, Ph.D.***
President
The Ethics and Public Policy Center

***Penny Nance***
CEO and President
Concerned Women for America

***Tony Perkins***
President
Family Research Council

***Tim Chapman***
President
Advancing American Freedom

***Most Rev. Michael F. Burbidge***
Bishop
Catholic Diocese of Arlington

***Jor-El Godsey***
President
Heartbeat International

***Robert P. George, JD, DPhil, DCL, DLitt***
McCormick Professor of Jurisprudence
Princeton University

***Dr. Gary Hollingsworth***
Interim President, Ethics and Religious Liberty Commission
The Southern Baptist Convention

***Mathew D. Staver, Esq., B.C.S.***
Founder and Chairman
Liberty Counsel

***Noah Brandt***
Executive Director
Live Action Victory

***Peter Breen***
Executive Vice President & Head of Litigation
Thomas More Society

***Representative Rachel Rodriguez-Williams***
Wyoming State Representative

***Representative Melissa Oremus***
South Carolina Representative

***Ryan Bomberger***
Chief Creative Officer
Radiance Foundation

***David Bereit***
Executive Director
Life Leadership Conference

***Kelsey W. Reinhardt***
President & Chief Executive Officer
CatholicVote

***Andrew T. Walker***
Associate Professor of Christian Ethics & Public Theology
The Southern Baptist Theological Seminary

***Dr. Christina Francis, MD***
CEO
American Association of ProLife OB/GYNs

***Seth Dillon***
CEO
The Babylon Bee

***Jonathan M. Alexandre, Esq.***
VP of Governmental Affairs
Liberty Counsel Action

***Christian McGrew***
President and Founder
Defending Life Alliance of Florida

***Dr. William Lile, D.O.***
FACOG
Founder of ProLifeDoc.org

***Representative Reagan Paul***
Maine State Representative

***Kathi A. Aultman, MD FACOG***

***Senator Janne Myrdal***
North Dakota State Senator