January 22, 2025

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear FDA Commissioner,

We the undersigned respectfully request that immediate action be taken to safeguard public health with respect to Mifeprex, the "chemical abortion" pill regimen approved by FDA in 2000. Recent developments and growing concerns regarding the safety and widespread misuse of the mifepristone abortion regimen have raised urgent questions about the FDA's responsibility to protect public health, and now mandate its withdrawal from the market or, at the very least, the reinstatement of the original Risk Evaluation and Mitigation Strategy (REMS) that accompanied its approval.

The FDA's recent and ongoing actions to loosen safeguards on abortion pills, including the removal of key REMS, represent a grave threat to women's health and the lives of preborn children. These decisions contradict the agency's duty to protect public health and prioritize safety.

Abortion pills—primarily the two-drug Mifeprex regimen of mifepristone and misoprostol—have become the method of over 60% of abortions in the United States, ending the lives of hundreds of thousands of preborn children each year. According to the most recent national estimates, approximately 642,700 chemical abortions occur annually—one every 49 seconds within the formal healthcare system. These numbers exclude abortions carried out illicitly through online orders or international trafficking, which are undoubtedly rising due to the FDA's actions.

These pills pose significant, well-documented risks to women. The physical dangers include septic infection, hemorrhage, and death. Especially when used without proper medical oversight, such as in the absence of an ultrasound to rule out ectopic pregnancy, the risks become life-threatening. Yet, in a series of reckless actions, the FDA has:

1. 2016: Extended the gestational limit for mifepristone use from 49 to 70 days.
2. 2021: Allowed the dispensing of abortion pills via mail without any in-person medical evaluation.
3. 2023: Further undermined patient safety by permitting retail pharmacies like CVS and Walgreens to dispense these dangerous drugs.

These changes have eliminated vital safeguards and ignored the FDA's own acknowledgment that mifepristone requires stringent oversight. This abdication of responsibility endangers women's health and violates the FDA's mandate to uphold safety.

We call on your administration to reverse these disastrous policies and protection women and children.

Respectfully,

John Mize, CEO, Americans United for Life

Lila Rose, President and CEO, Live Action

Josh Craddock, Affiliated Scholar, James Wilson Institute

Benjamin Watson, VP of Strategic Relationships, Human Coalition

Dr. Christina Francis, CEO, AAPLOG Action

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

R. Albert Mohler, Jr., President, Centennial Professor of Theology, The Southern Baptist Theological Seminary

Tim Chapman, President, Advancing American Freedom

Dan Steiner, Founder & President, Preborn!

Kristan Hawkins, President, Students for Life of America

Carol Tobias, President, National Right to Life

Ralph Reed, Founder & Chairman, Faith and Freedom Coalition

Abby Johnson, CEO & Founder, ATTWN & ProLove Ministries

Penny Nance, President & CEO, Concerned Women for America LAC

Brent Leatherwood, President, Ethics and Religious Liberty Commission of the Southern Baptist Convention

Kristen Day, President, Democrats for Life

Herbert M. Newell I.V., President & Executive Director, Lifeline Children's Services

Jor-El Godsey, President, Heartbeat International

Roland Warren, President and CEO, Carenet

Tom Brejcha, President and Chief Counsel, Thomas More Society

Brandy Meeks, President & CEO, Vitae Foundation

Monica Snyder, Executive Director, Secular Pro-Life

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Alexandra Snyder, CEO, Life Legal Defense Foundation

Destiny Herndon-De La Rosa, Founder, New Wave Feminists

Catherine Glenn Foster, President & CEO, First Rights Global Centennial

John L. Rustin, President, North Carolina Family Policy Counsel

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