

**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,**

Live Action writes to formally memorialize the concerns raised during today's press conference held at the United States House of Representatives with members of Congress regarding the abortion drug mifepristone, and to accompany the public release of Live Action's investigative video documenting the dangerous real-world distribution of this drug by Planned Parenthood and affiliated providers. The purpose of both the press conference and the investigative release is straightforward: to place clear evidence of regulatory noncompliance and patient harm on the public record and to urge immediate corrective action by the Department of Health and Human Services and the Food and Drug Administration.

For more than two decades, mifepristone has remained on the market under an approval process that was politically accelerated, shielded from transparency, and repeatedly expanded without regard for patient safety, adverse event reporting, or statutory compliance. Since its approval in 2000, this drug has ended the lives of approximately 7.5 million children in the United States. Live Action's investigation now publicly documents how those regulatory failures in safety manifest in clinical practice, particularly within Planned Parenthood facilities tasked with administering this drug under federal safeguards.

The investigative video released alongside this letter captures Planned Parenthood staff discussing and describing practices related to the administration of the abortion pill that raise serious concerns about the adherence to established medical safeguards. These include inconsistent verification of gestational age, no ultrasound requirement, and dispensing of abortion pills without thorough screening, counseling, or follow-up care. In multiple instances, staff were recorded minimizing potential risks and treating key safeguards as optional or secondary in the provision of abortion pills. The video further shows staff not checking Rh status, sending abortion pills to a friend's address to avoid parental notice, failing to require a medical history before administration, telling women they do not need a facility visit for follow-up, referring to a baby as "tissue," not being transparent about symptoms that mimic labor, and downplaying the extent of bleeding. Planned Parenthood even says that taking the abortion pill is safer for the mother than "carrying to term."

In addition to these investigative findings, [The Ethics & Public Policy Center](#) released a large real-world study based on all-payer insurance claims database covering 865,727 mifepristone abortions from 2017 to 2023, which found that 10.93% of women experienced sepsis, infection, hemorrhaging, or another serious adverse event within 45 days of taking mifepristone—an adverse event rate at least 22 times higher than the “less than 0.5 percent” rate reported in the FDA-approved clinical trials. These results show that serious complications in everyday use are much more common than the current label suggests and highlight that real-world risks have not been fully addressed.

Our findings further confirm that Mifeprex and its generics are not a therapeutic drug in the ordinary sense. Its purpose as prescribed by Planned Parenthood and other abortion businesses, is to end an unborn child's life by blocking progesterone, destabilizing the uterine environment, and initiating fetal demise, followed by chemically induced labor through misoprostol. This process is inherently violent, medically unpredictable, and frequently unmanaged. Contrary to public assurances of safety, real-world data and patient experiences continue to demonstrate serious adverse events, including hemorrhage, infection, sepsis, incomplete abortion requiring surgical intervention, and emergency room admission.

Live Action's investigation also documents underreporting of complications. Women experiencing adverse events are routinely instructed to seek emergency care without disclosing that abortion pills caused their condition. This practice distorts safety data, undermines pharmacovigilance, and deprives regulators of the accurate information necessary to fulfill their statutory obligations. The FDA's continued reliance on outdated clinical trials and incomplete reporting has produced a regulatory record that no longer reflects actual use or risk.

The expansion of mifepristone distribution through mail-order services, telehealth, and retail pharmacies has further intensified these concerns. In many cases, drugs are provided without in-person evaluation, without clear confirmation of gestational age, and without meaningful continuity of care. When complications arise, emergency departments are often left to manage outcomes without prior clinical context.

The FDA's mission is to protect public health, and that mission requires ongoing reassessment when new evidence demonstrates emerging risks, gaps in oversight, or unintended consequences of regulatory expansion.

Today's press conference and the release of this investigative video make clear that this issue warrants immediate and thorough review and action. Live Action requests that the Department of Health and Human Services and the Food and Drug Administration reevaluate the approval and current regulatory status of mifepristone, strengthen transparency and data collection, and remove this dangerous drug from the market.

In light of the evidence now before the agency, Live Action respectfully urges the Department and the Food and Drug Administration to take the following actions without delay:

1. Immediately suspend the approval of Mifepristone as an abortifacient.
2. Prohibit the distribution of abortion pills through mail-order services, telehealth platforms, and retail pharmacies, and limit any access to settings where in-person medical evaluation and follow-up care can be ensured.
3. Reinstate comprehensive adverse-event reporting requirements to ensure regulators receive accurate and complete data on complications and outcomes.
4. Release a full public accounting of the scientific and clinical evidence relied upon in prior expansions of mifepristone access, including an explanation of data limitations, reporting gaps, and assumptions related to patient safety.

Continued inaction risks further harm and erosion of confidence in the regulatory process. The responsibility to protect patients and ensure a credible, evidence-based regulatory framework rests with your agencies, and we expect that responsibility to be met.

**For Life,**

A handwritten signature in black ink, appearing to read 'Lila Rose', with a stylized, cursive script.

Lila Rose  
Founder and President  
Live Action