July 7, 2025

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

Re: *Urgent Call for Improved Safety Protocols and Health Protections Concerning Telemedicine Chemical Abortions*

Dear Commissioner Makary,

In response to your recent public commitment to review the safety profile of mifepristone, we—the undersigned representatives of national Catholic healthcare and pastoral ministry organizations—write to express our strong support and alignment with the concerns detailed in the position paper, "Telemedicine Chemical Abortion: A Catholic Medical Association Policy with Recommendations." The totality of the medical evidence shows that the FDA has an ethical obligation to protect women from the dangers that mifepristone presents to women's health and safety. We respectfully urge you to act.

The Catholic Medical Association's (CMA) important document thoroughly details significant ethical, clinical, and societal issues associated with telemedicine chemical abortions involving mifepristone, and provides essential recommendations aimed at safeguarding women's health and dignity. We hope that you will find it to be of assistance in your review and in your work to achieve a healthier America, including as it relates to mifepristone use in telemedicine chemical abortions.

Among the primary concerns raised in the CMA paper are inadequate informed consent due to misleading adverse event data, insufficient disclosure of alternatives, increased risks of coercion especially for vulnerable populations, promotion of patient and provider dishonesty, and conflicts of interest favoring abortion ideology over public transparency. These deficiencies fundamentally violate principles of autonomy, beneficence, and non-maleficence, undermining patient safety and public trust.

Compounding these ethical and societal concerns is independent evidence from a recent comprehensive study by the Ethics and Public Policy Center. The study, covering 865,727 chemical abortion cases from 2017 to 2023, found that 10.93% of women experienced serious adverse events such as infection, sepsis, hemorrhage, and incomplete abortion—a rate shockingly 22 times higher than previously acknowledged by the FDA.

We are particularly troubled by the FDA's prior decisions to eliminate critical Risk Evaluation and Mitigation Strategies (REMS), such as requirements for multiple in-person physician visits, pelvic ultrasounds for

accurate gestational assessment, and comprehensive adverse event reporting. These protocols were essential safeguards protecting women's health and safety. Their removal has contributed to a dramatic 137% increase in chemical abortions since 2016, now accounting for 63% of all abortions in the U.S., often without adequate medical oversight.

Given these alarming ethical and clinical findings, the FDA has an urgent obligation to prioritize women's health and safety. Consistent with the administration's broader commitment to improve America's health, we strongly urge the FDA to take immediate and decisive actions, including:

- Reinstating essential REMS safeguards such as mandatory in-person medical consultations, pelvic ultrasounds, and comprehensive reporting of adverse events to the FDA MedWatch website;
- Conducting a thorough investigation into discrepancies in adverse event reporting highlighted by recent studies; and,
- Ensuring transparency and accuracy in informing patients about true risks and safe alternatives, thus upholding the principles of informed consent and patient autonomy.

While in this initiative we are focusing on the well-being of women, we want to stress that society is never served well by losing sight of the precious gift of life violated by abortion. As HHS Secretary Robert Kennedy Jr. has stated, every abortion is a tragedy.

Our coalition is ready to collaborate with the FDA to address these critical health issues effectively. Through the restoration and enhancement of safety protocols, the FDA will better protect women's health, advance public trust, and genuinely contribute to a healthier America for all. Consequently, we are requesting a meeting with you this summer to further discuss this matter. Dr. Michelle Stanford and Dr. Steven White can be reached at the following contact information respectively to schedule a meeting: mstanford@centennialpeds.com and president@catholichealthalliance.org.

Thank you for your prompt attention to this pressing matter. May your efforts safeguard the health and dignity of all Americans.

Sincerely,

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President, Catholic Health Care Leadership Alliance

Kathleen Raviele, M.D. FACOG
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Enclosure
"Telemedicine Chemical Abortion: A Catholic Medical Association Policy with Recommendations"

cc: Pastor Paula White-Cain, White House Faith Office