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

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Enclosure
"Telemedicine Chemical Abortion: A Catholic Medical Association Policy with Recommendations"

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

CATHOLIC MEDICAL ASSOCIATION

Upholding the Principles of the Catholic Faith in the Science and Practice of Medicine

Telemedicine Chemical Abortion: A Catholic Medical Association Policy with Recommendations

PROVISO

Direct abortion, in any form, is firmly opposed by the Catholic Medical Association (CMA) under any conditions. It is contrary to natural moral law and conflicts with the CMA's organizational mission to uphold the principles of the Catholic faith within medical science and practice.[1]

Abortion deliberately ends an innocent human life at its most vulnerable stage, violating the clear Catholic teaching that "*from the first moment of his existence, a human being must be recognized as having the rights of a person—among which is the inviolable right of every innocent being to life*" (CCC).[2]

The CMA acknowledges that abortion is legal in many U.S. states. Recent loosening of common-sense federal restrictions has made telemedicine chemical abortion essentially accessible nationwide, and it has become the predominant method used to end pregnancy.[3] CMA healthcare professionals are deeply concerned about its inherent ethical violations and harms, as currently practiced.

In this essay, CMA details these concerns, and proposes regulatory and patient-provider reforms to correct or minimize them. These recommendations are offered with CMA's recognition that all patients – including patients undergoing an abortion – are owed fundamental ethical protections and medical measures that minimize harm, which are absent in the telemedicine chemical abortion protocol. These recommendations are presented along with the CMA's reiteration of its constant objection to direct abortion as authentic healthcare, under any circumstances.

BACKGROUND: CHEMICAL ABORTION

Chemical Abortion, also referred to as 'medication abortion,' 'at home abortion,' and 'The Abortion Pill,' involves the pregnant woman taking two medications in consecutive order: mifepristone is taken first, to block progesterone which is essential for supporting growth of the embryo/fetus,

[1] Catholic Medical Association, Mission and Vision. https://www.cathmed.org/mission-vision/, Accessed 5-10-25.

[2] Catechism of the Catholic Church, § 2270-75. https://usccb.cld.bz/Catechism-of-the-Catholic-Church/566/.

[3] Guttmacher Institute. (2025, April 23). Medication abortion accounted for 63% of all US abortions in 2023 – An increase from 53% in 2020. Accessed 5-8-25

followed 24-48 hours later by misoprostol, which causes uterine contractions to expel the dead embryo/fetus.

Mifepristone was approved by the FDA in 2000 for abortion with restrictive protocols in place, including: requiring a physician with access to ultrasonography to see the patient three times,[4] and restricting use up to 49 days (7 weeks) of pregnancy.[5] In 2011, the FDA imposed a Risk Evaluation and Mitigation Strategy (REMS) which included in-person dispensing and patient counseling requirements. [6] In 2016, the FDA extended the approved gestational period to 70 days (10 weeks), expanded medical professionals who could dispense the drug and removed reporting requirements on adverse effects, except for death.

In 2021, during the COVID-19 pandemic, the FDA permitted mailing of chemical abortion medication after a telemedicine visit with a healthcare professional, and authorized mail-order providers. In 2021, the REMS was revised, and the pills were permanently allowed to be distributed via pharmacies and mail-order distributors, without an in-person visit. As of 2024, chemical abortion accounts for 63% of all abortions in the U.S.[3] These regulatory changes have raised significant ethical and societal concerns, outlined below.

ETHICAL & SOCIETAL CONCERNS

The chemical abortion protocol, as currently approved by the FDA, produces numerous violations of universally held bioethical standards which seek to ensure patient autonomy, health, and well-being. These include deficient informed consent due to biased, under-reporting of potential adverse effects, and the intentional withholding of viable alternatives such as progesterone-based protocols, should the patient change her mind. Additionally, today's telemedicine chemical abortion landscape increases risks of coercion and harm to minors, promotes provider and patient dishonesty, does not address psychological and/or spiritual distress, and presents conflict of interests between abortion stakeholders and patient safety. These are each described in detail below, with recommendations for mitigation.

1. Deficient Informed Consent, Threatening Patient Autonomy

The fundamental ethical principle of Respect for Patient Autonomy – one of the four pillars of the *Principlism* ethical framework applied in most non-faith-based U.S. healthcare settings,[7] relies

[4] Note: Ultrasonography is used to determine gestational age and screen for ectopic pregnancy - a contraindication for chemical abortion.

[5] Gottlieb S. (2000, October 7). Abortion pill is approved for sale in United States. *BMJ.* 321:7265, 854. DOI:10.1136/bmj.321.7265.854/e.

[6] U.S. Food and Drug Administration. (2025, January 17). Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation. Accessed April 30, 2025.

[7] Beauchamp TL, and Childress, JF. (2013). *Principles of Biomedical Ethics*, 7th Ed., Chapter 1. *Moral Norms*, Oxford University Press, New York.

heavily upon obtaining valid informed consent from the patient, in order that the patient may make a well-considered, autonomous decision about their healthcare.[8,9] The American Medical Association (AMA) Code of Medical Ethics on Informed Consent (AMA Code)[9] specifies that when obtaining informed consent for a medical treatment, physicians should provide information about "…*the burdens, risks, and expected benefits of all options, including forgoing treatment.*" (Section 2.1.1 (b) iii).[9] The chemical abortion protocol fails to meet this crucial imperative on two grounds: A) failure to provide accurate and current data on adverse risks, and B) failure to disclose important options to the patient. These failures are described below.

1A. Failure to provide accurate and current data on adverse effects: Valid informed consent requires that patients receive current, unbiased data on potential risks and adverse effects of considered treatments.[8,9] However, estimates of adverse effects from U.S. studies have generally been far lower than those from international studies, raising concerns about their validity and bias. Commonly cited U.S. complication rates from chemical abortion range between 0.18% and 0.32%, [10,11] and are based primarily on limited, outdated clinical trials.

In contrast, a recent European study with close medical supervision reported a 20.0% overall complication rate, including 15.6% with significant bleeding and 6.7% requiring surgical intervention for an incomplete abortion.[12] Most recently, a large-scale U.S. study using an all-payer insurance claims database covering 865,727 mifepristone abortions between 2017 and 2023, found that 10.93% of women experienced serious adverse events—such as sepsis, infection, hemorrhage, or incomplete abortion—within 45 days.[13] This real-world rate is at least 22 times higher than the "less than 0.5%" figure commonly cited on FDA labeling and by drug manufacturers. [11] These discrepancies have neither been acknowledged nor addressed.

Minimizing the adverse effects of chemical abortion became more problematic with the FDA's removal of common-sense safety measures, especially mandatory in-person visits with a physician, and expanded permitted use from 49 days gestation to 70 days.[14]

These circumstances combined to put women at even greater medical risk. For example, the FDA's decision to increase the upper allowable gestational age from 49-70 days results in a 62.5% increase in development of the fetus and placenta, further increasing the risks and severity of adverse effects

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[8] Beauchamp TL and Childress, JF (2013). Chapter 4. I*nformed Consent*, Oxford University Press, New York.

[9] American Medical Association. (2024). Opinion 2.1.1 – Informed Consent. AMA Code of Medical Ethics. Accessed 4-17-2025.

[10] Grossman D, and Grindlay K. (2017). Safety of medical abortion provided through telemedicine compared with in person. *Obstet and Gynecol*. 130(4): 778-782.

[11] Mifeprex FDA-Approved Label, Table 2. Accessed 4-30-25.

[12] Niinimaki M, Pouta A, Bloigu A, et al. (2009). Immediate complications after medical compared with surgical termination of pregnancy. *Obstet Gynecol*. 114(4):795-804.

[13] Hall, JB and Anderson, RT. (2025, April 28). The Abortion Pill Harms Women: Insurance data reveals one in ten patients experiences a serious adverse event. Ethics and Public Policy Center. Accessed 4-29-2025.

[14] U.S. Food and Drug Administration. (2025, February 11). Questions and answers on mifepristone for medical termination of pregnancy through ten weeks gestation. Accessed 4-25-25.

from chemical abortion, which are likely not reflected in older data. This issue becomes more concerning given that chemical abortions have increased approximately 137% since 2016, when the FDA suspended its adverse risk reporting mandate.[15]

Recommendations:

- Require reporting of all adverse effects (not just deaths) to the Centers for Disease Control (CDC), by prescribers and emergency room care providers
- Provide unbiased and updated information of adverse effects to women considering chemical abortion
- Analyze conflicting data on adverse effects, to determine sources of discrepancies

1B. Failure to disclose options, including abortion reversal: Patients are ethically owed information on options and alternatives to medical treatments, as iterated in the AMA Code of Ethics:

- "Transparency with patients regarding all medically appropriate options of treatment is critical to fostering trust…"
- "Physicians should assess the ability to understand relevant medical information and the implications of treatment alternatives…"
- "The physician should include information about: …expected benefits of all options, including forgoing treatment."[9] *(underlined emphasis added)*

In spite of these robust recommendations, information on treatment options to chemical abortion, such as pregnancy continuance, adoption, and the possibility of reversing the chemical abortion once started, are often underplayed or excluded. In fact, patients are sometimes counseled that stopping the abortion process after taking mifepristone alone could result in birth defects.[16]

To make a truly informed and autonomous decision, women seeking chemical abortion should be informed of all their options and alternatives, including pregnancy continuance and adoption. Information on community services should be provided, as should the option to view the embryo/fetus via ultrasound, since it has been shown to provide critical information impacting a woman's decision to abort.[17]

Additionally, information on reversing the abortion process, once begun, should be provided. Women can and do change their minds about continuing with chemical abortions after they ingest the first medication. For these reasons, women should receive information on the Abortion Pill Reversal (APR) protocol or similar protocols which incorporate high-

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[15] Note: Estimate based upon 270,971 chemical abortions in 2016 and 642,700 in 2023, derived from the Guttmacher Institute's March 2024 News Release "Medication Abortions accounted for 63% of all US abortions in 2023, an increase from 53% in 2020."Accessed 4-25-25.

[16] Starkman E. (2024, May 27). Medical abortion (abortion pill): What to know. Accessed 5-5-25.

[17] Fletcher JC, Evans MI. (1983). Maternal bonding in early fetal ultrasound examinations. *NEJM* 308(7), 392-393.

dose natural progesterone to restore pregnancy-sustaining hormones to counter the progesterone-blocking effects of mifepristone – the first medication in the two-medication chemical abortion procedure.[18]

The American College of Obstetricians and Gynecologists (ACOG), however, contests APR as a viable option, claiming that *"There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing."*[19] Further, they suggest that cases of women choosing to reverse their abortion are "*very rare*," and that such patients "*...should be monitored expectantly."*[13]

But ACOG is in error on both claims. The effectiveness of a progesterone-based protocol like APR is supported by the fact that natural progesterone is used routinely in cases of habitual miscarriages due to luteal phase defects.[20] Further, research has shown that APR achieves a 66% success rate in continuing pregnancies,[21] compared to a 25% continuance when no progesterone is administered.[22] The effectiveness of APR is also corroborated by over 6,000 births (as of November 2024) which have occurred in women who changed their mind after initiating the chemical abortion procedure and underwent a progesterone protocol.[23]

Recommendations:

- Require that informed consent include non-abortion alternatives including pregnancy continuance and adoption
- Require disclosure of progesterone-based options for abortion reversal, should the patient change her mind
- Require a pelvic ultrasound to rule out an ectopic pregnancy and to allow the patient, if she desires, to view the embryo/fetus

2. Potential for Coercion and Use Abuse

The lack of direct medical supervision in telemedicine chemical abortions creates opportunities for coercion, particularly by abusive partners, family members, or sex traffickers. Without an in-person visit, abusers can more easily procure abortion pills for a woman without her consent or under pressure to terminate her pregnancy. In domestic abuse scenarios, women often have limited control over their healthcare decisions, and telemedicine allows perpetrators to exploit the system while

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[18] American Pregnancy Association. Abortion Pill Reversal, Accessed 4-26-25.

[19] American College of Obstetricians and Gynecologists. (2020, reaffirmed 2023). Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. *Am J Obstet Gynecol* 136:e31–47.

[20] Coomarasamy A, Harb HM, Devall AJ, et al. (2020). Progesterone to prevent miscarriage in women with early pregnancy bleeding: the PRISM RCT. Health Technol Assess. 2020 Jun;24(33):1-70. DOI: 10.3310/hta24330. PMID: 32609084.

[21] Delgado G, Condly SJ, Davenport M, et al. (2018). A case series detailing the successful reversal of the effects of mifepristone using progesterone. *Issues Law Med*. 33(1):21-31.

[22] Delgado G, Harrison, MP and Khauv, V. (2017). Embryo survival after mifepristone: A systematic review of the literature. *Issues Law Med*. Spring 32, no. 1; 3–18. PMID:29108160.

[23] Heartbeat International. (2024, November 20). Abortion Pill Reversal has Saved 6,000 Lives Despite Big Abortion's Attempts to Discredit Science Behind it. Accessed 5-17-25.

concealing their actions. Healthcare providers have an ethical obligation to protect patient autonomy, yet telemedicine chemical abortions remove essential safeguards that could shield vulnerable women from forced or coerced procedures.

Recommendation:

- Require in-person, physician consultations before beginning the chemical abortion protocol

3. Risks to Minors and Lack of Oversight

In many states, minors can access abortion pills without parental consent and/or notification,[24] placing young girls at significant medical and psychological risk. Without parental guidance, minors may not fully understand the procedure, its complications, or its emotional impact. Moreover, the absence of in-person oversight in telemedicine chemical abortions means that cases of sexual abuse, incest, or coercion may go undetected, as providers cannot observe warning signs that an in-person consultation might reveal. Healthcare providers have an ethical duty to protect vulnerable patients, yet telemedicine policies allow minors to make life-altering decisions without adequate support or safeguards, compromising their safety.

Recommendation:

- Require in-person physician consultation
- Require parental consent/notification for minors

4. Encouraged Patient Dishonesty and Provider Dishonesty

Women who are experiencing serious complications from telemedicine chemical abortions are frequently advised by women's groups and pro-abortion sources[25,26,27,28] to misrepresent their true situation in emergency rooms. A few examples illustrate this point:

- *"The person seeking medical care should be careful not to say that they have used abortion pills. Instead, all they need to say is that they think they're having a miscarriage."*[27] AbortionPillInfo.org.

- *"You do NOT have to say that you took abortion pills. They cannot be detected. You can just say you are pregnant and bleeding."*[25] AidAccess.org.

- "*...you can say "I had a positive pregnancy test and I'm now having a lot of bleeding. I want to check that I'm OK.*"[29] National Abortion Federation.

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[24] KFF - Henry J. Kaiser Family Foundation. (2024, September). Parental Consent/Notification Requirements for Minors Seeking Abortions. Accessed 4-22-25.

[25] Aid Access. How to use abortion pills. Accessed 4-17-25.

[26] Women help women. (2019, September 23) Will a doctor be able to tell if you've taken abortion pills? Accessed 5-17-25.

[27] Abortion Pill Information. Q: Is it legal to use abortion pills without a clinician? Accessed 4-17-25.

[28] Grant R. and Gold EI. (2022, June 28). How to have a medication abortion. Where to find the pill and what to expect. *The Cut*. Accessed 4-17-25.

[29] National Abortion Federation. Using abortion pills on your own: What to expect. Accessed 4-25-25.

A more egregious breach of professional ethics occurs when women with serious complications are advised by their abortion provider to misrepresent their situation as a natural miscarriage in the emergency room[30] or when emergency room physicians purposely do not ask questions or withhold accurate documentation about the source of the complication, as suggested by The Society of Family Planning to its 'reproductive care worker' members.[31]

In fact, by instructing a woman to go to the emergency room if/when complications occur, the abortion provider is deserting her in her time of need, constituting medical abandonment, defined as "*neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care...*"[32]

Whether coming from abortion advocacy groups or medical professionals, the practice of encouraging women to conceal or misrepresent their accurate medical history jeopardizes the woman's health by risking inappropriate or delayed treatment, and is coercive. Further, it erodes trust between patients and emergency care providers, undermining the integrity of medical providers.

Recommendations:

- ACOG and hospital administrators should denounce promotion of medical deception for patients who experience complications
- Abortion advocacy groups should cease public and private promotion of medical dishonesty
- Require providers to manage (and report) complications, should they occur

5. Misleading Perception of Treatment Simplicity

The accessibility of telemedicine chemical abortions may foster a misconception that the procedure is routine and low-risk, akin to managing a minor illness with an online prescription. This misperception can lead women to underestimate potential complications, such as excessive bleeding, infection, severe cramping, or incomplete abortion requiring surgical intervention. Without an in-person consultation, women may also be less inclined to seek follow-up care if issues arise, heightening their medical risks. Ethical medical practice demands that patients fully grasp the gravity of any procedure, but the convenience-driven nature of telemedicine diminishes the perceived seriousness of chemical abortion.

Recommendation:

- Providers should not minimize the procedure nor its adverse effects

[30] Kitchener, C. (2024, April 11). In states with bans, women often take abortion pills alone, afraid. Washington Post. Accessed 4-22-25.

[31] Society of Family Planning. (2022, Sept 8). SFP Interim Clinical Recommendations. Accessed 4-28-25.

[32] USLegal. Medical abandonment law and legal definition. Accessed 5-8-25.

6. Unaddressed Psychological & Spiritual Consequences

While advocates of chemical abortion frequently frame the process as straightforward and emotionally inert or even positive,[33,34,35] a growing body of research has exposed its many serious psychological costs. Women undergoing abortion of any type (surgical and/or chemical) have been shown to face increased risks of guilt, remorse, anxiety, depression, decreased self-esteem, worry about future conceptions, substance abuse, suicide ideation, and endure lingering emotional trauma.[36,37,38,39,40,41,42] Women with a pre-existing vulnerability to mental illness are at even higher risk of experiencing some of these mental health problems.[41] It is important to note that there is no clear evidence supporting the oft-cited claim that abortion *reduces* mental health risks associated with unwanted pregnancies.[38]

The spiritual effects of abortion must also be considered, as women holding religious beliefs are more likely to experience long-term remorse (55%) and emotional problems (16.1%) one-year after their abortion.[37]

These adverse psychological and spiritual consequences are not surprising given the inherent nature of abortion, which ends a life. It is reasonable to propose that such sequalae may be more manifest from chemical abortion, since the process is completed alone at home without medical supervision, and may involve the woman seeing, handling, and disposing of her embryo/fetus.

Recommendations:

- Require a pre-and post-abortion visit with a physician, with attention to a history of pre-existing mental health problems; referrals should be made as warranted
- Inform women of possible adverse mental health effects

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[33] Abrams, Z. (2023, April 23). American Psychological Association. The facts about abortion and mental health. Accessed 5-6-25.

[34] Planned Parenthood. What facts about abortion do I need to know? Accessed 5-6-25.

[35] American College of Obstetricians and Gynecologists (ACOG). Abortion Access Fact Sheet Evidence-Based Talking Points Accessed 5-8-25.

[36] Sullins, DP. (2016). Abortion, substance abuse and mental health in early adulthood: Thirteen-year longitudinal evidence from the United States. *Sage Open Medicine* 4:1-11, 2016. DOI: 10.1177/205031216665997.

[37] Söderberg, H, Janzon, L, Sjöberg, NO. (1998). Emotional distress following induced abortion. A study of its incidence and determinants among abortees in Malmö, Sweden. *Euro J Ob Gyn Repro Bio.* 79:173-178. doi:10.1016/S0301-2115(98)00084-1

[38] Fergusson DM, Horwood LJ and Boden, JM. (2008). Abortion and mental health disorders: evidence from a 30-year longitudinal study. *Br J Psych.* 193:441-445. Doi: 10.1192/bjp.bp.108.056499.

[39] Moto NP, Burnett M, and Sareen J. (2010). Associations between abortion, mental disorders, and suicidal behavior in a nationally representative sample. *Can J Psych,* 55(4): 239-246.

[40] Coleman PK. (2011). Abortion and mental health: quantitative synthesis and analysis of research published 1995-2009. *Br J Psych*. 199(3): 180-186. doi:10.1192/bjp.bp.110.077230.

[41] Reardon DC. (2018). The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities. *Sage Open Medicine* 6:1-38. DOI: 10.1177/2050312118807624.

[42] Studnicki J, Longbons T, Fisher J, Reardon DC, et al. (2023). *Int J Women's Health* 15:955-963.

7. Conflicts of Interest

As previously described, there has been a rapid dismantling of common-sense safety measures overseeing chemical abortions. Support for these changes comes from various quarters, including reproductive health organizations like Planned Parenthood, professional organizations such as ACOG and the AMA, and the distributors of mifepristone.

For example, Danco Laboratories (Danco) - the largest U.S. distributor of mifepristone under the trade name Mifeprex - has been able to secure secretive meetings with FDA officials when discussing regulations related to its product,[43] and the FDA admits redacting generally published information about its documentation on Mifeprex, recounting that some omitted information "… *is the type of information that would not ordinarily be redacted from FDA records*."[44]

Further, in 2000, the New York State Supreme Court, Appellate Division, ruled against attempts to disclose Danco's corporate board and other information generally made public, in spite of filings by groups including the Washington Post.[45]

Each of these entities have afforded chemical abortion providers special approvals and legislative treatment, which favors abortion stakeholders at the expense of women's health and well-being.

Recommendation:

- Disallow special treatment of chemical abortion stakeholders in regulatory and judicial proceedings, enabling full transparency for public scrutiny

Collectively, these concerns and recommendations are set forth in Figure 1 below.

[43] Rutherford F. (2023, April 13). "Why you've never heard of the company behind the abortion pill," Los Angeles Times.

[44] U.S. Food & Drug Administration, (2017, April 28). Mifepristone (Mifeprex) Post market drug safety information for patients and providers. Accessed 5-8-25.

[45] DANCO LABORATORIES LIMITED v. The Washington Post Company, Intervenor-Appellant. (2000). Supreme Court, Appellate Division, First Department, New York. Accessed 5-8-25.

Figure 1

Ethical and Societal Concerns of Telemedicine Chemical Abortion, with Recommendations to Minimize

ETHICAL & SOCIETAL CONCERN	RECOMMENDATION to MINIMIZE
1. Deficient Informed Consent, Impacting Autonomy, owing to: A. *Questionable Adverse Effect Data*	• Require reporting of all adverse effects (not just death) to the CDC • Provide unbiased and updated information to patients • Analyze conflicting data, to determine source of discrepancies
B. *Failure to Disclose Alternatives*	• Require disclosure of alternatives to abortion • Require disclosure of progesterone-based options for abortion reversal • Require a pelvic ultrasound
2. Potential for Coercion and Abuse	• Require in-person, physician consultation
3. Risks to Minors	• Require in-person, physician consultation • Require parental consent/notification
4. Encouraged Patient & Provider Dishonesty	• Denounce dishonest provider practices which promote medical deception • Cease advising patients to misrepresent abortion history during complications • Require providers to manage (and report) complications, should they occur
5. Misleading Perception of Treatment Simplicity	• Accurately represent the procedure and its adverse effects
6. Unaddressed Psychological/Spiritual Effects	• Require pre- and post-abortion visits, with psychological attention and referral, if warranted • Inform women of possible adverse mental health effects
7. Conflicts of Interest	• Disallow special treatment of abortion stakeholders in regulatory and judicial proceedings

SUMMARY

In recent years, chemical abortion has experienced significant reductions in FDA-mandated safety guidelines, and simultaneously has become the primary method of choice for U.S. women seeking an abortion. However substantial deficiencies exist in obtaining valid informed consent for the procedure, including the woman being provided inaccurate and biased information on potential adverse effects, and incomplete information on viable alternatives such as the possibility of reversing the abortion, once begun. This negates patient autonomy– a foundational obligation of medical care provision.

This essay describes these and other problematic impacts of telemedicine chemical abortion, with recommendations to eliminate or minimize such effects. These recommendations, however, should not be construed as approval or endorsement of direct abortion, which the Catholic Medical Association firmly and consistently rejects on moral and theological grounds. Rather, they are presented to advocate for common sense changes at both the regulatory level and in the patient-provider setting, in order to ensure that women are given complete and unbiased information to make a life-impacting decision, and to better safeguard women's rights and health.

Approved by the Board of Directors - June 2025.