



May 16, 2025

The Honorable Martin A. Makary, M.D., M.P.H. Commissioner U.S. Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993

### **RE:** The Danger Abortion Drugs Pose to Women and Babies

Dear Commissioner Makary:

The American Center for Law & Justice (ACLJ) submits this letter and the attached memorandum are on behalf of over 220,400 of its supporters who oppose abortion and value innocent human life.<sup>1</sup> By way of introduction, the ACLJ is an organization dedicated to the defense of constitutional liberties secured by law, including the defense of the sanctity of human life. Counsel for the ACLJ have presented expert testimony before state and federal legislative bodies, and have presented oral argument, represented parties, and submitted amicus curiae briefs before the Supreme Court of the United States and numerous state and federal courts in cases involving a variety of issues, including the right to life, and in particular, issues surrounding chemical abortions.<sup>2</sup>

We appreciate the Trump Administration's strong stance protecting both the sanctity of life and women's safety and health. We write to raise a specific concern implicating both. We have enclosed a memorandum explaining the harms women have suffered and will continue to suffer under current federal policy initiated by the Biden Administration regarding abortion pills if you do not intervene to protect women's lives. Current regulations provide insufficient safety measures

<sup>&</sup>lt;sup>1</sup> Petition: Defend Life, Defeat Abortion in All 50 States, ACLJ, <u>https://aclj.org/pro-life/defend-life-defeat-abortion-in-all-50-states</u> (last visited Feb. 24, 2025).

 <sup>&</sup>lt;sup>2</sup> See, e.g., FDA v. All. for Hippocratic Med., 602 U.S. 367 (2024); Dobbs v. Jackson Women's Health Org., 597 U.S.
 215 (2022); June Medical Servs. v. Russo, 591 U.S. 299 (2020); Livingwell Med. Clinic, Inc. v. Becerra, 585 U.S.
 1027 (2018); Whole Women's Health v. Hellerstedt, 579 U.S. 582 (2016); Pleasant Grove City v. Summum, 555 U.S.
 460 (2009); Gonzales v. Carhart, 550 U.S. 124 (2007); Schenck v. Pro-Choice Network, 519 U.S. 357 (1997).

for women and what little protections they do provide are openly flouted by organizations that mislead women as to the true risks of the abortion pill regimen.

Chemical abortions, or "drug-induced" abortions, through the abortion pill regimen (i.e. mifepristone and misoprostol), are harmful to women. Further, drug-induced abortions facilitate the ability of others to coerce women into abortions. Finally, faulty and insufficient reporting standards do not allow a full analysis of the risks of drug-induced abortions – a fact well-known to abortion advocates who, both nationally and internationally, have consistently undermined safety regulations and opposed reporting and informed consent laws. We have every faith that the current Administration will appreciate the severity of the dangers to women and babies and take steps to protect the women of this country from the manipulation, deceit, and coercion of others who gain from abortion.

We hope that you will correct the dangerous and reckless course set by the Biden Administration. Should this Administration decide to move forward in this regard, the ACLJ stands ready to assist in whatever way possible.

Sincerely,

Joelan Schlas

Jordan Sekulow Executive Director American Center for Law & Justice

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### **EXECUTIVE SUMMARY**

### I. The dangers of chemical abortions and the elimination of safety measures

According to several studies, anywhere from 64–74% of women received an abortion because of coercion.<sup>*i*,*ii*</sup> Over 58% "reported aborting to make others happy."<sup>*iii*</sup> While 28.4% of the women specifically chose abortion "out of fear of losing their partner if they did not abort."<sup>*iv*</sup> Another study revealed women who "chose" abortion, "the probability of being a victim of [intimate partner violence] in the past year . . . was almost <u>three times higher</u> than for women [who chose to continue their pregnancy]."<sup>*v*</sup> Abortion is a means for human traffickers, sexual predators, and domestic abusers to hide their illegal activities.<sup>*vi*, *vii*</sup>

#### Even absent coercion, the chemical abortion pill physically harms women

The rate of abortion pill-related ER visits has increased by more than 500% in the past fifteen years.<sup>viii</sup> Chemical abortions have nearly <u>four times</u> the complication rate of surgical abortion.<sup>ix</sup> In a brand-new study released on April 28, 2025, the largest-known study of the abortion pill based on 865,727 cases where women were prescribed mifepristone from 2017–2023 provides the following data: 10.93% experienced some adverse event in the 45-days after a chemical abortion, including, but not limited to: 28,658 cases of hemorrhage, 40,960 ER visits, 3,062 ectopic pregnancies, 24,563 cases required surgical abortion, and 49,169 other abortion specific complications.<sup>x</sup> This is drastically different than Mifeprex, which claims on its label only a 0.05% rate of adverse events from its product.<sup>xi</sup>

Reporting of abortion harm is inconsistent, with study attempting to show the pill's "safety" reported that only 74% of women followed up with researchers.<sup>xii, xiii</sup> In other words, over 25% failed to follow up. The numbers previously reported are drastically inaccurate.

### II. The harm to women has increased since FDA deregulation

The numbers have skyrocketed. Since 2000, there have been nearly six-million chemical abortions.<sup>xiv, xv</sup> In 2023, 63% of all abortions reported in the U.S. were chemical abortions.<sup>xvi</sup> Even with these numbers, the Guttmacher Institute estimates that, due to the deregulation of the pill and the boom of telehealth, access has astronomically increased, therefore there is an almost certainty that the numbers are undercounted.<sup>xvii</sup>

### <u>Continuing the current deregulation scheme for abortion-related drugs amplifies the</u> <u>risk to women and children</u>

Telehealth appointments allow online abortion pill providers to dispense abortion drugs without appropriate medical monitoring. This presents a problem when appropriately estimating gestational age in dispensing the pills or diagnosing an ectopic pregnancy.<sup>xviii, xix, xx, xxi</sup>

Providing these pills past gestational limits is not new information to the CDC, who reported 12,231 chemical abortions that occurred within 10-13 weeks of gestational age, despite an 11-week cutoff while nearly 1,000 chemical abortions occurred after 13 weeks, with almost half of those occurring after 21 weeks.<sup>xxii, xxiii</sup> Because this reflects only voluntary reporting, the true scope of how many instances where pills are prescribed after the 11-week limit is impossible to determine under current reporting conditions.<sup>xxiv</sup>

#### *i.* Chemical abortions necessitate more emergency interventions

The consequences of incomplete and flawed reporting do not end at prescriptions that exceed the 11-week gestational cutoff. As noted above, the FDA has not required any adverse consequences other than the death of the woman to be listed as a "complication" of chemical abortions.<sup>xxv</sup> However, one study found that 75% of women treated at ERs after taking abortion pills were in "severe" or "critical" condition.<sup>xxvi</sup> From 2004 to 2015, the number of complications designated as severe or critical increased by 4,041.1% for chemical abortions.<sup>xxvii</sup>

"Successful" chemical abortions still carry risks. For example, after several abortions, a young woman attempted a chemical abortion.<sup>xxviii</sup> She was given the first pill in an abortion center and sent home to weather the experience alone.<sup>xxix</sup> After intense pain, she delivered the baby in the bathroom and watched the live baby die in her hands.<sup>xxx</sup> This young woman suffered from severe back pain and intense bleeding for *months* after taking the pill, while Planned Parenthood refused to offer her any help.<sup>xxxi</sup> Eventually, she was rushed to the emergency room with dark purple urine and diagnosed with toxic shock as a result of the placenta failing to expel itself from her uterus.<sup>xxxiii</sup> The nurse told her that if she had not come in that morning she would have died.<sup>xxxiii</sup>

## *ii.* Domestic and foreign businesses profit from chemical abortion and encourage circumventing state law

Pro-abortion businesses and organizations profit from FDA deregulation of chemical abortions and promote telehealth abortion pills despite any differing state regulation and in defiance of the FDA's 11-week cutoff, providing abortion drugs well past that cutoff. For example, the website, Plan C, provides a list of telehealth providers who supply to all or most of the 50 states.<sup>xxxiv</sup> The following are websites referred to by Plan C as options for obtaining abortion pills: A Safe Choice: uses California's "Abortion Shield Law" to skirt other state laws.<sup>xxxv</sup> We Take Care of Us: provides pills nationwide and "prepper kits" to "have on hand, just in case."<sup>xxxvii</sup> Abuzz Health: provides abortion drugs in most states for pregnant women and in advance of pregnancy.<sup>xxxviii, xxxii</sup> The Map: provides pills in all 50 states and provides pills "for future use in the future" for an extra fee.<sup>xl</sup>

Foreign entities also take advantage of this deregulation for easy profit: Women on Web: a Canadian organization, provides abortion pills to U.S. users nationwide and provides the pill to nonpregnant users and offers advice on how to ensure traces of the drug are not found in the user's system. <sup>xli, xlii</sup> Other foreign organizations smuggle drugs across the southern border and provide "prepper kits" for "emergencies." <sup>xliii</sup>, <sup>xliv</sup>, <sup>xlvi</sup>, <sup>xlvi</sup>, <sup>xlvi</sup>

#### **III.** Conclusion

The ACLJ has and will always take the position that abortion takes an innocent human life. There is no more an innocent or helpless a state for a human being than while still forming in their mother's womb. These innocent human beings deserve the full protection of the law.



## MEMORANDUM

# I. The Dangers of Drug-Induced Abortions and the Elimination of Their Safety Measures

Contrary to the false notion and oft-pushed narrative that abortion is "liberating" for women and a fundamental "right," abortion largely serves as a form of oppression or exploitation of women. This is so not only because women are often coerced into abortions but also because of the dangerous complications from abortions that threaten women's health. This is especially true regarding drug-induced abortions that in various respects exceed the negative aspects of surgical abortions.

### A. Abortion is Not Synonymous with "Choice"

A study from the early 2000s showed that 64% of the American women surveyed reported feeling pressured by others to obtain an abortion.<sup>3</sup> Another study from 2017 similarly found that nearly 74% of the post-abortive women surveyed admitted "that their decision to abort was [not] entirely free from even subtle pressure from others to abort," over 58% "reported aborting to make others happy," and 28.4% of the women specifically chose abortion "out of fear of losing their partner if they did not abort."<sup>4</sup> A more recent study, published in January 2023, shows that "61% of the women reported experiencing a high level of pressure to abort."<sup>5</sup> The study concluded that "[w]omen frequently choose abortion due to perceived pressures from other people, financial concerns, or other circumstantial pressures." Further,

[t]hese pressures, individually and/or together are strongly associated with more negative emotions about their abortion; more disruptions of their daily life, work, or relationships; more frequent feelings of loss, grief, or sadness about their abortions; more moral and maternal conflict over their abortion decisions; a perceived decline in their overall mental health that they attribute to their abortions; and a higher degree of desire or need for help to cope with negative feelings about their abortions.<sup>6</sup>

<sup>&</sup>lt;sup>3</sup> Vincent M. Rue, et al., *Induced Abortion and Traumatic Stress: A Preliminary Comparison of American and Russian Women*, 10 MED. SCI. MONITOR 9 (2004).

<sup>&</sup>lt;sup>4</sup> Priscilla K. Coleman, Ph.D., Women Who Suffered Emotionally from Abortion: A Qualitative Synthesis of Their Experiences, 22 J. AMER. PHYSICIANS & SURGEONS 113, 115 (2017).

<sup>&</sup>lt;sup>5</sup> David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, CUREUS (Jan. 31, 2023), <u>https://www.cureus.com/articles/124269-effects-of-pressure-to-abort-on-womens-emotional-responses-and-mental-health#!/</u>.

Contrary to the narrative that abortion offers women "choice," the reality is that a majority of women have been and continue to be pressured and coerced into abortion, and then are left, often without support, to navigate the negative effects of abortion. Often, pressure comes from those who prioritize their own interests above the best interests and wishes of the pregnant woman: "once abortion becomes available, it becomes the most attractive option for everyone *around* the pregnant woman."<sup>7</sup>

In addition, abortion is frequently exploited by perpetrators of human trafficking, sexual predators, and domestic abusers. Forced abortions are an especially prevalent trend in sex trafficking and most abortions by survivors of sex trafficking were not freely chosen.<sup>8</sup> Abortion also supplies a too-convenient means for sexual predators to conceal obvious evidence—pregnancy and childbirth—of their exploitation.<sup>9</sup> One study revealed that among women who "chose" abortion, "the probability of being a victim of [intimate partner violence] in the past year . . . was almost three times higher than for women [who chose to continue their pregnancy]."<sup>10</sup> This is not the "freedom" promised by the abortion industry, but a highly effective means by which abuse and coercion are perpetrated.

Moreover, according to abortion advocates, a woman should be able to obtain an abortion on the theory that acceding to her abuser's desires will reduce future abuse, but the truth is that abortion—even as appeasement—does not free a woman from abuse.<sup>11</sup> Importantly, in the context of drug-induced abortions, it is far easier for an abuser to coerce a woman into taking abortion pills than to compel her to go to a facility for a surgical procedure.<sup>12</sup> There is also the obvious risk that abusers will deceive women into consuming these pills unknowingly.<sup>13</sup>

<sup>&</sup>lt;sup>7</sup> Frederica Mathewes-Green, *When Abortion Suddenly Stopped Making Sense*, Nat'l Rev., (Jan. 22, 2016), https://www.nationalreview.com/2016/01/abortion-roe-v-wade-unborn-children-women-feminism-march-life/, (emphasis in original).

<sup>&</sup>lt;sup>8</sup> Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, 23 ANNALS HEALTH L. 61, 73 (2014), <u>https://tinyurl.com/3hvjednk</u>.
<sup>9</sup> See, e.g., United States v. Raniere, 2019 U.S. Dist. LEXIS 84634 (E.D. N.Y. May 3, 2019) (abortions for women impregnated by leader of apparent cult); Tonya Alanez, 58 Porno Videos of 15-Year-Old Girl Lead to Davie Man's Arrest, S. FLA. SUN SENTINEL (Oct. 23, 2019) <u>https://www.sun-sentinel.com/2019/10/23/58-porno-videos-of-15-year-old-girl-lead-to-davie-mans-arrest/</u> ("The victim stated that she got pregnant from the defendant and he took her to the clinic to have an abortion."); Carole Novielli, Man Took 14-Year-Old For Three Abortions After Impregnating Her, Clinics Ignored the Rapes, LIFE NEWS (July 30, 2014), <u>https://www.lifenews.com/2014/07/30/man-took-14-year-old-for-three-abortions-after-impregnating-her-clinics-ignored-the-rapes/; David McFadden, Probation Revoked for Man in Impregnating 11-Year-Old, Forcing to Get Abortion, ABC13 NEWS (July 19, 2018), <a href="https://www.liteps://www.log.luly19.2018">https://www.liteps://www.luly19.2018</a>), <a href="https://www.liteps://www.luly19.2018">https://www.luly19.2018</a>), <a href="https://www.luly19.2018">https://www.luly19.2018</a>), <a href="https://www.luly19.2018">https://www.luly1</u>

<sup>&</sup>lt;sup>10</sup> Dominique Bourassa, MD, & Jocelyn Bérubé, MD, *The Prevalence of Intimate Partner Violence Among Women and Teenagers Seeking Abortion Compared with Those Continuing Pregnancy*, 29 J. OBSTETRICS GYNAECOLOGY CAN. 415, 415 (2007).

<sup>&</sup>lt;sup>11</sup> See Gillian Aston & Susan Bewley, *Abortion and Domestic Violence*, 11 THE OBSTETRICIAN & GYNAECOLOGIST 163, 165 (2009).

<sup>&</sup>lt;sup>12</sup> E.g., Nancy Dillon, *California Man Accused of Forcing Pregnant Girlfriend to Take Miscarriage Pills at Gunpoint*, N.Y. DAILY NEWS (Dec. 12, 2019), <u>https://www.nydailynews.com/2019/12/12/california-man-accused-of-forcing-pregnant-girlfriend-to-take-miscarriage-pills-at-gunpoint/;</u> Assoc. Press, *Police: NY Man Forced Woman to Swallow Abortion Pill*, FOX NEWS (Jan. 8, 2015), <u>https://www.foxnews.com/us/police-ny-man-forced-woman-to-swallow-abortion-pill</u>.

<sup>&</sup>lt;sup>13</sup> *E.g.*, Jerry Lambe, "Attorney who secretly slipped abortion pills in wife's drink 7 times because pregnancy would 'ruin his plans' sentenced to 6 months," *Law & Crime*, (Feb. 8, 2024), https://lawandcrime.com/crime/attorney-who-

#### **B.** Even Absent Coercion, Drug-Induced Abortions Themselves Harm Women

Aside from psychological and emotional harm, abortion drugs themselves pose a significant threat to the women who take them. The rate of abortion pill-related ER visits has increased by more than 500% over the past decade and a half.<sup>14</sup> Additionally, drug-induced abortions have nearly <u>four times</u> the complication rate of surgical abortion.<sup>15</sup> According to one study, 75% of visits to the emergency department within 30 days of the use of abortion drugs were coded as severe or critical – conditions that require urgent medical attention or pose an immediate threat to life.<sup>16</sup> Mifepristone specifically may not work in a safe or effective way nearly one out of every four times it is taken for an abortion.<sup>17</sup> Because of these serious risks, the U.S. Food and Drug Administration (FDA) had safety protocols to mitigate the risks of these abortion drugs for two decades.<sup>18</sup> The FDA's Risk Evaluation and Mitigation Strategy ("REMS") policy pertaining to mifepristone was intended to "mitigate the risk of serious complications associated with mifepristone" chiefly by "[e]nsuring that mifepristone [was] only dispensed in certain healthcare settings by or under the supervision of a certified prescriber."<sup>19</sup>

A more recent study, studying over 800,000 women who were prescribed the abortion pill, reveals an alarming—yet unsurprising—number of adverse events for women, contrary to the decades-old false facts peddled by chemical abortion proponents that the pills are "safe." Spanning data from 2017–2023, the Ethics and Public Policy Center's profound study elucidates the real risks that face women from a drug much more dangerous than Tylenol.<sup>20</sup> Overall, adverse events, including sepsis, infection, hemorrhaging or other serious or life-threatening events, occurring in almost 11% of cases.<sup>21</sup> That figure is 22 times higher than the 0.05% number reported on the drug's

secretly-slipped-abortion-pills-in-wifes-drink-7-times-because-pregnancy-would-ruin-his-plans-sentenced-to-6months/; "A US doctor laced his ex-girlfriend's tea with abortion pills and got three years in prison," *The Straits Times*, (May 20, 2018), https://www.straitstimes.com/world/united-states/a-us-doctor-laced-his-ex-girlfriends-teawith-abortion-pills-and-got-three-years; Jeff Truesdell, "Pregnant Woman's Boyfriend Tried to Force Abortion with Spiked Drink: 'I Have No Excuse," *People*, (Oct. 10, 2018), https://people.com/crime/man-spiked-pregnantgirlfriend-drink-abortion-drug/.

<sup>&</sup>lt;sup>14</sup> Abortion Drug Facts, Introduction, CHARLOTTE LOZIER INST., <u>https://lozierinstitute.org/fact-sheet-risks-and-complications-of-chemical-abortion/(last visited May 3, 2025)</u>.

<sup>&</sup>lt;sup>15</sup> Abortion Drug Facts, CHARLOTTE LOZIER INST., <u>https://lozierinstitute.org/getthefacts/abortion-drugs/</u> (last visited May 3, 2025).

<sup>&</sup>lt;sup>16</sup> New Study Reveals Increasing Severity and Frequency of Emergency Department Visits Following Use of Abortion Drug, CHARLOTTE LOZIER INST. (Sept. 10, 2024), <u>https://lozierinstitute.org/getthefacts/abortion-drugs/</u> (last visited May 3, 2025).

<sup>&</sup>lt;sup>17</sup> Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENGLAND J. MED. 1243–44 (1998).

<sup>&</sup>lt;sup>18</sup> Abortion Drug Facts, Introduction, supra note 14.

<sup>&</sup>lt;sup>19</sup> Approved Risk Evaluation and Mitigation Strategies (REMS): Mifepristone, FDA,

https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390(last updated Mar. 23, 2023).

<sup>&</sup>lt;sup>20</sup> Jamie Bryan Hall and Ryan T. Anderson, *The Abortion Pill Harms women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, (April 28, 2025), <u>https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf.</u>

label.<sup>22</sup> 11,707 women developed infections within 45 days of a chemical abortion.<sup>23</sup> 28,658 women hemorrhaged after a chemical abortion.<sup>24</sup> 24, 563 women required a "repeated" abortion, referring a surgical abortion.<sup>25</sup> And almost 50,000 women had other complications that were specific to taking chemical abortion drugs.<sup>26</sup>

The FDA has long-turned a blind eye to abundant and well-known risks and increased those risks under the Biden Administration. In part prompted by a letter from multiple Attorneys General with political aspirations that advance pro-abortion ideology over protections for women,<sup>27</sup> and legal decisions during the COVID-19 crisis,<sup>28</sup> long-standing safety measures were abandoned. The FDA's rolling back of REMS for abortion drugs and lack of medical oversight regarding access to drug-induced abortions have put women at an increased risk of complications and abuse, to say nothing of the devastating effect that they have on preborn babies.

## II. The Harm Toward Women Has Increased Since the FDA Deregulation.

Since the FDA removed the critical life-protecting restrictions—including in-person doctor visit requirements—from the prescription of drug-induced abortions, the number of abortions that occur via medication has skyrocketed. Since the year 2000, there have been nearly six million drug-induced abortions.<sup>29</sup> In 2022, drug-induced abortions were the most common way women chose to abort their babies.<sup>30</sup> In 2023, abortions reached the highest numbers seen in a decade, and 63% of all abortions reported in the U.S., or 642,700, were drug-induced abortions.<sup>31</sup> Even with these numbers, the Guttmacher Institute warned that the numbers were "almost certainly" an undercount of the actual numbers of abortions, as they only documented abortions within the healthcare system.<sup>32</sup> The deregulation of the pill, boom of telehealth, and increased access to drug-induced abortions via unregulated national and international abortion pill providers, make "undercount" a severe minimalization.

As the public controversy surrounding the legality, safety, and availability of drug-induced abortions has increased in recent years, abortion pill providers have actively and openly sought ways for customers to illegally stockpile pills without prescriptions and hide their drug-induced

<sup>&</sup>lt;sup>22</sup> *Id.* citing Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprix (mifepristone)," <u>https://www.earlyoptionpill.com.</u>

<sup>&</sup>lt;sup>23</sup> Id.

<sup>&</sup>lt;sup>24</sup> Id.

<sup>&</sup>lt;sup>25</sup> Id.

<sup>&</sup>lt;sup>26</sup> Id.

<sup>&</sup>lt;sup>27</sup> Letter from Xavier Becerra, California A.G. *et al.* to Sec'y Alex M. Azar II, U.S. Dep't of Health and Hum. Services & Comm'r Stephen Hahn, FDA (Mar. 30, 2020), <u>https://www.oag.ca.gov/system/files/attachments/press-docs/FINAL AG Letter HHS Medication Abortion 2020 %289%29%5B1%5D.pdf</u>.

 <sup>&</sup>lt;sup>28</sup> Michael Kunzelman, Federal Judge Rules Women Can Get Abortion Pill Without Doctor Visits, PBS (Jul. 13, 2020) <u>https://www.pbs.org/newshour/health/federal-judge-rules-women-can-get-abortion-pill-without-doctor-visits</u>.
 <sup>29</sup> Carole Novielli, FDA Estimates Show Abortion Pill Killed Almost 6 Million Preborn Humans Since 2000, LIVE

ACTION (Sept. 27, 2023), https://www.liveaction.org/news/fda-abortion-pill-6-million-preborn-2000/.

<sup>&</sup>lt;sup>30</sup> Rachel K. Jones et. al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER, <u>https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions</u> (last updated Dec. 1, 2022).

<sup>&</sup>lt;sup>31</sup> Carole Novielli, *Abortions are Skyrocketing, With a Whopping 63% Done by Abortion Pill. Here's Why.*, LIVE ACTION (Mar. 20, 2024), <u>https://www.liveaction.org/news/abortions-skyrocketing-63-percent-abortion-pill/</u>. <sup>32</sup> *Id.* 

abortions. In fact, the largest increases in requests for abortion drugs have occurred in states where abortions are banned.<sup>33</sup> These findings stem from a review of Aid Access,<sup>34</sup> an "online telemedicine service providing self-managed drug-induced abortions (abortion conducted outside the formal health care setting) in the US," and does not account for international abortion pill businesses that ship abortion pills into the U.S. without any sort of telehealth consultation or prescription in "prepper" kits intended for women who are <u>not pregnant</u>.<sup>35</sup>

# A. The Data that Pro-Abortion Activists Use is Based on Faulty Data Created by Lax FDA Reporting Requirements.

This Administration should review and strengthen reporting requirements for complications from drug-induced abortions. Based on the current reporting requirements, there are no accurate numbers with which to analyze the dangers of drug-induced abortions. In 2016, the FDA removed all reporting requirements for any adverse health outcomes other than death that resulted from drug-induced abortions.<sup>36</sup> This means that there has not been accurate reporting from the healthcare industry of the complications from drug-induced abortions for years. Any number of serious complications have been unreported so long as they do not result in a patient's death. And the groups providing abortion pills have no obligation to do any kind of follow-up care or follow-up reporting beyond the prescription and delivery of the abortion pills. Instead, the expectation is placed on <u>the woman</u> to monitor her medical condition and to know when to seek help during or after abortion pill complications.<sup>37</sup> And (discussed *infra*), when a woman does seek care, she may have been instructed to lie to the medical personnel at the hospital and state that she is merely having a miscarriage.

### **B.** The Risks of Telehealth Drug-Induced Abortions Under FDA Deregulation.

As discussed above, drug-induced abortions have greatly increased since the FDA's deregulation. As a result, the flaws in reporting and increased prevalence of drug-induced abortions are accompanied by a veritable minefield of health and safety risks to the women taking these pills. With the advent of telehealth as the primary means of prescribing these drugs, misdiagnosis or even non-diagnosis of gestational age or an ectopic pregnancy is becoming increasingly common. It's been observed that some international online abortion pill providers will mail pills with no verification of gestational age at all, let alone the appropriate standard medical examinations that would normally accompany such a prescription.<sup>38</sup> These foreign businesses are "neither monitored

 <sup>&</sup>lt;sup>33</sup> Abigail R. A. Aiken et. al., Requests for Self-managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the Dobbs v Jackson Women's Health Organization Decision, JAMA NETWORK (Nov. 1, 2022), <u>https://jamanetwork.com/journals/jama/fullarticle/2797883</u>.
 <sup>34</sup> Id.

<sup>&</sup>lt;sup>35</sup> Carole Novielli, *Company 'Out of Compliance' With Federal Law Begins Selling Abortion Pill 'Prepper' Kits Online*, LIVE ACTION (Dec. 18, 2024), <u>https://www.liveaction.org/news/company-out-compliance-law-abortion-prepper-kits/</u>.

<sup>&</sup>lt;sup>36</sup> Katherine A. Rafferty & Tessa Longbons, *Medication Abortion and Abortion Pill Reversal: An Exploratory* Analysis on the Influence of Others in Women's Decision-Making, CUREUS (Dec. 5, 2023),

https://www.cureus.com/articles/200722-medication-abortion-and-abortion-pill-reversal-an-exploratory-analysis-on-the-influence-of-others-in-womens-decision-making?email share=true&expedited modal=true - !/.

<sup>&</sup>lt;sup>37</sup> See Ingrid Skop, *The Evolution of "Self-Managed" Abortion: Does the Safety of Women Seeking Abortion Even Matter Anymore?*, CHARLOTTE LOZIER INST. (Mar. 1, 2022), <u>https://lozierinstitute.org/the-evolution-of-self-managed-abortion/</u>.

<sup>&</sup>lt;sup>38</sup> See KATHERINE VAN DYKE, BENEATH THE SURFACE: EXPOSING THE ABORTION PILL DRUG CARTEL 6 (American Life League, Sept. 2024), <u>https://www.all.org/wp-content/uploads/2024/09/ALL\_AbortionPillReport2024.pdf</u>.

nor approved by the U.S. government and remain undisturbed."<sup>39</sup> Even some U.S.-based companies that refer women to these websites emphasize that, while some lab testing has been done, they cannot ensure that the drug will continue to be reliable or safe.<sup>40</sup>

Also, since there is no longer a required in-person checkup before the prescription of abortion pills, determining the true gestational age of the child and the ability to detect ectopic pregnancies is greatly hindered. The American College of Obstetricians and Gynecologists reports that

approximately one-half of women inaccurately recall the date of their most recent menstrual period; therefore, the estimated gestational age in the first trimester is adjusted in 40% of pregnancies after ultrasonography. Without ultrasound visualization to determine an intrauterine pregnancy, it is difficult to diagnose or rule out an early ectopic pregnancy. Telehealth evaluation should not replace an adequate physical examination with vital signs, a speculum, bimanual examination, ultrasonography (for location, dating, and viability), and appropriate laboratory studies, including beta human chorionic gonadotropin, hemoglobin, and Rh status.<sup>41</sup>

Normally, gestational age is determined via ultrasound and is highly reliable at correctly determining age. During that procedure, an ectopic pregnancy may also be discovered if the ultrasound technician finds that the baby has implanted somewhere other than the uterine wall. Now that the in-person checkup is no longer required, women are at greater risk of using abortion pills past the safe gestational age or while ectopically pregnant; either of which can lead to health risks for the woman, especially if the pregnancy is ectopic.

Furthermore, CDC data reveals that it is <u>known</u> that abortion pills are being prescribed well past the current gestational limits.<sup>42</sup> In a 2021 report, the CDC recorded 12,231 drug-induced abortions that occurred within 10-13 weeks of gestational age.<sup>43</sup> The cutoff date is supposed to be 11 weeks.<sup>44</sup> The CDC gave no breakdown as to the number of drug-induced abortions that occurred in weeks 12-13 within that 10-13 week window, so it cannot be known how many of those 12,231 occurred one or two weeks past the limit.<sup>45</sup> However, the report also showed that nearly 1,000 chemical abortions occurred at gestational age.<sup>46</sup>

These numbers are only generated via *voluntary* reporting to the CDC from 48 reporting areas.<sup>47</sup> The true scope of how many pills are being prescribed after the 11-week limit is impossible to determine under current reporting conditions. Given the admissions of even self-reporting

<sup>&</sup>lt;sup>39</sup> Id.

<sup>&</sup>lt;sup>40</sup> *Id*.

 <sup>&</sup>lt;sup>41</sup> Letter from Karen Poehailos MD to Editor of Journal of Am. Fam. Physician: Risks of and Indications for Mifepristone for Medication Abortion, (Apr. 15, 2011), <u>https://www.aafp.org/pubs/afp/issues/2022/0100/p5.html</u>.
 <sup>42</sup> Carole Novielli, *CDC Report Shows Abortion Pill is Being Prescribed Past FDA Limits*, LIVE ACTION (Nov. 30, 2023), <u>https://www.liveaction.org/news/cdc-report-abortion-pill-prescribed-past-limits/</u>.

<sup>&</sup>lt;sup>43</sup> Id.

<sup>&</sup>lt;sup>44</sup> Id.

<sup>&</sup>lt;sup>45</sup> Id.

<sup>&</sup>lt;sup>46</sup> *Id*.

abortion providers that they are exceeding gestational limits, it does not strain belief to infer the true scope of the problem to be even greater.

The consequences of flaws in reporting do not end at prescriptions that exceed the 11week gestational cutoff. As noted above, the FDA has not required reporting of any adverse consequences other than the death of the woman as a "complication" of drug-induced abortions. <sup>48</sup> However, one study found that 75%—three-quarters—of women treated at ERs after taking abortion pills were in "severe" or even "critical" condition.<sup>49</sup> From 2004 to 2015, the number of complications designated as severe or critical increased by 4,041.1% for drug-induced abortions.<sup>50</sup> That means that in just eleven years, the prevalence of serious medical conditions among women visiting the ER after taking abortion pills increased by a factor of over forty; and this was still five years before the Biden administration's irresponsible deregulation. If these kinds of complications were occurring even when the drug was more regulated than it is today, at the very least the former restrictions, and ideally even greater ones, ought to be implemented immediately.

In the years since the FDA deregulation, reliable numbers are hard to come by, but some medical professionals are reporting very similar trends. In 2022, the ACLJ was directly informed by a California doctor that women are taking the abortion pill late in their pregnancy, which has led to an increase in women seeking treatment in California emergency rooms. One such woman who came in with complications was 32 weeks pregnant and gave birth to a live baby in a hospital toilet while she was waiting to be seen. She fled the scene, leaving the baby in need of medical attention, and without receiving appropriate medical attention for herself. The doctor informed the ACLJ that at that time, this was occurring at least once a week in *every* emergency room in Orange County, California. This story, underscored by unfettered access to abortion pills by women who are not even pregnant and will have no medical oversight whatsoever when taking the pills, highlights perfectly the risk that unregulated drug-induced abortions pose to women and their preborn babies.

Even when the woman survives, a "successful" chemical abortion still carries a great risk of psychological harm for a woman. For example, after several abortions—some of which were coerced after sexual abuse when she was a minor—a young woman attempted a chemical abortion.<sup>51</sup> She was given the first pill in an abortion center and then was sent home to weather the experience alone.<sup>52</sup> After intense pain, the young woman delivered the baby in the bathroom and watched its last heartbeats as it died in her hands.<sup>53</sup> This woman suffered from severe back pain and intense bleeding for *months* after taking the pill, with Planned Parenthood refusing to offer her any help.<sup>54</sup> Eventually, she had to be rushed to the emergency room where her urine was dark purple and she was diagnosed as being in toxic shock as a result of the placenta failing to expel from her uterus.<sup>55</sup> The nurse told her that if she had not come in that morning she would have

<sup>55</sup> Id.

<sup>&</sup>lt;sup>48</sup> RAFFERTY, *supra* note 36.

<sup>&</sup>lt;sup>49</sup> Valerie Richardson, *Study Finds 75% of Women Treated at ERs After Taking Abortion Pills Rated 'Severe or Critical'*, THE WASHINGTON TIMES (Sept. 5, 2024), <u>https://www.washingtontimes.com/news/2024/sep/5/three-quarters-of-women-seen-at-ers-after-taking-a/</u>.

<sup>50</sup> *Id*.

<sup>&</sup>lt;sup>51</sup> Cassy Cooke, *Woman "Screamed" When She Saw Baby's Heart "Still Beating" After Taking the Abortion Pill*, LIVE ACTION (Jan. 12, 2024), <u>https://www.liveaction.org/news/woman-screamed-babys-heart-beating-abortion-pill/</u> <sup>52</sup> *Id*.

<sup>&</sup>lt;sup>53</sup> Id.

<sup>&</sup>lt;sup>54</sup> Id.

died.<sup>56</sup> Though she has recovered from the medical trauma, this young woman is still affected by the psychological trauma of watching her baby die. The experience "about killed her" and she screamed when it became inescapably clear to her what she had done.<sup>57</sup> That kind of trauma is all-too-prevalent with drug-induced abortions and serves as merely one example among many. It is yet another reason why drug-induced abortions pose a threat to women.

Pro-abortion businesses and organizations jumped on the deregulation of drug-induced abortions by the FDA to promote telehealth abortion pills in states where the pills are illegal and in states where abortions are banned or prohibited before the FDA's 11-week cutoff—though some provide the pill up to 13-weeks' gestation. For example, the website, Plan C, provides a list of telehealth providers who supply to all or most of the 50 states.<sup>58</sup> The following are all websites referred to by Plan C as options for obtaining abortion pills:

A Safe Choice is a referral website that connects users with doctors licensed in California who will prescribe to women in all 50 states, reliant on California's "Abortion Shield Law" to be immune from prosecution by states where abortion is illegal or restricted prior to 11/12 weeks' gestation.<sup>59</sup> Not only is a full faith and credit question implicated here, but this practice undermines the Supreme Court's recent decision in *Dobbs v. Women's Health Organization* returning the question of abortions to each state. That decision is blatantly undermined by pro-abortion groups who are actively assisting women in avoiding the laws of the states in which they live. So not only are these providers callously exposing women to a medical risk, but they are engaging in legally dubious conduct.

Similarly, We Take Care of Us is a website that "provides safe and supported medication abortion during the first 12 weeks of pregnancy, throughout the United States."<sup>60</sup> This website also allows users to "[o]rder abortion pills when you're not pregnant to have on hand, just in case."<sup>61</sup> These "prepper kits" represent an enormous risk to the women who purchase them. Since they are being sent before a pregnancy is even confirmed, there is no way for *anyone* to ensure that the woman takes the pills at the appropriate gestational age. As discussed in more detail below, only half of all women accurately recall the date of their most recent menstruation.<sup>62</sup> For that reason, the gestational age of a pre-born child is adjusted in 40% of pregnancies after an ultrasound is taken.<sup>63</sup> The older the gestational age of the baby, the harder the abortion pill process is on the woman's body and the greater the risk of complications. Thus, if a woman is mistaken about the gestational age of the baby and takes the pill past the 10-11-week gestational period, she opens herself up to much greater medical risk. Without an ultrasound to confirm the true gestational age, and indeed without the woman needing to inform *anyone* of her pregnancy or plans to take the abortion pill, these prepper kits are extremely risky and an unconscionable abuse of women by abortion distributors. We Take Care of Us is not the only distributor participating in this scheme.

<sup>&</sup>lt;sup>56</sup> Id.

<sup>&</sup>lt;sup>57</sup> *Id*.

<sup>&</sup>lt;sup>58</sup> Home, PLAN C, <u>https://www.plancpills.org/</u> (last visited Mar. 25, 2025).

<sup>&</sup>lt;sup>59</sup> Home, A SAFE CHOICE, <u>HTTPS://ASAFECHOICENETWORK.COM/(last visited May 3, 2025)</u>.

<sup>&</sup>lt;sup>60</sup> Home, WE TAKE CARE OF US, <u>https://www.wetakecareof.us/</u> (last visited May 3, 2025).

<sup>&</sup>lt;sup>61</sup> Id.

<sup>&</sup>lt;sup>62</sup> Letter from Karen Poehailos MD to Editor of Journal of Am. Fam. Physician, *supra* note 41.

<sup>&</sup>lt;sup>63</sup> Id.

Abuzz Health offers the abortion pill up to 13 weeks' gestation in all but four states: Texas, Georgia, Alabama, and Missouri.<sup>64</sup> It also provides abortion pills in advance of pregnancy "just in case."<sup>65</sup> The Map, a group of Cambridge Reproductive Health Consultants, offers abortion pills in all 50 states, <sup>66</sup> and will also provide the pills "for use in the future" where the user is "not pregnant now but want[s] them on hand," for a \$150 fee. Finally, Women on Web (a Toronto-based organization) also provides abortion pills in all 50 states, as well as in advance to users who are not pregnant, because "[p]roviding access to abortion pills before they are needed overcomes the abortion pill to "hold the Misoprostol under [their] tongue to ensure no remains can be found in [their] system," just in case they need to "seek medical attention, [because] Misoprostol will not show up on any blood tests and therefore there is no way to prove [they] have tried to terminate [their] pregnancy."<sup>68</sup> This recommendation is an egregious abuse of the women seeking druginduced abortions. While it may be interpreted as protecting a woman's "privacy," it is a highly convenient way for Women on the Web to deny liability in the event of a medical complication. Moreover, Women on the Web is essentially urging women to deceive their medical providers by withholding crucial information – generally not a practice conducive to a patient's health. This level of deception from abortion pill distributors cannot be allowed to continue unchallenged.

These problems extend beyond national distributors, as some foreign groups have also taken advantage of the opportunity for easy profit. The Mexico-based group "Las Libres"<sup>69</sup> has advocated extreme measures to conceal, even from a doctor providing post-abortion emergency medical care, that the issues the patient is having are the result of drug-induced abortion.

Tell all intake and medical staff that you think you're having a miscarriage. Do not reveal that you took abortion medications—there is absolutely no way for them to know. The pills will not show up in blood tests or scans. ER staff can provide the appropriate post miscarriage medical care without knowing that you took pills. This also applies to interactions or consultation with your doctor or gynecologist: there is no need to tell them that your miscarriage was self-induced. To be on the safe side, you should erase messages and emails about your abortion from your phone.<sup>70</sup>

Groups like "Las Libres" also advocate using encrypted communication via VPN to avoid law enforcement, indicating they know they are potentially violating state or federal law.<sup>71</sup> There is a well-documented network of illegally smuggling abortion pills across the southern border,<sup>72</sup>

<sup>&</sup>lt;sup>64</sup> Home, ABUZZ, https://www.abuzzhealth.com (last visited May 3, 2025).

<sup>&</sup>lt;sup>65</sup> FAQs, ABUZZ, <u>HTTPS://WWW.ABUZZHEALTH.COM/FAQS/</u>(last visited May 3, 2025).

<sup>&</sup>lt;sup>66</sup> The MAP, CAMBRIDGE REPROD. HEALTH CONSULTANTS,

https://www.cambridgereproductivehealthconsultants.org/map(last visited Mar. 25, 2025).

<sup>&</sup>lt;sup>67</sup> Abortion Pills for Future Use, WOMEN ON WEB, <u>https://www.womenonweb.org/en/survey/22051/abortion-pills-for-future-use</u> (last visited Mar. 25, 2025).

<sup>&</sup>lt;sup>68</sup> *Mifepristone & Misoprostol Abortion Pills*, WOMEN ON WEB, <u>https://www.womenonweb.org/en/abortion-pill</u> (last visited Mar. 25, 2025).

 <sup>&</sup>lt;sup>69</sup> Stephania Taladrid, *The Post-Roe Abortion Underground*, THE NEW YORKER (Oct. 10, 2022), <u>https://www.newyorker.com/magazine/2022/10/17/the-post-roe-abortion-underground</u>; Ciara Nugent, *This Mexican Activist Is Helping Americans Defy Abortion Bans*, TIME, March 2, 2023, Ciara Nugent, *This Mexican Activist Is Helping Americans Defy Abortion Bans*, March 2, 2023, <u>https://time.com/6259106/veronica-cruz-sanchez-2/</u>.
 <sup>70</sup> See VAN DYKE, supra note 38 at 3.

<sup>&</sup>lt;sup>71</sup> Instructions, LAS LIBRES, https://laslibres.org/Instructions/ (last visited Jan. 30, 2025).

<sup>&</sup>lt;sup>72</sup> See VAN DYKE, supra note  $3\overline{8}$ .

something we know is important to this Administration. Additionally, as previously mentioned, other foreign groups openly disregard the requirements that the FDA still has when they send abortion pills with no prescription to stockpile for "emergencies."<sup>73</sup> With dangerous illegal activity like this, the claim that we "know" that drug-induced abortions are safe and effective can be rejected on its face. This Administration should act to tighten reporting requirements and improve security at the border and within the federal postal system to track down illegally obtained abortion pills.

We know from statistics that we have inaccurate reporting numbers regarding drug-induced abortion and its negative side effects. The Charlotte Lozier Institute reported that in one study that claimed to show drug-induced abortion is safe, only 74% of women in the study followed up with the researchers.<sup>74</sup> "We know that the women who feel the most negative reactions following their abortions are least likely to participate in follow ups, and FDA data shows that women who have been harmed by abortion frequently end up seeking care from another doctor."<sup>75</sup> This gap, over a quarter of participants, shows how difficult and unreliable reported complication statistics are to compile. This Administration must act to ensure higher standards of care, rigorous reporting of all adverse events, and if the evidence thus collected supports it, a federal restriction of medication abortion.

The risk that drug-induced abortions pose to women and their pre-born babies is one that should not be, but is, understated. Knowing that this Administration cares for the safety of both women and preborn children, we respectfully request that—at the very least—the previous FDA regulations of the abortion drug be reinstated. Preferably, drug-induced abortions should be removed from the market entirely.

# III. Deregulation has led to an increase in dangerous and illicit activity surrounding abortion pills.

### A. Foreign groups are illegally disbursing abortion pills to American citizens.

The ACLJ has received information and evidence regarding the illegal movement of abortion pills within the United States from one of the Pregnancy Resource Centers (PRCs) we have assisted in the past. A staff member at the Gate Pregnancy Resource Center in North Carolina requested abortion pills using the Plan C website, which then connected her to the recently-defunct, pro-abortion organization, National Women's Health Network (NWHN). The website's chatbot assured the volunteer that abortion pills are "very safe and effective" while assuring her that the information was "private, secure, and anonymous." After a question to help the bot estimate gestational age, to which the staff member responded that she wasn't sure, the bot asked for an estimate. When there was no estimate, the bot assured the volunteer that although accurate gestational age was missing, they could still find the "right care for you," completely ignoring the FDA's current gestational age guidelines. The bot then asked for a city, state, and zip code, assuring that the information was private (suggesting the organization knew it might be providing abortion pills to states that have made them illegal). After assuring the volunteer that "doctors generally say

<sup>&</sup>lt;sup>73</sup> Prepper Kits 3,5,10, MEDSIDE24.COM, <u>HTTPS://WWW.MEDSIDE24.COM/PRODUCT-PAGE/PREPPER-KITS</u>(last visited May 3, 2025); Carole Novielli, *Company 'Out of Compliance,' supra* note 35.

 <sup>&</sup>lt;sup>74</sup> CLI Scholars React to Nature Medicine Study, CHARLOTTE LOZIER INST. (Feb. 16, 2024), https://lozierinstitute.org/cli-scholars-react-to-nature-medicine-study/.
 <sup>75</sup> Id.

it's safe to take pills without seeing a provider first" the volunteer ordered abortion pills by mail from the chatbot.

The volunteer received the pills, which were packaged to hide the nature of the contents and their origin. The abortion pills were sent in a large manilla envelope with the return address for "The Winchester Family" with the street address of a hotel in Oakland California named "Jack London Inn." This obviously deceptive packaging contained three small resealable baggies, each with one disposable makeup pad folded upon itself inside. Upon inspection, these pads contained pills that the PRC's pharmacist could not identify based on visual inspection.

This is a concrete example of the unregulated, dangerous, and illegal activity by which women in the United States are obtaining abortion pills largely due to deregulation and lack of enforcement by the FDA and other government entities. We urge the Administration to take enforcement action to end these illegal shipments and protect the women these organizations target.

### B. This Administration Has Addressed Similar Problems Before.

This is not the first time this Administration has had to address the issue of foreign actors creating health hazards for women and circumventing U.S. regulations regarding the abortion pill. In 2019, President Trump's FDA sent a warning letter to Europe-based abortion pill provider Aid Access to "cease the introduction of the violative drugs into U.S. commerce."<sup>76</sup> Among other issues, Aid Access was introducing unregulated abortion pills without adequate directions for use or warnings of the serious side effects that FDA-approved Mifeprex included.<sup>77</sup> Similar action was taken by the Administration that year against Rablon, a pharmacy network of at least eighty-seven websites that shipped unregulated and unapproved abortion pills to customers in the United States.<sup>78</sup>

The first Trump Administration's FDA warned of mislabeling, inadequate directions, and violation of the then-active common-sense safety requirements for the administration of abortion pills: doctor visits and ultrasounds. This second Trump Administration should follow that precedent and continue to actively and resolutely protect women from access to dangerous and unregulated abortion pills from organizations (both national and international) like Aid Access, Rablon, NWHN, and the previously mentioned Las Libres.<sup>79</sup> Additionally, consistent with the standard practice before the Biden Administration's deregulation, this Administration should reimplement the measures that protected women using these dangerous pills.

<sup>&</sup>lt;sup>76</sup> Letter from the FDA, Ctr. for Drug Evaluation and Research to Aidaccess,org (Mar. 8 2019),

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019.

<sup>&</sup>lt;sup>77</sup> Id.

<sup>&</sup>lt;sup>78</sup> Letter from the FDA to Rablon (Mar. 8, 2019), <u>https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/rablon-111111-03082019</u>.

<sup>&</sup>lt;sup>79</sup> See supra Section II(B).

#### **IV. Conclusion**

The ACLJ has and will always take the position that abortion takes an innocent human life. There is no more innocent or helpless a state for a human being than when growing in the mother's womb. These innocent human beings deserve the full protection of the law. However, preborn babies are not the *only* victims of the abortion industry's callous exploitation of human life. Women are consistently deceived, physically harmed, and psychologically traumatized by the abortion process in all its iterations. The increase in the sale and use of drug-induced abortions, accompanied by the numerous risks and harms to women detailed in this letter, is a manifestation of the severe consequences of abortion ideology. We have great confidence in this Administration and its desire to protect the lives and well-being of American women. That is why, considering the discussion above, we ask that—at the very least—the previous FDA restrictions on the use of abortion pills be reinstated while more data can be gathered under more robust reporting requirements. However, we believe that even with the information currently available it would be entirely prudent to ban these drugs from the market completely.

https://www.lifenews.com/2014/07/30/man-took-14-year-old-for-three-abortions-after-impregnating-her-clinicsignored-the-rapes/; David McFadden, *Probation Revoked for Man in Impregnating 11-Year-Old, Forcing to Get Abortion*, ABC13 NEWS (July 19, 2018), https://wset.com/news/local/probation-revoked-for-man-in-forcedabortion-case.

<sup>&</sup>lt;sup>i</sup> Vincent M. Rue, et al., *Induced Abortion and Traumatic Stress: A Preliminary Comparison of American and Russian Women*, 10 MED. SCI. MONITOR 9 (2004).

<sup>&</sup>lt;sup>ii</sup> Id.

<sup>&</sup>lt;sup>iii</sup> Id.

<sup>&</sup>lt;sup>iv</sup> Id.

<sup>&</sup>lt;sup>v</sup> Dominique Bourassa, MD, & Jocelyn Bérubé, MD, *The Prevalence of Intimate Partner Violence Among Women and Teenagers Seeking Abortion Compared with Those Continuing Pregnancy*, 29 J. OBSTETRICS GYNAECOLOGY CAN. 415, 415 (2007).

<sup>&</sup>lt;sup>vi</sup> Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, 23 ANNALS HEALTH L. 61, 73 (2014), <u>https://tinyurl.com/3hvjednk</u>. <sup>vii</sup> See, e.g., United States v. Raniere, 2019 U.S. Dist. LEXIS 84634 (E.D. N.Y. May 3, 2019) (abortions for women impregnated by leader of apparent cult); Tonya Alanez, 58 Porno Videos of 15-Year-Old Girl Lead to Davie Man's Arrest, S. FLA. SUN SENTINEL (Oct. 23, 2019) <u>https://www.sun-sentinel.com/2019/10/23/58-porno-videos-of-15-year-old-girl-lead-to-davie-mans-arrest/</u> ("The victim stated that she got pregnant from the defendant and he took her to the clinic to have an abortion."); Carole Novielli, Man Took 14-Year-Old For Three Abortions After Impregnating Her, Clinics Ignored the Rapes, LIFE NEWS (July 30, 2014),

<sup>&</sup>lt;sup>viii</sup> Abortion Drug Facts, Introduction, CHARLOTTE LOZIER INST., https://lozierinstitute.org/fact-sheet-risks-and-complications-of-chemical-abortion/ (last visited May 3, 2025).

ix Abortion Drug Facts, CHARLOTTE LOZIER INST., https://lozierinstitute.org/getthefacts/abortion-drugs.

<sup>&</sup>lt;sup>x</sup> Jamie Bryan Hall and Ryan T. Anderson, *The Abortion Pill Harms women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, (April 28, 2025), https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf.

<sup>&</sup>lt;sup>xi</sup> *Id.* citing Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprex (mifepristone)," <u>https://www.earlyoptionpill.com</u>.

<sup>&</sup>lt;sup>xii</sup> CLI Scholars React to Nature Medicine Study, CHARLOTTE LOZIER INST. (Feb. 16, 2024), <u>https://lozierinstitute.org/cli-scholars-react-to-nature-medicine-study/</u>.

<sup>&</sup>lt;sup>xiii</sup> Id.

<sup>&</sup>lt;sup>xiv</sup> Carole Novielli, *FDA Estimates Show Abortion Pill Killed Almost 6 Million Preborn Humans Since 2000*, LIVE ACTION (Sept. 27, 2023), <u>https://www.liveaction.org/news/fda-abortion-pill-6-million-preborn-2000/</u>.

<sup>xv</sup> Rachel K. Jones et. al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER, <u>https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions</u> (last updated Dec. 1, 2022).

pill/.

<sup>xvii</sup> Id.

<sup>xviii</sup> See KATHERINE VAN DYKE, BENEATH THE SURFACE: EXPOSING THE ABORTION PILL DRUG CARTEL 6 (American Life League, Sept. 2024), <u>https://www.all.org/wp-content/uploads/2024/09/ALL\_AbortionPillReport2024.pdf</u>. <sup>xix</sup> Letter from Karen Poehailos MD to Editor of Journal of Am. Fam. Physician, Apr. 15, 2011, <u>https://www.aafp.org/pubs/afp/issues/2022/0100/p5.html</u>.

<sup>xx</sup> Id.

<sup>xxi</sup> Id.

<sup>xxii</sup> Id.

<sup>xxiii</sup> Id.

<sup>xxiv</sup> Id.

<sup>xxv</sup> Katherine A. Rafferty & Tessa Longbons, *Medication Abortion and Abortion Pill Reversal: An Exploratory* Analysis on the Influence of Others in Women's Decision-Making, CUREUS (Dec. 5, 2023),

https://www.cureus.com/articles/200722-medication-abortion-and-abortion-pill-reversal-an-

exploratory-analysis-on-the-influence-of-others-in-womens-decision-

making?email share=true&expedited modal=true - !/.

<sup>xxvi</sup> Valerie Richardson, *Study Finds 75% of Women Treated at ERs After Taking Abortion Pills Rated 'Severe or Critical'*, THE WASHINGTON TIMES (Sept. 5, 2024), <u>https://www.washingtontimes.com/news/2024/sep/5/three-guarters-of-women-seen-at-ers-after-taking-a/</u>.

<sup>xxvii</sup> Id.

xxviii Cassy Cooke, *Woman "Screamed" When She Saw Baby's Heart "Still Beating" After Taking the Abortion Pill*, LIVE ACTION (Jan. 12, 2024), <u>https://www.liveaction.org/news/woman-screamed-babys-heart-beating-abortion-pill/</u>.

 $\frac{\text{pm}/.}{\text{xxix}}$  Id.

<sup>xxx</sup> Id.

<sup>xxxi</sup> Id.

<sup>xxxii</sup> Id.

<sup>xxxiii</sup> Id.

xxxiv Home, PLAN C, https://www.plancpills.org.

xxxv Home, A SAFE CHOICE, https://asafechoicenetwork.com.

xxxvi Home, WE TAKE CARE OF US, <u>https://www.wetakecareof.us</u>.

<sup>xxxvii</sup> Id.

xxxviii Home, ABUZZ, https://www.abuzzhealth.com.

xxxix FAQs, ABUZZ, <u>https://www.abuzzhealth.com/faqs/</u>.

 $^{\rm xl}$  The MAP, Cambridge Reprod. Health Consultants, .

<sup>xli</sup> Abortion Pills for Future Use, WOMEN ON WEB, <u>https://www.womenonweb.org/en/survey/22051/abortion-pills-for-future-use</u>.

<sup>xlii</sup> *Mifepristone & Misoprostol Abortion Pills*, WOMEN ON WEB, <u>https://www.womenonweb.org/en/abortion-pill</u>.

<sup>xliii</sup> Home, LAS LIBRES, <u>https://www.laslibres.org/</u> (last visited Mar. 25, 2025); Stephania Taladrid, *The Post-Roe Abortion Underground*, THE NEW YORKER (Oct. 10, 2022),

https://www.newyorker.com/magazine/2022/10/17/the-post-roe-abortion-underground; Ciara Nugent, *This Mexican Activist Is Helping Americans Defy Abortion Bans*, March 2, 2023,

https://time.com/6259106/veronica-cruz-sanchez-2/.

<sup>xliv</sup> See VAN DYKE, supra note 20 at 3.

<sup>xlv</sup> Instructions, LAS LIBRES, <u>https://laslibres.org/Instructions/</u> (last visited Jan. 30, 2025).

<sup>xlvi</sup> See VAN DYKE, supra note 20.

<sup>xlvii</sup> Prepper Kits 3,5,10, MEDSIDE24.COM, <u>https://www.medside24.com/product-page/prepper-kits</u> (last visited May 3, 2025); Carole Novielli, *Company 'Out of Compliance' With Federal Law Begins Selling Abortion Pill* 

<sup>&</sup>lt;sup>xvi</sup> Carole Novielli, *Abortions are Skyrocketing, With a Whopping 63% Done by Abortion Pill. Here's Why.*, LIVE ACTION (Mar. 20, 2024), <u>https://www.liveaction.org/news/abortions-skyrocketing-63-percent-abortion-</u>

*'Prepper' Kits Online*, LIVE ACTION (Dec. 18, 2024), <u>https://www.liveaction.org/news/company-out-compliance-law-abortion-prepper-kits/</u>.