



# The Next Abortion Battleground: Chemical Abortion

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## Key Points

Although the overall number of abortions in the United States is in decline, the number of chemical abortions has risen dramatically, increasing by 73 percent between 2008 and 2017.

The abortion pill regimen poses serious health risks to women, including severe bleeding, infection, retained fetal body parts, and death.

It is evident that the abortion industry's promotion of "self-managed" abortions is about its political, ideological, and financial goals—not women's health care.

The removal of the in-person dispensing requirement for the abortion pill has radical implications for women's health and safety, especially as it pertains to intimate partner violence, sexual abuse and sex trafficking, and accurate patient assessment.

## Summary

**T**he number of abortions being carried out in the United States continues to decline. The Centers for Disease Control and Prevention (CDC) reports that abortions have declined 24 percent between 2009 and 2018. Meanwhile, chemical abortions are at an all-time high, increasing by 73 percent from 2008 to 2017.

This rapid increase in chemical abortions is part of the abortion industry's long-term strategy to make abortions "self-managed" and unrestricted—despite the profound dangers such poorly supervised medical care poses to women's health.

This report can be read online at [frc.org/chemicalabortion](https://frc.org/chemicalabortion)

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## Introduction

The number of abortions being carried out in the United States continues to decline. According to the latest Centers for Disease Control and Prevention (CDC) data, the abortion rate has declined 24 percent between 2009 and 2018.<sup>1</sup> However, the chemical abortion rate is at an all-time high. The latest abortion statistics from the Guttmacher Institute show that 39 percent of abortions in 2017 were chemical<sup>2</sup> (reported as “medical” or “medication abortion”), a 25 percent increase since 2014.<sup>3</sup> Looking further back, the numbers are even more alarming. Between 2008 and 2017, chemical abortion increased by 73 percent, even as overall abortion numbers declined over that same period.<sup>4</sup> The abortion industry has been driving this rapid increase; it regards drug-based, do-it-yourself abortions as the best means of getting around the many state-level pro-life laws being enacted around the country.<sup>5</sup> Chemical abortions are accomplished through a pill regimen of mifepristone (distributed under the brand name Mifeprex®) and misoprostol. Mifeprex was previously subject to the Food & Drug Administration’s (FDA) drug safety program—Risk Evaluation and Mitigation Strategies (REMS)—because it carries life-threatening risks.

Under the pro-life Trump administration, the FDA supported keeping the REMS in place. However, on May 27, 2020, the American Civil Liberties Union (ACLU) filed a lawsuit demanding that the FDA temporarily suspend the enforcement of the REMS for the duration of the COVID-19 pandemic so that women could receive the abortion regimen through the mail without having to see a health care provider in person. On July 13, a Maryland district judge granted a preliminary injunction that waived enforcement of the REMS, but the U.S. Supreme Court subsequently reinstated them in January 2021. The Court’s decision was grounded in supporting the Agency—not the merits of the REMS.

In April 2021, the Biden administration compromised women’s health and safety by expressing support for the removal of the REMS. Under the Biden administration, the FDA changed its policy from requiring in-person dispensing to “exercis[ing] enforcement discretion.” On December 16, 2021, the Biden administration permanently removed the in-person dispensing requirement for mifepristone. This in-person dispensing requirement was in place so that a health care provider could assess patient

eligibility, diagnose ectopic pregnancies, and provide or facilitate emergency surgical intervention in the case of an incomplete abortion or severe bleeding.

This move has once again allowed abortion pills to be available through the pharmacy and the mail, further solidifying do-it-yourself abortions as the future of the abortion industry. The abortion industry is not shy about this goal. They have strategically discussed how the absence of the REMS would significantly expand abortion locations and providers, broaden remote prescription, and eventually achieve over-the-counter (OTC) status for Mifeprex.

Abortion activists used to claim that legalized abortion would alleviate the danger of “back-alley” abortions for women. However, the health complications that often result from the induced chemical abortions activists love to promote are eerily similar to those of “back-alley” abortions. These complications include severe bleeding, infection, retained fetal parts, the need for emergency surgery, and even death.<sup>6</sup> In addition, the woman, who may or may not have health insurance coverage, is expected to bear the additional cost of these complications.

By removing the REMS, abortion businesses, which claim they provide “care no matter what,” have now placed all the burdens of abortion—including diagnosing ectopic pregnancy, accurately assessing the length of pregnancy, determining Rh negativity, carrying out the actual abortion, properly disposing of the remains of the aborted baby, and judging the appropriate amount of bleeding—on women.

OTC abortion drugs have radical implications for women’s health and safety, especially as it pertains to intimate partner violence (IPV), sexual abuse and sex trafficking, and accurate patient assessment.

With all of chemical abortion’s documented dangers, it is increasingly evident that the advancement of the abortion industry’s agenda for the chemical abortion regimen is about political, ideological, and financial goals—not women’s health care.

Here are some statistics that demonstrate the sharp increase in chemical abortion pill usage in recent years. In 2014, Guttmacher reported that “medication abortions” accounted for 31 percent of all nonhospital abortions and 45 percent of abortions before nine weeks gestation. “Medication abortions” increased from six percent of all clinical abortions in 2001 to 31 percent in 2014.<sup>7</sup> The CDC reports that the use of early “medication abortion” increased 114 percent from 2006 to 2015.<sup>8</sup>

## **What Is a Chemical Abortion?**

Mifepristone (Mifeprex®; also known as RU-486 or simply “the abortion pill”) was approved by the FDA in September 2000 to chemically induce an abortion. Technically speaking, mifepristone is the first drug in a two-drug regimen. The second, misoprostol (Cytotec®), is taken 24 to 48 hours after mifepristone to induce uterine contractions intended to expel the remaining fetal tissue.

Prior to 2020, the chemical abortion regimen was typically administered under a physician’s supervision in a clinical setting—although the FDA does not require a physician’s participation. Mifepristone is a synthetic steroid that acts as an anti-progestin to block the release of the hormone progesterone, a chemical critical for the pregnancy’s progression. Progesterone is needed to stabilize the uterine wall and nourish the developing child. Mifepristone blocks progesterone from functioning as required, which leads to the deterioration of the uterine lining—thereby causing the unborn child’s death.

After taking the mifepristone, the patient was then sent home to take the regimen’s second drug, misoprostol, 24 to 48 hours after the mifepristone was taken. Misoprostol causes intense uterine contractions soon after ingestion. Misoprostol is needed to expel embryonic or fetal tissues from the uterus that were not expelled after the mifepristone was taken.<sup>9</sup> Using mifepristone alone frequently results in incomplete abortions; therefore, misoprostol is necessary in order for chemical abortion to be considered a viable alternative to surgical abortions.

A chemical abortion can produce severe cramping, contractions, and bleeding. Once the embryo or fetus is expelled, there will be human remains (the unborn baby as well as tissue) that must be disposed of:

While she could lose her baby anytime and anywhere during this process, the woman will often sit on a toilet as she prepares to expel the remains, which she will usually then flush—she may even see her dead baby within the pregnancy sac.<sup>10</sup>

Such symptoms can last from several hours to several days, and they can be very intense and painful. Hemorrhage may last much longer, requiring transfusions. Many women also experience nausea, vomiting, diarrhea, abdominal pain, and headache.<sup>11</sup> Maternal deaths have occurred, most frequently due to infection or an undiagnosed ectopic pregnancy.<sup>12</sup>

Disturbingly, the physical trauma that happens to a woman's body as a result of a chemical abortion is a sign that the "treatment is working."<sup>13</sup> According to the Mifeprex medication guide:

Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working...Bleeding or spotting can be expected for an average of 9 to 16 days and may last for up to 30 days...You may see blood clots and tissue. This is an expected part of passing the pregnancy.<sup>14</sup>

The abortion industry markets chemical abortions as straightforward and safe.<sup>15</sup> In reality, chemical abortions are a multi-day traumatic process that could take up to 30 days to complete, according to the Mifeprex medication guide.<sup>16</sup> Incomplete abortion occurs up to 10 percent of the time and occurs more frequently as gestational age increases.<sup>17</sup> If an abortion is incomplete, a woman can be prescribed multiple doses of misoprostol. If that fails, a physician must carry out a surgical abortion to remove the fetal remains through the cervix by vacuum or suction aspiration.<sup>18</sup>

## Health Effects and Danger to Women

The data clearly shows the negative health consequences of chemical abortion on women. Between 2000 and 2021, a total of 4,207 adverse events related to chemical abortions were reported to the FDA. These events include 26 maternal deaths, 97 ectopic pregnancies, and 1,045 hospitalizations. It is important to note that these numbers only represent the adverse events voluntarily *reported* to the FDA, so we do not have a full picture of the data.<sup>19</sup>

A Finnish study of 42,600 women found that the women who had undergone a chemical abortion were nearly four times more likely to suffer severe complications than those who had undergone surgical abortions—20 percent compared to 5.6 percent. The two side effects observed to be more prevalent during chemical abortions than surgical abortions were hemorrhage (15.6 percent compared to 2.1 percent) and incomplete abortion (6.7 percent compared to 1.6 percent).<sup>20</sup>

As already discussed, cramping and bleeding due to chemical abortions can last from several hours to several days and can be very intense and painful. Hemorrhage may occur and may be even more prolonged, requiring transfusions. Many women also experience nausea, vomiting, diarrhea, abdominal pain, and headache from chemical abortions.<sup>21</sup>

We know that abortion also negatively impacts a woman's mental health. One review in the *British Journal of Psychiatry* analyzed 22 studies of women who were post-abortive and found that post-abortive women had higher rates of substance abuse, anxiety, depression, and suicidal thoughts than non-abortive women.<sup>22</sup> What makes chemical abortions uniquely traumatic is that a mother sees and must dispose of the remains of her aborted child. To put this trauma into context, mifepristone is used for aborting babies that are up to 10 weeks gestation—although Planned Parenthood advertises use for up to 11 weeks—at which point the baby already has a head, hands, feet, fingers, and toes. The baby also has a heartbeat and brain activity.<sup>23</sup>

A study published in *Frontiers in Neuroscience*<sup>24</sup> “found significant adverse behavioral changes in the pregnant rats [that were] given ... abortion-inducing drugs compared to the rats who did not receive the

drugs and rats that received the drugs, but were not pregnant.”<sup>25</sup> Dr. Stephen Sammut, the professor of psychology at Franciscan University who led the research, wrote, “This is breaking new ground ... In the animal model, we observed depression-like behaviors, and we saw anxiety-like behaviors. The biochemistry indicated potentially long-term effects.”<sup>26</sup> The study acknowledged that more research is needed to evaluate the psychological and physiological effects of a chemical abortion.

## **FDA and Regulatory Overview**

Because mifepristone carries life-threatening and health-endangering risks such as hemorrhage, infection, incomplete pregnancy, retained fetal parts, the need for emergency surgery, and death,<sup>27</sup> it had been subject to the FDA’s drug safety program, known as the Risk Evaluation and Mitigation Strategies (REMS). That changed in 2020 when the ACLU filed a lawsuit against the FDA demanding the temporary suspension of the REMS.<sup>28</sup> Although this was done under the guise of keeping women safe during the COVID-19 pandemic, it has always been the abortion industry’s intent to remove the REMS.<sup>29</sup>

After the U.S. Supreme Court issued a preliminary injunction reinstating the REMS under the pro-life Trump administration’s FDA, the Biden administration ultimately removed these necessary safety measures in 2021 for the remainder of the pandemic, arguing that the REMS put women in danger due to the likelihood of contracting COVID-19.<sup>30</sup> <sup>31</sup> On December 16, 2021, the Biden administration permanently removed the in-person dispensing requirement. This requirement had provided a way to monitor and mitigate the risks of the chemical abortion regimen while also preventing the sale and provision of mifepristone tablets outside a clinical setting. With the in-person dispensing requirement no longer in place, there will be no way to monitor the harms caused by the drug, placing women in extreme danger.

The REMS are the product of the pro-abortion Clinton administration’s effort to ensure that the chemical abortion regimen—which carries life-threatening and health-endangering risks such as hemorrhage, infection, incomplete pregnancy, retained fetal parts, the need for emergency surgery, and even death—could be administered safely. The REMS mandated that mifepristone can only be

dispensed in certain health care settings and under the supervision of a certified prescriber.<sup>32</sup> A certified mifepristone prescriber is required to have the ability to properly assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding.<sup>33</sup>

The American distributor of mifepristone (Mifeprex) is Danco Laboratories, and the manufacturer of the recently approved generic version is GenBio Pro. Currently, both versions are restrained by the REMS and cannot be sold or distributed online or through pharmacies without the supervision of a certified prescriber.<sup>34</sup>

The REMS had historically stipulated that only a licensed physician could be a certified prescriber of mifepristone.<sup>35</sup> The REMS had also required the manufacturer to report complications with Mifeprex to the FDA.<sup>36</sup> However, in March 2016, under the Obama administration, the FDA approved numerous significant changes to the Mifeprex REMS (submitted by manufacturer Danco Laboratories) that have made the abortion pill even less safe.<sup>37</sup>

Under the 2016 changes, a certified prescriber need only be a “health care provider,” not a physician. The provider only had to be a person with certain medical capabilities. Henceforth, that person would only need to have the ability to assess patient eligibility, diagnose ectopic pregnancies, or provide or facilitate emergency surgical intervention in the case of an incomplete abortion or severe bleeding.<sup>38</sup> Also, under the 2016 approval, manufacturers were no longer required to report any adverse events to the FDA other than death.<sup>39</sup> Word alterations like this are not accidental. There was a clear downgrading of the required proximity of the drug regimen’s provision to a physician. Clearly, these changes are about abortion providers’ profits, not women’s health and safety. “Safe, legal, and rare” has given way to unsafe, unregulated, do-it-yourself abortion.

In 2015, a peer-reviewed study on the safety, efficacy, and acceptability of self-administered abortion pills through 70 days found that nearly 30 percent of the 40 pregnant women self-administering the abortion pill had taken the regimen *after* the approved time of 63 days—thereby resulting in 62 percent of those women having incomplete abortions. Surgical evacuation had to be performed in 68 percent of



the patients, 22.5 percent had failed abortions, and 12.5 percent required surgical evacuation with blood transfusion.<sup>40</sup>

Despite the troubling results of studies such as this and the many adverse events already reported,<sup>41</sup> the FDA—under the sway of the abortion activist movement—made the drug regimen even more dangerous by altering the drug dosage and increasing the gestational limit from 49 days to up to 70 days.<sup>42</sup>

The initially approved dosage was 600 mg of mifepristone (3 tablets of 200 mg each), and after 24 to 48 hours, 400 mg of misoprostol (2 tablets of 200 mg each). The FDA has altered the dosage to decrease mifepristone from 600 mg to 200 mg and increase misoprostol from 400 mg to 800 mg. This new dosage, combined with the gestational age increase, means this abortion pill regimen has essentially become a “chemical coat hanger.” Women are now taking less of the drug that stops the pregnancy but more of the drug that “yanks” the baby out.<sup>43</sup> This alteration will likely increase the probability of adverse events and life-threatening complications.

Even more egregious, the FDA coupled these new changes with the elimination of a required second office visit. The purpose of this visit was to confirm a completed abortion and check for any health complications that might have arisen as a result of taking the drugs.<sup>44</sup> Less oversight provided by less-qualified medical personnel for an even more violent regimen suggests this was never about “women’s health.”

## **The Abortion Industry’s Goal: Do-It-Yourself Abortions**

The abortion industry was not satisfied with loosened restrictions on chemical abortion. The industry desired the full and permanent removal of the REMS’ in-person dispensing requirement, making do-it-yourself abortions the norm and abortion pills available through the pharmacy, the mail, and even on college campuses.<sup>45</sup> Complete removal of all the REMS requirements is the abortion industry’s goal. Proponents of abortion are not shy about this goal. They have strategically discussed how the absence

of the REMS would significantly expand abortion locations and providers, broaden remote prescription, and eventually achieve OTC status for Mifeprex.<sup>46</sup>

Industry advocates disclosed their support for the December 16, 2021, change, stating:

Lifting the REMS could significantly expand access to medication abortion and increase the options available to people seeking abortion care. In theory, anyone could access medication abortion in the absence of the REMS just like most other prescription drugs: by receiving a prescription from a provider and purchasing the medication from a pharmacy. The potential significance of this change should not be overlooked.<sup>47</sup>

The ramifications of removing the in-person dispensing requirement and the potential of lifting the remaining REMS should not be overlooked, especially since do-it-yourself abortion is the abortion industry's vision for the future of abortion in the United States:<sup>48</sup>

Medication abortion, in particular, holds great promise for the future of self-managed abortion care in the United States, and understanding the steps and barriers to achieving a fully independent model of self-managed medication abortion is critical to normalizing and advancing this vision.<sup>49</sup>

Lifting the REMS offers new possibilities, like obtaining the abortion pill without a prescription, thus normalizing it as an easily acquired drug.<sup>50</sup> With all of chemical abortion's documented dangers, it is increasingly evident that the advancement of the abortion industry's agenda for the chemical abortion regimen is about political, ideological, and financial goals—*not* women's health care.

Drug-based abortions are regarded as the best way to get around the increasing restrictions being put in place by pro-life laws around the United States. Even commonsense regulations requiring basic clinic safety and sanitary standards appear to be more than any abortion business can stomach.<sup>51</sup> Do-it-yourself chemical abortion is primarily about ensuring that the abortion industry can survive in any

future pro-life legal and policy environment. Secondly, it's about incentivizing abortion as an option for low-income women by lowering the costs associated with it.

Abortion and eugenics have a long-shared history in the United States, and it is no coincidence that approximately 79 percent of Planned Parenthood's surgical abortion centers are located within walking distance of minority communities.<sup>52</sup> When defending "abortion access," proponents will consistently dog-whistle about how any pro-life protections will hurt "low-income" women. Yet such claims—usually made by cultural elitists—should not hinder women from keeping their babies and avoiding the emotional, psychological, and physical scars of abortion.

The abortion industry seeks to reduce abortion's cost by making the abortion pill the "go-to" product, thereby expanding the number of abortions without incurring the overhead cost for facilities or staff. Reducing the FDA-approved dosage of mifepristone gave an official seal of approval to the drug industry's off-label regimen, which reduced the number of these tablets used from three to one. Given the drug's high cost, this single change greatly increased profit margins.<sup>53</sup> Misoprostol is a more stable drug at room temperature, which can give it a longer shelf life—even so, its costs are a fraction of mifepristone's.<sup>54</sup>

A study comparing chemical abortions to surgical abortions revealed several reasons why the chemical abortion method is so appealing to the abortion industry: "Medical methods [their term for chemical abortions] have several advantages over surgical evacuation, particularly for use in low-resource settings, including reducing the need for surgery, sterilization of instruments, specific clinic rooms and surgically trained personnel."<sup>55</sup> Chemical abortion is a way to shift costs and patient oversight from the surgical provider to the patient herself. Thus, it is not surprising that international abortion leaders like MSI Reproductive Choices (formerly known as Marie Stopes International)<sup>56</sup> have already made extensive use of this easily transportable product—a shift that has been supported by the World Health Organization (WHO).<sup>57</sup>

## **The Dangerous Implications of Over-the-Counter Abortion Pills for Women**

Making mifepristone a “self-managed” OTC drug product has radical implications for women’s health and safety, especially as it pertains to intimate partner violence, sexual abuse and sex trafficking, and accurate patient assessment. Furthermore, it would also dangerously bypass state laws governing parental rights and informed consent on the issue of abortion.

### **Informed Consent and Intimate Partner Violence**

Not all pregnant women live in an environment free from the threat of violence against their babies and themselves. Homicide is a leading cause of death during pregnancy, and intimate partner violence (IPV) occurs so frequently during pregnancy that the American College of Obstetricians and Gynecologists (ACOG) recommends screening for violence:

[H]ealth care providers should screen women and adolescent girls for intimate partner violence and reproductive and sexual coercion at periodic intervals such as annual examinations, new patient visits, and during obstetric care (at the first prenatal visit, at least once per trimester, and at the postpartum checkup).<sup>58</sup>

Reproductive coercion is a form of IPV in which a (typically male) partner uses threats and coercion to enforce his decision regarding the pregnancy outcome. Reproductive coercion can include “forcing a female partner to terminate a pregnancy when she does not want to, or injuring a female partner in a way that may cause a miscarriage.”<sup>59</sup> One study found that the prevalence of IPV was nearly three times greater for women seeking an abortion compared with women who were continuing their pregnancies.<sup>60</sup>

An OTC chemical abortion regimen, if approved by the FDA, would eliminate the physician’s ability to evaluate whether the woman is under pressure or is being coerced to abort.<sup>61</sup> The pro-abortion

ACOG Committee on Ethics reaffirmed in 2019 that “the patient’s freedom to choose among alternatives—is also an important element of informed consent, which should be free from coercion, pressure, or undue influence.”<sup>62</sup>

Even the National Abortion Federation, a radically pro-abortion trade and activist group in the United States, implores that ethical practices for abortion care must include the ability to “ascertain before providing an abortion that the patient, unless unable to comprehend or participate in the decision, has freely chosen to end her pregnancy, is prepared to do so and has not been coerced in any way.”<sup>63</sup>

A 2017 qualitative study of women’s abortion experiences found that nearly 60 percent of the women had an abortion to make others happy, and over 70 percent said their decision to abort included subtle pressure from others.<sup>64</sup>

Women compelled to abort are often subjected to violence. A systematic review and meta-analysis of 74 studies worldwide confirmed that IPV is associated with abortion and is even more strongly associated with repeat abortion.<sup>65</sup> There are numerous documented incidents of women being unknowingly slipped abortion pills by partners who were unwilling to become fathers or by family members who were unsupportive of the pregnancy.<sup>66</sup>

## **Sexual Abuse and Sex Trafficking**

Spousal and non-marital abusers, along with those in the sexual exploitation industry (*i.e.*, pimps and traffickers), would love an environment in which they can compel women to repeatedly have abortions. Furthermore, men who have sex with minor females would love nothing more than to have unrestricted access to get rid of the “evidence” of their abuse. Making mifepristone a “self-managed” OTC drug would complicate the detection of sexual abuse and sex trafficking. The removal of in-person interaction with someone who is professionally trained<sup>67</sup> and mandated to report sexual abuse will only further isolate victims.<sup>68</sup>

It is common for sex-trafficked, pregnant women to be coerced into having an abortion, and women under the control of exploiters (pimps and traffickers) by definition have no voice.<sup>69</sup> A groundbreaking study published by the Beazley Institute, titled “The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities,” found that many survivors of sex trafficking reported they had been forced into having multiple abortions, only to be back on the streets following the procedure to continue making a profit for their trafficker. More than half of the women surveyed reported having had at least one abortion, and nearly 30 percent said they had multiple abortions.<sup>70</sup> The same 2014 report also disturbingly found that the majority of sex trafficking survivors (87.8 percent) reported that they had had contact with the health care system, but their abuse and exploitation went unrecognized and therefore unreported. As our country becomes more aware of the prevalence of sex trafficking in our communities, health professionals and law enforcement are getting more training to identify victims of sexual exploitation. Online and OTC mifepristone removes the opportunity for victims to interact with someone who may recognize the signs and get the victim to safety.

Sadly, we have seen evidence of abortion businesses such as Planned Parenthood being willing to aid traffickers for the sake of carrying out abortions. Planned Parenthood employees in various states have been caught on camera arranging abortions for women who were obviously victims of trafficking and sexual abuse, as well as aiding pimps and traffickers in evading the law.<sup>71</sup>

## **Accurate Patient Assessment and Safety**

The FDA’s removal of the in-person dispensing requirement will have tragic results. In-person dispensing allows medical professionals to assess a woman’s pregnancy more accurately before she takes the chemical abortion regimen and to provide emergency care if needed. Such a lack of direct contact places pregnant patients in a precarious situation.

Many abortionists do not have hospital admitting privileges. Consequently, if serious complications arise, patients are often told to go to an emergency room with no expectation of seeing their prescriber

again. On the other hand, a competent, conscientious physician would be fully aware of the patient's medical history and current health circumstances.<sup>72</sup> Already, illegal online abortion pill peddlers like Aid Access<sup>73</sup> and abortion activists have instructed women who experience health complications to avoid telling their doctor that they had a chemical abortion and instead say that they had a miscarriage.<sup>74</sup>

There is nothing safe or straightforward about chemical abortion, and women should not be encouraged to take this burden upon themselves. Even the ACOG has acknowledged this:

Compared with surgical abortion, medical abortion takes longer to complete, requires more active patient participation, and is associated with higher reported rates of bleeding and cramping. With medical abortion, expulsion of the products of conception most likely will occur at home, but a few women will still require surgical evacuation to complete the abortion. An early surgical abortion takes place most commonly in one visit and involves less waiting and less doubt about when the abortion occurs compared with medical abortion. In addition, women who undergo surgical abortion will not see any products of conception or blood clots during the procedure.<sup>75</sup>

If a woman needs an emergency procedure following a chemical abortion regimen gone awry, who bears the additional cost? Chemical abortion activists rarely, if ever, mention that the cost is assumed by the patient, who may or may not have health insurance coverage.

The risks that come with taking abortion pills are eerily similar to those of a self-induced abortion. Placing the burden on women to “self-manage” their abortions is not very different from the “coat hanger abortions” that abortion activists have said they want to avoid.<sup>76</sup>

## **Overriding State Interests in Preserving Life**

The availability of mifepristone online effectively overrides a significant number of pro-life protections that are currently law or are in the process of becoming law in several states. If the FDA approves an OTC chemical abortion regimen, it will effectively override by administrative fiat parental notification laws, waiting periods, and informed consent requirements for abortion that have been upheld by the courts as legitimate exercises of a state's interest.<sup>77</sup>

In just the past 10 years, the people's elected representatives have enacted almost as many state protections for the unborn as were enacted in the first 30 years following *Roe v. Wade*. Abortion activists—who are starting to lose the battle of public opinion in the states and may be facing a less sympathetic judiciary—are seeking an extra-legislative, extra-judicial bailout to keep abortion, and the abortion industry, afloat.

## **The Way Forward**

Here are some areas in which there should be increased oversight of chemical abortions to improve the health and safety of women.

### **Reinstate the REMS**

Prior to the Biden administration's decision to remove the in-person dispensing requirement for mifepristone, this requirement—as well as the additional REMS precautions—were the sole means of monitoring and mitigating the risk of death and other adverse events. And yet, the legion of adverse events mentioned previously have taken place under the previous REMS protocol. Therefore, the mifepristone REMS framework needs to be reinstated and strengthened beyond its prior reach.

Although the FDA operates under the executive branch, a department responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs should not be a



political organization. Its original decision to put restrictions on mifepristone was based on the drug's ability to harm women—not on a political agenda. Doctors, not politicians, should make medical decisions, and doctors, not patients, should be responsible for assessing a patient's pregnancy. In today's world, where politicians become the authority on "health care," doctors—as Alan Guttmacher feared—have simply become a "rubber stamp."<sup>78</sup>

With the removal of the mifepristone REMS, the doctor's role has been relegated even further—this time to placing a stamp on an envelope to mail deadly abortion pills to a woman who will become her own abortionist.

In order for the FDA to properly protect women, their review of the REMS should include the complete removal of the chemical abortion regimen from the market.

## **Require Proper Reporting**

Manufacturers must be required to report all adverse events related to mifepristone (both Mifeprex and the generic version), not just death. Public health authorities must track cases of incomplete abortion, infection, severe hemorrhaging (especially cases requiring transfusions), ectopic pregnancy, and any other case requiring a visit to an emergency room.

## **Safer Gestational Eligibility**

The Obama administration's political move to change the FDA label should be reversed, and the gestational limit should be returned to 49 days from last menstrual period (LMP) instead of the dangerous 70-day (10 week) limit. Mifepristone should be administered under the supervision of a licensed physician required to physically examine the woman (*e.g.*, to diagnose an ectopic pregnancy), administer the regimen, oversee the abortion, and be on hand in case of an emergency.

It should be noted that, although the FDA approves the use of medical abortions for up to 10 weeks, Planned Parenthood (which has repeatedly demonstrated a lack of care for women) advertises the regimen may be available in some states up to 11 weeks, making this do-it-yourself abortion even less safe.<sup>79</sup>

## **Prohibit Telemed Abortions**

Although the Biden administration has removed the in-person dispensing requirement, states should prohibit abortions attained via telemedicine because they do not require the patient to speak to a doctor face-to-face before beginning the chemical abortion regimen. States should require the physical presence of a physician who can accurately assess the woman's eligibility and provide emergency care if needed.

Telemed practices may be adequate for some types of medical care. Elective abortion is not medical care, and a telemed abortion is not a proper use of telemedicine.

Even apart from the question of caring for the life of the unborn child, abortions require a high level of physical interaction between the mother and a physician who can examine, diagnose, evaluate, and treat her. Abortion activists routinely compare inducing a chemical abortion to taking Tylenol<sup>®</sup>,<sup>80</sup> but a chemical abortion is a multi-day process that involves heavy bleeding and cramping. It also carries life-threatening risks, including incomplete abortion, infection, hemorrhaging, blood transfusions, and death. Pretending for ideological reasons that chemical abortion can be monitored by a physician remotely or even done as a do-it-yourself OTC regimen is extremely dangerous and negligent.

Furthermore, telemedicine is not suited to the provision of immediate emergency care. A telemed physician or health care provider would not even have to live in the woman's state and, consequently, would be unable to meet the patient at an emergency care facility like a local hospital. Indeed, "[s]ince telemed abortions were devised as a way to offset the scarcity of physicians in rural areas this is not a mere theoretical concern."<sup>81</sup>

## **Crack Down on Illegal Abortion Pills**

The FDA must crack down on the illegal sale of the drugs in the chemical abortion regimen, primarily mifepristone. With chemical abortions on the rise, illegal abortion pill traffickers, including the infamous Aid Access, have received much-warranted attention lately. Aid Access, as orchestrated by Dutch doctor Rebecca Gomperts, has been selling reduced-cost abortion pills online by purchasing the drugs from Indian pharmacies and having them shipped to Americans by mail.<sup>82</sup>

The FDA issued letters to Aid Access<sup>83</sup> and Rablon (an online pharmacy network that includes at least 87 websites, such as AbortionPillRx.com and AbortPregnancy.com), warning them to stop selling unapproved versions of the abortion drugs.<sup>84</sup> Soon after, 117 members of Congress sent a letter<sup>85</sup> to the FDA urging it to “continue to conduct oversight” of entities such as Aid Access and Rablon. Aid Access has refused to comply, instead deciding to sue the FDA.<sup>86</sup>

## **Prohibit Studies that Intentionally Destroy Life**

The FDA must not approve any drug trials and studies that intentionally destroy human embryos or fetuses. The FDA has approved Gynuity Health Projects’ TelAbortion study, and since 2016, clinical trials have begun in eight states (Colorado, Georgia, New York, Oregon, Hawaii, Maine, New Mexico, and Washington).<sup>87</sup>

## **Conclusion**

Abortion activists once claimed that legalizing abortion would eliminate life-threatening risks to women. Now they are attempting to make abortion completely “self-managed” despite chemical abortion’s life-threatening and health-damaging risks to women.

The removal of the in-person dispensing requirement is the first step toward the abortion industry's goal of rolling these safety regulations back even further. We must ensure that the FDA is protecting women from the dangers of the chemical abortion regimen.

Ultimately, we want to see the sale and the approval of drugs meant to intentionally kill life in the womb eliminated from our society. The rise of chemical “coat-hanger” abortion is just another reminder that abortion is an ideologically-based business and that its activists are willing to sacrifice women's safety for the sake of the business's expansion. The abortion industry knows that “having medication abortion available alongside other prescription drugs could help reduce stigma and further normalize this method of abortion.”<sup>88</sup> Further trivializing the taking of innocent life by making the abortion pill an easily attainable prescription or OTC drug would be a destructive blow to women's health and the moral fabric of our country. As the abortion industry continues to cleverly disguise its money-hungry business model as “women's health care,” pro-life activists will need to stay vigilant and alert to counter the growing threat of chemical abortion.

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