



## The Next Abortion Battleground: Chemical Abortion

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### SUMMARY:

The number of abortions being performed in the United States continues to decline annually and is currently at its lowest level since *Roe v. Wade*. Yet the rate of chemical abortions in the United States is at an all-time high. This rapid increase is primarily being driven by the abortion industry, which regards drug-based, do-it-yourself abortions as the best way to get around the many state-level pro-life laws being enacted around our country. Such abortions are accomplished through the abortion pill regimen, distributed under the brand name Mifeprex, which is subject to the FDA's drug safety program – Risk Evaluation and Mitigation Strategies (REMS) – because it carries such life-threatening risks.

The abortion industry wants to remove the FDA's REMS in order to have abortion pills available through the pharmacy and the mail, making do-it-yourself abortions 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 (in which a woman is never even examined by the prescriber), and eventually achieve over-the-counter (OTC) status for Mifeprex.

Abortion advocates once claimed that legal abortion would alleviate the danger of “back-alley” abortions for women, but now they want to place the burden of inducing abortions completely on women – despite the fact that the health complications that often result from an induced chemical abortion are eerily similar to those of “back-alley” abortions. They include severe bleeding, infection, retained fetal parts, the need for emergency surgery, and even death. In addition, the woman, who may or may not have health insurance coverage, is expected to bear the additional cost of these complications.

OTC abortion drugs could have 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.

With all the documented dangers, it is increasingly evident that the advancement of the abortion industry's agenda for the Mifeprex regimen is about political, ideological, and financial goals – *not* care for women.

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### Introduction

The number of abortions being performed in the United States continues to decline annually and is currently at its lowest level since *Roe v. Wade*.<sup>1</sup> At the same time, however, the types of abortion being performed have changed dramatically. The rate of chemical abortions is currently at an all-time high.

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The latest statistics on abortion 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> This rapid increase in chemical abortions is part of the abortion industry’s long-term strategy to make abortions “self-managed” and unrestricted<sup>4</sup>—despite the profound dangers such poorly-supervised medical care poses to women’s health.

To demonstrate this rise in use of the chemical abortion pill, it’s important to note that 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 6 percent of all clinical abortions in 2001 to 31 percent in 2014.<sup>5</sup> The Centers for Disease Control and Prevention (CDC) reports that from 2006 to 2015, the use of early “medication abortion” increased 114 percent.<sup>6</sup>

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

Mifepristone (Mifeprex®; also known as RU-486) 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. Before the abortion, the regimen requires a woman to have an ultrasound in order to confirm the pregnancy, ensure that the pregnancy is not beyond the safe gestational age, and diagnose any complicating factors like ectopic pregnancy.<sup>7</sup>

The mifepristone regimen is 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.

The patient is then sent home to take the regimen’s second drug, misoprostol, 24 to 48 hours after the mifepristone is 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 by the uterus after the mifepristone was taken.<sup>8</sup> Because using mifepristone alone frequently results in incomplete abortions, the second drug misoprostol is necessary in order for a mifepristone regimen to be considered an alternative to surgical abortions.

A mifepristone-misoprostol abortion can produce severe cramping, contractions, and bleeding. Once the embryo or fetus is expelled, there will be human remains (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>9</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>10</sup> Maternal deaths have occurred, most frequently due to infection or to an undiagnosed ectopic pregnancy.<sup>11</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>12</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>13</sup>

The abortion industry markets the abortion pill as straightforward and safe.<sup>14</sup> In reality, chemical abortions are a multi-day traumatic process that, according to the Mifeprex medication guide, could take up to 30 days to complete.<sup>15</sup> Incomplete abortion occurs up to 10 percent of the time and occurs more frequently as gestational age increases.<sup>16</sup> If an abortion is incomplete, a woman can be prescribed multiple doses of misoprostol. If that fails, a physician must perform a surgical abortion to remove the fetal remains through the cervix by vacuum or suction aspiration.<sup>17</sup>

## Health Effects and Danger to Women

The data clearly shows the negative health consequences of chemical abortion on women. Between 2000 and 2018, a total of 4,195 adverse events related to chemical abortions were reported to the FDA. These events include 24 maternal deaths, 97 undiagnosed ectopic pregnancies, 1,042 hospitalizations, 599 blood transfusions, and 412 infections (including 69 severe infections). (It is important to note that these numbers only represent the adverse events *reported* to the FDA, so we do not have a full picture of the data.<sup>18</sup>)

In 2009, 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 as 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>19</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 too.<sup>20</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>21</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, Mifeprex is used for aborting babies that are up to 10 weeks old, at which point the baby already has a head, hands, feet, fingers, and toes. The baby also has a heartbeat and brain activity.<sup>22</sup>

A study published in *Frontiers in Neuroscience* titled, “Biological, Behavioral, and Physiological Consequences of Drug-Induced Pregnancy Termination at First-Trimester Human Equivalent in an Animal Model”<sup>23</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>24</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>25</sup> The study acknowledged that more research is needed to evaluate the psychological and physiological effects of a chemical abortion.

## FDA and Regulatory Overview

The abortion pill regimen, distributed under the brand name Mifeprex, was approved for abortion by the FDA under the Clinton administration in 2000. Because Mifeprex carries life-threatening and health-endangering risks such as hemorrhage, infection, incomplete pregnancy, retained fetal parts, the need for emergency surgery, and death,<sup>26</sup> it is subject to the FDA's drug safety program, known as the Risk Evaluation and Mitigation Strategies (REMS).<sup>27</sup> The Mifeprex REMS provide a way to monitor and mitigate the risks of the Mifeprex regimen while also preventing the sale and provision of mifepristone tablets outside a clinical setting.

The REMS mandate that Mifeprex can only be dispensed in certain healthcare settings and under the supervision of a certified prescriber.<sup>28</sup> A certified Mifeprex 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>29</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.<sup>30</sup>

The REMS had historically stipulated that only a licensed physician could be a certified prescriber of Mifeprex.<sup>31</sup> The REMS had also required the manufacturer to report complications with Mifeprex to the FDA.<sup>32</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>33</sup>

Under the 2016 changes, a certified prescriber merely needed to be a "healthcare 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>34</sup> Also, under the 2016 approval, manufacturers were no longer required to report any adverse events to the FDA other than death.<sup>35</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 about 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>36</sup>

Despite the troubling results of studies such as this, and despite the many adverse events already reported,<sup>37</sup> the FDA – under the sway of the abortion advocacy 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>38</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>39</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>40</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**

Not satisfied with this weakened approach, the abortion industry wants to fully remove the FDA’s REMS, making do-it-yourself abortions the norm and making abortion pills available through the pharmacy, the mail, and even on college campuses.<sup>41</sup> 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 (in which a woman is never even examined by the prescriber), and eventually achieve OTC status for Mifeprex.<sup>42</sup>

Industry advocates disclose that:

“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>43</sup>

They are correct. The potential ramifications of lifting the REMS should not be overlooked, especially since do-it-yourself abortion is their vision for the future of abortion in the United States:<sup>44</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>45</sup>

Lifting the REMS offers new possibilities like obtaining the abortion pill without a prescription, thus normalizing it as an easily acquired drug – whether it be over-the-counter, through the mail, or online.<sup>46</sup> With all these documented dangers, it is evident that the advancement of the abortion industry’s agenda for the Mifeprex regimen is about political, ideological, and financial goals – *not* care for women.

Drug-based abortions are regarded as the best way to get around the increasing restrictions on abortion being put in place by pro-life laws around the United States. Even regulations requiring basic clinic safety and sanitary standards appear to be more than any abortion provider can stomach.<sup>47</sup> Do-it-yourself chemical abortion is primarily about making sure that abortion can survive in any future pro-life legal and policy environment, and, secondarily, incentivizing abortion as an option for low-income women by lowering the costs associated with it.

The legacy of abortion is rooted in eugenics, and it is not a mistake that abortion is promoted in predominantly African-American and Hispanic communities. 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>48</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>49</sup>

A 2011 study comparing chemical abortions to surgical abortions revealed several reasons why the abortion pill 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>50</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 Marie Stopes<sup>51</sup> have already made extensive use of this easily-transportable product – a shift that has been supported by the World Health Organization (WHO).<sup>52</sup>

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

Making the abortion pill a “self-managed” over-the-counter (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>53</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>54</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>55</sup>

An OTC Mifeprex 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>56</sup> The pro-abortion American College of Obstetrics and Gynecology (ACOG) Committee on Ethics reaffirmed this year (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>57</sup>

Even the National Abortion Federation, the radically pro-abortion trade and advocacy group in the U.S., 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>58</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>59</sup>

Women compelled to abort are often subjected to violence in order to force them into having the abortion. A systematic review and meta-analysis of 74 studies worldwide confirmed that intimate partner violence is associated with abortion, and is even more strongly associated with repeat abortion.<sup>60</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>61</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 the abortion pill a "self-managed" OTC drug would complicate the detection of sexual abuse and sex trafficking. Removing the need to have in-person interaction with someone who is professionally trained<sup>62</sup> and mandated to report sexual abuse would only further isolate victims.<sup>63</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>64</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 profit for their trafficker. More than half of the women surveyed reported at least one abortion, and nearly 30 percent said they had multiple abortions.<sup>65</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 healthcare 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 learn how to identify victims of sexual exploitation. Online abortion pills and OTC Mifeprex remove the opportunity for victims to interact with someone who may be able to 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 providing 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, and aiding pimps and traffickers in evading the law.<sup>66</sup>

## Accurate Patient Assessment and Safety

If approved by the FDA, an OTC Mifeprex regimen would remove any direct physical oversight by a medical doctor or healthcare provider of the chemical abortion process. Those professionals are able to more accurately assess a woman's pregnancy prior to taking the Mifeprex regimen, and would be in a far better position to provide emergency care if needed. Such a lack of direct contact would place pregnant patients in a precarious situation.

Many abortionists do not have hospital admitting privileges. Consequently, if serious complications do arise, Mifeprex 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>67</sup> Already, illegal online abortion pill peddlers like Aid Access<sup>68</sup> and abortion advocates 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>69</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>70</sup>

If a woman needs an emergency procedure following a Mifeprex regimen gone awry, who bears the additional cost? Chemical abortion advocates 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 the abortion pill 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 "back-alley coat-hanger abortions" that abortion activists have said they wanted to avoid.<sup>71</sup>

## Overriding State Interests in Preserving Life

The availability of the abortion pill online or OTC would effectively override 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 over-the-counter Mifeprex regimen, it would 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>72</sup>

The people, through their elected representatives, have in just the last ten years enacted almost as many state protections for the unborn as were enacted in the first 30 years since *Roe v. Wade*. Abortion activists, who are starting to lose the battle of public opinion in the states and are now on the verge of losing a sympathetic activist 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.

### Strengthen the REMS

The Mifeprex REMS remain the sole means of monitoring and mitigating the risk of death and other adverse events of the abortion pill regimen. And yet, the legion of adverse events mentioned previously have taken place under the current REMS protocol. Therefore, the Mifeprex REMS framework needs to be strengthened – not weakened or removed.

Congress has begun to take action along these lines. Representative Robert E. Latta (R-Ohio) recently introduced H.R. 4399, the *Support and Value Expectant (SAVE) Moms & Babies Act*.<sup>73</sup> This bill would prevent the FDA from approving new abortion drugs or loosening restrictions (such as the REMS) for mifepristone. It would also prevent the “dispensing” of drugs remotely, by mail or through telemedicine. This bill is critical to codifying the REMS and protecting women and girls.

In addition, Representative Jim Banks (R-Ind.) recently led a congressional letter addressed to FDA Acting Commissioner Ned Sharpless. In that letter, 53 members of Congress expressed concern “about the effectiveness of the current REMS for mifepristone in light of the recent approval of a generic version of Mifeprex.” The letter asks the Commissioner to reinstate four components of the 2000 REMS that carried stronger protections for women. Those components include reverting the gestational age limit to 49 days, requiring the drug to be administered under the supervision of a physician, requiring three office visits by the patient, and requiring that *all* adverse events related to the drug be reported to the FDA, not just “death” of the mother.

### Require Proper Reporting

Manufacturers must be required to report all adverse events related to the abortion pill (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. The abortion pill should be administered under the supervision of a licensed physician who is 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.

### Prohibit Telemed Abortions

States should prohibit telemed (over the internet) abortions because they do not require the patient to speak to a doctor face-to-face before beginning the abortion pill 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, diagnosis, evaluate, and treat her. Abortion advocates routinely compare inducing a chemical abortion to taking Tylenol®,<sup>74</sup> but a chemical abortion is a multi-day process that involves heavy bleeding and cramping, and carries life-threatening risks including incomplete abortion, infection, hemorrhaging, blood transfusions, and death. Pretending for ideological reasons that chemical abortion can be done remotely (commonly using Skype) or even as a do-it-yourself, over-the-counter regimen is extremely dangerous and negligent.

Furthermore, telemedicine is not suited to the provision of immediate emergency care. A telemed physician or healthcare 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>75</sup>

Currently, only 18 states require the physical presence of a physician to administer abortion pills.<sup>76</sup> Representative Ron Wright (R-Texas) has introduced H.R. 4935, the *Teleabortion Prevention Act of 2019*, which would prohibit chemical abortions from being performed without the physical presence of a physician. Regardless of whether this federal-level protection passes, states should continue to safeguard the health of women by prohibiting "Skype" and mail-order abortions. Skyping with a doctor and filling out a questionnaire carries many of the same risks as ordering pills online from a doctor you have never met and who cannot physically assess you.

### Crack Down on Illegal Abortion Pills

The FDA must crack down on the illegal sale of the drugs in the Mifeprex 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>77</sup>

The FDA issued letters to Aid Access<sup>78</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>79</sup> Soon after, 117 members of Congress sent a letter<sup>80</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>81</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>82</sup>

## Conclusion

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

While the abortion pill is currently regulated, the Obama administration weakened the regulations and the abortion industry is actively working to roll these safety regulations back even further. We must ensure that the FDA is protecting women from the dangers of this 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 advocates are willing to sacrifice the safety of women 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>83</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 their money-hungry business model as care for women, pro-life activists will need to stay vigilant and alert to counter the growing threat of chemical abortion.

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<sup>1</sup> “Induced Abortion in the United States,” Guttmacher Institute, September 2019, accessed November 19, 2019, <https://www.guttmacher.org/fact-sheet/induced-abortion-united-states>.

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