

# MISSED, MISCLASSIFIED, AND MINIMIZED:

Why Abortion Pill Complications

Are Underreported

Randall K. O'Bannon, Ph.D.

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## Missed, Misclassified, and Minimized:

## Why Abortion Pill Complications Are Underreported

Randall K. O'Bannon, Ph.D., National Right to Life Director of Education & Research

#### **Executive Summary**

Independent research demonstrates that complications from the abortion drug **mifepristone** (RU-486) occur at far higher rates than abortion advocates and the media typically report. While abortion industry studies claim serious complications occur in **less than 0.5% of cases**, a major 2024 analysis of over 865,000 insurance claims found serious adverse events—hemorrhage, infection, failed abortions, and surgical follow-up—occurred in **about 11% of women**, a figure supported by international studies

This discrepancy between recent reports and industry research is not accidental but reflects a deliberate effort by abortion advocates and their media allies to make abortion pills seem safer than they really are. Here's how this has been done:

- Women are told to conceal complications. Encouraging unwarranted fears of exposure and prosecution, abortion pill providers and advocacy groups have convinced women to keep their chemical abortions secret if and when seeking treatment.
- A contemptible lack of curiosity in the media. The press often repeats abortion industry talking points, ignores FDA data, and downplays or misattributes women's injuries and deaths. Even documented cases of hemorrhage, infection, and death are minimized or reframed as rare or unrelated.
- **Abortion industry spin.** Researchers frequently dismiss significant complications as "minor." For example, failed abortions, hemorrhages, and infections have been reclassified in studies as routine or insignificant. When both "major" and "minor" complications are included, rates climb well above the advertised figures.

This report will document these claims and show how miscalculations, misinterpretations, and misrepresentations of mifepristone safety and efficacy data have taken hold.<sup>1</sup>

Better reporting and more objective research may be needed to ascertain just how dangerous chemical abortions with mifepristone really are, but clearly the risk is more common and serious than the abortion industry and its allies would have people believe.

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<sup>&</sup>lt;sup>1</sup> This is independent of basic problems with counting these chemical abortions and complications that will be discussed in APPENDICES A and B at this document's end.

#### Introduction

Recently released studies give clear indications that serious complications among abortion pill users are much more common than have generally been reported.

The media has repeated the claims of abortion advocates that the incidence of serious complications among mifepristone patients are "less than half a percent." However, a report released in May by the Ethics & Public Policy Center (EPPC) looking at the insurance claims of more than 865,000 users, found "serious adverse events" like hemorrhage, infection, failed abortion, and required surgical follow-up to be *closer to 11*%, a figure more in keeping with studies of tens of thousands of abortion pill users in Canada, Britain, and Finland.

This raises an obvious question. If so many women are using mifepristone to abort their babies in America and there are supposed to be all these wounded women across the country, why aren't we seeing more of these women coming forward, why are we hearing more of their stories?

It's a legitimate question. If these complications are real, how did all those expert studies miss so many of these adverse incidents? Is this just a dispute over terminology? Are opponents of the abortion pill mislabeling or exaggerating mifepristone's ordinary side effects?

These claims will not just be asserted, but documented, in many cases by abortion pill advocates' own studies.

This report will help you understand not just where these women are but will also reveal more about the concerted effort to keep this critical information from you.

# ISSUE #1: WOMEN HAVE BEEN TOLD TO CONCEAL THEIR COMPLICATIONS

If numbers of mifepristone complications from the EPPC report are accurate, only about one in 22 women having serious reactions is ever recorded and reported as such by recognized U.S. abortion experts. It isn't necessarily that those other 21 patients do not experience serious adverse events, but that they just aren't reported or reported as such.

That means women are showing up at the emergency room with infections, hemorrhages, severe cramping, etc., but their chemical abortions and their use of abortion pills are not being noted in the hospital record.

As far as the official report goes, these women are counted as simply having miscarriages, unexpected fetal losses, along with the accompanying symptoms. Or maybe an ectopic pregnancy that got missed before rupturing.

One reason the ER doctors may not enter any note about the chemical abortion on the chart is that they don't know patients have taken abortion pills or that patients have been told by those who prescribed their abortion pills not to reveal this to the doctors.

Women are made to think that revealing their use of mifepristone will expose them to possible prosecution or at least exposure to their friends or relatives and advocates say this may make them reluctant to seek needed treatment.

They are advised to tell the treating physician they are simply having a miscarriage and that none of the hospital staff will be able to tell the difference. They are also told that this will not affect their treatment in any way.

#### Directed to conceal

In 2020, the Aid Access website directly told women,

If you think you might have a complication you should go to a doctor immediately. You do not have to tell the medical staff that you tried to induce an abortion; you can tell them that you had a spontaneous miscarriage....The symptoms of a miscarriage and an abortion with pills are exactly the same and the doctor will not be able to see or test for any evidence of an abortion, as long as the pills have completely dissolved.<sup>2</sup>

In 2024, Rebecca Gomperts, the Dutch physician who started Aid Access, Women on Web, the abortion ship, etc., told *Ms.* magazine,

... if they have to go, we want them to be able to go and not to be afraid and scared to be prosecuted, as long as if the correct information [sic] and say that they had a miscarriage and not that they took abortion pills.<sup>3</sup>

Whether doctors can tell or not, the American College of Obstetricians and Gynecologists (ACOG) advises that Ob-Gyns "should not report pregnancy outcomes unless legally compelled to do so." ACOG tells health care professionals that even if a patient discloses their attempted chemical abortion "documenting and reporting of the information can cause harm to the patient as well as the health care professional involved in the patient's care."

There is no place in the country where women are prosecuted for ordering abortion pills for themselves or attempting chemical abortions. While the injured woman surely ought to be able to hold her prescriber accountable for any difficulties or injuries she suffers, abortion advocates clearly raise the specter of her prosecution to keep providers illegally prescribing and selling the pills from being identified or held legally accountable.

#### Stoking unwarranted fears

This tactic of convincing the woman to ally with her abuser to supposedly keep both out of jail goes back to the 1800s, when injured women were kept from coming forward and speaking out against their abortionists by thinking it was the only way to keep both from getting caught.<sup>5</sup>

<sup>&</sup>lt;sup>2</sup> See Aid Access website, "How do you know if you have complications and what should you do?" page, 11/1/20 at https://web.archive.org/web/20201204195545/https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do.

<sup>&</sup>lt;sup>3</sup> "Uncharted Waters: What's Next for Abortion (with Rebecca Gomperts)," On the Issues with Michelle Goodwin, Ms. Studios, January 25, 2024. Found at https://msmagazine.com/podcast/uncharted-waters-whats-next-for-abortion-with-rebecca-gomperts/

<sup>&</sup>lt;sup>4</sup> "Self-Managed Abortion," ACOG Committee Statement, No. 13 (December 2024).

<sup>&</sup>lt;sup>5</sup> Generally, see Marvin Olasky, Abortion Rites (Wheaton, IL: Crossway Books, 1992), but also Olasky, "How Americans Got Away with Abortion Before 'Roe v. Wade'," Christianity Today, August 22, 2022.

Again, even after *Dobbs* allowed states to make some abortions illegal, no state prosecutes women for seeking or attempting abortions. Women can reveal the one responsible for their injury without fear of exposure or prosecution.

Knowledge of mifepristone use critical to emergency treatment Furthermore, it simply isn't true that miscarriages and chemical abortions are medically identical.

Beyond the fact that one involves the intentional willful destruction of a healthy, innocent human being, whom the woman may traumatically encounter during her abortion, experts tell us that those taking abortion pills have compromised immune systems, and face higher risks of hemorrhage, infections, and unusual sepsis.<sup>6</sup>

Doctors need to know this information to better understand and address what it is they are seeing.

In a larger sense, however, this directed concealment has the effect of causing government regulators and the health care system to get a false idea of mifepristone's safety and efficacy. Sudden and dramatic increases of complications among mifepristone patients coming in for treatment at the emergency room may be incorrectly attributed to pregnancy in general and may appear to indicate a disturbing and unexplained jump in miscarriage, rather than a direct outcome of growing mifepristone use.

Perpetuating myths of mifepristone safety

A study recently published in the journal Family Medicine and Primary Care: Open Access found just that.

Looking at Medicaid claims data of nearly 29,000 women visiting the ER within 30 days of a surgical or drug-induced abortion, researchers found that nearly 84% of those visits of chemical abortion patients were miscoded as complications related to "miscarriages" rather than the previous abortion, though a miscarriage following a new pregnancy within that short time frame was highly unlikely.<sup>7</sup>

Clearly women and doctors were following the advice of abortion advocates in classing these complications as miscarriage rather than abortion related.

Beyond individual misdiagnosis and possibly compromised treatment, this leads the medical community, government health care regulators, and the general public to get a false idea of mifepristone safety and to make normal pregnancy seem riskier than it really is. This has the unusual simultaneous effect of making people unnecessarily wary of conceiving children and inappropriately comfortable with chemical abortion.

<sup>6</sup>Ingrid Skop, "Dangerous Deception: Not Telling Your Doctor About Abortion Pill Use Increases Health Risk" Lozier Institute 5/25/22.

<sup>&</sup>lt;sup>7</sup> Studnicki, J. et al, "Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortion: An Analytic Observational Prospective Cohort Study," Family Medicine and Primary Care: Open Access, Volume 9, Issue 01 (published May 23, 2025). Available <a href="https://www.gavinpublishers.com/assets/articles-pdf/Determining-the-Period-Prevalence-and-Acuity-of-Emergency-Department-Visits-Following-Induced-Abortion-Mistakenly-Identified-as-Spontaneous-Abortion-Analytic-Observational-Prospective-Cohort-Study.pdf.">https://www.gavinpublishers.com/assets/articles-pdf/Determining-the-Period-Prevalence-and-Acuity-of-Emergency-Department-Visits-Following-Induced-Abortion-Mistakenly-Identified-as-Spontaneous-Abortion-Analytic-Observational-Prospective-Cohort-Study.pdf.</a>

#### Hidden Figures

All this means that the reason you're not hearing about more of these abortion-related complications is that women, unnecessarily spooked by fears of being exposed, are not coming forward to report their experiences. The complications are there, but they aren't being reported.

A more realistic fear is that complications are even higher than what these recent, better, more independent studies have found. How many mifepristone patients decided to skip the ER altogether, to see their local doctor instead, or visit the nearest abortion clinic, or maybe just hope for the best in order not to have their abortions reported or exposed?

You aren't hearing about them because abortion advocates have successfully convinced them to remain silent.

#### ISSUE #2: A CONTEMPTIBLE LACK OF CURIOSITY IN THE MEDIA

It's not always easy to find, but there is evidence of a significant number of complications out there.

#### FDA documented deaths and injuries

Even the FDA has admitted in its regular post-marketing reports that there have been at least 36 deaths and thousands of complications among American users of the abortion pill since approval in 2000.8

Rather than use these as a basis for further investigation, with the knowledge that government reports are nearly always selective and incomplete, the media have generally followed the lead of the abortion industry and have either ignored the FDA data or amplified the industry spin that these complications were somehow not really related to mifepristone use.<sup>9</sup>

Again, these were only the deaths and complications made known to the FDA. Many serious adverse events are never reported, especially since the FDA made the decision in 2016 to no longer require the reporting of complications—other than death—back to the FDA.

It is probably worth noting that many of these deaths do not appear to have been first made known by the distributor, the government, or the abortion industry, but by aggrieved relatives who shared their stories with the media.<sup>10</sup>

#### Stories in the popular press

There are stories of women who have bled to death, hemorrhaging from taking drugs to wrest their child's body and her placental cocoon from the uterine wall. And there are a few stories of

 $<sup>^8</sup>$  FDA "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024" at www.fda.gov/media/185245/download

<sup>&</sup>lt;sup>9</sup> A couple of the deaths, involving homicide or suicide, may not have been directly medically connected, but media and industry have also tried to say the abortion pill was not implicated when it was clearly the administration and action of mifepristone and/or misoprostol that triggered the uncontrolled bleeding or exposed the woman to a rare, deadly bacteria.

<sup>&</sup>lt;sup>10</sup> You can find some details of some of the early deaths here: <a href="https://nrlc.org/uploads/factsheets/FS10pilldanger.pdf">https://nrlc.org/uploads/factsheets/FS10pilldanger.pdf</a>
. Obviously there have been many more since.

women who died of rare but deadly infections caused by bacteria that just happens to grow in open wounds when they are closed off from fresh air.

There are cases of women who took the pills, began to experience the horrific pain and bleeding but told to expect this as part of the chemical abortion process, only to find out too late that they had an ectopic pregnancy that went undetected and then ruptured, triggering off the misinterpreted symptoms.<sup>11</sup>

As we know from FDA reports and subsequent studies, these were not the only women experiencing problems. In nearly every study coming out since approval, there have always been numbers of women reporting hemorrhaging, infection, failure, surgical intervention, etc. The spin from the industry, picked up by the government and the media, has generally not been that these do not occur, but that they are usually mild and exceedingly rare.

The point is that there has been some reporting of a few of these cases and some counting of complications, but the numbers and cases have usually been relatively small, limited, and treated as inconsequential.

When the media has talked to a few of these women or published their stories describing the agony of the process and the trauma of losing their children, their experiences are generally downplayed or dismissed as transitory or even blamed on pro-life laws or policies.

#### The media hasn't done its job

If the new reports and data are to be believed, the experiences of these women and their injuries are a lot more common than what the industry typically admits. Hemorrhage, infection, and failure are more frequent. Abortions are more painful and traumatic. And many more women are going through these nightmares than most people know.

If the abortion industry and medical establishment didn't frighten these women into believing that they'd risk prosecution if their chemical abortions were discovered, we might know more of their stories.

And the media might uncover more of these stories if they'd just look, investigate, ask a few questions, and stop blindly accepting the claims and spin of the abortion industry.

#### **ISSUE #3: ABORTION INDUSTRY SPIN**

We have already seen how the abortion industry convinces women (and doctors) not to report or to misreport their complications by holding the unwarranted prospect of prosecution over their heads.

And we have already talked a bit about how the abortion industry, on the basis of that unreported or misreported data, has claimed that deaths and complications among mifepristone patients were rare and generally mild.

<sup>&</sup>lt;sup>11</sup> Again, some of these early stories can be found in the NRLC fact sheet mentioned above "Deaths Associated with RU-486," 5/2006, at https://nrlc.org/uploads/factsheets/FS10pilldanger.pdf.

So, what happened to all these injured women, the ones featured in the EPPC report? Where are they? Why aren't they showing up in the studies, <sup>12</sup> in the records?

#### Failure to account for missing patients

There are reasons that abortion researchers have missed so many of these women. Every study deals with patients "lost to follow up" – patients who do not return for follow up appointments or fail to call back to report how they are doing. This is a particular problem for abortion pill patients. The process of aborting the child—initiating the painful contractions, the bleeding, the expulsion of the child (if that happens)—does not generally occur until sometime *after* the woman has taken mifepristone and then the second pill, misoprostol, a few days later.

It is important to see how this affects safety and efficacy calculations. If there are 150 women in a mifepristone trial, and 98 successful abortions among the 100 women who returned or called in their results, that might be reported as a 98% success rate. But if there were 8 failed abortions and another ten who had significant bleeding among the 50 who did not return – who may have gotten help at the local ER or their own personal physician – then the failure and complication rate is really more than 13%, not the 2% that might be reported.<sup>13</sup>

#### Reclassifying major complications as "minor"

There is another way, more insidious, that abortion researchers minimize the numbers and seriousness of the complications experienced by users of mifepristone. That is to record the complications, but to count or categorize those complications as minor. So long as the patient doesn't die, the crises can be averted, and the safety reasserted by mere redefinition.

A 2015 study of Emergency Room visits by California Medi-Cal abortion patients done by researchers affiliated with the University of California San Francisco (UCSF) shows how that is done. Looking at patient records (billing records) of women having mifepristone abortions later visiting the ER, Ushma Upadhyay and her UCSF team reported that they found just 0.31% experiencing "major" complications. This is one of the studies widely reported in support of the claim that significant adverse events or serious complications are "less than half a percent."

According to the study, "Major complications were defined as serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion." Fair enough. Anyone experiencing those events clearly did experience a significant adverse event.

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<sup>&</sup>lt;sup>12</sup> Ironically, one of the reasons more women weren't uncovered in earlier studies is that abortion industry researchers in controlled trials did a better job screening patients in their studies than abortion pill prescribers later did in the field. Because of that screening, because many used ultrasounds to better ascertain fetal age and identify ectopic pregnancies, they were able to ensure that women over the gestational limit (when failures and complications increase) or women with ectopic pregnancies (which the pills do not treat) were never given the pills in the first place.

When that sort of screening is not done (such as when these pills are ordered and shipped from online sellers), there are more women getting the pills with pregnancies past the deadline, more women with ectopic pregnancies or other medical contraindications taking the pills, leading to more women experiencing failures or complications <sup>13</sup> At least 2,470 women were lost to follow up in Mary Gatter, Kelly Cleland, and Deborah Nucatola's "Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days," Contraception, Vol. 91, No. 4 (April 2015). The Gatter study is one often cited by the FDA in assertions of mifepristone safety (see FDA Center for Drug Evaluation and Research, "Summary Review," for Mifeprex, March 29, 2016).

Minor complications, though, were defined as "All other expected adverse events." Read on and one finds that this included not just things like "diagnosis of cervical injury requiring suture repair," but failed or incomplete abortion, hemorrhage, infection, and subsequent surgery (aspiration) or even "uterine perforations." <sup>14</sup>

#### "Minor" to whom?

Perhaps it is understandable to discount a situation as "minor" if a woman shows up at her local ER concerned about her bleeding only to find that she is simply experiencing the normal progress of a chemical abortion, that the bleeding will resolve on its own, and no treatment is necessary. The length and amount of bleeding may be traumatic to her, but perhaps her health is in no immediate danger. Still, this is traumatic to her, enough to prompt an ER visit, and should not be blithely discounted.

But if this is a full-blown hemorrhage or infection, when those are known to have proven deadly for some women, if this failed or incomplete abortion requires surgical intervention, it seems inappropriate to dismiss these as "minor" as researchers appear to have done in this study.

It is difficult not to see this as researchers (who are really just abortion pill promoters and providers engaging in their vocations) putting their thumbs on the scale to get the sort of results that will ensure the continued use and availability of mifepristone.

#### Recalibrated numbers tell a different story

It is worth noting that when Upadhyay and team include both "major" and "minor" complications, their total complication rate is not "less than half of a percent" but actually 5.19%, closer to one in 19 than the one out of every 200 often reported in the press.

It is true that other more objective studies (some mentioned above), particularly those from other western countries, indeed found much higher rates of complications, and that even studies of U.S. abortion advocates reveal significantly higher complication rates. But the reader may see that clearly only once the spin is separated out from the data.

#### Doubling down on calling these "minor"

One more word about Upadhyay and this idea that a lot of these complications can be dismissed if they are categorized as "minor." Upadhyay was continuing to make this case as recently as Spring of 2025, shortly after the report from the Ethics and Public Policy Center (EPPC) came out with its estimate of 10.93%.

In an April 30, 2025 letter to U.S. FDA commissioner Martin Makary, Upadhyay asserted that the EPPC study "contradicts 100 peer-reviewed studies demonstrating that mifepristone is safe and effective" and "is plagued by numerous methodological flaws." <sup>15</sup>

<sup>&</sup>lt;sup>14</sup> Ushma D. Upadhyay, Tracy A. Weitz, Daniel Grossman, et al, "Incidence of Emergency Department Visits and Complication After Abortion," Obstetrics & Gynecology, Vol. 125, No. 1 (January 2015), pp. 175-183.

The chart identifying numbers and percentages of "major" versus "minor complications" associated with chemical abortions is found on Table 3, p. 178. Data cited here and the delineation of what counts as a major or minor complication is found on Figure 1 on p. 176, though it does not distinguish there between complications from chemical and from surgical abortions.

<sup>&</sup>lt;sup>15</sup> See "Comment by Ushma Upadhyay" link at FDA public submissions site <a href="https://www.regulations.gov/comment/FDA-2025-P-0377-0017">https://www.regulations.gov/comment/FDA-2025-P-0377-0017</a>.

The majority of her complaints were that the EPPC report was including too many adverse events that weren't, to her thinking and those of her fellow abortion researchers, truly serious or significant, not really "major" complications.

#### ER visits no big deal?

Her first and possibly most telling complaint, is that ER visits are not in and of themselves "serious adverse events." This is true, to a point. Just because someone shows up at a hospital ER rather than an urgent care or visiting their doctor may be more a matter of timing or convenience; maybe it was the middle of the night, and her regular doctor's office was closed.

And not every visit ends up requiring emergency treatment or surgery.

But some do. And the mere fact that the woman was not comfortable enough with just sitting at home and waiting for daylight and her doctor's office to open or waiting things out and hoping and praying that the bleeding would finally stop says something. At a minimum, it is an indication that either that she was not appropriately counseled, adequately warned about the process and the side effects, that she lacked the trust or the ability to contact her prescriber, or simply that her experience was more harrowing and fraught than she was led to believe. To dismiss this as "minor," to label most of these adverse events as "not serious" is to worry more about the abortion pill and the industry's reputation and the impact of these reports on sales rather than upon these patient's experience and their welfare. There IS something wrong with a pill that sends more than 5% of women taking it to the ER.<sup>16</sup>

#### Surgery no big deal?

Likewise, with Upadhyay's contention that the need for surgery or additional medication to complete the abortion is "not a serious adverse event." If the pills don't work and a woman has to come back for surgery or to take more pills to amplify and encourage her bleeding, cramping and passage of the baby, this is significant.

If nothing else, it is a risky, painful, time-consuming medical failure, not simply a minor inconvenience.

#### Dismissing the assessments of other doctors

More specificity about "other abortion-specific complications" would have been helpful, as well as more information about the doctors coding these adverse events, but this does not mean that these complications can automatically be written off and ignored. There were real doctors using recognized medical criteria<sup>17</sup> in assessing these events.

#### What about those reports?

Disputing over whether doctors should have used diagnosis or treatment codes, or whether some Grade 3 (severe) events should have been coded as Grade 2 (moderate) misses the point. These were real women experiencing real adverse events so serious that it prompted them to seek

<sup>&</sup>lt;sup>16</sup> Again, this 5%+ is what Upadhyay's own study from 2015 says. EPPC found a similar number visiting the ER, while independent (not connected to the abortion industry) studies from elsewhere found even higher (e.g., study of more than 40,000 patients from Ontario found nearly 10.3%. Liu and Ray, *Annals of Internal Medicine* 1/3/23).

<sup>&</sup>lt;sup>17</sup> NIH Common Terminology Criteria for Adverse Events (CTCAE version 5)

professional medical help – help with complications for which physicians felt they could legitimately bill and for which insurers would reimburse.

These weren't illusions or fantasies or hypochondriac complaints.

If Upadhyay and her fellow abortion researchers want to assert that they are not denying these adverse events outright, one needs to ask what they mean to accomplish by minimizing the seriousness of these events.

It wasn't pro-lifers or abortion pill opponents who made these women come forward, who had to convince them to seek treatment. There is something about the abortion pill and the chemical abortion experience that is not as simple and safe and satisfactory as Upadhyay and the industry would have women believe.

Denying the clear link between missed ectopic pregnancy and chemical abortion Finally, Upadhyay complains that the listing of ectopic pregnancy as an adverse event is not appropriate as ectopic pregnancy is not caused by and is "not a complication of medication abortion."

Given that Upadhyay would clearly be knowledgeable about and understand the dangerous connection between chemical abortions with mifepristone and undiagnosed ectopic pregnancy, this claim is particularly disingenuous and damning.

No one is trying to say here that mifepristone *causes* any of these pregnancies to become ectopic or thinks that there is something about it that makes the tiny child implant outside the womb. That is not the danger being discussed here.

But because mifepristone does not work in conditions of ectopic pregnancy, and because the signs and symptoms of a rupturing ectopic pregnancy are disturbingly similar to the expected actions of mifepristone and misoprostol on a woman's body – pain, sharp abdominal cramping, bleeding – it is critical that doctors eliminate this possibility before prescribing these drugs. <sup>18</sup>

If a physician does not rule out ectopic pregnancy (the best is by ultrasound), the woman could begin to cramp, bleed and think she is simply living through the process of a chemical abortion, and thus perhaps fail to get treatment until it is too late.

This is quite **definitely** a complication and a serious, life-threatening one. And it is one most definitely connected to mifepristone abortions where no special ultrasound screening for ectopic pregnancy is done, a protocol Upadhyay is willing to endorse.<sup>19</sup>

<sup>&</sup>lt;sup>18</sup> This is not simply common medical knowledge, but it is noted multiple times on even the latest FDA label for Mifeprex, which not only notes that mifepristone in contraindicated in situations of ectopic pregnancy, but that "Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy." FDA Mifeprex Label, 1/2023. Ref ID 5103833, www.accessdata.fda.gov/drugsatfda docs/label/2023/020687Orig1s025Lbl.pdf

<sup>&</sup>lt;sup>19</sup> Leah Koenig, Elizabeth Raymond, Ushma Upadhyay, et al, "Effectiveness and safety of medication abortion vs without screening ultrasonography or pelvic examination," American Journal of Obstetrics & Gynecology, June 19, 2025 (online).

Mifepristone may not cause ectopic pregnancy, but mifepristone's use by women who have not been adequately screened for ectopic pregnancy is a serious, life-threatening and avoidable risk, and can lead to a serious adverse event among mifepristone users.

#### Not worth counting

So where are all the women some of these later reports and studies say have been injured and abused by these drugs and their prescribers? Once again, we see that they have been silenced and minimized, told their pain and blood and trauma are "minor complications" that somehow just don't rise to the level worthy of being noticed.

But they suffer and bleed just the same.

## **SUMMARY**

There are women out there who have been injured by abortion pills – every study, every involved government agency says so. Many of their stories have been told, and they are chilling. But exactly how many women suffer serious complications from use of these pills is still very much an open question. The industry has taken many steps and engaged in various practices, detailed in this report, to keep these from being published in the press, acknowledged by the FDA, and recognized by their potential customers.

That there have been foreign studies, and analyses by industry independent sources in the U.S., finding much higher rates of complications is significant.

Even if there are legitimate discussions to be had over how these complications are classified and counted, at a minimum, it calls for an objective, independent media investigation and for additional government scrutiny, a reinstatement of federal reporting requirements and reexamination of insurance claims after an attempted mifepristone abortion.

People should not be surprised that a drug designed to kill human beings (the child in the womb) or at least intended to interfere with the natural human reproductive process might also pose dangers to the healthy women who take it.

Clearly a number of women do have problems. And it is important that we have accurate information and numbers on the women who do.

Assertions of mifepristone safety on the basis of flawed, slanted industry studies are not good enough.

# APPENDIX A HOW THE SITUATION SETS UP REPORTING PROBLEMS

If a woman reports this back to her prescriber, the data can potentially be noted and recorded, but that will only happen if the prescriber chooses to share that data. Even absent some intent to conceal such data, whether and how this is recorded will be subject to the criteria her prescriber uses for recording or classifying these adverse events.

If a woman orders her abortion pills online and has them shipped to her home, it gets more complicated, depending on how much responsibility her seller is willing to take for her case. If they allow her to call back and have a nurse she can talk to or a hotline operator who will take her call, what they record, report, or recommend is up to them. As is whether they direct the woman to visit her local ER or a nearby provider and what it is they tell her to tell them.

The FDA's regulations on reporting and follow-up requirements have gotten weaker with new protocols, reducing prescriber responsibility in collecting and sharing data on adverse events.<sup>20</sup>

If she is directed to visit her local ER, or simply decides to do so on her own because she decides the prescribers is just too far away or is just someone she doesn't know well enough to trust, then whether her attempted chemical abortion is entered on her chart and her complications are attributed to mifepristone depends on how much she tells the physician and how much they choose to put in the record.

In all these cases, how much is recorded and reported depends on how much the woman reveals and how much the health care provider treating her complication puts in the record.

Agreement, these are not present in the 2023 version.

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<sup>&</sup>lt;sup>20</sup> For reference, compare what FDA REMS (Risk Evaluation and Mitigation Strategy) guidelines for Mifepristone for 2011 (<a href="www.fda.gov/media/164648/download?attachment">www.fda.gov/media/164648/download?attachment</a>) ask prescribers to report with what the FDA asks of prescribers for 2023 (<a href="www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_03\_23\_REMS\_Full.pdf">www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_03\_23\_REMS\_Full.pdf</a>). While "any hospitalization, transfusion or other serious event" is to be reported in the 2011 REMS, prescribers are only required to report deaths after 2016. And though there are explicit follow-up directions in the 2011 Prescriber">www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifepristone\_2023\_03\_23\_REMS\_Full.pdf</a>).

### APPENDIX B INFLATED USAGE CLAIMS

One more thing to consider. One is wary of making too much of it, but one reason why we haven't heard from large numbers of women is that use of these pills may not be as widespread as promoters and sellers of mifepristone say. In other words, though the percentages may be right and the risk of complications may be real, with a smaller pool, the actual numbers won't be as high.

#### How chemical abortions are counted

In estimating uses of the abortion pill, particularly in states where their use is not allowed or limited, activists have relied on the reports of groups like Aid Access, the Massachusetts Medication Abortion Access Project etc. offering mifepristone online or by telehealth.<sup>21</sup>

Even putting aside any motivation to inflate sales or exaggerate the group's effectiveness, one commits a fundamental mistake when automatically conflating orders and uses.

#### $Orders \neq Uses$

Women may order pills and not use them, saving them for possible use in the future – something these groups have specifically advised.<sup>22</sup> How were abortion pills counted that various states stockpiled in anticipation of court rulings they thought might cut off access?<sup>23</sup>

Other women may order the pills and then change their minds and decide not to go through with the abortion.

We already know from the FDA that the pills may not work for 2-7% of women who take them, even for those who take them as directed (failure rates increase with gestational age; prescribers and promoters of the pills often ignore those limits in their determination to make a sale).

#### Fewer Cases ≠ Less Risk, Less Danger

None of this minimizes the difficulty and the trauma of those who do take the pills and suffer from their ill effects. But it does mean that even with the same level of risk, the raw numbers will be correspondingly lower.

Though fewer actual sufferers would be a good thing, there is little comfort in this mathematical reprieve, since many more would suffer if and when use rose from women given a false sense of safety and security from suppressed reports.

<sup>&</sup>lt;sup>21</sup> See, for example, the Society of Family Planning's "We Count" report of October 22, 2024, covering April 2022 to June 2024, which estimated an average of over 19,000 telehealth abortions a month between April and June of 2024 and reported high numbers of these in states like Alabama. Arkansas, Kentucky, Louisiana and others where these abortions were not legal. For an early assertion of heavy sales in pro-life states like Texas, see Abigail Aiken, Jennifer Starling, Rebecca Gomperts in "Factors Associated with Use of an Online Telemedicine Service to Access Self-managed Medical Abortion in the US," JAMA Network Open, Vol 4, No. 5, (published online May 21, 2021).

<sup>&</sup>lt;sup>22</sup> Note comments to that effect by Rebecca Gomperts, founder of Aid Access, in Patrick Adams' opinion piece, "What if You Had Abortion Pills in Your Medicine Cabinet?" New York Times, October 13, 2021.

<sup>&</sup>lt;sup>23</sup> Alice Park, "Democratic States are Stockpiling Abortion Pills to Preserve Access," TIME, April 18, 2023.

But as far as the current situation goes, one reason we may not have heard of more cases of serious adverse events may be that use is not as high as advocates would have us believe.