



Addressing Many of the Myths
the Media is Repeating
about the FDA's Approval
and Management of

Mifeprex

(mifepristone)

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Addressing Many of the Myths the Media is Repeating about the FDA’s Approval and Management of Mifeprex (Mifepristone)

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By the time you read this article, Matthew Kacsmaryk, a judge from the United States District Court for the Northern District of Texas may have already ruled on a suit brought by the Alliance for Hippocratic Medicine and other pro-life groups challenging the 2000 approval of Mifeprex (mifepristone*), the abortion pill, by the U.S. Food and Drug Administration (FDA).

And whatever way he rules, you will see the press talk about how unwarranted the lawsuit was, that there was nothing at all wrong with the FDA’s original approval, that the drug has been looked at again and again and has proven absolutely safe and effective in more than twenty years of use.

But what are the merits of the case? What are the real issues involved? Many people are hearing about this story for the first time, suddenly recognizing that the Supreme Court’s *Dobbs* decision overturning *Roe* means that states now possess the legal capacity to outlaw these baby killing drugs. They know little or nothing about these pills except that they’re supposed to be a quick, safe, and simple way to have an abortion.

They aren’t, of course. The abortions brought on by these pills are messy, painful, bloody, and dangerous. They have taken the lives of millions of innocent unborn children and put the lives and health of so many of their mothers at risk. Rather than admit and respond to these risks, abortion pill advocates have pushed the FDA to dial back safety restrictions imposed on mifepristone so that they can increase the number of prescribers and expand the market.

Given the many voices, interests, and claims of expertise, separating the truth from the myth here can be difficult, even for a journalist. In the interest of bringing some clarity to the issue, National Right to Life offers this assessment of some of the more common claims being made about the abortion pill mifepristone and how the FDA has handled its approval and modifications made to mifepristone’s protocol.

*Throughout this paper, when we talk about the “abortion pill,” we will be talking about Mifeprex (mifepristone), the drug the FDA actually approved for abortion in September of 2000. But the abortion pill regimen, as approved, actually involves at least two drugs – mifepristone, which blocks the action of the pregnancy hormone progesterone responsible for managing and maintaining life support for the early human embryo, and misoprostol, a prostaglandin taken a day or so later, which stimulates powerful uterine contractions to expel the dead or dying baby. Unless we are specifically speaking about just the first drug, assume we are talking about the mifepristone-misoprostol combination when we say “abortion pill.”

In the next few pages, we'll be addressing the following popular mistakes and misunderstandings about the process:

MYTH 1: Mifeprex (mifepristone) is the kind of ordinary drug that the FDA considers every day to improve Americans' health.

MYTH 2: The FDA are experts at drug evaluation and applied the same rigorous assessment standards to Mifeprex (mifepristone) that it uses for all other drugs.

MYTH 3: After going through the same rigorous testing and evaluative processes the agency requires of all other drugs, the FDA gave Mifeprex (mifepristone) its full and unqualified approval.

MYTH 4: Approval and modifications to the abortion pill protocol were supported by the best, most objective scientific studies.

MYTH 5: Mifeprex (mifepristone) has an excellent safety record.

MYTH 6: If the FDA approval for Mifeprex is disallowed, the availability and use of mifepristone and misoprostol for therapeutic purposes may be negatively affected.

MYTH 7: Pro-Lifers are challenging the FDA's legitimate authority and expertise.

In the end, it should become clear that the FDA's approval of mifepristone was no ordinary approval for any ordinary drug, and that while the abortion industry has been successful at convincing the FDA to reduce restrictions on the distribution and prescription of the drug, it has done little to mitigate the risks and dangers associated with it.

Mifepristone was and is a drug that kills unborn children, risks the lives and health of their mothers, and never should have been approved by the FDA.

MYTH 1: Mifeprex (mifepristone) is the kind of ordinary drug that the FDA considers every day to improve Americans' health.

Reality: *Unlike other drugs the FDA considers to enhance or improve public health, mifepristone was a drug designed and developed to take human lives, which is something in which a public health agency should not be involved.*

The FDA has, as a matter of principle, refused to regulate drugs used by states in lethal injections, determining that the safety or efficacy of those kind of drugs is beyond its purview. It should have applied that same logic to mifepristone and refused to consider an application of the abortion pill.

The FDA should never have asked for or taken an application for such a drug, no matter the political pressure, because it is fundamentally inconsistent with the agency's purpose and mission.

The FDA's own mission statement begins by saying that "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices..."

The FDA's commitment to public health, to ensuring the safety, efficacy, and security of drugs used by the American public clearly means a commitment to the authorization of drugs that cure, that heal, that treat various ailments, illnesses, or conditions, not to those which take human life or put it at unnecessary risk.

Unless pregnancy is redefined as a disease and the health and well-being of the unborn child is somehow determined not to be a part of public health, the FDA has no business considering, much less approving, a drug explicitly developed, intended, or sold for the killing of innocent human beings.

Pregnancy is NOT a disease, but is, in the vast majority of cases, a natural, normal, perfectly healthy condition experienced by millions of women each year. It is not an ailment or condition for which medical science seeks a cure.

If this had been one of those rare instances like ectopic pregnancy where a continued pregnancy posed a risk to the life or health of the mother, the FDA could have considered mifepristone for this application, weighing the benefits versus the risks of this treatment against alternatives, but this was not the purpose for which the sponsor sought approval (and mifepristone does not work in circumstances of ectopic pregnancy anyway).

No, the only purpose for which the sponsor sought FDA's approval was for the purpose of aborting the healthy children of healthy mothers who were in the first trimesters of healthy pregnancies.

One must also ask how the termination of human life is consistent with the FDA's commitment to "public health." Either "public health" includes the human child carried in the mother's womb

or it doesn't. One can't have it both ways. It doesn't make sense for the FDA to consider or approve drugs and treatments for continuation of pregnancy and the preservation of an unborn child's life on the one hand, while at the same time authorizing drugs that would result in the death of a child of the same age and health on the other.

The value of human life, the child's status as a patient, the agency's commitment to their "public health," cannot rest simply on whether the child is wanted or not.

The only way that the FDA could justify considering, much less approving, an application for a drug developed for killing human children was ignoring its own mandate, by going against the basic principles of medicine, by ignoring the basic facts of biology, and by giving politics priority over public health.

MYTH 2: The FDA’s scientists are experts at drug evaluation and applied the same rigorous assessment standards to Mifeprex (mifepristone) that it uses for all other drugs.

Reality: *The FDA's normal evaluative process was ill-suited to assess a drug intended to kill rather than cure patients.*

If you were evaluating a drug to treat ulcers, or cancer, or even a critical hormone imbalance, evidence that it triggers considerable pain, copious bleeding, or that for pregnant women it usually leads to loss of the baby, would all be taken as clear signs that the drug was not safe, had compromised effectiveness, and was certainly not appropriate for market approval.

Only by flipping the approval process on its head and making the negative features the desired application rather than disqualifying side effects can any sort of evaluation proceed, even though the process is clearly tainted and contorted and quickly reveals itself as a tool ill-fitted for the task.

What do “safety” and “efficacy” mean when killing babies is the aim?

How do we “safely” kill a child? Are we saying that a drug that kills more babies is more “effective?” What sort of cost-benefit analysis is this?

As Mary Jo O’Sullivan, one of the members of the FDA’s original Reproductive Health Drugs Advisory Committee asked her fellow members, “Benefit to whom?” O’Sullivan was willing to grant “if you are talking about a woman, it may be a benefit to her, but it is certainly no benefit to her baby whatever.” (FDA Committee Transcript of Mifepristone Hearing, July 19, 1996)

That these were the wrong sort of questions was only part of the problem. How high a percentage of dead babies do you have to have to call an abortion pill “effective?” 77%? 83%? 92%? How do you decide that pills which work by inducing horrible bleeding and cramping are “safe?” Is it enough that a woman survives the ordeal?

It is one thing if you are calculating the costs of dangerous or debilitating side effects against the possible benefit of restoring the health or functioning of an extremely sick or suffering person and another entirely if you are talking of how much risk you can impose on a healthy mother in the middle of a healthy pregnancy to force her body to abort her child.

What do you do if a few women die, if they bleed to death, if they come down with rare, deadly infections, if women and doctors miss signs of a rupturing ectopic pregnancy because they’re expecting the pain and the bleeding that accompanies every chemical abortion?

These certainly don’t appear to be the signature of a safe drug, yet the record clearly shows that these are the sort of things mifepristone patients can expect.

MYTH 3: After going through the same rigorous testing and evaluative processes the agency requires of all other drugs, the FDA gave Mifeprex (mifepristone) its full and unqualified approval.

Reality: *The FDA approved mifepristone under a special process that allowed for accelerated approval and more limited initial testing but enabled the agency to more closely monitor and control distribution in light of identified safety risks.*

Much has been made of the FDA's use of its special Subpart H designation to authorize "accelerated approval" for Mifeprex (mifepristone), a status reserved for "new drugs for serious or life-threatening illnesses." Given that normal pregnancy is neither a "serious" nor "life-threatening illness," this obviously represents a misapplication of the statute, merely reinforcing that the FDA had no business considering a drug to kill babies in the first place.

This did enable the agency to cut some corners for the FDA's consideration of the drug in terms of the number or depth of the studies required before the application was filed. But it is not clear that this ultimately gave mifepristone much of a time or procedural advantage; the drug's sponsor still had to collect and present data from U.S. trials and took at least four years to get approval when the average approval time for other drugs was a year and a half.

Perhaps more importantly, use of the Subpart H status resulted in mifepristone's approval coming with a strict set of distribution controls, many of which still exist today in some form, much to the dismay of the abortion industry.

The data presented to the FDA showed a drug whose efficacy diminished the farther along the gestation and customarily came with a lot of serious cramping, bleeding, and other significant side effects, some significant enough to put women in the hospital or even threaten their lives.

Acting upon that data, the FDA approved the drug but used its Subpart H authority to require further post-marketing data and to limit mifepristone's distribution, requiring that these pills only be distributed through "certified" prescribers. Those prescribers (originally only doctors) had to sign agreements indicating they were familiar with mifepristone's complex regimen and special risks, shared these with patients, screened patients for gestational age and ectopic pregnancy, and made sure patients knew where to find help in the event of an emergency.

This hampered rollout and still serves as a disincentive for many potential prescribers today who are not willing or are unable to comply with the certification requirements.

MYTH 4: Approval and modifications to the abortion pill protocol were supported by the best, most objective scientific studies.

Reality: *The FDA relied too heavily on flawed studies and incomplete data from partisan abortion advocates and ignored strong scientific evidence to the contrary.*

In the drug evaluation hearing and later in the published results of the U.S. trials, the abortion pill's sponsors admitted that their "success" or efficacy rates in U.S. trials lagged behind that of their European counterparts. They attributed this, in part, to abortionists' unfamiliarity with the drug and the amount of bleeding involved.

The FDA noted that efficacy dropped off with gestational age and limited use to women no more than 49 days past their last menstrual period (LMP), but in doing so accepted a 92% completion rate as sufficiently efficacious.

Of course, sponsors promised to do better with more experience and new protocols and in due course, once the drug had been on the market for a few years, the abortion industry produced new studies claiming much higher rates (98-99%). These studies were offered not just as proof of greater efficacy, but as efforts to get the FDA to loosen its protocols, alter dosages, to extend the gestational cutoff, to reduce the number of required visits, to expand the pool of prescribers.

It appears to be a tactic that worked, with the FDA announcing exactly those changes in March of 2016 and citing such studies in its 3/29/16 Clinical Review recommending those changes.

Whether it was 1) inappropriately applying safety and efficacy standards commonly used for drugs given to ill or suffering patients in need of treatment to perfectly health patients where the drugs were meant to *induce* ill effects, or whether 2) the FDA had accepted the idea that dead babies and suffering but surviving mothers were the agency's evaluative criteria, the agency, in taking these abortion industry studies at face value and making these concessions, ignored some serious methodological flaws and some serious data gaps.

Ignoring lost patients

Consider for example the study "Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days" by Mary Gatter, Kelly Cleland, and Deborah L. Nucatola, from the April 2015 issue of *Contraception*, cited more than thirty times in the FDA's 2016 official Clinical Review.

Gatter and her team studied the records from 15,980 patients who had chemical abortions at Planned Parenthood between April of 2006 and May of 2011. Among the 13,373 who completed the regimen and returned for follow-up, researchers reported an efficacy rate of 97.7% with rates of infection and transfusion at less than a tenth of a percent.

Discerning readers will note that data from 2,470 patients are missing from the analysis.

Regarding this, the FDA's Clinical Review notes the high percentage (15.5%) of patients in Gatter's study lost to follow up, says that "Follow-up after taking Mifeprex and misoprostol is

necessary,” but simply allows that this sometimes happens in studies.

While the FDA must work with the data it has, it simply cannot ignore the implications of a data gap like this, particularly given what it knows about this drug and what it should know about the abortion industry and its clients.

Some patients with problems may return to the clinic where they got their pills, but others, particularly if they are having problems, may be much more likely to visit their own doctor or the local emergency room.

If those patients are the ones having most of the complications and the failed or incomplete abortions, not only might the safety and efficacy reports from industry studies be wildly off, but ignoring this data could make an unnecessary, avoidable health crisis more likely.

This is not mere speculation. Studies that rely on emergency room data, rather than the reports of abortion advocates or clinic staff of just those women who return to the clinic or respond to clinic phone calls, obtain much different safety and efficacy data.

Complications show up in the emergency room

A 2015 study of emergency room visits by University of California, San Francisco researcher Ushma Upadhyay (“Incidence of emergency department visits and complications after abortion,” *Obstetrics & Gynecology* January 2015) found more than one in twenty (5.19%) chemical abortion patients reporting a complication of some sort.

(Upadhyay maintains that most of these complications were minor, but this ignores the fact that for the women involved here, they were serious enough to merit a trip to the ER).

Simply accepting and repeating official safety and efficacy figures isn’t good enough. When the British government was reporting just one single complication among 23,061 chemical abortions performed between April and June of 2020 (*The New Statesman*, 12/15/20), a former executive and public health researcher with family planning giant Marie Stopes International did his own direct survey of the National Health Service’s Trusts (which manage the country’s acute hospital services and emergency care) and obtained much different results.

Kevin Duffy of Percuity found that 5.9% of chemical abortion patients were treated during that time for complications connected to incomplete abortions or “retained products of conception.” Three percent of women there required surgery to deal with incomplete abortions and 2.3% of these patients were treated in Trust hospitals for hemorrhage (Percuity, 10/27/21, at <https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf>).

Where the government identified just one patient reporting a complication, Kevin Duffy of Percuity found more than a thousand by contacting the hospitals directly.

Relying on studies performed under other conditions

The FDA’s most recent changes to the protocol were justified, at least in part, by appeals to studies that did not really establish the safety of those changes.

For example, the most recent FDA “Summary Review” looking at revisions to protocol spelled out in the agency’s special Risk Evaluation and Mitigation Strategies (REMS) for mifepristone (FDA 1/3/23, at www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf) appeals to a study by long time abortion activist Daniel Grossman and several colleagues “Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment” that appeared in the March 2022 issue of *Contraception*.

Offered in support of a change that involved dropping requirement that the patient visit the prescriber in person to pick up their pills, the study actually did little to establish that this visit was medically unnecessary, since all patients involved in the study were still screened in person and gestational ages were still determined by an in-person ultrasound or a physical examination.

The only difference was that they were able to pick up their pills at the pharmacy rather than the prescriber’s office.

While this might theoretically show, at most, that pills picked up at the pharmacy worked as well as those picked up at the office, what it does not show is that the in-person screening for gestational age, ectopic pregnancy is unnecessary and can be done away with or that it can be done just as well by a phone call or a video interview. This is not something the study examined.

There are no grounds from the study to conclude that women who do not have in-person ultrasounds or undergo physical examinations fare as well as those who did receive such in-person screening.

The FDA’s commitment to scientific objectivity, to public health, to patient health and safety must mean something more than uncritically accepting deficient data and claims or flawed, biased studies and simply taking the word of researchers who are trying to help the industry find more prescribers and sell more product.

Ignoring inconvenient truths

Perhaps it was a matter of timing or access, but notably the FDA ignored a Canadian study of 39,856 patients that appeared in the January 3, 2023 online edition of the *Annals of Internal Medicine* by Ning Liu and Joel G. Ray, two researchers from the University of Toronto. What was interesting about this study was that it already used a system in some ways similar to that now being authorized in the U.S., allowing women to obtain their prescriptions from regular medical personnel but actually having them pick up mifepristone at pharmacies.

The results show that this is not nearly as safe or benign as the FDA and the mifepristone lobby would have us believe. Under that protocol, emergency room visits jumped to 10.3% — at least one out of every ten patients.

There is no reasonable way that a drug with this profile can be considered safe, no way that data like this could be grounds for loosening controls on distribution.

Arguments that this study came out too late for FDA consideration ring hollow. The Grossman

study mentioned above had not yet been published when the FDA used it to justify its latest REMS modifications, but the FDA had a close enough relationship with Grossman to know of and obtain a copy of his study before it actually went to press. While the FDA clearly had a close relationship with members of the American abortion establishment, they appear to have lacked any similar relationship or access with the Canadian team.

Clearly, the FDA needs to critically and objectively assess all relevant data bearing on its drug decisions rather than cherry picking only that data and those studies that support the industry's — or administration's — public policy agenda.

MYTH 5: Mifeprex (mifepristone) has an excellent safety record.

Reality: *Mifepristone has been connected to more than two dozen maternal deaths and thousands of maternal injuries and “adverse events.”*

Every “successful” chemical abortion is arduous, painful, bloody, and messy and results in the death of at least one innocent child. Millions of babies have died. Thousands of women have been injured. This is hardly the profile of a “safe” drug.

It must be remembered that this drug works by turning a healthy pregnant woman’s body against its natural course and against the mother’s own child. Mifepristone blocks the signal of the pregnancy hormone progesterone, causing the body to have to suddenly “switch gears” and initiate a menstrual cycle while the young child is settling and beginning his or her growth spurt in the protective, nourishing environment in the womb.

Mifepristone effectively cuts off that supply of nourishment to the womb, essentially starving or suffocating the child to death.

Misoprostol, the prostaglandin, which is the second drug used in the process, comes along a day or so later to stimulate powerful uterine contractions to dislodge and expel the child.

This triggers a round of painful cramps and bleeding with the mother. Some abortion advocates liken this to a standard heavy period, but women who’ve gone through it say that it is much worse.

Pain can be severe and last for hours. Prescription pain killers may prove inadequate. Cramps can be almost violent, culminating in episodes of nausea, vomiting, and diarrhea. Again, these are consequences faced by healthy women taking this “safe” drug.

Women bleed more from chemical abortions than they do from surgical ones. Bleeding can be heavy and may go on for days, even weeks. Women may pass enormous clots. Recall that women are not merely passing what might be thought of as the normal menstrual load of shedding uterus, but the child and all the tissue connected to the pregnancy.

Complications are common

The bleeding normally tapers off, but not always. A certain number of women hemorrhage and require some sort of surgical or medical intervention. Add to that the women who go on to have surgical abortions after their chemical abortions fail.

Extended bleeding in a closed place offers a perfect environment for a deadly anaerobic bacterium like *Clostridium sordellii*. The bacterium is common but infections are rare, but there was a sudden surge in cases once abortion with mifepristone began to be done, particularly among those who followed the advice of the sort of abortion “experts” the FDA consults regularly and self-administered the misoprostol vaginally.

About 1-2% of pregnancies are ectopic, that is, they implant somewhere outside the uterus. They can prove fatal to both mother and child if they go undetected and rupture. Mifepristone does not treat these pregnancies. But if a woman with an ectopic pregnancy takes mifepristone and starts to cramp and bleed – normal signs of an ectopic pregnancy and the need for immediate medical intervention – both patients and doctors may not recognize the emergency until too late.

Problems, failures, adverse events tend to increase the farther along the pregnancy, which is why the FDA has always had a cut-off date and tried to ensure that prescribers could accurately determine gestational age and screen for ectopic pregnancies.

Even with those precautions, a number of mifepristone patients died.

The FDA's most recent post-marketing report says its records show 28 deaths among U.S. mifepristone patients, 97 ectopic pregnancies, and more than two thousand women dealing with "adverse events" including infections, hemorrhage, transfusions, or hospitalizations for some related effects.* An additional 13 deaths were reported from other countries (FDA, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022").

Abortion pill advocates argue that the FDA never claims that mifepristone caused these deaths and says that this report includes deaths from unrelated causes, such as homicide, suicide, or drug overdose, but this ignores the cases where use of abortion pills were clearly connected, such as deaths from hemorrhage, infection, and the rupture of ectopic pregnancies.

Claims that the pills were not directly, causally responsible for the infections, the ectopic pregnancies, or any of the other precipitating events neglects how the chemical abortion process exposed them to such dangers by creating the conditions where the bacteria might be introduced and thrive, or by masking or mimicking the symptoms of an ectopic pregnancy that would have, under normal circumstances, likely been noted and addressed.

Many problems never reported

The truth is that these reports only represent the tip of the iceberg. These are only the cases which have been reported back to the FDA. There is reason to think that there are many, many more which the FDA never hears about.

Early on, when a woman had a problem and contacted the office of the prescriber who gave her the abortion pills, that prescriber was supposed to not only address her problem but record her complication and pass it along on to the sponsor (the distributor) who was to send this information to the FDA. In 2016, though, upon determining that it had a sufficient record to build an adequate "safety profile" of the drug, the FDA decided to drop the requirement that all serious adverse events be reported back to the agency, though it still asked that any patient deaths be reported.

There was record of a substantial number of deaths and injuries at that point, but still reason to

* The report shows numbers of adverse events of which the agency has record may be closer to four thousand, since the FDA changed its recording system in 2012. The FDA received 2,740 reports of adverse events between 9/28/00 and 10/31/12 under one counting system and then 1,473 cases from 11/1/12 to 6/30/22 under another.

believe that many were being missed.

As we have already pointed out in earlier sections, women experiencing problems with their chemical abortions often go to the emergency room or their own personal doctor rather than returning to the clinic or calling the prescriber who they may have met only once (if at all) and who may have counseled them to go elsewhere in the event of emergency.

If they do not return the clinic's phone calls or answer the abortion pill provider's emails, the prescriber will likely have no record of the woman's crisis.

This is only compounded by the fact that many prescribers have explicitly advised women not to reveal to medical personnel in the emergency room that they have taken the abortion pill, but merely to say that they are suffering from a miscarriage. In these instances, a woman's case would probably never be connected to the abortion pill, and she would probably end up counted as one more safe use of mifepristone.

The FDA used to direct women to take their medication guides with them to the emergency room and tell medical personnel there that they had taken the abortion pill, but the agency decided in its most recent guidance to drop that instruction from its latest REMS and Patient Guides, allowing more and more of these cases to escape being attributed to the mifepristone/misoprostol combination.

The record still shows significant risk

Nevertheless, what we do have gives us a clear picture of a drug with numerous serious risks. It is difficult, painful, and bloody for nearly everyone who takes it. When it works, it takes the life of an innocent human being. It has been connected, time and again, to hemorrhages, infections, and ruptured ectopic pregnancies. Healthy women in the prime of their lives have taken this drug and died.

While the FDA appears to have dismissed these reports as significant grounds for withdrawing the agency's approval of the drug, it has taken them seriously enough to impose and maintain significant limits on this drug's distribution, such as the required certification of prescribers and pharmacies.

This is why, over objections from the administration and from the abortion industry, they have kept these regulations in force, in some form, even to the present day.

There is no way to look at this drug and its record and call it unqualifiedly "safe."

MYTH 6: If the FDA approval for Mifeprex is disallowed, the availability and use of mifepristone and misoprostol for therapeutic purposes may be negatively affected.

Reality: *A decision to nullify the FDA’s 2000 approval and/or any subsequent modifications made to regulations on the distribution of Mifeprex or its generic equivalent should have no bearing on any of the therapeutic, non-abortifacient uses of these drugs.*

At this point, the full extent of the judge’s decision and the ultimate outcome of the appeals process is unknown, but even a complete negation of the FDA’s 2000 approval of the abortion pill Mifeprex is not expected to affect the availability and use of either mifepristone or its accompanying prostaglandin misoprostol for their approved, non-abortifacient uses.

It is true that mifepristone was originally developed and approved as an abortifacient. The sole reason that the original sponsor filed the application with the FDA and sought and obtained the agency’s approval was for use as an abortifacient, to subvert the normal pregnancy process and end the life of a developing child.

Mifepristone does this as a progesterone blocker, chemically getting in the way of the body’s normal hormonal signal that directs the woman’s body to provide nutrients and build a protective “cocoon” around the child who is safely implanted in the mother’s uterine wall.

If the FDA’s approval of Mifeprex is overturned, or if additional regulations are imposed or reimposed upon mifepristone’s use as an abortifacient, it will affect its use for this purpose and this purpose alone.

Other medical uses of mifepristone

As an antiglucocorticoid, mifepristone not only blocks progesterone, but also blocks cortisol, the body’s so-called “stress hormone.” This makes it an effective treatment for Cushing’s syndrome, where the body overproduces cortisol, affecting the body’s ability to regulate metabolism, blood sugar levels, blood pressure, fluid balance, and its response to stress. In 2012, researchers with a company called Corcept sought and received a separate FDA approval to produce mifepristone as a treatment for Cushing’s syndrome, selling the drug under the trade name Korlym.

Use as a treatment for Cushing’s syndrome should not be affected in any way by the judge’s decision. Korlym is prescribed and sold at a different price and a different dose.[†]

For a woman seeking a chemical abortion, a standard month-long prescription for Korlym would be prohibitively expensive and would entail the delivery of dozens of pills which would not be used. A prescription of a single Korlym pill would be unnecessarily expensive and would raise questions, as it would clearly not be being prescribed as a treatment for Cushing’s syndrome, the condition for which the FDA approved that drug.

[†]This involves 300 mg taken daily for Korlym versus a single dose 200 mg taken once for Mifeprex; according to drugs.com, Korlym costs upwards of \$600 a pill, so that a standard month’s supply runs more than \$18,000, while Mifeprex sells for less than \$100 a pill.

In a state where chemical abortions are not legal, this odd prescription which does not fit the drug's standard medical profile may lead to a pharmacist's refusal to fill the order and could give authorities reason to investigate physicians who write such prescriptions (the laws are typically written, however, so that the patient is not to be investigated or prosecuted for seeking or using the pills to abort her child).

Misoprostol still available to prevent ulcers

The situation is somewhat similar for misoprostol, the prostaglandin that has been used for more than twenty years in conjunction with Mifeprex (or its generic counterpart mifepristone). The protocol that the FDA approved for Mifeprex specified that misoprostol, a drug already separately approved to fight ulcers, be given a day or so after the mifepristone essentially starved or suffocated the child in order to stimulate powerful contractions to expel the child's dead or dying corpse.

Significantly, though, in authorizing misoprostol's use with mifepristone, the FDA did not alter the label for Cytotec, the brand name under which the FDA originally approved misoprostol for G.D. Searle in 1988. Searle developed and submitted Cytotec to the FDA as an anti-ulcer medication for people who have to take a lot of NSAIDs (non-steroidal anti-inflammatory drugs); it has never sought or endorsed the use misoprostol as an abortifacient or in use with another abortifacient like mifepristone.

It is still prescribed and used as an anti-ulcer medication today.

However, because of its chemical properties and because it can initiate powerful uterine contractions and expulsion of the child from the uterus on its own, it has in recent years often been used as an abortifacient in its own right, particularly in countries where abortion or other chemical abortifacients are not legal, or in places where chemical abortifacients like mifepristone are either considerably more expensive or harder to find.

It is generally not considered the preferred method because it is not as effective as an abortifacient as the mifepristone-misoprostol combination and can come with more unpleasant side effects (N.T. Ngoc, *Contraception*, May 2011).

Again, this is not a use that the original manufacturer endorses nor is it a use recognized on the drug's official label.

As a matter of fact, the FDA has given Cytotec (misoprostol) its "Category X" designation, reserved for drugs where "Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits."

The point of all this is that misoprostol is a drug approved for a legitimate medical purpose and that the FDA has no reason to disallow that original approval or to revise its current label.

Could a rogue abortionist still prescribe misoprostol off-label as an abortifacient? Yes, but if he

or she does so in a state where chemical abortions are prohibited or unborn children are legally protected, and that intent is clear in the prescription, the pharmacy can and should refuse to fill that prescription and the prescriber could be prosecuted for violating the law.

Allowed for legitimate medical purposes

The intent of medicine—and of the health care personnel and concerned citizens raising these issues with the FDA’s approval and handling of mifepristone—is the promotion and preservation of human life and public health. Most people are convinced that this should be the FDA’s aim as well.

The use of mifepristone, misoprostol or any other drugs for the purpose of promoting, protecting, or preserving of human life and health are not a problem. Their use to take innocent human lives, and to do so with the government’s imprimatur, *is* a problem.

The answer lies not in prohibiting the use of these drugs for legitimate therapeutic purposes, but in rescinding their official approval for use as abortifacients.

This won’t solve all of the problems with the misuse of these drugs. But at least it will put the government back on the side of protecting the public health of its residents.

MYTH 7: Pro-Lifers are challenging the FDA's legitimate authority and expertise.

Reality: *Pro-Lifers are trying to restore the FDA's authority and legitimacy by getting the agency back to its mission of bringing lifesaving, not life taking, drugs to the market.*

With the FDA's dealings with mifepristone reaching back more than thirty years, we now have enough of a record to see a pattern.

A Democrat administration takes charge and, with strong backing by the abortion industry and its media allies, pushes the FDA to approve mifepristone or otherwise loosen regulations and expand its distribution.

After going through its various committees and panel reviews, giving abortion advocates an opportunity to conduct the necessary studies and present their findings, the FDA generally accedes to those requests, but usually with some sort of caveat or condition to show that they still have some reservations about the drug being widely available and used in the marketplace without any control or oversight.

The aim of abortion pill advocates is clearly to have the drug available over the counter, something women can order online and have delivered to their homes, without any sort of government or unwanted medical interference – the “no-test” self-managed abortion.*

Under enormous political pressure, the FDA has gradually moved their way, granting approval, modifying the protocol, loosening certification requirements, etc. Perhaps to its credit, the FDA seemed to do this grudgingly—requiring post-marketing studies, establishing a rigorous protocol, a strong certification process, and, at least at the beginning, heavily controlled distribution—but these rules and conditions have been watered down as the years have passed.

The FDA might argue that this has been in response to new data, to years of subsequent experience with the drug showing many of these controls unnecessary, but, as we have shown, the FDA has been far too selective in the studies they have used and not nearly critical enough with their claims and results.

Their own data from official FDA “Post Marketing Adverse Events” summaries for mifepristone show more than two dozen known deaths of American mifepristone patients (and an additional 13 reported deaths from other countries) and thousands of other complications or crises such as infections, hemorrhage, transfusions, ectopic pregnancy, etc. This is not the record of safe, effective, life-saving medication.

Clouding the issue of causality

Dutifully offering mifepristone sponsors and supporters a defense, the FDA reminds people that they are not claiming a causal relationship between these drugs and these negative sequelae, but this is disingenuous.

* Elizabeth Raymond, Daniel Grossman, Ushma Upadhyay, Mitchell Creinin, et al., “Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond,” *Contraception*, June, 2020.

No one believes that the young women who died of deadly clostridial infections contracted the bacteria from the pills; women likely introduced this common bacterium into their bodies by vaginally self-administering misoprostol into their reproductive tract, where the anaerobic bacteria thrived in the blood rich environment of a bleeding, aborting uterus.

No one is saying that mifepristone causes ectopic pregnancy, but the expectation of significant bleeding and cramping that accompanies the standard chemical abortion has caused both patients and doctors to miss signs of a rupturing ectopic pregnancy, which can prove deadly if unrecognized and untreated.

It is much more difficult to say that there is no connection between mifepristone and misoprostol and bleeding. These drugs work by initiating bleeding and cramping, chemically triggering the menstruation process as if there were not a baby present. The amount of pain and bleeding may vary from woman to woman, but more may be expected the farther a woman is along, which is why determination of gestational age is such an important part of screening.

If the FDA allows prescribers and patients to forego the sort of in-person counseling and screening that ensures a woman knows how to properly administer these drugs and detects conditions and gestations where the drugs will not be effective, more of these “adverse events” are to be expected, regardless of the “causal” analysis.

Giving the abortion industry more control over the distribution of mifepristone is not a good thing. In advocating the “no-test” self-managed protocol, industry leaders have made clear their willingness to accept or at least tolerate a lot of women misestimating their child’s gestational age, a great number of missed ectopic pregnancies, and the possibility that a woman might unintentionally pronounce a death sentence on the children of any future pregnancies by failing to be tested and treated for Rh factor.

The FDA needs to recommit itself to the health and safety of Americans

Even if the agency won’t reconsider its approval of mifepristone on the grounds of what it does to the unborn child, the FDA still has got to have and enforce higher safety standards than that for the sake of their mothers.

It is clear that public health matters to the FDA and that they jealously guard their institutional integrity. But mifepristone and its politically powerful promoters have forced the FDA into areas and issues the agency is not designed to handle and ill equipped to navigate or manage.

Until this approval is rescinded, and the agency gets out of the business of killing patients, the FDA will continue to flounder and compromise its mission and authority.