

#### Q & A: Mail-Order Abortion Pills

#### Q: Doesn't this amount to a national abortion ban, which conservatives say they don't support?

A: No. This case is about the FDA's reckless decision to remove important safety standards for dangerous abortion drugs and allow for mail-order abortion drugs. The FDA put politics before safety and gambled with countless lives. **A majority of Americans oppose sending abortion drugs through the mail** without seeing a doctor in person because they understand it is not safe.

Q: Vice President Kamala Harris <u>called this case</u> "an attack on the very foundation of our public health system." The New England Journal of Medicine says it could "chill pharmaceutical research by creating uncertainty about the meaning of FDA approval." Is that something you're worried about?

A: The FDA should not be taking shortcuts to appease the abortion lobby. The law mandates the FDA protect the safety of Americans, not approve dangerous mail-order drugs in a politicized process. What we need is for the FDA to stop sidestepping safety and ignoring its own rules. The FDA's commitment should be to the American people.

#### Q. It took years for mifepristone to be approved for telehealth. Why do you say it was rushed?

A: First of all, we're talking about the federal government. The length of time indicates nothing about the quality of the work. We know that during that time the FDA was not following the data; instead they deliberately decided not to collect data on any serious complications other than death. This is politics at its worst.

When we hear the word "telehealth," it's crucial to understand the majority of websites selling abortion drugs don't involve any personal interaction with a doctor. Anyone can <u>fill out a form and get the drugs sent to them</u>. They're not screening for domestic abuse or trafficking, or for dangerous conditions like ectopic pregnancies (for which half of women have no risk factors).

### Q: The FDA has already determined mifepristone is safe for telehealth – a court ordering them to roll back that decision would be unprecedented. How does that not have a domino effect on the entire system?

Every year dozens of FDA-approved products have some kind of status change – just search "FDA drug recalls." The idea that agency decisions are set in stone and no one can ever question them is not just inaccurate but undemocratic, and in the case of mail-order abortion drugs it's downright dangerous.

Both sides of the aisle have challenged FDA decisions. It was a Massachusetts Democrat governor who sued to block Zohydro (an opioid) in Massachusetts due to concerns about abuse. The FDA left it on the market for almost a decade before it was finally pulled for being unsafe.

Not many drug companies only sell one product that ends a human life by design. But the drug manufacturer for mifepristone – that's all they do, one drug. Do you really think a company that banks all its revenue on one drug will regulate itself? No! They're too busy protecting their profits from their one money maker.

## Q: You said the abortion issue shouldn't be decided by unelected judges, yet now the Supreme Court is back in the middle. Isn't that hypocritical?

A: The FDA is an unelected bureaucracy. Where else would the checks and balances be when they ignore the lawmaking branch? It's appropriate for the courts to remind them that they're required to follow existing laws. What's hypocritical is pro-abortion Democrats continually using the courts to impose partisan policy agendas and fight tooth and nail against the will of the people who want commonsense protections for women and babies.

The <u>majority of Americans</u> don't trust the FDA or believe their claims that mail-order abortion drugs are safe. Accountability has to be the first step toward repairing the damage to the public's trust.

Q: New data from the Association of American Medical Colleges <u>says</u> applications for OB-GYN residencies are down more than 10% in states with [pro-life laws] since *Dobbs*. Won't this worsen a shortage of doctors?

A: Most doctors want to help their patients heal and live healthy lives, not end their lives. Around 90% of OB-GYNs don't perform elective abortions. For them nothing changes about the way they practice, except that we hope fewer women will suffer emergencies from complications of abortion drugs, like bleeding, infection and the need for surgery.

What would help recruit new students is <u>not kicking OB-GYNs who represent the majority out of major</u> <u>educational conferences</u>. We need more inclusion – prospective medical students deserve to hear their fact- and science-based perspective.

Q: The New York Times reviewed more than 100 studies that say mifepristone is safe. Why do you say it's not?

A: Let's see them. The New York Times hasn't been transparent. They didn't publish the list and haven't provided it to independent researchers even after repeated request. If they stand behind their journalism, then release the study names.

The little information they did publish shows a heavy pro-abortion bias. Most of their "experts" have financial ties to abortion drug manufacturers and some are abortionists themselves. They even went to Planned Parenthood to double check their work. In contrast, a <u>major U.S. study</u> of over 400,000 confirmed abortions used 17 years of paid Medicaid claims records – not voluntary surveys cherry-picked by the abortion industry – and found the rate of abortion drug related ER visits spiked 500%. Analysis shows that when women show up in ERs after taking abortion drugs, their complications are miscoded as a miscarriage over 60% of the time, and this puts them at twice the risk of being admitted for surgery.

Q: In 2021 the Supreme Court ruled that a district court did not have "a sufficient basis . . . to compel the FDA to alter the regimen for medical abortion." Chief Justice Roberts wrote, "Here as in related contexts concerning government responses to the pandemic, my view is that courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" Why is this case any different?

A: That quote is out of context. The district court judge was trying to grant policy changes that the abortion lobby demanded, based on an alleged "right" to abortion on demand that seven men in black robes suddenly discovered hiding out in the Constitution after 200 years. Speaking of hypocrisy, abortion activists would have been happy with that outcome had Chief Justice Roberts not pushed back. In fact, the Supreme Court concluded that in-person doctor supervision for abortion drugs should stay in place.

The Court in 2021 (ACOG v. FDA) was not asked to weigh in on whether the FDA broke the law when it ignored the data and rolled back critical safety standards that were included in early studies. It's clear the FDA broke the rules and that's what the courts are being asked to weigh in on now.

Q: Mifepristone has been used off-label for miscarriage management for years. Medical groups <u>say</u> it's the most effective regimen. If the Supreme Court restricts mifepristone, won't it be harder for women to get the care they need?

A: Abortion advocates are exaggerating. Around 90% of OB-GYNs don't perform elective abortions yet they are still able to care for women experiencing a miscarriage. Mifepristone is rarely used for miscarriage management because it requires a special certification that most OB-GYNs don't have. All OB-GYNs have several effective options available for miscarriage management that don't depend on the availability of this one abortion drug – which carries a "Black Box" warning, the strongest possible safety warning. The bottom line is, women will still receive appropriate and safe miscarriage care without dangerous abortion drugs being shipped in the mail.

It took pro-abortion groups like ACOG <u>four months after Dobbs</u> to petition the FDA to change the label and add miscarriage management. Ask them what took them so long.

### Q: Experts say "medical abortion" is safe and blocking it will cause a catastrophic burden on women's access to health care. Why do you say it's dangerous?

<u>Major international studies</u> show that abortion drugs pose four times the risks of surgical abortion. As many as one in five women will suffer a complication. Furthermore, this case does not have any impact on the legality of surgical abortion or even whether abortion drugs stay on the market – only whether they can be purchased and sent over the mail without any of the safeguards that existed up until the Obama years.

Federal Medicaid data show that the rate of abortion-drug-related ER visits has gone up more than 500% since mifepristone was approved.

Compared to surgical abortions, the science <u>shows</u> abortion drugs put women at <u>over 50% greater risk</u> of an ER visit for complications within 30 days, affecting one in 20 women.

Three to seven out of every hundred women who take abortion drugs early in pregnancy will need surgery to finish the abortion. As many as 15% will experience hemorrhage, and 2% will have an infection.

#### Q: Why would we let a 150-year-old anti-vice law dictate modern medicine?

A: You're referring to the "Comstock Laws" (18 USC 1461-2), which make it illegal to send abortion drugs in the mail. It's worth noting that longstanding federal law was updated under President Clinton, in the 1994 Crime Bill and the 1996 Telecommunications Act. So even while Clinton made it a priority to bring abortion drugs to market, Congress was passing and Clinton was signing laws that had the effect of strengthening federal safeguards against abortion-by-mail.

The FDA ignoring federal law is yet another example of the agency putting politics over people. The law aligns with the majority (63%) of Americans who oppose mail-order abortion drugs. It's clearly in the public interest. Like the plaintiffs, we're not aware of any case that says the FDA can just pick and choose which federal laws it doesn't want to follow.

# Q: <u>22 attorneys general</u> say that restricting abortion drugs will lead to an "unprecedented spike" in maternal mortality. A total ban on abortion could ultimately lead to a 21% increase in pregnancy-related deaths or an additional 140 deaths a year – your response?

A: This case has no impact on the availability of surgical abortion for those seeking one, or even whether mifepristone remains available (it will). This case is about the FDA breaking the law and its own rules by taking a drug four times as risky as surgical abortion nd sending it to women and girls through the mail without their even seeing a doctor in person.

The FDA should do its job to protect women and girls from life-threatening complications. They need to stop ignoring science and be held accountable. Moreover, it's offensive to suggest the solution to maternal mortality is to tell women not to have babies.

#### Q: Is banning birth control next?

A: This case is about the dangerous, controversial and politicized approval of mail-order abortion drugs. In every instance abortion is aimed at ending the life of a baby in the womb. Birth control is approved to prevent, not end, pregnancy. There is no law anywhere in the U.S. that bans birth control.

#### **Q:** Is the Morning After Pill next?

A: This case is not about the morning-after pill, which is a form of emergency contraception. It is about dangerous abortion drugs being mail-ordered to women and young teens, with no in-person doctor visit, no comprehensive collection of complications and – at least until now – no accountability for the FDA.

#### Q: What about other drugs like...(PrEP, Viagra, STD treatments, vaccines, Gardasil, etc.)?

A: Again, this case is about a mail-order abortion drug that is designed to end a human life on purpose. Abortion drugs are never safe for unborn babies, and the data show they're four times as dangerous for women as surgical abortion.

That said, it's true the FDA hasn't always followed science or its own rules. Here are some examples of why we shouldn't have blind trust:

- Look at Vioxx, which was taken off the market after 20 million Americans had used it and many died.
- Look at the historic settlements over opioids and the Biden administration <u>bringing back in-person doctor</u> visits for certain medications.
- One controversial opioid known as Zohydro ER (hydrocodone) was <u>pulled from the market</u> almost a decade after it was first approved.
- Last September, an FDA advisory panel conceded that a decongestant used for decades in over 200 over-thecounter cold medicines <u>doesn't work</u> which is something most people who had ever tried it already knew.
- And just recently, the maker of a pricey new Alzheimer's drug <u>halted all sales and studies</u> after the FDA had already rushed to fast-track its approval. An independent committee had voted against approval based on a lack of evidence that it worked, and the FDA official responsible <u>resigned</u>.

It's disturbing that the FDA has escaped accountability for rolling back safeguards on abortion drugs for so many years. Necessary corrections won't cause the system to collapse, not when the alternative is taking unsafe drugs. No American should have to worry that the FDA is breaking its rules and putting politics over patients. Their job is to keep Americans safe, not to be pals with the pharma companies.

#### Q: This drug has been on the market over two decades, how can you say it's not safe?

A: If the FDA had done its job properly, we wouldn't be having this discussion today. Instead, they put politics first and ignored their own rules to fast-track for approval, jeopardizing the health and safety of women and girls. Then they intentionally stopped collecting data on complications. Now they say it's perfectly safe to get these drugs via the mail without seeing a doctor, despite clear evidence. The FDA's "see no evil, hear no evil, report no data on evil" approach does not mean this drug is safe. Women have died and the rate of ER visits due to these drugs is up 500% since the drug was approved. The FDA approved sending mail-order drugs based on studies that used in-person exams, ultrasounds and labs. It's time to correct years of egregious decisions.

#### Q: Why pick this fight over mifepristone now, after 20 years?

A: Again, when government bureaucracies are involved, length of time doesn't necessarily equal quality of work. The FDA actually has been challenged about their handling of abortion drugs going all the way back to the late '90s, but they have stonewalled opposition and multiple citizen petitions for decades now while the science and data on the dangers of these drugs have piled up. Unfortunately, this is their M.O. They wield the legal system to their benefit. At times they've even have kept unsafe or ineffective drugs on the market for years after it was clear. Accountability is long overdue.

#### O: Won't women who miscarry suffer even more from having less access to medication they need?

A: This case ONLY has to do with drugs for induced abortions, not miscarriages and the FDA's decision to change the safety standards for these drugs. Doctors are still allowed to prescribe medication for another medical condition, like preventing ulcers or managing a miscarriage, and their patients aren't in trouble.

Ironically, the FDA is <u>reinstating</u> in-person visits for ADHD medications, pain medications and other drugs but not for these dangerous abortion drugs. Don't women deserve the same quality of care with a drug that can cause serious complications?

This question seems to be part of an intentional effort to conflate abortion and miscarriage. Miscarriage management happens when the unborn child dies of natural causes. Abortion drugs intentionally block the hormones needed to keep the baby alive to end his or her life and then expel him or her from the womb. Two entirely different things.

### Q: Mifepristone was the most affordable abortion method. Won't the burden fall hardest on Black women and women of color who can't afford a child? What are you going to do about that?

A: By sidestepping safety, the FDA was the one who turned a blind eye and failed communities of color. To best help vulnerable communities, we must link them with financial and physical resources. Right now, there are nearly 3,000 pregnancy centers and maternity homes across the United States that serve women and families of all races, creeds and socioeconomic backgrounds. Community-based health clinics and pregnancy centers <a href="https://doi.org/10.1001/journal.org/10.1001/jour

### Q: Won't desperate women find a way to get abortions anyway, or resort to dangerous coat-hanger methods – and be at risk of going to jail?

A: The pro-life movement <u>unequivocally rejects</u> penalizing the woman or girl who undergoes an abortion. Abortionists and abortion drug suppliers who exploit them for profit should be the ones held accountable.

Unsafe mail-order abortion drugs put women and young teens at risk. Abortion activists are playing a dangerous game with the lives of women and girls. By putting the act of abortion over the needs of the woman, they have persuaded the Biden FDA to approve dangerous mail-order abortion drugs. Based on Medicaid data, these drugs send women to the ER at alarming rates.

#### Q: Why are (white, male) politicians obsessed with controlling women's bodies?

A: The FDA's job is to protect all Americans by ensuring that our drugs and our food are safe. Their <u>mission</u> <u>statement</u> promises to help us "get accurate, science-based information" to make informed decisions about our health care. With mail-order abortion drugs, they've failed to do that and they must be held accountable.

#### Q: (General) What is your response to recent actions by Democrat and Republican state attorneys general?

A: The contrast is clear: Democrats want to mandate abortion on demand up to birth for any reason across the country, requiring fewer safety controls for mail-order abortion drugs, while Republicans stand with young women and girls advocating better health care and safety.

#### Q: So if the FDA does its job you'd be okay with safe abortions?

A: If the FDA did its job by looking at the available data, they'd see that mail-order abortion drugs are not safe.

# Q: You say mifepristone isn't safe, but don't you promote the experimental and unproven treatment known as abortion pill reversal?

A: Abortion Pill Reversal (APR) uses the natural hormone progesterone to reverse the effects of the first drug when a woman changes her mind after starting the abortion process. Progesterone has been used safely to support healthy pregnancies since the 1950s – it is commonly used today to reduce the risk of premature birth and multiple miscarriages. Pro-abortion researchers with a vested interest have tried to discredit APR, but even their biased studies <u>demonstrate that it works</u>. One doctor from the Yale School of Medicine even <u>told the New York Times</u> it "makes biological sense" and he would recommend it for his own daughter.

APR offers a second chance at choice and is credited with <u>saving at least 4,000 babies</u> in the last decade. Women deserve to know that safe, effective treatment exists that could save their child if quick action is taken.

Q: Research has found that women are 14 times more likely to die from carrying a pregnancy to term than by having an abortion. Why would you want to deny them safer options?

A: This statistic created by abortion advocates has been **thoroughly debunked** and doesn't even make logical sense. Abortion is a violent act that kills the unborn child and harms the mother. In Scandinavian countries with far more accurate and complete data on pregnancy outcomes, including abortion and childbirth, **study after study** shows that a woman is almost four times more likely to die from abortion than childbirth.

In America, medical care is so advanced that even in high-risk pregnancies, it's rare not to have a safe delivery of a healthy baby alongside a healthy mother. Meanwhile abortion on demand is so unpopular, the abortion lobby has to use fear to sell its agenda. The FDA did their bidding by rubber-stamping mail-order abortion drugs. Pregnancy isn't a disease and abortion isn't health care.

