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Fight Rages Over Chemical Abortions

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A federal judge in Texas has ruled that the U.S. Food and Drug Administration (FDA) violated its "statutory duty" when it approved the abortion pill mifepristone more than 20 years ago.

U.S. District Judge Matthew Kacsmaryk ordered a hold on mifepristone and allowed one week for the government to appeal his ruling before it goes into effect.

The FDA approved mifepristone, also known as RU-486, in the year 2000. Kacsmaryk stayed that approval. If his ruling goes into effect, it will prohibit pharmacies from selling the drug, and the ban would apply nationwide.

This would greatly reduce the number of abortions in America. More than half of all abortions in the U.S. are medication-induced, according to the pro-abortion Guttmacher Institute, and RU-486 is the most commonly used product in chemical abortions.

There is plenty of pushback against Trump-appointed Kacsmaryk. Last Tuesday, Washington Governor Jay Inslee warned that the Texas judge might jeopardize the availability of the drug. On Friday, Inslee tweeted a video message saying that Washington has already stocked up on the abortion pill to make sure it remains available.

This came as a federal judge in Washington state issued a conflicting order. U.S. District Judge Thomas O. Rice, an Obama appointee, directed the FDA not to make any changes that would restrict access to RU-486 in 17 Democratic-majority states that sued over the issue.

Connecticut is one of the states involved in that suit. Attorney General William Tong said in a statement:

> Abortion — including medication abortion — is safe and legal in Connecticut tonight, and I'm fighting with everything I've got to keep it that way, and to keep out-of-state extremists out of our private healthcare decisions. The Texas decision has zero basis in science, fact, or the law. It substitutes one reactionary judge's political determination for more than 20 years of scientific evidence and threatens access to medication abortion nationwide. This is precisely the dangerous and radical decision we feared, and why I joined with my fellow Attorneys General to launch our own defense of medication abortion in federal court in Washington state. Because we must fight fire with fire. And a decision in that case — also handed down tonight — preserves access to medication abortion in plaintiff states, including Connecticut. I will never back down, and we are going to keep taking this fight to those who attack women and patients and their fundamental rights.

Oregon, Arizona, Colorado, Delaware, Illinois, Michigan, Nevada, New Mexico, Rhode Island, Vermont,

Hawaii, Maine, Maryland, Minnesota, and Pennsylvania joined Connecticut, Washington, and the District of Columbia in that suit.

But they are not the only ones sneering at the Texas judge. After Kacsmaryk's ruling, U.S. Representative Alexandria Ocasio-Cortez (D-N.Y.) urged the Biden administration to simply ignore the decision:

Does the Biden administration agree with her? Asked about this, U.S. Health and Human Services Secretary Xavier Becerra told CNN that "everything is on the table," and confirmed that his agency is appealing the decision.

FDA's approval of the drug in 2000 was a wildly contentious issue. Opponents argued that the agency had not sufficiently monitored deaths and adverse events associated with the drug. Then U.S. Representative Mark Souder (R-Ind.) chaired a 2006 Government Reform Subcommittee on Drug Policy hearing, which he introduced by leveling this harsh criticism:

> We are here today because there is a drug on the market associated with the deaths of at least eight women, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection. There have been more than 950 adverse event cases associated with RU-486 out of only 575,000 prescriptions at most. Adverse events are typically underreported since they are offered voluntarily by consumers and healthcare professionals. So it is most likely there are many more cases that we don't even know about. It is very clear that there is a serious problem with RU-486. In failing to address this problem by disguising it, ignoring it, minimizing it, or causing confusion is a shameful failure for anyone with the ability and desire to protect women from needless harm.

The *Annals of Pharmacotherapy* also published a 2006 study entitled "Analysis of severe adverse events related to the use of mifepristone as an abortifacient." Researchers concluded that mifepristone is a dangerous drug, and that bleeding and infection are the main causes of morbidity and mortality. Additionally, adverse event reports "relied upon by the FDA to monitor mifepristone's post-marketing safety are grossly deficient due to extremely poor quality."

Another report in the same journal the previous year, "First Analysis of FDA's Mifepristone Adverse Event Reports," noted the alarming number of deaths in "otherwise healthy women" who used the drug. The authors called "for increased research into the allergic and fatal septic reactions associated with mifepristone." They also urged "that ultrasound imaging be performed before use of the drug to rule out ectopic pregnancies." (Ectopic pregnancy occurs when the fertilized egg implants outside the womb. No developing baby can survive it, but it is a life-threatening condition to the mother without proper medical care. Chemical abortion can exacerbate the threat.)

Researchers also criticized the FDA's adverse event reporting system as inadequate, and called for a fetal registry "to track birth defects in mifepristone survivors." That has never been established. On the contrary, RU-486 proponents insist on touting the drug's supposed safety record.

Classified as an abortifacient, mifepristone stimulates uterine contractions to cause complete abortion. The drug bears a black box warning — the strongest measure short of pulling a drug from the market —

because it can cause vaginal bleeding, infection, and sepsis. In other words, it is a dangerous drug.

iVoteArizona tweeted a short video produced by LiveAction describing how mifepristone works to kill the growing baby inside his mother's body:

The American Association of Pro-life Obstetricians and Gynecologists (AAPLOG) were among the plaintiffs in the Texas case. The organization posted this statement Friday on its website:

> Today's ruling in the U.S. District Court for the Northern District of Texas is a victory for all our patients. The FDA began a pattern of prioritizing the interests of the abortion industry over the health and safety of our nation's women and girls 23 years ago by illegally and recklessly approving dangerous drugs for use in chemical abortions, and then continuing to remove safeguards for women. Today's ruling places women's welfare back at the forefront of the conversation on this issue. Our patients deserve excellent healthcare and fully informed consent; this decision helps ensure they receive that.

Kacsmaryk agreed with the plaintiffs that FDA overstepped its authority when it approved mifepristone. He said that the agency employed a specialized review process intended only for drugs that treat "serious or life-threatening illnesses." The FDA argued that pregnancy can be serious and life-threatening, but the judge countered that it is a "natural process essential to perpetuating human life."

He also invoked an 1873 law known as the Comstock Act, which prohibits mailing contraceptives and instruments that can be used to procure abortion. He agreed with the plaintiffs that the law bans mailing mifepristone.

The topic arose because in late 2021, the Biden administration eased a restriction requiring women to pick up RU-486 in person at a pharmacy. That opened the door for mail-order pharmacies to disseminate the dangerous drug without assurance of a doctor's oversight.

"Today's decision out of Texas is a win for the health and safety of women and girls. The ruling reaffirms that pregnancy is not an illness and abortion is not health care. Finally the FDA is being held accountable for its egregious violation of its own rules to fast-track dangerous abortion drugs to market," said Katie Glenn, state policy director for Susan B. Anthony's Pro-Life America, in a press release issued Friday. "The abortion drug regimen rubber-stamped by the FDA has proven disastrous for women as well as unborn children, with the FDA's own data showing women have died. The Biden FDA ignored the science and approved abortion drugs for sale by mail-order, without any in-person doctor visit, which the strong majority of Americans oppose."