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Appeals Court Seems Skeptical of F.D.A.'s Steps to Ease Access to Abortion Pill

A panel of three judges heard arguments by anti-abortion groups that the federal government should withdraw approval for a widely used drug.

By Abbie VanSickle and Pam Belluck
Abbie VanSickle reported from New Orleans, and Pam Belluck from New York.

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A three-judge panel of a federal appeals court appeared skeptical of the government on Wednesday as lawyers for the Food and Drug Administration argued that a commonly used abortion pill should remain widely available.

At issue is whether to uphold a preliminary ruling from a federal judge in Texas, who declared in April that the F.D.A.'s 23-year-old approval of the pill, mifepristone, was invalid.

From the outset of the two-hour hearing in New Orleans, questions and comments from the three judges on the U.S. Court of Appeals for the Fifth Circuit reflected criticism of the F.D.A. and a lack of familiarity with medication abortion.

Although the case is still in its early stages and any decision is likely to be appealed, it could ultimately have profound implications.

If the initial judge's ruling is upheld, access to medication abortion would be upended in states where abortion is legal, not just in states where bans and restrictions are in force. The F.D.A.'s regulatory authority over other drugs could be challenged with other lawsuits, and pharmaceutical companies say that uncertainty about the F.D.A.'s role could chill drug development in the United States.

The arguments included whether the parties who brought the suit — a coalition of organizations and doctors who oppose abortion and do not prescribe the pill — could show they would suffer real harm if the medication continued to be available and whether they waited too long to challenge the approval of mifepristone, the first pill in a two-drug regimen.

The plaintiffs claim that mifepristone is unsafe and that the F.D.A. did not follow proper regulatory protocols in approving it in 2000 — contentions that the government strongly disputes, citing years of research and other support for the agency's actions.

The panel, composed of two appointees by President Donald J. Trump, Judges James C. Ho and Cory T. Wilson, and a George W. Bush appointee, Judge Jennifer Walker Elrod, did not issue a decision at the hearing on Wednesday. That will come later, though there is no deadline for the court to decide. Any decision is likely to be appealed, first to the full appellate court and then to the Supreme Court.

In a preliminary ruling in April, Judge Matthew J. Kacsmaryk of the Northern District of Texas, a Trump appointee who is a longtime opponent of abortion, suspended the F.D.A.'s approval of the drug.

Less than a minute into the presentation by a lawyer for the F.D.A., Sarah Harrington of the Justice Department, Judge Ho interrupted to criticize her description of the case as "an unprecedented and unjustified attack on F.D.A. scientific expertise."

"I hate to cut you off so early, but you've said unprecedented," he said. "We had a challenge to the F.D.A. just yesterday."

Ms. Harrington replied, "I don't think there's ever been any court that has vacated F.D.A.'s determination that a drug is safe to be on the market." She added, "F.D.A. can make that determination based on exercising its own scientific expertise, but it's not a court's role to come in and second-guess that expertise, and no court has ever done that."

Judge Ho replied, "I'm just wondering, why not just focus on the facts of this case rather than have this sort of F.D.A.-can-do-no-wrong theme?"

Later, Judge Ho rattled off descriptions of drugs that the F.D.A. had withdrawn from the market over the years because they were unsafe.

Central to the arguments on Wednesday was whether the plaintiffs — four anti-abortion doctors and an umbrella group called the Alliance for Hippocratic Medicine — can show they would suffer actual injuries if access and approval of the pill remains unchanged. Lawyers call this requirement standing.

In the hearing, both Ms. Harrington and a lawyer for a manufacturer of mifepristone, Danco Laboratories, said that the doctors who are plaintiffs cited no examples of cases where they were compelled to provide treatment for patients who experienced complications from medication abortion.

"They've never alleged that any identified plaintiff has been required to perform an abortion against their religious or conscience beliefs," Ms. Harrington said. She said that even if anti-abortion doctors encountered a patient with a complication from mifepristone that required

intervention, they could ask a colleague to treat that patient instead since state and federal laws give health care providers "robust conscience protections and religious belief protections" under which they can decline to give treatment.

Judge Wilson asked Ms. Harrington: "You're not disputing the idea that in the future because of the F.D.A.'s actions, more women will turn up in emergency rooms needing emergency care?"

She replied: "We are absolutely disputing that many women will show up in emergency rooms or that more will show up in emergency rooms needing emergency care from taking mifepristone. All of the evidence establishes that mifepristone is an extremely safe drug."

Judge Wilson did not seem convinced. "It just strikes me," he said, "that what the F.D.A. has done in making this more available and doing it by mail order and removing the doctor visits as well as the requirement that the prescriber be a doctor is you've made it much more likely that patients are going to go to emergency care or a medical clinic where one of these doctors is a member. I don't see how you square that circle."

"I don't think any of that is right, and that hasn't been borne out by the evidence," Ms. Harrington replied.

A lawyer for the plaintiffs, Erin Hawley, claimed that ending a pregnancy with medication — she used the anti-abortion term "chemical abortion" — is extremely unsafe.

Judge Elrod noted that the appeals court had received many friend-of-the-court briefs with impassioned arguments on both sides, including some from women in sexually abusive relationships who have said "if you don't give them the pill by mail, then they will never get away because they will be trapped by the abuser."

The judge asked Ms. Hawley how the court should view such cases.

"There are other methods of obtaining abortion that are available to people in the tragic circumstances you detailed," Ms. Hawley said, adding that "this case is not about ending abortion. It's about ending a particularly dangerous type of abortion."

A lower-court order invalidating approval of the drug "would upend the status quo based on the court's deeply misguided assessment of mifepristone's safety," the F.D.A.'s brief added. Mifepristone is also used to help patients who are experiencing miscarriages, so any decision in this case could affect miscarriage treatment as well.

Also in dispute is whether the plaintiffs can even challenge the approval process for a drug that has been on the market for 23 years.

The plaintiffs' brief claimed the F.D.A. unlawfully approved mifepristone in a flawed process that "put politics above women's health" and then made "politically driven decisions to unlawfully push a dangerous regimen."

The government strongly pushed back in its brief, saying the "F.D.A.'s actions were amply supported by a record developed over decades of safe and effective use of mifepristone in the United States and around the world."

The agency also argued that the plaintiffs waited too long to bring their case.

"They did not sue until more than two decades after mifepristone's approval," the lawyers for the F.D.A. wrote.

More than a dozen medical associations filed friend-of-the-court briefs in support of the agency.

In one brief, medical associations questioned the reasoning behind a ruling by the federal judge in Texas, saying it relied on "pseudoscience and on speculation."

Judge Kacsmaryk, they wrote, ignored "decades of unambiguous analysis supporting the use of mifepristone in miscarriage and abortion care."

Judge Elrod seemed to take particular exception to the way briefs filed by the defendants strongly criticized Judge Kacsmaryk's ruling, including calling it a "relentless one-sided narrative."

Speaking to Jessica Ellsworth, the lawyer representing Danco, the judge said that is the type of language "we normally don't see from learned counsel, and I'm wondering if you would have had more time and not been in a rush and probably exhausted from this whole process, would those have been statements that would have been included in your brief?" The judge said the statements "attack the district court personally."

Ms. Ellsworth responded, "Your honor, I think those statements reflect our view that the district court was very far outside the bounds" and were not intended "as any sort of personal attack."

Judge Elrod said: "Normally, you don't say the court ruling is an unprecedented judicial assault. That's an unusual remark, don't you think?" She added, "I just wanted to give you a chance to comment on that."

Ms. Ellsworth replied, "I certainly think with more time we may have ratcheted down some of that, and I appreciate your honor's comment on that very much."

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