Fifth Circuit Court Permits Abortion Pill to Remain on the Market with Limitations



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On August 16, 2023, the Fifth Circuit Court of Appeals in New Orleans issued a ruling on the appeal of a lower court's decision regarding the validity of the U.S. Food & Drug Administration's (the FDA) approval and regulation of the prescription drug Mifepristone. In 2020, the FDA approved the use of Mifepristone in medical abortions. Since Mifepristone's approval, the FDA has relaxed regulations concerning how it may be dispensed and approved a generic version. The Justice Department appealed the United States District Court for the Northern District of Texas ruling of April 7, 2023, which issued a nationwide injunction on the FDA's approval of Mifepristone and ruled that the FDA's regulation of the drug was improper.

The Court of Appeals held that the FDA's approval of Mifepristone remains valid. The Court found that the challenge to the FDA's approval was too late as the statute of limitations had run. Therefore, Mifepristone remains as an approved FDA drug. However, the Court of Appeals did uphold parts of the District Court's ruling regarding regulating the use of the drug, specifically that it may not be prescribed via telehealth or by mail but may be prescribed after an in-person visit and within the first seven weeks of pregnancy.

The U.S. Supreme Court had previously issued an administrative stay on the District Court's decision in April of 2023, which puts a hold on any decisions made by the lower courts regarding the use of Mifepristone. Therefore, despite the Court of Appeals' ruling, until the matter is ruled on by the U.S. Supreme Court, Mifepristone will maintain its FDA approval and may be prescribed in compliance with the FDA's previously approved regulations.

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