FEDERAL COURT OF APPEALS PANEL ISSUES RULING IN LITIGATION CHALLENGING FDA APPROVAL OF MIFEPRISTONE

On August 16, 2023, a three-judge panel of the Fifth Circuit Court of Appeals issued an opinion in the ongoing litigation regarding the U.S. Food & Drug Administration ("FDA") approval and regulation of mifepristone (brand name Mifeprex), a drug used in medically induced abortions. The panel vacated in part and affirmed in part a decision by a District Court judge in Texas that would have suspended the FDA's approval of mifepristone. While the Fifth Circuit's decision will not take effect until the United States Supreme Court either rejects or takes up and decides an appeal of the District Court's decision from the FDA, the decision, if and when it goes into effect, will substantially roll back recent regulatory changes intended to enhance access to mifepristone following the Supreme Court's decision in *Dobbs v. Jackson Women's Health*. This could in turn undermine the FDA's scientific evidence-based drug approval process for existing and new prescription drugs.

BACKGROUND

In 2000, the FDA approved mifepristone for the medical termination of pregnancy subject to a number of restrictions, including, among others, that: (i) mifepristone could be used for termination of pregnancy only through seven weeks' gestation; (ii) only physicians could prescribe mifepristone; and (iii) dispensing and administration of mifepristone and of a related drug, misoprostol, and a follow-up appointment must each occur at separate, in-person doctor's-office visits. These restrictions were later included in the first Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, which was approved by the FDA in 2011.

In 2016, the FDA amended the mifepristone REMS by: (i) permitting the use of mifepristone for termination of pregnancy through ten weeks' gestation; (ii) allowing non-physician prescribers to prescribe mifepristone; and (iii) removing the requirements that misoprostol administration and the follow-up visit occur in person. In 2019, the FDA approved a generic version of mifepristone.

Most recently, in 2021, the FDA announced that it would not enforce the in-person dispensing requirement for mifepristone as a result of the COVID-19 pandemic. The FDA formalized this change with an updated mifepristone REMS in January 2023, which also expanded access to mifepristone by allowing pharmacies, including large chain and mail-order companies, to dispense mifepristone directly to patients with a prescription from a certified provider.

STATUS OF LITIGATION

In April of 2023, a Texas District Court Judge issued an order purporting to suspend the FDA's approval of mifepristone in 2000 and all regulatory changes made since that date. Later that month, the Supreme Court issued a stay on the District Court's ruling pending disposition of an appeal in the Fifth Circuit and, if an appeal to the Supreme Court were sought and granted, the disposition of that appeal.

In its recent ruling, the Fifth Circuit:

- Vacated the District Court's decision to suspend the FDA's original approval of mifepristone because it determined that the challenge filed in the District Court was not timely;
- Vacated the District Court's decision to suspend the FDA's 2019 approval of a generic version of mifepristone; and
- Affirmed the District Court's decision to reverse the amendments to the mifepristone REMS as approved by the FDA in 2016 and 2023. If enforced, this decision would once again limit the approved use of mifepristone to termination of pregnancies at or before seven weeks' gestation, prohibit administration of mifepristone by non-physicians and reinstate the requirement for three in-person doctor's office visits.

Because the FDA has signaled that it intends to challenge the Fifth Circuit's decision, enforcement of the Fifth Circuit's ruling will be stayed until the Supreme Court reviews the case during its next term, which starts in October 2023.

LOOKING AHEAD AND PRACTICAL TAKEAWAYS

For the time being, as a result of the Supreme Court's stay, mifepristone is available under the 2023 mifepristone REMS. This allows administration of mifepristone through ten weeks' gestation, does not require in-person dispensing and allows for prescription by non-

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physicians. While the current REMS allows for greater flexibility in dispensing mifepristone, both prescribers and pharmacists should be aware of applicable state laws affecting the permissibility of prescribing and dispensing the drug for both abortion care and for the common off-label use of miscarriage management.

Health care providers and pharmacies should continue to closely monitor ongoing developments, including litigation at the federal level and state law actions related to the prescribing of mifepristone, and should further review current policies and procedures related to the prescribing and dispensing of mifepristone to ensure consistency with the updated mifepristone REMS and relevant state law.

Hall Render is actively tracking the ongoing litigation and regulatory activity related to mifepristone as well as the related state law issues. If you have questions regarding mifepristone or need assistance in reviewing and updating practices related to mifepristone use, please contact:

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