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UPDATE: CURRENT STATUS OF MIFEPRISTONE

August 28, 2023

On August 16, 2023, the United States Court of Appeals for the Fifth Circuit issued an opinion in the ongoing dispute regarding the status of mifepristone prescriptions. Specifically, the Fifth Circuit VACATED in part and AFFIRMED in part the stay order from the Northern District of Texas in *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.* Pursuant to the Fifth Circuit's opinion, mifepristone, and generic mifepristone, will remain available under the safety regulations that were in place prior to 2016. However, this decision remains subject to the prior order by the United States Supreme Court should there be a petition to the highest Court within 90 days of the Fifth Circuit's August 16 decision. If the Supreme Court declines to review the matter, then the Fifth Circuit's decision will go into effect. If the Supreme Court reviews the matter, the stay will terminate upon the judgment of the Supreme Court. In sum, the Fifth Circuit's recent opinion is not yet in effect.

PROCEDURAL HISTORY

As detailed previously, this case began in November 2022 when a group of doctors and medical associations sued the Food and Drug Administration ("FDA"), the Department of Health and Human Services, and several agency heads in their official capacities, seeking to withdraw the FDA's approval of mifepristone. The case was heard by the United States District Court for the Northern District of Texas, Amarillo Division, which, on April 7, stayed the FDA's 2000 approval of mifepristone and all subsequent agency actions related to that approval, but delayed the applicability of its opinion and order for seven days to allow the federal government time to seek emergency relief from the United States Court of Appeals for the Fifth Circuit. Mem. Op & Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 2:22-CV-00223 (N.D. Tex. Apr. 7, 2023).

On April 12, the Fifth Circuit issued an unpublished order ruling that the FDA's 2000 approval of mifepristone could stand because the statute of limitations had run for the Plaintiffs to challenge that decision. However, the Fifth Circuit held the Plaintiffs could challenge FDA actions that began in 2016 to lift restrictions and make it easier for patients to obtain mifepristone. The Fifth Circuit held that its ruling would stand until the case could be heard on the merits and expedited the case to the next available oral argument calendar. Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023). Following this ruling, the Justice Department, on behalf of the FDA, sought emergency relief from the United States Supreme Court.

Danco, the manufacturer of mifepristone, also sought a stay, which was granted by the United States Supreme Court on April 21. The effect of the stay was to maintain nationwide access to mifepristone, as it was before the April 7 order, ending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari to the Supreme Court. Order, *U.S. Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, No. 22A902 (U.S. Apr. 21, 2023).

On May 17, the Fifth Circuit heard oral arguments in the case and on August 16 it issued its opinion. Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 23-10362 (5th Cir. Aug. 16, 2023).

THE FIFTH CIRCUIT DECISION

Standing

In order to bring a case, plaintiffs have to show they have standing. In other words, plaintiffs must show they suffered an injury, this injury is traceable to the defendant's actions, and this injury can be redressed by the courts. Here, the Fifth Circuit considered whether Plaintiffs had standing with respect to the FDA's 2016 Amendments (relating to the parameters for prescribing mifepristone), the FDA's 2021 Non-Enforcement Decision (regarding the FDA's decision not to enforce the requirement of in-person dispensing), and the FDA's 2019 Generic Approval (approving a generic version of mifepristone).

Regarding the FDA's 2016 Amendments and 2021 Non-Enforcement Decision, the Court found that the Plaintiff Doctors and Plaintiff Medical Organizations had standing, as the Doctors are injured when they treat mifepristone patients for four reasons: (1) they will often be required to perform or complete an abortion or otherwise participate in medical treatment that facilitates an abortion in conflict with their sincerely held religious beliefs and rights of conscience; (2) "treating mifepristone patients imposes mental and emotional strain above what is ordinarily experienced in an emergency-room setting;" (3) "providing emergency treatment forces the Doctors to divert time and resources away from their ordinary patients;" and (4) "Doctors allege that mifepristone patients involve more risk of complication than the average patient, and so expose the Doctors to heightened risk of liability and increased insurance costs." The Court reasoned that these injuries are traceable to the FDA because it approved mifepristone.

The Court found that Plaintiffs did not have standing to challenge the FDA's 2019 Generic Approval, as Plaintiffs did not provide any evidence that 2019 Generic Approval contributes to the risk of harm, such as evidence that the women the Doctors treated took the generic version of mifepristone. Thus, the Court vacated the part of the district court's order staying the effective date of the FDA's approval of generic mifepristone. Generic mifepristone will remain available under the same conditions as mifepristone (detailed below).

The Fifth Circuit did not reach the issue of standing with respect to the FDA's 2000 Approval of mifepristone finding instead that the claim was time barred.

2016 Amendments and 2021 Non-Enforcement Decision

The Fifth Circuit found that Plaintiffs were substantially likely to succeed on the merits of their claims regarding the FDA's 2016 Amendments and the agency's 2021 Non-Enforcement Decision. With respect to the 2016 Amendments, the Court

found that the FDA did not consider the cumulative effect of the 2016 Amendments, but instead relied on studies that examined the amendments individually. The FDA also did not explain why it did not conduct such cumulative studies. The Court stated, "[a]t a minimum, the agency needed to acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning." Second, the Court found that the FDA failed to consider whether it needed to continue to collect data of non-fatal adverse events in light of the changes it was making to the availability of mifepristone.

Regarding the 2021 Non-Enforcement Decision, the Fifth Circuit held that this action was also likely arbitrary and capricious because the FDA relied on adverse-event data in the FDA Adverse Event Reporting System ("FAERS"), a voluntary reporting website, which the Court found was "insufficient to draw general conclusions about adverse events." The Court also found that the Non-Enforcement Decision was defective because it relied on literature relating to the remote prescription of mifepristone "despite FDA's admission that the literature did not affirmatively support its position."

Having found that Plaintiffs were substantially likely to succeed on the merits of these claims, the Fifth Circuit concluded that Plaintiffs were also likely to sustain irreparable harm without a stay and that a stay serves the public interest. Thus, the Fifth Circuit found that Plaintiff Medical Organizations and Doctors satisfied the requirements for a stay of the FDA's 2016 Amendments and 2021 Non-Enforcement Decision.[*]

As noted above, due to the Supreme Court's prior order, this stay is not yet in effect. If, however, the stay does go into effect, mifepristone will only be available under the safety regulations that were in place prior to 2016. This means that: (1) mifepristone would be approved up to seven weeks (49 days), down from ten weeks (70 days); (2) mifepristone would have to be prescribed and administered by a physician; (3) patients would have to undergo three in-person office visits, as opposed to one; (4) all adverse events would have to be reported; and (5) mifepristone could no longer be dispensed through the mail.

Our team is continuing to monitor post-*Dobbs* developments on all fronts, including any changes in the prescribing of mifepristone. For questions regarding any post-*Dobbs* issues, please contact any of the following Hancock, Daniel & Johnson attorneys: Ashley Calkins, Annie Howard, Sandi Douglas, or Mary Malone.

[*] As the Court explained, the preliminary-injunction factors apply even though the district court entered a stay under 5 U.S.C. § 705. "That is so because a stay has the practical effect of an injunction" (citations omitted).