CURRENT STATUS OF MIFEPRISTONE

April 28, 2023

On April 21, 2023, the United States Supreme Court settled almost a month-long dispute regarding the current status of mifepristone prescriptions. Specifically, the Court granted a stay to Danco Laboratories, LLC, ("Danco") the manufacturers of mifepristone and the Food and Drug Administration ("FDA"), following a request for emergency relief of an injunction from a federal district court in the Northern District of Texas, which would have prohibited the distribution of mifepristone throughout the United States. Pursuant to this stay, the current legal status of mifepristone remains unchanged and as it did before April 7, 2023, the date of the orders described below.

WHAT IS MIFEPRISTONE?

Mifepristone is a drug that blocks progesterone, a hormone that is needed for a pregnancy to continue. Mifepristone, when taken together with another medicine called misoprostol, is used to end a pregnancy. The FDA first approved mifepristone for medical termination of pregnancy, up to seven weeks gestation, in 2000. In 2016, the FDA (1) extended the use of mifepristone for up to ten weeks; (2) eliminated the requirement for prescribers to report all non-fatal adverse events; (3) reduced the number of in-person clinic visits from three to one; and (4) allowed healthcare providers other than physicians to dispense mifepristone. The FDA also approved a generic version of mifepristone to GenBioPro, Inc. in 2019.

In 2021, the FDA suspended the in-person dispensing requirement for mifepristone during the COVID-19 public health emergency, allowing it to be dispensed through the mail or a through a mail-order pharmacy. The FDA permanently removed the in-person dispensing requirement for mifepristone in 2023, although pharmacies must be specially certified to dispense mifepristone. Under its Risk Evaluation Mitigation Strategy ("REMS"), the FDA also maintained the Prescriber and Patient Agreement Form requirements, which require prescribers to attest to their qualifications and review the risks of mifepristone with patients.

TEXAS DISTRICT COURT DECISION

In November 2022, a group of doctors and medical associations brought a lawsuit against the 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 before the United States District Court for the Northern District of Texas, Amarillo Division which found that Plaintiffs had a substantial likelihood of success on the merits of their case both with

respect to the Plaintiff's challenges to the FDA's 2021 elimination of the in-person dispensing requirement and with respect to the FDA's action pre-2021. Specifically, the District Court stated that the FDA's 2000 approval of mifepristone, as well as the agency's 2016 changes and its 2019 approval of a generic version of mifepristone, were arbitrary and capricious.

On April 7, 2023, the district court 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).

WASHINGTON DISTRICT COURT DECISION

Mere hours after release of that opinion from the United States District Court for the Northern District of Texas, a United States District Court for the Eastern District of Washington issued a separate mifepristone opinion. The case before the Washington District Court was brought by a number of states – Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, New Mexico, Rhode Island, Vermont, Hawaii, Maine, Maryland, Minnesota, and Pennsylvania – and the District of Columbia seeking to enjoin the FDA from removing mifepristone from the market and to remove the FDA's "unnecessary and burdensome" 2023 REMS requirements. While the FDA's 2023 restrictions are less restrictive than any prior mifepristone regulations, Plaintiffs sought "to enjoin the application of *any* REMS, such that mifepristone can be prescribed just like the 20,000+ other drugs that don't have one." The Court noted the relief Plaintiffs sought by enjoining the FDA from enforcing its REMS was inconsistent with Plaintiff's request for the drug to remain available. Specifically, enjoining the 2023 REMS would eliminate the ability of pharmacies to provide the drug and thus reduce its availability. The Court preliminarily enjoined the FDA from altering the status or rights of the parties under the operative mifepristone REMS program. Order Granting in Part Pls.' Mot. for Preliminary Injunction, *State of Washington et al. v. United States Food and Drug Administration et al.*, No. 1:23-CV-3026 (E.D. Wash. Apr. 7, 2023).

On April 13, the District Court for the Eastern District of Washington issued an order clarifying its April 7 injunction in light of the apparently contradictory ruling from the Northern District of Texas. The Court stated that "irrespective of the Northern District of Texas Court ruling or the Fifth Circuit's anticipated ruling, Defendants and their officers, agents, servants, employees, attorneys," etc. remain enjoined from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy. . . in Plaintiff States and the District of Columbia." Order Granting Mot. for Clarification, *State of Washington et al. v. United States Food and Drug Administration et al.*, No. 1:23-CV-3026 (E.D. Wash. Apr. 13, 2023).

FIFTH CIRCUIT DECISION

On April 10, the Justice Department filed a notice of interlocutory appeal to the United States Court of Appeals for the Fifth Circuit asking the Fifth Circuit to stay the Texas District Court's ruling in *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.* until the Justice Department's appeal of the case could be heard.

On April 12, the Fifth Circuit issued an 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, while noting the "significant public

consequences" of withdrawing mifepristone from the market, 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. These changes included: (1) approving mifepristone for up to ten weeks into pregnancy instead of seven; (2) reducing the number of required in-person visits to one; (3) permitting mifepristone to be provided by certain health care providers other than physicians; (4) eliminating reporting of non-fatal adverse events; (5) approving GenBioPro, Inc.'s mifepristone generic; and (6) permitting mifepristone to be dispensed through the mail. In other words, the Fifth Circuit changed the availability of mifepristone to how it was pre-2016. 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 announced that it would seek emergency relief from the United States Supreme Court.

SUPREME COURT STAY

On April 14, the Justice Department, on behalf of the FDA, sought from the United States Supreme Court a stay of the order entered by the United States District Court for the Northern District of Texas that would have blocked the distribution of mifepristone. Danco also filed an emergency application for a stay noting the "regulatory chaos" that the Fifth Circuit's order had created particularly as it appeared to conflict with the order the Eastern District of Washington enjoining Danco from changing its regulation and approval of mifepristone in the seventeen Plaintiff states plus the District of Columbia. In response, the United States Supreme Court initially issued a five-day stay. Order, *U.S. Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, No. 22A902 (U.S. Apr. 14, 2023).

On April 19, the Court extended its stay until 11:59 p.m. (EDT) on Friday, April 21. Order, *U.S. Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, No. 22A902 (U.S. Apr. 19, 2023).

On the night of April 21, the United States Supreme Court granted a stay to the FDA and Danco. This stay maintains access nationwide to mifepristone pending 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, if a writ is sought. Should certiorari be denied by the Supreme Court, the stay will automatically terminate. If certiorari were to be granted, the stay will terminate upon the judgment of the Supreme Court. Oral arguments in the Fifth Circuit are currently scheduled for **May 17, 2023**. Order, *U.S. Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, No. 22A902 (U.S. Apr. 21, 2023).

GENBIOPRO, INC. LITIGATION

On April 19, GenBioPro, Inc., the company which makes the generic version of mifepristone, also filed suit in the United States District Court of Maryland. The case seeks to block the FDA from complying if the courts ultimately order mifepristone off the market. The lawsuit claims the FDA has failed to stipulate it would follow the regulatory process established by Congress and afford the drug company due process rights if the agency was ordered to suspend or revoke its approval of GenBioPro's product. Complaint for Declaratory & Injunctive Relief, *GenBioPro, Inc. v. U.S. Food and Drug Administration et al.* (Md. Apr. 19, 2023).

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.