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ALERT

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Mifepristone Litigation Update: Supreme Court Preserves Status Quo of FDA Approvals

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On April 21, 2023, the U.S. Supreme Court granted applications from the FDA and Danco Laboratories ("Danco"), the manufacturer of Mifeprex, for a stay of the district court's order in *Alliance for Hippocratic Medicine ("AHM") v. FDA*. Had the Supreme Court not provided emergency relief, the order in *AHM v. FDA*, as modified by the U.S. Court of Appeals for the Fifth Circuit, would have stayed the effect of several FDA approvals and actions related to mifepristone for use in medication abortion.

The Supreme Court's action occurred just two weeks after the Northern District of Texas in *AHM v. FDA* and the Eastern District of Washington in *Washington v. FDA* issued conflicting preliminary injunction orders on April 7, 2023, regarding FDA's approval and oversight of mifepristone, as explained in a prior Ropes & Gray Alert. This Alert summarizes the latest developments in *AHM v. FDA, Washington v. FDA*, and other mifepristone-related litigation to keep life sciences and health care industry stakeholders up to speed.

Developments in *AHM v. FDA*

Both FDA and Danco immediately appealed the Northern District of Texas's decision on April 7 and sought a stay pending appeal. On April 12, 2023, following expedited briefing, the Fifth Circuit granted this request in part, finding at this "preliminary stage" and based on "necessarily abbreviated review" that the statute of limitations barred the plaintiffs' challenges to the FDA's original approval of mifepristone in 2000. The Fifth Circuit further qualified this conclusion by acknowledging that the plaintiffs "could very well prevail" later in the litigation on their theory that the FDA had "reopened" its consideration of the 2000 approval through later actions, thereby restarting the statute of limitations period.

The Fifth Circuit otherwise denied FDA and Danco's requests for a stay pending appeal, leaving in place the district court's order staying the challenged FDA actions in 2016 and subsequent years. The Fifth Circuit found that the plaintiffs had standing; that their challenges to FDA's actions in 2016 and subsequent years were timely; that any failure by the plaintiffs to exhaust administrative remedies was excusable; and that the government had failed to carry its burden to show that FDA's actions were *not* arbitrary and capricious. While in the district court the plaintiffs had the burden of establishing they met all criteria for a preliminary injunction (including a likelihood of success on the merits and likely irreparable harm in the absence of the requested relief), the Fifth Circuit panel reviewing the emergency requests for a stay held that the burden on these issues flipped to the FDA and Danco.

The effect of the Fifth Circuit's decision would have been to maintain FDA approval of Mifeprex, but only under the conditions specified in the labeling and risk evaluation and mitigation strategy ("REMS") in effect prior to 2016. FDA's approval of generic mifepristone in 2019 would have been completely stayed.

The Fifth Circuit also addressed the relevance of the Comstock Act to the validity of the district court's order. While the court acknowledged it had not conducted a "conclusive exploration" of the Comstock Act, it asserted that a user of the mails or other designated shipping channels "violates the plain text merely by knowingly making use of the mail for a prohibited abortion item." Additionally, the court suggested that "under a plain view" of the Comstock Act, Danco violates the law "every time it ships mifepristone" (a point that the plaintiffs had not even argued).

On April 14, 2023, FDA and Danco filed applications for stay pending appeal with the Supreme Court. Although the district court's order was initially set to take effect at the end of April 14, the Court twice extended an administrative stay—first through April 19 and then through April 21—to provide the Court more time to consider the applications.

On April 21, 2023, the Supreme Court granted the applications for a stay pending disposition of the appeal in the Fifth Circuit and a potential petition for certiorari to the Supreme Court. The effect of the Supreme Court's brief order is that no part of the district court's April 7 order will take effect at this time. Only Justices Thomas and Alito would have denied the applications for a stay, and only Justice Alito issued an opinion explaining his reasoning. Justice Alito reasoned that the FDA and Danco were not entitled to a stay because they had not shown a likelihood of irreparable harm in the interim. Justice Alito observed that the Fifth Circuit appeal was on a "fast track" and questioned whether there was an actual conflict between the orders in *AHM v. FDA* and *Washington v. FDA*. Additionally, Justice Alito asserted that there were "legitimate doubts" that the government "would even obey an unfavorable order in this case" and suggested that FDA would avoid any irreparable harm to manufacturers through an exercise of enforcement discretion, despite FDA having said that in the absence of a stay it would have needed to take certain administrative actions for Mifeprex to not be considered misbranded under the Federal Food, Drug, and Cosmetic Act.

The litigation next returns to the Fifth Circuit, where oral argument on the merits of FDA and Danco's appeals of the district court's order is scheduled for May 17, 2023.

Developments in *Washington v. FDA* and Other Mifepristone Litigation

In *Washington v. FDA*, on April 10, 2023, FDA filed a "motion to clarify" the Eastern District of Washington's April 7 order, requesting further clarity around FDA's preliminary injunction obligations in the event that the *AHM v. FDA* order takes effect. On April 13, 2023, the district court granted the motion to clarify and restated that its April 7 order applies "irrespective of" the district court and Fifth Circuit rulings in *AHM v. FDA*. On April 21, 2023, the Eastern District of Washington denied a motion to intervene by several additional states[1] that wished to argue that FDA's January 2023 mifepristone REMS changes were unlawful.

In *GenBioPro, Inc. v. Sorsaia*, the manufacturer of generic mifepristone has challenged West Virginia's abortion ban on federal preemption grounds because it impermissibly restricts patients' access to mifepristone in the state. On April 21, 2023, the Southern District of West Virginia denied a motion by the defendants to stay the case pending the outcome of *AHM v. FDA*. The district court noted that it "accord[ed] . . . little weight" to the *AHM v. FDA* opinion from the Northern District of Texas. On April 24, 2023, the district court heard oral argument on the issue of GenBioPro's standing.

On April 19, 2023, while the FDA and Danco's applications for a stay were pending before the Supreme Court, GenBioPro filed a new lawsuit against FDA in the District of Maryland. GenBioPro argues that even if the order in *AHM v. FDA* were to take effect, FDA cannot consider generic mifepristone to be unapproved and unlawful without first following the statutory and regulatory processes for withdrawing an approved drug application.

In *Bryant v. Stein*, a physician has challenged on federal preemption grounds North Carolina's restrictions on the prescribing and dispensing of mifepristone that go beyond the FDA's requirements in the January 2023 REMS. Leaders of the North Carolina legislature representing the state's interests have successfully intervened in the case, and they have moved to dismiss the plaintiff's claims. The plaintiff's response to the motion to dismiss is due by April 29, 2023.

[1] The proposed intervenor states were Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah.

Key Takeaways

Based on the Supreme Court's order in *AHM v. FDA* and the latest developments in the other mifepristone-related cases, below are the key takeaways that industry stakeholders should know:

- *The status quo regarding FDA's approval and oversight of mifepristone remains.* All existing FDA approvals for mifepristone, including Mifeprex, generic mifepristone, and the shared mifepristone REMS program, are still in effect. Health care providers should continue to follow the requirements of the January 2023 REMS.

- *A majority of the Supreme Court appears to agree that the Court would hear an appeal from the government in* AHM v. FDA *on the merits if the Fifth Circuit merits panel affirms the district court's order.* An applicant seeking an emergency stay pending appeal in the Supreme Court must establish (1) a reasonable probability that the Court would eventually grant review; (2) a "fair prospect" that the Court would reverse; and (3) a likelihood of irreparable harm in the absence of a stay. Of these three, the hardest hurdle for most litigants to overcome is the first—*i.e.*, establishing that the issue is worthy of Supreme Court review. Although the members of the Court that granted the applications for stay did not explain their reasoning, these justices logically must have concluded that the FDA and Danco have at least a likelihood that the Court would hear an appeal on the merits should the Fifth Circuit affirm the district court's order. The other two factors are treated as more of a sliding scale, with a particularly strong showing on one or the other often being sufficient. Here, it is possible the justices were convinced by FDA's contention that the district court's order would create "regulatory chaos" if implemented.

- *The holdings of the district court and the Fifth Circuit in* AHM v. FDA, *if accepted by the Supreme Court, would have significant implications for FDA's authority over drugs and other medical products.* As Ropes & Gray attorneys explained in a recent Daily Journal article,[2] the precedent created by *AHM v. FDA,* if it were affirmed on the merits by the Supreme Court, could have significant adverse consequences for FDA. These could include reduced judicial deference to FDA's expert determinations of safety and effectiveness, less latitude for FDA to draw inferences from clinical trial data, and potential limits to FDA's ability to exercise enforcement discretion. For the moment, fears of these consequences have been lessened, but the final resolution of *AHM v. FDA* remains to be seen. How the Fifth Circuit and the Supreme Court apply the burden of proof as the litigation proceeds will be an important issue to watch.

- *Litigation over the approval and availability of mifepristone is likely to take months, if not years, to play out.* Notwithstanding the intense legal briefing and order-drafting over the last few weeks, the recent actions and decisions in *AHM v. FDA* and the other mifepristone-related cases will not be the end of the story for mifepristone access. Each case could take months, if not years, to resolve when taking into account the timeframe for potential appeals. Additionally, the FDA may have to grapple with new administrative challenges related to mifepristone—the Students for Life of America, for example, filed a citizen petition with FDA on April 19, 2023, requesting that FDA revoke its approvals of mifepristone until the FDA can complete certain environmental assessments to determine whether trace amounts of mifepristone in wastewater pose any risk to "endangered or threatened species or designated critical habitats." Further administrative challenges are likely to follow, and each such challenge may give rise to additional federal court litigation.

Ropes & Gray will continue to monitor developments relating to this area. If you have any questions regarding this Alert, please contact any of the attorneys listed below or your usual Ropes & Gray advisor.

[2] This article was submitted for publication prior to the issuance of the Fifth Circuit's decision on April 12.