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ALERT

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AHM v. FDA and *Washington v. FDA*: Dueling Federal Court Decisions Raise Uncertainty Related to FDA Regulation of Mifepristone

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On April 7, 2023, two federal district courts issued orders in closely watched cases relating to the U.S. Food and Drug Administration's ("FDA") approval and oversight of mifepristone for use in medication abortion.1 First, in *Alliance for Hippocratic Medicine ("AHM") v. FDA*, the U.S. District Court for the Northern District of Texas issued an unprecedented preliminary injunction that imposes a nationwide "stay" of FDA's approvals of mifepristone, including the original approval that has been in effect for more than two decades, subject to a seven-day delay in the order's enforceability to enable the federal government to seek emergency appellate relief. Second, in *Washington v. FDA*, the U.S. District Court for the Eastern District of Washington issued a preliminary injunction that points in the opposite direction, enjoining FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" under the current FDA-approved risk evaluation and mitigation strategy ("REMS") in 17 states and the District of Columbia.

This Alert summarizes these two conflicting decisions and what life sciences and healthcare industry stakeholders need to know in this rapidly evolving landscape.

Mifepristone Background

A brief history of key FDA actions related to mifepristone is useful to understanding the *AHM* and *Washington* decisions.

- In 2000, FDA approved a new drug application ("NDA") for Mifeprex (mifepristone) for use in a regimen with another drug, misoprostol, for the medical termination of intrauterine pregnancy through 49 days gestation. FDA imposed restrictions on the distribution of mifepristone, including, among others, an in-person dispensing requirement, provider attestation and reporting requirements, and a patient agreement requirement.
- In 2011, following enactment of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") that authorized FDA to require REMS, FDA approved a REMS with elements to assure safe use ("ETASU") for mifepristone that incorporated the same restrictions on distribution as the original approval.
- In 2012, FDA approved a separate new drug application for mifepristone 300mg tablets for chronic use in controlling hyperglycemia associated with a certain metabolic disease. This version of mifepristone has never been subject to any of the REMS requirements of other mifepristone products.
- In 2016, FDA approved a supplemental NDA for use of Mifeprex through 70 days gestation.
- In 2019, FDA approved an abbreviated NDA for a generic version of mifepristone and established a mifepristone REMS program that included both Mifeprex and generic mifepristone.
- In 2020, a federal district court temporarily enjoined FDA from enforcing the in-person dispensing requirement for mifepristone during the COVID-19 pandemic, and then in April 2021, FDA announced it would exercise enforcement discretion with respect to the in-person dispensing requirement.
- After completing a review of the mifepristone REMS program in December 2021, FDA approved a modified REMS in January 2023 that removed the in-person dispensing requirement and created a pharmacy certification requirement (hereafter the "January 2023 REMS").

AHM v. FDA

In November 2022, several physician associations and individual physicians sued FDA under the Administrative Procedure Act ("APA") in the Northern District of Texas and sought a preliminary injunction ordering FDA to "withdraw or suspend" the original approvals of Mifeprex (2000) and generic mifepristone (2019), the 2016 supplemental NDA approval for Mifeprex, and the April 2021 decision to exercise enforcement discretion with respect to the in-person dispensing requirement. The government argued in response that no court had ever "second-guessed FDA's safety and efficacy determination and ordered a widely available FDA-approved drug to be removed from the market," that the plaintiffs lacked standing to sue, and that the plaintiffs' "two-decade delay" in filing suit made their challenge untimely.

In its April 7, 2023, opinion, the district court first found that the plaintiffs have standing and that their claims were timely, even though the applicable statute of limitations is six years. Specifically, the court held that the doctors and medical associations' interest in promoting public health gave them standing, and that the FDA's 2016 denial of certain plaintiffs' citizen petition and 2021 decision not to enforce the in-person dispensing requirement had restarted the time for bringing suit.

On the merits, the district court found that the plaintiffs have a substantial likelihood of success. Regarding FDA's original approval of Mifeprex in 2000, the district court determined that mifepristone did not satisfy the criteria under the FDA's "Subpart H" regulations that the agency invoked as part of the 2000 approval. Specifically, the court concluded that pregnancy was not a "serious or life-threatening illness." Furthermore, the court concluded that mifepristone did not provide a "meaningful therapeutic benefit" to patients over existing treatments. On this point, the court disagreed with the FDA's evaluation of the safety and efficacy of mifepristone, finding instead that mifepristone offers "little to no benefit over surgical abortion," which the court found was "a statistically far safer procedure."

The court also held that FDA's approvals of mifepristone were arbitrary and capricious because FDA did not require the conditions of use stated in mifepristone labeling to match the protocol requirements for the clinical trials supporting its approval, such as the use of a transvaginal ultrasound to determine gestational age and identify potential ectopic pregnancies. The court characterized FDA's approval as having "acquiesced to the pressure to increase access to chemical abortion at the expense of women's safety."

Regarding FDA's actions to remove the in-person dispensing requirement for mifepristone and permit dispensing through the mail, the district court construed the Comstock Act, a federal criminal statute enacted in 1873, to prohibit mailing abortion drugs. The Comstock Act declares as "nonmailable" in violation of the law "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion, or for any indecent or immoral purpose."2 Although the government argued that federal courts of appeals had adopted a "consensus view" that the Comstock Act applies only where the sender intends the article to be used "unlawfully," the district court rejected that interpretation as inconsistent with the plain language of the statute. The court also rejected the government's argument that the Comstock Act should be read narrowly in light of the enactment of FDAAA in 2007, when Congress would have been aware that it was directing the existing distribution scheme of mifepristone to continue.

After determining that all of the elements for a preliminary injunction were met, the district court concluded that the appropriate relief was to order a "stay" of the FDA's 2000 approval and all subsequent challenged actions related to that approval, pending further litigation and a final ruling. The court delayed the injunction's enforceability for seven days—until April 14, 2023—to allow the government time to seek emergency relief in the U.S. Court of Appeals for the Fifth Circuit.

Washington v. FDA

Just one hour after a judge in the Northern District of Texas issued the order to stay FDA's approval of mifepristone nationwide, a judge in the Eastern District of Washington ordered FDA to maintain the regulatory status of mifepristone in a third of the country. In February 2023, a group of 17 states3 and the District of Columbia sued FDA under the APA in the Eastern District of Washington seeking to expand, rather than narrow, the availability of mifepristone. Those plaintiffs sought a preliminary injunction to stop FDA from enforcing the January 2023 REMS and from changing the current status quo "to make mifepristone less available in Plaintiff States."

In its April 7 opinion, the district court held that the plaintiffs had standing because the states were suing on behalf of themselves and as *parens patriae* to protect the health and well-being of their residents. The court also excused the plaintiffs' failure to exhaust administrative remedies with FDA because the court determined that filing a new citizen petition with FDA would be futile.

On the plaintiffs' request for injunctive relief, the court found there were "serious questions going to the merits" of plaintiffs' claims and that the balance of hardships tipped sharply in the plaintiffs' favor. The government defended its January 2023 REMS modification by arguing that FDA only needed to consider whether a *modification* was appropriate under a specific statutory provision and need not reconsider its earlier decision to impose the REMS4. The court determined that implicit in this assessment should be a determination of whether the drug still requires a REMS or ETASU in the first place, which is governed by separate statutory criteria.5 Because FDA did not assess whether mifepristone still qualifies for a REMS and ETASU under these latter criteria, the court found that FDA "failed to consider an important aspect of the problem."

Regarding the scope of a preliminary injunction, the court determined that enjoining FDA from enforcing the mifepristone REMS entirely would go well beyond the status quo that a preliminary injunction is intended to maintain. The court issued a narrower order that preliminarily enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] in Plaintiff States." The court rejected a request for a nationwide injunction.

Key Takeaways

The contradictory nature of the two injunctions is itself a reason for the government to appeal, and the legal situation will quite possibly change over the coming days and weeks as the government's request for emergency relief is considered. In the meantime, below are key takeaways based on the current legal landscape as of the date of this Alert listed above:

- *As of now, nothing has changed with respect to FDA approval of mifepristone or the mifepristone REMS*. The order in *AHM v. FDA* was stayed until April 14 to provide the government time to seek emergency relief, and both the government and the manufacturer of Mifeprex have already filed notices of appeal. Attorney General Garland issued a statement making clear that the Department of Justice "will continue to defend the FDA's decision" that mifepristone is safe and effective. Healthcare providers who prescribe, administer, or dispense mifepristone should continue to follow the January 2023 REMS currently in effect.
- *The conflicting injunctions in AHM v. FDA and Washington v. FDA make it more likely that the government will seek emergency relief in the U.S. Supreme Court, if necessary.* FDA will not be able to comply with both injunctions. Thus, if the Fifth Circuit declines to stay the district court's order in AHM v. FDA pending appeal, the government will likely seek emergency relief from the Supreme Court.
- *The stay order in AHM v. FDA would not require FDA to take any specific enforcement action regarding mifepristone*. If the order in AHM v. FDA takes effect, it would mean that Mifeprex and generic mifepristone are no longer considered approved by FDA. Yet it does not necessarily follow that FDA would take action to stop the manufacture, distribution, or dispensing of "unapproved" mifepristone, especially pending an appeal while the FDA is continuing to defend the safety and effectiveness of the drug. Under the pivotal Supreme Court case

of *Heckler v. Chaney*,6 FDA's decision not to pursue enforcement action for violations of FDA requirements is generally not reviewable under the APA. Whether FDA would apply enforcement discretion, either expressly or implicitly, regarding Mifeprex and generic mifepristone remains to be seen. And even if FDA were to apply enforcement discretion, other questions would remain regarding potential legal exposure for those who manufacture, distribute, or dispense mifepristone.

- *Even if the stay order in AHM v. FDA takes effect, there will still be an FDA-approved form of mifepristone*. As previously noted, FDA has approved a 300 mg tablet version of mifepristone for a different indication. This version of mifepristone is not subject to the mifepristone REMS, and it is not covered by the plaintiffs' claims in AHM v. FDA or the court's order. The FDA does not regulate the practice of medicine, including the prescribing of FDA-approved drugs for uses other than those indicated in the FDA-approved labeling.
- *The stay order in AHM v. FDA, if it takes effect, will not alter the FDA approval status or availability of misoprostol*. If mifepristone is no longer considered "approved" and becomes unavailable, healthcare providers may elect to prescribe and dispense misoprostol alone for the termination of pregnancy. Although the plaintiffs' complaint in *AHM v. FDA* included a broad request that the court "order[] Defendants to withdraw mifepristone *and misoprostol* as FDA-approved chemical abortion drugs," the plaintiffs' motion for a preliminary injunction did not seek any relief with respect to misoprostol. Moreover, the FDA-approved indication of misoprostol is reducing the risk of certain gastric ulcers; misoprostol is not FDA-approved for its use in the termination of pregnancy. Hence, it is unclear what relief plaintiffs could obtain against FDA with respect to misoprostol even if they sought it. As with the version of mifepristone indicated for treating Cushing's syndrome, physicians' decisions to prescribe misoprostol for medication abortion is considered the "practice of medicine," which is subject to regulation under state law rather than federal law.
- *More cases are coming on this subject*. The decisions in *AHM v. FDA* and *Washington v. FDA* will not be the end of the story for mifepristone access in a post-Dobbs legal environment. Besides these two cases, there are two other challenges pending in federal court that relate to the regulation of mifepristone. In *GenBioPro, Inc. v. Sorsaia*,7 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. In *Bryant v. Stein*,8 a North Carolina physician has challenged on federal preemption grounds the state's restrictions on the prescribing and dispensing of mifepristone that go beyond the FDA's requirements in the January 2023 REMS. Decisions in these cases could also influence the ultimate resolution of the broader legal issues related to mifepristone access and regulation.
- *If the district court's interpretation of the Comstock Act in AHM v. FDA were upheld on appeal, access to mifepristone could be significantly reduced in addition to other broader impacts.* If the district court is correct that the abortion-related provisions of the Comstock Act can apply to any abortion and not merely unlawful abortions, questions may arise as to whether the Comstock Act prohibits the distribution through mail or private carriers of misoprostol, medical devices, or other products used to perform abortions or that arguably might be designed, adapted, or intended to cause abortion. Additionally, the Comstock Act's prohibitions on the sharing of information about abortion services could affect all providers of abortion services. While these information-sharing prohibitions would likely be vulnerable to challenge under the First Amendment, such a challenge would take time to resolve in the courts, and the ultimate outcome would not be a certainty.

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.

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1. For the purposes of this Alert, we use "mifepristone" as shorthand for versions of the drug approved for the medical termination of intrauterine pregnancy, except where specifically noted, such as when discussing FDA's approval of a version of mifepristone for a different indication.
2. 18 U.S.C. § 1461. The Comstock Act also declares as "nonmailable" anything that gives "notice of any kind giving information" about the availability of abortion services. *Id.* Another provision imposes similar prohibitions to the use of private carriers or communications via computer. *See* 18 U.S.C. § 1462.
3. These states are Washington, Arizona, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, Oregon, Pennsylvania, Rhode Island, and Vermont.
4. 21 U.S.C. § 355-1(g)(4)(B).
5. 21 U.S.C. § 355-1(a)(1), (f)(1).
6. 470 U.S. 821 (1985).
7. *GenBioPro, Inc. v. Sorsaia*, No. 23-cv-00058 (S.D.W.V. Jan. 25, 2023).
8. *Bryant v. Stein*, No. 23-cv-00077 (M.D.N.C. Jan. 25, 2023).