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Beyond Mifepristone: The potential implications of *AHM v. FDA* on FDA's authority

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On April 7 two federal district courts issued conflicting orders in cases relating to the U.S. Food and Drug Administration's (FDA) approval and oversight of mifepristone for use in medication abortion. In *Alliance for Hippocratic Medicine (AHM) v. FDA, the U.S. District Court* for the Northern District of Texas issued an unprecedented preliminary injunction imposing a nationwide "stay" of FDA's approvals of mifepristone, subject to a seven-day delay in the order's enforceability to enable the federal government to seek emergency appellate relief. In *Washington v. FDA*, the U.S. District Court for the Eastern District of Washington issued a preliminary injunction enjoining FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" in 17 states and the District of Columbia.

Much has already been written regarding the impact these cases could have on the availability of mifepristone. But some have also raised the potential that the decision could have broader ramifications for FDA's regulatory authority and oversight of drugs. President Biden, for example, has asserted that if the AHM ruling were to stand, "then there will be virtually no prescription, approved by the FDA, that would be safe" from challenge.

How might the precedent created by the *AHM* decision, if it hypothetically were affirmed in all material respects through the 5th Circuit and Supreme Court, have such effects?

· Reduced deference to FDA's determinations of safety and effectiveness. Ordinarily, courts give significant deference to matters within FDA's scientific expertise, such as the determination of the safety and effectiveness of a prescription drug. The district court in *AHM* expressly "second-guess[ed]" FDA's decision-making regarding the safety and effectiveness of mifepristone. The court disagreed with FDA and found based on its own assessment that mifepristone offers "little to no benefit over surgical abortion," which the court considered "a statistically far safer procedure." The prospect of other judges in future cases similarly substituting their own judgment for FDA's expert scientific determination would insert significant unpredictability into the FDA approval process. *Washington v. FDA* could present a similar concern, albeit to a lesser degree. While the Washington court recognized that it is FDA's role and not the court's "to review the scientific evidence," the court nevertheless pointed to "potentially internally in-consistent FDA findings regarding mifepristone's safety profile" in assessing the merits of the plaintiffs' challenge. Whether future courts might view the *AHM* and *Washington* cases as outliers driven by unique circumstances specific to medication abortion also remains to be seen.

· Less latitude for FDA to draw inferences from clinical trial data. The district court in *AHM* found it arbitrary and capricious that FDA did not require the conditions of use stated in mifepristone labeling to match certain safety-related protocol requirements for the clinical trials supporting its approval. The court did not credit that FDA, in determining appropriate drug labeling, routinely draws inferences from clinical trial data that go beyond the particulars of those trials. The court's rigid approach to FDA approvals would hinder FDA's ability to grant approval for less restrictive conditions of use or for a broader indication or patient population than were studied, even in circumstances where FDA has determined the evidence is sufficient to establish safety and effectiveness. If manufacturers had to conduct a new study to support every minor variation from the clinical trials that supported a drug's approval, this would significantly increase the cost and time associated with drug development in the U.S. and could discourage manufacturers from seeking such approvals.

· Reduced certainty regarding the running of the statute of limitations on FDA decisions. Challenges to FDA actions are subject to a six-year statute of limitations. Yet the

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district court in *AHM* permitted a challenge to a 23-year-old approval decision because the court found that FDA's 2016 denial of a citizen petition by certain plaintiffs and 2021 decision not to enforce an in-person dispensing requirement had restarted the time for bringing suit. The court's logic would effectively mean that the statute of limitations never runs on FDA approvals, because (1) a party can restart the clock by filing a citizen petition challenging at least certain aspects of that FDA decision or (2) the original decision would become subject to renewed challenge whenever FDA alters some aspect of its original decision, such as by approving a supplemental new drug application for modified labeling.

· Potential limits to FDA's ability to exercise enforcement discretion. FDA routinely issues guidance documents and other statements announcing its intent to exercise enforcement discretion regarding certain activities that would otherwise violate FDA requirements. Under the Supreme Court case of *Heckler v. Chaney*, 470 U.S. 821 (1985), FDA's decision not to pursue enforcement action for violations of FDA requirements is presumptively unreviewable by a court. The district court in *AHM* rejected FDA's 2021 decision to exercise enforcement discretion regarding the in-person dispensing requirement for mifepristone, initially adopted during the COVID-19 pandemic, reasoning that the *Heckler* presumption did not apply. Yet the court's logic could raise questions about FDA enforcement discretion in other contexts, potentially exposing FDA to new litigation challenges to its enforcement policies and priorities.

· Loosened standing requirements that open the door to more challengers. The district court in *AHM* adopted a broad interpretation of standing in finding that the plaintiff medical associations and their members could sue FDA based on allegations of speculative future harm. The district court's logic would seemingly permit concerned healthcare providers to rely on a public health rationale to establish standing to challenge the FDA approval of any drug.

The outcome of *AHM* remains to be seen, including whether the 5th Circuit (or the Supreme Court, if necessary) will grant a stay of the district court's order in the coming days. Drug manufacturers and other life sciences industry stakeholders should monitor closely and be mindful of the broader potential impact on FDA.