DUELING RULINGS: Conflict Between Federal Courts Sets Up Further Challenges on Access to Mifepristone

April 2023

Federal district courts in Texas and Washington State issued conflicting rulings within an hour of each other on April 7 regarding the Food and Drug Administration's (FDA's) approval and regulation of the drug mifepristone, which is used in medication abortion and for other purposes. These conflicting rulings set up additional court action that is expected as soon as this week.

This Aon bulletin addresses the following:

- Background on the two cases;
- What's next in the courts; and
- What should employer group health plans do now.

Background on the Two Cases

The Northern District of Texas Case

In *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration*, the plaintiffs sued the FDA alleging that the FDA's approval of mifepristone in 2000 was invalid and asked the court to withdraw mifepristone as an FDA-approved drug. Judge Matthew Kacsmaryk held that the FDA used an invalid process when approving mifepristone and that the FDA's subsequent decisions expanding the use of mifepristone exceeded its authority. As a result, the judge suspended the FDA's actions related to the approval and expansion of mifepristone since 2000 but paused his order for seven days to give the FDA time to appeal the order to the Fifth Circuit Court of Appeals.

The Eastern District of Washington Case

In *State of Washington et al. v. U.S. Food and Drug Administration*, 17 states plus the District of Columbia challenged the FDA's restrictions on prescribing and dispensing mifepristone that became effective in January 2023. The states asked the court to block the FDA from restricting access to mifepristone and argued that the FDA's more stringent requirements for mifepristone (compared to other drugs) should be lifted. While Judge Thomas O. Rice did not grant the states' request to lift those requirements, at least while the case plays out, the judge ordered the FDA to continue to make mifepristone available under the January 2023 restrictions in the plaintiff jurisdictions (AZ, CO, CT, DE, DC, HI, IL, ME, MD, MI, MN, NV, NM, OR, PA, RI, VT, WA). The judge's ruling maintains the status quo for FDA-approval of mifepristone in those states. The judge declined to make his ruling apply nationwide.

What's Next in the Courts

The two rulings—one potentially banning mifepristone nationwide and one ordering mifepristone to continue to be available in at least 17 states and the District of Columbia—set up a conflict that could

end up in the U.S. Supreme Court. In the Texas case, the FDA has appealed the court's order to the Fifth Circuit Court of Appeals. If the Fifth Circuit upholds Judge Kacsmaryk's order or declines to stay the order during further litigation, then the FDA is likely to appeal that ruling to the U.S. Supreme Court.

Complicating the issue further is the FDA's process for withdrawing approval of a drug, if Judge Kacsmaryk's order suspending the FDA's approval of mifepristone goes into effect. The FDA is required to use a specific regulatory process when withdrawing approval of a drug, which includes studies, advisory committee hearings, and a public comment period. The process is lengthy, and the status of mifepristone during that process is unclear if Judge Kacsmaryk's order is upheld.

Additionally, the manufacturers of mifepristone could sue to block the FDA from acting in accordance with Judge Kacsmaryk's order. And given the contradictory rulings by the two federal district courts, the U.S. Supreme Court may quickly get involved.

What Should Employers Do Now

In the short term, mifepristone is still an FDA-approved drug so there is no immediate change for group health plans covering this drug. Moreover, the Washington State case allows mifepristone to continue to be available in the plaintiff states noted above who are parties to that litigation. However, plans should continue to monitor the ongoing litigation. In the meantime, plans should talk to their carriers and pharmacy benefit managers to understand their perspective on administration and access to mifepristone in light of the litigation.

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