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Generic And Branded Mifepristone Remain On US Market Following Supreme Court Stay

No New Restrictions Will Be Placed On The Drug As Court Cases Play Out

by **Chloe Kent**

GenBioPro will be able to continue selling its generic mifepristone, after the Supreme Court overruled a stay from the Fifth Circuit which could have seen generic approval rescinded and significant restrictions placed on the drug's use.

The US Supreme Court on Friday temporarily blocked lower court orders that would have imposed new restrictions on mifepristone, the first drug taken during a medical abortion, preserving access to both generic and branded versions.

The Court of Appeals for the Fifth Circuit initially granted a limited stay to the original court order, which would have withdrawn approval for GenBioPro's generic mifepristone to be sold. (Also see "[Fifth Circuit Mifepristone Ruling May Temporarily Halt Pharmacy Dispensing, Generic Approval](#)" - Pink Sheet, 13 Apr, 2023.)

On Friday night the Supreme Court granted applications by the Food and Drug Administration and Danco Laboratories – manufacturer of branded mifepristone product Mifeprex – to halt the 7 April preliminary injunction order issued by district judge Matthew Kacsmaryk of the Northern District of Texas. (Also see "[FDA's Woodcock To](#)

Turbulence In Court

Justice Clarence Thomas and Justice Samuel Alito were the only two Supreme Court judges who opposed granting a stay. Alito issued a provocative dissent in which he alleged that

[Supreme Court: Mifepristone Ruling Will Create 'Significant Chaos'](#) - Pink Sheet, 15 Apr, 2023.)

This order will remain in effect until an appeal on the merits of the original case, *Alliance for Hippocratic Medicine v. FDA*, is decided. (Also see "[What's Next For FDA In Face Of Opposing Mifepristone Injunctions](#)" - Pink Sheet, 9 Apr, 2023.)

The Fifth Circuit is now scheduled to hear oral arguments on 17 May, following which it will rule on whether or not the preliminary injunction order was rightfully granted, potentially banning or restricting mifepristone sales. This decision will be subject to review in the Supreme Court through a petition for certiorari and the current stay granted by the Supreme Court will remain in place until it makes a judgement. Following this ruling, the losing side could then petition for an en banc rehearing in the Fifth Circuit and petition the Supreme Court a second time.

When all appeals over the preliminary injunction are complete – assuming that the Supreme Court doesn't rule in such a way as to render further proceedings unnecessary, such as holding that the plaintiffs lack standing – then the case can finally proceed to a trial on the merits before Kacsmaryk. He may then choose to decide the case without trial through a summary judgement, or hold a trial including witness testimony. Following any trial verdict, the losing side will again have the opportunity to appeal to the Fifth Circuit and eventually the Supreme Court.

As such, any final judgement in this case is likely months or even years away.

GenBioPro's West Virginia Case To Continue Despite Bid To Halt

On 18 April, Prosecuting Attorney for Putnam County Mark Sorsaia and West Virginia Attorney General Patrick Morrissey moved for a stay in the case of *GenBioPro v. West Virginia* pending the outcome of *Alliance for Hippocratic Medicine v. FDA*, given that "the outcome of that case may well render this lawsuit moot." (Also see "[Generic Mifepristone Manufacturer Sues West Virginia Over Abortion Ban](#)" - Generics Bulletin, 26 Jan, 2023.)

On 21 April, the court *denied* the motion, saying it found it "inadvisable" to pause the case "based upon a district court opinion granting a preliminary injunction, which merely forecasts

"the government has not dispelled legitimate doubts that it would even obey an unfavorable order [against mifepristone], much less that it would choose to take enforcement actions to which it has strong objections." (Also see "[Supreme Court's Stay Of Mifepristone Ruling Gives FDA Respite For Next Round](#)" - Pink Sheet, 22 Apr, 2023.) A statement issued by President Biden reads: "I continue to stand by FDA's evidence-based approval of mifepristone, and my administration will continue to defend FDA's independent, expert authority to review, approve and regulate a wide range of prescription drugs."

that FDA approval of generic mifepristone may eventually be set aside.”

“Decisions from the Northern District of Texas and the Fifth Circuit are not binding on this Court,” it continued. “Not would a Supreme Court decision as to the preliminary injunction issued by the District impact proceedings here.”

The West Virginia court added that the Alliance for Hippocratic Medicine’s case “has been met with broad criticism from legal commentators. Therefore, the Court accords that opinion little weight.”

Oral arguments on the issue of standing in *GenBioPro v. West Virginia* were recently scheduled by the court, with an argument scheduled for 24 April in which the plaintiff, GenBioPro, will present its arguments first. (Also see "[Generics Bulletin Podcast – GenBioPro v. West Virginia: The Future Of Mifepristone In America, With Professor Greer Donley](#)" - Generics Bulletin, 8 Feb, 2023.)