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# Client Alert: What's Next for Mifepristone?

**Publications**

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Medication abortions using mifepristone and misoprostol now account for more than half of all abortions performed in the United States today.[1] In the post-*Dobbs* era, medication abortion is critical to reproductive rights because its accessibility, compared to surgical procedures, generally is not as dependent on geographic proximity to an abortion clinic or hospital. Indeed, distribution via mail, grassroots delivery networks, and online sources make medication abortion both more accessible and more difficult to regulate than surgical abortions.[2]

New federal guidance sought to expand access to mifepristone, the first of the two medications used in the two-drug regimen. First approved in 2000, mifepristone is authorized by the Federal Drug Administration (FDA) to be taken in the first ten weeks of pregnancy. In January 2023, the FDA published regulatory changes that permit certified retail pharmacies to dispense mifepristone with a prescription from a certified health provider.[3] Prior to the FDA's rule change, mifepristone could only be distributed by certain mail-order pharmacies or by specially certified clinics. On the same day, the Department of Justice (DOJ) Office of Legal Counsel (OLC) published an opinion concluding that the Comstock Act "does not prohibit the mailing, or the delivery, or receipt by mail, of mifepristone or misoprostol where the sender lacks the intent that the recipient of the drugs will use them unlawfully."[4]

A federal lawsuit filed in the Northern District of Texas challenging the FDA's decades-old approval of mifepristone now poses an immediate threat to nationwide access to the medication. On April 7, 2023, the district court granted a preliminary injunction and stayed the FDA's approval of mifepristone. The decision appeared to be the first time a court had ordered an FDA-approved drug's approval to be revoked over the agency's objection.[5] The Supreme Court, in fact, affirmed the authority of the FDA with regard to mifepristone as recently as 2021.[6] The decision has been stayed for 7 days by the district court and absent further relief from the Fifth Circuit or the Supreme Court, will go into effect on April 15. Should the decision take effect, it would make it illegal for manufacturers to sell or distribute mifepristone nationwide, even in states where abortion is legal.[7]

## FDA Regulation of Mifepristone

The FDA first approved the marketing of mifepristone (also known as RU486) in 2000 under the brand name Mifeprex.[8] In approving the medication's distribution, the FDA determined that mifepristone is a safe and effective form of medication abortion when used in a regimen with misoprostol.[9] The FDA drew on its authority under "Subpart H" to approve mifepristone.[10] Subpart H lays out the agency's accelerated approval process for new drugs to treat serious or life-threatening illnesses and requires the agency to impose post-approval distribution limitations where appropriate.[11] In applying Subpart H, the FDA imposed an in-person dispensing requirement for Mifeprex and limited the distribution of the drug to prescribers who agreed to dispense in certain healthcare settings, under the supervision of certified physicians.

In recent years, however, the FDA has eased access to mifepristone.[12] In March 2016, the FDA increased the gestational age limit, reduced the number of required in-person clinic visits to one, and determined the at-home administration of misoprostol to be safe. In 2019, the FDA approved the application for a generic version of mifepristone, finding that it was materially the same as the brand-name Mifeprex. Then, in April 2021, in the midst of the coronavirus pandemic, the agency announced that it would stop enforcing the in-person dispensing requirement. The FDA's most recent regulatory change in January 2023 removes the in-person dispensing requirement altogether.

**The Lawsuit**

In November 2022, conservative legal group Alliance Defending Freedom filed a lawsuit in NDTX on behalf of the Alliance for Hippocratic Medicine, the American Association of Pro-Life Obstetricians and Gynecologists, and other medical groups and physicians, seeking to overturn the FDA's decades-old authorization of mifepristone. Plaintiffs sought a nationwide preliminary injunction to: (i) withdraw the FDA's 2000 and 2019 approval of marketable versions of mifepristone, (ii) withdraw the agency's approval of its 2016 and 2021 regulatory decisions removing in-person dispensing requirements, and (iii) enjoin application of the Food, Drug, and Cosmetic Act ("FDCA") in any manner inconsistent with these orders.[13] Plaintiffs also sought a declaration that the FDA is prohibited from approving a new drug application that fails to limit distribution of medication abortions in accordance with the Comstock Act.[14] Plaintiffs raised three main arguments in favor of a nationwide injunction:

- *First*, plaintiffs challenged the FDA's use of Subpart H to approve mifepristone in 2000 as improper because pregnancy is not an illness. Mifepristone, the Complaint argued, "do[es] not treat serious or life-threatening illnesses" because "pregnancy is a normal physiological state."[15]

- *Second*, plaintiffs alleged that the FDA's regulatory changes in 2000, 2016, 2019, and 2021 violated the FDCA's safety and effectiveness requirements.[16] Plaintiffs claimed that, in

expanding access to medication abortion in each of these instances, the FDA's failed to sufficiently evaluate the safety and effectiveness of mifepristone and misoprostol for use under the conditions prescribed.[17]

- *Third*, plaintiffs argued that the FDA's approval of mifepristone violated the Comstock Act, which they interpret to prohibits the distribution of medical abortion drugs by mail.[18]

On January 13, 2023, DOJ filed its opposition to plaintiffs' motion for a preliminary injunction. The brief raises a host of jurisdictional and procedural challenges to plaintiffs' suit including:

- *Lack of Article III Standing:* DOJ contended that the various parties that comprise plaintiffs in this case lack Article III standing to sue.[19]

- *Ripeness & Administrative Exhaustion:* DOJ argued that most of plaintiffs' legal challenges are untimely or unripe as plaintiffs failed to exhaust available administrative remedies prior to seeking judicial review.[20] The government also asserted that plaintiffs' challenge to the FDA's 2000 decision to approve mifepristone is precluded by the six-year statute of limitations for challenging agency action.[21]

- *Deference to the FDA:* DOJ argued that plaintiffs' claims are likely to fail on the merits as a matter of law because each of the regulatory decisions at issue were made based on the FDA's expert scientific judgment with respect to the conditions of use, reasonably explained.[22] Further, the government asserted that the court should defer to the FDA's interpretation of Subpart H.[23] Last, the government argued that plaintiffs misinterpret the Comstock Act, citing the OLC opinion (and the consensus among federal courts of appeals) that the law does not prohibit the mailing or conveyance of items designed to produce abortions where the sender does not intend them to be used unlawfully.[24]

Urging the court to reject plaintiffs' preliminary injunction motion, DOJ concluded that plaintiffs' claim of irreparable harm is undermined by the fact that mifepristone has been available for over two decades.[25]

This lawsuit quickly became a flashpoint in the post-*Dobbs* fight over reproductive rights, eliciting participation from several interested stakeholders. For example, on February 6, 2023, the district court granted a motion from Danco Laboratories, LLC—the manufacturer of Mifeprex—to intervene in opposition to Plaintiffs' preliminary injunction motion. Moreover, in recent weeks, a significant number of parties have filed amicus briefs. Amici who have filed in support of plaintiffs include sixty-seven members of Congress, twenty-two Republican Attorneys General, the Susan B. Anthony Pro-Life America group, and other anti-abortion advocacy groups. Amici who have filed in support of the government include a group of food and drug law scholars, twenty-two Democratic Attorneys General, and the American College of Obstetricians and Gynecologists along with other professional

organizations of physicians and public health experts. On March 7, 2023, Texas Attorney General Ken Paxton joined the Mississippi-led Republican Attorneys General amicus brief.[26]

The attention this lawsuit has garnered highlights the high stakes for abortion access—and the unprecedented nature of plaintiffs' request for relief. In the run-up to the court's decision, legal commentators observed that if plaintiffs succeed, "it would be the only time a court has revoked a New Drug Approval (NDA) unilaterally and over the FDA's objection, bypassing the procedural protections for NDA holders explicitly required by Congress before the agency can remove a product from the market."[27] To this point, over 400 pharmaceutical executives signed on to an open letter stating that "Judge Kacsmaryk's act of judicial interference has set a precedent for diminishing FDA's authority over drug approvals, and in so doing, creates uncertainty for the entire biopharma industry" noting that "if courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone. "[28] The lawsuit also garnered significant attention for the judicial assignment. The case was assigned to Judge Kacsmaryk in the Northern District of Texas, who had previously ruled against pro-choice arguments.[29] Judge Kacsmaryk hears 100% of civil cases filed in the Amarillo division of the Northern District of Texas—a fact that has resulted in accusations of forum shopping.[30]

**The District Court's Order**

Judge Kacsmaryk held a hearing on the preliminary injunction on March 15, 2023. The hearing lasted over four hours, during which Judge Kacsmaryk pressed both parties on the full range of issues briefed.

On April 7, 2023, Judge Kacsmaryk granted in part the plaintiffs' request for a preliminary injunction, staying the FDA's various approvals of mifepristone.[31] The District Court also stayed the applicability of the order for seven days to allow the federal government time to seek emergency relief from the Fifth Circuit.[32]

The District Court rejected the government's jurisdictional and procedural objections to the lawsuit. Instead, the District Court held that plaintiff medical associations have both associational standing and organizational standing to bring suit.[33] The Court also rejected the government's argument that plaintiffs' claims are largely untimely or unexhausted on grounds that the "reopening doctrine"—which allows an otherwise untimely challenge where an agency has reexamined its original decision—applies in this case, citing the FDA's expansion of mifepristone access in 2016 and 2021.[34]

On the merits, Judge Kacsmaryk concluded that plaintiffs' challenges to the FDA's actions have a substantial likelihood of success. The District Court held that the plain text of the Comstock Act prohibits the mailing of abortion medication.[35] Additionally, the District Court concluded that the

FDA's 2021 and pre-2021 actions were likely arbitrary and capricious and thus violate the Administrative Procedure Act.[36] Finally, the court agreed with plaintiffs' claim that the FDA's 2000 approval of mifepristone violated Subpart H because pregnancy is not an "illness" and abortion medication does not provide a "meaningful therapeutic benefit."[37] The Court concluded that the FDA's violation was not cured by subsequent statutory amendments. Advancing an argument that plaintiffs did not raise in their briefs, the Court noted that in 2000 the FDA chose not to implement additional restrictions to access mifepristone after a letter was leaked and public controversy ensued, which the Court held violated the administrative law principle that an agency must offer a reasoned justification to change positions when its position conflicts with a prior decision taken by the agency. The Court went on to state that it is authorized to overturn agency decisions that are "in any material way influenced by political concerns," and concluded that such concerns dominated the FDA's 2000 approval process rendering the decision improper.[38]

Shortly after the release of Judge Kacsmaryk's order, the Department of Justice filed a notice of appeal at the US. Court of Appeals for the Fifth Circuit.[39] Absent emergency relief on appeal, the District Court's order is slated to take effect at midnight (CDT) on April 15, 2023. Should that occur, mifepristone will lose its status as an FDA-approved drug and, as a result, it will be illegal for companies to manufacture, market, or distribute mifepristone.

**What Remains of Access to Medication Abortion**

On the same day that Judge Kacsmaryk released his Order in the NDTX suit, a conflicting order from a federal district court in Washington was also released. The two orders have sown confusion about the practical consequences for access to mifepristone.

The Washington litigation arose in response to the NDTX suit. In February 2023, a coalition of seventeen Democratic states and the District of Columbia sued the FDA in the Eastern District of Washington, alleging that a number of the agency's mifepristone restrictions unlawfully burdened access to that drug.[40] Specifically, the suit challenged the FDA's Risk Evaluation and Mitigation Strategy (REMS) program which is comprised of a unique set of restrictions on who can prescribe and dispense mifepristone. Plaintiffs argued that, in light of the proven safety and effectiveness of mifepristone, the REMS designation unnecessarily and unlawfully burdened access to the drug. Plaintiff sought a preliminary injunction, asking the court to (i) declare that mifepristone is safe and effective, (ii) to enjoin enforcement of the challenged REMS, and (iii) to enjoin the FDA from further restricting access to mifepristone.[41] At the time the Complaint was filed, legal commentators speculated that the Washington suit had been filed in an attempt to hasten the cases' resolution by the Supreme Court.[42]

On April 7, 2023, the same day the ruling in the NDTX case was issued, Judge Thomas Rice of the Eastern District of Washington preliminarily enjoined the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk

Evaluation and Mitigation Strategy."[43] However, Judge Rice refused to issue a nationwide injunction, instead granting a preliminary injunction as applied to the seventeen plaintiff states and the District of Columbia.[44] The FDA has not yet stated whether it will file an appeal in the Washington case, though Attorney General Garland's statement indicated that the Department of Justice was reviewing the case.[45]

In light of the conflicting orders, the immediate ramifications of Judge Kacsmaryk's order are somewhat unclear. In response to the NDTX ruling, the FDA could attempt to approve mifepristone again without drawing on its authority under Subpart H, but that process could take months or years. A number of public officials and advocacy groups have instead urged the FDA and Biden Administration to openly defy the district court's decision.[46] These advocates point out that the FDA possesses significant authority in determining how to enforce actions against unlawful drug distribution and that the FDA does not seek enforcement for every unapproved drug on the market. Senator Ron Wyden, for instance, argued that "the Food and Drug Administration has the authority to ignore this ruling, which is why I'm again calling on President Biden and the FDA to do just that."[47]

On April 10, 2023, the FDA filed a motion to stay before the Fifth Circuit, as did intervenor Danco Laboratories. The Fifth Circuit has ordered the Plaintiffs to respond to the two motions by midnight April 11, 2023. FDA's stay motion requests that the Fifth Circuit grant a stay by noon on April 13 to allow the government time to seek emergency relief from the Supreme Court if required to ensure that the district court's order does not go into effect.

Meanwhile, in the Washington suit, FDA has filed two motions: (i) a motion to clarify Judge Rice's order in light of the contradictory ruling from NDTX; and (ii) a motion to expedite a hearing before Judge Rice on the motion to clarify by April 14, 2023. Plaintiffs in the EDWA case oppose the motion to expedite, arguing that unless or until the Fifth Circuit denies the emergency relief requested in the appeal of the NDTX litigation, it is wholly speculative that Judge Kacsmaryk's order will go into effect on April 15.

The contradictory nature of the two orders will likely expedite the cases' arrival at the Supreme Court. In the interim, if the Fifth Circuit grants the government's stay request, mifepristone will continue to remain available pursuant to the FDA's 2023 REMS guidance while the case remains pending. Even if the government ultimately prevails, litigation over the FDA's mifepristone approval—and regulatory and legal changes in the medication abortion space more broadly—will continue to occupy centerstage in the reproductive rights fight in the months and years to come. The Jenner & Block Post-*Dobbs* Task Force will continue to monitor this volatile legal landscape.

## Footnotes

[1] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, The Guttmacher Institute, Feb. 24, 2022, https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[2] *See* Caroline Kitchener, *Covert Network Provides Pills for Thousands of Abortions in US. Post Roe*, Wash. Post (Oct. 18, 2022), https://www.washingtonpost.com/politics/2022/10/18/illegal-abortion-pill-network/.

[3] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, US. Food & Drug Admin. (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[4] US. Department of Justice Office of Legal Counsel, Memorandum Opinion for the General Counsel United States Postal Service, *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions* (Dec. 23, 2022), available at https://www.justice.gov/olc/opinion/file/1560596/download.

[5] Abbie VanSickle & Pam Belluck, *With Dueling Ruling, Abortion Pill Cases Appear Headed to the Supreme Court*, N.Y. Times (Apr. 8, 2023), https://www.nytimes.com/2023/04/08/us/politics/abortion-pill-supreme-court.html.

[6] *See US. Food & Drug Administration et al. v. Am. College of Obstetricians and Gynecologists, et al.*, 141 S. Ct. 578 (2021) (granting application for a stay of a Maryland judge's order overturning FDA's in-person requirement for mifepristone); *see also* Adam Liptak, Abortion Pill ruling May Face Headwinds at the Supreme Court, NYTimes (Apr. 11, 2023), https://www.nytimes.com/2023/04/10/us/supreme-court-abortion-pill-fda.html (discussing recent rulings from the Supreme Court upholding the FDA's authority to regulate drugs).

[7] *Alliance for Hippocratic Medicine v. US. Food & Drug Administration*, No. 2:22-cv-00223-Z (N.D. Tex. 2022).

[8] Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 3, *Alliance for Hippocratic Medicine v. US. Food & Drug Administration*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023) ["Opposition Brief"].

[9] Misoprostol has been approved by the FDA only for the prevention and treatment of gastric ulcers. Its use for abortion, miscarriage treatment or other pregnancy-related purposes is all considered "off label." See Sarah McCammon, *Why an ulcer drug could be the last option for many abortion patients*, NPR, February 24, 2023, available at: https://www.npr.org/2023/02/24/1159075709/abortion-drug-mifepristone-misoprotol-texas-case

[10] 21 C.F.R. §§ 314.500–314.560.

[11] *See* 21 C.F.R. § 314.520.

[12] *See* Opposition Brief at 3–7.

[13] Plaintiffs' Brief in Support of Their Motion for Preliminary Injunction at 25, *Alliance for Hippocratic Medicine v. US. Food & Drug Administration*, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022) ["Preliminary Injunction Brief"].

[14] *See* Complaint at 111, *Alliance for Hippocratic Medicine v. US. Food & Drug Administration*, No. 2:22-cv-00223-Z (N.D. Tex. Nov. 18, 2022) ["Complaint"] ("Declare that 18 US.C. § 1461 and 18 US.C. § 1462 prohibit the FDA from approving a new drug application or a supplemental new drug application that fails to limit distribution of chemical abortion drugs in accordance with these laws.").

[15] *Id.* at 15

[16] *See* 21 US.C. § 355(a), (b).

[17] Preliminary Injunction Brief at 19.

[18] 18 US.C. § 1641 prohibits the mailing or delivery by any letter carrier of "[e]very article or thing designed, adapted, or intended for producing abortion" 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." And 18 US.C. § 1462 forbids the use of "any express company or other common carrier" to transport chemical abortion drugs "in interstate or foreign commerce."

[19] Opposition Brief at 9–14.

[20] *Id.*

[21] *Id.* at 16 (citing 28 US.C. § 2401(a)).

[22] *Id.* at 22–23.

[23] *Id.* at 26.

[24] *Id.* at 28–29.

[25] *Id.* at 31.

[26] *Paxton Supports Efforts to Stop FDA from Expanding Access to Abortion-Inducing Drugs*, Ken Paxton (Mar. 7, 2023), https://www.texasattorneygeneral.gov/news/releases/paxton-supports-efforts-stop-fda-expanding-access-abortion-inducing-drugs.

[27] David S. Cohen, Greer Donley & Rachel Rebouche, *Abortion Pills*, 76 Stan. L. Rev. (forthcoming 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4335735.

[28] *See* Pam Belluck & Chirstina Jewett, *Drug Company Leaders Condemn Ruling Invalidating FDA's Approval of Abortion Pill*, N.Y. Times (Apr. 10, 2023), https://www.nytimes.com/2023/04/10/health/abortion-ruling-pharma-executives.html; Annika Kim Constantino, *Pfizer CEO Signs Open Letter Calling for Reversal of Texas Abortion Pill Ruling*, CNBC (Apr. 10, 2023), https://www.cnbc.com/2023/04/10/abortion-pill-ruling-pfizer-ceo-signs-letter-in-support-of-fda.html.

[29] *See, e.g.*, *Deanda v. Becerra*, No. 2:20-cv-00092, Dkt. 63 (N.D. Tex. Dec. 8, 2022) (Kacsmaryk, J.) (holding that it violates Texas state law and the US. Constitution for minors to obtain birth control through the Title X program without parental consent); *United States ex rel. Doe v. Planned Parenthood Federation of Am.*, 2:21-cv-00022, Dkt. 71 (N.D. Tex. April 29, 2022) (Kacsmaryk, J.) (denying motion to dismiss on the grounds that plaintiff had sufficiently alleged that three Planned Parenthood Texas affiliates and Planned Parenthood Federation of America had defrauded the state's Medicaid system by getting reimbursed for birth control and other basic health care services).

[30] *See* Steve Vladeck, *A Federal Judge Couldn't Handle My Criticism. So He Made Fun of My Tweets.*, Slate (Mar. 29, 2023), https://slate.com/news-and-politics/2023/03/trump-judge-matthew-kacsmaryk-steve-vladeck-tweets.html.

[31] *See* Memorandum Opinion and Order, *Alliance for Hippocratic Medicine v. US. Food & Drug Admin.*, No. 2:22-cv-00223-Z (N.D. Tex. Apr. 7, 2023).

[32] *Id.* at *67.

[33] *Id.* at *6-13.

[34] *Id.* at *19-23.

[35] *Id.* at *32-38.

[36] *Id.* at *49-60.

[37] *Id.* at *40-47.

[38] *Id.* at 56.

[39] *See Statement from Attorney General Merrick B. Garland*, Justice (Apr. 7, 2023), https://www.justice.gov/opa/pr/statement-attorney-general-merrick-b-garland-2. Intervenor Danco Laboratories, the manufacturer of the branded version of mifepristone, Mifeprex, also filed a notice of appeal.

[40] *See Washington et al. v. US. Food & Drug Admin.*, No. 1:23-CV-3026-TOR (E.D. Wa.).

[41] *See* Complaint at 81-82, *Washington et al. v. US. Food & Drug Admin.*, No. 1:23-CV-3026-TOR (E.D. Wa. Feb. 23, 2023).

[42] *See, e.g.*, Sarah McCammon, *Democratic State Attorneys General Sue Biden Administration over Abortion Pill Rules*, NPR (Feb. 24, 2023), https://www.npr.org/2023/02/24/1159375337/democratic-state-attorneys-general-sue-biden-administration-over-

abortion-pill-r.

[43] Dkt. 80, *Washington et al. v. US. Food & Drug Admin.*, No. 1:23-CV-3026-TOR, at 30 (E.D. Wa. Apr. 7, 2023).

[44] The 17 plaintiff states are Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Michigan, Nevada, New Mexico, Rhode Island, Vermont, Hawaii, Maine, Maryland, Minnesota, and Pennsylvania.

[45] *See supra* n.41.

[46] Alice Miranda Ollstein, *Ignore the Courts? Some Democrats Say Texas Abortion Pill Ruling Demands It.*, Politico (Apr. 8, 2023), https://www.politico.com/news/2023/04/08/biden-appeals-abortion-pill-ruling-texas-mifepristone-00091105.

[47] *Id.*

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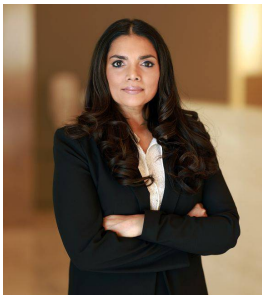

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