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Maintaining Status Quo: The Supreme Court Preserves Access to Mifepristone

On June 13, 2024, the United States Supreme Court (the "Supreme Court") issued its *FDA v. Alliance for Hippocratic Medicine* decision unanimously rejecting attempts to restrict access to mifepristone – a drug typically used as part of a two-drug protocol to treat miscarriages and terminate pregnancy during the first trimester. The Supreme Court held that the parties seeking to challenge the regulation of mifepristone lacked standing to do so (i.e., there was no injury to the doctors or to the anti-abortion groups that sued). This means that mifepristone will remain an available option at this time, preserving:

1) Access during the first 10 weeks of pregnancy,
2) The ability to receive the drug without an in-person appointment (including through telemedicine), and
3) The ability to receive the drug through mail delivery (including across state lines).

The Supreme Court's decision preserves the status quo, and employers sponsoring group health plans providing access to and/or coverage for mifepristone do not need to make any changes.

This Alert outlines the events leading up to the Supreme Court's decision, what the decision means for mifepristone drug coverage today, potential uncertainty for the future, and employer considerations regarding abortion coverage in their group health plans.

Background

In 2000, the U.S. Food and Drug Administration (FDA) approved the use of mifepristone – marketed under the brand name Mifeprex – to terminate pregnancies during the first seven weeks, subject to certain restrictions (including doctor prescription or supervision and requiring three in-person visits in a clinic, medical office, or hospital, referred to as the "in-person dispensing requirement"). The FDA lessened these restrictions in 2016, allowing Mifeprex to be:

- Used during the first ten weeks of pregnancy;
- Prescribed by other healthcare providers, such as nurse practitioners; and
- Prescribed following only one in-person visit.

Highlights

Overview

The Supreme Court rejected a challenge to the availability of mifepristone (a drug typically prescribed as part of a two-drug protocol to terminate pregnancy in the first trimester).

This decision maintains the existing status quo and preserves access to mifepristone:

- for the first 10 weeks of pregnancy;
- without an in-person appointment (including via telemedicine); and
- through mail delivery, including across state lines.

Employer Action

While this decision and Alert is generally relevant to all employers, the Supreme Court decision does not require any employer action.

The Future of Mifepristone

This ruling does not prevent other challenges targeting mifepristone, and future litigation that reaches the Supreme Court seems likely.

In 2019, the FDA approved a generic form of mifepristone. In 2021, the FDA removed the in-person dispensing requirement and added a pharmacy certification process which enabled pharmacies meeting the requirements to deliver mifepristone by mail (including across state lines).[1] In particular, this enabled the prescription of mifepristone by telemedicine health care providers and mail delivery across state lines.

Shortly after the Supreme Court's 2022 *Dobbs v. Jackson Women's Health Organization* decision overturned *Roe v. Wade* and ended the federal protection of abortion rights*, s*everal doctors and four pro-life medical associations (the "plaintiffs") sued the FDA in the U.S. District Court for the Northern District of Texas (the "District Court") under the Administrative Procedure Act, challenging the FDA's approval of Mifeprex in 2000 and its subsequent 2016, 2019, and 2021 actions.[2]

The District Court agreed with the plaintiffs and ordered mifepristone be taken off the market, which prompted the FDA to appeal. On appeal, the U.S. Court of Appeals for the Fifth Circuit (the "5th Circuit") restored the FDA's initial 2000 approval but upheld the injunction on the expanded approvals, preventing the prescription of mifepristone beyond the seventh week of pregnancy or outside of a medical facility and blocking delivery by mail.

The Supreme Court agreed to hear the case and delayed the 5th Circuit's ruling, which preserved access to mifepristone under the FDA's relaxed requirements in the meantime.

Supreme Court ruling

The Supreme Court declined to rule on the merits of the case, including whether the FDA's mifepristone approvals were lawful. Instead, it issued a unanimous decision holding that the plaintiffs lacked standing to sue the FDA (i.e., they had no "personal stake" in the matter) as required under Article III of the U.S. Constitution. The plaintiffs do not prescribe or use mifepristone, and the FDA does not require anything of them in relation to the drug. Instead, the Supreme Court found that the plaintiffs were trying to make mifepristone more difficult for providers to prescribe and for pregnant individuals to obtain. By itself, this did not give them standing to challenge the FDA.

What's next?

Broad, nationwide access to mifepristone remains available for now. Since the Supreme Court did not rule on whether the FDA's mifepristone approvals were valid, they remain vulnerable to challenge by parties that can demonstrate legal standing to sue,[3] which potentially includes under the relatively dormant Comstock Act.[4]

The Attorneys General for Idaho, Kansas, and Missouri previously tried to intervene in the mifepristone case at the Supreme Court level but were denied. They have signaled an interest in continuing the litigation following the Supreme Court's decision and believe the states can show standing, because the availability of mifepristone by mail affects the states' abilities to regulate abortion within their own borders.[5] It is possible other states explore this option.

Given that the *FDA v. Alliance for Hippocratic Medicine* case is technically over, it appears further litigation must start over at the district court level. Future litigation that eventually reaches the Supreme Court seems likely.

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[1] The FDA's 2021 announced modifications were approved on January 3, 2023. Although not approved until this date, there were periods of time prior to January 2023 where the in-person dispensing requirement was not enforced due to *ACOG v. FDA* (an injunction was issued to prevent the FDA from enforcing the in-person dispensing requirement from July 13, 2020, to January 12, 2021). In response to COVID-19, the FDA indicated on April 12, 2021, that it would use discretion with respect to the in-person dispensing requirement.

[2] The repeal of *Roe v. Wade* triggered the litigation over mifepristone. In particular, the FDA's 2021 approval of mifepristone by mail delivery is seen by opponents as conflicting with state efforts to prohibit or restrict access to abortion services. For more details on the impact of the overturn of *Roe v. Wade*, please see our Guide.

[3] See Medication Abortion: New Litigation May Affect Access, Congressional Research Service Legal Sidebar, August 28, 2023, which discusses challenges to state law restrictions on medication abortion.

[4] See The Comstock Act: Implications for Abortion Care Nationwide, April 15, 2024.

[5] It is not clear to us how Kansas can demonstrate standing. Abortion is generally legal in Kansas up to 22 weeks, which is far beyond the FDA's 10-week authorization for mifepristone.

Considerations for employers

Mifepristone remains legally available. The Supreme Court's decision does not require any changes to employer-provided group health plans providing access to and/or coverage for mifepristone.

Employers should continue to consider how state laws affect access to and coverage for abortion-related services.[6] Employers sponsoring self-insured ERISA plans (including telemedicine) generally have the flexibility to decide whether to provide abortion coverage, as they can claim ERISA preemption against state laws relating to plan design and administration. This includes preemption from state laws that may prevent plans from providing coverage for medication used to terminate pregnancies. State laws may still restrict access to other abortion-related services within a given state, necessitating travel elsewhere to receive those services.

By contrast, state insurance laws present greater issues for fully insured plans and self-insured non-ERISA plans, and they may impact the availability of coverage for abortion-related services.

[6] See Interactive: How State Policies Shape Access to Abortion Coverage, Kaiser Family Foundation, December 11, 2023, for an outline of the states that require private insurance plans to provide coverage for abortions and the states that prohibit abortion coverage.

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