Now & Next
Healthcare Alert

June 21, 2024

Supreme Court decision on mifepristone does not address FDA's regulatory approval authority

By Alexandra Busto and April Schweitzer[i]

SCOTUS's unanimous dismissal of *FDA v. Alliance for Hippocratic Medicine* means that the FDA's approval of mifepristone remains intact, and states may decide whether to restrict its availability.

What's the impact?

- Dismissal for lack of standing is not a ruling on the merits; pro-choice and anti-abortion groups have no answer on the constitutionality of the FDA's regulatory authority regarding mifepristone.
- The SCOTUS decision avoids a determination on the constitutionality of the FDA's drug approval process outside of the abortion context and sidesteps widespread implications for other federal agencies' decision-making authority.
- Several states have indicated that they will continue to challenge the FDA's reduced restrictions for mifepristone.

On June 13, 2024, the US Supreme Court unanimously dismissed the suit, *FDA v. Alliance for Hippocratic Medicine*, due to a legal technicality: lack of plaintiff's standing. On its basis, the case

raises challenges regarding the authority of the US Food and Drug Administration (FDA) to approve drugs and, more broadly, whether courts can reverse federal agency rulemaking.

What is mifepristone?

Mifepristone was approved by the FDA in 2000 for use in terminating pregnancies up to seven weeks. To ensure the drug was used safely, the FDA placed restrictions on its use, including requiring doctors to prescribe or supervise the prescription and patients to attend three in-person appointments. In 2016, the FDA approved the drug for terminating pregnancies up to ten weeks and, at the same time, relaxed the prior restrictions by lowering the in-person appointment requirement to one visit and allowing non-physicians to prescribe the drug. In 2019, the FDA approved an application for generic mifepristone. Responding to the COVID-19 pandemic, the FDA announced in 2021 that the in-person requirement would no longer be enforced, allowing mifepristone to be prescribed via telehealth and dispensed through mail orders.

Path to the Supreme Court

Following the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health* to overturn *Roe v. Wade and Planned Parenthood of Southern Pa. v. Casey*, which eliminated the constitutional right to an abortion, the use of abortion medications that could be delivered via mail order, such as mifepristone, became a viable alternative for patients who could not access abortion services in person due to state restrictions. In 2023, the Alliance for Hippocratic Medicine, an anti-abortion medical association, filed a lawsuit against the federal government.

The Alliance for Hippocratic Medicine, alongside other anti-abortion medical associations, argued that the FDA improperly used an accelerated approval process for drugs that treat life-threatening illnesses when it approved mifepristone in 2000. The groups argued that the process was improper for a pregnancy medication and claimed the drug itself was too dangerous. Through this suit, the Alliance for Hippocratic Medicine sought a preliminary injunction that would require the FDA to rescind mifepristone's approval or require the FDA to rescind their 2016 and 2021 actions.

In April 2023, the federal district court judge hearing the case issued a preliminary injunction blocking the drug's approval and leaving the Biden administration one week to appeal. On appeal, the Fifth Circuit held that challenges to the 2000 and 2019 FDA approvals of the drug were unlikely to succeed due to the statute of limitations and no showing of injury. Additionally, until final judgment, the Fifth Circuit reinstated the conditions that existed prior to the FDA's 2016 and 2021 amendments for the drug. These conditions included the requirements that only physicians can prescribe the drug and that it must be dispensed in person rather than allowing mifepristone to be prescribed remotely and sent via mail. The FDA's primary concern was that the Fifth Circuit's decision threatened the agency's scientific drug approval process and decision-making

authority as a federal agency. Parties on both sides asked that the Supreme Court review the issue.

The Supreme Court's unanimous decision

Despite several theories presented to the Supreme Court connecting the FDA's actions to the alleged injury, the Supreme Court unanimously held in its June 13, 2024, decision, authored by Justice Kavanaugh, that the Alliance for Hippocratic Medicine lacked Article III standing to challenge the FDA's mifepristone regulations.

Standing requires a plaintiff to show that (1) they have suffered or will likely suffer an injury in fact, (2) the injury was or will likely be caused by the defendant, and (3) the injury would likely be redressed by the requested judicial relief. The Supreme Court reasoned that the plaintiff's "legal, moral, ideological, and policy objections" to mifepristone use by others while not prescribing or using mifepristone themselves was insufficient to show injury in fact and establish standing.

The outcome of this case, thus, maintains the status quo. By basing its decision on lack of standing, the Supreme Court did not address the question of the FDA's rulemaking authority and, as a result, avoided creating ramifications for the decision-making and authority of other federal agencies. Further, the Supreme Court did not address the question of access to mifepristone, meaning that, under the Dobbs framework, states are free to restrict or protect access to abortion services, including medication abortion. The remanded decision will result in groups advocating for regulatory and legislative changes and expressing their views through political and electoral processes.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Alexandra Busto
213.629.6146
abusto@nixonpeabody.com

April E. Schweitzer
312.977.4365
aeschweitzer@nixonpeabody.com

[i] Philip Cramer, legal intern in the Healthcare group, assisted with the preparation of this alert.