Published on *The National Law Review* https://natlawreview.com

Supreme Court Rejects Challenge to FDA Approval of Mifepristone on Standing, but the Battle Continues

Article By:

Erin Sutton

On June 13, 2024, a unanimous Supreme Court held that physicians and medical associations opposed to abortion lacked standing to challenge the U.S. Food and Drug Administration's (FDA's) approval of the drug mifepristone, which is primarily used in terminating pregnancy.

The Court's decision in *FDA v. Alliance for Hippocratic Medicine* affirms the status quo—mifepristone will remain available to patients without in-person dispensing requirements and for pregnancies up to 10 weeks.

In April 2023, the U.S. District Court for the Northern District of Texas ruled that the physicians and medical associations in this case did have standing to sue the FDA for approving mifepristone in 2000. Based on that standing, the District Court determined that the FDA's approval of mifepristone was invalid under the Administrative Procedure Act and enjoined the FDA's original approval. The District Court delayed its decision for seven days and, as we have previously discussed on this blog, set off a flurry of filings before the Fifth Circuit and Supreme Court, ultimately leading the latter to issue a stay on the District Court's injunction of the FDA's original approval of mifepristone. The stay allowed mifepristone to remain on the market under its current approval and remained in effect through the June 13, 2024 decision by the Court.

FDA v. Alliance for Hippocratic Medicine Decision

The Supreme Court's decision in *FDA v. Alliance for Hippocratic Medicine* affirmed the Court's precedent that standing serves as a bulwark against separation of powers issues—the judiciary established by Article III of the U.S. Constitution can only hear "cases" or "controversies". Justice Brett M. Kavanaugh wrote for the unanimous Court to emphasize that Article III courts are not the appropriate forum for policy debates: "Article III does not contemplate a system where 330 million citizens can come to federal court whenever they believe that the government is acting contrary to the Constitution or other federal law."

The Court rejected each of the physician plaintiffs' and medical association plaintiffs' arguments alleging that the physicians or medical associations had suffered or were likely to suffer an injury if mifepristone—a medication that has been on the market for more than 20 years—remained available to

patients. The Court emphasized that the plaintiff physicians did not themselves prescribe mifepristone and, due to federal and state conscience protections, they could not be compelled to participate in an abortion or other medical act contrary to the physician's moral beliefs. Instead, plaintiffs sought to challenge the availability of mifepristone for others. The Court rejected this theory, reasoning that "a plaintiff's desire to make a drug less available for others does not establish standing to sue."

The Court was similarly unpersuaded by both the plaintiff physicians' and medical associations' allegations of "downstream" conscience or economic injuries to establish standing, calling the plaintiffs' theories "attenuated" and "speculative." The Court also rejected what it deemed a "novel" interpretation of standing that would have opened the door for physicians to challenge government regulations because the changed regulations might result in more patients needing care. The Court acknowledged that such a broad interpretation of standing could result in limitless challenges to FDA approvals of other drugs. The Court further rejected the theory that devoting resources to counter a new government policy was grounds for standing. "An organization cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action," Kavanaugh wrote.

Justice Clarence Thomas agreed with the Court's decision but wrote separately to express that he was "particularly doubtful" of associational standing. "Associational standing" is a theory of standing that would allow a membership organization to establish standing if at least one member of the association could themselves establish harm. Associational standing was not at issue before the Court, though Justice Thomas has often used his dissents or concurrences to signal which way he might vote given the appropriate future set of facts.[1]

The Battle Continues

The Court's decision in *FDA v. Alliance for Hippocratic Medicine* may have manufacturers and distributors of drugs approved by the FDA breathing a sigh of relief. Pharmaceutical companies, executives, and investors as well as representatives of the pharmaceutical research and manufacturing industry, filed *amicus* briefs urging the Court to uphold the FDA's regulatory process for approving new drugs. With the Court focusing on standing as a threshold issue, the Court did not reach merits arguments such as whether the FDA acted within its authority to approve mifepristone. Furthermore, the Court left open the possibility that some party may still be able to challenge the FDA's regulation of mifepristone.

Indeed, shortly after the decision was released, the Attorneys General of Kansas and Missouri vowed to continue to litigate the FDA's approval of mifepristone. The District Court allowed the states of Idaho, Kansas, and Missouri to intervene in the case in January 2024. By that time, the Supreme Court had already granted *certiorari* to review the case, so the three states filed a notice of intervention before the Supreme Court in lieu of an *amicus* brief. The states take the position that the District Court's original injunction against the FDA's approval of mifepristone would still be effective as long as the states remain parties to the case.

The intervenor states allege harm in the form of medication abortion pills being shipped into the states, contrary to state law, and allege that the states are forced to bear the cost of medication abortion through state Medicaid programs. However, similar arguments to establish state standing were unsuccessful in the most recent challenge to the Affordable Care Act—*California v. Texas* .[2] The intervenor states in *FDA v. Alliance for Hippocratic Medicine* will still need to establish "how [their] injury is directly traceable to any actual or possible unlawful Government conduct." *Id*. Unless

the three states can trace these harms to the FDA, as opposed to, for example, third parties who ship medication abortion from other countries into these states, the states' standing theories may prove to be just as attenuated as the physician and medical association plaintiffs.

The Comstock Act of 1873

Advocates opposed to medication abortion are also eager to revive the Comstock Act. The 1873 law declares "[e]very article or thing designed, adapted, or intended for producing abortion," as well as "[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," to be "nonmailable matter."[3] So long as *Roe v. Wade* was the law of the land, Comstock was not enforceable, but it also was never repealed.

After the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, the general counsel of the U.S. Postal Service requested an opinion from the Department of Justice (DOJ) on how to apply Comstock now that *Roe* has been overturned. In December 2022, the Biden Administration issued an advisory opinion to the general counsel of the U.S. Postal Service and determined that, based on existing case law, the Comstock Act should only apply to those materials that are intended to cause an *unlawful* abortion.

A future possible Trump Administration could seek to enforce Comstock strictly, prohibiting mailing of any material used for abortion. Alternately, opponents of abortion may seek to find a plaintiff who would have standing to sue the FDA for its approval of mifepristone and raising the Comstock Act as the plaintiffs in *FDA v. Alliance for Hippocratic Medicine* attempted.

EMTALA Case

We are still awaiting a decision in the cases *Idaho v. United States* and *Moyle v. United States* on whether the federal Emergency Medical Treatment and Active Labor Act (EMTALA) preempts state laws that do not allow health exemptions for abortion. EBG continues to monitor this case and any other significant updates regarding reproductive health.

Epstein Becker Green Staff Attorney Ann W. Parks contributed to the preparation of this post.

ENDNOTES

[1] *E.g.*, Justice Thomas's critique of the substantive due process doctrine in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022) (Thomas, J., concurring).

[2] 593 U.S. 659 (2021).

[3] 18 U.S.C. § 1461.

National Law Review, Volume XIV, Number 166