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What's it to You? Justice Scalia's 41-Year-Old Gatekeeping Question on "Standing" Influences Court to Uphold FDA's Regulation of Mifepristone

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By Noam B. Fischman

Mifepristone is safe for now. On June 13, 2024, the Supreme Court unanimously held that the plaintiffs — doctors and medical associations alike — lacked standing to challenge 2000 and 2019 FDA approvals of mifepristone (brand name: Mifeprex), a drug used to terminate pregnancies through ten weeks gestation. Avoiding a substantive decision on the merits of the plaintiffs' case, the Court held that the plaintiffs' legal and moral objections to elective abortion and the FDA's increasingly relaxed regulation of mifepristone are *not* sufficient to establish Article III standing to advance this lawsuit. The Court noted that a win for the plaintiffs would have had widespread repercussions, not only to the ability of patients to use mifepristone, but also to the regulatory authority of Executive branch agencies to fulfill their regulatory obligations amidst an increasingly divided American citizenry.

Doctors and Associations Lack an Injury in Fact *vis a vis* FDA conduct

The Court's decision overturns an April 7, 2023, decision by the U.S. District Court for the Northern District of Texas, which held that the plaintiffs had

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standing under Article III to bring this case and were likely to win.

Here, the Court did not reach the merits. Justice Kavanaugh, who wrote for the Court, noted that to establish standing a plaintiff must demonstrate:

- That they have suffered or likely will suffer an injury in fact;
- The injury likely was caused or will be caused by the defendant; and
- The injury likely would be redressed by the requested judicial relief.

Government regulations that require or forbid *the plaintiff* from doing something almost always satisfy the first and second prong of the causation requirements noted above. Where government regulation impacts individuals other than the plaintiff(s), standing is far more difficult to establish. Here, the doctors were not themselves seeking to use mifepristone, or to prescribe it. Doctors were not forced to treat patients suffering complications from mifepristone. Rather, doctors alleged a theoretical risk that could happen. Theoretical risks do not suffice to create Article III standing.

As an unregulated party, plaintiffs had to establish causation by demonstrating a "predictable chain of events leading from the government action to the asserted injury. Put differently, plaintiffs had to show that government action had caused or likely would cause injury *to the plaintiff*." For example, causation might have existed here if the doctors could have shown downstream economic injuries. They could not.

Plaintiffs Cannot *Stand* on Conscience Alone

The doctor plaintiffs argued that more pregnant women would suffer complications from mifepristone, which would then force the doctors to perform abortions or to provide abortion-related medical treatment for these women despite their

conscience objections. But the Court rejected this argument. The doctors alleged no evidence to support this theory.

Next, the doctors argued that statutes like the Emergency Medical Treatment and Labor Act (EMTALA) could force doctors to perform procedures that they could not perform based on their moral and religious beliefs. Here, however, the doctor plaintiffs' theory collided with the Church Amendments, which broadly protect doctors from having to perform procedures as these doctor-plaintiffs alleged.

Ultimately, the Court skirted a potential collision between the Church Amendments and EMTALA by noting that EMTALA applies to Medicare participating hospitals with emergency departments (Covered Hospitals) rather than to individual practitioners. As a result, EMTALA does not force any doctor to do anything against their conscience. Rather, EMTALA places a burden on covered providers to ensure that they have adequate staffing ready, willing, and able to perform necessary procedures.

The Potential for More Doctor Visits Does not Suffice Either

Plaintiff doctors also posited that they would suffer monetary and related injuries as a result of the FDA's actions, which plaintiffs alleged would cause them to divert resources and time from other patients to treat patients with mifepristone complications. The Court noted the absence of evidence that mifepristone routinely causes serious side effects. There appears to be no causal link between FDA's de-regulation of mifepristone and any sort of uptick in medical needs for previously pregnant patients who had used mifepristone to terminate the pregnancy. Nor would the Court countenance generalized notions of Article III "doctor standing." Doctors cannot bring these types of challenges by simply alleging that general safety regulations are

too lax. If this were permitted, there "would be an unprecedented and limitless approach and would allow doctors to sue in federal court to challenge almost any policy affecting public health."

Medical Associations Do not Have Standing Here and May Increasingly Face Future Challenges to Their Associational Standing

The medical association plaintiffs argued that they have associational standing because the FDA "caused" them to conduct their own studies on mifepristone. As such, the FDA allegedly placed the medical associations in the position to educate the public about mifepristone's risks. The Court dismissed this argument as well. It held that an organization cannot manufacture standing (e.g., "spend its way into standing simply by expending money to gather information and advocate against the defendant's action."). Moreover, Justice Thomas, in his concurrence, questioned the propriety of the Court's associational standing jurisprudence *writ large*, and invited a future attempt to challenge Article III standing for associations.

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More than perhaps any other Supreme Court case in recent memory, the Court here expressed comfort with the idea that some cases will simply have no judicial resolution. At various points in the opinion, the Court seemed to urge the legislative branch of government to resolve this issue.

What Does This Mean to You?

- **Mifepristone continues to be approved for use in accordance with FDA requirements.** The FDA has approved the use of mifepristone. Although the Court has not placed its imprimatur on the FDA's regulation of mifepristone, that option to induce abortion remains in accordance with the FDA's mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program (see here).

- **State laws may impact the prescription of mifepristone.** Although the FDA has approved prescribing mifepristone, when done so in accordance with FDA requirements, state laws may impose other consequences. For example, in Florida, pursuant to Florida Statute § 390.0111, mifepristone can only be dispensed in-person by a physician and cannot be prescribed for abortions after *six weeks* gestation, with limited exceptions. In other states, prescribing providers must take steps to avoid tripping over criminal statutes or laws that could create civil liability for aiding and abetting in the end of a pregnancy.

- **There is heightened attention to EMTALA and the Church Amendments**. As discussed above, this case highlights the potential friction that could exist between EMTALA and the Church Amendments. EMTALA requires Covered Hospitals to provide abortions when necessary to stabilize a patient with an emergency medical condition, while the Church Amendments allow doctors to refuse to perform abortions if they invoke their federal conscience protections. State conscience laws may also add additional protections for doctors. For these reasons, the Court noted that Covered Hospitals and doctors typically try to plan ahead to ensure they have appropriate coverage in the event a doctor raises a conscience objection. It follows that to plan ahead for these types of situations, Covered Hospitals must know which doctors refuse to perform what procedures. Covered Hospitals must consider what types of policies are appropriate under the law to ensure proper coverage for pregnancy related complications, while ensuring employees are also protected.

- **Additional legal challenges may follow.** The legal battle over mifepristone may move to other theories, which pit state laws against federal law.Anti-abortion groups may also search for a plaintiff with a clearer path to standing to challenge the FDA's actions here. Justice Thomas,

in his concurrence, hinted at this possibility, while simultaneously criticizing the theory of associational standing.

Akerman's Healthcare team is available to answer any questions that you might have regarding the impact of the Court's decision on your practice.
