JENNER & BLOCK

Client Alert: Access to Mifepristone Still Standing for Now, but Questions Remain

Publications

June 13, 2024
By: Jessica Ring Amunson, Ann O'Leary, Shoba Pillay, Dawn L. Smalls, Josh Hsu, Katie B. Johnson, Mary Marshall, Illyana A. Green

On Thursday morning, the Supreme Court issued its decision in *FDA v. Alliance for Hippocratic Medicine*. Justice Kavanaugh wrote for a unanimous Court dismissing the Alliance for Hippocratic Medicine from the case for lack of Article III standing. Justice Thomas joined the Court's opinion in full but wrote a separate concurrence to address the issue of associational standing. Although the decision has generally been hailed as a victory for reproductive rights, the litigation over access to mifepristone is far from over. What is more, the implications for standing doctrine are likely to be litigated for years to come—both in this case and others. In this client alert, we provide insight into how the decision will affect the ongoing litigation over mifepristone, as well as suits brought by entities to vindicate individual rights or interests, including suits by corporations, governments, and nonprofit organizations.

Of note, the Court's decision does not address the merits of the Alliance's claims about the Food and Drug Administration's ("FDA") regulation of mifepristone. Instead, the opinion narrowly resolves the case, as predicted, on the ground that the Alliance had not sufficiently asserted Article III standing to challenge FDA's actions. As the Court described it, the Alliance had three theories of injury, each of which failed to meet the injury-in-fact standard required to establish standing. First, the Alliance argued its members are required to perform incomplete abortions that allegedly occur when a woman takes mifepristone. The Court rejected this argument because federal law provides broad conscience protections that would allow them to refuse to complete the abortion. Second, the Alliance argued that its members suffer monetary and related injuries from the dispensing of mifepristone because they must divert resources to treat patients who present with complications from mifepristone and are exposed to more liability risk as a result. The Court determined that this was unduly speculative, and, moreover, that no doctor had ever been allowed to challenge the FDA's approval of a drug simply because people might arrive in the emergency room with complications. Finally, the Court rejected the Alliance's organizational standing claim, determining that the only reason the organization was suing was the "intensity of its interest" in the subject, which cannot be grounds for standing.

There are three key takeaways from this decision:

- **The litigation over mifepristone is far from over.** First and foremost, this decision does not spell the end of the mifepristone litigation. While this case was pending at the Supreme Court, three states—Missouri, Idaho, and Kansas—successfully intervened at the district court. Now that the case has been remanded, these three states will continue their challenge to the FDA's regulation of mifepristone, and based on their complaint, they intend to make many of the same arguments as the Alliance. Specifically, the three states have challenged the FDA's decisions to expand access to mifepristone from 2016 onward, including the ability to have mifepristone dispensed via telehealth services and distributed by retail pharmacies. Given the district court's willingness to enjoin the FDA's approval entirely and the Supreme Court's failure to reach the merits, it is likely that the states will prevail on at least some of their claims. This would mean another year or more of appeals to the Fifth Circuit and the Supreme Court, with continuing uncertainty surrounding the regulation of mifepristone in the interim.

  Moreover, this stage of the litigation will pose interesting questions of standing, as the three states, like the Alliance plaintiffs, are not regulated by the FDA's actions. However states do receive "special solicitude" under the Supreme Court's standing jurisprudence. Given the frequency with which we have seen states challenge agency action over the past few presidential administrations, the rulings on standing in this case could significantly impact the ability of states and other interested parties to challenge all sorts of agency action in the future.

- **Limits on litigation from unregulated parties.** Although Justice Kavanaugh does not portend to break new ground on the Court's Article III standing doctrine, the opinion adds to a growing line of cases that provide only a narrow window for unregulated parties to challenge a law or regulation. The opinion highlights that unregulated parties will often struggle to establish that their injuries are indeed caused by the regulation or law itself. This emphasis is part of a broader trend, which we saw in the EMTALA oral argument, of limiting litigation to only those plaintiffs or defendants that are directly regulated by an agency action or law. In the EMTALA argument, some of the Justices expressed skepticism that the government could sue the state of Idaho, who was not regulated by EMTALA, as a means of protecting the government's interest in EMTALA's enforcement. The *Alliance* opinion now emphasizes limitations on plaintiffs as well. This narrowing could in turn limit the ability of interest groups representing both public and private entities to litigate against regulations they are not directly affected by—forcing businesses and even individuals whose interests the interest groups purport to represent to litigate cases themselves.

- **Narrowing of organizational and associational standing.** The majority opinion and Justice Thomas's concurrence, which focused on organizational and associational standing, may exacerbate pressure for businesses or entities to litigate independently, rather than as part of a trade group or association.[1] The majority opinion suggests that, in order to establish organizational standing, an organization may need to assert more than the fact that it needed to divert its resources to respond to a problem. Instead, it may need to show that it cannot fulfill its

mission. Depending on how it is interpreted by the lower courts, this may represent a narrowing of organizational standing. Going further, Justice Thomas's concurrence suggests that the Court should eliminate associational standing entirely. According to Justice Thomas, third-party standing, whether organizational or associational, has no support in the Constitution. If this view were to gain traction on the Court, it could significantly limit the ability of trade groups and other organizations to challenge laws that regulate businesses going forward.

Mifepristone remains on the market and the FDA's expansion of access remains the law of the land.

Footnotes

[1] Organizational standing allows organizations to sue when their mission and work is impacted by a law or regulation. *Havens Realty Corp. v. Coleman*, 455 U. S. 363, 379, n. 19 (1982). Associational standing, by contrast, allows membership organizations to sue on behalf of their members, provided their members would have their own independent standing. *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977). Here, the Alliance plaintiffs raised both organizational and associational standing arguments.

Related Attorneys

Jessica Ring Amunson
Partner
jamunson@jenner.com
+1 202 639 6023

Ann O'Leary
Partner
aoleary@jenner.com
+1 415 293 5942

Shoba Pillay
Partner
spillay@jenner.com
+1 312 923 2605

Dawn L. Smalls
Partner
dsmalls@jenner.com
+1 212 891 1639

Josh Hsu
Partner
jhsu@jenner.com
+1 202 637 6344

Katie B. Johnson
Partner
kbjohnson@jenner.com
+1 202 637 6355

Mary Marshall
Associate
mmarshall@jenner.com
+1 202 637 6360

Illyana A. Green
Associate
igreen@jenner.com
+1 202 637 6371

Related Capabilities

Post-*Dobbs* Task Force

Stay Informed →