SUPREME COURT FINDS CHALLENGERS DO NOT HAVE STANDING TO CHALLENGE THE LEGALITY OF MIFEPRISTONE

June 18, 2024

On June 13, 2024, after over a year and a half of litigation, the United States Supreme Court issued an opinion in the mifepristone case. The Supreme Court held (9-0 with Justice Thomas writing a concurring opinion) that the plaintiffs in the case, four pro-life medical associations and several individual doctors, lacked Article III standing to challenge the Food and Drug Administration's ("FDA") approval and regulation of mifepristone. As Justice Kavanaugh wrote for the Court: "Under Article III of the Constitution, a plaintiff's desire to make a drug less available *for others* does not establish standing to sue. Nor do the plaintiffs' other standing theories suffice. Therefore, the plaintiffs lack standing to challenge the FDA's actions."

HISTORY OF MIFEPRISTONE

As discussed in a prior advisory, the FDA first approved mifepristone for medical termination of pregnancy, up to seven weeks gestation, in 2000. In 2016, the FDA (1) extended the use of mifepristone for up to ten weeks; (2) eliminated the requirement for prescribers to report all non-fatal adverse events; (3) reduced the number of in-person clinic visits from three to one; and (4) allowed healthcare providers other than physicians to dispense mifepristone. The FDA also approved a generic version of mifepristone to GenBioPro, Inc. in 2019. In 2021, the FDA suspended the in-person dispensing requirement for mifepristone during the COVID-19 public health emergency, allowing it to be dispensed through the mail or a through a mail-order pharmacy.

PROCEDURAL HISTORY

As previously detailed, this case first arose in November 2022 when a group of doctors and medical associations sued the FDA, the Department of Health and Human Services, and several agency heads in their official capacities, seeking to withdraw the FDA's approval of mifepristone. The United States District Court for the Northern District of Texas, Amarillo Division, agreed with the plaintiffs and stayed the FDA's 2000 approval of mifepristone and all subsequent agency actions stemming from that approval, but delayed the applicability of its order to allow the federal government time to seek emergency relief from the United States Court of Appeals for the Fifth Circuit. Mem. Op & Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 2:22-CV-00223 (N.D. Tex. Apr. 7, 2023).

Following this opinion, the government sought emergency relief from the Fifth Circuit. The Fifth Circuit issued an unpublished order ruling that the FDA's 2000 approval of mifepristone could stand but holding that the plaintiffs could challenge FDA actions that began in 2016 to lift restrictions and make it easier for patients to obtain mifepristone. The Fifth Circuit held that its ruling would stand until the case could be heard on the merits and expedited the case to the next available oral argument calendar. Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023). Following this ruling, the Justice Department, on behalf of the FDA, sought emergency relief from the United States Supreme Court.

Danco, the manufacturer of mifepristone, also sought a stay, which was granted by the United States Supreme Court on April 21, 2023. The effect of the stay was to maintain nationwide access to mifepristone, as it was before the District Court order, ending disposition of the appeal in the United States Court of Appeals for the Fifth Circuit and disposition of a petition for a writ of certiorari to the Supreme Court. Order, *U.S. Food and Drug Administration et al. v. Alliance for Hippocratic Medicine et al.*, No. 22A902 (U.S. Apr. 21, 2023).

A few months later, the Fifth Circuit issued its opinion on the merits of the District Court's order. Order, *Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al.*, No. 23-10362 (5th Cir. Aug. 16, 2023). The Fifth Circuit found that plaintiffs satisfied the requirements for a stay of the FDA's 2016 and 2021 actions. However, due to the Supreme Court's prior order, this stay did not go into effect. Rather, the Supreme Court granted certiorari with respect to the 2016 and 2021 FDA actions held unlawful by the Fifth Circuit.

The Supreme Court heard oral arguments in the matter on March 26, 2024. On June 13, 2024, the Supreme Court issued its opinion holding that plaintiffs did not have standing, reversing the judgment of the U.S. Court of Appeals for the Fifth Circuit, and remanding the case for further proceedings.

OPINION: IT COMES DOWN TO STANDING

The threshold question at issue in this case was whether the plaintiffs had standing to sue under Article III of the Constitution. For a plaintiff to have standing, they must have a "personal stake" in the dispute; they cannot be a mere bystander. This means that a plaintiff must demonstrate that (i) they have suffered or are likely to suffer an injury in fact, (ii) the injury likely was caused or will be caused by the defendant, and (iii) the injury likely would be redressed by the requested judicial relief. Disputes regarding standing generally center around two issues: injury in fact and causation.

"An injury in fact must be 'concrete,' meaning that it must be real and not abstract." Such an injury must also be "particularized" meaning that "the injury must affect 'the plaintiff in a personal and individual way' and not be a generalized grievance." Requiring plaintiffs to show an injury in fact is intended to "screen[] out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action."

Causation requires the plaintiff to "establish that the plaintiff's injury likely was caused or likely will be caused by the defendant's conduct." When a plaintiff challenges the government's regulation, or lack thereof, of other individuals, standing is "ordinarily substantially more difficult to establish." This is usually because it is more difficult for unregulated parties to link their asserted injuries to the government's regulation, or lack of regulation, or someone else.

Plaintiffs in this case offered several theories to connect the FDA's actions to plaintiff's alleged injuries in fact, none of which the Supreme Court found sufficient to establish standing.

Downstream Conscience Injuries

One standing theory advanced by the plaintiffs was that the FDA's relaxed regulation of mifepristone causes them conscience injuries. Specifically, the plaintiffs contended that the "FDA's 2016 and 2021 actions will cause more pregnant women to suffer complications from mifepristone, and those women in turn will need more emergency abortions by doctors." Thus, plaintiffs asserted that "they therefore may be required—against their consciences—to render emergency treatment completing the abortions or providing other abortion-related treatment."

The Supreme Court rejected this argument noting that even if it were true that the FDA's 2016 and 2021 changes caused more women to require emergency abortions and that some women might seek treatment from plaintiffs that "the plaintiff doctors have not shown that they could be forced to participate in an abortion or provide abortion-related medical treatment over their conscience objections," as federal conscience laws protect doctors from being required to perform abortions. The fact that federal law protects doctors from being required to perform abortions "therefore breaks any chain of causation between the FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors."

Downstream Economic Injuries

Plaintiffs also alleged monetary and related injuries due to the FDA's actions. In particular, "diverting resources and time from other patients to treat patients with mifepristone complications; increasing risk of liability suits from treating those patients; and potentially increasing insurance costs." The Supreme Court found that such claims lacked support in the record and were "highly speculative." Furthermore, the Court noted that "the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might show up at emergency rooms or in doctor's offices with follow-on injuries." In other words, "there is no Article III doctrine of 'doctor standing' that allows doctors to challenge general government safety regulations" and the Court declined to create such a doctrine.

Organizational Standing

Lastly, the plaintiff medical associations argued that they had organization standing "to sue on their own behalf for injuries they have sustained" and that "the FDA has 'impaired' their 'ability to provide services and achieve their organizational missions.'" Here, the Court concluded that the medical associations could not establish standing based simply on their interests and strong opposition to the FDA's conduct. The medical organizations asserted that they showed more than a disagreement with the FDA, but that the FDA caused them to incur costs to oppose the FDA's actions, such as conducting their own studies on mifepristone and exerting time, energy, and resources into drafting petitions and engaging in advocacy. However, the Court rejected this argument as well noting that "an organization that has not suffered a concrete injury caused by a defendant's action cannot simply spend its way into standing simply by expending money to gather information and advocate against the defendant's action."

While the plaintiffs also suggested that they must have standing because if they do not, then no one would have standing to challenge the FDA's 2016 and 2021 actions, the Supreme Court concluded that it was not clear no one else would

have standing and that, even if this were the case, the "Court has long rejected that kind of 'if not us, who?' argument as a basis for standing."

CONCLUSION

In conclusion, the Supreme Court's opinion found that the plaintiffs did not have standing but did not address the merits of the case. Thus, while mifepristone currently remains available under the same terms as it did before this litigation, this case remains ongoing and other cases challenging mifepristone are expected.

Our team is continuing to monitor post-*Dobbs* developments on all fronts, including any changes around the regulations regarding mifepristone. For questions regarding any post-*Dobbs* issues, please contact any of the following Hancock, Daniel & Johnson attorneys: Ashley Calkins, Annie Howard, Sandi Douglas, or Mary Malone.