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The Supreme Court Signals That Access to Mifepristone Will Likely Remain Safe for Now

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03/27/2024
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Yesterday, the Supreme Court heard arguments in the two consolidated cases concerning access to mifepristone pending before the Court, *FDA v. Alliance for Hippocratic Medicine*, Case No. 23-235 and *Danco Laboratories, LLC v. Alliance for Hippocratic Medicine*, Case No. 23-236. Mifepristone is one of two medications commonly used in medication abortion since its approval by the Food and Drug Administration (FDA) in September 2000. Since FDA's initial approval of mifepristone for abortion in 2000, FDA has taken a series of actions to alter its "risk evaluation and mitigation strategy" ("REMS")[1] for prescribing mifepristone, which culminated in 2021 with FDA allowing prescribers to prescribe mifepristone via telemedicine, greatly improving access to the drug.

In fact, according to a Guttmacher Institute report, last year almost two thirds of all abortions that took place in the United States were induced via the mifepristone and misoprostol FDA-approved medication abortion regimen.[2] Guttmacher notes that FDA's 2021 suspension of the in-person prescription requirement, finalized in January 2023, "meant that health care providers and online pharmacies could mail abortion medication to patients, including those who live far from a provider or are otherwise unable to make an in-person visit."[3] Although FDA's initial approval of mifepristone and whether it will remain on the market is not at issue, FDA's subsequent actions to expand access to mifepristone and eliminate certain barriers to abortion medication is at the heart of these cases. Whether and how the Court rules in these cases will have broad implications on abortion access in the United States, particularly for patients seeking this care in states in which abortion has been criminalized post-*Dobbs*.

As Solicitor General Prelogar confirmed at argument, these cases mark the first time, to the government's knowledge, that any court has restricted access to an FDA-approved drug by second-guessing FDA's expert judgment about the conditions required to assure that drug's safe use. In its review of a drug, FDA must carefully consider all existing data concerning the drug, including patient experience, in addition to clinical studies. Yet, the district court and the Fifth Circuit both overruled FDA's expert scientific judgment, finding fault with FDA's decision-making process by making a series of legal errors concerning both Article III standing and reliance on flawed scientific studies, which Petitioners (both the government and Danco Laboratories) effectively highlighted at argument.

By way of background, these cases originated in the Northern District of Texas, when the Alliance for Hippocratic Medicine, an association formed in 2022 and comprised of member groups (not individuals) whose doctors oppose abortion on religious and moral grounds, filed suit challenging: (i) FDA's 2000 approval of the branded form of mifepristone, Mifeprex; (ii) FDA's 2016 changes to the drug's conditions of use; (iii) FDA's 2019 approval of generic mifepristone; (iv) the 2021 exercise of enforcement discretion in the midst of the COVID-19 pandemic that suspended the in-person prescribing requirement; and (v) the 2016 and 2021 denials of the Alliance's citizen petitions filed under FDA's administrative procedure to challenge the agency's actions. The district court granted the Alliance for Hippocratic Medicine's motion for a preliminary injunction and granted relief in the form of a stay of FDA's 2000 approval of Mifeprex and all subsequent challenged FDA actions, even though those actions had already been in effect for years. The government and Danco both appealed and sought a stay pending appeal. The Fifth Circuit granted a stay as to FDA's 2000 approval of mifepristone but otherwise denied relief. The government and Danco applied to the Supreme Court for a stay pending appeal, which the Supreme Court granted—thereby staying the district court's order in its entirety pending the outcome in this case.

Yesterday's arguments concerned the Fifth Circuit's decision on the merits, which rejected the district court's arguments concerning FDA's initial approval of mifepristone in 2000, but which affirmed the district court's suspension of FDA's subsequent actions to expand access to the drug. The bulk of argument time concerned whether the Alliance for Hippocratic Medicine had sufficiently asserted Article III standing to challenge FDA's actions. A party seeking to file suit in federal court must demonstrate that they have "standing" to sue, which requires that the party has (1) a concrete and particularized injury, (2) that is traceable to the allegedly unlawful actions at issue; and (3) that can be redressed by a favorable judicial decision. Here, a majority of the Justices seemed skeptical of the Alliance's arguments that two declarations from individual doctors alleged sufficient past harm to clear the Article III hurdle. When pressed by Justice Kagan on their standing argument, Erin Hawley who argued for the Alliance for Hippocratic Medicine, noted that 3.1% of patients who had undergone a medication abortion would later require a dilation & curettage ("D&C") procedure to remove tissue from inside the uterus. Hawley's point seemed to be that some of these patients would inevitably end up in their doctors' ERs where they would be forced to undertake a procedure that they objected to on religious or moral grounds. Justice Sotomayor summarized Hawley's standing argument as "probabilistic," to which Justice Kagan agreed, noting that she did not read the doctors' declarations as sufficient to allege any cognizable past harm.

On the remedy sought, Justices Gorsuch and Jackson pressed Hawley on the mismatch between the handful of doctors facing harm in the form of having to undertake procedures that violate their conscience objections versus the type of nationwide injunction that the district court instituted that would affect every patient's access to mifepristone. Solicitor General Prelogar pointed out that federal conscience protections already provide the remedy the doctors in this case purport to seek, and Justice Kagan affirmed that most hospitals have procedures in place to ensure that conscience objections are respected even in emergency situations.

Two of the nine Justices seemed inclined to bypass the Article III standing question and decide the case on the merits. Justices Thomas and Alito questioned the advocates on whether FDA should have considered the Comstock Act when considering its 2016 and 2021 actions to expand access to the drug. The Comstock Act of 1873 makes it illegal to use the mail and common carriers to mail "obscene materials" defined to include drugs that induce abortions. Solicitor General Prelogar noted that at no time had FDA affirmatively approved dispensing of mifepristone via mail, and both Prelogar and Jessica Ellsworth who argued for Danco Laboratories repeatedly asserted that this question was not before the Court. Justice Alito, meanwhile, appeared troubled by statistics suggesting that in the wake of FDA's 2019 action, emergency room visits related to mifepristone use increased. Here again, Prelogar and Ellsworth worked in tandem to dispel the Justice's suggestion that FDA had not sufficiently taken this into account in studies, noting that most of these emergency room visits did not involve serious adverse events and that FDA expressly reviewed and considered this data in its 2021 action administrative record. These Justices seemed squarely in the minority at argument, though, and the most likely outcome appears to be that a majority vacates the Fifth Circuit decision on Article III standing grounds. Justices Thomas and Alito's interest in the Comstock Act could foreshadow a separate writing on this point that could be used by anti-abortion advocates to attempt to further curtail abortion access in states where abortion is now illegal.

Footnotes

[1]The REMS program is a drug safety framework to ensure that benefits of certain drugs outweigh their risk before bringing them to market.

[2]*See* Rachel K. Jones & Amy Friedrich-Karnik, Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020, Guttmacher Institute, available at https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

[3]*Id.*

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