

On June 13th, the SCOTUS published its opinion in *FDA v. Alliance for Hippocratic Medicine* (2024), in which it unanimously ruled that the plaintiffs lacked standing and therefore could not even legally sue the FDA. This decision reversed a ruling by the Fifth Circuit Court of Appeals, which I discussed in a 2023 article.

This fascinating case involves a medication used for abortion called “mifepristone” which is used in combination with misoprostol for abortions in early pregnancy. It’s currently sold under the brand name “Mifeprex” but was previously known as “RU-486.” The legal controversy mostly focuses on the FDA’s approval and expansion of that approval for mifepristone and whether those agency actions violated federal law. In general, agencies do not have lawmaking power. The Congress is the only branch authorized by the Constitution to propose and pass new laws. Decades ago, the Congress created many agencies and delegated broad regulatory powers to them. But the non-delegation doctrine ostensibly limits how much lawmaking these agencies could do on their own. Additionally, the Administrative Procedures Act stipulates how federal agencies can pass new regulations. One of those requirements establishes a “public comment period” that an agency must hold after publishing a proposed new rule. These periods are generally 30-60 days (or longer) and the agency is supposed to take public comment into account.

Another SCOTUS case heard this term addresses how much power federal agencies have, and I will address that in a future article.

In 2000, the FDA approved the use of mifepristone tablets for terminating pregnancies up to seven weeks. The FDA imposed restrictions on the drug's use and distribution, including requiring doctors to prescribe or supervise the prescription of Mifeprex and requiring patients to have three in-person visits with the doctor to receive the drug. In 2016, the FDA expanded

approval for mifepristone from seven weeks to 10 weeks of pregnancy. In 2021, it announced that it would no longer enforce the initial in-person visit requirement.

This case began when four pro-life medical associations and several doctors sued for a preliminary injunction that would require the FDA to either rescind approval of mifepristone or rescind the FDA's 2016 and 2021 regulatory actions.

The District Court agreed with the plaintiffs and effectively enjoined the FDA's approval of mifepristone, ordering it off the market. The FDA and Danco Laboratories, which sponsors Mifeprex, appealed and moved to stay the District Court's order pending appeal. On the merits, the Fifth Circuit held that plaintiffs had standing and concluded that plaintiffs were unlikely to succeed on their challenge to FDA's 2000 and 2019 drug approvals, but were likely to succeed in showing that FDA's 2016 and 2021 actions were unlawful.

In addition to Danco's lawyer, the federal government's Solicitor General was allowed to make an oral argument and present her case in favor of the broad use of mifepristone in the SCOTUS. I found it interesting that the lawyer for the pro-life doctors was Erin Hawley, the wife of Senator Josh Hawley from Missouri (they apparently met at Yale Law School).

The Alliance for Hippocratic Medicine and the emergency and obstetrical doctors relied on some unique forms of standing (the legal right to sue). The plaintiffs obviously were not personally hurt by taking the abortion medication, because they did not take it. They argued that the FDA unlawfully approved and expanded access to the medication. They also argued that the widespread and reckless use of mifepristone harmed the doctors by forcing them to spend their scarce resources on side-effects and failed abortions due to mifepristone. They attested that they sometimes had to complete the abortion, which violated their core beliefs. They also used the theory that the doctors cherished life and generally enjoyed delivering babies and did not like

seeing or knowing of babies being killed in the womb. This distant third-party theory of standing was successfully utilized by progressives a few years prior. In 2018, the SCOTUS held that kids had standing to sue the government because they felt generally harmed by global warming. The doctors had a more legitimate claim to “injury-in-fact” than those kids, didn’t they?

Solicitor General Prelogar told the SCOTUS at oral arguments that she didn’t believe anyone would have standing to sue the FDA for illegally approving the abortion drug.

The SCOTUS unanimously held that the plaintiffs did not have standing to sue in the first place, so the lawsuit cannot proceed to the actual merits of their claims.