Standing and the Arbitrary and Capricious Standard Pertaining to Reproductive Rights: An Examination of the Fifth Circuit's Decision in *Alliance for Hippocratic Medicine v. FDA*

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Introduction

Since the Supreme Court ruled in *Dobbs v. Jackson Women's Health* that abortion decisions should be given to legislatures[1], reproductive rights have been under attack. *Alliance for Hippocratic Medicine v. FDA* exemplifies this– in August 2023, the Fifth Circuit ruled that the Federal Drug Administration's ("FDA") regulation of mifepristone is arbitrary and capricious, and thus must be returned to pre-2016 regulations.[2] While the Supreme Court has stayed the issue, the Fifth Circuit's ruling, if effected, would severely limit access to abortion, and is yet another step back for women's rights.

Mifepristone is an abortion-inducing drug that was approved by the FDA in 2000 as a safe and effective way to terminate early pregnancies.[3] It is administered in one dose, followed by a dose of misoprostol, to induce an abortion over a period of days.[4] Since its introduction, the FDA has approved administrative changes, including 2016 changes to the administration of the drug, a 2019 approval of a generic form, and a 2021 non-enforcement decision.[5] The 2000 approval and 2019 generic approval issues were dismissed by the 5th Circuit[6]; this Note will focus on the 2016 Amendments and 2021 non-enforcement as the actions subjected to the arbitrary and capricious standard.

Part One of this Note describes the history and administrative changes to mifepristone, and how the Fifth Circuit has ruled to regress the drug's administration. Part Two discusses the plaintiffs' standing to bring this case as physicians on behalf of their patients and as injured parties themselves. Part Three describes and discusses the arbitrary and capricious standard that was used to rule that the FDA improperly altered the drug's administration. Part Four contemplates the potential repercussions of this decision, including standing for abortion providers and the use of the arbitrary and capricious standard in the broader reproductive rights context moving forward.

I. Mifepristone and *Alliance for Hippocratic Medicine v. FDA*

The Alliance for Hippocratic Medicine is a pro-life group of physicians who sued the FDA for its approval of, and subsequent changes to the administration of, mifepristone.[7] The FDA is a

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[1] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2277 (2022).
[2] All. for Hippocratic Med. v. FDA, No. 23-10362 at 62 (5th Cir. 2023).
[3] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMINISTRATION (Mar. 23, 2023), https://perma.cc/57T2-G7DS.
[4] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMINISTRATION (Sept. 1, 2023) https://perma.cc/P3N3-N3TB.
[5] For a full timeline of the FDA's actions leading to this suit, *see* Lorie Sobel, Alina Salganicoff, & Mabel Felix, *Legal Challenges to the FDA Approval of Medication Abortion Pills*, KFF (Mar 13, 2023), https://perma.cc/RP4U-EDGW.
[6] *Alliance*, at 3.
[7] *Id.*

subagency of the Department of Health and Human Services, and is charged with the responsibility of implementing the Federal Food, Drug, and Cosmetic Act.[8]

When the FDA originally approved the use of Mifeprex[9], the applicants included several conditions for effectiveness, and the FDA imposed a number of safeguards for the administration of the drug.[10] The drug was approved under 21 C.F.R. §314 subpart H for treating serious or life-threatening illness.[11] Subpart H authorizes the FDA to approve new drugs "that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments."[12] In 2002, the American Association of Pro-Life Obstetricians and Gynecologists (a party to *Alliance*) filed a citizen petition asking the FDA to revoke its approval of mifepristone, alleging that it was unsafe.[13] The FDA denied the petition in 2016.[14]

In 2007, Congress amended the Food, Drug, and Cosmetic Act, authorizing the FDA to require a "risk evaluation and mitigation strategy" ("REMS") if it determines that it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[15] The FDA approved a REMS for mifepristone in 2011 which imposed essentially the same restrictions as those in place when Mifeprex was approved in 2000.[16]

The FDA imposed several changes to Mifeprex's administration in 2016, including an increased gestational age limit from 7 to 10 weeks, a reduced number of required in-person clinical visits from 3 to 1, a modification to the REMS to allow certain non-physician healthcare providers licensed under state law to prescribe and dispense drugs, an altered dosing regimen, and modified adverse effects reporting requirements.[17] Following these changes and the COVID-19 outbreak, the FDA announced in 2021 that it would no longer enforce the in-person dispensing requirement.[18]

The medical organizations and doctors who formed the plaintiffs in *Alliance* alleged that the FDA's approval of and subsequent changes to Mifeprex's administration violate the Administrative Procedure Act ("APA").[19] The Act requires federal courts to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of

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[8] 21 U.S.C. § 393.
[9] Mifeprex is the brand name of mifepristone.
[10] *Alliance*, at 6-7 (citing *FDA Approval Memorandum to Population Council* at 6).
[11] *Id.* ("'FDA has determined that the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H. The meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure.'... 'Subpart H applies when FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted'").
[12] 21 C.F.R. §314.500 (1992).
[13] *See generally Citizen Petition and Request for Administrative Stay*, (August 2002), https://perma.cc/2LRX-CGBS.
[14] *Citizen Petition Denial Response from FDA CDER to the American Association of Pro Life Obstetricians and Gynecologists, et al*, U.S. FOOD & DRUG ADMINISTRATION (Mar. 30, 2016), https://perma.cc/K6FV-JBWJ.
[15] Pub. L., No. 110-85, tit. IX, § 901, 121 Stat. 823, 922-43; 21 U.S.C. § 355-1(a)(1).
[16] *Mifeprex Risk Evaluation and Mitigation Strategy (REMS)*, U.S. FOOD & DRUG ADMINISTRATION (June 2011), https://perma.cc/6B5C-CJKQ.
[17] *Mifeprex Label*, U.S. FOOD & DRUG ADMINISTRATION (June 2011), https://perma.cc/92EA-Q86Y,
[18] *FDA Response to ACOG April 2021*, ACLU (April 12, 2021), https://perma.cc/84M2-5258.
[19] *Alliance*, at 2.

discretion, or otherwise not in accordance with the law."[20] The alleged injuries for the physicians included (1) that they might have to perform an abortion, which is against their beliefs, (2) mental and emotional strain "above what is ordinarily experienced in an emergency-room setting," (3) diverted time and resources away from ordinary patients, and (4) more risk of complication than the average patient, leading to heightened risk of liability and increased insurance costs.[21]

The Fifth Circuit held that the FDA failed to address or prove important safety concerns, and that the plaintiffs made a substantial showing that the FDA's 2016 amendments and 2021 non-enforcement decision violate the APA.[22] The Court reasoned that the physicians had standing due to injury, traceability, and redressability– more specifically, the physicians treat women who have adverse effects when they take mifepristone, and this is traceable to the FDA because it approved the drug.[23] While a few physicians recited their experiences, some stories were from their colleagues rather than the plaintiff physicians themselves.[24] The Court accepted the physicians' arguments that chemical abortions frequently cause "regret" and "trauma" for patients, which is then extended to the physicians themselves.[25] The court also said that mifepristone patient care involves "enormous stress and pressure" and "a unique level of trauma and distress, due to the high amount of emotional and physical strain often associated with the experience."[26] Furthermore, the Court affirmed the physicians' contention that their involvement with chemical abortions did conceivably divert time and resources away from other patients.[27] Most notably for purposes of this Note's discussion, the Court found that the FDA did not consider the cumulative effects of the 2016 amendments, nor whether the FDA needed to continue to collect data of non-fatal adverse events in light of the REMS changes.[28] The Court concluded that the physicians "face a substantial risk of irreparable harm to their medical practice, mental and emotional health, and conscience," and Mifeprex must be marketed and sold under the conditions in effect prior to the 2016 amendment.[29]

II. Standing

The medical organizations and doctors in *Alliance* made third-party claims on behalf of their patients, as well as firsthand injury claims through associational standing. While the Fifth Circuit decided that associational standing was present and sufficient, it went a step further and discussed third-party standing in its opinion anyway.[30]

Third-Party Standing

[20] 5 U.S.C. § 706(2)(A).
[21] *Alliance*, at 14-15.
[22] *Id.* at 62.
[23] *Id.* at 12, 14.
[24] *Id.* at 16-21.
[25] *Id.* at 21.
[26] *Id.* at 29.
[27] *Alliance*, at 24-25.
[28] *Id.* at 62.
[29] *Id.* at 56.
[30] *Id.* at 14-15.

The Fifth Circuit found that the *Alliance* plaintiffs had associational standing and thus did not need to decide whether the doctors and medical organizations had third-party standing.[31] Nonetheless, the Court stated that the plaintiffs would likely have third-party standing due to the "sufficiently close relationship" with patients and the Supreme Court's precedent allowing physicians to bring claims on behalf of their patients.[32] The plaintiffs did not assert specific injuries on behalf of their patients; rather, the plaintiffs simply stated that they were bringing suit on behalf of their members' patients, and that this is permitted.[33]

A party cannot usually "rest his claim to relief on the legal rights or interests of third parties."[34] There are exceptions, however. For a litigant to assert claims on behalf of a third party, the litigant must (1) have a close relationship to the third party such that the litigant is as effective (or nearly as effective) a proponent of the right as the third party, and (2) there is a hindrance to the third party's ability to protect his or her own interests.[35] Abortion providers have historically been given the ability to litigate on behalf of their patients: A woman cannot safely proceed with an abortion without a provider, and the decision to have an abortion is one in which the provider "is intimately involved," thus giving abortion providers a sufficiently close relationship with the women seeking abortions.[36] The Supreme Court has also recognized hindrances to women's assertion of their own rights, including the desire to maintain privacy rather than litigate in a public suit, and the "imminent mootness" of an individual woman's claim.[37]

At first glance, it does seem as though the medical organizations and doctors in this suit may have third-party standing to litigate on behalf of their patients. However, it is important to acknowledge that the Supreme Court's precedent has upheld rights to providers who seek to *provide* abortions, not *refrain* from providing them. Furthermore, Justices Thomas, Alito, Gorsuch, and Kavanaugh wrote extensively in their dissents in these cases to disparage third-party standing. For example, in his *June Medical Services* dissent, Justice Thomas wrote, "Under a proper understanding of Article III's case-or-controversy requirement, plaintiffs lack standing to invoke our jurisdiction because they assert no private rights of their own, seeking only to vindicate the putative constitutional rights of individuals not before the Court."[38] In his *Kowalski v. Tesmer* concurrence, Justice Thomas wrote, "It is doubtful whether a party who has no personal constitutional right at stake in a case should ever be allowed to litigate the constitutional rights of others."[39] Justice Gorsuch wrote against upholding third-party standing in

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[31] *Id.*
[32] *Id.*
[33] Complaint at 8, All. for Hippocratic Med. v. FDA, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023).
[34] Warth v. Seldin, 422 U.S. 490, 499 (1975).
[35] Powers v. Ohio, 499 U.S. 400, 410-11 (1991).
[36] *See* Singleton v. Wulff, 428 U.S. 106, 117 (1976) ("A woman cannot safely secure an abortion without the aid of a physician… The woman's exercise of her right to an abortion, whatever its dimension, is therefore necessarily at stake here. Moreover, the constitutionally protected abortion decision is one in which the physician is intimately involved."). *See also* June Medical Services v. Russo, 140 S. Ct. 2103, 2118 (2020) ("We have long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations[.]"); Whole Woman's Health v. Hellerstedt, 579 U.S. 582 (2016) (allowing abortion providers to bring suit on behalf of their patients who were detrimentally affected by a Texas law imposing obstacles to abortion).
[37] *Singleton*, 428 U.S. at 117-18.
[38] *June Medical Services*, 140 S. Ct. at 2143 (Thomas, J., dissenting).
[39] Kowalski v. Tesmer, 543 U.S. 125, 135 (2004) (Thomas, J., dissenting).

physician-patient contexts and stated that parent-child and guardian-ward relationships are the kind of "close" relationship needed– the litigator's relationship must be "so aligned with those of a particular right-holder that the litigation will proceed in much the same way as if the right-holder herself were present."[40]

Thus, two questions are most prominent: (1) What is the right of the patients at issue in this case?, and (2) Are the physicians' interests aligned with their patients'? For standing under Article III of the federal constitution, a litigant must have a case or controversy arising under the U.S. Constitution.[41] The right to abortion is no longer constitutionally guaranteed through the right to privacy[42], so it is unclear which constitutional right of the patients the physicians are seeking to protect. Relatedly, the physicians' interests seem counter to their patients' interests: If a patient is seeking an abortion, a pro-life physician aiming to disallow abortion drug usage is likely not "so aligned with those of [the right-holder] that the litigation will proceed in much the same way as if the right-holder herself were present."[43] The Fifth Circuit insists that this is the wrong perspective, and instead that the plaintiffs' interest is protecting patients from mifepristone's potential side effects.[44] This view narrows the interest to side-step the reality that pro-life physicians' quest to prohibit drug-induced abortion reaches beyond only side effects, yet broadens the interest to encompass the notion that people who use medication wish to avoid adverse side effects. In short, suggesting and allowing a loose "protection against side effects" stance is overly simplistic.

In light of distinguishable precedent, Justices' distaste for third-party standing, and a misalignment of physicians' and patients' interests, it is unlikely that the third-party claims in *Alliance* would stand in the Supreme Court.

Injury-In-Fact

Regardless of the third-party claims, the plaintiffs in *Alliance* also made claims of injury towards themselves. The Alliance for Hippocratic Medicine filed suit on behalf of their members and their members' patients by asserting associational standing, which allows organizations to represent the interests of their members.[45] These claims included the possibility of performing abortion, which is against their beliefs; extraordinary mental and emotional strain; diverted time and resources; and greater risk of liability and increased insurance costs.[46] To show an injury-in-fact, a plaintiff must show that he or she has suffered an invasion of a legally protected interest that is concrete and not hypothetical.[47] Beyond this, a plaintiff must allege personal injury "fairly

[40] *June Medical Services*, 140 S. Ct. at 2174 (Gorsuch, J., dissenting).
[41] U.S. Const. art. III.
[42] *Dobbs*, 142 S. Ct. at 2277.
[43] *June Medical Services*, 140 S. Ct. at 2174 (Gorsuch, J., dissenting); *June Medical Services*, 140 S. Ct. at 2167 (Alito, J., dissenting) (citing Elk Grove Unified School Dist. v. Newdow, 542 U.S. 1, 15 (2004)).
[44] *Alliance*, at 35.
[45] *Id.* at 14.
[46] *Id.* at 14-15.
[47] Los Angeles v. Lyons, 461 U.S. 95, 102 (1983).

traceable to the defendant's allegedly unlawful conduct" that is "likely to be redressed by the requested relief."[48] Abstract, past, or speculative injury is insufficient.[49]

The plaintiffs in *Alliance* make speculative and abstract claims. The claim that there is a risk of greater liability and increased insurance costs from providing follow-up care to a woman who took mifepristone may have shown a financial stake, but this situation is hypothetical: No doctor had said that this had actually happened to him or her.[50] Even the doctors' claims of violation of their beliefs rest on a "speculative chain of possibilities," namely, that women will require emergency care, and doctors will not or cannot refer to a non-objecting doctor.[51] The FDA's approval and administrative changes for mifepristone do not require these doctors to administer the drug or perform surgical abortions; these doctors are free to refer patients to other providers.[52] The Court does not allow claims when "[s]peculative inferences are necessary to connect [the plaintiffs'] injury to the challenged actions."[53], as is the situation here.

Even if the doctors have injuries fairly traceable to the FDA's allegedly unlawful conduct, it is questionable whether these injuries would be redressed by the requested relief. As mentioned previously, the doctors are not required to perform abortions. The Fifth Circuit reasoned that the physicians' consciences and monetary injuries have no other legal remedy[54], but a legal remedy hardly seems necessary when the physicians can already opt out of the abortions and avoid the injuries altogether. The restriction of mifepristone's administration would affect women's abilities to have a drug-induced abortion, but even if complications were to occur and/or a woman who had taken mifepristone needed emergency care, the doctors have the choice of whether or not to be involved. One could argue that choosing not to become involved would force the doctors to forego the monetary benefits of performing the abortion, but this falls in line with the doctors' claims that they must divert time and resources away from other patients– by choosing not to become involved, the doctors would get these time and resources back for other patients (putting aside the fact that many plaintiff-physicians are emergency room doctors who would have the same time and resources for any patient who enters, and thus would not be losing resources either way). It would be a stretch to find that the plaintiff-physicians would directly benefit or have injury redress from imposed restrictions on the FDA's decisions regarding mifepristone.

III. The Arbitrary and Capricious Standard

The Administrative Procedure Act establishes the arbitrary or capricious test for agency action.[55] The Supreme Court has explained that this standard "requires that agency action be reasonable

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[48] Allen v. Wright, 468 U.S. 737, 751 (1984).
[49] *Id.*; *Lyons*, 461 U.S. at 102; O'Shea v. Littleton, 414 U.S. 488, 495-96 (1974).
[50] Brief for Petitioner at 18, All. for Hippocratic Med. v. FDA, No. 23-10362 (5th Cir. Sept. 2023) ("Nor did [the respondents or Fifth Circuit] identify any instance in which respondents or any of their members have ever been sued, threatened with a lawsuit, or required to pay increased insurance premiums.")
[51] *Id.* at 14.
[52] *Id.*
[53] Simon v. Eastern Kentucky Welfare Rights Organization, 426 U.S. 26, 45 (1976).
[54] *Alliance*, at 54.
[55] 5 U.S.C. § 706(2)(A).

and reasonably explained."[56] The standard is deferential, which accords with the general principle that courts will not substitute their own judgment for that of the agency.[57] Furthermore, the Court has allowed for changing times, recognizing that "'"'[regulatory] agencies do not establish rules of conduct to last forever,' … an agency must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'"'[58]

The arbitrary and capricious standard has been used to examine agencies' actions for a range of agencies and actions[59], and the Supreme Court explicitly errs on the side of deference.[60] As articulated in *Motor Vehicle Mfrs*, an agency rule would be considered arbitrary and capricious if the agency relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be scribed to a difference in view or the product of agency expertise.[61] In a decision that did *not* uphold agency action, *Motor Vehicle Mfrs.*, the Court found that the National Highway Traffic Safety Administration's ("NHTSA") actions were arbitrary and capricious because the agency failed to consider modifying a standard to require that airbags be utilized, but instead relied on automobile industry preferences and changes.[62] Still, due to the deferential nature of the standard, finding an agency acted arbitrarily and capriciously is a high bar. In the reproductive rights context, the Supreme Court has upheld agency action when confronted with other contraception and abortion-related issues.[63] For instance, in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, Justice Thomas wrote for the majority in holding that the Departments of Health and Human Services, Labor, and the Treasury had not acted arbitrarily or capriciously in carving out religious exemptions for a contraceptive coverage requirement for employer-offered health insurance.[64] The Court based this on precedent, public comment, and other court filings, and emphasized that if the Departments had not taken the Religious Freedom Restoration Act ("RFRA") as part of their actions, they might have been susceptible to arbitrary and capricious claims for neglecting an important part of the problem.[65]

The Fifth Circuit used the arbitrary and capricious standard articulated in the APA to rule that the FDA acted inappropriately in allowing for the 2016 administrative changes and 2019 mail distribution of mifepristone.[66] The Court reasoned that the FDA acted arbitrarily in failing to consider the cumulative effects of the 2016 Amendments that changed the administrative

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[56] FCC v. Prometheus Radio Project, 141 S. Ct. 1150, 1158 (2021).
[57] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Insur. Co., 463 U.S. 29, 43 (1983).
[58] *Id.* at 42 (citing American Trucking Assns., Inc. v. Atchison, T. & S. F. R. Co., 387 U.S. 397, 416 (1967) and Permian Basin Area Rate Cases, 390 U.S. 747, 784 (1968)).
[59] *See* FCC v. Prometheus Radio Project, 141 S. Ct. 1150, 1160 (2021) (upholding the FCC's elimination of certain ownership rules based on market changes and a likelihood that these changes would not harm minority and female ownership); Rust v. Sullivan, 500 U.S. 173, 183, 187 (1991) (upholding the Department of Health and Human Services' regulations limiting the ability of Title X fund recipients to engage in abortion-related activity because the Secretary provided a reasoned analysis for doing so).
[60] *Prometheus Radio Project*, 141 S. Ct. at 1155.
[61] *Motor Vehicle Mfrs.*, 463 U.S. at 43.
[62] *Id.* at 38, 46.
[63] *See also* Rust v. Sullivan, 500 U.S. 173, 183, 187 (1991).
[64] Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2383-84 (2020).
[65] *Id.* at 2384.
[66] *Alliance*, at 62.

requirements for mifepristone, and did not determine whether it needed to continue collecting data of non-fatal adverse effects after REMS changes to Mifeprex.[67]

The Fifth Circuit erred in several ways. For one thing, the Court's determination that the FDA failed to adequately study the effects of mifepristone's 2016 administrative changes is faulty. The FDA has conducted numerous studies and considered 15 years' worth of reporting regarding the safety of mifepristone since its 2000 approval.[68] The drug is used in over half of abortions in the U.S., giving the FDA millions of data points in its safety and effectiveness.[69] The 2016 changes were enacted years before the 2021 non-enforcement action, giving the agency thousands, if not millions, of data points for the changes' effects.[70] Regarding the non-fatal adverse effects, the agency determined based on a decade and a half's worth of reporting that it would be appropriate to continue to monitor these events via periodic safety update reports and annual reports submitted to the FDA by the drug's sponsor.[71] Unlike *Mfrs Auto* but similarly to *Little Sisters,* the agency here explicitly considered and rejected alternative actions such as expressly deciding to collect data on non-fatal adverse effects through sponsor reporting, and based its updated regulations on abundant empirical evidence.[72]

In the broader context, the Fifth Circuit's ruling is an abuse of the standard of review. As explained above, the FDA has conducted extensive research about mifepristone's safety, and has explained its decision-making process thoroughly.[73] The FDA's decisions are based on years of scientific study and adverse event reporting. The arbitrary and capricious standard for review serves a beneficial purpose in ensuring that agencies are held accountable for careful reasoning when action is taken. Still, the Supreme Court of the United States has repeatedly emphasized that agencies should be given deference[74]; if the FDA does not receive deference after utilizing empirical evidence and expressly addressing opposing concerns, it would be difficult to find any agency action that should receive deference.

IV. Potential Repercussions

For the time being, the Supreme Court has stayed this issue, so the Fifth Circuit's ruling will not affect the distribution of mifepristone in states in which it is still legal.[75] However, if the Supreme Court does not revisit the issue, the Fifth Circuit's restrictions are likely to go into effect unless further litigation or stays occur.[76] This would drastically change how the drug is administered, eliminating telemedicine appointments and restricting access to the very first weeks of pregnancy, as well as harming patients by making their only other safe option to undergo more invasive surgical abortions.[77] The implications for both women and the healthcare

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[67] *Id.*
[68] *See* U.S. FOOD & DRUG ADMINISTRATION *supra* note 14.
[69] *The Availability and Use of Medication Abortion*, KFF (Jun. 01, 2023), https://perma.cc/ZV69-Y8F7.
[70] *See* U.S. FOOD & DRUG ADMINISTRATION *supra* note 14.
[71] *Id.* at 25-26.
[72] *See* U.S. FOOD & DRUG ADMINISTRATION *supra* note 14.
[73] *Id.*
[74] *Prometheus Radio Project*, 141 S. Ct. at 1158.
[75] Danco Labs., LLC v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023).
[76] Selena Simmons-Duffin, *Restrictions on abortion pill mifepristone upheld by U.S. appeals court*, NPR (Aug. 18, 2023 4:58 PM ET), https://perma.cc/3JMS-UU89.
[77] *Id.*

system are tremendous– those in limited or no access states will have to travel out of state to receive care[78] (the option of which is also hotly contested)[79]; the much more physically impactful surgical abortion route will be the only safe pregnancy termination option for those who were unable to access the drug; and, as with all abortion restrictions, the healthcare system will be further burdened[80] by reverting back to the pre-2016 differences in dosage and physician involvement.

In February 2023, the Attorneys General from several states filed suit in federal court against the FDA from the other direction, claiming that the administration scheme for mifepristone is too restrictive.[81] The states allege that the FDA unnecessarily singled out mifepristone for excessive regulation, as one of 60 drugs (out of 20,000 FDA-approved drugs) subjected to REMS, despite evidence that it is extremely safe.[82] Whether the courts rule that the regulations are reasonable, or on the other hand that the regulations are too restrictive, the holding will depart from the *Alliance* stance that the regulations were not restrictive enough. Whether the Eastern District Court of Washington, and likely the appellate court afterward, holds for or against the FDA, the ruling will create a regional split.

Alliance has potential implications for both third-party and injury-in-fact standing. While the Fifth Circuit only briefly discussed and approved of the possibility for third-party standing for the plaintiff-doctors to litigate on behalf of their patients, the Supreme Court could still clarify its stance on this issue in this case. Conservative Justices Thomas, Alito, Gorsuch, and Kavanaugh were dissenters in previous cases that allowed third-party standing, who spent much of their dissents on discrediting the notion of third-party standing.[83] Yet, the Court has changed over the last few years: Justices Sotomayor and Kagan are now the liberal minority, with the previously-dissenting Justices now comprising part of a conservative majority. It would not be surprising for the current Court to do away with third-party standing for physicians; although those who are pro-life would want it permitted in this case to help uphold abortion restrictions, eliminating third-party standing would be a greater victory for them in the long run so as to limit plaintiff-physicians' abilities to bring pro-choice claims on behalf of abortion patients moving forward.

Beyond a partisan shift in the Court, allowing standing in this case presents floodgates problems. Permitting physicians to bring suit based on third-party claims for their patients due to side effects would allow virtually any claim to be brought against the FDA for approving medication because every medication has potential side effects. The relative seriousness of side effects

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[78] Kimya Forouzan, Amy Friedrich-Karnik, & Isaac Maddow-Zimet, *The High Toll of U.S. Abortion Bans: Nearly One in Five Patients Now Traveling Out of State for Abortion Care*, GUTTMACHER INSTITUTE (Dec. 7, 2023), https://perma.cc/8643-V48X.

[79] Several states, including Texas, Missouri, Tennessee, and Idaho, have or are working towards restrictions on out-of-state travel for abortions. Jayne Williamson-Lee, *Do all state laws allow people to travel to get abortion access?*, MINNPOST (July 17, 2023), https://perma.cc/7DR8-LR4S.

[80] Margot Sanger-Katz, Claire Cain Miller, & Josh Katz, *Interstate Abortion Travel Is Already Straining Parts of the System*, THE NEW YORK TIMES (July 23, 2022), https://perma.cc/N3V7-5FPV.

[81] *Attorney General Ford Sues FDA Over Unlawful, Unnecessary Restrictions on Medication Abortion Drug*, STATE OF NEVADA (Feb. 24, 2023) https://perma.cc/65FZ-5WBF; Complaint at 49, Washington v. FDA, No. 1:23-cv-03026, (E.D. Wash. filed Feb. 23, 2023).

[82] *Id.*

[83] *See June Medical Services*, 140 S. Ct. at 2143, 2167, 2174 (Thomas, J., Alito, J., Gorsuch, J., dissenting); *Kowalski*, 543 U.S. at 135 (Thomas, J., dissenting).

varies, which may lead to arbitrary line drawing. Similarly, allowing standing for hypothetical injuries would also bring the potential for a floodgates issue. *303 Creative LLC v. Elenis*, which dealt with a hypothetical scenario of forced business with same-sex couples, had already started down this path.[84] If the *Alliance* plaintiffs are permitted to litigate on claims that had not happened yet and are part of a speculative chain, any foreseeable injury, no matter how probable or insignificant, may be litigated.

Particularly important for regulatory schemes as a whole, *Alliance* has implications for guiding agencies on what is arbitrary and capricious. If the FDA's expertise and extensive body of research regarding mifepristone are found to be insufficient for justifying its regulatory decisions, it is unclear what kind or amount of evidence would pass muster to allow agency action to be upheld. The Supreme Court historically leans towards deference, noting empirical evidence, precedent, and consideration of alternatives as relevant factors.[85] The FDA's reasoning checks these boxes. However, it is unclear how precedent will hold up. The current Court is not always one to stick to precedent (Justice Thomas himself has explicitly written that even the doctrine of stare decisis need not be strictly followed)[86]; it is not a stretch of the imagination to think the Court may once again use moral and partisan views to stray from precedent in *Alliance*. While *Little Sisters* upheld agency action in the abortion context and gave deference where deference was due, this case upheld contraception limitation.[87] It is to be determined whether the same deference would be given to an agency attempting to maintain as much accessibility to abortion as possible; the current Court's conservative majority could very well reason along the Fifth Circuit's lines. Should the Court rule in favor of the physician-plaintiffs, despite the FDA's empirical and relatively longstanding evidence, the arbitrary and capricious standard would be further muddied, and may as well not exist as practical guidance moving forward.

Conclusion

Precedent seems to be on the FDA's side regarding standing and the arbitrary and capricious standard of review. Still, the Fifth Circuit's decision disregards this and regresses women's options for reproductive care. It is up in the air if and how the Supreme Court might rule, but affirming the Fifth Circuit's ruling would blur guidance for standing and agency action, and be detrimental to women.

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[84] *See* 303 Creative LLC v. Elenis, 143 S. Ct. 2298, 2308 (2022) (allowing a plaintiff graphic design business owner to clarify her rights in court in anticipation of being forced to do business with same-sex couples).
[85] *See Little Sisters*, 140 S. Ct. at 2384.
[86] *See June Medical Services*, 140 S. Ct. at 2151 (Thomas, J., dissenting) ("Stare decisis is 'not an inexorable command").
[87] *Little Sisters*, 140 S. Ct. at 2384.