Nos. 23-235 & 23-236

# In The Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,

*Petitioners,*

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

*Respondents.*

DANCO LABORATORIES, L.L.C.,

*Petitioner,*

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

*Respondents.*

**On Writs Of Certiorari To The United States Court Of Appeals For The Fifth Circuit**

## BRIEF *AMICI CURIAE* OF PROFESSORS DAVID S. COHEN AND RACHEL REBOUCHÉ IN SUPPORT OF PETITIONERS


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## INTEREST OF *AMICI CURIAE*

*Amici curiae*[1] are two law professors who have taught, practiced, and written extensively about abortion law and the regulation of medication abortion. They are co-authors of *New Abortion Battleground*, 123 Colum. L. Rev. 1 (2023) (with Greer Donley), which was cited by the dissenting opinion in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 394 (2022) (dissenting opinion), and *Abortion Pills*, 76 Stan. L. Rev. (forthcoming 2024) (with Greer Donley).[2]

Professor David S. Cohen teaches constitutional law, including standing and justiciability, at Drexel University's Kline School of Law. He has litigated cases involving standing, including before the Pennsylvania Supreme Court. He also teaches reproductive rights and justice and sex discrimination and the law. Dean Rachel Rebouché is the dean of Temple University Beasley School of Law and the James E. Beasley Professor of Law. She is a leading scholar in reproductive health law and family law.

*Amici* support both Petitioners' argument that Respondents—Alliance for Hippocratic Medicine, other organizations of doctors who oppose abortion, and individual doctors—lack standing because they have

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[1] No counsel for a party authored this brief in whole or in part. No party or party's counsel financially supported this brief, and no one other than *amici* and their counsel financially contributed to this brief.

[2] The third co-author of these articles, Greer Donley, appears as *amicus* in this case on the Brief for Food and Drug Law Scholars as *Amici Curiae* in Support of Petitioners.

failed to demonstrate any concrete, particularized, and actual or imminent injury and that their claimed injuries are fairly traceable to the FDA's actions. *Amici* submit this brief to further examine the causation prong of the Article III standing test and to illuminate the third prong, redressability. Because of unique aspects of the regulation and provision of medication abortion, not only do Respondents fail to satisfy the standing requirement of injury, but they also fail to demonstrate that their claimed injuries are fairly traceable to the FDA and are redressable by the Fifth Circuit's order.

## SUMMARY OF ARGUMENT

The Alliance for Hippocratic Medicine and the other Respondents (hereinafter, collectively, "the Alliance") lack Article III standing to sue. Of the three constitutional requirements for standing—injury, causation, and redressability—the lower courts have focused almost exclusively on injury. However, the Alliance also fails to establish the constitutional requirements of causation and redressability in at least three different ways.[3]

First, the Alliance has failed to establish causation because the harms alleged by the Alliance stem from the independent decisions of third parties not before

[3] *Amici*'s arguments apply with equal force to the state intervenors at the district court level, who filed a motion on January 22, 2024, to intervene before this Court.

the court and are not fairly traceable to the FDA's 2016 and 2021 changes to mifepristone's distribution. Rather, the causes of any such injury are a series of independent decisions of independent third parties: the provider's decision to offer and prescribe mifepristone, the patient's decision to take mifepristone, the patient's decision to seek follow-up medical care, the patient's decision to seek that care from an emergency room physician rather than the prescribing provider, and finally the Alliance doctor's decision to treat the patient rather than transfer or refer to a non-objecting doctor. Simply put, the chain of causation is too attenuated to support standing.

Second, the Alliance has failed to establish that its injuries can be redressed by the requested relief because the FDA regulates drug companies, not the Alliance. As the Alliance conceded in the district court hearing, providers of abortion care, not parties to this case, may turn to other forms of medication abortion if mifepristone becomes too difficult to prescribe because of this case. These other regimens are, like mifepristone followed by misoprostol, safe and effective, but would not change the risk to the Alliance's doctors of providing follow-up care to abortion patients. In addition, the Alliance has not shown that, if the Fifth Circuit's stay is affirmed, the FDA will take action against the drug manufacturers and distributors, who are regulated by the FDA but are not subject to any relief requested or ordered in this case, in a way that will redress the Alliance's claimed injury. Because of the

FDA's discretion to enforce its requirements, redressability is absent here.

Third, redressability is also absent because, even if the Alliance's alleged injury were cognizable, the relief ordered by the Fifth Circuit could very likely increase the possibility that a patient might seek follow-up care from Alliance doctors. The Fifth Circuit's order reinstated the pre-2016 regulatory regime for mifepristone which included a drug label dose of 600mg of mifepristone, triple the current dose of the drug the Alliance claims is causing problems. It also included a different delivery mechanism for the second drug of the two-drug regimen, misoprostol. Collectively, this old regimen—while safe and effective—leads to more side effects than the current regimen. Thus, if anything, reverting to these outdated protocols could *increase* the likelihood that the Alliance's doctors would suffer their claimed injury of being asked to provide follow-up care. Finally, if affirming the Fifth Circuit's stay results in fewer people accessing abortion, the Alliance would be more likely to face people seeking follow-up care because continuing a pregnancy poses greater health risks than abortion. Redressability cannot be found if the cure is worse than the disease.

Accordingly, this Court should reverse the Court of Appeals for the Fifth Circuit for lack of standing.

## ARGUMENT

### I. CAUSATION AND REDRESSABILITY ARE CONSTITUTIONALLY REQUIRED ELEMENTS OF STANDING UNDER ARTICLE III.

Even if the Alliance's claimed injuries were cognizable under Article III, the Alliance fails to satisfy the causation and redressability requirements of standing. This Court has frequently stated that, for a party to establish that it has standing to sue, the asserted injury must be "fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *California v. Texas*, 141 S. Ct. 2104, 2113 (2021) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006)). These two requirements, often referred to simply as "causation" and "redressability," require a close connection between the plaintiff's asserted injuries and the defendant's actions as well as between the asserted injuries and the sought-after court remedy. *See United States v. Texas*, 599 U.S. 670, 676-77 (2023); *Haaland v. Brackeen*, 599 U.S. 255, 291-94 (2023).

As this Court explained in *Allen v. Wright*, there is overlap between causation and redressability: "To the extent there is a difference, it is that the former examines the causal connection between the assertedly unlawful conduct and the alleged injury, whereas the latter examines the causal connection between the alleged injury and the judicial relief requested." 468 U.S. 737, 753 n.19 (1984). Some commentators have suggested that causation and redressability are actually

one inquiry into "remedy." *See* William Baude & Samuel L. Bray, *Proper Parties, Proper Relief*, 137 Harv. L. Rev. 153 (2023) (analyzing this Court's recent focus on the two requirements). However, in case after case, this Court has treated them as separate requirements each needing their own separate analysis; thus, this brief will do the same.

The requirements of causation and redressability are rooted in this Court's prohibition against advisory opinions. Dating to the Court's earliest opinions, the doctrine against advisory opinions buttresses the separation of powers. It is a recognition of the principle that if federal courts were to offer opinions on matters in which they could not order binding remedies, then they would be acting outside of the judicial function. *Hayburn's Case*, 2 U.S. (2 Dall.) 409, 410-14 (1792). Offering such an advisory opinion "would threaten to grant unelected judges a general authority to conduct oversight of decisions of the elected branches of Government. Article III guards against federal courts assuming this kind of jurisdiction." *California*, 141 S. Ct. at 2116 (internal citation omitted); *see also Carney v. Adams*, 592 U.S. 53, 58 (2020).

In this case, the Alliance relies on claims of several different types of injury. The organizations and the individual doctor plaintiffs claim they are forced to care for patients experiencing complications related to mifepristone as a result of the FDA's actions. Doing so allegedly injures them because it "(1) violates their conscience rights, (2) interferes with their medical practices by consuming limited resources, and (3)

increases their exposure to malpractice actions, along with higher insurance costs." Respondents' Br. in Opp. to Cert., at 33. *Amici* agree with Petitioners FDA and Danco that these are not cognizable injuries under this Court's standing precedent.

Yet, even if these injuries are cognizable under Article III, there are too many intervening decisions of independent third-party actors that cause the Alliance's asserted injuries, and the Fifth Circuit's order will not alleviate those injuries; in fact, it could make them worse. Thus, if this Court were to affirm the Fifth Circuit's erroneous holding that the Alliance has standing to bring this lawsuit against Petitioner FDA, it would amount to an unconstitutional advisory opinion because the alleged injury would not be redressed by the court-ordered remedy. *See California*, 141 S. Ct. at 2116 ("To find standing here to attack an unenforceable statutory provision would allow a federal court to issue what would amount to an advisory opinion without the possibility of any judicial relief." (internal quotations omitted)). For this reason, the Alliance's assertion of standing should be rejected, and the Fifth Circuit's opinion holding that the Alliance did have standing should be reversed.

## II. THE ALLIANCE FAILED TO ESTABLISH THE CAUSATION AND REDRESSABILITY REQUIREMENTS FOR ARTICLE III STANDING.

### A. The Alliance's claimed injuries are caused by third parties' intervening actions and are not fairly traceable to the FDA.

When independent decisions of third-party actors not parties to the case are the cause of a plaintiff's asserted injuries, the causation requirement of standing fails. This Court explained this principle in depth in *Allen v. Wright*, 468 U.S. 737 (1984). There, parents of Black children alleged that the IRS's grant of tax exemptions to racially-segregated private schools injured their children by denying them a desegregated education. The Court recognized that this was a serious, cognizable injury. *Id.* at 756. However, the Court called the "line of causation between [the IRS's] conduct and desegregation" of the challenged schools "attenuated at best." *Id.* at 757.

To explain the deficiency, the Court pointed to the independent actions of third parties not before the court. In particular, the Court noted that it was "entirely speculative" whether the administrators at any particular challenged school had adopted the policy of prohibiting Black children from attending the school because of the IRS's tax exemption. *Id.* at 758. It was "just as speculative" whether the parents of the white children attending the private segregated schools had decided to send their children to those schools because

of the IRS's tax exemption. *Id.* at 758. And finally, it was "pure speculation" that the critical mass of school officials and parents in the community had made their attendance policies and decisions based on the IRS's tax exemption. *Id.* at 758. Because of these third-party decisions, "[t]he links in the chain of causation between the challenged Government conduct and the asserted injury are far too weak for the chain as a whole." *Id.* at 759; *see also Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 40-46 (1976) (finding that the causal chain between the grant of tax-exempt status to hospitals and the denial of medical care to indigent patients was broken by the decisions of independent hospital administrators, who were not parties to the case); *see also Warth v. Seldin*, 422 U.S. 490, 508-10 (1975) (finding the causal chain between city's zoning ordinance and neighboring city's lack of low- and moderate-income housing broken by the decisions of neighboring city authorities, who were not parties to the case).

To be clear, standing is not entirely unattainable when the decisions of independent third parties are a part of the chain of causation; however, it is "ordinarily substantially more difficult to establish" standing in such situations. *California*, 141 S. Ct. at 2117 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992)). Causation in such situations can be found only when the plaintiff sets forth specific facts showing that the independent third parties "will likely react in predictable ways" to the challenged government action. *Id.* (quoting *Department of Commerce v. New York*, 139 S. Ct. 2551, 2566 (2019)). For instance, in *California v.*

*Texas*, this Court found that state challengers had not shown that the Affordable Care Act's "unenforceable mandate" caused their state residents, independent third parties not a part of the case, to enroll in the program. The state challengers thus failed to show causation and failed to establish standing generally. *Id.* at 2118-19; *see also Simon*, 426 U.S. at 40-46 (finding that injury caused by hospitals, not parties to the case, was insufficient to show causation).

Here, the causal chain via which the Alliance seeks to link its injury to the FDA's actions is lengthy and attenuated at best, filled with "pure speculation," *Allen*, 468 U.S. at 758, and created by "unfettered choices made by independent actors." *Lujan*, 504 U.S. at 562 (citation omitted). First, doctors and other healthcare providers make independent decisions whether to offer patients a mifepristone prescription. The provider of abortion care must decide whether, as a general matter, to offer patients medication abortion rather than or in addition to procedural abortion. Then, if the provider decides to offer medication abortion, the provider chooses which protocol to offer. While most providers in the United States offer mifepristone followed by misoprostol, some providers offer misoprostol alone. This regimen, endorsed by reputable medical organizations like the World Health Organization and the American College of Obstetricians and Gynecologists and supported by extensive evidence-based research, has been found to be safe and effective.[4] Whether a

[4] *See* World Health Org., *Abortion Care Guideline*, at 67-68, 71 (2022), *available at* https://perma.cc/RU75-EAE3; Am. Coll. of

provider offers mifepristone to patients generally as an abortion option is based on medical and professional judgments about cost, availability, staffing, logistics, experience, and more. This multitude of factors is independent of the FDA's challenged actions.

Second, patients make independent decisions about which method of abortion they want. These decisions are based on a wide range of factors common to patients considering any medical intervention, including cost, insurance coverage, appointment wait times, familiarity, stigma, recommendations, past experience, duration and timing of care, and much more.[5] Studies have found that, when choosing among abortion methods, patients also consider factors such as pregnancy duration, the reactions of others in their life,

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Obstetricians & Gynecologists, Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation* (2020), *available at* https://perma.cc/CD5B-AR6P (hereinafter ACOG Practice Bulletin).

[5] Laura Jacques et al., *Medication or Surgical Abortion? An Exploratory Study of Patient Decision Making on a Popular Social Media Platform*, 225 Am. J. of Obstetrics & Gynecology 344, 346 (2021); Tecora Turner et al., *'I Knew Which One I Wanted': Interviews With Illinois Patients to Explore Abortion Method Decision-Making After Insurance Expansion*, 3 Reproductive, Female & Child Health 1, 2-6 (2024); *see* ACOG Practice Bulletin, *supra* note 4. Some trauma survivors seeking abortion care choose medication abortion, which is less physically invasive than procedural abortion, to safeguard their own physical and emotional well-being. *See* ACOG Committee Opinion No. 825, *Caring for Patients Who Have Experienced Trauma* 3 (2021), *available at* https://perma.cc/89KB-SURH; Lauren Sobel et al., *Pregnancy and Childbirth After Sexual Trauma: Patient Perspectives and Care Preferences*, 132 Obstetrics & Gynecology 1461 (2018).

past experiences with trauma, religious judgment, the effect of abortion on their mental health, future fertility, whether they have a private space at home, pain expectations, experiences with sedation, and more.[6] These factors, which are present whether the 2016 and 2021 FDA changes are in effect or not, mean the choice to obtain an abortion with mifepristone is within the individual decision-making control of patients, not the FDA.

Third, patients make the independent decision, even further removed from the challenged FDA actions, whether to seek follow-up care. Studies show that there is wide variation in when patients, if they feel it is needed, seek follow-up care following a medication abortion.[7] Sometimes patients misinterpret the bleeding and other aspects of the medication abortion process as a sign that something has gone wrong, rather than the medication working as expected, and seek follow-up care for that reason alone.[8] As with any medical treatment, how well patients recall the

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[6] Jane Seymour et al., *What Attributes of Abortion Care Affect People's Decision-making? Results From a Discrete Choice Experiment*, Contraception (2023) (article in press); Erin Wingo et al., *Abortion Method Preference Among People Presenting for Abortion Care*, 103 Contraception 269, 272 (2021).

[7] *See* Ushma D. Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 Obstetrics & Gynecology 616, 619-20 (2017).

[8] *See* Heidi Moseson et al., *Effectiveness of Self-managed Medication Abortion With Accompaniment Support in Argentina and Nigeria (SAFE): A Prospective, Observational Cohort Study and Non-Inferiority Analysis With Historical Controls*, 10 Lancet Glob. Health e105, e109-e112 (2022).

counseling they received from their provider and anyone else familiar with the medication abortion regimen plays a large role in how patients interpret their condition. Thus, the patient's decision about when to seek care, a decision influenced by their own experience and their interaction with others, is a significant factor in whether the Alliance will be asked to see any patients experiencing complications. These patient decisions have no connection to the FDA's 2016 and 2021 actions.

Fourth, patients seeking follow-up care after mifepristone have many options to choose from in making the independent decision where to obtain such care: from the provider from whom they obtained the medication or the prescription; from another health care provider they already have a relationship with, such as their primary care provider; from hotlines that work with people following medication abortions; from online support groups; from an urgent care facility; or from a local emergency room. Patients make these decisions based on factors such as insurance coverage, physical proximity, retention of follow-up care information, online searches, experiences with different healthcare providers in the past, and more. Nothing in the FDA's 2016 or 2021 actions has any impact on the decisions patients make in this regard. Rather, patients, independent of any FDA actions challenged in this case, make these decisions about where to seek follow-up care.

Finally, the Alliance's doctors make their own independent decisions that also break the chain of

causation. If, after all of the other independent decisions in the chain set forth above, a patient seeking post-medication abortion care were to present to an Alliance doctor who objects to treating that patient, that doctor has the option to refer the patient to another provider. Thus, Alliance providers objecting to abortion who encounter a patient following an abortion are making their own choice to treat the patient rather than referring to another provider. Moreover, federal laws extend protections to objecting providers. *See*, *e.g.*, 42 U.S.C. § 300a-7 (Church Amendment); Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022) (Weldon Amendment). With these options and protections, the Alliance doctors have the choice to decline to care for the patient. By failing to exercise that choice, they are "inflicting harm on themselves," the last break in the chain of causation from the FDA to their asserted injuries.[9] *See Clapper v. Amnesty International, USA*, 568 U.S. 398, 416 (2013) (stating that

[9] Less removed from the FDA's changes than the factors explained here but still relevant to the causation inquiry are the initial decisions of the drug manufacturers (the entities regulated by the FDA). Like any regulated drug manufacturer, Danco and GenBioPro make their own business decisions about how much mifepristone to put on the market. These are decisions related to familiar market factors such as expenses, staffing capacity, manufacturing facilities, distribution networks, customer demand, customer ability to pay, and more. These business decisions determine how much mifepristone is on the market. While certainly the regulatory environment forms the backdrop of these business decisions, many other independent considerations also factor into Danco's and GenBioPro's choices.

"respondents cannot manufacture standing merely by inflicting harm on themselves").

Because of this long chain of causation involving many different actors making many different decisions, the Alliance's alleged injury is not fairly traceable to the FDA's 2016 and 2021 changes. Those changes may influence some of the choices made early in the chain of causation, but the chain grows too long, leaving the FDA's changes far too removed from the Alliance's claimed injury. When the asserted harm is too attenuated from the challenged action, federal courts must dismiss the action for lack of standing. Here, there are many more actions and decisions of multiple independent third parties than were present in *Allen* and *California*, breaking the chain of causation between the FDA's actions and the Alliance's asserted injuries. Thus, the Alliance has failed to establish standing to pursue this action.

### B. Because the Alliance is not regulated by the FDA, redressability is substantially more difficult to prove, and the Alliance fails to satisfy this heightened requirement.

Redressability is much more difficult to prove for a plaintiff like the Alliance because the defendant agency does not regulate it. Writing for the Court in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), Justice Scalia explained that "[w]hen the suit is one challenging the legality of government action or inaction

. . . standing depends considerably upon whether the plaintiff is himself an object of the action (or foregone action) at issue." *Id.* at 561. Where, as in this case, "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of someone else," Justice Scalia wrote that "much more is needed. In that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction—and perhaps on the response of others as well." *Id.* at 562. The plaintiff must "adduce facts showing that" the decisions made by independent actors not before the court "have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.*

Summarizing these principles, Justice Scalia concluded, "[t]hus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Id.* at 562 (quoting *Allen*, 468 U.S. at 758). Applying these rules to the facts in *Lujan*, a plurality of the Court[10] found that environmentalists challenging the Secretary of the Interior's funding of foreign construction projects failed to meet the redressability requirement because a ruling prohibiting such funding was unlikely to affect

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[10] The rules about third parties and causation and redressability come from Justice Scalia's majority opinion in *Lujan*. The application of those rules to the facts in that case appear in the four-Justice plurality section of Justice Scalia's opinion.

the challengers, as they were not regulated by the Secretary. *Id.* at 568-71 (Scalia, J., plurality).

Just this past Term, this Court once again emphasized the importance of redressability by applying this principle from *Lujan* to deny standing to states challenging the constitutionality of the Indian Child Welfare Act (ICWA). In *Haaland v. Brackeen*, 599 U.S. 255 (2023), the Court found that state courts and agencies implemented ICWA, and therefore that a lawsuit against the federal agency responsible for ICWA did not satisfy the redressability requirement. Justice Barrett's opinion for the Court reasoned that "[t]he state officials who implement ICWA are 'not parties to the suit, and there is no reason they should be obliged to honor an incidental legal determination the suit produced.'" *Id.* at 293 (citing *Lujan*, 504 U.S. at 569). The Court concluded, "an injunction would not give petitioners legally enforceable protection from the allegedly imminent harm." *Id.*

That the state courts might change their behavior in light of an opinion from this Court was not enough. Redressability requires that the court's exercise of its remedial power, not its persuasive opinion-writing, alleviate the plaintiff's asserted injury. *Id.* at 294 ("It is a federal court's judgment, not its opinion, that remedies an injury; thus it is the judgment, not the opinion, that demonstrates redressability."); *see also United States v. Texas*, 599 U.S. at 691 (Gorsuch, J., concurring in judgment) ("We measure redressability by asking whether a court's judgment will remedy the plaintiff's harms.").

The same circumstances present in *Lujan* and *Brackeen* are present here. The FDA regulates drug companies, not the Alliance or any Respondent in this case. Thus, as did the plaintiffs in *Lujan* and *Brackeen*, here the Alliance bears the burden of proving that, under standing's redressability requirement, the independent actors not before the court[11] will change their behavior in a way that will remedy the asserted injury as a result of a court injunction. The Alliance is unable to show redressability here for at least two different reasons.

First, if the FDA enforces its pre-2016 regulatory regime in response to the Fifth Circuit's order, the Alliance cannot prove that providers of abortion care will limit their provision of medication abortion. As previously discussed, there is more than one evidence-based regimen for medication abortion. The regimen challenged in this case involves the use of mifepristone followed by a second drug, misoprostol. However, some providers in the United States and many providers around the world prescribe misoprostol alone as a form of abortion. As noted above, this regimen is endorsed by the World Health Organization and the American College of Obstetricians and Gynecologists as a safe and effective method of abortion.[12]

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[11] Danco has intervened and is now a party to this case. However, neither the Alliance's requested relief nor the relief ordered by either of the lower courts imposes any direct obligation on Danco, GenBioPro, providers, or patients. Rather, the requested and ordered relief is directed entirely at the FDA.

[12] *See supra* note 4.

No matter the outcome of this case, doctors and other healthcare professionals will be able to prescribe misoprostol for patients who choose this method to end their pregnancies, and the Fifth Circuit's stay will not affect them doing so. Importantly, misoprostol is not the subject of this challenge (or any similar challenge), nor is it subject to any distribution restrictions from the FDA. During the hearing in the district court, the Alliance recognized that misoprostol's availability would not be affected by this case and that it was likely that some providers who currently offer mifepristone-misoprostol medication abortion would offer a misoprostol-only regimen if the Alliance prevailed. ROA 4418-20. The Alliance overlooks the fact that continued availability of misoprostol, regardless of the outcome of this case, would leave its alleged injuries unredressed. Indeed, because of the misoprostol-only regimen, the Alliance cannot argue that a ruling in its favor would reduce the number of people using medication to end early pregnancies. This is almost identical to the redressability deficiency the Court found in *Simon*, where it held that it was "purely speculative" that the court-ordered relief would alleviate the lack of care being provided to indigent patients because hospitals, who were not party to the case, could continue with their challenged denial of care even if the plaintiffs succeeded. 426 U.S. at 42.

Further, if providers of abortion care began more widely offering misoprostol-only regimens for medication abortions because of a ruling changing the conditions of use for mifepristone, not only will the Alliance's

asserted harms not be redressed, but they may also increase. Misoprostol-only abortions, though safe and effective, can result in higher rates of various common side effects, including nausea, fever, and diarrhea.[13] Thus, it is possible that an increased number of patients would seek follow-up care if more providers offer misoprostol-only abortions. Again, even if the Alliance had a cognizable harm, which it does not, increasing the number of patients who receive misoprostol-only abortions would not redress their injury; indeed, it could increase it.

Second, the Alliance has not shown that, if it obtained its requested relief, the FDA would take action against the drug companies that would redress its alleged injuries. The FDA has broad and long-recognized discretion in whether and how to enforce its restrictions against drugs, like mifepristone, that are safe and effective. *Heckler v. Chaney*, 470 U.S. 821, 827-38 (1985) (affirming the FDA's broad enforcement discretion). This past Term, Justice Kavanaugh, in an opinion for the Court, reviewed at length the nature of

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[13] *See, e.g.*, Elizabeth G. Raymond et al., *Medication Abortion With Misoprostol-Only: A Sample Protocol*, 121 Contraception 1, 5 (2023) ("Misoprostol causes uterine cramping, nausea, and vomiting, and some research studies report a higher incidence of fever, chills, and diarrhea after misoprostol-only regimens than after mifepristone and misoprostol."); Nguyen Thi Nhu Ngoc et al., *Comparing Two Early Medical Abortion Regimens: Mifepristone+Misoprostol vs. Misoprostol Alone*, 83 Contraception 410-12, 415 (2011) (study participants who received misoprostol alone were significantly more likely to report experiencing diarrhea (71%) compared to participants given mifepristone followed by misoprostol (58.5%)).

executive branch agencies' enforcement discretion and the rationale behind such discretion not presenting a justiciable issue under Article III. *See United States v. Texas*, 599 U.S. at 676-78. As Justice Gorsuch further explained in *Texas* with respect to immigration-enforcement guidelines, "[a] judicial decree rendering the Guidelines a nullity does nothing to change the fact that federal officials possess the same underlying prosecutorial discretion. Nor does such a decree require federal officials to change how they exercise that discretion in the Guidelines' absence." *Id.* at 691 (Gorsuch, J., concurring in judgment). Replace "the Guidelines" with "FDA's 2016 and 2021 changes" and the redressability problem here becomes obvious.

The FDA has used enforcement discretion before for mifepristone, as it decided in April 2021 that, because of the pandemic, it would not enforce its requirements related to in-person dispensation of the drug. J.A. 364-65.[14] The possibility that the FDA might exercise its discretion once more, this time in response to an affirmance of the Fifth Circuit's stay, defeats the Alliance's attempt to show that its asserted injury would be redressed by a successful outcome. As this Court concluded last Term in *Department of Education v. Brown*, redressability is absent when "redress turns on the Government's wholly discretionary decision." 600 U.S. 551, 564 (2023).

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[14] Moreover, the possibility of FDA enforcement discretion in response to an unfavorable order in this case has already been discussed by Justice Alito. *Danco Laboratories v. FDA*, 143 S. Ct. 1075, 1076 (2023) (Alito, J., dissenting).

Thus, because of the decisions by independent third parties and the FDA that would ensue after a ruling granting its requested relief, the Alliance has failed to meet the heightened burden of showing that a ruling in its favor will redress its claimed injuries.

### C. The Alliance's alleged injury is not redressable because the requested relief would make the Alliance's claimed injuries worse, not better.

Finally, it is axiomatic that redressability is absent if the relief obtained from the court would make the claimed injury worse. This Court has never addressed such a situation, but several circuit court decisions have agreed that when the requested relief exacerbates the asserted injury, standing fails for a lack of redressability. *See*, *e.g.*, *Waterkeeper Alliance, Inc. v. Regan*, 41 F.4th 654, 662 (D.C. Cir. 2022); *Beehive Telephone Co., Inc. v. FCC*, 179 F.3d 941, 944 (D.C. Cir. 1999).

Here, the relief ordered by the Fifth Circuit would exacerbate the injuries advanced by the Alliance in at least two ways. First, the Fifth Circuit's order rolls back the labeling indications in several ways that, for doctors who follow these requirements in response to the Fifth Circuit's order,[15] could increase the Alliance's

[15] Before 2016, many doctors were already using the lower dosage because FDA regulation does not bind prescribers, who frequently prescribe drugs off-label. However, some states require

purported injuries. Most obviously, the Fifth Circuit reinstates the label-indicated dosage of mifepristone to 600mg, a change from the 200mg on the current label. The relief ordered by the Fifth Circuit here would thus *triple* the label-indicated dosage—of a drug that the Alliance claims is so harmful that its distribution must be altered by federal court intervention.

The Fifth Circuit's stay that would triple the label-indicated dose of mifepristone would thus not redress the claimed injury here. This conclusion is almost self-evident. As a general matter, to lower safety risks and minimize drug exposure leading to adverse events, the FDA advises selecting "the lowest dose that will provide a desired therapeutic effect."[16] Particular to mifepristone, studies have shown that the current label indications are safe and more effective than those in place prior to 2016.[17] These studies show that the

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on-label prescription of medication abortion, such as Ohio. Ohio Rev. Code § 2919.123; *Cordray v. Planned Parenthood Cincinnati Region*, 911 N.E.2d 871 (Ohio 2009) (interpreting § 2919.123 to require Ohio physicians to follow the FDA label).

[16] *See* FDA Office of Clinical Pharmacology, *Request for Qualification of MCP-Mod as an Efficient Statistical Methodology for Model-Based Design and Analysis of Phase II Dose Finding Studies Under Model Uncertainty* 10 (2015), *available at* https://perma.cc/DP3V-XXCQ (explaining that finding the lowest effective dose "minimize[s] unnecessary drug exposure that will not lead to additional benefit to the patient but may increase the risk or severity of adverse events").

[17] *See*, *e.g.*, Ushma D. Upadhyay et al., *Comparison of Outcomes Before and After Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study*, PLOS Medicine (2016), *available at* https://perma.cc/6MU7-YWSW.

increased dose used as part of the pre-2016 protocol was safe and effective, but led to more bleeding and side effects. Clearly an order reimposing outdated labeling with a higher dosage indication does not redress the Alliance's alleged injuries.[18]

Second, even if the Alliance's and the Fifth Circuit's assumptions about causation are true—in other words, even if reinstating the pre-2016 landscape for mifepristone leads to fewer people accessing mifepristone[19]—in that scenario, the Alliance's claimed injuries would also increase. Certainly, some people unable to access mifepristone in this new environment would still obtain a procedural abortion. However, given travel, cost, and logistical barriers, many of the people

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[18] The labeling protocol reinstated by the Fifth Circuit could create other problems that would worsen the Alliance's alleged injuries. The pre-2016 dosing regimen was effective, but relatively less effective than the current one; returning to this less effective regimen could lead to more patients seeking follow-up care. *See* Brief for Danco Labs. at 33. Also, the Fifth Circuit order would return label-indicated misoprostol administration to oral rather than buccal, which could also increase the risk of common adverse effects and lead to more follow-up care. *See* Melissa J. Chen & Mitchell D. Creinin, *Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstetrics & Gynecology 12, 12 (2015) ("The transition from oral to alternative routes of administration, including vaginal, buccal, and sublingual, is associated with increased efficacy and fewer side effects."). Each of these changes that are part of the Fifth Circuit's order increases the risk that Alliance doctors will see medication abortion patients for follow-up care.

[19] If there is no reduction in mifepristone use as a result of this case, it almost goes without saying that there is no redress here.

unable to access mifepristone would not be able to obtain an abortion at all.[20] Those people will be forced to remain pregnant, subjecting them to all the risks associated with continuing a pregnancy and then giving birth. These risks are much more significant and frequent than the risks associated with any form of abortion.[21] Thus, if more people remain pregnant as a result of the Alliance's successful claims, more people will need emergency care during their pregnancies, consuming even more of the Alliance doctors' limited resources and increasing their risk of malpractice lawsuits, two of the injuries they claim as the basis of their standing here.

Therefore, if the Fifth Circuit's stay were to reinstate the pre-2016 landscape, the claimed injuries in this case would be exacerbated, not lessened. This is the opposite of redressability.

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[20] Elizabeth A. Pleasants et al., *Association Between Distance to an Abortion Facility and Abortion or Pregnancy Outcome Among a Prospective Cohort of People Seeking Abortion Online*, 5 JAMA Network Open e2212065 (2022); Kristen M. Thompson et al., *Association of Travel Distance to Nearest Abortion Facility With Rates of Abortion*, 4 JAMA Network Open e2115530 (2021) (findings suggest that people who would want abortion care are unable to because of greater travel distances to access abortion services).

[21] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (2012).

## CONCLUSION

For the foregoing reasons, the Alliance fails to satisfy the Article III requirements of causation and redressability. Therefore, the judgment of the Fifth Circuit should be reversed.

Respectfully submitted,

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