PRELIMINARY PRINT

VOLUME 602 U. S. PART 1

PAGES 367–402

OFFICIAL REPORTS

OF

THE SUPREME COURT

JUNE 13, 2024

REBECCA A. WOMELDORF
REPORTER OF DECISIONS

Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.* ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 23–235. Argued March 26, 2024—Decided June 13, 2024*

In 2000, the Food and Drug Administration approved a new drug application for mifepristone tablets marketed under the brand name Mifeprex for use in terminating pregnancies up to seven weeks. To help ensure that Mifeprex would be used safely and effectively, FDA placed additional restrictions on the drug's use and distribution, for example requiring doctors to prescribe or to supervise prescription of Mifeprex, and requiring patients to have three in-person visits with the doctor to receive the drug. In 2016, FDA relaxed some of these restrictions: deeming Mifeprex safe to terminate pregnancies up to 10 weeks; allowing healthcare providers, such as nurse practitioners, to prescribe Mifeprex; and approving a dosing regimen that required just one in-person visit to receive the drug. In 2019, FDA approved an application for generic mifepristone. In 2021, FDA announced that it would no longer enforce the initial in-person visit requirement. Four pro-life medical associations and several individual doctors moved for a preliminary injunction that would require FDA either to rescind approval of mifepristone or to rescind FDA's 2016 and 2021 regulatory actions. Danco Laboratories, which sponsors Mifeprex, intervened to defend FDA's actions.

The District Court agreed with the plaintiffs and in effect enjoined FDA's approval of mifepristone, thereby ordering mifepristone off the market. FDA and Danco appealed and moved to stay the District Court's order pending appeal. As relevant here, this Court ultimately stayed the District Court's order pending the disposition of proceedings in the Fifth Circuit and this Court. On the merits, the Fifth Circuit held that plaintiffs had standing. It 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. This Court granted certiorari with respect to the 2016 and 2021 FDA actions.

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*Together with No. 23–236, *Danco Laboratories, L.L.C.* v. *Alliance for Hippocratic Medicine*, also on certiorari to the United States Court of Appeals for the Fifth Circuit.

Syllabus

Held: Plaintiffs lack Article III standing to challenge FDA's actions regarding the regulation of mifepristone. Pp. 378–397.

(a) Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." *United States* v. *Texas*, 599 U. S. 670, 675. Standing is "built on a single basic idea—the idea of separation of powers." *Ibid.* Article III confines the jurisdiction of federal courts to "Cases" and "Controversies." Federal courts do not operate as an open forum for citizens "to press general complaints about the way in which government goes about its business." *Allen* v. *Wright*, 468 U. S. 737, 760. To obtain a judicial determination of what the governing law is, a plaintiff must have a "personal stake" in the dispute. *TransUnion LLC* v. *Ramirez*, 594 U. S. 413, 423.

To establish standing, a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief. See *Summers* v. *Earth Island Institute*, 555 U. S. 488, 493. The two key questions in most standing disputes are injury in fact and causation. By requiring the plaintiff to show an injury in fact, Article III standing screens 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. Causation is "ordinarily substantially more difficult to establish" when (as here) a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of someone else." *Lujan* v. *Defenders of Wildlife*, 504 U. S. 555, 560–561. That is because unregulated parties often may have more difficulty linking their asserted injuries to the government's regulation (or lack of regulation) of someone else. Pp. 378–385.

(b) Plaintiffs are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used *by others*. Because plaintiffs do not prescribe or use mifepristone, plaintiffs are unregulated parties who seek to challenge FDA's regulation *of others*. Plaintiffs advance several complicated causation theories to connect FDA's actions to the plaintiffs' alleged injuries in fact. None of these theories suffices to establish Article III standing. Pp. 385–396.

(1) Plaintiffs first contend that FDA's relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctors. Even assuming that FDA's 2016 and 2021 changes to mifepristone's conditions of use cause more pregnant women to require emergency abortions and that some women would likely seek treatment from these plaintiff doctors, 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. Federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences. Federal law protects doctors from repercussions when they have "refused" to participate in an abortion. §300a–7(c)(1). The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience since mifepristone's 2000 approval. Further, the Emergency Medical Treatment and Labor Act (or EMTALA) neither overrides federal conscience laws nor requires individual emergency room doctors to participate in emergency abortions. Thus, there is a break in any chain of causation between FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors. Pp. 386–390.

(2) Plaintiffs next assert they have standing because FDA's relaxed regulation of mifepristone may cause downstream economic injuries to the doctors. The doctors cite various monetary and related injuries that they will allegedly suffer as a result of 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. But the causal link between FDA's regulatory actions in 2016 and 2021 and those alleged injuries is too speculative, lacks support in the record, and is otherwise too attenuated to establish standing. Moreover, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries. Citizens and doctors who object to what the law allows others to do may always take their concerns to the Executive and Legislative Branches and seek greater regulatory or legislative restrictions. Pp. 390–393.

(3) Plaintiff medical associations assert their own organizational standing. Under the Court's precedents, organizations may have standing "to sue on their own behalf for injuries they have sustained," *Havens Realty Corp.* v. *Coleman*, 455 U. S. 363, 379, n. 19, but organizations must satisfy the usual standards for injury in fact, causation, and redressability that apply to individuals, *id.*, at 378–379. According to the medical associations, FDA has "impaired" their "ability to provide services and achieve their organizational missions." Brief for Respondents 43. That argument does not work to demonstrate standing. Like an individual, an organization may not establish standing simply based on the "intensity of the litigant's interest" or because of strong opposi-

tion to the government's conduct, *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 486. The plaintiff associations therefore cannot establish standing simply because they object to FDA's actions. The medical associations claim to have standing based on their incurring costs to oppose FDA's actions. They say that FDA has "caused" the associations to conduct their own studies on mifepristone so that the associations can better inform their members and the public about mifepristone's risks. Brief for Respondents 43. They contend that FDA has "forced" the associations to "expend considerable time, energy, and resources" drafting citizen petitions to FDA, as well as engaging in public advocacy and public education, all to the detriment of other spending priorities. *Id.*, at 44. But an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action. Contrary to what the medical associations contend, the Court's decision in *Havens Realty Corp.* v. *Coleman* does not stand for the expansive theory that standing exists when an organization diverts its resources in response to a defendant's actions. *Havens* was an unusual case, and this Court has been careful not to extend the *Havens* holding beyond its context. So too here.

Finally, it was suggested that plaintiffs must have standing because otherwise it may be that no one would have standing to challenge FDA's 2016 and 2021 actions. That suggestion fails because the Court has long rejected that kind of argument as a basis for standing. The "assumption" that if these plaintiffs lack "standing to sue, no one would have standing, is not a reason to find standing." *Schlesinger* v. *Reservists Comm. to Stop the War*, 418 U. S. 208, 227. Rather, some issues may be left to the political and democratic processes. Pp. 393–396.

78 F. 4th 210, reversed and remanded.

KAVANAUGH, J., delivered the opinion for a unanimous Court. THOMAS, J., filed a concurring opinion, *post*, p. 397.

Solicitor General Prelogar argued the cause for federal petitioners in No. 23–235. With her on the briefs in both cases were *Principal Deputy Assistant Attorney General Boynton*, *Deputy Solicitors General Fletcher* and *Kneedler*, *Deputy Assistant Attorney General Harrington*, *Erica L. Ross*, *Charles L. McCloud*, *Michael S. Raab*, *Cynthia A. Barmore*, and *Samuel R. Bagenstos.*

Counsel

Jessica L. Ellsworth argued the cause for petitioner Danco Laboratories, L. L. C. in No. 23–236. With her on the brief in both cases were *Catherine E. Stetson*, *Jo-Ann Tamila Sagar*, *Danielle Desaulniers Stempel*, *Marlan Golden*, *Dana A. Raphael*, and *Philip Katz*.

Erin M. Hawley argued the cause for respondents in both cases. With her on the brief were *John J. Bursch*, *Matthew S. Bowman*, *James A. Campbell*, *Erik C. Baptist*, and *Cody S. Barnett*.*

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*Briefs of *amici curiae* urging reversal in both cases were filed for the State of New York et al. by *Letitia James*, Attorney General of New York, *Barbara D. Underwood*, Solicitor General, *Ester Murdukhayeva*, Deputy Solicitor General, *Galen Sherwin*, by *Brian L. Schwalb*, Attorney General of the District of Columbia, and by the Attorneys General for their respective States as follows: *Kris Mayes* of Arizona, *Rob Bonta* of California, *Philip J. Weiser* of Colorado, *William Tong* of Connecticut, *Kathleen Jennings* of Delaware, *Anne E. Lopez* of Hawaii, *Kwame Raoul* of Illinois, *Aaron M. Frey* of Maine, *Anthony G. Brown* of Maryland, *Andrea Joy Campbell* of Massachusetts, *Dana Nessel* of Michigan, *Keith Ellison* of Minnesota, *Aaron D. Ford* of Nevada, *Matthew J. Platkin* of New Jersey, *Raúl Torrez* of New Mexico, *Joshua H. Stein* of North Carolina, *Ellen F. Rosenblum* of Oregon, *Michelle A. Henry* of Pennsylvania, *Peter F. Neronha* of Rhode Island, *Charity R. Clark* of Vermont, *Robert W. Ferguson* of Washington, and *Joshua L. Kaul* of Wisconsin; for the City of New York et al. by *Sylvia O. Hinds-Radix*, *Richard Dearing*, *Devin Slack*, *Elina Druker*, *Tony LoPresti*, *Meredith A. Johnson*, *Rachel A. Neil*, and *Jessica M. Scheller*; for the American Civil Liberties Union et al. by *Julia Kaye*, *Andrew D. Beck*, *Jennifer Dalven*, *Lorie A. Chaiten*, *David D. Cole*, *Rabia Muqaddam*, *Autumn Katz*, *Rupali Sharma*, and *Stephanie Toti*; for the American College of Obstetricians and Gynecologists et al. by *Shannon Rose Selden*; for the American Psychological Association et al. by *Jessica Ring Amunson* and *Deanne M. Ottaviano*; for the Association of American Medical Colleges by *Douglas Hallward-Driemeier*, *Deanna Barkett FitzGerald*, and *Frank R. Trinity*; for the Disability Rights Education & Defense Fund et al. by *Maria Michelle Uzeta* and *James P. Gagen*; for Doctors for America et al. by *Christopher J. Morten* and *Thomas S. Leatherbury*; for Food and Drug Law Scholars et al. by *Robert A. Long*; for Former Commissioners of the U. S. Food and Drug Administration by *William B. Schultz*, *Margaret M. Dotzel*, and *Alyssa M. Howard*; for Former Military Officials et al. by *Susanne Sachsman Grooms*, *Carmen Iguina*

JUSTICE KAVANAUGH delivered the opinion of the Court.

In 2016 and 2021, the Food and Drug Administration relaxed its regulatory requirements for mifepristone, an abor-

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González, and *Kate Epstein*; for Former U. S. Department of Justice Officials by *Alan Schoenfeld*, *Kimberly A. Parker*, *Daniel S. Volchok*, and *Colleen Campbell*; for the Freedom From Religion Foundation et al. by *Patrick C. Elliott* and *Geoffrey T. Blackwell*; for GenBioPro, Inc., by *John P. Elwood*, *Daphne O'Connor*, *Robert J. Katerberg*, *Kolya D. Glick*, *David C. Frederick*, *Derek C. Reinbold*, *Skye L. Perryman*, and *Carrie Y. Flaxman*; for Honeybee Health, Inc., by *Stephanie L. Gutwein*, *A. Scott Chinn*, *Matthew K. Giffin*, *Elizabeth A. Charles*, and *Libby L. Baney*; for Legal Voice et al. by *Matthew Gordon*; for Local Governments et al. by *Jonathan B. Miller*, *Cheran Ivery*, *Anne L. Morgan*, *Myriam Zreczny Kasper*, *Suzanne M. Loose*, *Mark D. Griffin*, *Valerie L. Flores*, *Scott Marcus*, *Shaun Dabby Jacobs*, *John P. Markovs*, and *Lyndsey M. Olson*; for Medical Students for Choice by *Jayme Jonat*; for the NAACP Legal Defense & Educational Fund, Inc., by *Janai S. Nelson* and *Samuel Spital*; for the National Council of Jewish Women et al. by *Eugene M. Gelernter*; for Patient and Provider Advocacy Organizations by *Caroline L. Wolverton* and *Aileen M. McGrath*; for Pharmaceutical Companies et al. by *Eva A. Temkin*, *Paul Alessio Mezzina*, *Joshua N. Mitchell*, and *Anne M. Voigts*; for the Pharmaceutical Research and Manufacturers of America by *Peter Safir*, *David M. Zionts*, *Daniel G. Randolph*, *Kendall T. Burchard*, *James C. Stansel*, and *Melissa B. Kimmel*; for Physicians for Reproductive Health by *Janice Mac Avoy*; for Public Citizen et al. by *Nicolas A. Sansone* and *Allison M. Zieve*; for the Reproductive Freedom Alliance by *Jaime A. Santos*, *Annaka Nava*, *Dorothy Hazan*, *Jennifer Fisher*, and *Daryl L. Wiesen*; for Women Who Have Obtained Medication Abortion Via Telemedicine by *Vanessa K. Burrows* and *Julie F. Kay*; for the Women's Bar Association of the District of Columbia by *Candace Beck*; for David S. Cohen et al. by *David S. Cohen*, *pro se*, and *Susan J. Frietsche*; for 237 Reproductive Health Organizations et al. by *Lindsay C. Harrison*; for 263 Members of Congress by *Boris Bershteyn* and *Jennifer L. Bragg*; and for Over 640 State Legislators by *Amanda Shafer Berman*. F. Andrew Hessick, *pro se*, and *Richard A. Simpson* filed a brief as *amicus curiae* urging vacatur in both cases.

Briefs of *amici curiae* urging affirmance in both cases were filed for the State of Mississippi et al. by *Lynn Fitch*, Attorney General of Mississippi, *Whitney H. Lipscomb*, Deputy Attorney General, *Scott G. Stewart*, Solicitor General, and *Justin L. Matheny* and *Anthony M. Shults*, Deputy Solicitors General, and by the Attorneys General for their respective States as

tion drug. Those changes made it easier for doctors to prescribe and pregnant women to obtain mifepristone. Several pro-life doctors and associations sued FDA, arguing that FDA's actions violated the Administrative Procedure Act.

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follows: *Steve Marshall* of Alabama, *Treg Taylor* of Alaska, *Tim Griffin* of Arkansas, *Ashley Moody* of Florida, *Christopher M. Carr* of Georgia, *Theodore E. Rokita* of Indiana, *Brenna Bird* of Iowa, *Russell Coleman* of Kentucky, *Liz Murrill* of Louisiana, *Austin Knudsen* of Montana, *Michael T. Hilgers* of Nebraska, *Drew H. Wrigley* of North Dakota, *Dave Yost* of Ohio, *Gentner F. Drummond* of Oklahoma, *Alan Wilson* of South Carolina, *Marty J. Jackley* of South Dakota, *Jonathan Skrmetti* of Tennessee, *Ken Paxton* of Texas, *Sean D. Reyes* of Utah, *Patrick Morrisey* of West Virginia, and *Bridget Hill* of Wyoming; for the American Center for Law and Justice by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, *Walter M. Weber*, *Geoffrey R. Surtees*, and *Laura B. Hernandez*; for Americans United for Life by *Steven H. Aden* and *Clarke D. Forsythe*; for the Charlotte Lozier Institute by *Gene C. Schaerr*; for Democrats for Life of America by *Rachel N. Morrison* and *Eric N. Kniffin*; for the Elliot Institute et al. by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, and *Walter M. Weber*; for the Family Policy Alliance et al. by *Randall L. Wenger*, *Jeremy L. Samek*, and *Janice Martino-Gottshall*; for the Family Research Council et al. by *Christopher E. Mills*; for Former U. S. Department of Health and Human Services Officials et al. by *James R. Lawrence III*; for Heartbeat International by *Thomas Brejcha* and *B. Tyler Brooks*; for Judicial Watch, Inc., by *Meredith L. Di Liberto*; for the Life Legal Defense Foundation by *Catherine Short* and *Sheila A. Green*; for the National Hispanic Leadership Conference et al. by *Mathew D. Staver*, *Anita L. Staver*, and *Horatio G. Mihet*; for Operation Rescue et al. by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, and *Walter M. Weber*; for Priests for Life by *Robert Joseph Muise* and *David Yerushalmi*; for the Prolife Center at the University of St. Thomas (MN) by *Teresa Stanton Collett*; for the Robertson Center for Constitutional Law by *Christopher T. Hollinger* and *Bradley J. Lingo*; for the Southeastern Legal Foundation et al. by *Thomas R. McCarthy*, *Braden H. Boucek*, and *Robert Henneke*; for Stanton International by *Erin Mersino* and *Robert J. Muise*; for Susan B. Anthony Pro-Life America et al. by *Heather Gebelin Hacker*; for the United States Medical Association by *Nathan W. Kellum*; for Women and Families Harmed by Mifepristone et al. by *Linda Boston Schlueter*; for Women Injured by Abortion by *Mary J. Browning*, *Allan E. Parker*, *R. Clayton Trotter*, and *Catherine Glenn Foster*; for the World Faith Foundation et al. by *James L. Hirsen*, *Tami Fitzgerald*, and *Deborah J. Dewart*;

But the plaintiffs do not prescribe or use mifepristone. And FDA is not requiring them to do or refrain from doing anything. Rather, the plaintiffs want FDA to make mifepristone more difficult for other doctors to prescribe and for pregnant women to obtain. 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 FDA's actions.

I

A

Under federal law, the U. S. Food and Drug Administration, an agency within the Executive Branch, ensures that

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for Former Secretary David Longly Bernhardt by *John C. Sullivan*; for Gianina Cazan-London et al. by *William Wagner*; for Grazie Pozo Christie et al. by *Megan M. Wold*; for Former U. S. Attorney General Edwin Meese III by *David H. Thompson*, *Brian W. Barnes*, and *Clark L. Hildabrand*; for Calum Miller by *Kristine Brown*; for Allan Sawyer by *Michael S. Overing* and *Edward C. Wilde*; and for 145 Members of Congress by *Steven H. Aden*.

Briefs of *amici curiae* were filed in both cases for the State of Missouri et al. by *Andrew Bailey*, Attorney General of Missouri, *Joshua M. Divine*, Solicitor General, and *Maria A. Lanahan* and *Samuel C. Freedlund*, Deputy Solicitors General, by *Raúl R. Labrador*, Attorney General of Idaho, *Alan M. Hurst*, Solicitor General, *Joshua N. Turner*, Deputy Solicitor General, and *James E. M. Craig*, and by *Kris W. Kobach*, Attorney General of Kansas, *Anthony J. Powell*, Solicitor General, and *Erin B. Gaide*, Assistant Attorney General; for Advancing American Freedom et al. by *J. Marc Wheat*; for Business Leaders by *Jonathan R. Whitehead*; for the Ethics and Public Policy Center by *M. Edward Whelan III*, *Charles W. Fillmore*, and *H. Dustin Fillmore III*; for the Human Coalition et al. by *Elissa M. Graves* and *Chelsey D. Youman*; for the Jewish Coalition for Religious Liberty by *Howard Slugh*; for the Mountain States Legal Foundation by *Jennifer L. Mascott*, *R. Trent McCotter*, and *Ivan L. London*; for the National Association of Nurse Practitioners in Women's Health et al. by *Jonathan K. Youngwood* and *Simona G. Strauss*; and for Over 300 Reproductive Health Researchers by *Melissa Goodman* and *Claudia Hammerman*; and for Students for Life of America by *William Bock III*.

Niyati Shah and *Noah Baron* filed a brief for AANHPI et al. as *amici curiae* in No. 23–235.

drugs on the market are safe and effective. For FDA to approve a new drug, the drug sponsor (usually the drug's manufacturer or potential marketer) must submit an application demonstrating that the drug is safe and effective when used as directed. 21 U. S. C. § 355(d). The sponsor's application must generally include proposed labeling that specifies the drug's dosage, how to take the drug, and the specific conditions that the drug may treat. 21 CFR §§ 201.5, 314.50 (2022).

If FDA determines that additional safety requirements are necessary, FDA may impose extra requirements on prescription and use of the drug. 21 U. S. C. § 355–1(f)(3). For example, FDA may require that prescribers undergo specialized training; mandate that the drug be dispensed only in certain settings like hospitals; or direct that doctors monitor patients taking the drug. *Ibid.*

In 2000, FDA approved a new drug application for mifepristone tablets marketed under the brand name Mifeprex. FDA approved Mifeprex for use to terminate pregnancies, but only up to seven weeks of pregnancy. To help ensure that Mifeprex would be used safely and effectively, FDA placed further restrictions on the drug's use and distribution. For example, only doctors could prescribe or supervise prescription of Mifeprex. Doctors and patients also had to follow a strict regimen requiring the patient to appear for three in-person visits with the doctor. And FDA directed prescribing doctors to report incidents of hospitalizations, blood transfusions, or other serious adverse events to the drug sponsor (who, in turn, was required to report the events to FDA).

In 2015, Mifeprex's distributor Danco Laboratories submitted a supplemental new drug application seeking to amend Mifeprex's labeling and to relax some of the restrictions that FDA had imposed. In 2016, FDA approved the proposed changes. FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks rather than 7 weeks. FDA allowed healthcare providers such as nurse practitioners to

prescribe Mifeprex. And FDA approved a dosing regimen that reduced the number of required in-person visits from three to one—a single visit to receive Mifeprex. In addition, FDA changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities—a reporting requirement that was still more stringent than the requirements for most other drugs.

In 2019, FDA approved an application for generic mifepristone. FDA established the same conditions of use for generic mifepristone as for Mifeprex.

In 2021, FDA again relaxed the requirements for Mifeprex and generic mifepristone. Relying on experience gained during the COVID–19 pandemic about pregnant women using mifepristone without an in-person visit to a healthcare provider, FDA announced that it would no longer enforce the initial in-person visit requirement.

B

Because mifepristone is used to terminate pregnancies, FDA's approval and regulation of mifepristone have generated substantial controversy from the start. In 2002, three pro-life associations submitted a joint citizen petition asking FDA to rescind its approval of Mifeprex. FDA denied their petition.

In 2019, two pro-life medical associations filed another petition, this time asking FDA to withdraw its 2016 modifications to mifepristone's conditions of use. FDA denied that petition as well.

This case began in 2022. Four pro-life medical associations, as well as several individual doctors, sued FDA in the U. S. District Court for the Northern District of Texas. Plaintiffs brought claims under the Administrative Procedure Act. They challenged the lawfulness of FDA's 2000 approval of Mifeprex; FDA's 2019 approval of generic mifepristone; and FDA's 2016 and 2021 actions modifying mifepristone's conditions of use. Danco Laboratories, which

sponsors Mifeprex, intervened to defend FDA's actions. The plaintiffs moved for a preliminary injunction that would require FDA to rescind approval of mifepristone or, at the very least, to rescind FDA's 2016 and 2021 actions.

The District Court agreed with the plaintiffs and in effect enjoined FDA's approval of mifepristone, thereby ordering mifepristone off the market. 668 F. Supp. 3d 507 (ND Tex. 2023). The court first held that the plaintiffs possessed Article III standing. It then determined that the plaintiffs were likely to succeed on the merits of each of their claims. Finally, the court concluded that the plaintiffs would suffer irreparable harm from FDA's continued approval of mifepristone and that an injunction would serve the public interest.

FDA and Danco promptly appealed and moved to stay the District Court's order pending appeal. The U. S. Court of Appeals for the Fifth Circuit granted the stay motion in part and temporarily reinstated FDA's approval of Mifeprex. 2023 WL 2913725, *21 (Apr. 12, 2023). But the Court of Appeals declined to stay the rest of the District Court's order. The Court of Appeals' partial stay would have left Mifeprex (though not generic mifepristone) on the market, but only under the more stringent requirements imposed when FDA first approved Mifeprex in 2000—available only up to seven weeks of pregnancy, only when prescribed by doctors, and only with three in-person visits, among other requirements.

FDA and Danco then sought a full stay in this Court. This Court stayed the District Court's order in its entirety pending the disposition of FDA's and Danco's appeals in the Court of Appeals and ultimate resolution by this Court. 598 U. S. —— (2023). As a result of this Court's stay, Mifeprex and generic mifepristone have remained available as allowed by FDA's relaxed 2016 and 2021 requirements.

A few months later, the Court of Appeals issued its decision on the merits of the District Court's order, affirming in part and vacating in part. 78 F. 4th 210, 222–223 (CA5 2023). The Court of Appeals first concluded that the indi-

vidual doctors and the pro-life medical associations had standing. The Court of Appeals next concluded that plaintiffs were not likely to succeed on their challenge to FDA's 2000 approval of Mifeprex and 2019 approval of generic mifepristone. So the Court of Appeals vacated the District Court's order as to those agency actions. But the Court of Appeals agreed with the District Court that plaintiffs were likely to succeed in showing that FDA's 2016 and 2021 actions were unlawful.

The Court of Appeals' merits decision did not alter this Court's stay of the District Court's order pending this Court's review. This Court then granted certiorari with respect to the 2016 and 2021 FDA actions held unlawful by the Court of Appeals. 601 U. S. —— (2023).

II

The threshold question is whether the plaintiffs have standing to sue under Article III of the Constitution. Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." *United States* v. *Texas*, 599 U. S. 670, 675 (2023). Standing is "built on a single basic idea—the idea of separation of powers." *Ibid.* (quotation marks omitted). Importantly, separation of powers "was not simply an abstract generalization in the minds of the Framers: it was woven into the document that they drafted in Philadelphia in the summer of 1787." *TransUnion LLC* v. *Ramirez*, 594 U. S. 413, 422–423 (2021) (quotation marks omitted). Therefore, we begin as always with the precise text of the Constitution.

Article III of the Constitution confines the jurisdiction of federal courts to "Cases" and "Controversies." The case or controversy requirement limits the role of the Federal Judiciary in our system of separated powers. As this Court explained to President George Washington in 1793 in response to his request for a legal opinion, federal courts do not issue advisory opinions about the law—even when requested by

the President. 13 Papers of George Washington: Presidential Series 392 (C. Patrick ed. 2007). Nor do federal courts operate as an open forum for citizens "to press general complaints about the way in which government goes about its business." *Allen* v. *Wright*, 468 U. S. 737, 760 (1984) (quotation marks omitted); see *California* v. *Texas*, 593 U. S. 659, 673 (2021); *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 487 (1982); *United States* v. *Richardson*, 418 U. S. 166, 175 (1974); *Ex parte Levitt*, 302 U. S. 633, 634 (1937) (*per curiam*); *Massachusetts* v. *Mellon*, 262 U. S. 447, 487–488 (1923); *Fairchild* v. *Hughes*, 258 U. S. 126, 129–130 (1922).

As Justice Scalia memorably said, Article III requires a plaintiff to first answer a basic question: " 'What's it to you?' " A. Scalia, The Doctrine of Standing as an Essential Element of the Separation of Powers, 17 Suffolk U. L. Rev. 881, 882 (1983). For a plaintiff to get in the federal courthouse door and obtain a judicial determination of what the governing law is, the plaintiff cannot be a mere bystander, but instead must have a "personal stake" in the dispute. *TransUnion*, 594 U. S., at 423. The requirement that the plaintiff possess a personal stake helps ensure that courts decide litigants' legal rights in specific cases, as Article III requires, and that courts do not opine on legal issues in response to citizens who might "roam the country in search of governmental wrongdoing." *Valley Forge*, 454 U. S., at 487; see, *e.g.*, *Schlesinger* v. *Reservists Comm. to Stop the War*, 418 U. S. 208, 227 (1974); *Richardson*, 418 U. S., at 175; *Tyler* v. *Judges of Court of Registration*, 179 U. S. 405, 406 (1900). Standing also "tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *Valley Forge*, 454 U. S., at 472. Moreover, the standing doctrine serves to protect the "autonomy" of those who are most directly affected so that they can decide

whether and how to challenge the defendant's action. *Id.*, at 473.

By limiting who can sue, the standing requirement implements "the Framers' concept of the proper—and properly limited—role of the courts in a democratic society." J. Roberts, Article III Limits on Statutory Standing, 42 Duke L. J. 1219, 1220 (1993) (quotation marks omitted). In particular, the standing requirement means that the federal courts decide some contested legal questions later rather than sooner, thereby allowing issues to percolate and potentially be resolved by the political branches in the democratic process. See *Raines* v. *Byrd*, 521 U. S. 811, 829–830 (1997); cf. *Clapper* v. *Amnesty Int'l USA*, 568 U. S. 398, 420–422 (2013). And the standing requirement means that the federal courts may never need to decide some contested legal questions: "Our system of government leaves many crucial decisions to the political processes," where democratic debate can occur and a wide variety of interests and views can be weighed. *Schlesinger*, 418 U. S., at 227; see *Campbell* v. *Clinton*, 203 F. 3d 19, 23 (CADC 2000).

A

The fundamentals of standing are well-known and firmly rooted in American constitutional law. To establish standing, as this Court has often stated, a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief. See *Summers* v. *Earth Island Institute*, 555 U. S. 488, 493 (2009); *Lujan* v. *Defenders of Wildlife*, 504 U. S. 555, 560–561 (1992). Those specific standing requirements constitute "an essential and unchanging part of the case-or-controversy requirement of Article III." *Id.*, at 560.

The second and third standing requirements—causation and redressability—are often "flip sides of the same coin." *Sprint Communications Co.* v. *APCC Services, Inc.*, 554

U. S. 269, 288 (2008). If a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury. So the two key questions in most standing disputes are injury in fact and causation.[1]

First is injury in fact. An injury in fact must be "concrete," meaning that it must be real and not abstract. See *TransUnion*, 594 U. S., at 424. The injury also must be particularized; the injury must affect "the plaintiff in a personal and individual way" and not be a generalized grievance. *Lujan*, 504 U. S., at 560, n. 1. An injury in fact can be a physical injury, a monetary injury, an injury to one's property, or an injury to one's constitutional rights, to take just a few common examples. Moreover, the injury must be actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon. *Clapper*, 568 U. S., at 409. And when a plaintiff seeks prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of future injury. *Id.*, at 401.

By requiring the plaintiff to show an injury in fact, Article III standing screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action. For example, a citizen does not have standing to challenge a government regulation simply because the plaintiff believes that the government is acting illegally. See *Valley Forge*, 454 U. S., at 473, 487. A citizen may not sue based only on an "asserted right to have the Government act in accordance with law." *Allen*, 468 U. S., at 754; *Schlesinger*, 418 U. S., at 225–227. Nor may citizens sue merely because their legal objection is accompanied by a strong moral, ideological, or policy objection to a government action. See *Valley Forge*, 454 U. S., at 473.

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[1] Redressability can still pose an independent bar in some cases. For example, a plaintiff who suffers injuries caused by the government still may not be able to sue because the case may not be of the kind "traditionally redressable in federal court." *United States* v. *Texas*, 599 U. S. 670, 676 (2023); cf. *California* v. *Texas*, 593 U. S. 659, 671–672 (2021).

The injury in fact requirement prevents the federal courts from becoming a "vehicle for the vindication of the value interests of concerned bystanders." *Allen*, 468 U. S., at 756 (quotation marks omitted). An Article III court is not a legislative assembly, a town square, or a faculty lounge. Article III does not contemplate a system where 330 million citizens can come to federal court whenever they believe that the government is acting contrary to the Constitution or other federal law. See *id.*, at 754. Vindicating "the *public* interest (including the public interest in Government observance of the Constitution and laws) is the function of Congress and the Chief Executive." *Lujan*, 504 U. S., at 576.

In sum, to sue in federal court, a plaintiff must show that he or she has suffered or likely will suffer an injury in fact.

Second is causation. The plaintiff must also establish that the plaintiff's injury likely was caused or likely will be caused by the defendant's conduct.

Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish. See *Lujan*, 504 U. S., at 561–562; see, *e.g.*, *Susan B. Anthony List* v. *Driehaus*, 573 U. S. 149, 162–163 (2014).

By contrast, when (as here) a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of *someone else*," "standing is not precluded, but it is ordinarily substantially more difficult to establish." *Lujan*, 504 U. S., at 562 (quotation marks omitted); see *Summers*, 555 U. S., at 493. That is often because unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else. See *Clapper*, 568 U. S., at 413–414; *Lujan*, 504 U. S., at 562; *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U. S. 59, 74 (1978); *Simon* v. *Eastern Ky. Welfare Rights Organization*, 426

U. S. 26, 41–46 (1976); *Warth* v. *Seldin*, 422 U. S. 490, 504–508 (1975).

When the plaintiff is an unregulated party, causation "ordinarily hinge[s] 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." *Lujan*, 504 U. S., at 562. Yet the Court has said that plaintiffs attempting to show causation generally cannot "rely on speculation about the unfettered choices made by independent actors not before the courts." *Clapper*, 568 U. S., at 415, n. 5 (quotation marks omitted); see also *Bennett* v. *Spear*, 520 U. S. 154, 168–169 (1997). Therefore, to thread the causation needle in those circumstances, the plaintiff must show that the "'third parties will likely react in predictable ways'" that in turn will likely injure the plaintiffs. *California*, 593 U. S., at 675 (quoting *Department of Commerce* v. *New York*, 588 U. S. 752, 768 (2019)).

As this Court has explained, the "line of causation between the illegal conduct and injury"—the "links in the chain of causation," *Allen*, 468 U. S., at 752, 759—must not be too speculative or too attenuated, *Clapper*, 568 U. S., at 410–411. The causation requirement precludes speculative links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs. See *Allen*, 468 U. S., at 757–759; *Simon*, 426 U. S., at 41–46. The causation requirement also rules out attenuated links—that is, where the government action is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing. See *Allen*, 468 U. S., at 757–759; cf. *Department of Commerce*, 588 U. S., at 768.

The causation requirement is central to Article III standing. Like the injury in fact requirement, the causation requirement screens out plaintiffs who were not injured by the defendant's action. Without the causation requirement,

courts would be "virtually continuing monitors of the wisdom and soundness" of government action. *Allen*, 468 U. S., at 760 (quotation marks omitted).

Determining causation in cases involving suits by unregulated parties against the government is admittedly not a "mechanical exercise." *Id.*, at 751. That is because the causation inquiry can be heavily fact-dependent and a "question of degree," as private petitioner's counsel aptly described it here. Tr. of Oral Arg. 50. Unfortunately, applying the law of standing cannot be made easy, and that is particularly true for causation. Just as causation in tort law can pose line-drawing difficulties, so too can causation in standing law when determining whether an unregulated party has standing.

That said, the "absence of precise definitions" has not left courts entirely "at sea in applying the law of standing." *Allen*, 468 U. S., at 751. Like "most legal notions, the standing concepts have gained considerable definition from developing case law." *Ibid.* As the Court has explained, in "many cases the standing question can be answered chiefly by comparing the allegations of the particular complaint to those made in prior standing cases." *Id.*, at 751–752. Stated otherwise, assessing standing "in a particular case may be facilitated by clarifying principles or even clear rules developed in prior cases." *Id.*, at 752.

Consistent with that understanding of how standing principles can develop and solidify, the Court has identified a variety of familiar circumstances where government regulation of a third-party individual or business may be likely to cause injury in fact to an unregulated plaintiff. For example, when the government regulates (or under-regulates) a business, the regulation (or lack thereof) may cause downstream or upstream economic injuries to others in the chain, such as certain manufacturers, retailers, suppliers, competitors, or customers. *E. g.*, *National Credit Union Admin.* v. *First Nat. Bank & Trust Co.*, 522 U. S. 479, 488, n. 4 (1998); *Gen-*

eral Motors Corp. v. *Tracy*, 519 U. S. 278, 286–287 (1997); *Barlow* v. *Collins*, 397 U. S. 159, 162–164 (1970); *Association of Data Processing Service Organizations, Inc.* v. *Camp*, 397 U. S. 150, 152 (1970). When the government regulates parks, national forests, or bodies of water, for example, the regulation may cause harm to individual users. *E. g.*, *Summers*, 555 U. S., at 494. When the government regulates one property, it may reduce the value of adjacent property. The list goes on. See, *e.g.*, *Department of Commerce*, 588 U. S., at 766–768.

As those cases illustrate, to establish causation, the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff.[2]

B

Here, the plaintiff doctors and medical associations are unregulated parties who seek to challenge FDA's regulation *of others*. Specifically, FDA's regulations apply to doctors prescribing mifepristone and to pregnant women taking mifepristone. But the plaintiff doctors and medical associations do not prescribe or use mifepristone. And FDA has not required the plaintiffs to do anything or to refrain from doing anything.

The plaintiffs do not allege the kinds of injuries described above that unregulated parties sometimes can assert to demonstrate causation. Because the plaintiffs do not prescribe, manufacture, sell, or advertise mifepristone or sponsor a competing drug, the plaintiffs suffer no direct monetary inju-

[2] In cases of alleged future injuries to unregulated parties from government regulation, the causation requirement and the imminence element of the injury in fact requirement can overlap. Both target the same issue: Is it likely that the government's regulation or lack of regulation of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?

ries from FDA's actions relaxing regulation of mifepristone. Nor do they suffer injuries to their property, or to the value of their property, from FDA's actions. Because the plaintiffs do not use mifepristone, they obviously can suffer no physical injuries from FDA's actions relaxing regulation of mifepristone.

Rather, the plaintiffs say that they are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used *by others*. The plaintiffs appear to recognize that those general legal, moral, ideological, and policy concerns do not suffice on their own to confer Article III standing to sue in federal court. So to try to establish standing, the plaintiffs advance several complicated causation theories to connect FDA's actions to the plaintiffs' alleged injuries in fact.

The first set of causation theories contends that FDA's relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctor plaintiffs and the specified members of the plaintiff medical associations, who are also doctors. (We will refer to them collectively as "the doctors.") The second set of causation theories asserts that FDA's relaxed regulation of mifepristone may cause downstream economic injuries to the doctors. The third set of causation theories maintains that FDA's relaxed regulation of mifepristone causes injuries to the medical associations themselves, who assert their own organizational standing. As we will explain, none of the theories suffices to establish Article III standing.

1

We first address the plaintiffs' claim that FDA's relaxed regulation of mifepristone causes conscience injuries to the doctors.

The doctors contend that FDA's 2016 and 2021 actions will cause more pregnant women to suffer complications from mifepristone, and those women in turn will need more emer-

gency abortions by doctors. The plaintiff doctors say that they therefore may be required—against their consciences—to render emergency treatment completing the abortions or providing other abortion-related treatment.

The Government correctly acknowledges that a conscience injury of that kind constitutes a concrete injury in fact for purposes of Article III. See Tr. of Oral Arg. 11–12; *TransUnion*, 594 U. S., at 425; see, *e.g.*, *Holt* v. *Hobbs*, 574 U. S. 352 (2015). So doctors would have standing to challenge a government action that likely would cause them to provide medical treatment against their consciences.

But in this case—even assuming for the sake of argument that FDA's 2016 and 2021 changes to mifepristone's conditions of use cause more pregnant women to require emergency abortions and that some women would likely seek treatment from these plaintiff doctors—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.

That is because, as the Government explains, federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences. See 42 U. S. C. §300a–7(c)(1); see also H. R. 4366, 118th Cong., 2d Sess., Div. C, Title II, §203 (2024). The Church Amendments, for instance, speak clearly. They allow doctors and other healthcare personnel to "refus[e] to perform or assist" an abortion without punishment or discrimination from their employers. 42 U. S. C. §300a–7(c)(1). And the Church Amendments more broadly provide that doctors shall not be required to provide treatment or assistance that would violate the doctors' religious beliefs or moral convictions. §300a–7(d). Most if not all States have conscience laws to the same effect. See N. Sawicki, Protections From Civil Liability in State Abortion Conscience Laws, 322 JAMA 1918 (2019); see, *e.g.*, Tex. Occ. Code Ann. §103.001 (West 2022).

Moreover, as the Government notes, federal conscience protections encompass "the doctor's beliefs rather than particular procedures," meaning that doctors cannot be required to treat mifepristone complications in any way that would violate the doctors' consciences. Tr. of Oral Arg. 37; see § 300a–7(c)(1). As the Government points out, that strong protection for conscience remains true even in a so-called healthcare desert, where other doctors are not readily available. Tr. of Oral Arg. 18.

Not only as a matter of law but also as a matter of fact, the federal conscience laws have protected pro-life doctors ever since FDA approved mifepristone in 2000. The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience. Nor is there any evidence in the record here of hospitals overriding or failing to accommodate doctors' conscience objections.

In other words, none of the doctors' declarations says anything like the following: "Here is the treatment I provided, here is how it violated my conscience, and here is why the conscience protections were unavailable to me." Cf. App. 153–154 (Dr. Francis saw a patient suffering complications from an abortion drug obtained from India; no allegation that Dr. Francis helped perform an abortion); *id.*, at 154 (Dr. Francis witnessed another doctor perform an abortion; no allegation that the other doctor raised conscience objections or tried not to participate); *id.*, at 163–164 (doctor's hospital treated women suffering complications from abortion drugs; no allegation that the doctors treating the patients had or raised conscience objections to the treatment they provided); *id.*, at 173–174 (doctor treated a patient suffering from mifepristone complications; no description of what that treatment involved and no statement that the doctor raised a conscience objection to providing that treatment).

In response to all of that, the doctors still express fear that another federal law, the Emergency Medical Treatment

and Labor Act or EMTALA, might be interpreted to override those federal conscience laws and to require individual emergency room doctors to participate in emergency abortions in some circumstances. See 42 U. S. C. § 1395dd. But the Government has disclaimed that reading of EMTALA. And we agree with the Government's view of EMTALA on that point. EMTALA does not require doctors to perform abortions or provide abortion-related medical treatment over their conscience objections because EMTALA does not impose obligations on individual doctors. See Brief for United States 23, n. 3. As the Solicitor General succinctly and correctly stated, EMTALA does not "override an individual doctor's conscience objections." Tr. of Oral Arg. 18; see also Tr. of Oral Arg. in *Moyle* v. *United States*, O. T. 2023, No. 23–726 etc., pp. 88–91 (*Moyle* Tr.). We agree with the Solicitor General's representation that federal conscience protections provide "broad coverage" and will "shield a doctor who doesn't want to provide care in violation of those protections." Tr. of Oral Arg. 18, 36.

The doctors say, however, that emergency room doctors summoned to provide emergency treatment may not have time to invoke federal conscience protections. But as the Government correctly explained, doctors need not follow a time-intensive procedure to invoke federal conscience protections. Reply Brief for United States 5. A doctor may simply refuse; federal law protects doctors from repercussions when they have "refused" to participate in an abortion. § 300a–7(c)(1); Reply Brief for United States 5. And as the Government states, "[h]ospitals must accommodate doctors in emergency rooms no less than in other contexts." *Ibid.* For that reason, hospitals and doctors typically try to plan ahead for how to deal with a doctor's absence due to conscience objections. Tr. of Oral Arg. 18; *Moyle* Tr. 89–90. And again, nothing in the record since 2000 supports plaintiffs' speculation that doctors will be unable to successfully invoke federal conscience protections in emergency circumstances.

In short, given the broad and comprehensive conscience protections guaranteed by federal law, the plaintiffs have not shown—and cannot show—that FDA's actions will cause them to suffer any conscience injury. Federal law fully protects doctors against being required to provide abortions or other medical treatment against their consciences—and therefore breaks any chain of causation between FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors.[3]

2

In addition to alleging conscience injuries, the doctors cite various monetary and related injuries that they allegedly will suffer as a result of 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.

Those standing allegations suffer from the same problem—a lack of causation. The causal link between FDA's regulatory actions and those alleged injuries is too speculative or otherwise too attenuated to establish standing.

To begin with, the claim that the doctors will incur those injuries as a result of FDA's 2016 and 2021 relaxed regulations lacks record support and is highly speculative. The doctors have not offered evidence tending to suggest that FDA's deregulatory actions have both caused an increase in

[3] The doctors also suggest that they are distressed by others' use of mifepristone and by emergency abortions. It is not clear that this alleged injury is distinct from the alleged conscience injury. But even if it is, this Court has long made clear that distress at or disagreement with the activities of others is not a basis under Article III for a plaintiff to bring a federal lawsuit challenging the legality of a government regulation allowing those activities. See, *e.g.*, *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 473, 485–486 (1982); *United States* v. *Richardson*, 418 U. S. 166, 175 (1974); *Sierra Club* v. *Morton*, 405 U. S. 727, 739 (1972).

the number of pregnant women seeking treatment from the plaintiff doctors *and* caused a resulting diversion of the doctors' time and resources from other patients. Moreover, the doctors have not identified any instances in the past where they have been sued or required to pay higher insurance costs because they have treated pregnant women suffering mifepristone complications. Nor have the plaintiffs offered any persuasive evidence or reason to believe that the future will be different.

In any event, and perhaps more to the point, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries. Stated otherwise, there is no Article III doctrine of "doctor standing" that allows doctors to challenge general government safety regulations. Nor will this Court now create such a novel standing doctrine out of whole cloth.

Consider some examples. EPA rolls back emissions standards for power plants—does a doctor have standing to sue because she may need to spend more time treating asthma patients? A local school district starts a middle school football league—does a pediatrician have standing to challenge its constitutionality because she might need to spend more time treating concussions? A federal agency increases a speed limit from 65 to 80 miles per hour—does an emergency room doctor have standing to sue because he may have to treat more car accident victims? The government repeals certain restrictions on guns—does a surgeon have standing to sue because he might have to operate on more gunshot victims?

The answer is no: The chain of causation is simply too attenuated. Allowing doctors or other healthcare providers to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach and would

allow doctors to sue in federal court to challenge almost any policy affecting public health.[4]

And in the FDA drug-approval context, virtually all drugs come with complications, risks, and side effects. Some drugs increase the risk of heart attack, some may cause cancer, some may cause birth defects, and some heighten the possibility of stroke. Approval of a new drug may therefore yield more visits to doctors to treat complications or side effects. So the plaintiffs' loose approach to causation would also essentially allow any doctor or healthcare provider to challenge any FDA decision approving a new drug. But doctors have never had standing to challenge FDA's drug approvals simply on the theory that use of the drugs by others may cause more visits to doctors.

And if we were now to invent a new doctrine of doctor standing, there would be no principled way to cabin such a sweeping doctrinal change to doctors or other healthcare providers. Firefighters could sue to object to relaxed building codes that increase fire risks. Police officers could sue to challenge a government decision to legalize certain activities that are associated with increased crime. Teachers in border states could sue to challenge allegedly lax immigration policies that lead to overcrowded classrooms.

We decline to start the Federal Judiciary down that uncharted path. That path would seemingly not end until virtually every citizen had standing to challenge virtually every government action that they do not like—an approach to standing that this Court has consistently rejected as flatly inconsistent with Article III.

We recognize that many citizens, including the plaintiff doctors here, have sincere concerns about and objections to others using mifepristone and obtaining abortions. But citi-

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[4] A safety law regulating hospitals or the doctors' medical practices obviously would present a different issue—either such a law would directly regulate doctors, or the causal link at least would be substantially less attenuated.

zens and doctors do not have standing to sue simply because *others* are allowed to engage in certain activities—at least without the plaintiffs demonstrating how they would be injured by the government's alleged under-regulation of others. See *Coalition for Mercury-Free Drugs* v. *Sebelius*, 671 F. 3d 1275, 1277 (CADC 2012). Citizens and doctors who object to what the law allows others to do may always take their concerns to the Executive and Legislative Branches and seek greater regulatory or legislative restrictions on certain activities.

In sum, the doctors in this case have failed to establish Article III standing. The doctors have not shown that FDA's actions likely will cause them any injury in fact. The asserted causal link is simply too speculative or too attenuated to support Article III standing.[5]

3

That leaves the medical associations' argument that the associations themselves have organizational standing. Under this Court's precedents, organizations may have standing "to sue on their own behalf for injuries they have sustained." *Havens Realty Corp.* v. *Coleman*, 455 U. S. 363, 379, n. 19 (1982). In doing so, however, organizations must

[5] The doctors also suggest that they can sue in a representative capacity to vindicate their patients' injuries or potential future injuries, even if the doctors have not suffered and would not suffer an injury themselves. This Court has repeatedly rejected such arguments. Under this Court's precedents, third-party standing, as some have called it, allows a narrow class of litigants to assert the legal rights of others. See *Hollingsworth* v. *Perry*, 570 U. S. 693, 708 (2013). But "even when we have allowed litigants to assert the interests of others, the litigants themselves still must have suffered an injury in fact, thus giving them a sufficiently concrete interest in the outcome of the issue in dispute." *Ibid.* (quotation marks and alterations omitted). The third-party standing doctrine does not allow doctors to shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries.

satisfy the usual standards for injury in fact, causation, and redressability that apply to individuals. *Id.*, at 378–379.

According to the medical associations, FDA has "impaired" their "ability to provide services and achieve their organizational missions." Brief for Respondents 43. That argument does not work to demonstrate standing.

Like an individual, an organization may not establish standing simply based on the "intensity of the litigant's interest" or because of strong opposition to the government's conduct, *Valley Forge*, 454 U. S., at 486, "no matter how long-standing the interest and no matter how qualified the organization," *Sierra Club* v. *Morton*, 405 U. S. 727, 739 (1972). A plaintiff must show "far more than simply a setback to the organization's abstract social interests." *Havens*, 455 U. S., at 379. The plaintiff associations therefore cannot assert standing simply because they object to FDA's actions.

The medical associations say that they have demonstrated something more here. They claim to have standing not based on their mere disagreement with FDA's policies, but based on their incurring costs to oppose FDA's actions. They say that FDA has "caused" the associations to conduct their own studies on mifepristone so that the associations can better inform their members and the public about mifepristone's risks. Brief for Respondents 43. They contend that FDA has "forced" the associations to "expend considerable time, energy, and resources" drafting citizen petitions to FDA, as well as engaging in public advocacy and public education. *Id.*, at 44 (quotation marks omitted). And all of that has caused the associations to spend "considerable resources" to the detriment of other spending priorities. *Ibid.*

But an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action. An organization cannot manufacture its own standing in that way.

The medical associations respond that under *Havens Realty Corp.* v. *Coleman*, standing exists when an organization diverts its resources in response to a defendant's actions. 455 U. S. 363. That is incorrect. Indeed, that theory would mean that all the organizations in America would have standing to challenge almost every federal policy that they dislike, provided they spend a single dollar opposing those policies. *Havens* does not support such an expansive theory of standing.

The relevant question in *Havens* was whether a housing counseling organization, HOME, had standing to bring a claim under the Fair Housing Act against Havens Realty, which owned and operated apartment complexes. *Id.*, at 368, 378. Havens had provided HOME's black employees false information about apartment availability—a practice known as racial steering. *Id.*, at 366, and n. 1, 368. Critically, HOME not only was an issue-advocacy organization, but also operated a housing counseling service. *Id.*, at 368. And when Havens gave HOME's employees false information about apartment availability, HOME sued Havens because Havens "perceptibly impaired HOME's ability to provide counseling and referral services for low- and moderate-income homeseekers." *Id.*, at 379. In other words, Havens's actions directly affected and interfered with HOME's core business activities—not dissimilar to a retailer who sues a manufacturer for selling defective goods to the retailer.

That is not the kind of injury that the medical associations have alleged here. FDA's actions relaxing regulation of mifepristone have not imposed any similar impediment to the medical associations' advocacy businesses.

At most, the medical associations suggest that FDA is not properly collecting and disseminating information about mifepristone, which the associations say in turn makes it more difficult for them to inform the public about safety risks. But the associations have not claimed an informational injury, and in any event the associations have not suggested

that federal law requires FDA to disseminate such information upon request by members of the public. Cf. *Federal Election Comm'n* v. *Akins*, 524 U. S. 11 (1998).

Havens was an unusual case, and this Court has been careful not to extend the *Havens* holding beyond its context. So too here.

Finally, it has been suggested that the plaintiffs here must have standing because if these plaintiffs do not have standing, then it may be that no one would have standing to challenge FDA's 2016 and 2021 actions. For starters, it is not clear that no one else would have standing to challenge FDA's relaxed regulation of mifepristone. But even if no one would have standing, this Court has long rejected that kind of "if not us, who?" argument as a basis for standing. See *Clapper*, 568 U. S., at 420–421; *Valley Forge*, 454 U. S., at 489; *Richardson*, 418 U. S., at 179–180. The "assumption" that if these plaintiffs lack "standing to sue, no one would have standing, is not a reason to find standing." *Schlesinger*, 418 U. S., at 227. Rather, some issues may be left to the political and democratic processes: The Framers of the Constitution did not "set up something in the nature of an Athenian democracy or a New England town meeting to oversee the conduct of the National Government by means of lawsuits in federal courts." *Richardson*, 418 U. S., at 179; see *Texas*, 599 U. S., at 685.

* * *

The plaintiffs have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone. But under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court. Here, the plaintiffs have failed to demonstrate that FDA's relaxed regulatory requirements likely would cause them to suffer an injury in fact. For that reason, the federal courts are the wrong forum for addressing the plaintiffs' concerns about

FDA's actions. The plaintiffs may present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process. And they may also express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon*, 426 U. S., at 37. We reverse the judgment of the U. S. Court of Appeals for the Fifth Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE THOMAS, concurring.

I join the Court's opinion in full because it correctly applies our precedents to conclude that the Alliance for Hippocratic Medicine and other plaintiffs lack standing. Our precedents require a plaintiff to demonstrate that the defendant's challenged actions caused his asserted injuries. And, the Court aptly explains why plaintiffs have failed to establish that the Food and Drug Administration's changes to the regulation of mifepristone injured them. *Ante*, at 385–396.

The Court also rejects the plaintiff doctors' theory that they have third-party standing to assert the rights of their patients. *Ante*, at 393, n. 5. Our third-party standing precedents allow a plaintiff to assert the rights of another person when the plaintiff has a "close relationship with the person who possesses the right" and "there is a hindrance to the possessor's ability to protect his own interests." *Kowalski* v. *Tesmer*, 543 U. S. 125, 130 (2004) (internal quotation marks omitted). Applying these precedents, the Court explains that the doctors cannot establish third-party standing to sue for violations of their patients' rights without showing an injury of their own. *Ante*, at 393, n. 5. But, there is a far

simpler reason to reject this theory: Our third-party standing doctrine is mistaken. As I have previously explained, a plaintiff cannot establish an Article III case or controversy by asserting another person's rights.[1] See *June Medical Services L. L. C.* v. *Russo*, 591 U. S. 299, 366 (2020) (THOMAS, J., dissenting); *Kowalski*, 543 U. S., at 135 (THOMAS, J., concurring). So, just as abortionists lack standing to assert the rights of their clients, doctors who oppose abortion cannot vicariously assert the rights of their patients.

I write separately to highlight what appear to be similar problems with another theory of standing asserted in this suit. The Alliance and other plaintiff associations claim that they have associational standing to sue for their members' injuries.[2] Under the Court's precedents, "an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt* v. *Washington State Apple Advertising Comm'n*, 432 U. S. 333, 343 (1977). If an association can satisfy these requirements, we allow the association to pursue its members' claims, without joining those members as parties to the suit.

Associational standing, however, is simply another form of third-party standing. And, the Court has never explained or justified either doctrine's expansion of Article III stand-

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[1] Certain forms of standing that may be representational in a general sense, such as next friend standing, are "not inconsistent with this point." *June Medical Services, L. L. C.* v. *Russo*, 591 U. S. 299, 365, n. 2 (2020) (THOMAS, J., dissenting).

[2] By "associational standing," I do not refer to standing premised upon an association's own alleged injuries. Instead, I refer to the doctrine that permits a plaintiff association to assert the rights of its members. See *Warth* v. *Seldin*, 422 U. S. 490, 511 (1975).

ing. In an appropriate case, we should explain just how the Constitution permits associational standing.

I

Associational standing raises constitutional concerns by relaxing both the injury and redressability requirements for Article III standing. It also upsets other legal doctrines.

First, associational standing conflicts with Article III by permitting an association to assert its members' injuries instead of its own. The "judicial power" conferred by Article III "is limited to cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process." See *June Medical*, 591 U. S., at 364 (opinion of THOMAS, J.) (internal quotation marks omitted). "[T]o ascertain the scope of Article III's case-or-controversy requirement," courts therefore "refer directly to the traditional, fundamental limitations upon the powers of common-law courts." *Ibid.* (internal quotation marks omitted). Traditionally, a plaintiff had to show a violation of his own rights to have his claim considered by a common-law court. See *id.*, at 364–366. So, "private parties could not bring suit to vindicate the constitutional [or other legal] rights of individuals who are not before the Court." *Id.*, at 359. "After all, '[t]he province of the court is, solely, to decide on the rights of individuals,'" not to answer legal debates in the abstract. *Acheson Hotels, LLC* v. *Laufer*, 601 U. S. 1, 10 (2023) (THOMAS, J., concurring in judgment) (quoting *Marbury* v. *Madison*, 1 Cranch 137, 170 (1803)); see also *ante*, at 378–380.

Associational standing seems to run roughshod over this traditional understanding of the judicial power. Our doctrine permits an association to have standing based purely upon a member's injury, not its own. If a single member of an association has suffered an injury, our doctrine permits that association to seek relief for its entire membership—even if the association has tens of millions of other, non-injured members. See Brief for Professor F. Andrew

Hessick as *Amicus Curiae* 28 (explaining that, among other associations, the American Association of Retired People's "potential standing is staggering" because our doctrine permits it to "sue to redress" the injury of a single member out of its "almost thirty-eight million members"). As I have already explained in the context of third-party standing, Article III does not allow a plaintiff to seek to vindicate someone else's injuries. See *June Medical*, 591 U. S., at 364–366 (opinion of THOMAS, J.); *Kowalski*, 543 U. S., at 135 (opinion of THOMAS, J.). It is difficult to see why that logic should not apply with equal force to an association as to any other plaintiff. I thus have serious doubts that an association can have standing to vicariously assert a member's injury.

The Alliance's attempted use of our associational-standing doctrine illustrates how far we have strayed from the traditional rule that plaintiffs must assert only their own injuries. The Alliance is an association whose members are other associations. See 1 App. 9–10. None of its members are doctors. Instead, the Alliance seeks to have associational standing based on injuries to the doctors who are members of its member associations. Thus, the allegedly injured parties—the doctors—are two degrees removed from the party before us pursuing those injuries.

Second, our associational-standing doctrine does not appear to comport with the requirement that the plaintiff present an injury that the court can redress. For a plaintiff to have standing, a court must be able to "provid[e] a remedy that can redress *the plaintiff's* injury." *Uzuegbunam* v. *Preczewski*, 592 U. S. 279, 291 (2021) (emphasis added). But, as explained, associational standing creates a mismatch: Although the association is the plaintiff in the suit, it has no injury to redress. The party who needs the remedy—the injured member—is not before the court. Without such members as parties to the suit, it is questionable whether "relief to these nonparties . . . exceed[s] constitutional bounds." *Association of American Physicians & Surgeons*

v. *FDA*, 13 F. 4th 531, 540 (CA6 2021); see also *Department of Homeland Security* v. *New York*, 589 U. S. ——, —— (2020) (GORSUCH, J., concurring in grant of stay) (explaining that remedies "are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit"); Brief for Professor F. Andrew Hessick as *Amicus Curiae* 18 ("A bedrock principle of the Anglo-American legal system was that the right to a remedy for an injury was personal").

Consider the remedial problem when an association seeks an injunction, as the Alliance did here. See 1 App. 113. "We have long held" that our equity jurisdiction is limited to "the jurisdiction in equity exercised by the High Court of Chancery in England at the time of the adoption of the Constitution." *Grupo Mexicano de Desarrollo, S. A.* v. *Alliance Bond Fund, Inc.*, 527 U. S. 308, 318 (1999). And, "as a general rule, American courts of equity did not provide relief beyond the parties to the case." *Trump* v. *Hawaii*, 585 U. S. 667, 717 (2018) (THOMAS, J., concurring). For associations, that principle would mean that the relief could not extend beyond the association. But, if a court entered "[a]n injunction that bars a defendant from enforcing a law or regulation against the specific party before the court—the *associational plaintiff*—[it would] not satisfy Article III because it w[ould] not redress an injury." *Association of American Physicians & Surgeons*, 13 F. 4th, at 540 (internal quotation marks omitted).[3]

Our precedents have provided a workaround for this obvious remedial problem through the invention of the so-called

[3] This also raises the question of who should pick the remedy. Associations "may have very different interests from the individuals whose rights they are raising." *Kowalski* v. *Tesmer*, 543 U. S. 125, 135 (2004) (THOMAS, J., concurring). For example, an association might prefer an injunction preventing the enforcement of a law that harms its members, while an injured member may instead want damages to compensate him for his injuries. Or perhaps a member would wish to settle the litigation, whereas an association might want to continue the fight. Our associational-standing doctrine ignores these obvious concerns.

"universal injunction." Universal injunctions typically "prohibit the Government from enforcing a policy with respect to anyone." *Trump*, 585 U. S., at 713, n. 1 (THOMAS, J., concurring). By providing relief beyond the parties to the case, this remedy is "legally and historically dubious." *Id.*, at 721; see also *Labrador* v. *Poe*, 601 U. S. ——, —— – —— (2024) (GORSUCH, J., concurring in grant of stay). It seems no coincidence that associational standing's "emergence in the 1960s overlaps with the emergence of [this] remedial phenomenon" of a similarly questionable nature. *Association of American Physicians & Surgeons*, 13 F. 4th, at 541. Because no party should be permitted to obtain an injunction in favor of nonparties, I have difficulty seeing why an association should be permitted to do so for its members. Associational standing thus seems to distort our traditional understanding of the judicial power.

In addition to these Article III concerns, there is tension between associational standing and other areas of law. First, the availability of associational standing subverts the class-action mechanism. A class action allows a named plaintiff to represent others with similar injuries, but it is subject to the many requirements of Federal Rule of Civil Procedure 23. Associational standing achieves that same end goal: One lawsuit can provide relief to a large group of people. "As compared to a class action," however, associational standing seems to require "show[ing] an injury to only a single member," and the association "need not show that litigation by representation is superior to individual litigation." 13A C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure §3531.9.5, pp. 879–880 (3d ed., Supp. 2023); see also Fed. Rule Civ. Proc. 23(a). Associational standing thus allows a party to effectively bring a class action without satisfying any of the ordinary requirements. Second, associational standing creates the possibility of asymmetrical preclusion. The basic idea behind preclusion is that a party gets only one bite at the apple. If a party

litigates and loses an issue or claim, it can be barred from reasserting that same issue or claim in another suit. In general, preclusion prevents the relitigation of claims or issues only by a party to a previous action, and we have been careful to limit the exceptions to that rule. See *Taylor* v. *Sturgell*, 553 U. S. 880, 892–893 (2008). In the context of associational standing, the general rule would mean that preclusion applies only to the association, even though the purpose of the association's suit is to assert the injuries of its members. See *id.*, at 893–896. But, if the association loses, it is not clear whether the adverse judgment would bind the members. See *Automobile Workers* v. *Brock*, 477 U. S. 274, 290 (1986) (suggesting that, if an association fails to adequately represent its members, "a judgment won against it might not preclude subsequent claims by the association's members without offending due process principles"). Associational standing might allow a member two bites at the apple—after an association's claims are rejected, the underlying members might be able to assert the exact same issues or claims in a suit in their own names.

In short, our associational-standing doctrine appears to create serious problems, both constitutional and otherwise.

II

I am particularly doubtful of associational-standing doctrine because the Court has never attempted to reconcile it with the traditional understanding of the judicial power. Instead, the Court departed from that traditional understanding without explanation, seemingly by accident. To date, the Court has provided only practical reasons for its doctrine.

For over a century and a half, the Court did not have a separate standing doctrine for associations. As far as I can tell, the Court did not expressly contemplate such a doctrine until the late 1950s. In *NAACP* v. *Alabama ex rel. Patterson*, 357 U. S. 449 (1958), the Court permitted an association

to assert the constitutional rights of its members to prevent the disclosure of its membership lists. While the Court allowed the NAACP to raise a challenge on behalf of its members, it also acknowledged that the NAACP had arguably faced an injury of its own. *Id.*, at 459–460. The Court, however, soon discarded any notion that an association needed to have its own injury, creating our modern associational-standing doctrine. In *National Motor Freight Traffic Assn., Inc.* v. *United States*, 372 U. S. 246 (1963) (*per curiam*), the Court suggested that an uninjured industry group had standing to challenge a tariff schedule on behalf of its members. *Id.*, at 247. The Court offered no explanation for how that theory of standing comported with the traditional understanding of the judicial power. In fact, the Court's entire analysis consisted of a one-paragraph order denying rehearing. Since then, however, the Court has parroted that "*[e]ven in the absence of injury to itself*, an association may have standing solely as the representative of its members." *Warth* v. *Seldin*, 422 U. S. 490, 511 (1975) (emphasis added; citing *National Motor Freight Traffic Assn.*, 372 U. S. 246); see also, *e.g.*, *Automobile Workers*, 477 U. S., at 281. The Court has gone so far as to hold that a state agency—not a membership organization at all—had associational standing to "asser[t] the claims of the Washington apple growers and dealers who form its constituency." *Hunt*, 432 U. S., at 344.

Despite its continued reliance on associational standing, the Court has yet to explain how the doctrine comports with Article III. When once asked to "reconsider and reject the principles of associational standing" in favor of the class-action mechanism, the Court justified the doctrine solely by reference to its "special features, advantageous both to the individuals represented and to the judicial system as a whole." *Automobile Workers*, 477 U. S., at 288–289. Those "special features" included an association's "pre-existing reservoir of expertise and capital," and the fact that people

often join an association "to create an effective vehicle for vindicating interests that they share with others." *Id.*, at 289–290. But, considerations of practical judicial policy cannot overcome the Constitution's mandates. The lack of any identifiable justification further suggests that the Court should reconsider its associational-standing doctrine.

* * *

No party challenges our associational-standing doctrine today. That is understandable; the Court consistently applies the doctrine, discussing only the finer points of its operation. See, *e.g.*, *Students for Fair Admissions, Inc.* v. *President and Fellows of Harvard College*, 600 U. S. 181, 199–201 (2023). In this suit, rejecting our associational-standing doctrine is not necessary to conclude that the plaintiffs lack standing. In an appropriate case, however, the Court should address whether associational standing can be squared with Article III's requirement that courts respect the bounds of their judicial power.

PRELIMINARY PRINT

VOLUME 602 U. S. PART 1

PAGES 367–402

OFFICIAL REPORTS

OF

THE SUPREME COURT

JUNE 13, 2024

REBECCA A. WOMELDORF
REPORTER OF DECISIONS

Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.* ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 23–235. Argued March 26, 2024—Decided June 13, 2024*

In 2000, the Food and Drug Administration approved a new drug application for mifepristone tablets marketed under the brand name Mifeprex for use in terminating pregnancies up to seven weeks. To help ensure that Mifeprex would be used safely and effectively, FDA placed additional restrictions on the drug's use and distribution, for example requiring doctors to prescribe or to supervise prescription of Mifeprex, and requiring patients to have three in-person visits with the doctor to receive the drug. In 2016, FDA relaxed some of these restrictions: deeming Mifeprex safe to terminate pregnancies up to 10 weeks; allowing healthcare providers, such as nurse practitioners, to prescribe Mifeprex; and approving a dosing regimen that required just one in-person visit to receive the drug. In 2019, FDA approved an application for generic mifepristone. In 2021, FDA announced that it would no longer enforce the initial in-person visit requirement. Four pro-life medical associations and several individual doctors moved for a preliminary injunction that would require FDA either to rescind approval of mifepristone or to rescind FDA's 2016 and 2021 regulatory actions. Danco Laboratories, which sponsors Mifeprex, intervened to defend FDA's actions.

The District Court agreed with the plaintiffs and in effect enjoined FDA's approval of mifepristone, thereby ordering mifepristone off the market. FDA and Danco appealed and moved to stay the District Court's order pending appeal. As relevant here, this Court ultimately stayed the District Court's order pending the disposition of proceedings in the Fifth Circuit and this Court. On the merits, the Fifth Circuit held that plaintiffs had standing. It 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. This Court granted certiorari with respect to the 2016 and 2021 FDA actions.

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*Together with No. 23–236, *Danco Laboratories, L.L.C.* v. *Alliance for Hippocratic Medicine*, also on certiorari to the United States Court of Appeals for the Fifth Circuit.

Syllabus

Held: Plaintiffs lack Article III standing to challenge FDA's actions regarding the regulation of mifepristone. Pp. 378–397.

(a) Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." *United States* v. *Texas*, 599 U. S. 670, 675. Standing is "built on a single basic idea—the idea of separation of powers." *Ibid.* Article III confines the jurisdiction of federal courts to "Cases" and "Controversies." Federal courts do not operate as an open forum for citizens "to press general complaints about the way in which government goes about its business." *Allen* v. *Wright*, 468 U. S. 737, 760. To obtain a judicial determination of what the governing law is, a plaintiff must have a "personal stake" in the dispute. *TransUnion LLC* v. *Ramirez*, 594 U. S. 413, 423.

To establish standing, a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief. See *Summers* v. *Earth Island Institute*, 555 U. S. 488, 493. The two key questions in most standing disputes are injury in fact and causation. By requiring the plaintiff to show an injury in fact, Article III standing screens 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. Causation is "ordinarily substantially more difficult to establish" when (as here) a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of someone else." *Lujan* v. *Defenders of Wildlife*, 504 U. S. 555, 560–561. That is because unregulated parties often may have more difficulty linking their asserted injuries to the government's regulation (or lack of regulation) of someone else. Pp. 378–385.

(b) Plaintiffs are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used *by others*. Because plaintiffs do not prescribe or use mifepristone, plaintiffs are unregulated parties who seek to challenge FDA's regulation *of others*. Plaintiffs advance several complicated causation theories to connect FDA's actions to the plaintiffs' alleged injuries in fact. None of these theories suffices to establish Article III standing. Pp. 385–396.

(1) Plaintiffs first contend that FDA's relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctors. Even assuming that FDA's 2016 and 2021 changes to mifepristone's conditions of use cause more pregnant women to require emergency abortions and that some women would likely seek treatment from these plaintiff doctors, 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. Federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences. Federal law protects doctors from repercussions when they have "refused" to participate in an abortion. §300a–7(c)(1). The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience since mifepristone's 2000 approval. Further, the Emergency Medical Treatment and Labor Act (or EMTALA) neither overrides federal conscience laws nor requires individual emergency room doctors to participate in emergency abortions. Thus, there is a break in any chain of causation between FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors. Pp. 386–390.

(2) Plaintiffs next assert they have standing because FDA's relaxed regulation of mifepristone may cause downstream economic injuries to the doctors. The doctors cite various monetary and related injuries that they will allegedly suffer as a result of 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. But the causal link between FDA's regulatory actions in 2016 and 2021 and those alleged injuries is too speculative, lacks support in the record, and is otherwise too attenuated to establish standing. Moreover, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries. Citizens and doctors who object to what the law allows others to do may always take their concerns to the Executive and Legislative Branches and seek greater regulatory or legislative restrictions. Pp. 390–393.

(3) Plaintiff medical associations assert their own organizational standing. Under the Court's precedents, organizations may have standing "to sue on their own behalf for injuries they have sustained," *Havens Realty Corp.* v. *Coleman*, 455 U. S. 363, 379, n. 19, but organizations must satisfy the usual standards for injury in fact, causation, and redressability that apply to individuals, *id.*, at 378–379. According to the medical associations, FDA has "impaired" their "ability to provide services and achieve their organizational missions." Brief for Respondents 43. That argument does not work to demonstrate standing. Like an individual, an organization may not establish standing simply based on the "intensity of the litigant's interest" or because of strong opposi-

tion to the government's conduct, *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 486. The plaintiff associations therefore cannot establish standing simply because they object to FDA's actions. The medical associations claim to have standing based on their incurring costs to oppose FDA's actions. They say that FDA has "caused" the associations to conduct their own studies on mifepristone so that the associations can better inform their members and the public about mifepristone's risks. Brief for Respondents 43. They contend that FDA has "forced" the associations to "expend considerable time, energy, and resources" drafting citizen petitions to FDA, as well as engaging in public advocacy and public education, all to the detriment of other spending priorities. *Id.*, at 44. But an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action. Contrary to what the medical associations contend, the Court's decision in *Havens Realty Corp.* v. *Coleman* does not stand for the expansive theory that standing exists when an organization diverts its resources in response to a defendant's actions. *Havens* was an unusual case, and this Court has been careful not to extend the *Havens* holding beyond its context. So too here.

Finally, it was suggested that plaintiffs must have standing because otherwise it may be that no one would have standing to challenge FDA's 2016 and 2021 actions. That suggestion fails because the Court has long rejected that kind of argument as a basis for standing. The "assumption" that if these plaintiffs lack "standing to sue, no one would have standing, is not a reason to find standing." *Schlesinger* v. *Reservists Comm. to Stop the War*, 418 U. S. 208, 227. Rather, some issues may be left to the political and democratic processes. Pp. 393–396.

78 F. 4th 210, reversed and remanded.

KAVANAUGH, J., delivered the opinion for a unanimous Court. THOMAS, J., filed a concurring opinion, *post*, p. 397.

Solicitor General Prelogar argued the cause for federal petitioners in No. 23–235. With her on the briefs in both cases were *Principal Deputy Assistant Attorney General Boynton*, *Deputy Solicitors General Fletcher* and *Kneedler*, *Deputy Assistant Attorney General Harrington*, *Erica L. Ross*, *Charles L. McCloud*, *Michael S. Raab*, *Cynthia A. Barmore*, and *Samuel R. Bagenstos.*

Counsel

Jessica L. Ellsworth argued the cause for petitioner Danco Laboratories, L. L. C. in No. 23–236. With her on the brief in both cases were *Catherine E. Stetson*, *Jo-Ann Tamila Sagar*, *Danielle Desaulniers Stempel*, *Marlan Golden*, *Dana A. Raphael*, and *Philip Katz*.

Erin M. Hawley argued the cause for respondents in both cases. With her on the brief were *John J. Bursch*, *Matthew S. Bowman*, *James A. Campbell*, *Erik C. Baptist*, and *Cody S. Barnett*.*

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*Briefs of *amici curiae* urging reversal in both cases were filed for the State of New York et al. by *Letitia James*, Attorney General of New York, *Barbara D. Underwood*, Solicitor General, *Ester Murdukhayeva*, Deputy Solicitor General, *Galen Sherwin*, by *Brian L. Schwalb*, Attorney General of the District of Columbia, and by the Attorneys General for their respective States as follows: *Kris Mayes* of Arizona, *Rob Bonta* of California, *Philip J. Weiser* of Colorado, *William Tong* of Connecticut, *Kathleen Jennings* of Delaware, *Anne E. Lopez* of Hawaii, *Kwame Raoul* of Illinois, *Aaron M. Frey* of Maine, *Anthony G. Brown* of Maryland, *Andrea Joy Campbell* of Massachusetts, *Dana Nessel* of Michigan, *Keith Ellison* of Minnesota, *Aaron D. Ford* of Nevada, *Matthew J. Platkin* of New Jersey, *Raúl Torrez* of New Mexico, *Joshua H. Stein* of North Carolina, *Ellen F. Rosenblum* of Oregon, *Michelle A. Henry* of Pennsylvania, *Peter F. Neronha* of Rhode Island, *Charity R. Clark* of Vermont, *Robert W. Ferguson* of Washington, and *Joshua L. Kaul* of Wisconsin; for the City of New York et al. by *Sylvia O. Hinds-Radix*, *Richard Dearing*, *Devin Slack*, *Elina Druker*, *Tony LoPresti*, *Meredith A. Johnson*, *Rachel A. Neil*, and *Jessica M. Scheller*; for the American Civil Liberties Union et al. by *Julia Kaye*, *Andrew D. Beck*, *Jennifer Dalven*, *Lorie A. Chaiten*, *David D. Cole*, *Rabia Muqaddam*, *Autumn Katz*, *Rupali Sharma*, and *Stephanie Toti*; for the American College of Obstetricians and Gynecologists et al. by *Shannon Rose Selden*; for the American Psychological Association et al. by *Jessica Ring Amunson* and *Deanne M. Ottaviano*; for the Association of American Medical Colleges by *Douglas Hallward-Driemeier*, *Deanna Barkett FitzGerald*, and *Frank R. Trinity*; for the Disability Rights Education & Defense Fund et al. by *Maria Michelle Uzeta* and *James P. Gagen*; for Doctors for America et al. by *Christopher J. Morten* and *Thomas S. Leatherbury*; for Food and Drug Law Scholars et al. by *Robert A. Long*; for Former Commissioners of the U. S. Food and Drug Administration by *William B. Schultz*, *Margaret M. Dotzel*, and *Alyssa M. Howard*; for Former Military Officials et al. by *Susanne Sachsman Grooms*, *Carmen Iguina*

JUSTICE KAVANAUGH delivered the opinion of the Court.

In 2016 and 2021, the Food and Drug Administration relaxed its regulatory requirements for mifepristone, an abor-

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González, and *Kate Epstein*; for Former U. S. Department of Justice Officials by *Alan Schoenfeld*, *Kimberly A. Parker*, *Daniel S. Volchok*, and *Colleen Campbell*; for the Freedom From Religion Foundation et al. by *Patrick C. Elliott* and *Geoffrey T. Blackwell*; for GenBioPro, Inc., by *John P. Elwood*, *Daphne O'Connor*, *Robert J. Katerberg*, *Kolya D. Glick*, *David C. Frederick*, *Derek C. Reinbold*, *Skye L. Perryman*, and *Carrie Y. Flaxman*; for Honeybee Health, Inc., by *Stephanie L. Gutwein*, *A. Scott Chinn*, *Matthew K. Giffin*, *Elizabeth A. Charles*, and *Libby L. Baney*; for Legal Voice et al. by *Matthew Gordon*; for Local Governments et al. by *Jonathan B. Miller*, *Cheran Ivery*, *Anne L. Morgan*, *Myriam Zreczny Kasper*, *Suzanne M. Loose*, *Mark D. Griffin*, *Valerie L. Flores*, *Scott Marcus*, *Shaun Dabby Jacobs*, *John P. Markovs*, and *Lyndsey M. Olson*; for Medical Students for Choice by *Jayme Jonat*; for the NAACP Legal Defense & Educational Fund, Inc., by *Janai S. Nelson* and *Samuel Spital*; for the National Council of Jewish Women et al. by *Eugene M. Gelernter*; for Patient and Provider Advocacy Organizations by *Caroline L. Wolverton* and *Aileen M. McGrath*; for Pharmaceutical Companies et al. by *Eva A. Temkin*, *Paul Alessio Mezzina*, *Joshua N. Mitchell*, and *Anne M. Voigts*; for the Pharmaceutical Research and Manufacturers of America by *Peter Safir*, *David M. Zionts*, *Daniel G. Randolph*, *Kendall T. Burchard*, *James C. Stansel*, and *Melissa B. Kimmel*; for Physicians for Reproductive Health by *Janice Mac Avoy*; for Public Citizen et al. by *Nicolas A. Sansone* and *Allison M. Zieve*; for the Reproductive Freedom Alliance by *Jaime A. Santos*, *Annaka Nava*, *Dorothy Hazan*, *Jennifer Fisher*, and *Daryl L. Wiesen*; for Women Who Have Obtained Medication Abortion Via Telemedicine by *Vanessa K. Burrows* and *Julie F. Kay*; for the Women's Bar Association of the District of Columbia by *Candace Beck*; for David S. Cohen et al. by *David S. Cohen*, *pro se* and *Susan J. Frietsche*; for 237 Reproductive Health Organizations et al. by *Lindsay C. Harrison*; for 263 Members of Congress by *Boris Bershteyn* and *Jennifer L. Bragg*; and for Over 640 State Legislators by *Amanda Shafer Berman*. F. Andrew Hessick, *pro se*, and *Richard A. Simpson* filed a brief as *amicus curiae* urging vacatur in both cases.

Briefs of *amici curiae* urging affirmance in both cases were filed for the State of Mississippi et al. by *Lynn Fitch*, Attorney General of Mississippi, *Whitney H. Lipscomb*, Deputy Attorney General, *Scott G. Stewart*, Solicitor General, and *Justin L. Matheny* and *Anthony M. Shults*, Deputy Solicitors General, and by the Attorneys General for their respective States as

tion drug. Those changes made it easier for doctors to prescribe and pregnant women to obtain mifepristone. Several pro-life doctors and associations sued FDA, arguing that FDA's actions violated the Administrative Procedure Act.

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follows: *Steve Marshall* of Alabama, *Treg Taylor* of Alaska, *Tim Griffin* of Arkansas, *Ashley Moody* of Florida, *Christopher M. Carr* of Georgia, *Theodore E. Rokita* of Indiana, *Brenna Bird* of Iowa, *Russell Coleman* of Kentucky, *Liz Murrill* of Louisiana, *Austin Knudsen* of Montana, *Michael T. Hilgers* of Nebraska, *Drew H. Wrigley* of North Dakota, *Dave Yost* of Ohio, *Gentner F. Drummond* of Oklahoma, *Alan Wilson* of South Carolina, *Marty J. Jackley* of South Dakota, *Jonathan Skrmetti* of Tennessee, *Ken Paxton* of Texas, *Sean D. Reyes* of Utah, *Patrick Morrisey* of West Virginia, and *Bridget Hill* of Wyoming; for the American Center for Law and Justice by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, *Walter M. Weber*, *Geoffrey R. Surtees*, and *Laura B. Hernandez*; for Americans United for Life by *Steven H. Aden* and *Clarke D. Forsythe*; for the Charlotte Lozier Institute by *Gene C. Schaerr*; for Democrats for Life of America by *Rachel N. Morrison* and *Eric N. Kniffin*; for the Elliot Institute et al. by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, and *Walter M. Weber*; for the Family Policy Alliance et al. by *Randall L. Wenger*, *Jeremy L. Samek*, and *Janice Martino-Gottshall*; for the Family Research Council et al. by *Christopher E. Mills*; for Former U. S. Department of Health and Human Services Officials et al. by *James R. Lawrence III*; for Heartbeat International by *Thomas Brejcha* and *B. Tyler Brooks*; for Judicial Watch, Inc., by *Meredith L. Di Liberto*; for the Life Legal Defense Foundation by *Catherine Short* and *Sheila A. Green*; for the National Hispanic Leadership Conference et al. by *Mathew D. Staver*, *Anita L. Staver*, and *Horatio G. Mihet*; for Operation Rescue et al. by *Jay Alan Sekulow*, *Jordan A. Sekulow*, *Stuart J. Roth*, and *Walter M. Weber*; for Priests for Life by *Robert Joseph Muise* and *David Yerushalmi*; for the Prolife Center at the University of St. Thomas (MN) by *Teresa Stanton Collett*; for the Robertson Center for Constitutional Law by *Christopher T. Hollinger* and *Bradley J. Lingo*; for the Southeastern Legal Foundation et al. by *Thomas R. McCarthy*, *Braden H. Boucek*, and *Robert Henneke*; for Stanton International by *Erin Mersino* and *Robert J. Muise*; for Susan B. Anthony Pro-Life America et al. by *Heather Gebelin Hacker*; for the United States Medical Association by *Nathan W. Kellum*; for Women and Families Harmed by Mifepristone et al. by *Linda Boston Schlueter*; for Women Injured by Abortion by *Mary J. Browning*, *Allan E. Parker*, *R. Clayton Trotter*, and *Catherine Glenn Foster*; for the World Faith Foundation et al. by *James L. Hirsen*, *Tami Fitzgerald*, and *Deborah J. Dewart*;

But the plaintiffs do not prescribe or use mifepristone. And FDA is not requiring them to do or refrain from doing anything. Rather, the plaintiffs want FDA to make mifepristone more difficult for other doctors to prescribe and for pregnant women to obtain. 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 FDA's actions.

I

A

Under federal law, the U. S. Food and Drug Administration, an agency within the Executive Branch, ensures that

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for Former Secretary David Longly Bernhardt by *John C. Sullivan*; for Gianina Cazan-London et al. by *William Wagner*; for Grazie Pozo Christie et al. by *Megan M. Wold*; for Former U. S. Attorney General Edwin Meese III by *David H. Thompson*, *Brian W. Barnes*, and *Clark L. Hildabrand*; for Calum Miller by *Kristine Brown*; for Allan Sawyer by *Michael S. Overing* and *Edward C. Wilde*; and for 145 Members of Congress by *Steven H. Aden*.

Briefs of *amici curiae* were filed in both cases for the State of Missouri et al. by *Andrew Bailey*, Attorney General of Missouri, *Joshua M. Divine*, Solicitor General, and *Maria A. Lanahan* and *Samuel C. Freedlund*, Deputy Solicitors General, by *Raúl R. Labrador*, Attorney General of Idaho, *Alan M. Hurst*, Solicitor General, *Joshua N. Turner*, Deputy Solicitor General, and *James E. M. Craig*, and by *Kris W. Kobach*, Attorney General of Kansas, *Anthony J. Powell*, Solicitor General, and *Erin B. Gaide*, Assistant Attorney General; for Advancing American Freedom et al. by *J. Marc Wheat*; for Business Leaders by *Jonathan R. Whitehead*; for the Ethics and Public Policy Center by *M. Edward Whelan III*, *Charles W. Fillmore*, and *H. Dustin Fillmore III*; for the Human Coalition et al. by *Elissa M. Graves* and *Chelsey D. Youman*; for the Jewish Coalition for Religious Liberty by *Howard Slugh*; for the Mountain States Legal Foundation by *Jennifer L. Mascott*, *R. Trent McCotter*, and *Ivan L. London*; for the National Association of Nurse Practitioners in Women's Health et al. by *Jonathan K. Youngwood* and *Simona G. Strauss*; and for Over 300 Reproductive Health Researchers by *Melissa Goodman* and *Claudia Hammerman*; and for Students for Life of America by *William Bock III*.

Niyati Shah and *Noah Baron* filed a brief for AANHPI et al. as *amici curiae* in No. 23–235.

drugs on the market are safe and effective. For FDA to approve a new drug, the drug sponsor (usually the drug's manufacturer or potential marketer) must submit an application demonstrating that the drug is safe and effective when used as directed. 21 U. S. C. § 355(d). The sponsor's application must generally include proposed labeling that specifies the drug's dosage, how to take the drug, and the specific conditions that the drug may treat. 21 CFR §§ 201.5, 314.50 (2022).

If FDA determines that additional safety requirements are necessary, FDA may impose extra requirements on prescription and use of the drug. 21 U. S. C. § 355–1(f)(3). For example, FDA may require that prescribers undergo specialized training; mandate that the drug be dispensed only in certain settings like hospitals; or direct that doctors monitor patients taking the drug. *Ibid.*

In 2000, FDA approved a new drug application for mifepristone tablets marketed under the brand name Mifeprex. FDA approved Mifeprex for use to terminate pregnancies, but only up to seven weeks of pregnancy. To help ensure that Mifeprex would be used safely and effectively, FDA placed further restrictions on the drug's use and distribution. For example, only doctors could prescribe or supervise prescription of Mifeprex. Doctors and patients also had to follow a strict regimen requiring the patient to appear for three in-person visits with the doctor. And FDA directed prescribing doctors to report incidents of hospitalizations, blood transfusions, or other serious adverse events to the drug sponsor (who, in turn, was required to report the events to FDA).

In 2015, Mifeprex's distributor Danco Laboratories submitted a supplemental new drug application seeking to amend Mifeprex's labeling and to relax some of the restrictions that FDA had imposed. In 2016, FDA approved the proposed changes. FDA deemed Mifeprex safe to terminate pregnancies up to 10 weeks rather than 7 weeks. FDA allowed healthcare providers such as nurse practitioners to

prescribe Mifeprex. And FDA approved a dosing regimen that reduced the number of required in-person visits from three to one—a single visit to receive Mifeprex. In addition, FDA changed prescribers' adverse event reporting obligations to require prescribers to report only fatalities—a reporting requirement that was still more stringent than the requirements for most other drugs.

In 2019, FDA approved an application for generic mifepristone. FDA established the same conditions of use for generic mifepristone as for Mifeprex.

In 2021, FDA again relaxed the requirements for Mifeprex and generic mifepristone. Relying on experience gained during the COVID–19 pandemic about pregnant women using mifepristone without an in-person visit to a healthcare provider, FDA announced that it would no longer enforce the initial in-person visit requirement.

B

Because mifepristone is used to terminate pregnancies, FDA's approval and regulation of mifepristone have generated substantial controversy from the start. In 2002, three pro-life associations submitted a joint citizen petition asking FDA to rescind its approval of Mifeprex. FDA denied their petition.

In 2019, two pro-life medical associations filed another petition, this time asking FDA to withdraw its 2016 modifications to mifepristone's conditions of use. FDA denied that petition as well.

This case began in 2022. Four pro-life medical associations, as well as several individual doctors, sued FDA in the U. S. District Court for the Northern District of Texas. Plaintiffs brought claims under the Administrative Procedure Act. They challenged the lawfulness of FDA's 2000 approval of Mifeprex; FDA's 2019 approval of generic mifepristone; and FDA's 2016 and 2021 actions modifying mifepristone's conditions of use. Danco Laboratories, which

sponsors Mifeprex, intervened to defend FDA's actions. The plaintiffs moved for a preliminary injunction that would require FDA to rescind approval of mifepristone or, at the very least, to rescind FDA's 2016 and 2021 actions.

The District Court agreed with the plaintiffs and in effect enjoined FDA's approval of mifepristone, thereby ordering mifepristone off the market. 668 F. Supp. 3d 507 (ND Tex. 2023). The court first held that the plaintiffs possessed Article III standing. It then determined that the plaintiffs were likely to succeed on the merits of each of their claims. Finally, the court concluded that the plaintiffs would suffer irreparable harm from FDA's continued approval of mifepristone and that an injunction would serve the public interest.

FDA and Danco promptly appealed and moved to stay the District Court's order pending appeal. The U. S. Court of Appeals for the Fifth Circuit granted the stay motion in part and temporarily reinstated FDA's approval of Mifeprex. 2023 WL 2913725, *21 (Apr. 12, 2023). But the Court of Appeals declined to stay the rest of the District Court's order. The Court of Appeals' partial stay would have left Mifeprex (though not generic mifepristone) on the market, but only under the more stringent requirements imposed when FDA first approved Mifeprex in 2000—available only up to seven weeks of pregnancy, only when prescribed by doctors, and only with three in-person visits, among other requirements.

FDA and Danco then sought a full stay in this Court. This Court stayed the District Court's order in its entirety pending the disposition of FDA's and Danco's appeals in the Court of Appeals and ultimate resolution by this Court. 598 U. S. —— (2023). As a result of this Court's stay, Mifeprex and generic mifepristone have remained available as allowed by FDA's relaxed 2016 and 2021 requirements.

A few months later, the Court of Appeals issued its decision on the merits of the District Court's order, affirming in part and vacating in part. 78 F. 4th 210, 222–223 (CA5 2023). The Court of Appeals first concluded that the indi-

vidual doctors and the pro-life medical associations had standing. The Court of Appeals next concluded that plaintiffs were not likely to succeed on their challenge to FDA's 2000 approval of Mifeprex and 2019 approval of generic mifepristone. So the Court of Appeals vacated the District Court's order as to those agency actions. But the Court of Appeals agreed with the District Court that plaintiffs were likely to succeed in showing that FDA's 2016 and 2021 actions were unlawful.

The Court of Appeals' merits decision did not alter this Court's stay of the District Court's order pending this Court's review. This Court then granted certiorari with respect to the 2016 and 2021 FDA actions held unlawful by the Court of Appeals. 601 U. S. —— (2023).

II

The threshold question is whether the plaintiffs have standing to sue under Article III of the Constitution. Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." *United States* v. *Texas*, 599 U. S. 670, 675 (2023). Standing is "built on a single basic idea—the idea of separation of powers." *Ibid.* (quotation marks omitted). Importantly, separation of powers "was not simply an abstract generalization in the minds of the Framers: it was woven into the document that they drafted in Philadelphia in the summer of 1787." *TransUnion LLC* v. *Ramirez*, 594 U. S. 413, 422–423 (2021) (quotation marks omitted). Therefore, we begin as always with the precise text of the Constitution.

Article III of the Constitution confines the jurisdiction of federal courts to "Cases" and "Controversies." The case or controversy requirement limits the role of the Federal Judiciary in our system of separated powers. As this Court explained to President George Washington in 1793 in response to his request for a legal opinion, federal courts do not issue advisory opinions about the law—even when requested by

the President. 13 Papers of George Washington: Presidential Series 392 (C. Patrick ed. 2007). Nor do federal courts operate as an open forum for citizens "to press general complaints about the way in which government goes about its business." *Allen* v. *Wright*, 468 U. S. 737, 760 (1984) (quotation marks omitted); see *California* v. *Texas*, 593 U. S. 659, 673 (2021); *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 487 (1982); *United States* v. *Richardson*, 418 U. S. 166, 175 (1974); *Ex parte Levitt*, 302 U. S. 633, 634 (1937) (*per curiam*); *Massachusetts* v. *Mellon*, 262 U. S. 447, 487–488 (1923); *Fairchild* v. *Hughes*, 258 U. S. 126, 129–130 (1922).

As Justice Scalia memorably said, Article III requires a plaintiff to first answer a basic question: " 'What's it to you?' " A. Scalia, The Doctrine of Standing as an Essential Element of the Separation of Powers, 17 Suffolk U. L. Rev. 881, 882 (1983). For a plaintiff to get in the federal courthouse door and obtain a judicial determination of what the governing law is, the plaintiff cannot be a mere bystander, but instead must have a "personal stake" in the dispute. *TransUnion*, 594 U. S., at 423. The requirement that the plaintiff possess a personal stake helps ensure that courts decide litigants' legal rights in specific cases, as Article III requires, and that courts do not opine on legal issues in response to citizens who might "roam the country in search of governmental wrongdoing." *Valley Forge*, 454 U. S., at 487; see, *e.g.*, *Schlesinger* v. *Reservists Comm. to Stop the War*, 418 U. S. 208, 227 (1974); *Richardson*, 418 U. S., at 175; *Tyler* v. *Judges of Court of Registration*, 179 U. S. 405, 406 (1900). Standing also "tends to assure that the legal questions presented to the court will be resolved, not in the rarified atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *Valley Forge*, 454 U. S., at 472. Moreover, the standing doctrine serves to protect the "autonomy" of those who are most directly affected so that they can decide

whether and how to challenge the defendant's action. *Id.*, at 473.

By limiting who can sue, the standing requirement implements "the Framers' concept of the proper—and properly limited—role of the courts in a democratic society." J. Roberts, Article III Limits on Statutory Standing, 42 Duke L. J. 1219, 1220 (1993) (quotation marks omitted). In particular, the standing requirement means that the federal courts decide some contested legal questions later rather than sooner, thereby allowing issues to percolate and potentially be resolved by the political branches in the democratic process. See *Raines* v. *Byrd*, 521 U. S. 811, 829–830 (1997); cf. *Clapper* v. *Amnesty Int'l USA*, 568 U. S. 398, 420–422 (2013). And the standing requirement means that the federal courts may never need to decide some contested legal questions: "Our system of government leaves many crucial decisions to the political processes," where democratic debate can occur and a wide variety of interests and views can be weighed. *Schlesinger*, 418 U. S., at 227; see *Campbell* v. *Clinton*, 203 F. 3d 19, 23 (CADC 2000).

A

The fundamentals of standing are well-known and firmly rooted in American constitutional law. To establish standing, as this Court has often stated, a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief. See *Summers* v. *Earth Island Institute*, 555 U. S. 488, 493 (2009); *Lujan* v. *Defenders of Wildlife*, 504 U. S. 555, 560–561 (1992). Those specific standing requirements constitute "an essential and unchanging part of the case-or-controversy requirement of Article III." *Id.*, at 560.

The second and third standing requirements—causation and redressability—are often "flip sides of the same coin." *Sprint Communications Co.* v. *APCC Services, Inc.*, 554

U. S. 269, 288 (2008). If a defendant's action causes an injury, enjoining the action or awarding damages for the action will typically redress that injury. So the two key questions in most standing disputes are injury in fact and causation.[1]

First is injury in fact. An injury in fact must be "concrete," meaning that it must be real and not abstract. See *TransUnion*, 594 U. S., at 424. The injury also must be particularized; the injury must affect "the plaintiff in a personal and individual way" and not be a generalized grievance. *Lujan*, 504 U. S., at 560, n. 1. An injury in fact can be a physical injury, a monetary injury, an injury to one's property, or an injury to one's constitutional rights, to take just a few common examples. Moreover, the injury must be actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon. *Clapper*, 568 U. S., at 409. And when a plaintiff seeks prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of future injury. *Id.*, at 401.

By requiring the plaintiff to show an injury in fact, Article III standing screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action. For example, a citizen does not have standing to challenge a government regulation simply because the plaintiff believes that the government is acting illegally. See *Valley Forge*, 454 U. S., at 473, 487. A citizen may not sue based only on an "asserted right to have the Government act in accordance with law." *Allen*, 468 U. S., at 754; *Schlesinger*, 418 U. S., at 225–227. Nor may citizens sue merely because their legal objection is accompanied by a strong moral, ideological, or policy objection to a government action. See *Valley Forge*, 454 U. S., at 473.

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[1] Redressability can still pose an independent bar in some cases. For example, a plaintiff who suffers injuries caused by the government still may not be able to sue because the case may not be of the kind "traditionally redressable in federal court." *United States* v. *Texas*, 599 U. S. 670, 676 (2023); cf. *California* v. *Texas*, 593 U. S. 659, 671–672 (2021).

The injury in fact requirement prevents the federal courts from becoming a "vehicle for the vindication of the value interests of concerned bystanders." *Allen*, 468 U. S., at 756 (quotation marks omitted). An Article III court is not a legislative assembly, a town square, or a faculty lounge. Article III does not contemplate a system where 330 million citizens can come to federal court whenever they believe that the government is acting contrary to the Constitution or other federal law. See *id.*, at 754. Vindicating "the *public* interest (including the public interest in Government observance of the Constitution and laws) is the function of Congress and the Chief Executive." *Lujan*, 504 U. S., at 576.

In sum, to sue in federal court, a plaintiff must show that he or she has suffered or likely will suffer an injury in fact.

Second is causation. The plaintiff must also establish that the plaintiff's injury likely was caused or likely will be caused by the defendant's conduct.

Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So in those cases, standing is usually easy to establish. See *Lujan*, 504 U. S., at 561–562; see, *e.g.*, *Susan B. Anthony List* v. *Driehaus*, 573 U. S. 149, 162–163 (2014).

By contrast, when (as here) a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of *someone else*," "standing is not precluded, but it is ordinarily substantially more difficult to establish." *Lujan*, 504 U. S., at 562 (quotation marks omitted); see *Summers*, 555 U. S., at 493. That is often because unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else. See *Clapper*, 568 U. S., at 413–414; *Lujan*, 504 U. S., at 562; *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U. S. 59, 74 (1978); *Simon* v. *Eastern Ky. Welfare Rights Organization*, 426

U. S. 26, 41–46 (1976); *Warth* v. *Seldin*, 422 U. S. 490, 504–508 (1975).

When the plaintiff is an unregulated party, causation "ordinarily hinge[s] 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." *Lujan*, 504 U. S., at 562. Yet the Court has said that plaintiffs attempting to show causation generally cannot "rely on speculation about the unfettered choices made by independent actors not before the courts." *Clapper*, 568 U. S., at 415, n. 5 (quotation marks omitted); see also *Bennett* v. *Spear*, 520 U. S. 154, 168–169 (1997). Therefore, to thread the causation needle in those circumstances, the plaintiff must show that the "'third parties will likely react in predictable ways'" that in turn will likely injure the plaintiffs. *California*, 593 U. S., at 675 (quoting *Department of Commerce* v. *New York*, 588 U. S. 752, 768 (2019)).

As this Court has explained, the "line of causation between the illegal conduct and injury"—the "links in the chain of causation," *Allen*, 468 U. S., at 752, 759—must not be too speculative or too attenuated, *Clapper*, 568 U. S., at 410–411. The causation requirement precludes speculative links—that is, where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs. See *Allen*, 468 U. S., at 757–759; *Simon*, 426 U. S., at 41–46. The causation requirement also rules out attenuated links—that is, where the government action is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing. See *Allen*, 468 U. S., at 757–759; cf. *Department of Commerce*, 588 U. S., at 768.

The causation requirement is central to Article III standing. Like the injury in fact requirement, the causation requirement screens out plaintiffs who were not injured by the defendant's action. Without the causation requirement,

courts would be "virtually continuing monitors of the wisdom and soundness" of government action. *Allen*, 468 U. S., at 760 (quotation marks omitted).

Determining causation in cases involving suits by unregulated parties against the government is admittedly not a "mechanical exercise." *Id.*, at 751. That is because the causation inquiry can be heavily fact-dependent and a "question of degree," as private petitioner's counsel aptly described it here. Tr. of Oral Arg. 50. Unfortunately, applying the law of standing cannot be made easy, and that is particularly true for causation. Just as causation in tort law can pose line-drawing difficulties, so too can causation in standing law when determining whether an unregulated party has standing.

That said, the "absence of precise definitions" has not left courts entirely "at sea in applying the law of standing." *Allen*, 468 U. S., at 751. Like "most legal notions, the standing concepts have gained considerable definition from developing case law." *Ibid.* As the Court has explained, in "many cases the standing question can be answered chiefly by comparing the allegations of the particular complaint to those made in prior standing cases." *Id.*, at 751–752. Stated otherwise, assessing standing "in a particular case may be facilitated by clarifying principles or even clear rules developed in prior cases." *Id.*, at 752.

Consistent with that understanding of how standing principles can develop and solidify, the Court has identified a variety of familiar circumstances where government regulation of a third-party individual or business may be likely to cause injury in fact to an unregulated plaintiff. For example, when the government regulates (or under-regulates) a business, the regulation (or lack thereof) may cause downstream or upstream economic injuries to others in the chain, such as certain manufacturers, retailers, suppliers, competitors, or customers. *E. g.*, *National Credit Union Admin.* v. *First Nat. Bank & Trust Co.*, 522 U. S. 479, 488, n. 4 (1998); *Gen-*

eral Motors Corp. v. *Tracy*, 519 U. S. 278, 286–287 (1997); *Barlow* v. *Collins*, 397 U. S. 159, 162–164 (1970); *Association of Data Processing Service Organizations, Inc.* v. *Camp*, 397 U. S. 150, 152 (1970). When the government regulates parks, national forests, or bodies of water, for example, the regulation may cause harm to individual users. *E. g.*, *Summers*, 555 U. S., at 494. When the government regulates one property, it may reduce the value of adjacent property. The list goes on. See, *e.g.*, *Department of Commerce*, 588 U. S., at 766–768.

As those cases illustrate, to establish causation, the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff.[2]

B

Here, the plaintiff doctors and medical associations are unregulated parties who seek to challenge FDA's regulation *of others*. Specifically, FDA's regulations apply to doctors prescribing mifepristone and to pregnant women taking mifepristone. But the plaintiff doctors and medical associations do not prescribe or use mifepristone. And FDA has not required the plaintiffs to do anything or to refrain from doing anything.

The plaintiffs do not allege the kinds of injuries described above that unregulated parties sometimes can assert to demonstrate causation. Because the plaintiffs do not prescribe, manufacture, sell, or advertise mifepristone or sponsor a competing drug, the plaintiffs suffer no direct monetary inju-

[2] In cases of alleged future injuries to unregulated parties from government regulation, the causation requirement and the imminence element of the injury in fact requirement can overlap. Both target the same issue: Is it likely that the government's regulation or lack of regulation of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?

ries from FDA's actions relaxing regulation of mifepristone. Nor do they suffer injuries to their property, or to the value of their property, from FDA's actions. Because the plaintiffs do not use mifepristone, they obviously can suffer no physical injuries from FDA's actions relaxing regulation of mifepristone.

Rather, the plaintiffs say that they are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used *by others*. The plaintiffs appear to recognize that those general legal, moral, ideological, and policy concerns do not suffice on their own to confer Article III standing to sue in federal court. So to try to establish standing, the plaintiffs advance several complicated causation theories to connect FDA's actions to the plaintiffs' alleged injuries in fact.

The first set of causation theories contends that FDA's relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctor plaintiffs and the specified members of the plaintiff medical associations, who are also doctors. (We will refer to them collectively as "the doctors.") The second set of causation theories asserts that FDA's relaxed regulation of mifepristone may cause downstream economic injuries to the doctors. The third set of causation theories maintains that FDA's relaxed regulation of mifepristone causes injuries to the medical associations themselves, who assert their own organizational standing. As we will explain, none of the theories suffices to establish Article III standing.

1

We first address the plaintiffs' claim that FDA's relaxed regulation of mifepristone causes conscience injuries to the doctors.

The doctors contend that FDA's 2016 and 2021 actions will cause more pregnant women to suffer complications from mifepristone, and those women in turn will need more emer-

gency abortions by doctors. The plaintiff doctors say that they therefore may be required—against their consciences—to render emergency treatment completing the abortions or providing other abortion-related treatment.

The Government correctly acknowledges that a conscience injury of that kind constitutes a concrete injury in fact for purposes of Article III. See Tr. of Oral Arg. 11–12; *TransUnion*, 594 U. S., at 425; see, *e.g.*, *Holt* v. *Hobbs*, 574 U. S. 352 (2015). So doctors would have standing to challenge a government action that likely would cause them to provide medical treatment against their consciences.

But in this case—even assuming for the sake of argument that FDA's 2016 and 2021 changes to mifepristone's conditions of use cause more pregnant women to require emergency abortions and that some women would likely seek treatment from these plaintiff doctors—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.

That is because, as the Government explains, federal conscience laws definitively protect doctors from being required to perform abortions or to provide other treatment that violates their consciences. See 42 U. S. C. §300a–7(c)(1); see also H. R. 4366, 118th Cong., 2d Sess., Div. C, Title II, §203 (2024). The Church Amendments, for instance, speak clearly. They allow doctors and other healthcare personnel to "refus[e] to perform or assist" an abortion without punishment or discrimination from their employers. 42 U. S. C. §300a–7(c)(1). And the Church Amendments more broadly provide that doctors shall not be required to provide treatment or assistance that would violate the doctors' religious beliefs or moral convictions. §300a–7(d). Most if not all States have conscience laws to the same effect. See N. Sawicki, Protections From Civil Liability in State Abortion Conscience Laws, 322 JAMA 1918 (2019); see, *e.g.*, Tex. Occ. Code Ann. §103.001 (West 2022).

Moreover, as the Government notes, federal conscience protections encompass "the doctor's beliefs rather than particular procedures," meaning that doctors cannot be required to treat mifepristone complications in any way that would violate the doctors' consciences. Tr. of Oral Arg. 37; see § 300a–7(c)(1). As the Government points out, that strong protection for conscience remains true even in a so-called healthcare desert, where other doctors are not readily available. Tr. of Oral Arg. 18.

Not only as a matter of law but also as a matter of fact, the federal conscience laws have protected pro-life doctors ever since FDA approved mifepristone in 2000. The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment that violated the doctor's conscience. Nor is there any evidence in the record here of hospitals overriding or failing to accommodate doctors' conscience objections.

In other words, none of the doctors' declarations says anything like the following: "Here is the treatment I provided, here is how it violated my conscience, and here is why the conscience protections were unavailable to me." Cf. App. 153–154 (Dr. Francis saw a patient suffering complications from an abortion drug obtained from India; no allegation that Dr. Francis helped perform an abortion); *id.*, at 154 (Dr. Francis witnessed another doctor perform an abortion; no allegation that the other doctor raised conscience objections or tried not to participate); *id.*, at 163–164 (doctor's hospital treated women suffering complications from abortion drugs; no allegation that the doctors treating the patients had or raised conscience objections to the treatment they provided); *id.*, at 173–174 (doctor treated a patient suffering from mifepristone complications; no description of what that treatment involved and no statement that the doctor raised a conscience objection to providing that treatment).

In response to all of that, the doctors still express fear that another federal law, the Emergency Medical Treatment

and Labor Act or EMTALA, might be interpreted to override those federal conscience laws and to require individual emergency room doctors to participate in emergency abortions in some circumstances. See 42 U. S. C. § 1395dd. But the Government has disclaimed that reading of EMTALA. And we agree with the Government's view of EMTALA on that point. EMTALA does not require doctors to perform abortions or provide abortion-related medical treatment over their conscience objections because EMTALA does not impose obligations on individual doctors. See Brief for United States 23, n. 3. As the Solicitor General succinctly and correctly stated, EMTALA does not "override an individual doctor's conscience objections." Tr. of Oral Arg. 18; see also Tr. of Oral Arg. in *Moyle* v. *United States*, O. T. 2023, No. 23–726 etc., pp. 88–91 (*Moyle* Tr.). We agree with the Solicitor General's representation that federal conscience protections provide "broad coverage" and will "shield a doctor who doesn't want to provide care in violation of those protections." Tr. of Oral Arg. 18, 36.

The doctors say, however, that emergency room doctors summoned to provide emergency treatment may not have time to invoke federal conscience protections. But as the Government correctly explained, doctors need not follow a time-intensive procedure to invoke federal conscience protections. Reply Brief for United States 5. A doctor may simply refuse; federal law protects doctors from repercussions when they have "refused" to participate in an abortion. § 300a–7(c)(1); Reply Brief for United States 5. And as the Government states, "[h]ospitals must accommodate doctors in emergency rooms no less than in other contexts." *Ibid.* For that reason, hospitals and doctors typically try to plan ahead for how to deal with a doctor's absence due to conscience objections. Tr. of Oral Arg. 18; *Moyle* Tr. 89–90. And again, nothing in the record since 2000 supports plaintiffs' speculation that doctors will be unable to successfully invoke federal conscience protections in emergency circumstances.

In short, given the broad and comprehensive conscience protections guaranteed by federal law, the plaintiffs have not shown—and cannot show—that FDA's actions will cause them to suffer any conscience injury. Federal law fully protects doctors against being required to provide abortions or other medical treatment against their consciences—and therefore breaks any chain of causation between FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors.[3]

2

In addition to alleging conscience injuries, the doctors cite various monetary and related injuries that they allegedly will suffer as a result of 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.

Those standing allegations suffer from the same problem—a lack of causation. The causal link between FDA's regulatory actions and those alleged injuries is too speculative or otherwise too attenuated to establish standing.

To begin with, the claim that the doctors will incur those injuries as a result of FDA's 2016 and 2021 relaxed regulations lacks record support and is highly speculative. The doctors have not offered evidence tending to suggest that FDA's deregulatory actions have both caused an increase in

[3] The doctors also suggest that they are distressed by others' use of mifepristone and by emergency abortions. It is not clear that this alleged injury is distinct from the alleged conscience injury. But even if it is, this Court has long made clear that distress at or disagreement with the activities of others is not a basis under Article III for a plaintiff to bring a federal lawsuit challenging the legality of a government regulation allowing those activities. See, *e.g.*, *Valley Forge Christian College* v. *Americans United for Separation of Church and State, Inc.*, 454 U. S. 464, 473, 485–486 (1982); *United States* v. *Richardson*, 418 U. S. 166, 175 (1974); *Sierra Club* v. *Morton*, 405 U. S. 727, 739 (1972).

the number of pregnant women seeking treatment from the plaintiff doctors *and* caused a resulting diversion of the doctors' time and resources from other patients. Moreover, the doctors have not identified any instances in the past where they have been sued or required to pay higher insurance costs because they have treated pregnant women suffering mifepristone complications. Nor have the plaintiffs offered any persuasive evidence or reason to believe that the future will be different.

In any event, and perhaps more to the point, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries. Stated otherwise, there is no Article III doctrine of "doctor standing" that allows doctors to challenge general government safety regulations. Nor will this Court now create such a novel standing doctrine out of whole cloth.

Consider some examples. EPA rolls back emissions standards for power plants—does a doctor have standing to sue because she may need to spend more time treating asthma patients? A local school district starts a middle school football league—does a pediatrician have standing to challenge its constitutionality because she might need to spend more time treating concussions? A federal agency increases a speed limit from 65 to 80 miles per hour—does an emergency room doctor have standing to sue because he may have to treat more car accident victims? The government repeals certain restrictions on guns—does a surgeon have standing to sue because he might have to operate on more gunshot victims?

The answer is no: The chain of causation is simply too attenuated. Allowing doctors or other healthcare providers to challenge general safety regulations as unlawfully lax would be an unprecedented and limitless approach and would

allow doctors to sue in federal court to challenge almost any policy affecting public health.[4]

And in the FDA drug-approval context, virtually all drugs come with complications, risks, and side effects. Some drugs increase the risk of heart attack, some may cause cancer, some may cause birth defects, and some heighten the possibility of stroke. Approval of a new drug may therefore yield more visits to doctors to treat complications or side effects. So the plaintiffs' loose approach to causation would also essentially allow any doctor or healthcare provider to challenge any FDA decision approving a new drug. But doctors have never had standing to challenge FDA's drug approvals simply on the theory that use of the drugs by others may cause more visits to doctors.

And if we were now to invent a new doctrine of doctor standing, there would be no principled way to cabin such a sweeping doctrinal change to doctors or other healthcare providers. Firefighters could sue to object to relaxed building codes that increase fire risks. Police officers could sue to challenge a government decision to legalize certain activities that are associated with increased crime. Teachers in border states could sue to challenge allegedly lax immigration policies that lead to overcrowded classrooms.

We decline to start the Federal Judiciary down that uncharted path. That path would seemingly not end until virtually every citizen had standing to challenge virtually every government action that they do not like—an approach to standing that this Court has consistently rejected as flatly inconsistent with Article III.

We recognize that many citizens, including the plaintiff doctors here, have sincere concerns about and objections to others using mifepristone and obtaining abortions. But citi-

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[4] A safety law regulating hospitals or the doctors' medical practices obviously would present a different issue—either such a law would directly regulate doctors, or the causal link at least would be substantially less attenuated.

zens and doctors do not have standing to sue simply because *others* are allowed to engage in certain activities—at least without the plaintiffs demonstrating how they would be injured by the government's alleged under-regulation of others. See *Coalition for Mercury-Free Drugs* v. *Sebelius*, 671 F. 3d 1275, 1277 (CADC 2012). Citizens and doctors who object to what the law allows others to do may always take their concerns to the Executive and Legislative Branches and seek greater regulatory or legislative restrictions on certain activities.

In sum, the doctors in this case have failed to establish Article III standing. The doctors have not shown that FDA's actions likely will cause them any injury in fact. The asserted causal link is simply too speculative or too attenuated to support Article III standing.[5]

3

That leaves the medical associations' argument that the associations themselves have organizational standing. Under this Court's precedents, organizations may have standing "to sue on their own behalf for injuries they have sustained." *Havens Realty Corp.* v. *Coleman*, 455 U. S. 363, 379, n. 19 (1982). In doing so, however, organizations must

[5] The doctors also suggest that they can sue in a representative capacity to vindicate their patients' injuries or potential future injuries, even if the doctors have not suffered and would not suffer an injury themselves. This Court has repeatedly rejected such arguments. Under this Court's precedents, third-party standing, as some have called it, allows a narrow class of litigants to assert the legal rights of others. See *Hollingsworth* v. *Perry*, 570 U. S. 693, 708 (2013). But "even when we have allowed litigants to assert the interests of others, the litigants themselves still must have suffered an injury in fact, thus giving them a sufficiently concrete interest in the outcome of the issue in dispute." *Ibid.* (quotation marks and alterations omitted). The third-party standing doctrine does not allow doctors to shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries.

satisfy the usual standards for injury in fact, causation, and redressability that apply to individuals. *Id.*, at 378–379.

According to the medical associations, FDA has "impaired" their "ability to provide services and achieve their organizational missions." Brief for Respondents 43. That argument does not work to demonstrate standing.

Like an individual, an organization may not establish standing simply based on the "intensity of the litigant's interest" or because of strong opposition to the government's conduct, *Valley Forge*, 454 U. S., at 486, "no matter how long-standing the interest and no matter how qualified the organization," *Sierra Club* v. *Morton*, 405 U. S. 727, 739 (1972). A plaintiff must show "far more than simply a setback to the organization's abstract social interests." *Havens*, 455 U. S., at 379. The plaintiff associations therefore cannot assert standing simply because they object to FDA's actions.

The medical associations say that they have demonstrated something more here. They claim to have standing not based on their mere disagreement with FDA's policies, but based on their incurring costs to oppose FDA's actions. They say that FDA has "caused" the associations to conduct their own studies on mifepristone so that the associations can better inform their members and the public about mifepristone's risks. Brief for Respondents 43. They contend that FDA has "forced" the associations to "expend considerable time, energy, and resources" drafting citizen petitions to FDA, as well as engaging in public advocacy and public education. *Id.*, at 44 (quotation marks omitted). And all of that has caused the associations to spend "considerable resources" to the detriment of other spending priorities. *Ibid.*

But an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action. An organization cannot manufacture its own standing in that way.

The medical associations respond that under *Havens Realty Corp.* v. *Coleman*, standing exists when an organization diverts its resources in response to a defendant's actions. 455 U. S. 363. That is incorrect. Indeed, that theory would mean that all the organizations in America would have standing to challenge almost every federal policy that they dislike, provided they spend a single dollar opposing those policies. *Havens* does not support such an expansive theory of standing.

The relevant question in *Havens* was whether a housing counseling organization, HOME, had standing to bring a claim under the Fair Housing Act against Havens Realty, which owned and operated apartment complexes. *Id.*, at 368, 378. Havens had provided HOME's black employees false information about apartment availability—a practice known as racial steering. *Id.*, at 366, and n. 1, 368. Critically, HOME not only was an issue-advocacy organization, but also operated a housing counseling service. *Id.*, at 368. And when Havens gave HOME's employees false information about apartment availability, HOME sued Havens because Havens "perceptibly impaired HOME's ability to provide counseling and referral services for low- and moderate-income homeseekers." *Id.*, at 379. In other words, Havens's actions directly affected and interfered with HOME's core business activities—not dissimilar to a retailer who sues a manufacturer for selling defective goods to the retailer.

That is not the kind of injury that the medical associations have alleged here. FDA's actions relaxing regulation of mifepristone have not imposed any similar impediment to the medical associations' advocacy businesses.

At most, the medical associations suggest that FDA is not properly collecting and disseminating information about mifepristone, which the associations say in turn makes it more difficult for them to inform the public about safety risks. But the associations have not claimed an informational injury, and in any event the associations have not suggested

that federal law requires FDA to disseminate such information upon request by members of the public. Cf. *Federal Election Comm'n* v. *Akins*, 524 U. S. 11 (1998).

Havens was an unusual case, and this Court has been careful not to extend the *Havens* holding beyond its context. So too here.

Finally, it has been suggested that the plaintiffs here must have standing because if these plaintiffs do not have standing, then it may be that no one would have standing to challenge FDA's 2016 and 2021 actions. For starters, it is not clear that no one else would have standing to challenge FDA's relaxed regulation of mifepristone. But even if no one would have standing, this Court has long rejected that kind of "if not us, who?" argument as a basis for standing. See *Clapper*, 568 U. S., at 420–421; *Valley Forge*, 454 U. S., at 489; *Richardson*, 418 U. S., at 179–180. The "assumption" that if these plaintiffs lack "standing to sue, no one would have standing, is not a reason to find standing." *Schlesinger*, 418 U. S., at 227. Rather, some issues may be left to the political and democratic processes: The Framers of the Constitution did not "set up something in the nature of an Athenian democracy or a New England town meeting to oversee the conduct of the National Government by means of lawsuits in federal courts." *Richardson*, 418 U. S., at 179; see *Texas*, 599 U. S., at 685.

* * *

The plaintiffs have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone. But under Article III of the Constitution, those kinds of objections alone do not establish a justiciable case or controversy in federal court. Here, the plaintiffs have failed to demonstrate that FDA's relaxed regulatory requirements likely would cause them to suffer an injury in fact. For that reason, the federal courts are the wrong forum for addressing the plaintiffs' concerns about

FDA's actions. The plaintiffs may present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process. And they may also express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes.

"No principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies." *Simon*, 426 U. S., at 37. We reverse the judgment of the U. S. Court of Appeals for the Fifth Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE THOMAS, concurring.

I join the Court's opinion in full because it correctly applies our precedents to conclude that the Alliance for Hippocratic Medicine and other plaintiffs lack standing. Our precedents require a plaintiff to demonstrate that the defendant's challenged actions caused his asserted injuries. And, the Court aptly explains why plaintiffs have failed to establish that the Food and Drug Administration's changes to the regulation of mifepristone injured them. *Ante*, at 385–396.

The Court also rejects the plaintiff doctors' theory that they have third-party standing to assert the rights of their patients. *Ante*, at 393, n. 5. Our third-party standing precedents allow a plaintiff to assert the rights of another person when the plaintiff has a "close relationship with the person who possesses the right" and "there is a hindrance to the possessor's ability to protect his own interests." *Kowalski* v. *Tesmer*, 543 U. S. 125, 130 (2004) (internal quotation marks omitted). Applying these precedents, the Court explains that the doctors cannot establish third-party standing to sue for violations of their patients' rights without showing an injury of their own. *Ante*, at 21, n. 5. But, there is a far

simpler reason to reject this theory: Our third-party standing doctrine is mistaken. As I have previously explained, a plaintiff cannot establish an Article III case or controversy by asserting another person's rights.[1] See *June Medical Services L. L. C.* v. *Russo*, 591 U. S. 299, 366 (2020) (THOMAS, J., dissenting); *Kowalski*, 543 U. S., at 135 (THOMAS, J., concurring). So, just as abortionists lack standing to assert the rights of their clients, doctors who oppose abortion cannot vicariously assert the rights of their patients.

I write separately to highlight what appear to be similar problems with another theory of standing asserted in this suit. The Alliance and other plaintiff associations claim that they have associational standing to sue for their members' injuries.[2] Under the Court's precedents, "an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt* v. *Washington State Apple Advertising Comm'n*, 432 U. S. 333, 343 (1977). If an association can satisfy these requirements, we allow the association to pursue its members' claims, without joining those members as parties to the suit.

Associational standing, however, is simply another form of third-party standing. And, the Court has never explained or justified either doctrine's expansion of Article III stand-

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[1] Certain forms of standing that may be representational in a general sense, such as next friend standing, are "not inconsistent with this point." *June Medical Services, L. L. C.* v. *Russo*, 591 U. S. 299, 365, n. 2 (2020) (THOMAS, J., dissenting).

[2] By "associational standing," I do not refer to standing premised upon an association's own alleged injuries. Instead, I refer to the doctrine that permits a plaintiff association to assert the rights of its members. See *Warth* v. *Seldin*, 422 U. S. 490, 511 (1975).

ing. In an appropriate case, we should explain just how the Constitution permits associational standing.

I

Associational standing raises constitutional concerns by relaxing both the injury and redressability requirements for Article III standing. It also upsets other legal doctrines.

First, associational standing conflicts with Article III by permitting an association to assert its members' injuries instead of its own. The "judicial power" conferred by Article III "is limited to cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process." See *June Medical*, 591 U. S., at 364 (opinion of THOMAS, J.) (internal quotation marks omitted). "[T]o ascertain the scope of Article III's case-or-controversy requirement," courts therefore "refer directly to the traditional, fundamental limitations upon the powers of common-law courts." *Ibid.* (internal quotation marks omitted). Traditionally, a plaintiff had to show a violation of his own rights to have his claim considered by a common-law court. See *id.*, at 364–366. So, "private parties could not bring suit to vindicate the constitutional [or other legal] rights of individuals who are not before the Court." *Id.*, at 359. "After all, '[t]he province of the court is, solely, to decide on the rights of individuals,'" not to answer legal debates in the abstract. *Acheson Hotels, LLC* v. *Laufer*, 601 U. S. 1, 10 (2023) (THOMAS, J., concurring in judgment) (quoting *Marbury* v. *Madison*, 1 Cranch 137, 170 (1803)); see also *ante*, at 378–380.

Associational standing seems to run roughshod over this traditional understanding of the judicial power. Our doctrine permits an association to have standing based purely upon a member's injury, not its own. If a single member of an association has suffered an injury, our doctrine permits that association to seek relief for its entire membership—even if the association has tens of millions of other, non-injured members. See Brief for Professor F. Andrew

Hessick as *Amicus Curiae* 28 (explaining that, among other associations, the American Association of Retired People's "potential standing is staggering" because our doctrine permits it to "sue to redress" the injury of a single member out of its "almost thirty-eight million members"). As I have already explained in the context of third-party standing, Article III does not allow a plaintiff to seek to vindicate someone else's injuries. See *June Medical*, 591 U. S., at 364–366 (opinion of THOMAS, J.); *Kowalski*, 543 U. S., at 135 (opinion of THOMAS, J.). It is difficult to see why that logic should not apply with equal force to an association as to any other plaintiff. I thus have serious doubts that an association can have standing to vicariously assert a member's injury.

The Alliance's attempted use of our associational-standing doctrine illustrates how far we have strayed from the traditional rule that plaintiffs must assert only their own injuries. The Alliance is an association whose members are other associations. See 1 App. 9–10. None of its members are doctors. Instead, the Alliance seeks to have associational standing based on injuries to the doctors who are members of its member associations. Thus, the allegedly injured parties—the doctors—are two degrees removed from the party before us pursuing those injuries.

Second, our associational-standing doctrine does not appear to comport with the requirement that the plaintiff present an injury that the court can redress. For a plaintiff to have standing, a court must be able to "provid[e] a remedy that can redress *the plaintiff's* injury." *Uzuegbunam* v. *Preczewski*, 592 U. S. 279, 291 (2021) (emphasis added). But, as explained, associational standing creates a mismatch: Although the association is the plaintiff in the suit, it has no injury to redress. The party who needs the remedy—the injured member—is not before the court. Without such members as parties to the suit, it is questionable whether "relief to these nonparties . . . exceed[s] constitutional bounds." *Association of American Physicians & Surgeons*

v. *FDA*, 13 F. 4th 531, 540 (CA6 2021); see also *Department of Homeland Security* v. *New York*, 589 U. S. ——, —— (2020) (GORSUCH, J., concurring in grant of stay) (explaining that remedies "are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit"); Brief for Professor F. Andrew Hessick as *Amicus Curiae* 18 ("A bedrock principle of the Anglo-American legal system was that the right to a remedy for an injury was personal").

Consider the remedial problem when an association seeks an injunction, as the Alliance did here. See 1 App. 113. "We have long held" that our equity jurisdiction is limited to "the jurisdiction in equity exercised by the High Court of Chancery in England at the time of the adoption of the Constitution." *Grupo Mexicano de Desarrollo, S. A.* v. *Alliance Bond Fund, Inc.*, 527 U. S. 308, 318 (1999). And, "as a general rule, American courts of equity did not provide relief beyond the parties to the case." *Trump* v. *Hawaii*, 585 U. S. 667, 717 (2018) (THOMAS, J., concurring). For associations, that principle would mean that the relief could not extend beyond the association. But, if a court entered "[a]n injunction that bars a defendant from enforcing a law or regulation against the specific party before the court—the *associational plaintiff*—[it would] not satisfy Article III because it w[ould] not redress an injury." *Association of American Physicians & Surgeons*, 13 F. 4th, at 540 (internal quotation marks omitted).[3]

Our precedents have provided a workaround for this obvious remedial problem through the invention of the so-called

[3] This also raises the question of who should pick the remedy. Associations "may have very different interests from the individuals whose rights they are raising." *Kowalski* v. *Tesmer*, 543 U. S. 125, 135 (2004) (THOMAS, J., concurring). For example, an association might prefer an injunction preventing the enforcement of a law that harms its members, while an injured member may instead want damages to compensate him for his injuries. Or perhaps a member would wish to settle the litigation, whereas an association might want to continue the fight. Our associational-standing doctrine ignores these obvious concerns.

"universal injunction." Universal injunctions typically "prohibit the Government from enforcing a policy with respect to anyone." *Trump*, 585 U. S., at 713, n. 1 (THOMAS, J., concurring). By providing relief beyond the parties to the case, this remedy is "legally and historically dubious." *Id.*, at 721; see also *Labrador* v. *Poe*, 601 U. S. ——, —— – —— (2024) (GORSUCH, J., concurring in grant of stay). It seems no coincidence that associational standing's "emergence in the 1960s overlaps with the emergence of [this] remedial phenomenon" of a similarly questionable nature. *Association of American Physicians & Surgeons*, 13 F. 4th, at 541. Because no party should be permitted to obtain an injunction in favor of nonparties, I have difficulty seeing why an association should be permitted to do so for its members. Associational standing thus seems to distort our traditional understanding of the judicial power.

In addition to these Article III concerns, there is tension between associational standing and other areas of law. First, the availability of associational standing subverts the class-action mechanism. A class action allows a named plaintiff to represent others with similar injuries, but it is subject to the many requirements of Federal Rule of Civil Procedure 23. Associational standing achieves that same end goal: One lawsuit can provide relief to a large group of people. "As compared to a class action," however, associational standing seems to require "show[ing] an injury to only a single member," and the association "need not show that litigation by representation is superior to individual litigation." 13A C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure §3531.9.5, pp. 879–880 (3d ed., Supp. 2023); see also Fed. Rule Civ. Proc. 23(a). Associational standing thus allows a party to effectively bring a class action without satisfying any of the ordinary requirements. Second, associational standing creates the possibility of asymmetrical preclusion. The basic idea behind preclusion is that a party gets only one bite at the apple. If a party

litigates and loses an issue or claim, it can be barred from reasserting that same issue or claim in another suit. In general, preclusion prevents the relitigation of claims or issues only by a party to a previous action, and we have been careful to limit the exceptions to that rule. See *Taylor* v. *Sturgell*, 553 U. S. 880, 892–893 (2008). In the context of associational standing, the general rule would mean that preclusion applies only to the association, even though the purpose of the association's suit is to assert the injuries of its members. See *id.*, at 893–896. But, if the association loses, it is not clear whether the adverse judgment would bind the members. See *Automobile Workers* v. *Brock*, 477 U. S. 274, 290 (1986) (suggesting that, if an association fails to adequately represent its members, "a judgment won against it might not preclude subsequent claims by the association's members without offending due process principles"). Associational standing might allow a member two bites at the apple—after an association's claims are rejected, the underlying members might be able to assert the exact same issues or claims in a suit in their own names.

In short, our associational-standing doctrine appears to create serious problems, both constitutional and otherwise.

II

I am particularly doubtful of associational-standing doctrine because the Court has never attempted to reconcile it with the traditional understanding of the judicial power. Instead, the Court departed from that traditional understanding without explanation, seemingly by accident. To date, the Court has provided only practical reasons for its doctrine.

For over a century and a half, the Court did not have a separate standing doctrine for associations. As far as I can tell, the Court did not expressly contemplate such a doctrine until the late 1950s. In *NAACP* v. *Alabama ex rel. Patterson*, 357 U. S. 449 (1958), the Court permitted an association

to assert the constitutional rights of its members to prevent the disclosure of its membership lists. While the Court allowed the NAACP to raise a challenge on behalf of its members, it also acknowledged that the NAACP had arguably faced an injury of its own. *Id.*, at 459–460. The Court, however, soon discarded any notion that an association needed to have its own injury, creating our modern associational-standing doctrine. In *National Motor Freight Traffic Assn., Inc.* v. *United States*, 372 U. S. 246 (1963) (*per curiam*), the Court suggested that an uninjured industry group had standing to challenge a tariff schedule on behalf of its members. *Id.*, at 247. The Court offered no explanation for how that theory of standing comported with the traditional understanding of the judicial power. In fact, the Court's entire analysis consisted of a one-paragraph order denying rehearing. Since then, however, the Court has parroted that "*[e]ven in the absence of injury to itself*, an association may have standing solely as the representative of its members." *Warth* v. *Seldin*, 422 U. S. 490, 511 (1975) (emphasis added; citing *National Motor Freight Traffic Assn.*, 372 U. S. 246); see also, *e.g.*, *Automobile Workers*, 477 U. S., at 281. The Court has gone so far as to hold that a state agency—not a membership organization at all—had associational standing to "asser[t] the claims of the Washington apple growers and dealers who form its constituency." *Hunt*, 432 U. S., at 344.

Despite its continued reliance on associational standing, the Court has yet to explain how the doctrine comports with Article III. When once asked to "reconsider and reject the principles of associational standing" in favor of the class-action mechanism, the Court justified the doctrine solely by reference to its "special features, advantageous both to the individuals represented and to the judicial system as a whole." *Automobile Workers*, 477 U. S., at 288–289. Those "special features" included an association's "pre-existing reservoir of expertise and capital," and the fact that people

often join an association "to create an effective vehicle for vindicating interests that they share with others." *Id.*, at 289–290. But, considerations of practical judicial policy cannot overcome the Constitution's mandates. The lack of any identifiable justification further suggests that the Court should reconsider its associational-standing doctrine.

* * *

No party challenges our associational-standing doctrine today. That is understandable; the Court consistently applies the doctrine, discussing only the finer points of its operation. See, *e.g.*, *Students for Fair Admissions, Inc.* v. *President and Fellows of Harvard College*, 600 U. S. 181, 199–201 (2023). In this suit, rejecting our associational-standing doctrine is not necessary to conclude that the plaintiffs lack standing. In an appropriate case, however, the Court should address whether associational standing can be squared with Article III's requirement that courts respect the bounds of their judicial power.

Reporter's Note

The attached opinion has been revised to reflect the usual publication and citation style of the United States Reports. The revised pagination makes available the official United States Reports citation in advance of publication. The syllabus has been prepared by the Reporter of Decisions for the convenience of the reader and constitutes no part of the opinion of the Court. A list of counsel who argued or filed briefs in this case, and who were members of the bar of this Court at the time this case was argued, has been inserted following the syllabus. Other revisions may include adjustments to formatting, captions, citation form, and any errant punctuation. The following additional edits were made:

None