Nos. 23-235 and 23-236

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writs of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE STATE OF MISSISSIPPI AND 21 OTHER STATES AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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INTRODUCTION AND INTEREST OF AMICI CURIAE

This case challenges the U.S. Food and Drug Administration's actions adopting an elective-abortion policy that Congress could never pass, that States have rejected, and in which the American people had no say. The FDA claims that this Court "owe[s] significant deference" to those actions and should review them "deferential[ly]." FDA Br. 34, 44.

The FDA is wrong. This Court gives agencies deference on matters of special agency competence, on granular questions requiring technical expertise, and on issues over which an agency enjoys clear authority. But this Court does not defer when an agency tests constitutional boundaries.

That is because federal agencies present special risks to the constitutional design. Our Constitution establishes a limited federal government and leaves power over important issues with the people. Agencies imperil that design. Where the Constitution separates the national government's powers, agencies seek to concentrate power. The Constitution vests lawmaking authority—the power to make national policy—in a vigorous Congress. But federal executive agencies now routinely exert broad lawmaking power and impose major national policies. The Constitution also divides power between the national government and state governments. Federalism prevents the national government from wielding so much power that it can trample liberty and keeps most power with state governments that the people can better hold accountable. Federal agencies undercut this framework. They regularly adopt policies that thwart state laws—without the public accountability that

comes with state lawmaking—causing federal power to swell and liberty to shrink. And agencies imperil what may be the Constitution's core feature: that the people decide the hardest, most important issues. As agencies engulf more of American life, the people lose control over those issues.

The FDA actions challenged here present these risks to the constitutional design. Start with the separation of powers. The FDA has adopted a nationwide elective-abortion regime. It has extended that regime deeper into pregnancy, with ever fewer guardrails, and despite abortion's unique challenges. Congress has never enacted—and could not now enact—any such policy. Yet the FDA does not just claim power to impose such a policy. It demands "significant deference" to its actions imposing that policy. This extraordinary claim of lawmaking authority tests the separation of powers.

Now take federalism. Under the Constitution, States have the primary authority to protect health, safety, and welfare. Using that power, many States have regulated and restricted abortion—including chemical abortion. Yet the FDA has greenlighted a permissive elective-abortion policy—undercutting States' laws, thwarting States' ability to enforce them, and hobbling the interests that those laws serve. This intrusion on state authority exerts serious pressure on the federal-state balance of power.

Last, consider how this all affects the American people. Few issues are as important and controversial as abortion. Federal lawmaking on abortion has thus long proceeded incrementally: sweeping action has not gained the consensus needed to become federal

law. And because questions on abortion are so important, it is critical that the people decide them. Yet the FDA's actions rob the people of power to decide central questions—whether chemical abortion should be lawful, in what circumstances, and under what conditions—on this vital issue. That state of affairs departs from our constitutional order, which leaves the most important matters to the people.

These tests to the constitutional design—and what they mean for resolving this case—are of great importance to amici curiae, the States of Mississippi, Alabama, Alaska, Arkansas, Florida, Georgia, Indiana, Iowa, Kentucky, Louisiana, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. In adopting the Constitution, the people reserved most power to themselves and to States that would protect liberty. Because of their duty to protect liberty, amici have a strong interest in rigorous enforcement of constitutional limits—including searching judicial review of federal agency actions that press constitutional boundaries. The FDA's actions press those boundaries and this Court should subject those actions to searching review.

SUMMARY OF ARGUMENT

Our Constitution establishes a limited federal government that leaves most power with—and accountable to—the people. Federal agencies present special risks to that design. So when agency action pushes constitutional bounds, this Court's review of that action is searching—not deferential. The FDA's actions here push constitutional bounds. Those

actions test the separation of powers, sap federalism, and take important decisions from the people. This Court should therefore exercise searching review of those actions and reject the FDA's plea for deference.

ARGUMENT

I. When Agency Action Pushes Constitutional Boundaries, Judicial Review Of That Action Is Searching—Not Deferential.

This Court often decides challenges to agency action. At times this Court reviews such action deferentially. But that is not so when agency action bristles against the constitutional design. When that happens, this Court's review is searching.

A. The Constitution Establishes A Limited Federal Government And Leaves Power With—And Accountable To—The People.

The Constitution protects liberty by limiting government power. It does this mainly through "structural protections." *Bowsher v. Synar*, 478 U.S. 714, 730 (1986). It divides power at the national level, further divides power between the national and state governments, and otherwise reinforces that power remains with and is accountable to the people—particularly on what is most important.

Start at the national level, with the separation of powers. The Constitution "divide[s] the ... powers of the ... Federal Government into three defined categories, Legislative, Executive, and Judicial." *INS v. Chadha*, 462 U.S. 919, 951 (1983). The Framers understood that "unit[ing]" different powers in the "same person or body" destroys "liberty." The Federalist No. 47 (James Madison) (quoting

Montesquieu). By "diffus[ing] power," then, the Constitution aims to "better ... secure liberty." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 635 (1952) (Jackson, J., concurring). All the Constitution's divisions of national power are critical. But the division most important to national policymaking is the one between the legislative and executive branches. The Constitution establishes "a vigorous Legislative Branch and a separate and wholly independent Executive Branch, with each branch responsible ultimately to the people." *Bowsher*, 478 U.S. at 722. Each of those branches must "confine itself to its assigned responsibility" and not "exceed" constitutional limits by exercising power assigned to the other branch. *Chadha*, 462 U.S. at 951.

Next, take the division between the national and state governments: federalism. The Constitution embraces a system of "dual sovereignty," in which "States possess sovereignty concurrent with that of the Federal Government." *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991). By striking a proper "balance of power between the States and the Federal Government," federalism complements the separation of powers by "secur[ing] to citizens the liberties that derive from the diffusion of sovereign power." *New York v. United States*, 505 U.S. 144, 181 (1992). And instead of forcing the people "to rely solely upon the political processes that control a remote central power," the federal structure lets States take different approaches that respond "to the diverse needs of a heterogeneous society." *Bond v. United States*, 564 U.S. 211, 221 (2011). By leaving most power with the States, the Constitution makes those who most wield power over everyday life accountable

to the people as a distant national government can never be. *See Gregory*, 501 U.S. at 458.

Last, take the core aim of the Constitution: protecting liberty by leaving power with—and making power accountable to—the people. *See* U.S. Const. amend. X. "Our Constitution was adopted to enable the people to govern themselves, through their elected leaders." *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 499 (2010). The constitutional design ensures that the officials who wield government power remain "accountable to political force and the will of the people," *Freytag v. Commissioner*, 501 U.S. 868, 884 (1991), and face "electoral ramifications" when they use power poorly, *New York*, 505 U.S. at 169. The separation of powers and federalism of course serve this aim. And the Constitution reinforces those protections by limiting federal power—particularly national lawmaking power. The Constitution makes that power hard to exercise. A policy can become federal law only by majority vote of two differently composed houses of Congress and approval by the President. U.S. Const. art. I, § 7. This process is deliberately challenging. *See Chadha*, 462 U.S. at 944, 949, 959. Requiring hard work and buy-in from a wide cross-section of the people's elected representatives ensures that "dependence on the people" remains the "primary contro[l] on the government." *Free Enterprise Fund*, 561 U.S. at 501.

B. Federal Agencies Present Special Dangers To The Constitutional Design.

Against the constitutional design stand federal agencies. Agencies pose many risks to that design, but three are especially acute.

First, agencies erode the separation of powers. Agencies are housed in the executive branch yet often assert legislative power over matters of "vast economic and political significance." *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam) (internal quotation marks omitted). Agencies have adopted many national policies—on heated, important issues—that operate as federal law even though those policies would never have been enacted by Congress. *See infra* Part I-C (giving examples). That is especially so in the modern day, when "the vast majority" of federal "lawmaking" no longer "take[s] place in Congress, but within the hundreds of federal agencies spread across the modern regulatory state." Jonathan H. Adler & Christopher J. Walker, Delegation and Time, 105 Iowa L. Rev. 1931, 1975 (2020); *see* Ronald A. Cass, Rulemaking Then and Now: From Management to Lawmaking, 28 Geo. Mason L. Rev. 683, 694 (2021) (Congress passes 200-400 laws each year; federal agencies adopt some 3000-5000 final rules each year). Agencies have thus overtaken much of Congress's "assigned responsibility." *Chadha*, 462 U.S. at 951.

Second, federal agencies imperil federalism. Just as there is "hydraulic pressure inherent within each of the separate [federal] Branches to exceed the outer limits of its power," *Chadha*, 462 U.S. at 951, there is inherent pressure for the federal government to exceed its authority by invading the domain of States. *Cf. Free Enterprise Fund v. PCAOB*, 537 F.3d 667, 694 n.4 (D.C. Cir. 2008) (Kavanaugh, J., dissenting) ("Power abhors a vacuum."), *aff'd in part*, *rev'd in part*, *and remanded*, 561 U.S. 477 (2010). As federal power expands, it does so at the expense of state power. That expense is costly indeed: the people can

far better channel power and hold officials accountable at the state level. Disrupting the traditional federal-state balance is thus an "extraordinary power" that Congress "does not exercise lightly." *Gregory*, 501 U.S. at 460. Yet federal agencies now routinely "intrude[ ] into" the "domain of state law." *Alabama Ass'n*, 141 S. Ct. at 2489. And they often do so using stale, vague, or inapt delegations of power that do not reflect Congress's "clear and manifest" "intent to intrude on state governmental functions." *Gregory*, 501 U.S. at 461, 470. "[T]he background principles of our federal system ... belie the notion that Congress would use" "obscure grant[s] of authority to regulate areas traditionally supervised by the States' police power." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). Yet agencies plow ahead, claiming more for themselves—and less for States.

Third, agencies seize power from the people. Only a "vigorous" Congress—"responsible ultimately to the people" through elections—enjoys national lawmaking authority. *Bowsher*, 478 U.S. at 722. When elected representatives in Congress "make[ ] ... decision[s] in full view of the public," those officials "suffer the consequences if" a decision "turns out to be detrimental or unpopular." *New York*, 505 U.S. at 168. And the challenges of the federal-lawmaking process ensure that "the people" retain ultimate policymaking control. *Free Enterprise Fund*, 561 U.S. at 501. But agencies operate outside these constraints. They are staffed by faceless functionaries who are "neither elected nor reelected" and are "controlled only spasmodically by officials who are." John Hart Ely, Democracy and Distrust 131 (1980); *see Free Enterprise Fund*, 561 U.S. at 499 ("The

growth of the Executive Branch, which now wields vast power and touches almost every aspect of daily life, heightens the concern that it may slip from the Executive's control, and thus from that of the people."). This "insulat[ion]" from "electoral ramifications" "diminishe[s]" the "[a]ccountability" the Constitution envisions. *New York*, 505 U.S. at 169. As a result, agencies often adopt policies, on major issues, that the people as a whole do not want. *Cf. West Virginia v. EPA*, 142 S. Ct. 2587, 2608-09 (2022) (describing cases where agencies adopted policies that would likely have failed legislatively).

C. Because Agencies Present Special Dangers, This Court Has Been Searching—Not Deferential—In Reviewing Agency Action That Pushes Constitutional Boundaries.

Given the risks that agencies pose to the constitutional design, this Court has been vigilant in policing agency actions that test constitutional limits.

First, this Court has safeguarded the separation of powers by blocking agency actions that arrogate legislative power from Congress. In *West Virginia v. EPA*, for example, this Court rejected the EPA's claim of authority to "restructure the American energy market" by "forc[ing] a nationwide transition" to renewable energy sources. 142 S. Ct. at 2610, 2616. "A decision of such magnitude and consequence," the Court ruled, "rests with Congress itself"—or at least with "an agency acting pursuant to a clear delegation from that representative body." *Id.* at 2616. Similarly, in *NFIB v. OSHA*, 142 S. Ct. 661 (2022) (per curiam), this Court rejected the Occupational Safety and Health Administration's attempt to impose a

nationwide vaccine mandate on "roughly 84 million workers." *Id.* at 662. The "responsibility" for "weigh[ing] [the] tradeoffs" of such "a significant encroachment" on the American public, the Court stressed, belongs to "those chosen by the people through democratic processes." *Id.* at 665, 666.

This Court has rejected many other agency actions that intruded on Congress's legislative authority. *E.g.*, *Alabama Ass'n*, 141 S. Ct. at 2486, 2490 ("Congress, not the CDC," is responsible for deciding "whether the public interest merits" a "nationwide moratorium on evictions" during a pandemic); *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014) (rejecting view of Clean Air Act that would have "br[ought] about an enormous and transformative expansion in EPA's regulatory authority without clear congressional authorization"); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000) (rejecting FDA's claim that its power over "drugs" and "devices" includes power to regulate or ban tobacco products). In doing so, this Court has applied a "presum[ption]" that "Congress intends to make major policy decisions itself"—through legislation—and "not leave those decisions to agencies." *West Virginia*, 142 S. Ct. at 2609. This Court thus looks skeptically—not deferentially—when agencies make broad uses of legislative power.

Second, this Court has halted agency actions that erode federalism. The Court has been especially wary of actions that "intrude[ ] into an area that is the particular domain of state law." *Alabama Ass'n*, 141 S. Ct. at 2489. Thus in *Alabama Association of Realtors*, this Court rejected the CDC's claimed authority to impose a nationwide eviction moratorium in part because that action "intrude[d]" on "landlord-

tenant relationship[s]" traditionally regulated by States. *Ibid.* And in *Gonzales v. Oregon*, this Court refused to read the federal Controlled Substances Act to give the Attorney General power "to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide." 546 U.S. at 248-49. This Court rejected the claimed power of "a single executive officer" "to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality." *Id.* at 275. Similarly, in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159 (2001), this Court refused to read the Clean Water Act to give a federal agency control over certain lands traditionally regulated by States. *Id.* at 162. A contrary view would have "result[ed] in a significant impingement of the States' traditional and primary power over land and water use." *Id.* at 174. In these cases this Court scrutinized agency action not deferentially but vigilantly—in a way that honored federalism and preserved the "proper balance between the States and the Federal Government." *Gregory*, 501 U.S. at 459.

Third, this Court has closely examined agency actions that take major issues away from the people. A prominent recent example is the Court's rejection of a workplace-safety agency's effort to mandate vaccination for much of the U.S. workforce. *See NFIB*, 142 S. Ct. at 664-66. Such a consequential, debated issue was for the people's elected representatives, not unelected federal functionaries. This Court's careful scrutiny was particularly apt because the agency's actions set a national policy that cut off an "earnest and profound debate" "across the country" on a matter of great importance. *Gonzales*, 546 U.S. at 267. The

Constitution largely leaves such "political and moral debate[s]," *id.* at 249, to the people, to resolve through persuasion and voting. This respect for the people "is vital because" (as "the framers believed") "a republic—a thing of the people—[is] more likely to enact just laws than a regime administered by a ruling class of largely unaccountable 'ministers.'" *West Virginia*, 142 S. Ct. at 2617 (Gorsuch, J., concurring). So when unaccountable ministers test our constitutional design, this Court subjects their work to searching review.

II. The FDA's Actions Push Constitutional Boundaries And Thus Warrant Searching Judicial Review.

This case challenges the FDA's actions on the chemical-abortion drug mifepristone. Those actions test constitutional boundaries. This Court should therefore reject the FDA's plea for "significant deference" (FDA Br. 34; *see id.* at 34-44) and subject the FDA's actions to searching review.

A. The FDA's Actions Undercut The Separation Of Powers.

The FDA's actions impose a nationwide elective-abortion regime. This raises serious separation-of-powers problems.

First consider the landscape under the FDA's actions. In 2000, the FDA approved mifepristone for chemical abortions. J.A. 225. Whatever else could be said of that approval, it at least included measures addressing mifepristone's risks. The approval extended only through 49 days of pregnancy; allowed mifepristone to be dispensed only in clinics, medical

offices, or hospitals (all under a qualified physician's supervision); mandated three in-person office visits; and required providers to report serious adverse events from the drug. J.A. 225-32, 296. Yet in 2016, the FDA rolled back safety requirements—allowing mifepristone to be prescribed through 70 days of pregnancy, by non-doctors, with only one in-person visit—and stopped requiring prescribers to report non-fatal adverse events. J.A. 293-320. In 2021, the FDA dropped the in-person-dispensing requirement. J.A. 364-65, 371. Through these actions, the FDA has imposed a nationwide elective-abortion regime.

Adopting a nationwide elective-abortion regime would be a breathtaking feat of federal legislation. Abortion is "unique" and "fraught with consequences," *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 852 (1992)—after all, it "presents an irreconcilable conflict between the interests of a pregnant woman who seeks an abortion and the interests in protecting fetal life," *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2304 (2022) (Kavanaugh, J., concurring). Many federal legislative proposals have sought to address abortion. *E.g.*, States Choose Life Act of 2023, H.R. 4414, 118th Cong. (2023); Abortion Justice Act of 2023, H.R. 4303, 118th Cong. (2023); Women's Public Health and Safety Act, S. 471, 118th Cong. (2023); Women's Health Protection Act of 2023, S. 701, 118th Cong. (2023). Yet few have gained the consensus needed to become federal law. The rare successes have been targeted laws that, far from endorsing abortion, restrict or discourage it. *E.g.*, 136 Stat. 49, 496 (2022) (Hyde Amendment, restricting use of federal funds for certain abortions); 18 U.S.C. § 1531 (Partial-Birth Abortion Ban Act); *id.* §§ 1461,

1462 (criminal laws making abortion drugs nonmailable and nonshippable by common carrier).

This all points up the obvious: Congress has never enacted (and could not now enact) a nationwide elective-abortion regime. Yet the FDA here claims the power to itself impose such a policy—and, incredibly, demands that this Court defer to its actions imposing that policy. But by claiming the power to make a "decision of such magnitude and consequence," *West Virginia*, 142 S. Ct. at 2616, the FDA has invaded Congress's "assigned responsibility" and eviscerated the Constitution's checkpoints for democratic accountability. *INS v. Chadha*, 462 U.S. 919, 951 (1983); *see id.* at 946-51. Under our constitutional design, the "responsibility" for "weigh[ing] [the] tradeoffs" of a widescale elective-abortion regime is with elected officials "chosen by the people through democratic processes." *NFIB*, 142 S. Ct. at 666. The FDA's actions undermine this design and thus warrant this Court's close scrutiny.

B. The FDA's Actions Erode Federalism.

The FDA's broad endorsement of chemical abortion is also hostile to federalism.

Under the Constitution, States have "primar[y]" authority over health and safety. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985). "[T]he structure and limitations of federalism" "allow the States great latitude" to enact laws protecting "the lives, limbs, health, comfort, and quiet of all persons." *Gonzales*, 546 U.S. at 270 (internal quotation marks omitted). This authority includes overseeing the medical profession, *ibid.*, setting standards of care, *see ibid.*, and

regulating or restricting abortion to protect life and health, *Dobbs*, 142 S. Ct. at 2284.

Using their retained constitutional authority, States take varying approaches to abortion. Some States have adopted permissive regimes. Other States impose tighter regulations or restrictions. Abortion laws in those latter States ubiquitously protect a woman's life, *e.g.*, Miss. Code Ann. § 41-41-45(2), and commonly include other exceptions, *e.g.*, *ibid.* (exception for rape). Many state laws address the risks of chemical abortions. Such laws recognize, for example, that "abortion-inducing drugs": "present[ ] significant medical risks to women," such as "uterine hemorrhage, viral infections, pelvic inflammatory disease, severe bacterial infection and death," *id.* § 41-41-103(1)(a); "are associated with an increased risk of complications relative to surgical abortion" that surge "with increasing gestational age," *id.* § 41-41-103(1)(b); and "are contraindicated in ectopic pregnancies," *id.* § 41-41-107(2). States combat those risks by, among other things, requiring that only physicians may provide such drugs, that a physician may do so only after "physically examin[ing] the woman and document[ing] ... the gestational age and intrauterine location of the pregnancy," and that these drugs "must be administered in the same room and in the physical presence of the physician." *Id.* § 41-41-107(1)-(3); *see*, *e.g.*, Ind. Code Ann. § 16-34-2-1 (requiring in-person exam and dispensing); Okla. Stat. Ann. tit. 63, § 1-729.1 (requiring in-person dispensing); Tex. Health & Safety Code Ann. § 171.063(b-1) (prohibiting shipment of abortion drugs "by courier, delivery, or mail service"). And, like all elective abortions, elective chemical abortions are generally unlawful in several States. *E.g.*, Miss. Code

Ann. § 41-41-45(2) (abortion unlawful except "where necessary for the preservation of the mother's life or where the pregnancy was caused by rape").

The FDA's actions undermine these laws, undercut States' efforts to enforce them, and thus erode the federalism the Constitution deems vital. Those actions have led to the widespread shipment of abortion drugs. *See* Pam Belluck, More Women Who Are Not Pregnant Are Ordering Abortion Pills Just in Case, N.Y. Times (Jan. 2, 2024), nyti.ms/3SVJLWy (tens of thousands of abortion pills have been provided by telehealth in recent years, including in States that restrict abortion); Caroline Kitchener, Blue-State Doctors Launch Abortion Pill Pipeline Into States With Bans, Wash. Post (July 19, 2023), wapo.st/3M29JUq (detailing "new pipeline of legally prescribed abortion pills flowing into states with abortion bans"); Alice Miranda Ollstein & Lauren Gardner, Retail Pharmacies Can Now Offer Abortion Pill, FDA Says, Politico (Jan. 3, 2023), bit.ly/3wCPl3V ("[t]elemedicine and mail delivery ... has allowed patients to circumvent state bans"). The FDA has thus facilitated violations of many States' laws. The FDA's actions force States to divert resources to investigate and address the harms that this lawbreaking will inflict on women, children, and the public interest. *See* Blue-State Doctors (one "small group" of providers has mailed abortion pills into more-restrictive States on a pace that will "facilitate at least 42,000 abortions" over the next year).

The FDA's actions thus "intrude on state governmental functions," *Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991), and hobble States' efforts to protect health and safety. Without any federal law expressing Congress's "exceedingly clear" wish "to

significantly alter the balance between federal and state power," *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam), the FDA has "effect[ed] a radical shift of authority from the States to the Federal Government" on abortion. *Gonzales*, 546 U.S. at 275; *see Dobbs*, 142 S. Ct. at 2284 (the "authority" to "regulat[e] or prohibit[ ] abortion" belongs to "the citizens of each State."). Given these harms to federalism, this Court should view the FDA's actions with skepticism.

C. The FDA's Actions Rob From The People Decisions Of Great Importance.

Finally, the FDA's actions depart from the central tenet of our Constitution: that power—particularly over important, hard, controversial issues—resides with and must be accountable to the people.

Few issues are as important, hard, and controversial as abortion. *Supra* pp. 13-14. The Constitution thus leaves the task of regulating and restricting abortion to "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. Yet the FDA's actions rob from the people important decisions on this vital issue.

To start, the FDA approved mifepristone for elective abortions—despite strong opposition across the country. *E.g.*, J.A. 201-23, 238-70. It did so based on problematic, contested grounds, including its determination that an "unwanted pregnancy" is an "illness[ ]" in need of the "therapeutic benefit" that mifepristone provides. J.A. 230. Next, the FDA expanded mifepristone's use. In 2016, it extended mifepristone's approved use from 49 days of pregnancy to 70 days of pregnancy. *E.g.*, J.A. 295, 299,

302. The FDA made this decision even though the risk of complications increases with gestational age. *E.g.*, J.A. 165, 171, 197, 209-12. And it did so even though abortion becomes increasingly problematic as pregnancy progresses. *Cf. Roe v. Wade*, 410 U.S. 113, 162-63 (1973) (interests in protecting "the health of the pregnant woman" and "the potentiality of human life" "grow[ ] in substantiality" as pregnancy progresses). Last, the FDA cast aside safety measures. When the FDA approved mifepristone, it recognized the drug's risks and imposed measures to mitigate those risks. J.A. 225-32. But the FDA has dispensed with many of those measures. It now condones use of mifepristone without a physician prescriber, without assessing gestational age, without reporting of non-fatal adverse events, and without any in-person visits to a doctor—the "primary tool for ensuring the safe distribution and use of mifepristone." FDA Pet. App. 229a. At every turn—in approving mifepristone, expanding its use, and dropping safeguards around it—the FDA acted without buy-in from, or accountability to, the people.

For decades, then, the FDA has seized control over one of the most important, contested issues of our time. The agency has denied the people a say, "through their elected leaders," on fraught and consequential questions of policy. *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 499 (2010). Its actions have short-circuited "an earnest and profound debate" on the "morality, legality, and practicality" of chemical abortion—including whether to allow it and how to regulate it. *Gonzales*, 546 U.S. at 249. And those actions have undermined state laws on abortion that strike a balance among the competing interests, are the results of hard-fought democratic processes,

and embody the considered judgments of "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. Far from meriting "significant deference," FDA Br. 34, the FDA's actions on mifepristone should for this reason—and those given above—face this Court's searching review.

CONCLUSION

The Court should exercise searching—not deferential—review over the FDA's actions, hold that those actions are unlawful, and affirm the judgment below.

Respectfully submitted.

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