No. 23-235

In the Supreme Court of the United States

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

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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The Fifth Circuit's unprecedented decision contradicts fundamental principles of Article III and administrative law and affirms disruptive nationwide relief. The pharmaceutical industry has warned that the court's legal holdings would "upend[]" a "settled regulatory scheme" and "stifle pharmaceutical innovation." PhRMA Br. 3. And organizations representing hundreds of thousands of medical professionals have emphasized that the decision below would undermine "patient safety" and "impede the provision of quality health care" by compelling the Food and Drug Administration (FDA) to return to an obsolete regulatory regime for mifepristone. ACOG Br. 6.

Respondents' attempts to rehabilitate the Fifth Circuit's decision only underscore the need for this Court's

review. Most obviously, respondents do not even try to defend the Fifth Circuit's reliance on a statistical theory of associational standing that contradicts *Summers* v. *Earth Island Institute*, 555 U.S. 488 (2009). Respondents also fail to justify the Fifth Circuit's other holdings, including its novel and unworkable demand that a drug's approved conditions of use exactly replicate the conditions of a prior clinical study.

Nor do respondents offer any persuasive reason to deny review. Their attempt to portray the Fifth Circuit's decision as factbound and inconsequential strains credulity. And although respondents emphasize the case's interlocutory posture, this Court often grants certiorari when lower courts impose broad preliminary relief blocking important federal actions or programs. Here, the Court has already recognized the importance of the questions presented by granting a stay. For the same reasons, the Court should grant certiorari and reverse.

A. The Fifth Circuit's Decision Is Wrong

1. Respondents lack standing

a. The Fifth Circuit held that respondents have standing because the court believed it is statistically likely that some of their members will provide emergency care for women who take mifepristone. The court reasoned that "millions of women take mifepristone"; that a "percentage of women who take mifepristone will require emergency-room care"; and that "hundreds" of respondents' members "are OB/Gyns and emergency-room doctors." Pet. App. 26a; see *id.* at 26a-28a.

The petition explained (Pet. 15-16) that the Fifth Circuit's statistical approach contradicts this Court's decision in *Summers*, which emphatically rejected the theory that an association has standing whenever "there is

a statistical probability that some of [its] members are threatened with concrete injury." 555 U.S. at 497; see *id.* at 497-498. Instead, the Court reaffirmed that an association must show that "at least one identified member" meets the requirements of Article III. *Id.* at 498.

Respondents concede (Br. in Opp. 26) that *Summers* forecloses a statistical approach to associational standing. They insist, however, that the Fifth Circuit did not rely on such an approach. Instead, respondents assert that the court held that "*named* Respondent doctors and association members" satisfy Article III because those specific individuals face concrete, imminent injuries. *Id.* at 21; see *id.* at 25-26. That contention contradicts the Fifth Circuit's opinion.

The Fifth Circuit explained that respondents' theory of standing was that, given "the large number of association members who are emergency-room doctors," it is "highly likely that one or more of their members will be required to provide emergency care to a mifepristone patient in the near future." Pet. App. 23a-24a. The court embraced that statistical theory, repeatedly emphasizing that respondents have "hundreds" of members who provide emergency care. *Id.* at 16a, 23a, 26a, 28a, 31a. And the court specifically rejected the government's interpretation of *Summers*, asserting that "[t]he problem in that case was *not* that plaintiffs' standing theory was invalid" and holding that standing can be established by a "likelihood that some members of a discrete group, but not all, will be injured." *Id.* at 28a.

b. Respondents' refusal to acknowledge—much less defend—the actual basis for the Fifth Circuit's decision powerfully confirms the need for this Court's review. And respondents' alternative theory that the individual

doctors who provided declarations below satisfy Article III is also inconsistent with this Court's precedent.

Respondents' theory relies on a "speculative chain of possibilities," *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 414 (2013), in which a woman (i) chooses to obtain mifepristone from another provider; (ii) suffers an extremely rare serious event requiring emergency care (iii) that would not have occurred but for FDA's 2016 and 2021 actions; and (iv) happens to seek treatment from a particular respondent doctor. See Pet. 14. Respondents have not cited any decision, from any court, endorsing such an attenuated theory of standing.

Respondents attempt to make their speculation more plausible by conflating statistics on mifepristone's (low) failure rate with the (far lower) number of women who require emergency care after taking it. See, *e.g.*, Br. in Opp. 23. The fact that mifepristone "will not work" in a small number of cases, *ibid.*—and thus that women may need follow-up care such as an additional dose of misoprostol or a surgical abortion—does not mean that those women will require emergency care.

Respondents emphasize (*e.g.*, Br. in Opp. at 24-25) that FDA recognized the need for emergency care in some cases. But they ignore the Prescriber Agreement's requirement that prescribers "have the ability to provide" follow-up or emergency care "or that they have made plans to provide such care through others." C.A. ROA 814; see 2023 Prescriber Agreement. Respondents fail to provide any basis to conclude that mifepristone prescribers would plan for respondents or their members, who oppose abortion, to provide that care.

c. Respondents rely heavily (*e.g.*, Br. in Opp. 21-22) on declarations from doctors who have cared for mifepristone patients in the past. But it is hornbook law that

past injury does not establish the imminent harm required to seek forward-looking relief. See *Los Angeles* v. *Lyons*, 461 U.S. 95, 105-106 (1983).

Here, respondents' assertions of past injury are especially weak. The Fifth Circuit primarily relied on respondents' alleged conscience injury, *e.g.*, Pet. App. 24a, but respondents have identified *not one* respondent or member who has been required by his or her employer to perform an abortion or other procedure despite a conscience-based objection. Instead, respondents cite (Br. in Opp. 33) a secondhand account of a single purported experience of a declarant's unnamed "colleague."

Respondents also rely (Br. in Opp. 21) on a declarant's assertion that she has cared for "at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion." Resp. C.A. App. 15. But the declarant, Dr. Skop, does not say whether she had a conscience-based objection to providing that care or why, if she did, she was required to provide it despite her objection. Respondents' inability to muster any actual evidence of conscience injury over the decades mifepristone has been available confirms that it is pure speculation to infer that Dr. Skop (or "other [unnamed] doctors," Br. in Opp. 21) will be compelled to treat mifepristone patients against their consciences in the future—much less that any such incidents would be fairly traceable to FDA's 2016 and 2021 actions.

Respondents' other theories fare no better. Respondents assert (Br. in Opp. 34-35) that they suffer emotional "distress" from treating mifepristone patients. But respondents cite no authority for that extravagant theory, which would allow doctors to challenge any policy that

allegedly increases the risk of injuries or diseases they find distressing—from gun violence to tobacco use to car accidents. Even the Fifth Circuit thus recognized that respondents' alleged distress "does not provide a separate basis for Article III standing." Pet. App. 35a.

Respondents also invoke purported "economic harm" to their "business interests" and increased liability and insurance costs. Br. in Opp. 35 (brackets and citation omitted). But respondents cite no authority to support the counterintuitive notion that doctors suffer cognizable economic harm when they are presented with patients requiring care. And respondents offer *no* evidence that treating mifepristone patients will expose them to increased liability or insurance costs.

d. Respondents fall back (Br. in Opp. 37-39) to a theory of organizational standing that the Fifth Circuit did not adopt. They assert that FDA's actions have caused them to "divert[] resources" to conduct "'studies and analyses'" of mifepristone and to prepare their citizen petition challenging FDA's 2016 actions. *Id.* at 37 (citation omitted); see *id.* at 37-38. But respondents cite no precedent suggesting that an organization suffers an Article III injury merely because the government lifts reporting requirements applicable to third parties. And if the cost of opposing agency action were sufficient to satisfy Article III, any party could bootstrap its way into standing to challenge any agency action merely by challenging it.

2. FDA's actions were lawful

a. In 2016, FDA increased mifepristone's gestational age limit, reduced the number of required visits, and allowed certain non-physicians to prescribe the drug, among other changes. The Fifth Circuit's sole basis for deeming those changes arbitrary and capricious

was its assertion that FDA failed to consider the changes "as a whole" because no study combined all three of them. Pet. App. 53a. But the court and respondents ignore that Olavarietta 2015, for example, combined all three changes (plus others). See Pet. 23. In any event, neither the Fifth Circuit nor respondents offer any reason to think that changes that had been shown to be safe in varying combinations would become dangerous when combined as a full set.

Respondents object (Br. in Opp. 43) that although FDA considered some studies that included "ultrasounds and follow-up visits," it did not impose those requirements in mifepristone's approved conditions of use. But FDA explained at length why those requirements were unnecessary. C.A. Add. 820-822, 831, 849-855. Respondents simply ignore those parts of the record, which demonstrate that FDA did not "fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). And respondents' contrary approach would call into question countless other drug approvals, because "[t]here are virtually always differences between clinical trial conditions and approved labeling." Pharmaceutical Cos. Br. 15.

b. Respondents also assert (Br. in Opp. 44) that FDA acted arbitrarily by modifying mifepristone's reporting requirements in 2016. But FDA made those changes after *fifteen years* of adverse event data that showed "known risks occurring rarely." C.A. Add. 856. And while FDA changed the reporting requirements, it did not eliminate them. Pet. 24. Indeed, mifepristone is subject to reporting requirements at least as stringent as "the vast majority of other drugs." Food & Drug Scholars Br. 15.

c. As to FDA's later actions addressing the in-person dispensing requirement, respondents fault (Br. in Opp. 44-45) the agency for relying on adverse event data that was supposedly tainted by the 2016 reporting changes. But it is not plausible to assert that mifepristone's post-2016 adverse event reporting regime—which, again, is at least as demanding as the regime applicable to the vast majority of other drugs—cannot be a basis for reasoned decisionmaking.

Respondents also criticize (Br. in Opp. 48) the "limitations" of some of the studies FDA reviewed. FDA acknowledged those limitations and explained why they did not alter its conclusion. C.A. Add. 864; Pet. 26-27. FDA's evaluation of those studies spans eight pages of its response to respondents' 2019 citizen petition. C.A. Add. 865-872. Again, respondents do not even discuss that part of the record.

d. Respondents briefly assert (Br. in Opp. 49-50) that the 1873 Comstock Act provides an additional basis for invalidating FDA's elimination of the in-person dispensing requirement. But the Fifth Circuit did not rely on that argument, which is doubly flawed. First, it misunderstands the Comstock Act, which has long been understood to prohibit only the mailing of drugs for *unlawful* abortions. See *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. ___, (Dec. 23, 2022) (C.A. Add. 258-278) (collecting cases). Second, and in any event, FDA is required to approve drugs and set their conditions of use based on safety and effectiveness. 21 U.S.C. 355(d), 355-1. Nothing in the FDCA requires FDA to incorporate any requirements that other, unrelated laws may impose on a drug's distribution or use.

3. The district court's remedy was improper

The district court erroneously invoked 5 U.S.C. 705 to "postpone" the effective date of agency actions that had long been in effect. Respondents do not attempt to reconcile that relief with the plain text of Section 705. Nor do respondents dispute that Section 705 relief—like preliminary relief generally—should preserve the status quo. Here, however, the lower courts' orders upend the status quo, with disruptive consequences for women, the Nation's healthcare system, FDA, and mifepristone's sponsors. Pet. 27-30. At most, the Fifth Circuit should have given FDA an opportunity to correct any supposed errors of explanation without imposing such disruptive preliminary relief. Pet. 29-30.[*]

B. The Fifth Circuit's Decision Warrants Review

Respondents assert (Br. in Opp. 13-19) that further review is unwarranted because the decision below is interlocutory and because it is purportedly factbound and lacking in practical significance. Those arguments are badly mistaken.

1. This Court often grants review when lower courts issue preliminary relief blocking significant federal programs or actions. See, *e.g.*, *Murthy* v. *Missouri*, No. 23-411 (Oct. 20, 2023); *Biden* v. *Nebraska*, 143 S. Ct. 2355 (2023); *DHS* v. *New York*, 141 S. Ct. 1370 (2021); *Wolf* v. *Innovation Law Lab*, 141 S. Ct. 617 (2020); *Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania*, 140 S. Ct. 2367, 2378-2379 (2020). And here, the

[*] Respondents err in asserting (Br. in Opp. 51) that FDA took a contrary position in other litigation. FDA actually argued that the injunction there was unlawful because it would "preclud[e] future agency decisionmaking." FDA Br. at 32, *Washington* v. *FDA*, No. 23-cv-3026 (E.D. Wash. Mar. 17, 2023) (citation omitted).

Court has already recognized the important legal and practical stakes of this case by granting a stay pending appeal and certiorari.

Respondents provide no good reason to delay plenary review. They speculate (Br. in Opp. 17-18) that further proceedings might allow them to "bolster[] their standing" with additional evidence or to develop other arguments on the merits. But the same could be said in every case that comes to the Court in a preliminary-injunction posture. Parties that have secured disruptive preliminary relief based on inadequate standing and merits theories should not be permitted to insulate that relief from this Court's review by suggesting that they might develop other, better theories if given another bite at the apple.

Respondents further assert (Br. in Opp. 18-19) that the Court should defer review until the lower courts address an intervention motion recently filed by three States that assert different theories of standing. But the States' belated effort to intervene could not cure respondents' lack of standing or save this suit from dismissal because intervention "cannot create jurisdiction if none existed before." 7C Charles Alan Wright et al., *Federal Practice and Procedure* § 1917 (3d ed. 2007); see, *e.g.*, *Disability Advocates, Inc.* v. *New York Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 160-162 (2d Cir. 2012).

2. Respondents' insistence (Br. in Opp. 16) that the Fifth Circuit's decision is "fact-bound" blinks reality. The Fifth Circuit adopted an unprecedented *legal* holding that Article III allows an association of doctors to challenge agency action based on speculation that it will result in future injuries to third parties who some unknown association members might be asked to treat.

And on the merits, the Fifth Circuit adopted a novel and unworkable *legal* framework for reviewing FDA's drug approvals. The amicus briefs from the pharmaceutical industry underscore the extent to which the Fifth Circuit strayed from settled principles of standing and administrative review—and the destabilizing effects that its "impossibly rigid" mode of analysis would have on the industry's investment-backed expectations. Pharmaceutical Cos. Br. 12-17; see PhRMA Br. 12-19.

Respondents argue that it is not unprecedented for courts to enjoin or invalidate actions by FDA. But the government does not contend that FDA is "infallible" (Br. in Opp. 10), or that its decisions are "immun[e]" from judicial scrutiny (*id.* at 16). The point is that respondents cannot identify any prior decision invalidating FDA's approval of a drug based on a disagreement with FDA's assessment of safety and effectiveness—much less a decision that did so at the behest of speculative allegations of attenuated harms to parties who do not take or prescribe that drug.

3. Finally, respondents attempt (Br. in Opp. 14-15) to minimize "the practical effects of the decision below" by emphasizing that the Fifth Circuit "did *not* take mifepristone off the market" entirely. But the Fifth Circuit's decision would inflict profound disruption by reimposing a pre-2016 regulatory regime that includes outdated dosing and conditions that FDA has now determined are unjustified.

As FDA's Principal Deputy Commissioner explained, staying FDA's 2016 and 2021 actions would "create significant chaos for patients, prescribers, and the health care delivery system" by rendering all extant doses of mifepristone misbranded. No. 22A902 Appl. App. 116a. FDA and Danco would be required to take

time-consuming actions to reinstate the pre-2016 regime, including by determining whether the Fifth Circuit's decision "compels reversion to the pre-2016 labeling even though it contains information that is now scientifically out of date." *Id.* at 115a. And the Fifth Circuit's decision would also appear to require FDA "to reinstate a superseded dosing regimen" that provides for "a substantially *higher* dose of the drug than FDA has deemed necessary." *Ibid.*

Respondents insist (Br. in Opp. 1) that the pre-2016 restrictions they seek to reimpose are merely "commonsense safeguards." But FDA has determined, based on decades of experience and scientific evidence, that those restrictions are unnecessary and thus unjustified. And the Nation's leading medical organizations have warned that doctors and patients have "come to rely on the FDA's current regulatory approach" and would be seriously harmed by "rolling the clock back" to the "pre-2016 regulatory regime." ACOG Br. 5-6.

* * * * *

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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