Nos. 23-235 and 23-236

In the Supreme Court of the United States

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

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

DANCO LABORATORIES, L.L.C., PETITIONER

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

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

FEDERAL PETITIONERS' RESPONSE IN OPPOSITION TO THE MOTION OF MISSOURI, IDAHO, AND KANSAS FOR LEAVE TO INTERVENE

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The Solicitor General, on behalf of the federal petitioners, respectfully submits this response in opposition to the motion for leave to intervene as respondents filed by the States of Missouri, Idaho, and Kansas.

The States filed their motion four months after the government and Danco sought this Court's review, a month after this Court granted certiorari, and one day before the government and Danco filed their opening briefs. And notwithstanding the Court's frequent ad-

monition that it is "a court of review, not of first view," *Johnson* v. *Arteaga-Martinez*, 596 U.S. 573, 583 (2022) (citation omitted), the States ask the Court to grant intervention to consider in the first instance new standing theories that no lower court has addressed and that the government and Danco would not have the opportunity to fully brief.

The States base that remarkable request on an equally remarkable premise: They assert that because they were recently allowed to intervene in the district court, this Court would have no authority to reverse the lower courts' grant of preliminary relief even if it agreed with the government that respondents lack Article III standing. Instead, the States insist that the Court would also have to decide whether the States would have standing to seek the same relief.

The States' premise is wrong. The decisions below rest on the lower courts' holdings that *respondents* have Article III standing and face irreparable harm sufficient to justify preliminary relief. If this Court disagrees, the States' intervention below would pose no obstacle to reversal. The fact that another party or intervenor might have different grounds for seeking relief on its own claim does not insulate a lower-court decision from reversal if this Court holds that it rests on legal error. And that is especially so here: If this Court concludes that respondents lack standing because of the attenuated and speculative nature of their asserted injuries—and thus that this suit was never within the district court's jurisdiction to begin with—this suit will have to be dismissed whether or not the States have standing. The motion should be denied.

STATEMENT

1. This case concerns actions the U.S. Food and Drug Administration (FDA) has taken addressing the drug mifepristone. In 2000, FDA approved mifepristone for termination of early pregnancy based on the agency's scientific judgment that the drug is safe and effective. FDA has maintained that judgment across five presidential administrations, and it has modified mifepristone's conditions of use as decades of experience have further confirmed the drug's safety.

Respondents are doctors and associations of doctors who oppose abortion on religious and moral grounds. They do not prescribe mifepristone, and FDA's approval of the drug does not require them to do or refrain from doing anything. Nonetheless, respondents filed this suit in November 2022, challenging FDA's 2000 approval of mifepristone, as well as the agency's changes to the conditions of use in 2016; the approval of a generic version of the drug in 2019; FDA's 2021 decision to remove a requirement that the drug be dispensed in person; and the agency's denial of respondents' citizen petitions in 2016 and 2021. See Gov't Br. 4-8.

2. In April 2023, the district court granted respondents' motion for preliminary relief. Pet. App. 111a-195a.[1] The court rejected the government's arguments that respondents lack standing, *id.* at 118a-133a, and that their challenge to the 2000 approval of mifepristone was time-barred, *id.* at 134a-141a. On the merits, the court held that FDA's actions were arbitrary and capricious under the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq*. Pet. App. 171a-187a. Although respondents had sought a preliminary injunction, the

[1] All references to "Pet. App." are to the appendix to the petition for a writ of certiorari filed in No. 23-235.

court instead purported to invoke 5 U.S.C. 705 to postpone the effective date of the relevant FDA actions, which had already been in effect for years. Pet. App. 194a.

3. The government and Danco (the drug's sponsor, which had intervened) appealed and sought a stay pending appeal. The Fifth Circuit granted a stay as to FDA's 2000 approval of mifepristone, but otherwise denied relief. Pet. App. 196a-244a. The government then sought a stay in this Court, arguing, among other things, that respondents lack standing. This Court stayed the district court's order in full. *Id.* at 245a.

4. On August 16, 2023, after further briefing and argument, the Fifth Circuit affirmed the suspension of FDA's 2016 and 2021 actions. Pet. App. 1a-110a. The Fifth Circuit held that respondents have associational standing to challenge FDA's decisions with respect to branded mifepristone and that respondents are likely to succeed on their claims that FDA's 2016 and 2021 actions were arbitrary and capricious. *Id.* at 14a-42a, 51a-63a. And the Fifth Circuit affirmed the district court's conclusion that respondents would be irreparably harmed absent relief and that the balance of the equities favored respondents. *Id.* at 63a-69a.

5. The government and Danco filed petitions for writs of certiorari on September 8, 2023. The petitions challenged the lower courts' holdings that respondents have Article III standing, that FDA's 2016 and 2021 actions were arbitrary and capricious, and that preliminary relief was appropriate. FDA Pet. i; Danco Pet. i. This Court granted certiorari on December 13, 2023.

6. In the meantime, on November 3, 2023, the States of Missouri, Kansas, and Idaho filed a motion to intervene in the district court. The States sought to inter-

vene nearly a year after the litigation commenced; nearly nine months after they filed amicus briefs in the district court, see D. Ct. Docs. 100 (Feb. 13, 2023), 110 (Feb. 14, 2023); more than six months after the district court granted preliminary relief (and this Court stayed that order); and nearly two months after the government and Danco sought this Court's review. The States candidly acknowledged that they sought to intervene because they hope to step in and pursue this suit before the same courts that have already concluded that FDA's 2016 and 2021 actions were arbitrary and capricious if this Court holds that respondents lack standing. See D. Ct. Doc. 152, at 5-6 (Nov. 3, 2023).

a. The government moved to hold the intervention motion in abeyance pending this Court's resolution of the then-pending certiorari petitions. D. Ct. Doc. 155 (Nov. 9, 2023). The government explained that if this Court held that respondents lack standing, the district court would lack jurisdiction over respondents' suit and there would thus be no Article III case in which the States could intervene. *Id.* at 3-4. The government further explained that the States could not themselves satisfy the requirements for relief, including because they had not challenged the 2016 actions within six years or presented their claims to the agency, as required by regulation. *Id.* at 5. And the government noted that because the States' intervention motion "requests only to participate in this district court action to protect their interests prior to any final judgment, without seeking to 'reconsider phases of the litigation that had already concluded,'" the court's resolution of the intervention motion would not "by itself[] entitle the States to participate in the ongoing appellate proceedings." *Id.* at 6 n.1 (citation omitted); cf. D. Ct. Doc. 158, at 4 (Nov. 16,

2023) (observing that the States did not dispute this point).

b. The district court issued an unexplained order declining to hold the intervention motion in abeyance. D. Ct. Doc. 159 (Nov. 16, 2023). In further briefing opposing intervention, the government argued, among other things, that granting the motion would be futile because the States could not cure respondents' lack of standing; that the States themselves lack standing; that venue for the States' claims would be improper even if they had standing; and that the States do not meet the criteria for intervention. See D. Ct. Doc. 163, at 8-31 (Dec. 15, 2023).

c. On January 12, 2024, the district court granted the States' motion to intervene. D. Ct. Doc. 175. The court did not decide whether the States have Article III standing or whether they are entitled to preliminary relief. Instead, the court determined only that the States satisfied the criteria for intervention in district court. *Id.* at 2-14; see Fed. R. Civ. P. 24(a) and (b).

7. Ten days later, on January 22, 2024, the States moved to intervene in this Court.

ARGUMENT

The motion to intervene should be denied. The States' central premise—that the district court's post-certiorari grant of intervention somehow renders this Court powerless to "redress" the government's injury if it holds that respondents lack standing, Mot. 2—is plainly wrong. Nor would intervention promote judicial efficiency. Quite the opposite: The States seek to inject new and contested questions of their own standing into these cases after the Court has granted certiorari and petitioners have filed their opening briefs. The Court would have to consider the States' various theories in

the first instance, without the benefit of full briefing or any lower court's decision on their standing. The States cite no precedent for intervention in such circumstances, and the Court should not countenance their novel effort to use a belated intervention motion to try to cure a jurisdictional defect that has been apparent since this suit was filed, all in hopes of keeping this case alive in a desired—but improper—venue. Instead, the States should "simply * * * submit an amicus brief," Mot. 1, as they did in the district court long before they ever sought to intervene.

1. "No statute or rule provides a general standard to apply in deciding whether intervention on appeal should be allowed," and this Court has accordingly "considered the 'policies underlying intervention' in the district courts." *Cameron* v. *EMW Women's Surgical Ctr., P.S.C.*, 595 U.S. 267, 276-277 (2022) (citation omitted). But the Court has applied a particularly demanding standard for intervention in this Court, reserving that step for "rare" cases where it is justified by "extraordinary factors." Stephen M. Shapiro et al., *Supreme Court Practice* Ch. 6.16(c), at 6-62 (11th ed. 2019). The States have not come close to meeting that high bar.

2. As a threshold matter, the States waited far too long to seek intervention. The government and Danco filed petitions for writs of certiorari more than four months ago; this Court granted review more than a month ago; and the government and Danco have already filed their opening briefs. Adding the States to these cases at this late stage would prejudice both the Court and petitioners by preventing full briefing on the novel questions the States seek to raise concerning their own standing.

The States assert (Mot. 10) that their intervention motion is timely because they filed it ten days after the district court granted intervention. But the States ignore their nearly year-long delay in seeking to intervene in the district court. And although the district court found the States' motion timely, see D. Ct. Doc. 175, at 2-5, it provided no persuasive response to the government's arguments. Among other things, the States were clearly aware of their asserted interest in the litigation when they filed amicus briefs nearly nine months before they sought to intervene, and the purportedly new information the States invoked to excuse their delay actually showed a *decrease* in the number of Missouri residents who obtained abortions in Kansas—reducing, not increasing, the States' asserted interest in this litigation. D. Ct. Doc. 163, at 18; see *id.* at 17-21. And for the reasons the government argued in opposing the States' intervention in the district court, that court's order granting the States' motion to intervene was erroneous in other respects as well. The States thus cannot rely on their belated intervention in district court to justify their delay in seeking to intervene in this Court.

3. That is especially true because the States err in asserting (Mot. 1, 4-7) that the district court's grant of intervention provides any basis for intervention here.

a. The States premise their motion on the remarkable assertion that the district court's post-certiorari order allowing the States to intervene in that court renders this Court powerless to provide "redress" to the government and Danco on the first question presented. Mot. 5. Specifically, the States assert that their intervention makes them "beneficiaries of all the district court's 'orders and adjudications of fact and law as though [the States] had been a party from the com-

mencement of the suit.'" *Ibid.* (quoting 7C Charles Alan Wright et al., *Federal Practice and Procedure* § 1920 n.8 , at 611 (3d ed. 2007)) (brackets in original). Thus, the States contend, even if this Court holds that respondents lack standing, that "would not free FDA" from the district court's order granting preliminary relief, because the States would remain entitled to the "'benefi[t]'" of that order. Mot. 5 (citation omitted).

That chain of reasoning is badly mistaken. The decisions below rest on the lower courts' holdings that *respondents*—not the States—have associational standing and are likely to suffer irreparable harm. See Pet. App. 14a-42a, 63a-64a (Fifth Circuit); *id.* at 118a-131a, 187a-190a (district court). If this Court disagrees, then the decisions below must be reversed because they rest on legal errors. And the fact that the States might assert different theories of their own standing to seek the same relief on remand would provide no obstacle to that result.

That remains true whether or not the district court's grant of intervention was proper and makes the States "beneficiaries" of the court's prior order granting preliminary relief. Mot. 5 (citation omitted). The question on which this Court granted certiorari is not which parties are entitled to benefit from the district court's order; it is whether that order is legally valid. And the States cite no precedent or principle supporting their assertion that a district court that grants preliminary relief to parties lacking Article III standing can insulate its error from review by granting intervention to other parties with different standing theories while the case is already pending before this Court.

b. The States' belated effort to inject themselves into this litigation as parties also suffers from another

fundamental defect. The States have openly acknowledged that they seek to intervene because they fear that this Court will hold that respondents lack standing. See D. Ct. Doc. 152, at 5-6, 9. The States concede that they could simply file their own suit in a district where venue would be proper—that is, in Idaho, Kansas, Missouri, or a district where one of the federal defendants resides, see 28 U.S.C. 1391(e)(1). See D. Ct. Doc. 152, at 26-27. But the States instead hope to step into respondents' shoes and pursue this litigation before courts where venue over their claims is improper but that have already granted and affirmed preliminary relief. There is no legal basis for that maneuver.

If this Court holds that respondents lack standing, then the district court *never* had jurisdiction over this case because standing is "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The States' intervention could not retroactively cure that jurisdictional defect; instead, it is black-letter law that intervention "cannot create jurisdiction if none existed before." *Federal Practice and Procedure* § 1917, at 581-582; see, *e.g.*, *Disability Advocates, Inc. v. New York Coal. for Quality Assisted Living, Inc.*, 675 F.3d 149, 160-162 (2d Cir. 2012) (collecting authority).

The States suggest (Mot. 6) that because this case comes to the Court on review of an order granting preliminary relief, "[t]he suit would survive [on remand] pending a motion to dismiss." But if this Court holds that respondents lack standing, their suit cannot proceed. The Court could itself direct that the case be dismissed. See, *e.g.*, *Munaf* v. *Geren*, 553 U.S. 674, 691-692 (2008). And even if the Court does not take that step, respondents' claims plainly could not go forward if the

Court agrees with the government that their theories of standing are legally insufficient.

c. The States alternatively contend (Mot. 6-7) that even if respondents' claims were dismissed, the district court could still grant relief based on *the States'* claims. But that (again) says nothing about this Court's ability to provide relief to FDA and Danco by reversing the decisions below because, at a minimum, the States would have to demonstrate their *own* entitlement to a new order granting relief. And because the Northern District of Texas would plainly lack venue over a suit in which Idaho, Kansas, and Missouri were the only remaining plaintiffs, the court would have to dismiss or transfer the States' complaint. Cf. *Georgia Republican Party* v. *Securities & Exch. Comm'n*, 888 F.3d 1198, 1205 (11th Cir. 2018) (transferring case to proper court where only party satisfying venue lacked standing).

The States suggest (Mot. 6-7) that the district court might nevertheless choose to consider their claims on the merits, but that course is appropriate only if an intervenor's claim "satisfies by itself the requirements of jurisdiction and venue," *Federal Practice and Procedure* § 1918, at 605-606—which the States' claims plainly do not. Nor can the States avoid dismissal or transfer through some sort of venue-free grace period, during which they could "retain the preliminary injunction while amending their complaint" to add a new and as-yet-unnamed party that could establish venue in the Northern District of Texas. Mot. 7.

In sum, the States' belated intervention in district court does not affect this Court's authority to hold that respondents lack standing, reverse the decisions below, and put an end to this suit.

4. The States separately assert that intervention would "enable this Court to more easily reach the merits." Mot. 5; see Mot. 7-10. But like respondents, the States lack standing. Rather than simplifying matters, therefore, adding the States to this litigation would only complicate the proceedings by requiring the Court to address new theories of standing—and to do so without the benefit of consideration and decisions by the lower courts, or even full briefing. There is no justification for that result.

a. The States' first theory of standing is that FDA's actions regarding mifepristone will cause them "'monetary harms'" because those actions will lead some additional number of their residents to choose to take mifepristone; because some small fraction of those women will experience an exceedingly rare serious adverse event requiring "emergency room care"; and because the States might pay some portion of the resulting costs "through Medicaid and the like." Mot. 8 (citation omitted). That speculative and attenuated theory does not satisfy Article III.

Indeed, this Court recently warned against allowing States to challenge federal actions based on such indirect effects on the States' own expenditures. In *United States* v. *Texas*, 599 U.S. 670 (2023), two States sought to challenge federal immigration-enforcement guidelines on the theory that the guidelines "impose[d] costs on the States" by, for example, causing them to "continue to incarcerate or supply social services such as healthcare and education to noncitizens." *Id.* at 674. This Court rejected that theory, emphasizing that "federal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer." *Id.* at 680 n.3. In particular,

the Court explained that "in our system of dual federal and state sovereignty, federal policies frequently generate indirect effects on state revenues or state spending," which may be too "attenuated" to satisfy Article III. *Ibid.*

That aptly describes the States' theory here. Even if the States were correct that FDA's actions addressing mifepristone's conditions of use may ultimately result in some marginal increase in the States' Medicaid expenditures, such an indirect financial effect would not constitute an imminent injury fairly traceable to FDA's actions. The States' contrary assertion has no limiting principle: Virtually any federal action could be said to have some incidental effect on state finances. If such effects satisfy Article III, "what limits on state standing remain?" *Arizona* v. *Biden*, 40 F.4th 375, 386 (6th Cir. 2022) (Sutton, C.J.).[2]

b. The States next suggest that FDA's actions regarding mifepristone harm their sovereign interests in the "continued enforceability" of their laws because a court might hold that FDA's actions preempt those state laws. Mot. 9 (citation omitted). But the States do not identify any actual or imminent controversy over whether any of their laws are preempted. The States cannot establish standing to challenge FDA's actions on the theory that someone, at some point, in some other

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[2] Contrary to the States' assertion (Mot. 7-8), the government has never "tacitly admitted" that States have standing to challenge FDA's actions. Mot. 7 (emphasis omitted). To the contrary, government counsel simply distinguished *Department of Commerce* v. *New York*, 139 S. Ct. 2551 (2019), which involved a far more direct theory of financial harm—specifically, a claim that the challenged government action would cause the plaintiff States to "lose out on federal funds" in the form of direct payments from the federal government. *Id.* at 2565.

case might rely on those actions to argue that one of their laws is preempted. Nor can the States establish standing based on the possibility that FDA's challenged actions might make it easier for their residents to access mifepristone in violation of state law. Like their financial theory, that suggestion of harm is too attenuated to support standing. See *Texas*, 599 U.S. at 680 n.3. And it would permit any State to bootstrap its decision to prohibit certain conduct into standing to challenge a failure by other States or the federal government to prohibit that conduct. That would be inconsistent with our federal system, in which a State cannot "impose its own policy choice on neighboring States" or the federal government. *BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 571 (1996).

5. The States cite no precedent supporting intervention here. In particular, this case involves none of the "special circumstances," *Mullaney* v. *Anderson*, 342 U.S. 415, 417 (1952), present in the intervention decisions on which the States rely. See Mot. 5, 10-11. In those cases, the original plaintiff had standing at the outset of the case, and reason to doubt this Court's continued jurisdiction arose *after* this Court had granted certiorari to consider other issues. See Mot. 10-11 (citing cases in which parties were added following a grant of certiorari because "[the] existing plaintiff was terminally ill"; the "lead plaintiff enter[ed] bankruptcy"; and the "original party" in a school desegregation case "graduated"). The Court then granted intervention to a party with undisputed standing to ensure that it could reach the questions on which it had granted review. Intervention in those cases thus streamlined, rather than complicated, the proceedings.

Here, in contrast, the question whether respondents lack standing is not a new development unrelated to the issues on which this Court granted review; it *is* one of the issues on which this Court granted review. And far from simplifying the proceedings by eliminating a late-breaking jurisdictional question, granting intervention would only serve to prejudice petitioners and the Court by injecting additional contested jurisdictional questions into the litigation. The States cite no case where the Court has taken such a step, and it should not do so here.

CONCLUSION

The motion for leave to intervene should be denied.

Respectfully submitted.

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