No. 23-235, 23-236

In the
Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, et al.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,
Respondents.

DANCO LABORATORIES, L.L.C, et al.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,
Respondents.

On Writs of Certiorari to the U.S. Courts of Appeals for the Fifth Circuit

Reply in Support of Motion of Missouri, Idaho, and Kansas to Intervene

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INTRODUCTION

In response to the States' proposal that the Court grant intervention for the limited purpose of assessing State standing, Petitioners counter-propose expanding the first question presented. Currently, that question asks whether the private plaintiffs submitted enough evidence to establish standing for the preliminary injunction. Petitioners ask this Court to *also* decide whether the private plaintiffs' case should be dismissed entirely (even though Petitioners never filed a motion to dismiss). Doing so, they say, would resolve the issue created by the States intervening below.

Thus, Petitioners and the States both ask this Court to expand beyond the questions presented in the certiorari petitions. But only the States' request is consistent with resolving the merits issues efficiently. Petitioners' invitation to litigate the merits of FDA's challenged actions in piecemeal fashion, with multiple trips up and down the federal courts, would only cause delay.

Petitioners offer no persuasive reason not to grant State intervention limited to the question of State standing. They each blow well past the 3,000 word limit to vigorously assert that the States lack standing.[1] One wonders, then, why they so strongly oppose this Court granting intervention to consider the very question on which they express so much confidence.

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[1] The Federal Government exceeds the limit by 28.5%, Danco by 49.1%.

It cannot be prejudice. The States moved to intervene before this Court solely to argue State standing. Petitioners say they have had no opportunity to brief the issue. Not so. They briefed the issue before the district court and in response to the States' motion here, and they will have a third opportunity in their reply brief if this Court grants intervention. Petitioners also say no lower court has assessed State standing. But even if the States had been parties from the beginning (and thus parties here), no court would have needed to assess State standing. Only "one plaintiff" need establish standing, *Biden* v. *Nebraska*, 143 S. Ct. 2355, 2365 (2023), and every court determined that the private plaintiffs did.

Nor can it be timeliness. Petitioners cannot seriously argue that the motion in this Court was untimely. It was printed and served on the fifth business day after the district court granted intervention (fewer business days than Petitioners took to respond to the motion). Instead, Petitioners argue that the motion before the *district court* was untimely. But the district court already rejected that argument. Petitioners did not appeal and cannot relitigate that issue here.

Perhaps Petitioners instead simply seek to avoid a ruling on whether FDA's actions are unlawful. That would explain why they insist the States not be permitted to press a standing argument that the Federal Government last year acknowledged was sufficient. But delaying an inevitable ruling on the merits is not a legitimate interest.

As the States explained in their initial motion, the States moved to intervene primarily to notify the

Court of a redressability problem that arose in recent weeks. But Petitioners ask this Court to solve that problem by expanding the first question presented to consider whether to dismiss the action entirely (even though Petitioners never filed a motion to dismiss). The better avenue is to grant State intervention on the limited question of State standing.

ARGUMENT

I. Petitioners propose expanding the first question presented, but the States' proposal of intervention is better.

As argued at greater length in the original motion, a ruling in favor of Petitioners on the existing standing question would not provide redressability. The States, having intervened below, are now beneficiaries of all the district court's "orders and adjudications of fact and law as though [the States] had been a party from the commencement of the suit." C. Wright & A. Miller, Federal Practice and Procedure § 1920 n.8 (citation omitted). So even if the Court determined that the private plaintiffs lack standing for the preliminary injunction, the preliminary injunction would still exist as to the States.

None of Petitioners' arguments against this basic fact has merit.

1. Petitioners try to solve this problem by asking the Court to dismiss the case entirely. Although the first question presented asks only whether the private plaintiffs have standing to obtain preliminary injunctive relief, Petitioners invite the Court to go further and determine whether the entire action should be dismissed—even though Petitioners never

filed a motion to dismiss in the district court.[2] U.S. Br. 10–11; Danco Br. 7–8. They believe that extinguishing the private plaintiffs' entire action would solve the redressability issue by also extinguishing the States' action.[3]

But that is not true. The States' suit could continue. Petitioners do not deny that an intervenor suit can continue if the original suit is dismissed. They instead deny that the States' suit *would* continue because they think the States cannot establish venue. But they tellingly ignore the States' argument that venue is not jurisdictional and need not be independently satisfied by the intervening party after dismissal of the original action "if a particular claim or party is so closely related to the original action that it can be considered ancillary." Wright & Miller, *supra*, § 1918; Mot. 6–7. Petitioners' request that this Court go beyond the questions presented and dismiss the entire action is not just judicially inefficient; it also would not solve the redressability problem. The preliminary injunction that benefits the States would still exist.

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[2] Petitioners do not deny that establishing standing for a preliminary injunction requires a "degree of evidence" different from surviving a motion to dismiss, *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992), and so a ruling vacating a preliminary injunction does not automatically require dismissal.

[3] Ironically, in support of their request, Petitioners cite *Munaf* v. *Geren*, 553 U.S. 674 (2008), but that case criticized the lower courts for focusing solely on "jurisdictional issues" when "reaching the merits [wa]s the wisest course." *Id.*, at 690, 692. Here, "reaching the merits is the wisest course," and the Court should grant intervention to better enable the Court to do so.

2. No better is the Federal Government's assertion (at 9) that federal courts can vacate the States' injunction by determining that some *other* party lacks standing to receive the same injunction. The Federal Government (at 2) lambasts the States' position as "remarkable" but provides no support for their own "remarkable" position.

3. Danco presses an argument the Federal Government rightly avoids. Ignoring authorities cited by the States, Danco asserts (at 6) that the district court had no jurisdiction to enter an order giving the States the benefit of injunctive relief. But Danco has not appealed the district court's intervention order (which automatically gave the States the benefit of the preliminary injunction), and Danco is wrong. Appeals from preliminary injunctions are interlocutory, which always makes them suboptimal vehicles for certiorari precisely because the district court retains jurisdiction to enter other orders. *E.g.*, *Grupo Mexicano de Desarrollo S.A.* v. *All. Bond Fund, Inc.*, 527 U.S. 308, 314 (1999). While the appeal from the preliminary injunction is pending in this Court, the district court may not alter *that* preliminary injunction order, but it can do all kinds of other things, including issuing a different preliminary injunction, giving other parties the benefit of the order, or even entering a permanent injunction that moots the preliminary injunction. *See ibid.*

4. Out of other options, Danco misrepresents the States' filings in the district court to create the misimpression that the States flip-flopped. Danco says the States "conceded" that "a Supreme Court ruling that [Respondents] lack standing for the preliminary injunction *would vacate that injunction*."

Danco Br. 5 (emphasis and brackets by Danco); *see also id.*, at 1, 4. What Danco neglects to tell this Court is that the States acknowledged this was true *before* the States intervened, when the private plaintiffs were the only parties receiving the benefit of the preliminary injunction. The redressability issue arose only after the States became parties to the injunction,

Similarly, Danco suggests the States "urged" the district court not to consider State standing at all. Danco Br. 1, 4. But in fact, the States briefed standing at length before the district court and simply reminded the district court of the rule that only one plaintiff needs to establish standing. ECF 172, at 1–7.

II. Petitioners would suffer no prejudice from intervention.

Petitioners assert they would be prejudiced by intervention because then they could not fully brief the issue of State standing. That assertion is immediately undermined by Petitioners' decision to file overlong responses to the intervention motion, expressly arguing the issue of State standing. The States of course would not oppose this Court considering that briefing, and if the Court granted intervention, Petitioners would no doubt further expand their arguments in their merits reply briefs.

The Federal Government is similarly wrong (at 6) to assert that the States moved to intervene "after the Court has granted certiorari and petitioners have filed their opening briefs." In fact, the States notified Petitioners of the upcoming motion on January 19 and filed it on January 22. Petitioners' opening briefs

were not due until January 29, but they chose to file six days early—still after the States moved to intervene. *Every* time the States have notified Petitioners of an intent to move to intervene (in the district court or this Court) Petitioners have accelerated their filings in this Court and then complained that they did not have enough time to address the States' arguments.

No better is the Federal Government's contention that this Court would be reviewing the issue "without the benefit of … any lower court's decision on their standing." *Ibid.* Again, the Federal Government ignores that, because of the one-plaintiff rule for standing, no lower court would have needed to assess State standing given that every court held that the private plaintiffs have standing.

III. The States have standing.

As the States previously explained, State standing is so clear that the Federal Government in effect conceded it last May in oral argument before the Fifth Circuit, saying that States (but not private parties) could "rely on population wide statistics and probabilities" to show "the effects [of challenged federal action] on them happened at the population level." Oral arg. rec. 17:16–17:42; Mot. 7. The Federal Government formally denies making this concession, but tellingly never provides *any* citation of the oral argument recording to back its *ipse dixit* denial.

None of Petitioners' other standing arguments have merit.

1. Consider the States' sovereign injuries. As explained earlier and at more length before the

district court, organizations are relying on an "FDA-approved pipeline"—created by FDA's unlawful actions—to mail abortion pills into all 50 States, frustrating the ability of States to enforce their laws. ECF 152, at 3–5; ECF 172, at 7–8 (citing sources). The States of course have "sovereign interests" in "the power to create and enforce a legal code." *Alfred L. Snapp & Son, Inc.* v. *Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601 (1982). And this "FDA-approved pipeline" frustrates that interest.

The Federal Government asserts (at 14) that this harm "is too attenuated to support standing." But just a few years ago, this Court unanimously held that States establish standing when they raise claims based not on "mere speculation" but "instead on the predictable effect of Government action on the decisions of third parties." *Dept. of Com.* v. *New York*, 139 S. Ct. 2551, 2566 (2019). When FDA unlawfully removed its prohibition against mailing abortion pills, it was "predictable" that private parties would start mailing those pills. There is nothing "attenuated" about people doing what FDA expressly encourages them to do.

Indeed, the link here is much more direct than in *Department of Commerce*. There, this Court unanimously determined that States could sue under the theory that a citizenship question would cause private parties to "unlawfully" decline to fill out the Census, causing an undercount in various States. 139 S. Ct., at 2566. Here, FDA expressly told the world it is *lawful* to mail abortion pills into all 50 States. The actions of private parties in *Department of Commerce* were a "predictable" but *unintended* effect of the agency. Here, mailing abortions into all 50 States is the *intended* effect of FDA's actions.

Danco asserts that standing was appropriate in *Department of Commerce* because the "administrative record showed that the challenged census question historically resulted in significant undercounting and would continue to do so at a predictable rate." Danco Br. 13 (brackets omitted). But here, FDA has acknowledged that mifepristone leads to a "predictable rate" of emergency room visits—up to 4.6 percent of women obtaining chemical abortions. *All. for Hippocratic Med.* v. *U.S. Food & Drug Administration*, 78 F.4th 210, 229 (CA5 2023). This "predictable rate" is twice as high as for surgical abortions. ECF 176 ¶ 269 ("[A]bortion related ER visits as a percentage of total ER visits was consistently about twice as high for chemical abortions as surgical abortions."). And this "predictable rate" is expected to continue in the future. Despite knowing that chemical abortions cause much higher rates of emergency room visits, FDA has nonetheless acted to make chemical abortions—and their associated emergency room visits—more common.

2. Similarly, the States have a sovereign injury because FDA's actions pose a serious threat of preemption to state laws. Indeed, just two weeks before Petitioners filed for certiorari, a federal court held that these actions preempt West Virginia law. *GenBioPro, Inc.* v. *Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D.W. Va., Aug. 24, 2023).[4]

[4] Danco notes (at 11 n.5) that the plaintiff then voluntarily dismissed its (successful) preemption claim. But Danco omits that the plaintiff did so because the court dismissed all other counts. The plaintiff needed to drop the one count that was not

The Federal Government suggests that the States' concerns will be unripe until some private plaintiff or the United States brings a preemption suit against the States. U.S. Br. 13–14. But the States are not "required to await and undergo a … prosecution" by some other party. *Holder* v. *Humanitarian L. Project*, 561 U.S. 1, 15 (2010) (internal quotation marks omitted). States can assert their own rights offensively, not just defensively. Indeed, given the statute of limitations, States often *must* bring offensive suits against agencies where those agencies engage in actions that risk preempting state law.

3. Then there are the States' economic harms. As explained in the intervention motion, the States have established by statistical certainty—through expert evidence and FDA's own admissions—that FDA's actions necessarily send a definite percentage of woman to emergency rooms, draining States of resources, especially Medicaid resources. Mot. 8–9.

This connection between FDA's actions and loss of revenue (including Medicaid revenue) is much closer than in *Department of Commerce*. "Medicaid … is designed to advance cooperative federalism." *Wisconsin Dept. of Health and Fam. Services* v. *Blumer*, 534 U.S. 473, 495 (2002). And yet FDA's actions *increase* the number of women who must seek emergency medical care, including care paid for by Medicaid. At the same time that the States have agreed to operate a cooperative-federalism program to

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dismissed so that the ruling dismissing all other counts would become a final judgment that could be appealed. *See GenBioPro*, ECF 78 (filing a notice of appeal three days after dropping its successful preemption argument).

cover emergency medical costs, FDA has taken action to drain state resources that go into that program.

It is of course true that the States experience loss only after private parties engage in certain actions. But it the "predictable effect of Government action," *Dept. of Com.*, 139 S. Ct., at 2566, that women harmed by mifepristone because of FDA's actions will seek emergency services. Indeed, FDA acknowledges that up to 4.6 percent of the women who obtain chemical abortions because of FDA's actions are forced into the emergency room. *All. for Hippocratic Med.*, 78 F.4th, at 229. Before 2016, women could obtain mifepristone only up until 7 weeks. FDA expanded that to 10 weeks, despite knowing that mifepristone abortions have much higher complication rates than surgical abortions. So the class of women who obtain abortions between 7 and 10 weeks are now much more likely to be forced to seek emergency services—all because of FDA's actions. That increase in emergency services necessarily and directly strains the resources of States.

The States need only identify one dollar in harm to establish standing. *E.g.*, *Uzuegbunam* v. *Preczewski*, 592 U.S. 279 (2021). But the States have in fact presented expert evidence that the true cost is much higher than captured by state or federal statistics because chemical abortions that land women in the emergency room routinely are miscoded as natural miscarriages. "[B]etween one-third and two-thirds of women who obtained chemical abortions paid for by Medicaid and then had an abortion-related ER visit were improperly coded by ER staff as having had a natural miscarriage instead of an abortion." ECF 176 ¶ 275 (citing expert affidavit). Danco faults the States for not identifying *specific* women harmed by

FDA's actions. Danco Br. 10–11. But the States have established by statistical certainty that women obtain chemical abortions due to FDA's regulatory regime and then are forced to seek emergency services paid for by States.

In response, the Federal Government argues (at 12–13) that these kind of claims, despite this Court unanimously permitting them in *Department of Commerce*, are no longer valid after this Court's decision in *United States* v. *Texas*, 599 U.S. 670 (2023), which considered a challenge to immigration-enforcement guidelines. But *Texas* is no sea change. To the contrary, this Court stressed that its decision "is narrow and simply maintains the longstanding jurisprudential status quo." *Id.*, at 686. Standing was improper in that case, which concerned "both a highly unusual provision of federal law and a highly unusual lawsuit," *id.*, at 684, because the States' challenge there would have required the executive to "make more arrests or bring more prosecutions," *id.*, at 680.

* * *

Danco says this Court should not rely on the Federal Government's earlier concession of State standing because "this Court has 'an independent obligation to assure that standing exists.'" Danco Br. 12 (citation omitted). The States agree. This Court should grant intervention and resolve all standing theories together rather than through the wasteful, piecemeal fashion Petitioners advocate.

CONCLUSION

The States moved to intervene primarily to notify the Court of the district court's intervention order,

which affects redressability. But Petitioners now ask this Court to expand the first question presented to assess whether the private plaintiffs' entire action should be dismissed. If this Court is going to expand a question, the States' proposal makes more sense. The Court should grant the States intervention for the limited purpose of asserting State standing.

Respectfully submitted,

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