Nos. 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,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,
Respondents.

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

Brief of Missouri, Idaho, & Kansas in support of Alliance for Hippocratic Medicine, et al.

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INTEREST OF *AMICI* STATES

Missouri, Idaho, and Kansas have an exceptionally strong interest in the outcome of this case because the States are parties to the preliminary injunction this Court is reviewing. As explained in more detail in the States' intervention motion in this Court, the States moved to intervene in the district court in early November, before this Court granted certiorari. The district court granted intervention in early January (after certiorari). When the district court did so, the States automatically became "bound by all prior orders and adjudications of fact and law as though [they] had been a party from the commencement of the suit." C. Wright & A. Miller, *Federal Practice and Procedure* § 1920 n.8 (citation omitted). That includes the preliminary injunction order. *E.g.*, *Miller* v. *Alamo*, 975 F.2d 547, 551 (CA8 1992) ("[T]here is no principled justification for binding intervenors to unfavorable prior decisions while at the same time denying intervenors the benefits of favorable prior decisions.").

The States agree with the amicus brief led by Mississippi but file this separate amicus brief because of Missouri, Idaho, and Kansas's unique interest as parties to the injunction being reviewed. In particular, the States explain herein that because the States are parties before the district court but not before this Court, FDA cannot obtain vacatur of the preliminary injunction through FDA's standing argument.

SUMMARY OF ARGUMENT

FDA principally argues that the private plaintiffs lack standing. That is wrong. To fail to find

standing for the private plaintiffs here would blow a hole in this Court's standing jurisprudence, allowing federal agencies to conscript third parties without judicial recourse.

FDA's standing argument doubly fails because even if this Court agreed with it, that would not entitle FDA to relief from the preliminary injunction. That is because the private plaintiffs are not the only plaintiffs who are party to the preliminary injunction order. The States are parties to the same order, and it is well settled that only "one plaintiff" needs standing to maintain a preliminary injunction. *Biden* v. *Nebraska*, 143 S. Ct. 2355, 2365 (2023). FDA cannot obtain vacatur merely by arguing that *some* of the plaintiffs to the preliminary injunction lack standing. To vacate the order, FDA bears the burden of proving that *all* the plaintiffs to the preliminary injunction lack standing. It cannot do so before this Court because FDA successfully opposed the States becoming parties before this Court. Thus, if this Court accepts FDA's standing argument about the private plaintiffs, the only remedy FDA could receive is remand to the district court without vacatur.

If that happens, FDA will no doubt have to petition this Court again for relief quite soon because FDA will not be able to succeed in obtaining vacatur in the district court. FDA has primarily contended that the States lack standing. Not so. The States have standing for several independent reasons: (1) the States have suffered traditional economic injuries; (2) the States have suffered injuries to their sovereign interests; and (3) the States have suffered quasi-sovereign injuries. Indeed, FDA in effect conceded at

oral argument before the Fifth Circuit that States would have standing to challenge FDA's actions.

The Federal Government conceded States can sue when they experience population-level effects from federal actions that cause economic harm. The States have shown exactly that. FDA does not dispute that a known proportion—up to about 5 percent—of women obtaining chemical abortions must seek emergency medical services, and that this number is much higher than with surgical abortions. By promoting chemical abortions over surgical abortions and removing longstanding safety precautions for chemical abortions, FDA has imposed increased costs to state-funded medical insurance and public hospitals. FDA's unlawful actions have also imposed sovereign harms that radically interfere with the ability of the States to set policy on what this Court recently described as one of the most "profound" issues of public policy. *Dobbs* v. *Jackson Women's Health Org.*, 597 U.S. 215, 223 (2022). In particular, FDA's decision to illegally permit mailing of abortion pills nationwide frustrates the ability of States to enforce their laws.

Other arguments raised by FDA likewise fail. FDA asserts that it will be able to vacate the preliminary injunction order with respect to the States because FDA believes the States lack venue. But when a party successfully intervenes in a case, that party's case may proceed even if the original plaintiffs are dismissed and even if the intervening party could not independently establish venue.

The Court should speedily reach the merits and affirm for the reasons argued by the private plaintiffs. But if this Court accepts FDA's argument that the

private plaintiffs lack standing, then remand to the district court without vacatur is the only remedy appropriate. The States are party to the preliminary injunction order, and so FDA cannot obtain relief from that order until the case returns to the district court.

ARGUMENT

I. Because the States are parties to the preliminary injunction, but are not parties before this Court, FDA cannot challenge the standing of *all* plaintiffs to the preliminary injunction, so the injunction cannot be vacated on standing grounds.

The private plaintiffs possess standing. FDA has long told women harmed by abortion drugs to seek emergency care from the private plaintiffs. Resp. Br. 25 (quoting FDA Approval Memorandum, J.A. 229 ("direct[ing] patients to hospitals" for "emergency services")). That women take FDA at its word and seek emergency care from the private plaintiffs is not speculative; it is predictable. Nor can FDA deny that the private plaintiffs sincerely object to being complicit in elective abortion. Their conscience and other injuries are both concrete and imminent. To hold otherwise, would create an exception to standing for third parties harmed by agency action—even when the agency expressly conscripts those third parties. That is not the law.

That rule would also make a mockery of this Court's standing jurisprudence. For example, if persons have standing to assert *aesthetic* injuries in *plants* (as courts have concluded), certainly the private plaintiff physicians have standing to sue over their much more serious conscience injuries. *All. for*

Hippocratic Med. v. *U.S. Food & Drug Admin.*, 78 F.4th 210, 259–60 (CA5 2023) (Ho, J., concurring in part).

But if this Court accepts FDA's standing argument, the proper remedy is to remand to the district court for further proceedings without vacatur. It is well settled that a preliminary injunction can be vacated for lack of jurisdiction only if *none* of the plaintiffs have standing to maintain it. *Biden* v. *Nebraska*, 143 S. Ct., at 2365. But because FDA successfully opposed the States participating as parties before this Court, FDA presently can challenge the standing of only some of the parties to the preliminary injunction. FDA will not be able to challenge the standing of all plaintiffs unless and until the case returns to the district court.

In its briefing opposing the States' motion to intervene before this Court, FDA argued that the States also are not entitled to the preliminary injunction. They argue that the States lack standing and venue. But because FDA opposed the States from participating before this Court, FDA's arguments are premature. Only if this Court accepts FDA's flawed standing argument about the private plaintiffs and remands to the district court will FDA be able to press its arguments for vacating the preliminary injunction on jurisdiction grounds.

II. If the Court does not reach the merits, FDA will no doubt have to quickly return to this Court and seek further relief because it will not prevail in its attempt in the district court to vacate the injunction on jurisdictional grounds.

If this Court remands to the district court, FDA will no doubt be back at this Court seeking relief very soon. In its opposition to the intervention motion, FDA asserts that the States lack standing and venue, and so FDA will be able to vacate the injunction if this Court returns the case to the district court. Not so. The States plainly have standing and need not independently establish venue. Indeed, State standing is so clear that FDA in effect conceded it last May in oral argument before the Fifth Circuit. FDA changed its position only after the States intervened.

A. The States have standing.

1. The States have suffered traditional economic injuries from FDA's unlawful actions.

The States have standing because they have suffered traditional economic injury. See *Biden* v. *Nebraska*, 143 S. Ct., at 2366 ("financial harm is an injury in fact"); *TransUnion LLC* v. *Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. The most obvious are traditional tangible harms, such as physical harms and monetary harms.").

The States allege and present evidence of many economic harms caused by Defendants, including (1) increased public insurance costs for emergency

medical procedures and mental health support for women who experience complications from chemical abortions; and (2) diversion of resources by public hospitals to care for those who experience complications. Compl., ECF 176, at 68–78.

FDA does "not dispute that a significant percentage of women who take mifepristone experience adverse effects," with close to 5 percent requiring emergency room care. *All. for Hippocratic Med.*, 78 F.4th, at 229. Nor can there be dispute that these costs, at the population level, are borne by the States through Medicaid and similar programs. ECF 176, ¶¶ 257–315. The States also submitted evidence that these tragedies impose costs on States for mental health support, *id.*, ¶¶ 307–315, and state-run hospitals, *id.*, ¶¶ 301–306. These "monetary harms," under established precedent, "readily qualify as concrete injuries under Article III." *TransUnion*, 594 U.S., at 425.

To give a concrete example, Missouri submitted evidence that 1,718 Missourians obtained chemical abortions in 2022 by traveling to just one of Missouri's eight neighboring States (four of which permitted elective abortions). ECF 176, ¶ 281. That means up to 86 Missourians (5% of 1,718) in 2022 who traveled to just one neighboring State were forced to go to the emergency room because of serious complications from mifepristone. About 400,000 women and girls in Missouri ages 14 through 45 are eligible for Medicaid, *id.* ¶ 291—about one-third of all women and girls of that age range in the State. That means Missouri, through Medicaid, directly pays for the cost of emergency care for at least dozens of women each year who travel to just one of the four neighboring States that perform elective abortions.

The States need only establish a "'substantial risk' that the harm will occur." *Susan B. Anthony List* v. *Driehaus*, 573 U.S. 149, 158 (2014) (citation omitted). Missouri has established, by near-certain statistical evidence, that FDA's actions harm the States.

This is exactly the kind of argument FDA previously conceded is sufficient to establish standing. At oral argument before the Fifth Circuit, the Federal Government was asked why the private plaintiffs lack standing given this Court's unanimous ruling that plaintiffs in *Department of Commerce* v. *New York*, 139 S. Ct. 2551 (2019), had standing. The Federal Government responded that, in *Department of Commerce*, "the plaintiffs were states," meaning "the effects [of challenged federal action] on them happened at the population level," and the States could thus "rely on population-wide statistics and probabilities." Oral Arg. Rec. at 17:16–17:42 (May 17, 2023), *All. for Hippocratic Med.*, No. 23-10362.[1]

In other words, the States need not identify *specific* women for whom they have paid and will pay for emergency medical care caused by FDA's policies—just like the States in *Department of Commerce* were not obliged to identify specific people who would refuse to fill out the Census correctly. It is enough to note that FDA acknowledges that close to 5 percent of women are forced to seek emergency medical services and then rely on those "population-wide statistics and probabilities" to show that the States bear the cost of emergency care for dozens of women each year

[1] https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3

because of FDA's policies. 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 paid for by the States.

Take another concrete example: Idaho identified that $12,658.05 of its 2022 expenditures covered medical costs of botched abortions. ECF 176, ¶ 296. Most of these costs come from chemical abortions because the complication rate for chemical abortions is "much higher than … for women receiving surgical abortions." *Id.*, ¶ 268 (citing affidavit). That number also understates the true cost because the substantial majority of chemical abortions are miscoded as natural miscarriages and thus not correctly captured in databases as abortion costs. *Id.*, ¶ 298 (citing affidavit).

These connections 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 Dep't 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 cover emergency medical costs, FDA has taken action to drain state resources that go into that program.

In their opposition to the States' motion to intervene, Defendants were unable to dispute that the States have clear economic injuries, so they instead argued that *United States* v. *Texas*, 599 U.S. 670

(2023), overturned what this Court described as a "traditional" basis for standing just two years before, *TransUnion*, 594 U.S., at 425. But *Texas* is no sea change. To the contrary, this Court stressed that the *Texas* decision "is narrow and simply maintains the longstanding jurisprudential status quo." 599 U.S., 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.

With *Texas* inapplicable, Defendants questioned in their response to the States' motion to intervene whether the States can muster "factual" proof for their allegations, arguing that the States have only established "isolated instances" of harm. But, as is oft-repeated, "[f]or standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'" *Czyzewski* v. *Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

Moreover, in addition to affidavits detailing specific instances of fiscal harm, the States presented expert evidence that financial harm is pervasive. While "FDA's own data shows that a definite percentage of women who take mifepristone will require emergency-room care," *All. for Hippocratic Med.*, 78 F.4th, at 233, the States have shown by expert evidence that the true figure is much higher because emergency room staff systemically miscode abortion complications as natural miscarriages. *E.g.*, ECF 176-1, App. 588–89 (Ex. 36). "[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).

2. The States have suffered sovereign injuries from FDA's unlawful actions.

FDA's actions also harm the States' "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). "[F]ederal preemption of state law" and "federal interference with the enforcement of state law" both create standing. *Texas* v. *United States*, 809 F.3d 134, 153 (CA5 2015). That is because "a State clearly has a legitimate interest in the continued enforceability of its own statutes." *Maine* v. *Taylor*, 477 U.S. 131, 137 (1986).

A number of Missouri laws are threatened by FDA's unlawful actions. These include (1) Missouri's prohibition on abortions "except in cases of medical emergency," Mo. Rev. Stat. § 188.017.2; (2) Missouri's prohibition on providers administering chemical abortion drugs without first submitting a sufficient plan to address complications from chemical abortions, *id.* § 188.021.2; (3) Missouri's regulations passed under § 188.021.2 requiring physicians who perform abortions to prearrange for backup physicians to address complications if needed, 19 C.S.R. 10-15.050; and (4) Missouri's requirement that chemical abortion drugs be dispensed in-person, not through the mail, Mo. Rev. Stat. § 188.021.1. FDA's actions directly interfere with Missouri's ability to create and enforce a legal code—both through a substantial risk of federal preemption and federal

interference with enforcement of state law. ECF 176, ¶¶ 316–60.

First, consider preemption. The States have sovereign injuries because FDA's actions impose a serious threat of preemption to state laws. Indeed, just two weeks before Petitioners filed for certiorari, a federal court held that FDA's actions preempt West Virginia law, which is similar to, for example, Missouri law. *GenBioPro, Inc.* v. *Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D.W. Va., Aug. 24, 2023).[2] To be sure, the States are not presently defending lawsuits by private parties asserting preemption. But FDA's actions still place the States' laws at substantial risk, and 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. The *GenBioPro* decision makes clear that FDA's unlawful decisions create a substantial risk of injury to the States in the form of interference with their ability to create and enforce a legal code.

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[2] Although the plaintiff later voluntarily dismissed its (successful) preemption claim, it appears the plaintiff did so because it needed to drop the one count that was not dismissed so that the district court's 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).

Next, consider that FDA, through its unlawful actions, has encouraged and enabled private parties to evade the States' laws. For example, FDA's decision—in flagrant violation of 18 U.S.C. § 1461—to endorse private parties distributing chemical abortion pills through the mail has created a robust industry designed to evade the States' laws. Beginning in summer 2023, organizations started shipping abortion drugs into all 50 States in large quantities in an attempt to evade state laws. These organizations expressly relied on what they called "an FDA-approved pipeline" created by the FDA actions challenged here. ECF 152, at 3–5; ECF 172, at 7–8 (citing sources). According to just one report, in less than a month, seven U.S. based providers mailed 3,500 doses of mifepristone to States that have banned the use of chemical abortions or have prohibited distribution of those chemical by mail. Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned States*, Wash. Post (July 20, 2023).[3] Their capacity has only grown since then.

In its response to the motion to intervene, FDA asserted 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.*, 139 S. Ct., at 2566. When FDA unlawfully removed its prohibition against mailing

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[3] https://www.washingtonpost.com/politics/2023/07/20/shield-laws-make-it-easier-send-abortion-pills-banned-states

abortion pills, it was "predictable" that private parties would start mailing those pills. There is nothing "attenuated" about people doing exactly 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 (and wrongly) 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.

FDA's decisions have similarly deprived Plaintiff States of their sovereign "benefits that are to flow from participation in the federal system." *Snapp*, 458 U.S., at 608. One such benefit is the uniform application of federal law and the ability of States to rely on the backdrop of federal law when enacting their own regulations. See *ibid.*; *Crow Indian Tribe* v. *United States*, 965 F.3d 662, 676–77 (CA9 2020). FDA's actions have the direct effect of enabling and encouraging third parties to provide, through the mail, mifepristone to citizens of Plaintiff States for the purpose of inducing risky abortions that are expressly contrary to the policies expressed in many of those States' statutes.

3. The States have suffered quasi-sovereign injuries from FDA's unlawful actions, and while this Court has consistently barred *third*-party *parens patriae* actions, it has consistently permitted *first*-party *parens patriae* actions to proceed.

The States have also suffered quasi-sovereign injuries due to FDA's unlawful actions.

a. The Court's precedents consistently prohibit one kind of *parens patriae* suit against the Federal Government but consistently permit the second kind.

A century ago, this Court ruled that Massachusetts could not bring its *parens patriae* action against the Federal Government. *Massachusetts* v. *Mellon*, 262 U.S. 447, 485–486 (1923). The rule announced in that decision has become known as the "*Mellon* bar" and was recently stated in *Haaland* v. *Brackeen*, 599 U.S. 255, 295 n.11 (2023).

But there are several kinds of *parens patriae* actions, and this Court has treated them differently. Under this Court's precedents, the *Mellon* bar applies only when two circumstances are present: (1) a State is suing solely on behalf of a private party, rather than asserting any interests of its own (such as "quasi-sovereign" interests); and (2) the State is challenging the constitutionality of a federal statute. Outside those circumstances, this Court has *always* permitted *parens patriae* suits to proceed.

It is thus no use simply to appeal to broad and out-of-context statements like the one found in *Brackeen* where this Court, quoting dictum from a case that did not involve the Federal Government, said "a State does not have standing as *parens patriae* to bring an action against the Federal Government." *Brackeen*, 599 U.S., at 295 (brackets accepted) (quoting *Snapp*, 458 U.S., at 610 n.16). As this Court has repeatedly cautioned, "'general language in judicial opinions' should be read 'as referring in context to circumstances similar to the circumstances then before the Court and not referring to quite different circumstances that the Court was not then considering.'" *Turkiye Halk Bankasi A.S.* v. *United States*, 143 S. Ct. 940, 950 (2023) (citation omitted)). *Brackeen* involved only one kind of *parens patriae* case, and so the Court had no occasion to opine on the other kind. But *every* time the Court has faced the second kind of *parens patriae* action, the Court has permitted the suit to proceed against the Federal Government.

State *parens patriae* suits "encompass[ ] two distinct concepts": (1) purely "third-party" suits where the State is only a "nominal party"; and (2) a "second, more modern conception" where a State "assert[s] some injury to [its] own interests"—for example, "*quasi-sovereign* interests." *Kentucky* v. *Biden*, 23 F.4th 585, 596–97 (CA6 2022) (emphasis in original).

Only the first kind of *parens patriae* action against the Federal Government is barred. In every case where this Court has announced a bar on *parens patriae* suits against the government, the Court noted that the State failed to assert its own interests. *Mellon*, 262 U.S., at 484–85 ("[W]e are called upon to adjudicate, not rights of person or property, not rights

of dominion over physical domain, *not quasi sovereign rights* actually invaded or threatened, but abstract questions of political power, of sovereignty, of government.") (emphasis added); *Brackeen*, 599 U.S., at 295 n.11 (faulting Texas for failing to assert a "concrete injury to the State" and instead asserting only the equal-protection rights of a tiny segment of its population).

In contrast, *every* time a State has asserted a quasi-sovereign interest, which is an "injury to the state *itself*," *Biden*, 23 F.4th, at 596–601 (emphasis in original), this Court has permitted a *parens patriae* suit against the Federal Government to proceed. *Nebraska* v. *Wyoming*, 515 U.S. 1, 20 (1995) (permitting a *parens patriae* suit to proceed because it was not "'in reality for the benefit of particular individuals'"); *Massachusetts* v. *EPA*, 549 U.S. 497, 520 & n.17 (2007) (permitting a *parens patriae* suit to proceed where the State asserted a "stake in protecting its quasi-sovereign interests" rather than purely third-party interests). *Mellon* itself previewed that this development would occur. While rejecting a *parens patriae* suit in that case, the Court said, "We need not go so far as to say that a state may never intervene" against the Federal Government through a *parens patriae* suit, and it suggested States could do so if they asserted "quasi sovereign rights." *Mellon*, 262 U.S., at 484–85.

This Court's precedents thus create a sharp dividing line. Third-party *parens patriae* suits—where a State fails to assert any of its *own* interests—are barred against the Federal Government. But *first*-party *parens patriae* suits—where a State does assert an interest of its own—are permitted against the Federal Government.

That rule makes sense given the ordinary jurisdictional requirement that a party assert an interest of its own. Purely third-party *parens patriae* actions are barred because the Federal Government is "the ultimate *parens patriae* of every American citizen." *South Carolina* v. *Katzenbach*, 383 U.S. 301, 324 (1966). When a State asserts a third-party *parens patriae* suit, it asserts only an interest already shared by the Federal Government. It is like an aunt suing a mother on behalf of the mother's daughter. But that logic does not apply, and a suit is not barred, when a State asserts its own interest, because the Federal Government is *not* the "ultimate *parens patriae*" of the States. When a State asserts its own interest, that interest is not shared by the Federal Government, so the State can press it in a *parens patriae* action.

In fact, it would be exceptionally strange if States were not permitted to sue the Federal Government when the States identify their own interest. That rule would be a stark exception to the ordinary rules of standing. And it would thwart the original federalism design explained by Madison, where "[t]he different governments will control each other" to create "a double security." The Federalist No. 51, at 320 (Clinton Rossiter ed., Signet Classic 2003) (1788). The Founders envisioned that the States would "guard one part of the society against the injustice of the other part." *Ibid.* A rule that treated States with special disfavor by not permitting them to bring suit when they undisputedly have asserted their own interests—separate and apart from the Federal Government's—would gut the ability of States to keep the Federal Government in check.

In addition, the *Mellon* bar applies only when a State challenges the validity of a federal statute. As this Court put it in *Massachusetts* v. *EPA*, "there is a critical difference between allowing a State 'to protect her citizens from the operation of federal statutes' (which is what *Mellon* prohibits) and allowing a State to assert its rights under federal law (which it has standing to do). Massachusetts does not here dispute that the Clean Air Act *applies* to its citizens; it rather seeks to assert its rights under the Act." *Massachusetts* v. *EPA*, 549 U.S., at 520 n.17 (emphasis in original). Like Massachusetts, the States here are not challenging the validity of a statute; the States are instead seeking to vindicate 18 U.S.C. § 1461 and their rights under the Administrative Procedure Act. Indeed, because the APA gives any "aggrieved" party a right to bring an action, that language "reflect[s] 'Congressional intent to permit states to enforce the rights protected by federal statutes through *parens patriae* actions.'" *Clearing House Assn., L.L.C. v. Cuomo*, 510 F.3d 105, 125 (CA2 2007) (applying the same logic to the Fair Housing Act), *aff'd in part, rev'd in part on other grounds*, 557 U.S. 519 (2009).

Multiple courts after *Massachusetts* v. *EPA* have recognized that the *Mellon* bar applies only to challenges to the validity of federal statutes. *Missouri* v. *Biden*, No. 3:22-CV-01213, 2023 WL 4335270, at *57–58; *Aziz* v. *Trump*, 231 F. Supp. 3d 23, 31 (E.D. Va. 2017) (collecting cases) ("[R]eading *Mellon* as a complete ban on *parens patriae* actions by states against the federal government would contradict *Massachusetts* v. *EPA*."); *see also Challenge* v. *Moniz*, 218 F. Supp. 3d 1171, 1178 (E.D. Wash. 2016) ("[T]he Court cannot ignore the Supreme

Court's 2007 decision in *Massachusetts* v. *E.P.A.*, wherein the majority acknowledged a state's ability to sue the federal government under a federal statute in seeking to protect its quasi-sovereign interests concerning greenhouse gas emissions.").[4]

b. The States have quasi-sovereign injuries because FDA's actions put countless women and girls in these States at risk.

Here, the States do not bring third-party *parens patriae* suits; they instead assert quasi-sovereign injuries to the States themselves. When "a sufficiently substantial segment of [a State's] population" is injured, that harm becomes an injury to the State itself. *Snapp*, 458 U.S., at 599, 607 (quasi-sovereign injury to Puerto Rico when "787" people were affected). An injury to a substantial population in a State becomes an injury to the State itself and "suffices to give the State[s] standing to sue" because that injury to the population "is one that the State, if it could, would likely attempt to address through its

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[4] Cases before *Massachusetts* v. *EPA* likewise recognized that *Mellon* bars only some *parens patriae* suits. *E.g.*, *Puerto Rico Pub. Hous. Admin.* v. *U.S. Dep't of Hous. & Urban Dev.*, 59 F. Supp. 2d 310, 326 (D.P.R. 1999); *Kansas* v. *United States*, 748 F. Supp. 797, 802 (D. Kan. 1990); *Abrams* v. *Heckler*, 582 F. Supp. 1155, 1159 (S.D.N.Y. 1984); *City of New York* v. *Heckler*, 578 F. Supp. 1109, 1122–25 (E.D.N.Y. 1984); *State of Ala. ex rel. Baxley* v. *Tennessee Valley Auth.*, 467 F. Supp. 791, 793–94 (N.D. Ala. 1979) (holding that *Mellon* did not apply because the State "seeks only to vindicate the will of the people as it has been expressed by their duly elected representatives in the national legislature").

sovereign lawmaking powers." *Id.*, at 607. FDA's actions have imposed harm on a large number of individuals in each State, and the States have exercised their sovereign lawmaking powers to try to address those harms.

1. FDA cannot reasonably dispute that its actions impose harm on a substantial number of individuals in each State. In Missouri alone, 1,718 residents obtained chemical abortions in 2022 in just one of Missouri's eight neighboring States (four of which permitted elective abortions). ECF 176, ¶ 281. By removing longstanding safety protocols for chemical abortion drugs, FDA's actions have made chemical abortions riskier. Worse, given FDA's concession that about 5 percent of these women required emergency room care, *All. for Hippocratic Med.*, 78 F.4th, at 229, FDA's challenged actions are directly responsible for sending up to 86 women from Missouri to the emergency room in 2022. And that is just women in Missouri who obtained abortions in *one* year from *one* of Missouri's four neighboring States that permit elective abortion.

FDA's unlawful actions make chemical abortions riskier in a number of ways. For example, FDA's removal of previous requirements of physician supervision, patient follow-up, reporting of adverse outcomes, and in-person distribution of drugs expose individuals in the States to increased risk of suffering complications from chemical abortion and requiring emergency medical care. ECF 176, ¶¶ 203, 255–56, 262–274, 349. Indeed, because FDA does not require *any* physician supervision, women and girls typically experience the most painful and complicated parts of the chemical abortion drug regimen at home—away from any medical assistance. And because the

person providing the drug is almost always absent when complications arise—and very often unqualified to treat those complications—thousands of women a year are denied continuity of care and forced to go to emergency rooms. ECF 176, ¶¶ 167, 271, 282, 350.

FDA also has eliminated all procedural safeguards that would rule out ectopic pregnancies, verify gestational age, identify any contraindications to prescribing mifepristone, or identify potential complications until the patient is at a critical time or it is too late to help her. As a result, patients are more likely to suffer unexpected episodes of heavy bleeding or severe pain and must rush to the emergency room of the nearest hospital. ECF 176, ¶¶ 203, 255–56, 262–274, 351.

All these harms occur on top of the distress and regret individuals often suffer after undergoing chemical abortion. ECF 176-1, App. 601–03 (Ex. 37). Unlike with surgical abortions, an individual obtaining a chemical abortion often sees the body of the lifeless child after taking chemical abortion drugs. *Ibid.*

FDA's actions also make coerced abortion much easier and contribute to human trafficking. ECF 176-1, App. 285, 608–10 (Ex. 14, 37). With no physician supervision required, and with individuals able to easily obtain chemical abortion drugs through the mail, a coerced abortion is now as easy as slipping a pill into a girlfriend's or trafficking victim's drink or food. Human trafficking and coerced abortion have of course long been illegal in the Plaintiff States. *E.g.*, Mo. Rev. Stat. §§ 188.027, 566.209. But FDA's actions make human trafficking and coerced abortion worse.

2. Nor can FDA dispute that these are the kinds of harms a "State, if it could, would likely attempt to address through its sovereign lawmaking powers." *Snapp*, 458 U.S., at 607. The States have passed laws to guard against these harms. For instance, Missouri has outlawed elective abortions except in cases of medical emergency. Mo. Rev. Stat. § 188.017.2. Missouri has also put in place safeguards for women and girls who undergo chemical abortions, such as requiring that abortion drugs be dispensed in-person and requiring that physicians who perform abortions provide a plan for and care for complications that arise. Mo. Rev. Stat. § 188.021.1–.2; 19 C.S.R. 10-15-050. And Missouri has long banned human trafficking and coerced abortions. Mo. Rev. Stat. §§ 188.027, 566.209. These laws exist to protect women and girls, but FDA frustrates them by aggravating all these harms. Having exhausted its sovereign capabilities—the States, of course, cannot regulate FDA—the States have no remaining option other than to sue.

c. The States have quasi-sovereign injuries because FDA's actions harm doctors in the States.

Likewise, certain Missouri statutes and regulations were designed to prevent injuries to doctors and hospitals, but they are being undermined by FDA's unlawful actions. Missouri statutes and regulations require physicians to plan for and provide care for abortion complications so that persons receiving abortions are not forced to go to emergency rooms. See Mo. Rev. Stat. § 188.021.1–.2; 19 C.S.R. 10-15-050. But FDA's challenged actions cause doctors who live and work in Plaintiff States to treat

more women and girls who have suffered complications from chemical abortion drugs because physicians are not providing follow-up care when individuals experience complications. ECF 176, ¶¶ 363–68. Increased complications consume limited medical resources, such as physician time and attention, space in hospitals, blood for transfusions, and other equipment and medicines—in both public and private hospitals. ECF 176, ¶¶ 301–06, 369–76. The Plaintiff States have an interest in preventing these harms and have passed laws to prevent them. FDA's unlawful actions have hindered their efforts, harming the States. Again, unable to use their sovereign authority to regulate FDA, the States are forced to sue.

B. FDA's arguments about venue lack merit.

No better is FDA's confident assertion that if this Court remands to the district court, FDA will be able to vacate the preliminary injunction by arguing that the States lack venue.

FDA's argument—expressed in their opposition to the intervention motion—rests on the fundamentally flawed premise that a determination by this Court on standing favorable to FDA would automatically dismiss the private plaintiffs from this suit. FDA never filed, and the district court never ruled on, a motion to dismiss. FDA instead appeals a preliminary injunction. But 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). A holding by this Court that the private plaintiffs failed to submit sufficient evidence

to establish standing for a preliminary injunction would not require dismissal. FDA would have to wait until the case returned to the district court before moving to dismiss.

But even if the private plaintiffs were dismissed, it is well established that the district court may "treat the intervenor's claim as if it were a separate suit" and permit it to continue—with all previous orders still in effect. Wright & Miller, supra, § 1918. Venue is not jurisdictional, 28 U.S.C. § 1406(b), and a plaintiff who successfully intervenes in a case where venue was satisfied by the original party need not independently satisfy venue 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. Here, every FDA action the States challenge is also challenged by the private plaintiffs, so the States' challenge satisfies the "closely related" test.

CONCLUSION

The Court should affirm the preliminary injunction, but if this Court accepts FDA's flawed argument that the private plaintiffs lack standing, the only proper remedy is a remand to the district court without vacatur.

Respectfully submitted,

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