No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD & DRUG ADMINISTRATION; MICHAEL DAVIS, IN HIS OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

v.

GENBIOPRO, INC.,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana
No. 25-cv-1491, Hon. David C. Joseph

PLAINTIFFS-APPELLANTS' REPLY AND RESPONSE BRIEF

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The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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The State of Louisiana

Rosalie Markezich

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U.S. Department of Health and Human Services

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GenBioPro, Inc. (GenBioPro represents that its parent company is Xenia Holdco LLC, and there is no publicly held corporation that owns 10% or more of GenBioPro's stock.)

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INTRODUCTION AND SUMMARY OF ARGUMENT

Just days ago, Acting Attorney General Todd Blanche testified before Congress that "we are not defending what Biden did, and will not": The 2023 REMS is "wrong," and Louisiana's laws are "really what's being violated here."[1] *Contra* FDA.Br.42 ("[I]t is not a violation of Louisiana's laws at all."). He is exactly right—and Judges Southwick, Duncan, and Engelhardt were exactly right at the motions stage, when they joined two prior Fifth Circuit panels in rejecting the 2023 REMS's removal of the longstanding in-person dispensing requirement for mifepristone. FDA's light briefing (which the Manufacturers unsuccessfully attempt to shore up) only confirms the appropriateness of issuing a stay under 5 U.S.C. § 705 in line with the motions panel's order.

* * *

At the outset, it is necessary to dispose of two procedural issues raised by FDA.

First, FDA strangely spends significant time slaying a straw man—insisting that the district court's decision to stay proceedings below was

[1] *Attorney General Nominee Todd Blanche Testifies at Confirmation Hearing, Day 1 Part 2* at 1:48:50–55, 1:51:10–15, 1:52:00–09, C-SPAN (July 15, 2026), tinyurl.com/mrxww2m4.

not an abuse of discretion. FDA.Br.3, 4, 5, 15–21. But buried in FDA's brief (at 21) ultimately is a concession that Plaintiffs "never" argued otherwise in their opening brief. The reason Plaintiffs did not argue otherwise is that the district court's existing stay of proceedings would cause no material harm *if* it were coupled with a § 705 stay of the 2023 REMS—hence Plaintiffs' challenge on appeal to the district court's denial of relief under § 705.[2] They do not challenge the district court's existing stay of proceedings. The Court should thus ignore FDA's efforts to transform this appeal into one FDA wishes Plaintiffs had filed. *See* FDA.Br.15–16 (claiming the question presented "is not ... whether this Court should grant a § 705 stay of the 2023 REMS," but "whether this Court should affirm the district court's decision to stay this litigation").

Second, citing the Supreme Court's stay of the motions panel's § 705 stay pending appeal, *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192 (2026), FDA also claims that Plaintiffs are asking the merits panel to

[2] To the extent FDA (but not the Manufacturers) hints (at 5, 15–16, 22) that somehow Plaintiffs have not sought reversal of the district court's denial of a § 705 stay, that is incorrect. By expressly asking this Court to enter a § 705 stay, Plaintiffs necessarily are asking the Court to reverse the district court's denial of such a stay. Moreover, as FDA admits (at 22), Plaintiffs' request is keyed to the specific language of § 705, which gives "the reviewing court, including the court to which a case may be taken on appeal," the authority to enter such a stay.

"defy the Supreme Court" by staying the 2023 REMS. FDA.Br.5, 14; *see id.* at 22 ("There is simply no way to argue that this Court could grant the relief plaintiffs now seek in a manner consistent with the Supreme Court's ruling.").

That rhetoric is severely overblown. As FDA admits (at 23–24), Plaintiffs have agreed that this Court should stay its own decision in Plaintiffs' favor pending Supreme Court review, even though the Supreme Court's stay decision is "not conclusive as to the merits" of this appeal. *See Trump v. Boyle*, 145 S. Ct. 2653, 2654 (2025); *contra* FDA.Br.22 (claiming the stay decision is conclusive on "at least one" unknown merits issue). As *Boyle* contemplates, that interim stay decision does not preclude this Court's independent merits assessment of whether a § 705 stay is warranted. Indeed, that is precisely what Chief Judge Elrod previously explained for this Court by (a) holding that FDA's removal of the in-person dispensing requirement "will be stayed [under § 705] pending final judgment" but (b) recognizing that the § 705 stay itself "is subject to the Supreme Court's prior [stay] order." *All. for Hippocratic Med. v. FDA* (*Alliance II*), 78 F.4th 210, 256 (5th Cir. 2023). That careful procedure ensures that this Court treats a "like case[]"—

where the question is whether a § 705 stay itself should be stayed—just as the Supreme Court did. *Boyle*, 145 S. Ct. at 2654.

Relatedly, FDA suggests (at 24) that no "practical difference" exists between the motion's panel's § 705 stay pending appeal and Plaintiffs' request that the merits panel enter a § 705 stay. The difference is that the motion panel's order (which applies only "pending appeal," ECF 119-1 at 2–3, 18) likely will never take effect again because the Supreme Court has stayed it "pending disposition of the appeal in [this Court] and disposition of a petition for a writ of certiorari, if such a writ is timely sought," *Danco Lab'ys*, *LLC*, 146 S. Ct. at 1192—in other words, until this appeal has concluded and thus the motions panel's order has expired on its own terms. By contrast, the merits panel's reversal of the district court by entering a § 705 stay would not be limited to the lifecycle of this appeal; it would extend throughout the duration of this lawsuit. That is why Plaintiffs have asked the merits panel to issue a § 705 stay in line with the decisions issued by three prior Fifth Circuit panels.[3]

[3] FDA spends two pages (at 26–27) urging the unremarkable point that the motions panel's order is not binding on the merits panel. Of course that is true—and Plaintiffs have never argued otherwise. Plaintiffs simply urge this merits panel to follow the eminently correct decisions issued by the three prior panels.

To be sure, Plaintiffs acknowledge the Supreme Court's unshakeable interest in resolving issues surrounding mifepristone. *See Danco Lab'ys, LLC*, 146 S. Ct. 1192; *FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024); *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023); *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021); *see also Trump v. CASA, Inc.*, 606 U.S. 831, 877–78 (2025) (Kavanaugh, J., concurring) ("[D]etermining the nationally uniform *interim* legal status for several years of, say, ... mifepristone rules is a role that the American people appropriately expect this Court—and not only the courts of appeals or district courts—fulfill."). But that impending Supreme Court review makes this Court's role easier, not harder—for this Court need only hew to the path marked by Judges Southwick, Duncan, and Engelhardt (and the panels before theirs) and leave for the Supreme Court the responsibility of ultimately determining the status of the 2023 REMS during this litigation.

* * *

With that procedural underbrush cleared, the merits of this appeal are remarkably straightforward—confirmed, in significant part, by the Acting Attorney General's agreement that the 2023 REMS's removal of

the in-person dispensing requirement is "wrong" and the U.S. Department of Justice's refusal to "defend[] what Biden did." *Supra* n.1.

FDA only nominally opposes Louisiana's standing to sue. Indeed, it concedes that Louisiana is suffering completely predictable economic Article III injuries from the 2023 REMS. FDA's only concern (echoed by the Manufacturers) is that ruling for Louisiana would purportedly allow any state to sue over any federal policy it dislikes. But that concern is unfounded because this appeal arises from the district court's factual finding that Louisiana (among other pro-life states) was the target or object of the 2023 REMS—a finding nowhere acknowledged or disputed by FDA and Danco. That ensures that this Court's finding of jurisdiction would be limited. And the same goes for Louisiana's sovereign injuries: Much of the Manufacturers' briefing goes to attenuation, but that is not a serious issue given the unique circumstance presented by the Biden Administration's "perpetration of a scheme to undermine" *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), by facilitating the flood of mifepristone into pro-life states. *Danco Lab'ys, LLC*, 146 S. Ct. at 1193 (Alito, J., dissenting).

The merits and remaining preliminary-relief factors are just as straightforward. The most recent briefing offers no reason to depart from the sound decisions of the three prior Fifth Circuit panels to consider the REMS. *See All. for Hippocratic Med. v. FDA* (*Alliance I*), 2023 WL 2913725 (5th Cir. Apr. 12, 2023); *Alliance II*, 78 F.4th 210; ECF.119-1. And to the extent that the Manufacturers bound their equities and public interest arguments up in supposed fear about the immediate uncertainty of a stay, those arguments are now moot: By granting the Manufacturers' own request for a stay of the motions panel's order (a stay that Plaintiffs agree should extend to a decision in their favor by this merits panel), the Supreme Court has ensured that no supposed sudden and deleterious consequences could befall the Manufacturers or the public if the merits panel rules in Plaintiffs' favor.

For these reasons, the Court should stay the 2023 REMS under § 705, while staying that decision pending the "disposition of a petition for a writ of certiorari, if such a writ is timely sought," *Danco Lab'ys*, *LLC*, 146 S. Ct. at 1192. As to the cross appeal, the Court should affirm the district court's denial of the Manufacturers' motions to dismiss.

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

Start with Plaintiffs' likelihood of success on the merits, which is blindingly clear given the district court's and the motions panel's agreement that (A) Louisiana has Article III standing and (B) the 2023 REMS is likely unlawful.

A. Louisiana Has Article III Standing.

1. Louisiana's economic injuries establish standing.

The Court can begin and end its standing analysis with economic injuries, particularly given how much ground FDA concedes. FDA rightly concedes (at 27) that the "two types of economic harms to Louisiana" relevant here—the Medicaid costs from emergency care due to FDA-approved mifepristone, and the costs of Louisiana's investigations into the illegal mailing of mifepristone into Louisiana—"satisfy the 'injury' component of the Article III standard." *See* Op.Br. 36–37. FDA also rightly concedes (at 28), or at least does not dispute, that these economic harms are the "completely predictable" consequence of the 2023 REMS. *See* Op.Br.38–40. And FDA notably does not reference redressability at all, let alone dispute that a stay of the 2023 REMS would redress Louisiana's economic injuries. *See* Op.40–41.

Having folded on virtually every aspect of the Article III standing analysis, FDA has little else to go on—save for its claim that "the problem here is ... attenuation": "these sorts of 'ripple effects' of government action are simply too 'far removed' from the action to establish standing to challenge it[.]" FDA.Br.28 (citing *Alliance*, 602 U.S. at 383). That claim is incorrect. And GBP's solitary attempts to shore up the FDA brief go nowhere.

a. FDA's attenuation argument fails as a matter of law and fact. The argument rests on the Supreme Court's statement that the Article III "causation requirement [] rules out attenuated links—that is, where the government action is so far removed from its distant (even if predictable) ripple effects that the plaintiffs cannot establish Article III standing." *Alliance*, 602 U.S. at 383. In the same breath, however, the Supreme Court said that this inquiry is not "a 'mechanical exercise'" and "can be heavily fact-dependent." *Id.* at 384.

Those general principles exist alongside two others from *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), that are relevant here. *First*, "[t]he government generally may not target [an entity] through stringent and allegedly unlawful regulation, and then evade the

resulting lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders." 606 U.S. at 125. *Second*, even where such a target is not a "directly regulated" entity, it nonetheless "might be considered an object of" the challenged regulation insofar as "the government might seek to indirectly target [the entity's operations] 'through a conduit'"—in which case the entity is subject to the general rule that "there should 'ordinarily' be 'little question' that the regulation causes injury to the plaintiff and that invalidating the regulation would redress the plaintiff's injuries." *Id.* at 114–16 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)); *cf. Nat'l Rifle Ass'n v. Vullo*, 602 U.S. 175, 190 (2024) ("[A] government official cannot do indirectly what she is barred from doing directly[.]").

These principles resolve this standing question—and end FDA's attenuation argument. That is because this appeal arises on the district court's factual finding—based on unrebutted record evidence—"that the 2023 REMS was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion." ROA.9104. Among other evidence, that includes:

- President Biden's day-of-*Dobbs* announcement that he would pursue pro-life states that "severely restrict access to medication

for reproductive health care" and directive that his administration should "identify all ways to ensure that mifepristone is as widely accessible as possible ... including when prescribed through telehealth and sent by mail";

- His HHS Secretary's statement that *Dobbs* was "despicable" and "HHS has been preparing for this for some time";
- President Biden's threats to pro-life states that they "may not ban mifepristone" and his pledge "to allow mifepristone to continue to be prescribed by telehealth and sent by mail"; and
- His administration's statement that, "[s]ince *Dobbs*, HHS has worked to protect and expand access to reproductive care amidst unprecedented efforts by Republican officials at the national and state level to restrict access to abortion," specifically citing the 2023 REMS.

Op.Br.9–11, 45–46 (collecting record citations).

As the district court recognized, Louisiana is not randomly, accidentally, or incidentally experiencing the economic injuries that are the "completely predictable" (FDA.Br.28) consequence of the 2023 REMS. Quite the contrary: Louisiana was one of the pro-life states disparaged by President Biden for its commitment to life—and is now suffering the consequences of his pledge to facilitate the mailing of mifepristone into Louisiana and other pro-life states. Put in *Diamond*'s terms, the superseding of Louisiana law (among laws of its sister states, *see* ECF 202 at 1, 4–6) was the "target" and "object," *Diamond*, 606 U.S. at 114–15, 125, of the 2023 REMS, which was the Biden Administration's crown

jewel in "that post-*Dobbs* regulatory environment," ROA.9104. There thus is no serious argument that Louisiana is an "unaffected bystander[]" who can "be locked out of court." *Diamond*, 606 U.S. at 125. Nor is there any serious argument about "distant ... ripple effects." *Alliance*, 602 U.S. at 383. As water goes, the 2023 REMS is a wave pool, and Louisiana suffers the economic consequences of 1,000 illegal abortions each month due to the REMS.

That is why this standing analysis is straightforward—and presumably why FDA whiffs on both the factual record and *Diamond*. FDA ignores the Biden Administration's statements entirely. Relegating *Diamond* to one paragraph at the very end of its standing argument, FDA simply says that *Diamond* involved targeting "in a manner plainly absent here." FDA.Br.35. But FDA does not elaborate on that *ipse dixit*, nor does FDA acknowledge that it is chafing against the district court's factual finding "that the 2023 REMS was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion." ROA.9104. That finding, of course, can be reviewed only for clear error. *E.g.*, *Tex. All. for Retired Ams. v. Scott*, 28 F.4th 669, 671 (5th Cir. 2022). And FDA rightly does

not even try to mount that futile challenge. Standing based on Louisiana's economic injuries is open-and-shut.

b. The foregoing illustrates why the rhetoric in FDA's and the Manufacturers' briefing is all flourish, no facts. By their telling, holding that Louisiana has standing based on its economic injuries would mean that every state automatically would have standing to challenge every federal policy it dislikes. *See, e.g.*, FDA.Br.35–36 ("Louisiana offers no defense for the 'boundless[ness] of its 'theory of standing,' 'in which all peripheral costs imposed on States' by federal actions can allow the States to challenge the actions in federal court[.]").

That telling is utterly unserious if—as FDA and Danco do—the storyteller ignores the fact the district court found significant: The 2023 REMS, and thus this case, arises out of the federal government's "effort to circumvent anti-abortion states' ability to regulate abortion." ROA.9104. That fact is central to Louisiana's standing theory—and it shuts down the parade of horribles about giving states a free pass to federal court to challenge policies on drugs, immigration, banking, power plants, speed limits, vaccines, and gun restrictions, none of which (unlike

this case) involve a putative plaintiff who is the target and object of the challenged action. *Contra* FDA.Br.30–32; Danco.Br.29; GBP.Br.27–32.

FDA's and the Manufacturers' cited cases are thus inapposite. They invoke *United States v. Texas*, 599 U.S. 670, 680 n.3 (2023), insofar as it explains that a "State's claim for standing can become more attenuated" where it rests on "indirect effects on state revenues or state spending." *See* FDA.Br.28–29; Danco.Br.27–28; GBP.Br.26–27. But *Texas* answered only the "highly unusual" and "narrow" question "whether the Federal Judiciary may in effect order the Executive Branch to take enforcement actions against violators of federal law[.]" 599 U.S. at 684–85. It said nothing about when indirect effects on state revenues or state spending become too attenuated to satisfy the causation standard.[4] And it certainly

[4] Indeed, the absence of any elaboration begs the question of what the Court might say about attenuation where "the fundamental Article III problem with [*Texas*]"—*i.e.*, the request for a judicial order directing executive enforcement actions—is *not* present. *Texas*, 599 U.S. at 680 n.3. As Justice Gorsuch (joined by Justices Thomas and Barrett) separately pointed out, injury-in-fact and causation in *Texas* were not a problem; the problem was the demand for a federal court to direct executive enforcement actions, which in his view went to redressability. *See id.* at 689–90 (Gorsuch, J., concurring in the judgment) (noting that the plaintiff states proved not only that the challenged federal action "increase[d] the number of aliens ... released into the States," but also "that, as a result, [the states] spend more money on everything from law enforcement to healthcare"). Louisiana does not need that broader theory to prevail here for the reasons explained above, but, out of an abundance of caution, Louisiana notes that this theory would equally assure Article III jurisdiction in this case.

said nothing about either direct or indirect effects on state revenue and spending in the *Diamond*-like context of a regulation aimed at the state.

Arizona v. Biden, 40 F.4th 375 (6th Cir. 2022) (cited at FDA.Br.31, 35–36; Danco.Br.28; GBP.Br.37–38), is unilluminating for the same reason. That case involved essentially the same issues addressed by *Texas*—and it expressed a similar sentiment: "Are we really going to say that any federal regulation of individuals through a policy statement that imposes peripheral costs on a State creates a cognizable Article III injury for the State to vindicate in federal court?" *Id.* at 386. But, like *Texas*, *Arizona* did not consider anything like Medicaid and investigatory costs that were the predictable consequence of federal action trained on a plaintiff state.

So, too, with *Washington v. FDA*, 108 F.4th 1163, 1174 (9th Cir. 2024) (cited at FDA.Br.29–30; Danco.Br.27, 30; GBP.Br.28–29), where the Ninth Circuit rejected Idaho's argument "that elimination of the in-person dispensing requirement will cause the state economic injury in the form of increased costs to the state's Medicaid system." For starters, unlike Louisiana, Idaho did not produce Medicaid receipts. More, while the Ninth Circuit explained in passing that "an alleged uptick in

Medicaid costs is exactly the kind of 'indirect effect[] on ... state spending' that the Supreme Court has rejected as a basis for standing," *id.* at 1176 (citing *Texas* and *Arizona*), *Washington* predated *Diamond*. And again unlike Louisiana, Idaho "d[id] not allege" that its pro-life laws were "the object of regulation," *id.* at 1175, nor did Idaho put at issue the Biden Administration's statements about ensuring the availability of mifepristone in pro-life states like Louisiana. The Ninth Circuit thus did not consider these key ingredients of Louisiana's economic-injury theory, and they readily distinguish *Washington*.

The same goes for *Alliance* itself. *See* FDA.Br.31–32, 34; Danco.Br.26–27; GBP.Br.27–28. The Manufacturers are fond of saying that, "[i]f doctors [in *Alliance*] lacked standing based on 'downstream economic injuries' from treating patients with mifepristone complications, Louisiana cannot establish standing because the doctor later sends an invoice to the State." GBP.Br.28 (citation omitted); Danco.Br.27 (same). But that ignores at least four obvious distinctions: (i) unlike the doctors' economic claim which "lack[ed] record support," *Alliance*, 602 U.S. at 390, Louisiana has the receipts; (ii) Louisiana's investigatory costs are triggered by the commission of the crime (the

mailing of mifepristone into Louisiana) itself, not a doctor's subsequent administration of care; (iii) unlike Louisiana, the doctors in *Alliance* were not alleged to be the objects or targets of the 2023 REMS; and (iv) unlike Louisiana, the doctors in *Alliance* did not have the federal government's concession (FDA.Br.28) that Louisiana is suffering "completely predictable" Article III injuries due to the 2023 REMS. Those facts both distinguish *Alliance* and confirm Louisiana's standing.

c. GBP (but not Danco or FDA) raises other issues—all meritless, as signaled by GBP's solitary position.

First, GBP disputes (at 20–24) whether Louisiana was a target or object of the 2023 REMS. GBP's discussion of this issue is not forthcoming. One, GBP never acknowledges or disputes the district court's factual finding controlling this question. *See* ROA.9104 (finding "that the 2023 REMS was approved without adequate consideration, at least in part, as part of an effort to circumvent anti-abortion states' ability to regulate abortion"). Two, GBP claims that an assessment of Article III jurisdiction must be limited to the administrative record, even though (i) the rule of *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), applies only to APA review of the agency action itself, *see Biden v. Texas*, 597

U.S. 785, 812 (2022), not an assessment of Article III jurisdiction, and (ii) *Department of Commerce v. New York*, 588 U.S. 752, 758 (2019), plainly illustrates the propriety of extra-record considerations for jurisdictional purposes. Not only that, but GBP also misleadingly claims that *Trump v. Hawaii*, 585 U.S. 667 (2018), "does not allow inferring an agency's purpose from 'extrinsic' political statements and unsupported innuendo." GBP.Br.22. Based on that statement, one might think *Trump* says something about ignoring extrinsic evidence in assessing Article III jurisdiction; it does not. Not just that, but on the merits, the Court *did* "consider plaintiffs' extrinsic evidence." 585 U.S. at 705.

Three, when GBP gets around to trying to explain away some of the Biden Administration's statements, it severely misrepresents them. To take one example: GBP characterizes President Biden's day-of-*Dobbs* announcement as an innocuous statement about "distribution 'by mail' of FDA-approved medication 'in light of the FDA's determination that the drug is safe and effective,' not as a pledge to circumvent state law." GBP.Br.22. In fact, GBP continues, "[t]he same statement recognized that nationwide abortion access would require '*Congress* to restore the

protections of *Roe* as federal law.'" GBP.Br.22 (emphasis GBP's). Omitted from GBP's characterization:

- "Today, President Biden announced actions that his Administration is taking to protect women who will face the grave consequences of today's Supreme Court decision."
- "This decision will have devastating consequences in the lives of women around the country."
- "The President has directed the Secretary of Health and Human Services to protect women's access to critical medications for reproductive health care that are approved by the Food and Drug and Administration—including essential preventive health care like contraception and medication abortion."
- "In the face of threats from state officials saying they will try to ban or severely restrict access to medication for reproductive health care, the President directed the Secretary of Health and Human Services to identify all ways to ensure that mifepristone is as widely accessible as possible in light of the FDA's determination that the drug is safe and effective including when prescribed through telehealth and sent by mail."

ROA.955-56. GBP's omissions speak for themselves.

Second, GBP claims that Louisiana was required "to establish" whether its economic injuries would be same or higher in a world with no 2023 REMS and no FDA-approved mifepristone abortions in Louisiana. *See* GBP.Br.29–30, 31–32 (questioning "the net economic effect" of the REMS). GBP does not disclose that, "[i]n resolving standing, courts do

not engage in such an 'accounting exercise.'" *Texas v. United States*, 50 F.4th 498, 518 (5th Cir. 2022). Indeed, "[o]nce injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." 13A Wright & Miller, Fed. Prac. & Proc. § 3531.4 (3d ed.); *see Missouri v. Trump*, 128 F.4th 979, 989–90 (8th Cir. 2025) (collecting cases).

Third, GBP claims (at 30) Louisiana's investigative costs are not a cognizable Article III injury. GBP admits (*id.*) that "private litigants" may incur Article III injuries by expending "preventive costs to avoid a 'substantial risk' of harm," but says that states should be subject to a higher standard—otherwise states could "have standing merely because they incurred costs in the ordinary course of enforcing State law." GBP cites no authority for rendering states *inferior* to private individuals—and there likely is none because, if anything, sovereignty means something in our constitutional system. *See, e.g.*, *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 769 (5th Cir. 2023) ("States are not normal litigants for purposes of invoking federal jurisdiction." (citation omitted)). That is especially so in this context where the state sovereign functionally is the object of the challenged federal action.

Fourth, GBP oddly claims (at 32–33) that Louisiana failed to show a likelihood that its Medicaid injuries will recur. As an initial matter, this argument does not address Louisiana's investigative costs, which increase every month given the monthly rate of approximately 1,000 abortions. And as to the Medicaid injuries, GBP does not acknowledge, let alone dispute, the district court's factual findings on exactly this point. *See* ROA.9107 (establishing that many of the residents obtaining FDA-approved mifepristone by mail "are likely to be on Medicaid"), ROA.9107 (establishing that emergency room visits are "'statistically certain'" according to FDA's own documents), ROA.9108 (establishing that, in addition to actual evidence of Medicaid costs from just two cases alone, "it is likely that many more Medicaid patients have required similar care due to complications from mifepristone" (providing record citations)). Those findings unquestionably are not clearly erroneous.

Fifth, GBP riffs on the allegedly "long chain of independent decisions" connecting the 2023 REMS to Louisiana's Medicaid costs, suggesting that there is impermissible attenuation. GBP.Br.25–26.

This argument, too, does not address Louisiana's investigatory costs which, as discussed above, are triggered by the illegal act facilitated

by the 2023 REMS—the mailing of FDA-approved mifepristone into Louisiana. But more fundamentally, GBP's argument is fluff: It engages in hand-wringing (at 26) about whether an out-of-state prescriber will mail FDA-approved mifepristone into Louisiana, or whether a Louisiana resident will receive and then take the mifepristone. *Accord* Danco.Br.36–37. But no guesswork is required since nobody disputes that this happens approximately 1,000 times every month in Louisiana. *See* Op.Br.13 (compiling record citations). Similarly, GBP wonders (at 26) whether such a Louisiana resident might also be on Medicaid and seek care, causing Louisiana's financial injuries. But, as discussed above, GBP omits that the district court made factual findings on this precise issue—findings GBP neither acknowledges nor challenges for clear error.

Sixth, GBP claims (at 29) that Louisiana's Medicaid costs are traceable only "to the use of" FDA-approved mifepristone, as opposed to the 2023 REMS's removal of the in-person dispensing requirement. The reason, says GBP, is that, as FDA's mifepristone label confirms, emergency room visits would occur all the same *even if* the in-person dispensing requirement remained in place. That is a logical error. If FDA-approved mifepristone were not mailed into Louisiana (*i.e.*, if the in-

person dispensing requirement were restored), then no emergency room visits due to the use of such mail-order mifepristone would occur and no related Medicaid costs would arise. Indeed, emergency room visits in general would plummet because abortion is unlawful in Louisiana. That harm is directly traceable to the 2023 REMS and redressable by a stay.

Seventh, at various points (at 23, 24, 31, 33), GBP tries to cast blame on third-party prescribers for Louisiana's injuries. But once again, GBP makes no attempt to dispute the district court's own handling of this issue. The district court recognized that, of course, "there are factors other than the 2023 REMS that influence the arrival of mifepristone in Louisiana"—including out-of-state prescribers themselves and pro-abortion states that have enacted "shield laws" attempting to immunize those prescribers from liability. ROA.9106. "But there can be little doubt," the district court continued, "that the 2023 REMS is a factor, which is all that is required for Louisiana to show injury-in-fact and traceability." ROA.9106 (citing *Texas*, 50 F.4th at 519, which holds that federal action "exacerbat[ing]" an injury is "sufficient" even if it "is not the sole cause").

That is exactly right. As Louisiana has explained time and again, the 2023 REMS is the indispensable ingredient for Louisiana's injuries. Without the 2023 REMS, those shield laws would accomplish nothing because out-of-state prescribers could not lawfully (under federal law) mail FDA-approved mifepristone into Louisiana. The Manufacturers, therefore, cannot hide behind their own prescribers' conduct taken under the claimed protection of shield laws—for Louisiana's economic injuries are equally traceable to the 2023 REMS. *Contra* Danco.Br.37–38. Nor can they pretend that they are not themselves aiding and abetting their prescribers' illegal conduct through links on their websites directing visitors to networks designed to facilitate unlawful mail-order abortions in Louisiana. *See* ECF 174 at 5. With the restoration of the in-person dispensing requirement, the Manufacturers would need to ensure their prescribers' compliance, confirming causation and redressability.

Last, GBP includes a troubling argument that should give the Court pause—namely, that the Court cannot order effectual relief by staying the 2023 REMS because GBP's own prescribers could independently choose to violate FDA's regulations by continuing to mail FDA-approved mifepristone into Louisiana. GBP cannot plausibly claim that it could

wash its hands of that affront to federal law.[5] But, in all events, the argument is frivolous, not least because, well, why else would the Manufacturers be spending so much time and money to bury the in-person dispensing requirement? Because its elimination is the "lifeline" (Op.Br.28) for sending thousands of their drugs into pro-life states. As GBP told the district court, "[a] significant portion of GenBioPro's revenue" is on the line because that portion comes "from the sale of mifepristone prescribed via telehealth services" and, "[w]ithout the in-person dispensing requirement," "dispense[d] [] by mail[.]" ROA.2834, 2837.

California unsuccessfully tried a version of this argument in *Diamond*, and it is just as frivolous here. *See* 606 U.S. at 118 ("[T]hat is an odd argument for EPA and California to advance. After all, if invalidating the regulations would change nothing in the market, why are EPA and California enforcing and defending the regulations?").

[5] As sponsors, Danco and GBP must ensure that mifepristone reaches patients only through REMS-compliant prescribers or face "enforcement action[s] such as product seizure, injunction or civil money penalties." REMS Compliance Program, FDA (Sep. 22, 2022), perma.cc/KE9P-UKGU. Prescribers themselves must certify their compliance directly to the manufacturers, risking decertification and loss of access to the drug if they violate that certification. And that says nothing of the FDCA's independent prohibition on introducing misbranded drugs into the market. *See* 21 U.S.C. § 331(a).

"[T]he fact that a regulation was designed to produce a particular effect on the market ordinarily means that the likely result of vacating that regulation would be to reduce that effect on the market." *Id.* at 117. Just so here.

2. Louisiana's sovereign injuries confirm standing.

Although Louisiana's economic injuries end the analysis, Louisiana's concomitant sovereign injuries are icing on the cake. That is best illustrated by FDA's brief, which gives up entirely (FDA.Br.36–43) on the attenuation argument that it presses against Louisiana's economic injuries—indeed, FDA has nothing to say about causation and redressability when it comes to the issue of sovereign injuries. And rightly so: There is no denying that the 2023 REMS facilitates approximately 1,000 violations of Louisiana's pro-life laws every month, rendering those laws practically impossible to enforce. Nor is there any denying that a stay of the 2023 REMS would substantially, if not entirely, halt those violations.

Rather than deny the obvious, FDA focuses exclusively on whether Louisiana has identified a cognizable sovereign injury; it has. And the Manufacturers' alternate arguments do not change that fact.

a. Plaintiffs' opening brief explains that Louisiana suffers "two distinct sovereign injuries" from the 2023 REMS—the actual violations of Louisiana law that occur each month because of the REMS, and, as a byproduct, the practical unenforceability of Louisiana's laws. Both roads lead to an Article III sovereign injury, and FDA stumbles on each.

First, FDA protests (at 36–39) that the mere fact of a violation of Louisiana law cannot give Louisiana standing to bring this suit. Instead, as FDA reads this Court's decision in *Harrison* and the Supreme Court's decision in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), Louisiana not only must suffer a violation of its law but also must file an enforcement action and then be "hinder[ed]" from prosecuting that action. FDA.Br.38 (quoting *Harrison*, 78 F.4th at 771). FDA badly misreads *Harrison*, not least because that decision confirms Louisiana's standing here.

As relevant here, *Harrison* involved Louisiana's "attempts to invoke federal jurisdiction to enforce mostly state law against a subordinate [school board]." 78 F.4th at 771. This Court recognized that longstanding precedents recognize a state's sovereign interest in its "power to create and enforce a legal code," and that sovereign interest gives rise to a

cognizable injury from both the "federal preemption of state law" and "federal interference with the enforcement of state law." *Id.* at 770 (citation omitted). The Court hastened to add that, "for a sovereign interest to serve as a cognizable injury for federal standing, the acts of the defendant must invade the government's sovereign right, resulting in some tangible interference with its authority to regulate or to enforce its laws." *Id.* (citation modified). And that pointed up two problems in Louisiana's attempt to sue a school board for non-compliance with the law: (i) it makes little sense to say a law *violator* is "hindering its enforcement," and (ii) Louisiana could simply use its "full arsenal of enforcement mechanisms" to force the school board's compliance. *Id.* at 770, 772.

It was in that context that this Court said, in considering what is effectively a state-court action in federal court, "a violation does not become an injury until Louisiana brings an enforcement action" to force "compliance with the law, and [the school board] or another entity hinders the state from doing so." *Id.* at 771. "Only then would there exist a controversy for us to resolve within the limits of federalism." *Id.*

This case is self-distinguishing. Unlike *Harrison*, this is an APA suit presenting a federal question in a federal court; so, there is no question about "the limits of federalism." *Id.* Also unlike *Harrison*, this is a suit not against law *violators* (here, out-of-state prescribers) but against the federal agency facilitating the violations of Louisiana law, *i.e.*, "hinder[ing]" the enforcement of Louisiana law. *Id.* Those two distinctions are enough to recognize that the violation of Louisiana law itself is sufficient to constitute a sovereign Article III injury. *See Stevens*, 529 U.S. at 771 (referring to "the injury to [the United States'] sovereignty arising from violation of its laws").

But if the Court needed more, unlike in *Harrison*, Louisiana *has* filed enforcement actions against the law violators; it has outstanding arrest warrants and extradition requests for the California and New York doctors responsible for illegally mailing FDA-approved mifepristone into Louisiana; and those enforcement actions have gone nowhere, precisely because the 2023 REMS's removal of the in-person dispensing requirement allows these perpetrators to physically remain outside Louisiana's territorial jurisdiction when committing their crimes.

Op.Br.16–17. So, even if *Harrison* otherwise applied here, Louisiana satisfies the *Harrison* inquiry on its own terms.

To be sure, FDA disputes (at 40–41) whether the 2023 REMS has sufficiently "hindered" the enforcement of Louisiana's pro-life laws—so it is important to be precise about the gambit in play. Everyone agrees that, if President Biden had signed a law authorizing the mailing of FDA-approved mifepristone into Louisiana, Louisiana would have standing to challenge that law on the ground that it preempts Louisiana's laws forbidding such remote dispensing of mifepristone. *See Harrison*, 78 F.4th at 771 ("federal preemption of state law" is one example of a cognizable injury (citation omitted)); *accord* Danco.Br.31. The 2023 REMS accomplishes *the same result* except through administrative fiat—call it *functional* preemption. By dropping the in-person dispensing requirement, it makes Louisiana's laws attempting to regulate abortion within the State meaningless. Indeed, the unrebutted record evidence shows that 100% of the abortions occurring in Louisiana are now at the hands of out-of-state prescribers. *E.g.*, Op.Br.64–66.

All this is why it is remarkable to read FDA's assurances (at 38, 43) that Louisiana retains "the power to enforce its abortion laws against

conduct that violates those laws" and that "Louisiana's abortion laws have full force." Prosecutions under those laws are virtually impossible because the 2023 REMS created a new and exclusive class of violators: out-of-state prescribers who can sit outside Louisiana's territorial jurisdiction while mailing mifepristone into the State. To return to *Harrison*'s terminology, perhaps the most offensive hindrance to a state law's enforceability is functional preemption rendering the law entirely useless. For these reasons, the 1,000 violations of Louisiana's laws every month under the 2023 REMS themselves constitute sovereign Article III injuries.

Second, insofar as FDA disputes Louisiana's related position "that it suffers sovereign injury by virtue of its 'inability to enforce [its] pro-life laws,'" respectfully it is difficult to understand FDA's three paragraphs. FDA.Br.41–43. FDA's clearest statement is that there is no "violation of Louisiana's laws at all" and thus there is no issue of Louisiana being unable to enforce its laws. FDA.Br.42. That is an astounding representation—and thankfully, the Acting Attorney General testified that it is not true. *See supra* n.1 (reflecting his testimony that laws like Louisiana's are "really what's being violated here").

FDA's representation also rests on a misunderstanding of law: the notion that Louisiana somehow seeks to punish exclusively extra-territorial conduct, which generally is impermissible. *See* FDA.Br.42. That is incorrect. The Supreme Court has long recognized that "[a]cts done outside a jurisdiction, but intended to produce and producing detrimental effects within it, justify a state in punishing the cause of the harm as if he had been present at the effect, if the state should succeed in getting him within its power." *Strassheim v. Daily*, 221 U.S. 280, 285 (1911) (collecting authorities). That is precisely what Louisiana law targets: the remote dispensing and distribution of mifepristone into Louisiana, regardless of the sender's location. *See* Op.Br.8 (citing Louisiana statutes).

FDA is thus wrong to proclaim (at 42) that "there is no issue of enforceability here." The issue is that, with the in-person dispensing requirement in place, out-of-state prescribers like Margaret Carpenter (New York) or Remy Coeytaux (California) would have had to come to Louisiana to dispense mifepristone to a Louisiana resident (barring an arrangement to meet in New York or California). If those doctors entered Louisiana's borders, Louisiana plainly could assert jurisdiction over them

in enforcing the State's abortion laws. But because of the 2023 REMS, both doctors can simply thumb their noses at Louisiana's laws while launching mifepristone into the State from afar. There is no enforceability to speak of. And that is a textbook sovereign injury.

b. None of the Manufacturers' related arguments change this fact.

First, Danco tries to downplay Louisiana's sovereign injuries as mere "logistical enforcement burden[s]." Danco.Br.35, 38. They are not. As discussed above, they reflect the very gutting of any meaning to Louisiana's pro-life laws.

Second, the Manufacturers claim that there is no history and tradition of recognizing suits such as this. *See* Danco.Br.31, 33, 36; GBP.36–37. That is incorrect. As explained above, this suit falls squarely within the long line of precedents reaffirmed in cases like *Harrison*—precedents expressly recognizing that "federal preemption of state law" and "federal interference with the enforcement of state law" are quintessential examples of sovereign Article III injuries. 78 F.4th at 770 (citation omitted).

Third, Danco tries to limit those precedents to situations where a state law can be deemed "*legally* unenforceable" (as opposed to practically

unenforceable?). Danco.Br.32, 34. That language appears nowhere in the cases Danco cites. And more fundamentally, it is wrong: When *Harrison* and its predecessors speak of "interference" and "hindrance," they do not care about the *means* of such interference or hindrance—only about the *result*. Put otherwise, whether a president overrides state law through the signing of a duly enacted law or through an administrative regulation, the result is the same. And as detailed above, the 2023 REMS's removal of the in-person dispensing requirement fits the bill.

Fourth, Danco tries to poison the well by implying that Louisiana rests on a *parens patriae* theory. Danco.Br.33–34. In particular, Danco characterizes Louisiana "itself [as] conceptualiz[ing] violations of its law as 'injur[ies] [to] the community,'" particularly with respect to Louisiana's arguments about the violation of public rights. *Id.* That is inaccurate. As the full context of the cited Blackstone quotation reveals, *the sovereign* "is supposed by the law to be the person injured by infraction of the public rights belonging to th[e] community." Op.Br.43 (citation omitted). And so, in this case, Louisiana—as the sovereign—has sued solely with respect to *its own injuries*, not the rights or injuries of its citizens. *See* ROA.120.

Last, the Manufacturers reprise their old attenuation and *Texas* arguments to no avail. Danco, for example, claims to have identified "a speculative chain of third-party discretionary actions"—without acknowledging the record evidence and district court findings showing not just predictability but certainty in linking the 2023 REMS to Louisiana's sovereign harms. *See* Danco.Br.36–37; *accord* GBP.Br.35. The Manufacturers also revive *Texas*, claiming that, insofar as that decision can be read as rejecting a standing theory based on the costs of "individuals committing more crimes in Texas," GBP.Br.36; Danco.Br.38; *accord* FDA.Br.40, Louisiana's theory is identical and should likewise be rejected. That is untrue principally because, as discussed above, *supra* n.4, *Texas* did not actually pass on that attenuation question; it said only that "the fundamental Article III problem" in asking federal courts to direct executive enforcement actions was fatal to all the standing theories raised in the case. 599 U.S. at 680 n.3. In all events, unlike in *Texas*, Louisiana's theory here is sovereign, not economic—and unlike in *Texas*, Louisiana's theory depends on the functional nullification of its laws' effect altogether, not the fact of violations of those laws.

* * *

Here, as before (Op.Br.52), the Supreme Court's admonition that lower courts must not "make standing law more complicated than it needs to be" is directly relevant. *Diamond*, 606 U.S. at 125 (citation omitted). As both the district court and motions panel concluded, Louisiana has standing.

B. The 2023 REMS Is Likely Unlawful.

The merits of this APA challenge to the 2023 REMS are even more straightforward. Three panels of this Court, two district judges, and now FDA's own leadership have looked at the 2023 REMS and reached the same conclusion: It is likely unlawful. Or, as the Acting Attorney General testified a few days ago, the 2023 REMS is "wrong." *Supra* n.1. FDA's refusal to defend the 2023 REMS is understandable. For the reasons expressed below (and by the three prior panels of this Court), the Court should hold that Plaintiffs are likely to succeed in their APA challenge to the REMS.

1. The Manufacturers' threshold arguments are meritless.

Take first the Manufacturers' procedural attempts to avoid merits consideration. None succeeds.

a. *Exhaustion*. No statutory or regulatory exhaustion requirement applies, and the Manufacturers' exhaustion arguments fail. *See* Danco.Br.39–40; GBP.Br.39–41. The APA mandates exhaustion only when required by statute or when a rule makes agency action "inoperative" during appeal. 5 U.S.C. § 704; *accord Darby v. Cisneros*, 509 U.S. 137, 154 (1993). No statute here so mandates exhaustion, and because FDA does not hold its REMS "inoperative" when it receives a petition, exhaustion is unnecessary. Michael Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, 77 Vand. L. Rev. 937, 977–78, 980 (2024), perma.cc/3BHM-WRQE; *MCR Oil Tools, L.L.C. v. U.S. Dep't of Transp.*, 110 F.4th 677, 691 (5th Cir. 2024).

Even if exhaustion applied (it does not), at least three "traditionally recognized" exceptions defeat it here. *Wash. Ass'n for Television & Child. v. FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983).

First, when an agency fails to follow its own regulations, exhaustion may be waived. *Alliance I*, 2023 WL 2913725, at *16; *see also Way of Life Television Network, Inc. v. FCC*, 593 F.2d 1356, 1359–60 (D.C. Cir. 1979). FDA's regulations require a 180-day response to citizen petitions, 21

C.F.R. § 10.30(e)(2), yet the average REMS petition languishes for 937.6 days. Krupka, *supra*, at 957–63. In *Alliance I*, FDA subjected the *Alliance* plaintiffs to "*sixteen* years of delay, dawdle, and dithering," before eventually rejecting their petitions. *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 538 (N.D. Tex. 2023) (emphasis added). "FDA's repeated failure to follow its own regulations" thus ensures that waiver of any exhaustion requirement would be appropriate. *Alliance I*, 2023 WL 2913725, at *16.

Second, the record shows FDA would have denied any stay request. *Alliance II*, 78 F.4th at 255. FDA denied a petition requesting that it reaffirm in-person dispensing on January 3, 2023—the day it approved the 2023 REMS. ROA.757-758. As a sister court found, FDA could not "credibly argue that its decision ... would change upon another citizen petition." Order Denying in Part and Granting in Part Mot. for Prelim. Inj. at 17, *Washington v. FDA*, No. 1:23-cv-03026, (E.D. Wash. Apr. 7, 2023), ECF 80. And FDA's very position in this litigation—refusing to stay the 2023 REMS—confirms futility. *Alliance II*, 78 F.4th at 255. This means that GBP's preferred "certainty of an adverse decision" rule is satisfied twice over: FDA's 2023 denial of the in-person petition and its

clinging to the 2023 REMS even now. In short, as the *Alliance II* Court correctly concluded, it would be "clearly useless" to raise the same challenge again. 78 F.4th at 255 (citation omitted).

Third, for all the reasons Louisiana otherwise has Article III standing and is suffering irreparable harm under the 2023 REMS, irreparable injury would result unless immediate judicial review is permitted. *See, e.g.*, *Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 107 (D.C. Cir. 1986) (collecting cases).

b. *Ripeness*. The Manufacturers' related ripeness argument is likewise meritless. Danco.Br.40–42; GBP.Br.42–43. The FDA's 2023 REMS was final agency action—and this case is ripe backwards and forwards. The Manufacturers nevertheless suggest that this Court should apply long-discredited prudential ripeness concerns. Even if valid, that judge-inspired test is satisfied. *First*, this lawsuit merely asks the Court to apply the settled APA principle that "[c]ourts must set aside agency action where there are 'shortcomings in the agency's explanations' or where '[n]o record evidence affirmatively makes' the agency's case." *Alliance II*, 78 F.4th at 250 (citation omitted). *Second*, a hypothetical *future* FDA REMS decision would not, and could not,

unwind the finality of the *2023* REMS. Absent a time machine, there can be no further factual development. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983). *Third*, withholding judicial review would not conserve resources but waste them. The 2023 REMS rises or falls on the cold contemporaneous record. That means that a delay would only put off the inevitable legal determination while prolonging Louisiana's irreparable harm.

c. *Administrative Record*. Danco labels the administrative record in this case "limited." Danco.Br.43. It is not. The record is now complete—as the Manufacturers are forced to concede. And FDA's decisional document has long been part of the record, along with the various hot documents undergirding Plaintiffs' claims. Regardless, the APA allows a court to grant relief based on "the whole record *or those parts of it cited by a party*." 5 U.S.C. § 706 (emphasis added); *cf.* Danco Br. at 44 (omitting disjunctive phrase). This is not the first time the administrative record has been produced in a court case, and the Manufacturers and FDA have had *years* to produce and cite any additional material that might advance their case. Their failure to do so does not somehow strip this Court of its power to grant relief. Indeed, if the rule were that a court could only grant

relief after reviewing the entire administrative record (as Danco appears to advocate), then virtually no court could enter the emergent preliminary relief provided for in § 705—because the federal government notoriously takes months, and even years, to compile the administrative record.

d. *Leadership Statements*. Next, the Manufacturers complain that the serious concerns regarding the safety of in-person dispensing raised by FDA's current leadership should not factor into the merits analysis in this case. But those concerns simply confirm what three panels of this court have already concluded: The REMS is likely unlawful. *See* ROA.9110-9111; *see supra* n.1 (Acting Attorney General acknowledging that the REMS was "wrong").

2. The Manufacturers cannot rehabilitate FDA's reliance on FAERS data.

Turning to the real merits, Plaintiffs' opening brief principally explained the conclusion reached by three other Fifth Circuit panels—that "FDA arbitrarily concluded that FAERS data supported removing the in-person dispensing safeguard." Op.54–57. In response, the Manufacturers offer little more than tired FAERS arguments this Court's panels have already rejected.

The Manufacturers first claim that FDA's reliance on FAERS data was not "dispositive." Danco.Br.48–49; GBP.Br.46. If that were true, it would leave the 2023 REMS with *less* support, not *more*.[6] In fact, FDA conceded that a literature review was "not adequate on [its] own" to establish mail-order safety, ROA.1093, and as a panel of this Court reasoned, the Manufacturers' residual duty to report adverse events is so woefully underinclusive that it cannot cure the data gap. *Alliance II*, 78 F.4th at 250. Meanwhile, GBP's position that adverse events "continue to reach FAERS" through drug sponsor reporting, GBP.Br.48, is at best disingenuous.[7] For busy prescribers have the same responsibility to report adverse events to the drug sponsors as they do to FDA: zero. ROA.367-368; ROA.1078 (noting that the sponsors' adverse event

[6] The best reading of the administrative record is that FDA arbitrarily used FAERS to indicate drug safety—the very purpose the agency itself publicly disclaims. *Compare* ROA.373; ROA.1075-1078, *with* ROA.1106; ROA.1108; *Alliance II*, 78 F.4th at 249–50 (finding such reliance arbitrary and capricious).

[7] There is no question that the FAERS database fails to accurately capture adverse events. For instance, according to the FDA adverse event summary through 12/31/2018, there were 97 ectopic pregnancies reported out of the 3.7 million women who had taken mifepristone through that date. *See* AE Report through 12/31/2018: perma.cc/64LH-RXG5. *Six* years later (12/31/2024), there were still only 97 ectopic pregnancies reported. *See* AE Report through 12/31/2024: perma.cc/F8QL-BUQX. While the number of women taking mifepristone more than doubled to 7.5 million, there were zero ectopic pregnancies reported during that 6-year span. The only explanation is that adverse events are not voluntarily being reported to FAERS.

summary "included the same cases identified by [redacted] from FAERS").

Danco next speculates that finding the 2023 REMS unlawful would leave FDA "powerless" to consider FAERS data when deciding whether to add or modify a REMS. Danco.Br.47. Wrong again. Plaintiffs do not dispute that FAERS may be a "useful tool" to flag an emerging safety concern or to identify trends. Danco.Br.46. But "FAERS data have limitations." Danco.Br.47; *see also* ROA.2596-2598. In FDA's own words: "FAERS data cannot be used to calculate the incidence of an adverse event." ROA.1106. It was arbitrary and capricious for FDA to use FAERS data for that precise statistical purpose here. ROA.374; ROA.1074; ROA.1077-1078; *see* GBP.Br.47 (conceding that "FAERS alone [cannot] establish rates of adverse events").

Danco next insists that 21 U.S.C. § 355-1 directs FDA to rely on FAERS to remove a REMS safeguard. Danco.Br.46–47. That is flat wrong. Section 355-1 directs FDA to consider adverse events reports generally when deciding whether a REMS is needed. Using FAERS data specifically to calculate the overall incidence of an adverse event, however—what FDA needed to do to conclude mail dispensing was safe—

is prohibited by FDA's own concessions. *See* ROA.374; ROA.1074-1078; ROA.1106; ROA.1108.

Nor can the Manufacturers wave away mifepristone's Black Box warning, which heightens the significance of FDA crediting its self-imposed data gap. As a panel of this Court acknowledged: "This ostrich's-head-in-the-sand approach is deeply troubling—*especially*" for a high-risk drug that "*necessitates a REMS program … and a 'Black Box' warning*." *Alliance I*, 2023 WL 2913725, at *17 (emphasis added). Mifepristone's high-risk profile makes FDA's reliance on unreliable, voluntarily reported data especially unreasonable. It also resolves the Manufacturers' complaint that mifepristone's adverse event reporting regime is "more stringent than the requirements for most other drugs." GBP.Br.48. As the parties, this Court, and the American public well know, mifepristone is not "most other drugs."

Finally, the Manufacturers blame women for the high rate of mifepristone-induced emergency room visits. They insist that many such visits "capture patient behavior," "not clinical harm," Danco.Br.52, and are merely for "reassurance," GBP.Br.51—as if women ordinarily endure crowded emergency rooms just for reassurance. In this vein, GBP even

insists that emergency room visits are not themselves—contra FDA's own label—"serious adverse events." *Compare* GBP.Br.51, *with* ROA.334-335. They are serious for the women who suffer them. That's why even FDA was concerned that the studies it relied upon showed an increase in emergency room visits when mifepristone was dispensed by mail. *E.g.*, ROA.1086 (showing telemedicine-plus-mail emergency department visits at 5.8 percent—nearly three times higher than the 2.1 percent rate for women who had an in-person visit). At the end of the day, blaming women doesn't work.

3. FDA's arbitrary reliance on scientific literature is indisputable.

Plaintiffs' opening brief also recounted this Court's prior holdings that "FDA arbitrarily relied on scientific literature to justify removing the in-person dispensing requirement." Op.Br.57–62. And here, too, the Manufacturers have no serious response.

The Manufacturers principally dispute whether the 2023 REMS is subject to the strictures of 21 U.S.C. § 355(d), including its requirement of sufficient information to demonstrate drug safety. Danco.Br.52; GBP.Br.45; *contra* Op.Br. 58–59. But even FDA acknowledges that REMS modifications are permitted only if the evidence shows the drug is

safe under both §§ 355-1 and 355(d). *Defs.' Reply in Supp. of Cross-Mot. for Summ. J.* at 11, *Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. May 3, 2025), ECF 181 (citing 21 C.F.R. § 314.1) ("providing that new drug application requirements apply to supplemental applications")). Regardless, the APA requires a rational connection between the facts and the decision. *See State Farm*, 463 U.S. at 52 ("The agency must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made.") (citation modified)). And neither statutory provision relieves the agency of its duty to "provide a reasoned explanation" for changing its longstanding position that in-person dispensing is both "necessary" and "minimally burdensome." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).[8]

The 2023 REMS flunks these standards. And the Manufacturers' cherry-picked statements from the FDA decisional document cannot override the agency's explicit concessions regarding the scientific

[8] Danco, but not GBP, argues (Danco.Br.44 n.9) this was not a change in position. That makes little sense. The drug was approved in 2000 with in-person dispensing as part of the REMS to ensure the benefits outweighed the risks, and through 2020 the agency continued to state the requirement was necessary and minimally burdensome. Appl. for Stay at 4, 13, *FDA v. Am. Coll. of Obstetricians and Gynecologists*, No. 20A34, (U.S. Aug. 26, 2020).

literature. For starters, GBP repeatedly references the 15 studies FDA supposedly relied upon. GBP.Br.50, 51. Yet given the multitude of study limitations, FDA chose not to rely on most of them *at all*. Meanwhile, both Manufacturers claim that "none [of the 15 studies] identified any new or increased risks associated with dispensing mifepristone outside of an in person visit to the prescriber," Danco.Br.54, and that Plaintiffs "identified no study showing that distributing mifepristone through means other than in-person dispensing at a hospital or clinic increases serious adverse events," GBP.Br.50. Come again? The Hyland study saw hospitalization rates soar 330% over the labeled rate. ROA.1030-1031. The Raymond, Chong, and Kerestes studies "all suggest[ed] there may be an increase in ED/urgent care visits with telemedicine visits and dispensing by mail." ROA.1037. And the Anger study suggested "a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care." ROA.1037. It is the Manufacturers who seek to reverse FDA's "scientific judgment."

Danco touts three retail-pharmacy studies as having "efficacy and safety outcomes within labeled frequency." Danco.Br.53. But FDA

conceded that "*[n]one of the three studies* ... allow a determination regarding differences in safety between in-person dispensing by a certified prescriber in a health care setting and dispensing through a retail pharmacy, due to limitations on the generalizability of the studies to the current retail pharmacy environment in the US." ROA.1029 (emphasis added). So much for the ringing endorsement.

Danco also points to the three studies evaluating mail-order pharmacy dispensing. Danco.Br.53. But FDA discredited each of them: one included only subjects who had an in-person visit and examination (ROA.1029), another was of "limit[ed] [] usefulness" because of "deviations, limited follow-up information, and small sample size" (ROA.1030), and the third had "[s]afety findings [that were] difficult to interpret" and "d[id] not allow *any* conclusions about safety findings," (ROA.1031). Those statements are hardly a vote of confidence from the agency.

Finally, Danco looks to five studies evaluating clinic dispensing by mail—studies it claims "support that dispensing by mail is safe and effective." Danco.Br.53. But in FDA's own words: Those studies "are not adequate on their own to establish the safety of the model of dispensing

mifepristone by mail." ROA.1093. It's not hard to see why: As FDA explained, one study failed to "capture all serious safety outcomes" (ROA.1037), a second needed to be "interpreted carefully" (ROA.1033), two more (and three total) suggested that ED/urgent care visits would increase with mail dispensing (ROA.1037), and the fifth required *every patient* to have a screening test at laboratories and radiology offices (ROA.1032). It's thus no surprise that FDA found that four out of the five studies indicated that in-person visits decrease emergency room and follow-up care. ROA.1037.

The best FDA could say was that the studies were "not inconsistent with" its conclusion. ROA.1037. That thin reed does not satisfy APA review. *See State Farm*, 463 U.S. at 52 ("The agency must explain the evidence which is available, and must offer a rational connection between the facts found and the choice made." (citation modified)). Combining flawed studies with unreliable data doesn't fix the problem—it compounds it. Zero plus zero still equals zero. No wonder the current FDA has conceded that the 2023 REMS approval "lack[ed] [] adequate consideration." ROA.2201.

In a last-ditch effort to avoid such a conclusion, the Manufacturers cite various cases for the proposition that courts must be "at [their] most deferential" where agencies' scientific predictions are concerned. GBP.Br.48 (citing *Balt. Gas & Electric Co. v. NRDC*, 462 U.S. 87, 103 (1983), and *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 923 (D.C. Cir. 2013)). Fair enough. Yet Appellants do not ask the Court to second-guess the science but simply to take FDA at its word. As the motions panel put it, this case presents an ordinary "APA challenge to a regulation, a task courts routinely undertake." ECF 119-1 at 16–17.

Undaunted, the Manufacturers maintain that FDA must have the "freedom" to rely on FAERS or other data as an exercise of its "reasonable predictive judgment." Danco.Br.55 (citing *FCC v. Prometheus Radio Project*, 592 U.S. 414 (2021)); GBP.Br.47. But that *Prometheus*-rooted idea arose in the context of an open-ended statutory delegation to the Federal Communications Commission, not a statutory directive to FDA to determine whether a drug is safe before unleashing it on the American public. Agencies are not clairvoyant and no amount of "predictive judgment" can rescue an agency decision built on a foundation the agency has disclaimed. *See* ROA.1106 (conceding FAERS data "cannot be used

to calculate the incidence of an adverse event"); ROA.1093 (conceding literature review was "not adequate on [its] own" to establish the safety of mail dispensing).

4. The 2023 REMS violates the Comstock Act.

Last in their opening brief, Plaintiffs explained that, "[a]lthough the district court did not need to proceed further, it bears noting that the 2023 REMS independently violates the APA in light of the Comstock Act." Op.Br.62; *see* 18 U.S.C. § 1461. The Manufacturers try three responses. None works.

First, Danco says (at 59–60) that this issue is nonjusticiable because it functionally directs the Executive to "enforce" the law. Hardly. Plaintiffs do not ask this Court to order the Executive to *do anything* but rather to determine whether an agency's actions comport with federal law. That is basic judicial review—not enforcement.

Second, Danco claims that administrative agencies may disregard federal law outside their enabling statutes. Danco.Br.60–61. Taken seriously, that argument would allow federal agencies to ignore the Religious Freedom Restoration Act and a multitude of environmental statutes. Unsurprisingly, that argument is refuted by (a) the APA's

mandate to set aside actions that are "otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and (b) the Supreme Court's unqualified statement in *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003), that this phrase means "any law." *Id.* (emphasis omitted). Danco also notes that FDA routinely approves drugs subject to other statutes like the Controlled Substances Act ("CSA"). But FDA approval does not authorize conduct the CSA prohibits. By contrast, the 2023 REMS authorizes using the mails to distribute an abortion-producing drug—conduct the Comstock Act expressly forbids.

Third and finally, the Manufacturers would rewrite the Comstock Act to prohibit only "illegal abortions" based on post-enactment history. Danco.Br.62–63; GBP.Br.54. But the text contains no such limitation—a limitation that Congress expressly considered and rejected in 1978. H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978) (rejecting amendment limiting Comstock to "illegal abortions"); *accord* Rep. of the Subcomm. on Crim. Just. on Recodification of Fed. Crim. L., H.R. Rep. No. 95-29, pt. 3, at 42 (1978) (explaining the amendment would "change[] current law by requiring proof … to produce an illegal abortion"); *see also* ROA.5506-5507; ROA.5545-5550. And to the extent the Manufacturers

rely on old dicta from a smattering of circuit courts, the prior-construction canon modifies statutory text only when pre-enactment meaning is settled by "a uniform interpretation by inferior courts"—a standard not remotely satisfied here. *Tex. Dep't of Hous. & Cmty. Affs. v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 536 (2015) (citation omitted). As Judge Ho—and now Justice Thomas—have explained, mailing a drug to produce abortion is precisely what the Comstock Act prohibits and exactly what the 2023 REMS authorizes. *See Alliance II*, 78 F.4th at 268 (Ho, J., concurring); *Danco Lab'ys, LLC*, 2026 WL 1345578, at *1 ((Thomas, J., dissenting). That alone is fatal to the 2023 REMS.

II. THE REMAINING FACTORS FAVOR A § 705 STAY.

With respect to the remaining preliminary-relief factors, there is no question that they favor a § 705 stay. And the Manufacturers' quibble with the form of relief is unavailing.

Equities. Begin with the equities. The Manufacturers do not dispute that if, as both the district court and motions panel concluded, Louisiana's sovereign injuries are cognizable for standing purposes, then Louisiana also is suffering irreparable harm. They likewise do not seriously dispute that Louisiana's unrecoverable financial costs

independently constitute irreparable harm. Instead, they back-door their complaints about "boundless claims of indirect financial injury," Danco.Br.69, which are unavailing for all the reasons expressed above, *see supra* Section I.A(1). The Manufacturers thus effectively concede that, if Louisiana is likely to succeed on the merits (and it is), then Louisiana likely has also established irreparable harm.

Note also that the Manufacturers cannot establish their own irreparable harm. They principally worry about "enforcement risk if [they] distribute[] [their drugs] without an approved REMS"—and "substantial uncertainty about [their] obligations ..., which could include revising product labels, packaging, and promotional materials; recertifying providers; and amending [their] supplier- and distributor-contracts and policies[.]" Danco.Br.71–72; *accord* GBP.Br.59.

None of that is irreparable harm, but more importantly, they overlook that they have argued themselves out of this claim to irreparable harm. By virtue of their securing a Supreme Court stay of the motions panel's § 705 stay of the REMS, they (a) have been on notice about the § 705 stay for three months now, (b) will be on notice for several months more until the Supreme Court decides this case, and thus (c) will

have had all the time in the world to prepare for any alleged uncertainties on a normal timeline and under the protection of a stay. They cannot gamble by sitting on their hands for a year or more, only to express surprise at the consequences of a § 705 stay if and when such a stay finally takes effect.

The Manufacturers also omit that a significant number of their mifepristone sales are unlawful mail-order sales in violation of various states' laws—saying nothing of all mail-order sales' unlawfulness under existing federal law. *See* Society of Family Planning, #WeCount Report April 2022 to December 2025 (June 10, 2026), perma.cc/97KH-6M7N; *Danco Lab'ys, LLC*, 146 S. Ct. at 1193 (Thomas, J., dissenting) ("[The Manufacturers] cannot, in any legally relevant sense, be irreparably harmed by a court order that makes it more difficult for them to commit crimes."). They thus have no cognizable claim of irreparable harm—and that easily resolves the balancing of the equities.

Public Interest. The public-interest inquiry unfolds much the same way. As an initial matter, the Manufacturers do not seriously contest this Court's repeated conclusions that (a) "neither the FDA nor the public has any interest in enforcing a regulation that violates federal law," and

(b) "given FDA's concessions about the 'procedural deficits' and 'lack of adequate consideration' undergirding the 2023 REMS, '[t]he public interest is not served by perpetuating a medical practice whose safety the agency admits was inadequately studied. Indeed, the public interest demands the opposite." Op.Br.69 (citing ECF.119-1 at 15–16). And the arguments the Manufacturers do raise are unavailing.

First, the Manufacturers claim that "the public interest favors denial because the 2023 REMS is lawful and adequately supported by the evidence." Danco.Br.73. Relatedly, they claim (Danco.Br.74–75) that a stay would "'undermin[e] patients' access to medicine'" and "impos[e] medically unnecessary barriers" to mifepristone. These claims simply rehash their failed merits arguments—and, if this Court concludes as three prior panels have concluded that the 2023 REMS is likely unlawful, then the Manufacturers' claims hardly justify maintaining an unlawful regulation in the name of the public interest.

Second, the Manufacturers complain that it is "not in the public interest for federal courts to sit as super-legislatures deciding between states' competing policy views." Danco.Br.76. That complaint misrepresents the nature of this case—which, as the motions panel

emphasized, is a basic APA case. It "does not ask the Court to arbitrate a policy dispute." *Id.*; ECF 119-1 at 16–17. And insofar as the Manufacturers protest "the possibility of conflicting judicial outcomes" or "one district court [making] a binding judgment for the entire country," GBP.Br.65 (citations omitted), those protestations are moot. By granting the Manufacturers' request for a stay, the Supreme Court has preserved the current status quo en route to a singular decision by that Court resolving these issues. *See CASA, Inc.*, 606 U.S. at 877–78 (Kavanaugh, J., concurring) ("[D]etermining the nationally uniform *interim* legal status for several years of, say, ... mifepristone rules is a role that the American people appropriately expect this Court—and not only the courts of appeals or district courts—fulfill.").

Third, the Manufacturers reiterate the district court's stated concern about the issuance of relief on a rushed timeline. Danco.Br.76. As just discussed, however, that concern has no basis today in light of the Supreme Court's ensuring that this appeal proceeds under the protection of a stay. The same goes for the Manufacturers' supposed fear of "a sudden, externally imposed change" from a stay that might "interfer[e] with FDA's ongoing review of the mifepristone REMS[.]" GBP.Br.65. No

such change will occur because Plaintiffs agree a decision by this merits panel in their favor should be stayed pending Supreme Court review. And, as the motions panel correctly concluded, "a stay would do nothing to prevent FDA from completing its review of mifepristone's safety protocols" anyway. ECF 119-1 at 17.

Fourth, Danco takes quotes from Chief Justice Roberts and then-Judge Kavanaugh out of materially different contexts to suggest that Plaintiffs are asking this Court to parse scientific evidence and make public health judgments. Danco.Br.76–77; *accord* GBP.Br.64. Not so. Plaintiffs are not asking the Court to substitute its "own evaluation of the impact of the COVID-19 pandemic" for FDA's. *Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. at 579 (Roberts, C.J., concurring in the grant of application for stay). Nor are Plaintiffs asking the Court to decide whether "fat is [] blood" and whether "the difference matters." *Cytori Therapeutics, Inc.*, 715 F.3d at 927. (But importantly, then-Judge Kavanaugh's panel did not throw up its hands when faced with those questions; instead, it proceeded to engage in a "careful review" of whether "FDA's [own] assessment [was] both reasonable and reasonably explained." *Id.*) The motions panel saw through the

Manufacturers' misrepresentation otherwise and rightly rejected it. *See* ECF 119-1 at 16–17. There is thus no question that the public interest favors a § 705 stay.

Vacatur. Lastly, the Manufacturers try to head off a § 705 stay on the ground that Plaintiffs at most should receive a remand (not vacatur) of the REMS if successful in this litigation. Danco.Br.64–67; GBP.Br.56–58. By the Manufacturers' telling, Plaintiffs should thus be unable to obtain the preliminary equivalent of vacatur. But they omit that they previously raised and lost this exact argument in the persuasive *Alliance II* opinion by Chief Judge Elrod.

"[V]acatur of an agency action is the default rule in this Circuit." 78 F.4th at 255 (alteration omitted). "Given that presumption, remand without vacatur is appropriate only if 'there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so.'" *Id.* (citation omitted). Here, however, "[r]emand without vacatur is likely not appropriate because 'it is far from certain' that FDA could cure its mistakes with further consideration." *Id.* (citation omitted). That is because "FDA erred by," among other things, "disregarding the lack of recent data on adverse events when removing

the in-person dispensing requirement"—and "[t]he record does not tend to show that FDA would have arrived at the same decision if it had considered those things." *Id.* Accordingly, if Plaintiffs "succeed on the merits, it is likely that the default remedy—vacatur—will be appropriate. And the temporary version of vacatur is a stay." *Id.*

CONCLUSION

The Court should grant a § 705 stay of the 2023 REMS, though staying that decision pending Supreme Court review. In the cross appeal, the Court should affirm the district court's denial of the Manufacturers' motions to dismiss.

Dated: July 29, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 29, 2026, I filed the foregoing brief with the Court's CM/ECF system, which will automatically send an electronic notice of filing to all counsel of record.

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

CERTIFICATE OF COMPLIANCE

Pursuant to Fifth Circuit Rule 32.3, the undersigned certifies that this motion complies with:

(1) the type-volume limitations of Federal Rules of Appellate Procedure 28.1(e) and 32(a)(7) because it contains 12,046 words; and

(2) the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 2016 (the same program used to calculate the word count).

/s/ J. Benjamin Aguiñaga
J. BENJAMIN AGUIÑAGA

Dated: July 29, 2026