UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, PLAINTIFFS, v. U.S. FOOD AND DRUG ADMINISTRATION, et al. DEFENDANTS.	Civ. No.: 6:25-cv-01491 Judge: David C. Joseph Mag. Judge: David J. Ayo

STATE OF LOUISIANA AND ROSALIE MARKEZICH'S REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION FOR PRELIMINARY RELIEF AND IN OPPOSITION TO DEFENDANTS' MOTION TO STAY

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INTRODUCTION

The Federal Defendants (collectively, "FDA"), Danco, and GenBioPro do not dispute that certified prescribers are mailing FDA-approved mifepristone into Louisiana in violation of Louisiana law and ending the lives of nearly 1,000 babies in the State each month.[1] They also do not dispute that FDA's removal of the in-person dispensing requirement through the 2023 REMS is the indispensable ingredient in those unlawful abortions: Prescribers could not lawfully (under federal law) mail mifepristone without the 2023 REMS. And FDA *concedes* the 2023 REMS was "informed by [a] lack of adequate consideration." ECF 51 at 1. Indeed, FDA has virtually embraced "the concerns about removing the in-person dispensing requirement foreshadowed by the Fifth Circuit." *Id.*

All this makes for an easy case as "some judges" (ECF 52-4 at 17)—Chief Judge Elrod and Judges Ho, Wilson, Engelhardt, and Oldham—already have concluded. The proper route is to preliminarily stay the 2023 REMS.

Perhaps because the route is so easy, FDA and the drug manufacturers try to scuttle the case on standing grounds. But that tactic does not work. That is because they do not seriously dispute that Louisiana is suffering injuries in fact, whether they are sovereign or economic; instead, they dispute only traceability, trying to cast prescribers, pro-abortion states, and even domestic-abuse victims as the real perpetrators of Louisiana's harms. But, as just explained, if the Court stays the 2023 REMS, then the whole mail-order abortion scheme will fall apart—that is the best indication Louisiana has satisfied both traceability and redressability and thus has Article III standing.

All this is unsurprising. FDA and the manufacturers now brush aside the Biden Administration's statements about overriding pro-life state laws through widespread distribution of abortion drugs. And they ignore statements from abortion activists who admit that this was their plan all along. But history cannot be rewritten. It is thus unsurprising that an avowed assault on pro-life states through the 2023 REMS naturally gives those states standing to sue in defense of their sovereign

[1] Although Plaintiffs initially opposed Danco and GenBioPro's motions to intervene, they now do not oppose intervention in light of FDA's subsequent (a) concession that the 2023 REMS lacked legally adequate consideration and (b) refusal to defend the 2023 REMS.

and economic interests. As this Court said recently, where states "have unambiguously expressed their opposition to purely elective abortions by passing laws prohibiting the same," "principles of federalism" "clearly" give the states Article III standing to challenge a federal agency's intrusion upon that sovereign prerogative. *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 653–54 (W.D. La. 2024).

That leaves only FDA's puzzling attempt to shelve this case for a few years. The Court can and should reject that request out of hand since, because Louisiana is entitled to preliminary relief, FDA cannot obtain a stay without satisfying the ordinary *Nken* factors—an impossible burden FDA does not even try to carry. And even if that were not so, FDA does not cite a single case where a court has stayed proceedings and denied preliminary relief even though the defendant (a) concedes that its conduct is unlawful and (b) would suffer no irreparable harm from the grant of preliminary relief. This Court should not be the first. The Court should preliminarily stay the 2023 REMS and deny FDA's motion to stay.

ARGUMENT

I. PLAINTIFFS HAVE STANDING.

Start with the attacks on this Court's jurisdiction. To establish standing, "a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief." *FDA v. All. for Hippocratic Med. (Alliance)*, 602 U.S. 367, 380 (2024). Louisiana has suffered pocketbook and sovereign harms from the 2023 REMS—harms that led tragically to bodily harms for Plaintiff Rosalie.[2] Those injuries are traceable to FDA's removal of the in-person dispensing requirement. And those injuries are redressable by a decision staying or vacating the 2023 REMS.

[2] While there is no question that Rosalie suffered an Article III injury, Plaintiffs here focus on Louisiana's standing in particular for the sake of judicial efficiency.

A. Louisiana Has Suffered Injuries in Fact.

1. Louisiana suffers classic pocketbook injuries.

Classic pocketbook harms resolve this case. "Pocketbook harm is a traditional Article III injury." *Bost v. Ill. State Bd. of Elections*, No. 24-568, 2026 WL 96707, at *6 (U.S. Jan. 14, 2026) (Barrett, J., concurring) (citation omitted). After all, "an economic injury is the quintessential injury upon which to base standing." *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 309 (5th Cir. 2023) (citation modified). Indeed, "[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); *United States v. Texas*, 599 U.S. 670, 687–88 (2023) (Gorsuch, J., concurring). These well-recognized economic injuries can often take the form of the "effect on the states' fiscs." *Texas v. United States (DAPA)*, 809 F.3d 134, 152 (5th Cir. 2015); *see also, e.g.*, *Biden v. Nebraska*, 600 U.S. 477, 490 (2023) (Missouri's "financial harm is an injury in fact"). Here, Louisiana has suffered two types of classic pocket injuries, either or both of which assure the Court's jurisdiction: (a) economic harms incurred while enforcing Louisiana law against violations caused by the 2023 REMS; and (b) the expenditure of Medicaid dollars to treat adverse events caused by the 2023 REMS.

a. Consider first the pocketbook harms from violations of Louisiana's pro-life laws. Pocketbook harm occurs when a plaintiff "reasonably incur[s] costs to mitigate or avoid" the "'substantial risk'" of a harm caused by government action. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013) (collecting cases). In *Monsanto Co. v. Geertson Seed Farms*, 561 U. S. 139, 153–154 (2010), for example, the question was whether alfalfa farmers could seek judicial relief against agency action permitting the planting of genetically modified alfalfa. The farmers "established a reasonable probability that their organic and conventional alfalfa crops [would] be infected with [an] engineered gene" through cross-contamination. *Id.* at 153 (internal quotation marks omitted). And because the farmers took costly preventative measures to "minimize the likelihood of potential contamination," they suffered an Article III injury. *Id.* at 154–55.

Justices Barrett and Kagan recently reprised that reasoning to confirm a congressman's standing in his challenge to a state election law: "Like the farmers in *Monsanto*," they said, the

congressman "will 'reasonably incur costs to mitigate or avoid' the 'substantial risk' of harm caused by the challenged statute." *Bost*, 2026 WL 96707, at *7 (Barrett, J., concurring) (quoting *Clapper*, 568 U.S. at 414 n.5). They noted that the congressman's campaign "has spent, and will spend, money, time, and resources" to avoid alleged harms from the challenged law. *Id.* Because those "expenditures mitigate a substantial risk of harm, [the congressman] has pleaded Article III injury." *Id.*

So here, as Louisiana explained in its opening brief, ECF 20-26 at 21, and as FDA, Danco, and GenBioPro do not dispute: Like the alfalfa farmers and the congressman, Louisiana has expended substantial money, time, and resources attempting to mitigate the avowedly intended harm caused by the 2023 REMS. As recounted in the Complaint and opening brief, for example, Louisiana has indicted two out-of-state prescribers who violated Louisiana law by sending FDA-approved mifepristone into Louisiana. The State has issued warrants for their arrest. And Governor Landry has completed the necessary paperwork and formally asked the governors of California and New York to extradite these fugitive prescribers.[3] To be even more precise: In just *three* distinct investigations alone regarding the unlawful mailing of mifepristone into Louisiana, the State has spent at least $17,604.40.[4] Through these efforts, Louisiana is incurring costs every day to bring criminal prescribers to justice and deter others from breaking the State's pro-life laws. *Cf. Texas*, 599 U.S. at 687–88 (Gorsuch, J., concurring) (discussing States' standing to "challenge [] Executive Branch policies that indirectly caused them monetary harms" where "the States have spent, and continue to spend, more money on law enforcement, incarceration, and social services").

Even though Plaintiffs raised these harms in support of their motion, ECF 20-26 at 21–23, neither FDA nor the manufacturers dispute these expenditures. Their failure to dispute these harms alone ends the injury-in-fact analysis.[5]

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[3] Governors Newsom and Hochul have refused extradition. ECF 1 ¶¶ 100–02; Governor Gavin Newsom (@GavinNewsom), X (Feb. 5, 2026, 8:43 PM), perma.cc/46CV-HMZ9.

[4] Ex. A, Toner Decl. ¶ 4–6.

[5] To add "extra icing on a cake already frosted," *Yates v. United States*, 574 U.S. 528, 557 (2015) (Kagan, J., dissenting), it bears noting that FDA's elimination of the in-person dispensing requirement also forced the Louisiana Legislature to take legislative action accounting for the dangers inherent in

b. If that were not enough, Louisiana's Medicaid pocketbook harms would be. Federal law places on state Medicaid programs the financial burden for Medicaid-covered women who suffer complications from mifepristone—which is why the State suffers quintessential pocketbook harm every time such complications arise. This is a demonstrable fact.

We know—and neither FDA nor the manufacturers dispute—that Louisiana already has spent over $90,000 in Medicaid dollars for emergency room care and hospitalizations directly traceable to just *two* FDA-approved mifepristone-induced abortions. ECF 20-26 at 6, 23. And the total amount spent is likely much higher, considering the number of abortions occurring and that prescribers are counseling women to conceal the fact that they took mifepristone. Louisiana's ongoing costs are thus plainly "certainly impending," or at the least there is a "substantial risk" these costs will occur. *Clapper*, 568 U.S. at 414 & n.5.

This fact is unsurprising because it is an obvious consequence of mifepristone's documented complication rate. When it removed the in-person dispensing requirement, FDA anticipated that emergency-room visits would increase—with the baseline being a 2016 warning that roughly 1 in 25 women would end up in the emergency room. *See generally* ECF 1-10. So, there was a "reasonable probability" and "substantial risk" that Medicaid-covered women would seek care, especially in Louisiana where half a million women are on Louisiana Medicaid. *See Monsanto*, 561 U.S. at 153–54; ECF 20-26 at 23. In the end, Medicaid costs are indisputable economic harm—and they plainly reinforce Louisiana's standing as a matter of dollars and cents.

2. Louisiana suffers classic sovereign harms.

In addition to its pocketbook harm, Louisiana has established injury to its sovereign interests in enforcing its pro-life laws. *See Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *cf. Abbott*

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prescribing mifepristone without an in-person visit. *See* State Senator Sharon Hewitt (@sharonhewitt), X (May 21, 2022, 6:17 PM), perma.cc/4BCD-PYFK. The Legislature followed that up by also listing mifepristone as a controlled substance and outlawing coerced abortion, while the Louisiana Department of Health for its part was compelled to issue its own implementation guidance. *See* La. R.S. §§ 40:964(F), 14:87.6; La. Dep't of Health, *Memorandum and Guidance on Act 246 Regarding Mifepristone and Misoprostol* (effective Oct. 1, 2024), perma.cc/5K34-MSUW.

v. Perez, 585 U.S. 579, 602 n.17 (2018) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State[.]"). States have standing to vindicate their sovereign (or quasi-sovereign) interests. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601–02 (1982). And as a corollary, they also have standing based on "federal interference with the enforcement of state law." *DAPA*, 809 F.3d at 153 (cleaned up and citations omitted). Those basic rules carry the day here: "Because the principles of federalism afford the states a sovereign interest in creating and enforcing their own laws and public policy," Louisiana "clearly ha[s] Article III standing to challenge" the 2023 REMS. *Louisiana*, 705 F. Supp. 3d at 654.

Louisiana's argument on this point is very simple: (a) it is undisputed that Louisiana law bars the dispensing of mifepristone within Louisiana to cause an unlawful abortion; (b) it is undisputed that some 1,000 such abortions are occurring every month in violation of Louisiana law; and (c) it is undisputed that it has become nearly impossible for Louisiana to prosecute those violations. Those undisputed—and unremedied—violations of Louisiana law are quintessential sovereign harms. Now, FDA and the manufacturers can dispute *who* is doing the violating and *who* bears responsibility for the violating, but that is better viewed as a *causation* question than a question about whether Louisiana is suffering sovereign injury in fact.

The closest FDA and the manufacturers come to squarely disputing Louisiana's injuries in fact is to say that the 2023 REMS does nothing to render "Louisiana's abortion laws unenforceable." ECF 52-4 at 6; ECF 51 at 14–16; ECF 54-4 at 9. But that, too, goes to whether the 2023 REMS is legally at fault versus whether Louisiana actually is suffering sovereign harms. And on that latter point, it is telling of course that neither FDA nor the manufacturers could identify a single instance in which Louisiana has been able to enforce its criminal code to stop the onslaught of illegal abortions. It also is important to recognize that FDA and the manufacturers rest on a false premise: that so long as a State can find some other way to stop a violation of its laws, the State lacks Article III standing to sue the federal government for causing the violation in the first place. That is emphatically wrong. Just as "federal interference with the *enforcement* of state law" is a sound basis for Article III standing, *DAPA*, 809 F.3d at 153 (emphasis added), so too is the federal government's "encourage[ment]" that "doctors

[] *violate* [Louisiana's] abortion laws" to begin with, *Texas v. Becerra*, 623 F. Supp. 3d 696, 714 (N.D. Tex. 2022) (emphasis added). Or, put in this Court's words, a State plainly may defend its "sovereign interest in creating ... [its] own laws and public policy" against the federal government's attack. *Louisiana*, 705 F. Supp. 3d at 654. Such an attack "interferes with adherence to—and, therefore, enforcement of—[Louisiana's] laws." *Texas*, 623 F. Supp. 3d at 714. This assault on state sovereignty constitutes a concrete injury-in-fact.

Whether viewed as making out an injury-in-fact or proving up causation, this assault on state sovereignty squarely provides Article III standing to an affected State. For present purposes, Louisiana respectfully submits that it is analytically clearer to resolve the injury-in-fact prong on the undisputed facts surrounding the ongoing violations of Louisiana law, which is sovereign harm—and save the question of FDA's and the 2023 REMS' responsibility for the traceability analysis.

B. Louisiana's Harms Are Traceable to the 2023 REMS.

Because it is undisputed that Louisiana is currently suffering sovereign and economic harms (in the form of violations of Louisiana law that, in turn, cause pocketbook injuries), the only real issue in the Article III standing analysis is traceability. But that is a straightforward issue best answered as a practical matter and as a historical matter—and the other side has no answer.

1. Practicality first. The best way to determine whether Louisiana's harms are traceable to the 2023 REMS is to ask whether those harms would be mitigated or eliminated if the 2023 REMS were vacated. *Cf. Alliance*, 602 U.S. at 380 ("The second and third standing requirements—causation and redressability—are often 'flip sides of the same coin.'"). The answer is yes. Pro-abortion groups like the ACLU (*see infra*) have publicly criticized Louisiana's filing of this lawsuit because, they say, doing away with the 2023 REMS would bar doctors in pro-abortion states from mailing mifepristone into pro-life states like Louisiana—for the reinstated in-person dispensing requirement would limit dispensing to, well, in-person visits. On this score, common sense leads the way: Why is this such an important case? Why does Louisiana care so much about reinstating the in-person dispensing requirement, and why do FDA's *amici* care so much about retaining the 2023 REMS? Because the in-

person dispensing requirement (or absence thereof) dictates whether some 1,000 abortions a month may continue to occur in Louisiana.

This reality explains the logical error in FDA's and the manufacturers' attempts to shift the blame elsewhere. For example, they claim that third-party providers and the anonymous people who order the drugs online (rather than FDA or the 2023 REMS) are responsible for the actual violations of Louisiana's law. They also emphasize that pro-abortion states' "shield" laws are what have made it nearly impossible for Louisiana to enforce its pro-life laws. But that is not how causation works: The third-party providers could not legally (under federal law) mail mifepristone into Louisiana without the 2023 REMS' removal of the in-person dispensing requirement, and the "shield" laws would be meaningless without the 2023 REMS because providers in "shield" law states could not legally mail mifepristone.

The 2023 REMS is the indispensable ingredient in the 1,000 abortions occurring in Louisiana every month—and that is why Louisiana easily satisfies the Article III causation standard. "Article III requires no more than *de facto* causality." *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019) (citation omitted). And for the practical reasons just explained, the 2023 REMS meets that standard.

2. History confirms as much because, if anything is clear from the record, it is that this assault on pro-life states like Louisiana was not just the "predictable" effect of the 2023 REMS, *id.*—it was the "whole point" of the 2023 REMS, *Tex. Corn Prod'rs v. EPA*, 141 F.4th 687, 700 (5th Cir. 2025). Indeed, this case presents one of the most egregious—and most stark—examples of "federal interference with the enforcement of state law," *DAPA*, 809 F.3d at 153, coupled with the obvious economic harms that would flow from such interference.[6]

[6] For this reason, to the extent FDA and the manufacturers worry about the ramifications of Louisiana's standing, that worry is unfounded. "It is only if the violation of the federal law or the Constitution interferes with state law that a state suffers a sovereign injury supporting sovereign standing." F. Andrew Hessick, *Quasi-Sovereign Standing*, 94 Notre Dame L. Rev. 1927, 1932 (2019), perma.cc/76HK-3MNS. And the key facts in this case are even more inherently limiting: agency action pursuant to a directive from the President of the United States to facilitate mailing mifepristone into pro-life states. If ever there were a case where state sovereignty established standing, this is it.

a. This story begins at least as far back as 1994, when the former Director of FDA's Office of Women's Health stated that mifepristone "was going to be very important especially in states where surgical abortions are not permitted. And if they overturn *Roe v. Wade*, it's going to be really important." ECF 1, ¶ 54. As abortion activists grew increasingly worried about *Roe*'s future in the 2010s, they began "to push harder to make abortion pills available by telemedicine and mail."[7] In March 2021, the ACLU wrote a letter to President Biden demanding that he direct FDA to review the REMS and "eliminate" these "barriers" to "accessing" abortion particularly in "state[s with] abortion restrictions."[8] Advocates even arranged for "high net-worth major donors" to personally meet with President Biden and lobby for him to remove the in-person dispensing requirement.[9] President Biden obliged one month later.

And by May 2022, abortion activists knew *Roe* would fall and thus argued that mifepristone would be necessary to ensure people could obtain abortions even where restricted.[10] President Biden was listening, and on the day the Supreme Court issued *Dobbs*, he explicitly directed the Secretary of HHS to protect access to "medication abortion" and identify all ways to make mifepristone as widely accessible as possible, including by "mail." ECF 1, ¶ 59. And he later recommitted to doing everything in his power to protect access to abortion, noting that some States are trying to "ban or severely restrict access to these medications." *Id.* at ¶ 57. This culminated in the 2023 REMS. *Id.* at ¶ 62. Evidence that undermining *Dobbs* was the avowed purpose for the 2023 REMS does not get much stronger.

b. This history brings this case squarely in line with precedents like *Texas Corn Producers* and *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025)—precedents that say "the object" of a regulation obviously has standing to challenge it. FDA urges this Court to deny Louisiana standing on

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[7] Ex. B, Carrie Baker, Abortion Pills US History and Politics 93 (2024), perma.cc/24G8-ALWA.

[8] ACLU, *Reproductive Health, Rights, and Justice Groups Letter to Biden Administration on Mifepristone* (March 16, 2021) (perma.cc/VP9K-ETUN).

[9] Baker, *supra* n.7 at 115.

[10] Abigail Abrams and Jamie Ducharm, Inside the Effort to Promote Abortion Pills For a Post-Roe America, Time (May 31, 2022) (perma.cc/H6SD-BMGD).

the ground that it is not "the object" of the 2023 REMS. *See* ECF 51 at 16. But that is wrong on the law and the facts.

The Supreme Court recently explained that an entity can be "the object" of a regulatory regime even if other parties are "the directly regulated parties." *Diamond*, 606 U.S. at 115. That's because officials often "seek to indirectly target" people "through a conduit." *Id.* at 116. Whether an entity "is in fact an object of a regulation is a flexible inquiry rooted in common sense." *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 265 (5th Cir. 2015). So private schools can be the object of a law barring parents from sending children to private schools, and sugar producers can be the target of FDA actions making it "harder for soda manufacturers to use sugar." *Diamond*, 606 U.S. at 115; *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (Kavanaugh, J.). What matters is who the government "targets." *Diamond*, 606 U.S. at 115–16 (citing *Energy Future Coal.*, 793 F.3d at 144–145). If the government seeks to "impede[]" an entity by regulating intermediaries, the targeted entity is one of the "objects of the government action." *Id.* at 115.

In *Diamond*, for example, the Supreme Court said that fuel producers "might be considered an object" of California restrictions on automakers' use of gasoline in cars. *Id.* at 114. The "entire purpose of California's fleet-wide emissions standards and electric-vehicle mandate" was to reduce gas-powered cars. *Id.* at 112. Even though the fuel producers were not directly regulated, they were "the targets of government regulations" and had standing to challenge California's "regulations that threaten" their interests. *Id.* at 120.

So too here. FDA "target[ed]" pro-life states—through the "conduit" of abortion-drug prescribers—seeking to "impede" state pro-life laws. *Id.* at 116. "Indeed, that is the whole point of the regulations." *Id.* at 114.

FDA, Danco, and GenBioPro argue that *Diamond* doesn't apply here because Louisiana isn't in the "link" or "chain." ECF 51 at 16; ECF 52-4 at 9; ECF 54-4 at 9. Nonsense. Louisiana was the target—it's in the chain just as much as the fuel producers in *Diamond*. Though not a "directly regulated part[y]," *Diamond*, 606 U.S. at 115, Louisiana was the intended target of FDA's regulatory regime. ECF

20-26 at 24–25. The "whole point" was to increase access to mifepristone, especially in pro-life states. *Texas Corn Producers*, 141 F.4th at 700. So Louisiana has established both injury-in-fact and traceability.

c. Because Louisiana's standing is plain, the opposing parties offer a litany of distractions—none availing.

First, GenBioPro tries to rewrite history altogether. It claims, for example, that the story above is "pure fiction," ECF 54-4 at 9, and it revises the historical record to claim that the 2023 REMS was just an innocuous extension of the pandemic-era 2021 enforcement decision suspending the in-person dispensing requirement. *See* ECF 1, ¶ 51. This lawsuit, of course, does not challenge that temporary suspension, which no longer exists. But, more importantly, the Fifth Circuit already has determined that "FDA simply did not tether its [2023] action" in permanently removing the in-person dispensing requirement "to the continued existence of the public health emergency" that prompted the 2021 decision. *All. for Hippocratic Med. v. FDA (Alliance II)*, 78 F.4th 210, 248 (5th Cir. 2023), *rev'd and remanded sub nom. FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024).

GenBioPro also tries to cover the Court's eyes to the fact that President Biden was quite literally directing this assault into pro-life states. These were all just statements from "various public officials," GenBioPro says—and besides, President Biden is not even an FDA official. ECF 54-4 at 10. With all respect, the idea that the Court should disregard the President's involvement in abridging pro-life states' laws is unserious.

Second, the parties on the other side run through a number of precedents—none of which help them. For example, FDA, Danco, and GenBioPro assert that *United States v. Texas* precludes any state standing based on indirect effects of federal agency actions. 599 U.S. 670 (2023). But that "extraordinarily unusual lawsuit" involved Texas's challenge to federal prosecutorial discretion—a core executive power. *Id.* at 684, 686. It addressed "only the narrow Article III standing question of whether the Federal Judiciary may in effect order the Executive Branch to take enforcement actions against violators of federal law," *id.* at 684–85—a question that is worlds away from the issues presented here. *See id.* at 686 ("The Court's standing decision today is narrow and simply maintains the longstanding jurisprudential status quo."). But, more fundamentally, insofar as *Texas* gestured at

"federal policies [that] frequently generate indirect effects on state revenues or state spending," *id.* at 680 n.3, the 2023 REMS is nothing of the sort: By design, the 2023 REMS was intended to authorize a *direct* attack on pro-life states, and that attack, in turn, has caused natural sovereign and economic harms. There is nothing "indirect" or coincidental about it.

The opposing parties also rely on the Ninth Circuit's nonbinding decision in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024). *Washington* deemed "highly speculative" a State's Medicaid costs incurred under the 2023 REMS, and it dismissed as based "heavily on speculation" the State's argument that the 2023 REMS would make it more difficult to enforce the State's pro-life laws. *Id.* at 1174, 1177. *Washington* is self-distinguishing because Louisiana does not need speculation: It has the Medicaid receipts to prove that the 2023 REMS has caused tens of thousands of dollars in unrecoverable financial harm. And subsequent to *Washington*, pro-abortion groups published rounds of data showing that, although Louisiana has significantly restricted abortion, there are nearly 1,000 abortions occurring in the State every month—all through mail-order abortion. ECF 20-26 at 5. The *Washington* court had none of this evidence and did not purport to issue a decision on facts like these.

Finally, the opposing parties try to shoehorn Louisiana into the *Alliance* decision where the Supreme Court found that plaintiff doctors did not have standing. That attempt is misplaced. The doctors' problem was that they did not show "that they could be forced to participate in an abortion or provide abortion-related medical treatment over their conscience objections." *Alliance*, 602 U.S. at 387. Here, by contrast, the State has demonstrated that it not only "could be" forced to pay for the medical costs attributable to FDA-approved mifepristone, but it also *has* been so forced—to the tune of tens of thousands of dollars. That is precisely the direct line of causation that the *Alliance* Court believed lacking. And that is in addition to the even-more-direct sovereign (and economic) harms that flow from the 2023 REMS' permitting doctors to mail mifepristone in violation of Louisiana law.

C. Plaintiffs' Injuries Are Redressable.

As the traceability discussion suggests, the redressability inquiry is open-and-shut—and indeed, no one contests this point: A judicial decision staying the 2023 REMS (in particular, its removal of the in-person dispensing requirement) would leave prescribers no choice but to comply with the

in-person dispensing requirement. Put otherwise, prescribers could not continue violating Louisiana law by mailing mifepristone into Louisiana. Just listen to the ACLU: "If the court grants Louisiana's motion, [requesters] will no longer be able to fill their mifepristone prescription by mail[.]"[11]

That is the very definition of redressability.[12] For, without the in-person dispensing requirement, prescribers cannot blanket Louisiana with mailed mifepristone. Without that flood of mifepristone, 1,000 illegal abortions each month in Louisiana cannot occur. And without 1,000 illegal abortions (and attendant emergency costs) each month, Louisiana's sovereignty and fisc are restored. Now, to be sure, that restoration may not be fully complete if a prescriber or two opt to violate the (newly reinstated) federal in-person dispensing requirement.[13] But redressability does not require certainty that the injury will be entirely eliminated; a substantial likelihood that the injury at least will be partially redressed is sufficient. *See Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). And that is the case here, illustrating that Plaintiffs satisfy all three elements of Article III standing.

D. Plaintiffs Fall Within the Relevant Zones of Interest.

Among other efforts to get around Plaintiffs' standing, Danco and GenBioPro (but not FDA) argue Plaintiffs are not within the zone of interests of the FDCA and the Comstock Act. ECF 52-4 at 14–15; ECF 54-4 at 12 n.2. They are wrong. The prudential zone-of-interests test "is not meant to be especially demanding and is applied in keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable." *DAPA*, 809 F.3d at 162 (citation modified). This court-constructed test "looks to the law's substantive provisions to determine what interests (and hence which plaintiffs) are protected." *Simmons v. UBS Fin. Servs., Inc.*, 972 F.3d 664, 669 (5th Cir.

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[11] Press Release, Louisiana Lawsuit Seeks Immediate Nationwide Restrictions on Medication Abortion, ACLU (Dec. 17, 2025), perma.cc/MB39-DSAV.

[12] *See, e.g.*, Carrie Baker, *Mifepristone Manufacturers Move to Block GOP Lawsuit Seeking Nationwide Telehealth Abortion Ban*, Ms. Magazine, perma.cc/5P43-CBEJ ("Telehealth abortion from out of states is a critical avenue of access for women living in states that restrict abortion providers located inside the states from providing abortion services.").

[13] In this respect, GenBioPro appears to argue that—even without the 2023 REMS—there is no evidence that prescribers would be less likely to mail abortion drugs. The Court should be aware that this is a suggestion GenBioPro will not follow the law. GenBioPro has an affirmative duty to audit prescribers to ensure a REMS is being followed. ECF 20-16 at 4; 21 U.S.C. § 355-1.

2020). "That interest, at times, may reflect aesthetic, conservational, and recreational as well as economic values." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 154 (1970) (citation modified). The "benefit of any doubt" must go to the plaintiff. *Simmons*, 972 F.3d at 666 n.3 (citation omitted). That "lenient approach" is necessary to preserve the APA's "generous review provisions," as well as a federal court's "virtually unflagging" obligation to hear cases within its jurisdiction, *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126, 130 (2014) (internal marks omitted). "The test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *DAPA*, 809 F.3d at 162 (internal marks omitted). In other words, "[t]here is no presumption against judicial review and in favor of administrative absolutism unless that purpose is fairly discernible in the statutory scheme." *Camp*, 397 U.S. at 157 (internal marks and citation omitted).

Danco and GenBioPro complain that Plaintiffs identify no particular provision of the FDCA protecting their interests. But "no explicit statutory provision" is necessary. *Id.* at 155. Moreover, Plaintiffs' interests are far more than "marginally related" to the purposes implicit in the FDCA. *DAPA*, 809 F.3d at 162. The FDCA prohibits the introduction and delivery of adulterated or misbranded drugs into interstate commerce. 21 U.S.C. § 331. The FDCA's mandates to "protect the public health," Public Law No. 87-781, 76 Stat. 780, "assure the safety, effectiveness, and reliability" of FDA-approved drugs, *id.*, and consider the "seriousness of any known or potential adverse events that may be related to the drug," 21 U.S.C. § 355-1(a)(1)(E), are intended "to ensure that the [FDCA] not be implemented haphazardly," *Bennett v. Spear*, 520 U.S. 154, 176 (1997). Certainly, Louisiana has an interest in protecting public health and safety and in keeping adulterated or misbranded drugs from entering its borders. And "[t]he threatened injury to a State's enforcement of its safety laws is within

the zone of interests of the Administrative Procedure Act[.]" *State of Ohio ex rel. Celebrezze v. U.S. Dep't of Transp.*, 766 F.2d 228, 233 (6th Cir. 1985).[14]

Likewise, Louisiana is within the zone of interests of the Comstock Act. This statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 70 n.19 (1983) (the "thrust" of the Act was "to prevent the mails from being used to corrupt the public morals"). Louisiana is well within this zone of interest because it has a "longstanding policy" protecting the "right to life of every unborn child from conception" and finding that abortion is "impermissible." La. R.S. § 40:1061.1(A)(2). It also has an interest in protecting public health and the well-being of its citizens, promoting public morals in seeing that the scheme passed by its Legislature is properly enforced, and in protecting its self-governing authority. *Sierra Club v. City of San Antonio*, 115 F.3d 311, 315 (5th Cir. 1997). As to both statutes, there is no evidence that Congress "sought to preclude judicial review of administrative rulings" by FDA "as to the legitimate scope of activities available" concerning chemical abortion drugs. *Camp*, 397 U.S. at 157. Accordingly, the zone-of-interests argument is meritless.

II. The Court Should Preliminarily Stay the 2023 REMS.

A. As FDA Does Not Dispute—and As Two Fifth Circuit Panels Have Held—Plaintiffs Are Likely to Succeed on the Merits.

Because Plaintiffs have standing, the rest of the preliminary-relief analysis is eminently straightforward under *Alliance I* and *Alliance II*, beginning with the merits.

1. Plaintiffs are likely to succeed on the merits of their arbitrary-and-capricious challenge to the 2023 REMS—so likely that FDA does not defend the 2023 REMS. Indeed, FDA itself agrees with "the *concerns* about removing the in-person dispensing requirement foreshadowed by the Fifth Circuit" in *Alliance II* and "the *lack of adequate consideration* underlying" the 2023 REMS. ECF 51 at 1 (emphases

[14] So, too, for Rosalie. As the *Alliance* district court recognized (before the Supreme Court reversed on standing grounds), patients are within the FDCA's zone of interests because they seek safe and effective medical procedures. *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 530 (N.D. Tex. 2023).

added). That lack of adequate consideration is what led two prior Fifth Circuit panels to affirm a stay of the 2023 REMS, finding it "defect[ive]," "unreasonable," and "deeply troubling." *See All. for Hippocratic Med. v. FDA (Alliance I)*, No. 23-10362, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023); *Alliance II*, 78 F.4th at 249–50.

Danco claims that those conclusions by "some judges" improperly second-guessed FDA's scientific judgment. ECF 52-4 at 17; *see also* ECF 51 at 10. That is wrong. In determining that the 2023 REMS likely is neither reasonable nor reasonably explained, the Fifth Circuit panels did what judges do every day: They applied the APA to call an agency's strike a strike. Waving a "scientific judgment" flag does not magically relieve FDA from the APA's strictures.

Danco also recycles its failed *Alliance* argument that FDA reasonably relied on FAERS data in removing in-person dispensing. ECF 52-4 at 18–19. But FAERS data "are not an indicator of the safety profile of the drug." ECF 1-52 at 5. Rather, FDA itself warns that "[r]ates of occurrence [for an adverse event] cannot be established with [FAERS] reports." *Id.* Yet to approve the 2023 REMS, FDA "analyzed the FAERS data" from parts of 2020 and 2021 "to determine if there was a difference in adverse events when in-person dispensing was and was not enforced." ECF 1-10 at 27; *see also* ECF 1-50 at 64–65. But, as the Fifth Circuit recognized, "considerable evidence shows that FAERS data is insufficient to draw general conclusions about adverse events." *Alliance II*, 78 F.4th at 249. It was thus arbitrary for FDA to use data that "cannot be used to calculate the incidence of an adverse event," ECF 1-52 at 3, to determine the incidence of mifepristone's adverse events.

Danco waves away this problem because drug sponsors must report the adverse events that come to their attention. But abortion providers are not required to submit non-fatal adverse event reports to the drug sponsors. ECF 1-10 at 20 (acknowledging some events may not be reported because reporting is voluntary). And the sponsors have "no direct relationship with [mifepristone] patients and little ability to track events." *Alliance II*, 78 F.4th at 247. The Fifth Circuit thus correctly concluded that the sponsors' "residual reporting requirements do not cure this APA violation." *Id.*

Danco next says that FDA concluded that the published literature "supported" the 2023 REMS. ECF 52-4 at 18–19. That is not the full story. FDA also conceded the studies were "not

adequate on their own to establish the safety of … dispensing mifepristone by mail." ECF 1-10 at 35. They were merely "not inconsistent with [FDA's] conclusion" that removing the last remaining in-person doctor visit was safe. *Id.* at 28. As two different Fifth Circuit panels concluded, it was arbitrary and capricious for FDA to remove what it recently acknowledged was both "minimally burdensome" and "necessary to mitigate" mifepristone's "serious risks," Appl. for Stay, *FDA v. ACOG*, No. 20A34, 4, 7, 13 (U.S. Aug. 26, 2020), based on FAERS data that "cannot be used to calculate the incidence of an adverse event," plus studies that were "not adequate on their own to establish the safety of … dispensing mifepristone by mail." *See Alliance II*, 78 F.4th at 249, 250 (rejecting claim that studies "supported [FDA's] conclusion that mifepristone would still be safe and effective even with a relaxed in-person dispensing requirement").

2. Although this Court need not reach the Comstock Act issue Judge Ho reached, it also bears noting that the 2023 REMS directly conflicts with the Comstock Act. Indeed, "using the mails for the mailing of a drug for producing abortion is *precisely* what the Comstock Act prohibits." *Id.* at 267–68 (Ho, J., concurring) (citation modified and emphasis added).

Danco's responses are difficult to follow. For example, Danco claims that administrative agencies may disregard federal law outside of their enabling statutes—a claim directly refuted by (a) the APA's mandate to set aside actions that are "otherwise not in accordance with law" and (b) the Supreme Court's unqualified statement in *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293 (2003), that "otherwise not in accordance with law" means "any law." *Id.* at 300; *contra* ECF 52-4 at 21–22. More, Danco's argument would mean that federal agencies need not concern themselves with the Religious Freedom Restoration Act or a multitude of environmental statutes. That obviously is not the law.

Danco also notes that FDA routinely approves drugs that are subject to other statutes, like the Controlled Substances Act ("CSA"). But FDA approval does not authorize conduct prohibited by the CSA. Here, in contrast, the 2023 REMS authorizes using the mails to distribute an abortion-producing drug—conduct that the Comstock Act expressly forbids.

Finally, both Danco and GenBioPro would rewrite the Comstock Act to prohibit only "illegal abortions" based on post-enactment history. ECF 54-4 at 20–21; ECF 52-4 at 21–22. But the text contains no such limitation, and Congress in 1978 considered—and rejected—an amendment limiting the law to "illegal abortions." H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978); *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* ECF 101 at 5; ECF 103-1 at 9. As a result, the post-enactment history of the Comstock Act "only reinforces the natural reading of the text." *Alliance II*, 78 F.4th at 270 (Ho, J., concurring). And to the extent the manufacturers cling to a smattering of old dicta from some circuit courts, the prior-construction canon modifies a statute's text only when the pre-enactment meaning is settled by "a uniform interpretation by inferior courts"—a standard plainly not satisfied here. *Tex. Dep't of Hous. & Cmty. Affs. v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 536 (2015) (citation omitted).

B. The Equities Favor Plaintiffs.

FDA's refusal to defend the 2023 REMS is dispositive on the equities. Neither FDA nor the public have an interest in enforcing a concededly unlawful regulation—and that is all the Court need say in resolving the equities. *Alliance II*, 78 F.4th at 251–52. But if the Court is inclined to say more, it need only identify Louisiana's undisputed irreparable harm, the public interest in favor of a stay, and FDA's failure to identify countervailing interests.

First, Louisiana faces concrete, irreparable harm absent preliminary relief. No one disputes that Louisiana is being blanketed by contraband mifepristone. For every month that the 2023 REMS remains in effect, nearly 1,000 FDA-approved mail-order abortion drugs enter Louisiana, causing abortions that violate Louisiana law and generating economic harms associated with those violations. For all the reasons Louisiana has standing, *see supra* Section I, its sovereign and economic harms are irreparable. *See Louisiana*, 705 F. Supp. 3d at 663 (finding Article III standing and irreparable harm "[f]or the same reasons"); ECF 20-26 at 15.

Second, the public interest here cuts in favor of women's health and thousands of unborn Louisiana children. The near-certain increase in emergency room visits caused by the 2023 REMS

(which FDA does not dispute) is reason enough to warrant a stay. *See* ECF 1 ¶¶ 32–40, 124–129, 156; ECF 20-26 at 15–16. But consider also that some women like Rosalie are forced to ingest abortion drugs against their will—a direct consequence of removing the in-person dispensing requirement. *See generally* ECF 1-92. Consider also that the "public interest" here arises from an express statement by the Louisiana people: their policy is to "protect the right to life of every unborn child from conception by prohibiting abortion." *Louisiana*, 705 F. Supp. 3d at 653 (quoting La. R.S. § 40:1061). The only way to vindicate the public interest in protecting mother and baby is to stay the 2023 REMS.

Third, and finally, FDA and the manufacturers identify no irreparable harm that *they* stand to suffer, nor anything that even comes close. Without elaboration (or a sworn declaration), FDA insists that this Court's review of the concededly unlawful 2023 REMS might somehow "disrupt" its own. *E.g.*, ECF 51 at 10. This argument is puzzling. FDA's review can continue apace with the in-person dispensing guardrail back in place. Whether FDA acted lawfully (it concedes it did not) is a legal question, not a scientific one, so it will not "short-circuit the agency's orderly review." ECF 51 at 3. And any "administrative inconvenience" cannot outweigh Louisiana's irreparable harms, especially where that inconvenience arises from the agency's own unlawful actions. *See Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022) ("Despite the administrative inconvenience caused by this litigation, DHS has no interest in the perpetuation of unlawful agency action.") (citation modified); *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers).

FDA speculates about "administrative and judicial chaos" if Plaintiffs were to prevail here while another court vacates the 2023 REMS for different reasons. ECF 51 at 4. That speculation is misguided. The possibility of conflicting lower court rulings is, in part, why courts consider the "likelihood of success on the merits as an essential factor in determining when to grant emergency relief in individual cases." *Labrador v. Poe by & through Poe*, 144 S. Ct. 921, 931 (2024) (Kavanaugh, J., concurring). That standard minimizes such conflicts. And here FDA already has conceded that the 2023 REMS is unlawful. Regardless, our federal system leaves "determining the nationally uniform *interim* legal status ... of, say, the Clean Power Plan or Title IX regulations or mifepristone rules" to the Supreme Court—not the self-serving speculation of a federal agency in a district court. *Trump v.*

CASA, Inc., 606 U.S. 831, 876–77 (2025) (Kavanaugh, J., concurring) (describing the U.S. Supreme Court's "proper role" in deciding the interim status of new agency actions). The possibility that judges might disagree has never been cause to abdicate the judicial role.

For their part, Danco and GenBioPro speculate that reinstating the in-person dispensing requirement might take months to implement. Hardly. The infrastructure for this safeguard was in place for over 20 years. The Fifth Circuit was thus rightly unpersuaded by this speculation because Danco did "not deny" it "already has drug labels and documentation that comply with the [previous] mifepristone REMS." *Alliance II*, 78 F.4th at 252. The drug sponsors will have every incentive to swiftly recertify prescribers via an online two-page form. ECF 20-16 at 5. And to the extent GenBioPro set up a distribution model around mail-order mifepristone, ECF 54-4 at 24, that regime has been subject to uninterrupted litigation from its inception. GenBioPro cannot avoid a stay simply because it built its business on a rocky legal and regulatory foundation.

C. FDA's "Delay" Argument Is Meritless.

Apparently sensing that Plaintiffs are plainly entitled to a preliminary stay of the 2023 REMS, FDA (joined by Danco and GenBioPro) suggests that Plaintiffs' alleged "delay" in seeking such relief undercuts any claim of ongoing urgency. FDA misunderstands both the law and the facts. The standard for assessing whether a delay might weigh against preliminary relief is "reasonable diligence." *Benisek v. Lamone*, 585 U.S. 155, 159 (2018). And courts routinely "permit delays when determining the imminence of alleged irreparable harm where delays were 'caused by [plaintiff's] good faith efforts to investigate facts and law.'" *ADT, LLC v. Cap. Connect, Inc.*, 145 F. Supp. 3d 671, 699 (N.D. Tex. 2015) (collecting cases). FDA does not come close to displacing these principles.

First, as this Court is aware, Plaintiffs' interests were represented in the *Alliance* litigation. The *Alliance* lawsuit was initiated in November 2022 and the Fifth Circuit affirmed preliminary relief against the removal of the in-person dispensing requirement. The Supreme Court stayed that relief, however, which means that any lawsuit filed by Louisiana would almost certainly have been stayed pending the outcome in *Alliance*. In June 2024, the Supreme Court reversed on standing grounds, saying nothing

about the merits. And on remand, three state intervenors—which, again, represented Louisiana's interests—continued to press the argument that the 2023 REMS were unlawful.

Second, a presidential election occurred, and Louisiana sought to force an administrative reversal of the 2023 REMS through political negotiations—a possibility that seemed substantial given public statements by the new Administration. *See, e.g.*, ECF 51 at 1. When DOJ instead filed a reply in support of its motion to dismiss the still-pending *Alliance* litigation, Louisiana sought to intervene in that lawsuit. And when the *Alliance* court transferred the case to Missouri and dismissed Louisiana's intervention motion as moot, Louisiana filed this lawsuit six days later. And all the while, Louisiana has been pursuing its own criminal avenues attempting to stop the problem. That is diligence.

Third, and perhaps most significant, abortion providers began documenting illegal, mail-order abortions in July 2023, but it was not until October 2024—on the eve of the presidential election—that the nature and extent of Louisiana's harm became apparent. The Society of Family Planning's #WeCount data revealed for the first time the number of mail-order abortions taking place in Louisiana. And new data, showing that the number has ballooned to nearly 1,000 abortions a month, was released just days before Louisiana filed this suit.

FDA and the manufacturers take issue with the two months that passed between Plaintiffs' complaint and their motion for preliminary relief. But that brief interval reflects Plaintiffs' diligent pursuit of fact-intensive standing-related evidence reflected in the robust record Plaintiffs provided the court at this preliminary stage. That due diligence is not somehow fatal. *E.g.*, *ADT, LLC*, 145 F. Supp. 3d at 699 (eight-month delay with imminent need); *Optimus Steel, LLC v. U.S. Army Corps of Eng'rs*, 492 F. Supp. 3d 701, 719 (E.D. Tex. 2020) (eleven-month delay with "good explanation"). Nor does it compare to the examples of unreasonable delay cited by FDA. *E.g.*, *Parker v. Dacres*, 130 U.S. 43, 49 (1889) (waiting nine years to assert rights under a statute that required the same within six months); *Tate v. LeBlanc*, No. CIV.A. 13-1253-P, 2014 WL6455794, at *2 (W.D. La. Nov. 17, 2014) (waiting more than a year after the complaint to ask for preliminary relief).

In any event, Plaintiffs' supposed "delay" especially is not fatal given FDA's concession that the 2023 REMS is unlawful and Plaintiffs' victory on the equities. None of the cases Danco and

GenBioPro cite involve ongoing harms caused by conduct the defendant itself acknowledged to be unlawful. Those differences are dispositive. Here, FDA has conceded that the 2023 REMS is unlawful, and the ongoing and irreparable harms suffered by Plaintiffs warrant preliminary relief. That distinguishes FDA's best case, *AMID, Inc., v. Medic Alert Found. U.S.*, 241 F. Supp. 3d 788 (S.D. Tex. 2017), where the court declined to award relief on two claims—one because there was no likelihood of success and the other because there was no ongoing harm. Here, FDA does not dispute the merits, and Louisiana is suffering severe and ongoing harm. The Court should ignore FDA's attempt to manufacture a "delay" issue that ignores Plaintiffs' clear satisfaction of the preliminary-relief factors.

D. As the Fifth Circuit Has Held, a Universal Preliminary Stay Is the Appropriate Relief.

As Plaintiffs explained, ECF 20-26 at 16–17, all that is left is for the Court to enter the same relief that the Fifth Circuit previously entered: a preliminary stay of the 2023 REMS under 5 U.S.C. § 705, which would ensure that the longstanding in-person dispensing requirement "will continue to apply." *Alliance II*, 78 F.4th at 254.

FDA recycles (at 11) its failed *Alliance II* argument that a court may not "postpone" the effective date of any agency action already in effect. But the Fifth Circuit expressed "strong[] doubt[s]" about that argument for which FDA has "no authority." *Alliance II*, 78 F.4th at 255–56. And for good reason: Section 705 broadly authorizes a court to issue "all necessary and appropriate process to postpone the effective date of an agency action *or* to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705 (emphasis added). Because that statutory disjunctive forecloses FDA's myopic focus on the word "postpone," FDA deflects by claiming that "to preserve" likewise can remedy only agency action that has not yet gone into effect. ECF 51 at 11. Wrong again. The "status quo" protected by section 705 is "'the status quo' *before the unlawful agency action took place*." *Louisiana v. EEOC*, 784 F. Supp. 3d 886, 909–10 (W.D. La. 2025) (emphasis added); *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1144 (5th Cir. 2021) ("[T]he relief sought here would simply suspend *administrative* alteration of the *status quo*."); *Nken v. Holder*, 556 U.S. 418, 429 & n.1 (2009) (status quo is "the state of affairs before" the challenged agency action). Thus, "[w]hether the effective

date of the [2023 REMS] has passed is irrelevant to this Court's ability to issue a Section 705 stay." *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022) (collecting cases); *see also Texas v. United States Dep't of Health & Hum. Servs.*, 770 F. Supp. 3d 940, 957 (E.D. Tex. 2025).

Relatedly, Danco argues that this Court may not award preliminary relief without a full administrative record. ECF 52-4 at 17. But the APA expressly 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). That is why two panels of the Fifth Circuit affirmed preliminary relief in *Alliance I* and *II* based on a materially identical record. *Alliance II*, 78 F.4th at 250; *Alliance I*, 2023 WL 2913725, at *8. Were the rule otherwise, agencies could block preliminary relief indefinitely by, for example, hoarding part of the record in "cold storage." *See Alliance II*, Oral Arg. at 24:30 (5th Cir. May 17, 2023). Here, FDA has had years to produce any additional materials—beyond the "decisional documents" in the record—that it believes would advance its case. Its failure to do so does not deprive this Court of the power to issue preliminary relief.

E. The Manufacturers' Exhaustion Argument Is Meritless.

In the same desperate vein, the manufacturers assert that Plaintiffs failed to exhaust administrative remedies. That is doubly wrong.

First, the APA requires exhaustion only when required by statute or a rule "provides that the [agency] action ... is inoperative" during appeal. 5 U.S.C. § 704; *accord Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (exhaustion required "*only* when expressly required by statute or when an agency rule requires appeal before review and the administrative action is made inoperative pending that review"). No such statute or rule exists here. 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. Because FDA does not hold its REMS "inoperative" upon receiving a petition, exhaustion does not apply. *MCR Oil Tools, L.L.C. v. United States Dep't of Transp.*, 110 F.4th 677, 691 (5th Cir. 2024).

Second, and in any event, courts do not require exhaustion where one of the "traditionally recognized" exceptions applies. *Wash. Ass'n for Television & Child. v. FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983). At least three are relevant here.

Start with administrative abuse of process. It is "well-established that where an agency fails to follow its own regulations, exhaustion may not be required." *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 own regulations require it to respond to citizen petitions within 180 days. *See* 21 C.F.R. § 10.30(e)(2). Yet the average REMS petition languishes for 937.6 days. *See* Krupka, *supra*, at 957–63. Worse, in *Alliance I*, FDA subjected 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). Plaintiffs here can expect no better. Based on "FDA's repeated failure to follow its own regulations," this Court should waive exhaustion (if such a requirement existed). *Alliance II*, 2023 WL 2913725, at *16.

Next take futility. "[T]he record shows that FDA would have denied any request for an administrative stay." *Alliance II*, 78 F.4th at 255. Indeed, FDA "expressly reaffirmed its commitment to mail-order abortion drugs" in a 2021 petition denial—the day FDA decided to permanently remove in-person dispensing and direct the abortion-drug companies to submit a proposed REMS without that requirement. *Alliance I*, 2023 WL 2913725, at *15. And FDA doubled down on its mail-order scheme by denying a similar petition on January 3, 2023—the day FDA formally approved the 2023 REMS. ECF 1-34. That is why the *Alliance II* Court concluded that it would have been clearly useless to raise the same challenge again. 78 F.4th at 255. In fact, another court found that a coalition of states did not need to file a petition that others had already filed and FDA had rejected because the agency could not "credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." Order Granting in part Pls.' Mot. Prelim. Inj., *Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. Apr. 7, 2023), ECF No. 80 at 17 (perma.cc/J9Q4-85FU). Just so here.

Last, a typical exception "is where irreparable injury would result unless immediate judicial review is permitted." *Randolph-Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 107 (D.C. Cir. 1986) (collecting cases). That exception plainly applies here given the irreparable harms articulated above.

III. The Court Should Deny FDA's Request to Indefinitely Stay This Case.

The foregoing discussion also resolves FDA's puzzling attempt to shutter this case for years at the expense of quite literally thousands of unborn Louisiana children who would lose their lives in the meantime. When a party seeks to forestall adjudication of a motion for preliminary relief, a court must first decide whether the movant is entitled to preliminary relief. *E.g.*, *Procter & Gamble Co. v. Kraft Foods Global, Inc.*, 549 F.3d 842, 847–50 (Fed. Cir. 2008). Only after resolving that issue would the question of a stay properly arise—and at that juncture, the governing standard comes from *Nken v. Holder*, 556 U.S. 418, which FDA does not cite much less attempt to satisfy. *See, e.g.*, *Community Television of Utah, LLC v. Aereo, Inc.*, 997 F. Supp. 2d 1191, 1195–1205, 1209–11 (D. Utah 2014) (granting preliminary injunction and then considering *Nken* stay factors). And in all events, a free-floating *Landis* inquiry would not help FDA because Plaintiffs' satisfaction of the preliminary-relief factors all but forecloses any attempt to stay relief against a regulation that FDA refuses to legally defend. *See Alliance I*, 2023 WL 2913725, at *4, *21; *cf. Procter & Gamble Co.*, 549 F.3d at 849.

A. Begin with the *Nken* factors. *First*, for all the reasons explained above, FDA cannot muster the "strong showing" of a likelihood of success on the merits of Plaintiffs' APA claims—indeed, FDA does not even defend the 2023 REMS. *Nken*, 556 U.S. at 426.[15]

Second, FDA does not even try to claim irreparable harm. *Id.* The most FDA identifies is a worry that a challenge to the 2023 REMS—agency action FDA concedes is unlawful—might cause administrative burdens and disrupt FDA's own purported safety review. That is not irreparable harm. Thus, the two "most critical" factors—likelihood of success and irreparable injury—weigh decisively in Plaintiffs' favor. *Alliance I*, 2023 WL 2913725, at *4 (citing *Nken*, 556 U.S. at 434).

[15] Notwithstanding Defendants' and the manufacturers' objections to the applicability of the Comstock Act, the Fifth Circuit found that it "nevertheless undermines applicants' showing on the final three *Nken* factors." *Alliance I*, 2023 WL 2913725, at *20.

Third, FDA cannot carry its burden to show that a stay would not harm Plaintiffs. *Nken*, 556 U.S. at 426. Louisiana suffers irreparable sovereign and economic harms every day that the 2023 REMS remains in effect due to the 1,000 abortions that everyone agrees are occurring each month in Louisiana. And as Rosalie's tragic story shows, the 2023 REMS allows domestic abusers to order abortion drugs and force pregnant women to take them.

And *fourth*, FDA's nondefense of the 2023 REMS settles the public interest inquiry. As recounted above, hornbook law says there is no public interest in the perpetuation of unlawful agency action—much less indefinitely for years into the future. FDA counters that "it is not in the public interest to interrupt the administrative process." ECF 51 at 10 (quoting *Peak v. D.C.*, No. CV 06-0373 (JGP), 2006 WL 8445985, at *6 (D.D.C. Mar. 20, 2006)). But *Peak* merely said there was no need to disrupt an administrative process in the absence of a likelihood of success on the merits. *Id.* Here, FDA concedes the 2023 REMS is unlawful. FDA also says judicial relief "may prove [] unnecessary" if its purported safety review culminates in the agency's attempt to rescind the 2023 REMS. ECF 51 at 3. Setting aside FDA's speculation (through only a lawyer's pen, no less), FDA's post-hoc study cannot cure its prior unlawful action. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 20–21 (2020). Meanwhile, Louisiana and its women and children suffer harm with each day that passes.

At bottom, FDA wants this Court to allow a "plainly unconstitutional or otherwise illegal [agency action]" to "remain in effect ... for several years pending" FDA's planned safety review. *Labrador*, 144 S. Ct. at 931 (2024) (Kavanaugh, J., concurring). FDA calls this the "status quo," ECF 51 at 11, which is just wrong as explained above: The status quo is the last lawful state of affairs—*i.e.*, before removal of the in-person dispensing requirement. If the status quo were the unlawful agency action, recalcitrant agencies could always avoid APA injunctions. That is not the law.

FDA also cites no case allowing an unlawful agency action that imposes irreparable harm to remain in place just because the agency said it was studying the unlawful action. *Ali v. Quarterman* vacated an administrative closure and directed the lower court to "*move forward with the case* so far as is practicable." 607 F.3d 1046, 1049 (5th Cir. 2010). In *Purcell*, the court granted an unopposed stay only once plaintiffs had secured relief from their alleged injuries. *Chelius v. Becerra*, No. CV 17-00493 JAO-

RT, 2023 WL 5041616, at *2–3 (D. Haw. Aug. 8, 2023). Similarly, the *Landis* plaintiffs faced no ongoing harm while their case was stayed. *Landis v. N. Am. Co.*, 299 U.S. 248, 251–52 (1936). And *Ricci v. Chicago Mercantile Exchange* upheld a stay where there was no ongoing or irreparable harm. 409 U.S. 289, 291, 305 (1973). Plus, FDA has had *five years* to study this issue since the Biden Administration first removed the in-person dispensing requirement. FDA made its bed, and now the APA provides for judicial review.[16]

B. The results do not change under *Landis*. FDA still "bears the burden of showing that the circumstances justify an exercise of [the Court's] discretion." *Nken*, 556 U.S. at 434. FDA "must make out a *clear case of hardship or inequity* in being required to go forward, if there is *even a fair possibility* that the stay for which he prays will work damage to some one [sic] else." *Landis*, 299 U.S. at 255 (emphases added). FDA identifies no hardship beyond the ordinary burdens of litigation and administrative review—generated by its own concededly unlawful action—while Plaintiffs face ongoing irreparable harm. FDA also makes no "showing that the difficulties inherent in the general situation, including potential judicial inefficiency, constitute a sufficient offset to the plaintiffs' rights to proceed without inordinate delay to a resolution of their claims." *Wedgeworth v. Fibreboard Corp.*, 706 F.2d 541, 546 (5th Cir. 1983). Particularly here, where the "realities of the hardship of a stay on the plaintiffs" is "substantial" and "permanent," and the stay "hinged on completion of" a study that "is manifestly 'indefinite,'" FDA can't sustain its burden under *Landis*. *Id.* at 545.

One last point about practicalities: The earliest time FDA could reasonably reinstate the in-person dispensing requirement is 2027. FDA (well, FDA's lawyer) says it might complete its study

[16] For similar reasons, the manufacturers' claim that this case is not ripe because FDA might change course in the future misunderstands the law. Ripeness ensures that federal courts do not adjudicate disputes prematurely—where, for example, an agency has not yet acted. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148–49 (1967) (explaining that ripeness "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties"). Here, there is no dispute that the 2023 REMS is final agency action. The lawfulness of that action is fully fit for judicial resolution—and in fact, there can be no further factual development vis-a-vis the 2023 REMS. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 41 (1983); *contra* ECF 52-4 at 16.

(but not its review) "sooner than" "a year or more." ECF 51 at 3.[17] But FDA puts forth zero evidence that it has even requested or commissioned the data necessary to initiate its purported review—other than vague statements on its own website that its efforts purportedly began in late January 2026. And this, after first promising this review over a year ago.[18] Worse, even once the agency achieves "Gold Standard Science and rigorous, transparent, and objective evidence," ECF 51 at 1, after "a year or more," that review is only the first step under 21 U.S.C. § 355-1. Next, the Secretary may direct the drug sponsor to modify the REMS "within 120 days or within [a] reasonable time." 21 U.S.C. § 355-1(g)(4)(B). At the expiration of the 120 days, the sponsor may challenge the REMS changes before the Drug Safety Oversight Board, which Danco and GenBioPro inevitably will. 21 U.S.C. § 355-1(h)(4)(A)(i); 21 U.S.C. § 355-1(j)(2). The Board reviews the parties' submissions, hears the dispute, and provides a written recommendation to the Secretary, who issues an action letter. 21 U.S.C. § 355-1(h)(4). All of this takes time. So even assuming that FDA takes the least time estimated for its study, by law the earliest FDA could restore in-person dispensing is about 18 months now. Worse, there is no evidence that FDA has even requested or commissioned the data it needs to start its review. Put another way, FDA's stay request asks this Court to ignore at least 18,000 illegal abortions, 18,000 unborn lives, at least 720 emergency room visits, and tens of thousands of dollars in unrecoverable costs from now—just in Louisiana.

CONCLUSION

The Court should preliminarily stay the 2023 REMS and deny FDA's motion to stay.

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[17] U.S. Food & Drug Administration, Questions & Answers — Mifepristone Medical Termination of Pregnancy Through Ten Weeks Gestation (Feb. 2, 2026), perma.cc/M6YM-7MK5.

[18] Andrew Stanton, RFK Jr. Says He Would Study Abortion Pill Mifepristone Safety Issues, Newsweek (Jan. 29, 2025) perma.cc/5T8R-MU7S.

Dated: February 17, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 17, 2026, pursuant to Federal Rule of Civil Procedure 5(b)(2)(C), a true and correct copy of the foregoing memorandum, and all attachments thereto, was served by CM/ECF.

/s/ *Caitlin Huettemann*
Caitlin Huettemann

EXHIBIT A

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No.: 6:25-cv-01491-DCJ-DJA Judge David C. Joseph Magistrate Judge David J. Ayo

DECLARATION OF ERIN TONER

Pursuant to 28 U.S.C. § 1746, I, Erin Toner, affirm under penalty of perjury:

1. I am over the age of 18, have personal knowledge of the matters set forth herein, and am competent to make this Declaration.

2. I serve as the Human Resources Program Director in the Louisiana Department of Justice ("DOJ"). In my role, I manage the Louisiana DOJ's HR department, aligning HR strategy with business goals. I oversee talent acquisition, compensation, compliance, and employee relations. I also act as a vital link between staff and executive leadership.

3. The Louisiana Bureau of Investigation ("LBI") is a department of the Louisiana DOJ. LBI is responsible for the investigation of criminal activity, intelligence gathering, and case and technical support in Louisiana. LBI contains several "divisions," including the Criminal Investigations Division and the Special Investigations Division.[1]

[1] *See About the Bureau of Investigations*, Louisiana State Police, https://lsp.org/about/leadershipsections/bureau-of-investigations/ (last visited Feb. 12, 2026).

4. LBI is involved in the investigation of the shipment of abortion drugs into Louisiana for the purpose of causing illegal abortions within Louisiana's borders..

5. In just three distinct matters covered by that investigation, LBI reports that it has spent approximately 440 hours dedicated to investigation, travel, and other related operations.

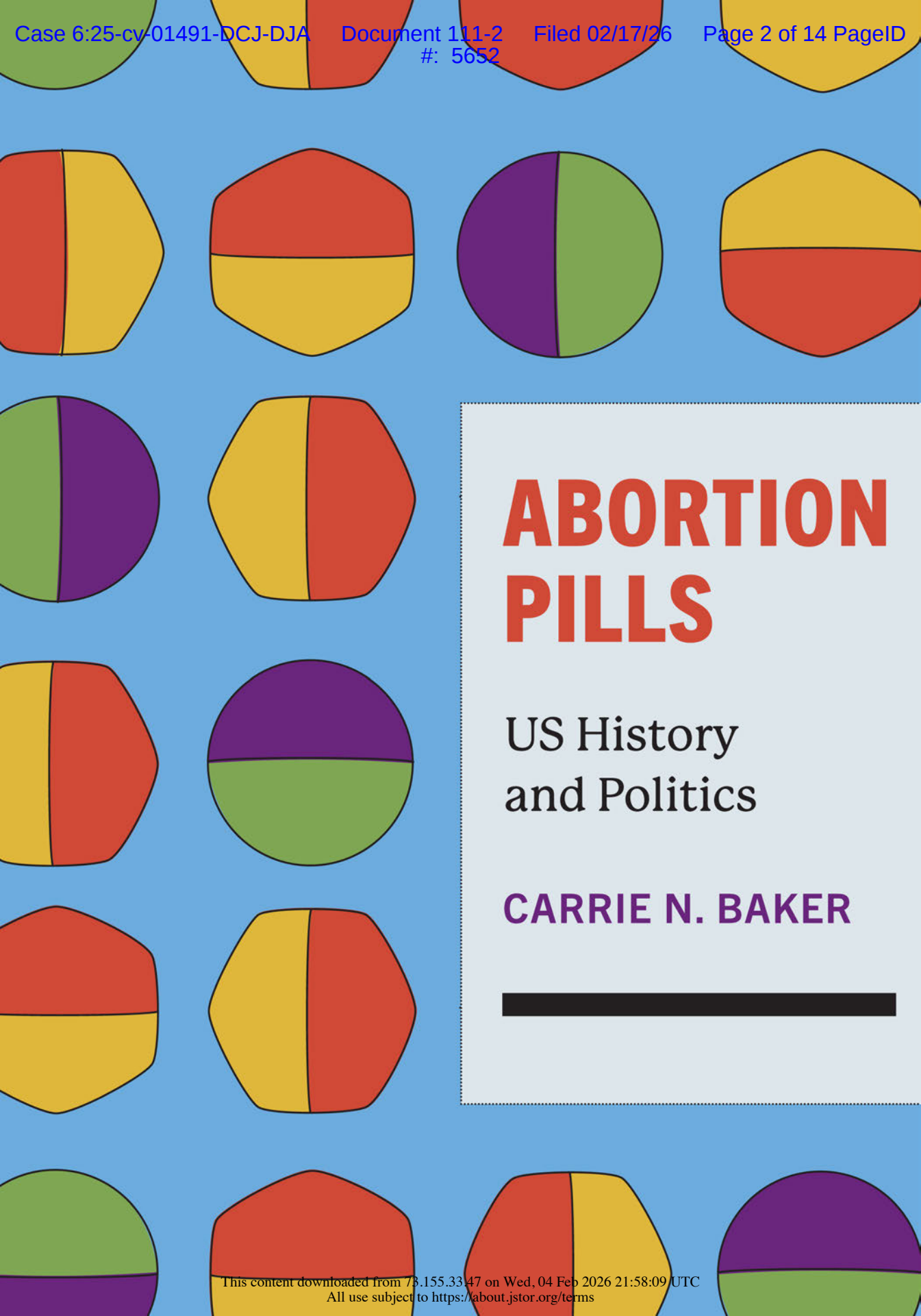
6. The lead LBI investigator's current hourly rate is $40.01. Therefore, in the course of the 440 hours devoted to these three distinct matters, LBI has expended approximately $17,604.40 of the investigator's time, not including the investigator's travel and other operational expenses.

Executed in Louisiana, Louisiana, this 17 day of February 2026, 2026.

Signed by:
Erin Toner
CB07722D99CB48F...

Erin Toner

EXHIBIT B



ABORTION PILLS

US History and Politics

CARRIE N. BAKER

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Acronyms

AAP	Abortion Access Project
ACLU	American Civil Liberties Union
ACOG	American College of Obstetricians and Gynecologists
ADF	Alliance Defending Freedom
AHT	Advances in Health Technology
ANSIRH	Advancing New Strategies in Reproductive Health
ARM	Abortion Rights Mobilization
CPC	crisis pregnancy center
CRR	Center for Reproductive Rights
EMAA	Expanding Medication Abortion Access
ETASU	Elements to Assure Safe Use
FDA	US Food and Drug Administration
FMF	Feminist Majority Foundation
FRC	Family Research Council
FTC	Federal Trade Commission
GLC	Generative Learning Community for self-managed abortion
HHS	Department of Health and Human Services
HIS	Indian Health Service
IND	Investigational New Drug
M+A Hotline	Miscarriage and Abortion Hotline
NAF	National Abortion Federation
NARAL	National Abortion Rights Action League
NAWHERC	Native American Women's Health Education Resource Center
NDA	New Drug Application
NOW	National Organization for Women
NRLC	National Right to Life Committee
NWHN	National Women's Health Network
OARS	Online Abortion Resource Squad

REMS	Risk Evaluation and Mitigation Strategy
RHEDI	Reproductive Health Education in Family Medicine
RHTP	Reproductive Health Technologies Project
SASS	Self-Managed Abortion. Safe and Supported
SHERo	Sisters Helping Every Woman Rise and Organize
SIA Legal Team	Self-Induced Abortion Legal Team
S.T.O.P.	Surveillance Technology Oversight Project
WRRAP	Women's Reproductive Rights Assistance Project

approval of a generic with the FDA. The head of the FDA at the time, Dr. Scott Gottlieb, was focused on increasing the number of generic medications on the market in order to encourage competition, especially for drugs in the REMS program.[219] On April 11, 2019, the FDA approved GenBioPro's generic mifepristone.[220] Coeytaux said the generic made a huge difference:

> The minute GenBioPro was in the act, all sorts of things started happening. Danco reduced its price because there was competition. All the stuff that we did with the providers during COVID—we couldn't have done it with Danco. Danco wasn't interested at all in anything innovative because they were happily doing their thing and already had their people on board. So having competition in the market was critical.[221]

FDA approval of the generic set price competition in motion: GenBioPro set their price lower than Danco, which then dropped their price. Lower prices and more options increased access to mifepristone for clinicians and patients across the country. The generic also established competition for new services from the drug sponsors, such as mail order at scale, but it also extinguished the rationale for Danco to pursue the miscarriage indication since most pharmacies could swap out brand-named mifepristone for the generic, regardless of what the prescription was written for.[222] Dr. Mitchell Creinin, however, believed that the drop in price had only a "marginal benefit" for patients because clinics did not drop their prices for medication abortion.[223]

But anti-abortion advocates pushed back against increasing access. In March of 2019, the Trump administration's FDA issued a warning letter to Dr. Gomperts, demanding that she stop "causing the introduction of a misbranded and unapproved new drug into interstate commerce."[224] The FDA threatened to seize the drugs. Gomperts explained what she did next: "I stayed in my bed for three days, researching and reading everything that existed on the FDA regulations, calling all the people I could call in the US. I came to the conclusion that it's okay, I can do this."[225] Then she fought back. In September 2019, Gomperts sued the FDA, alleging they had seized between three and ten doses of abortion drugs she had prescribed through Aid Access since March and that the government had blocked Aid Access from receiving payments from some patients.[226] The lawsuit was eventually dismissed, but Gomperts continued to mail the medication and did not experience any more interference.

Anti-abortion states also tried to block the increasing access by fighting for restrictions at the state level, including passing laws banning mailing of abortion pills, requiring ultrasounds which limited telemedicine access, and requiring that physicians alone may prescribe mifepristone. For three weeks in June of 2019, the Missouri health department required doctors prescribing abortion pills to conduct an extra medically unnecessary pelvic exam on their patients before the state-mandated waiting period so that patients had to have two pelvic exams to receive the pills—one when they initially

saw the doctor and a second when patients came back for the pills. In other words, doctors were forced by the state to insert their fingers into patients' vaginas while pressing their abdomens to feel their reproductive organs, for no medical reason. One doctor described the requirement as "state sanctioned, essentially, sexual assault."[227] After three weeks, doctors at the one remaining abortion clinic in Missouri, a Planned Parenthood clinic in Kansas City, refused to comply with the order, and the state health department backed down, rescinding the requirement.[228] During that time period, over one hundred women experienced invasive, medically unnecessary, and unwanted vaginal probes, by order of the state. In response, Planned Parenthood created a new clinic across the river in Illinois so as not to be subject to the Missouri Department of Health.[229] Meanwhile, states increasingly passed abortion bans, hoping to tee up a case for the Supreme Court to finally overturn *Roe v. Wade*. These developments spurred Plan C to push harder to make abortion pills available by telemedicine and mail. The declaration of a pandemic in March 2020 created new opportunities to make this vision a reality.

falsely deemed "nonessential," but the number of abortions in surrounding states increased, likely due to women traveling from restrictive states to find abortion health care. The Guttmacher report noted other factors that likely contributed to state variation and overall increase in the number of abortions, including increased fundraising by local and national abortion funds so they could help more people pay for their abortions, increased abortion restrictions and bans (twenty-five states enacted 168 laws between 2017 and 2020, some of which were blocked by courts), and seventy-five new provisions to protect abortion rights (repealing restrictions, expanding insurance coverage, and allowing more qualified clinicians such as nurse practitioners, physician assistants, or certified nurse midwives to provide at least some abortion care). "The Supreme Court is poised to overturn *Roe v. Wade* at a time when need for abortion care has been increasing," concluded the report. "This means the impact of the ruling could be even more devastating than predicted by prior analyses, particularly for people across the country who already struggle to access abortion care."[78]

In December of 2020, the Generative Learning Community (GLC) for self-managed abortion expanded, opening membership to more organizations. GLC grew to over seventy organizations and held meetings every other month as a "gathering space" for "shared learning and problem solving" on self-managed abortion. GLC also engaged in "culture change work" to normalize self-managed abortion.[79] GLC had two goals: "to give every person the option to end a pregnancy safely and with support, within the formal healthcare system, or outside it" and to "ensure no one risks punishment or imprisonment for their reproductive choices or for supporting a person who is self-managing the end of a pregnancy."[80] Their purpose was to normalize self-managed abortion by promoting a "positive narrative, and avoiding harmful messages, about self-managed abortion."[81] They focused on "developing tools and actions for use in communications" and committed to "do nothing that puts pregnant people, or those who support them, at increased risk of investigation, prosecution, and punishment for their reproductive choices." This limited approach later led to a break with Plan C because of their work to make pills available to people in states with abortion bans, which inevitably created some legal risks.[82]

The GLC focused primarily on normalizing abortion pills inside the reproductive health movement. "The medical community could get overly controlling about mifepristone," explained Kirsten Moore. "What the GLC did was hold a mirror up to the medical professionals and say, 'you know you're overthinking this, you're overtraumatizing this.' They consistently normalized the idea that patients can manage their abortions on their own," said Moore, noting that GLC held a full-day workshop on self-managed abortion at a NAF meeting in early 2022. "It's about getting the movement itself to move into the twenty-first century."[83]

THE PENDULUM SWINGS: BIDEN ADMINISTRATION EXPANDS ABORTION PILL ACCESS

Immediately after the 2020 election of Joseph Biden, reproductive rights advocates asked the new administration to review the FDA's abortion pill restrictions. "These restrictions place more of a burden than a benefit on providers and their patients," said Kirsten Moore, referring to the FDA standard for imposing the REMS restriction. "Based on opinion research we conducted last year, people like the idea that women have access to an option for ending an early pregnancy," said Moore. "And they like the idea that it's an FDA-approved drug that's been around for twenty years. We think it's time to revisit these restrictions and move forward."[84]

Even before the election, medical professionals and activists were calling on Biden to reverse the Trump policy and end the FDA restriction on the abortion pill altogether. A coalition of more than ninety women's rights organizations released a "Blueprint for Sexual and Reproductive Health, Rights and Justice" that made two demands with regard to mifepristone. The first was that President Biden issue an executive order on his first day in office directing the Secretary of Health and Human Services to lift the in-person distribution requirement for mifepristone during the pandemic. The second demand was that within ninety days of assuming office, the president direct the FDA to review the mifepristone REMS to determine whether it should be modified or removed to "best reflect scientific evidence and real-world use."[85] On January 27, 2021, Guttmacher Institute's president and CEO Herminia Palacio and Dr. Daniel Grossman of ANSIRH wrote an op-ed in *The Washington Post* urging Biden to remove the in-person distribution requirement. "Facts matter, and the facts couldn't be clearer," they wrote. "In this moment, when the country is looking to the administration to heed public health experts, it must suspend this requirement for the duration of the public health emergency and direct the FDA to ensure its medication abortion policies are aligned with the scientific evidence."[86] At a more personal level, Sarah Christopherson of NWHN found people to speak directly with President Biden about mifepristone. "I spent some time organizing high-net-worth major donors. I had some leftover contacts and some leftover favors to call in from people I knew would be receptive and get it, and be good spokeswomen for it," said Christopherson.[87]

On February 9, 2021, eleven female Democratic members of the House Committee on Oversight and Reform wrote a letter to the Acting Commissioner of the FDA Janet Woodcock[88] urging her to lift the in-person abortion pill distribution requirement. In the letter, they emphasized the FDA's illogical policy on mifepristone: "Of the more than 20,000 drugs regulated by FDA, mifepristone is the only drug that FDA requires patients to obtain in person at a hospital, clinic, or medical office, but it does not restrict the ability of patients to self-administer—unsupervised—at home or at a location of

their choosing." They described a strong safety record of mifepristone, and the risks imposed on patients by the in-person distribution requirement. They concluded, "In light of the clear danger that the reinstated requirement poses to people seeking comprehensive reproductive health care at the height of the coronavirus pandemic, we urge you to immediately eliminate the medically unnecessary in-person dispensing requirement for mifepristone."[89]

On March 18, fifty-five reproductive health, rights, and justice groups sent a letter to President Biden urging his administration to lift FDA restrictions on mifepristone. The letter emphasized the burden of the FDA restrictions on marginalized communities:

> Consistent with your important commitment to follow the science in responding to COVID-19, as well as your critical promise to tackle issues of systemic equity across the government, it is imperative that your administration prioritize safe access to medication abortion. Burdensome restrictions on medication abortion, which are not based in medical evidence, deepen the health inequities already experienced by those who are struggling to make ends meet, particularly people of color, who comprise a majority of medication abortion patients and are now being hit hardest by the COVID-19 pandemic.[90]

Along with the letter, they delivered a petition with over 200,000 signatures of supporters.

On April 12, 2021, under the leadership of Dr. Janet Woodcock, the FDA finally lifted the in-person distribution requirement for the duration of the COVID-19 public health emergency, allowing clinicians to resume telemedicine abortion services.[91] In a letter to ACOG and the Society for Maternal-Fetal Medicine, Dr. Woodcock wrote that the FDA would waive the requirement that clinicians dispense mifepristone to their patients in a clinic or hospital setting. The letter said research studies on telemedicine abortion "do not appear to show increases in serious safety concerns occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic."[92] ACOG issued a statement praising the new guidelines: "We are pleased to see mifepristone regulated on the basis of the scientific evidence during the pandemic, rather than political bias against comprehensive reproductive health care, and we look forward to working with policy makers to ensure this principle governs post-pandemic care."[93] Advocates celebrated the decision for following the science. "We know from twenty years of research that medication abortion is extremely safe—even safer than some over-the-counter medications. It's past time to permanently lift the restrictions and make medication abortion more accessible for those who need it," said Dr. Grossman of ANSIRH. Online pharmacies resumed distribution of mifepristone by mail. Sarah Christopherson said all the strategies contributed toward their success: "I don't think any one strategy would have been sufficient on its own. I think it took all of them. It took the medical studies, proving how safe it was. It took EMAA