IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients, et al.,

Plaintiffs,

v.

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

Defendants.

Case No. 2:22-cv-00223-Z

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The FDA's unlawful actions to approve chemical abortion drugs and remove necessary safeguards have harmed countless women and girls. After stonewalling Plaintiffs for nearly two decades, Defendants FDA and Danco Laboratories, LLC, essentially admitted Plaintiffs' allegations: pregnancy is not an "illness" under the FDA's accelerated approval regulations; the agency lacked the evidence required by the Federal Food, Drug, and Cosmetic Act (FDCA) to show the drugs' safety and effectiveness "for use under the conditions . . . in the proposed labeling"; and the FDA approved distribution of these dangerous drugs in direct conflict with clear prohibitions of longstanding federal criminal laws.

Given these concessions, Defendants spend most of their briefs retreating to procedural arguments. But those are fruitless. Binding judicial precedent supports each Plaintiff's standing. The FDA has repeatedly reopened and revised its decision to approve chemical abortion drugs, thus resetting the statute of limitations to challenge the approval each time. And Plaintiffs complied with any duty to exhaust administrative remedies.

Preventing irreparable harm to women and their doctors outweighs the lost profits of the abortion industry. Chemical abortions do not improve health outcomes and often worsen them. Pls.' App. 225–38, 398–488 (App.). The public interest in protecting women's health also trumps the Biden administration's justification that chemical abortion drugs are needed because "the children of people who seek but are unable to obtain an abortion . . . have lower earnings as adults, poorer health, and an increased likelihood of criminal involvement." Ex. 2 to FDA Br., Lindo Decl., ¶ 20. Leaning into the eugenic ideologies of the past is *never* in the public interest.

Because the FDA refuses to comply with the law and to prioritize science over politics, Plaintiffs ask the Court to grant their motion for a preliminary injunction and end the harms that chemical abortion drugs wreak on women in this country.

ARGUMENT

I. This Court has jurisdiction over Plaintiffs' claims.

A. Plaintiffs have standing.

Plaintiffs have standing six ways from Sunday.

1. Organizational standing

Organizational standing exists here. As the FDA's own case concedes, "the Supreme Court and the Fifth Circuit have repeatedly acknowledged[] [that] [a]n entity can show an organizational injury by alleging that it must divert resources from its usual activities in order to lessen the challenged restriction's harm to its mission." *La Union del Pueblo Entero v. Abbott*, No. 5:21-CV-0844-XR, 2022 WL 3052489, at *32 (W.D. Tex. Aug. 2, 2022) (cleaned up). In response to the FDA's actions on chemical abortion drugs, Plaintiff organizations have "calibrated [their] outreach efforts to spend extra time and money educating [their] members" about the dangers of such drugs. *See OCA-Greater Houston v. Texas*, 867 F.3d 604, 610 (5th Cir. 2017). These organizations have been diverting crucial, limited resources to challenge the FDA's actions to legalize and deregulate these drugs. App. 091–93. They have been forced to divert "time, energy, and resources" away from their missions to "conduct[] their own studies and analyses of the available data" to share accurate information on chemical abortions with member physicians, their patients, and the public. *Id.* at 091. Plaintiffs engaged in these activities as a *direct result* of the FDA's approval of chemical abortion drugs and its removal of basic safeguards.

Defendants say that Plaintiffs must "identify" an "Article III injury that their alleged diversion of resources is necessary to avoid." FDA Br. 14; Danco Br. 10. But "there can be no question" that an organization suffers an Article III injury, where, as here, its ability to pursue its mission is "perceptibly impaired" because it "had to devote significant resources to . . . counteract the defendant's [conduct]." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). "Such concrete and demonstrable

injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Id.* (citing *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972) (no standing because "mere 'interest in a problem[]' . . . is not sufficient by itself")); 13A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3531.9.5 (3d ed. 2022) (standing where "organization has devoted specific effort and expense to combat the challenged activity").

The Defendants also fault Plaintiffs for not identifying specific forgone projects. FDA Br. 15; Danco Br. 9–10. But the Fifth Circuit has already rejected such a requirement and held that an Article III injury exists whenever an organization goes "out of its way to counteract the effect of [unlawful government action]" with a view "toward mitigating its real-world impact on [its] members and the public." *OCA-Greater Houston*, 867 F.3d at 612. Here, for example, Plaintiffs have standing because they have "undert[aken] to educate [patients and doctors] about [the dangers of chemical abortion drugs]—an undertaking that consumed . . . time and resources in a way they would not have been spent absent [the FDA's approval]." *Id.* Plaintiffs' "injury-in-fact is the 'additional time and effort spent explaining [the dangers of chemical abortions]'" because such efforts "frustrate[] and complicate[] [their] routine [medical] activities." *Id.* at 610. In all events, Plaintiffs' allegations are specific and supported by evidence: Plaintiffs attest that they have been forced to divert valuable resources away from other advocacy and educational efforts, including efforts over "the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages." App. 091–93. The Court must also "assume, for purposes of the standing analysis," that Plaintiffs are "correct on the merits" of their claims, including their organizational injuries. *Texas v. E.E.O.C*, 933 F.3d 433, 447 (5th Cir. 2019).

The FDA also labels Plaintiffs' injuries as "self-inflicted." FDA Br. 14. Quite the contrary, the FDA's approval and deregulation of chemical abortion drugs have harmed Plaintiffs. App. 074–93. It was the FDA, not Plaintiffs, that established the citizen petition process as the *only* formal means to request that the agency withdraw its approval of a dangerous new drug or strengthen basic protections for an already-approved drug. The FDA's regulations *required* Plaintiffs to file citizen petitions in making such requests. Plaintiffs dutifully complied and waited a combined 16 years for the FDA to respond. They meanwhile sought to combat the misinformation about the dangers of chemical abortion drugs through their own research, outreach, and communications. The FDA essentially argues that Plaintiff medical associations and their physicians can never have standing to sue and so they must continue to be harmed by dangerous chemical abortion drugs without recourse. That's wrong as a matter of law and disgraceful as a matter of policy.

In light of Plaintiffs' evidence, Defendants' cases reveal why Plaintiffs have standing here. *See, e.g.*, *Tex. State LULAC v. Elfant*, 52 F.4th 248, 254 (5th Cir. 2022) (no standing because organization failed to "show it diverted resources as a direct result of the challenged law—not as a result of the challenged law and others like it") (cleaned up); *Tenth St. Residential Ass'n v. City of Dallas*, 968 F.3d 492, 500 (5th Cir. 2020) (organization lacked standing because it "provided no evidence that its members were required to forego other projects or causes"); *NAACP v. City of Kyle*, 626 F.3d 233, 238 (5th 2010) (lobbying group failed to explain how holding a meeting, sending six emails and one fax, drafting a two-page speech, and obtaining a copy of meeting minutes differed from its "routine lobbying activities").

2. Associational standing

Plaintiff medical organizations also have associational standing to sue on behalf of their members—medical professionals who treat women harmed by chemical abortion drugs—and on behalf of their members' patients. *See Tex. Ass'n of*

Mfrs. v. U.S. Consumer Prod. Safety Comm'n, 989 F.3d 368, 377 (5th Cir. 2021). Defendants never dispute that protecting women from dangerous chemical abortion drugs is germane to the organizational Plaintiffs' purpose. Nor do they dispute that, if doctors have standing to sue on their own behalf, then Plaintiff medical associations can sue on behalf of their members. Instead, Defendants argue that the member doctors lack standing. FDA Br. 14; Danco Br. 12–13. But these doctors have standing to sue on behalf of themselves and their patients. Pls. Br. 8.

3. Physician standing

The FDA dismisses as "speculation" the harms to doctors flowing from the agency's approval of dangerous chemical abortion drugs and removal of safeguards for women. Hardly. Plaintiffs' complaint and supporting declarations specified many injuries-in-fact that the FDA's actions have inflicted on Plaintiff doctors and their patients. App. 080–90; Pls. Br. 8–10. Without a hint of irony, the FDA's own declarants assert that abortionists would suffer many of the same injuries if the Court were to grant Plaintiffs' motion. *See, e.g.*, Ex. 2 to FDA Br., ¶¶ 17, 21, 50, 59; Ex. 4 to FDA Br., Kieltyka Decl. ¶ 37. One declarant admitted that her 17 satellite offices cannot provide surgical intervention to treat complications, Ex. 4, ¶ 37, thus guaranteeing that doctors, such as Plaintiffs, will provide care for these women.

In fact, Defendants concede that Plaintiffs' declarations have shown that chemical abortion drugs have *already* harmed Plaintiffs. *See* FDA Br. 11 (acknowledging the "existence of adverse events" and "incidents" from these drugs among Plaintiff doctors' patients and their medical practices); Danco Br. 12 (recognizing "alleged harm of treating patients who experience complications").

This should end the standing inquiry. Standing exists when harm has already occurred. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992).

Even so, Defendants challenge the proximity of the causal link between the FDA's actions and Plaintiffs' injuries, claiming that their patients are independent

actors who could have been hurt from childbirth, pregnancy, or surgical abortion even if they had not taken chemical abortion drugs. FDA Br. 10–11; Danco Br. 12-13. But the Article III "traceability standard is much lower than is the standard for proximate cause." *Jackson v. City of Dallas*, No. 3:20-CV-00967-M, 2021 WL 3406728, at *2 (N.D. Tex. Aug. 4, 2021) (citations omitted). Indeed, "an indirect causal relationship will suffice, so long as there is a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant." *Id.* (cleaned up). Plaintiffs' injuries are more than fairly traceable to the FDA's actions: the FDA approved chemical abortion drugs and removed basic safeguards; many women suffered adverse events that they would not have suffered but for the FDA's approval of these drugs and removal of necessary safeguards; and these women foreseeably ended up in Plaintiff doctors' care.

The likelihood of these complications ensures that Plaintiff doctors will inevitably need to treat women suffering from incomplete chemical abortions, adding patients to emergency rooms who would otherwise not be there if the FDA had rejected these drugs and preserved basic safeguards. Being forced to perform or participate in elective abortions is an unwanted effect on doctors cognizable under Article III. *Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525, at *12 (N.D. Tex. Aug. 23, 2022).

While the FDA callously calls such emergency procedures "one-off incidents" (as if this is relevant to any legal analysis), FDA Br. 11, they also cause Plaintiffs to feel complicit in completing an elective abortion, causing them emotional and spiritual distress. App. 085–86. The FDA says this emotional harm too is pure speculation and that "no complaining physician alleges that he or she has ever been forced to complete an unfinished elective abortion." FDA Br. 12. But Plaintiffs submitted declarations from three doctors asserting just such an injury. *See* App. 886 (needed to "perform[] a dilation and curettage procedure"); 085–86

(required "to perform a suction aspiration to resolve [patient's] complication."); 195–96 (left with "no choice but to perform an emergency D&C" despite detecting a fetal heartbeat). The Supreme Court has also recognized that this mental distress, along with Plaintiffs' other actual emotional and psychological harms, App. 085–87, "could suffice for Article III purposes." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2211 & n.7 (2021). And since *Roe v. Wade*, Congress has legislated to prevent physicians from being pressured to abort. *See* 42 U.S.C. § 300a-7.

The FDA additionally claims that Plaintiffs' "declarations nowhere allege facts plausibly showing that such one-off incidents interfere with Plaintiffs' practices or with the treatment of other patients." FDA Br. 11. But again, Plaintiffs submitted a directly on-point declaration. *See* App. 196 (treating a woman for complications required doctor "to call in a back-up physician to care for another critically ill patient"). Finally, the FDA asserts that "no Plaintiff or medical association member claims to consult with patients on whether they should take mifepristone." FDA Br. 12–13. Once again, Plaintiffs offered this evidence. App. 195 (patient "expressed to me that she was considering abortion . . . but was unsure").

The FDA implies that the very parties who profit from a dangerous drug—the companies that manufacture the drug and those who prescribe it—comprise the narrow, unlikely pool of potential plaintiffs who can sue the agency over an unlawful approval of that drug. *See* FDA Br. 9. This conflicts with the "strong presumption favoring judicial review of administrative action." *Salinas v. U.S. R.R. Ret. Bd.*, 141 S. Ct. 691, 698 (2021). The FDA also argues that "Plaintiffs' approach to standing would entitle physicians to sue over virtually any FDA action." FDA Br. 13. That argument ignores that the FDA's approach would essentially eliminate any suits over a wrongful drug approval, and it ignores that a plaintiff must not only establish standing but also prove unlawful agency action. Both are satisfied here.

4. Third-party standing

No Defendant argues that Plaintiffs' injured patients lack standing to sue. The FDA does not dispute that Plaintiffs have third-party standing to raise the claims of their patients if Plaintiffs themselves have standing. The FDA also does not dispute that third-party standing exists when, as here, a plaintiff "share[s] a 'close' relationship with third-parties who face an obstacle inhibiting them from bringing the claim on their own behalf." *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583, 589 (5th Cir. 2014) (quoting *Kowalski v. Tesmer*, 543 U.S. 125, 129–30 (2004)). Nor does the FDA dispute that Plaintiff physicians "share a sufficiently close relationship with their patients" and a woman harmed by chemical abortion drugs "faces obvious hindrances" in bringing a timely lawsuit. *Id*. By contrast, only Danco asserts that Plaintiffs have not alleged a close relationship or any obstacle their patients face. Danco Br. 13.

But courts have recognized "the inherent closeness of the doctor-patient relationship" and "a woman's desire to protect her privacy could discourage her from bringing suit." *Pa. Psychiatric Soc'y v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 289–90 (3d Cir. 2002). Indeed, the Supreme Court has observed that courts "have long permitted abortion providers to invoke the rights of their actual or potential patients in challenges to abortion-related regulations." *June Med. Servs. L.L.C. v. Russo*, 140 S. Ct. 2103, 2118 (2020), abrogated on other grounds by *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022); 13A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 3531.9.3 (3d ed. 2022) ("Doctors regularly achieve standing to protect the rights of patients and their own related professional rights."). Thus, in *Jackson Women's Health Org. v. Dobbs*, the Fifth Circuit allowed an abortion facility to pursue claims on behalf of its patients. 945 F.3d 265, 275 (5th Cir. 2019), rev'd and remanded, 142 S. Ct. 2228 (2022); *see also Causeway Med. Suite v. Ieyoub*, 109 F.3d 1096, 1102 (5th Cir. 1997) (finding

physician standing "to assert the claims of those minors who seek abortions by way of a judicial bypass"). If "a regulated party can invoke the right of a third party for the purpose of attacking legislation enacted to protect the third party," *June Med. Servs.*, 140 S. Ct. at 2153 (Alito, J., dissenting), then Plaintiffs can sue on behalf of their injured patients—as they both seek protection from chemical abortion drugs.

5. Zone of interests

Finally, the FDA asserts that Congress has not created a cause of action that encompasses a particular Plaintiff's claim. FDA Br. 15–16. But the zone-of-interests test is not demanding. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014). The "benefit of any doubt" must go to the plaintiff, and such a suit is foreclosed "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 authorized that plaintiff to sue." *Id.* (cleaned up). That "lenient approach" is necessary to preserve the Administrative Procedure Act's (APA) "generous review provisions." *Id.*

Plaintiffs are squarely within the FDCA's zone of interests. When the FDA approves drugs, doctors both prescribe them and treat patients for their effects. Indeed, the FDA does not dispute that patients are within the zone of interests of all federal drug laws. The FDCA's mandates to "protect the public health," Public Law No. 87-781, 76 Stat. 780, "assure the safety, effectiveness, and reliability" of 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), are intended "to ensure that the [FDCA] not be implemented haphazardly," s*ee Bennett v. Spear*, 520 U.S. 154, 176 (1997). Doctors and patients' "claim that they are victims of such a mistake is plainly within the zone of interests that the provision protects"—all the more so for doctors who treat adverse events due to the unlawful approval or deregulation of dangerous drugs. *See id.* at 177.

B. Plaintiffs' claims are properly before the Court.

Plaintiffs timely filed their challenges to the 2000 Approval and 2016 Petition Denial because the statute of limitations was reset when the 2016 Major Changes and the 2021 Petition Response reopened the basic regulatory scheme for chemical abortion drugs and removed necessary safeguards essential to the 2000 Approval and 2016 Petition Denial. In addition, for a host of reasons, Plaintiffs' challenges to the 2000 Approval, 2016 Petition Denial, 2016 Major Changes, and 2019 ANDA Approval satisfy any exhaustion requirements. The 2021 Non-Enforcement Decision remains subject to judicial review. And, as the FDA admits, Plaintiffs' challenge to the 2021 Petition Response is properly before this Court.

1. Reopening

When issuing its 2000 Approval, the FDA included safeguards for women who take chemical abortion drugs. But the FDA eviscerated these safeguards with the 2016 Major Changes and then eliminated one of the few remaining protections with the 2021 Petition Response. *See* App. 073. Without these safeguards, the FDA would not have issued its 2000 Approval. The FDA does not dispute this fact.

The FDA issued the 2016 Major Changes in response to Danco's request to reconsider and revise the terms of the 2000 Approval. App. 616, 627–28. In this express reopening of the 2000 Approval (and the related 2016 Petition Denial), the FDA revised the drug regimen and removed the predicate safeguards that served as the basis for the initial approval. But the FDA still asserts that it "did not reconsider the underlying approval of mifepristone when it modified the REMS in 2016" because the 2016 Major Changes "made *targeted* alterations to the conditions of approval for mifepristone." FDA Br. 19 (emphasis added). Likewise, even though the FDA's 2021 Petition Response authorized abortion-by-mail by eliminating the safeguard of in-person dispensing, the FDA asserts that "[i]n no way did the 2021 petition response reconsider the underlying approval of mifepristone." *Id.*

"The reopener doctrine allows an otherwise untimely challenge to proceed 'where an agency has—either explicitly or implicitly—undertaken to reexamine its former choice.'" *Nat'l Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1017 (D.C. Cir. 2016) (quoting *Nat'l Mining Ass'n v. U.S. Dept. of Interior*, 70 F.3d 1345, 1351 (D.C. Cir. 1995)). Indeed, "the time for seeking review starts anew where the agency reopens an issue." *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008). Defendants do not dispute that the Fifth Circuit recognizes the reopening doctrine. The only question for the Court thus is whether the reopening doctrine applies here.

When applying the reopening doctrine analysis, a court should determine whether the agency "altered its original decision" and thus "reopened the proceeding." *Sendra Corp. v. Magaw*, 111 F.3d 162, 167 (D.C. Cir. 1997); *see also Nat'l Biodiesel Bd.*, 843 F.3d at 1017 (asking whether "the basic regulatory scheme remains unchanged"). When an agency subsequently removes "necessary safeguards" that were essential to an underlying action, that subsequent agency action reopens the underlying action and restarts the statute of limitations to challenge that underlying action. *Sierra Club*, 551 F.3d at 1025–26.

The D.C. Circuit has unequivocally applied the reopening doctrine analysis outside of rulemakings and to adjudications. *See, e.g.*, *Nat'l Biodiesel Bd.*, 843 F.3d at 1012–18 (applying reopening analysis to adjudication); *Sendra Corp.*, 111 F.3d at 166–67 (same). Although the FDA's dilatory citizen petition process historically has deterred challenges to drug approvals, Plaintiffs are unaware of any case in which a court held that the reopening doctrine is inapplicable to adjudications, let alone inapplicable to drug approvals. And for good reason—revising a prior adjudication involves a literal reopening of that prior action. In fact, a supplemental new drug application necessarily reopens a prior approval because the FDA relies on previous safety determinations *and* new information to make the requested changes. *See* App. 024–25; 21 C.F.R. § 314.71(b) ("information required in the supplement is

limited to that needed to support the change"); 21 C.F.R. § 314.54 ("application need contain only that information needed to support the modification(s)").

The 2016 Major Changes reopened and revised the 2000 Approval and 2016 Petition Denial by: (1) increasing the maximum gestational age from 49 days to 70 days; (2) allowing non-doctors to perform chemical abortions; (3) eliminating the requirement for an in-person follow-up examination after a chemical abortion; (4) removing the in-person administration requirement of misoprostol; (5) decreasing mifepristone dose from 600 to 200 mg while increasing misoprostol dose from 400 mcg to 800 mcg; (6) changing the administration of misoprostol from vaginal to buccal; (7) allowing administration of misoprostol at 24–48 hours instead of 48 hours after mifepristone; (8) adding a repeat 800 mcg buccal dose; and (9) abolishing the requirement for prescribers to report non-fatal adverse events from chemical abortion. App. 627–28. Despite these changes, Danco argues that its supplemental new drug application "did not substantively alter FDA's 2000 Approval." Danco Br. 16. But the FDA changed almost every significant facet of the 2000 Approval's scheme. The "basic regulatory scheme" was dramatically altered, *Nat'l Biodiesel Bd.*, 843 F.3d at 1017, and indeed there were few "targets" remaining. And yet the FDA was not finished.

The 2021 Petition Response reflected the FDA's final determination to remove the in-person dispensing requirement for mifepristone—effectively authorizing mail-order chemical abortions. Without requiring an abortionist to meet with a woman in a clinical setting before prescribing her chemical abortion drugs, there is a dramatically reduced chance that the prescriber can confirm pregnancy and gestational age, discover ectopic pregnancies, and identify a victim of abuse or human trafficking being coerced into having a chemical abortion. As with the 2016 Major Changes, the FDA would not have issued its 2000 Approval without the in-person dispensing requirement because the agency considered it essential to assure

safe use of chemical abortion drugs. The FDA's removal of this "necessary safeguard[]" restarted the statute of limitations. *Sierra Club*, 551 F.3d at 1025–26.

Both the 2016 Major Changes and the 2021 Petition Response removed necessary safeguards essential to the 2000 Approval and 2016 Petition Denial. Thus, *both* the 2016 Major Changes and the 2021 Petition Response *reopened* the 2000 Approval and 2016 Petition Denial, each time *resetting* the statute of limitations to sue the FDA over the initial approval. Under 21 C.F.R. § 10.45(b), the 2016 Major Changes became a final agency action subject to judicial review only upon issuance of the 2021 Petition Response. As a result, Plaintiffs are well within the six-year statute of limitations to challenge the 2000 Approval.

2. Administrative exhaustion of claims

Defendants also argue some of Plaintiffs' challenges are "unexhausted." FDA Br. 16–18; Danco Br. 17, 22. Once again, Defendants' protestations fail.

a) The Administrative Procedure Act

Neither the APA nor Supreme Court precedent interpreting it requires additional exhaustion of administrative remedies in this case. The APA directs parties to exhaust administrative remedies *only if* required by statute or an agency rule that "provides that the action meanwhile is inoperative, for an appeal to superior agency authority." 5 U.S.C. § 704; *see also Darby v. Cisneros*, 509 U.S. 137, 154 (1993) (holding that exhaustion is 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." (emphasis in original)).[1] No such statute or FDA rule exists. And no cherry-picked, out-of-context quote from *Darby* or atextual decisions from other circuits change this analysis. But

[1] If a person voluntarily starts an administrative appeal, then the Supreme Court has required exhaustion before suing. *See, e.g.*, *Interstate Com. Comm'n v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 284–85 (1987). This is exactly what Plaintiffs did while patiently waiting for the FDA to respond to their petitions.

the Court need not resolve this issue here. Widely recognized exceptions to exhaustion requirements apply to Plaintiffs' challenges.

b) Exceptions to exhaustion

Courts do not require exhaustion when: (1) an "agency action [] is patently in excess of the agency's authority"; (2) "it would have been futile to raise before the agency"; or (3) the agency already "considered the issue." *Wash. Ass'n for Television & Child. v. FCC*, 712 F.2d 677, 682 (D.C. Cir. 1983) (cleaned up); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 30–31 (D.D.C. 1997) (not requiring exhaustion when forcing plaintiffs to wait for the FDA to respond would continue irreparable harm). The Fifth Circuit has held that "there is a judicial exception to exhaustion when exhaustion would be futile or inadequate." *Gardner v. Sch. Bd. Caddo Par.*, 958 F.2d 108, 112 (5th Cir. 1992). This "exception to the exhaustion requirement" is available "when the plaintiff demonstrates that 'it would be futile to comply with the administrative procedures because it is clear that the claim will be rejected.'" *DCP Farms v. Yeutter*, 957 F.2d 1183, 1189 (5th Cir. 1992) (cleaned up).

First, as discussed above, the 2000 Approval is properly before this Court because the FDA's 2016 Major Changes and 2021 Petition Response reopened that initial approval and reset the statute of limitations, thus satisfying any exhaustion requirement. But it would have also been futile for Plaintiffs to include a challenge to the 2000 Approval in their 2019 Citizen Petition because the 2016 Petition Denial made "clear that the claim will be rejected." *See id.*

Second, Plaintiffs would be excused from any exhaustion requirement on their claim that the FDA's action violated longstanding federal criminal statutes because the agency's violation of these laws is patent and raising this claim with the FDA would have been futile. As discussed in Section IIC, the FDA's actions violate the plain terms of these statutes. Any citizen petition would also be an exercise in futility. Given that the FDA has twice rejected Plaintiffs' legal and scientific

arguments, it would be "clearly useless" to raise this additional claim in another petition. *See Tesoro Refin. & Mktg. Co. v. FERC*, 552 F.3d 868, 874 (D.C. Cir. 2009) (futility applies when exhaustion would be "clearly useless" and "it is certain that [a] claim will be denied"). Indeed, after Plaintiffs filed this lawsuit, the FDA and the U.S. Department of Justice have both considered and rejected Plaintiffs' claim.[2]

Third, Plaintiffs have asked the Court to withdraw or suspend the 2019 ANDA Approval because it relied on the unlawful 2000 Approval and 2016 Major Changes, thereby lacking the requisite showing of safety and effectiveness. Pls. Br. 21–23. Given the FDA's 2016 Petition Denial and 2021 Petition Response, the FDA certainly would deny any citizen petition that Plaintiffs were to file in challenging the 2019 ANDA Approval. It thus would be futile to file a petition with the FDA.

c) 2021 Non-Enforcement Decision

The FDA does not argue that Plaintiffs' challenge to the 2021 Non-Enforcement Decision is unexhausted. Instead, the FDA asserts that this "challenge would be foreclosed under *Heckler v. Cheney*" and is also "moot." FDA Br. 20. But the presumption that non-enforcement policies are committed to agency discretion by law does not apply "to agency actions that qualify as rules under 5 U.S.C. § 551(4)." *Texas v. Biden*, 20 F.4th 928, 985 (5th Cir. 2021). And the 2021 Non-Enforcement Decision expires only at the end of the COVID-19 Public Health Emergency. App. 715. The FDA has submitted nothing that shows otherwise.

II. Plaintiffs have a substantial likelihood of success on the merits.

The APA directs a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory

[2] App. 890, Memorandum from FDA on Review of Supplemental Drug Applications Proposing Modifications to the Mifepristone REMS Program (Dec. 23, 2022); Ex. 1C to FDA Br.

jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). The FDA's actions to approve chemical abortion drugs and remove necessary safeguards for women and girls violated the plain text of federal laws and the agency's own regulations, and thus must be set aside.

A. The FDA violated the requirements of Subpart H.

The FDA issued the 2000 Approval using its accelerated review authority under 21 C.F.R. § 314.500, Subpart H, which applies to "certain new drug products that . . . treat[] serious or life-threatening illnesses." Conceding that pregnancy is not an illness, the FDA argues that the preamble to the Subpart H rule stated that this pathway was also available for drugs that treat "conditions," an undefined term. FDA Br. 26. But the FDA fails to address the legal principle that a preamble cannot override clear regulatory text. *See Cuomo v. Clearing House Ass'n*, 557 U.S. 519, 533 (2009) (invalidating agency interpretation of regulation inconsistent with regulation's text and statute). Nor does the FDA's interpretation get any deference. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("If uncertainty does not exist, there is no plausible reason for deference."). And under canons of interpretation, the FDA's "argument is fatally undermined principally not by what [the regulation] includes but by what it omits." *Env't Integrity Project v. EPA*, 969 F.3d 529, 541 (5th Cir. 2020); *see, e.g.*, 21. C.F.R. § 312.300(a) (FDA drug approval pathway including "disease or condition"). In the end, the FDA is left with two unpersuasive defenses: (1) doubling down on its preamble argument; and (2) asserting the Food and Drug Administration Amendments Act of 2007 (FDAAA) supersedes the 2000 Approval.

The preamble did not expand the scope of Subpart H beyond illnesses to include normal physiological processes such as pregnancy. The FDA fails to specify the preamble text where the agency purportedly "explained that Subpart H was available for serious or life-threatening 'conditions.'" FDA Br. 26. Upon Plaintiffs' review of the FDA-cited Federal Register page, the agency *itself* used "conditions"

once in one paragraph to describe depression and psychoses, but that same paragraph also twice called them "diseases," a term that is an actual synonym for "illnesses." App. 494, 57 Fed. Reg. 58,942, 58,946 (Dec. 11, 1992). If anything, this example reveals why regulatory text must always prevail over imprecise preambles.

In the FDAAA, Congress directed that drugs with elements to assure safe use, which had been previously approved under Subpart H, were deemed to have in effect an approved risk evaluation and mitigation strategy (REMS). Under the FDAAA, mifepristone, like many other approved drugs, was deemed to have in effect a REMS because the FDA had determined that the drug was dangerous for use without restrictions. In approving mifepristone under Subpart H, the FDA necessarily determined that the drug could be safely used only if its distribution or use was modified or restricted. The FDAAA simply required that drugs approved under Subpart H needed continued measures in place to mitigate risks.

Remarkably, the FDA contends that the approval of a REMS in 2011 cured any errors in the FDA's initial reliance on its Subpart H authority. FDA Br. 26. But the implementation of a REMS under the FDAAA did not repeal or supplant the accelerated approval process under Subpart H. Congress's general reiteration that dangerous drugs should carry a REMS in no way codified the FDA's specific approval of mifepristone. And an agency must defend its decisions based on its actual contemporaneous grounds for decision, not on post-hoc rationalizations. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909–10 (2020). The mere requirement of a REMS under the FDAAA could not remedy the unlawful approval of chemical abortion drugs as a treatment for a serious or life-threatening illness. Nor did it expand the universe of what could qualify for approval under Subpart H.

B. The FDA violated the requirements of the FDCA.

The FDCA requires that substantial evidence, adequate tests, *and* sufficient information show the safety and effectiveness of a drug "for use under the

conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 312.21 ("Phase 3 studies . . . are intended . . . to provide an adequate basis for physician labeling."); *Glossary*, Weill Cornell Medicine[3] ("In Phase 3 studies, the drug is used the way it would be administered when marketed.").

Plaintiffs established that the clinical investigations for the FDA's 2000 Approval failed to evaluate the conditions of use under the approved label. *See* Pls. Br. 18. In fact, these studies contained crucial safeguards that the FDA omitted from the approved label. *Id*. Similarly, Plaintiffs explained that *none* of the studies on which the FDA relied for its 2016 Major Changes aimed to evaluate the safety and effectiveness of chemical abortion drugs under the proposed labeling. *Id.* at 19. And the agency improperly took a piecemeal approach to evaluating the wholesale changes to the regimen. *Id*. Finally, the 2021 Non-Enforcement Decision and 2021 Petition Response relied on the FDA's admittedly unreliable Adverse Event Reporting System (FAERS) and a handful of inadequate studies. *Id.* at 19–20.

Defendants' response? It's all true. So, they resort to arguing that the FDCA does not require such studies and thus the Court must afford the agency unfettered deference. FDA Br. 21–25; Danco Br. 19–22. But this deference "is not tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act to set aside agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (cleaned up). As then-Judge Garland wrote, the FDA "must cogently explain why it has exercised its discretion in a given manner . . . and that explanation must be sufficient to enable us to conclude that the agency's action was

[3] https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/glossary-faqs-medical-terms-lay-3 (last visited Feb. 23, 2023).

the product of reasoned decisionmaking." *Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C. Cir. 2006) (cleaned up) (rejecting FDA's explanation for new drug approval).

The FDA had multiple opportunities to explain why it deviated from the FDCA's requirements and how it concluded chemical abortion drugs were safe and effective under the labeled conditions of use—despite relying solely on studies that included significant differences from the proposed labeled uses. But the FDA failed to provide a reasoned explanation for each of these actions.

In defending its 2000 Approval, the FDA claimed that clinical trials may be "more restrictive" because "this additional level of caution is exercised until the safety and efficacy of the product is demonstrated." FDA Br. 22–23. That may be true for preliminary studies, but not for the pivotal Phase 3 studies on which the FDA relies to approve a new drug. Otherwise, the FDA would be conducting real-world experiments on unsuspecting women in the general population. The FDCA demands more from the FDA before approving a new drug.

For example, the FDA has argued that an ultrasound "does not ensure *complete accuracy* in dating a pregnancy" and "does not *guarantee* that an existing ectopic pregnancy will be identified." App. 579 (emphasis added). But the FDA has never denied that an ultrasound is the *most accurate* method to determine gestational age and the *best* means to identify ectopic pregnancies. *See* App. 338–41 ("Ultrasound, in addition to providing the best information for gestational age determination . . . can also provide useful diagnostic information regarding a wide variety of pathologies of early pregnancy, including ectopic pregnancies.") (cleaned up). In attempting to comply with the FDCA and recognizing the dangers of chemical abortion drugs, the FDA proposed requiring ultrasounds and other protections used in the clinical investigations. *See* App. 332–35 (discussing FDA's June 2000 proposal and abortion industry's reaction). Just months later, the FDA changed its mind. *Id*. The science had not changed. But the political pressure had.

The FDA thus lacked substantial evidence, adequate tests, and sufficient information to show the safety and effectiveness of chemical abortion drugs under the labeled conditions of use. As a result, the FDCA compelled the FDA to reject the Population Council's application. The FDA's failure to do so was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Defendants do not dispute that the FDA lacked a single study for the 2016 Major Changes that evaluated these changes as a whole or under the labeled conditions of use—and, instead, argue it did not need one, especially given the number of studies cited in its decision. FDA Br. 21–23; Danco Br. 21. But the quality of the studies matters more than their quantity. The FDA also incorrectly asserts that Plaintiffs do not challenge all the studies on which the agency relied. *Compare* FDA Br. 22, *with* Pls. Br. 19. To reiterate, *none* of these studies compared the safety of the changes against the then-current regimen, nor under the labeled conditions of use. App. 891–907, Decl. of Dr. Harrison. Without this comparison, the FDA could not have known whether the 2016 Major Changes were safe.

Finally, the FDA's decision to remove the in-person dispensing requirement in the 2021 Petition Response impermissibly relied on significantly flawed studies and meaningless adverse event reports. Pls. Br. 19–20. Defendants argue that the FDA is allowed to rely on such "imperfect data." FDA Br. 23; Danco Br. 21. But the FDA conceded that "the studies [it] reviewed are not adequate on their own to establish safety of the model of dispensing mifepristone by mail." App. 764. And the FDA admitted that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." *Id.* at 763. Even more troubling, the FDA's reliance on these studies has its obligations under the FDCA backwards: "Despite the limitations of the studies . . . the outcomes of these studies *are not inconsistent with our conclusion* that . . . mifepristone will remain safe." App. 757 (emphasis added). In addition, the FDA incorrectly asserts

that "Plaintiffs offer no explanation for why it was impermissible [for the FDA] to rely on the reported [adverse event] data." FDA Br. 23. This assertion ignores and waives any objection to the substantial shortcomings of the FAERS data that Plaintiffs highlighted in their brief and complaint. *See* Pls. Br. 20; App. 070–72.

C. The FDA's actions violate longstanding federal criminal laws.

All of the FDA's actions at issue authorized the distribution of chemical abortion drugs through means that violate longstanding federal criminal laws. These federal laws explicitly prohibit the distribution of chemical abortion drugs by mail, express company, or common carrier. *See* 18 U.S.C. §§ 1641, 1642.

Defendants assert that the FDA need not (or cannot) "incorporate into its drug approvals purported criminal-law restrictions on modes of transporting drugs." FDA Br. 28; Danco Br. 22. But the FDA's 2000 Approval required and approved a distribution plan for the delivery of chemical abortion drugs by mail, express company, or common carrier.[4] And the FDA's 2021 Non-Enforcement Decision and 2021 Petition Response explicitly authorized mail-order chemical abortions in direct violation of these federal criminal laws. *See, e.g.*, App. 714–15, 734, 763.

The FDA contends that these laws "could not constitutionally have been enforced against the mailing of items for abortions." FDA Br. 28. But no court ever enjoined the application of these laws to the distribution of chemical abortion drugs. The Supreme Court's prior precedent imposed only a balancing test, which the FDA failed to perform. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). Even more to the point, the APA requires federal agencies to follow all laws. *FCC v.*

[4] *See* App. 908–14, 2000 Letter from Danco to FDA at 155 (Jan. 21, 2000) (sending FDA "a comprehensive distribution plan . . . at all points in the supply chain"); App. 514 (FDA letter approving Danco's distribution plan); s*ee also* Ex. 1C to FDA Br at 14 n.18 (conceding that "the FDA's 2000 approval had resulted in the distribution of mifepristone to certified physicians through the mail or by common carrier").

NextWave Pers. Commc'ns Inc., 537 U.S. 293, 300 (2003). And there is no constitutional obstacle to these laws. *Dobbs*, 142 S. Ct. 2228. The FDA's failure to acknowledge and address these laws, at minimum, violated the APA.

The FDA also relies on a failed congressional amendment and two floor statements to claim that the agency could ignore these federal laws forever because "Congress affirmatively endorsed mifepristone's availability and distribution." FDA Br. 29–30. But "repeals by implication are not favored," a court cannot find such repeals to have occurred "unless Congress' intention to repeal is clear and manifest, or the two laws are irreconcilable." *Me. Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1323 (2020) (cleaned up); *see also In re Lively*, 717 F.3d 406, 410 (5th Cir. 2013) ("Repeals by implication are disfavored and will not be presumed unless the legislature's intent is clear and manifest." (cleaned up)).

Finally, Defendants rely on an opinion issued by the U.S. Department of Justice's Office of Legal Counsel, which asserts that these longstanding federal laws did not mean what they say. FDA Br. 28–29; Danco Br. 22. The opinion claims that the proper interpretation of these laws is "narrower than a literal reading might suggest." FDA Br. 29–30; Ex. 1C to FDA Br. This is because Congress supposedly "ratified the federal courts' narrowing construction" of those laws to address only "unlawful abortion" by failing to amend them. *Id*. The FDA agrees with the strained argument that Congress "implicitly adopted" an atextual interpretation of these laws. FDA Br. 29. But congressional acquiescence arguments are of limited persuasive value, and wholly irrelevant where, as here, the prior judicial decisions (from lower federal courts of appeals no less) fail to support the government's "nonliteral" reading. This is all the more true because Congress addressed drugs used for "unlawful abortions" in a separate section of the same statute and chose not to impose that limit on this section. It is thus no surprise that many legal scholars have thoroughly refuted the OLC Memo. *See, e.g.*, Dkt. 56-1; App. 915–28,

Legal Memorandum from The Heritage Foundation on The Justice Department is Wrong: Federal Law Does Prohibit Mailing Abortion Drugs (Feb. 8, 2023).

D. The FDA's 2019 ANDA Approval was unlawful.

Defendants did not respond to the merits of Plaintiffs' challenge to the 2019 ANDA Approval and thus waived any objection. If the Court finds that the 2000 Approval and the 2016 Major Changes lacked the requisite safety and effectiveness showings, it should withdraw the 2019 ANDA Approval. Pls. Br. 21–23.

III. Irreparable harm will continue unless this Court enjoins the FDA.

Without an injunction, these dangerous drugs will result in physical complications, emotional trauma, and death for women. App. 074–80. At least two women died just last year,[5] and more will die without an injunction. *See Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 760 (5th Cir. 2018) ("sufficient risk of irreparable harm" because plaintiff could "suffer additional strokes, heart attacks, and other life-threatening . . . complications"); *Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981) (finding irreparable harm to third-party pregnant women). Plaintiff medical associations and doctors will need to continue to spend their limited time, energy, and resources to deal with the tragic effects of these dangerous drugs that deeply affect them. App. 080–93; *see Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 56, 59 (D.D.C. 2020) ("obstacles that unquestionably make it more difficult for an organization to accomplish its primary mission . . . provide injury for purposes *both* of standing and irreparable harm," especially because the APA "does not allow for recover of monetary damages") (cleaned up); *E.E.O.C. v. Chrysler Corp.*, 733 F.2d 1183, 1186 (6th Cir. 1984) (affirming irreparable harm for plaintiffs' "emotional distress").

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[5] Carole Novielli, *Abortion pill deaths, infant born alive linked to Indiana abortionist suing to end state's pro-life law*, Live Action (Jan. 26, 2023, 8:43 AM), https://www.liveaction.org/news/reported-abortion-pill-deaths-tied-indiana-abortionist/.

Despite stonewalling Plaintiffs for over 16 years, the FDA musters the temerity to assert that "Plaintiffs seek to upend longstanding agency action" for a drug that "has been on the market for more than twenty years." FDA Br. 31. But "[i]f the currently existing status quo itself is causing one of the parties irreparable injury, it is necessary to alter the situation so as to prevent the injury . . . by the issuance of a mandatory injunction." *Canal Auth. of State of Fla. v. Callaway*, 489 F.2d 567, 576 (5th Cir. 1974). The FDA also criticizes Plaintiffs for taking just eleven months to analyze every study that the FDA has relied on, draft a detailed complaint, and submit this motion. *See Optimus Steel, LLC v. U.S. Army Corps of Eng'rs*, 492 F. Supp. 3d 701, 719–20 (E.D. Tex. 2020) (suing after 11 months did not militate against issuance of preliminary injunction); *KeyCorp v. Holland*, No. 3:16-CV-1948-D, 2017 WL 345645, at *6 (N.D. Tex. Jan. 24, 2017) (suing after 10 months was excusable because plaintiff had "a persuasive explanation" and "diligently pursued claim to the extent possible"). Indeed, the only "extreme delay" and "dilatory approach" in this case were the FDA's responses to Plaintiffs' citizen petitions—strategically timed to match significant changes to the regimen. Such agency malfeasance cannot undermine Plaintiffs' claims of irreparable harm.

The substantial threat of harm that these drugs pose cannot be brushed aside as "speculative" or untested in the face of the definitive examples from doctors who have treated many women experiencing serious complications from the drugs. Even so, the FDA dismisses these harms by relying on its previous flawed studies and imploring the Court to defer to the agency's "expertise." FDA Br. 33–38. When robust studies evaluate reliable datasets, however, the evidence shows that many women experience serious adverse events after taking these drugs. App. 391–433. And politicized, pretextual agency actions need not receive any deference. *Dep't of Com. v. New York*, 139 S. Ct. 2551 (2019); *see, e.g.*, Dkt. 55-1, 63-1, 65-1.

IV. The balance of the equities favors relief.

The harms to women and their doctors must outweigh any financial or reliance interests of the chemical abortion drug industry.[6] Despite the oft-repeated myth, childbirth is not more dangerous than abortion. App. 225–38.[7] And many amici filed briefs elaborating on the broad harms of these drugs—including physical, psychological, financial, and societal harms. *See, e.g.*, Dkt. 18-1, 45-1, 48-2, 51-1, 55-1, 58-1, 66-1, 69-2, 82, 84, 89-1, 97-1. In particular, the FDA's argument that society benefits when chemical abortion drugs end the lives of children who may "have lower earnings as adults, poorer health, and an increased likelihood of criminal involvement," Ex. 2 to FDA Br. ¶ 20, ignores the potential contributions of these children. Nor do the Defendants recognize the many resources available to women to support them during their pregnancies and after childbirth.[8]

Women and girls have lost their lives, suffered physical injuries, and experienced emotional trauma because of the FDA's actions. This must stop.

CONCLUSION

The Court should set aside both FDA approvals that allowed mifepristone and misoprostol to be used as chemical abortion drugs. If a sponsor of these drugs submits a new drug application, the FDA must conduct its review in accordance with the FDCA and APA. And any approval must comply with the longstanding federal criminal laws restricting the distribution of these drugs.

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[6] App. 929–38, Hannah Levintova, *The Abortion Pill's Secret Money Men*, Mother Jones, March-April 2023.

[7] *See* also App. 939–55, David C. Reardon & John M. Thorp, *Pregnancy associated dealth in record linkage studies relative to delivery, termination of pregnancy, and natural losses: A systematic review with a narrative syntheseis and meta-anylysis*, 5 SAGE Open Medicine 1 (2017); Dkt. 97-1 at PageID 3694–99.

[8] *See, e.g.*, Michael J. New, *Pregnancy Centers Offer Better Service Than Abortion Facilities, a New Study Shows*, National Review (Feb. 5, 2023, 10:48 PM), https://www.nationalreview.com/corner/pregnancy-centers-offer-better-service-than-abortion-facilities-a-new-study-shows/.

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