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

Plaintiff medical associations and doctors sued the FDA because it has harmed women and girls by approving chemical abortion drugs and removing commonsense safeguards. Plaintiff doctors treat and care for countless victims of this dangerous drug regimen. After stonewalling Plaintiffs for nearly two decades, the FDA admitted what Plaintiffs have been saying all along: the agency never required or relied on a single study that evaluated the safety and effectiveness of these drugs under real-world conditions. Without these vital studies, the harms that these drugs inflict on women are a heartbreaking, yet unsurprising, reality.

The FDA also effectively conceded that its actions violated the plain letter of its regulations and federal laws. No amount of imaginative argumentation can create ambiguity in clearly written text or ignore what the words require: the FDA's accelerated drug approval authority applies only to new drugs that treat "illnesses," but pregnancy is not an illness; the Federal Food, Drug, and Cosmetic Act (FDCA) requires substantial evidence, adequate testing, and sufficient information that show a drug's safety and effectiveness "for use under the conditions prescribed, recommended, or suggested in the proposed labeling," but the FDA never had any such evidence under the labeled conditions; and longstanding federal criminal laws prohibit the distribution of chemical abortion drugs by postal mail, common carrier, or express service, but the FDA approved openly non-compliant distribution plans.

Given these dispositive concessions, the FDA spends most of its brief retreating to procedural arguments. But they are fruitless. Binding judicial precedent—and indeed, the FDA's own declarations—support each Plaintiff's standing. The FDA's actions have repeatedly reopened and revised the conditions that served as the basis for the agency's 2000 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 profits that the abortion industry may lose. Chemical abortions do not improve health outcomes and often worsen them. Pls.' App. 225–38, 398–488 (App.). And the public interest in protecting the health of women must also trump the Biden administration's shocking argument that chemical abortion benefits society because it eradicates children who may "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 prioritizes politics over science, 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

Plaintiffs meet the requirements for a prompt preliminary injunction.

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 cases concede, "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). Because of 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). For decades, these associations have been diverting crucial resources to

challenge the FDA's actions to legalize and deregulate dangerous chemical abortion drugs. App. 091–93. They have been forced to divert "time, energy, and resources" away from their medical mission in order to "conduct[] their own studies and analyses of the available data" on chemical abortion. *Id.* 091. Plaintiffs engaged in these activities in response to the FDA's approval of chemical abortion drugs—long before the FDA gutted its adverse event reporting requirements—and in response to its removal of necessary safeguards.

The FDA says that Plaintiffs must "identify" an "Article III injury that their alleged diversion of resources is necessary to avoid." FDA Br. at 14. But an organization suffers an Article III injury, where, as here, its ability to pursue its mission is "perceptibly impaired" because of a "significant" diversion of "resources to . . . counteract the defendant's [conduct]." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); 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 FDA also faults Plaintiffs for not identifying specific forgone projects. FDA Br. At 15. 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 [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 the Plaintiffs are "correct on the merits" of their claims, including their organizational injuries. *Texas v. Equal Emp. Opportunity Comm'n*, 933 F.3d 433, 447 (5th Cir. 2019)

The FDA also labels Plaintiffs' injuries as "self-inflicted." FDA Br. at 14. Quite the contrary, the FDA itself has inflicted the injuries on Plaintiffs. Indeed, 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 to their petitions. They have also 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.

2. Associational standing

Plaintiff medical organizations also have associational standing to bring claims 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). The FDA never disputes that protecting women from dangerous chemical abortion

drugs is germane to the organizational Plaintiffs' purpose. Nor does the FDA dispute that, if doctors have standing to sue on their own behalf, then they also have standing to sue on behalf of their patients or that medical associations can sue on behalf of their members and their members' patients. FDA Br. at 13–14. Instead, the FDA argues only that the physician members lack standing.

The FDA is wrong. And, as shown below, Plaintiffs also have standing to sue on behalf of themselves and their patients. Pls. Br. at 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. at 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.*, FDA Ex. 2, ¶¶ 17, 21, 50, 59; Ex. 4 to FDA Br., Kieltyka Decl. ¶ 37.

In fact, the FDA concedes that Plaintiffs' declarations have shown that chemical abortion drugs have *already* harmed Plaintiffs. *See* FDA Br. at 11 (acknowledging the "existence of adverse events" and "incidents" from these drugs among Plaintiff doctors' patients and their medical practices).

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).

Nevertheless, the FDA challenges the proximity of the causal link between the FDA's actions and Plaintiffs' injuries, claiming that Plaintiffs' patients could still have been hurt from childbirth, pregnancy, or surgical abortion even if they had not taken chemical abortion drugs. FDA Br. 10–11. 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), aff'd, No. 21-10888, 2022 WL 2156831 (5th Cir. June 15, 2022) (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 dangerous chemical abortion drugs and removed basic safeguards; many women suffer serious adverse events; and these women end up in Plaintiff doctors' care.

The statistical reality of these adverse events, App. 398–420, and Plaintiffs' inability to avoid the burdens of treating women experiencing complications underscore the Biden administration's impermissible attempt to compel doctors to complete elective chemical abortions under the 1986 Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd. The likelihood of complications ensures that Plaintiff doctors will inevitably have to treat women suffering from incomplete chemical abortions, adding patients to emergency rooms who would otherwise not be there if the FDA had not approved these drugs and then removed 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. at 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. at 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 also 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. at 11. But the FDA again ignores a directly on-point declaration. *See* App. 196 (treating a woman for complication 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, the FDA misses this testimony. *See* 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—(1) the companies that manufacture the drug and (2) the doctors who prescribe it—comprise the narrow and unlikely universe of potential plaintiffs who can sue the agency over an unlawful approval of that drug. *See* FDA Br. at 9. This is contrary to 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. at 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

The FDA does not dispute that, if Plaintiffs have standing, then Plaintiffs also have third-party standing to raise the claims of their patients. As shown above, 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*.

The Supreme Court has observed that federal 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 clinic 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 certainly bring a lawsuit on behalf of their

injured patients. Indeed, they both share the common interest in ensuring that the FDA protects the American public from dangerous chemical abortion drugs.

5. Zone of interests

In one last attempt to evade this Court's review, the FDA asserts that Congress has not created a cause of action that "encompasses a particular plaintiff's claim." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014). But the zone-of-interests test is not demanding. 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 APA's "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." *See Bennett v. Spear*, 520 U.S. 154, 176 (1997). "Petitioners' claim that they are victims of such a mistake is plainly within the zone of interests that the provision protects"—considerations of specific import to 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 that were 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 Laboratories, LLC'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 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. at 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 law and the facts belie the FDA's contentions.

"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). The FDA does not dispute that the Fifth Circuit recognizes the well-established reopening doctrine. FDA Br. at 19 (citing *Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021)). The only question for the Court 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 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). And for good reason—revising a prior adjudication involves a literal reopening of that prior action. The FDA's supplemental new drug approval process follows a similar process as it both relies on and revises the prior approval. *See* App. 024–25; 21 C.F.R. § 314.71(b) ("the 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) of the listed drug").

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. 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 prior to 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 that were 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

The FDA also argues some of Plaintiffs' challenges are "unexhausted." FDA Br. at 16–18. Once again, the FDA's protestations fail.

a) The APA and Supreme Court precedent

Neither the APA nor the Supreme Court requires exhaustion of administrative remedies. 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) (emphasis in original) (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.")[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 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). The Fifth Circuit has held that "there is a judicial exception to exhaustion when exhaustion would be

[1] If a person voluntarily initiates an administrative appeal, then the Court has required exhaustion prior to filing a lawsuit. *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.

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). Given these exceptions, Plaintiffs need not exhaust certain claims.

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. Federal agencies must comply with federal laws, and no party need remind any agency of such an obligation. *See FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003). Any citizen petition would also be an exercise in futility because, since Plaintiffs filed this lawsuit, the FDA and the U.S. Department of Justice have both considered and rejected Plaintiffs' position.[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

[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., Mem. Op. from the U.S. Dept. of Just. on the Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions to the General Counsel USPS (Dec. 23, 2022).

Changes, thereby lacking the requisite showing of safety and effectiveness. Pls. Br. at 21–23. Given the FDA's 2016 Petition Denial and 2021 Petition Response, the FDA would assuredly deny any citizen petition that Plaintiffs were to file in challenging the 2019 ANDA Approval. Futility thus precludes any obligation to file a citizen petition before challenging the 2019 ANDA Approval.

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. at 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 at 985. 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 the agency has revoked this action.

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

The FDA's actions to approve and deregulate chemical abortion drugs violated the plain text of federal laws and the agency's regulations. No amount of imagination can redefine the relevant words or create confusion on what they mean.

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 illness, the FDA argues that the preamble to the Subpart H rule stated that this pathway was also available for drugs that treat "conditions," a term that FDA fails to define. FDA Br. at 26. But the FDA has no answer for 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) (holding a court should not afford deference to agency interpretation unless regulation is genuinely ambiguous). 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.

Contrary to the FDA's assertion, the preamble did not expand the scope of Subpart H beyond illnesses to include normal physiological processes such as pregnancy. The FDA fails to provide the specific preamble text where the agency purportedly "explained that Subpart H was available for serious or life-threatening 'conditions.'" FDA Br. at 26. Based on 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 less precise preamble language.

When Congress enacted the FDAAA, it 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 such drugs, which had been granted accelerated approval with required safety restrictions, needed continued measures in place to mitigate risks.

Remarkably, the FDA contends that the implementation and approval of a REMS in 2011 cured the errors in the FDA's initial improper reliance on its Subpart H authority. This argument disregards that 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 improper 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 thereof." 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.").

[3] https://research.weill.cornell.edu/compliance/human-subjects-research/institutional-review-board/glossary-faqs-medical-terms-lay-3 (last visited Feb. 9, 2023).

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. at 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.

The FDA's response? It's all true. So, the agency resorts to arguing that the FDCA does not require such studies and thus the Court must afford the agency unfettered deference. FDA Br. at 21–25. But even "[d]eferring to an agency's exercise of its discretion . . . 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). "To enable [the court] to fulfill [its] duty, an agency 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 the product of reasoned decisionmaking." *Id.* (cleaned up) (disagreeing with FDA's scientific conclusions).

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. at 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. The FDA otherwise would be experimenting on unsuspecting women in the real world. Indeed, the FDCA demands more from the agency prior to approving a new drug. The FDA has also 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 an ultrasound is the *most accurate* method to determine gestational age and the *best* means to identify ectopic pregnancies.[4] The mother's health and safety depends on the accuracy of these assessments. App. 044–45. The FDA thus lacked substantial evidence, adequate tests, and sufficient information that showed 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 new drug application. The FDA's failure to do so was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

The FDA does not dispute that it lacked a single study for the 2016 Major Changes that evaluated these interrelated changes as a whole or under the labeled conditions of use—and, instead, argues it did not need one, especially in light of the number of studies it cited in its decision. FDA Br. at 21–23. But the quality of the studies matters more than their quantity.[5] The FDCA required the FDA to compare

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[4] *See, e.g.*, App. 337–41; App 891–895, Committee Opinion, ACOG, Methods for Estimating the Due Date (May 2007); App. 896–902, Tommaso Bignardi et al., *Is Ultrasound the New Gold Standard for the Diagnosis of Ectopic Pregnancy?*, 29 Seminars in Ultrasound, CT and MRI, no. 2, Apr. 2008, at 114.

[5] The FDA incorrectly asserts that Plaintiffs do not challenge all of the studies on which the agency relied. *Compare* FDA Br. at 22, *with* Pls. Br. at 19.

the safety profile of the proposed sweeping changes against the current regimen. Without this comparison, the FDA could not have possibly known if the 2016 Major Changes were safe. The agency again thus lacked substantial evidence, adequate tests, and sufficient information showing safety and effectiveness. And again, the FDCA required the FDA to deny Danco's supplemental new drug application.

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. at 19–20. The FDA argues that it is allowed to rely on such "imperfect data." FDA Br. at 23. But the 2021 Petition Response's reliance on these studies has the FDA's 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). Moreover, 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. at 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. at 20; App. 070–72.

If the Court does not compel the FDA to comply with the FDCA, the agency will continue to use flawed studies in pursuit of a politically driven abortion agenda.

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. None of the FDA's arguments overcome the plain meaning and application of these laws.

The FDA asserts that it need not "incorporate into its drug approvals purported criminal-law restrictions on modes of transporting drugs." FDA Br. at 28.

But the FDA does not dispute that its 2000 Approval specifically required a distribution plan that included the delivery of chemical abortion drugs by mail, express company, or common carrier.[6] Nor can the FDA dispute that its 2021 Non-Enforcement Decision and 2021 Petition Response authorized mail-order chemical abortions in direct violation of these federal criminal laws. *See, e.g.*, App. 714–15.

The FDA contends that these laws "could not constitutionally have been enforced against the mailing of items for abortions." FDA Br. at 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 act in accordance with any law, 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 the Supreme Court has warned that "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

[6] *See* App. 036; App. 903–909, 2000 Letter from Danco to FDA at 155 (Jan. 21, 2000) (sending FDA "a comprehensive distribution plan . . . at all points in the supply chain"); 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").

disfavored and will not be presumed unless the legislature's intent is clear and manifest." (cleaned up)).

Finally, the FDA relies on a memorandum issued by the U.S. Department of Justice's Office of Legal Counsel after the filing of this lawsuit, which asserts that these longstanding federal laws did not mean what they say. The memorandum 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. at 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 especially true given that 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 not surprising that many legal scholars have thoroughly refuted the OLC Memo.[7] Regardless, the Court owes no deference to the OLC Memo. *See Trump v. Vance*, 941 F.3d 631, 645 (2d. Cir. 2019), *aff'd and remanded*, 140 S. Ct. 2412 (2020) (quoting *Pub. Citizen v. Burke*, 843 F.2d 1473, 1478 (D.C. Cir. 1988)).

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

The FDA 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

[7] *See, e.g.,* Ed Whelan, *Unreliable OLC Opinion on Mailing of Abortion Drugs—Part 2*, National Review (Jan. 5, 2023), https://www.nationalreview.com/bench-memos/unreliable-olc-opinion-on-mailing-of-abortion-drugs-part-2/; App. 910–923, Legal Memorandum from The Heritage Foundation on The Justice Department is Wrong: Federal Law Does Prohibit Mailing Abortion Drugs (Feb. 8, 2023).

Approval and the 2016 Major Changes lacked the requisite safety and effectiveness showings, it should withdraw the 2019 ANDA Approval. Pls. Br. at 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[8] and more will die without an injunction. *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 760 (5th Cir. 2018) (finding "sufficient risk of irreparable harm" because plaintiff could "suffer additional strokes, heart attacks, and other life-threatening . . . complications"). Plaintiff doctors and medical associations will need to continue to spend their limited time, energy, and resources to deal with the tragic effects of these dangerous drugs. *Id.* at 080–93.

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. at 31. The FDA then criticizes Plaintiffs for taking just eleven months to analyze every study that the FDA has relied on, draft a detailed complaint, and submit the instant motion. Indeed, the only "extreme delay" and "dilatory approach" in this case was the FDA's response to Plaintiffs' citizen petitions—both of which the agency timed to match significant changes to the chemical abortion 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

[8] Carole Noviell, *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/.

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. at 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.[9] And the Court does not need to afford its typical deference to undisputedly political agency actions. *See Dep't of Com. v. New York*, 139 S. Ct. 2551 (2019).

IV. The balance of the equities favors relief.

Plaintiffs have shown a strong likelihood of success on the merits. There is a strong public interest "in having governmental agencies abide by the federal laws that govern their existence and operations." *Texas v. Biden*, 10 F.4th 538, 559 (5th Cir. 2021). And "[t]here is generally no public interest in the perpetuation of unlawful agency action." *Id.* at 560 (cleaned up). The "public interest weighs strongly in favor of preventing unsafe drugs from entering the market." *Hill Dermaceuticals, Inc. v. FDA*, 524 F. Supp. 2d 5, 12 (D.D.C. 2007).

The FDA failed to comply with the plain terms of its own regulations, the FDCA's strict safety requirements, and longstanding federal criminal laws when approving unsafe chemical abortion drugs and removing commonsense protections—irreparably injuring Plaintiffs and their patients. These harms must outweigh any financial or reliance interests of the chemical abortion drug industry. Despite the oft-repeated myth, childbirth is not more dangerous than abortion. App. 225–38.[10] And Plaintiffs expect that many amici will file briefs elaborating on the

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[9] *See also* App. 924–940, Christina A. Cirucci, *Self-Managed Medication Abortion: Implications for Clinical Practice*, Lincare Quarterly (Dec. 12, 2022) (discussing the findings, data, and weaknesses of studies on which FDA relied).

[10] *See* also App. 941–957, David C. Reardon & John M. Thorp, *Pregnancy associated death in record linkage studies relative to delivery, termination of pregnancy, and natural losses: A systematic review with a narrative syntheseis and meta-analysis*, 5 SAGE Open Medicine 1 (2017) ("[Abortion] associated mortality rates are higher

broad harms of these drugs—including physical, psychological, financial, and societal harms. In particular, the FDA's appalling 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 achievements and public contributions of these children.[11] Nor does the FDA recognize the many medical, financial, and educational resources available to women to support them during their pregnancies and after childbirth.[12]

Women and girls have lost their lives, suffered physical injuries, and experienced emotional trauma because of the FDA's unlawful approval of chemical abortion drugs. This must stop. The public interest so insists.

CONCLUSION

Plaintiffs request that the Court grant their motion for preliminary injunction in full. The Court should withdraw 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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than birth associated mortality during the first 180 days and remains higher for six or more years.").

[11] *See, e.g.*, Cerith Gardiner, *6 Celebrities who were nearly aborted*, Aleteia (July 11, 2022), https://aleteia.org/2022/07/11/6-celebrities-who-were-nearly-aborted/.

[12] *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/.

Respectfully submitted February 10, 2023.

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