No. 23-10362

# In the United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,

*Plaintiffs-Appellees,*

v.

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

*Defendants-Appellants,*

and

DANCO LABORATORIES, LLC,

*Intervenor-Appellant.*

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division, Case No. 2:22-cv-00223-Z, Judge Matthew J. Kacsmaryk

**INTERVENOR-APPELLANT'S EMERGENCY MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL AND FOR A TEMPORARY ADMINISTRATIVE STAY PENDING CONSIDERATION OF MOTION**

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## CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.1.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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   American College of Pediatricians

   Christian Medical & Dental Associations

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## INTRODUCTION AND NATURE OF EMERGENCY

The District Court enjoined a 23-year-old approval of a drug FDA has found safe and effective. That decision is directly contrary to longstanding precedent on Article III standing, statute of limitations, exhaustion, and the Administrative Procedure Act. The court's standing conclusions rest on speculative harms and statistical possibilities drawn from an impermissibly "liberal" construction of Plaintiffs' allegations. The court excused multiple limitations periods and exhaustion requirements—bending every rule to reach stale, unexhausted challenges to agency action. On the merits, the court selectively referenced statistical data and second-guessed FDA's scientific judgments to find FDA acted arbitrarily and capriciously—relying in significant part on materials *post-dating* the agency's approvals, and all without the benefit of the administrative record. And the court capped it off by issuing a plainly mandatory injunction poorly cloaked as a prohibitory one. The court's relentlessly one-sided narrative also omits crucial facts: The opinion never mentions the millions of women who have benefitted from the availability of medication abortion or the harms an injunction would wreak on Danco, a one-product company.

The decision below is an extreme outlier: No court has ever "stayed" or "suspended" the longstanding approval of a drug consistently found safe and effective by FDA. The court's mandatory injunction is an unprecedented judicial

assault on a careful regulatory process that has served the public for decades. It should be immediately stayed. Without a stay, the injunction is certain to cause irreparable harm: to women who will lose access to the medication abortion regimen that is the standard of care; to Danco; to the pharmaceutical and biotechnology industries; and to the separation of powers undergirding judicial and regulatory action.

The District Court stayed the injunction for seven days. Danco requests an administrative stay or a stay pending appeal by April 13 at 12:00 p.m. If this Court is inclined to deny the emergency or administrative stay, Danco also requests an administrative stay of at least fourteen days to allow Danco the opportunity to seek emergency relief from the Supreme Court.

## STATEMENT

1. Danco holds the approved New Drug Application (NDA) for Mifeprex (mifepristone) Tablets. Mifeprex is Danco's only product.

Following a lengthy approval process where FDA reviewed extensive data demonstrating Mifeprex's safety and efficacy, and consistent with the recommendation from its outside expert advisors, FDA approved the Mifeprex NDA in 2000 under 21 C.F.R. Part 314 Subpart H (Subpart H) for the medical termination of intrauterine pregnancy through 49 days' pregnancy.

In 2002, some Plaintiffs petitioned FDA to revoke Mifeprex's approval. FDA denied that petition in 2016 in a response that meticulously reviewed the meaningful therapeutic benefit medical abortion provides over surgical abortion and thoroughly explained why Mifeprex was safe and effective. An independent review by the U.S. Government Accountability Office (GAO) confirmed that FDA's approval and oversight processes for Mifeprex were consistent with its processes for other Subpart H drugs. U.S. Gov't Accountability Off., GAO-08-751, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf.

In 2008, Danco submitted a risk evaluation and mitigation strategy (REMS) pursuant to 21 U.S.C. § 355-1(a)(1), which FDA approved in June 2011. ECF No. 1-30 at 2.[1] Mifepristone's approval has been pursuant to the approved REMS since then.

In March 2016, FDA approved some changes to Mifeprex's indication and dosing regimen after reviewing substantial data demonstrating Mifeprex continued to be safe and effective under the revised conditions. ECF No. 1-32 at 1; ECF No. 1-33 at 7-19. GAO again found this approval process followed FDA's standard procedures. U.S. Gov't Accountability Off., GAO-18-292, Food and Drug

[1] Unless otherwise specified, ECF references are to the District Court docket, No. 2:22-cv-00223-Z (N.D. Tex.). ECF page numbers reference the blue ECF headers.

Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts (Mar. 2018), https://www.gao.gov/assets/gao-18-292.pdf.

In 2019, Plaintiffs petitioned FDA to rescind the 2016 changes. They did not ask FDA to rescind the 2000 Mifeprex approval. Again, FDA's denial thoroughly addressed Plaintiffs' concerns, assertions, and sources.

In April 2021, after reviewing substantial supporting evidence, FDA temporarily suspended the in-person dispensing requirement during the COVID-19 pandemic, explaining that it would exercise enforcement discretion to allow dispensing of mifepristone through the mail or mail-order pharmacies.

2. In November 2022, Plaintiffs filed suit challenging FDA's actions regarding the 2000 approval, 2002 petition denial, 2016 changes, 2019 generic approval, 2019 petition denial, and 2021 non-enforcement decision under the Administrative Procedure Act (APA). Plaintiffs' claims are based on the Federal Food, Drug, and Cosmetic Act (FDCA), the Comstock Act, the Pediatric Research Equity Act of 2003 (PREA), and FDA's regulations. ECF No. 1. Plaintiffs sought preliminary and permanent injunctive relief.

FDA approved a modified mifepristone REMS on January 3, 2023, which superseded the 2021 non-enforcement decision by lifting the in-person dispensing requirement. Plaintiffs have not challenged this action.

All parties supported consolidating Plaintiffs' preliminary injunction motion with a merits proceeding on the full administrative record, an essential part of APA review. ECF Nos. 68, 92, 98. The District Court declined. ECF No. 117. Instead, the court ordered that "FDA's approval of mifepristone is hereby STAYED." Op. 67. The court allowed the parties seven days to obtain emergency relief from this Court. *Id.*

## ARGUMENT

Danco is entitled to a stay pending appeal because (1) Danco is likely to succeed on the merits; (2) Danco will be irreparably injured absent a stay; (3) a stay will not substantially injure other parties; and (4) a stay serves the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009). Factors one and two "are the most critical." *Id*. Where, as here, a "serious legal question is involved" and "the balance of the equities weighs heavily" in favor of a stay, the movant need only show a "substantial case on the merits." *Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir. Unit A June 1981) (per curiam).

### I. DEFENDANTS WILL LIKELY PREVAIL ON APPEAL.

#### A. Plaintiffs Lack Standing.

The District Court's "unusually broad and novel view of standing" is directly contrary to Supreme Court precedent. *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 470 (1982).

1. To start, the court used the wrong standard: It "applie[d] the minimal showing of standing that a plaintiff must show to overcome a motion to dismiss, rather than the 'clear showing' of standing required to maintain a preliminary injunction." *Texas All. for Retired Americans v. Hughs*, 976 F.3d 564, 567 n.1 (5th Cir. 2020) (per curiam); *cf.* Op. 12 ("[A]t the pleading stage, we liberally construe allegations of injury." (cleaned up)). Plaintiffs did not meet the correct standard: Their assertions of injury were internally contradictory, inconsistent with other parts of the record, and do not show that any Plaintiff-physician or Plaintiff-member-physician personally faces an actual and imminent—not statistically possible—risk of concrete and particularized injury. *E.g.*, ECF No. 1-8 at 7-8 (eliminating adverse event reporting requirement is allegedly harmful, but reporting adverse events is "time that should be spent in patient care"); ECF No. 28-1 at 13 (Danco "still required by law" to report adverse events to FDA). Article III demands more.

2. The District Court's associational standing analysis is similarly flawed. *First*, the court found associational standing based on Plaintiff-physicians' "close relationship" with patients prescribed mifepristone by another physician. Op. 10. That is directly contrary to the record. Plaintiff-physicians said they had no such close relationship. *E.g.*, ECF No. 1-10 at 6 ("These physicians must treat women … without an existing relationship with the patient …."); ECF No. 1-4 at 5 ("[E]mergency department doctors do not have a prior relationship with these

patients."). *Second*, the court maintained that Plaintiff-physicians "have no potential conflicts of interest" with these patients, Op. 10, despite Plaintiff-physicians' avowed opposition to abortion, *e.g.*, ECF No. 1-9 at 9 (caring for these patients "harms my conscience rights"); ECF No. 1-8 at 6 (doctor treated patient in procedure that "she did not want to be a part of"). *Third*, the court credited Plaintiff-physicians' assertion that they could not practice "evidence-based medicine" and receive "informed consent" from patients *seeking* medication abortion. Op. 8 (quoting ECF No. 7 at 15). But Plaintiffs averred that they "do not support or practice chemical abortion." ECF No. 1-5 at 11.

In reality, Plaintiff-physicians' alleged injury relied upon a chain of discretionary third-party actions that, at most, makes it statistically possible they could treat a patient for a complication of medication abortion if: some other provider prescribes mifepristone to a patient, the patient experiences a rare side effect or "complication"; that patient might go to an emergency room for follow-up care where a Plaintiff-physician might be on duty and might treat that patient; which might mean the Plaintiff-physician treats a patient who previously had a medication abortion. ECF No. 7 at 14. Standing cannot be based on discretionary, independent actions of third parties, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013), "hypothetical harms," *Louisiana v. Biden*, No. 22-30087, slip op. at 13 (5th Cir. Apr. 5, 2023), or statistical possibilities, *Summers v. Earth Island Inst.*, 555 U.S. 488,

497-498 (2009). Doing so "would make a mockery" of established standing law. *Summers*, 555 U.S. at 498.

The District Court's other associational-standing rationales fare no better. The need to treat patients cannot suffice to confer standing anytime a doctor objects to the underlying cause of a patient's condition. Consider the ramifications: ER doctors could challenge laws easing handgun restrictions that made them "feel complicit" in treating patients injured by gun violence; pediatricians could challenge regulations rescinding air pollution controls that caused them to treat asthmatic children, taking time away from other patients; the list goes on.

3. The District Court's organizational standing analysis is just as wrong. It theorized that FDA's actions forced Plaintiffs to divert resources from their core mission, Op. 12, but Plaintiff-organizations oppose all forms of abortion. Actions to limit abortion access *support* Plaintiff-organizations' purpose and cannot substantiate a diversionary-injury claim. *See Tenth Street Residential Ass'n v. City of Dallas*, 968 F.3d 492, 500 (5th Cir. 2020). Every "diversion" the District Court identified falls into Plaintiff-organizations' "duties and responsibilities." ECF No. 1-4 at 4, 7; ECF No. 1-5 at 5-7. That "radical" approach to organizational standing would "wedge open the courthouse doors to a wide range of plaintiffs … who were previously barred by bedrock standing requirements." *Barber v. Bryant*, 860 F.3d 345, 354 n.7 (5th Cir. 2017) (quotation marks omitted).

4. Plaintiffs have failed to demonstrate "substantial likelihood" of future injury. Their "theory of standing, which relies on a highly attenuated chain of possibilities, does not satisfy the requirement that threatened injury must be certainly impending." *Clapper*, 568 U.S. 410; *accord City of Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983). Across decades of practice from all Plaintiffs and their members, Plaintiffs have come up with only a handful of instances in which they have treated women who experienced *any* complications—let alone serious adverse events—from medication abortion. Such "inherently contextual and episodic" past occurrences cannot provide "standing to obtain prospective relief." *Society of Separationists, Inc. v. Herman*, 959 F.2d 1283, 1286 (5th Cir. 1992). That is particularly true here, where these rare past occurrences are in line with the FDA-approved label's statement that less than 1% of women may have serious adverse events, ECF No. 28-1 at 47, and depend entirely on a series of third-party discretionary actions. "[S]peculation" about future harm "cannot satisfy the requirement" for injunctive relief. *Clapper*, 568 U.S. at 410-411.

### B. Plaintiffs' Challenges To The 2000 Approval And 2021 Non-Enforcement Decision Are Time-Barred And Unexhausted.

1. To the extent Plaintiffs' challenge to the 2000 approval is based on the denial of their 2002 petition, they filed suit more than six years after FDA denied that petition, rendering that claim time-barred. 28 U.S.C. § 2401(a). To the extent that challenge is based on Plaintiffs' 2019 petition, they did not challenge the 2000

approval there, rendering that claim unexhausted. 21 C.F.R. § 10.45(b). Plaintiffs' request for an injunction as to the 2000 approval should have been dismissed on that basis alone. The District Court's contrary reasoning is unpersuasive.

*First*, FDA did not "reopen" the 2000 approval in 2016 or 2021 such that Plaintiffs' challenge to the 2000 approval is timely. Plaintiffs' suit comes more than six years after FDA's 2016 changes. The 2019 petition did not challenge the 2000 approval. And FDA's 2021 denial of that petition did nothing "sufficient to trigger the reopener doctrine." *Nat'l Min. Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1352 (D.C. Cir. 1995). FDA's 2021 announcement that it would not enforce the in-person dispensing requirement did not reopen the 2000 approval either; the 2021 action was not a "sea change" or alteration of "the basic regulatory scheme," *Nat. Res. Def. Council v. EPA*, 571 F.3d 1245, 1266 (D.C. Cir. 2009) (per curiam), nor did it "significantly alter[ ] the stakes of judicial review," *Nat'l Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1017 (D.C. Cir. 2016) (quotation marks omitted). If the 2021 change counts as reopening, any time any agency changed any aspect of an earlier decision or exercised ongoing oversight over a product or project, plaintiffs could challenge *every part of the agency's initial decision*. That would inject destabilizing uncertainty into countless industries. And it is not the law.

*Second*, the District Court concluded that Plaintiffs' challenge to the 2000 approval is timely as a result of equitable tolling—a theory Plaintiffs never invoked

in their briefing. "Equitable tolling applies only in rare and exceptional circumstances," *Teemac v. Henderson*, 298 F.3d 452, 457 (5th Cir. 2002) (quotation marks omitted), when "the litigant establishes" that she diligently pursued her rights and extraordinary circumstances prevented timely filing. *Menominee Indian Tribe of Wisconsin v. United States*, 577 U.S. 250, 255, 257 (2016). There are no extraordinary circumstances here. Plaintiffs had ample notice, time, and resources to sue—they simply failed to do so, even though FDA's delay in adjudicating the 2002 petition *extended the time in which Plaintiffs could file suit*. No case supports using equitable tolling in circumstances like this.

Plaintiffs also failed to diligently pursue their rights in court or before FDA. *See Irwin v. Dep't of Veterans Affs.*, 498 U.S. 89, 96 (1990) (equitable tolling warranted where claimant "actively pursued" "judicial remedies"). Plaintiffs could have—but did not—seek to "compel" FDA to act on their petition. 5 U.S.C. § 706(1). They also did not actively pursue remedies from FDA; *another* group that was not party to the 2002 petition twice "called upon" FDA to respond to the petition. Op. 25 (quoting ECF No. 1-4 at 6). There is no excuse for Plaintiffs' failure to timely file suit.

2. The District Court also found an injunction warranted based on Plaintiffs' challenge to FDA's 2021 statements of enforcement discretion. Plaintiffs never exhausted that claim, *see* 21 C.F.R. § 10.45(b), and any claim based on enforcement

discretion was mooted when, in January 2023, FDA permanently removed the in-person dispensing requirement. *See* Center for Drug Evaluation and Research, Approval Package for NDA 20-687/S-025 (Jan. 3, 2023), https://tinyurl.com/yrdunhdu.

### C. Plaintiffs Lack Any Viable Merits Claims.

#### *1. Plaintiffs' Comstock Act claim is unlikely to succeed.*

The District Court concluded that FDA's 2021 exercise of enforcement discretion likely violated the Comstock Act. That claim is unexhausted and moot. The court thus lacked jurisdiction to issue a preliminary injunction on that basis. *See In re Cigar Ass'n of Am.*, 812 F. App'x 128, 136 (4th Cir. 2020) (per curiam) (challenge to FDA guidance mooted when subsequent agency action "supersede[d]" the guidance); *Theodore Roosevelt Conservation P'ship v. Salazar*, 661 F.3d 66, 79 (D.C. Cir. 2011) (courts cannot invalidate agency policy "superseded by intervening regulatory events").

Regardless, the court's analysis fails on the merits. Its order assumes that FDA was obligated to evaluate the Comstock Act in considering approval conditions for mifepristone. But when all the FDA action occurred, *Roe v. Wade* was governing law making the Comstock Act constitutionally unenforceable. In any event, Plaintiffs never raised this statute to FDA. In the face of that silence, it is unsurprising that FDA did not address an 1873 criminal statute that it is not charged

with interpreting or enforcing. *Nat'l Elec. Mfrs. Ass'n v. U.S. Dep't of Energy*, 654 F.3d 496, 515 (4th Cir. 2011) (agency not obligated to "provide exhaustive, contemporaneous legal arguments to preemptively defend its action").

Nor *could* FDA have invoked the Comstock Act as a basis to deny the 2000 NDA. FDA may consider only seven grounds for refusing to approve an NDA. 21 U.S.C. § 355(d). If none applies, FDA "shall issue an order approving the application." *Id*. Compliance with criminal laws—or any other laws that FDA is not tasked with administering—is not on that list.

In any event, in 2007, Congress affirmatively endorsed mifepristone's availability and distribution without any Comstock-related restrictions. The Food and Drug Administration Amendments Act of 2007 (FDAAA) expressly "deemed" certain drugs originally approved under Subpart H—which included Mifeprex—to have a REMS in effect with the drug's then-existing distribution restrictions. *See* Pub. L. No. 110-85, tit. IX, § 909(b) (codified at 21 U.S.C. § 331 note). The District Court's interpretation strips these Executive and Legislative actions of their effect.

*2. FDA's approval was not arbitrary and capricious.*

The District Court held that FDA should not have approved Mifeprex under Subpart H in 2000. That purported error is certainly not a basis for enjoining mifepristone's approval *today*. FDA's REMS-based approval renders irrelevant any purported error in FDA's earlier reliance on Subpart H. *See Ctr. for Sci. in the Pub.*

*Int. v. Regan*, 727 F.2d 1161, 1165 (D.C. Cir. 1984). On even the court's logic, if FDA "full[y] review[ed]" and reapproved mifepristone as safe and effective under FDA's REMS authority when it made changes to the REMS, as the court said in finding the reopener doctrine applies, then the purported Subpart H error has no effect. Op. 22-23 (quoting ECF No. 1-44 at 7).

The District Court is also wrong that Mifeprex's 2000 approval violated Subpart H because "[p]regnancy is not an '[i]llness.'" Op. 40. Subpart H extends to drug approvals for serious or life-threatening "conditions." 57 Fed. Reg. 58,942, 58,946 (Dec. 11, 1992). FDA did not distinguish between "illness," "disease," or "condition" in promulgating Subpart H. *E.g.*, *id.* at 58,945. Consistent with the FDCA, the agency uses illness, disease, and condition interchangeably in multiple contexts. FDA, Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics 3 (May 2014), https://www.fda.gov/media/86377/download. FDA reasonably interpreted Subpart H in the same way. That interpretation warrants deference under *Kisor v. Wilkie*, 139 S. Ct. 2400, 2412 (2019) (plurality op.). And even Plaintiffs do not dispute that pregnancy can be a serious condition. *See* ECF No. 70-1 at 7-8.

Nor did FDA act arbitrarily and capriciously in concluding that mifepristone qualifies for approval under Subpart H because it carries a "meaningful therapeutic benefit." The District Court lacked *any* administrative record on which to base its

contrary conclusion. *See* Op. 44-47. Even the incomplete preliminary injunction record refutes the court's conclusion that "the clinical trials did not compare chemical abortion with surgical abortion." Op. 45. FDA considered data comparing medical and surgical abortion from multiple clinical trials and reasonably concluded that medical abortion is safer. ECF No. 28-1 at 18, 262-263.

FDA's 2000 NDA approval and 2016 changes were not arbitrary and capricious either. The District Court concluded that FDA's analysis and decisionmaking was "unsound" or incomplete, Op. 50-60—but the District Court *did not even review the administrative record*, despite the parties' agreement to proceed to a merits decision based on that record. *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971) (judicial "review is to be based on the full administrative record"), *abrogated on other grounds by Califano v. Saunders*, 430 U.S. 99 (1977).

In the absence of the full record, the court freely second-guessed FDA's decisionmaking based on its own analysis of the limited record before it, including the court's independent research and sources *post-dating the agency's various approvals*. *See* Op. 55 nn.59, 60; 57 n.61; 7 n.9; 29 n.22; 45 n.37; 47 n.45. It repeatedly drew conclusions about the strength and reasonableness of FDA's decision-making *without seeing the evidence or FDA's analysis.* It analyzed an FDA proposal limiting the distribution of Mifeprex *without seeing the contents of the*

*actual proposal*. Op. 55. And the court rejected FDA's decision not to impose distribution limitations as arbitrary and capricious *without seeing FDA's final explanation of its reasoning.*[2] *Id.*

Even on the limited record before it, the court's decision is wrong for at least three reasons. *First*, FDA did not err in exercising its scientific judgment about what conditions of use should be in the final label based on the underlying clinical trials. Despite supposedly disclaiming any "study match" requirement, Op. 50 n.48, the court held FDA acted arbitrarily and capriciously by approving Mifeprex under conditions that differed from the clinical trials. Op. 49-50, 59-60. FDA regularly requires more limitations in clinical trials than ultimately appear on the label. For good reason: trials are often designed to determine what conditions are, and are not, necessary to include in a label when the drug goes to market. This court's ruling injects instability into the entire pharmaceutical industry, because nothing in the FDCA, FDA regulations, established practice, or common sense limits FDA's discretion in this way.

*Second*, even the limited record shows that FDA evaluated whether mifepristone would be safe for use under the approved label and reasonably

[2] The court reiterates Plaintiffs' misstatement that FDA never studied the effects of mifepristone in individuals under 18. Data submitted in the original approval and 2016 changes included testing in under-18 patients. ECF No. 28-1 at 51, 268. FDA waived the pediatric study requirements for pre-menarchal patients; the requirements for post-menarchal pediatric patients were met. *Id.* at 30.

explained its decision. The court takes issue with FDA's decision to give providers discretion on the method to diagnose ectopic pregnancies and date gestational age, rather than requiring an ultrasound. Op. 51-54. FDA relied on two French clinical trials using those exact conditions. The court acknowledged as much, but rejected those trials because they were smaller than a U.S. clinical trial. Op. 49 n.47. But it is up to the agency—not the Court—to determine whether evidence from a clinical trial is relevant to its decisionmaking. Courts are *not* supposed to cherry-pick evidence and second-guess expert findings when reviewing agency decisions, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), especially ones involving FDA's "scientific expertise." *Serono Lab'ys, Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998). And even the limited record shows FDA repeatedly concluded that Mifeprex was safe under the approved conditions and, in the exercise of its reasoned judgment and expertise, deemed the court's preferred conditions unnecessary. *See, e.g.*, ECF No. 28-1 at 19-21; ECF No. 1-44 at 12-15; ECF No. 1-25 at 3.

*Third*, the court substituted its judgment for FDA's reasoned risk-benefit analysis about Mifeprex's safety and efficacy. The rationale underpinning the court's entire order is that FDA downplayed concerns that mifepristone is unsafe, leading it to approve a drug that will harm women more often than it will help them. Once again, the data and the expert agency say otherwise. The court points to 97

cases where women with ectopic pregnancies took mifepristone out of 5.6 million women over 23 years—a rate of less than 0.0017%. Op. 53; FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary Through 6/30/2022, https://www.fda.gov/media/164331/download. Other data similarly show that the risk of complications and serious adverse effects are likewise comparatively rare. ECF No. 28-1 at 33-37, 52; Goldberg Decl. ¶ 12. And even if these data undercount certain harms to some degree—another assertion belied by the record, and that FDA has repeatedly rejected, ECF No. 1-44 at 21-22—this risk-benefit calculation is FDA's to make. No drug is 100% safe or 100% effective. The expert agency's job is to evaluate this tradeoff. FDA has affirmed time and again that Mifeprex is safe under the listed conditions.

## II. THE EQUITIES OVERWHELMINGLY FAVOR A STAY.

The harm to Danco and the public interest overwhelmingly favor a stay and significantly outweigh any speculative injury to Plaintiffs.

### A. Danco Faces Substantial, Certain, Unrecoverable Harm.

Danco sells one product: Mifeprex. It relies on FDA's approval to sell that product in interstate commerce. By "stay[ing]" or alternatively "suspend[ing]" those FDA actions, the court's order irreparably threatens Danco with certain, unrecoverable harm: If the injunction remains in effect pending appeal and litigation drags on an extended time, Danco may be unable to continue operating. *See* Long

Decl. ¶ 11.[3] Economic harms are indisputably irreparable when the "alleged financial injury threatens the very existence of [the movant's] business." *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (internal quotation marks omitted). The District Court entirely ignored Danco in weighing the equities, abdicating its "duty … to balance the interests of all parties and weigh the damage to each." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009); *see Am. Radio Ass'n v. Mobile S.S. Ass'n*, 483 F.2d 1, 4 (5th Cir. 1973) (court must "balance … harm to all parties").

**B. The Public Interest Favors A Stay.**

1. The public interest overwhelmingly favors a stay. The District Court's contrary analysis rests on a false narrative that does not account for the interests of the vast majority of women for whom mifepristone is safe and effective. More than 99.9% of women who take the drug do not experience any serious adverse event. ECF No. 28-1 at 52. The drug is effective in more than 96% of cases. *Id.* at 33-37. Women choose medication abortion for many reasons based on their individual circumstances, and absent a stay from this Court, many of them will be unable to obtain mifepristone during this appeal even if their individual circumstances make them a better candidate for a medication abortion. Goldberg Decl. ¶¶ 10-11;

[3] It is unclear what precise effect a "stay" would have here; no court has ever stayed (or suspended) a longstanding NDA approval. Either remedy would threaten Danco's existence. *See* Long Decl. ¶¶ 6, 11, 12.

Schreiber Decl. ¶¶ 18-21. Many patients will be pushed to a surgical abortion at a later gestational age given limited availability, or to unapproved regimens with a lower complete success rate and more intense side effects. Goldberg Decl. ¶¶ 13-14; Schreiber Decl. ¶¶ 12, 21-22. Preventing doctors from exercising their medical judgment as to the best course of treatment for particular patients and restricting women's access to the standard of care for medication abortion while appellate review plays out will inflict irreparable physical and psychological harm on large numbers of women. Goldberg Decl. ¶ 15; Schreiber Decl. ¶¶ 19, 21.

Plaintiffs could not identify a single case in which a court intervened and pulled a drug that had "been in use for so long" from the market. Prelim. Inj. Hr'g Tr. 51-52. The court's first-of-its-kind order "set[s] a dangerous precedent for undermining FDA and creating regulatory uncertainty that will impede the development of important new treatments and therapies." *See* Press Release, Biotechnology Innovation Org., New Ruling Out of Texas Sets "Dangerous Precedent for Undermining the FDA" (Apr. 8, 2023), https://www.bio.org/press-release/new-ruling-out-texas-sets-dangerous-precedent-undermining-fda. The injunction also leaves manufacturers, suppliers, and distributors without statutory or regulatory guidance as to the effect of the Order. *See* Long Decl. ¶¶ 9, 12.

2. The public interest also strongly favors a stay given the procedural irregularity underlying the District Court's sweeping order. Without waiting for the

administrative record, the court issued a mandatory injunction upending a decades-old drug approval. The court claimed the "status quo" is the world as it existed more than 23 years ago, Op. 64-65, but there is no reasonable debate that the injunction here would—and was intended to—disrupt the longstanding status quo. In fact, Plaintiffs admitted they sought a mandatory injunction. ECF No. 7 at 23. "Mandatory preliminary relief, which goes well beyond simply maintaining the status quo," "is particularly disfavored." *Martinez v. Mathews*, 544 F.2d 1233, 1243 (5th Cir. 1976). The court never addressed the heightened standard for a mandatory injunction. A stay of the court's order is necessary to "hold things in stasis" pending appeal. *In re Manges*, 29 F.3d 1034, 1040 (5th Cir. 1994) (citation omitted).

A stay that leaves mifepristone on the market pending appeal also serves the public interest because, even if Plaintiffs win on the merits, the appropriate remedy would be *remand without vacatur* to allow FDA to consider and remedy any issue with its decisionmaking that the court identifies. *Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000). A preliminary injunction cannot award a party more relief than would be available on the merits—but that is exactly what the District Court did.

Finally, a stay is warranted given that FDA has been enjoined in 17 States and the District of Columbia from "altering the status quo and rights as it relates to the availability of Mifepristone under the" January 2023 REMS. Order Granting in Part

Plaintiffs' Motion for Preliminary Injunction at 30, *Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. Apr. 7, 2023), ECF No. 80. The public is understandably confused by these two orders, issued the same day. Staying the nationwide injunction that alters the status quo would avoid creating an unnecessary judicial conflict.

### C. Plaintiffs Face No Irreparable Harm From A Stay Pending Appeal.

Plaintiffs' claimed irreparable harm consists of speculative concern about follow-up care from third-party discretionary actions, which rarely occur, and procedural injuries related to FDA's initial approval of Mifeprex under Subpart H. Neither is irreparable harm. *See Google, Inc. v. Hood*, 822 F.3d 212, 228 (5th Cir. 2016) (requiring "imminent, non-speculative irreparable injury"); *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531 (1987) (procedural injury not irreparable). Even if Plaintiffs' purported harms were present in the record or grounded in fact, such small numbers of speculative future injuries pale in comparison to the certain injuries to Danco and the many women who will be unable to obtain medication abortion for the foreseeable future.

Plaintiffs' dilatory actions further undermine any claims of irreparable injury. *See Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) (per curiam) ("party requesting a preliminary injunction must generally show reasonable diligence"). Plaintiffs waited 2,438 days after FDA denied their 2002 petition, and 337 days after FDA

denied their 2019 petition, to file suit. They chose not to seek judicial relief to compel "unreasonably delayed" agency action, *see* 5 U.S.C. § 706(1), or to otherwise negotiate with FDA in the interim, *cf. Optimus Steel, LLC v. U.S. Army Corps of Eng'rs*, 492 F. Supp. 3d 701, 720 (E.D. Tex. 2020). Nor did they seek a temporary restraining order. Plaintiffs even proposed a schedule that would have delayed any merits ruling by several months. *See* ECF No. 68. Plaintiffs cannot now credibly claim irreparable harm from a short stay pending appeal.

## CONCLUSION

The Court should enter an administrative stay and stay the preliminary injunction pending appeal.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the requirements of Federal Rule of Appellate Procedure 27(d) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I further certify that this motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,193 words, according to the count of Microsoft Word.

I further certify that this emergency motion complies with the requirements of Fifth Circuit Rule 27.3 because it was preceded by a telephone call to the Clerk's Office on April 10, 2023 and electronic correspondence to counsel for the Plaintiffs and the Government on April 9, 2023, advising of Danco's intent to file this emergency motion. I further certify that the facts supporting emergency consideration of this motion are true and complete and that this motion is being served at the same time it is being filed.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

*Counsel for Intervenor-Appellant*

## CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2023, I electronically filed the foregoing emergency motion for stay pending appeal with the Clerk of Court by using the appellate CM/ECF system. I further certify that the participants in the case are CM/ECF users and that service will be accomplished by using the appellate CM/ECF system.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

*Counsel for Intervenor-Appellant*

## CERTIFICATE OF CONFERENCE

On April 10, 2023, counsel for Plaintiffs indicated by way of e-mail that they oppose this motion and intend to file a brief in opposition.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

*Counsel for Intervenor-Appellant*