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

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

JESSICA L. ELLSWORTH
CATHERINE E. STETSON
KAITLYN A. GOLDEN
DANIELLE DESAULNIERS STEMPEL
MARLAN GOLDEN
DELIA SCOVILLE
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
jessica.ellsworth@hoganlovells.com

Counsel for Intervenor-Appellant

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INTRODUCTION

Mifepristone has been approved for decades and used safely by over 5 million women. Plaintiffs defend the District Court's unprecedented decision to second-guess FDA's longstanding approval of this drug with rhetoric, instead of precedent or legal principles. For Danco to be likely to succeed on appeal, it must be right on just one of the following: standing; limitations; exhaustion; FDA's obligations under the Food, Drug and Cosmetic Act ("FDCA"); the impropriety of a non-expert judge second-guessing or ignoring FDA's detailed scientific analysis and re-weighing its risk-benefit analysis; the impropriety of ignoring FDA's reasoning; or the impropriety of using a mandatory injunction to negate a longstanding drug approval–all before even reviewing the administrative record.

Plaintiffs' standing arguments conflict with Supreme Court precedent at every stage. Their limitations argument transforms the "reopening" doctrine from an exception to the rule every time an agency adjusts its oversight of a product or project, and their exhaustion argument changes the narrow futility exception into a "didn't feel like it" exception. Plaintiffs' APA merits arguments misrepresent FDA's statutory obligations and openly buck the agency's decades of considered conclusions that mifepristone is safe and effective—allowing a single judge to both freely second-guess an expert agency and dictate a rigid view of FDA approval that every drug on the market would flunk. And their Comstock Act argument would

require agencies to scour the capacious U.S. Code and affirmatively address any statute that might possibly bear on an agency action—even when Congress specifically limited that agency's discretion.

Absent a stay, women across the nation will face serious, unnecessary health risks from the elimination of access to a drug FDA has repeatedly deemed safe and effective and that is the standard of care. The biopharmaceutical industry would be upended by the instability caused by the District Court's approach. The list goes on: the court's order will wreak havoc on States' sovereign interests, the separation-of-powers, the entire healthcare system, and Danco. The Court should grant the stay.

Plaintiffs' last-ditch argument to avoid a stay by claiming the District Court's order is not appealable is a give-away of the weaknesses in the order and their argument. A district court cannot shield its order from appellate review by using the word "stay." Nor did the court here try to. It understood the order was appealable and gave the parties seven days to seek emergency relief from this Court. Op. 67; *Abbott v. Perez*, 138 S. Ct. 2305, 2319 (2018) ("'practical effect' of granting or denying an injunction" governs, not "label"). If there is any doubt, the Court should grant the stay and refer Plaintiffs' motion to the merits panel or enter an administrative stay to allow Appellants to fully oppose Plaintiffs' motion to dismiss.

ARGUMENT

I. DEFENDANTS WILL LIKELY PREVAIL ON APPEAL.

A. Plaintiffs Lack Standing.

To satisfy Article III, "threatened injury must be certainly impending," *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013), meaning "sufficiently imminent and substantial," *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210 (2021). A theory "reli[ant] on a highly attenuated chain of possibilities" or "speculation about 'the unfettered choices made by independent actors not before the court'" does not suffice. *Clapper*, 568 U.S. at 410, 414 n.5. There must be "a real and immediate threat" of future harm to have standing for injunctive relief. *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983). Just as allegations of "past injury" "do[] not suffice," *Summers v. Earth Island Inst.*, 555 U.S. 488, 493-495 (2009), neither does "a statistical probability" that some (unidentified) Plaintiff-physician will treat some (unidentified) patient who visits some (unidentified) hospital for post-medication abortion follow-up care some (unidentified) time in the future. *Id.* at 497.

Plaintiffs do not attempt to show how their vague allegations satisfy these rigorous standards: Because their standing theory relies on a series of links between FDA's regulations and a chain of other people's independent and unpredictable decisions, Plaintiffs just repeat the District Court's false paradigm that past harm

proves a likelihood of future harm, ignoring that *Summers* and *Lyons* expressly reject that.

These failures doom Plaintiffs' associational standing argument. *See Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977) (association members must have standing "in their own right"). Plaintiffs' assertions about an "overwhelm[ed] . . . medical system" and "potential liability" lack footing even in past injury, and a claimed inability to practice "evidence-based medicine" is contradicted by the fact that they do not prescribe mifepristone. Opp'n 10.

Plaintiffs' organizational standing theory amounts to a claim they diverted resources from disagreeing with abortion, to disagree with abortion. Opp'n 9. The only case they cite, *Texas State LULAC v. Elfant*, 52 F.4th 253, 255-256 (5th Cir. 2022), denied organizational standing where plaintiffs made similarly "vague assertions that they diverted resources." And their mention of time spent on citizen petitions contravenes precedent and common sense: Self-inflicted pre-litigation expenses cannot provide organizational standing for injunctive relief. *NAACP v. City of Kyle*, 626 F.3d 233, 236 (5th Cir. 2010). If it were otherwise, organizations could always manufacture standing just by preparing to sue.

Plaintiffs also fundamentally misunderstand third-party standing. To claim third-party standing, Plaintiffs must first establish their own. *Powers v. Ohio*, 499 U.S. 400, 410-411 (1991). As explained, they cannot. Nor do they have standing to

sue on behalf of the tiny fraction of women who may suffer adverse events from medication abortions. Physicians who fundamentally oppose medication abortions and patients who sought medication abortions lack the sort of aligned interests that third-party standing requires; their interests are diametrically opposed. Plaintiffs do not dispute that without aligned interests, no close relationship exists.

B. Plaintiffs' Claims Are Unreviewable.

Plaintiffs do not dispute: (1) Even if FDA reopened the 2000 approval in 2016, Plaintiffs sued more than six years later; (2) the 2019 petition denial cannot plausibly support reopening; and (3) their challenge to the 2021 non-enforcement decision is moot given the 2023 REMS. Mot. 10-12.

Their response to Danco's other arguments speaks volumes.

FDA's 2021 actions did not reopen FDA's 2000 conclusion that mifepristone is safe and effective. FDA in 2021 did not "significantly alter[]" the incentive to seek judicial review or the "stakes" of doing so. *Sierra Club v. EPA*, 551 F.3d 1019, 1025-26 (D.C. Cir. 2008). Plaintiffs had a sufficient incentive to and did challenge the 2000 approval in their 2002 petition. They simply waited too long to sue over FDA's petition denial.

Plaintiffs also are not entitled to equitable tolling. They make no suggestion they meet the doctrine's reasonable-diligence or extraordinary-circumstances requirements. *See Menominee Indian Tribe of Wisconsin v. United States*, 577 U.S.

250, 255, 257 (2016). That FDA did not deny their petition for years was *to Plaintiffs' benefit*; the statute of limitations only started running in 2016. They were not reasonably diligent after that, and no extraordinary circumstances prevented them from suing before March 2022. Plaintiffs could have sued earlier—to compel agency action or to assert the petition had been effectively denied. 5 U.S.C. § 706(1). Equitable tolling is not a substitute for an available statutory remedy.

Plaintiffs' litany of exhaustion excuses is baseless. The cases they cite *declined* to excuse the failure to exhaust, explaining that "exceptions to administrative exhaustion apply only in extraordinary circumstances." *Gulf Restoration Network v. Salazar*, 683 F.3d 158, 176 (5th Cir. 2012) (cleaned up); *see Gardner v. Sch. Bd. Caddo Par.*, 958 F.2d 108, 112 (5th Cir. 1992). A belated challenge to a longstanding drug approval is not such a circumstance.

C. Plaintiffs' Claims Lack Merit.

1. FDA's actions were not arbitrary and capricious.

1. Plaintiffs have no answer—none—to the fact that the initial use of Subpart H for distribution restrictions has no legal significance today. They claim Congress's decision to create a new regulatory framework in 2008 is irrelevant because FDA still had to comply with that authority. Opp'n 19-20. It did. In 2011, FDA exercised its new authority to approve Danco's REMS as the governing distribution restrictions. ECF No. 1-30 at 2. When FDA did so, it transferred

Mifeprex's approval from authorized by 21 U.S.C. § 355 to its new authority under 21 U.S.C. § 355-1. *Id.*; *see also* 240 Members of Congress Br. 11-12. Subpart H is irrelevant to mifepristone's REMS-based approval.

Plaintiffs do not defend the District Court's view that "meaningful therapeutic benefit" can be analyzed based only on clinical trials comparing treatments, because it is wrong. Pharmaceutical Companies, Executives, and Investors Br. 16-18. They point to one article and one comment during FDA's review. Opp'n 18-19. The article finds medical abortion "safe" and "associated with a low level of serious complications." ECF 1-17 at 5, 10. And the commenter concluded that "the U.S. clinical trials confirm the safety and efficacy of mifepristone and misoprostol." ECF No 28-1 at 261.

2. Plaintiffs' remaining FDCA-based arguments are equally flawed. The FDCA impose no rigid matching requirement between clinical trials and labeling or labeling changes. *See* Pharmaceutical Companies, Executives, and Investors Br. 15-16, 18-19. Such a rule would upend the entire system for drug approval, stifle innovation, and delay critical care for patients by effectively precluding *any* drug approval. *Id.* Plaintiffs' bold insistence that FDA "violated" the FDCA by not including an ultrasound requirement cites no statute and ignores FDA's explanation for allowing providers to use their medical judgment. ECF No. 1-28 at 19-21. On adverse events, too, Plaintiffs ignore that FDA eliminated *heightened* nonfatal-

adverse-events reporting based on analysis of sixteen years of data, ECF No. 1-44 at 21, leaving Danco subject to the same adverse-event reporting applicable to every drug manufacturer, ECF No. 28-1 at 13. The District Court disagreed with FDA's scientific judgment rather than analyzing whether it was supported by substantial evidence, the APA standard.

2. There is no Comstock Act violation.

Neither Plaintiffs nor the District Court can point to a single case holding an one agency violated the APA by limiting itself to the issue assigned to it—here, mifepristone's safety and efficacy—and not addressing the potential applicability of a any statute in the U.S. Code that might govern some aspect of a regulated entity's operations. The Comstock Act does not supplant or alter the FDCA's mandate that the agency *only* consider specific factors bearing on a drug's safety and efficacy in making approval decisions. 21 U.S.C. § 355(d) .

FCC v. NextWave Personal Communications, Inc., 537 U.S. 293 (2003) does not obligate FDA to search out and affirmatively address the Comstock Act. The statute there expressly limited actions by *any* "governmental unit"; after *NextWave* asked the agency to comply with it, the Court held the FCC was bound to do so. *Id.* at 300–01 (2003). Comstock is not directed at FDA, Plaintiffs did not direct FDA to Comstock, and FDA routinely approves drugs subject to restrictions under statutes

or regulations FDA does not administer. *See* Former DOJ Officials Amicus Br. 3-8.

Plaintiffs say that the Circuits' uniform interpretation of Comstock and Congress's direction that mifepristone be deemed to have a REMS in place in 2008 do not matter. That is wrong, for the reasons articulated by OLC and because "even under the court's erroneous broad interpretation, the Comstock laws still permit non-in-person distribution of mifepristone under some circumstances." *Id.* at 8-22. Moreover, the APA does not create a roving private-attorney-general commission to second-guess DOJ's criminal-law interpretation any more than it does to second-guess FDA's scientific determinations.

II. THE EQUITIES AND PUBLIC INTEREST STRONGLY SUPPORT A STAY.

Absent a stay, Danco faces substantial, certain, existential economic harm. *See* Long Decl. ¶¶ 6, 11, 12. The District Court ignored this fact. Plaintiffs do not dispute it.

A stay is also in the public interest. Without a stay, women face serious health risks and the denial of access to essential medical care, including both use of mifepristone on-label for medication abortion and use off-label for miscarriage management, to reduce the duration of bleeding during certain serious pregnancy complications, and for maternal health purposes. *See, e.g.*, Medical and Public

Health Societies Br. 20-21.[1] For many women, "medication abortion is by far the safest and most accessible option." *Id.* at 17.

Absent a stay, women will be pushed to more invasive, burdensome, surgical abortions; to an unapproved misoprostol-only regimen that requires follow-up care more frequently and has more side effects; or to carrying unwanted or unviable pregnancies—which itself causes psychological and physical harm. *E.g.*, Physicians for Reproductive Health Br. 17-23; Reproductive Health, Rights, and Justice Organizations Br. 10-19. Neither the District Court nor Plaintiffs accounts for these harms. Yet, FDA's analysis of the data showed that for over 96% of women, medication abortion is a complete treatment, ECF 28-1 at 33-37 (reviewing 20-plus studies), and that for over 99.9%, there would be no serious adverse event, *id.* at 52, 61, 87-90 (reviewing fifteen years of adverse event reports).

The biopharmaceutical industry will also be significantly harmed absent a stay: Under the District Court's "novel, unworkable standards," it is unlikely that *a single drug* currently on the market is approvable. Pharmaceutical Companies, Executives, and Investors Br. 10, 22. The decision will "chill crucial research and development, undermine the viability of investments in this important sector, and

[1] Plaintiffs suggest "off-label use is not at issue." Opp'n 26. Of course it is. Without an approved on-label use, there can be no off-label use. And they misrepresent that FDA rejected miscarriage management as a new indication; the petition denial they cite says no such thing. FDA, Agency Response Letter to ACOG (Jan. 3, 2023), https://perma.cc/24HJ-K6SF.

wreak havoc on drug development and approval generally, causing widespread harm to patients, providers, and the entire pharmaceutical industry." *Id.* at 3, 10-14, 16-18.

The court's order also harms States' sovereign interests and the separation-of-powers. *Dobbs* consciously "returned the issue of abortion to the people's elected representatives." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022). The injunction eviscerates that sovereign authority for States that "wish to protect rather than restrict abortion access," *see* New York et al. Amicus Br. 3, 8; imposes "heightened health and economic costs" on local governments, *see* Local Governments' Br. 1-2; and upsets Congress's decision to assign FDA responsibility for safety and efficacy determinations, which courts review for substantial evidence and with significant deference, *see* 240 Members of Congress Amicus Br. 4-8.

The injunction's consequences will ripple across the entire healthcare system. Medication abortion *reduces* the burdens on our healthcare system; staying or suspending its approval "threaten[s] to overwhelm" those systems, as increased demand for surgical abortion will limit the availability of other critical health care services the same physicians provide, such as pre- and post-natal care, contraceptive care, and cancer screening. New York et al. Br. 12-13; Medical & Public Health Societies Br. 5.

An injunction that causes these harms is not in the public interest for additional reasons that Plaintiffs never dispute: (1) remand *without vacatur* is the remedy in APA cases like this one, precisely to avoid the disruption the injunction order will cause, and (2) mandatory preliminary injunctions are especially disfavored. Mot. 20-21.

That leaves whether Plaintiffs face irreparable harm from a stay pending appeal. They do not. Their opposition spends only 45 words, total, on this issue. Opp'n 28. A doctor's job is to treat patients—regardless of whether the doctor agrees with the patient's choices causing a need for care (smoking, legal (or illegal) drugs, poor nutrition); no Plaintiff-physician factually demonstrated a concrete or imminent *personal* risk of having to treat a patient experiencing an adverse event from mifepristone. And Plaintiffs dilatory actions undermine any claimed irreparable injury from a stay pending appeal.

CONCLUSION

Danco's stay motion should be granted.

Respectfully submitted,

/s/ Jessica L. Ellsworth
JESSICA L. ELLSWORTH
CATHERINE E. STETSON
KAITLYN A. GOLDEN
DANIELLE DESAULNIERS STEMPEL
MARLAN GOLDEN
DELIA SCOVILLE
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004
(202) 637-5600
jessica.ellsworth@hoganlovells.com

Counsel for Intervenor-Appellant

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 2,600 words, according to the count of Microsoft Word.

/s/ Jessica L. Ellsworth
Jessica L. Ellsworth

Counsel for Intervenor-Appellant

CERTIFICATE OF SERVICE

I hereby certify that, on April 12, 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