No. 23-10362

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, Commissioner of Food and Drugs; JANET WOODCOOK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services,

Defendants-Appellants,

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant.

REPLY IN SUPPORT OF EMERGENCY MOTION UNDER CIRCUIT RULE 27.3 FOR A STAY PENDING APPEAL

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INTRODUCTION AND SUMMARY

There is no basis in science or fact for plaintiffs' repeated claims that mifepristone is unsafe when used in the manner approved by FDA. Nor is there any basis in administrative law for the district court's unprecedented overriding of FDA's considered scientific judgment. Plaintiffs' claims of widespread harm from the use of mifepristone are refuted by the reality of mifepristone's safe use for more than two decades. And *plaintiffs'* novel theory of legally cognizable injury to doctors rests on a hypothetical and attenuated series of events that *might* lead women to seek treatment from them for an exceedingly rare adverse event. Their allegations fall far short of establishing standing, let alone irreparable harm from maintaining the status quo pending appeal. Moreover, plaintiffs are unlikely to succeed on the merits of any of their claims. All of their arguments about the Subpart H regulations, the Comstock Act, and the requirements of the FDCA are thoroughly rebutted in the government's stay motion, leaving only plaintiffs' misguided attempts to substitute their views for the science-based conclusions of FDA.

The district court purported (Add.65-66) to be acting in a restrained manner; but there is nothing modest about upending the decades-long status quo by blocking access nationwide to a safe and effective drug. If allowed to take effect, the court's order will cause irreparable harm across the country. The laws of every State allow patients to use mifepristone in some circumstances, reflecting the importance of a drug that millions of women have relied on to safely terminate their pregnancies. States also have preserved access to mifepristone for other purposes, including to help women manage miscarriages. The district court's order would impair the interests of women across the country, supplant the judgments of every State, and arrogate to itself the power that Congress entrusted to FDA to evaluate drug safety.

I. This Court Has Appellate Jurisdiction

Plaintiffs contend (at 7) that this Court lacks appellate jurisdiction to review the district court's order under 28 U.S.C. § 1292(a)(1), which allows immediate appeal of orders that have the practical effect of an injunction. But they cite no case holding that § 705 stays are unappealable, for good reason: An order staying even a

discrete agency action pending judicial review is equivalent to a preliminary injunction. Courts routinely note that the standard for a § 705 stay "is the same as the standard for issuance of a preliminary injunction." *Monumental Task Comm., Inc. v. Foxx*, 157 F. Supp. 3d 573, 586 (E.D. La. 2016), *aff'd sub nom. Monumental Task Comm., Inc. v. Chao*, 678 F. App'x 250 (5th Cir. 2017); *see, e.g.*, *Cronin v. USDA*, 919 F.2d 439, 446 (7th Cir. 1990). And because they are tantamount to preliminary injunctions, § 705 stays are appealable just as preliminary injunctions are. *See Wyoming v. U.S. Dep't of Interior*, 2018 WL 2727031, at *1 (10th Cir. June 4, 2018) ("The district court's 'stay' effectively enjoins enforcement of the Rule."); *see also Abbott v. Perez*, 138 S. Ct. 2305, 2319-20 (2018) (explaining that "practical effect" test of 28 U.S.C. §§ 1292(a)(1) and 1293 "prevents [the] manipulation" that could occur "if the availability of interlocutory review depended on the district court's use of the term 'injunction'"); *Aberdeen & Rockfish R.R. v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 422 U.S. 289, 307, 308 n.11 (1975). In any event, the government would be entitled to mandamus relief.

In their accompanying motion to dismiss, plaintiffs invoke *Nken v. Holder*, 556 U.S. 418 (2009), for the proposition that stays and injunctions are distinct. But *Nken* did not address the scope of § 1292(a)(1); nor did it involve a § 705 stay. It addressed whether a stay of a removal order pending judicial review is an injunction against "the removal of any alien" within the meaning of a provision, 8 U.S.C. § 1252(f)(2), that limits such injunctions. That holding turned on the text, structure, and context of the statute at issue, *see* 556 U.S. at 428-433, none of which matters here. And even under *Nken*'s framework, the district court's order is an injunction because it does not merely "suspend[] ... the order or judgment in question"; rather, it radically upends the status quo. *Id.* at 428-429. The district court certainly understood its order to have the practical effect of an injunction. Add.65-66.

II. Plaintiffs Lack Standing And Their Central Claims Are Time-Barred

1. Plaintiffs lack standing because their assertions of harm rest on layer upon layer of speculation. Stay Mot. 6-9. Plaintiffs claim (at 10-11) that their sporadic examples of allegedly treating patients for past complications establish their standing. But the Supreme Court

has made clear that *past* harm is insufficient to establish standing to seek *prospective* injunctive relief. In *Summers v. Earth Island Institute*, 555 U.S. 488 (2009), an environmental association challenged regulations facilitating fire-rehabilitation and timber-salvage projects. At least one of the association's members had been harmed by a past timber-salvage project, and the association claimed that its members would be harmed by projects in the future. *Id.* at 495. The Court held, however, that past harm "does not suffice" to show standing in part "because it relates to past injury rather than imminent future injury that is sought to be enjoined." *Id.* at 495-96. So too here: Plaintiffs have not identified any particular physician who faces "*certainly impending*" rather than "*possible*" future injury sufficient to show injury-in-fact. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013).

Plaintiffs also claim (at 8-9) that they have organizational standing because they have "diverted valuable resources" to promote their mission. But surely the same was true of the environmental association in *Summers*. Plaintiffs offer no limiting principle for their boundless theory of standing, which would entitle any organization to seek judicial review of any governmental action it opposes. Stay Mot. 7-

8. And their theory of third-party standing (at 11-12) is entirely divorced from any injury-in-fact suffered by plaintiffs. Stay Mot. 8-9.

2. Plaintiffs' central claims are also time-barred. Stay Mot. 10-14. Plaintiffs contend that FDA reopened the approval of mifepristone, but they cite no case applying the reopening doctrine under similar circumstances. Plaintiffs rely (at 14) on *Sierra Club v. EPA*, 551 F.3d 1019 (D.C. Cir. 2018), but that case is inapposite; that framework applies only where the original rule "may not have been worth challenging" on its own. *Id.* at 1025-26. Plaintiffs *did* challenge FDA's original approval of mifepristone but failed to timely seek judicial review of FDA's denial of that challenge. And while plaintiffs defend (at 14) the district court's sua sponte application of equitable tolling, they make no attempt to reconcile it with controlling precedent or to explain why they did not meet the generous six-year limitations period. Stay Mot. 13-14.

III. Mifepristone Is Safe When Used Under Its Approved Conditions Of Use

The available evidence overwhelmingly shows that mifepristone is safe under the approved conditions of use, underscoring the speculative nature of plaintiffs' claims. Stay Mot. 14-16. "A reviewing court must

be 'most deferential' to the agency where, as here, its decision is based upon its evaluation of complex scientific data within its technical expertise." *Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019). Plaintiffs' unsubstantiated factual claims, adopted by the district court, offer no basis to override FDA's considered scientific judgment.

1. At the outset, plaintiffs suggest (at 2, 22) that FDA's findings should be overturned even without evidence that mifepristone is unsafe. In their view, because FDA changed the reporting requirements for certified prescribers in 2016, the true frequency of adverse events is higher than the data show. But FDA made those changes after *fifteen years* of adverse event data that showed "known risks occurring rarely." Add.856. By that point, mifepristone's "well-characterized safety profile" was firmly established. *Id.* Serious adverse events were "exceedingly rare," as demonstrated by eleven different studies and data from "well over 30,000 patients." Add.707, 710. And while FDA changed the reporting requirements for certified prescribers to report certain adverse events to the sponsors, it did not eliminate them. FDA still requires prescribers to report any deaths. And as FDA requires for all drug sponsors, "serious and unexpected" adverse events must be

reported to FDA within 15 days, and all other adverse events must be reported annually. *See* 21 C.F.R. §§ 314.80, 314.98.

2. It is thus unsurprising that *none* of the studies invoked by plaintiffs concludes that mifepristone is unsafe. Plaintiffs (at 18, 27) embrace the district court's reliance on a 2009 study purportedly showing that mifepristone has a higher rate of adverse events than surgical abortion. But that study found that both abortion methods "are generally safe" (as did a 2011 study by the same author) with low overall rates of serious adverse events, and it ultimately recommended informing women about their options so they can make their own choices regarding the best medical treatment for them. *See* Add.873 (discussing 2009 Niinimaki study); *see also* ECF 8, Preliminary Injunction App. (PI.App.) 422 (2011 Niinimaki study). Noting that medication and surgical abortion each have "benefits, side effects, and potential complications," FDA also concluded that "[p]atients and their healthcare providers should discuss which method is preferable and safer according to each woman's unique situation." Add.874.

Plaintiffs also note (at 18-19, 27) that the district court relied on several studies from the 1990s, but those studies have minimal

relevance in light of more recent and comprehensive studies and decades of clinical experience. For example, other studies examined by the agency identified "no difference in major adverse events" between mifepristone and surgical abortion. Add.873-74 (discussing 2015 Ireland study); Add.874 (for 2018 Carlsson study, "no statistically significant difference between the overall complication rates between an 'at home' and 'at the hospital' abortion").

Similarly, plaintiffs cite (at 27) the court's reliance on two studies that are outside the administrative record; neither shows that mifepristone is unsafe. *See* PI.App.418 (acknowledging that the 2021 Studnicki study was based on Medicaid claims data that were subject to inconsistencies); PI.App.431 (finding in the 2022 Studnicki study that "[w]omen experiencing chemical abortion and a subsequent emergency room (ER) visit within 30 days were *less likely* … to be hospitalized for any reason in that same time period than women who had experienced surgical abortion." (emphasis added)).*

* While the 2021 Studnicki study found a higher rate of emergency room visits following medication versus surgical abortion, the overall rate for both methods was low. *See* PI.App.413. Moreover, other studies have found lower rates of emergency room visits, underscoring

Plaintiffs further claim (at 27) that mifepristone causes psychological harms, citing the district court's reliance on anonymous blog posts. Those blog posts provide no basis to overturn FDA's scientific judgments. Stay Mot. 16. Plaintiffs also rely (at 28) on an amicus brief that, like the district court, cited two other articles about mental health (one by Priscilla Coleman in 2011 and one by David Reardon in 2002), but those articles did not even purport to evaluate mifepristone's effect on women. They compared outcomes between women who obtained abortions (by any method) and women who gave birth, thus providing no suggestion that all women would be better served by surgical versus medication abortion.

3. Finally, plaintiffs rely on risks from using mifepristone in ways that FDA has *not* approved. For example, they claim (at 28) that women have been harmed by using mifepristone to abort viable fetuses. Plaintiffs likewise rely on studies that found various adverse events

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the importance of limiting judicial review to the administrative record that reflects FDA's evaluation of all evidence before the agency. *E.g.*, Add.715-16 (discussing 2015 Ireland study, which reported 0.1% of women experienced a "major complication," defined to include "emergency department presentation" or "hospitalization," among other things).

associated with using mifepristone during the *second* trimester. *E.g.*, Add.734-35 (discussing 2011 Niinimaki study, which studied use of mifepristone up to 20 weeks' gestation). FDA has approved mifepristone as safe and effective for use only through 10 weeks' gestation. The cited risks associated with using mifepristone *after* 10 weeks do not justify withdrawing FDA's approval of the drug for use *through* 10 weeks.

Any drug can be unsafe when not used in accordance with its labeling. Obvious harms such as addiction or overdose can follow from misuse of pain management drugs, but those drugs have important uses for patients recovering from surgery, undergoing cancer treatment, and otherwise. The fact that someone could be harmed by consuming an entire bottle of Tylenol does not mean that *no one* should have access to Tylenol.

IV. The Equities Overwhelmingly Favor A Stay

The governmental and public interests also overwhelmingly favor a stay. Mot. 25-28. Effectively requiring Danco Laboratories and GenBioPro to cease distribution of mifepristone after more than two decades would upend the status quo, severely harming women,

healthcare systems, and the public. Doctors have explained that mifepristone is "part of the standard of care" for "gynecological procedures, obstetric care, medication abortion, and miscarriage management," such that "withdrawal of mifepristone will have far reaching impacts on reproductive health, medical ethics, and patient autonomy." Amicus Br. of Physicians for Reproductive Health 2-3; *see also* Amicus Br. of Doctors for America and the Reproductive Health Coalition 8-17; Amicus Br. of Over 100 Reproductive Health, Rights, and Justice Organizations 10-19; Amicus Br. of NAACP Legal Defense and Educational Fund, Inc. 8-20; Amicus Br. of Medical and Public Health Societies 15-22.

These harms would be felt in every State. Nearly half of the States caution that the court's order would have "devastating consequences" for their citizens and healthcare systems and undermine their substantial reliance interests. Amicus Br. of New York, et al., 6-14. Dozens of local governments highlight similar harms. Amicus Br. of Local Governments 1-2, 15-16; Amicus Br. of City of New York, et al., 1-28. Contrary to plaintiffs' suggestion (at 1), this is not truly a political divide: Mifepristone has lawful uses in *every* State. In this Circuit, for

instance, mifepristone may be used for abortions that are lawful under each State's laws. *See* Add.274-77; *e.g.*, Tex. Health & Safety Code § 170A.002(b) (permitting abortion in cases of certain health risks); La. R.S. §§ 40:1061(I), 14:87.1(1)(b)(vi) (permitting abortion if the fetus is not expected to survive); Miss. Code Ann. §§ 41-41-34.1, 41-41-45(2) (permitting abortion in certain cases of rape).

Furthermore, as more than 400 members of the biopharmaceutical industry have warned, the court's order puts "an entire industry focused on medical innovation at risk." *In Support of FDA's Authority to Regulate Medicines*, https://perma.cc/ZF96-ZTHH. By setting "a precedent for diminishing FDA's authority over drug approvals," the order "creates uncertainty for the entire biopharma industry." *Id.* "If courts can overturn drug approvals without regard for science or evidence, or for the complexity required to fully vet the safety and efficacy of new drugs, any medicine is at risk for the same outcome as mifepristone." *Id.*; *see also* Amicus Br. of Pharmaceutical Companies, Executives & Investors 9-25 (highlighting the "ripple effects" of the court's approach that would "delay patient access to life-saving medications" and "discourage development in the first instance");

Amicus Br. of 240 Members of Congress 15 ("The consequences of the district court's remedy could extend far beyond mifepristone, for it undermines the science-based, expert-driven process that Congress designed for determining whether drugs are safe and effective.").

CONCLUSION

The Court should immediately extend the administrative stay and then stay the district court's order pending appeal.

Respectfully submitted,

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APRIL 2023

CERTIFICATE OF SERVICE

I hereby certify that, on April 12, 2023, I electronically filed the foregoing motion with the Clerk of the 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/ Cynthia A. Barmore
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CERTIFICATE OF COMPLIANCE

I hereby certify that this reply complies with the requirements of Federal Rule of Appellate Procedure 27(d) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font. I further certify that this reply complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 2,554 words according to the count of Microsoft Word.

/s/ Cynthia A. Barmore
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