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.

DEFENDANTS-APPELLANTS' OPPOSITION TO PLAINTIFFS-APPELLEES' MOTION TO DISMISS

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INTRODUCTION AND SUMMARY

Plaintiffs' motion to dismiss should be denied. The district court's order staying the effectiveness of FDA's mifepristone approvals under 5 U.S.C. § 705 has the practical effect of an injunction and is thus appealable under 28 U.S.C. § 1292(a)(1). Section 705 orders have long been recognized as the equivalent of preliminary injunctions. Plaintiffs do not cite any decision, from any court, holding that such an order is not appealable. And it would be astonishing if a district court could enter a nationwide order upending a decades-old regulatory regime, yet insulate its decision from immediate appellate review merely by invoking § 705. In any event, even if this Court did not have jurisdiction under § 1292(a)(1), the district court's order could and should be reviewed through the Court's mandamus jurisdiction.

This Court Has Appellate Jurisdiction

1. Plaintiffs filed suit in district court to challenge several agency actions related to mifepristone, including the name-brand drug's approval in 2000, modifications to the mifepristone REMS in 2016, the generic drug's approval in 2019, and certain actions related to in-person dispensing. Plaintiffs filed a motion for a preliminary injunction,

arguing that FDA's actions violated the Administrative Procedure Act and that the district court should order FDA to withdraw or suspend its approval of the drug. Add.66.

The district court "grant[ed]" plaintiffs' motion "in part." Add.67. The court applied the traditional "standards" that apply to a motion for a preliminary injunction. Add.6. It agreed with plaintiffs that they had satisfied the requirements for preliminary injunctive relief, including a "substantial likelihood of prevailing on the merits." Add.65. The court thus found that "injunctive relief is generally appropriate." Add.66. But rather than formally granting an injunction, the court chose what it characterized as "less drastic" relief by issuing a stay under 5 U.S.C. § 705 to suspend the effective date of the challenged agency actions. Add.65. The court asserted that its order "temporarily suspend[s]" the challenged agency actions, including FDA's initial approval of mifepristone in 2000. Add.66 (quoting *Nken v. Holder*, 556 U.S. 418, 428-29 (2009)).

The district court also specified that, if this Court were to hold that it could not rely on § 705 to "postpone" the effective date of agency actions that have long been in effect, the court "alternatively would

have ordered Defendants to suspend the chemical abortion approval and all subsequent challenged actions related to that approval." Add.67. As the district court appeared to recognize, the alternative preliminary injunctive relief it described would have had precisely the same consequence as the court's actual order—that is, the suspension of the challenged agency actions.

2. Because the district court's order has the practical effect of a preliminary injunction, it is immediately appealable under 28 U.S.C. § 1292(a)(1). *See Wyoming v. U.S. Dep't of Interior*, 2018 WL 2727031, at *1 (10th Cir. June 4, 2018) (holding that a § 705 stay is immediately appealable under § 1292(a)(1)); *see also, e.g.*, *Colorado v. EPA*, 989 F.3d 874, 879, 883 (10th Cir. 2021) (reviewing a § 705 stay "under 28 U.S.C. § 1292").

Section 1292(a)(1) provides for appellate jurisdiction over certain interlocutory orders, including orders "granting … injunctions." *Id.* The Supreme Court has "made clear" that "where an order has the 'practical effect' of granting or denying an injunction, it should be treated as such for purposes of appellate jurisdiction" under both § 1292(a)(1) and the parallel language in 28 U.S.C. § 1253. *Abbott v.*

Perez, 138 S. Ct. 2305, 2319 (2018) (citation omitted). As particularly relevant here, the Supreme Court has long allowed interlocutory appeals "from orders … not cast in injunctive language but which by their terms simply 'set aside' or declined to 'set aside' orders of the [agency]." *Aberdeen & Rockfish R.R. Co. v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 422 U.S. 289, 307, 308 n.11 (1975) (collecting cases). By evaluating the "practical effect" of the district court's order rather than its label, appellate courts prevent "manipulation" that could occur "if the availability of interlocutory review depended on the district court's use of the term 'injunction.'" *Abbott*, 138 S. Ct. at 2319-20.

Here, the district court's order "postpon[ing] the effective date of the challenged actions," Add.66, had—and was intended to have—the same "practical effect" as an order expressly styled as a mandatory injunction directing FDA to suspend those actions, *Abbott*, 138 S. Ct. 2319-20. Indeed, the court's order closely resembles the type of orders the Supreme Court described as paradigmatically appealable in *SCRAP*, which were likewise equivalent to injunctions directing agencies to withdraw the challenged actions. *See* 422 U.S. at 308 n.11.

The district court described its order as "reinstat[ing]" the status quo by "temporarily suspend[ing]" the challenged actions. Add.66 (quoting *Nken*, 556 U.S. at 428-29). In other words, under the court's order, FDA's more than two-decades-old approval of mifepristone would no longer be in effect. And without an effective drug approval, mifepristone's sponsors (Danco Laboratories and GenBioPro) could not lawfully introduce that drug into interstate commerce. Add.66; *see* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). For purposes of the FDCA, the "practical effect" of the court's order is thus indistinguishable from a preliminary injunction compelling FDA itself to suspend its prior actions.

Moreover, the district court's decision to stay FDA's actions rested on the same factors that govern a preliminary injunction. The court recognized that "[m]otions to stay agency action pursuant to [§ 705] are reviewed under the same standards used to evaluate requests for interim injunctive relief." Add.66 (quoting *Texas v. Biden*, 2022 WL 17718634, *10 (N.D. Tex. 2022)); *see Monumental Task Comm., Inc. v.*

Foxx, 157 F. Supp. 3d 573, 586 (E.D. La. 2016) (noting that the standard for a § 705 stay "is the same as the standard for issuance of a preliminary injunction"), *aff'd sub nom. Monumental Task Comm., Inc. v. Chao*, 678 F. App'x 250 (5th Cir. 2017); *Cronin v. USDA*, 919 F.2d 439, 446 (7th Cir. 1990). Consequently, the court reasoned that "[b]ecause the Court finds injunctive relief is generally appropriate," § 705 also authorized a stay. Add.66.

Plaintiffs do not cite any precedent holding that a § 705 stay is not appealable under § 1292(a)(1). Instead, they invoke *Nken v. Holder*, 556 U.S. at 418, 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 428-33, 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 that

predated the court's order, under which FDA approval of mifepristone permitted the drug's sponsors to introduce it into interstate commerce. *Id.* at 428-29.

Plaintiffs' reliance on *Alsea Valley Alliance v. Department of Commerce*, 358 F.3d 1181 (9th Cir. 2004), is also misplaced. The court there was addressing not a stay pursuant to 5 U.S.C. § 705, but rather a district court order that vacated a National Marine Fisheries Service rule and remanded the matter to the agency. And the reason the court did not regard that stay as an injunction was that it left the agency free, on remand, to take the same action as it had previously taken. *See* 358 F.3d at 1186 ("The order does not compel the Service to remove Oregon coast coho salmon from the threatened species list or take any other actions."). Here, by contrast, the district court did not remand for FDA to reconsider whether to approve mifepristone; it simply stayed FDA's approval. And even if the order here could somehow be read as akin to the one in *Alsea*, the implication would not be that this Court lacks jurisdiction to review the order; it would be that this Court's jurisdiction would lie under § 1291 rather than § 1292(a)(1). *See Alsea*, 358 F.3d at

1184 (agencies can immediately appeal remand orders under the collateral-order doctrine).

3. In any event, the government would be entitled to mandamus relief. Even if this Court "lacks jurisdiction under § 1291 to review the district court's order, a writ of mandamus may still be appropriate." *Leonard v. Martin*, 38 F.4th 481, 488 (5th Cir. 2022). In such circumstances, this Court may "treat an appeal as a petition for a writ of mandamus." *Id.* at 488 n.4. This Court "will grant a petition for a writ of mandamus" if the petitioner shows "that there are 'no other adequate means to attain the relief he desires,'" that "the writ is appropriate under the circumstances," and that the petitioner has "a 'clear and indisputable right to the writ.'" *Defense Distributed v. Bruck*, 30 F.4th 414, 426 (5th Cir. 2022) (quoting *Cheney v. U.S. Dist. Court*, 542 U.S. 367, 380-81 (2004)).

A writ of mandamus would be warranted if this Court holds that it lacks jurisdiction over this appeal under § 1292. All three factors are satisfied here: If this Court could not exercise immediate appellate review under § 1292(a)(1), mandamus relief would be the only "adequate means" to obtain relief. *Defense Distributed*, 30 F.4th at 426.

Allowing the district court's order to take effect nationwide, and effectively vacate FDA's approval of mifepristone, while this case proceeds on the merits would work immense irreparable harm on women, healthcare systems, and the public. *See* Stay Mot. 25-26; Stay Mot. Reply 6-14. For the same reasons, mandamus relief would be "appropriate under the circumstances." *Defense Distributed*, 30 F.4th at 426.

Finally, the government has a "clear and indisputable right" to the writ, *Defense Distributed*, 30 F.4th at 426, for the same reasons that this Court should stay the district court's order. *See* Stay Mot. 6-28; Stay Mot. Reply 4-14. As detailed in the government's stay briefing, plaintiffs' speculative assertions of harm fail to establish standing; their central claims are manifestly untimely; and all of their claims fail on the merits. The equities also decisively favor mandamus relief. Plaintiffs will suffer no harm from maintaining the status quo pending appeal, as is evident by their years-long delay in seeking judicial review of FDA's approval of mifepristone. In contrast, the public interest plainly favors maintaining access to a safe and effective drug that has

been on the market for over two decades, consistent with Congress's determination to entrust to FDA responsibility to ensure drug safety.

CONCLUSION

For the foregoing reasons, plaintiffs' motion to dismiss should be denied.

Respectfully submitted,

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APRIL 2023

CERTIFICATE OF SERVICE

I hereby certify that, on April 12, 2023, I electronically filed the foregoing 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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Counsel for Appellants

CERTIFICATE OF COMPLIANCE

I hereby certify that this response 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 response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 1,815 words according to the count of Microsoft Word.

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