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

On Appeal from the United States District Court
for the Northern District of Texas
No. 2:22-cv-00223-Z

PLAINTIFFS-APPELLEES' MOTION TO DISMISS

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INTRODUCTION

The district court's stay order is not a "final decision[ ]" appealable as of right under 28 U.S.C. § 1291. So Appellants have appealed the order as though it were a preliminary injunction under 28 U.S.C. § 1292(a)(1). But the district court did not enter a preliminary injunction; rather, it specifically *denied* Plaintiffs-Appellees' request for a preliminary injunction and instead entered its order under Section 705 of the Administrative Procedures Act, 5 U.S.C. § 705, staying "the effective date of FDA's September 28, 2000 approval of mifepristone and all subsequent challenged actions related to that approval." FDA.Add.67.[1] Stays of agency action are not injunctions, as the Supreme Court has recognized. *E.g.*, *Nken v. Holder*, 556 U.S. 418, 429–30 (2009).

Accordingly, this Court should dismiss Defendants' appeal for lack of jurisdiction. Even if the Court were to construe Appellants' notices of appeal and emergency motions for a stay as mandamus petitions—and thus review the district court's order to determine whether that court "clearly and indisputably erred" in a way that is "irremediable on

[1] All citations to the "FDA.Add." refer to the Addendum that FDA filed concurrently in this Court with its April 10, 2023, Emergency Motion Under Circuit Rule 27.3 for a Stay Pending Appeal. "Alliance.Add." refers to Plaintiff's Addendum, filed concurrently with Plaintiffs' opposition to FDA's motion on April 11, 2023.

ordinary appeal," *In re Occidental Petroleum Corp.*, 217 F.3d 293, 295 (5th Cir. 2000) (cleaned up)—this Court should not disturb or stay the district court's fastidious 67-page order for all the reasons explained in Plaintiffs-Appellees' opposition to the stay motions.

BACKGROUND

The FDA's chemical abortion regimen requires two drugs: mifepristone (also known as "RU-486" and "Mifeprex") and misoprostol. FDA.Add.84. Mifepristone is a synthetic steroid that blocks nutrition to the unborn baby, starving the baby to death. *Id*. Misoprostol induces contractions to expel the dead baby from the mother's womb. FDA.Add.84–85.

The FDA fast-tracked mifepristone's approval under Subpart H, a regulation that authorizes accelerated approval of new drugs that safely and effectively treat "serious or life-threatening illnesses" and "provide [a] meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500. To mitigate acknowledged, serious, and adverse complications, the FDA's 2000 Approval imposed a seven-week gestational limit, limited prescribing authority to physicians, and required three in-person office visits: (1) the Day 1 in-person dispensing

and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 office visit to confirm no fetal parts or tissue remain. FDA.Add.182–83, 186, 189. Abortion providers were required to report all adverse events. FDA.Add.186.

In 2002, Plaintiffs AAPLOG and CMDA timely filed a citizen petition with the FDA challenging the 2000 Approval (2002 Citizen Petition). FDA.Add.281–372. Fourteen years later, the FDA rejected the 2002 Citizen Petition (2016 Petition Denial). FDA.Add.562–94. The same day, the FDA approved "major changes" to the chemical abortion drug regimen, eviscerating crucial safeguards (2016 Major Changes). FDA.Add.768–75. The agency increased the maximum gestational age from seven to ten weeks gestation; reduced the number of required in-person office visits from three to one; allowed non-doctors to prescribe and administer chemical abortions; and eliminated non-fatal adverse event reporting. FDA.Add.778.

In March 2019, Plaintiffs AAPLOG and ACPeds timely filed another citizen petition challenging the 2016 Major Changes (2019 Citizen Petition). FDA.Add.192–21. The following month, the FDA

approved a generic version of mifepristone with the same postmarketing restrictions as the Danco drug, Mifeprex (2019 ANDA Approval). Alliance.Add.456, 463. And in April 2021, the FDA stated it would "exercise enforcement discretion" and allow "dispensing of mifepristone through the mail … or through a mail-order pharmacy" during the COVID pandemic (2021 Non-Enforcement Decision). Alliance.Add.249. The FDA took this action even though the Comstock Act expressly prohibits distribution of chemical abortion drugs by mail, express company, or common carrier. Then, on December 16, 2021, the FDA denied almost all the 2019 Citizen Petition (2021 Petition Response). FDA.Add.876. The FDA rejected the 2019 Citizen Petition's request to keep the in-person dispensing requirements and announced it would permanently allow abortion by mail. FDA.Add.842.

The district court found that FDA's approval and continual deregulation of mifepristone placed politics above women's health. That court's order paints an alarming picture of decades-long agency lawlessness—all to the detriment of the women and girls the FDA is charged to protect.

Analyzing Plaintiffs' claims in detail, the district court concluded that Plaintiffs were likely to prevail on their challenges to the FDA's 2000 Approval, 2016 Petition Denial, 2016 Major Changes, 2019 ANDA Approval, 2021 Petition Response, and 2021 Non-Enforcement Decision. In fact, Defendants *admit* that pregnancy is not an illness and cannot prove mifepristone provides a therapeutic benefit—the two independent prerequisites for the FDA's approval here. And the FDA's mail-order approval flagrantly violates the Comstock Act. The district court also found that the government has engaged in decades' long obfuscation and delay, and that its failure to abide by federal law resulted in the death of "many" women and caused a serious physical and emotional toll—a toll minimized by the FDA's "systematic" concealment. FDA.Add.29 n.22, 58–59.

Although Plaintiffs requested a preliminary injunction, the district court expressly declined to grant it and instead issued "less drastic relief." FDA.Add.65. By its order, the district court "**STAY[ED]** the effective date of" the challenged agency actions under 5 U.S.C. § 705. *Id.* at 67.

The Court chose this form of relief specifically in light of the "meaningful differences between an injunction, which is a 'drastic and extraordinary remedy,' and vacatur, which is 'a less drastic remedy.'" *Id.* at 66 (quoting *Texas v. Biden*, No. 2:21-CV-067-Z, 2022 WL 17718634, at *7 (N.D. Tex. Dec. 15, 2022)). The district court explained that "a vacatur reinstates 'the status quo absent the unlawful agency action and neither compels nor restrains further agency decision-making.'" *Id.* (quoting *Texas v. Biden*, 2022 WL 17718634, at *7). Just as a preliminary injunction is an interim version of a permanent injunction, "[a] Section 705 stay can 'be seen as an interim or lesser form of vacatur under Section 706." *Id.* (quoting *Texas v. Biden*, 2022 WL 17718634, at *7).

Finally, the district court stayed its own stay order for seven days to give "the federal government time to seek emergency relief from the United States Court of Appeals for the Fifth Circuit." *Id.* at 67. Appellants could have done exactly that by moving to certify the order for interlocutory appeal or filing a mandamus petition in this Court. But Appellants chose to do neither of those things. Instead, they immediately filed notices of appeal without specifying the basis for this Court's jurisdiction. ECF 138; ECF 139. That's because there isn't any.

ARGUMENT

Concurrently with the filing of this Motion, Plaintiffs-Appellees are filing their brief opposing Defendants' emergency motions for a stay pending appeal. That brief defends the district court's comprehensive order, which laid bare the FDA's two decades of unlawful actions promoting abortions over women's health and contravening the agency's Congressionally circumscribed statutory authority.

But Appellants cannot invoke this Court's appellate jurisdiction to review the stay order in any event. A stay granted under Section 705 of the APA is interim relief postponing the effective date of challenged agency action, not an injunction subject to interlocutory appeal under 28 U.S.C. § 1292(a)(1). Courts routinely distinguish stays from injunctions, and a temporary stay under Section 705 is not a final decision appealable under 28 U.S.C. § 1291. Accordingly, if Appellants wanted to seek this Court's review, they should have filed a petition for a writ of mandamus or moved the district court to certify its order under 28 U.S.C. § 1292(b). As they have done neither, this Court should dismiss their appeal.

I. The Stay in This Case Is Not an Injunction under Section 1292(a)(1).

This Court's appellate jurisdiction is normally limited to reviewing "final decisions," 28 U.S.C. § 1291. But Congress enacted a limited exception for review of preliminary injunctions. This Court can review "[i]nterlocutory orders … granting, continuing, modifying, refusing or dissolving injunctions." *Id.* § 1292(a)(1). "[T]he statute creates an exception from the long-established policy against piecemeal appeals, which this Court is not authorized to enlarge or extend." *Gardner v. Westinghouse Broad. Co.*, 437 U.S. 478, 480 (1978). "The exception is a narrow one," *id.*, and it has gotten narrower as the Supreme Court has overruled older precedent that previously allowed a broader category of orders to be considered injunctions, *e.g.*, *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 279–88 (1988).

A stay of agency action is not an injunction. *Nken*, 556 U.S. at 429–30 (2009). And if an order "ordinarily is not considered an injunction," then it "is not appealable under § 1292(a)(1)." *Gulfstream Aerospace Corp.*, 485 U.S. at 279. The history and nature of stays under Section 705 demonstrate that they are not injunctions.

Section 705 codified a practice in which courts had long engaged. "It has always been held … that, as part of its traditional equipment for the administration of justice, a federal court can stay the enforcement of a judgment pending the outcome of an appeal." *Scripps-Howard Radio v. FCC*, 316 U.S. 4, 9–10 (1942) (cleaned up). The power to stay, "a power as old as the judicial system of the nation," is not limited to judicial orders. *Id.* at 17. It extends to stays of "administrative order[s]" as well. *Id.* at 10.

Section 705 "was primarily intended to reflect existing law under the Scripps-Howard doctrine." *Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974). It did so by providing that "the reviewing court" may "postpone the effective date of an agency action or … preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. These *Scripps-Howard*-type stays of administrative orders differ meaningfully from injunctions, as the Supreme Court explained in *Nken*.

Nken asked whether "a statutory provision that sharply restricts the circumstances under which a court may issue an injunction blocking the removal of an alien from this country … applies to the granting of a stay by a court of appeals while it considers the legality of a removal

order." *Nken*, 556 U.S. at 422. Answering no, the Supreme Court rejected the government's "argu[ment] that a stay is simply a form of injunction." *Id.* at 426.

In light of the differences between injunctions and stays, the Supreme Court held that the provision limiting permissible injunctive relief did not apply to stays. *Id.* at 433. The Court was not concerned by the "functional overlap" shared by a stay and an injunction. *Id.* at 428. That "[b]oth can have the practical effect of preventing some action before the legality of that action has been conclusively determined" was immaterial. *Id.* at 428–29.

Just as a stay of an administrative order was not an injunction for purposes of the statute in *Nken*, a stay of an administrative order is not an injunction for purposes of Section 1292(a)(1). True, Section 1292(a)(1) can cover not only an order granting or denying a motion for an injunction but also an order that "has the practical effect of [granting or] refusing an injunction." *Carson v. Am. Brands, Inc.*, 450 U.S. 79, 84 (1981); *see also United States v. Garner*, 749 F.2d 281 (5th Cir. 1985), *supplemented*, 752 F.2d 116 (5th Cir. 1985) (per curiam). But the *Carson* rule does not apply just because a defendant claims that a non-injunctive form of relief

has the same "practical effect" that an injunction would. It requires that supposedly non-injunctive orders "have the practical effect of granting or denying injunctions." *Gulfstream Aerospace Corp.*, 485 U.S. at 287–88.

In *Garner*, for example, an order did not satisfy the *Carson* rule even though it "purport[ed] to require significant regulatory action by the" government. 749 F.2d at 286. The district court's order had merely "establish[ed] a prerequisite for [the government's] proceeding with [its] foreclosure action." *Id.* So the order's "practical effect" was not to enter an injunction. *Id.* at 286–87.

Applying similar reasoning, the Ninth Circuit held that vacatur of agency action is not an injunction immediately appealable under Section 1292(a)(1). In *Alsea Valley Alliance v. Department of Commerce*, the National Marine Fisheries Service listed certain salmon populations as "threatened" under the Endangered Species Act. 161 F. Supp. 2d 1154, 1156 (D. Or. 2001). Reviewing that listing decision, the district court "declared [it] unlawful and set [it] aside." *Id.* at 1163–64. When environmental groups defending the listing attempted to appeal that interlocutory ruling, the Ninth Circuit dismissed for lack of jurisdiction because the district court's order did not "have the practical effect of

entering an injunction." *Alsea Valley All. v. Dep't of Com.*, 358 F.3d 1181, 1186 (9th Cir. 2004). Although vacatur "prohibit[ed], as a practical matter, the enforcement of the Service's listing decision as is," it did "not compel the Service to [delist the salmon] or take any other actions." *Id.* "It would be far too tenuous … to maintain that this is the practical equivalent of 'enjoining' the Service." *Id.* A contrary rule "would classify as 'injunctive' all declaratory relief that deems an agency rule unlawful" and extend Section 1292(a)(1) far beyond its text. *Id.* at 1186–87.

This Circuit has followed a similar rule when it comes to contracts. An order "denying rescission" of an agreement is not the same as an order "refus[ing] to grant an injunction" against enforcement of the agreement. *Pettinelli v. Danzig*, 644 F.2d 1160, 1163 (5th Cir. 1981). An order staying agency action is no more like an injunction than an order rescinding a contract is.

And that's the situation here. The district court's order "**STAYS** the effective date of" various agency actions. FDA.Add.67. As the government conceded in related litigation, "the order would—of its own force and without any further action by FDA—stay the effectiveness of FDA's prior approvals of mifepristone nationwide." Defendants' Motion for

Clarification, *Washington v. U.S. Food & Drug Admin.*, No. 1:23-cv-03026-TOR, ECF No. 81 at 3 (E.D. Wash. Apr. 10, 2023).

This is in keeping with the way stays of agency action are supposed to operate. Section 705 provides that "the reviewing court" may "postpone the effective date of an agency action." 5 U.S.C. § 705. That bears little resemblance to an injunction. *See* Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 1016 (2018) (explaining how "[p]reliminary relief under section 705 differs from a preliminary injunction"). As a result, this Court lacks jurisdiction over the district court's interlocutory order.

II. A Temporary Stay Is Not a Final Decision Appealable under Section 1291.

Appellants do not contend that the district court's order is an appealable final decision. *See* ECF 138 (entered on the district court docket as a "notice of interlocutory appeal"); ECF 139 (same). But to avoid any doubt, Appellees note that the order is not appealable under 28 U.S.C. § 1291. Consistent with Section 705, the district court granted temporary relief "pending conclusion of the review proceedings," not permanent relief. 5 U.S.C. § 705; *see* FDA.Add.066–67.

This appeal does not fit within the "modest scope" of the collateral-order doctrine. *Will v. Hallock*, 546 U.S. 345, 350 (2006). The stay order does not "conclusively determine" anything, much less "an important issue completely separate from the merits of the action" that would "be effectively unreviewable on appeal from a final judgment." *Id.* at 349. For example, it assessed Appellees' "likelihood of prevailing on the merits" rather than reaching a final conclusion on the merits. FDA.Add.065.

Moreover, there is no interpretation of Section 1291 that would include stay orders under Section 705 but exclude preliminary injunctions, which are separately covered by Section 1292(a)(1). And preliminary injunctions cannot be final decisions under Section 1291 for two reasons. First, that would render Section 1292(a)(1) superfluous. *See Corley v. United States*, 556 U.S. 303, 314 (2009) (canon against superfluity); *In re Tronox Inc.*, 855 F.3d 84, 97 (2d Cir. 2017) (rejecting an interpretation of Section 1291 that would leave "§ 1292 (a)(1) … at least partially[ ] superfluous"). Second, it would contradict the history of congressional enactments governing appellate review. Congress first enacted the provision now in Section 1292(a)(1) because preliminary injunctions were not considered final decisions appealable under Section

1291. *See Baltimore Contractors v. Bodinger*, 348 U.S. 176, 180–81 (1955), *overruled on other grounds by Gulfstream Aerospace Corp.*, 485 U.S. 271. That means Appellants lack an appeal as of right.

III. If Appellants Wanted Interlocutory Review from this Court, They Should Have Petitioned for Mandamus or Moved for Certification under Section 1292(b).

Appellants do not have a right to an immediate appeal, but that did not leave them without options for seeking this Court's immediate review. First, they could have petitioned for a writ of mandamus. Second, Appellants could have moved the district court to certify its order for an interlocutory appeal under 28 U.S.C. § 1292(b). But again, Appellants chose not to do so, despite this Court's precedent reminding litigants of this option. *See, e.g.*, *Garner*, 752 F.2d 116.

Given the importance of the issues presented and the government's obvious desire for a speedy ruling—after "stonewall[ing] judicial" review for nearly 20 years, FDA.Add.1—this Court could exercise its equitable power and construe Appellants' Notices of Appeal and Emergency Motions for a Stay Pending Appeal as functional petitions for mandamus. In that event, all of Plaintiffs-Appellees' arguments supporting the district court's order hold true. But this Court would review the district

court's order to determine whether that court "clearly and indisputably erred" in a way that is "irremediable on ordinary appeal." *In re Occidental Petroleum Corp.*, 217 F.3d 293, 295 (5th Cir. 2000) (footnote and emphasis omitted). For the reasons stated in Plaintiffs-Appellees' brief opposing Appellants' Emergency Motions for Stay, the district court's order should be upheld even under a less deferential standard of review and so must be upheld in the context of a mandamus petition, too.

CONCLUSION

The Court should dismiss this appeal for lack of jurisdiction. Alternatively, the Court should construe Appellants' Notices of Appeal and Emergency Motions for a Stay Pending Appeal as petitions for mandamus and review the district court's order under the appropriate mandamus standard.

Respectfully submitted,

/s/ Erik C. Baptist

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CERTIFICATE OF COMPLIANCE

This motion complies with the word limit of Fed. R. App. P. 27(d)(2)(A) because it contains 3,026 words.

This motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in Word 365 using a proportionally spaced typeface, 14-point Century Schoolbook.

Dated: April 11, 2023

s/Erik C. Baptist
Erik C. Baptist

Counsel for Plaintiffs-Appellees

CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2023, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Erik C. Baptist
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