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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

CIV. NO. 1:17-00493-JAO-RT

**DEFENDANTS' REPLY IN
SUPPORT OF A STAY PENDING
DISTRICT COURT
PROCEEDINGS IN
WASHINGTON V. FDA**

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INTRODUCTION

As Defendants explained in their June 20 letter, the Court should stay this case pending resolution of district court proceedings in *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash.). ECF No. 184. Such a stay would promote “the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law.” *Hawai’i v. Trump*, 233 F. Supp. 3d 850, 853 (D. Haw. 2017) (quotations omitted). Moreover, Plaintiffs have not shown harm from a stay, and a stay would prevent harm to Defendants from potentially conflicting orders. *See id.* Plaintiffs’ June 28 brief does not show otherwise.¹

ARGUMENT

I. A Stay Would Promote the Orderly Course of Justice

A stay would promote the orderly course of justice because it would avoid the risk of conflicting orders, be efficient, and have a reasonable duration.

A stay would avoid the risk of conflicting orders. The final relief Plaintiffs seek in their amended complaint includes “an injunction prohibiting Defendants”

¹ Defendants continue to believe it is appropriate to stay this case pending the resolution of appellate proceedings in *Alliance for Hippocratic Medicine v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex.), *appeal filed*, No. 23-10362 (5th Cir. Apr. 10, 2023). ECF Nos. 171, 175. If the Court declines to stay this case pending *Alliance* or *Washington*, Defendants request that the Court set a deadline of September 1, 2023, for production of the supplemental administrative record, consistent with *Washington*, and set a deadline of September 1, 2023, or later for Defendants to respond to the amended complaint.

from “requiring a REMS” for mifepristone. ECF No. 169 (“Am. & Suppl. Compl.”) at 95. That relief, if granted, would require Defendants to “alter[] the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [Mifepristone Risk Evaluation and Mitigation Strategy (‘REMS’) Program] under 21 U.S.C. § 355-1 in Plaintiff States [which include Hawaii] and the District of Columbia,” which the *Washington* preliminary injunction prohibits.² *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 13, 2023), ECF No. 91, Order Granting Motion for Clarification, at 5–6; see June 15, 2023, Hearing Tr. (“Tr.”) at 12:18–21.

If this Court were to grant Plaintiffs’ requested relief while the *Washington* preliminary injunction remains in place, the conflicting orders would risk injecting further confusion into the medication abortion landscape. See Tr. 19:3–15. It would also waste this Court’s resources to issue an order that Defendants potentially could not implement consistent with their obligation to comply with the *Washington* injunction. Moreover, “seek[ing] clarification from [the *Washington* court] or, if necessary, the Ninth Circuit,” Pls.’ Br. 5, might not resolve the conflict. A stay would likely avoid these threats to “the orderly course of justice,” *Hawai’i*, 233 F. Supp. 3d at 853, because the *Washington* preliminary injunction will no

² The text of the *Washington* preliminary injunction does not merely “prevent FDA from making mifepristone *less* available.” ECF No. 186 (“Pls.’ Br.”) at 4.

longer be in effect when district court proceedings in that case conclude, and the final relief requested in the *Washington* amended complaint is consistent with the final relief requested in the amended complaint here. *Compare Washington*, ECF No. 35, Am. Compl., at 90, with *Chelius*, Am. & Suppl. Compl., at 94–95. A stay is therefore warranted to “reduce the risk of inconsistent rulings that the appellate courts might then need to disentangle.” *Hawai’i*, 233 F. Supp. 3d at 856.

A stay would be efficient. A stay would avoid the inefficiency of two district courts in the same circuit simultaneously considering the same claims³ challenging the same agency action based on the same administrative record. It would also respect “the general principle” that district courts “avoid duplicative litigation.” *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976); *see also M.M. v. Lafayette Sch. Dist.*, 681 F.3d 1082, 1091 (9th Cir. 2012); *Hawai’i*, 233 F. Supp. 3d at 856.

A stay would allow the claims here and in *Washington* to be addressed by a single court. And it would be efficient for those claims to be addressed first in *Washington* because that court recently engaged with the merits to an extent in

³ The amended complaints in both *Washington* and this case allege that the January 2023 REMS modification violated the Fifth Amendment’s Equal Protection Clause and was contrary to constitutional right, in excess of statutory authority, and arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law in violation of the Administrative Procedure Act, 5 U.S.C. § 706. *See Washington*, ECF No. 35, Am. Compl., ¶¶ 257–69; *Chelius*, Am. & Suppl. Compl., ¶¶ 213–25.

deciding the preliminary injunction motion, whereas this Court has not had occasion to issue a decision on the merits.⁴ Following the stay, moreover, this Court might benefit from “insight” on the merits from the final decision in *Washington*. Tr. 18:21–24. Thus, it would be “efficient for [this Court’s] own docket and the fairest course for the parties” to stay this case “pending resolution of independent proceedings” in *Washington* that, even if not “controlling,” could “bear upon the case.” *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863–64 (9th Cir. 1979).

Plaintiffs argue that the issues should be allowed to “percolate” among district courts. Pls.’ Br. 6. But the cases Plaintiffs cite do not contradict the principle that courts avoid duplicative litigation—indeed, those cases have nothing to do with whether a district court should stay proceedings. Furthermore, there is no need for “a factual record” of Plaintiffs’ alleged harms, *id.*, because the merits of an APA case are decided on the administrative record, *see* 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973).

The stay’s duration would be reasonable. The stay would not be indefinite,

⁴ Although Plaintiffs previously moved for summary judgment, Pls.’ Br. 5 n.4, those summary judgment motions were never presented to the Court for decision. Moreover, whereas Plaintiffs originally challenged the 2016 REMS modification and argued that it imposed an undue burden on the constitutional right to abortion, ECF Nos. 1, ¶¶ 226–27; 86-1, at 39–41; 141-1, at 35–40, Plaintiffs’ amended complaint challenges the January 2023 REMS modification and does not include the undue burden claim.

contra Pls.’ Br. 2, but would be “defined by the duration of the [*Washington*] proceedings presently under way, even if the exact date on which those proceedings will conclude is not yet known.” *Ramachandran v. City of Los Altos*, No. 18-CV-01223-VKD, 2022 WL 2479652, at *3 (N.D. Cal. July 6, 2022) (granting stay pending resolution of proceedings in trial and appellate courts). Moreover, the relevant question is whether the stay will last “a reasonable time in relation to the urgency of the claims.” *Leyva*, 593 F.2d at 864. Here, FDA notified Plaintiffs in December 2021 that mifepristone for termination of early pregnancy would continue to be subject to a REMS that included prescriber certification and Patient Agreement Form requirements, yet Plaintiffs waited over a year to seek to reopen this case.⁵ ECF No. 157, ¶ 11; *see* Am. & Suppl. Compl. ¶ 107.⁶

II. A Stay Would Not Harm Plaintiffs, but Would Prevent Harm to Defendants

In addition to the orderly course of justice, courts consider “the possible damage which may result from the granting of a stay” and “the hardship or

⁵ The pharmacy certification requirement was incorporated into the January 2023 REMS modification when the in-person dispensing requirement was removed, Am. & Suppl. Compl. ¶¶ 107–09, but no Plaintiff alleges that it is a pharmacist or operates a pharmacy. Furthermore, the net effect of the January 2023 REMS modification was to lessen the restrictions on mifepristone.

⁶ *See also* Letter from FDA to Am. Ass’n of Pro-Life Obstetricians and Gynecologists and Am. Coll. of Pediatricians (Dec. 16, 2021), at 6–7, <https://www.regulations.gov/document/FDA-2019-P-1534-0016>.

inequity which a party may suffer in being required to go forward.” *Hawai’i*, 233 F. Supp. 3d at 853 (quotations omitted). These factors favor a stay.

A stay would not harm Plaintiffs. Even if this case moved forward, Defendants might not be able to do what Plaintiffs request while complying with their obligations under the *Washington* preliminary injunction. *See supra* pp. 1–3. Plaintiffs’ allegations of harm from a stay are also undermined by their delay in prosecuting their claims. *See supra* p. 5; *contra* Pls.’ Br. 1.

Although the *Washington* district court judgment might provide guidance to this Court, that judgment would not be precedential and thus would not “settle[] the rule of law that will define [Plaintiffs’] rights.” *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936); *contra* Pls.’ Br. 5–6. Moreover, *Landis* explained that “[e]specially in cases of extraordinary public moment, the individual may be required to submit to delay not immoderate in extent and not oppressive in its consequences if the public welfare or convenience will thereby be promoted.” 299 U.S. at 256. Any possible harms to Plaintiffs from a stay would not be “oppressive,” as all of Plaintiffs’ claims are presented in *Washington* and are being prosecuted by well-represented Plaintiff States.

A stay would prevent harm to Defendants. Defendants “need not make a showing of hardship or inequity” in going forward because Plaintiffs have not shown “a ‘fair possibility’ that a stay will cause [them] injury.” *Hawai’i*, 233 F.

Supp. 3d at 854 (citation omitted). But even if Plaintiffs had shown harm from a stay, such harm would be outweighed by the harm to Defendants from being “forced to litigate on [at least] two fronts” and being “subjected to the possibility of inconsistent rulings in the two actions.” *Citizens Ins. Co. of Am. v. Chief Digital Advisors*, No. 20-CV-1075-MMA (AGS), 2020 WL 8483913, at *2 (S.D. Cal. Dec. 22, 2020). These are “particularly compelling reasons why proceeding forward with this litigation will constitute hardship” to Defendants. *Id.*; see *Franklin v. Scripps Health*, No. 22-CV-367-MMA (MDD), 2022 WL 4389691, at *5 (S.D. Cal. Sept. 21, 2022).⁷

CONCLUSION

Defendants respectfully request that the Court stay proceedings in this case pending the resolution of district court proceedings in *Washington*.

Dated: July 5, 2023

Respectfully submitted,

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⁷ Contrary to Plaintiffs’ argument, Pls.’ Br. 4, *Landis* did not deny that litigating multiple duplicative lawsuits could harm the government. See *Landis*, 299 U.S. at 258–59 (remanding so the district court could decide whether to stay the case pending another district court proceeding). And although Plaintiffs argue that “[t]he federal government regularly defends concurrent lawsuits against the same policies,” Pls.’ Br. 7, Plaintiffs identify no example where the federal government litigated a case in which the ultimate relief sought conflicted with preliminary relief in effect from another case.

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Certificate of Service

I hereby certify the foregoing document was served via ECF on all counsel of record on July 5, 2023.

/s/ Isaac C. Belfer

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