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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

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|---|---|
| GRAHAM T. CHELIUS, M.D., *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>XAVIER BECERRA, *et al.*,<br><br>Defendants. | CIV. NO. 1:17-00493-JAO-RT<br><br>**DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO STAY PROCEEDINGS** |

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## INTRODUCTION

Defendants seek a stay of limited duration to promote judicial economy and efficiency and to conserve the parties' resources. 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), which are proceeding in an expedited fashion, could change the legal landscape relevant to Plaintiffs' claims. Absent a stay, the parties and the Court may waste resources on summary judgment proceedings now, only to repeat that process once *Alliance* is decided.

Temporarily pausing Plaintiffs' challenges to the Mifepristone Risk Evaluation and Mitigation Strategy ("REMS") Program will not impair Plaintiffs' interests. FDA notified Plaintiffs in December 2021 that mifepristone would continue to be subject to a REMS and that the prescriber certification requirement and patient agreement form requirement remained necessary, but that the REMS would be modified to remove the in-person dispensing requirement and add the pharmacy certification requirement. Plaintiffs then waited over a year to seek to reopen this case (on February 27, 2023); during that time, they did not seek to proceed on their original claims or seek any other relief from the Court. And after FDA approved the REMS modifications on January 3, 2023, Plaintiffs waited until March 30, 2023 to seek leave to file an amended complaint. Plaintiffs' delay in seeking to

redress their alleged injuries undermines their argument that they would be harmed by a stay.[1]

Plaintiffs note that in *State of Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash.), the parties jointly proposed, and the court entered, a schedule under which Defendants will respond to the amended complaint by June 23, 2023 and produce the same administrative record as in this case by September 1, 2023, without setting any dates for further proceedings, including summary judgment. Defendants proposed the same schedule to Plaintiffs here, both before and after filing their stay motion, but Plaintiffs declined to agree to that schedule. Defendants also offered to produce the administrative record on a rolling basis between now and September 1, as they agreed to do in *Washington*, but Plaintiffs declined that offer.

Plaintiffs object to a schedule that provides for production of the supplemental administrative record by September 1, 2023, Opp. 25 n.7, but Defendants do not have sufficient resources to commit to producing the complete record before that time. Defendants need to assemble that record, which dates back to 2019 and spans several thousand pages, and carefully review it to redact protected information

[1] Plaintiffs suggest that Defendants delayed this case by moving to dismiss for lack of standing in February 2018 and then withdrawing that motion in May 2018. ECF No. 173 ("Opp.") 5. But Defendants withdrew their motion because, after they filed the motion, the organizational plaintiffs submitted new declarations relating to standing, ECF No. 40.

pursuant to Defendants' statutory and regulatory obligations. Unable to reach agreement and faced with the inefficiencies of litigating this case both on an unreasonable schedule and before obtaining guidance in *Alliance*, Defendants elected to seek a stay of this case. If the requested stay is not granted, Defendants request that the Court adopt the schedule entered in *Washington*.

## ARGUMENT

### I. A Stay Would Be Efficient

Defendants explained in their motion that a stay would be efficient because the appellate proceedings in *Alliance* may resolve, narrow, or provide guidance on the issues in this case. For example, both *Alliance* and the amended complaint in this case raise the issue of the standard by which to judge FDA's actions concerning the Mifepristone REMS Program. *See* ECF No. 222, Br. for Fed. Appellants, at 38–62, *Alliance for Hippocratic Medicine v. FDA*, No. 23-10362 (5th Cir. Apr. 26, 2023); ECF No. 169 ("Am. & Supp. Compl.") ¶ 223. Although the plaintiffs in the two cases make different arguments, a decision in *Alliance* may address issues relevant to resolving the claims in this case, such as the degree of deference due FDA's decisions. The Fifth Circuit's decision, though not binding on this Court, could provide guidance on those issues. *Contra* Opp. 17 n.5. And if the Supreme Court hears the case, its decision could provide both guidance and binding precedent, which could resolve or narrow those issues.

Under these circumstances, "it is efficient for [the court's] own docket and the fairest course for the parties to enter a stay of [the] action before it, pending resolution of independent proceedings" in *Alliance* that could "bear upon the case." *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863–64 (9th Cir. 1979) (holding that granting a stay on this basis "does not require that the issues in such [independent] proceedings are necessarily controlling of the action before the court"). If the resolution of appellate proceedings in *Alliance* changes the legal landscape relevant to Plaintiffs' claims, the Court and the parties would have wasted resources on summary judgment proceedings only to have to undertake them again. The parties would again need to submit cross-motions for summary judgment, and the Court would need to consider and decide those motions.

Plaintiffs argue that *Alliance* will likely "be resolved based not on the plaintiffs' administrative law claims but on threshold questions of Article III standing and statutes of limitations that have no bearing on *Chelius*." Opp. 22. Defendants agree—and have vigorously argued—that the *Alliance* plaintiffs lack standing and that their challenge to mifepristone's initial approval is untimely. But *Alliance* could be resolved on any of the issues presented, including merits issues regarding the standard by which to judge FDA's actions concerning the Mifepristone REMS Program. *See generally* Oral Argument Tr., *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. May 17, 2023), *available at*

https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3 (discussing, *inter alia*, merits issues regarding the Mifepristone REMS Program).

Precedent is not to the contrary. *Contra* Opp. 23. In *Landis v. North American Co.*, 299 U.S. 248 (1936), the Court did not deny a stay. Rather the Court remanded the case so the district court could exercise its discretion based on the facts and the principles set out in the Court's opinion. *Id.* at 258–59. *Landis* is also readily distinguishable on the facts: the other case at issue in *Landis* was still proceeding in the district court whereas *Alliance* has already been briefed and argued in the Fifth Circuit. Moreover, the *Landis* plaintiffs might have faced harm during a stay pending resolution of the other case, *id.* at 256–57, unlike here, *see infra* pp. 8–11. Nevertheless, the Court recognized it was relevant to the stay analysis whether a decision in the other case would likely resolve or simplify the issues presented. *Landis*, 299 U.S. at 256. The Court also 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." *Id.*

Plaintiffs also cite *Dependable Highway Express, Inc. v. Navigators Insurance Co.*, 498 F.3d 1059 (9th Cir. 2007), for the proposition that "case management standing alone is not necessarily a sufficient ground to stay proceedings." Opp. 23 (quoting *Dependable Highway Exp.*, 498 F.3d at 1066). But in that case, "the

district court overlooked" other relevant factors, including that a stay would likely prejudicially harm the plaintiff and would not prevent harm to the defendant. *Dependable Highway Exp.*, 498 F.3d at 1066. Here, by contrast, Defendants have shown that the requested stay would not harm Plaintiffs and would prevent harm to Defendants, in addition to promoting judicial economy. Finally, *Yong v. INS*, 208 F.3d 1116 (9th Cir. 2000), *see* Opp. 23, is inapposite because it involved habeas proceedings, which are designed to provide a "swift and imperative remedy in all cases of illegal restraint or confinement" and "implicate special considerations that place unique limits on a district court's authority to stay a case in the interests of judicial economy." *Yong*, 208 F.3d at 1120.

Plaintiffs also argue that a stay would cause unreasonable delay. Opp. 16–19. In evaluating claims of delay in the stay context, courts consider whether the other case will likely "be concluded within a reasonable time in relation to the urgency of the claims presented to the court." *Leyva*, 593 F.2d at 864. Here, the lack of urgency of Plaintiffs' claims is evidenced by the fact that FDA informed Plaintiffs in December 2021 that allegedly harmful provisions of the Mifepristone REMS Program would remain in place, yet Plaintiffs waited over a year to seek to reopen this case. And after FDA approved REMS modifications on January 3, 2023, Plaintiffs waited several months to seek leave to file an amended complaint. *See infra* pp. 8–10. Meanwhile, appellate proceedings in *Alliance* have been moving

swiftly. The Fifth Circuit expedited the *Alliance* appeal and already heard oral argument on May 17, 2023. *See All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *21 (5th Cir. Apr. 12, 2023). Any appeal to the Supreme Court could well be decided by the end of next Term. Given this, a stay pending resolution of *Alliance* would be reasonable. *See Landis*, 299 U.S. at 258–59 (a stay is a discretionary judgment based on the facts currently before the court).

The requested stay is not unreasonable simply because there is uncertainty about exactly when *Alliance* will be resolved. For example, in *Ramachandran v. City of Los Altos*, No. 18-CV-01223-VKD, 2022 WL 2479652 (N.D. Cal. July 6, 2022), the court explained that "the duration of the stay [it granted] is not truly indefinite; it will be defined by the duration of the state court proceedings presently under way, even if the exact date on which those proceedings will conclude is not yet known." *Id.* at *3. Moreover, this Court has twice implicitly rejected Plaintiffs' argument. First, on January 23, 2020, it stayed this case until the Supreme Court decided *June Medical Services L.L.C. v. Russo*, 140 S. Ct. 2103 (2020), *abrogated by Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022), where the stay was expected to be of limited duration, though the timing of the Supreme Court's decision was uncertain. ECF No. 107. Second, on October 28, 2020, the Court vacated a conference based on the parties' joint request to continue it until the Supreme Court ruled on the Government's stay application in *FDA v. American*

*College of Obstetricians & Gynecologists*, No. 20A34 (U.S.), despite the uncertainty of when the Supreme Court would rule. ECF Nos. 117, 118.

Similarly, in *Leyva*, the district court had entered a stay until an arbitration was completed. 593 F.2d at 859. Even though it found the claims to be urgent, the Ninth Circuit did not hold that a stay was unreasonable. Rather, it remanded the case so the district court could determine whether the circumstances "justif[ied] continuance of the stay." *Id.* at 864. The circuit court noted that the arbitrator's findings "may be of valuable assistance to the court in resolving" the plaintiff's claims, even if "the court is not bound and controlled by the arbitrator's conclusions." *Id.* at 863.

**II. Plaintiffs Have Not Shown They Will Be Harmed by a Stay**

In their opposition, Plaintiffs repeat the allegations in their amended complaint regarding harm from the Mifepristone REMS Program. Opp. 20–21. But Plaintiffs' delay in challenging the REMS undercuts those allegations. Plaintiffs allege harm from the mere existence of the Mifepristone REMS Program, *e.g.*, Am. & Supp. Compl. ¶¶ 170–72, from the prescriber certification requirement, *e.g.*, *id.* ¶¶ 173–77, and from the patient agreement form requirement, *e.g.*, *id.* ¶¶ 173–75, 178–81. But FDA notified Plaintiffs in December 2021 that mifepristone for termination of early pregnancy would continue to be subject to a REMS and that the prescriber certification requirement and patient agreement form requirement remained

necessary. *Id.* ¶ 107. FDA also disclosed this information in a Citizen Petition response that was posted online in December 2021. *See* Letter from FDA to Am. Ass'n of Pro-Life Obstetricians and Gynecologists and Am. Coll. of Pediatricians (Dec. 16, 2021), at 6–7, *available at* https://www.regulations.gov/document/FDA-2019-P-1534-0016. Yet Plaintiffs waited over a year after December 2021 to seek to reopen this case, only making that request in a February 27, 2023 Joint Status Report that was ordered by the Court. ECF No. 157, ¶ 11; *see* ECF No. 155. During that time, Plaintiffs did not seek to proceed on their original claims or seek any other relief from the Court.

FDA also concluded in December 2021 that mifepristone will remain safe and effective if the in-person dispensing requirement is removed, provided all the other requirements of the REMS are met and pharmacy certification is added. FDA approved those REMS modifications on January 3, 2023. Am. & Supp. Compl. ¶¶ 107, 109. But Plaintiffs waited nearly two months to seek to reopen this case and another month to seek leave to file an amended complaint that challenged the pharmacy certification requirement. ECF No. 159; *see, e.g.*, Am. & Supp. Compl. ¶¶ 182–85. Moreover, this requirement does not directly harm Plaintiffs because none of the Plaintiffs alleges that it is a pharmacist or operates a pharmacy. Furthermore, the January 2023 REMS modifications broadened access to mifepristone, which if anything would benefit, not harm, Plaintiffs. Thus, Plaintiffs

have not shown that they would be harmed by a limited stay of this case until *Alliance* is resolved.

Contrary to Plaintiffs' argument, *Lockyer v. Mirant Corp.*, 398 F.3d 1098 (9th Cir. 2005), does not establish that plaintiffs would be harmed by a stay whenever they "'seek[] injunctive relief against ongoing and future harm' and their claims potentially have 'merit.'" Opp. 20 (alteration in original) (quoting *Lockyer*, 398 F.3d at 1112). Instead, *Lockyer* held that a stay was not justified in the particular "circumstances of th[at] case," and the fact that the plaintiff sought "injunctive relief against ongoing and future harm" was simply one of the factors the court considered. *Lockyer*, 398 F.3d at 1100, 1112. The court also noted that "it is highly doubtful that the [other lawsuit] will provide a legal resolution" to the plaintiff's claim, and so "the prospect of narrowing the factual and legal issues in the other proceeding" did not justify a stay. *Id.* at 1112. Here, by contrast, the prospect that the resolution of *Alliance* will resolve, narrow, or provide guidance on the issues in this case supports a stay. *See supra* pp. 3–8.

Finally, Plaintiffs' argument is further undercut by the preliminary injunction issued by the U.S. District Court for the Eastern District of Washington in April 2023. That court preliminarily enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 [REMS] under 21 U.S.C. § 355-1 in Plaintiff States and the District

of Columbia," which includes Hawaii. ECF No. 91, Order Granting Motion for Clarification, at 5–6, *State of Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. Apr. 13, 2023). To the extent Plaintiffs are seeking to change the REMS requirements in the jurisdictions subject to the *Washington* injunction, they might not be able to obtain the relief they seek even if a stay were denied and this case moved forward, thereby eliminating any harm from a stay.

## III. A Stay Would Prevent Harm to Defendants

In their motion, Defendants explained that a stay would conserve the parties' resources by avoiding having to re-litigate the case if the resolution of appellate proceedings in *Alliance* changes the legal landscape as to issues in the case. Plaintiffs respond that "being required to defend a suit, without more, does not constitute a 'clear case of hardship or inequity'" that could warrant a stay. Opp. 21–22 (quoting *Lockyer*, 398 F.3d at 1112). But Defendants are not required to make out a "clear case of hardship or inequity" absent a stay, *Lockyer*, 398 F.3d at 1112 (quoting *Landis*, 299 U.S. at 255), because there is not a "fair possibility that the stay" will harm Plaintiffs, *see supra* pp. 8–11. Moreover, even if Defendants were required to make this showing, they have done so. Absent a stay, Defendants would be harmed, not just by having to defend the present lawsuit, but by 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).

Plaintiffs note that Defendants "agreed to continue defending the REMS" in *Washington*. Opp. 22. But that is because Defendants and the *Washington* plaintiffs were able to agree on a reasonable schedule, which the court entered, setting dates for Defendants to respond to the amended complaint and produce the administrative record, without setting any dates for further proceedings, including summary judgment. ECF No. 119, Order, *State of Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. May 11, 2023). Defendants proposed the same schedule to Plaintiffs here before filing their stay motion, but Plaintiffs declined to accept it. After Defendants filed their stay motion and the *Washington* court entered the compromise schedule, Defendants again proposed that schedule to Plaintiffs. But Plaintiffs again declined to agree. In light of the parties' inability to reach agreement on a workable schedule, litigating this case before *Alliance* is decided will be particularly burdensome and inefficient.

## IV. If a Stay Is Not Granted, the Court Should Adopt the *Washington* Schedule

Plaintiffs ask the Court to require Defendants to produce the supplemental

administrative record by June 30, 2023. Opp. 25. That is unworkable. The supplemental administrative record is several thousand pages long and dates back to 2019, and Defendants need time to assemble and carefully review the record to redact protected information pursuant to their statutory and regulatory obligations. In particular, Defendants need to redact the names of FDA employees, as "redacting the names of [those] agency personnel [i]s necessary to reasonably assure [their] safety." *Jud. Watch, Inc. v. FDA*, 407 F. Supp. 2d 70, 77 (D.D.C. 2005), *aff'd in part, remanded in part*, 449 F.3d 141 (D.C. Cir. 2006) (quotations omitted) (addressing request for information regarding mifepristone). Defendants also must redact certain private individuals' identifying information, private companies' confidential commercial and/or trade secret information, and information protected by the attorney-client or deliberative-process privileges.

Defendants would be able to complete their review for protected information and produce the supplemental administrative record by September 1, 2023, just two months beyond Plaintiffs' requested deadline. Defendants offered to make rolling productions of the supplemental administrative record, as they will do in *Washington*, but Plaintiffs declined. If the Court declines to grant a stay, Defendants request that the Court enter the same schedule set in *Washington*: Defendants would respond to the amended complaint by June 23, 2023, and produce the supplemental administrative record by September 1, 2023. Defendants

would make rolling productions of the supplemental administrative record on June 16, July 14, August 11, and September 1, as they will do in *Washington*.

## CONCLUSION

Defendants respectfully request that the Court stay proceedings in this case until the resolution of appellate proceedings in *Alliance*. If the Court does not grant a stay, Defendants respectfully request that the Court adopt the schedule entered in *Washington.*

Dated: May 22, 2023

Respectfully submitted,

*/s/ Noah T. Katzen*
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**Certificate of Service**

I hereby certify the foregoing document was served via ECF on all counsel of record on May 22, 2023.

*/s/ Noah T. Katzen*

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