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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, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

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

JOINT MOTION TO STAY CASE PENDING AGENCY REVIEW

District Judge: Jill A. Otake
Summary Judgment Hearing: July 9, 2021, at 9:00 AM
Trial Date: Vacated per Dkt. 82

The Parties jointly seek a stay of this matter in light of Defendant U.S. Food and Drug Administration's ("FDA") current review of the risk evaluation and mitigation strategy ("REMS") at issue in this case. The Parties agree that the outcome of FDA's review could have a material impact on the course of this litigation. Accordingly, to conserve the resources of the Court and the Parties, the Parties seek a stay of this matter until December 1, 2021, with a joint status report, to include an update on the status of FDA's review, due on November 1, 2021.

FDA is reviewing the elements of the REMS for Mifeprex and its approved generic, Mifepristone Tablets, 200 mg, in accordance with the REMS assessment provisions of Section 505-1 of the Federal Food, Drug, and Cosmetic Act. In conducting this review, FDA is relying on information submitted by the sponsors of the new drug application ("NDA") and the abbreviated new drug application ("ANDA") and information from other sources, including published literature. FDA also commits to review any relevant data and evidence submitted by the Plaintiffs.

FDA recently completed a review of the in-person dispensing requirement (and related provisions) of the REMS in the context of the COVID-19 public health emergency ("PHE"). On April 12, 2021, in response to an April 2020 request from the American College of Obstetricians and Gynecologists ("ACOG"), the Agency decided that it intends to exercise enforcement discretion with respect

to the in-person dispensing requirement (and related provisions) during the pendency of the PHE.

In a letter announcing its decision, FDA stated that "provided the other requirements of the Mifepristone REMS Program are met," the Agency "intends to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form." Joint Stips. of Facts, Ex. J, at 2, Dkt. 140-10. FDA also stated that, "to the extent all of the other requirements of the Mifepristone REMS Program are met," the Agency "intends to exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of mifepristone through the mail either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber." *Id.* If FDA's review of the REMS is not completed before the expiration of the PHE, FDA agrees that it intends to exercise this enforcement discretion for a further 30 days following the end of the PHE to afford an opportunity for the mifepristone drug sponsors and mifepristone prescribers to modify their operational protocols.

In light of FDA's decision, the parties in *ACOG v. FDA*, No. 8:20-cv-1320-TDC (D. Md.), recently filed a joint status report indicating that the plaintiffs intend to voluntarily dismiss their case challenging the restricted dispensing

requirement (and related provisions) during the PHE. The parties also stated their intention to jointly move for dismissal of appeals pending in the U.S. Court of Appeals for the Fourth Circuit, No. 20-1784.

Similarly, the outcome of FDA's review of the REMS could have a material effect on the issues before this Court. Thus, to conserve the resources of the Court and the Parties, the Parties jointly seek a stay of proceedings until December 1, 2021. *See, e.g.*, *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863 (9th Cir. 1979) (recognizing district court authority to stay litigation in the interest of efficiency and fairness "pending resolution of independent proceedings which bear upon the case"); EO (Jan. 23, 2020), Dkt. 107.

Previously, the Court stayed this case *sua sponte* pending the Supreme Court's ruling in *June Medical Services, L. L. C. v. Russo*, 140 S. Ct. 2103 (2020). *See* EO (Jan. 23, 2020), Dkt. 107; EO (Jan. 13, 2020), Dkt. 102. Following the *June Medical* decision and certain proceedings in the *ACOG* litigation, the Court recently lifted its stay in response to Plaintiffs' unopposed motion. *See* EO (Mar. 5, 2021), Dkt. 128; Pls.' Unopposed Mot. to Lift Stay & Reactivate Summ. J. Briefing, Dkt. 127. Plaintiffs made their request to lift the stay, however, prior to FDA's April 2021 decision and prior to FDA's current review of the REMS. In light of these developments, the stay presently sought by the Parties would once again enable the Court to handle this case "with economy of time and effort for

itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936).

For the foregoing reasons, the Parties respectfully propose that the Court enter an Order: (1) staying this litigation until December 1, 2021; (2) directing the Parties to submit a joint status report by November 1, 2021; and (3) permitting any Party to move to lift or extend the stay for good cause.

Dated: May 7, 2021

Respectfully submitted,

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