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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' MOTION TO  
STAY PROCEEDINGS**

Defendants respectfully move this Court to stay proceedings. Good cause exists for such a stay because a pending appeal may resolve, narrow, or provide guidance on some or all of the issues in this case, and thus a stay pending resolution of that appeal would appropriately conserve the parties' and the Court's resources. Plaintiffs have informed Defendants that they oppose this Motion and intend to respond.

1. On April 7, 2023, the United States District Court for the Northern District of Texas entered an order invoking 5 U.S.C. § 705 to stay the approval of the new drug application (NDA) and abbreviated new drug application (ANDA) for mifepristone for the medical termination of early pregnancy. *See Alliance for Hippocratic Medicine v. FDA*, No. 2:22-cv-00223-Z, ECF No. 137 (N.D. Tex. Apr. 7, 2023).

2. The Government filed its Notice of Appeal of the *Alliance* order that same day, and moved for a stay pending appeal in the United States Court of Appeals for the Fifth Circuit on April 10. On April 12, the Fifth Circuit granted in part and denied in part the Government's requested relief. *See Alliance for Hippocratic Medicine v. FDA*, 2023 WL 2913725 (5th Cir. Apr. 12, 2023). As modified by the Fifth Circuit's decision, the *Alliance* district court order would have stayed various actions FDA has taken with respect to the NDA and ANDA

for mifepristone for medical termination of early pregnancy since 2016, including the January 2023 modifications to the Risk Evaluation and Mitigation Strategy (REMS) for such products. However, on April 21, the Supreme Court stayed the *Alliance* district court order “pending disposition of the appeal in [the Fifth Circuit] and disposition of a petition for writ of certiorari, if such a writ is timely sought.” *Danco Labs., LLC v. Alliance for Hippocratic Medicine*, 2023 WL 3033177, at \*1 (U.S. Apr. 21, 2023). The Fifth Circuit is scheduled to hear oral argument in that appeal on May 17.

3. The district court in *Alliance* has stayed the Government’s deadline to answer or otherwise respond to the complaint in that case pending resolution of all appellate avenues. *Alliance for Hippocratic Medicine*, No. 2:22-cv-00223-Z, Dkt. 144 (Apr. 25, 2023).

4. The appeal in *Alliance* may resolve, narrow, or provide guidance on some or all of the issues that this Court would have to decide were this case to move forward. For instance, if the Supreme Court ultimately grants certiorari in *Alliance*, its decision may address (among other things) the standard under which FDA’s decisions relating to mifepristone for medical termination of early pregnancy should be reviewed.

5. “A district court has inherent authority and discretion to stay

proceedings in the interest of the conservation of resources ‘for itself, for counsel, and for litigants.’” *Ramachandran v. City of Los Altos*, 2022 WL 2479652, at \*2 (N.D. Cal. Jul. 6, 2022) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)); see also *Dependable Highway Exp., Inc. v. Navigators Ins. Co.*, 498 F.3d 1059, 1066 (9th Cir. 2007) (acknowledging “the general principle that a district court possesses the inherent power to control its docket and promote efficient use of judicial resources”). The Court should exercise that authority here to stay proceedings because it makes little sense for the parties and the Court to spend time and resources on further litigation of Plaintiffs’ claims when pending appellate proceedings in *Alliance* may resolve, narrow, or provide guidance on the very issues to be litigated.

6. For these reasons, Defendants respectfully move this Court to stay proceedings until the resolution of the Government’s appeal of the *Alliance* district court order. Defendants further propose that, within two weeks of the resolution of all appellate avenues with respect to that order—including any petitions for certiorari and related subsequent proceedings, if applicable—the parties will propose a schedule regarding further proceedings.

Dated: May 4, 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 4, 2023.

/s/ Noah T. Katzen

Noah T. Katzen