ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director

HILARY K. PERKINS
Assistant Director

JONATHAN E. AMGOTT (DCBN 1031947)
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
450 5th Street, N.W.
Washington, D.C. 20530
(202) 532-5025
Jonathan.E.Amgott@usdoj.gov

Attorneys for Defendants Xavier Becerra, et al.
(see signature page for complete list)

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 STATUS REPORT** District Judge: Jill A. Otake Summary Judgment Hearing: Vacated per Dkt. 149 Trial Date: Vacated per Dkt. 82

Pursuant to this Court's May 7, 2021 Order Granting Joint Motion to Stay Case Pending Agency Review (Dkt. 149), the Parties submit the following status update:

As stated in the Joint Motion to Stay Case Pending Agency Review (Dkt. 148), and again in the August 5, 2021 Joint Status Report (Dkt. 151), Defendant U.S. Food and Drug Administration ("FDA") is reviewing the elements of the risk evaluation and mitigation strategy ("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 and the abbreviated new drug application, information from other sources (including published literature), and any relevant data and evidence submitted by the Plaintiffs.

FDA has been working diligently to conduct this review, will continue to do so, and anticipates completing its review by December 16, 2021. FDA will communicate the agency's determinations to Plaintiffs upon completion of FDA's review. In order to give the Parties time to determine appropriate next steps in this litigation, the Parties request an extension of the current stay until January 14, 2022. If FDA's review of the REMS, and implementation of any changes to the REMS that result from such review, are not completed before the expiration of the

COVID-19 Public Health Emergency ("PHE"), FDA agrees that it intends to exercise its enforcement discretion with respect to the in-person dispensing requirement of the mifepristone REMS (*see* Dkt. 148, at 2-3) for a further 30 days following the end of the PHE.

Dated: November 3, 2021

Respectfully submitted,

/s/ Jonathan E. Amgott
JONATHAN E. AMGOTT
Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice

Attorney for Defendants Xavier Becerra, J.D., in his official capacity as Secretary, U.S. Department of Health and Human Services; U.S. Food and Drug Administration; and Janet Woodcock, M.D., in her official capacity as Acting Commissioner of Food and Drugs

/s/ Julia Kaye
JULIA KAYE*
RACHEL REEVES*
LORIE CHAITEN*
WHITNEY WHITE*
RUTH HARLOW*
American Civil Liberties Union Foundation

JONGWOOK "WOOKIE" KIM
ACLU of Hawai'i Foundation

JOHN FREEDMAN*
Arnold & Porter Kaye Scholar, LLP

* admitted *pro hac vice*

Attorneys for Plaintiffs Graham T. Chelius, M.D., Society of Family Planning, and California Academy of Family Physicians