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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

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

Plaintiffs,

vs.

NORRIS COCHRAN,[1] *in his official capacity as* ACTING SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

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

PLAINTIFFS' UNOPPOSED MOTION TO LIFT STAY AND REACTIVATE SUMMARY JUDGMENT BRIEFING

Judge: Hon. Jill A. Otake
Magistrate Judge: Hon. Rom A. Trader
Trial Date: Vacated per ECF No. 82

[1] Per Fed. R. Civ. P. 25(d), where a public officer is a named party in his official capacity, his successor is automatically substituted as the named party.

In October 2017, Plaintiffs brought this litigation challenging the U.S. Food and Drug Administration's (FDA) singular restrictions on Mifeprex®,[2] a safe and effective prescription medication used for early abortion and miscarriage care.[3] In January 2020, with only reply briefs remaining on the Parties' cross-motions for summary judgment, this Court stayed this matter *sua sponte* pending the U.S. Supreme Court's decision in *June Medical Services, LLC v. Russo*, 140 S. Ct. 2103 (2020). *See* ECF No. 107. The Court provided that any Party could move to lift the stay once *June* had been decided, and that the Parties could also request reactivation of the summary judgment motions. *Id.* Plaintiffs now file this unopposed motion seeking to both lift the stay and reactivate briefing, pursuant to a compromise proposal negotiated between the Parties.

To inform the Court's consideration of this motion, Plaintiffs first briefly summarize key events over the past year relating to the challenged FDA restrictions, known as the FDA's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex.

Background on Related Proceedings

In early 2020, the COVID-19 pandemic arrived in the United States. In light of the

[2] Plaintiffs use Mifeprex® herein to refer both to the brand name and generic versions of mifepristone used for abortion, which are subject to identical FDA restrictions.

[3] U.S. Food & Drug Admin., Ctr. For Drug Eval. & Res., *Application Number 020687Orig1s020: Medical Review(s)* 12 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (since 2000, Mifeprex "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare"); *accord* Pls.' Concise Statement Facts Supp. Mot. Summ. J., ECF No. 87, at ¶ 4.

viral exposure risks associated with traveling for health care, Defendants Secretary of Health and Human Services ("the Secretary") and FDA acted swiftly to encourage the use of telemedicine and relax in-person requirements for highly regulated medications. For instance, in March 2020, the Secretary suspended a mandatory requirement that patients meet with a clinician in person to be evaluated and counseled before being prescribed controlled substances, including opioids; FDA issued guidance stating its intention not to enforce REMS requirements that patients undergo laboratory testing or imaging studies to obtain certain drugs carrying serious risks; and FDA authorized sponsors of clinical trials to forgo in-person visits, even for unapproved drugs whose safety has not yet been determined.[4] Nevertheless, despite urgent requests from leading medical authorities, FDA refused to suspend its REMS requirement that patients pick up Mifeprex in person at a hospital, clinic, or medical office, rather than obtain their prescription by mail or through a mail-order pharmacy.[5]

In late May, a coalition of plaintiffs led by the American College of Obstetricians and Gynecologists ("ACOG") brought new litigation in the U.S. District Court for the

[4] *COVID-19 Information Page: Telemedicine*, U.S. Dep't of Justice, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 3, 2021); U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency 7 (2020), https://www.fda.gov/media/136317/download; U.S. Food & Drug Admin., Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency 3 (2020, updated 2021), https://www.fda.gov/media/136238/download.

[5] *See ACOG v. FDA*, 472 F. Supp. 3d 183, 218 (D. Md. 2020).

District of Maryland challenging the Mifeprex REMS to the extent it requires patients to obtain the medication only in person at a health center, rather than by mail or through a pharmacy, during the COVID-19 pandemic. *See ACOG v. FDA*, No. 20-cv-1320-TDC (D. Md. May 27, 2020). The plaintiffs sought a preliminary injunction, arguing that the FDA's in-person requirements for Mifeprex are unconstitutional under present circumstances because they subject patients to heightened COVID-19 exposure risks. *See generally id.*, ECF Nos. 11-12. The instant matter remained stayed during this time.

Meanwhile, on June 29, 2020, the Supreme Court decided *June Medical Services, LLC v. Russo*, finding that the Louisiana abortion provider plaintiffs had third-party standing to raise the substantive due process rights of their patients and potential patients, and striking down the challenged restrictions on abortion despite the "State's asserted interests in promoting women's health and safety." 140 S. Ct at 2112-13, 2118-20, 2132-33 (plurality opinion); *id*. at 2133-34, 2139 n.4, 2141-42 (Roberts, C.J., concurring).

Shortly thereafter, on July 13, 2020, the Honorable Judge Theodore D. Chuang granted in part a nationwide preliminary injunction barring Defendants from enforcing the Mifeprex in-person requirements during the COVID-19 Public Health Emergency and permitting the dispensing of Mifeprex to patients by mail or delivery service by or under the supervision of a certified healthcare provider, including supervised delivery through a mail-order pharmacy subject to certain conditions. *ACOG v. FDA*, 472 F. Supp. 3d at 229, 232-33 (D. Md. 2020); *ACOG v. FDA*, No. 20-cv-1320-TDC, 2020 WL 8167535,

at *1-2 (D. Md. Aug. 19, 2020) (clarifying that injunction permitted dispensing by mail-order pharmacy).

The preliminary injunction remained in effect for six months, while the parties briefed Defendants' multiple motions in the district court and court of appeals for a stay of the injunction pending appeal, as well as Defendants' two stay applications in the U.S. Supreme Court.[6] On January 12, 2021, the Supreme Court granted Defendants' stay application. *FDA v. ACOG*, 141 S. Ct. 578 (2021) (mem.). The majority gave no explanation for its ruling. *Id.* at 578. Chief Justice Roberts, who concurred in the judgment, issued a one-paragraph opinion explaining:

> The question before us is not whether the requirements for dispensing mifepristone impose an undue burden on a woman's right to an abortion as a general matter. The question is instead whether the District Court properly ordered the Food and Drug Administration to lift those established requirements because of the court's own evaluation of the impact of the COVID-19 pandemic. Here as in related contexts concerning government responses to the pandemic, my view is that courts owe significant deference to the politically accountable entities with the "background, competence, and expertise to assess public health." In light of those considerations, I do not see a sufficient basis here for the District Court to compel the FDA to alter the regimen for medical abortion.

[6] Notably, in denying Defendants' renewed motion to stay, dissolve, or modify the preliminary injunction, the district court noted that, four months after the injunction took effect, "Defendants have offered no evidence that their temporary inability to enforce the In-Person Requirements has injured them or, for that matter, harmed a patient." *ACOG v. FDA*, No. CV TDC-20-1320, 2020 WL 7240396, at *12 (D. Md. Dec. 9, 2020).

Id. at 578-79 (citation omitted). As of January 12, the REMS in-person requirements are back in effect, while merits briefing in *ACOG* continues in the Fourth Circuit.[7]

The Parties' Compromise Proposal

On January 26, 2021, Magistrate Judge Trader held a status conference with the Parties here. Plaintiffs represented that they seek to reinstate summary judgment briefing promptly now that all of the challenged restrictions are back in effect, while Defendants represented that they seek additional time for officials in the new Administration to familiarize themselves with this matter. Following that status conference, the Parties negotiated a compromise proposal, which Plaintiffs now present to the Court in this unopposed motion:

Plaintiffs respectfully request that the Court lift the stay in this matter and reactivate the summary judgment briefing terminated in January 2020, for which the Parties have already submitted joint stipulations of fact, opening and response briefs, and supporting and opposing concise statements of fact, and for which Plaintiffs have also submitted several unrebutted declarations. *See* ECF Nos. 85-91, 96-101. The Parties believe that it serves their best interests and the interest of judicial economy for the Court to resolve these motions based on the briefing and evidence the Parties have already submitted, plus

[7] The consolidated briefing in the Fourth Circuit also includes an appeal by the State of Indiana and nine other States of the denial of intervention, and an appeal by Plaintiffs of the denial in part of preliminary injunctive relief. *See generally ACOG v. FDA & State of Ind.*, No. 20-1784 (4th Cir. *appeal docketed* July 15, 2020), No. 20-1824 (4th Cir. *appeal docketed* July 22, 2020), No. 20-1970 (4th Cir. *appeal docketed* September 10, 2020).

reply briefs addressing the contested issues as well as recent developments, rather than starting briefing anew at this stage. The Parties respectfully request that the Court set a deadline of April 23, 2021, for reply briefs.

This Court previously granted the Parties' request to increase the word limit for reply briefs from 3,750 (pursuant to LR 7.4(c)) to 4,500, to enable the Parties to fully address FDA's regulatory processes for drugs, Mifeprex's lengthy regulatory history, and Plaintiffs' multiple claims under both administrative and constitutional law. *See* ECF Nos. 79, 82. The Parties now respectfully request a further increase of the word count to 7,500 words, to enable them to fully address recent developments in other pertinent cases, including *June*.

Dated: March 4, 2021.

Respectfully submitted,

/s/ Julia Kaye
JULIA KAYE*
RACHEL REEVES*
American Civil Liberties Union Foundation

/s/ Jongwook "Wookie" Kim
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[1] Per Fed. R. Civ. P. 25(d), where a public officer is a named party in his official capacity, his successor is automatically substituted as the named party.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on March 4, 2021, true and correct copies of the foregoing documents were electronically transmitted to the Clerk's Office using the CM/ECF System, which will send notification of such filing to all counsel of record.

DATED: Honolulu, Hawaii, March 4, 2021.

Respectfully submitted,

/s/ Jongwook "Wookie" Kim
JONGWOOK "WOOKIE" KIM
ACLU of Hawai'i Foundation

Attorney for Plaintiffs