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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

HEIDI PURCELL, M.D., FACOG, *et al.*

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION
Case No. 1:17-cv-00493-JAO-RT

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT, MEMORANDUM OF LAW, AND CERTIFICATE OF SERVICE

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Plaintiffs challenge Defendant U.S. Food and Drug Administration's ("FDA" or "the Agency") January 3, 2023, decision to subject mifepristone[1]—a prescription medication that millions of U.S. patients have used to end an early pregnancy or treat a miscarriage—to a set of medically unjustified restrictions that FDA does not impose on countless other equally or less safe drugs, and which reduce access to this essential medication. Plaintiffs hereby move this Court for an order (1) granting summary judgment in their favor, (2) declaring Defendants' Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone unlawful under the Administrative Procedure Act ("APA"),[2] and (3) remanding to FDA with instructions to reconsider the 2023 mifepristone REMS, including addressing the statutory criteria for REMS and for Elements to Assure Safe Use ("ETASU")—the most restrictive kind of REMS and those at issue here—as well as other relevant evidence and key considerations the Agency previously ignored.

FDA's 2023 decision reauthorizing the mifepristone REMS, including

[1] Plaintiffs use "mifepristone" to refer to both the brand-name drug, Mifeprex, and its generic, mifepristone, which are subject to identical regulations. Pls.' Concise Statement of Facts ("PCSF") ¶43, filed concurrently with this motion.

[2] FDA's 2023 REMS Decision is also unlawful under the Equal Protection Clause and under the APA as "contrary to constitutional right," 5 U.S.C. §706(2)(B), because it singles out clinicians who prescribe, and pharmacists who dispense, medication abortion for onerous, illogical restrictions to which clinicians and pharmacists prescribing other, *less safe* drugs are not subject. However, while preserving those claims, Plaintiffs do not move for judgment on them at this time.

retaining two preexisting ETASU (Patient Agreement and Prescriber Certification) and adding a new Pharmacy Certification ETASU ("2023 REMS Decision"), was arbitrary and capricious and contrary to law in numerous ways: ***First***, FDA refused to examine unquestionably relevant data, including the nation's leading medical associations' statements opposing the mifepristone REMS and a peer-reviewed study showing *no* reduction in safety after Canada eliminated its REMS-like restrictions on mifepristone. ***Second***, FDA's decision was unreasoned. The Agency failed to address mandatory statutory criteria, ignored objections and evidence contrary to its conclusions, and nowhere addressed (much less justified) the fact that FDA regulates mifepristone—which medical experts agree is safer than Tylenol, Viagra, and penicillin—more stringently than deadly opioids. Moreover, rather than basing its conclusions on evidence and expertise, FDA's implausible explanations rested on speculation. ***Third***, the Agency did not adhere to the strict statutory standards established by Congress to limit when and how FDA constrains patients' access to an approved medication.

Plaintiffs make this Motion pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56.1, following numerous conferences of counsel pursuant to Local Rule 7.8 starting on July 19, 2024, and conferences and communications with the Court. *See, e.g.*, Dkt. 211. Summary judgment is supported by Plaintiffs' Memorandum of Law and Concise Statement of Facts, filed herewith,

as well as any reply or other submissions Plaintiffs file hereafter. Oral argument has been vacated, Dkt. 107, and will be rescheduled following receipt of this motion, Dkt. 128, 130, 172.

Plaintiffs respectfully request that the Court:

1) Declare, pursuant to 28 U.S.C. §2201, that the mifepristone REMS in its entirety violates the APA; and/or
2) Declare, pursuant to 28 U.S.C. §2201, that certain components of the mifepristone REMS violate the APA:
    a. ETASU A (Prescriber Certification); and/or
    b. ETASU B (Pharmacy Certification); and/or
    c. ETASU D (Patient Agreement Form); and/or
    d. Implementation System; and/or
    e. Timetable for Assessments; and
3) Remand to FDA with instructions to reevaluate the Mifepristone REMS Program while maintaining the approvals of the brand name Mifeprex (mifepristone), NDA 020687, and the generic mifepristone, ANDA 091178. Plaintiffs respectfully request that the Court specify that the Agency's forthcoming review must weigh each of the statutory factors for REMS and ETASU set out at 21 U.S.C. §355-1(a)(1), (f)(1)-(2), and (g)(4)(B), and that the Agency also must consider and address, *inter alia*, the following materials

to the extent that they are already part of the administrative record in this case, are identified by FDA during its forthcoming literature review, or are submitted to FDA by Plaintiffs or by third parties during the course of its forthcoming review:

a. Policy statements, opinions, commentary, letters, and citizen petitions relating to the mifepristone REMS, and the references cited therein, submitted and/or signed by professional medical societies with members who routinely prescribe mifepristone for abortion care;

b. The Schummers et al. study that FDA failed to consider prior to its 2023 REMS decision,[3] and similarly relevant safety data;

c. Quantitative and qualitative studies, reports, and testimonials by stakeholders (e.g., physicians, advanced practice clinicians, and pharmacists who currently prescribe or dispense mifepristone, or who seek to do so) relevant to whether the REMS and ETASU are necessary and appropriate for mifepristone, *see* 21 U.S.C. §355-1(a)(1), (f)(1)-(2), (g)(4)(B)(i), and how the mifepristone REMS and its ETASU burden "patient access" and "the health care delivery system," *id.* §355-1(f)(2)(C)-(D), (g)(4)(B)(ii);

[3] Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57–67 (2022), PCSF ¶57 (at 2022CP99–109).

d. Data reflecting whether and how mifepristone patients "have difficulty accessing health care," *id.* §355-1(f)(2)(C)(ii);

e. Whether there can be a reasonable, evidence-based explanation that the three mifepristone ETASU "conform with [ETASU] for other drugs with similar, serious risks," *id.* §355-1(f)(2)(D)(i), in light of the fact that FDA does not impose comparable restrictions on equally or far *less* safe drugs, including those identified by Plaintiffs and by other medical experts, *see supra* (a).

4) Direct FDA to provide periodic reports to the Court as to the status of its mifepristone REMS review and anticipated timeframe for completion;

5) Award to Plaintiffs costs, expenses, and attorneys' fees pursuant to 28 U.S.C. §2412; and

6) Award such other, further, and different relief as the Court deems just and proper.

DATED: Honolulu, Hawai‘i, October 2, 2024.

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