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

GRAHAM T. CHELIUS, M.D., *et al.*, Plaintiffs, vs. ALEX M. AZAR, II,[1] *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC **DEFENDANTS' MOTION TO DISMISS COMPLAINT** Judge: Hon. Derrick K. Watson Related Documents: Dkt. No. 1

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

Defendants, Alex M. Azar, in his official capacity as Acting Secretary of the United States Department of Health and Human Services, United States Food and Drug Administration ("FDA"), and Scott Gottlieb, M.D., in his official capacity as Commissioner of Food and Drugs, hereby move the Court to dismiss this action in its entirety. *See* Fed. R. Civ. P. 12. The grounds for this motion are set forth in the accompanying memorandum of law.

Dated: February 5, 2018.

Respectfully submitted,

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INTRODUCTION

Plaintiffs in this case have filed suit without standing. Plaintiffs claim that the U.S. Food and Drug Administration's (FDA) decision to approve a drug manufacturer's application to ease restrictions on an abortion drug somehow established an undue burden on abortion access, caused an equal protection problem, and violated the Administrative Procedure Act (APA). But Plaintiffs lack standing to make these claims because no plaintiff asserts a cognizable harm traceable to FDA's decision that the relief sought could remedy. Indeed, Plaintiffs identify no patient who has been unable to obtain the drug at issue. The Court thus should dismiss Plaintiffs' complaint.

Mifeprex (mifepristone) is the drug at issue in this case. Mifeprex was the first—and remains the only—approved drug for non-surgical abortions. Since FDA first approved Mifeprex in 2000, the agency has required compliance with certain safeguards related to, and as a condition of, the drug's prescribing and dispensing. FDA has required these safeguards because of the substantial health risks associated with Mifeprex, including incomplete abortion or serious bleeding that can cause death and requires surgical intervention in 2-7 out of every 100 women who take the drug.

Mifeprex's required safeguards include, in relevant part, that the drug be dispensed only in certain healthcare settings by a certified healthcare provider who

can accurately assess the duration of a pregnancy, diagnose an ectopic pregnancy (for which Mifeprex is contraindicated), and provide—or otherwise assure access to—surgical intervention in cases of incomplete abortion or severe bleeding. These safeguards are incorporated in a Risk Evaluation and Mitigation Strategy (REMS) designed to protect against Mifeprex's risks. The REMS, along with the accompanying approved labeling, mitigates the serious health consequences associated with Mifeprex's use.

In 2015, Mifeprex's manufacturer, Danco Laboratories, LLC, submitted a supplemental new drug application (SNDA) to FDA, seeking to change the dose and dosing regimen in Mifeprex's approved labeling and to make certain correlating REMS adjustments. Medical experts and professional associations—including one of the Plaintiff organizations in this case—provided FDA with information regarding the SNDA. Notably, Danco did not ask FDA to remove the REMS entirely or to lift safeguards in the REMS requiring that only certified providers be able to prescribe and dispense Mifeprex in certain healthcare settings.

Responding to Danco's SNDA, FDA in 2016 approved several changes for Mifeprex, including a revision of its REMS and labeling. FDA made the revisions after considering evidence submitted by Danco. Consistent with Danco's SDNA and FDA's finding that Mifeprex's "safety profile" had "not substantially changed," the revised REMS and labeling maintained necessary safeguards against

Mifeprex's risks but changed other provisions, including by extending the gestational period of approved use from 49 to 70 days, allowing certain non-physicians to prescribe the drug, and allowing patients to take the drug somewhere other than a "provider's office."

Plaintiffs now contest FDA's 2016 approval of the modified REMS, arguing that FDA should not merely have modified the restrictions in the REMS as Danco requested, but should have eliminated the REMS entirely. Dr. Graham T. Chelius, an obstetrician, sues on behalf of himself and his patients. Three nonprofit organizations, Society of Family Planning (SFP), California Academy of Family Physicians (CAFP), and Pharmacists Planning Services, Inc. (PPSI), all sue on behalf of their members (who are doctors, pharmacists, and pharmacies) and their members' patients. None of the Plaintiffs or their members have alleged that they are certified providers of Mifeprex. Nor do plaintiffs identify any members who have ever sought to become certified providers. Nevertheless, Plaintiffs claim the revised Mifeprex REMS—and especially the maintained safeguard that only certified healthcare providers may prescribe and dispense the drug in appropriate healthcare settings—(1) violate their patients' and members' due process rights to liberty and privacy by assertedly placing undue burdens on access to abortion; (2) violate their patients' and members' equal protection rights by assertedly treating them differently from recipients and prescribers of other drugs; and (3) violate the

APA by assertedly stemming from agency action that was contrary to the Fifth Amendment, exceeded statutory authority, and was arbitrary, capricious, an abuse of discretion, and otherwise unlawful.

Plaintiffs lack standing to assert these claims. As an initial matter, although they ask this Court to remove *all* the REMS requirements, Plaintiffs focus almost entirely on the REMS requirements that only certified providers prescribe and dispense the drug in appropriate healthcare settings. But they fail to demonstrate a redressable injury traceable even to those REMS requirements. That is, Plaintiffs allege that the process of becoming, and the hypothetical professional stigma associated with being, a certified healthcare provider of Mifeprex limits their ability to provide the drug to their patients. But that allegation is purely conjectural: Plaintiffs, who do not claim ever to have attempted becoming certified providers, cite no instance where such injury has occurred. Moreover, any alleged harms from the potential reactions or inaction of Plaintiffs' colleagues or others are, at best, entirely speculative actions of third parties not traceable to FDA's reauthorization of the REMS. Plaintiffs also cannot show that their requested relief will redress their alleged harms, since any alleged stigma would likely attach even if they prescribed Mifeprex without distributing it from their offices. For the same reasons, Plaintiffs fail to identify at least one member doctor, pharmacist, or pharmacy that has been harmed, as required to establish

organizational standing to sue on behalf of their members; and they likewise fail to establish that their member doctors have third-party standing to assert the rights of their patients.

The Court, therefore, should dismiss Plaintiffs' complaint under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction.

BACKGROUND

I. Statutory and Regulatory Background

FDA is responsible for considering whether and how to approve new drugs for use. 21 U.S.C. § 355(a). A drug sponsor requests FDA approval of a new drug through a new drug application (NDA). In certain circumstances, FDA also may approve specified changes to a previously approved NDA, which a drug sponsor may request through a supplemental NDA (SNDA). *See generally* 21 C.F.R. § 314.70.

The Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, authorizes FDA to require a REMS for a drug if the agency determines that the REMS is necessary to ensure the drug's benefits outweigh its risks. *See* 21 U.S.C. § 355-1(a). A REMS may include a specific labeling requirement, such as incorporation of a Medication Guide, to explain a drug's risks and offer important instructions. *See* 21 U.S.C. § 355-1(e). A REMS also may

include the imposition of certain elements to assure safe use (ETASU) if a drug is associated with a serious adverse drug experience that makes its approval contingent on the existence of those elements to mitigate its serious risks. *See* 21 U.S.C. § 355-1(f). ETASU can include, among other things, requirements that a drug's prescribers have particular training or experience, and that prescribers dispense a drug only in certain healthcare settings and/or only after providing patients with documentation of safe use conditions. *See id.* In addition, a REMS may require an implementation system to monitor and evaluate the REMS's operation and effectiveness. *See* 21 U.S.C. § 355-1(f)(4).

FDA may require a REMS for a new or previously approved drug. For a new drug requiring a REMS, FDA requires the sponsor of the NDA to propose the REMS. FDA considers this proposal in approving the REMS if and when it approves the NDA. Once FDA approves a drug with a REMS, the drug sponsor later may seek to revise the REMS in conjunction with a SNDA. *See* 21 U.S.C. § 355-1(g)(4).

II. Factual Background

A. FDA's Regulatory Proceedings Concerning Mifeprex

On September 28, 2000, FDA approved a NDA for Mifeprex, authorizing the drug's use in a 600-mg dose, in a regimen with another drug (misoprostol), to terminate intrauterine pregnancy through 49 days' pregnancy (NDA 20-687). FDA

approved the NDA with certain restrictions under 21 C.F.R. part 314, subpart H, to assure safe use of the drug by providing patients information about Mifeprex's risks, and allowing only certified doctors qualified to manage serious complications to prescribe and dispense Mifeprex.

In 2007, pursuant to Section 909(b)(1) of the newly enacted FDAAA, Mifeprex was "deemed to have in effect an approved risk evaluation and mitigation strategy" (*i.e.*, a REMS) because FDA previously had approved it with certain restrictions under 21 C.F.R. part 314, subpart H.

In 2011, FDA then affirmatively approved Mifeprex's REMS with certain ETASU, maintaining the safeguards initially imposed in 2000 and subsequently deemed a REMS in 2007. FDA determined that the safeguards in the REMS with ETASU remained necessary for Mifeprex because, like any drug requiring ETASU, "it was associated with serious adverse drug experiences, [could] be approved only if, or would be withdrawn unless, such elements [were] required" as part of a strategy to mitigate the specific serious risks listed in its labeling. *See* 21 U.S.C. § 355-1(f). Mifeprex's 2011 REMS with ETASU specifically required the following:

First, dispensation of a Medication Guide explaining Mifeprex's risks and providing important information and instructions with each Mifeprex prescription. Included within the Medication Guide were information and instructions that—

- Mifeprex was for use in terminating "early pregnancy," defined as "49 days (7 weeks) or less since your last menstrual period began."

- The patient would need to take Mifeprex with another drug (misoprostol) to end her pregnancy.

- "[A]bout 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding."

- After receiving Mifeprex from a certified prescriber, a patient takes the Mifeprex tablets "at [her] provider's office."

- A patient returns to her provider's office about 14 days after taking Mifeprex to ensure that her pregnancy has "completely ended" and, if it has not, to discuss the "chance that there may be birth defects" and the possible need for "a surgical procedure."

Second, three types of ETASU (A, C, and D) were imposed—

- ETASU A: Certification of healthcare providers who prescribe Mifeprex. Danco will ensure that healthcare providers who prescribe Mifeprex will be specially certified. To become specially certified, each prescriber must complete and fax to the Mifeprex distributor a one-time (and one-page) Prescriber's Agreement, by which prescribers—described as "physicians"—agree that they:

    - Have the ability to assess the duration of a pregnancy accurately, diagnose an ectopic pregnancy, provide a surgical intervention in cases of incomplete abortion or severe bleeding (or have made plans to provide such care through others), and assure patient access to medical facilities equipped to provide blood transfusions and resuscitation if necessary;

    - Will explain the Mifeprex/misoprostol abortion procedure to each patient, provide each patient with a copy of the Medication Guide and Patient Agreement, give each patient an opportunity to read and discuss those documents, obtain each patient's signature on the Patient Agreement and sign it, and record in the patient's record the serial number of each Mifeprex package dispensed;

- Will provide for a patient follow-up visit at approximately 14 days after prescribing and dispensing Mifeprex to confirm that a complete termination of pregnancy has occurred and that there have been no complications; and

- Will notify Danco in writing of any cases of hospitalizations, transfusion, or other serious event, to include occurrences of incomplete abortion following the treatment regimen.

- ETASU C: Dispensation of Mifeprex only in certain health care settings, specifically clinics, medical offices, and hospitals. Danco will ensure that Mifeprex will only be available to be dispensed in a clinic, medical office, or hospital, by or under the supervision of a specifically certified prescriber. Mifeprex will not be distributed to or dispensed through retail pharmacies.

- ETASU D: Dispensation of Mifeprex only to patients with documentation of safe use conditions. Danco will ensure that Mifeprex will only be dispensed to patients with documentation of the following safe use conditions: (1) the patient has completed and signed the Patient Agreement, and the Patient Agreement has been placed in the patient's medical record; and (2) the patient has been provided copies of the signed Patient Agreement and the Medication Guide.

Third, that Danco establish an Implementation System to ensure that, in relevant part, Mifeprex distributors are certified, agree to ship the drug only to site locations identified by specially certified prescribers in signed Prescriber's Agreements, and maintain secure and confidential records of shipments.

Fourth, that Danco—as Mifeprex's sponsor—submit REMS assessments to FDA one year after the date of the REMS's approval and every three years thereafter.[1]

In 2015, Danco submitted an SNDA to FDA, seeking approval to alter Mifeprex's indication, labeling, and REMS to reflect a new evidence-based prescription regimen. Danco did not propose to eliminate or significantly modify the REMS. It did, however, request, among other things, that FDA approve: (1) an increase in the gestational age through which Mifeprex can be used from 49 days to 70 days; (2) a reduction in the Mifeprex dosage from 600-mg to 200-mg; (3) making an in-person patient follow-up visit with a healthcare provider a recommended advisement rather than a requirement; (4) elimination of the instruction that patients take Mifeprex at their "provider's office"; (5) an expansion of the universe of healthcare providers who may prescribe Mifeprex to include all "healthcare providers," rather than just "physicians"; and (6) modifying the Medication Guide's risk-expectation advisement to note that "2-7 out of 100," rather than "5-8 out of 100," women "taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding."

[1] *See* U.S. Food & Drug Admin., Mifeprex (mifepristone) Information, available at https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf (last visited Jan. 26, 2018).

After a careful review of Danco's SNDA, FDA approved each of the changes Danco proposed, with some modifications, concluding that the proposed alterations were supported by appropriate data and information. At the same time, FDA also determined that all of the REMS requirements that Danco did not seek to change remained necessary to assure Mifeprex's safe use because the drug's "safety profile" had "not substantially changed." Compl. Ex. E.

B. Procedural Posture

In October 2017, Plaintiffs filed suit in this Court challenging FDA's 2016 determination that the REMS remained necessary to safeguard against Mifeprex's risks. Plaintiff Dr. Chelius is a board-certified family medicine physician with a focus in obstetrics and is the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region, which includes two hospitals on the island: Kauai Veterans Memorial Hospital in Waimea, Kaua'i and Samuel Mahelona Memorial Hospital in Kapa'a, Kaua'i. *See* Compl. ¶27. Dr. Chelius purports to sue on his own behalf and on behalf of his patients, alleging that the Mifeprex REMS prevents him from providing the drug to his patients. *See id*. ¶28. Dr. Chelius does not allege that he has attempted to obtain certification to prescribe Mifeprex, despite being the Chief Medical Officer for two major Kaua'i hospitals.

Plaintiff SFP is a non-profit corporation located in Philadelphia, Pennsylvania. *See id.* ¶29. SFP describes itself as a national member association

of "clinician-researchers with expertise in family planning" that works "to advance sexual and reproductive health by providing evidence-based insight to improve clinical care in the areas of contraception and abortion." *Id.* SFP's membership includes nearly 800 fellows trained in obstetrics and gynecology, internal medicine, family medicine, pediatrics, and public health, among other specialties. SFP purports to sue on behalf of its members and its members' patients, alleging that the Mifeprex REMS prevents them from providing the drug to their patients. *See id.* ¶30. SFP does not allege that any of its members have attempted to obtain certification to prescribe Mifeprex. *See id.*

Plaintiff CAFP is a non-profit professional association located in San Francisco, California. *See id.* ¶31. CAFP is the largest primary care medical society in California, with more than 9,000 family physician, family medicine resident, and medical student members. CAFP describes itself as engaging in "advocacy and education to help family physicians . . . expand access to high-quality and cost-effective patient care in California." *Id.* CAFP purports to sue on behalf of its members and its members' patients, alleging that the Mifeprex REMS prevents them from providing the drug to their patients. *See id.* ¶32. CAFP has not alleged that any of its members have attempted to obtain certification to prescribe Mifeprex.

Plaintiff PPSI is a non-profit professional association located in San Rafael, California. *Id.* ¶33. PPSI has hundreds of independent pharmacist and pharmacy members nationwide. PPSI states that it arranges for and conducts education programs for pharmacists and advocates on behalf of independent pharmacists before regulatory bodies. *See id*. PPSI sues on behalf of its members and its members' patients, alleging that the Mifeprex REMS prevents them from stocking and dispensing the drug. *See id*. ¶35. PPSI neither alleges that any of its members has attempted to obtain certification to prescribe or dispense Mifeprex, nor does it identify any specific provider willing and able to stock Mifeprex in the absence of the REMS.

Plaintiffs now seek a declaration that the Mifeprex REMS, in its entirety, violates the Fifth Amendment and/or the APA, or that specific REMS requirements violate the Fifth Amendment and/or the APA; an injunction prohibiting Defendants from requiring REMS for Mifeprex; a remand to FDA to remove the Mifeprex REMS; and costs and attorneys' fees.

STANDARD OF REVIEW

A motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) is premised on the fundamental concept that federal courts are courts of limited jurisdiction. *See Vacek v. United States Postal Serv.*, 447 F.3d 1248, 1250 (9th Cir. 2006). "It is to be presumed that a cause lies outside this limited

jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Id.* (quoting *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)). At the pleading stage, although the courts "presume that general allegations embrace those specific facts that are necessary to support the claim," the plaintiff, at a minimum, must allege "general factual allegations of injury resulting from the defendant's conduct" that justify federal jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal quotations omitted). Factual allegations in a plaintiff's complaint "'will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim.'" *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 13-14 (D.D.C. 2001) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1990)). In deciding a 12(b)(1) motion, a court need not limit itself to the allegations of the complaint, and it may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction in the case. *See id*. at 14; *Herbert v. Nat'l Acad. Of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992). Moreover, when a plaintiff's injury arises from the government's regulation of someone else, standing is "substantially more difficult to establish." *Lujan*, 504 U.S. at 562.

ARGUMENT

To establish the "irreducible constitutional minimum" for Article III standing, a plaintiff must both plead and prove three familiar and essential elements:

First, "[t]he plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560; *see also Novak v. United States*, 795 F.3d 1012, 1017-18 (9th Cir. 2015). A "concrete" injury is one that is "distinct and palpable," *Warth v. Seldin*, 422 U.S. 490, 501 (1975), not merely "[a]bstract," *O'Shea v. Littleton*, 414 U.S. 488, 494, (1974). To be "particularized," the alleged injury must be "personal, individual, distinct, and differentiated—not generalized or undifferentiated." *Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 489 F. 3d 1279, 1292 (D.C. Cir. 2007); *see also Parr v. L & L Drive-Inn Restaurant*, 96 F. Supp. 2d 1065, 1077 (D. Haw. 2000). An injury is "actual or imminent" only if it has already occurred or is "certainly impending and immediate—not remote, speculative, conjectural, or hypothetical." *Id.* at 1078; *see also Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). Moreover, a plaintiff resting his claim to standing on the rights and interests of third-parties will face a "substantially more difficult" time establishing standing. *Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009) (quoting *Lujan*, 504 U.S. at 562).

Second, a plaintiff must show that any such injury "fairly can be traced to the challenged action of [a defendant], and [is] not injury that results from the independent action of some third party not before the court." *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976); *see also Allen v. Wright*, 468 U.S. 737, 757 (1984). A self-inflicted harm does not amount to an injury cognizable under Article III, in part because "it would not be fairly traceable to defendant's challenged conduct." *Nat'l Family Planning & Reproductive Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006); *see also Boating Indus. Assoc. v. Marshall*, 601 F.2d 1376, 1380–81 (9th Cir. 1979).

Third, a plaintiff must demonstrate that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561. Where a plaintiff "is not the object of an alleged government action or inaction," it is "ordinarily 'substantially more difficult' to establish" standing because redressability, like causation, frequently turns on actions of "independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Id*. at 562 (quotation marks omitted). As a result, a plaintiff bears the burden "of adduc[ing] facts showing that those [third-party] choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id*.

As the parties invoking the Court's jurisdiction, Plaintiffs bear the burden "clearly to allege facts demonstrating" each of the three elements required for Article III standing. *Warth*, 422 U.S. at 518. The necessary facts "must affirmatively appear in the record" and "cannot be inferred argumentatively from averments in the pleadings." *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990). Moreover, "[s]ince they are not mere pleading requirements but rather an indispensable part of the [Plaintiffs'] case, each [standing] element must be supported in the same way as any other matter on which the [P]laintiff[s] bear the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561. The standing inquiry is "'especially rigorous when reaching the merits of the dispute would force [a court] to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional.'" *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138 (2013) (citation omitted).

None of the Plaintiffs in this case have alleged facts sufficient to demonstrate that they possess standing to pursue their constitutional and statutory challenges to the Mifeprex REMS. Accordingly, this Court lacks jurisdiction to resolve those challenges.

I. Dr. Chelius Lacks Standing To Sue On His Own Behalf And On Behalf Of His Patients

Plaintiffs' complaint identifies only one specific physician allegedly affected by the Mifeprex REMS, Dr. Graham Chelius, an obstetrician who practices family medicine on the island of Kaua'i and serves as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region. Compl. ¶¶ 170-172. For the reasons explained below, Dr. Chelius fails to allege facts sufficient to demonstrate that he has suffered a concrete and particularized injury that is fairly traceable to the Mifeprex REMS and would be redressed by a favorable decision or that he has third-party standing to bring suit on behalf of his patients.

A. Dr. Chelius Lacks Standing To Sue On His Own Behalf

Although Dr. Chelius seeks an order invalidating the Mifeprex REMS in its entirety, *see* Compl. 62, he fails to explain how any provision of the REMS aside from ETASU C (indicating locations where Mifeprex may be dispensed) causes him harm. For example, Dr. Chelius nowhere asserts that the provider certification requirement (ETASU A) has harmed him. Nor would any such allegation be plausible. As Plaintiffs' submissions indicate, to become a certified prescriber, a healthcare provider need only complete and submit a one-page form that merely requires the provider to give his name, billing and shipping information, signature, medical license number, and agree that he meets the qualifications of—and will

follow the guidelines for use stated in—the Prescriber Agreement. *See* Compl. at 385-386. Dr. Chelius does not allege any injury stemming from this minimal requirement, and, indeed, he acknowledges that he routinely completes "referral and other paperwork" on behalf of patients who require abortion care. Compl. ¶178. Dr. Chelius similarly fails to allege any injury to himself or his patients stemming from the requirement that patients complete a Patient Agreement (ETASU D), a one-page form that Plaintiffs concede is at most "duplicative" of other informed consent laws and standards, Compl. ¶125. Thus, as to all but one of the REMS requirements, Dr. Chelius fails to even allege, much less demonstrate, that the REMS has injured him.

Instead, the sole focus of Dr. Chelius's claims is ETASU C, which requires that Mifeprex be dispensed only in certain healthcare settings. Dr. Chelius alleges that this requirement has injured him by limiting his ability to provide Mifeprex to his patients. *See* Compl. ¶¶173-175. But such allegations fall well short of establishing Dr. Chelius's standing to challenge the distribution limitation. Dr. Chelius does not allege that ETASU C itself bars him from distributing Mifeprex at the two hospitals or various clinics where he works, *see* Compl. ¶172, all of which would qualify as authorized healthcare facilities under ETASU C. Rather, Dr. Chelius asserts that he has chosen not to prescribe Mifeprex at those facilities because he is "aware that some of his colleagues are opposed to abortion"

and "would be upset, angry, and/or uncomfortable if asked to be involved . . . in the process of procuring, stocking, and dispensing Mifeprex." Compl. ¶172; *see also* Compl. ¶174 (stating that Dr. Chelius "believes" that dispensing Mifeprex at his workplace "would create internal conflict"). Dr. Chelius's claimed injury thus depends entirely on "speculation about the decisions of independent actors." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013).

Both the Supreme Court and the Ninth Circuit have refused "to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment." *Clapper*, 568 U.S. at 398 (citing cases); *Physicians for Integrity in Med. Research, Inc. (PIMR) v. Hamburg*, 556 F. App'x 621, 622 (9th Cir. 2014). In *PIMR*, for example, the plaintiff was a physician who alleged that certain actions FDA had taken would injure him because it would cause him to lose patients and harm his reputation. *Id.* at 622. The Ninth Circuit concluded that such claimed injuries were insufficient to support the physician's standing. *Id.* The court emphasized "that [the physician's] alleged injuries, for lost patients and loss of credibility, will occur only if one of [the physician's] patients makes an independent choice—either to find another physician or to view [the complaining physician] less favorably." *Id.* And "[b]ecause [the physician's] theory of standing with respect to these injuries rests on speculation about the decisions of

independent actors," the court held, the injuries were "not fairly traceable to the FDA." *Id.*

Dr. Chelius's claimed injury similarly rests on speculation about how "*some* of his colleagues," Compl. ¶173 (emphasis added), may react to his decision to dispense Mifeprex at the hospitals and clinics where he works. Dr. Chelius's guesswork regarding how "some" independent actors might respond to his decision to dispense Mifeprex cannot support his standing. Any injury, moreover, would be traceable to the independent actions of those colleagues, not to FDA. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976) ("Art. III still requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court.").

That Dr. Chelius's asserted injury is insufficient to support his standing is further underscored by his failure to allege that the hypothesized "internal conflict" would in fact prevent him from procuring and dispensing Mifeprex. His inability to dispense Mifeprex is thus also a "self-inflicted injur[y]," *Clapper*, 568 U.S. at 418, that is traceable to his assumptions about his colleagues and his desire to avoid conflict with some colleagues, not to FDA's actions. *See National Family Planning and Reproductive Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) (recognizing that "self-inflicted harm doesn't satisfy the basic requirements

for standing" and concluding that the plaintiff lacked standing because its "asserted injury appears to be largely of its own making").

For similar reasons, Dr. Chelius fails to demonstrate that his alleged inability to dispense Mifeprex would be redressed by a decision invalidating the distribution limitation. "There is no standing if, following a favorable decision, whether the injury would be redressed would still depend on the 'unfettered choices made by independent actors not before the courts.'" *Novak v. United States*, 795 F.3d 1012, 1020 (9th Cir. 2015) (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989)). To the extent Dr. Chelius seeks to avoid an "internal conflict" with colleagues who are opposed to abortion, that same conflict would arise if the distribution limitation is lifted and Dr. Chelius becomes a regular prescriber of Mifeprex. Dr. Chelius's suggestion that, absent the distribution limitation, he could prescribe Mifeprex to his patients without the knowledge or involvement of "his small clinical team," Compl. ¶¶172, 175, is not plausible.

Moreover, Dr. Chelius fails to establish that his, or his patients', alleged injuries would be redressed by the relief they seek for another reason. Plaintiffs ultimately seek removal of the REMS from Mifeprex, but, because FDA's approval of Mifeprex is contingent on the REMS, which the agency determined to be "necessary to ensure that the benefit[] of [the] drug outweigh[s] [its] risks" 21 U.S.C. § 355-1(a)(1), invalidation of the REMS potentially could undermine the

statutory basis for Mifeprex's approval. Thus, granting Plaintiffs' requested relief to remove the REMS could have the unintended consequence of *eliminating* access to Mifeprex should FDA conclude that the drug cannot remain on the market without a REMS, which is surely not the result that Plaintiffs seek.

B. Dr. Chelius Lacks Standing To Sue On Behalf Of His Patients

Dr. Chelius's failure to establish his own standing necessarily means he lacks standing to bring suit on behalf of his patients. *See McCormack v. Herzog*, 788 F.3d 1017, 1027–28 (9th Cir. 2015) ("To determine whether a physician has third-party standing to assert the rights of patients in the abortion context, the panel must determine: (1) whether the physician alleges 'injury in fact' to himself or herself; and (2) whether the physician is a proper proponent of the legal rights on which he or she bases the suit."). Moreover, it is not clear that Dr. Chelius's patients, whose rights he seeks to vindicate, have suffered an injury that is traceable to the REMS. Plaintiffs concede that Dr. Chelius's patients have been able to procure Mifeprex without leaving Kaua'i, notwithstanding the REMS, pursuant to an ongoing study involving the University of Hawaii. *See* Compl. ¶187. In any event, to the extent Dr. Chelius's patients suffer injury from his failure to dispense Mifeprex in accordance with the REMS, those injuries are not traceable to FDA's actions, but rather to Dr. Chelius's decision not to seek

certification, which is in turn based on his speculation about the possible reaction of some of his colleagues and his desire to avoid an unspecified conflict.

II. The Organizational Plaintiffs Also Lack Standing To Challenge The REMS

The three organizational plaintiffs, who bring suit on behalf of their members and their members' patients, also lack standing to challenge the Mifeprex REMS. To establish standing to sue on behalf of its members, an organization must show: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Associated General Contractors of America, San Diego Chapter, Inc. v. California Department of Transportation*, 713 F.3d 1187, 1194 (9th Cir. 2013). To meet the first requirement, an organization must assert "specific allegations establishing that at least one *identified* member had suffered or would suffer harm." *Id.* (quoting *Summers*, 555 U.S. at 498 (emphasis in original)).

The organizational plaintiffs' claim to standing fails at the threshold: None of the three organizations specifically identify a member who would have standing to sue in his or her own right. *See Associated General Contractors*, 713 F.3d at 1194-95 (concluding that the organizational plaintiff lacked standing because it did "not identify any affected members by name"). This is not a case, moreover,

"'[w]here it is relatively clear, rather than merely speculative, that one or more members have been or will be adversely affected" by the challenged actions, and "where the defendant need not know the identity of a particular member to understand and respond to an organization's claim of injury." *National Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015).

As Dr. Chelius's case illustrates, it is not clear that even physicians interested in prescribing Mifeprex have standing to challenge the REMS. Indeed, like Dr. Chelius, the alleged injuries suffered by the organizational plaintiffs' members are traceable to the independent actions of third parties, not to FDA. *See, e.g.*, Compl. ¶207 (alleging that CAFP members are unable to prescribe Mifeprex currently because of "opposition among *colleagues* to procuring, stocking, or dispensing Mifeprex at the health care facilities where CAFP members work, and complicated, multi-layer approval processes for stocking a medication [that are imposed by the] *hospital, clinic, or medical office*" where members work); ¶¶192-198 (emphasis added). As Plaintiffs acknowledge, some institutions where the organizational plaintiffs' members work have imposed "unique procedural hurdles" with respect to Mifeprex "[b]ecause of the stigma surrounding abortion." Compl. ¶195; *see also* Compl. ¶198 (noting that "some hospitals require special staff training before allowing clinicians to start prescribing Mifeprex"). Plaintiffs provide no reason to believe these institutions would lift these "unique procedural

hurdles" and special requirements if the Mifeprex REMS were invalidated. In short, because the organizational Plaintiffs' members' alleged injuries rely on the independent actions of third parties, those members would lack standing even if they were specifically identified. *See supra* pp. 19-22.

There are additional reasons why individual members of the organizations might lack standing and thus need to be specifically identified. Plaintiffs concede that the overwhelming majority of doctors surveyed indicated that they would not prescribe Mifeprex even if the REMS were removed. *See* Compl. ¶154 (noting that in "a recent, nationally representative survey of ACOG Fellows (who are currently practicing OB-GYNS)" fewer than one in five indicated that they would start prescribing Mifiprex if not for the REMS). In submissions to FDA, moreover, abortion rights advocates (including one of the organizational Plaintiffs) expressed the fear that many pharmacies would similarly refuse to stock Mifeprex even if they were permitted to do so. *See* Compl. at ¶340. It is therefore not clear that the organizations can identify members who would be both willing and able to prescribe Mifeprex absent the REMS. Accordingly, the organizations have not sufficiently alleged that they have members who are injured by the REMS and whose injuries would be redressed by a favorable decision.

The problems with the organizational plaintiffs' alleged injuries are particularly apparent in their claim that "some health care providers, aware of the

long history and ongoing threat of violence and harassment against abortion providers, are fearful of having their names included among a list of abortion providers maintained by Danco and the distribution company with which it partners." *See* Compl. at ¶157. The organizational Plaintiffs do not allege that any of their members are among the health care providers who are fearful of having their names disclosed to the drug company and its distributor. And even assuming that alleged fear of having their information disclosed "deter[s]" some member physicians from prescribing Mifeprex currently, that injury is self-inflicted and relies on speculation about the independent actions of at least two third parties—the drug company that would negligently or intentionally disclose the list of physicians who prescribe Mifeprex (a hypothesized possibility for which plaintiffs offer no evidence) and those individuals who might target physicians on the list. In addition, even if such an injury could support the organizational Plaintiffs' members' standing, it would not be redressed by a decision invalidating the REMS. Drug companies may maintain records, including the identity of the physicians who prescribe their drugs, whether those drugs are subject to a REMS or not. A physician's fear of having his identity as a Mifeprex prescriber revealed by a drug company would thus not be alleviated by the elimination of the REMS.[2]

[2] Moreover, just as with Dr. Chelius, invalidation of the REMS may not provide the organizational Plaintiffs relief as that action potentially could lead FDA to determine that Mifeprex cannot remain on the market without the REMS.

The organizational Plaintiffs also seek to assert the rights of their members' patients. Because the organizational Plaintiffs have not identified an individual member who has standing to challenge the REMS, their attempt to assert the rights of their members' patients necessarily fails. *See supra* p. 23.[3]

For all these reasons, neither Dr. Chelius nor the organizational Plaintiffs have demonstrated standing to pursue their claims.

[3] Like Dr. Chelius, the organizational Plaintiffs do not assert any injury stemming from ETASU D, which requires patients to sign a Patient Agreement before obtaining Mifeprex. Accordingly, even assuming the organizational Plaintiffs had standing to challenge the other REMS (which they do not), they lack standing to challenge the Patient Agreement requirement.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the Complaint for lack of subject matter jurisdiction.

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Respectfully submitted,

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