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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, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' 12(b)(1) MOTION TO DISMISS** Judge: Hon. Derrick K. Watson Hearing Date: June 1, 2018 Hearing Time: 9:30 AM Related Documents: Dkt. No. 30

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

Regulations

INTRODUCTION

Ignoring the detailed allegations in the Complaint that Plaintiffs, their members, and their patients are suffering an array of injuries caused by the Mifeprex Risk Evaluation and Mitigation Strategy ("REMS"), Defendants argue that this suit should be dismissed for lack of standing. But it is patently clear that all Plaintiffs have a sufficient "personal stake in the outcome" of this litigation to support standing, *Ctr. For Biological Diversity v. Kempthorne*, 588 F.3d 701, 707 (9th Cir. 2009) (citation omitted), and Defendants' efforts to muddle this straightforward conclusion fail.

First, it is undisputed that the REMS, which expressly prohibits retail pharmacists from dispensing Mifeprex to their patients, injures those members of Plaintiff Pharmacists Planning Services, Inc. ("PPSI" or "the Pharmacists") who "would stock and dispense Mifeprex to patients who present with a prescription" if they could—but because of the REMS, lose this business and this opportunity to care for their patients. Compl. ¶¶ 33, 223. This alone disposes of Defendants' motion to dismiss. *Brown v. City of L.A.*, 521 F.3d 1238, 1240 n.1 (9th Cir. 2008) ("[T]he presence in a suit of even one party with standing suffices to make a claim justiciable." (citation omitted)).

Second, the remaining Plaintiffs are equally harmed by the REMS. Dr.

Chelius and members of the Society of Family Planning ("SFP")[1] and the California Academy of Family Physicians ("CAFP") (collectively, "the Physicians") have alleged—and now testify to—a range of injuries in attempting to comply with the REMS; injuries threatened by the REMS that deter them from attempting to comply; and injuries every day that they cannot provide this safe and effective medication to their patients who desperately need it. They must expend valuable time and professional resources lobbying co-workers to agree to procure, stock, and dispense Mifeprex onsite; helping patients try to access abortion care elsewhere when this cajoling is unsuccessful; or counseling patients about the outdated clinical standards fossilized in the REMS's Patient Agreement Form. They must jeopardize their reputations and professional relationships to try to stock Mifeprex onsite, rather than simply writing a prescription from the privacy of their offices. Most significantly, the Physicians cannot treat their patients in accordance with their medical judgment—and as a result, their patients are delayed in accessing abortion care, if they can access it at all.

And all this, so that a patient to whom this medication has been prescribed, *and who can take the medication at home*, will receive it in her hand at the prescriber's office instead of in her hand at the pharmacy. *See* Defs.' Mem. in

[1] In a minor error, the Complaint refers to Plaintiff SFP as incorporated in Pennsylvania. Compl. ¶ 29. While the SFP *Research Fund* is incorporated in Pennsylvania, SFP is incorporated in Illinois.

Support of Mot. to Dismiss 3 [hereinafter "MTD"] (noting that the REMS "allow[s] patients to take the drug somewhere other than a 'provider's office"). It is no surprise that Defendants' lengthy Background section does not include any theory as to why the "FDA . . . determined that all of the REMS requirements . . . remained necessary to assure Mifeprex's safe use," MTD 11, how receiving the medication in a physician's office rather than in a pharmacy in any way mitigates the risk of complications, or how the purported safety benefits outweigh the burdens on Plaintiffs, their members, and their patients.

Plaintiffs' injuries are directly traceable to the FDA's final action reauthorizing the REMS, and removing the REMS would eliminate or dramatically reduce these injuries. Plaintiffs unequivocally have standing to show this Court why doing so is constitutionally and statutorily required.

STANDARD OF REVIEW

In evaluating a motion to dismiss under Rule 12(b)(1), "all factual allegations in [the] complaint are taken as true and all reasonable inferences are drawn in [plaintiff's] favor." *Pride v. Correa*, 719 F.3d 1130, 1133 (9th Cir. 2013) (citations omitted).[2]

[2] Defendants do not specify whether their motion is "facial or factual," *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004), but it is clearly facial: Defendants "assert[] that the allegations contained in [the] complaint are insufficient on their face to invoke federal jurisdiction." *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004) (quoting *Safe Air*, 373 F.3d at 1039); *see, e.g.*, MTD

The key question in a standing challenge is whether the plaintiffs have "a direct stake in the outcome." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 473 (1982) (citation omitted); *accord Kempthorne*, 588 F.3d at 707 (citation omitted). Plaintiffs must establish that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citations omitted). These are "'relatively modest' requirements." *San Luis & Delta-Mendota Water Auth. v. Salazar*, 638 F.3d 1163, 1169 (9th Cir. 2011) (citing *Bennett v. Spear*, 520 U.S. 154, 171 (1997)). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice," and courts should "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

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18 ("Dr. Chelius fails to allege facts sufficient to demonstrate" standing). As explained *infra*, the presumptively valid allegations in the Complaint alone establish standing at this stage. Nevertheless, in an abundance of caution and to further illuminate the harms caused by the REMS, Plaintiffs also provide declarations that specifically counter Defendants' claims. As even Defendants acknowledge, "a court may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction in the case," MTD 14 (citations omitted); *see also McCarthy v. U.S.*, 850 F.2d 558, 560 (9th Cir. 1988), "without converting the motion to dismiss into a motion for summary judgment," *Safe Air*, 373 F.3d at 1039 (citation omitted).

ARGUMENT

Plaintiffs' Complaint contains extensive factual allegations of injury to themselves, their members, and their patients, resulting from the FDA's 2016 final action reauthorizing the Mifeprex REMS. That is more than sufficient to establish standing at the pleading stage, but Plaintiffs nonetheless provide declarations from Dr. Chelius and members of SFP, CAFP, and PPSI containing further support for their standing. To satisfy Article III, Plaintiffs need show only that they are suffering a cognizable injury, which the REMS is at least a "substantial factor" in causing, *Mendia v. Garcia*, 768 F.3d 1009, 1012–13 (9th Cir. 2014), and which would "likely" be redressed by a decision in Plaintiffs' favor. *Barnum Timber Co. v. U.S. E.P.A.*, 633 F.3d 894, 897 (9th Cir. 2011) (quoting *Lujan*, 504 U.S. at 560–61). With or without the declarations, all Plaintiffs have amply met this standard.

I. The Allegations of Harm to the Associational Plaintiffs' Members Are More Than Sufficient at the Pleading Stage, But Plaintiffs Nonetheless Provide Declarations from Injured Members.

Plaintiffs SFP, CAFP, and PPSI all have standing to sue on behalf of their members, notwithstanding Defendants' erroneous attempt to heighten the pleading standard. MTD 4, 12–13, 24. "'An association has standing to bring suit on behalf of its members when [1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization's purpose, and [3] neither the claim nor the relief requested requires the participation of individual

members in the lawsuit.'" *Colwell v. Dep't of Health & Human Servs.*, 558 F.3d 1112, 1122 (9th Cir. 2009) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). Defendants do not contest the second or third prong of the test, nor could they.[3]

Instead, Defendants claim that the associational Plaintiffs' members would lack standing to sue in their own right. That claim is without merit. The Complaint details the burdens that the REMS imposes on them: PPSI members are "uniformly prohibited from stocking and dispensing Mifeprex" because of the REMS. Compl. ¶¶ 221, 224. Some SFP and CAFP members must spend valuable time and expend significant professional capital advocating within their institutions for multiple approvals to dispense Mifeprex. *Id.* ¶¶ 196, 207. Some suffer delays of months or years during which they are unable to offer their patients medication abortion, *id.* ¶¶ 195, 198–199, 207–08, while others are unable to offer it at all, *id.* ¶¶ 197, 209. As discussed below, these allegations establish that members of SFP, CAFP, and PPSI would have individual standing.

Defendants contend that these specific allegations are insufficient and that

[3] The associational plaintiffs have alleged how the interests at stake in this case are germane to their purpose: each organizes and advocates to improve patient care and advance public health. Compl. ¶¶ 29, 31, 33–34. And there is no reason why this Court cannot adjudicate questions about the lawfulness of the REMS without the participation of individual members as plaintiffs. This is not, for instance, a case involving individualized claims for damages. *Warth v. Seldin*, 422 U.S. 490, 515 (1975) (typical case involving associational standing is one seeking prospective relief rather than damages).

the associational Plaintiffs must identify, at the pleading stage, an individual member who cannot provide Mifeprex because of the REMS. MTD 4, 12–13, 24. But Defendants rely on two cases decided on summary judgment, not a motion to dismiss. *See* MTD 17, 24 (citing *FW/PBS, Inc. v. City of Dall.*, 493 U.S. 215 (1990); *Ass'd Gen. Contractors of Am., San Diego Chapter, Inc. v. Cal. Dep't of Transp.*, 713 F.3d 1187 (9th Cir. 2013)). And Defendants ignore that, in the Ninth Circuit, "it is not necessary to identify specific names of members at the pleading stage." *Coal. for a Sustainable Delta v. F.E.M.A.*, 711 F. Supp. 2d 1152, 1164 (E.D. Cal. 2010) (citation omitted); *see also Cal. Rural Legal Assistance, Inc. v. Legal Servs. Corp.*, 917 F.2d 1171, 1174–75 (9th Cir. 1990) (finding associational standing when plaintiff merely alleged harm to "many of its members" without identifying specific individuals).

Indeed, Defendants' own citations to binding precedent establish that such specificity is *not* required at the pleading stage. Defendants cherry-pick language from *Lujan* stating that "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[.]" MTD 17 (quoting 504 U.S. at 561). But Defendants omit the next line in the Court's opinion, which clarifies: "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are

necessary to support the claim." *Id.* (internal quotation marks and alterations omitted). Defendants also quote from a Ninth Circuit decision finding that the plaintiffs need *not* identify specific members, with only a conclusory preface that "[t]his is not [such] a case." MTD 24–25 (quoting *Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015)). To the contrary, *Cegavske* supports Plaintiffs' position, stating:

> Where it is relatively clear, rather than merely speculative, that one or more members have been or will be adversely affected by a defendant's action, and where the defendant need not know the identity of a particular member to understand and respond to an organization's claim of injury, we see no purpose to be served by requiring an organization to identify by name the member or members injured.

800 F.3d at 1041; *accord League of Women Voters of Cal. v. Kelly*, No. 17-CV-2665, 2017 WL 3670786, at *8 (N.D. Cal. Aug. 25, 2017) ("The court cannot discern why—at the pleadings stage—the identity of particular members is required for fair notice of the claims.").

Here, Plaintiffs have not merely alleged an abstract belief that members of SFP, CAFP, and PPSI are harmed by the REMS—it is *more* than "relatively clear," *Cegavske*, 800 F.3d at 1041, from the specific allegations in the Complaint that each organization has members who would be willing and able to provide Mifeprex absent the REMS, and that such members are adversely affected by the REMS, Compl. ¶¶ 190–225. The detailed descriptions of the time spent,

reputations harmed, delays endured, and in some cases, complete inability to dispense Mifeprex is enough for Defendants to "understand and respond to [Plaintiffs'] claim of injury." *Cegavske*, 800 F.3d at 1041.[4] Defendants' demand for identified individual members goes well beyond what is required to establish standing at this stage.

Nevertheless, Plaintiffs provide declarations from at least one member of each associational Plaintiff that, for the reasons articulated below, would easily give those members standing. The allegations in the Complaint and the testimony from members of SFP, CAFP, and PPSI are more than adequate to establish the organizations' standing to sue on their members' behalf.

II. The Mifeprex REMS Injures Plaintiffs Who Attempt to Comply; Threatens Injuries that Deter Plaintiffs' Compliance; and Injures All Plaintiffs and Their Members Who Cannot Provide Medication Abortion to Their Patients Because of These Restrictions.

The REMS both compels and constrains Plaintiffs' action: It expressly prohibits the Pharmacists from dispensing Mifeprex under any circumstances, and expressly prohibits the Physicians from prescribing Mifeprex unless they take

[4] Nor can Defendants credibly claim that it is "merely speculative," *Cegavske*, 800 F.3d at 104, that members' colleagues object to being involved in procuring, stocking, or dispensing Mifeprex: The very Department that Defendant Azar heads is currently seeking to expand the rights of any person in the "workforce" of a health care facility receiving any federal funding to decline "to participate in any activity with an articulable connection" to abortion care. *E.g.*, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3892 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

certain actions. Standing is a relatively low threshold under these circumstances. *Compare L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011) (presumption of standing where plaintiff is an object of the challenged regulatory action) (citing *Lujan*, 504 U.S. at 561-62), *with Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009) (standing more difficult to establish when challenged regulations "neither require nor forbid any action on the part of the [plaintiffs]"); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 419 (2013) ("chilling effect" of policy insufficient to confer standing where policy "does *not* regulate, constrain, or compel any action on [plaintiffs'] part" (emphasis added)). Plaintiffs' "personal stake" in this challenge is incontrovertible. *Kempthorne*, 588 F.3d at 707. This is particularly evident for the Pharmacists, whose injury is undisputed. Their presence alone defeats Defendants' motion. *Brown*, 521 F.3d at 1240 n.1.

Plaintiffs have alleged an array of "actual or imminent" and "concrete and particularized" injuries flowing directly from the REMS. *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 916 (9th Cir. 2004); Compl. ¶¶ 173–86, 189, 191, 195–201, 202–05, 207–18, 221–25.[5] Plaintiffs' supporting declarations add

[5] Moreover, all Plaintiffs have alleged that the REMS causes constitutional injury by treating them differently from similarly situated parties without a sufficient state interest. Compl. ¶ 229. This would be sufficient for injury-in-fact even absent the additional harms Plaintiffs have alleged. *Cf., e.g., Ne. Fla. Chapter of Assoc. Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 657 (1993) (where government erects barrier making it more difficult for members of one group to obtain a benefit, injury-in-fact "is the denial of equal treatment . . . not the ultimate

detail and underscore the magnitude of these harms. The declarants are differently situated with respect to the REMS, but uniformly injured by its restrictions: SFP members Jane Roe, M.D., and Amy Potter, M.D., are injured in attempting to comply; Dr. Chelius is threatened with injuries that deter him from complying; and *all* Plaintiffs are injured because the REMS prevents them and some or all of their members (including CAFP member Jared Garrison-Jakel, M.D. and PPSI member Paul Lofholm, Pharm.D.) from providing medication abortion care to their patients who urgently need it. Each of these injuries is more than sufficient for standing. *See e.g.*, *Wasden*, 376 F.3d at 917 (plaintiff's "liberty will be concretely affected" "[w]hether he continues to perform abortions subject to the statute, desists from performing them to avoid the statute's penalties, or violates the statute so as to practice his profession in accord with his medical judgment").

A. Defendants Do Not Contest that the REMS Injures the Pharmacists, Which Alone Defeats Defendants' Motion to Dismiss.

Defendants do not—because they cannot—contest that the REMS's prohibition on dispensing Mifeprex in retail pharmacies causes injury to retail pharmacists who wish to dispense this medication. *See generally* MTD 15–28

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inability to obtain the benefit"); *Estate of Macias v. Ihde*, 219 F.3d 1018, 1027–28 (9th Cir. 2000) (constitutional violation sufficient to establish "injury" under § 1983, regardless of whether plaintiff can "demonstrat[e] that the deprivation of his or her constitutional rights caused any actual harm" (citation omitted)); *Duran v. City of Porterville*, 47 F. Supp. 3d 1044, 1053 (E.D. Ca. 2014) ("[E]ven minor constitutional injuries that justify only nominal damages may be sufficient to establish an injury-in-fact" (citations omitted)).

(argument section in which the word "pharmacies" appears only once and the word "pharmacists" not at all). As alleged in the Complaint and reinforced in the affidavit of Paul Lofholm, Pharm.D., this prohibition causes the Pharmacists to lose business; impedes their ability to practice in accordance with their professional judgment; and undermines their relationships with patients. Compl. ¶¶ 219–25; Lofholm Decl., attached hereto as Ex. A, at ¶¶ 9–19. Each such injury constitutes cognizable harm. *E.g.*, *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153–54 (1970) (financial injury); *Wasden*, 376 F.3d at 917 (professional judgment); *Colwell*, 558 F.3d at 1122 (patient relationships). And, as discussed *infra*, excluding pharmacists from the abortion care team also harms patients. *See, e.g.*, Lofholm Decl. ¶¶ 8–10, 12, 17–19.

The Pharmacists are further injured by the REMS's certification requirement. Defendants note, as if it were meaningful, that no PPSI member "has attempted to obtain certification to prescribe or dispense Mifeprex." MTD 13. Of course not: the REMS expressly bars such certification. First, the registrant must identify at least one hospital, clinic, or medical office where he will dispense Mifeprex—a practice setting that retail pharmacists lack. Compl. Ex. K at 14; *see* Lofholm Decl. ¶ 12. Second, the certification conflates the traditional prescribing and dispensing roles, such that any person seeking to *dispense* Mifeprex must also be capable of, or supervised by a health care provider capable of, dating and

locating the pregnancy—which retail pharmacists are not. Compl. Ex. K at 14; *see* Lofholm Decl. ¶ 13. Standing does not demand that the Pharmacists engage in an incontestably futile attempt to gain certification. *See, e.g.*, *Safari Club Int'l v. Jewell*, 842 F.3d 1280, 1285–86 (D.C. Cir. 2016) (plaintiffs need not apply for government benefit in order to establish standing when doing so would be futile).

The Pharmacists have thus adequately pled injury-in-fact resulting from both the REMS's distribution restriction and certification requirement; Defendants have not, and cannot, contest this. That alone defeats Defendants' motion to dismiss. *E.g.*, *Brown*, 521 F.3d at 1240 n.1; *Bates v. United Parcel Serv., Inc.*, 511 F.3d 974, 985 (9th Cir. 2007) (en banc) ("[W]e consider only whether at least one named plaintiff satisfies the standing requirements . . . .").

B. The REMS Injures the Physicians Who Attempt to Comply.

Because of the REMS, the Physicians cannot simply issue a prescription from the privacy of their offices for a patient to fill at a retail or mail-order pharmacy. Instead, they must gain assistance and approval from numerous individuals and committees within their institutions to procure, stock, and dispense Mifeprex onsite. Compl. ¶¶ 173, 192–96, 198, 207. As detailed in the declarations of Drs. Roe and Potter, the approval process necessitated by the REMS forces them to expend time and resources, and "jeopardize" and "harm[]" their professional reputations, "lobbying, cajoling and maneuvering" their colleagues. Roe Decl.,

attached hereto as Ex. B, at ¶¶ 3, 8–9, 12–17, 19; *see also* Potter Decl., attached hereto as Ex. C, at ¶¶ 11–12, 15–16. *If* they are successful in gaining approval to procure, stock, and dispense Mifeprex, they must then expend additional time and resources, and further "compromise . . . important professional relationship[s]," completing the extensive paperwork to establish an account with the drug distribution company. Roe Decl. ¶ 16.

Such harms are more than sufficient to overcome the minimal threshold for injury-in-fact. *See, e.g.*, *Meese v. Keene*, 481 U.S. 465, 473–74 (1987) (sufficient injury where plaintiff feared his "personal, political, and professional reputation would suffer" due to law designating films he wished to screen as "political propaganda"); *The Presbyterian Church (U.S.A.) v. United States*, 870 F.2d 518, 522–23 (9th Cir. 1989) ("reputational" and "professional" harm to church from undercover immigration operation sufficient injury); *N.C.A.A. v. Gov. of N.J.*, 730 F.3d 208, 220–24 (3d Cir. 2013) (reputational harm to sports league from law legalizing sports betting sufficient for injury-in-fact; law creates an association between the league and gambling, an activity that "large portions of the population . . . disapprove of"); *Little Sisters of the Poor Home for the Aged v. Sebelius*, 6 F. Supp. 3d 1225, 1235–36 (D. Colo. 2013) (annual expense of $41 that plaintiffs will incur by completing and processing forms sufficient injury), *aff'd*, 794 F.3d 1151 (10th Cir. 2015), *vacated and remanded on other grounds sub nom. Zubik v.*

Burwell, 136 S. Ct. 1557 (2016); *cf. Kempthorne*, 588 F.3d at 707–08 (sufficient injury where members alleged that they enjoy viewing polar bears and challenged regulations threatened this activity by harming the environment).

Dr. Roe also faces a "realistic" threat of "repeated injury"—in reputational harm, compromised professional relationships, and wasted time and resources—that suffices for standing. *Blum v. Yaretsky*, 457 U.S. 991, 1000–01 (1982) (citation omitted). Specifically, although Dr. Roe—after approximately eight months of lobbying, negotiations, and paperwork—currently has approval to prescribe and dispense Mifeprex, her ability to do so is precarious. Unable to secure approval to add Mifeprex to her hospital's drug formulary, she had to settle for the atypical status of a "non-formulary drug" subject to "routine review" by a committee that is likely to experience significant conflict over this issue, as evidenced by their past behavior and as predicted by the Chief Medical Officer of her health care system. Roe Decl. ¶¶ 3, 9, 12, 13–15; *see Blum*, 457 U.S. at 1000–01 (standing where nursing homes "remain[ed] free to determine" that plaintiffs' current levels of care were not medically necessary, and "similar determinations already made" indicate that "the threat is quite realistic" (citations omitted)).

Finally, Dr. Roe is injured by the Patient Agreement Form, which "undermines [her] informed consent process" by forcing her to provide patients with information about Mifeprex that is misleading and inconsistent with her

clinical practices, thus impeding the exercise of her professional judgment. Roe Decl. ¶ 18; *Wasden*, 376 F.3d at 917; Wright & Miller § 3531.9.1 ("[A]n interference . . . in practicing [one's] profession . . . clearly would be an allegation of sufficient injury in fact to satisfy the minimal requirements of Article III"); *Planned Parenthood Ariz., Inc. v. Brnovich*, 172 F. Supp. 3d 1075, 1092 (D. Ariz. 2016) ("Physicians have a direct stake in the informed consent process as a corollary of their professional responsibilities . . . .").

C. The REMS Threatens Injuries to Dr. Chelius that Deter Him from Attempting to Comply.

Article III is satisfied by "actual *or* threatened" injury. *Valley Forge*, 454 U.S. at 472 (emphasis added) (citation omitted); *see also, e.g.*, *Blum*, 457 U.S. at 1000 ("Of course, [o]ne does not have to await the consummation of threatened injury . . . . The question becomes whether any perceived threat . . . is sufficiently real and immediate to show an existing controversy." (internal citations, brackets, and quotation marks omitted)); *Nat. Res. Def. Council v. U.S. E.P.A.*, 735 F.3d 873, 878 (9th Cir. 2013) ("credible threat" sufficient); *see also Brandt v. Village of Winnetka, Ill.*, 612 F.3d 647, 649–50 (7th Cir. 2010) (probability of injury must be "materially greater than zero").

The restricted distribution scheme for Mifeprex threatens to cause Dr. Chelius reputational harm and professional repercussions, which deters him from attempting to comply. Compl. ¶¶ 172–74. Dr. Chelius states:

> Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff.

Chelius Decl., attached hereto as Ex. D, at ¶ 27; *accord id.* at ¶¶ 28, 34. He explains that "[t]hese consequences to my professional reputation and carefully nurtured workplace dynamics deter me from attempting to comply with the Mifeprex REMS." *Id.* at ¶ 28. This threat is sufficient for injury-in-fact. *E.g.*, *Meese*, 481 U.S. at 473–74; *Robins v. Spokeo, Inc.*, 867 F.3d 1108, 1112 (9th Cir. 2017), *cert. denied*, 138 S. Ct. 931 (2018) ("[H]arm to one's reputation . . . may be sufficient for Article III standing"); *N.C.A.A.*, 730 F.3d at 220–24.

Defendants argue to no avail that the imminent threat of reputational and professional harm is insufficient to establish injury-in-fact. *See* MTD 19–22. They do so principally on the basis of an unpublished, three-paragraph decision affirming a district court's conclusion that "[t]he entirely speculative prospect that some asthmatic patient might feel negatively about physicians who do not challenge the FDA approval of [an asthma medication] is insufficient to confer Article IIII standing on Plaintiff." *Physicians for Integrity in Med. Research, Inc. v. Comm'r*, No. CV11-08334 GAF (FMOx), 2012 WL 12882760, at *3 (C.D. Cal.

May 23, 2012), *aff'd*, 556 F. App'x 621 (9th Cir. 2014); MTD 20–21.[6] By contrast, Dr. Chelius's fears of conflict among his staff are based on his decade of experience at Kauai Veterans, where, formerly as Chief Medical Officer and now as Chief of Staff, he is directly responsible for managing such internal conflict. Chelius Decl. ¶¶ 4, 27–28, 34. The risk of harm to his reputation and professional relationships is a "credible threat." *Nat. Res. Def. Council*, 735 F.3d at 878.

Also contrary to Defendants' arguments, *see* MTD 21, Plaintiffs need not show that this threat renders compliance with the REMS wholly *impossible*: It is enough that such concerns deter Dr. Chelius from attempting to comply. For instance, in *Meese v. Keene*, the plaintiff challenged a law classifying three Canadian films he wished to exhibit as "political propaganda." 481 U.S. at 473. The Supreme Court concluded that Keene had standing because he was deterred from engaging in desired action based on his perception that doing so might cause him reputational harm:

> While Keene did not and could not allege that he was unable to receive or exhibit the films at all, he relies on the circumstance that he wished to exhibit the three films, but was 'deterred from exhibiting the films by a statutory

[6] Defendants otherwise rely on *Clapper v. Amnesty International USA*, which is similarly inapposite. MTD 20–21. In *Clapper*, the plaintiffs' theory of standing "relie[d] on a highly attenuated chain of possibilities," including a sequence of discretionary actions by the U.S. Attorney General, the Director of National Intelligence, and Article III judges, 568 U.S. 398, 410 (2013), that bears no resemblance to the final action taken by Defendants that has already caused injuries to Plaintiffs here.

> characterization of the films as 'political propaganda' . . . . [H]e establishes that the term 'political propaganda' threatens to cause him cognizable injury [because] [h]e stated that 'if he were to exhibit the films while they bore such characterization, his personal, political, and professional reputation would suffer and his ability to obtain re-election and to practice his profession would be impaired.'

Id. So too here.[7] Indeed, Dr. Chelius's fears about conflict within his "tight-knit workplace," Chelius Decl. ¶ 27, are far less speculative than those in *Meese*, where the plaintiff's concerns were based on the assumptions that (1) his political opponents would "seize upon the opportunity" to broadcast the fact that he had screened films so designated, (2) some members of the public would thus become aware that he had screened them, and (3) some of those people would view him less favorably. *Meese*, 481 U.S. at 473 n.7.[8] Here, Dr. Chelius is not speculating about the hypothetical actions and reactions of strangers—he is describing the realities of the small-town hospital where he has practiced for the past decade. *See*

[7] The Court also acknowledged that Keene "could have minimized these risks by providing the viewers of the films with an appropriate statement concerning the quality of the motion pictures . . . . Even on that assumption, however, the need to take such affirmative steps to avoid the risk of harm to his reputation constitutes a cognizable injury . . . ." *Meese*, 481 U.S. at 475; *accord N.C.A.A.*, 730 F.3d at 223 ("[T]hat the [Plaintiffs] may have been successful at rehabilitating their images does not deprive them of standing." (citing *Meese*)). Thus, any future speculation by Defendants that Dr. Chelius could provide assurances to his staff that would somehow mitigate this cognizable risk of harm would be fruitless.

[8] *Meese* thus also disposes of Defendants' irrelevant observation that only "some" of Dr. Chelius's colleagues would respond negatively if he attempted to dispense Mifeprex onsite. MTD 21.

N.C.A.A., 730 F.3d at 220–21 (sports league's fear of reputational harm resulting from law allowing betting on games was "based in reality" and "fairly intuitive").

Dr. Chelius also identifies a plausible threat that injecting additional staff into the abortion process, as the REMS necessitates, would compromise his patients' confidentiality. This is a credible threat in a town of "fewer than 2,000 people," where "[m]any members of the community have a family member, friend, or neighbor employed at Kauai Veterans." Chelius Decl. ¶ 31. The threat that his patients' privacy will be jeopardized by involving more members of their small town community in their abortion care further deters Dr. Chelius from attempting to comply with the REMS. *Id.*

Curiously, Defendants also argue that Dr. Chelius lacks standing because he "does not allege that he has attempted to obtain certification to prescribe Mifeprex." MTD 11. But Dr. Chelius cannot become a certified Mifeprex prescriber without identifying a hospital, clinic, or medical office where he can stock and dispense the medication. Compl. Ex. K at 14. Moreover, as Plaintiffs alleged and as Dr. Roe testified, becoming certified and setting up an account requires significant paperwork and logistics. Compl. ¶¶ 158–59 & Ex. K at 14; Roe Decl. ¶ 16; Chelius Decl. ¶ 33–34. This, too, is cognizable injury. *See Little Sisters of the Poor*, 6 F. Supp. 3d at 1235–36 ($41 annually "that Plaintiffs will incur by completing and processing the self-certification forms" is sufficient injury-in-fact).

Finally, as is true for Dr. Roe, the Patient Agreement Form threatens Dr. Chelius's ability to practice his profession in accordance with his medical judgment. Chelius Decl. ¶ 35. This satisfies injury-in-fact. *See supra* pp. 18–19*; Wasden*, 376 F.3d at 917.

D. The REMS Injures All Plaintiffs and Their Members Who Cannot Provide Medication Abortion Because of These Restrictions.

Because of the REMS, Dr. Chelius, all PPSI members, and some SFP and CAFP members cannot provide Mifeprex to their patients—preventing them from practicing in accordance with their professional judgment; costing them time and money; and causing them severe distress. The REMS expressly prohibits the Pharmacists from dispensing Mifeprex, which costs them business; impedes them from providing individualized drug consultations; and limits their patients' ability to obtain this medication at all. *See* Compl. ¶¶ 224–25; Lofholm Decl. ¶¶ 9–19. Dr. Chelius, SFP member Dr. Potter, and CAFP member Dr. Garrison-Jakel have not been able to procure, stock, and dispense Mifeprex at the health centers where they work, forcing them to turn away patients against their medical judgment (and to their great distress), and causing an array of other harms. Compl. ¶¶ 174–189, 191–209, 213–217; Chelius Decl. ¶¶ 7–20, 22, 25, 36; Potter Decl. ¶¶ 7–9, 11–12, 14, 16; Garrison-Jakel Decl., attached hereto as Ex. E, at ¶¶ 8–14. For instance, Dr. Chelius has spent "many hours," including after-work hours, attempting to assist his patients in obtaining care from the University of Hawai‘i on O‘ahu. Chelius

Decl. ¶¶ 20, 22. And Dr. Potter still has not been able to stock Mifeprex at her residency clinic after months of efforts, and thus cannot train her residents in medication abortion care, despite their expressed interest. Compl. ¶ 200; Potter Decl. ¶¶ 11, 14.

These harms, and in particular the REMS's interference with Plaintiffs' ability to practice their professions, are sufficient to establish injury-in-fact as to all Plaintiffs. *See, e.g.*, Wright & Miller § 3531.9.1 (alleged interference with interest in "practicing [one's] profession . . . . clearly would . . . satisfy the minimal requirements of Article III"); *Wasden*, 376 F.3d at 917; *McCormack v. Hiedeman*, 900 F. Supp. 2d 1128, 1142 (D. Idaho 2013), *aff'd sub nom. McCormack v. Herzog*, 788 F.3d 1017 (9th Cir. 2015) ("[I]n the abortion context, the Ninth Circuit's decisions teach that the existence of an abortion regulation aimed at physicians that would prevent or chill a pregnant woman from seeking an abortion she would otherwise seek is sufficient to satisfy the injury requirement." (citing *Wasden*, 376 F.3d at 917)).

III. The Mifeprex REMS Causes the Injuries Alleged.

Article III requires "a causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560. Specifically, a plaintiff must demonstrate that the alleged "injury is 'fairly traceable' to the actions of the defendant." *Bennett*, 520 U.S. at 162 (citations omitted); *see also Mendia*, 768 F.3d at 1012.

Without question, the alleged injuries here are fairly traceable to the REMS.

The REMS completely bars the Pharmacists from providing Mifeprex in two ways: first, by expressly prohibiting its provision in retail pharmacies, and second, by requiring that anyone *dispensing* this medication have prescriptive authority and be qualified to date and locate a pregnancy, or be supervised by someone who meets those requirements. *See supra* pp. 15–16. PPSI's members do not and cannot meet these criteria, and so cannot dispense Mifeprex. *See id.*; Lofholm Decl. ¶¶ 12–13, 17. Thus, the injuries to PPSI members are directly traceable to the REMS.

The Physicians' alleged injuries are likewise traceable to the REMS. But for the REMS, they would not have to turn away eligible patients seeking medication abortion care. Compl. ¶¶ 175, 191, 201, 208–09, 223; Chelius Decl. ¶¶ 7–8, 13, 20, 25, 28, 32; Potter Decl. ¶¶ 10, 13; Garrison-Jakel Decl. ¶¶ 2, 9–10. They also would not suffer the injuries inherently caused or threatened by compliance with the REMS, such as harm to their professional relationships and the time, energy, and political capital necessary to try to add Mifeprex to their facilities' drug formularies. *See* Chelius Decl. ¶¶ 7, 17, 20, 22, 26–28, 33–34; Potter Decl. ¶¶ 11–12, 15-16; Garrison-Jakel Decl. ¶ 10; Roe Decl. ¶¶ 3, 8–9, 12–17, 19. Last, they would avoid the burdens explicitly imposed by the REMS, including enrolling as a certified prescriber and setting up an account with the drug distributor, and the requirement that they provide, discuss, and sign the outdated Patient Agreement

Form. *See* Roe Decl. ¶¶ 16, 18–19; Chelius Decl. ¶ 35.

The REMS also causes the injuries alleged to Plaintiffs' patients by delaying, or altogether blocking, their access to Mifeprex. *See* Compl. ¶¶ 18–20, 151–53, 176–86, 189, 191, 199, 201–05, 208–09, 213–17, 225; Chelius Decl. ¶¶ 7–16, 25, 36; Potter Decl. ¶¶ 7–9; Garrison-Jakel Decl. ¶¶ 11-13; Roe Decl. ¶¶ 6, 10; *Tummino v. Torti*, 603 F. Supp. 2d 519, 540-41 (E.D.N.Y. 2009) ("Here, the claimed injuries are clearly traceable to the FDA's actions," which prevent "plaintiffs from obtaining" emergency contraception "without a prescription."), *amended sub. nom. Tummino v. Hamburg*, No. 05-CV-366 (ERK) (VVP), 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013). Courts evaluating the burdens an abortion restriction imposes on patients must consider the restriction in its "real-world context." *Planned Parenthood Se., Inc. v. Strange*, 9 F. Supp. 3d 1272, 1299 (M.D. Ala. 2014); *see also Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312–13 (2016) (where abortion providers were unable to meet hospitals' criteria for granting admitting privileges, it was the "*requirement*" that abortion providers have admitting privileges that "led to the closure of half of Texas' clinics," not the hospitals' criteria (emphasis added)); *Planned Parenthood of Wis., Inc. v. Schimel*, 806 F.3d 908, 916–17 (7th Cir. 2015) (same). And in the real world, forcing would-be Mifeprex prescribers to procure, stock, and dispense the medication onsite at their facility delays or blocks patients' access to care.

Tellingly, Defendants nowhere deny that the FDA is a central actor, and the REMS reauthorization a central action, in the causal chain culminating in the injuries suffered by Plaintiffs, their members, and their patients. Instead, Defendants attempt to shift focus to the acts of "third parties"—such as Plaintiffs' colleagues opposed to abortion—which, they claim, break the causal chain. *See* MTD 4, 20–21, 25. This argument misconstrues the causation standard in three critical respects.

First, Plaintiffs need not show that Defendants are *exclusively* responsible for their injuries—only that the "government [defendant]'s unlawful conduct" is a "substantial factor" causing the injury. *Mendia*, 768 F.3d at 1013 (citation omitted). Indeed, the Ninth Circuit has found causation based on actions that merely "contribute" to injury, and even where "other factors may also cause additional" injury. *Ocean Advocates v. U.S. Army Corps of Engineers*, 402 F.3d 846, 860 (9th Cir. 2005); *see also, e.g.*, *Tribes v. Kelly*, No. C17-652 MJP, 2018 WL 453475, at *4 (W.D. Wash. Jan. 17, 2018) ("[E]ven if the decisions of independent third parties . . . were relevant to the chain of causation . . . , those decisions will not break the chain of causation where 'the government's unlawful conduct is at least a substantial factor motivating the third parties' actions.'"

(quoting *Mendia*, 768 F.3d at 1013)).[9] Here, the REMS is at least a "substantial factor" in the causal chain culminating in Plaintiffs' alleged injuries. But for the REMS, the Physicians would be able to write Mifeprex prescriptions for eligible patients who come to them seeking this care. Compl. ¶¶ 160, 175, 191, 201, 208–09, 223; Chelius Decl. ¶¶ 7–8, 13, 20, 25, 28, 32; Potter Decl. ¶¶ 10, 13; Garrison-Jakel Decl. ¶¶ 2, 9–10. And to do so, they would not need to seek approval from multiple individuals and committees to procure, stock, and dispense Mifeprex onsite, or face the other harms inherent to compliance with the REMS. Chelius Decl. ¶¶ 25, 28, 32; Potter Decl. ¶¶ 10, 13; Garrison-Jakel Decl. ¶ 10.

Second, the causation element can still be met despite intervening acts of "third parties." The Supreme Court has found Article III causation after rejecting an argument that—like Defendants' here, *see* MTD 21—"wrongly equate[d] injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." *Bennett*, 520 U.S. at 168–69. Similarly, the Ninth Circuit has held that "[c]ausation may be found even if there

[9] Other circuits use similar tests. *See, e.g.*, *Tozzi v. U.S. Dep't of Health & Human Servs.*, 271 F.3d 301, 308 (D.C. Cir. 2001) ("Where, as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties, we have required only a showing that the agency action is at least a substantial factor motivating the third parties' actions." (quotation marks and citation omitted)); *Loggerhead Turtle v. Cty. Council of Volusia Cty., Fla.*, 148 F.3d 1231, 1253 (11th Cir. 1998) (standing exists "even though the actions or inactions of those third parties not before the court may be another cause of the harm" (quotation marks and citations omitted)).

are multiple links in the chain connecting the defendant's unlawful conduct to the plaintiff's injury, and there's no requirement that the defendant's conduct comprise the last link in the chain." *Mendia*, 768 F.3d at 1012–13; *see also, e.g.*, *Maya v. Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011) ("A causal chain does not fail simply because it has several 'links[.]'" (citation omitted)); *Brnovich*, 172 F. Supp. 3d at 1094 ("[Defendant's] conduct need not be the first or final step in the chain of causation." (quotation marks and citations omitted)).[10]

Third, Defendants fail to recognize that the Article III causation standard is different from—and generally less strict than—the causation inquiry in other contexts. The Ninth Circuit has specifically rejected the position that Article III standing requires a showing of proximate cause. *Maya*, 658 F.3d at 1070; *see also, e.g.*, *Tozzi*, 271 F.3d at 308 ("[W]e have never applied a 'tort' standard of causation to the question of traceability.").

Because the REMS is, at the very least, a "substantial factor" in causing each of the Plaintiffs' injuries, Plaintiffs easily satisfy the causation element.[11]

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[10] Other circuits are in accord. *See, e.g.*, *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499 (D.C. Cir. 1996) (permitting plaintiffs to sue FDA based on claim that FDA's authorization decision caused "competitive injury," even though injury resulted most directly from independent purchasing decisions of third parties); *Lac Du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490, 500 (7th Cir. 2005) ("While the Secretary may not be the only party responsible for the injury alleged here, a plaintiff does not lack standing merely because the defendant is one of several persons who caused the harm." (citation omitted)).

[11] Throwing one last Hail Mary, Defendants argue that Dr. Chelius's injury is

IV. Eliminating the REMS Would Redress the Injuries Alleged.

The third element of Article III standing is redressability, which requires a showing that a decision in the plaintiff's favor is "'likely' to redress the injury-in-fact." *Barnum Timber Co.*, 633 F.3d at 897 (citation omitted). This element, too, is easily met here.

The FDA has exclusive control over whether "to impose a REMS," Compl. ¶ 46, so a court order that the FDA revise or eliminate the REMS would redress the injuries alleged. *See Barnum Timber Co.*, 633 F.3d at 899 (recognizing district court's power to "grant the declaratory judgment and injunctive relief" requested by plaintiffs in a challenge to federal agency action and finding redressability); *Tummino*, 603 F. Supp. 2d at 541 ("[T]hese plaintiffs have also shown that their injuries would be redressed if the FDA was ordered to approve" over-the-counter sale of emergency contraception).

Attempting to circumvent this Court's plenary authority to redress constitutional harm, Defendants offer several arguments why an order eliminating the REMS would somehow leave Plaintiffs empty-handed. None has merit.

First, Defendants argue that eliminating the REMS would not redress

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"self-inflicted," and thus not traceable to Defendants, because the professional and reputational harm threatened by the REMS would not "in fact *prevent*" him from providing Mifeprex. MTD 21 (emphasis added). But as previously explained, Dr. Chelius need not show that it is *impossible* for him to provide Mifeprex, only that the REMS threatens to injure him should he try.

Plaintiffs' injuries because Plaintiffs might still face stigma relating to their provision of Mifeprex, including among their colleagues, if they were able to provide this care simply by writing a prescription (or, for the Pharmacists, by filling a prescription). *See* MTD 4. Defendants similarly argue that the "same conflict would arise" for Dr. Chelius absent the REMS because the suggestion that he could prescribe Mifeprex "without the knowledge or involvement of 'his small clinical team' is not plausible." *Id.* at 22.

These arguments are wrong both factually and legally. As a factual matter, Dr. Chelius's declaration explains why his colleagues' *knowledge* that he supports, refers for, and (absent the REMS) would write prescriptions for Mifeprex is not what deters him; his concern is that stocking and dispensing Mifeprex at his hospital would require the *involvement and approval* of multiple colleagues—some of whom strongly oppose abortion. *See* Chelius Decl. ¶ 28. And, as a legal matter, that a favorable ruling would not relieve all of the harms of abortion stigma does not negate redressability. As long as "a favorable decision" would give "substantial and meaningful relief," redressability exists. *Larson v. Valente*, 456 U.S. 228, 243 (1982). A plaintiff "need not show that a favorable decision will relieve his *every* injury." *Id.* at 243 n.15 (emphasis in original); *see also Mass. v. E.P.A.*, 549 U.S. 497, 526 (2007) (petitioners had standing to challenge EPA action because risk of harm "would be reduced *to some extent* if petitioners received the relief they seek"

(emphasis added)); *Brnovich*, 172 F. Supp. 3d at 1099 (same). Relatedly, Plaintiffs "need not demonstrate that there is a 'guarantee' that their injuries will be redressed by a favorable decision." *Graham v. F.E.M.A.*, 149 F.3d 997, 1003 (9th Cir. 1998); *see also Beno v. Shalala*, 30 F.3d 1057, 1065 (9th Cir. 1994) ("[P]laintiff must show only that a favorable decision is *likely* to redress his injury, not that a favorable decision will *inevitably redress* his injury." (emphases in original) (citation omitted)). A court order removing the REMS would provide substantial and meaningful relief to Plaintiffs, and that is all that matters here.

Second, Defendants speculate that if this Court finds that the Mifeprex REMS violates the Constitution or the FDA's statutory authority, and accordingly grants Plaintiffs' requested relief, this "could have the unintended consequence of *eliminating* access to Mifeprex" because the FDA might elect to withdraw approval for this medication "without a REMS." MTD 23; *accord id.* at 27 n.2. In other words, Defendants argue that the Court should dismiss this lawsuit because Defendants, if forbidden from unjustifiably *restricting* access to this safe and effective medication, might instead try to *block* access altogether.

This argument is both galling and meritless. The only question at bar is whether an order eliminating the REMS is likely to redress Plaintiffs' current injuries "to some extent." *Mass.*, 549 U.S. at 526. Whether Defendants (or a third party) may take subsequent action that is "not the result that Plaintiffs seek," MTD

23, 27 n.2, is not relevant in assessing standing. *See, e.g.*, *Beno*, 30 F.3d at 1065 ("[T]he mere fact that, on remand, the Secretary might again issue a waiver does not defeat plaintiffs' standing."); *Seattle Audubon Soc'y v. Espy*, 998 F.2d 699, 703–05 (9th Cir. 1993) ("Speculation" that a court order forcing agency to "re-examine" its plan "might not change the Secretary's decision" is "not relevant to standing"); *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1518 (9th Cir. 1992) ("The fact that . . . redrafting an [environmental impact statement] might not in any way change the Secretary's recommendations to Congress is irrelevant.").

Moreover, were Defendants to make a rash decision in violation of the Administrative Procedure Act ("APA") or the Constitution, that too would be subject to judicial review: this Court has the power both to compel or set aside specific FDA action now, and—whether in the same or a subsequent action—to ensure that later FDA action does not violate any such order, the Constitution, or the APA. For example, in a 2005 lawsuit seeking to expand the availability of the emergency contraceptive drug marketed as Plan B, the district court concluded that the FDA had acted arbitrarily and capriciously in restricting access to this safe, though controversial, reproductive health medication. *See Tummino*, 603 F. Supp. 2d at 523. Accordingly, the court vacated the FDA's decision restricting over-the-counter access and "remanded to the FDA for reconsideration" of its decision consistent with the court's opinion. *Id.* at 524. Four years later, after determining

that the FDA's subsequent decision was again "arbitrary, capricious, and unreasonable," the court granted "the ultimate relief" the plaintiffs had originally sought, by remanding to the FDA with the "instruction" to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions." *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166, 197 (E.D.N.Y. 2013). In sum, this Court has the power to shape any eventual remedies so as to provide effective redress to Plaintiffs, and Defendants' compliance with this Court's order is not optional.

V. Plaintiffs Have Third-Party Standing To Assert the Rights of Their and Their Members' Patients.

"The Supreme Court has . . . repeatedly held that a physician may 'assert the rights of women patients as against governmental interference' in the abortion context," *McCormack*, 788 F.3d at 1027 (quoting *Singleton v. Wulff*, 428 U.S. 106, 118 (1976)); *see also, e.g.*, *Isaacson v. Horne*, 716 F.3d 1213, 1221 (9th Cir. 2013) (collecting cases); *Ragsdale v. Turnock*, 841 F.2d 1358, 1370 (7th Cir. 1988) (affirming that nurse who sought to begin offering abortion services at the health centers she operated had third-party standing to challenge restrictions that prevented her from doing so). Defendants do not challenge this well-established doctrine. They argue only that Plaintiffs lack standing to sue on their own behalf, which, as explained *supra*, fails. MTD 23–24, 28. Plaintiffs and their members are thus "proper proponent[s] of the legal rights" of their patients who are delayed in

obtaining, or unable to obtain, medication abortion. *McCormack*, 788 F.3d at 1027 (citation omitted).

Plaintiffs have alleged (and testified to) the significant harm the REMS imposes on their patients. Because the REMS prevents or delays Plaintiffs and their members from providing medication abortion care, their patients are forced to seek care elsewhere—often at great cost.[12] They must take more time off work, arrange and pay for more childcare, arrange and pay to travel farther to clinics, and endure the psychological and emotional stress of trying to access this time-sensitive medication elsewhere when Plaintiffs cannot provide it. Compl. ¶¶ 176–86, 202–203, 213–14; Chelius Decl. ¶¶ 10–16; Garrison-Jakel Decl. ¶ 8, 11, 13; Potter Decl. ¶¶ 7–9; Roe Decl. ¶ 6. Some patients are delayed in obtaining abortion care and must undergo riskier procedures, or are prevented from obtaining an abortion altogether. Compl. ¶¶ 179–82, 196–97, 204–05, 215–18; Chelius Decl. ¶¶

[12] Defendants argue that Dr. Chelius's patients are not injured because they can currently obtain Mifeprex through a temporary study. MTD 23. But the study—which operates as a *waiver* of the REMS, Chelius Decl. ¶ 21—provides relief to only some of his patients, *see* Compl. ¶¶ 187–88; Chelius Decl. ¶¶ 22–23, and is only temporary, Compl. ¶¶ 187–88; Chelius Decl. ¶¶ 21, 24. This certainly does not defeat standing. *See, e.g., White v. Lee*, 227 F.3d 1214, 1243 (9th Cir. 2000) ("The recent implementation of . . . a temporary policy [i]s insufficient to eliminate the plaintiffs' standing to seek prospective relief."); *Ctr. for Biological Diversity v. Tidwell*, 239 F. Supp. 3d 213, 222 (D.D.C. 2017) (standing doctrine "allow[s] a district court to retain jurisdiction over a dispute if the halt in offending conduct is more of a temporary reprieve than a bonafide resolution of the matter.").

12-16; Garrison-Jakel Decl. ¶¶ 11–14; Potter Decl. ¶ 9; Roe Decl. ¶ 10.[13] These hardships arise because the REMS prevents or delays the Physicians' ability to provide Mifeprex. Compl. ¶¶ 153, 158, 174, 197, 199, 208-09; Chelius Decl. ¶¶ 7–9, 13, 15–16; Garrison-Jakel Decl. ¶¶ 8–11, 13; Potter Decl. ¶¶ 7–13; Roe Decl. ¶ 10, 16.[14] And, even if the Physicians were able to dispense Mifeprex onsite, the REMS would still cause injury to their patients by necessitating the involvement of many more people and thus jeopardizing patient confidentiality. Chelius Decl. ¶¶ 31–32. Additionally, Defendant FDA has already admitted that the Patient Agreement Form burdens patients. Compl. ¶ 15, 96, 123–25.

Plaintiffs unequivocally have third-party standing to vindicate these factual and constitutional injuries.

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[13] Defendants also assert in passing that Plaintiffs do not identify any patient unable to obtain Mifeprex. MTD 1. This is simply wrong: Plaintiffs repeatedly alleged that patients have been turned away because of the REMS. Compl. ¶¶ 153, 174, 182, 202–03, 216–17. Though greater specificity is not required at this stage, Dr. Chelius, Dr. Garrison-Jakel, and Dr. Roe all describe instances in which specific patients were unable to obtain a medication abortion, or unable to obtain an abortion at all. Chelius Decl. ¶¶ 13–16; Garrison-Jakel Decl. ¶¶ 12-13; Roe Decl. ¶ 10. Moreover, patients need not be completely blocked from accessing abortion to prove that the REMS imposes an undue burden. *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 917 (9th Cir. 2014) ("[T]he burden imposed by the Arizona law is undue even if some women who are denied a medication abortion . . . will nonetheless obtain an abortion.").

[14] Defendants argue that Dr. Chelius's patients' injuries are traceable not to the REMS but to his decision to avoid institutional conflict. MTD 23–24. But as discussed *supra*, standing can be established "even if there are multiple links in the chain connecting the defendant's unlawful conduct to the plaintiff's injury." *Mendia*, 768 F.3d at 1012.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied.

Dated: April 12, 2018.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the length limit of Local Rule 7.5(b) because, excluding the parts of the document exempted by Local Rule 7.5(d), it contains 8,996 words. In compliance with Local Rules 7.5(e) and 10.2(a), I further certify that this document has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: April 12, 2018

/s/ Mateo Caballero
MATEO CABALLERO
ACLU of Hawai‘i Foundation

Attorney for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of April, 2018, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Mateo Caballero
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Exhibit A

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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, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **DECLARATION OF PAUL W. LOFHOLM, Pharm.D.**

Paul W. Lofholm, Pharm.D. declares and states as follows:

1. I make this declaration based on my own personal knowledge and if called to testify I could and would do so competently as follows.

2. I am an independent community pharmacist based in San Rafael, California, and a member of Pharmacists Planning Services Inc. ("PPSI"). I understand that PPSI is a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, the brand name for mifepristone. I provide this affidavit in support of that litigation.

3. I have a long history in the pharmacy profession. I received my Doctor of Pharmacy degree from the University of California, San Francisco ("UCSF") in 1964. Since receiving my degree, I have practiced as a pharmacy professional at two independent community pharmacies that I founded. In 1969, I founded Ross Valley Pharmacy, Inc., which was based in Larkspur, California. In 1995, I founded Golden Gate Pharmacy Services, Inc. ("Golden Gate Pharmacy"), which is based in San Rafael, California. I sold Ross Valley Pharmacy in May 2014, but kept the compounding service, known as Ross Valley Compounding Pharmacy. I continue to own Golden Gate Pharmacy today.

4. I am also proud to have nurtured a commitment to the pharmacy profession within my own family. Four of my immediate family members are

practicing pharmacists, and over ten other family members also practice pharmacy. Many of these family members work alongside me at Golden Gate Pharmacy. My pharmacist children manage all of the independent pharmacies in Marin County now.

5. Beyond my pharmacy practice, I have also been involved in pharmacy education. In 1966, two years after receiving my Doctor of Pharmacy degree, I joined the faculty at my alma mater, UCSF, and have continued to teach there for the past 50 years. I am currently a Clinical Professor of Pharmacy at UCSF. I am also an adjunct clinical professor at the University of the Pacific in Stockton, California, and Touro University on Mare Island, California. I have also taught many courses for the American College of Pharmacy, including in Women's Health.

6. I have received many honors and awards for my service to the pharmacy profession. For example, in 2011, I received the Remington Honor Medal, which is the highest honor given by the American Pharmacists Association. And in 2006, I was inducted into the California Pharmacy Hall of Fame. I am also involved with many professional organizations. At various points in my career I have served as President of the Marin County Pharmacist Association, President of the California Pharmacists Association, and President of the American College of Apothecaries.

7. As a pharmacist, I believe that providing personalized, professional care to our patients results in better health outcomes and more business. In my career, I have been part of the trend of transforming pharmacy from a chemical-based profession to a patient-centered medical practice. My pharmacies are at the forefront of providing enhanced services such as medication therapy management (*i.e.*, personalized consultations regarding patients' medication usage), immunizations, hospice services, compounding, and nutritional consulting. As part of the medication therapy management services, our pharmacists and employees meet with patients in a private area to review their drug history, discuss any possible interactions between the drugs they are taking (including over-the-counter medications or vitamin supplements), and otherwise answer any of their medication-related questions; as needed, we also consult with the prescribers and/or patients' caregivers (such as nurses or family members).

8. Over the course of my career, my pharmacies have served the health care needs of several thousand patients and their families by providing comprehensive medication services to them, sometimes for decades. However, because of the restrictions imposed by the Mifeprex REMS—which prohibits the distribution of Mifeprex at retail pharmacies including mine—we cannot fill a patient's prescription for Mifeprex. That is true even when a patient is pregnant, wishes to terminate the pregnancy, and a qualified clinician has determined that the

patient is medically eligible to receive Mifeprex in a regimen with misoprostol (the latter of which is a drug I already stock).

9. The Mifeprex REMS harms me, my patients, and my business in several ways.

10. First, the inability to stock and dispense Mifeprex prevents me and my pharmacies from providing comprehensive medication services to our patients, resulting in worse care for our patients and loss of business for my pharmacies.

11. Although I entered the pharmacy profession with the goal of taking care of patients, the reality is that I run a small family business, and the medication management services we provide are part of the business model that allows me to be profitable. In fact, a primary reason why my independent pharmacy business has succeeded in this age of pharmacy mega-chains is that we not only distribute medications but also provide personalized consultations about our patients' medication needs and drug interactions.

12. The Mifeprex REMS hurts my business and my relationships with patients by excluding me from the medication abortion care process—expressly prohibiting pharmacists from dispensing this prescription, and thus necessarily blocking us from providing the therapeutic consultation for Mifeprex that we provide for virtually all other prescription drugs. Indeed, notwithstanding the informed consent process that patients generally complete with their prescribing

clinician before receiving any prescription, patients often come to our pharmacy with additional questions about, for instance, any drug allergies we have on record for them or possible interactions with other drugs they are taking. By contrast, because the REMS prevents patients from coming to me for Mifeprex, I am less likely to have an opportunity to provide them with such support when it comes to this medication.

13. In addition to limiting where Mifeprex can be dispensed, the REMS requires that any person seeking to dispense Mifeprex have prescriptive authority, be qualified to assess accurately the duration of pregnancy, and be qualified to diagnose ectopic pregnancies—qualifications that I do not possess. Alternatively, one seeking to dispense Mifeprex must be supervised by someone else who meets these qualifications—but again, I am not under such supervision.

14. I have a long history of providing services to women of reproductive age. I have served as an advisor to Planned Parenthood, and to the California Group supporting direct pharmacy access to contraception. I am certified to dispense, and have dispensed, both Plan B (emergency contraception) and Depo-Provera (injectable hormonal contraception), and I have taught classes to pharmacists on the use and administration of these medications. I am more than willing to expand my services through the dispensing of Mifeprex, if only I could. If the Mifeprex REMS did not exist, I would stock and dispense Mifeprex to help

my patients and to advance my patient-centric business model.

15. I am passionate about meeting the reproductive health care needs of the patients of Marin County. We are a county of 260,000 people. I have provided services, including women's health services, to the Marin County Health Department for many years. Like many other places, Marin County needs abortion services, but availability through the traditional community pharmacies does not exist here.

16. I also want to be clear about just how close our relationships are with some of our patients. As part of our practice, our pharmacists strive to develop ongoing, trusting relationships with patients and their families. A strong foundation of trust in the pharmacist-patient relationship ensures that patients get the best medical care possible: when patients know that their pharmacists will reliably provide professional and non-judgmental services, they can be fully candid about their medication needs and concerns, and we have complete information on which to base our medical assessments and counseling. We have built this foundation with many members of our communities. As a result, we have provided pharmacy care to some of our patients and their families for years, and sometimes even decades. These patients come to our pharmacies for all of their prescription needs. They trust our judgment, rely on us to ensure that their medical needs are being comprehensively met, and see us as an added layer of safety to ensure there is no

contraindication for any of the medications they need to take, or any negative drug interactions.

17. I am aware of several patients who have obtained medication abortions, and have come to us to fill their prescriptions for misoprostol, which is the second drug in the two-drug regimen and can be obtained either directly from a patient's prescribing clinician *or* from a retail pharmacy. But those patients cannot also obtain Mifeprex from us. As I stated, the reason we cannot help our patients obtain Mifeprex is that the Mifeprex REMS categorically prevents us from stocking and dispensing Mifeprex.

18. Based on my close relationships with several of our patients, I have seen just how burdensome it is when they cannot obtain Mifeprex from my pharmacies as they normally would with practically any other prescription drug. I have had several patients come to me to ask about the pill for abortion but I have had to turn them away because I could not provide it.

19. In sum, I wish to—and would—stock and dispense Mifeprex at my pharmacies if the Mifeprex REMS were not in place. But because the Mifeprex REMS prohibits retail pharmacies like mine from stocking and dispensing Mifeprex, I cannot do so. This harms my pharmacy businesses, interferes with my ability to practice my profession in accord with my best judgment, and unfairly burdens my patients.

20. As a conscientious pharmacist trying to provide a reasonable solution to treat patients who desire an abortion, I want Mifeprex distribution expanded to any pharmacy that is willing to participate so that my patients have increased access to this safe and effective medication.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 5, 2018.

Paul W. Lofholm, Pharm.D.

Exhibit B

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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, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **DECLARATION OF [redacted] a/k/a JANE ROE, M.D.**

[redacted]., a/k/a/ Jane Roe, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a family medicine doctor trained in abortion care and a member of the Society of Family Planning ("SFP"). I live and practice in a rural area in the western United States, approximately 100 miles away from the nearest abortion clinic. I am seeking to proceed pseudonymously out of fear of being exposed—nationally and in my small, rural town—as an abortion provider. In light of the extreme harassment and violence, including murder, that has been perpetrated against abortion providers in the United States, I attempt to keep my provision of abortion care as private as possible; I am painfully aware that my primary practice does not have the safeguards in place that exist at the abortion clinics (several hours away) where I work part-time—bulletproof glass, violent intruder protocols, alarm button, separate entrance for providers, and so on. Moreover, given the significant abortion stigma in my community, I expect that I would lose many of my non-abortion patients at my primary practice if the fact of my abortion provision were widely known.

3. I submit this affidavit in support of SFP's litigation challenging the U.S. Food and Drug Administration's burdensome Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I do so only in my individual capacity and not on

behalf of any institution with which I am affiliated (other than SFP). Attempting to comply with the Mifeprex REMS has cost me significant time and professional capital, and caused me substantial stress, over the past year, and these injuries continue. Because of the REMS, my ability to care for my patients in accordance with their needs and my medical judgment is conditioned on my seeking (and gaining) approval and assistance from countless individuals and committees within my health care institution. If not for the REMS, this would not be necessary. If not for the REMS, I could and would simply write a prescription for my patients to fill at a local or mail-order pharmacy.

4. I am a full-spectrum Family Medicine physician. In addition to my three years of residency, I completed a Family Medicine fellowship in obstetrics. I often care for three or four generations within a family—delivering a baby one day and caring for her grandmother the next. I perform a range of obstetric and gynecological services, such as: cesarean sections, tubal ligations, leeps (which entails removing pre-cancerous lesions from the cervix), endometrial biopsies, insertion and removal of intrauterine contraceptive devices, and much more. I also provide miscarriage care, including performing procedures and prescribing misoprostol (which is the second drug in the FDA-approved medication abortion regimen) to evacuate the contents of a patient's uterus.

5. I work at a hospital and affiliated clinic within a large health care

system. Many of my patients are low-income; virtually all are rural; and many travel to us from medically underserved areas in our state. Indeed, some of my patients live in areas where there are no roads—only snowmobile access in the winters.

6. Over the years, I have had multiple patients who have come to me desperate to end a pregnancy, and repeatedly scheduled appointments at the nearest abortion clinic, only to have to cancel, again and again, because they simply could not make the over 200-mile round-trip journey to get there.

7. So, in February 2017, along with a few colleagues, I began the process of trying to get Mifeprex added to our hospital's formulary. The formulary is the list of medications approved for use by the pharmacy committees for our hospital and for our health care system, and then made available at our hospital for dispensing or administering to patients. Based on conversations I had with colleagues about attitudes towards abortion at our institution, I concluded that there was a greater likelihood of my gaining approval to add Mifeprex to our formulary and dispense it in my office, rather than gaining approval to perform surgical abortion services in our operating room. That is because the latter would require the involvement of many more clinicians, including nursing staff, certified scrub technicians, and anesthesia providers, and would thus require (at a minimum) approval from the CEO of the hospital and the departments overseeing each of

those categories of clinicians, as well as the development of opt-out procedures for the supporting clinical staff.

8. Attempting to add Mifeprex to our formulary was a major undertaking. First, we had to obtain approval from the pharmacy committee at our hospital. Once that committee agreed to move forward with the process, we could elevate the request to the pharmacy committee for the entire health care system. As an initial matter, this meant completing a form officially requesting that Mifeprex be added to the system formulary.

9. Over the next six months, we were delayed time and again in trying to get a decision from that system-level pharmacy committee—including being advised by a representative of the committee to delay raising the issue of Mifeprex until our request could undergo further "informal vetting," and then being bumped from the agenda for the committee's once-a-month meeting at least three times. In addition, the pharmacy committee representative insisted that *we* complete the "new drug review" analysis for Mifeprex—a time-consuming assignment that, to my knowledge, is always completed by the system-level pharmacy committee, not by the hospital-level pharmacy committee or the individual physicians or pharmacists making the request. I believe this was demanded of us only because of the controversy and stigma surrounding abortion in our community, as in many places in this country.

10. Throughout the six months that we were slogging through this process—which would not have been necessary if not for the REMS—I was forced to turn away patients who needed my care. I know with certainty that, as a result, at least one of my patients was delayed past the point in pregnancy when she could obtain a medication abortion at all—which is available only up to 10 weeks of pregnancy—and had to have a surgical abortion instead. While abortion is one of the safest procedures in modern American medicine, and far safer for a woman than remaining pregnant and carrying to term, the risks associated with abortion increase as pregnancy advances. Thus, delaying a woman's abortion care increases the risks she faces.

11. It is inconsistent with both my medical judgment and my deeply held values to deny a patient's urgent request for time-sensitive medical care that I am qualified to provide—but that is exactly what the REMS required of me.

12. In September 2017, I was contacted by the Chief Medical Officer of our health care system, who had apparently been informed of my request. To my knowledge, it is very unusual for the CMO to be involved in a formulary request, and I assume that my request was only elevated to this very high level because of the controversy surrounding abortion. He proposed a possible strategy to enable me to provide Mifeprex to my patients while avoiding the conflict that he expected would result from a system-wide debate on this question: namely, that I would

prescribe and dispense Mifeprex as a "non-formulary drug," which the policy defines as "[a]n agent, which has not been reviewed by the [pharmacy committee] or has been reviewed and denied admission to the formulary."

13. This is a highly unusual application of our policy on non-formulary drugs, which to my knowledge is typically invoked in situations where patients admitted to our hospital need to continue a pre-established medication regimen for the short period of time that they are admitted. The policy on non-formulary drugs also expressly provides that usage of such medications will be "tracked and routinely reviewed . . . to evaluate appropriateness" by the system-level pharmacy committee—the very same committee that this strategy was designed to avoid, given the expectation of conflict over the abortion issue. In other words, my approval to prescribe and dispense Mifeprex as a non-formulary drug may be withdrawn at any time.

14. Classifying Mifeprex as a non-formulary drug to be "tracked and routinely reviewed" means that I must continue to expend time, and put my professional reputation on the line, having discussions with leadership at my institution regarding my Mifeprex use. It also weighs on me in my everyday practice: for how many patients each month may I prescribe Mifeprex before the pharmacy committee determines that this is an inappropriate use of the non-formulary policy? It is just not clear. And, of course, this designation means that I

may suddenly lose the ability to provide this care to my patients. My ability to include Mifeprex within my practice, and my patients' access to this vital care, is precarious.

15. It is worth noting that formulary drugs are also subject to "annual" review by the system-level pharmacy committee (as compared to the "routine" review for non-formulary drugs). In other words, even if I had succeeded in persuading the leadership in my health care system to add Mifeprex to our formulary, its availability at our hospital still would be subject to debate every year. Notably, since making my request to add Mifeprex to our formulary, it appears that our health care system's medication policy has been revised to specify that the presence of a REMS is one of the factors to be considered in evaluating any "changes to the formulary." Given the timing, I suspect that this addition is designed to make it more difficult to ever add Mifeprex to our formulary. Again, *none* of this would be necessary if I could simply write a prescription for Mifeprex for my patient to fill at a retail pharmacy, as I can do for virtually every other prescription drug—including misoprostol. Nor must my colleagues expend such time or resources, or jeopardize their professional reputations, in order to prescribe other medications that are equally or less safe than Mifeprex.

16. After gaining this temporary, precarious approval to stock and dispense Mifeprex on-site as a non-formulary drug, I next had to sign up with

Danco as a certified prescriber and set up an account with the drug distribution company. This was a significant ordeal in and of itself, further delaying my ability to care for my patients by approximately two months. I completed as much of the paperwork myself as I could, but setting up an account requires information (including on billing and shipping) that, as a doctor within a large health care institution, I do not have. This meant that I had to involve yet another colleague in the process—my Practice Administrator, who oversees finances, staffing, and other significant matters in our practice—and then repeatedly bother that person, who I know to be personally opposed to abortion, until it got done. If not for the REMS, I would not have had to interfere with, and compromise, this important professional relationship in this manner.

17. I believe that the REMS has harmed my reputation among some of my colleagues by necessitating that I engage in an internal lobbying campaign to try to make Mifeprex available onsite, and necessitating the involvement of additional members of our staff in this care. For instance, I was informed about a senior leadership meeting at which a colleague raised as a "concern" that I was working to make Mifeprex available at our facility (mentioning me by name).

18. The Mifeprex REMS also requires me to provide my patients with and discuss, and for us each to sign, a "Patient Agreement Form" containing medical information about Mifeprex dated to March 2016. This is not merely unnecessary

from an informed consent perspective—it actively *undermines* my informed consent process by forcing me to discuss with my patients information that is inconsistent with my clinical approach and increasingly out-of-step with the research on Mifeprex as science moves forward. For instance, the form requires the patient's signature that, "[i]f my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy." However, I (like many clinicians) treat the small percentage of patients whose pregnancies continue following use of the Mifeprex and misoprostol regimen with additional medication doses in the first instance, not surgery. This is well within the standard of care, yet not reflected in the form—to the contrary, the form suggests to patients that surgery is the *only* option in such a case. Moreover, the statement that "the treatment will not work . . . . in about 2 to 7 out of 100 women" is misleading and not how I counsel my patients about the expected efficacy of the treatment. Thus, the Patient Agreement Form also interferes with my ability to practice my profession in accordance with my medical judgment.

19. I hope that other clinicians within our health care system will begin providing Mifeprex at their hospitals and clinics as well, and thus continue to expand access to this safe and effective medication. I have begun to have conversations with a few like-minded colleagues to that end, including giving them

advice about navigating the time-consuming process to become a certified prescriber and set up an account—which they will all have to duplicate. I also have to advise them that, at any point, we may lose the ability to provide this medication as a non-formulary drug. If and when that happens, we will have to reinitiate the process of lobbying, cajoling and maneuvering to try to convince our large health care system's bureaucracy to grant formulary approval for this stigmatized but essential medication. And even if we are somehow successful in that effort, our continued ability to provide this care to our patients will be up for annual debate by our pharmacy committee, the members of which change on a regular basis.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in [redacted] on [redacted], 2018.

[redacted]

[redacted] a/k/a Jane Roe, M.D.

Exhibit C

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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, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **DECLARATION OF AMY POTTER, M.D.**

Amy Potter, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a Family Medicine doctor in Rochester, New York, a trained abortion provider, and a member of the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in litigation challenging the FDA's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write this declaration in support of that litigation. The Mifeprex REMS has caused, and continues to cause, injury to me, my residents, and our patients. But for the REMS, I could and would be providing Mifeprex to my patients.

3. I received my undergraduate degree from the University of Pennsylvania in 2004 and my medical degree from the University of Rochester School of Medicine and Dentistry in 2011. I subsequently completed an internship and residency in Family Medicine at Swedish Medical Center in Seattle.

4. I am trained in both medication abortion and surgical abortion procedures, and currently provide both types of services part-time at a Planned Parenthood health center.

5. Since 2016, I have served on the faculty in the Family Medicine residency program at the University of Rochester. I submit this affidavit in my individual capacity (as an SFP member), and do not speak on behalf of the

University or any other institution.

6. I work in the University's Family Medicine residency clinic, where I, like other attending physicians, both provide direct patient services and supervise residents in providing care. Our clinic is large: there are approximately 40 attending physicians and 20 resident physicians on staff, as well as hundreds of other clinicians and staff members, including registered nurses, nurse practitioners, nurse practitioner residents, nursing administrators, medical assistants, licensed counselors, and secretaries.

7. Because of opposition to abortion within our broader health care system, we do not perform surgical abortion procedures within the residency clinic. And, as explained below, because of the REMS, I am not able to write a prescription for medication abortion for patients presenting at our residency clinic either. As a result, we regularly have to turn away patients who need abortion care. While there are a handful of places in Rochester where our patients can potentially access abortion, patients still experience significant burdens because we cannot provide the care they need. This is also antithetical to the principles underlying Family Medicine, which is to provide all primary health care services that a patient might need from birth until death.

8. For our patients, most of whom are low-income, having to make a second appointment at another facility often means a second day off work, and a

second round of child care arrangements. It often means arranging and paying for transportation twice. It means that the patient cannot get care from her regular Family Medicine doctor, and instead has to interface with a different health care system and a different provider. If a patient goes to Planned Parenthood, it typically means walking through a gauntlet of protestors and experiencing the stigma that too often surrounds abortion clinics.

9. In addition, turning away patients who need medication abortion *always* means that their care is delayed. While it's never a good thing to delay needed medical care, such delays are particularly significant in the time-sensitive context of abortion. Indeed, if being turned away delays a patient past 10 weeks of pregnancy, she will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure. This can be devastating to patients who strongly prefer a medication abortion—for instance, patients who perceive the experience as more "natural" and similar to a miscarriage. Moreover, while abortion procedures are very safe, the risk of complications grows as the pregnancy proceeds.

10. There is no medical reason why I cannot provide Mifeprex to patients who request a medication abortion. Rather, my inability to provide this care is directly caused by the highly unusual requirement in the REMS that I stock and dispense Mifeprex on site. If I could simply issue a prescription for Mifeprex that

my patients could fill at a local or mail-order pharmacy (such as the independently owned pharmacy adjacent to our clinic), I would already be doing so.

11. I started the process of trying to stock Mifeprex in my residency clinic months ago, but have yet to succeed. This has been, and continues to be, a substantial undertaking that is consuming a significant amount of my time and compelling me to put my professional reputation on the line.

12. Because Mifeprex would have to be stocked in our clinic in spaces used by multiple clinicians and staff, and then dispensed by nurses, there are numerous individuals and committees at my institution who have to approve the decision to stock Mifeprex on site. This includes, for instance, the residency director, the residency committee of 6 people, multiple staffing committees of approximately 8 people each, and the clinic's executive committee of 15 people. Before stocking Mifeprex, we would likely need to do what is known as a "values clarification" training, to give staff who are new to the provision of abortion an opportunity to assess their attitudes and beliefs regarding the issues surrounding abortion. And we would need to establish a system for enabling staff to opt-out of being involved in abortion care if they chose to do so. We would also have to determine whether Mifeprex would be stocked in every clinical suite, or only in those suites in which there are nurses, medical assistants, and front desk staff willing and trained to assist in the provision of this care. In a large institution like

ours, even seemingly minor decisions must be deliberated across multiple departments. And all the while, we are turning patients away.

13. If I could just write a prescription from the privacy of the examination room, virtually none of these conversations, approvals, and processes would be necessary, and I know that the few individuals I would still need to inform of my decision would be supportive (because we have already discussed this issue).

14. Because of the REMS, not only am I unable to treat my patients in accordance with my medical judgment—I'm also unable to teach my residents in accordance with my professional judgment. More than 10 residents have asked me to train them in medication abortion. But, because of the REMS, I cannot train my residents in this important health care service at the facility where they have come to learn how to be a Family Medicine doctor.

15. This is not the first time I have had to expend significant time, and jeopardize my professional reputation, to try to comply with the REMS. When I first moved to Rochester in 2014, I started a primary care practice with two other physicians within the University of Rochester network, where we provided full-spectrum Family Medicine including obstetric care. We opened our practice in January 2015. Even though that practice setting was tiny compared to the residency program, and the process therefore infinitely streamlined by comparison, it took almost a year—until the fall of 2015—before I was able to provide Mifeprex to my

patients. It required significant and time-consuming paperwork, as well as approval from the University pharmacy, before I was able to become an authorized prescriber, set up an account, and get the medication in stock. During that time, I had to turn away several patients seeking medication abortion care.

16. In sum, the Mifeprex REMS prevents me from providing the medical care I am trained and committed to provide, to the detriment of my residents and my patients, while also costing me time and professional capital.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 5, 2018, 2018, in Rochester, New York.

Amy Potter, M.D.

Exhibit D

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Attorneys for Plaintiffs

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

GRAHAM T. CHELIUS, M.D., *et al.*, Plaintiffs, vs. ALEX M. AZAR, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **DECLARATION OF GRAHAM T. CHELIUS, M.D.**

Graham T. Chelius, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge and if called to testify I could and would do so competently as follows.

2. I am a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I provide this affidavit in support of that litigation. I do so in my individual capacity, and not on behalf of any entity with which I am associated or where I practice, including my employer, Hawaii Health Systems Corporation.

3. I am a board-certified Family Medicine physician based on the island of Kaua'i in Hawai'i. I currently practice medicine at Kauai Veterans Memorial Hospital ("Kauai Veterans") and its associated clinics, West Kauai Clinics. Kauai Veterans is located on the western side of the island in the town of Waimea, Kaua'i. Kauai Veterans currently employs about 275 people.

4. I am currently the Chief of Staff at Kauai Veterans, a position I have held since February 2018. Immediately before that, and after serving for several years as a board member, I served as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region (which, in addition to Kauai Veterans, included Samuel Mahelona Memorial Hospital, on the eastern side of the island in Kapa'a, Kaua'i), but resigned from that position in December 2017 in

favor of this new opportunity as Chief of Staff. In my role as Chief Medical Officer, I was primarily responsible for managing the relationship between Hawaii Health Systems Corporation and the physicians who serve the Kaua‘i region, including participating in contract negotiations, overseeing physician staffing assignments, and responding to any complaints brought against physicians by both patients and staff. My position required that I be involved in resolving most conflicts that arise among the small clinical team at Kauai Veterans. As Chief of Staff, I have very similar responsibilities, but rather than acting as a representative of the administration I am an elected representative of the physicians who form the medical staff.

5. I received my medical degree from the University of Wisconsin in 2001, and completed my residency in Family Medicine at North Colorado Medical Center. Since January 2009, I have been practicing medicine in Hawai‘i at Kauai Veterans.

6. My specialty is Family Medicine. During the nine plus years that I have been practicing medicine in Hawai‘i, I would estimate that I have cared for more than 1,000 pregnant patients and delivered over 800 babies on the island of Kaua‘i. While many of my patients have much-wanted pregnancies, a substantial percentage choose to end their pregnancies, and come to me seeking abortion care. Most of these women are medically eligible for the FDA-approved medication

abortion regimen: Mifeprex followed by the drug misoprostol.

7. However, I am unable to prescribe Mifeprex to patients who need this medication because, as detailed below, complying with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my health care facility—rather than issuing a prescription, from the privacy of my office, for my patient to fill at a pharmacy—would damage my professional reputation and the workplace dynamics I am responsible for maintaining, and jeopardize my patients' confidentiality. I find that set of injuries intolerable, and so instead my patients and I suffer a different set of injuries resulting from my inability to provide medication abortion. In other words, my patients and I are harmed by the REMS whether I attempt to comply with its restrictions or not.

8. First and foremost, the distribution restriction substantially interferes with my ability to practice medicine in accordance with my professional judgment. Because of the Mifeprex REMS, I am unable to provide medication abortions to my patients, even in situations when my best medical judgment would strongly counsel in favor of providing this care.

9. There is only a narrow window in which a patient can take Mifeprex in combination with misoprostol to end a pregnancy: this method is available only in the first ten weeks of pregnancy. But patients cannot know they are pregnant until four weeks, and many patients do not realize they are pregnant until their

sixth to eighth week. By the time a patient sees me, she typically has only a few weeks—indeed, often only a few days—in which to take the medications; after that, her only option is a surgical abortion. Nevertheless, because of the REMS, I am unable to provide medication abortion care in these time-sensitive situations.

10. There are no abortion providers on Kauaʻi, a federally designated "medically underserved area." The closest provider of abortion services is on Oʻahu, which can be reached only by airplane. I have seen the anxiety, fear, and confusion in my patients' eyes when I tell them that they have to fly to Oʻahu to obtain an abortion. I have heard them describe their frustration, anger, and heartbreak. For some patients—many of whom are already experiencing significant anxiety as a result of the unwanted pregnancy, and some of whom are also struggling with the challenges and trauma of poverty, drug addiction, joblessness, and/or domestic violence—this news is simply devastating.

11. Traveling to Oʻahu for a surgical abortion costs my patients money and time, and causes them stress. Many are forced to make significant personal and financial sacrifices in order to get the health care they need. They must find the money to pay, or if possible make arrangements for insurance to pay, for the costs of transportation to and from the airports on both islands, and for the flights themselves. They must arrange to take time off from work or school, and arrange for child care if they have children, which most do. If a loved one is accompanying

them to O'ahu for support, that person must bear these costs as well. This travel and related logistics impose significant psychological and emotional strain on many of my patients, and in my experience can be especially hard on young women, women struggling with substance abuse, women for whom English is not their first language, and women who are homeless.

12. Raising the money and making arrangements to travel is often time-consuming. Indeed, even for those of my patients fortunate enough to have insurance coverage for the abortion procedure and travel to obtain it (though, of course, still not for child care, missed work, or food away from home), it typically takes one to two weeks for the paperwork to be approved. As previously noted, this delay often means that patients are no longer eligible for medication abortion at all, and instead must have a surgical procedure. Moreover, while abortion is very safe, the risks increase as pregnancy advances. And, on top of that, patients whose abortions are delayed also face health risks associated with continuing a pregnancy for additional days, weeks, or months. For such patients, delaying their abortion means they are sicker, longer.

13. I recall one patient whose experience powerfully illustrates many of the harms caused by the REMS. She is a woman whom I had been treating for substance use disorder and who had previously seen us for obstetrical care for her first child. She came to my office seeking an abortion prior to 10 weeks of

pregnancy. After evaluating her, I concurred that a medication abortion was an appropriate treatment and that she should utilize Mifeprex and misoprostol without delay. I wanted to—and would have—provided her with the medication abortion she desired if I could have written a prescription for Mifeprex for her to fill at a pharmacy. But, because of the REMS, I could not provide that care to my patient. Instead, she was forced to travel to O'ahu.

14. Because of the complications in this woman's life, by the time she was finally able to make the journey to O'ahu, more than six weeks had passed. At that point, she had to have a two-day dilation and evacuation ("D&E") abortion instead of the medication abortion she had wanted. Not only is D&E a significantly more complex and invasive procedure, but it also required her to bear the costs of staying on O'ahu—in a hotel, away from her home and her family—overnight. This was utterly unaffordable for her. Indeed, I understand that she called her sister on the day of her first appointment to tell her that she was on O'ahu for an abortion and had only $20 in her pocket. Her sister jumped on the plane to help my patient find lodging and provide her with emotional support during the procedure—which of course meant that my patient's sister also had to bear the costs of a round-trip flight, hotel, and food during her stay.

15. I still feel frustrated and upset that my patient and her family had to bear the emotional trauma, financial burdens, and medical risks of this experience.

And she is far from the only patient I have had who was eligible for medication abortion at the time I saw her, but ultimately had to have a surgical abortion procedure on O'ahu instead. Again, none of this would be necessary if I could have simply written this patient, and other patients like her, a prescription for Mifeprex when she was in my office early in her pregnancy.

16. Fortunately, that patient *was* ultimately able to have the abortion she desired—but not all of my patients are. In some cases, the travel burdens created by the Mifeprex REMS are simply untenable, and my patients end up carrying pregnancies to term against their will. For instance, one recent patient who struggles with chemical dependency never was able to get to O'ahu, despite her expressed desire for an abortion and despite extensive assistance with the travel arrangements. As a result, she was forced to carry the pregnancy to term (and her child was exposed to drugs throughout the entire pregnancy). I have continued to care for such patients through the course of their pregnancies and beyond, and have seen firsthand the emotional, physical, and financial burdens that an unwanted pregnancy can cause them.

17. Having to refer my patients to O'ahu for abortion care also injures me in multiple ways.

18. First, it causes me significant distress. I became a doctor to make my patients' lives easier, less painful, and more fulfilling. But, because of the REMS, I

must watch them suffer medical, emotional, and financial burdens when I cannot provide them with the abortion care that they desire. In addition, as a physician, I am concerned about continuity of care—yet the restrictions imposed by the Mifeprex REMS mean that I must hand off my patients to someone else, which breaks that continuity. I am confident that the providers to whom I refer my patients in O‘ahu provide high-quality care, and my patients frequently return to me for follow-up care. Still, I should be able to take care of my patients myself, on their home island. The Mifeprex REMS thus prevents me from providing uninterrupted, comprehensive primary health care to my patients, as I strive to do whenever possible.

19. Second, it violates my fundamental beliefs as a health care provider to have to deny a patient’s request for time-sensitive medical care—even though it is medically indicated and even though I am qualified to provide it—because of medically unjustified restrictions like the Mifeprex REMS.

20. Third, the referral process is time-consuming for both me and my patients. A typical abortion referral (including the paperwork necessary to obtain insurance coverage for the travel) takes about an hour. In the context of my busy practice, this is time that I (and the few trusted staff members who assist me with this work) cannot spend helping other patients. If the Mifeprex REMS were not in place, we would not have to spend time and energy making the referral and

completing travel-related paperwork—and, critically, my patients would not be delayed by weeks while they wait for insurance approval.

21. For the past year and a half, some of my patients have been able to avoid most of these burdens by participating in the Telemedicine Abortion Study ("TelAbortion"), which is run through the University of Hawai‘i. This study—which I understand operates as a temporary waiver of the REMS—allows certain qualifying patients to receive Mifeprex by overnight mail from the study's principal investigators on O'ahu without having to fly to that island for care. Recognizing how difficult the journey to O'ahu is for many of my patients, wherever possible, I have assisted them in participating in the study.

22. But the TelAbortion process carries its own burdens and complexities. A participating patient must first have a blood test and ultrasound performed, and then mail, fax, or email the results to a physician at the University of Hawai‘i. Then, that physician must connect with the patient by secure videoconference at a set appointment time. Some of my patients—including those who are homeless, those who are poor, or those who live in extremely remote parts of Kaua‘i—do not have reliable internet or cell phone service, access to technology with secure videoconferencing capability, or the ability to use this technology in a private space where they can speak confidentially. I thus often have to step in to help them. On several occasions, I have stayed late at my office to let a patient use my

computer to participate in the study, but this is not always possible: my patients' schedule, my schedule, and the schedule of the physicians on O'ahu do not always align, and certainly do not always align before the patient's window for a medication abortion closes. Helping my patients participate in the TelAbortion study has taken, and continues to take, many hours of my time—but some of my patients still cannot successfully use it.

23. As another example, participating patients must have a physical address to which a package can be securely and confidentially mailed. But my patients who are homeless do not have such a safe address. So the study also cannot provide relief to such patients.

24. And, critically, I understand that the TelAbortion study is only temporary. When it ends, it will no longer exist as an option for me and my patients.

25. The harms I have described that both my patients and I are experiencing flow directly from my inability to issue a prescription for Mifeprex to be filled by my patient's pharmacist of choice, as I can do with countless other equally or less safe drugs. Most of these harms would be entirely eliminated, or substantially reduced, if the REMS were eliminated.

26. On the other hand, attempting to comply with the REMS threatens its own set of injuries—injuries that I simply cannot sustain, and which thus deter me

from providing medication abortion care.

27. First, in order to comply with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my medical facility, I would have to risk seriously damaging my reputation and professional standing in my workplace and community. Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff. I cannot afford these personal and professional risks.

28. To be clear, many of my colleagues and staff already know that I provide abortion referrals. I know that some staff oppose even this; some have directly expressed such views to me. But if I were to comply with the Mifeprex REMS, I would be doing more than just supporting access to abortion in my *individual* professional capacity—I would also have to involve, and win the approval of, multiple colleagues and staff members in the process of procuring, stocking, dispensing, and billing for Mifeprex. Asking or demanding that my colleagues who have deeply held views against abortion participate in providing abortions would cause significant conflict among my staff—conflict that, as Chief of Staff, I would also be required to manage. These consequences to my

professional reputation and carefully nurtured workplace dynamics deter me from attempting to comply with the Mifeprex REMS.

29. Relatedly, I also have had serious personal safety concerns about the requirement in the REMS that I register with the drug manufacturer and drug distribution company as an abortion provider. I understand that they must keep confidential the list of clinicians registered to prescribe Mifeprex. But particularly in light of the many recent health care hacking incidents, I have been concerned about being inadvertently or maliciously exposed as an abortion provider, and the resulting public backlash to me and my family.

30. Of course, my name is now public in the context of this litigation, and my experience since filing this lawsuit has validated my earlier concerns. Over the past few months, I have received numerous phone calls and letters from strangers relating to this litigation. Many of those communications were positive and supportive. But a few were negative and concerning; based on the security consultations I undertook in preparation for filing this lawsuit, I now carefully examine envelopes for toxic material, and have tried to remember to only open packages that I have been expecting. We also recently installed a security system at our house. In a country where abortion clinic shootings are commonplace and abortion providers have been assassinated, I have feared risking my and my family's safety by following through with what the Mifeprex REMS requires. I

ultimately made the difficult choice to publicize my desire to provide abortion care through this lawsuit, because I believe this case has the potential to expand access to medication abortion for patients all across the country. My family and I felt that this goal was worth the risk to our safety and privacy. But we did not make that choice lightly, and I expect that I am not the only physician who has found the REMS requirement that I add my name to a list of all medication abortion providers in the country a deterrent to providing this care.

31. I am also concerned that compliance with the Mifeprex REMS would jeopardize my patients' privacy. By requiring that my facility be responsible for the purchasing, stocking, dispensing, and billing of Mifeprex—discrete responsibilities held by discrete members of our staff—the REMS injects many more people into the abortion care process. This raises real confidentiality concerns in the small town community in which I practice. Everybody knows you and you know everybody in Waimea, a town of fewer than 2,000 people on an island of just over 65,000. In fact, it is not uncommon for members of my staff to bump into my patients at the grocery store, gym, or on the street. For myself, going to either of the two grocery stores in Waimea is a social event due to the fact that I will certainly know someone either working or shopping at the store. Additionally, many members of the community have a family member, friend, or neighbor employed at Kauai Veterans, and, as a result, members of our community are

sometimes nervous about seeking intimate medical care from us out of fear for their confidentiality. Certain elements of a person's medical history (history of abortion, sexually transmitted diseases such as HIV or Gonorrhea, a history of rape, struggles with substance use disorder) are closely guarded by patients due to real or perceived stigma from those in the general population and medical providers. For instance, I currently have a patient who is pregnant ask that a specific doctor not be involved in her care because she was afraid that the provider might divulge her medical history to family members of the doctor whom the patient also knows. Fortunately, I was able to sufficiently reassure this patient that I trust this physician to respect her confidentiality, which resulted in this patient continuing to receive care from us. But there is no doubt that, in our community, patients struggle with the decision of whether to get adequate medical care due to concerns about their confidentiality. And, indeed, it would be entirely reasonable for a patient to fear for the privacy of her abortion decision if she happens to know, for instance, some of the numerous people who may be involved with the billing, ordering, recording, and physical dispensing of medication at our facility (which, again, is a perfectly plausible scenario in our small town). Complying with the REMS might deter such a patient from coming to us for care, thus impeding my ability to practice and causing our hospital to lose business.

32. By contrast, if the Mifeprex REMS did not exist, I would be able to

write a prescription for Mifeprex for my patient without needing to let anyone else know about the prescription except, at most, the patient's nurse, a medical records clerk, and the patient's trusted pharmacist (or a pharmacy on the other side of the island, or a mail-order pharmacy, if that is her preference). The risk to my patients' confidentiality is thus substantially higher under the Mifeprex REMS.

33. In addition to the serious reputational, professional, and safety concerns I have already identified, an attempt to comply with the Mifeprex REMS would impose significant logistical, time, and resource burdens on me. In order to stock and dispense Mifeprex onsite, I would need to first get a policy created for storing and dispensing the drug in the clinic, and then secure approval from the Pharmacy and Therapeutics ("P and T") committee at Kauai Veterans. I would also need to complete and submit all of the paperwork associated with becoming a certified prescriber under the Mifeprex REMS and setting up an account with the drug distribution company—a process that would take even more time and effort due to the purchasing agreement needing to go through our contracting office, which has to follow burdensome state guidelines. Of course, I am not now a certified prescriber, because the certification requires me to provide a billing address and a shipping address where the Mifeprex can be sent to and then dispensed from—which, for the reasons I have stated, I am unable to do.

34. As I have already noted, this approval process would be extremely

challenging in the tense political climate surrounding abortion at my hospital, and it would almost certainly be hindered by the interference of colleagues and others who vehemently oppose abortion and therefore would object to a decision to stock Mifeprex in our hospital system. As Chief of Staff tasked with maintaining good working relationships in my hospital, I find these risks unacceptable.

35. In addition, I understand that the Mifeprex REMS would also require me to provide my patients with, and discuss and sign, a "Patient Agreement Form" describing the proper usage of, and risks associated with, Mifeprex as of March 2016. Not only would this be a waste of my and my patients' time—since I do not need a special form to ensure that I provide every patient with informed consent counseling—it would also interfere with my informed consent process by forcing me to review with my patients an already outdated version of the science on medication abortion as of early 2016, even as evidence-based clinical practice evolves.

36. The bottom line is that my patients and I are harmed no matter what I do. On the one hand, if I attempt to comply with the Mifeprex REMS, I am taking action that will subject me, my patients, and my colleagues and staff to various risks and harms that I cannot in good conscience accept. On the other hand, because I am not in compliance with the Mifeprex REMS, I am constrained from treating my patients in accord with my best medical judgment, and must suffer the

anxiety, distress, and time expenditure of trying to come up with an alternative course of care for my patients—something that is sub-optimal or even harmful to my patients' health, thus going against my medical training and ethics. I am caught on the horns of this dilemma as a direct result of the Mifeprex REMS.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 4/6/18, 2018.

Graham T. Chelius, M.D.

Exhibit E

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Attorneys for Plaintiffs

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

GRAHAM T. CHELIUS, M.D., *et al.*, Plaintiffs, vs. ALEX M. AZAR, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*, Defendants.	CIV. NO. 1:17-cv-00493-DKW-KSC [CIVIL RIGHTS ACTION] **DECLARATION OF JARED GARRISON-JAKEL, M.D.**

Jared Garrison-Jakel, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a family medicine doctor in Guerneville, California, and a member of the California Academy of Family Physicians ("CAFP"). I understand that CAFP is a plaintiff in this litigation challenging the U.S. Food and Drug Administration's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write in support of that litigation. The Mifeprex REMS causes injury to me and my patients. But for the REMS, I could and would provide Mifeprex to my patients.

3. I received my undergraduate degree from Pomona College in 2005, a Master's in Public Health from the University of California Berkeley in 2009, and my medical degree from the University of California Irvine School of Medicine in 2010. I subsequently completed an internship and residency in family medicine at Sutter Medical Center of Santa Rosa in California.

4. I am trained in both medication and surgical abortion and provided those services while in my residency at Sutter Medical Center of Santa Rosa.

5. Since 2013, I have practiced at Russian River Health Center in Guerneville, California ("Russian River"). I submit this declaration in my individual capacity and— besides CAFP—not on behalf of any institution with

which I am associated, including the health center.

6. Russian River is a federally qualified health center ("FQHC"). FQHCs offer primary health care services to low-income populations in medically underserved areas. Guerneville, where Russian River is located, is an economically depressed city with virtually no other health care facilities. Our health center is located about 30 minutes away from any other doctor's office.

7. Many of my patients have little access to transportation outside of the community where Russian River is located. This lack of transportation makes it difficult to access even urgent health care services. For example, I treated one patient who had a terrible cut in her hand—the laceration reached the tendon. I told this patient that she needed to see a hand surgeon due to the severity of the laceration, but the patient explained that such travel would be impossible for her. She told me, "Doc, either you fix it now or no one's fixing it."

8. As explained below, because of the REMS, medication abortion is not available in the health center where I work. As a result, I have to turn away patients who need abortion care. The closest clinic that offers abortion services is a one-hour round-trip from our health center. Traveling such a distance is a significant impediment for the populations I serve, who generally struggle to afford and arrange for things like transportation and child care. And, making this journey may very well also require my patients to miss work, and therefore lose wages—

that is, if they can get time off work at all; at the low-wage jobs where my patients typically work, there is often no paid leave. The reality is that it can be difficult or impossible for my patients to overcome all of these barriers.

9. I am medically qualified to provide Mifeprex to my patients who request a medication abortion. The only reason why I am not able to do so is because of the requirement that I stock and dispense Mifeprex on site.

10. I am aware that at least one of my colleagues, who holds a position of authority at our institution, is opposed to abortion and would not consent to Mifeprex being stocked and dispensed in our health center. (For the same reason, we cannot provide surgical abortion services here.) However, I am also aware that this colleague would not interfere with my writing a prescription for Mifeprex in the privacy of my office for a patient to fill at a pharmacy—and there are two pharmacies very close to the health center where I work; one is only a block away. But for the REMS, I could and would provide medication abortion care to my patients (and would do so in compliance with all federal segregation guidelines for FQHCs that provide abortion services).

11. Because of the REMS, I am unable to treat my patients in accordance with my medical judgment. Multiple patients have come to me with unwanted pregnancies at less than ten weeks, who requested—and were eligible for—medication abortions. However, because of the REMS, I had to deny them this

care—delaying their abortion, to the extent that they could obtain the abortion at all. Indeed, I am always reluctant to refer a patient to another health care facility, whether for abortion or any other medical service; given the financial challenges that my patients almost uniformly face, which are often compounded by other barriers and stressors (such as mental health disorders, substance use disorders, or homelessness), such a referral usually means that they will be significantly delayed in accessing medical care, or not obtain it at all.

12. There are three central concerns with delaying abortion care. First, if a patient is delayed past ten weeks of pregnancy, she will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure, which may be an inferior option given her circumstances. Second, while abortion is extremely safe, and far safer than remaining pregnant and carrying to term, the risk of complications increases as the pregnancy progresses. I can recall at least one patient who came to me at a point in pregnancy when she was still eligible for a medication abortion but, because I could not write her a prescription for Mifeprex, ended up having a more invasive and time-consuming second-trimester dilation and evacuation abortion procedure over a month later. Third, delaying a patient's abortion means that the patient stays pregnant longer, and thus must incur the serious risks and discomforts associated with pregnancy for longer.

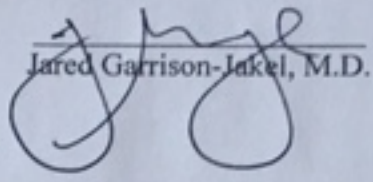
13. Moreover, because of the REMS, at least one of my patients was

prevented from having a desired abortion at all. This patient had a history of sexual trauma and struggled with substance use disorders. She was extremely distressed to learn that she was pregnant, and presented to me seeking a medication abortion. To add to the complications of her situation, she did not feel that she could disclose her desire for an abortion to her partner. I initially referred her to the nearest clinic providing first-trimester abortion services, but she was unable to make the journey to that clinic for her appointment. I saw her again in her second trimester, when she reiterated that she did not want to carry the pregnancy to term. At that point, I referred her to the nearest provider of second-trimester abortions, which is approximately three hours round-trip from Guerneville. I know that the care team at that facility worked diligently to support her in accessing abortion care, including trying to arrange transportation for her. Nevertheless, because of the many challenges in her life, she missed multiple appointments there as well. This patient ultimately ended up carrying the pregnancy to term. I have grave concerns about how this unintended pregnancy has affected her life; when I'd seen her, she communicated that the pregnancy had worsened her suffering around her sexual trauma history and medication dependency. Moreover, this patient did not obtain adequate prenatal care during her first or second trimesters because this was not a pregnancy she had intended to carry to term. Needless to say, denying this patient the care she so desperately wanted and needed was not in accordance with my best

medical judgment.

14. In short, the Mifeprex REMS prevents me from fulfilling my personal, professional, and ethical obligations to provide my patients with the medical care they need, which I am qualified to and would otherwise provide.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 9th, 2018, in Guerneville, California.



Jared Garrison-Jakel, M.D.