ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
lchaiten@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

American Civil Liberties Union Foundation
JULIA KAYE*
JENNIFER DALVEN*
WHITNEY WHITE*
JOHANNA ZACARIAS*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
jdalven@aclu.org
wwhite@aclu.org
jzacarias@aclu.org

American Civil Liberties Union Foundation
RACHEL REEVES*
915 15th Street NW
Washington, DC 20005
T: (212) 549-2633
F: (212) 549-2650
rreeves@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

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

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

Plaintiffs,

v.

DORIS FINK, J.D., *in her official capacity as* ACTING SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

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

PLS.' COMBINED BRIEF IN OPPOSITION TO DEFS.' MSJ AND REPLY IN SUPPORT OF MSJ

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

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INTRODUCTION

Defendants largely ignore the overwhelming record evidence that mifepristone does not meet the statutory requirements for a Risk Evaluation and Mitigation Strategy ("REMS")—much less for onerous Elements to Assure Safe Use ("ETASU")—and ask this Court to do the same. But their efforts to evade judicial review are unavailing. Defendants' theory that parties *directly regulated* by the mifepristone REMS lack standing squarely conflicts with the case law; in any event, Plaintiffs' declarations from members burdened by each ETASU put that argument to bed.[1] Defendants' perplexing assertion that this Court may not consider the full record defies decades of Administrative Procedure Act ("APA") precedent—and would render meaningless this Court's decision on Plaintiffs' motion to complete the record. ECF 207 (Apr. 5, 2024). Finally, this Court should not heed Defendants' demand that it rubber-stamp an agency action that "runs counter to the evidence," *Motor Vehicle Mrfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), fails to "acknowledge, let alone respond to" objections by key stakeholders, *Env't Health Tr. v. FCC*, 9 F.4th 893, 907, 909 (D.C. Cir. 2021), and—contrary to Defendants' revisionist history—expressly "excluded" highly relevant evidence that the U.S. Food and Drug Administration ("FDA") routinely considers

[1] The declarations are exhibits to Plaintiffs' LR56.1(e) Combined Opposing & Supplemental Concise Statement of Facts ("Supp.PCSF").

in other contexts, Pls.' Concise Statement of Facts ("PCSF") ¶¶58-60 (at 2021REMS1604-08), ECF 222. The Court should deny Defendants' motion and grant summary judgment to Plaintiffs on their APA claims.

ARGUMENT

I. Plaintiffs Have Standing.

There is no genuine dispute that the Plaintiff organizations have individual members who "have standing to sue in their own right," and thus associational standing.[2] *Colwell*, 558 F.3d at 1122 (quoting *Friends of the Earth, Inc. v. Laidlaw Envt. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). To satisfy Article III, Plaintiffs need only identify one member suffering a cognizable injury, *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009), 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. EPA*, 633 F.3d 894, 897 (9th Cir. 2011) (quoting *Lujan v. Defenders of*

[2] Plaintiffs readily satisfy the other two requirements for associational standing, which Defendants do not contest. *See* Defs.' Br. In Support of Cross-Mot. For Summ. J. 12-20 [hereinafter "Defs.' Br."]. The "interests at stake" here are "germane" to the Plaintiff organizations' "purpose," *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1122 (9th Cir. 2009); *see* Supp.PCSF ¶2; Corrected Second Am. Compl. ¶¶28-31, ECF 212, and "neither the claim asserted nor the relief requested" requires individual members' participation, *see Defenders of Wildlife v. EPA*, 420 F.3d 946, 958 (9th Cir. 2005), *reversed on other grounds, Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 664 (2007).

Wildlife, 504 U.S. 555, 560-61 (1992)). Plaintiffs easily satisfy these "relatively modest" requirements. *See San Luis & Delta-Mendota Water Auth. v. Salazar*, 638 F.3d 1163, 1169 (9th Cir. 2011) (citation omitted).

A. Plaintiffs and Their Members Suffer Concrete and Particularized Injury Because They Are Directly Regulated by the REMS.

Defendants' reliance on *FDA v. Alliance for Hippocratic Medicine ("AHM")*, 602 U.S. 367 (2024), is misplaced. In rejecting the *AHM* plaintiffs' standing arguments, the Court emphasized that the "plaintiff doctors and medical associations do not prescribe or use mifepristone" and that "FDA has not required [them] to do anything or to refrain from doing anything." *Id.* at 385. Instead, the *AHM* plaintiffs asserted "objections to mifepristone being prescribed and used by *others*" and claimed "downstream" injuries from the actions of third parties not before the court—neither of which created Article III standing. *Id.* at 386 (emphasis in original); *see also Washington v. FDA*, 108 F.4th 1163, 1175 (9th Cir. 2024) (no standing where alleged injuries were not incurred "directly as the object of regulation," but from "lack of regulation of *someone else*'" (quoting *Lujan*, 504 U.S. at 562 (emphasis in original))).

That is a far cry from this case, where Defendants do not contest that Plaintiff Dr. Purcell and members of the Plaintiff organizations *do* prescribe and dispense mifepristone. *See AHM*, 602 U.S. at 385 ("FDA's regulations apply to doctors prescribing mifepristone"). The REMS thus directly requires them "to do" and "to

refrain from doing" specified actions as a condition of prescribing mifepristone. *Id.* Unlike in *AHM*, they are not mere "concerned bystanders," and there are no "speculative" or "attenuated links" in the chain of causation. *Id.* at 382-83. Rather, the REMS directly compels and constrains their actions under threat of penalty, giving them a clear "personal stake." *Ctr. For Biological Diversity v. Kempthorne*, 588 F.3d 701, 707 (9th Cir. 2009) (citation omitted). *Compare, e.g., L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011) (presumption of standing where plaintiff is object of challenged regulatory action), *with Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 419 (2013) ("chilling effect" of policy insufficient where policy "does not regulate, constrain, or compel any action on [plaintiffs'] part").

The REMS compels and constrains Dr. Purcell and the Plaintiff organizations' members in numerous ways. For example, they are required to, *inter alia*, "become specially certified"; either stock and dispense mifepristone at their health centers, or else identify which pharmacies are REMS-certified and then send their Prescriber Certification form to each certified pharmacy they utilize; and adhere to reporting obligations. PCSF ¶50 (at 2023SUPP1466-67). If they fail to comply, they risk decertification as a mifepristone prescriber—which would prevent them from practicing their profession consistent with their medical judgment.[3] Supp.PCSF ¶20.

[3] The REMS likewise compels and constrains the behavior of Plaintiffs' pharmacist members who fill mifepristone prescriptions. PCSF ¶50 (at

Such compelled and constrained action under threat of coercive penalties constitutes concrete injury under Article III. *See Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004) (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"); *Doe v. Bolton*, 410 U.S. 179, 188 (1973) (penalties that "directly operate [on physician] in the event he procures an abortion that does not meet the [government-imposed] exceptions and conditions" created a "sufficiently direct threat of personal detriment"); *Singleton v. Wulff*, 428 U.S. 106, 112-13 (1976) (threatened loss of Medicaid reimbursement for non-compliance with abortion requirements created "concrete injury").

B. The Record Establishes Concrete Harms Caused by Each ETASU.

Although the direct regulation is sufficient alone, the evidence also establishes "concrete and particularized" harm from each ETASU. *Wasden*, 376 F.3d at 916.[4]

Prescriber Certification: Plaintiff Society of Family Planning ("SFP") member Honor MacNaughton, MD, identifies multiple ongoing burdens directly

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2023SUPP1468-69) (requiring pharmacies, *inter alia*, to "become specially certified"; verify and store Prescriber Certification forms; and ensure delivery within four calendar days).

[4] Plaintiffs' declarations demonstrate that at least one member of a Plaintiff organization has Article III standing, making the case justiciable. *See Brown v. City of Los Angeles*, 521 F.3d 1238, 1240 n.1 (9th Cir. 2008).

imposed by the REMS. Dr. MacNaughton has administrative responsibility within her large safety-net health care system for overseeing mifepristone REMS compliance, including ensuring that every clinician who seeks to prescribe mifepristone completes the Prescriber Certification form and transmits the form to the certified pharmacies within the system that fill mifepristone prescriptions. Supp.PCSF ¶3. She is also responsible for integrating information on mifepristone prescriber certification into her health system's onboarding procedures. *Id.* These administrative burdens and costs would not exist but for the REMS and constitute concrete and particularized injury for Article III purposes. *See Ariz. Contractors Ass'n v. Napolitano*, 526 F. Supp. 2d 968, 979 (D. Ariz. 2007) ("labor and out-of-pocket costs" associated with complying with mandated "E–Verify" process for new hires), *aff'd sub nom. Chicanos Por La Causa, Inc. v. Napolitano*, 558 F.3d 856 (9th Cir. 2009); *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 931-32 (9th Cir. 2008) ("administrative burdens" including requirement to obtain a "countersignature of a resident agent" as a condition "of doing business"); *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 from completing and processing forms), *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).

The record also establishes that Prescriber Certification imposes privacy harms on clinicians and deters some from prescribing mifepristone at all. *See* PCSF ¶76; *cf. Wasden*, 376 F.3d at 917 (plaintiff who "desists from performing" abortions because of regulatory action is "concretely affected"). By obligating prescribers to send signed forms not to a single distributor but to every certified pharmacy that fills a prescription for their patients, PCSF ¶50 (at 2023SUPP1467-68); *see* Supp.PCSF ¶7, the 2023 REMS Decision compounds these ongoing privacy harms.

Pharmacy Certification: SFP member Jessica Nouhavandi, Pharm.D., owner, co-founder, and Pharmacist-in-Charge at national mail-order pharmacy Honeybee Health, attests that compliance with this ETASU imposes substantial harm. Supp.PCSF ¶¶12-14, 17-19. Ensuring mifepristone delivery within four calendar days, as this ETASU requires, necessitates more expensive shipping services that cost Honeybee *thousands of dollars each month*. Supp.PCSF ¶14; *see* PCSF ¶80. Honeybee also incurs ongoing costs to maintain a "dashboard" it built to facilitate special communications with prescribers demanded by the mifepristone REMS. Supp.PCSF ¶17. And Honeybee faces annual REMS audits that demand staff time. Supp.PCSF ¶18. Honeybee has an employee whose principal job is to facilitate mifepristone REMS compliance—crystallizing the ongoing costs and burdens. Supp.PCSF ¶19. These injuries more than suffice under Article III. *See, e.g.*, *Ass'n*

of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153-54 (1970); *Ass'n of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 458 (D.C. Cir. 2012).

Pharmacy Certification also harms certified prescribers. Because of the burdens of Pharmacy Certification, Dr. MacNaughton and her colleagues are only able to send prescriptions to four certified pharmacies affiliated with their health system, even if their patient will have difficulty or face delays in accessing those locations. Supp.PCSF ¶¶6-8; *see also* PCSF ¶81 (FDA, 2023: admitting that REMS "will likely limit the types of pharmacies that ... certify"). They do not use external pharmacies because of the significant administrative burdens of investigating the REMS-certification status for hundreds of external pharmacies their patients might wish to use and each submitting their Prescriber Certification forms to each unaffiliated certified pharmacy. Supp.PCSF ¶7; *see also Larson v. Valente*, 456 U.S. 228, 241 (1982) ("registration and reporting requirements" that were more than "de minimis" constituted "distinct and palpable injury"). As a result, Dr. MacNaughton must expend time in each mifepristone appointment navigating with her patients the narrow set of options for where and how they can obtain their mifepristone prescription. Supp.PCSF ¶¶6, 11.

Given her role in overseeing mifepristone REMS compliance, Dr. MacNaughton also personally expends substantial time and effort overseeing

system-wide compliance with Prescriber and Pharmacy Certification—an ongoing process. Supp.PCSF ¶¶3-5.

Patient Agreement: This ETASU obligates Dr. MacNaughton to review and sign the Patient Agreement form with each patient and ensure the completed form (if in hard copy) is scanned into the system's patient records, Supp.PCSF ¶¶9, 11—another ongoing burden, *see Molasky-Arman*, 522 F.3d at 931-32. This ETASU also harms the counselling process and clinician-patient relationship, including because it is "inaccurate, confusing, and could cause additional emotional harm" for some mifepristone patients, ECF 207, at 5 (quoting American College of Obstetricians & Gynecologists et al.); *accord* PCSF ¶¶89-90-91; Supp.PCSF ¶10. In so doing, the Patient Agreement ETASU "interferes with [prescribers'] relationship[s] with [their] patients and with the exercise of [her] professional judgment." *Colwell*, 558 F.3d at 1122 (quotations omitted); Supp.PCSF ¶10; 13A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 3531.9.1 (3d ed. 2024) ("[Interference ... in practicing [one's] profession ... clearly would be an allegation of sufficient injury in fact to satisfy the minimal requirements of Article III"); *see also 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 ...."); *cf.* PCSF ¶¶40 (FDA 2016 review team conceding that this ETASU burdens patients).

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The burdens of these ETASU compound. Indeed, compliance with the ETASU *doubles* the length of Dr. MacNaughton's mifepristone appointments compared to other routine care, because of the need to navigate administrative tasks that do not enhance patient safety. Supp.PCSF ¶11. The cumulative administrative burdens deter some providers from prescribing mifepristone at all. Supp.PCSF ¶4.

In sum, it is beyond dispute that Plaintiffs are suffering cognizable injuries directly attributable to the REMS and each ETASU, and that eliminating the REMS would redress those injuries.

II. Plaintiffs Are Entitled to Summary Judgment on Their APA Claims.

A. Plaintiffs Properly Rely on Evidence in the Administrative Record.

To begin, the Court should reject Defendants' remarkable assertion that the Court cannot consider anything in the administrative record beyond the agency's own findings. *See* Defs.' Opp'n Statement of Facts ("DOSF") 2-3, ECF 227. Defendants would have the Court ignore even *FDA's own statements* when they do not support FDA's ultimate conclusion. *See, e.g.*, DOSF ¶12 (objecting to fact consisting almost entirely of FDA quotations); DOSF ¶56 (objecting to Plaintiffs' citation to FDA's review memoranda). That position is squarely contradicted by both the plain text of the APA, which requires that courts "shall review the whole record or those parts of it cited by a party," 5 U.S.C. § 706, and by long-standing APA

precedents confirming that APA review is no "rubber stamp." *Nat. Res. Def. Council v. Daley*, 209 F.3d 747, 755-56 (D.C. Cir. 2000). Rather, APA review involves "thorough, probing, in-depth review" of "the full administrative record of the agency's action." *Stop H-3 Ass'n v. Dole*, 740 F.2d 1442, 1449-50 (9th Cir. 1984) (cleaned up). It would be impossible for the Court to fulfil its duty to determine, e.g., whether the agency action "runs counter to the evidence before the agency," *State Farm*, 463 U.S. at 43, if, as FDA contends, the Court must ignore record evidence that the agency itself did not rely on. This theory would also effectively nullify this Court's order requiring Defendants to complete the administrative record with materials they admittedly disregarded. ECF 207, at 4-6, 9.

Nothing in the cases Defendants cite supports their position. *See* DOSF 2-3 They stand for the proposition that "summary judgment is an appropriate mechanism for deciding the legal question" in an APA case, and a trial on the facts is unnecessary. *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 770 (9th Cir. 1985); *accord Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994); *City & County of San Francisco v. United States*, 130 F.3d 873, 877 (9th Cir. 1997) (quoting *Occidental Eng'g Co.*, 753 F.2d at 770); *Conservation Council for Haw. v. Nat'l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1218 (D. Haw. 2015) (same). Far from displacing the APA requirement of a "searching and careful inquiry" into the full record, *Nw. Motorcycle Ass'n*, 18 F.3d at 1471, the decisions Defendants cite

performed just that, *see City & County of San Francisco*, 130 F.3d at 878 (considering "additional facts on record here"); *Conservation Council for Hawaii*, 97 F. Supp. at 1220, 1222 (finding agency action "insufficiently supported" based on review of the "voluminous administrative record"). This Court is not only permitted to consider the evidence Plaintiffs cite—the APA demands it. *Nw. Motorcycle Ass'n*, 19 F.3d at 1471.

B. FDA's Decision Was Arbitrary and Capricious.

Plaintiffs identified numerous bases on which FDA's 2023 REMS Decision fails arbitrary and capricious review. *See* Pls.' Br. In Support of Mot. For Summ. J. ("Pls.' Br.") 25-44. It failed to: (1) offer a "reasoned analysis" for its action supported by the record, *State Farm*, 463 U.S. at 43; (2) consider "statutorily mandated factor[s]" that are "by definition,… an important aspect of any issue before an administrative agency," *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216-17 (D.C. Cir. 2004) (cleaned up); (3) "examine the relevant data," *State Farm*, 463 U.S. at 42-43; (4) "acknowledge, let alone respond to" objections by key stakeholders, *Env't Health Tr.*, 9 F.4th at 907; and (5) "offer[] a reasonable and coherent explanation" for its "inconsistent treatment" of mifepristone compared to drugs with similar or greater risks, *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1245 (D.C. Cir. 2023). In response, FDA offers little more than its own conclusory statements that mifepristone satisfies REMS requirements and an

unsupported theory that it can ignore relevant evidence and statutory factors so long as it acknowledges their bare existence. The APA requires more.

1. FDA Failed to Offer a Reasoned Explanation Supported by the Record.

As Plaintiffs have detailed, *see* Pls.' Br. 35-44, FDA's justifications for the ETASU turned on "sheer speculation," *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014), and "conclusory statements," *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016). Defendants double down on that strategy in their brief, baldly restating FDA's conclusion that the mifepristone REMS is necessary without ever engaging with the contradictory record evidence or credibly explaining how mifepristone meets the statutory requirements in light of that evidence. Under the APA, agency actions are invalid absent a "reasoned explanation" supported by the record, *Am. Tel. & Tel. Co. v. F.C.C.*, 974 F.2d 1351, 1354 (D.C. Cir. 1992)—which Defendants cannot provide.

Patient Agreement: FDA's conclusion that the Patient Agreement "does not impose an unreasonable burden" and "remains necessary to assure safe use," Defs.' Br. 24, is directly contradicted by the conclusions of its 2016 scientific review team that the Patient Agreement is "burden[some]" and "does not add to safe use conditions," PCSF ¶40. And FDA never explained how the Patient Agreement could be justified as essential to ensure "consistently provided patient education" and "standardize[d] … medication information," Defs.' Br. 25, when (1) clinical

guidelines for abortion already ensure informed consent and FDA admits there is strong adherence to such guidelines by abortion providers, PCSF ¶35 (at 2021REMS1577); (2) FDA's own 2016 review team found the Patient Agreement "duplicative" of the safety information all patients receive via mifepristone's Medication Guide, PCSF ¶40; and (3) FDA does not require a Patient Agreement for 99.3% of prescription drugs, PCSF ¶70. FDA's bare assertion that it "considered" but "rejected th[ese] argument[s]" falls far short of the show-your-work reasoning the APA demands. Defs.' Br. 28; *see Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1407 (D.C. Cir. 1995) ("stat[ing] its conclusions" without "connect[ing]" them to the evidence is arbitrary and capricious); Pls.' Br. 36-39.

Prescriber Certification: Defendants justify FDA's decision to retain Prescriber Certification based on a purported lack of evidence "to contradict [FDA's] previous finding that" prescribers should have certain qualifications to prescribe mifepristone; an expected increase in prescribers; and the requirement to report patient deaths. Defs.' Br. 23-24, 27. But Defendants never addressed the crux of Plaintiffs' argument: that the evidence does not reflect anything specific to mifepristone or mifepristone prescribers that could justify this ETASU when FDA concedes that all licensed clinicians possess the skills to assess whether they are qualified to prescribe a certain medication, PCSF ¶36, and when FDA does not mandate such self-certification for 99.5% of prescription drugs, PCSF ¶69—

including *entirely new drugs* with which *every* new prescriber will be unfamiliar. *See* Pls.' Br. 39-41; *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) ("Conclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice ....").

Nor can the reporting obligation for deaths justify this ETASU. Deaths associated with mifepristone are infinitesimally rare (and other serious adverse events "exceedingly rare"). Supp.PCSF ¶24 (0.00048% associated-fatality rate); PCSF ¶13. Neither deaths nor other adverse events have ever been shown to be *caused* by mifepristone, rather than by pregnancy itself. PCSF ¶¶14-17. Indeed, many of the vanishingly few reported deaths are plainly unrelated to mifepristone (e.g. homicide). Supp.PCSF ¶24. And FDA admits that mifepristone's safety profile is "well-established by both research and experience" with "no new safety concerns" in decades, PCSF ¶12—while drugs with far higher death rates face no such Prescriber Certification requirement. *Contra* 21 U.S.C. § 355-1(f)(2)(A) (ETASU must be "commensurate" with specific risks); PCSF ¶¶64-72.

FDA's claim that it "minimized" this ETASU's privacy harms "by requiring prescribers to certify only one time," does not hold water. Defs.' Br. 27. The fear that prescribers will face anti-abortion hostility if their identity were exposed derives from having to complete a form identifying oneself as an abortion provider and submit it to a third party. *See* PCSF ¶76. FDA does not even attempt to explain why

that burden would be "minimized" by only having to complete one form—and FDA itself found confidentiality fears relating to mifepristone to be so grave that it would not reveal its own employees' names within this litigation *even subject to a protective order*. PCSF ¶77. Nor does prescriber certification impose a one-time burden, as FDA incorrectly claims. It requires certified prescribers to send their form to *every certified pharmacy* they utilize for mifepristone, PCSF ¶50 (at 2023SUPP1467), increasing the privacy burdens, *see Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decision making.").

Pharmacy Certification: FDA's sole justification for pharmacy certification was to ensure pharmacies follow other REMS requirements, including verification of prescriber certification. Defs.' Br. 25-26. But an unsupported decision to impose one ETASU, *see supra*, cannot support a decision to compound the burdens of compliance by creating an additional ETASU to enforce the first.

Nor did FDA provide a reasoned explanation for the especially burdensome aspects of this ETASU, such as the four-day-delivery requirement. *See* Supp.PCSF ¶¶14-16. FDA cites the "the time-sensitive nature of mifepristone's use" as its only justification, Defs.' Br. 29, but provided no evidence that patients would *not* get their medication promptly without an ETASU that more than 97% of prescription drugs—many time-sensitive—do not have, PCSF ¶¶23-24; Supp.PCSF ¶16. The APA

demands that the agency "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (quotations omitted). Time and again, FDA fell short.

2. FDA Failed to Apply Mandatory Statutory Factors.

Even setting aside that FDA's rationales were "so implausible that [they] could not be ascribed to a difference in view or the product of agency expertise," *id.*, its decision-making process was arbitrary and capricious—and outside the agency's statutory authority, *see infra* 28-29—for failure to consider mandatory statutory factors. Each of these failures is an independent APA violation.

Section 355-1(f): FDA implicitly concedes that it was obligated to consider the 21 U.S.C. § 355-1(f) factors, including in the context of a REMS modification. *See* Defs.' Br. 31-33. Yet in four discrete ways, it did not do so: *First*, section 355-1(f)(1)(A) permits FDA to impose ETASU only where so essential to mitigate a specific serious risk in the labeling that FDA would "withdraw[]" drug approval without them. FDA has never claimed that mifepristone's ETASU satisfy this requirement, and record evidence refutes any suggestion that they do: FDA's own scientific review team concluded that the Patient Agreement ETASU could be eliminated without jeopardizing safety because it "does not add to safe use conditions," and FDA retained it then (at the Commissioner's behest) only as an "additional assurance." PCSF ¶¶40-41 (at FDA437, FDA674); *see also* Pls.' Br. 12,

36, 38. FDA concedes that "clinicians with state-licensed prescribing authority are qualified to understand any prescribing information sufficiently to discern whether they are qualified to prescribe" it, and FDA relies on such qualifications without any additional Prescriber Certification ETASU for 99.5% of prescription drugs. PCSF ¶¶35-39, 69; *see also* Pls.' Br. 36-37. And FDA admits that it added the Pharmacy Certification ETASU principally as a backstop to prescriber certification, not because it was so independently necessary to mitigate a specific known risk that approval would be withdrawn without it. Defs.' Br. 25-26; *see* Pls.' Br. 42-43. To the contrary, Honeybee and other pharmacies safely dispensed mifepristone for years without a Pharmacy Certification ETASU. PCSF ¶46; Supp.PCSF ¶15.

In response, FDA argues only that it could ignore this specific requirement of section 355-1(f)(1)(A) because the agency separately concluded that mifepristone's ETASU are "necessary for safe use." Defs.' Br. 31. But—even leaving aside that the record does not support that conclusion—the necessity determination is a threshold requirement for the imposition of *any* REMS. *See* 21 U.S.C. § 355-1(a)(1). For ETASU, the most burdensome type of REMS, Congress created *additional* requirements using *different* language. Subsection 355-1(f) must require something more than the basic necessity determination, or else every REMS drug would satisfy the criteria for ETASU. FDA offered no explanation for how mifepristone satisfies the heightened threshold for ETASU under section 355-1(f)(1)(A).

Second, FDA failed to explain how mifepristone's ETASU satisfy section 355-1(f)(2)(A)'s requirement that ETASU be "commensurate" with specific risks identified on the label. *See* Defs.' Br. 31-34 (no discussion of this factor). In particular, FDA never explained how this criterion could be satisfied when it is undisputed that serious adverse events following mifepristone use are "exceedingly rare," PCSF ¶13, have never been shown to be caused by mifepristone, PCSF ¶¶15-16; Supp.PCSF ¶24, and occur less frequently than for many other drugs with no REMS or ETASU, *see* Pls.' Br. 20-21, 34-35.

Third, FDA failed to meaningfully engage with record evidence that the ETASU "unduly burden[]" patient access. 21 U.S.C. § 355-1(f)(2)(C)(ii), (g)(4)(B)(ii). As an initial matter, FDA expressly "excluded" much of the record evidence on burdens. *See infra* 24-26; PCSF ¶¶57-60. And even where FDA conceded that the ETASU burden access, *e.g.*, PCSF ¶¶40, 76-77, 81, its response lacked reasoned analysis, *see* Defs.' Br. 24, 27-29, 32. Defendants claim FDA's meager acknowledgement that the Pharmacy Certification ETASU would limit the number of pharmacies dispensing mifepristone "refutes Plaintiffs' suggestion that FDA ignored the burdens." Defs.' Br. 28. But FDA never grappled with how the deterrent effect on pharmacies would reduce mifepristone access for patients, PCSF ¶¶79-81, nor whether there were ways to modify this ETASU so as to "minimize the burdens" on pharmacies. 21 U.S.C. § 355-1(g)(4)(B)(ii); *contra* PCSF ¶67 (deciding

against a REMS for Korlym, the mifepristone product used for Cushing's Syndrome, based on concerns about "delays" and undermining "access").

FDA essentially argues that the burden evidence was irrelevant anyway because it could not have changed the outcome where FDA otherwise concluded that ETASU are "*necessary* for safety." Defs.' Br. 32. But 355-1(f) specifically contemplates drugs with "known serious risks" for which a REMS has already been deemed "necessary"—and obligates FDA to "assur[e] access and minimiz[e] burden" anyway. 21 U.S.C. § 355-1(f)(1), (f)(2)(C)(ii) ("[ETASU] *shall* ... not be unduly burdensome on patient access to the drug ...."). If safety concerns justified any ETASU without regard to the burden on access, Congress would not have included this statutory factor. Moreover, under subsection 355-1(g)(4), on which FDA relies (*see* Defs.' Br. 21-26), Congress specifically contemplated circumstances in which "1 or more ... [REMS] *elements* should be ... *removed* from the approved strategy to ... *minimize the burden* on the health care delivery system," § 355-1(g)(4)(B)(ii) (emphases added), confirming that Congress intended burden evidence to bear on decisions to modify or remove ETASU.

Finally, FDA claims it could ignore the requirement under section 355-1(f)(2)(D)(i) that ETASU "conform with" FDA's regulation of other drugs because, it contends, no drug is comparable to mifepristone. *See* Defs.' Br. 32-33. Here too, FDA's arguments would effectively read this requirement out of the statutory

scheme entirely. FDA fails to identify *any* drug that it thinks is an apt comparator and regulated similarly to mifepristone. But if differences in, *e.g.*, patient population or indications were enough to make a drug wholly sui generis, FDA would never be obligated to ensure consistency in how it regulates different drugs posing "similar, serious risks," contrary to the plain statutory language. 21 U.S.C. § 355-1(f)(2)(D)(i). Plaintiffs have identified drugs that, according to FDA's own statements and record evidence, pose *similar kinds* of risks to mifepristone (e.g. blood thinners, Korlym, misoprostol) and *greater overall* risks of death than mifepristone (e.g., Viagra, opioids).[5] *See* PCSF ¶¶ 64-74. With the exception of Korlym,[6] FDA does not even attempt to answer these objections and justify its disparate treatment of mifepristone.

[5] Defendants do not contest that the mifepristone REMS is significantly more stringent than the Opioid Analgesics REMS. *See* Defs.' Br. 32-33 & n.6. Instead, FDA points vaguely to "other regulatory regimes that may affect" the provision of opioids, such as a training requirement for opioid prescribers imposed by Congress in the Consolidated Appropriations Act of 2022. *Id.* FDA does not attempt to explain how these other federal laws suffice to mitigate the risks of opioids—which cause "staggering" numbers of deaths each year, PCSF ¶71—such that the mandatory certification and counseling requirements that FDA deems necessary for mifepristone are unnecessary for opioids. And Congress did not enact the Consolidated Appropriations Act until *years after* FDA first approved the Opioid Analgesic REMS, belying any suggestion that FDA's less stringent regulation of opioids relative to mifepristone was based on the existence of that other federal law. Supp.PCSF ¶¶22-23.

[6] As for Korlym, FDA offers no response to the undisputed fact that "[t]he rate of adverse events with [mifepristone for termination of pregnancy] is much lower," yet the latter is more stringently restricted. PCSF ¶66; *see* Defs.' Br. 33.

Section 355-1(a)(1): FDA admits it did not consider the statutory risk/benefit factors under subsection (a)(1), but claims it had no obligation to do so because the 2023 REMS decision was a REMS modification, not an initial approval. *See* Defs.' Br. 29-31. Defendants are wrong.

"Implicit in [the subsection (g)(4) modification] assessment is whether the drug's risks require REMS and/or ETASU" in the first place. *Washington v. FDA*, 668 F. Supp. 3d 1125, 1140 (E.D. Wash. 2023). Therefore, "it would be contrary to the plain language of the statute" for FDA to ignore the (a)(1) and (f) factors in a modification decision. *Id.* at 1140-41. It would make no sense for Congress to place explicit guardrails on FDA's initial decision to impose a REMS and ETASU but then allow FDA to retain those same REMS and ETASU forever onwards even if there is ample evidence that the threshold requirements are no longer satisfied.

Moreover, FDA implicitly concedes that the subsection 355-1(f) factors are relevant when conducting a REMS modification under (g)(4), even without an explicit cross-reference, because both concern the same risk-benefit and burden analysis. Defs.' Br. 31. But the (a)(1) factors are *also* statutorily enumerated factors bearing on the risk-benefit inquiry, and thus by Defendants' same reasoning remain relevant in a modification review as well.

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Defendants argue generally that because FDA concluded "that the REMS with ETASU is necessary" for safety, "none of the [statutory] factors ... could have changed the agency's conclusion" and therefore any deviation from the text was harmless. Defs.' Br. 34. This circular defense fails. "When Congress says a factor is mandatory, that expresses its judgment that such a factor is important," so failure to consider it "leaves [courts] with no alternative but to conclude that ... the agency's reasoning [was] arbitrary and capricious." *Pub. Citizen*, 374 F.3d at 1216 (internal quotation omitted). Here, if safety considerations were the only dispositive factor, Congress would not have specifically mandated *additional* factors under sections 355-1(a)(1) and (f) designed to protect patients and the health care system from burdensome restrictions that are not commensurate with a drug's risks and/or that do not conform with how FDA regulates other drugs. And if Congress had meant to wholly defer to FDA's judgment that a REMS is "necessary" to ensure a drug's benefits outweigh the risks, it would not have required FDA to consider certain enumerated factors before reaching that necessity finding. Even setting aside the glaring illogic of FDA's conclusions and assuming *arguendo* that its analysis was reasonable, *see supra* 13-17, FDA's failure to consider statutorily required factors means its decision-making process was defective under the APA. *See Nw. Env't Def. Ctr. v. Bonneville Power Admin.*, 477 F.3d 668, 690 (9th Cir. 2007) (setting aside agency action for failure to consider certain statutory requirements, even though

agency "may have the ability rationally to conclude" as it did "*after* giving due weight to the Act's requirement").

To avoid "gutting the APA's procedural requirements," courts advise "great caution in applying the harmless error rule in the administrative rulemaking context," applying it "only where the agency's mistake clearly had no bearing on the procedure used or the substance of decision reached." *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1487 (9th Cir. 1992) (quotations omitted)). "[I]f there is *any* uncertainty at all as to the effect of [an agency's] failure," the APA error is not harmless. *Sugar Cane Growers Co-op of Fla. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002) (emphasis added). FDA's failures here do not meet that strict test, given that FDA failed to consider *mandatory* statutory factors, *see Pub. Citizen*, 374 F.3d at 1216-17, and has never offered any rationale that could justify its decision in light of those mandatory considerations, *see supra*.

3. FDA Failed to Consider Relevant Evidence.

The Court should reject FDA's revisionist history that it "consider[ed]" evidence, Defs.' Br. 35-36, it expressly "excluded" from its REMS review, PCSF ¶58 (at 2021REMS1604-08), including medical association' statements opposing the REMS and studies specifically assessing the burdens of ETASUs, *see* Pls.' Br. 26-30. According to Defendants, "[t]he very existence of the chart" listing "excluded" sources shows that FDA considered them. Defs.' Br. 35. But the

agency's obligation to consider relevant evidence requires more than just acknowledging such evidence exists. *See Getty v. Fed. Sav. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986) ("Stating that a factor was considered … is not a substitute for considering it."). Rather, the agency must "*examine* the relevant data," *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 57 (D.C. 2015) (emphasis added), an obligation that requires substantive engagement with evidence, *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1216 (9th Cir. 2008) (requirement that agency consider "cumulative impact" of greenhouse gas emissions not met by "quantif[ying] the expected amount" of emissions without otherwise discussing them). Otherwise, the agency could evade its obligation to make reasoned decisions by ticking a box that it looked at unfavorable evidence without ever substantively grappling with it. *See Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) (agency must provide "reasoning," not "just a conclusion" (quotations omitted)).

Moreover, FDA admits that it "did not consider" the study on safety outcomes after Canada lifted its REMS-like restrictions for mifepristone, Defs.' Br. 36, notwithstanding that study's evident relevance to the 2023 REMS Decision. FDA's only explanation is that it did not possess the complete study until after the agency's self-imposed July 2021 cut-off date for its literature review. Defs.' Br. 36-37. But that defense is foreclosed by this Court's finding that FDA possessed the Canadian

study *months* before completing its 2023 REMS Review and releasing the updated REMS. ECF 207, at 4, 6, 12-14. "[A]n agency cannot *ignore* new and better data" in its possession. *Burwell*, 786 F.3d at 57 (emphasis in original); *see also Catawba County v. EPA*, 571 F.3d 20, 45 (D.C. Cir. 2009) (agency "ha[s] an obligation to deal with newly acquired evidence in some reasonable fashion" (quotations omitted)). As this Court already found, giving FDA a free pass to disregard relevant evidence submitted in the 1.5 years between July 2021 and January 2023 would amount to a "fictional account of the actual decisionmaking." ECF 207, at 16 (quoting *Portland Audubon Soc. v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993)).

FDA protests that holding it accountable for ignoring the Canadian study would mean an endless process of re-evaluation, Defs.' Br. 36-37, but the record belies any such concern. FDA considered multiple studies post-dating its July 2021 cut-off—including one study published on January 3, 2023, and addressed by FDA in a memo to file written on *the very day FDA released its 2023 REMS Decision*. Supp.PCSF ¶21. FDA's failure to address the Canadian study violated the APA.[7]

[7] FDA also speculates that there *might* be reasons why the Canadian study would not have changed FDA's conclusion, "[w]ere FDA to consider [it]." Defs.' Br. 38 n.7. But the time to examine the relevant data and determine how much weight to give it was before the challenged agency action, not in post-hoc litigation rationalizations. *See State Farm*, 463 U.S. at 50.

4. FDA Failed to Respond to Stakeholder Objections.

FDA also violated the APA by failing to respond to stakeholder objections. It is of no moment that FDA reviewed *some* relevant publications from medical stakeholders, *see* Defs.' Br. 8, 22-23, when it expressly refused to consider statements by expert medical societies explaining why a REMS is inappropriate, *see* PCSF ¶58 (at 2021REMS1604-08 ("Appendix A—Chart of Excluded Materials")); *see also Nw. Immigrant Rts. Project v. U.S. Citizenship & Immigr. Servs.*, 496 F. Supp. 3d 31, 75 (D.D.C. 2020) (agency "must provide reasons for disregarding the evidence" raised in comments, "especially when the contrary evidence is substantial"). FDA cannot identify any document in the record where it "acknowledge[d], let alone respond[ed] to" the specific objections raised by stakeholders, *Env't Health Tr.*, 9 F.4th at 909, that mifepristone does not meet the REMS requirements. *See* Pls.' Br. 10-11, 13-14, 33-34. That is dispositive.

5. FDA Failed to Explain Its Inconsistent Treatment.

FDA does not dispute the inconsistency of its mifepristone regulations relative to drugs posing similar or greater risks. Instead, FDA claims it was authorized to "make[] a case-by-case determination that involves weighing the drug's risks and benefits in light of its particular conditions of use and other factors," Defs.' Br. 33, without regard to any inconsistencies. That is incorrect. The REMS statute specifically obligates FDA to assess whether ETASU "conform with" that of "other

drugs with similar, serious risks," 21 U.S.C. § 355-1(f)(2)(D)(i); *see supra* 20-21. And as a general rule, agencies must "justify different results reached on similar facts to lend predictability and intelligibility to agency actions, promote fair treatment, and facilitate judicial review." *Grayscale Invs.*, 82 F.4th at 1245 (quotations omitted). Nothing in law or logic would exempt FDA from the foundational requirement of consistent and predictable agency decision-making, especially given the explicit 355-1(f)(2)(D) requirement here. This, too, is fatal.

C. FDA Exceeded Its Statutory Authority.

FDA does not directly respond to Plaintiffs' excess-of-authority arguments beyond contending that the most superficial engagement with a statutorily mandated requirement satisfies the APA. But as explained *supra* and in Plaintiffs' earlier brief (at 44-46), FDA ran afoul of congressional limits on its authority when it:

- ignored mandatory statutory factors, 21 U.S.C. § 355-1(a)(1), (f);
- failed to explain how a REMS and these ETASU are necessary to ensure that mifepristone's "meaningful" benefits, PCSF ¶10, outweigh its "exceedingly rare" risks, PCSF ¶13; 21 U.S.C. § 355-1(a)(1), (f)(1), (g)(4)(B)(i);
- never claimed (and could not credibly claim) that each ETASU is so essential for safety that drug approval would be withdrawn without it, 21 U.S.C. § 355-1(f)(1)(A);

- failed to explain how the ETASU are "commensurate" with mifepristone's rare risks, particularly given the substantial evidence that they significantly reduce access, *id.* § 355-1(f)(2)(A);
- failed to meaningfully consider evidence that the ETASU are "unduly burdensome," *id.* § 355-1(f)(2)(C); and
- failed to explain how the ETASU "conform" to FDA's regulation of other drugs, *id.* § 355-1(f)(2)(D)(i), 99% of which lack similar restrictions, including those, like opioids, posing far greater risks, PCSF ¶¶69-73.

For each of these reasons *alone*, the 2023 REMS Decision exceeded FDA's authority and violated the APA.

III. Defendants Are Not Entitled to Summary Judgment on Plaintiffs' Equal Protection Claim.

The Court should also deny Defendants' cross-motion for summary judgment on Plaintiffs' equal protection claim. FDA's more stringent regulation of mifepristone prescribers relative to prescribers of drugs with similar or greater safety risks violates equal protection, even under rational basis review, for the same reasons it is arbitrary and capricious under the APA. *See supra* 12-28.[8]

[8] Any suggestion that Plaintiffs' decision not to move for summary judgement on equal protection functions as a concession or waiver, *see* Defs.' Br. 38, ignores basic principles of constitutional avoidance, *see Nw. Austin Mun. Util. Dist. No. One*

Plaintiffs need not show that FDA treats them "differently than any other prescriber or user of mifepristone for termination of early pregnancy," Defs.' Br. 39. Plaintiffs need only show that FDA's regulation of mifepristone treats them differently than persons "similar[ly situated] *in those respects relevant* to the Defendants' policy." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1064 (9th Cir. 2014) (emphasis added); *accord Gallinger v. Becerra*, 898 F.3d 1012, 1017 (9th Cir. 2018). Here, Defendants assert an interest in "protecting public health," Defs.' Br. 39. But Plaintiffs have identified numerous other drugs posing similar or greater health and safety risks without their prescribers being subject to the burdens of a REMS and ETASU—and FDA has failed to offer any rational justification for the disparity. *See supra* 13-21, 27-28. While Plaintiffs maintain that this differential treatment violates the Constitution, at minimum, Plaintiffs' showing is sufficient to defeat summary judgment for Defendants on this claim.

CONCLUSION

Plaintiffs respectfully request that the Court grant Plaintiffs' Motion for Summary Judgment and deny Defendants' Cross-Motion in full.

v. Holder, 557 U.S. 193, 205 (2009). Because Plaintiffs move on their APA claim, the Court need not reach equal protection.

DATED: Honolulu, Hawai‘i, January 31, 2025

/s/ Jongwook “Wookie” Kim
JONGWOOK “WOOKIE” KIM
11020
ACLU of Hawaii Foundation
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

LORIE CHAITEN*
American Civil Liberties Union Foundation
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
lchaiten@aclu.org

American Civil Liberties Union Foundation
RACHEL REEVES*
915 15th Street NW
Washington, DC 20005
T: (212) 549-2633
F: (212) 549-2650
rreeves@aclu.org

JULIA KAYE*
WHITNEY WHITE*
JENNIFER DALVEN*
JOHANNA ZACARIAS*
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
wwhite@aclu.org
jdalven@aclu.org
jzacarias@aclu.org

JOHN A. FREEDMAN*
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

**admitted pro hac vice*

Attorneys for Plaintiffs

CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the word count limits set by the Court in ECF 211, because, excluding the parts of the document exempted by Local Rule 7.4(d), it contains 6,995 words. In compliance with Local Rules 7.4(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: January 31, 2025

/s/ Jongwook "Wookie" Kim
JONGWOOK "WOOKIE" KIM
ACLU of Hawaii Foundation
Attorney for Plaintiffs