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19 UNITED STATES DISTRICT COURT  
20 FOR THE EASTERN DISTRICT OF WASHINGTON  
21  
22

23 STATE OF WASHINGTON, *et al.*,

24 Plaintiffs,

25 v.

26 U.S. FOOD AND DRUG  
27 ADMINISTRATION, *et al.*,

Defendants.

No. 1:23-cv-03026

DEFENDANTS' RESPONSE IN  
OPPOSITION TO PLAINTIFF  
STATES' MOTION FOR  
PRELIMINARY INJUNCTION

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**TABLE OF CONTENTS**

1

2 INTRODUCTION.....1

3

4 BACKGROUND.....4

5 I. Statutory and Regulatory Background.....4

6 II. Factual and Procedural Background.....6

7 STANDARD OF REVIEW.....11

8 ARGUMENT.....12

9 I. Plaintiffs’ Claims Are Unlikely To Succeed On The Merits.....12

10 A. Plaintiffs Fail To Administratively Exhaust Their Claims.....12

11 B. Plaintiffs Lack Standing.....17

12 C. FDA’s Actions Were Lawful and Reasonable.....22

13 II. Plaintiffs Fail To Show Irreparable Harm.....27

14 III. The Equities And Public Interest Weigh Against An Injunction.....29

15 IV. Plaintiffs’ Requested Relief Exceeds Any Permissible Scope.....31

16 CONCLUSION.....34

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1 INTRODUCTION

2 More than 22 years ago, the U.S. Food and Drug Administration (FDA)  
3 approved mifepristone as safe and effective for termination of early pregnancy  
4 subject to certain restrictions on distribution.<sup>1</sup> While FDA has approved  
5 modifications to that set of restrictions (known since 2007 as a Risk Evaluation and  
6 Mitigation Strategy (REMS)) on several occasions, the restrictions have always  
7 required that patients sign a Patient Agreement Form and that health-care providers  
8 become certified and agree, among other things, that they have the ability to  
9 accurately date pregnancies, diagnose ectopic pregnancies, and provide or arrange  
10 for surgical intervention if necessary. And until January 3, 2023, the REMS  
11 required mifepristone to be dispensed in clinics, medical offices, and hospitals, by  
12 or under the supervision of a certified provider (the in-person dispensing  
13 requirement). Prior to that time, the REMS did not permit pharmacies to dispense  
14 the drug.  
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21 <sup>1</sup> This brief uses “mifepristone” as shorthand to refer to drug products that are  
22 approved for medical termination of early pregnancy. FDA has separately  
23 approved another manufacturer’s drug, Korlym, which has mifepristone as its  
24 active ingredient and is approved for the treatment of Cushing’s syndrome. This  
25 litigation does not affect Korlym.  
26  
27

1 During this more-than-two-decade period (spanning from September 2000 to  
2 January 2023), Plaintiffs did not object to *any* of these requirements by filing a  
3 citizen petition (*see* 21 C.F.R. §§ 10.25, 10.30, 10.45) or by seeking judicial relief.  
4 Then, on January 3, 2023, FDA approved supplemental applications that modified  
5 the REMS to remove the in-person dispensing requirement and permit certified  
6 pharmacies to dispense the drug. Plaintiffs now rely on FDA’s January 2023  
7  
8 REMS modification—which *reduced* the restrictions on the distribution of  
9 mifepristone—as a springboard to ask this Court to preliminarily enjoin FDA from  
10 applying restrictions that it first imposed when mifepristone was approved in 2000.  
11  
12 Plaintiffs also ask this Court to preliminarily enjoin FDA “from taking any action  
13 to remove mifepristone from the market or cause the drug to become less  
14 available,” despite bringing no claim supporting that relief.  
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17 The Court should deny Plaintiffs’ Motion for Preliminary Injunction.  
18  
19 Plaintiffs are unlikely to succeed on the merits. First, they failed to  
20 administratively exhaust their claims by filing a citizen petition with the agency (as  
21 agency regulations require), so as to give the agency an opportunity to apply its  
22 expertise in the first instance. Had Plaintiffs done so, FDA would have carefully  
23 evaluated their claims that the REMS is unnecessary to assure safe use of  
24 mifepristone and unduly impedes access to the drug. These matters lie at the heart  
25 of the agency’s core statutory mandate, and FDA is entitled to evaluate these issues  
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1 in the first instance. Second, Plaintiffs lack standing to challenge an agency action  
2 the sole effect of which was to make the REMS *less* restrictive and permit  
3 dispensing of the drug by certified pharmacies. Third, on the merits, Plaintiffs  
4 disregard FDA’s reasoned explanation for its 2023 REMS modification and fail to  
5 show that FDA acted unreasonably or contrary to law.  
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8 Nor have Plaintiffs met their burden on any of the other preliminary  
9 injunction factors. They cannot credibly claim to be irreparably harmed by FDA’s  
10 decision to retain two 22-year-old requirements, remove the in-person dispensing  
11 requirement, and permit certified pharmacies to dispense mifepristone. Tellingly,  
12 for over two decades, Plaintiffs did not challenge requirements that, on net, were  
13 *more* restrictive than the modified REMS FDA approved on January 3, 2023. At  
14 the very least, their delay shows that any harm is not so significant as to justify a  
15 preliminary injunction that would upset the status quo and enjoin FDA from  
16 “enforcing or applying” (Mot. 34) requirements that in its expert judgment are  
17 necessary to assure the drug’s safe use. Finally, even if Plaintiffs were entitled to  
18 some relief (they are not), the preliminary injunction that they request is not  
19 tailored to their claims, violates the well-established principle that the proper  
20 remedy in an Administrative Procedure Act (APA) case is limited to the  
21 challenged agency action, and is inconsistent with Federal Rule of Civil Procedure  
22 65(d).  
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1 **BACKGROUND**

2 **I. Statutory and Regulatory Background**

3  
4 The Federal Food, Drug, and Cosmetic Act (FDCA) generally prohibits the  
5 interstate distribution of new drugs that have not received FDA approval. 21  
6 U.S.C. § 355(a). In deciding whether to approve a new drug, FDA evaluates  
7 whether a new drug application contains scientific evidence demonstrating that the  
8 drug is safe and effective for its intended uses. *Id.* § 355(d); *see also* 21 C.F.R.  
9 §§ 314.50, 314.105(c). Similarly, when a sponsor submits a supplemental new  
10 drug application proposing changes to the conditions of approval for a drug (such  
11 as changes to a drug’s labeling or FDA-imposed restrictions), FDA reviews the  
12 scientific evidence submitted in support of the changes. *See* 21 C.F.R. § 314.70.

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16 Since 1992, FDA’s regulations (the Subpart H regulations) have authorized  
17 FDA to require conditions “needed to assure safe use” of certain new drugs. Final  
18 Rule, 57 Fed. Reg. 58,942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R.  
19 § 314.520). In the Food and Drug Administration Amendments Act of 2007  
20 (FDAAA), Congress codified and expanded the Subpart H regulations by giving  
21 FDA authority to require a REMS when it determines that such restrictions are  
22 necessary to ensure that the benefits of a drug outweigh the risks. *See* Pub. L. No.  
23 110-85, tit. IX, § 901 (codified at, *inter alia*, 21 U.S.C. § 355-1). FDA may require  
24 that a REMS include “elements to assure safe use” if necessary to mitigate a  
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1 serious health risk and if certain statutory criteria relating to ensuring safety and  
2 minimizing the burden of restrictions are satisfied. *See* 21 U.S.C. § 355-1(f)(1)-(2).  
3

4 FDAAA expressly addressed how to incorporate drugs with existing Subpart  
5 H restrictions into the new REMS framework. *See* Pub. L. No. 110-85, tit. IX,  
6 § 909 (21 U.S.C. § 331 note). Specifically, Congress “deemed” such drugs to have  
7 a REMS in effect, with the Subpart H restrictions serving as “elements to assure  
8 safe use.” *Id.* § 909(b). Thereafter, application holders were required to submit  
9 supplemental new drug applications with a proposed REMS, which FDA then  
10 reviewed. *See id.*  
11  
12

13 FDAAA also provides standards for modifying an existing REMS. *See* 21  
14 U.S.C. § 355-1(g)(4). As relevant here, FDA may require an applicant to “submit a  
15 proposed modification” to the REMS if the agency “determines that 1 or more  
16 goals or elements should be added, modified, or removed” from the approved  
17 REMS to “ensure the benefits of the drug outweigh the risks of the drug” or  
18 “minimize the burden on the health care delivery system of complying with the  
19 strategy.” *Id.* § 355-1(g)(4)(B); *see also id.* § 355-1(f)(5)(B)-(C). If FDA requires a  
20 modification to a REMS, the applicant must propose that modification within 120  
21 days. *Id.* § 355-1(g)(4)(B).  
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1       **II. Factual and Procedural Background**

2           In 2000, FDA approved the marketing of mifepristone (under the brand  
3 name Mifeprex) for medical termination of early intrauterine pregnancy when used  
4 in a regimen with an already-approved drug, misoprostol. At the same time, to  
5 assure its safe use, FDA placed certain Subpart H “restrictions to assure safe use”  
6 on the distribution and use of the drug product, including requirements that (1)  
7 patients sign a Patient Agreement Form, (2) healthcare providers certify (among  
8 other things) that they have the ability to accurately date pregnancies, diagnose  
9 ectopic pregnancies, and either perform surgical intervention or arrange for others  
10 to perform it if necessary, and (3) the drug be dispensed in person at a certified  
11 provider’s office. *See* Compl. Ex. D, at 4.

12           Because these restrictions were in place on the effective date of FDAAA,  
13 mifepristone was “deemed to have in effect an approved [REMS]” that continued  
14 these “elements to assure safe use.” Pub. L. No. 110-85, § 909(b)(1); *see also* 73  
15 Fed. Reg. 16,313 (Mar. 27, 2008). In 2011, FDA approved the post-FDAAA  
16 mifepristone REMS after determining that it remained “necessary ... to ensure the  
17 benefits of [mifepristone] outweigh the risks of serious complications.” Katzen  
18 Decl. Ex. A. After FDA approved a generic version of the drug in 2019, it  
19 approved a single, shared system REMS for both Mifeprex and the generic version,  
20 known as the Mifepristone REMS Program. Katzen Decl. Ex. B.



1 FDA has since reviewed and modified the Mifepristone REMS Program.<sup>2</sup>  
2  
3 On May 7, 2021, FDA announced that it would review elements of the  
4 Mifepristone REMS Program to determine whether those elements should be  
5 modified. Katzen Decl. Ex. C (REMS Modification Rationale Review) at 8. FDA’s  
6 review encompassed “multiple different sources of information,” including  
7  
8 “published literature,” “safety information,” adverse event reports, a “REMS  
9 assessment report” submitted by the applicants, and “information provided by  
10 advocacy groups, individuals, and the [a]pplica[tion holders].” *Id.* at 10. The  
11 agency’s literature review covered material published between March 29, 2016  
12 (the date of the last REMS modification) and July 26, 2021, and included  
13 publications found on PubMed and Embase or provided by “advocacy groups,  
14 individuals, plaintiffs in [*Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.)], and  
15 the [a]pplicat[ion holders],” as well as “healthcare providers and researchers.” *Id.*  
16 at 10-11.  
17  
18  
19

20 On December 16, 2021, FDA announced its conclusion that “certain  
21 elements of the Mifepristone REMS Program remain necessary to assure the safe  
22 use of mifepristone” and that “the Mifepristone REMS Program continues to be  
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25 <sup>2</sup> <https://perma.cc/7BQC-AJP9> (see Approval Date(s) and History, Letters,  
26 Labels, Reviews for NDA 020687).  
27

1 necessary to ensure the benefits outweigh the risk.” Katzen Decl. Ex. D at 6.  
2 Specifically, FDA found that prescriber certification and the Patient Agreement  
3 Form continue to be necessary components of the REMS. *Id.* at 22. At the same  
4 time, FDA found that the REMS “must be modified to remove” the in-person  
5 dispensing requirement, which would “allow, for example, dispensing of  
6 mifepristone by mail via certified prescribers or pharmacies.” *Id.* at 35. Thus, FDA  
7 concluded based on its review that “mifepristone will remain safe and effective if  
8 the in-person dispensing requirement is removed, provided all the other  
9 requirements of the REMS are met and pharmacy certification is added.” *Id.*

13 FDA explained its conclusions in a review memorandum. Katzen Decl. Ex.  
14 C. *First*, FDA explained its rationale for retaining the prescriber certification  
15 requirement, which allows mifepristone to be prescribed only by providers who are  
16 certified under the REMS and agree, among other things, that they can accurately  
17 date pregnancies, diagnose ectopic pregnancies, and perform or arrange for  
18 surgical intervention for patients who experience complications. *Id.* at 12-14. FDA  
19 explained that the prescriber certification requirement protected against the risk  
20 that providers would not detect and appropriately manage complications, such as  
21 missed ectopic pregnancy and heavy bleeding from incomplete abortion. *Id.*  
22 Because FDA’s review of the relevant literature “did not identify any studies  
23 comparing providers who met” the qualifications required by the prescriber  
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1 certification “with providers who did not,” there was “no evidence to contradict  
2 [FDA’s] previous finding that” the requirement is “necessary to mitigate the  
3 serious risks associated with the use of mifepristone in a regimen with  
4 misoprostol.” *Id.* Thus, the agency concluded that prescriber certification  
5 “continues to be a necessary component of the REMS to ensure the benefits of  
6 mifepristone for medical abortion outweigh the risks,” and that “[t]he burden of  
7 prescriber certification has been minimized to the extent possible” because each  
8 provider need only provide one certification to each of the two drug application  
9 holders for mifepristone. *Id.*

13         *Second*, FDA explained that the Patient Agreement Form “ensures that  
14 patients are informed of the risks of serious complications associated with  
15 mifepristone,” “serves as an important counseling component,” and “document[s]  
16 that the safe use conditions of the Mifepristone REMS Program have been  
17 satisfied.” *Id.* at 14-15. Although the agency considered removing this requirement  
18 in 2016, it ultimately decided to retain this requirement. *Id.* at 16. In 2021, FDA  
19 concluded that “literature that focused on the informed consent process” “d[id] not  
20 provide evidence that would support removing” the Patient Agreement Form  
21 requirement. *Id.* at 16-17. Among other things, the agency found that the Patient  
22 Agreement Form “is an important part of standardizing the medication information  
23 on the use of mifepristone that prescribers communicate to their patients,” “does  
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1 not impose an unreasonable burden on providers or patients,” and thus “remains  
2 necessary to assure the safe use of Mifepristone.” *Id.* at 18.

3  
4 *Third*, based on an extensive review of assessment reports submitted by the  
5 application holders, adverse event data, and the literature, FDA concluded that the  
6 in-person dispensing requirement was no longer necessary because, among other  
7 things, “there does not appear to be a difference in adverse events between periods  
8 during the COVID-19 [public health emergency] when the in-person dispensing  
9 requirement was being enforced and periods when the in-person dispensing  
10 requirement was not being enforced.” *Id.* at 38. The agency therefore concluded  
11 that “mifepristone will remain safe and effective for medical abortion if the in-  
12 person dispensing requirement is removed, provided all the other requirements of  
13 the REMS are met, and pharmacy certification is added.” *Id.* at 39.

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17 FDA expressly tied the addition of the pharmacy certification requirement to  
18 the removal of the in-person dispensing requirement. *See id.* at 40 (“Given this  
19 modification to the dispensing requirements in the REMS, it is necessary to add a  
20 requirement for certification of pharmacies ...”). Adding this requirement would  
21 “incorporate[] pharmacies into the REMS, ensur[ing] that [they] are aware of and  
22 agree to follow applicable REMS requirements, and ... that mifepristone is only  
23 dispensed pursuant to prescriptions that are written by certified prescribers.” *Id.*  
24  
25 “Without pharmacy certification, a pharmacy might dispense product that was not  
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1 prescribed by a certified prescriber.” *Id.* Consequently, to “ensure the benefits of  
2 mifepristone for medical abortion outweigh the risks while minimizing the burden  
3 imposed by the REMS on healthcare providers and patients,” FDA approved “the  
4 removal of the in-person dispensing requirement” and added the “requirement for  
5 pharmacy certification.” *Id.* at 41.  
6

7  
8 Accordingly, FDA directed the drugs’ application holders to submit  
9 supplemental applications proposing conforming modifications to the REMS.  
10 Katzen Decl. Exs. E & F. The application holders submitted their supplemental  
11 applications in 2022, and FDA approved them on January 3, 2023, confirming its  
12 December 16, 2021, determination that mifepristone will remain safe and effective  
13 if the in-person dispensing requirement is removed, provided all the other REMS  
14 requirements are met and pharmacy certification is added. Katzen Decl. Exs. G at  
15 9-15 & J.  
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#### 18 STANDARD OF REVIEW

19  
20 Preliminary injunctive relief is an “extraordinary and drastic” remedy that  
21 “may only be awarded upon a clear showing that the plaintiff is entitled to such  
22 relief.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 20-23 (2008); *Munaf v. Geren*, 553 U.S.  
23 674, 689-90 (2008). “A plaintiff seeking a preliminary injunction must establish  
24 that [it] is [1] likely to succeed on the merits, [2] that [it] is likely to suffer  
25 irreparable harm in the absence of preliminary relief, [3] that the balance of  
26  
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1 equities tips in [its] favor, and [4] that an injunction is in the public interest.”  
2 *Recycle for Change v. City of Oakland*, 856 F.3d 666, 669 (9th Cir. 2017) (internal  
3 quotation marks omitted; alterations in original). The third and fourth factors  
4 merge when the federal government is the non-movant. *Drakes Bay Oyster Co. v.*  
5 *Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014) (citing *Nken v. Holder*, 556 U.S. 418,  
6 435 (2009)). A preliminary injunction that “would alter, rather than preserve, the  
7 status quo” is “disfavored unless there is a very strong showing in favor of the  
8 moving party.” *Miracle v. Hobbs*, 808 F. App’x 470, 473 (9th Cir. 2020).  
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## 12 ARGUMENT

### 13 I. Plaintiffs’ Claims Are Unlikely To Succeed On The Merits

#### 14 A. Plaintiffs Failed To Administratively Exhaust Their Claims

15 Plaintiffs challenge FDA’s approval of supplemental applications proposing  
16 modifications to the Mifepristone REMS Program. That challenge is unlikely to  
17 succeed because Plaintiffs failed to exhaust their administrative remedies. As FDA  
18 has repeatedly demonstrated in approving modifications to the REMS over the past  
19 22 years, the agency is committed to carefully evaluating new evidence and  
20 determining whether particular restrictions remain necessary to assure safe use of  
21 mifepristone. There is no reason to think the agency would take a different  
22 approach to Plaintiffs’ evidence if Plaintiffs were to submit it to the agency.  
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1 The APA requires a party to exhaust any administrative remedy mandated  
2 by statute or agency rule. *See Darby v. Cisneros*, 509 U.S. 137, 153 (1993).  
3  
4 FDA regulations set forth a detailed (and mandatory) administrative process for  
5 challenging agency action. As relevant here, “[a] request that [FDA] take or refrain  
6 from taking any form of administrative action must first be the subject of a final  
7 administrative decision based on [a citizen petition.]” 21 C.F.R. § 10.45(b); *id.*  
8 §§ 10.25(a), 10.30; *see also id.* § 10.1 (defining “administrative action” as “every  
9 act, including the refusal or failure to act, involved in the administration of any law  
10 by the Commissioner”). Moreover, when challenging an agency action, a party  
11 “who wishes to rely upon information or views not included in the administrative  
12 record shall submit them to the Commissioner with a new petition to modify the  
13 action under § 10.25(a).” *Id.* § 10.45(f).  
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17 Exhaustion requirements “avoid premature claims and [] ensure that the  
18 agency possessed of the most expertise in an area be given first shot at resolving a  
19 claimant’s difficulties.” *Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957,  
20 965 (9th Cir. 2002). Congress empowered FDA to weigh the scientific evidence  
21 and determine whether a drug’s distribution restrictions are necessary to assure  
22 safe use. As the Ninth Circuit has explained, requiring a plaintiff challenging FDA  
23 approval of a drug application to first file a citizen petition is necessary to  
24 “prevent[] premature interference with agency processes so that the agency may  
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1 function efficiently and so that it many have an opportunity to correct is own  
2 errors, to afford the parties and courts the benefit of its experience and expertise,  
3 and to compile a record which is adequate for judicial review.” *Center for Food*  
4 *Safety v. Hamburg*, 696 F. App’x 302, 303 (9th Cir. 2017).

6 Plaintiffs’ claims turn on issues within the agency’s scientific expertise.  
7  
8 They involve technical and factual assertions about, for example, safety  
9 comparisons of mifepristone to other drugs and alleged unique burdens of REMS  
10 requirements on States—including burdens that Plaintiffs allege have arisen only  
11 after FDA’s determination on December 16, 2021, that the REMS must be  
12 modified. *See, e.g.*, Am. Compl. ¶¶ 3, 25, 147, 176, 178-88, 212, 219; Mot. 1, 6,  
13 16, 23. Their claims also rely on studies that were not before the agency at the time  
14 of that determination. *See, e.g.*, Am. Compl. ¶¶ 141 n.62, 143 n.66, 149 n.79, 150  
15 n.80; Godfrey Decl. ¶ 22 n.21; Janiak Decl. ¶ 15 n.7. Requiring exhaustion will  
16 ensure that these “technical and policy questions” will be “addressed in the first  
17 instance by the agency with regulatory authority over the relevant industry rather  
18 than by the judicial branch.” *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d  
19 753, 760 (9th Cir. 2015). This will “afford the parties and courts the benefit of  
20 [FDA’s] experience and expertise, and [allow it] to compile a record which is  
21 adequate for judicial review.” *Center for Food Safety*, 696 F. App’x at 303.  
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1 In similar cases, courts (including this one) have required a party  
2 challenging FDA’s approval of a drug application or other marketing authorization  
3 to first file a citizen petition presenting the challenge to the agency. *See, e.g.,*  
4 *Jensen v. Biden*, No. 4:21-cv-5119, 2021 WL 10280395 (E.D. Wash. Nov. 19,  
5 2021) (Rice, J.) (holding that plaintiff who failed to file a citizen petition did not  
6 exhaust administrative remedies in challenge to FDA emergency use  
7 authorizations); *Ass’n of Am. Physician & Surgeons, Inc. v. FDA (AAPS)*, 539 F.  
8 Supp. 2d 4, 21-24 (D.D.C. 2008) (holding that physicians and pharmacists who  
9 failed to file a citizen petition did not exhaust administrative remedies in challenge  
10 to FDA approval of a supplemental new drug application), *aff’d*, 358 F. App’x 179  
11 (D.C. Cir. 2009); *see also Doe #1-#14 v. Austin*, 572 F. Supp. 3d 1224, 1234 (N.D.  
12 Fla. 2021) (refusing to consider extra-record material in challenge to FDA  
13 approval of a vaccine where “plaintiffs have not pursued an available  
14 administrative route ... to force the FDA to consider the materials they submit  
15 here”) (citing 21 C.F.R. § 10.45(f)).

16 Likewise, Plaintiffs here seek judicial review of FDA’s approval of  
17 supplemental applications without first raising their challenge with the agency.  
18 Indeed, Plaintiffs never filed a citizen petition challenging *any* FDA action  
19 regarding *any* restriction on mifepristone in the 22 years that the drug has been  
20 marketed. While Plaintiffs objected to the REMS in a March 2020 letter  
21

1 referencing a public docket regarding unrelated FDA guidance documents, *see*  
2 FDA-2020-D-1106-0061 at regulations.gov, that letter did not include all of their  
3 present contentions or reference the studies they now rely upon. In any event,  
4 Plaintiffs have never sought relief through a citizen petition, the agency’s  
5 prescribed administrative remedy. *See* 21 C.F.R. § 10.30 (setting forth detailed  
6 requirements for citizen petitions); *Agua Caliente Tribe of Cuperño Indians of*  
7 *Pala Reservation v. Sweeney*, 932 F.3d 1207, 1219 (9th Cir. 2019) (holding that  
8 letter did not exhaust administrative remedies where statute prescribed a different  
9 process); *Reddic v. Evans*, 2011 WL 2181311, at \*3 (N.D. Cal. Jun. 3, 2011)  
10 (same).<sup>3</sup>

11  
12 Finally, Plaintiffs cannot satisfy the exhaustion requirements by pointing to  
13 the citizen petition submitted by the American College of Obstetricians and  
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19 <sup>3</sup> Nor is there anything in FDA’s response to that letter (*see* Katzen Decl. Ex.  
20 J) that suggests submitting a citizen petition would have been futile. *See Biotics*  
21 *Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (finding “nothing  
22 in the record to indicate that a citizen’s petition to the Commissioner” challenging  
23 agency conclusions set forth in a letter “would have been ineffective or futile”);  
24 *Agua Caliente*, 932 F.3d at 1219 (finding that agency’s response to a letter “does  
25 not suggest futility”).  
26  
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1 Gynecologists (ACOG) in 2022. *See* Am. Compl. ¶¶ 139-43; Mot. 21, 25. ACOG  
2 and the other petitioners are not plaintiffs in this case. Moreover, that petition  
3 requested different relief. ACOG requested that FDA ask the holder of the new  
4 drug application for Mifeprex to submit an application to add miscarriage  
5 management as a new indication for mifepristone. FDA denied that request  
6 because it is up to the new drug application holder to decide whether to seek  
7 approval for a new indication. Compl. Ex. S. That conclusion led FDA to reject the  
8 petition’s related request to eliminate or modify the REMS for mifepristone “so  
9 that it is not unduly burdensome for a miscarriage management indication.” *Id.* The  
10 related request, FDA explained, was “premature” because miscarriage  
11 management “is not a currently approved indication for mifepristone.” *Id.* ACOG’s  
12 citizen petition did not ask FDA to consider the new reasons now offered by  
13 Plaintiffs for eliminating the REMS.  
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### 18 **B. Plaintiffs Lack Standing**

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20 Plaintiffs also lack standing. To meet the “irreducible constitutional  
21 minimum of standing,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992),  
22 Plaintiffs “must show (i) that [they] suffered an injury in fact that is concrete,  
23 particularized, and actual or imminent; (ii) that the injury was likely caused by the  
24 defendant[s]; and (iii) that the injury would likely be redressed by judicial relief,”  
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1 *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Plaintiffs offer three  
2 theories of standing, but each of them fails.

3  
4 *First*, Plaintiffs lack standing to sue the federal government as *parens*  
5 *patriae* on behalf of their residents. *See* Mot. 15. In general, a “State does not have  
6 standing as *parens patriae* to bring an action against the Federal Government.”  
7  
8 *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16  
9 (1982) (citing *Massachusetts v. Mellon*, 262 U.S. 447, 485–486 (1923)). Plaintiffs  
10 suggest that they have a “quasi-sovereign interest in the health and well-being” of  
11 their residents, but the federal government is “the ultimate *parens patriae* of every  
12 American citizen.” *S. Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966); *see also*  
13 *Gov’t of Manitoba v. Bernhardt*, 923 F.3d 173, 180-83 (D.C. Cir. 2019) (applying  
14 this rule to APA claims); *cf. Challenge v. Moniz*, 218 F. Supp. 3d 1171, 1177-78  
15 (E.D. Wash. 2016) (Rice, J.) (holding that Congress had “overridden” *Mellon’s*  
16 limitation in a statute that “explicitly” defines the “person” who may sue “to  
17 include a state”).

18  
19  
20  
21 *Second*, Plaintiffs’ argument that they suffer direct “pecuniary harms,” Mot.  
22 14, fails because they have not established that the challenged agency action—*i.e.*,  
23 FDA’s January 3, 2023, approval of the supplemental applications modifying the  
24 Mifepristone REMS Program—caused those harms. Plaintiffs aver that their  
25 Medicaid programs incur greater costs when patients choose surgical abortion over  
26  
27

1 medication abortion, but apart from conclusory assertions, *see, e.g.*, Birch Decl.  
2 ¶ 10, they offer no support for their assertion that “the [January 2023] REMS  
3 *causes*” patients to obtain surgical abortions, *see* Mot. 15 (citing no evidence for  
4 this proposition). For example, they provide no evidence that, by requiring patients  
5 who wish to take mifepristone to sign a Patient Agreement Form and obtain the  
6 drug from or under the supervision of a certified prescriber or from a certified  
7 pharmacy, the REMS causes a substantial number of patients to obtain surgical  
8 abortion instead. Thus, Plaintiffs’ assertion that the REMS “encourage[s]” patients  
9 to seek surgical abortion “is purely speculative” and therefore cannot support their  
10 standing. *See Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 42-43 (1976)  
11 (rejecting as speculative plaintiffs’ unsupported contention that a tax policy would  
12 necessarily encourage hospitals to deny services to indigent patients).  
13  
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17 Plaintiffs likewise fail to establish that FDA’s January 2023 action caused  
18 the various “administrative burdens” on pharmacies of which Plaintiffs complain.  
19 Mot. 14. Many of the specific administrative tasks about which Plaintiffs complain  
20 reflect their independent choice to establish new systems that may facilitate their  
21 pharmacies’ efforts to dispense mifepristone, but they do not reflect burdens  
22 imposed by the REMS itself. For example, while the REMS requires patients to  
23 sign a Patient Agreement Form before obtaining mifepristone, it does not require  
24 providers to “change[.]” and “test” their information technology systems to “ensure  
25  
26  
27

1 that patients who seek telehealth medication abortion can readily sign the Patient  
2 Agreement Form,” Godfrey Decl. ¶ 35. And while the REMS requires pharmacies  
3 that wish to dispense mifepristone to first satisfy certain conditions, *see* Compl. Ex.  
4 P (“Pharmacy Agreement Form”), it does not require pharmacies to “develop[] new  
5 IT systems” to facilitate those efforts, or “creat[e] billing workflows specifically  
6 for insurance carriers that do not cover mifepristone,” DasGupta Decl. ¶ 15.  
7

8  
9 *Third*, Plaintiffs’ generalized “interest[] in delivering high-quality patient  
10 care,” Mot. 14, also does not confer standing. This vague theory fails to identify a  
11 concrete injury to their providers’ interest in practicing medicine. *See Spokeo, Inc.*  
12 *v. Robins*, 578 U.S. 330, 340-41 (2016) (to be concrete, an injury must be “real, not  
13 abstract” (citation and quotation marks omitted)). To the extent that Plaintiffs base  
14 this theory on their allegations that the REMS requirements they challenge harm  
15 patient care, that theory is speculative for the reasons explained above. *See supra*  
16 pp. 18-19. This theory of standing also lacks a limiting principle: it would give  
17 medical providers standing to challenge virtually any FDA action relating to drugs,  
18 since nearly every such action has some effect on the availability of drugs that  
19 providers may prescribe or recommend. Plaintiffs’ vague assertion of an injury to  
20 their providers’ interest in providing patient care therefore fails.  
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24

25 Finally, Plaintiffs’ theories of standing fail for yet another reason: Plaintiffs  
26 do not meet their burden to show that success on their claims would redress their  
27

1 injuries. Plaintiffs stress that they are challenging the specific action FDA took on  
2 January 3, 2023. *See* Am. Compl. ¶¶ 258, 262, 265, 269 (identifying the “2023  
3 REMS” as the object of Plaintiffs’ claims); Pls.’ Resp. to Defs.’ Mot. for Extension  
4 (Dkt. 19), 3 (“The REMS at the heart of this dispute did not take effect until  
5 January 3, 2023” such that Plaintiffs’ claims were “not ripe until that date.”). Yet it  
6 is unclear how enjoining or vacating that action<sup>4</sup> would redress Plaintiffs’ injuries.  
7  
8 After all, FDA’s January 2023 decision *eased* the approved restrictions on  
9 mifepristone’s distribution and made them less burdensome than they have ever  
10 been in the 22 years since the drug’s approval.<sup>5</sup>  
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16 <sup>4</sup> For the reasons explained *infra* Part IV, Plaintiffs could not be entitled to any  
17 broader relief.

18 <sup>5</sup> Plaintiffs’ claims should also fail for the additional reason that venue is  
19 improper. Plaintiffs assert venue is proper in this district based on the residence of  
20 the State of Washington. But a plaintiff entity “resides” only in the district where it  
21 has its “principal place of business,” 21 U.S.C. § 1391(c)(2), which here is the state  
22 capital in the Western District of Washington. Defendants recognize, however, that  
23 the Ninth Circuit has held otherwise. *See California v. Azar*, 911 F.3d 558, 570  
24 (9th Cir. 2018).  
25  
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27

### C. FDA's Actions Were Lawful And Reasonable

1  
2 Plaintiffs' claims are unlikely to succeed even if the Court reaches the  
3  
4 merits. Under the APA, the Court reviews agency action to determine whether it is  
5 arbitrary and capricious or contrary to law. 5 U.S.C. § 706. Applying the  
6 "forgiving" arbitrary-and-capricious standard, *Env'tl Def. Ctr., Inc. v. EPA*, 344  
7 F.3d 832, 359 (9th Cir. 2003), the Court must uphold agency action unless "the  
8 agency has relied on factors which Congress has not intended it to consider,  
9 entirely failed to consider an important aspect of the problem, offered an  
10 explanation for its decision that runs counter to the evidence before the agency, or  
11 if the agency's decision is so implausible that it could not be ascribed to a  
12 difference in view or the product of agency expertise." *Turtle Island Restoration*  
13 *Network v. U.S. Dep't of Commerce*, 878 F.3d 725, 733 (9th Cir. 2017). Review is  
14 "at its most deferential" with respect to an agency's scientific determinations  
15 within its area of expertise. *Baltimore Gas & Elec., Co. v. Nat. Res. Def. Council,*  
16 *Inc.*, 462 U.S. 87, 103 (1982). In particular, "[FDA's] judgments as to what is  
17 required to ascertain the safety and efficacy of drugs fall squarely within the ambit  
18 of the FDA's expertise and merit deference from [courts]." *A.L. Pharma, Inc. v.*  
19 *Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995) (quoting *Schering Corp. v. FDA*, 51  
20 F.3d 390, 399 (3d. Cir. 1995)); *see also FDA v. Am. Coll. of Obstetricians &*  
21 *Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring) (explaining



1 that the “significant deference” owed to FDA’s judgments weighed against  
2 “compel[ling] the FDA to alter the regimen for medical abortion”).  
3

4 Under these principles, FDA’s January 2023 decision should be upheld.

5 When determining whether to modify elements to assure safe use in an approved  
6 REMS, FDA considers both the need for restrictions to ensure that the benefits of  
7 the drug outweigh the risks and the burdens restrictions impose on patients and the  
8 healthcare system more generally. *See* 21 U.S.C. § 355-1(g)(4)(B); *see also id.*  
9 § 355-1(f)(1), (2), (5)(B). Here, in deciding whether and how the Mifepristone  
10 REMS Program should be modified, FDA asked whether evidence since the  
11 agency’s review of the REMS in 2016 established that a particular existing  
12 restriction either was no longer necessary to ensure that the benefits of the drug  
13 outweigh the risks or was unduly burdensome on patients or the healthcare system.  
14  
15 After weighing the evidence before it, the agency concluded that the Patient  
16 Agreement Form and prescriber certification requirements must be retained; that  
17 the in-person dispensing requirement must be removed; and that a pharmacy  
18 certification requirement must be added to permit certified pharmacies to dispense  
19 mifepristone. The agency’s explanation of these conclusions exemplified reasoned  
20 decisionmaking. *See supra* pp. 8-11. The APA requires no more.  
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24

25 Plaintiffs ignore (indeed, do not even mention) FDA’s reasoned explanation  
26 for its approval of the January 2023 modification to the Mifepristone REMS  
27

1 Program. Instead, they argue that FDA’s approval is “contrary to law” because  
2 mifepristone is safe and the REMS restrictions are “unrelated” to any medical risk  
3 and unduly burdensome on rural patients. *See* Mot. 16-19. But Plaintiffs’ argument  
4 misses the point—FDA has found mifepristone to be safe *with* the REMS  
5 requirements Plaintiffs seek to have removed. Katzen Decl. Ex. C at 39  
6 (“[M]ifepristone will remain safe and effective for medical abortion if the in-  
7 person dispensing requirement is removed, *provided all the other requirements of*  
8 *the REMS are met, and pharmacy certification is added ...*”) (emphasis added). In  
9 2023, FDA considered the burdens of the REMS restrictions and explained that  
10 they could be reduced but that certain restrictions nonetheless remained necessary  
11 to assure the safe use of the product. Were Plaintiffs to submit new evidence in a  
12 citizen petition to FDA showing that the REMS is unnecessary to assure safe use  
13 of mifepristone and unduly burdens access to the drug (which they have not done,  
14 *see supra* pp. 12-17), FDA would carefully weigh that evidence, just as it has  
15 always done when evaluating the necessity of particular restrictions.  
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21 Contrary to Plaintiffs’ suggestion (Mot. 21), the lack of a REMS for Korlym  
22 (a different drug with mifepristone as its active ingredient, *see supra* n.1) does not  
23 support a different conclusion. In deciding whether to require a REMS for a  
24 particular drug, FDA makes a case-by-case determination that involves weighing  
25 the drug’s risks and benefits in light of its particular conditions of use and other  
26  
27

1 factors. *See* 21 U.S.C. § 355-1(a)(1). Thus, the fact that there is no REMS for  
2 Korlym does not compel FDA to reach the same result for Mifeprex and its  
3 generic, which have conditions of use very different from Korlym’s. Indeed, FDA  
4 conducted this case-by-case inquiry for Korlym, explicitly considering the REMS  
5 for Mifeprex, and explained why Korlym does not require a REMS to assure safe  
6 use of the drug to treat Cushing’s syndrome. *See* Katzen Decl. Ex. H.  
7

8  
9 Plaintiffs’ remaining arguments simply underscore their failure to exhaust.  
10 They point to a single Canadian study which, according to Plaintiffs, shows that  
11 mifepristone is safe without restrictions. Mot. 21; Am. Compl. ¶ 143. But that  
12 study was conducted in 2022, after FDA had completed its literature review for the  
13 January 2023 REMS modification. Had Plaintiffs submitted a citizen petition  
14 asking FDA to consider this study, the agency would have done so. *See* 21 C.F.R.  
15 § 10.45(f) (providing that an interested party that wishes to rely on information not  
16 before FDA must first file a citizen petition). Similarly, if Plaintiffs believe they  
17 can identify burdens that FDA did not consider, they must raise those issues in a  
18 citizen petition to afford FDA an opportunity to consider them in the first instance.  
19  
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21

22 Plaintiffs’ arguments that FDA’s approval of the January 2023 REMS  
23 modification was arbitrary and capricious, Mot. 19-26, likewise fail. Despite  
24 having joined a recent amicus brief recognizing that “there can be no doubt that the  
25 FDA’s overall conclusions regarding medication abortion’s safety and efficacy are  
26  
27

1 based on substantial evidence,” *see* Katzen Decl. Ex. I at 2, Plaintiffs emphasize  
2 that the REMS is opposed by certain private medical organizations. Mot. 20-21.  
3  
4 But the APA requires deference to FDA. *See, e.g., Am. Coll. of Obstetricians &*  
5 *Gynecologists*, 141 S. Ct. at 579 (Roberts, C.J., concurring). Here, FDA met its  
6 burden to provide a reasoned explanation for its conclusion that the requirements  
7 of the REMS are scientifically justified, necessary to ensure the benefits of the  
8 drug outweigh the risks, and not unduly burdensome. Plaintiffs’ arguments to the  
9 contrary either raise issues never put before the agency or rest on disagreement  
10 with how FDA weighed the relevant factors.<sup>6</sup> None of these arguments overcomes  
11 FDA’s reasoned decisionmaking.  
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17 <sup>6</sup> In a footnote, Plaintiffs contend that the January 2023 REMS modification  
18 violates the equal protection component of the Fifth Amendment. *See* Mot. 18-19  
19 n.3. A conclusory argument presented in a footnote cannot provide the basis for a  
20 preliminary injunction. *See First Advantage Background Servs. Corp. v. Priv.*  
21 *Eyes, Inc.*, 569 F. Supp. 2d 929, 935 (N.D. Cal. 2008). Regardless, because  
22 Plaintiffs do not allege discrimination on the basis of any protected category, their  
23 claim is subject to rational basis review. *See, e.g., Vargas v. Chelan Cnty. Regional*  
24 *Justice Ctr.*, No. CV-09-39, 2010 WL 685002, at \*4 (E.D. Wash. Feb. 22, 2010).  
25  
26  
27

1       **II. Plaintiffs Fail To Show Irreparable Harm**

2           Plaintiffs also have not met their burden to establish that they will suffer  
3 irreparable harm absent a preliminary injunction. To meet that burden, “[a] plaintiff  
4 must do more than merely allege imminent harm sufficient to establish standing; a  
5 plaintiff must *demonstrate* immediate threatened injury as a prerequisite to  
6 preliminary injunctive relief.” *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011,  
7 1022 (9th Cir. 2016) (quoting *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844  
8 F.2d 668, 674 (9th Cir. 1988)). Because Plaintiffs fail to establish standing, they  
9 likewise cannot meet the higher burden to establish that they would likely face  
10 irreparable harm absent the requested relief.  
11

12           Plaintiffs’ two-decade delay in raising their claims to either FDA or any  
13 court further weighs against a finding of irreparable harm. Since 2000, restrictions  
14 on the distribution of mifepristone have been at least as restrictive as the 2023  
15 REMS modification. As explained above, the Patient Agreement Form and  
16 prescriber certification have been required that entire time. And until January 2023,  
17 the REMS did not permit *any* pharmacy to dispense mifepristone, either with or  
18 without a pharmacy certification. Thus, the restrictions allegedly causing Plaintiffs’  
19

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25           \_\_\_\_\_  
26 For all the reasons described above, FDA’s decision was rationally related to the  
27 legitimate governmental interest in ensuring drug safety.

1 injuries date back to 2000, and their delay in seeking relief “implies a lack of  
2 urgency and irreparable harm.” *Oakland Tribune, Inc. v. Chronicle Publ’g Co.*, 762  
3 F.2d 1374, 1377 (9th Cir. 1985). In short, Plaintiffs have “sle[pt] on [their] rights,”  
4 which “demonstrate[es] that there is not an urgent need for ‘speedy action.’” *ADM*  
5 *Milling Co v. Columbia Plateau Producers, L.L.C.*, 2:20-cv-0343, 2020 WL  
6 5802344, at \*6 (E.D. Wash. Sept. 28, 2020) (Rice, J.).  
7

9 Plaintiffs attempt to show irreparable harm from the pharmacy certification  
10 requirement in isolation, divorced from the 2023 REMS modification as a whole.  
11 But the net effect of the 2023 REMS modification was to *reduce* the burden  
12 associated with accessing mifepristone: by removing the in-person dispensing  
13 requirement and adding a pharmacy certification requirement, FDA *permitted* the  
14 dispensing of mifepristone in a manner that was previously *prohibited*. Plaintiffs  
15 cannot show irreparable harm from FDA allowing pharmacies to dispense  
16 mifepristone on the condition that they satisfy the pharmacy certification  
17 requirement when, prior to January 2023, the REMS did not permit pharmacies to  
18 dispense mifepristone under any circumstances.  
19

22 Moreover, even considering only the pharmacy certification requirement,  
23 Plaintiffs still waited nearly two months to file suit after the 2023 REMS  
24 modification was approved. *See Jensen*, 2021 WL 10280395, at \*9 (Rice, J.)  
25 (holding that a delay of “nearly two months” weighed against finding irreparable  
26  
27

1 harm); *Wise v. Inslee*, No. 2:21-cv-0288, 2021 WL 4951571, at \*6 (E.D. Wash.  
2 Oct. 25, 2021) (Rice, J.) (same). That delay is significant considering that Plaintiffs  
3 have known since December 16, 2021, about the forthcoming modification to the  
4 REMS and have been preparing for it since well before January 2023. *See, e.g.*,  
5 Reed Decl. ¶ 3 (“For the past four months, I have been participating in a work  
6 group at UW that is implementing the amended requirements for the FDA’s  
7 mifepristone [REMS].”); Singh Decl. ¶ 3 (“[F]or the past 6 months, I have  
8 participated [in] operationalizing ... FDA’s updated [REMS] for mifepristone.”);  
9 Prager Decl. ¶ 35 (averring that a workgroup to implement the modified REMS  
10 “has been meeting for 4 or 5 months”). Given this lead time in which Plaintiffs  
11 could have prepared to challenge the 2023 REMS modification, waiting almost  
12 two months after approval of that REMS evinces a lack of urgency.  
13  
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16

17 In sum, Plaintiffs have not shown that they will face irreparable harm absent  
18 an injunction.  
19

### 20 **III. The Equities And Public Interest Weigh Against An Injunction**

21 Plaintiffs have not shown that they are likely to succeed on the merits or that  
22 they are likely to suffer irreparable harm, so the Court need not address the  
23 balancing of equities or public interest. *Herb Reed Enters., LLC v. Fla. Ent. Mgmt.,*  
24 *Inc.*, 736 F.3d 1239, 1251 (9th Cir. 2013). Nevertheless, those factors also weigh  
25 heavily against granting the requested relief.  
26  
27

1 As noted, a preliminary injunction that “would alter, rather than preserve, the  
2 status quo” is “disfavored unless there is a very strong showing in favor of the  
3 moving party.” *Miracle*, 808 F. App’x at 473. “Where no new harm is imminent,  
4 and where no compelling reason is apparent, the district court [is] not required to  
5 issue a preliminary injunction against a practice which has continued unchallenged  
6 for several years.” *Oakland Tribune, Inc.*, 762 F.2d at 1377. Considering that the  
7 Patient Agreement Form and prescriber certification requirements have existed for  
8 22 years and the net effect of the 2023 REMS modification was to *reduce*  
9 restrictions on mifepristone’s distribution, Plaintiffs have shown “no new harm” or  
10 “compelling reason” justifying a preliminary injunction. *Supra* pp. 27-29.  
11  
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14 Plaintiffs’ request is especially unjustified because it would undermine  
15 Congress’s decision to delegate to FDA the responsibility for making scientific  
16 judgments about drug safety. *See* 21 U.S.C. § 393(b). The public interest is best  
17 served by deferring to FDA’s judgments about what restrictions are necessary to  
18 ensure drugs are safe. That is particularly true here, where the agency’s decisions  
19 regarding the conditions on the distribution of mifepristone reflect careful,  
20 deliberative decisionmaking informed by years of data. Had Plaintiffs contested  
21 those decisions by filing a citizen petition with FDA, the agency would have  
22 reached a considered expert judgment on Plaintiffs’ claims and created an  
23 administrative record fit for judicial review. Instead, through this lawsuit, Plaintiffs  
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1 seek to deprive FDA of that opportunity, asking the Court to declare that  
2 mifepristone is safe under conditions that FDA has never approved. As Congress  
3 recognized, there is a strong public interest in having an expert scientific agency  
4 make scientific judgments about drug safety, and the requested injunction is an  
5 impermissible attempt to flout that institutional design.  
6  
7

#### 8 **IV. Plaintiffs’ Requested Relief Exceeds Any Permissible Scope**

9 Even if it were appropriate to enjoin enforcement or application of the 2023  
10 REMS modification (it is not), relief beyond that would not be warranted. This  
11 includes Plaintiffs’ unprecedented request—untethered to any actual claim for  
12 relief or specific harm they assert—to “preliminary enjoin[] FDA from ... taking  
13 any action to remove mifepristone from the market or otherwise cause the drug to  
14 become less available.” Mot. 34. That request should be rejected for at least three  
15 reasons.  
16  
17

18 *First*, Plaintiffs’ proposed remedy fails a fundamental precept of preliminary  
19 injunctive relief: “[a]n injunction must be narrowly tailored to remedy the specific  
20 harm shown.” *E. Bay Sanctuary Covenant v. Barr*, 934 F. 3d 1026, 1029 (9th Cir.  
21 2019) (internal quotation marks omitted). Under that rule, an injunction is  
22 overbroad—and therefore impermissible—when it “reaches beyond the scope of  
23 the complaint and enjoins government regulations that were explicitly never  
24 challenged or litigated.” *Church of Holy Light of Queen v. Holder*, 443 F. App’x  
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1 302, 303 (9th Cir. 2011); *see also Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d  
2 1105, 1116 (9th Cir. 2012) (“Courts should not enjoin conduct that has not been  
3 found to violate any law.”). Plaintiffs make no effort to connect their request that  
4 the Court enjoin “any action to remove mifepristone from the market or otherwise  
5 cause the drug to become less available” to any of their claims. Rather, after  
6 devoting the entirety of their Amended Complaint and Motion to attacking the  
7  
8 January 2023 REMS modification, Plaintiffs simply announce that in addition to  
9 enjoining enforcement and application of that modification, they want this Court to  
10 prohibit FDA from doing anything that would make the drug less available.  
11  
12

13 *Second*, and relatedly, Plaintiffs’ request for relief against hypothetical and  
14 unchallenged future agency action violates basic principles of administrative law.  
15 The APA allows parties to seek review only of discrete “agency actions.” *See*  
16 *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 891 (1990) (“Under the terms of the  
17 APA, respondent must direct its attack against some particular ‘agency action’ that  
18 causes it harm.”); *Arrow Reliance, Inc. v. Califf*, No. 2:22-cv-1057, 2022 WL  
19 18027595, at \*2 (W.D. Wash. Dec. 30, 2022) (holding that the APA permits  
20 challenges to “circumscribed, discrete agency actions”). And when a party prevails  
21 on its APA challenge, the proper remedy—even in the context of a preliminary  
22 injunction—is “limited only to vacating the unlawful action, not precluding future  
23 agency decisionmaking.” *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1  
24  
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1 (D.C. Cir. 2013); *see also, e.g., Norton v. S. Utah Wilderness Alliance*, 542 U.S.  
2 55, 65 (2004) (“The [APA’s] limitation to *required* agency action rules out judicial  
3 direction of even discrete agency action that is not demanded by law.”); *Lujan*, 497  
4 U.S. at 893 (“[T]he flaws in the entire ‘program’—consisting principally of the  
5 many individual actions referenced in the complaint, and presumably actions yet to  
6 be taken as well—cannot be laid before the courts for wholesale correction under  
7 the APA, simply because one of them that is ripe for review adversely affects one  
8 of respondent’s members.”). Here, even if Plaintiffs had valid challenges to the  
9 2023 REMS modification (or to the imposition of the REMS generally), that would  
10 hardly justify injunctive relief against hypothetical future actions pertaining to  
11 mifepristone’s general availability on the market.

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16 *Third*, Plaintiffs’ broad, amorphous remedy also would violate Rule 65(d),  
17 which requires that every injunction “state its terms specifically” and “describe in  
18 reasonable detail ... the act or acts restrained or required.” Fed. R. Civ. P. 65(d);  
19 *see, e.g., Del Webb Communities, Inc. v. Partington*, 652 F.3d 1145, 1150 (9th Cir.  
20 2011) (holding that an injunction’s “general prohibition against using ‘illegal,  
21 unlicensed and false practices’ is too vague to be enforceable” because “[t]he  
22 examples of prohibited past conduct do not sufficiently define what additional  
23 future conduct will be covered”). Suppose, for example, FDA learns that a batch of  
24 mifepristone is contaminated. The FDCA authorizes FDA to recommend that the  
25  
26  
27

1 Department of Justice institute proceedings to seize the violative product. *See* 21  
2 U.S.C. § 334. Would Plaintiffs’ proposed remedy prohibit that seizure action  
3  
4 because it would reduce the availability of mifepristone? There is no limit in  
5 Plaintiffs’ requested relief that would account for that situation, or any other  
6 exercise of FDA’s statutorily conferred authority to execute the provisions of the  
7  
8 FDCA as they pertain to mifepristone. Such broad relief is not permitted by Rule  
9 65(d).

10  
11 **CONCLUSION**

12 For the foregoing reasons, the Court should deny Plaintiffs’ Motion for  
13 Preliminary Injunction.

14 March 17, 2023

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16  
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**CERTIFICATE OF SERVICE**

I hereby certify that, on March 17, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen  
NOAH T. KATZEN