IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, *et al*., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*., Defendants.	Case No. 3:23-cv-00019-RSB

PLAINTIFFS' COMBINED MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Introduction

Plaintiffs' motion for summary judgment lays out how FDA violated the APA when it maintained the Prescriber Certification and Patient Agreement ETASUs and imposed a new Pharmacy Certification ETASU as part of the 2023 REMS Decision. In response, Defendants invoke the doctrine of judicial deference at least three separate times.[1] But ***no*** deference to FDA's decisions is warranted unless Defendants can first show that FDA "engaged in reasoned decisionmaking." *Roe v. Dep't of Def.*, 947 F.3d 207, 220 (4th Cir. 2020) (quoting *Judulang v. Holder*, 565 U.S. 42, 53 (2011)). Because Defendants fail to make that showing, Plaintiffs' motion for summary judgment should be granted.

First, unable to point to any place in the record where FDA made the determinations mandated by 21 U.S.C. §§ 355-1(a)(1) and 355-1(f)(1)-(2), Defendants claim that FDA did not need to adhere to these statutory requirements when it modified the mifepristone REMS. But, as the court held in *State of Washington v. FDA*, 668 F. Supp. 3d 1125, 1140–41 (E.D. Wash. 2023), their reading of the statute is contrary to its plain text. *See* Section I, below.

Second, as FDA did in issuing the 2023 REMS Decision, Defendants do not "grapple[] with" the record evidence that undermines FDA's conclusions. *Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th 487, 502 (4th Cir. 2023) (quoting *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d 260, 293 (4th Cir. 2018)). Most notably, Defendants concede that FDA knew of the published Canadian study showing that mifepristone can be prescribed safely and effectively without REMS-like restrictions—they merely offer unconvincing excuses for why FDA didn't consider it when deciding to retain the mifepristone ETASU. FDA's creation of a chart listing the evidence it

[1] Defs.' Combined Memo. in Sup. of Mot. for Sum. J. and in Opp. to Pls.' Mot. for Sum. J. ("Defs.' Mem.") 10, 23, 24. Other abbreviations and acronyms not defined here are defined in the Mem. of L. in Sup. of Pls.' Mot. for Sum. J. ("Pls.' Mem.").

outright excluded from review cannot credibly be deemed "grappling with" contrary evidence, as Defendants maintain. And Defendants do not even try to defend FDA's failure to confront statements by leading medical professional societies explaining why the mifepristone REMS ought to be removed or to reconcile that action with the Fourth Circuit's en banc ruling in *Mayor of Baltimore v. Azar*, 973 F.3d 258, 266 (4th Cir. 2020), which held that HHS acted arbitrarily and capriciously when "it failed to recognize and address" the concerns of major medical organizations. *See* Section II.A., below.

Finally, when Defendants do try to justify FDA's reasoning, they merely parrot the rationales that FDA offered and declare them to be "reasonable." Critically, they never address the facts refuting FDA's justifications for the mifepristone ETASU, including the facts refuting FDA's baseless assumption that provider *certification* is necessary to assure provider *qualification* to prescribe mifepristone. *See* Section II.B., below.

Defendants' own motion for summary judgment attempts to re-litigate this Court's previous rulings that Plaintiffs have standing to challenge the 2023 REMS Decision and that administrative exhaustion would be futile. *See Whole Woman's Health All. v. U.S. Food and Drug Admin.*, No. 3:23-cv-00019, 2023 WL 5401885, at *5, *6 (W.D. Va. Aug. 21, 2023). But Defendants do not show that either ruling was wrong. As health care professionals and clinics that prescribe and dispense mifepristone to their patients, Plaintiffs are directly regulated by and required to comply with the mifepristone REMS. Plaintiffs' injuries from complying with those medically unjustified restrictions on their practice are set forth in the accompanying declarations of each Plaintiff. *See* Section III.A., below. Defendants have not submitted any new facts or made any new arguments that would require the Court to revisit its conclusion that FDA has already shown, through its past

actions and findings spanning over two decades, that it will not grant the relief Plaintiffs seek, rendering administrative exhaustion a futile act. *See* Section III.B., below.

For these reasons and those stated below, this court should declare that the 2023 REMS Decision maintaining two mifepristone ETASU and imposing a third one violates the APA.

Argument

I. Defendants' Claim that the 2023 REMS Decision Did Not Need to Comply with 21 U.S.C. § 355-1(a)(1) and 21 U.S.C. § 355-1(f)(1)-(2) Misreads the Statute

Defendants have not identified *any* portion of the record where FDA (i) considered the six statutory factors that 21 U.S.C. § 355-1(a)(1) requires FDA to consider when making a "determination" that a REMS is necessary; (ii) applied the test that 21 U.S.C. § 355-1(f)(1) requires FDA to apply in imposing an ETASU; or (iii) considered evidence on the logistics of medication abortion access relevant to whether the ETASU unduly burdened mifepristone access for "patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)," as required by 21 U.S.C. § 355-1(f)(2). These failures to adhere to statutory requirements mean that the 2023 REMS Decision exceeds FDA's statutory authority. *See* Pls.' Mem. 25–27. Defendants respond by trying to wish away those statutory requirements.

First, pointing to the heading of 21 U.S.C. § 355-1(a)(1), Defendants contend that because the 2023 REMS Decision was not an "Initial Approval" of a REMS, FDA was not obligated to consider the six statutory factors that Congress mandated FDA to consider when making a "determination" to impose a REMS. Defs.' Mem. 28. But "the heading of a section cannot limit the plain meaning of the text." *Bhd. of R.R. Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 529 (1947); *see also Miranda v. Garland*, 34 F.4th 338, 355 (4th Cir. 2022) ("[w]hile perhaps relevant, a statute's heading is still far less instructive than its actual text").

Here, the statutory text provides that when FDA issues a REMS modification, FDA must "*determine*[] that 1 or more goals or elements should be added, modified, or removed from the approved strategy to . . . ensure the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. § 355-1(g)(4)(B) (emphasis added). "Implicit in this assessment is whether the drug's risks require REMS," as the district court held in *State of Washington v. FDA,* 668 F. Supp. 3d at 1140—a case Defendants never address. Defendants' argument that FDA need not consider the six § 355-1(a)(1) factors to "determine[]" when "the benefits of the drug outweigh the risks of the drug," 21 U.S.C. § 355-1(a)(1), when that determination is made in the context of a REMS modification, is "contrary to the plain language of the statute."[2] *State of Washington*, 668 F. Supp. 3d at 1140.

Next, Defendants appear to contend that the standard for imposing an ETASU under 21 U.S.C. § 355-1(f)(1) requires only that the ETASU contribute to the drug's "safe use" or "ensure the benefits of [mifepristone] outweigh the risks." Defs.' Mem. 30. This interpretation of the statute ignores its text, which requires FDA to make a determination that "the drug . . . would be withdrawn unless" the ETASU were imposed, a much higher bar that Defendants do not contend FDA satisfied. 21 U.S.C. § 355-1(f)(1)(A).

Finally, Defendants appear to concede that FDA did not consider data relevant to the ETASUs' burdens on patients and the healthcare system while simultaneously averring that FDA did not need to do so because the Agency had concluded the ETASU were "necessary for safety." Defs.' Mem. 30–31. This circular argument would effectively allow FDA to ignore all evidence of an ETASU's burden once FDA decided to impose a REMS. Defendants cite no legal authority for

[2] Defendants' assertion that the § 355-1(a)(1) factors "are directed at drugs that have not yet been marketed," Defs.' Mem. 29, is incorrect. Although the six factors are written in prospective language, they also apply to REMS modifications, when FDA makes determinations applicable to *future* distribution of a drug.

this attempt to excise FDA's obligation to assure that ETASU are not "unduly burdensome" out of the statute. 21 U.S.C. § 355-1(f)(2)(C).

II. Defendants Continue to Evade the Facts Just as FDA Did When It Issued the 2023 REMS Decision

In an APA challenge, the court's initial task is to "conduct a searching and careful review to determine whether [FDA's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d at 270 (internal quotation marks and citation omitted). In particular, "[r]ecord evidence contrary to an agency's conclusion requires further elaboration and must be grapple[d] with." *Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th at 502 (internal quotation marks and citation omitted) (second alteration in original).

Defendants ignore this fundamental principle as well as *Mayor of Baltimore,* 973 F.3d at 266, 277, in which the Fourth Circuit, sitting en banc, held that HHS acted arbitrarily and capriciously when "it failed to recognize and address the ethical concerns of" major medical organizations regarding a proposed rule and did not "address head-on the arguments" those organizations made about the rule's impact on physician practice. *See* Pls.' Mem. 28, 29 (citing *Mayor of Baltimore*). FDA's failure to grapple with relevant evidence contrary to its conclusion, and its choice to rely instead on unsupported assumptions, render its decision to retain or impose new ETASU in the 2023 REMS Decision arbitrary and capricious.

A. FDA Could Not Have "Considered" Evidence that It Did Not Address

Remarkably, FDA asserts that it "considered all relevant evidence before it," Defs.' Mem. 33, when the administrative record plainly shows it did not. In some instances—such as the critical Canadian study—FDA's written analyses did not even acknowledge the existence of relevant

evidence. Other relevant evidence was set out in a five-page-long list of materials expressly "excluded from the REMS review." 2021 REMS 1604–08. Defendants' contention that FDA satisfied its obligation to consider record evidence by creating "a chart that lists the references that FDA 'excluded' from the review," Defs.' Mem. 33, has no support in Fourth Circuit precedent, which consistently holds that an agency does not engage in "reasoned decisionmaking" when it does not "reasonably reflect upon the information contained in the record and grapple with contrary evidence." *Sierra Club v. U.S. Dep't of Interior*, 899 F.3d at 293 (quoting *Fred Meyer Stores, Inc. v. NLRB*, 865 F.3d 630, 638 (D.C. Cir. 2017)); *see also Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th at 502; *Ergon-W. Va., Inc. v. EPA*, 896 F.3d 600, 613 (4th Cir. 2018); *Friends of Buckingham v. St. Air Pollution Control Bd.*, 947 F.3d 68, 92-93 (4th Cir. 2020). And Defendants' assertion that the evidence "'excluded' from the [REMS] review" was excluded only for "*some* of the modifications [FDA] was considering"—implying that it was considered with respect to other contemplated modifications—is refuted by the administrative record, which shows no sign that the excluded items were given *any* consideration. Defs.' Mem. 33 (emphasis added).

Safety data from Canada's deregulation of mifepristone. FDA concedes that it did not consider the Canadian study (2022 CP 99–109) demonstrating that mifepristone could safely be prescribed and dispensed without any REMS-like restrictions. Defs.' Mem. 34. This study directly refutes FDA's conclusion in 2021 that "there is no evidence to contradict our previous finding" that prescriber certification is "necessary to mitigate the serious risks associated with the use of mifepristone," 2021 REMS 1573, which it reiterated when it issued the 2023 REMS Decision, 2023 SUPP 1373. FDA should therefore have addressed it. *Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th at 502.

To justify its failure to consider the Canadian study, FDA says that it "was not published until 2022," after the 2021 REMS Modification Rationale had been completed. Defs.' Mem. 34. But the 2023 REMS Decision at issue here was not issued until January 3, 2023, nearly a full year *after* the Canadian study was published in the prominent New England Journal of Medicine. 2022 CP 99 (January 6, 2022 publication date). Tellingly, FDA never says that it was not aware of the Canadian study when it issued the 2023 REMS Decision. Nor could it credibly do so; the study was cited in the October 2022 citizens' petition that AMA, AAFP, ACOG, and other organizations filed in which they asked FDA to eliminate or modify the REMS as part of their request to broaden the use of mifepristone for miscarriage management. 2022 CP 71–98 (filed on October 4, 2022); *Id.* 87 (citing Canadian study). The Director of FDA's Center for Drug Development and Research ("CDER") rejected the medical societies' citizens' petition on the very same day that FDA (through CDER) issued the 2023 REMS Decision.[3] This timing indicates joint consideration of the two applications by CDER, precluding any possibility that FDA was unaware of the Canadian study when it issued the 2023 REMS Decision.

FDA also pleads that it is incapable of keeping track of "every time a new, potentially relevant study is published." Defs.' Mem. 35. But this hollow excuse is belied by FDA's own conduct. To prepare the 2021 REMS Modification Rationale, FDA did not merely rely upon the studies cited in the submissions made to it, but conducted its own extensive "literature search." 2021 REMS 1570. And to prepare the 2023 Joint Summary Review, FDA did not stop the clock on reviewing new scientific data; rather it identified and relied upon several publications issued *after* the 2021 REMS Modification Rationale was issued. *See*, *e.g.*, 2023 SUPP 1124 (citing

[3] Both decisions were issued on January 3, 2023. *See* 2022 CP 110–113 (citizens' petition denial); 2023 SUPP 1451–60 (Danco approval letter); 2023 SUPP 1461–65 (GenBioPro approval letter). The simultaneous issuance of the two decisions must have been purposeful, since FDA rejected the citizens' petition two months *before* 21 U.S.C. § 355(q)(1)(F) would have required the Agency to respond.

publications dated December 16, 2021 and June 10, 2022); 2023 SUPP 1133 (citing Grossman article published in March, 2022). FDA also reviewed the studies appended to the complaint in *Alliance for Hippocratic Medicine v. FDA,* filed in November, 2022, and concluded that they "d[id] not include safety data relevant to" the modifications made in the January 2023 REMS Decision. 2023 SUPP 1078–79.

Indeed, the record demonstrates that FDA actively keeps abreast of mifepristone research. On January 3, 2023—the day the 2023 REMS Decision was issued—FDA staff received a "weekly email listing the table of contents" for a medical journal that identified a new study comparing medication abortion to procedural abortion. 2023 SUPP 1259. FDA staff obtained a copy of the study, reviewed it "for the limited purpose of determining whether it contains information relevant to our review of the REMS modifications" and concluded "that the findings are not relevant to the Applicants' proposal to remove the [In-Person Dispensing ETASU] or to add a [Pharmacy Certification ETASU] because the study did not evaluate and compare outcomes when the drug is dispensed in person versus a manner other than in person." 2023 SUPP 1260.

By contrast, FDA did not give *any* reasoned consideration to the Canadian study, published a year earlier in one of the most prominent medical journals in the United States, even though that study was plainly relevant to the 2023 REMS Decision. FDA must have been aware of the Canadian study before issuing the 2023 REMS Decision. Its failure to consider scientific evidence that undermined the entire premise of the REMS and ETASU renders that decision arbitrary and capricious.

Qualitative data. FDA illogically defends its exclusion of critical qualitative data on the burdens imposed by the mifepristone REMS and ETASU by pointing to its reliance on *other* qualitative data, specifically "practice guidelines and data from practitioner surveys regarding

provider volume," that FDA invoked to support its projection that the number of medication abortion providers could potentially double upon removal of the In-Person Dispensing ETASU. Defs.' Mem. 34 (citing 2021 REMS 1572, 1577). But FDA's cherry-picking of the record's qualitative data merely confirms that its process was arbitrary and capricious.

The administrative record shows that FDA gave no consideration to surveys showing that compliance with the Patient Agreement ETASU and Prescriber Certification ETASU imposes "infrastructure requirements" on primary care practices that deter them from offering medication abortion to their patients, and that Canadian health care professionals—who had experienced first-hand their country's deregulation of mifepristone—believed that the Prescriber Certification and Patient Agreement ETASUs "would not enhance safety, would discourage other physicians from practice, and would limit access to abortion." *See* 2021 REMS 1607 (excluding Calloway [2021 REMS 979–83] and Srinivasulu [2021 REMS 973–78] studies); 2021 REMS 1608 (excluding Munro study [2021 REMS 984–92]).

Furthermore, while FDA claims to have read the "literature references" in the *Chelius* plaintiffs' submission, 2021 REMS 1570, it makes no such claim for their sworn declarations, which (i) recounted the logistical challenges of tracking the Prescriber Certification and signed Patient Agreement forms mandated by the mifepristone REMS and (ii) demonstrated how fears of anti-abortion violence deterred otherwise qualified clinicians from registering as certified mifepristone prescribers. *See* 2021 REMS 1989–90; 2021 REMS 1937–38; 2021 REMS 1962–64; 2021 REMS 1991–92. All of this qualitative evidence is relevant to one of the key factors FDA was required to consider pursuant to 21 U.S.C. § 355-1(f)(2)(C) and 21 U.S.C. § 355-1(g)(4)(B): whether the mifepristone ETASU were "unduly burdensome on patient access to the drug." By not

addressing this relevant evidence, FDA acted arbitrarily and capriciously. *See, e.g.*, *Defs. of Wildlife v. U.S. Dep't of Interior*, 931 F.3d 339, 355 (4th Cir. 2019).

Statements by medical professional societies. AMA, ACOG, and AAFP all urged FDA to remove the mifepristone REMS as outdated or unsupported by scientific evidence. 2021 REMS 139; 2021 ED 11–13; 2021 REMS 1168–71. FDA "excluded from the REMS review" these submissions on the ground that they were "policy/advocacy statement[s]." 2021 REMS 1604. Defendants do not even try to justify FDA's cavalier dismissal of the medical community's views, other than by asserting that FDA considered "all *relevant* evidence before it"—implying that the medical societies' views were not relevant. Defs.' Mem. 33 (emphasis added). But the opinions of these health care professional organizations are directly relevant to a key assumption undergirding the Prescriber Certification ETASU: that provider *certification* is necessary to assure provider *qualification* to prescribe mifepristone. Defendants make no effort to reconcile FDA's disregard of the medical community's views on the mifepristone REMS with FDA's written guidance to drug sponsors, which acknowledges that the medical community's views are relevant to REMS determinations. *See* Pls.' Mem. 19–20 (citing FDA guidance). Where HHS or FDA "fails to respond to (or in some cases, even acknowledge) the medical community's concerns" about agency action, the agency's analysis becomes "nothing but a long-winded 'because we said so'" that cannot sustain judicial review. *Mayor of Baltimore*, 973 F.3d at 277 n.8.

Data on the "logistics of accessing abortion care." FDA categorically refused to consider "[d]ata on the logistics of accessing abortion care." 2021 REMS 1572; *see also* 2021 REMS 1605–06. Again, Defendants do not even try to defend FDA's offhand dismissal of this data except by implying that it was not "relevant evidence." Defs.' Mem. 33. But the excluded logistical data that FDA did not address includes studies showing that abortion patients on average travel three times

further than other patients seeking medical care, and an analysis of "abortion deserts" that could be remedied by increasing the availability of medication abortion. 2021 REMS 1605 (excluding studies by Fuentes [2021 REMS 339–47] and Cartright [2021 REMS 1185–97]). This data is directly relevant to FDA's obligation to ensure that an ETASU "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)." 21 U.S.C. § 355-1(f)(2)(C)(ii). FDA's failure to consider such data renders the 2023 REMS Decision arbitrary and capricious.

B. Defendants' Mere Repetition of FDA's Rationales for the Mifepristone ETASU Does Not Make Them Reasonable

Plaintiffs' opening brief catalogs the many groundless assumptions and logical inconsistencies in FDA's explanations for maintaining the Prescriber Certification and Patient Agreement ETASUs and imposing a Pharmacy Certification ETASU. Pls.' Mem. 31–35. Defendants' first response is to recite FDA's explanations and pronounce them "reasonable." Defs.' Mem. 20–23. When Defendants do undertake to defend the Agency's stated justifications for the mifepristone ETASU, they adhere to FDA's strategy of blowing past inconvenient record facts.

1. Prescriber Certification ETASU

In finding that the Prescriber Certification ETASU is necessary to mitigate the risks of mifepristone, FDA assumed that the prescriber *certification* form—in which providers self-certify their competence to prescribe mifepristone—is necessary to assure prescriber *qualification*. 2021 REMS 1573. But, by definition, mifepristone prescribers are health care professionals who are already subject to many laws, policies, and standards of practice that ensure they accurately and safely prescribe *all* medications. SMF ¶¶ 20–21, 35, 44–45. FDA itself implicitly relies on the fact

that providers are already subject to those constraints—it does nothing to investigate or verify provider certifications, although it does review other aspects of REMS compliance. SMF ¶ 8. Defendants never explain how FDA's assumption that prescriber certification is somehow "necessary" to assure prescriber qualification, 2021 REMS 1573, could be reasonable in light of these facts. This failure is compounded by FDA's failure to acknowledge that the need to register as a certified mifepristone prescriber impedes patient access to mifepristone because it deters many providers from seeking certification. SMF ¶¶ 23, 42, 43.

Defendants' efforts to justify the Prescriber Certification ETASU by relying upon other aspects of FDA's stated rationale are just as defective.

First, they cite "the absence of new evidence," Defs.' Mem. 25, referring to FDA's statement that it had not found "any studies comparing providers who met these qualifications with providers who did not," 2021 REMS 1573. Defendants overlook that no ethical study would permit unqualified providers to prescribe medications to real patients, making this an impossible—and hence unreasonable—condition to satisfy. *See* Pls.' Mem. 33. And no such study was necessary in any event because the Canadian study established that uncertified providers can safely and effectively prescribe mifepristone.

Second, they note that certification requires prescribers to report "patient deaths" to FDA. Defs.' Mem. 25. Defendants disregard that (i) since 2005, FDA's post-marketing surveillance of mifepristone has not identified any new safety issues not already disclosed in the mifepristone label, SMF ¶ 61, (ii) the total number of deaths among U.S. patients taking mifepristone through 2022 was only 28 out of approximately 5.6 million, *id*., (iii) none of those deaths was causally connected to mifepristone with certainty, *id.*, and (iv) *all* drug sponsors are already required to report patient deaths to FDA, 21 C.F.R § 314.80. FDA's conclusion that mifepristone providers

must shoulder a special death-report requirement in order to ensure mifepristone's safety is unreasonable in light of mifepristone's well-established track record and safety profile over decades of use.

Third, Defendants note that FDA was concerned by the "potential for a significant increase in the number of prescribers following elimination of the" In-Person Dispensing ETASU. Defs.' Mem. 25. But this potential increase could justify continuation of the Prescriber Certification ETASU only if the new prescribers would be unqualified. No such assumption could reasonably be made on this record, given the contrary evidence from multiple professional medical societies, SMF ¶¶ 20–21, and FDA's own decisions in other drug programs to remove REMS requirements "based on the integration of the REMS safe use condition into clinical practice," SMF ¶ 27 (quoting FDA 465).

2. Patient Agreement ETASU

Defendants contend that the Patient Agreement ETASU is necessary because "standardizing the information patients receive about a drug can be an important part of ensuring the drug's safety." Defs.' Mem. 26. But Defendants, like FDA, do not address why the Medication Guide given to each patient is insufficient standardization when the Medication Guide "contains the same risk information" as the Patient Agreement Form. FDA 616; *see also* SMF ¶ 10. In their brief, Defendants pretend that FDA "rejected this argument," but the record refutes that claim. Defs.' Mem. 26 (citing 2021 REMS 1576, 1577, 1597). None of the pages cited by Defendants refers to the Patient Agreement's duplication of the risks listed in the Medication Guide. And Defendants' effort to explain away FDA's 2016 acknowledgment that a REMS requirement is no longer necessary where there has been an "integration of the REMS safe use condition into clinical practice," *id*., relies upon FDA's assumption that new mifepristone prescribers would be

unqualified to explain the drug's risk to their patients. This baseless assumption is refuted by record evidence that FDA never addressed. *See* Section II.B.1, above.

3. Pharmacy Certification ETASU

Defendants do not dispute that if FDA's imposition of the Prescriber Certification ETASU is arbitrary and capricious, so too is the Pharmacy Certification ETASU. *See* Pls.' Mem. 35. For the reasons discussed in Section II.B.1., above, the Pharmacy Certification ETASU cannot sustain judicial review.

Separately, Defendants contend that FDA had legal authority to issue the Pharmacy Certification ETASU because 21 U.S.C. § 355-1(f)(3)(B) contemplates pharmacy certification. Defs.' Mem. 27. But Defendants miss the point: a new Pharmacy Certification ETASU could not be imposed under 21 U.S.C. § 355-1(f)(1) unless FDA first made a finding that approval for mifepristone otherwise would have to be withdrawn. FDA *never made* that determination for the Pharmacy Certification ETASU, which was first issued in 2023. And even if FDA implicitly made that determination, as Defendants suggest, Defs.' Mem. 30, it would not have been reasonable since pharmacies had safely and effectively dispensed mifepristone during the COVID-19 pandemic without a Pharmacy Certification ETASU. This is yet another reason to hold FDA's approval of the Pharmacy Certification ETASU arbitrary and capricious.

C. Defendants Concede that FDA Did Not Acknowledge or Address the Record Evidence that Mifepristone Is Subject to More Restrictive Conditions than Other Drugs with Comparable Safety Profiles

Defendants expressly concede that FDA did not "specifically compar[e] mifepristone to a diverse array of other drugs." Defs.' Mem. 31. Defendants contend that they were not required to do so under 21 U.S.C. § 355-1(f)(2)(D)(i), but that argument is a distraction; Plaintiffs did not invoke that statute in their motion. More importantly, Defendants do not even try to address the

argument that Plaintiffs did make: that it was arbitrary and capricious for FDA to regulate mifepristone more restrictively than other drugs that numerous medical experts opined were comparably or less safe. *See* Pls.' Mem. 35 (*citing Kirk v. Comm'r of Soc. Sec. Admin.*, 987 F.3d 314, 321 (4th Cir. 2021)); SMF ¶¶ 64–65.

III. Defendants Have Not Demonstrated Any Reason for this Court to Depart from Its Prior Rulings on Standing and Exhaustion

This Court has already held that Plaintiffs have standing to bring their claims and that administrative exhaustion would be futile. *Whole Woman's Health*, 2023 WL 5401885, at *5, *6. Defendants say that they "disagree" with this Court's prior rulings, Defs.' Mem. 14 n.5, 16, but they do not and cannot establish that this Court erred in making either one.[4]

A. Plaintiffs Have Standing to Challenge the 2023 REMS Decision Because They Are Required to Adhere to the REMS Restrictions

This Court has held that "Plaintiffs have standing to bring this action asserting that FDA imposed REMS that have affected access to mifepristone which establishes a cognizable injury to their patients and business that may be remedied by removal of the REMS." *Whole Woman's Health*, 2023 WL 5401885, at *5. None of Defendants' efforts to undermine this ruling has merit.

First, Defendants suggest that "Plaintiffs rely on alleged harm *to others* to establish their Article III standing." Defs.' Mem. 11. Not so. Plaintiffs are health care professionals or clinics that offer medication abortion services to their patients. Hagstrom-Miller ¶ 1; Banks ¶ 1; Weems ¶ 2; Wannemacher ¶ 2. As such, they are required either to be a certified prescriber of mifepristone or

[4] Defendants also seek dismissal of Plaintiffs' Equal Protection claim. Defs.' Mem. 35. But even on rational basis review, Defendants must establish a *reason* for treating mifepristone prescribers differently from prescribers of other, similarly safe medications—a showing that they have not come close to making here. *Farm Labor Organizing Comm. v. Stein*, 56 F.4th 339, 354 (4th Cir. 2022). Defendants' generic invocation of "protecting public health," Defs.' Mem. 35, does not adequately explain the difference.

to employ at least one certified prescriber of mifepristone. 2023 SUPP 1466. The mifepristone ETASU impose numerous burdens upon Plaintiffs, including:

- the certification process can delay the ability of newly hired clinicians to provide medication abortion care by as much as two to four weeks, Hagstrom Miller ¶ 4; Banks ¶ 2;

- providers must adopt and implement manual procedures to record each pill's NDC and lot number in the patient's medical record, which they do not need to follow for other medications they dispense, Hagstrom Miller ¶ 5; Banks ¶ 3; Weems ¶ 4; Wannemacher ¶ 5;

- clinics may incur additional costs to translate Patient Agreement forms into multiple languages and to modify their electronic health record systems to incorporate Patient Agreement forms for each treating clinician, Hagstrom Miller ¶¶ 10–11;

- clinicians often need to spend additional time answering patient questions about discrepancies between (i) the certifications and disclosures in the Patient Agreement form and (ii) the patient's condition or actual clinical practice, Hagstrom Miller ¶¶ 6–9; Banks ¶ 6; Weems ¶¶ 5–6; Wannemacher ¶¶ 6–7;

- clinicians who are deterred from becoming certified refer patients experiencing miscarriages to certified prescribers solely to obtain mifepristone for miscarriage management, Hagstrom Miller ¶ 6; Banks ¶¶ 4–5; Wannemacher ¶ 6; and

- since the Pharmacy Certification ETASU deters most pharmacies from dispensing mifepristone, Plaintiffs must stock mifepristone at their clinics for their patients receiving in-person care, rather than giving them a prescription to be filled by a local pharmacy, imposing additional administrative work and expense, Hagstrom Miller ¶ 12; Banks ¶ 8; Weems ¶ 7; Wannemacher ¶ 10.

"Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation" elements of standing. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). Defendants' effort to compare Plaintiffs to the *Alliance* plaintiffs fails at the outset because those physicians emphatically did *not* prescribe mifepristone and thus were "unregulated parties who seek to challenge FDA's regulation *of others*." *All. for Hippocratic Med.*, 602 U.S. at 385. Since Plaintiffs *do* prescribe mifepristone and are required to comply with each of the mifepristone ETASU, they necessarily have suffered the injury required to challenge each of them.

Next, Defendants suggest that Plaintiffs' injuries are caused by "the independent actions of third parties," and not Defendants' actions. Defs.' Mem. 14. Again, not so. In the absence of the mifepristone REMS and ETASU promulgated by FDA, Plaintiffs would not have to: wait two to four weeks for clinicians to be certified; keep track of individual NDC and lot numbers in the patient's medical record; obtain, upload, and store duplicative Patient Agreement forms; pay for and store mifepristone that could be dispensed by an uncertified local pharmacy; and divert time away from patient care for this unnecessary and burdensome administrative work. That is a sufficient causal connection to establish Plaintiffs' standing. *Lujan*, 504 U.S. at 561–62; *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 212–13 (4th Cir. 2020).

B. This Court's Holding that Administrative Exhaustion Would Be Futile Is Law of the Case

When this Court ruled upon Plaintiffs' motion for a preliminary injunction, it thoroughly analyzed Defendants' defense of administrative exhaustion and concluded that "administrative exhaustion is futile, as FDA has demonstrated by its past actions and prior findings that it will not grant the relief sought by Plaintiffs." *Whole Woman's Health,* 2023 WL 5401885, at *6. Although Defendants "disagree" with this ruling on three grounds, Defs.' Mem. 16–17, each was previously raised in their preliminary injunction briefing:[5]

Defendants' SJ Argument	Defendants' PI Argument
A 2020 submission to FDA by a coalition of states seeking the removal of the REMS was not considered by FDA "in connection with a REMS modification decision." Defs.' Mem. 17.	The states' 2020 request to remove the REMS was not considered by FDA in connection with a REMS modification but rather when exercising "enforcement discretion during the pandemic." Defs.' PI Mem. 22.
"Plaintiffs' challenge raises points that could not have been considered in 2021, including their arguments about post-*Dobbs*	In 2021, FDA could not have considered "how the REMS interacts with post-*Dobbs* state

[5] *See Whole Woman's Health*, Dkt. 27, Defs.' Combined Mem. in Opp. to Pls.' Mot. for Prelim. Inj. and in Sup. of Mot. to Stay Proc. ("Defs.' PI Mem.").

Defendants' SJ Argument	Defendants' PI Argument
developments and a 2022 Canadian study." Defs.' Mem. 17.	legislation and studies and other material published in 2022." Defs.' PI Mem. 22.
ACOG's citizens' petition "did not relate to the agency's 2021 review of the REMS or to the January 2023 REMS modification." Defs.' Mem. 17.	ACOG's citizens' petition "requested that FDA ask the holder of the new drug application for Mifeprex to submit an application to add miscarriage management as a new indication for mifepristone." Defs.' PI Mem. 23.

This Court *accepted* Defendants' arguments when it held that (i) "[t]he citizens petitions cited by Plaintiffs are also not directly on point to the pending litigation."; and (ii) "[s]ome of the evidence and arguments cited by Plaintiffs have never been considered by FDA, specifically the status of abortion rights and access post-*Dobbs*." *Whole Woman's Health*, 2023 WL 5401885, at *6. Nonetheless, this Court held that because, over a course of 23 years of "past actions and prior findings," FDA "continues to find that the REMS remain necessary," FDA had demonstrated that it would not grant Plaintiffs relief if they were to file a citizens' petition. *Id.*

Because Defendants have not submitted any new facts and have not made any new arguments regarding administrative exhaustion, this Court's considered judgment on that issue of law at the preliminary-injunction stage should be considered law of the case. *See Naser Jewelers, Inc. v. City of Concord*, 538 F.3d 17, 20 (1st Cir. 2008) (preliminary-injunction ruling should be afforded law-of-the-case status when party presented same facts and same evidence that court considered); *L.J. v. Wilbon*, 633 F.3d 297, 308 (4th Cir. 2011) (applying law-of-the-case doctrine). Where, as here, a court has "carefully considered [an] issue after extensive briefing," addressed previous arguments "at length on the motions for preliminary injunction," and is presented with the same argument at a later stage of the case, it need not revisit its previous legal conclusions. *Latino v. Hirsch*, 1:23-CV-861, 2024 WL 2721873, at *2 (M.D.N.C. April 2, 2024).

IV. Vacatur Is an Appropriate Remedy

Section 706(2) of the APA provides that a reviewing court shall "set aside" agency action held to be arbitrary and capricious or in excess of the agency's authority. 5 U.S.C. § 706(2). Based on this statutory language, it is "standard practice" to vacate agency action that does not sustain judicial review. 33 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 8381 (3d ed. 2024). The Fourth Circuit adheres to this standard practice. *See*, *e.g.*, *Casa de Maryland v. DHS*, 924 F.3d 684, 691, 706 (4th Cir. 2019) (vacating agency's rescission of DACA after holding that it "was not adequately explained and thus was arbitrary and capricious"). Should the Court invite further briefing on "the appropriate remedy," as Defendants request, Defs.' Mem. 36, Plaintiffs will be happy to provide it.

Conclusion

For the foregoing reasons, Plaintiffs respectfully request that their motion for summary judgment be granted, that Defendants' cross-motion for summary judgment be denied, and that the Court declare that the retention or imposition of the three mifepristone ETASU in the 2023 REMS Decision violates the APA.

Respectfully submitted,

/s/ *Gail M. Deady*
Gail M. Deady
Virginia Bar Number: 82035
Linda C. Goldstein (*pro hac vice*)
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Counsel for Plaintiffs

Attachment 1

Declaration in Support of Defendant's Motion for Summary Judgment

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-RSB

DECLARATION OF AMY HAGSTROM MILLER IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

AMY HAGSTROM MILLER declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following statements are true and correct.

1. I am the President and Chief Executive Officer of (1) Whole Woman's Health Alliance ("WWHA"), which operates abortion clinics in Virginia and Minnesota; (2) 24/7 Abortion, LLC (formerly known as Whole Woman's Health of the Twin Cities, LLC) ("24/7 Abortion"), which operates a virtual healthcare program that provides telehealth services for medication abortion in California, Colorado, New York, Virginia, Maryland, Minnesota, New Mexico, and Illinois; and (3) Whole Woman's Health, LLC ("Whole Woman's Health"), which operates abortion clinics in Virginia, Maryland, and New Mexico and manages the WWHA clinics. I make this declaration to explain how the current mifepristone REMS, approved by FDA in January, 2023, injure the clinics managed by Whole Woman's Health by imposing unnecessary burdens on its operations.

2. As described in greater detail in my prior declaration, dated May 8, 2023, I have been working in the abortion care field since 1989. In my current role, I oversee all operations at

the WWH and WHHA clinics as well as WWH's Virtual Program, ranging from staff management, to finances, to clinic security, to clinical services for our patients. I am thoroughly familiar with the services we provide and the communities we serve. And I am well-versed in all aspects of abortion clinic operations and patient care.

3. The 2023 Mifepristone REMS require healthcare practitioners to register with a mifepristone drug manufacturer in order to prescribe mifepristone. The clinics managed by Whole Woman's Health and the virtual care program currently employ a total of 43 certified mifepristone prescribers: 15 in the three Virginia clinics; 10 in Maryland; 9 in Minnesota; 6 in New Mexico; and 3 in Illinois.

4. Prescriber certification is not a one-time occurrence for clinicians. Each time a healthcare practitioner starts to work at a new clinic, they have to be certified at that site, even if they were previously certified elsewhere. We have found that when a clinician starts to work at one of the clinics managed by Whole Woman's Health, it takes about two weeks to complete the certification process. During those two weeks, the clinician cannot prescribe mifepristone, meaning that the clinic cannot see as many patients for medication abortion as we could in the absence of the REMS. For clinicians who will be prescribing through our virtual care program, it takes another two weeks after certification with the manufacturer to get them up and running with the online pharmacy we use to dispense medication pills to patients. The prescriber certification requirement thereby delays our new clinicians' ability to provide medication abortion, limits the number of patients we can see at both our brick-and-mortar and online clinics, and backs up all patient care.

5. As part of the prescriber certification requirement, we also must key the lengthy NDC and lot numbers from the mifepristone package into each patient's medical record. This

requirement takes up staff and clinician time, as staff members must add the numbers manually to patients' electronic medical charts, and clinicians must check to confirm the numbers are there.

6. Our clinicians also see patients who are referred to us by their obstetrician-gynecologists, who would like to prescribe mifepristone to their patients for miscarriage management but, due to the fear of public disclosure, are deterred from registering with the manufacturer to become certified. The need to obtain care elsewhere, caused by the prescriber certification requirement, imposes a burden on our patients: clinics managed by Whole Woman's Health may not be local to them, and they usually must take time off work to travel to us. Some patients seeking care for miscarriage management become upset that, due to these extra steps, they have to continue carrying a non-viable pregnancy. It can also impose a burden on our clinicians, who may have to spend extra time with the patient trying to dispel patient shame around miscarriage that is deepened by this disruption in their care. Patients often wonder why they need to see another provider to obtain needed medication and cannot receive mifepristone from their trusted obstetrician. These patients must also sign the Patient Agreement form attesting that the purpose of taking mifepristone is to end their pregnancy, a statement that is potentially distressing to them and requires further explanation from their clinician.

7. The requirement that patients sign the Patient Agreement form likewise adds to the operational and financial burden of administering and dispensing mifepristone, particularly because clinics managed by Whole Woman's Health have their own, separate informed consent form for patients receiving medication abortion that is more detailed than the Patient Agreement form and conforms with the latest evidence-based clinical protocols for abortion providers.

8. The Patient Agreement form creates confusion and reinforces misperceptions about the safety of medication abortion for patients, both of which clinicians need to spend time

addressing. For instance, in the Patient Agreement form, patients must attest that they will take misoprostol tablets 24 to 48 hours after taking mifepristone. While this is the correct time frame for patients who administer misoprostol buccally or sublingually, patients who have opted to administer misoprostol vaginally can do so earlier, in accordance with the latest medical evidence. Our clinicians are up to date with this evidence, so, when they review our informed consent form with patients and tell patients when and how to take misoprostol, patients often ask why the FDA form and our form say different things. The Patient Agreement form therefore requires our clinicians and patients to spend time reviewing two different forms, and our clinicians to alleviate any uncertainties the Patient Agreement form creates by describing a protocol that differs from clinical practice.

9. The Patient Agreement form also gives patients the impression that mifepristone is less safe and effective than it is. The extra paperwork, and the fact that they are not required to sign a form for other medications of comparable safety and efficacy, conveys to patients a level of risk and concern that does not line up with the risk profile of the medication or people's experiences with its safety and effectiveness. And the form also suggests that mifepristone is ineffective in as many as 7 out of 100 treatments, a number that is not consistent with our experience or the most recent research for medication abortions using current evidence-based protocols for medication abortions at less than 8 weeks LMP. Our clinicians, again, must spend time allaying the misperceptions created by the Patient Agreement form.

10. The Patient Agreement form also imposes additional administrative burdens on our staff. Some of the clinics managed by Whole Woman's Health, such as WWH of Alexandria, where 6 or 7 languages are spoken by both our patients and our staff, serve a remarkably diverse population of patients. We must pay for and provide translation services for the Patient Agreement

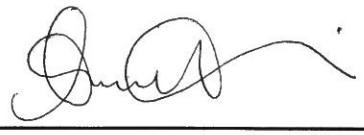
form because the drug manufacturers do not provide the form in multiple languages or pay for translation services.

11. We had to work with a medical software vendor to build out a template for adding the Patient Agreement form to each patient's chart. We are charged for each form per prescriber per clinic; thus, the cost is incurred each time we hire a new clinician who becomes a certified prescriber. And whenever a new certified prescriber starts or leaves, a staff member must spend time adjusting the template accordingly. Depending on the clinic, patients sign the form either virtually or electronically, and, for each form, staff members have to spend time uploading and adding it to the patient's electronic medical record. These costs and demands on staff time are entirely unnecessary as a matter of medical practice and are caused solely by the mifepristone REMS.

12. The requirement that pharmacies must register with the drug manufacturers in order to dispense mifepristone deters many pharmacies from becoming certified. As a result, the clinics managed by Whole Woman's Health must continue to purchase and stock mifepristone to provide in-person medication abortion care, because our clinicians are effectively unable to write a prescription for mifepristone that would allow our patients to pick up the drug at their local pharmacy. We have had to manage barriers to care that we otherwise would not if patients were able to pick up mifepristone at their local pharmacy, like any other medication. For example, we have no back-up option of giving a patient a prescription to be filled by a pharmacy if a shipment of mifepristone to a clinic is delayed by weather. And if a telehealth patient wants to receive a delivery of mifepristone on a weekend, we have no way of offering that service, since our on-line pharmacy does not offer weekend delivery.

13. In sum, the medically unnecessary REMS delay care when we hire new clinicians, create confusion or misperceptions about mifepristone that our clinicians have to dispel, and impose financial and administrative burdens on our already-strained resources and staff.

I declare under penalty of perjury that the foregoing is true and correct. Executed on January 31, 2025 at Charlottesville, Virginia.



Amy Hagstrom Miller

Attachment

Declaration in Support of Defendant's Motion for Summary Judgment

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-RSB

DECLARATION OF HELEN WEEMS, MSN, APRN-FNP, IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

HELEN WEEMS, MSN, APRN-FNP, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following statements are true and correct:

1. I am a nurse practitioner licensed to practice in Montana and am one of the plaintiffs in this case. I am the founder, owner, and sole clinician at All Families Healthcare ("All Families"), a sexual and reproductive health clinic in Montana. I make this declaration to explain how the current mifepristone REMS, approved by FDA in January, 2023, injures All Families.

2. As described in greater detail in my prior declaration, dated May 8, 2023, I have provided health care as a certified nurse practitioner for 25 years. At All Families, I provide medication abortion up to 11 weeks from the first day of the patient's last menstrual period and aspiration abortions up to 12 weeks and 6 days LMP. More than half of all the abortion care I provide is medication abortion.

3. Mifepristone REMS requires healthcare practitioners to register with one of the mifepristone drug manufacturers in order to prescribe mifepristone. I have been a certified

prescriber of mifepristone since 2018, and I am certified with both Danco, which manufactures the brand-name Mifeprex, and GenBioPro, which manufactures generic mifepristone.

4. The REMS imposes administrative burdens that I do not have to deal with in prescribing other drugs. For example, as part of the prescriber certification requirement, we must manually enter in each patient's electronic chart the lengthy NDC and lot numbers from each package of mifepristone dispensed. This is a cumbersome task that takes up staff time—time that, in the office of a solo practitioner with few staff members, is especially valuable. The Patient Agreement form also imposes administrative burdens on my staff. For each patient, they must spend time uploading the signed Patient Agreement form into the patient's electronic medical record.

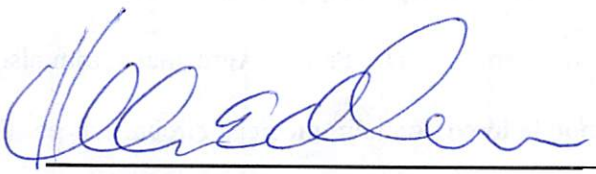
5. The Patient Agreement form also interferes with my patient interactions. I engage in a thorough informed-consent process with my patients, with extensive education and opportunities to address patients' questions and concerns. Being forced to engage in additional documentation of informed consent through the Patient Agreement form is redundant and confusing when the information on the form does not conform to my evidence-based practices. I must spend time alleviating that confusion, which would not arise if there were no Patient Agreement form. For example, the form requires patients to attest that they will take misoprostol 24 to 48 hours after taking mifepristone. That is the appropriate time frame for patients who administer misoprostol buccally or sub-lingually, but patients who chose to administer it vaginally can do so earlier. The Patient Agreement form also states that the mifepristone-misoprostol regimen will not work for as many as 7% of the patients who use it, but I do not see a 7% failure rate of the regimen in ending a pregnancy and recent research suggests that the failure rate is much less for patients who take mifepristone at 8 weeks LMP or earlier. The information conveyed in

the Patient Agreement form is thus inconsistent with the advice that I provide to many of my patients orally.

6. The Patient Agreement form also requires me to give patients information that is not tailored to their medical circumstances. Patients for whom I prescribe mifepristone for miscarriage management must attest that they are using it to end their pregnancy, which can be upsetting in an already distressing time. I must explain to them that, although the form says they are using mifepristone to terminate a pregnancy, I am prescribing it for miscarriage management, again requiring me to engage in unnecessary communication for care that is not congruent with the form.

7. The requirement that pharmacies register with the drug manufacturers in order to dispense mifepristone adds to the operational challenges of administering and dispensing mifepristone. That requirement effectively deters many pharmacies from becoming certified. None of the pharmacies in Whitefish, where I practice, is certified. As a result, I cannot write a prescription for mifepristone that a patient could pick up nearby, like I do for many other medications. And when patients do not want to wait to receive their prescription by mail from the on-line pharmacy that I use, their inability to pick up a prescription from their local pharmacy puts the onus on me to order, stock, and dispense mifepristone that they pick up from my office. All of those tasks involve costs, paperwork, and staff time. In addition, I shoulder the upfront cost of buying and storing mifepristone. In the absence of the REMS, I would not have these financial and administrative burdens.

I declare under penalty of perjury that the foregoing is true and correct. Executed on: January 31, 2025 at Whitefish, Montana.



Helen Weems, MSN, APRN-FNP

Attachment 4:
Declaration of Jessica Wannemacher in Opposition to Defendants' Motion for Summary Judgment

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-RSB

DECLARATION OF JESSICA WANNEMACHER IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Jessica Wannemacher declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following statements are true and correct:

1. I am the Senior Vice President of Strategy & Operations of Trust Women Foundation ("Trust Women"), one of the Plaintiffs in this case. In this role, I oversee all clinical and administrative operations at Trust Women, and I develop strategies to expand our health services. Previously, I was the Director of Clinic Operations at Trust Women. Before I joined Trust Women, I was the Health Center Manager at Planned Parenthood of South, East, and North Florida, where I oversaw patient and staff scheduling and the training and development of health center staff, managed inventory, helped coordinate patient care, and ensured compliance with the organization's quality assurance guidelines and relevant government regulations. Before my time at Planned Parenthood, I spent six years managing daily operations at reproductive healthcare clinics in Florida, working closely with patients, clinic staff, and physicians. I make this declaration to explain how the current mifepristone REMS, approved by FDA in January, 2023, injures Trust Women.

2. Trust Women operates a clinic in Wichita, Kansas, that provides medication abortion up to 11 weeks of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP") and procedural abortion up to 21 weeks, 6 days of pregnancy. It also provides miscarriage management and contraceptive services.

3. Trust Women's clinic employs three medical directors, one of whom is a certified prescriber of mifepristone and certified with GenBioPro. The clinic also contracts with thirteen clinicians who commute from their home states to provide abortion care in Kansas.

4. Compliance with both the prescriber certification requirement and the Patient Agreement form required by the mifepristone REMS creates logistical burdens and additional, unnecessary paperwork for Trust Women.

5. The prescriber certification requirement is burdensome for clinic staff since it usually requires them to go back and forth between clinicians and the drug manufacturer, in order to complete the certification process. The REMS also require staff to key in the lengthy NDC and lot numbers for each package of mifepristone dispensed. This is not required for medications of comparable safety and efficacy. Clinic staff also must devote more time to patient recordkeeping, because the FDA-required Patient Agreement form must be scanned into the patient's electronic records along with the more specific form that Trust Women uses.

6. The Patient Agreement form is also a source of unnecessary patient distress and confusion that our clinicians need to address during patients' appointments. For example, many obstetrician-gynecologists who are deterred from registering with one of the mifepristone manufacturers refer their patients to Trust Women for a mifepristone prescription when their patients suffer an early pregnancy loss. The Patient Agreement form makes patients who are receiving miscarriage management attest that they are taking mifepristone to end their pregnancy.

This puts an emotional toll on patients, and it requires our clinicians to spend additional time addressing the patient uneasiness and upset that comes from making patients sign a form that does not reflect their medical circumstances.

7. The Patient Agreement form gets in the way of clinician-patient interactions when patients receive medication abortion too. Trust Women clinicians engage in an extensive education process with patients, informing them that they can take misoprostol buccally, vaginally, or sublingually. Clinicians then give patients instructions on when and how to take misoprostol depending on which of those methods they choose. The Patient Agreement form, on the other hand, does not specify the different ways to take misoprostol. It also tells patients to attest that they will take misoprostol 24 to 48 hours after taking mifepristone, but patients who administer misoprostol vaginally can do so sooner. The discrepancy between the protocol on the Patient Agreement form and Trust Women's clinical practice confuses patients. It adds more time to patient interactions because clinicians need to address that confusion. Patient confusion resulting from the discrepancy can also cause patients to administer their misoprostol incorrectly, which can require more clinician-patient interactions.

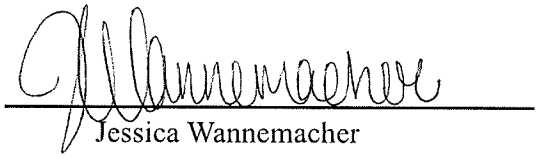
8. The time and administrative effort that Trust Women clinicians must devote to complying with the REMS, just to be able to prescribe and dispense mifepristone, takes time away from patient care. This additional time is an injury to Trust Women because our clinicians can see fewer patients, making it more challenging to quickly schedule patients who need to see us for time-sensitive care.

9. The medically unnecessary procedures required by the REMS also reinforce abortion stigma. We have seen patients who decide to have a procedural abortion when they otherwise could have chosen medication abortion because they are worried that the FDA's special

requirements for mifepristone mean that the drug is unsafe. Because appointments for procedural abortions take more time than for medication abortions, the REMS has an adverse impact on how many patients we can schedule and see.

10. Because of the mifepristone REMS, Trust Women must also stock mifepristone for use in patient abortions. Although FDA no longer requires mifepristone to be at a clinic or hospital, as a practical matter, we must continue to do so because there are no pharmacies in Wichita that have registered with the manufacturers and are certified to dispense mifepristone to our patients. The need to stock mifepristone causes Trust Women to incur additional administrative burdens and expense that we do not incur for other medications prescribed to patients for other out-patient care.

I declare under penalty of perjury that the foregoing is true and correct. Executed on: February 3, 2025 at Wichita, Kansas.



Jessica Wannemacher

Attachment

Declaration in Response to Defendant's Motion for Summary Judgment

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-RSB

DECLARATION OF JOEY BANKS, M.D., IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

JOEY BANKS, M.D., declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following statements are true and correct:

1. I am a board-certified family medicine physician licensed to practice in Montana, where I have practiced for over a decade. I have more than 23 years of experience providing primary care and reproductive health care, and I have been performing, supervising, and teaching abortion care for more than 17 years. I currently provide abortion care on a contract basis at Blue Mountain Clinic, one of the plaintiffs in this case, and at a clinic in Illinois. I also serve as Blue Mountain Clinic's reproductive medical director. Previously, I provided abortion care at many different clinics across the country, including Planned Parenthood of Alaska, Central Maine Family Medicine Residency Family Practice Clinic, Planned Parenthood of Northern New England, and Planned Parenthood Montana. I make this declaration to explain how the current mifepristone REMS, approved by FDA in January, 2023, injures Blue Mountain Clinic.

2. Mifepristone REMS requires healthcare practitioners to register with one of the mifepristone drug manufacturers in order to prescribe mifepristone. I have been a certified

prescriber of mifepristone since 2005-06. Currently, I am certified with both Danco and GenBioPro. Every time that I start to work at a new clinic, I have to get a new certification with each manufacturer. This is a process that delays my ability to prescribe mifepristone to patients at that clinic.

3. As part of the prescriber certification requirement, I must also ensure that the lengthy NDC and lot numbers from each package of mifepristone dispensed are recorded in the patient's chart. This takes up valuable time because, depending on the clinic at which I am working, the numbers must either be manually entered into the patient's electronic medical record or the sticker must be peeled off the medication box and placed in a paper chart, which is then scanned into an electronic medical record system. Recording the NDC and lot numbers in the patient's chart is unnecessary and does not apply to other medications that we dispense.

4. Many providers who need to prescribe mifepristone to their patients do not do so because they fear that registration could expose them to anti-abortion harassment if their identity as a certified prescriber were made public or because their employers do not want them to become certified. This deterrent effect has an impact on me as a certified prescriber because those providers refer their patients to me to prescribe mifepristone for patients suffering an early pregnancy loss.

5. Those one-time referrals from maternal fetal medicine specialists and obstetrician-gynecologists in private practice are not optimal for the patients referred to us, because it is a disruption in the continuity of their care at a vulnerable time in their lives. They also take valuable appointment slots, increasing wait times for Blue Mountain Clinic's established patients. Some patients who have experienced fetal demise need to return to their regular physician for an induction after we provide them with mifepristone, so Blue Mountain Clinic staff and I need to follow up if the patient does not arrive at their appointment to receive the medication. In addition,

when I prescribe mifepristone for miscarriage management, the patient must still sign the Patient Agreement form attesting that the purpose is to end their pregnancy. This requires making another explanation that I would not have to make if there were no FDA-mandated Patient Agreement form.

6. The REMS further requires me to provide patients with the Patient Agreement form. This means that I must present patients with information that I believe does not reflect the latest scientific evidence on the effectiveness and use of mifepristone. For instance, the form has patients attest that they will take misoprostol 24 to 48 hours after mifepristone. That is the correct time interval for patients who administer misoprostol buccally or sub-lingually. But at Blue Mountain Clinic, based on current research, we advise patients who opt to take misoprostol vaginally to do so 6 to 48 hours after taking mifepristone. The Patient Agreement form also states that the mifepristone-misoprostol regimen "will not work" for as many as 7 out of 100 women who use this treatment. That can be a misleading statement, depending on gestational age. Based on my own experience and current research, the efficacy for patients at 8 weeks LMP or less is 96 to 98 percent. The range in the Patient Agreement form is not tailored to the patient's circumstances and requires me to dispel unnecessary concerns about mifepristone's efficacy. These discrepancies lead to patient confusion and require additional time and counseling to explain.

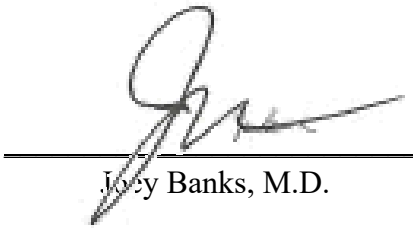
7. The Patient Agreement form differs from the documentation of informed consent in other contexts in which I prescribe medication. For almost every other medication, I can verbally

provide information on the risks, benefits, and use of medication. I am not required to ask patients to sign a form saying that they have been given that advice.

8. The requirement that pharmacies register with the drug manufacturers in order to dispense mifepristone deters many pharmacies from becoming certified. Indeed, I am not aware of any certified pharmacies in Missoula, where Blue Mountain Clinic operates. Thus, I cannot simply write a mifepristone prescription for patients to pick up at their local pharmacy, like I do with all other medications comparable in safety and efficacy. Instead, for patients who do not want to use an online pharmacy, Blue Mountain Clinic must buy mifepristone and keep it in stock or arrange for expedited delivery to the clinic from an online pharmacy.

9. Without the REMS, I would be able to devote more time to patient care, conduct the informed-consent process free from the risk of confusion due to unnecessary paperwork, and prescribe mifepristone in a manner in line with other medications.

I declare under penalty of perjury that the foregoing is true and correct. Executed on: February 3, 2025 at Missoula, Montana.



Joey Banks, M.D.