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

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*,	)	
Plaintiffs,	)	**Civil Action No.: 3:23-CV-00019**
v.	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	**By: Hon. Robert S. Ballou United States District Judge**
Defendants.	)	

MEMORANDUM OPINION

Since 2000, the U.S. Food and Drug Administration has determined that mifepristone is a safe and effective medication for early pregnancy termination. Each time the FDA has reviewed mifepristone, it has reaffirmed its safety and efficacy.[1] But the FDA has consistently imposed certain prescribing and dispensing restrictions, known as Risk Evaluation and Mitigation Strategies ("REMS"), because it concluded such restrictions were necessary to ensure that the drug's benefits outweighed its risks. The 2023 REMS imposed by the FDA on mifepristone require that (1) prescribing pharmacies be specially certified, (2) prescribing clinicians be specially certified, and (3) prescribers and patients sign a form acknowledging the treatment and its risks. Dkt. 78-7 at 389–92. Abortion providers in Virginia, Kansas, and Montana brought this case to challenge the 2023 REMS as excessively restrictive, unwarranted, and inconsistent with the requirements of the Federal Food, Drug, and Cosmetic Act of 1938. The issue before this

[1] *See, e.g.*, Dkt. 78-2 at 49 (2016 CDER Clinical Review concluding that "Medical abortion with the new proposed regimen of Mifeprex 200 mg followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation is safe").

Court is an administrative law question of whether, in accordance with its duty under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)–(C), the FDA conducted a sufficiently thorough review of mifepristone when it imposed the 2023 REMS for the prescription and use of the drug.

The FDA failed to consider relevant data, analyze restrictions with reference to the mandated statutory factors, or provide a reasonable justification for its 2023 REMS modification. Because of the inadequate FDA review, the decision to impose the 2023 REMS in the prescription of mifepristone was arbitrary and capricious under the Administrative Procedure Act. The 2023 REMS modification is unlawful and must be remanded to the FDA for review.

BACKGROUND

I. Regulatory Framework

The FDA regulates introduction of new drugs into interstate commerce by requiring the drug sponsor to apply for approval of distribution. 21 U.S.C. § 355(a). All drugs, even those without REMS, must comply with certain FDA requirements, such as approved, professional labeling. For drugs that are known to be effective but pose significant safety risks, the FDA may require a REMS "to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). A REMS is therefore an extraordinary safety measure employed only for drugs associated with serious risks. *See* Dkt. 69 ¶ 63 (noting that of the more than 20,000 drugs approved by the FDA, only 73 have a REMS). The FDA is directed to determine if a REMS is necessary to ensure that a drug's benefits outweigh its risks by considering six factors:

> (A) The estimated size of the population likely to use the drug involved.
> (B) The seriousness of the disease or condition that is to be treated with the drug.
> (C) The expected benefit of the drug with respect to such disease or condition.
> (D) The expected or actual duration of treatment with the drug.

> (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
> (F) Whether the drug is a new molecular entity.

21 U.S.C. § 355-1(a)(1). If, upon consideration of these factors, standard mechanisms like professional labeling are insufficient to mitigate the drug's risks, the FDA may impose a REMS, which has two components: (1) a timetable for submission of assessments of the REMS and (2) the strategy elements employed to effectuate the goal of the REMS. 21 U.S.C. § 355-1(c). The timetable component requires that, at minimum, a responsible person[2] submit an assessment 18 months, 3 years, and 7 years after the strategy is approved. 21 U.S.C. § 355(d)(1)–(3). Additional assessments may be mandated as part of the REMS, or if modification or elimination of the REMS is indicated. 21 U.S.C. § 355-1(d)(4).

The second component of a REMS—the strategy elements—are the mechanisms used to mitigate and evaluate risk. There are two types of strategy elements: general elements and Elements To Assure Safe Use, which are known as ETASUs. 21 U.S.C. § 355-1(e), (f). In imposing any additional strategy element, the FDA must determine that the element is necessary to ensure that the benefits of the drug outweigh its risks. General strategy elements, described in § 355-1(e), are not particularly burdensome, and include requirements like inclusion of a medication guide or patient package insert, communication with healthcare providers, or imposition of a specialized packaging system. 21 U.S.C. § 355-1(e)(2)–(4).

[2] A "responsible person" is defined as "a person who (i) has submitted to the Secretary a covered application that is pending; or (ii) is the holder of an approved covered application." 21 U.S.C. § 355(o)(2)(A). Responsible persons are also referred to as sponsors.

The second category of strategy elements, ETASUs, are only employed if medically necessary because a drug is inherently toxic or linked to a "serious adverse drug experience."[3] 21 U.S.C. § 355-1(f)(1). ETASUs impose a higher burden on patients, providers, and the healthcare delivery system. Therefore, they should be employed sparingly where the drug "can be approved only if, or would be withdrawn unless, such elements are requested as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1)(A). To ensure that these heightened burdens are not imposed lightly, the FDA must consider additional factors to determine if an ETASU is warranted. Those factors direct the FDA to conclude that the ETASU imposed (1) is "commensurate with the specific serious risk;" (2) does not unduly burden patient access to the drug; (3) minimizes the burden on the healthcare system; and (4) "conform[s] with elements to assure safe use for other drugs with similar, serious risks." 21 U.S.C. § 355-1(f)(2). Examples of ETASUs include prescriber certification, pharmacy certification, and in-person dispensing requirements, among others. *See* 21 U.S.C. § 355-1(f)(3).

Modification and assessment of an existing REMS, including required ETASUs, is governed by 21 U.S.C. § 355-1(g). A "responsible person" must submit an assessment of the REMS (1) if the responsible person submits a supplemental application for a new indication or use of the drug; (2) as required by the REMS timetable; or (3) if the FDA determines than an assessment is needed to evaluate if modification is appropriate. 21 U.S.C. § 355-1(g)(2). An assessment requested by the FDA because modification may be appropriate must address whether modification is needed to ensure that the (1) benefits of the drug outweigh the risks and (2) minimize burdens on the health care delivery system. 21 U.S.C. § 355-1(g)(2)(C)(i)–(ii).

[3] A "serious adverse drug experience" is defined as a reaction to the drug that results in death, immediate risk of death, hospitalization, significant incapacity, or a congenital anomaly. 21 U.S.C. § 355-1(b)(4)(A).

Assessments of a REMS under (g)(2) must include, "with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or elements should be modified." 21 U.S.C. § 355-1(g)(3).

Following the assessment, the FDA may request that a responsible person submit a proposed modification strategy if it "determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy." 21 U.S.C. § 355-1(g)(4)(B). The propriety of modification under § 355-1(g)(4) relies on the same factors considered under (g)(2): risk-benefit analysis and determining whether modification is needed to minimize the burdens a strategy imposes on the healthcare delivery system. *Id*.

II. Facts

A. History of Mifepristone REMS

i. Mifepristone Regulation Under Subpart H

On September 28, 2000, the FDA approved mifepristone under the name Mifeprex as a safe and effective means for a medically induced abortion. The FDA approval of the application by Mifeprex's sponsor, Danco Laboratories, LLC, permitted the administration of mifepristone for a medication abortion through 49 days of pregnancy when dosed as part of a two-drug regime with the already-approved drug misoprostol.[4] Dkt. 78-1 at 2–4, 8, 59–68. The FDA initially imposed restrictions on the prescription of mifepristone under the regulatory scheme at the time, 21 C.F.R. § 314 Subpart H. These regulations permitted the FDA to require special rules or conditions for drugs considered to have particular safety risks. 21 C.F.R. § 314.520 (2000). The

[4] Under the FDA-approved protocol, patients take a single 200 mg mifepristone tablet followed 24 to 48 hours later by four 200 mcg misoprostol tablets. Dkt. 78-7 at 396, 415.

2000 restrictions on mifepristone included requirements that: (1) physicians dispense the drug in person at a clinic, medical office, or hospital, either directly or under a certified provider's supervision; (2) prescribing clinicians certify their clinical abilities on a signed form kept by the manufacturer and comply with reporting requirements; and (3) prescribers and patients sign an agreement outlining the mifepristone regimen and its risks, with copies provided to patients and placed in their medical record. Dkt. 78-1 at 3, 29.

The passage of the Food and Drug Administration Amendments Act in 2007 removed Subpart H and imposed the current statutory scheme, which uses REMS and ETASUs to counteract the health concerns raised by particularly risky, toxic medications. When Congress passed the Food and Drug Administration Amendments Act replacing Subpart H, all drugs which had restrictions under Subpart H, like Mifeprex, were automatically deemed to have a REMS in effect, with Subpart H restrictions serving as ETASUs. Pub. L. No. 110-85, § 909(b); *see also* Dkt. 78-1 at 33. Thus, the original restrictions attached to mifepristone under Subpart H became the REMS affecting the prescribing and dispensing of the drug.

ii. 2011 REMS and ETASU

On September 16, 2008, Mifeprex's sponsor, Danco, submitted proposed a REMS for FDA review. Dkt. 78-1 at 32–58. In 2011, the FDA formally approved the Mifepristone REMS, which included three ETASUs: (1) a prescriber certification requirement; (2) a patient agreement form; and (3) an in-person dispensing requirement. *Id*. at 34, 59–60. In 2013, the FDA conducted a "Final Risk Evaluation and Mitigation Strategy (REMS) Review" and concluded that the 2011 REMS would remain in effect. *Id*. at 120–38.

iii. 2016 Revision

On May 28, 2015, Danco submitted a supplemental new drug application for mifepristone to the FDA including, as required by § 355-1(g)(2)(A), an assessment of the current mifepristone REMS. *Id*. at 149, 159–60. The application requested that the FDA permit administration of the drug at a later gestational age (beyond 49 days), revise the dosing regime, remove the requirement that the drug must be dispensed in-clinic, and modify the REMS to allow non-physician, state-licensed prescribers. *Id*. at 159. Danco also recommended, and the FDA reviewers agreed, that the patient agreement ETASU should be removed because it "does not add to safe use conditions for the patient for this REMS and is a burden for patients." *Id*. at 182. Initially, the FDA approved the application in full, including the proposed changes to the REMS. *Id*. at 181, 183. But, on March 28, 2016, the FDA revised its findings and retained the patient agreement ETASU without explanation. *Id*. at 183. Therefore, all three existing ETASUs (requiring in person dispensing, prescriber certification, and the patient agreement) remained in place. *Id*. at 182–83. Another sponsor, GenBioPro, received FDA approval on April 11, 2019, for a generic version of mifepristone under a new REMS covering both Mifeprex and the generic drug. Dkt. 78-6 at 91–92. In short, following approval of the generic version of mifepristone in 2019, the FDA promulgated a single, shared system REMS that applies to prescribing both Mifeprex and the generic version. *Id*. at 91. The new REMS maintained the same ETASUs for both Mifeprex and the generic version. *Id*.

iv. COVID-19 ETASU suspension

Twenty-one state attorneys general submitted a citizens' petition to the FDA in April 2020 requesting that the FDA eliminate completely all REMS restrictions on mifepristone, calling them unnecessary barriers to essential, time-sensitive care during the COVID-19 pandemic. Dkt. 1-18. Alternatively, the attorneys generals urged the FDA to suspend the in-person dispensing

ETASU and allow telehealth prescriptions. *Id*. That month, the American College of Obstetricians and Gynecologists ("ACOG") wrote a letter to the FDA expressing concerns about in-person dispensing requirements during the pandemic. Dkt. 78-4 at 277 n.1. In response, the FDA requested that mifepristone's sponsors, Danco and GenBioPro, prepare memoranda detailing their scientific opinion on the in-person dispensing requirements in light of the public health emergency. *Id*. at 277. The sponsors completed internal memoranda in June 2020, and submitted final responses to the requests for information to the FDA in April 2021. *Id*. at 277 n.1, 279 n.10. In July 2020, before the FDA acted on the citizens' petition, the District of Maryland temporarily enjoined the FDA from enforcing in-person dispensing requirements. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. Food and Drug Admin.*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The suspension remained in place for six months—from July 2020 until January 2021—until the Supreme Court stayed the district court's injunction. *See FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

In April 2021, mifepristone's sponsors submitted memoranda addressing the propriety of the in-person dispensing requirement during the pandemic. Dkt. 78-4 at 277–80. The review found no clear evidence linking the suspension of in-person dispensing to the small number of adverse events reported. *Id*. at 279. It also cited four publications that raised no new safety concerns associated with modifying the REMS in-person dispensing requirement during the pandemic. *Id*. at 279–81. The FDA's Center for Drug Evaluation and Research (CDER), agreed with the sponsors' conclusions. *Id*. at 281–82. Accordingly, on April 12, 2021, the FDA notified the drug's sponsors that it would exercise enforcement discretion as to the in-person dispensing requirement for the duration of the pandemic. *Id*. at 283–87; Dkt. 78-6 at 92–93. This decision allowed mail-order pharmacies to dispense mifepristone under a certified prescriber's

supervision, provided the other requirements of the REMS were met. Dkt. 78-6 at 92–93. The enforcement discretion continued until September 30, 2021. *Id*. at 105 ("During the timeframe from January 27, 2020 through September 30, 2021, there were periods when the in-person dispensing requirement was not being enforced.").

v. The Purcell *Litigation*

Parallel to increasing calls for the FDA to remove the mifepristone REMS, abortion providers challenged the restrictions in federal court. In October 2017, following the FDA's 2016 retention of the mifepristone REMS including the three ETASUs, abortion providers and advocacy groups challenged the mifepristone REMS under the APA and the Fifth Amendment in a Hawaii District Court. *See* Complaint*, Purcell v. Kennedy*, No. 1:17-cv-00493 (D. Haw. Oct. 3, 2017), Dkt. 1.[5] The plaintiffs alleged that the mifepristone REMS (1) violate the plaintiffs' Fifth Amendment substantive due process rights; (2) violate the plaintiffs' Fifth Amendment equal protection rights; (3) are contrary to a constitutional right in violation of 5 U.S.C. § 706(2)(B); (4) are in excess of the FDA's statutory authority; and (5) are arbitrary and capricious. *Id*. at 59–62.

On May 7, 2021, the *Purcell* parties jointly moved to stay the case, stating that the FDA intended to conduct a full review of the mifepristone REMS program under 21 U.S.C. § 355-1(g)(2).[6] Dkt. 78-5 at 46–52. According to the motion to stay, the FDA planned to undertake review "relying on information submitted by the sponsors . . . and information from other sources, including published literature . . . [and] any relevant data and evidence submitted by the

[5] The *Purcell* litigation was formerly known as *Chelius v. Becerra* and *Chelius v. Wright*.
[6] *See* Dkt. 78-7 at 318 ("In connection with the [*Purcell v. Kennedy*] litigation, [the] FDA agreed to undertake a full review of the Mifepristone REMS Program, in accordance with the REMS assessment provisions of the Federal Food, Drug, and Cosmetic Act.").

[*Purcell*] Plaintiffs." *Id*. at 47. The Hawaii District Court granted the motion to stay the case pending agency review. *Id*. at 52–53. On December 16, 2021, the *Purcell* plaintiffs received notice that the FDA planned to modify, rather than eliminate, the mifepristone REMS. Dkt. 78-6 at 145. The *Purcell* case remained administratively closed for almost two years, pending the FDA's mifepristone REMS modifications.

In January 2023, the FDA promulgated the 2023 REMS, which modified the existing strategy. The FDA's reasoning is contained mainly in the 2021 REMS Review Rationale, with explanations of minor changes made between 2021 and 2023 explained in the 2023 Joint Summary Rationale. *See id*. at 86–134; Dkt. 78-7 at 271–308. Ultimately, the *Purcell* plaintiffs filed an amended complaint challenging the 2023 REMS decision on the same grounds. Second Amended and Supplemental Complaint, *Purcell*, No. 1:17-cv-00493, Dkt. 209. The *Purcell* parties filed cross-motions for summary judgment. On July 8, 2025, while the *Purcell* summary judgment motions were pending, the Eastern District of Washington issued an opinion resolving cross-motions for summary judgment in a parallel challenge to the 2023 REMS. *See Washington v. United States Food & Drug Admin.*, No. 1:23-CV-3026, 2025 WL 1888794 (E.D. Wash. July 8, 2025); *see also* Dkt. 89-1. That court concluded that, "based on the present record, FDA did assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth under 21 U.S.C. § 355-1(g)(4)(B)," and determined that "FDA fully considered the important aspect[s] of the issues in this case and came to a reasonable conclusion." *Washington*, 2025 WL 1888794 at *3–4. Accordingly, the Eastern District of Washington held that the FDA's decision was not arbitrary and capricious, finding that the agency had not disregarded applicable law or regulatory obligations. *Id*.

On October 30, 2025, the Hawaii District Court reached a different conclusion and granted summary judgment for the plaintiffs, finding that the 2023 REMS decision was arbitrary and capricious. *Purcell v. Kennedy*, No. CV 17-00493, 2025 WL 3101785 (D. Haw. Oct. 30, 2025). The court held that "the Agency violated the APA by failing to provide a reasoned explanation for its restrictive treatment of [mifepristone], which was compounded by its decision to limit the scope of information it considered when evaluating the [2023] REMS." *Id*. at *2.

B. 2021 Review

In May 2021, under its agreement in the *Purcell* litigation, the FDA reviewed the Mifepristone REMS in 2021 "in accordance with the REMS assessment provisions of the Federal Food, Drug, and Cosmetic Act," specifically 21 U.S.C. § 355-1(g)(2). Dkt. 78-6 at 90; Dkt. 78-7 at 368 n.1.

In conducting this § 355-1(g)(2) assessment, the FDA gathered relevant publications from two sources: a literature search of PubMed and Embase publications dated between March 29, 2016[7] and July 26, 2021, and sources provided by "advocacy groups, individuals, plaintiffs in the [*Purcell*] litigation, and the Applicants, as well as letters from healthcare providers and researchers." Dkt. 78-6 at 95. To determine which publications would ultimately be considered in the FDA's assessment and modification, the FDA focused its review on publications pertaining to "objective safety data," *id.* at 96, which resulted in exclusion of large categories of data. This limited scope of review eliminated from FDA consideration opinions of major medical organizations, data on ease of abortion access, and literature regarding gynecological safety information outside the scope of the REMS. *Id*. at 96–98. The exclusion also eliminated all but three references submitted by the *Purcell* plaintiffs and evidence of provider burdens provided

[7] This was the date of the last major update to mifepristone labeling and REMS.

by the Society of Family Planning. *Id*. at 130–34. In contrast, the FDA widened its search beyond objective safety data to "publications that discussed changes in provider volume" because "changes in provider volume could only be obtained from well-conducted survey studies." *Id*. at 97. The FDA used this "provider volume" data to determine if retention of the patient agreement ETASU was warranted. *Id*. The FDA did not widen its literature review beyond objective safety data for any other categories of literature. Put simply, the FDA's research criteria sharply circumscribed the sources considered for most of its REMS analysis, but eliminated these criteria to consider if potential increases in provider volume justified retention of the patient agreement ETASU.

On December 16, 2021, FDA published its conclusions in the 2021 REMS Modification Rationale, declaring its decision to eliminate the in-person dispensing requirement (ETASU C), but to institute a new pharmacy certification requirement (ETASU B), and retain the prescriber certification (ETASU A) and patient agreement (ETASU D) requirements. *Id*. at 136–39, 141–43, 145. The FDA provided notice of the REMS modification and requested that Danco and GenBioPro, the drug's sponsors, submit proposed modified REMS adhering to the FDA's modifications. *Id*. Although the 2021 REMS Modification Rationale gave a detailed history of the regulation of mifepristone, its reasoning for imposing each specific ETASUs was sparse. For the retained prescriber certification and patient agreement ETASUs, the FDA stated, in conclusory fashion, that the restrictive elements remained necessary to outweigh the risks. *Id*. at 99 ("Healthcare provider certification continues to be a necessary component of the REMS to ensure the benefits of mifepristone outweigh the risk."); *id.* at 102 (relying on studies addressing informed consent, a standard practice, to justify the patient agreement requirement). To justify the new pharmacy certification requirement, the FDA asserted that pharmacy certification was

necessary due to the removal of the in-person dispensing requirement without explanation of how the two requirements are interrelated. *Id*. at 125. The FDA acknowledged that it had not considered any data addressing pharmacy certification specifically. *Id*. at 126 n.aa.

C. 2023 REMS Modification

On January 3, 2023, the FDA issued a final revised REMS decision in line with the modifications announced in December 2021. The FDA provided most of its rationale for the 2023 REMS modifications in the 2021 REMS Modification Rationale, but supplements this explanation in the 2023 Joint Summary Rationale, which provides the FDA's response to the sponsors' modification proposals and small changes to the REMS announced in the 2021 REMS Modification Rationale. *See* Dkt. 78-7 at 290 (2023 Joint Summary Review noting that the 2021 review indicated that modification was appropriate, and the proposed modification remains acceptable).

Before the Court in this action is a review of the FDA's reasoning from the 2021 REMS Modification Rationale, Dkt. 78-6 at 86–134, and the 2023 Joint Summary Rationale, Dkt. 78-7 at 271–308, to determine if the FDA acted in excess of its statutory authority or was arbitrary and capricious in its decision to impose the 2023 REMS.[8]

The stated goal of the 2023 REMS is "to mitigate the risk of serious complications associated with mifepristone." Dkt. 78-7 at 278; Dkt. 78-6 at 91. To accomplish this goal, the 2023 REMS include three ETASUs. The FDA retained the prescriber certification and the patient agreement form ETASUs. Dkt. 78-7 at 293–94, 296, 433, 437–40. The FDA removed the in-

[8] The 2021 REMS Modification Rationale and the 2023 Joint Summary Rationale are not final agency action and therefore are not challenged in this action. These documents merely provide the FDA's reasoning for the final agency action, promulgation of the 2023 REMS, at issue in this case.

person dispensing requirement but added a new pharmacy certification ETASU, *see id.* at 295, 434–36, that limits distribution of mifepristone to pharmacies specially certified under the REMS program to ensure "that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." Dkt. 78-6 at 125.

The prescriber certification form requires providers to certify that they (1) can accurately assess pregnancy duration, (2) can diagnose ectopic pregnancies, (3) can provide surgical intervention in instances of severe bleeding or incomplete abortions, or have established plans to provide such care through others and be able to assure access to medical facilities equipped to provide resuscitation and blood transfusions, and (4) have reviewed and understood the mifepristone prescribing information. Dkt. 78-7 at 437–40. Prescribers also must ensure that the patient agreement form is reviewed, explained, and signed by the patient and the provider, and fulfill various reporting requirements, among other guidelines. *Id*. at 389.

The patient agreement form requires the patient to certify, among other things, that she (1) "decided to take mifepristone and misoprostol to end [her] pregnancy," (2) has spoken with her healthcare provider about risks of heavy bleeding and infection, and (3) has been provided with the mifepristone medication guide. *Id.* at 433.[9] The agreement form is to be placed in the patient's medical record. *Id*. at 437.

Finally, the pharmacy certification form requires pharmacies to attest, among other things, (1) that the prescriber is certified in the mifepristone REMS program, (2) that the pharmacy will dispense mifepristone so that its delivered within 4 days of receipt of the prescription, or if delivery is later, confirm with the prescriber that it is still appropriate to

[9] Mifepristone's medication guide contains all risks discussed in the patient agreement form. Dkt. 78-7 at 413–32 (2023 SUPP 1490–1509).

dispense the drug, (3) that the pharmacy will track, verify, and maintain records of each mifepristone shipment, and (4) that the pharmacy will comply with mifepristone manufacturer audit requests. *Id*. at 391, 434–36.

The 2023 mifepristone labeling and medication guide also bears an FDA approved label that states "WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING – Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following Mifepristone tablets, 200 mg use." *Id*. at 413–14. The guide further asserts that "[n]o causal relationship between the use of mifepristone tablets, 200 mg and misoprostol and [serious and sometimes fatal infections and bleeding] has been established." *Id*. at 414.

III. Procedural History

On May 8, 2023, Plaintiffs filed this action challenging the FDA's 2023 REMS decision as violating the APA by exceeding the Agency's statutory authority, being arbitrary and capricious, and violating the constitutional right to equal protection under the law. They seek declaratory and injunctive relief, arguing that the 2023 REMS unduly burden patient access to mifepristone and are not supported by scientific evidence. Plaintiffs also bring an equal protection claim under the Due Process Clause of the Fifth Amendment contending that the "FDA treats providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication." Dkt. 1 ¶ 158.

The parties have filed cross-motions for summary judgment. Plaintiffs seek partial summary judgment on its APA claims that the 2023 REMS exceed the FDA's statutory authority

and are arbitrary and capricious. Dkt. 68 at 1. Defendants move the Court to award them summary judgment in full. Dkt. 71 at 1.

STANDARD OF REVIEW

A district court should grant summary judgment only when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. In determining whether a genuine issue of material fact exists, the Court must view the facts and all justifiable inferences in the light most favorable to the party opposing the motion for summary judgment. *See Jacobs v. N.C. Admin. Off. of the Cts.*, 780 F.3d 562, 565 n.1 (4th Cir. 2015).

The typical summary judgment standard under Fed. R. Civ. P. 56(c) does not apply to suits challenging final agency actions under the APA. *See All. for Nat. Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 118 (D.D.C. 2011); 5 U.S.C. § 706. Rather, "[s]ummary judgment in the APA review context serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *All. For Nat. Health*, 775 F. Supp. 2d at 118 (citing *Cottage Health Sys. v. Sebelius,* 631 F. Supp. 2d 80, 90 (D.D.C. 2009)). In such instances, review is limited to the administrative record and "resolution … does not require fact finding on behalf of [the] court." *Hyatt v. U.S. Pat. & Trademark Off.*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015) (quoting *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994) (alteration in original)); *see also* 5 U.S.C. § 706.

Under the APA, courts must set aside an agency's final action if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right," or exceeds the agency's statutory authority. 5 U.S.C. § 706(2)(A)–(C). An

agency's action is arbitrary and capricious if it does not examine the relevant data and provide a reasoned explanation for its action. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). An agency rule is generally arbitrary and capricious if it (1) relied on factors Congress did not intend it to consider; (2) failed to consider an important factor or aspect of the issue; (3) reached a contrary conclusion to the evidence before it; or (4) provides an entirely implausible explanation for the rule. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Equal protection claims in the context of an agency action are governed by rational basis review. *Roe v. Shanahan*, 359 F. Supp. 3d 382, 411 (E.D. Va. 2019). The standard for rational basis review in this context is similar to the standard for arbitrary and capricious review: agency action violates the equal protection clause if the agency's treatment of the Plaintiffs was not rational (i.e., was arbitrary and capricious). *Id*. (citing *Cooper Hosp./Univ. Med. Ctr. v. Burwell*, 179 F. Supp. 3d 31, 47 (D.D.C. 2016), *aff'd per curiam*, 688 F. App'x 11 (D.C. Cir. 2017)). Therefore, if an agency's action is found to be arbitrary and capricious, it also violates the equal protection clause, because it lacks a rational basis.

Courts must also invalidate agency actions taken in excess of the agency's statutory authority. 5 U.S.C. § 706(2)(C); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–16 (1971). The Court's review depends on the scope of the agency's authority and discretion. *Id*.; *see also Loper Bright Enterp. v. Raimondo*, 603 U.S. 369, 395 (2024) ("When . . . a statute . . . delegates discretionary authority to an agency, the role of the reviewing court under the APA is . . . to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. The court fulfills that role by . . . 'fixing the boundaries of the delegated authority.'" (internal citations omitted) (citation modified)). In evaluating such claims, courts

give due weight to the Executive Branch's judgment and honor lawful delegations of authority to agencies. *Loper Bright Enterp.*, 603 U.S. at 413.

ANALYSIS

The FDA contends that Plaintiffs lack standing and failed to exhaust their administrative remedies, preventing the Court from reaching the merits of their claims. I addressed these issues in denying the preliminary injunction, but will revisit these issues before turning to the merits.

I. Standing

The FDA relies upon the recent Supreme Court decision in *Food & Drug Administration v. Alliance for Hippocratic Medicine*, to argue that Plaintiffs lack standing to bring their claims since they allegedly incurred no direct concrete injury causally linked to the FDA's actions. 602 U.S. 367 (2024). Article III standing is a threshold issue affecting subject matter jurisdiction. *See Mejico v. Alba Web Designs, LLC*, 515 F. Supp. 3d 424, 430 (W.D. Va. 2021) (quoting *Beyond Sys., Inc. v. Kraft Foods, Inc.*, 777 F.3d 712, 715 (4th Cir. 2015)); s*ee also Arbaugh v. Y&H Corp.*, 546 U.S. 500, 506 (2006) ("The objection that a federal court lacks subject-matter jurisdiction . . . may be raised by a party, or by a court on its own initiative, at any stage in the litigation.").

Federal jurisdiction is confined to "Cases" and "Controversies" under Article III of the U.S. Constitution. U.S. Const. art. III, § 2. To meet this requirement, a plaintiff must establish that they have standing to sue, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013), which requires a plaintiff to demonstrate: (1) a concrete, particularized, and actual or imminent injury; (2) a causal connection between the injury and the defendant's conduct; and (3) a likelihood that judicial relief will redress the injury. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (citations omitted). The injury must be real, not hypothetical, and directly linked to the

challenged conduct, with a remedy that is more than speculative. *Oryn Treadway Sheffield, Jr., Trust v. Consol. Coal Co.*, 819 F. Supp. 2d 625, 628 (W.D. Va. 2011). To sue in federal court and obtain a ruling on the law, a plaintiff must have a "personal stake" in the dispute, not merely be a bystander. *TransUnion*, 594 U.S. at 423 (citations omitted). Federal courts are not "open forum[s] for citizens 'to press general complaints about the way in which government goes about its business.'" *All. for Hippocratic Med.*, 602 U.S. at 379 (quoting *Allen v. Wright*, 468 U.S. 737, 760 (1984)). In *Alliance for Hippocratic Medicine*, the Supreme Court stated that "[g]overnment regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements. So, in those cases, standing is usually easy to establish." 602 U.S. at 382 (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992)); *see also* 5 U.S.C. § 702 (The APA provides a claim to "person[s] . . .adversely affected or aggrieved by agency action.").

Here, Plaintiffs are a collection of health care providers and clinicians that prescribe mifepristone. Dkt. 1 at 1–2. Accordingly, they are subject to the challenged 2023 REMS that regulate the drug's prescription and distribution. *Cf. All. for Hippocratic Med.*, 602 U.S. at 374 (finding that pro-life doctors and associations that did not prescribe mifepristone were unregulated parties that lacked standing to challenge the FDA's regulation of others that did prescribe or take the drug). Plaintiffs in this case allege that the REMS directly injure them by causing delays in their certification of new hires, and generating significant administrative burdens including alleged unnecessary recordkeeping, patient agreement form translation and distribution challenges, and self-stocking of mifepristone given limitations placed on pharmacies certified to distribute the drug. Dkt. 74 at 20–21. Accordingly, Plaintiffs have standing to pursue their claims.

II. Exhaustion of administrative remedies

Defendants argue that Plaintiffs failed to exhaust their administrative remedies because they did not file a citizen petition, depriving the FDA a chance to address their claims. They also contend that Plaintiffs failed to show that using the administrative process would have been futile. Consistent with other courts[10] which have reviewed this issue, I concluded that Plaintiffs adequately established futility, rendering Defendants' exhaustion argument unpersuasive. I stand by that conclusion but revisit the issue in light of Defendants' renewed argument.

The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. But the APA also requires that a plaintiff exhaust all administrative remedies before seeking judicial review. *Volvo GM Heavy Truck Corp. v. U.S. Dep't of Lab.*, 118 F.3d 205, 209 (4th Cir. 1997) (citations omitted). Although the APA does not prescribe a specific exhaustion procedure, it mandates exhaustion "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." *Darby v. Cisneros*, 509 U.S. 137, 153 (1993).

Under the Federal Food, Drug, and Cosmetic Act, the FDA provides a formal mechanism for interested parties to challenge agency actions through a citizen petition. *See* 21 C.F.R. §§ 10.1(a), 10.25(a), 10.45(b). Any interested person may petition the Commissioner to issue,

[10] *See Washington*, 668 F. Supp. 3d at 1139; *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507 (N.D. Tex.), *aff'd in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023), *cert. granted sub nom. FDA v. All. for Hippocratic Med*., 144 S. Ct. 537, (2023), and *cert. granted sub nom. Danco Lab'ys, L.L.C. v. All. for Hippocratic Med*., 144 S. Ct. 537 (2023), and *cert. denied sub nom. All. for Hippocratic Med. v. FDA*, 144 S. Ct. 537 (2023), and *rev'd and remanded sub nom. FDA v. All. for Hippocratic Med*., 602 U.S. 367 (2024), and *vacated and remanded*, 117 F.4th 336 (5th Cir. 2024).

amend, or revoke a regulation or order, or to take or refrain from any other administrative action. 21 C.F.R. § 10.25(a). Thus, typically, prior to initiating litigation over an agency's action or inaction, a petitioner must first receive a final decision on its citizen petition. *See* 21 C.F.R. § 10.45(b). But courts may excuse the exhaustion requirement where it is clear the agency will deny the claim regardless of the petitioner's efforts. *See Carr v. Saul*, 593 U.S. 83, 93 (2021).

The Fourth Circuit demands a "'clear and positive' showing of futility" before it will excuse a party from exhausting administrative remedies. *Makar v. Health Care Corp. of Mid-Atl. (CareFirst)*, 872 F.2d 80, 83 (4th Cir. 1989) (citations omitted). The party asserting futility bears the burden of proof. *Googerdy v. N.C. Agr. and Tech. State Univ.*, 386 F. Supp. 2d 618, 628–29 (M.D.N.C. 2005). Courts typically excuse exhaustion only when the agency displays inherent bias or has made clear, through past decisions, its stance on the case's merits, or public statements, that it will not grant the relief sought. *McDonald v. Centra*, 118 B.R. 903, 923 (D. Md. 1990).

As I explained in denying Plaintiffs' motion for a preliminary injunction, some of their particular arguments and evidence were not previously presented to the FDA, and the 2022 ACOG citizen petition does not directly address the issues at stake here. Still, the heart of Plaintiffs' challenge echoes the longstanding efforts of various organizations that urged the FDA to lift the REMS requirements for mifepristone, arguing the drug is safe without them. Time and again, the FDA has declined to do so.

Plaintiffs allege that "FDA reevaluated the provisions of the mifepristone REMS in 2016, and again in 2019, 2021, and 2023, but it has continually decided to reimpose the REMS despite longstanding objections from the medical community and its own review of the data showing mifepristone's safety and efficacy." Dkt. 1 ¶ 85. Thirty organizations petitioned the FDA in 2016

to completely lift the REMS. *Id*. ¶ 87. In the face of these recurrent challenges, the FDA has repeatedly affirmed that REMS requirements for mifepristone were reasonable and necessary to ensure the drug's safe use for medication abortion. In 2016, the agency completed a four-year assessment of mifepristone, concluded that the drug remained safe, maintained the REMS, and determined that while the patient agreement ETASU could be removed as redundant, the prescriber certification ETASU should remain. *See* Dkt. 78-2 at 116–19. Despite acknowledging the redundancy, the FDA retained the patient agreement form, stating it "would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care." *Id*. at 111.

In 2021, the FDA conducted a comprehensive review of the mifepristone REMS pursuant to a litigation agreement with the *Purcell* plaintiffs, who challenged the 2016 REMS and sought their removal. *See* Dkt. 78-6 at 90. That review initially[11] included published studies and other sources cited by the *Purcell* plaintiffs. Dkt. 78-5 at 170–78; Dkt. 78-6 at 95–97. Despite significant evidence to the contrary, the FDA concluded that a REMS remained necessary to ensure the safe use of mifepristone. The Agency called for the removal of the in-person dispensing requirement and retention of the prescriber certification and patient agreement elements. It also added a pharmacy certification requirement and directed the drug sponsors to submit proposed modified REMS consistent with those findings. *See* Dkt. 78-6 at 87–134. The FDA subsequently approved the 2023 REMS, which reflected the FDA's 2021 Rationale's conclusions. *See* Dkt. 78-7 at 271–92, 389–92.

[11] Although the FDA originally considered the sources provided by the *Purcell* plaintiffs, it ultimately excluded all but three of them from serious consideration. Dkt. 78-6 at 130–34.

Considering this regulatory history, the FDA cannot plausibly claim that a new citizen petition would change its position that, despite the proven safety of mifepristone, the REMS remain necessary for its use to terminate a pregnancy. I therefore find that requiring further exhaustion through a citizen petition would be futile. The FDA's prior decisions and sustained adherence to its REMS framework demonstrate that it will not grant the relief Plaintiffs seek. *See Shanahan*, 359 F. Supp. 3d at 403; *Washington v. FDA*, 668 F. Supp. 3d 1125, 1139 (E.D. Wash. 2023) (holding that after multiple citizen petitions and a full FDA REMS review, the "FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition"), *opinion clarified*, 669 F. Supp. 3d 1057 (E.D. Wash. 2023), and *vacated*, No. 1:23- CV-3026-TOR, 2025 WL 1888794 (E.D. Wash. July 8, 2025).

III. Merits

The APA governs how federal agencies operate and ensures they remain accountable to the public. Although agencies are afforded deference in the performance of their congressionally delegated duties, the APA mandates that they base their decisions on sound reasoning. Courts may invalidate agency actions that are arbitrary and capricious, contrary to the Constitution, or in excess of their statutory authority. *See* 5 U.S.C. § 706(2)(A)–(C). Through the Federal Food, Drug, and Cosmetic Act, Congress instructed the FDA to implement a REMS only when necessary to address a drug's risks. *See* 21 U.S.C. § 355-1(a)(1). The statute further provides for periodic review and modification of these measures. *See* 21 U.S.C. § 355-1(d), (g). Plaintiffs contend that the FDA (1) exceeded its statutory authority by unreasonably applying the statutory criteria outlined in § 355-1(a) and (f) when issuing the 2023 REMS, (2) acted arbitrarily and capriciously in adopting the 2023 REMS, and (3) violated the Fifth Amendment's equal protection provision.

A. The FDA properly exercised its statutory authority in issuing the 2023 REMS

Federal agencies only possess the authority granted to them by Congress and must act within the boundaries set by statute. *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab.*, 595 U.S. 109, 117 (2022). The central question is whether an agency acted within the scope of its delegated authority. *City of Arlington v. FCC*, 569 U.S. 290, 298 (2013). In answering that question, courts exercise independent judgment in determining the limits of an agency's legal power. *Loper Bright Enterp*., 603 U.S. at 412. When an agency exceeds its statutory authority, the APA requires a court to set aside the unlawful action. *See* 5 U.S.C. § 706(2)(C). While the APA also permits courts to invalidate agency action that is arbitrary or capricious, that inquiry is distinct. Arbitrary and capricious review assesses the reasonableness of an agency's decision making, while questions of statutory authority focus on whether the agency had the legal power to act in the first place.

Plaintiffs argue that the FDA failed to comply with its statutory duties under the Federal Food, Drug, and Cosmetic Act in approving the 2023 REMS modifications. They claim the FDA: (1) failed to consider the six factors outlined in 21 U.S.C. § 355-1(a)(1); (2) neglected to conduct the burden analysis required for each of the ETASUs under § 355-1(f); and (3) did not determine that, without the protections afforded by the ETASUs, the drug would not be approved. Notably, however, Plaintiffs do not contend that the FDA lacked the authority to issue, review, or modify the REMS under the Statute. Rather, they challenge how the Agency exercised that authority. Thus, their statutory authority claim (Count I) fails. Plaintiffs' motion for summary judgment on Count I is therefore **DENIED**, and Defendants' cross-motion on this issue is **GRANTED**.

B. The FDA's 2023 REMS decision was arbitrary and capricious

Plaintiffs argue that the FDA's 2023 REMS Modification Rationale is arbitrary and capricious as a matter of law because the FDA (1) failed to provide a satisfactory explanation for its decision and (2) excluded relevant data. I agree. "Under that [APA] standard, a court asks not whether it agrees with the agency decision, but rather only whether the agency action was reasonable and reasonably explained." *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 180 (2025). The Court assesses whether the FDA considered the relevant data and provided a rational connection between the facts found and the decision to implement the 2023 REMS. *Sierra Club v. U.S. Dep't of the Interior*, 899 F.3d 260, 293 (4th Cir. 2018). The Court does not assess whether the 2023 REMS are in fact necessary to ensure that mifepristone's benefits outweigh its risks or to reduce the burden on the healthcare system. Instead, the court reviews the FDA's actions to determine whether its decision-making process provided an adequate basis to support its conclusions. I find that the FDA's analysis in support of the 2023 REMS fails to provide an adequate explanation of the reasoning behind its conclusions. As a result, the agency's decision to require the 2023 REMS is arbitrary and capricious under the APA.

Although agencies are afforded deference, the Court must examine the administrative record to be sure that "the agency has examined the relevant data and articulated a satisfactory explanation for its action.'" *Sierra Club v. W. Va. Dep't of Env't Prot.*, 64 F.4th 487, 501 (4th Cir. 2023) (quoting *Defs. of Wildlife v. Dep't of the Interior*, 931 F.3d 339, 345 (4th Cir. 2019)). An action may be arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43.

A satisfactory explanation requires that the agency provide a "rational connection between the facts found and the choice made." *U.S. Dep't of the Interior*, 899 F.3d at 293 (quoting *State Farm*, 463 U.S. at 43). Failure to consider statutorily mandated factors suggests that an agency's decision is insufficiently supported. *N.C. Growers' Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 764 (4th Cir. 2012). Despite narrow review of agency action, courts must "be strict in reviewing an agency's compliance with procedural rules." *Id*. (citing *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985)). In reviewing an agency's explanation, the Court "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *State Farm*, 463 U.S. at 43 (citing *Bowman Transp. Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)).

Thus, the Court must address three issues to determine if the FDA's 2023 REMS are arbitrary and capricious. First, the Court must determine which factors the FDA was required to consider in modifying the mifepristone REMS. Second, the Court must determine if the FDA considered those factors. Finally, the Court must determine if, upon consideration of those factors, the FDA reviewed the relevant data and articulated a satisfactory explanation for its decision.

1. Statutory Factors

As a threshold matter, the parties dispute which factors the FDA is directed to consider when modifying a REMS. An explanation by an agency of its action may not be satisfactory if the agency fails to address relevant statutory factors. *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004) ("A statutorily mandated factor, by definition, is an important aspect of any issue before an administrative agency, as it is for Congress in the first instance to define the appropriate scope of an agency's mission."); *see also Purcell*, 2025 WL

3101785, at *12 ("Failure to consider a statutorily-mandated factor renders an agency decision arbitrary and capricious."). Likewise, the relevance of particular data depends on the factors properly guiding an agency's review. Therefore, I first identify the factors that the FDA was required to consider in its decision to modify the mifepristone REMS.

There are three potentially relevant categories of statutory factors that the FDA must consider in modifying a REMS. The parties agree that 21 U.S.C. § 355-1(g)(4) governs modification of an existing REMS. Under that provision, the FDA may require the sponsor to submit a REMS modification to add, modify, or remove a current goal or element if necessary to (1) ensure the drug's benefits continue to outweigh its risks or (2) to reduce burdens on the healthcare system. 21 U.S.C. § 355-1(g)(4)(B). Plaintiffs argue that the FDA must also consider the initial approval factors, 21 U.S.C. § 355-1(a)(1), and the ETASU factors, 21 U.S.C. § 355-1(f)(1)–(2), to determine if modification is warranted. I agree.

The Food, Drug, and Cosmetic Act directs the FDA to consider the initial approval factors in modifying the REMS. Section 355-1(g), the modification provision, and § 355-1(a)(1), the initial approval provision, use identical standards required to impose a REMS: both require that the FDA find that a drug's benefits outweigh its risks. The initial approval provision includes six factors that are considered to determine if a drug's benefits outweigh its risks. *See* 21 U.S.C. § 355-1(a)(1). Therefore, to the extent that a modification is justified as essential to ensuring that the drug's benefits outweigh its risks, the FDA should consider the initial approval factors listed in § 355-1(a)(1)(A)–(F). *See Purcell*, 2025 WL 3101785 at *13 ("[T]he Court concludes that the Initial Approval Factors remain relevant at REMS modification or review because the Modification Provision effectively incorporates the Initial Approval Factors by using the identical phrase that mandates a REMS at the initial approval stage."). Those factors are:

> (A) The estimated size of the population likely to use the drug involved.
> (B) The seriousness of the disease or condition that is to be treated with the drug.
> (C) The expected benefit of the drug with respect to such disease or condition.
> (D) The expected or actual duration of treatment with the drug.
> (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.
> (F) Whether the drug is a new molecular entity.

21 U.S.C. § 355-1(a)(1). The FDA must perform the risk-benefit analysis required under § 355-1(a)(1) both at the initial approval stage and in promulgating modified REMS.

The FDA was also required to consider the ETASU factors in assessing each ETASU included in the 2023 REMS. In modifying a REMS, the FDA is required to determine whether "1 or more goals or elements should be added, modified, or removed from the approved strategy to—(i) ensure the benefits of the drug outweigh the risk." 21 U.S.C. § 355-1(g)(4)(B). ETASUs are required only if "the drug . . . can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." 21 U.S.C. § 355-1(f)(1)(A). Therefore, as part of the risk-benefit assessment, the FDA must consider whether an ETASU is necessary for continued safe use of the drug. *See Washington*, 668 F. Supp. 3d at 1140–41 ("Implicit in this [§ 355-1(g)(4)(B)] assessment is whether the drug's risks require REMS and/or ETASU. . . . [I]t would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1)."). The ETASU factors require than an ETASU

> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
> . . .
> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

(i) patients with serious or life-threatening diseases or conditions;
(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and
(iii) patients with functional limitations; and

(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

(i) conform with elements to assure safe use for other drugs with similar, serious risks; and
(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

21 U.S.C. § 355-1(f)(2). In considering these factors, the statute instructs the FDA to consult patients, providers, and pharmacists. 21 U.S.C. § 355-1(f)(5)(A).

In short, a REMS modification decision must consider if the changes are necessary (1) to ensure the benefits of the drug outweigh the risks or (2) to address the burdens the REMS impose on the healthcare system. 21 U.S.C. § 355-1(g)(4). If the modification is justified because it is necessary to ensure that the benefits of the drug outweigh the risks, that balancing test should apply the initial approval factors under 21 U.S.C. § 355-1(a). If the proposed modification includes an ETASU, that additional burden must be justified by reference to the ETASU factors outlined in 21 U.S.C. § 355-1(f).

2. The Challenged 2023 REMS Are Arbitrary and Capricious

Plaintiffs argue that the 2023 REMS requiring certification of prescribing pharmacies and providers and completion of the written patient acknowledgement form are arbitrary and capricious because the rationale given by the FDA provided insufficient justification and excluded several key categories of data. I agree.

The 2021 Rationale describes "how information relevant to the current Mifepristone REMS Program was retrieved, analyzed, and applied to each of the individual ETASUs." Dkt. 78-6 at 95. The proposed sources of information came from two sources: the FDA's proposed references, which came from its literature search and sources provided by third parties, including

the sponsors, and advocacy groups, and sources proposed by the *Purcell* plaintiffs. *Id*. To determine which of these sources would be included in the actual review, the FDA applied several selection criteria. First, the FDA limited its review of the REMS to publications related to objective safety data. *Id*. at 96. This exclusion removed vast swaths of data, including statements from leading medical societies, and data on provider and patient burdens. *See* Dkt. 69 at 7. Second, the FDA excluded all publications published before March 28, 2016, or after July 26, 2021, "systematic reviews and meta-analyses," and "references . . . limited to an abstract of the study methods and results." Dkt. 78-6 at 96. As a result, additional references were excluded, including a Canadian study that concluded that removal of REMS-like restrictions did not impact safety outcomes. *Id*. at 130. Failure to consider relevant data in explaining its decision may render agency action arbitrary and capricious. Therefore, the Court must consider if the FDA's selection criteria arbitrarily excluded relevant data.

i. The FDA only considered "objective safety data"

The restriction to "objective safety data" excluded relevant data that the FDA was statutorily required to consider in determining the appropriate mifepristone REMS modification. Applying this criterion, the FDA explicitly excluded "safety information unrelated to the REMS elements," including data on complication rates in the general pregnant population. *Id*. at 96. But the initial approval factors direct the FDA to consider the "seriousness of the condition" to determine if the drug's benefits outweigh its risks. 21 U.S.C. § 355-1(a)(1)(B). Data on pregnancy complications is relevant to the seriousness of the condition (pregnancy) treated by mifepristone.

Even considering that the FDA asserts it was not required to consider the initial approval or ETASU factors and could therefore ignore publications examining data relevant to those

factors, the objective safety limitation excluded data that the FDA acknowledges it was required to consider. Applying this selection criterion, the FDA excluded references that analyzed "clinician perspectives on access to mifepristone," and "provider stigma around abortion care." Dkt. 78-6 at 133–34. But, under the modification provision, § 355-1(g)(4)(B)(ii), the FDA was required to consider whether the strategy should be modified to "minimize the burden on the health care delivery system." Exclusion of this data, which is directly related to a statutorily mandated factor, suggests that the decision is arbitrary and capricious. *See Pub. Citizen*, 374 F.3d at 1216.

The "objective safety data" restriction also excluded position statements from leading medical organizations, including ACOG, Planned Parenthood, the American Medical Association, and the American Academy of Family Physicians. Dkt. 78-6 at 96, 130. The Fourth Circuit has found that an agency acted arbitrarily and capriciously when it "inadequately explained its decision 'to disagree with comments by every major medical organization.'" *Mayor of Baltimore v. Azar*, 973 F.3d 258, 276 (4th Cir. 2020). Further, these professional opinions are related to statutorily required factors, as they included data about the risks of pregnancy, and background incidence of serious adverse events among pregnant people not using the drug. 21 U.S.C. § 355-1(a)(1)(B), (E); *see, e.g.*, Dkt. 78-5 at 6 (ACOG provided its opinion, stating that "while the [FDA] notes rare cases of fatal infections, it is important to note that no specific connection exists between medication abortion and these infections, which can also occur with other obstetric and gynecologic processes and procedures."); *id*. at 56 (Planned Parenthood also supports removal of the REMS, stating that "the risk of mortality from childbirth in the United States is estimated to be 14 times higher than the same risk from induced abortion."). The FDA

did not provide justification for this exclusion, nor address its disagreement with these leading medical associations.

ii. The FDA misapplied the statutory burden to impose an ETASU

The FDA mischaracterized and misapplied the relevant statutory burden it must meet to impose a REMS. By nature, REMS, and especially ETASUs, create barriers to access to effective drugs. To ensure that these barriers are not imposed lightly, a REMS modification may only include an ETASU if, without that ETASU, approval for the drug would be withdrawn due to a "specific serious risk." 21 U.S.C. § 355-1(f)(1)(A). Throughout the 2021 REMS Modification Rationale, the FDA subtly shifts the burden when reviewing the modifications. Rather than satisfying its burden to confirm that the REMS are necessary for the benefits of the drug to outweigh its risk, the FDA places the burden on those challenging the REMS to show that they are no longer necessary. For example, the FDA retained the patient agreement ETASU and the prescriber certification requirement because the literature reviewed did not provide evidence to support removal of these requirements. Dkt. 78-6 at 98, 102. There are two problems with this reasoning. First, there was literature support for the removal of the ETASUs, but the FDA declined to consider it. *See, e.g.*, Dkt. 78-7 at 30–40 (study analyzing mifepristone safety and effectiveness "comparing trends in incidence before mifepristone was available with trends after its availability without restrictions"); Dkt. 78-6 at 133 (excluding Schummers study from FDA consideration). Second, beyond citing the absence of new studies, the FDA does not explain why approval for the mifepristone REMS would be withdrawn without each ETASU. The FDA retained the patient agreement ETASU because it "determined, consistent with section 505-1(f)(2) of the FD&C Act, that this does not impose an unreasonable burden on providers or patients." Dkt. 78-6 at 103. But the burden to justify an ETASU is not whether the ETASU

imposes an unreasonable burden. The appropriate showing to justify an ETASU is that without that particular safety element, approval for the drug must be withdrawn. Improperly shifting the burden to the challengers and applying a lower burden to justify the ETASUs suggests that the FDA's decision is arbitrary and capricious.

iii. The FDA considered factors outside its statutory mandate

The FDA allowed exceptions to the restrictive selection criteria only to consider factors outside its statutory mandate. Specifically, the FDA removed the selection criteria to allow review of "publications that discussed changes in provider volume." Dkt. 78-6 at 97. Although the FDA relies on projected increases in provider volume to justify retention of the patient agreement and prescriber certification ETASUs, it fails to connect data on provider volume to a relevant statutory factor. *See* Dkt. 78-6 at 122 ("[H]ealthcare provider certification continues to be necessary to ensure the benefits outweigh the risks, especially considering that, if the in-person dispensing requirement is removed from the Mifepristone REMS program, the number of new providers may increase."); *id*. ("Given the likelihood of a potential increase in new prescribers if the in-person dispensing requirement is removed from the Mifepristone REMS Program, we conclude that maintaining the Patient Agreement Form remains necessary to assure safe use at this time."). While the size of the population likely to use the drug is a relevant factor in considering whether the drug's benefits outweigh its risks, the FDA does not tie the projected increase in prescribers to a projected increase in users or, more importantly, to an increased risk in the use of the drug. Reliance on factors which Congress has not intended the agency to consider may render agency action arbitrary and capricious. *State Farm*, 463 U.S. at 43. Further, the FDA fails to address whether an increase in providers may decrease burdens on patient

access and decrease burdens on the healthcare system, which are both relevant factors in considering the propriety of each ETASU.

iv. The FDA's justifications are conclusory and contrary to the data before the agency

Plaintiffs also allege that the FDA provided only speculative rationales for its decision, and the decision is therefore arbitrary and capricious. Dkt. 69 at 32. Because the 2021 Rationale and 2023 Joint Summary Rationale provide only conclusory justifications for the mifepristone REMS and "offer[] an explanation that is contrary to the evidence before the agency," *State Farm*, 463 U.S. at 43, I agree.

The FDA did not justify the REMS in whole but went into detail as to each ETASU. *See* Dkt. 78-6 at 87–134. Insofar as these justifications translate to the challenged REMS generally, the FDA's conclusions were contrary to the data before the Agency. For example, professional opinions on the safety of mifepristone are relevant in analyzing whether the drug's benefits outweigh the risks. *See* 21 U.S.C. § 355-1(a)(1)(C), (E). And yet, the FDA failed to address multiple medical associations' conclusions that mifepristone is safe without a REMS. *See, e.g.*, Dkt. 78-4 at 52 ("ACOG recommends that mifepristone for reproductive health indications be made available in retail pharmacies like other prescription drugs and without unique provider certification or patient consent requirements."); Dkt. 78-5 at 45 (the American Academy of Family Physicians supporting the removal of the mifepristone REMS and ETASUs for medical abortion based on strong safety data and alignment with medical consensus, arguing that current restrictions create unnecessary barriers to care, especially for underserved women, despite the drug's proven efficacy, low complication rate, and safer profile compared to similarly regulated medications); *id*. at 4 (the American Medical Association adopted a policy to "support efforts urging the [FDA] to lift the [REMS] on mifepristone"). The 2023 Mifepristone Labeling and

Medication Guide acknowledges that "[n]o causal relationship" has been established between mifepristone and serious complications such as infection or bleeding and that such events are rare. Dkt. 78-7 at 414. The FDA did not address either of these data points, but concluded, without supporting evidence, that mifepristone required a REMS to assure that the drug's benefits outweighed the risks.

The agency also provided insufficient justification in addressing the access burdens REMS impose on the healthcare system. The FDA was required to determine if "1 or more goals or elements should be added, modified, or removed from the approved strategy to . . . minimize the burden on the health care delivery system of complying with the strategy." 21 U.S.C. § 355-1(g)(4)(B)(ii). The Agency emphasized that removing the in-person dispensing requirement significantly decreased patient burdens. But, to the extent that it addressed the burdens of the remaining 2023 REMS requirements, it did so narrowly. In reviewing the sponsor's 2023 REMS proposed modifications, consistent with the 2021 REMS Modification Rationale, the Agency concluded that any remaining burdens were mitigated by (1) limiting prescriber certification to a one-time requirement, (2) simplifying the patient agreement form, and (3) protecting confidentiality by restricting disclosure of patient and provider identities to personnel necessary for dispensing, payment, or insurance purposes. Dkt. 78-7 at 280, 283–94. The FDA, however, cited no authorities supporting its conclusions; it just made declaratory statements that these mitigation measures would sufficiently limit any undue burdens.[12] Requiring patients, providers,

[12] *See e.g.*, Dkt. 78-6 at 99 ("The burden of prescriber certification has been minimized to the extent possible by requiring prescribers to certify only one time for each applicant."); *id.* at 122 (finding that the patient agreement form, which may be signed in person or via other means "does not impose an unreasonable burden on providers or patients"); Dkt. 78-7 at 280 ("The burden of providing the Prescriber Agreement Form prior to or when the prescription is provided to a certified pharmacy does not create unreasonable burden for prescribers. The burden of prescriber certification has been minimized to the extent possible. The Prescriber Agreement

and pharmacies to comply with restrictions that do not make a drug safer places burdens on the health care delivery system and inhibits patient access. Certainly, the FDA may have addressed some burden-related concerns, but it failed to grapple with pertinent burden analysis evidence in instituting its 2023 REMS modification, so the modification was arbitrary and capricious. *See Roe v. Dep't of Def.*, 947 F.3d 207, 220–24 (4th Cir. 2020) (holding that an agency's reliance on generalized assumptions and failure to employ and individualized approach, as required by statute, was arbitrary and capricious).

Because the FDA's 2021 Modification Rationale and 2023 REMS failed to provide an evidence-based justification for maintaining the mifepristone REMS and failed to consider the relevant data, the decision was arbitrary and capricious.

3. The maintenance and addition of the challenged ETASUs to the 2023 REMS was also arbitrary and capricious

Plaintiffs also argue that each ETASU is arbitrary and capricious. In performing its assessment under § 355-1(g)(2), the FDA was required to consider "with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified." 21 U.S.C. § 355-1(g)(3). Thus, the Agency must also evaluate each element independently to determine whether it achieves the REMS's goals or requires modification to do so. Additionally, in promulgating the REMS modification, the FDA was

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Form is designed to require minimal time to complete and requires that the prescriber submit it to the authorized distributor once, and if the prescriber chooses to use a certified pharmacy to dispense mifepristone, they will need to submit the form to the certified pharmacy."); *id.* at 283–84 (concluding that limiting access to patient and prescriber identities is sufficient to mitigate the burden that threats and intimidation have on access to mifepristone for medication abortion); *id.* at 285 (simply stating that "[t]here is minimal burden to recertification and the timelines allow sufficient time to accomplish recertification")

required to consider whether the goals or elements should be modified to ensure that the benefits of the drugs outweigh the risks and to minimize the burden on the healthcare delivery system. 21 U.S.C. § 355-1(g)(4). In that analysis, the risk-benefit determination requires consideration of the initial approval factors under § 355-1(a)(1). As ETASUs impose heightened burdens on the healthcare system and patients, each ETASU must be justified according to the ETASU elements under § 355-1(f). In short, the FDA is directed to consider all three categories of factors—initial approval, modification, and ETASU factors—to determine if an ETASU is justified.

Here, the FDA justified maintaining these ETASUs primarily on the ground that eliminating the in-person dispensing requirement would reduce burdens and expand access to mifepristone for medication abortion—thereby requiring retention of the prescriber certification requirement and patient agreement form, and imposition of the pharmacy certification requirement, as safeguards. But that rationale, without more, falls short under the Federal Food, Drug, and Cosmetic Act.

Broadly, the FDA selection criteria excluded data that it was required to consider under the ETASU factors. First, the FDA explicitly excluded data relevant to the burden the ETASUs imposed on patient access. Specifically, the FDA excluded "[d]ata on the logistics of accessing abortion care in general, such as time to appointment or the distance traveled to obtain care." Dkt. 78-6 at 97. ETASUs, like those required in the 2023 REMS, shall "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). Therefore, distance traveled to obtain an abortion using mifepristone is a factor the FDA was directed to consider for ETASUs. But, without explanation, the FDA excluded this data.

Second, the FDA excluded data that would have provided insight on whether approval of mifepristone would be withdrawn without the ETASUs. The Schummers study examined safety outcomes in Canada following removal of REMS-like restrictions. Dkt. 78-7 at 30. This information examines safety outcomes without restrictions, which would clearly inform whether ETASUs are necessary for mifepristone approval. The FDA excluded this study because the *Purcell* plaintiffs originally only provided the abstract. Dkt. 78-6 at 133. In 2022, after the FDA notified the parties and sponsors of its intention to modify the REMS on December 16, 2021, leading medical organizations filed a citizen's petition asking for elimination or modification of the REMS to allow for mifepristone use for miscarriage management. Dkt. 78-7 at 2–29. The petition relied heavily on findings of safe use without restrictions in the Schummers study. Dkt. 69 ¶ 56. Defendant argues that the study was published in 2022 and therefore was excluded as outside the prescribed timeframe for the FDA's literature review because allowing additional resources would mean that the review "would never be completed." Dkt. 70 at 40.

As an initial matter, the Schummers study was published on December 8, 2021, before the FDA provided notice of its intent to modify the REMS or published the 2021 REMS Modification Rationale. Dkt. 78-7 at 30. In late 2021 and early 2022, the FDA was awaiting proposed modified REMS from the drug sponsors and had not promulgated the final REMS. *See* Dkt. 78-6 at 136–39, 141–43. The FDA made some minor changes to its initial 2021 proposed modification based on the sponsors' proposals. *See* Dkt. 78-7 at 271–308. While submission of additional literature would need to end at some point to allow for completion of the FDA's review, the FDA's reliance on an arbitrary timeline to exclude relevant information is unavailing. This decision is particularly stark because the FDA removed its selection criteria for other areas of its review: it allowed literature outside the "objective safety" criterion to assess removal of the

patient agreement form requirement. Dkt. 78-6 at 97. Further, the FDA had notice of the study because of the abstract submitted by the *Purcell* plaintiffs and repeated reference in the 2022 citizens petition. Given this uneven commitment to the selection criteria, particularly in light of the relevance of the Schummers study, the FDA did not provide sufficient justification for continuing to exclude the Schummers study.

Third, the Agency inadequately addressed the required factors to ensure that the ETASUs were not unduly burdensome on the health care delivery system, especially as compared to other drugs. To minimize that burden, ETASUs shall "conform with elements to assure safe use for other drugs with similar, serious risks." 21 U.S.C. § 355-1(f)(2)(D)(i). Plaintiffs note that other commonly prescribed drugs, comparable in safety to mifepristone, have been approved without any REMS requirements. For example, an analysis of medication abortion risk explained that the mortality rate associated with medical abortion is 0.65 deaths per 100,000 medication abortions, while the mortality rate of Penicillin, which does not have a REMS, is 2 deaths per 100,000 patients administered the drug. Dkt. 78-5 at 2–3. Congress contemplated consistent regulation for comparably risky drugs, making the treatment of similar drugs relevant to evaluating whether a REMS modification is justified by the specific risk and burden associated with the drug's use. Failure to consider a statutorily mandated factor suggests that an agency decision is arbitrary and capricious. *State Farm*, 463 U.S. at 43.

Most notably here, in 2012, the FDA approved mifepristone (marketed as Korlym) for the treatment of Cushing's syndrome at a higher dosage and for longer duration, *without imposing any REMS or ETASUs*. Dkt. 78-1 at 71–107. The principal risks associated with mifepristone for medication abortion are heavy bleeding and infection. *See* Dkt 78-7 at 414–18. The FDA's REMS review for Korlym highlighted fetal loss as a serious risk; thereby patients

using Korlym presumably face the same "serious risks" of heavy bleeding and infection that underlie the REMS for mifepristone used for medication abortion. Dkt. 78-1 at 76. While the FDA concluded that (1) pregnancy in this context would be rare and (2) the risk of fetal loss could be mitigated through drug labeling, *id*., its review reported the adverse event of endometrial hyperplasia and/or vaginal bleeding, an analogous risk to that underlying the REMS regulating mifepristone in the medication abortion context. *Id*. at 75, 106–07. Further, in summarizing the risks of mifepristone in the Korlym REMS review, the FDA noted that the risk of mifepristone in pregnant women is "the termination of her pregnancy," while the "serious risks" of bleeding and infection highlighted in the mifepristone REMS are not mentioned at all. *Compare* Dkt. 78-1 at 106 (identifying the risk to pregnant women as only the risk of termination of the pregnancy), *with* Dkt. 78-7 at 414 (identifying the principal risks of mifepristone as infection and heavy bleeding). The stark contrast between the regulation of mifepristone for medication abortion and its less-restricted use for treating Cushing's syndrome, despite the latter involving higher doses over longer periods, raises a serious question whether the 2023 REMS reflect a reasoned, consistent approach or are instead arbitrary and capricious. The FDA's failure to explain this differential regulation further signals that the Agency's 2023 REMS Modification decision was insufficient under the APA.

Aside from these broad failures to address required ETASU factors in the 2023 REMS Modification, Plaintiffs also assert that each ETASU is independently arbitrary and capricious. I address each ETASU separately.

i. Prescriber certification

The 2021 Rationale states that prescriber certification is necessary to ensure that providers are qualified to detect and mitigate serious risks associated with mifepristone—such as

undetected ectopic pregnancies and heavy bleeding. *See* Dkt. 78-6 at 97–98. Further, with the removal of the in-person dispensing requirement, the FDA anticipated an increase in prescribers and maintained that certification ensures providers meet qualifications and follow usage guidelines. *Id.* at 99. The FDA thus decreed that provider certification would remain a requirement, and that the one-time certification minimized its burden. *Id*. The FDA also cited the absence of any study comparing adverse event outcomes between certified and non-certified providers which would challenge its earlier determination. *Id.* at 98.

There are several problems with the FDA's reasoning. First, clinicians who treat pregnant patients are already bound by ethical, legal, and professional obligations to prescribe medications only when competent to do so. *See* Dkt. 78-3 at 37 (a 2015 letter to the FDA from doctors and medical organizations stating "[a] standard clinical license should be sufficient to assure that a provider meets these qualifications; an exceptional certification for mifepristone is unnecessary"); Dkt. 78-4 at 48 (the AMA Code of Medical Ethics stating physicians are ethically obligated to prioritize the patient's welfare and to care for patients and to alleviate suffering); Dkt. 78-3 at 54 (a letter from ACOG stating that "[a] standard clinical license should be sufficient to ensure that a practitioner meets qualifications for prescribing mifepristone"). "A material misapprehension of the baseline conditions" can support a finding that an agency action is arbitrary and capricious. *Friends of Back Bay v. U.S. Army Corps of Eng'rs*, 681 F.3d 581, 588 (4th Cir. 2012). Here, the ethical, legal, and professional obligations that render the prescriber certification unnecessarily duplicative are a relevant baseline condition.

Second, the FDA's assertion that a particular study is needed to demonstrate that the certification requirement is unnecessary would require providers to violate the 2023 REMS and prevailing medical codes of conduct. Conditioning the continuation of an ETASU on a

speculative and ethically dubious study is irrational. Speculation that (1) clinicians may defy their professional duties and (2) a study might disprove that possibility, is not a reasoned explanation for maintaining the prescriber certification requirement. *See Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 472 (4th Cir. 2013) (holding that it is arbitrary and capricious to rely on a flawed assumption); *Appalachian Voices v. U.S. Dep't of Interior*, 25 F.4th 259, 274 (4th Cir. 2022) (holding that failure to connect the assumptions underlying the agency's decision to the real world conditions is arbitrary and capricious).

The irrationality of the FDA's requirement is particularly stark in light of exclusion of the Schummers study. The Schummers study details patient outcomes after removal of REMS-like restrictions in Canada. Dkt. 78-7 at 30. Therefore, the FDA's assertion that "the literature did not identify any studies comparing providers who met these qualifications with those who did not" is true only because the FDA arbitrarily excluded the Schummers study from consideration. Dkt. 78-6 at 98, 133. This circular logic suggests that the justification for the prescriber certification ETASU is inadequate.

Third, the FDA failed to address statutorily required factors in determining that the prescriber certification ETASU should be retained. ETASUs are warranted only if approval would be withdrawn for the drug without the restrictive element. 21 U.S.C. § 355-1(f)(1)(A). The FDA does not provide any evidence that the risks of mifepristone are so high that approval would be withdrawn without the prescriber certification ETASU, stating only that "[h]ealthcare provider certification continues to be a necessary component of the REMS to ensure that the benefits of mifepristone for medical abortion outweighs the risks." Dkt. 78-6 at 99. This conclusory statement is insufficient to meet the heightened burden to justify an ETASU.

Ultimately, the Agency fails to explain why the certification is essential to confirm provider competency, offers no supporting studies or data, and does not justify why longstanding medical ethics are insufficient to ensure the drug's benefits outweigh its risks or to minimize the strategy's burden on the healthcare system. Instead, it shifts the burden, requiring the sponsor and petitioners to prove a negative. *Michigan* v. *EPA*, 576 U.S. 743, 759 (2015) (holding that agency action that ignored the clear statutory text is unreasonable). Such a justification fails to meet the APA's requirement for reasoned decision-making and is therefore arbitrary and capricious.

ii. Patient agreement

Although the FDA repeatedly acknowledged that informed consent is a standard medical practice, it nonetheless concluded that retaining the one-page patient agreement ETASU is necessary (1) to ensure patients receive accurate, clear, and standardized counseling on mifepristone's potential serious risks, and (2) to document compliance with the REMS. Dkt. 78-6 at 99–103. The FDA asserts that this requirement supports the 2023 REMS goal of helping ensure mifepristone's benefits outweigh its risks by informing patients about serious adverse events. *See* Dkt. 78-7 at 278–79 (explaining mifepristone REMS goals)

The Agency's analysis of the patient agreement requirement in the 2021 Rationale was limited to literature addressing general informed consent, none of which measured health outcomes. Dkt. 78-6 at 101–02. Based on this review, the FDA concluded that it could not determine whether the form was necessary and thus declined to remove it. *Id*. It further speculated, without evidence, that increased prescribing resulting from the elimination of the in-person dispensing requirement might impair adequate patient counseling, justifying retention of the patient agreement. *Id*. at 102–03. This reasoning misstates the requirements to impose an

ETASU, which may be required only if the risks of the drug are so substantial that without it, approval for the drug would be withdrawn. 21 U.S.C. § 355-1(f)(1)(A). The FDA instead shifted the burden, stating that its literature review "d[id] not provide evidence that would support removing ETASU D." Dkt. 78-6 at 102. The FDA also characterized ETASUs as permissible if they "do[] not impose an unreasonable burden on providers or patients." *Id*. at 103. This directly contravenes 21 U.S.C. § 355-1(f)(1)(A), a statutorily mandated factor.

The FDA's general reasoning is also thin and lacks adequate supporting evidence. The FDA did not identify how the patient agreement offers protections beyond those already provided by standard medical counseling, FDA-approved drug labeling, or the medication guide. In fact, in 2016, the Agency found that (1) mifepristone's safety profile was well-established; (2) informed consent was already standard practice, rendering the patient agreement duplicative; and (3) abortion providers already included the form's content in their own materials. *Id*. at 100–01. At that time, the FDA recommended eliminating the patient agreement form requirement so long as other REMS elements remained in place. *Id*. Nonetheless, the FDA Commissioner later rejected that recommendation, stating only that the form "would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care." Dkt. 78-2 at 111.

An agency action is arbitrary and capricious where an agency does not perform a reasoned analysis that includes "a rational connection between the facts found and the choice made." *See W. Va. Dep't of Env't Prot.*, 64 F.4th at 502 (quoting *Friends of Buckingham v. State Air Pollution Control Bd.,* 947 F.3d 68, 83 (4th Cir. 2020)). Here, the FDA fails to explain why the patient agreement ETASU is not redundant, or why it is necessary to achieve the REMS

objectives thereby ensuring the drugs benefits exceed its risks. Absent a reasoned analysis, the Agency's decision cannot stand.

iii. Pharmacy certification

The 2023 REMS incorporates a new pharmacy certification ETASU into its mifepristone regulatory strategy. The FDA stated this restriction may burden the healthcare system and patient access, as it "will likely limit the types of pharmacies that will choose to certify in the REMS." Dkt. 78-7 at 284. But the Agency concluded that this element advances the 2023 REMS goal of ensuring pharmacies comply with REMS requirements and dispense mifepristone only upon prescriptions from certified prescribers, thereby mitigating associated risks. *See id*. at 278–79.

The FDA may only institute a new ETASU when it determines such an element is essential because a drug poses a "serious adverse drug experience," including death, immediate risk of death, or hospitalization and its approval would be withdrawn but for the implementation of the prescribed ETASU. 21 U.S.C. § 355-1(f)(1)(A), (b)(4). Here, the FDA provides no authority or evidence that the pharmacy certification ETASU mitigates the identified serious risks associated with mifepristone. Instead, it offers only unsupported assertions that this requirement helps enforce the prescriber certification ETASU, particularly in light of a speculative increase in prescribers following the elimination of the in-person dispensing requirement. These justifications rest on unfounded assumptions that (1) the number of prescribers will significantly rise, and (2) this increase will compromise the safe distribution of mifepristone. *See Appalachian Voices*, 25 F.4th at 274 (holding that failure to explain speculations unsupported by data was arbitrary and capricious). Accordingly, the imposition of the pharmacy certification REMS is also arbitrary and capricious.

Ultimately, while the FDA is afforded deference, it cannot merely assert a belief without offering a reasoned basis. It is incumbent upon an agency to articulate a rational explanation for its decision, particularly when the administrative record suggests a different conclusion. *See State Farm*, 463 U.S. at 56–57. Agencies must do more than offer conclusory statements; the arbitrary and capricious standard does not permit rulemaking to rest on little more than "because we said so." *Azar*, 973 F.3d at 276 (citations omitted). The FDA failed to identify specific facts or offer a reasoned explanation to support its conclusion that REMS modifications removing the in-person dispensing requirement, maintaining the prescriber certification and patient agreement ETASUs, and adding a new pharmacy certification ETASU ensured that mifepristone's benefits outweigh its risks or reduced the burdens on the healthcare system. The 2023 REMS are accordingly arbitrary, capricious, and invalid under the APA. Plaintiffs' motion for summary judgment on Count II is therefore **GRANTED**, and Defendants' motion on Count II is **DENIED**.

C. The 2023 REMs violate Plaintiffs' constitutional right to equal protection

Under the APA, a court may set aside an agency action that is contrary to a constitutional right. *See* 5 U.S.C. § 706(2)(B). Counts III and IV of the Complaint allege that the 2023 REMS should be vacated for impermissibly violating the equal protection clause of the Fifth Amendment by treating "providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication." Dkt. 1 ¶ 158. In the agency context, rational basis review of an equal protection claim tracks the APA standard, requiring that the agency articulate a reasoned explanation grounded in the record for any differential treatment. *See Cooper Hosp./Univ. Med. Ctr.*, 179 F. Supp. 3d at 47. Since I conclude that the FDA acted arbitrarily and capriciously in issuing the 2023 REMS modification, I also find that the record lacks any rational basis for

subjecting mifepristone prescribers, providers, and patients to stricter requirements than those imposed for comparable drugs. Therefore, Defendants' motion for summary judgment on Plaintiffs' constitutional claims (Counts III and IV) is **DENIED**.

CONCLUSION

The REMS modifications are arbitrary and capricious. The FDA has steadfastly found, over the past quarter century, that mifepristone is a safe and effective medication. The explanation for the REMS and ETASUs imposed by the FDA in 2023 does not identify the risk alleviated by the restrictions. Nor does the FDA explain how, without these restrictions, prescribing the drug becomes an intolerable risk which would require withdrawal of the drug from the market. The FDA failed to reasonably justify its 2023 REMS modification decision, disregarding substantial contrary evidence from the medical community and comparative regulatory data, and inadequately addressing the burdens imposed on providers and patients. While Plaintiffs' claim that the FDA exceeded its statutory authority fails, the Agency's failure to consider relevant evidence and provide a reasoned explanation renders the 2023 REMS modification arbitrary and capricious in violation of the APA and the Fifth Amendment. Accordingly, Plaintiffs' motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART**; Defendants' cross-motion is likewise **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs' claim that the Agency exceeded its statutory authority (Count I) is **DISMISSED**. Plaintiffs prevail on their claim that the 2023 REMS modification violates the APA (Count II), and their constitutional claims survive summary judgment. "[T]he remedy of remand without vacatur principally is relevant in matters where agencies have 'inadequately supported rules.'" *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 655 (4th Cir. 2018) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir.

1993)). Because the 2023 REMS modification is inadequately supported, it will be **REMANDED** to the FDA for further proceedings consistent with this opinion following determination of the status of the constitutional claims.

It is so **ORDERED**.

Entered: July 23, 2026

Robert S. Ballou

Robert S. Ballou
United States District Judge