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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026-TOR PLAINTIFF STATES' RESPONSE TO NOTICE OF SUPPLEMENTAL INFORMATION

At the oral argument held in this matter on March 28, 2023, the Court asked Defendants' counsel what other drugs require pharmacy certification. Counsel responded that he did not have an example off the top of his head of such a drug. On March 29, 2023, Defendants filed a Notice of Supplemental Information (ECF No. 71) listing 43 medications. The Plaintiff States respectfully submit this response to Defendants' Notice.

Although the drugs listed in Defendants' Notice are subject to some form of pharmacy certification requirement, *none* of those requirements resemble the uniquely onerous pharmacy requirements imposed by the mifepristone REMS. The pharmacy certification requirement adopted by FDA for mifepristone in January 2023 is unique to that drug alone because it is the only REMS that requires individual pharmacies to independently create a secure system to verify prescriber certification (and, moreover, only applies when the drug is used for abortion or miscarriage care, not when a higher and more frequent dose is used to treat Cushing's disease). *See* ECF No. 35 ¶ 146.

This distinction is crucial in terms of the burdens it imposes on patient access and the healthcare delivery system. 21 U.S.C. §§ 355-1(f)(2)(C)-(D) (providing that ETASU must not be "unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system."). For the drugs listed in Defendants' Notice, certified pharmacies may simply look up the certified prescriber and/or the enrolled patient in a centralized database, which

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is maintained by the drug's sponsor, to verify the provider's certification and/or the patient's enrollment in the REMS program. *See generally* Appendix A. Indeed, the REMS for these drugs establish these national, centralized clearinghouses. *Id.* This allows pharmacists nationwide to quickly and easily check the database when dispensing a prescription. *See id.* As reflected by the list of drugs in Defendants' Notice, these pharmacy-certification requirements are imposed only on drugs with significant risk profiles that require additional safeguards at the point of dispensing to ensure patient safety.[1] These life-threatening and often fatal risks include serious liver injury and severe birth defects (Tracleer); heart failure (Camzyos); sudden death (Caprelsa); rapidly life-threatening and fatal infections (empaveli); liver toxicity, liver failure, and severe birth defects (Filspari); pulmonary embolisms (Sublocade); addiction and overdose (fentanyl and Xyrem/Xyway); and valvular heart disease and pulmonary arterial hypertension (Fintepla), among others. *See id.* Yet despite these potentially fatal side effects, the pharmacy certification requirements imposed on mifepristone—an extremely safe drug that does not qualify for any REMS whatsoever—are uniquely burdensome.

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[1] Indeed, several of the drugs listed in Defendants' Notice cannot be dispensed directly to patients at all, but only to health care providers in a healthcare setting, such as Sublocade, Tecvayli, Tysabri, Zulresso, Xiaflex, and Zyprexa Relprevv. *See* Appendix A.

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The mifepristone REMS alone impose the entire administrative burden solely on each individual certified pharmacy to create its own secure, dynamic system for tracking and storing providers' certification information. Unlike for the drugs listed in Defendants' Notice, there is no centralized system for pharmacists to check relevant information for purposes of a mifepristone prescription. Instead: (1) each provider must separately send their certification information to *each and every* certified pharmacy dispensing a prescription written by the provider; (2) each pharmacy must ensure it receives certification information from each prescriber on every mifepristone prescription; and (3) each pharmacy must separately track this information by creating its own secure, dynamic database of certified prescribers. *See* ECF No. 1-13 at 4; ECF No. 4-1: Colwill Decl. ¶ 19, DasGupta Decl. ¶¶ 8–9, Downing Decl. ¶ 8, Godfrey Decl. ¶ 26.

This is far more time-consuming and burdensome than for the high-risk drugs listed in Defendants' Notice. Instead of simply checking a centralized database, individual certified pharmacies must build and maintain their own secure, dynamic data-management systems to track and store the certification information they have received from each prescriber of mifepristone. DasGupta Decl. ¶ 15–16, Downing Decl. ¶¶ 10–11, Prager Decl. ¶ 35, Reed Decl. ¶ 6, Singh Decl. ¶¶ 12–13. And instead of sending their certifications and any other pertinent information to a single location, providers must likewise send them to *each and*

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every certified pharmacy before that pharmacy may dispense to their patients. Colwill Decl. ¶ 19, DasGupta Decl. ¶ 8, Downing Decl. ¶ 8, Godfrey Decl. ¶ 26, Gold Decl. ¶ 18, Shih Decl. ¶¶ 18, 23.

This decentralized, patchwork process negatively impacts patients, as well. Whereas the centralized systems that are in place for other REMS-restricted drugs allow *any* certified pharmacy to dispense a prescription written by *any* certified prescriber, the mifepristone REMS only allows a certified pharmacy to dispense a prescription written by a provider who has sent their certification to *that particular pharmacy*. Colwill Decl. ¶ 19, DasGupta ¶ 8, Downing Decl. ¶ 10, Godfrey Decl. ¶ 26, Gold Decl. ¶ 18, Shih Decl. ¶¶ 18, 23. This piles onto the complex and confusing requirements that patients already have to navigate to obtain a prescription for mifepristone in the first place, further delaying and blocking access to care to this time-sensitive medication. *See, e.g.*, Gold Decl. ¶ 24, Janiak Decl. ¶ 23, Lazarus Decl. ¶ 17, Shih Decl. ¶ 27. To be sure, a centralized database is not the answer for mifepristone, as the existence of any database poses threats to provider safety. *See* ECF No. 1-9 at 3–4; ECF No. 4-1: Godfrey Decl. ¶ 27, Gold Decl. ¶¶ 17–19, Janiak Decl. ¶ 20, Prager Decl. ¶¶ 38–40, Shih Decl. ¶¶ 23–25. The point is that the mifepristone pharmacy REMS are uniquely onerous and apply to a drug for which the imposition of *any* REMS is unlawful.

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In sum, as indicated at oral argument, the mifepristone REMS is uniquely burdensome—indeed, no other drug is subject to its uniquely onerous pharmacy certification requirement. Given mifepristone's proven safety record, FDA does not even attempt to argue the drug could possibly meet the statutory standard for a REMS in the first place. And, in square violation of the governing statute, FDA implemented the January 2023 REMS without ever considering how the REMS negatively impacted patient access, the blast radius from *Dobbs*, or the resulting (and compounding) effect of the REMS on rural and underserved patients. The mifepristone REMS—all three components of it—is contrary to law, arbitrary, and capricious.

DATED this 30th day of March, 2023.

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**Applications for pro hac vice admission forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 30th day of March, 2023, at Seattle, Washington.

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