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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 DEFENDANTS' MOTION FOR EXTENSION OF TIME 03/07/2023[1] Without Oral Argument

[1]Due to the urgency of this matter, the Plaintiff States are filing this response well in advance of the March 6, 2023, deadline. *See* ECF No. 18. Because the Court's briefing schedule on this motion authorized a response and no further briefing, the Plaintiff States understand this motion to now be ripe for decision. *Id.*

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I. INTRODUCTION

The Plaintiff States oppose Defendants' Motion for Extension of Time (ECF No. 16) to respond to the Plaintiff States' Motion for Preliminary Injunction (PI Motion) (ECF No. 3). The Plaintiff States moved for preliminary relief to protect access to critically important abortion and miscarriage care at a time when access to reproductive health care is under unprecedented attack. The FDA's newly-enacted REMS restrictions unnecessarily limit who can prescribe, dispense, and obtain mifepristone for medication abortion, which unduly restricts access to this time-sensitive and extremely safe medication, leading to worse outcomes for patients and creating substantial and continuing burdens on providers and pharmacies. This is an urgent matter, and Defendants' request for an extended briefing and hearing schedule should be denied.

II. ARGUMENT

A. The Fourteen-Day Time Period Prescribed in the Local Rules Controls

Local Civil Rule 7 provides Defendants with fourteen days to respond to the Plaintiff States' PI Motion, i.e., until March 10, 2023. *See* LCivR 7(c)(2)(B), (b)(3). Extending this deadline requires a showing of "good cause." Fed. R. Civ. P. 6(b)(1); *see also Algaier v. CMG Mortg., Inc.*, No. 13-CV-0380-TOR, 2014 WL 129286, at *12 (E.D. Wash. Jan. 14, 2014); *Dysart v. Ames*,

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No. 13-CV-0261-TOR, 2014 WL 1364961, at *2 (E.D. Wash. Apr. 7, 2014). Defendants fail to establish good cause for the extension they seek.

B. Plaintiff States Did Not Delay in Moving for a Preliminary Injunction

Defendants assert that the Plaintiff States "delay[ed]" in seeking a preliminary injunction—thus justifying a departure from the ordinary briefing schedule. ECF No. 16 at 2. This argument buries the most important facts. The REMS at the heart of this dispute did not take effect until January 3, 2023, and this challenge to final agency action was not ripe until that date. 5 U.S.C. § 704. In the time between the effective date of the REMS and the Plaintiff States' filings, this coalition of twelve states convened and drafted an 82-page Complaint and a 34-page PI Motion. In support of these filings, the Plaintiff States submitted approximately 800 pages of exhibits and evidence, including expert and technical evidence. Much of this evidence covers the impact of the REMS since its January 2023 effective date—evidence that would have been impossible to provide had the Plaintiff States filed their PI Motion sooner. In short, the seven weeks to prepare and file Plaintiff States' papers cannot be characterized as a "delay"—much less an "extreme delay"—under these circumstances. To the contrary, the timeline on which the Plaintiff States filed their Complaint and PI Motion were consistent with the level of urgency this case presents.

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C. An Extension Would Result in Severe Prejudice to Plaintiff States

A delay in hearing the PI Motion will severely prejudice the Plaintiff States. The 2023 REMS restrictions are harming the Plaintiff States every day that they remain in effect. In today's post-*Dobbs* landscape, in which the actions of anti-abortion state governments have strained access to abortion care even in states where abortion is a protected right, the 2023 REMS is exacerbating a crisis in abortion access of unprecedented proportions—warranting swift action by the Court.

Since *Dobbs*, the Plaintiff States have seen a huge influx of out-of-state patients seeking abortions. Cantrell Decl. ¶¶ 5, 7;[2] Dillon Decl. ¶¶ 8–13. For example, in January 2023, Planned Parenthood of Greater Washington and Northern Idaho saw a 75% increase in Idaho patients, as compared with January 2022. Dillon Decl. ¶ 10. "This includes a . . . 90% increase for medication abortion visits from Idaho." *Id.* This increased patient volume has led to delays in abortion care and other consequences, including higher risks of complications, increased costs, and unnecessary trauma and stress for patients in the Plaintiff States, as well as increasing burdens on an already overtaxed healthcare system. *Id.* at ¶¶ 14–22; Godfrey Decl. ¶¶ 28, 31; [FDA's] Opp'n to Pls.' Mot. for a Prelim. Inj., *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023), ECF No. 28 at 38–39; Compl. ¶ 142. By making mifepristone

[2]All declaration cites are to the declarations filed at ECF No. 4-1.

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harder to prescribe, dispense, and obtain, the REMS exacerbates these growing harms. Gold Decl. ¶¶ 15–16, 27; Godfrey Decl. ¶¶ 17–22; Shih Decl. ¶¶ 21–29; Colwill Decl. ¶¶ 18–25; Nichols Decl. ¶ 38; Janiak Decl. ¶¶ 15–20; Downing Decl. ¶¶ 9–16; Henry Decl. ¶¶ 6–8; Lazarus Decl. ¶¶ 17–20; Compl. ¶¶ 136–138.

Further, the 2023 REMS works in concert with post-*Dobbs* legislation in anti-abortion states to limit access to abortion even in states where it is legal. As medical expert Marji Gold explains:

> In the current hostile environment surrounding abortion care, which includes states passing bills that empower ordinary citizens to sue anyone they deem has "aided and abetted" a person seeking an abortion, clinicians may be reluctant to become certified and thus be identified as a person who prescribes mifepristone. Since the REMS requires certified prescribers to send their signed forms to *each* certified pharmacy at which they intend to prescribe, clinicians who wish to provide this care have reason to be concerned that an anti-abortion staff or pharmacist at a pharmacy might leak the confidential list and expose them to possible violence and/or civil or criminal liability. These concerns may be greater in communities with outspoken anti-abortion members, and thus decrease patient access to care.

Gold Decl. ¶ 18; *see also id.* at ¶ 19 (explaining the particular risk to patients who hold medical licenses in multiple states, including anti-abortion states); Prager Decl. ¶¶ 38–40; Shih Decl. ¶ 25.

For patients seeking to terminate a pregnancy, mere days can make a critical difference. The delays in treatment arising from the REMS—whether due to a lack of specifically "certified providers" (Godfrey Decl. ¶ 30) or pharmacies (Shih Decl. ¶ 27), a lack of access to technology required to e-sign the Patient

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Agreement Form (*id.* at ¶ 17), or lagging or incomplete REMS-required paperwork (DasGupta Decl. ¶ 10)—may cause patients to miss the narrow window for medication abortion. Compl. ¶ 81 (mifepristone is only approved for use up to 70-days' gestation); Shih Decl. ¶ 17 ("[D]elaying the process even by a few days may make [some patients] ineligible to select medication abortion."); Colwill Decl. ¶ 24. Even a few days' delay may force such patients to choose between undergoing an invasive procedural abortion or carrying an unwanted pregnancy to term. Compl. ¶ 152 (detailing negative outcomes experienced by patients who are denied abortions); *id.* at ¶¶ 143–44 (explaining why surgical abortion may be inappropriate or inaccessible to certain patients).

These increasing harms are falling most heavily on those furthest from healthcare justice, including rural and poor communities that have inferior access to reproductive health care. Gold Decl. ¶ 23; Janiak Decl. ¶¶ 14, 25–29; Downing Decl. ¶ 17; Dillon Decl. ¶ 7; Godfrey Decl. ¶¶ 15, 17, 19, 32; Nichols Decl. ¶ 38; Compl. ¶ 121.

Finally, implementing the new REMS requirements has created ongoing burdens for state healthcare providers, resulting in mounting costs and an ongoing diversion of resources from patient care and other critical work. University of Washington personnel, for example, have expended hundreds of hours implementing the 2023 REMS, with many tasks still outstanding. Compl. ¶ 152; DasGupta Decl. ¶¶ 15–18; Godfrey Decl. ¶ 35; Prager Decl. ¶¶ 25–36; Reed

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Decl. ¶¶ 16–17; Singh Decl. ¶¶ 20–21. These harms are occurring now, because of the 2023 REMS, and they are urgent. Any further delay in addressing them will continue to prejudice the Plaintiff States.

D. Defendants Would Suffer No Prejudice in Adhering to the Ordinary Briefing Deadlines

By contrast, Defendants will suffer no prejudice if they are required to respond to the Plaintiff States' motion on time. The U.S. Department of Justice's Consumer Protection Branch has represented the FDA in a number of recent challenges to its regulation of mifepristone, including its imposition of the REMS. *See, e.g.*, [FDA's] Opp'n to Pls.' Mot. for a Prelim. Inj., *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023), ECF No. 28 (Consumer Protection Branch defending challenge to FDA's approval of mifepristone; preliminary injunction motion pending); *Chelius v. Wright*, No. 1:17-cv-00493-JAO-RT (D. Haw. May 7, 2021), ECF No. 148 (Consumer Protection Branch defending challenge to FDA's previous version of REMS; stayed by joint agreement of parties after FDA agreed to re-examine the REMS); *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 189 (D. Md. 2020) (Consumer Protection Branch defending challenge to FDA's previous version of REMS; preliminary injunction granted against FDA). At this point, lawyers with the Consumer Protection Branch have been litigating the facts and law surrounding the REMS for years. In light of their familiarity

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with the issues, and the urgency facing the Plaintiff States, good cause does not support an extended briefing schedule.

E. The Plaintiff States' PI Motion Should Be Heard as Soon as Possible

In recognition of the urgency of the matter, the Plaintiff States propose to file a reply in support of their PI Motion within five days instead of the usual seven, *see* LCivR 7(d)(2)(B), allowing this matter to be fully briefed for a hearing on March 16, 2023, a date the Court had previously indicated may be available. Although that hearing date is earlier than the default time period under Local Rules, it is appropriate under Local Rule 7(i)(2)(C).

For all the reasons explained above and in the Plaintiff States' PI Motion, this case involves an urgent issue, and good cause supports an expedited hearing. LCivR 7(i)(2)(C)(1). Defendants' request for an extended briefing and hearing schedule indicates that Defendants oppose the Plaintiff States' request for an expedited hearing, LCivR 7(i)(2)(C)(2), but as detailed above, Defendants' request for an extension should be denied. Finally, the Plaintiff States' proposed March 16 hearing date is twenty days after the Motion for Preliminary Injunction was filed, and therefore well within the bounds for expedited hearings. LCivR 7(i)(2)(C)(3). Indeed, under the Plaintiff States' proposed five-day reply turnaround, briefing will be complete before March 16 without affecting Defendants' briefing schedule at all.

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III. CONCLUSION

For the foregoing reasons, the Plaintiff States respectfully request that the Court deny Defendants' motion for an extension of time and require Defendants to file their response to the Plaintiff States' PI Motion no later than March 10, 2023, in accordance with the local rules.

DATED this 1st day of March 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on March 1, 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 1st day of March 2023, at Seattle, Washington.

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