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18 UNITED STATES DISTRICT COURT
19 FOR THE EASTERN DISTRICT OF WASHINGTON

20 STATE OF WASHINGTON, *et al.*,

21 Plaintiffs,

22 v.

23 U.S. FOOD AND DRUG
24 ADMINISTRATION, *et al.*,

25 Defendants.

No. 1:23-cv-03026

DEFENDANTS' MOTION FOR
CLARIFICATION

05/10/23

WITHOUT ORAL ARGUMENT

1 Plaintiffs challenge FDA’s January 3, 2023, approval of modifications to the
2 Risk Evaluation and Mitigation Strategy (REMS) for mifepristone.¹ On April 7,
3 2023, this Court declined to preliminarily enjoin FDA from enforcing or applying
4 any requirement of mifepristone’s REMS. Order at 26-27. But the Court
5 preliminarily enjoined the agency from “altering the status quo and rights as it
6 relates to the availability of Mifepristone under the current operative January 2023
7 Risk Evaluation and Mitigation Strategy [(REMS)] under 21 U.S.C. § 355-1 in
8 Plaintiff States.” Order at 30.

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12 Shortly before this Court entered its order, the United States District Court
13 for the Northern District of Texas entered an order invoking 5 U.S.C. § 705 to stay
14 the approval of the new drug application and abbreviated new drug application for
15 mifepristone. *See Alliance for Hippocratic Medicine v. FDA*, 2:22-cv-00223-Z,
16 Dkt. 137 (Apr. 7, 2023). That court stayed its order for seven days to give FDA
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20 _____
21 ¹ This motion uses the term “mifepristone” to refer to drug products that are
22 approved for medical termination of early pregnancy, in both brand name and
23 generic form. FDA has separately approved another manufacturer’s drug, Korlym,
24 which has mifepristone as its active ingredient and is approved for the treatment of
25 Cushing’s syndrome. This litigation, including the Court’s order, does not affect
26 Korlym or its generic.
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DEFENDANTS’ MOTION FOR CLARIFICATION

1 time to seek relief from the United States Court of Appeals for the Fifth Circuit,
2 and FDA is seeking an emergency stay pending appeal. But if the Texas district
3 court’s order takes effect, the order would—of its own force and without any
4 further action by FDA—stay the effectiveness of FDA’s prior approvals of
5 mifepristone nationwide. *See id.*
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8 The result of that order appears to be in significant tension with this Court’s
9 order prohibiting FDA from “altering the status quo and rights as it relates to the
10 availability of Mifepristone” in Plaintiff States. Order at 30. The Court did not
11 address the interaction between the two orders, presumably because they were
12 issued less than 20 minutes apart. To ensure that Defendants comply with all court
13 orders in these unusual circumstances, Defendants respectfully request that this
14 Court clarify their obligations under its preliminary injunction in the event that the
15 *Alliance* order takes effect and stays the approval of mifepristone.
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1 April 10, 2023

HILARY K. PERKINS
Assistant Director

2
3 /s/ Noah T. Katzen
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DEFENDANTS' MOTION FOR CLARIFICATION

CERTIFICATE OF SERVICE

I hereby certify that, on April 10, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen

NOAH T. KATZEN