

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

WHOLE WOMAN’S HEALTH ALLIANCE, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Case No. 3:23-cv-00019-RSB

**PLAINTIFFS’ REPLY MEMORANDUM IN FURTHER SUPPORT OF
RETAINING JURISDICTION PENDING REMAND TO FDA**

Defendants do not dispute that this Court has the authority to retain jurisdiction over this case pending the completion of FDA’s mifepristone review. *See* ECF Doc. 101 at 4–5 (citing cases). Nor do they dispute that it would be improper for FDA to disregard the statutory factors that should guide its mifepristone review in favor of political considerations. Instead, Defendants disparage Plaintiffs’ concern about political interference with FDA’s review as “unfounded speculation.” ECF Doc. 102 at 4. Far from it — Plaintiffs have the receipts.

Last week, in response to a FOIA request, Plaintiffs’ counsel received a production of FDA documents that included a September 3, 2025 email from an “eop.gov” email address asking FDA and HHS for “a briefing on the status of the FDA [mifepristone] study design and proposed timelines.” Exhibit A. “EOP” stands for “Executive Office of the President” and “eop.gov” is the email address for the White House. An HHS employee agreed the agencies would “do our best to accommodate.” *Id.* This document confirms that the threat of political interference with FDA’s review of the scientific evidence is very real. This Court should exercise its authority to retain jurisdiction so that “if the need arises, further action could be taken by the Court,” just as the

district court did in *American Academy of Pediatrics v. Food and Drug Administration*, 399 F. Supp. 3d 479, 487 (D. Md. 2019).

CONCLUSION

For the reasons stated here and in Plaintiffs' initial memorandum, Plaintiffs respectfully request that the Court retain jurisdiction while the 2023 REMS Decision is on remand to the FDA.

Dated: October 9, 2026

Respectfully submitted,

/s/ Linda C. Goldstein

Gail M. Deady

Virginia Bar Number: 82035

Linda C. Goldstein (*pro hac vice*)

CENTER FOR REPRODUCTIVE RIGHTS

199 Water Street, 22nd Floor

New York, New York 10038

Telephone: (917) 637-3600

Fax: (917) 637-3666

Email: gdead@reprorights.org

Email: lgoldstein@reprorights.org

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of October, 2026, I filed the foregoing *Reply Memorandum of Law in Further Support of Retaining Jurisdiction Pending Remand to FDA* with the Clerk of Court using the CM/ECF system.

/s/ Linda C. Goldstein

Linda C. Goldstein

EXHIBIT A

From: (b)(6) <(b)(6)@hhs.gov>
Sent: Wednesday, September 10, 2025 7:01 PM
To: (b)(6) <(b)(6)eop.gov> (b)(6) <(b)(6)eop.gov>; (b)(6) <(b)(6)@fda.hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)eop.gov> (b)(6) <(b)(6)@hhs.gov>
Cc: (b)(6) <(b)(6)@hhs.gov> (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)s.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@fda.hhs.gov>; (b)(6) <(b)(6)@fda.hhs.gov>
Subject: RE: Reevaluation of Mifepristone

Good evening:

Attached is a clean version of the letter. We will wait to email this out tonight until we receive final WH clearance. We will do no press.

Thank you!

(b)(6)

U.S. Department of Health and Human Services

Predecisional, deliberative, confidential

From: (b)(6) <(b)(6)eop.gov>
Sent: Thursday, September 4, 2025 1:33 PM
To: (b)(6) <(b)(6)@hhs.gov> (b)(6) <(b)(6)eop.gov>; (b)(6) <(b)(6)@fda.hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)eop.gov> (b)(6) <(b)(6)@hhs.gov>
Cc: (b)(6) <(b)(6)@hhs.gov> (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov>
Subject: RE: Reevaluation of Mifepristone

Thank you all! (b)(6) we will need one more look at the WH before it goes out so please send back when you can.

(b)(6)

From: (b)(6) <(b)(6)@hhs.gov>
Sent: Wednesday, September 3, 2025 10:52 PM
To: (b)(6) <(b)(6)eop.gov> (b)(6) <(b)(6)eop.gov>; (b)(6) <(b)(6)@fda.hhs.gov>; (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)eop.gov> (b)(6) <(b)(6)@hhs.gov>
Cc: (b)(6) <(b)(6)@hhs.gov> (b)(6) <(b)(6)@hhs.gov>; (b)(6) <(b)(6)@hhs.gov> (b)(6)

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)

@hhs.gov>;

(b)(6)

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)@fda.hhs.gov>

Subject: Re: Reevaluation of Mifepristone

Thank you (b)(6). We are reviewing this and will get this letter out asap (b)(6), could you suggest some times for next week to meet with (b)(6) the study (b)(6) and I will do our best to accommodate.

(b)(6)

From: (b)(6)@eop.gov>**Sent:** Wednesday, September 3, 2025 11:17:01 AM**To:** (b)(6)@hhs.gov>; (b)(6)

(b)(6)

@eop.gov>;

(b)(6)

<(b)(6)

@fda.hhs.gov>;

(b)(6)

<(b)(6)@hhs.gov>;

(b)(6)

@eop.gov>;

(b)(6)

(b)(6)

@hhs.gov>

Cc: (b)(6)@hhs.gov>; (b)(6)

@hhs.gov>;

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>

(b)(6)

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)

@hhs.gov>;

(b)(6)

s.gov>;

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)@fda.hhs.gov>

Subject: RE: Reevaluation of Mifepristone

Hi all,

Please see attached edits from (b)(6). Let me know if we need to discuss – can do a call this evening.

I would also like to request a briefing on the status of the FDA study design and proposed timelines. Thank you!

Best,

(b)(6)

From: (b)(6)@hhs.gov>**Sent:** Friday, August 29, 2025 11:49 AM**To:** (b)(6)@eop.gov>; (b)(6)

(b)(6)

@eop.gov>;

(b)(6)

<(b)(6)

@fda.hhs.gov>;

(b)(6)

<(b)(6)@hhs.gov>;

(b)(6)

@eop.gov>;

(b)(6)

(b)(6)

@hhs.gov>

Cc: (b)(6)@hhs.gov>; (b)(6)

@hhs.gov>;

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>

(b)(6)

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)

@hhs.gov>;

(b)(6)

s.gov>;

(b)(6)

@hhs.gov>;

(b)(6)

<(b)(6)@fda.hhs.gov>

Subject: RE: Reevaluation of Mifepristone

Good morning:

Our (b)(6) has suggested a few additional edits to the letter (attached). We could also strike the words (b)(5) preferable, in the sentence where that occurs.

(b)(6)

(b)(6)

Pageid#: 3655

U.S. Department of Health and Human Services

Predecisional, deliberative, confidential

From: (b)(6)

Sent: Tuesday, August 26, 2025 9:07 PM

To: (b)(6)

eop.gov>

(b)(6)

(b)(6)

eop.gov>

(b)(6)

<(b)(6)

@fda.hhs.gov>

(b)(6)

<(b)(6)

@hhs.gov>

(b)(6)

eop.gov>

(b)(6)

(b)(6)

@hhs.gov>

Cc:

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>

(b)(6)

@hhs.gov>

(b)(6)

(b)(6)

@hhs.gov>

(b)(6)

<(b)(6)

@hhs.gov>

(b)(6)

s.gov>

(b)(6)

@hhs.gov>

(b)(6)

<(b)(6) @fda.hhs.gov>

Subject: RE: Reevaluation of Mifepristone

Good evening:

Attached, please find a draft of HHS/FDA's response the Attorneys General letter. We welcome WH feedback. This draft letter is also still subject to approval by Secretary Kennedy and Commissioner Makary.

Thanks,

(b)(6)

U.S. Department of Health and Human Services

Predecisional, deliberative, confidential

-----Original Appointment-----

From: (b)(6)

Sent: Monday, August 18, 2025 4:36 PM

(b)(6)

Subject: Reevaluation of Mifepristone**When:** Monday, August 18, 2025 5:00 PM-5:45 PM (UTC-05:00) Eastern Time (US & Canada).**Where:** <https://pitc.webex.com>

(b)(6)

Please see the call in information below if you keep it at 5p. Thanks!

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join
meeting

More ways to join:

Join from the meeting link

<https://pitc.webex>

(b)(6)

Join by meeting number

Meeting number (access code):

(b)(6)

Meeting password:

(b)(6)

when dialing from a phone)

Tap to join from a mobile device (attendees only)

+

(b)(6)

(b)(6)

(b)(6)

United States Toll

Some mobile devices may ask attendees to enter a numeric password.

Join by phone

+

(b)(6)

United States Toll

Global call-in numbers

Join from a video system or application

(b)(6)

You

(b)(6)

enter your meeting number.

If you are a host, [click here](#) and login site to view host information.

Need help? Go to <https://help.webex.com>