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10 **UNITED STATES DISTRICT COURT**
EASTERN DISTRICT OF WASHINGTON

11 STATE OF WASHINGTON, et al.,

12 Plaintiffs,

13 v.

14 UNITED STATES FOOD AND
 15 DRUG ADMINISTRATION, et al.,

16 Defendants.

NO. 1:23-cv-03026-TOR

DECLARATION OF KRISTIN
 BENESKI IN SUPPORT OF
 PLAINTIFF STATES' MOTION
 TO SUPPLEMENT THE
 ADMINISTRATIVE RECORD

02/20/2024
 Without Oral Argument

1 I, Kristin Beneski, declare as follows:

2 1. I am over the age of 18 and have personal knowledge of all the facts
3 stated herein.

4 2. I am the First Assistant Attorney General at the Washington State
5 Attorney General's Office, which represents the State of Washington in this matter.

6 3. Defendants produced the administrative record in this matter on a
7 rolling basis. The production consisted of 4 installments, which were provided on
8 June 16, July 14, August 10, and September 1, 2023. On September 1, 2023,
9 Defendants notified our office that their production of the administrative record
10 was complete and filed the Index of Administrative Record at ECF No. 127.

11 4. Following a comprehensive review of the administrative record by
12 attorneys in our office, we determined that a number of documents that were before
13 FDA when it decided to impose the current mifepristone REMS did not appear to
14 have been included in the produced record. On December 20, 2023, I emailed
15 Defendants' counsel to advise that certain documents or categories of documents
16 were missing from the filed administrative record, and requested that FDA
17 supplement the record accordingly. Defendants' counsel posed several follow-up
18 questions via phone on December 29, 2023, to which I responded via email on
19 January 2 and 3, 2024. A true and correct copy of my emails to Defendants' counsel
20 are attached hereto as **Exhibit A**.

21 5. I spoke with Defendants' counsel again on January 10 and January 19,
22 2024. During those calls, Defendants' counsel agreed to supplement the record to

1 include approximately seven of the documents or categories of documents I
2 identified, and advised that one of the documents I identified was already in the
3 produced record. Defendants' counsel stated that they declined to supplement the
4 record to include the following documents: (1) the October 4, 2022 citizen petition
5 submitted by the American College of Obstetricians and Gynecologists (ACOG)
6 and 48 other organizations (previously filed in this matter at ECF No. 61-1); (2) the
7 52 documents cited in the ACOG citizen petition; (3) FDA's January 3, 2023 letter
8 denying the ACOG citizen petition (previously filed in this matter at ECF No. 1-
9 20); and (4) the Turnaway Study.

10 I declare under penalty of perjury under the laws of the State of Washington
11 and the United States of America that the foregoing is true and correct.

12 DATED this 19th day of January, 2024, at Seattle, Washington.

13 /s/ Kristin Beneski
14 KRISTIN BENESKI, WSBA #45478
15 First Assistant Attorney General
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CERTIFICATE OF SERVICE

I hereby certify that on January 19th, 2024, 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 19th day of January 2024, at Seattle, Washington.

/s/ Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

Exhibit A

From: [Beneski, Kristin \(ATG\)](#)
To: "Katzen, Noah T."
Cc: [Melody, Colleen M \(ATG\)](#); [Fraas, Lauryn \(ATG\)](#); [Hughes, Andrew \(ATG\)](#); [REDACTED]
Subject: RE: Washington, et al. v. FDA (E.D. Wash.)
Date: Wednesday, January 3, 2024 5:20:21 PM

Noah and all,

I am following up regarding other studies/documents that are cited within the record but were not included in the produced administrative record. With a few significant exceptions noted below, the produced record generally includes the cited documents found within a record document. For example, as reflected in the Index (ECF No. 127), the produced record includes Dr. Chelius's letter to Dr. Woodcock dated 9/29/21 (2021 REMS 001159), and also includes each of the studies and other documents cited within that letter. Similarly, as reflected in the Index, the produced record includes the letter from a number of the plaintiff states to Sec. Azar dated 3/30/20 (2021 REMS 000035), and also includes each of the documents cited within that letter. There are other examples as well.

Like these other materials, the 2022 citizen petition filed by ACOG et al. was before FDA when it made the decision to impose the 2023 REMS. As with other portions of the record, the ACOG citizen petition should be included along with each of the 52 studies/documents cited therein (see the endnotes in the last 9 pages of that petition). Similarly, the 10/6/2021 ACOG letter listed in my original email contains a number of citations; the majority of those are included in the produced record, but two are missing, as indicated below. Additionally, per my last email, the Turnaway Study should also be included in the record.

In sum, the final bullet point from my original email below consists of:

- The Turnaway Study
- Each of the 52 documents cited in the 10/4/2022 ACOG citizen petition
- The following documents cited in the 10/6/2021 ACOG letter:
 - U.S. Food and Drug Administration. FDA Mission. Available at <https://www.fda.gov/about-fda/what-we-do>. Retrieved September 20, 2021.
 - Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2020;136:e31–47.

Thank you,
Kristin

Kristin Beneski
Direct: 206.464.7459 | Cell: 206.595.3024 | Email: kristin.beneski@atg.wa.gov

From: Beneski, Kristin (ATG)
Sent: Tuesday, January 2, 2024 10:40 AM
To: 'Katzen, Noah T.' <Noah.T.Katzen@usdoj.gov>
Cc: [Melody, Colleen M \(ATG\) <colleen.melody@atg.wa.gov>](mailto:Melody, Colleen M (ATG) <colleen.melody@atg.wa.gov>); [Fraas, Lauryn \(ATG\) <Lauryn.Fraas@ATG.WA.GOV>](mailto:Fraas, Lauryn (ATG) <Lauryn.Fraas@ATG.WA.GOV>); [Hughes, Andrew \(ATG\) <andrew.hughes@atg.wa.gov>](mailto:Hughes, Andrew (ATG) <andrew.hughes@atg.wa.gov>); [REDACTED] <[REDACTED]@fda.hhs.gov>; [REDACTED] <[REDACTED]@fda.hhs.gov>
Subject: RE: Washington, et al. v. FDA (E.D. Wash.)

Noah and all,

On our call last Friday, [REDACTED] requested that we identify the documents in the produced administrative record that cite the Turnaway Study (in reference to the last bullet point in my original email below). The citing references to the Turnaway Study are as follows:

- (2021 ED 000126-348) - *The Safety and Quality of Abortion Care in the United States*, National

Academies of Sciences, Engineering, and Medicine. (2018)

- o Cited three times at 2021 ED 000291
- (2021 REMS 001262-1269) - *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, American Journal of Public Health, (2014)
 - o Cited fourteen times at 2021 REMS 001262, 001263, 001265, 001266, 001267, 001268
- (2021 REMS 001052-1060) - *Who Seeks Abortions at or After 20 Weeks? Perspectives Sex & Reproductive Health* (2013)
 - o Cited twice at 2021 REMS 001053
- (2021 REMS 001784-1791) - *Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States*, Women's Health (2014)
 - o Cited seven times at 2021 REMS 001784, 001785, 001789, 001791
- (2021 REMS 000339-347) - *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, Journal of Women's Health (2019)
 - o Cited at 2021 REMS 000345
- (FDA 1254-1262) - Letter from ANSIRH, et al. to Ostroff, Califf, Woodcock & FDA (2016)
 - o Cited at FDA 1255
- (2023 SUPP 000229-238) - *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion A Prospective, Longitudinal Cohort Study*, JAMA (2017)
 - o Cited seven times at 2023 SUPP 000229, 000230, 000234

We will follow up with a further response regarding other studies/documents that are cited within the record but were not included in the produced administrative record.

Kristin

Kristin Beneski

Direct: 206.464.7459 | Cell: 206.595.3024 | Email: kristin.beneski@atg.wa.gov

From: Beneski, Kristin (ATG)

Sent: Friday, December 22, 2023 9:42 AM

To: Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>

Cc: Melody, Colleen M (ATG) <colleen.melody@atg.wa.gov>; Fraas, Lauryn (ATG)

<Lauryn.Fraas@ATG.WA.GOV>; Hughes, Andrew (ATG) <andrew.hughes@atg.wa.gov>; [REDACTED]
[REDACTED] <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>; [REDACTED] <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>

Subject: RE: Washington, et al. v. FDA (E.D. Wash.)

Thanks, Noah. That works for us. We'll circulate a calendar invitation with a dial-in shortly.

Kristin

Kristin Beneski

Direct: 206.464.7459 | Cell: 206.595.3024 | Email: kristin.beneski@atg.wa.gov

From: Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>

Sent: Friday, December 22, 2023 9:39 AM

To: Beneski, Kristin (ATG) <kristin.beneski@atg.wa.gov>

Cc: Melody, Colleen M (ATG) <colleen.melody@atg.wa.gov>; Fraas, Lauryn (ATG) <Lauryn.Fraas@ATG.WA.GOV>; Hughes, Andrew (ATG) <andrew.hughes@atg.wa.gov>; [REDACTED] <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>; [REDACTED] <[\[REDACTED\]@fda.hhs.gov](mailto:[REDACTED]@fda.hhs.gov)>

Subject: RE: Washington, et al. v. FDA (E.D. Wash.)

[EXTERNAL]

Kristin,

Thanks for reaching out and hope you are well, too. We are available during the Thursday and Friday windows below. Shall we say Friday at 1:30 ET?

Noah

From: Beneski, Kristin (ATG) <kristin.beneski@atg.wa.gov>

Sent: Wednesday, December 20, 2023 5:14 PM

To: Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>

Cc: Melody, Colleen M (ATG) <colleen.melody@atg.wa.gov>; Fraas, Lauryn (ATG) <Lauryn.Fraas@ATG.WA.GOV>; Hughes, Andrew (ATG) <andrew.hughes@atg.wa.gov>

Subject: [EXTERNAL] Washington, et al. v. FDA (E.D. Wash.)

Noah,

I hope you are well. We are writing to request that the FDA complete the administrative record by adding additional materials that were before the FDA when it decided to adopt the 2023 mifepristone REMS. We would like to confer with you about this request next week if possible. We would also like to discuss the status report that is due on January 12.

Our team is available on the following dates/times:

- Wednesday, Dec. 27: 1:00-5:30 ET / 10:00-2:30 PT
- Thursday, Dec. 28: 11:00-5:00 ET / 8:00-2:00 PT
- Friday, Dec. 29: 1:30-6:00 ET / 10:30-3:00 PT

The materials that we believe need to be included in the complete administrative record are the following:

- The 10/4/2022 citizen petition submitted by ACOG and 48 other organizations (ECF No. 61-1) and all documents/studies cited therein. As you know, Judge Rice has already recognized that this petition was "before FDA" when it decided to implement the REMS, and that therefore it would have been "futile" to file "another citizen petition" before challenging the REMS in court. ECF No. 80 at 17.
- The FDA's 1/3/2023 letter rejecting the 2022 ACOG petition. See ECF No. 80 at 17.
- The 10/6/2021 letter from ACOG to FDA (ECF No. 61-11).
- The appendix to the 9/29/2021 letter from the *Chelius* plaintiffs to the FDA (ECF No. 61-3).

- Certain webpages and FDA-approved labeling cited in the *Chelius* plaintiffs' 9/29/2021 letter—specifically:
 - FN 12: U.S. Food & Drug Admin., *Opioid Medications* (Mar. 29, 2021), <https://www.fda.gov/drugs/information-drug-class/opioid-medications>.
 - FN 16: U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Jeuveau) (Feb. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761085Orig1s000Lbl.pdf
 - FN 17: U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Propecia) (Apr. 2012), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020788s020s021s023lbl.pdf
 - FN 18: U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (NuvaRing) (Oct. 2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021187s022lbl.pdf
 - FN 21: U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Coumadin) (Oct. 2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf
- The 6/8/2011 Supplement Approval letter from FDA to Danco (ECF No. 51-2). This document is an exhibit to your declaration but was not included in the produced administrative record.
- The drug label for misoprostol. Since the FDA approved mifepristone for abortion as part of a two-drug regimen with misoprostol, the FDA necessarily would have considered the misoprostol label and it should be part of the administrative record.
- Prior mifepristone REMS from 2019 and 2021. Other prior mifepristone REMS were included in the produced administrative record, but these two are missing.
- All studies/documents cited in the materials above and in materials that are in the record. A notable example is the Turnaway Study, which is referenced in multiple record materials but was not included in the produced administrative record.

Thank you,
Kristin

Kristin Beneski
First Assistant Attorney General
Washington Attorney General's Office
Direct: 206.464.7459 | Cell: 206.595.3024 | Email: kristin.beneski@atg.wa.gov