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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

HEIDI PURCELL, M.D., FACOG, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIVIL ACTION
Case No. 1:17-cv-00493-JAO-RT

PLAINTIFFS' CONCISE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT; EXHIBIT VOLUMES A-D; CERTIFICATE OF SERVICE

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Mifepristone Regimen and Safety

1. To end an early pregnancy, patients can undergo a uterine aspiration in a clinical setting ("procedural abortion") or take prescription drugs to induce a miscarriage ("medication abortion"). 2021REMS748-49.
2. Both methods are very safe, and significantly safer than childbirth—which carries a risk of death 14 times higher than abortion. 2021REMS695-99; FDA859 & n.6; 2019CP46.
3. The FDA-approved medication abortion regimen involves: (1) *mifepristone* (*i.e.*, Mifeprex or generic), which blocks the effect of a hormone necessary to sustain pregnancy, and (2) *misoprostol*, which causes contractions and bleeding that empty the uterus. 2023SUPP1115; 2023SUPP104.
4. The same mifepristone-misoprostol regimen is the most effective regimen for medical miscarriage management. 2019CP402-11; 2022CP77-79.
5. FDA has approved mifepristone as part of this two-drug regimen through ten weeks of pregnancy. Joint Stips. of Facts ¶¶15, 46 (Apr. 15, 2021), Dkt. 140 ("Stips.").
6. Since 2016, mifepristone's labeling provides for 200mg of mifepristone orally, followed by four 200mcg tablets of misoprostol buccally, 24-48 hours later. Stips. ¶¶18, 46.
7. Mifepristone is a single tablet prescribed for a single use. Stips. ¶¶13, 46.

8. An estimated 5.6 million people in the U.S. used mifepristone for medication abortion between September 2000 and June 2022. 2023SUPP1045.

9. The World Health Organization classifies mifepristone and misoprostol as essential medicines. 2023SUPP104; FDA539.

10. Mifepristone offers a "meaningful therapeutic benefit" over procedural abortion that may be "preferable and safer in [a patient's] particular situation." FDA860 (FDA, 2016)[1]; *accord* FDA228.

11. Patients may prefer medication abortion, for instance, to avoid an invasive procedure or anesthesia, or because of contraindications for procedural abortion. 2021REMS749; 2021REMS963; FDA860.

12. Mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience," "serious complications have proven to be extremely rare," and "no new safety concerns" have arisen since 2005. FDA539; FDA535 (both FDA, 2016); FDA354 (FDA, 2013); *accord* 2019CP648.

13. Major adverse events associated with mifepristone are "exceedingly rare, generally far below 0.1% for any individual adverse event." FDA574 (FDA, 2016); *accord* 2021ED195.

[1] Direct quotations of FDA admissions appear as citations to the relevant source with "FDA" and the year in parentheses, if not evident from the citation.

14. Mifepristone's FDA-approved labeling identifies two potential risks: "[s]erious and sometimes fatal infections or bleeding." 2023SUPP1471-72; Stips. ¶¶19, 46.

15. Risks of serious infection and bleeding are not inherent to mifepristone but exist whenever a pregnancy ends, by any means. 2023SUPP1486 (FDA, 2023: "[R]arely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth."); *accord* 2023SUPP1471-72; Stips. ¶¶19, 46.

16. "No causal relationship between the use of Mifepristone tablets 200mg and misoprostol and [serious infections and bleeding] has been established." 2023SUPP1491 (FDA, 2023); 2023SUPP1472; Stips. ¶¶19, 46; *see also* 2019CP617.

17. FDA concluded that "the critical risk factor" for certain rare serious infections following mifepristone "[wa]s pregnancy itself." FDA880-81 n.69 (2016).

18. A small fraction of mifepristone users will have a follow-up procedure, typically for reasons FDA recognizes as "failed treatment rather than adverse events," like ongoing pregnancy or incomplete expulsion of pregnancy tissue. 2019CP664-65.

19. The follow-up procedure is identical to that used in procedural abortion or to treat an incomplete miscarriage. 2021ED199.

20. Leading medical authorities, including the American Medical Association ("AMA"), American College of Obstetricians and Gynecologists ("ACOG"), which represents more than 60,000 OBGYNS, and American Academy of Family Physicians ("AAFP"), oppose the mifepristone Risk Evaluation and Mitigation Strategy ("REMS") as "outdated," "medically unnecessary," detrimental to patients' access to abortion and miscarriage care, and "inconsistent with" FDA's regulation of "other medications with similar or greater risks." *E.g.*, 2021ED11-13 (ACOG: "inconsistent," "outdated and substantially limit[s] access to this safe, effective medication"); 2021REMS139; 2021REMS950-55 (SFP: "confers no benefit in terms of safety, efficacy, or acceptability" of mifepristone); 2021REMS2051-52; 2021REMS1168-71 (AAFP: "not based on scientific evidence and cause[s] significant barriers to accessing abortion care"); 2022CP71-98; 2023SUPP32-37.

Regulatory Background

21. All drugs have risks. Stips. ¶2.

22. FDA typically manages those risks through "labeling," FDA-approved prescribing information provided with the medication. Stips. ¶2.

23. There are over 20,000 FDA-approved prescription drugs. Stips. ¶59.

24. Only 611 (3%) of those are subjected to a REMS as of September 2024, according to FDA's website. *See Approved REMS*, FDA, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm [https://perma.cc/9APR-EHQS] (sum of individual drugs in each REMS program, divided by 20,000).[2]

25. Sixty-four percent of drugs with REMS are opioids. *Id.*

26. In 2000, FDA approved mifepristone (brand name Mifeprex), subject to certain restrictions, for medication abortion in a regimen with misoprostol. FDA223-30; Stips. ¶¶10, 22.

27. After enactment of the REMS statute in 2007, mifepristone was "deemed" to have a REMS encompassing the restrictions imposed in 2000. Stips. ¶23.

28. FDA retained the same restrictions after REMS reviews in 2011 and 2013. Stips. ¶¶24, 42; FDA232-243; FDA342-60.

29. In 2013, as a "possible rationale," FDA speculated that mifepristone's safety is "likely" attributable to the REMS, and it is "possible" unqualified clinicians "may" prescribe mifepristone without certification. FDA356-58.

30. FDA reviewed mifepristone's REMS in 2015-16. Stips. ¶¶25-26.

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[2] Courts may take judicial notice of "government documents available from reliable sources on the Internet, such as websites run by governmental agencies." *Won v. Nelnet Servicing, LLC*, No. 18-CV-00381 ACK-RLP, 2019 WL 1548572, at *5 (D. Haw. Apr. 9, 2019) (citation omitted); *accord Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010).

31. In 2016, FDA reauthorized the Mifepristone REMS, including three Elements to Assure Safe Use ("ETASU"): (1) Prescriber Certification, requiring prescribers to self-certify that they are qualified to prescribe mifepristone and will follow REMS requirements; (2) In-Person Dispensing, restricting dispensing of mifepristone to clinical settings, by or under the supervision of a certified prescriber; and (3) the Patient Agreement, requiring patients to sign a special counseling form. Stips. ¶¶27-28; FDA403-11.

32. The 2016 ETASU contained the same restrictions in place since 2000 with minor modifications, including making mifepristone's Medication Guide part of the labeling, not the REMS, and removing a requirement to report serious adverse events other than death. Stips. ¶¶42-43; FDA437-38; FDA535.

33. During the 2015-16 review, FDA received letters urging elimination of the REMS from signatories including Plaintiff Society of Family Planning, ACOG, the American Public Health Association, and expert OB/GYNs and researchers from leading universities. FDA1245-64.

34. The letters explained that the REMS is, *inter alia*: outdated; medically unnecessary given mifepristone's safety record and the laws and standards governing clinical care; inconsistent with FDA's regulation of other drugs; and burdensome. *E.g.*, FDA1247 ("inconsistent with requirements for prescribing other drugs that require careful patient screening to ensure

safety"); FDA1256-57 ("health care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications"; Patient Agreement is "medically unnecessary and interferes with the clinician-patient relationship"); FDA1263-64.

35. Professional and ethical standards require clinicians to assess patient eligibility for a drug, prescribe only drugs they are qualified to prescribe, and obtain informed consent, including counseling on a drug's risks and when to seek follow-up care. 2021REMS1577 (FDA, 2021: "informed consent in medicine is an established practice" embedded in professional guidelines for abortion, and record "reveal[ed] strong adherence to evidence-based guidelines" by abortion providers); FDA1264 (ACOG: "A standard clinical license should be sufficient to ensure that a practitioner meets qualifications for prescribing mifepristone."); 2019CP793 (AMA: ethical obligation to use "sound medical judgment"); FDA1247; 2021ED252; 2021REMS1942; 2021REMS1989-90; 2021REMS791-93; 2021REMS803-05.

36. "[C]linicians with state-licensed prescribing authority are qualified to understand any prescribing information sufficiently to discern whether they are qualified to prescribe or administer a particular drug." Defs.' Opp. Resp. 8 (Jan. 10, 2020), Dkt. 101.

37. "Any provider who is not comfortable using patient medical history or a clinical examination to assess the duration and location of a pregnancy can obtain that information by ordering an ultrasound." Stips. ¶68 (FDA, 2021).

38. The necessary qualifications to prescribe mifepristone are common among clinicians caring for pregnant patients. 2021ED240 (National Academies of Science, Engineering and Medicine ("National Academies"): "Prescribing medication abortion is no different from prescribing other medications"; providers must be able to determine patient eligibility, provide counseling "regarding medication risks, benefits, and side effects," and provide instructions on when to seek follow-up care); 2022CP83 (ACOG et al.: training in dating pregnancies and screening for ectopic pregnancies is standard among many clinicians, including ER doctors, OBGYNs, and family physicians); 2019CP606; 2021REMS1989-90.

39. All clinicians can refer patients to the nearest emergency department, ensuring access to surgery, blood transfusions, or resuscitation. Defs.' Opp. Resp. at 8; 2019CP640 (FDA, 2019: "provid[ing] emergency care coverage for other [clinicians'] patients" is "common practice"); 2021REMS749-50 (ACOG: "should a rare medical emergency arise, patients should be advised to seek care at the closest emergency facility"); 2023SUPP496 n.6; *see* FDA, *Labeling (Viagra)* (2014),

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/20895s039s042lbl.pdf [https://perma.cc/Q5WP-CNN3] ("Patients should seek emergency treatment if an erection lasts >4 hours.").

40. In 2016, FDA's scientific review team recommended eliminating the Patient Agreement, concluding it is "duplicative of information in [mifepristone's] Medication Guide and of information and counseling provided to patients under standard informed consent practices and under professional practice guidelines," FDA674; Stips. ¶¶37-41, "does not add to safe use conditions," and "is a burden for patients," FDA437.

41. FDA's Commissioner, a political appointee, overruled the scientific review team and requested retaining the Patient Agreement. Stips. ¶¶39-40; FDA674.

42. In its 2016 REMS memo, FDA's single-sentence justification for Prescriber Certification was that "the qualifications of a health care provider who prescribes [mifepristone] have not changed and continue to be necessary to ensure the benefits outweigh the risks." FDA706.

43. In 2019, FDA approved a generic version of mifepristone, subject to the same labeling and REMS as Mifeprex (the "Mifepristone REMS"). Stips. ¶46; 2023SUPP1466-1509.

44. In 2020-2021, In-Person Dispensing was enjoined by court order for approximately six months. 2021REMS1567.

45. In April 2021, FDA announced that it would not enforce In-Person Dispensing during the COVID-19 public health emergency. Stips. ¶58; 2021ED512-17.

46. FDA determined that, when mifepristone was available through mail-order pharmacies for more than a year without pharmacy certification, there was no increase in adverse safety events. Defs.' Answer ¶160 (Aug. 16, 2024), Dkt. 213; 2023SUPP1116-17; 2021REMS1583; 2021REMS1598.

2023 Mifepristone REMS Reauthorization

47. In connection with this litigation, FDA "agree[d] to undertake a full review of the Mifepristone REMS Program" in 2021-2022. 2021REMS1565; 2023SUPP1114-15.

48. In 2021, FDA received letters from Plaintiffs explaining why the REMS is medically unjustified and burdensome, 2021REMS950-55 (SFP); 2021REMS1159-67 (Chelius et al.), citing, *inter alia*:

- statements opposing the REMS by leading medical organizations, *see supra* ¶¶20, 33-34;
- data showing that, after Canada eliminated its REMS-like restrictions on mifepristone, medication abortion remained extremely safe, with a major complication rate of 0.33%, 2021REMS956-57; *see also* 2022CP99-109; 2022CP87; 2021REMS984-91;

- examples of medications posing greater or comparable risks not subject to a REMS, *e.g.*, 2021REMS1818; 2021REMS1831; 2021REMS1848; 2021REMS1868; 2021REMS1873-76; 2021REMS1885; 2021REMS1908-09; 2021REMS1942;
- sworn testimony from clinicians and other experts detailing how the REMS is medically unnecessary and burdensome, 2021REMS1921-2050.

49. In 2023, FDA reauthorized the REMS, permanently eliminating In-Person Dispensing, retaining the Prescriber Certification and Patient Agreement ETASU, and adding a Pharmacy Certification ETASU. 2023SUPP1120-27; 2023SUPP1134-38.

50. The current mifepristone ETASU are:

- ***Prescriber Certification***, requiring would-be prescribers to fax a form to the drug distributor attesting that they can date a pregnancy and diagnose an ectopic pregnancy; can ensure patient access to a procedure to evacuate the uterus in cases of incomplete abortion or severe bleeding and to medical facilities equipped to provide blood transfusions and resuscitation if necessary; and have read and understood the prescribing information. Clinicians also agree to review the Patient Agreement with the patient, answer questions, obtain a signature, retain the signed form, and provide

the patient a copy; and to report any patient deaths to the drug sponsor. As modified in 2023, this ETASU also requires clinicians to fulfill certain obligations if a pharmacy will dispense the mifepristone, including providing the pharmacy with their signed Prescriber Certification form and working with the pharmacy to determine an appropriate course of action any time the pharmacy cannot ensure delivery within four calendar days.

- ***Pharmacy Certification***, requiring pharmacies to, *inter alia*, agree to verify that mifepristone is only prescribed by certified prescribers by confirming receipt and keeping records of completed Prescriber Certification forms; ensure delivery of mifepristone to the patient within four days of receiving the prescription, track and verify each shipment, and contact the prescriber if the drug will not be delivered within that timeframe; record in each patient's record the National Drug Code and lot number for the mifepristone package; not transfer mifepristone to another pharmacy except other locations of the same pharmacy; ensure confidentiality of patient and prescriber identities; report any patient deaths to the prescriber and drug sponsor; designate an authorized representative to carry out the certification process; and be specially audited.
- ***Patient Agreement ETASU***, requiring the patient to sign an FDA-approved form stating that they are taking mifepristone because they have

> "decided ... to end [their] pregnancy," will follow a particular clinical protocol, and understand when and how to seek follow-up or emergency care.

2023SUPP1466-1517.

51. Two memoranda capture FDA's rationale for the 2023 REMS Reauthorization: 2021REMS1561-1609; 2023SUPP1112-33.

52. FDA's 2021-23 REMS review did not address evidence of mifepristone's safety beyond finding two pre-2016 studies "consistent with the existing safety profile" and, therefore, "support[ive]" of *maintaining* the REMS. 2021REMS1572.

53. FDA retained Prescriber Certification because its literature review found "no evidence to contradict our previous finding" that prescribers should have the skillset reflected in the agreement. 2021REMS1573-74.

54. FDA's principal justification for requiring Pharmacy Certification was that it was necessary to "ensure[] that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers." 2023SUPP1124-25.

55. Based on a study showing that eliminating In-Person Dispensing could increase the number of mifepristone prescribers, FDA reasoned that the Patient Agreement would ensure "each provider, including new providers," would "inform[] each patient of the appropriate use of mifepristone, risks

associated with the treatment, and what to do if the patient experiences symptoms that may require emergency care." 2021REMS1578.

56. FDA's 2021-23 REMS review nowhere addressed *supra* facts ¶¶2, 8, 12-17, 20, 33-39, 46, and 48, or *infra* facts ¶¶64-90. *See* 2021REMS1561-1609; 2023SUPP1112-33.

57. FDA refused to consider an abstract of the Canadian data, *supra* ¶48, or a full study by the same authors released one year before the 2023 Reauthorization, 2022CP87; 2022CP99-109; *see* 2021REMS1604; 2023SUPP1132-33.

58. FDA's 2021-23 REMS review purported to focus on "objective safety data," excluding from consideration relevant evidence including qualitative studies "assess[ing] REMS ETASUs," 2021REMS1571; statements by medical organizations like ACOG and AMA; stakeholder narratives; and data on abortion access challenges, 2021REMS1571-72; 2021REMS1604-08; *see* 2021REMS973-78 (study concluding that "removing the mifepristone REMS is a crucial evidence-based step to increase access to abortion and miscarriage care"); 2021REMS984-92; 2021REMS993-98.

59. FDA guidance states that, in determining whether a REMS meets statutory criteria, FDA may consider the types of evidence it excluded from the 2021-23 REMS review. *See* FDA, *REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary: Guidance for Industry* (2019),

https://www.fda.gov/media/100307/download [https://perma.cc/AV9U-5GUU] ("Factors Guidance"); FDA, *REMS Assessment: Planning and Reporting Guidance, Guidance for Industry* (2019), https://www.fda.gov/media/119790/download [https://perma.cc/D629-DZY3] ("Assessment Guidance").

60. FDA routinely relies on such evidence in other REMS reviews. *E.g.*, FDA, *REMS Modification Notification (Isotretinoin)*, https://www.fda.gov/media/174325/download [https://perma.cc/6RF4-XFA7] (citing "stakeholder feedback from prescribers, pharmacists, and patients"); FDA, *Supplemental Approval (Zydelig)* (July 6, 2022), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/205858Orig1s018ltr.pdf [https://perma.cc/7C5C-VD5Z] (citing "surveys of healthcare providers").

61. FDA has never explained in *any* REMS review how the mifepristone ETASU satisfy the statutory requirements, beyond unreasoned assertions that the ETASU do not burden access. *See* FDA231-36; FDA342-60; FDA673-709; 2021REMS1561-1609; 2023SUPP1112-50.

62. For instance, FDA has never claimed mifepristone's risks are such that FDA would withdraw approval absent the ETASU. *See* FDA231-36; FDA342-60; FDA673-709; 2021REMS1561-1609; 2023SUPP1112-50.

63. FDA "has removed REMS requirements ... based on the integration of the REMS safe use condition into clinical practice." FDA465 (FDA, 2016).

Disparate Treatment

64. According to medical experts, mifepristone is as safe or safer than Tylenol, Viagra, aspirin, penicillin, blood thinners, antibiotics, insulin, and multiple drugs used for purely cosmetic purposes, all available without a REMS. 2021ED219 (National Academies: risks are "similar in magnitude" to "antibiotics and NSAIDs"); 2021REMS1169 (AAFP: "acetaminophen and "aspirin" have "higher complication rates"); 2021REMS84-85 (Viagra's fatality rate six times higher than mifepristone; penicillin's fatality rate three times higher); 2022CP534 ("far safer" than "antibiotics" and "insulin"); 2021REMS1161; 2021REMS1885 (labeling for Coumadin, a common blood-thinner, warns of "major or fatal bleeding"); 2021REMS001818 (Jeuveau, approved for temporarily reducing facial lines, carries a black-box warning for "[s]wallowing and breathing difficulties" that "can be life threatening" and have resulted in "reports of death"); 2021REMS1831.

65. Korlym, the identical chemical compound, is available to treat Cushing's syndrome without a REMS and is prescribed for daily use in higher doses than mifepristone for abortion. FDA269; Stips. ¶¶63-66.

66. "[T]he rate of adverse events with Mifeprex is much lower" than with Korlym. FDA537 (FDA, 2016).

67. FDA noted that a Korlym REMS would "reduce[] access" and cause "treatment delays," FDA303-04 (2012), and the "challenge of this application is because of the more controversial use of this active ingredient for medical termination of pregnancy," FDA310 (2012).

68. Misoprostol alone is another evidence-based protocol for abortion and miscarriage care, carries the same rare risks associated with mifepristone (or any process that empties the uterus), and has no REMS. 2021REMS751; 2022CP531; 2022CP534-35; 2019CP409-10; Stips. ¶62.

69. Only 0.5% of FDA-approved prescription drugs have a REMS that includes a prescriber certification ETASU. *Approved REMS*, FDA, *supra* ¶24 (sum of drugs with "ETASU A" reflected under REMS Materials, divided by 20,000).

70. Only 0.65% of FDA-approved prescription drugs have a REMS that includes a patient agreement ETASU. *Id.* (same for "ETASU D").

71. "Opioids are claiming lives at a staggering rate, and overdoses from prescription opioids are reducing life expectancy in the United States." 2021REMS1813 (FDA, 2021).

72. Under the shared-system REMS covering hundreds of opioid analgesics (*e.g.*, fentanyl, OxyContin), optional educational materials must be made available,

but FDA does not require certification of prescribers or dispensers of opioids, or a patient agreement. FDA, *REMS Document*, *Opioid Analgesic REMS Program*, (2021), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2021_04_09_REMS_Document.pdf [https://perma.cc/X9HE-GJNF]; FDA, *Opioid Analgesic REMS*, https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17 [https://perma.cc/ZRA4-VYGA] (last updated Apr. 9, 2021) ("Products" tab).

73. Mifepristone carries no risk of dependency. Stips. ¶¶20, 46.

74. "[T]here are other drugs for which patient screening is the standard of care but that are not subject to ETASU." Defs. Answer ¶152 (FDA, 2024).

Harms of Mifepristone REMS

75. Prescriber Certification and the Patient Agreement may require health centers to develop special systems to track certifications and store signed forms, necessitating involvement of multiple colleagues (*e.g.*, administrators, information-technology staff), and complicating, delaying, or derailing clinicians' efforts to provide mifepristone. 2021REMS951; 2022CP1120-24; 2021REMS1989-90; 2021REMS980; 2022CP83; *see* 2023SUPP1514-15; 2023SUPP1510.

76. Prescriber Certification deters clinicians who fear anti-abortion harassment or violence if their certification were exposed. FDA1256 ("clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers" given "escalating harassment and violence against known abortion providers"); 2023SUPP1151-62; 2021REMS1163; 2021REMS1937-38; 2021REMS1963; 2021REMS1991-92; 2022CP83-84; FDA301 (FDA, 2012: "[p]rivacy may be better maintained if there are no systems in place to track formally prescribers and patients").

77. FDA redacted from the administrative record the names and offices of employees who worked on mifepristone, because, "[i]n light of the violence and harassment surrounding the provision of abortion," releasing them, even subject to a protective order, "could expose those employees to threats, intimidation, harassment, and/or violence." Stips. ¶47 (FDA, 2019).

78. In retaining the Patient Agreement, FDA relied on a survey finding that 9% of OBGYNs who did not provide a medication abortion within the past year despite patient demand cited Prescriber Certification as a reason why. 2021REMS970-71; 2021REMS1577-78.

79. Pharmacy Certification imposes significant burdens on pharmacies, including developing special systems to verify, track, and confidentially maintain prescriber agreements. 2023SUPP1511-12; *see* FDA1247; FDA1256.

80. The mifepristone drug sponsors told FDA that the four-day delivery requirement for pharmacies would necessitate "two-day or next day shipping," flagged concerns about "affordability of shipping services," and noted that "the professional practice of pharmacy requires that pharmacies promptly dispense products to patients … or swiftly communicate with the patient and prescriber if that is not possible…." 2023SUPP904; 2023SUPP556; 2023SUPP477.

81. Pharmacy Certification deters pharmacies from dispensing mifepristone. 2023SUPP1125 (FDA, 2023: "verification of prescriber enrollment will likely limit the types of pharmacies that will choose to certify"); 2022CP85-86 ("The extra administrative burden will disincentivize participation"); 2023SUPP34.

82. The REMS exacerbates abortion-related stigma by classifying mifepristone as presenting safety risks comparable to opioids. 2022CP776; 2021REMS995; 2021REMS979-80.

83. Stigma stemming from the REMS complicates, delays, and derails clinicians' efforts to provide mifepristone. 2022CP1124-25; 2022CP776; 2021REMS995; 2021REMS1963-64.

84. There is a dearth of abortion providers in the U.S., particularly in rural areas. 2022CP84; FDA540; 2021REMS2024-25; 2021REMS1163; 2021REMS678.

85. By reducing where mifepristone is prescribed and dispensed, the REMS decreases access and increases burdens on patients. 2021REMS2040-43 (expert declaration discussing extensive research demonstrating that increases in travel distance of as little as 10-12 miles prevent abortion); 2021REMS2027-39 ("The additional travel costs [such as transportation, lost wages, and childcare] necessitated by the REMS in order to access a medication abortion impose substantial burdens for low-income women."); 2021REMS1177; 2021REMS1182.

86. Being denied a wanted abortion negatively impacts patients' health, well-being, and families. 2019CP591; 2023SUPP237; 2023SUPP34-35.

87. By reducing where mifepristone is available and increasing burdens to access it, the ETASU disproportionately harm communities already facing difficulties accessing healthcare, including low-income populations, communities of color, homeless populations, people with limited English proficiency, people living in abusive households, and those in rural areas. 2022CP84-86; 2021REMS1929; 2021REMS1947-49; 2021REMS1953-55; 2021REMS2015-27; 2021REMS1163 (75% of abortion patients are low-income, 60% are people of color, 60% are parents).

88. "Most Americans rely on neighborhood retail pharmacies to obtain their prescription drugs, and retail pharmacy distribution of drugs can increase

access for rural residents," "adults who are not digitally literate," 2022CP86, and homeless patients who lack "a physical address to which a package can be securely and confidentially mailed," 2021REMS1935.

89. The REMS undermines informed consent and causes confusion by requiring patients to sign a form that may reflect outdated science and/or conflict with their clinical circumstances, such as if the clinician prescribes an evidence-based protocol in which misoprostol is taken at a shorter interval. FDA1247; FDA1257; 2021REMS2007; 2021REMS169; 2021REMS755; 2021REMS805; *see also* FDA437 (FDA, 2016: counseling should be "individualized to the patient" and the clinician's "own practice").

90. For miscarriage patients, attesting that they decided … to end [their] pregnancy" can cause confusion and emotional distress. 2021REMS2007-08; 2022CP82; *see* 2023SUPP510.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the word count limits set by the Court in Dkts. 82, 211, 219, because, excluding the parts of the document exempted by Local Rule 7.4(d), it contains 3,750 words. In compliance with Local Rules 7.4(e) and 10.2(a), I further certify that this document has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: October 2, 2024

/s/ Jongwook "Wookie" Kim
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