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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, *et al*., Plaintiffs, v. XAVIER BECERRA, *et al*., Defendants.	CIV. NO. 1:17-00493-JAO-RT **DEFENDANTS' CONCISE STATEMENT IN RESPONSE TO PLAINTIFFS' CONCISE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (ECF. NO. 222)**

Pursuant to Local Rule 56.1(e), Defendants respectfully submit this Concise Statement in Response to Plaintiffs' Concise Statement of Facts in Support of Motion for Summary Judgment. *See* ECF No. 222.

This case "does not require fact finding on behalf of this court." *Northwest Motorcycle Ass'n v. U.S. Dept. of Agriculture*, 18 F.3d 1468, 1472 (9th Cir. 1994). "[I]n the context of reviewing an administrative decision under the APA, 'there are no disputed facts that the district court must resolve.'" *Conservation Council for Haw. v. Nat'l Marine Fisheries Serv.*, 97 F. Supp. 3d 1210, 1218 (D. Haw. 2015) (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985)). Rather, the agency "is *itself* the finder of fact," and "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g*, 753 F.2d at 769-70 (emphasis added); *accord City & Cnty. of S.F. v. United States*, 130 F.3d 873, 877 (9th Cir. 1997).

Ignoring this principle, Plaintiffs use their concise statement in an attempt to adduce facts that the agency did not find and that are not subject to judicial notice. For example, throughout their statement, Plaintiffs allege as "facts" conclusions that they have drawn from record materials, but that FDA itself did not draw. For the Court to accept such "facts" would exceed its limited role in this APA case. Rather, the Court's function is simply to determine whether FDA "examine[d] the

relevant [evidence]" and "articulated a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S.29, 43 (1983).

Because there are no disputed material questions of fact for this Court to resolve, Defendants do not believe any further response to Plaintiffs' Concise Statement is necessary. However, out of an abundance of caution, Defendants respond as set forth below. Throughout their response, Defendants object to Plaintiffs' attempt to adduce facts not found by the agency on the ground that, in an APA case, evidence is not admissible for that purpose. *See* Fed. R. Civ. P. 56(c)(2). Defendants limit their disputes only to those alleged facts that (1) affirmatively contradict FDA's findings of fact or (2) purport to characterize regulatory history or agency findings, but do so inaccurately.[1]

Plaintiffs' Statement of Fact	**Defendants' Response**
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.	1. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
2. Both methods are very safe, and significantly safer than childbirth—which carries a risk of death 14	2. Objection. Because the role of the district court in an APA case is to review the

[1] Defendants are simultaneously cross-moving for summary judgment. Accordingly, all additional facts are contained in Defendants' own Concise Statement of Fact, which complies with the word limit set by this Court.

times higher than abortion. 2021REMS695-99; FDA859 & n.6; 2019CP46.	agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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.	3. Not disputed.
4. The same mifepristone-misoprostol regimen is the most effective regimen for medical miscarriage management. 2019CP402-11; 2022CP77-79.	4. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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.").	5. Disputed in part. Not disputed to extent this statement purports to describe a method for the medical termination of intrauterine pregnancy. Disputed that FDA has approved mifepristone as part of two-drug regimen through ten weeks of pregnancy for any other indication. Evidence: 2023 SUPP 001471-1489
6. Since 2016, mifepristone's labeling provides for 200mg of mifepristone	6. Not disputed.

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.	7. Disputed. FDA has approved another manufacturer's mifepristone product, Korlym (mifepristone 300mg), for daily use in the treatment of Cushing's syndrome.[2] Evidence: FDA 0269-291.
8. An estimated 5.6 million people in the U.S. used mifepristone for medication abortion between September 2000 and June 2022. 2023SUPP1045.	8. Not disputed.
9. The World Health Organization classifies mifepristone and misoprostol as essential medicines. 2023SUPP104; FDA539.	9. Not disputed, except to note that the WHO's classification is limited to mifepristone and misoprostol for termination of early pregnancy. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited documents for a full and accurate statement of their contents.
10. Mifepristone offers a	10. Not disputed.

[2] Unless context indicates otherwise, Defendants use "mifepristone" in this statement to refer to Mifeprex and its generic approved for use in termination of early pregnancy.

"meaningful therapeutic benefit" over procedural abortion that may be "preferable and safer in [a patient's] particular situation." FDA860 (FDA, 2016); *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.	11. Not disputed.
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.	12. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Noted that the first two quotations refer to "early medical abortion" generally, not mifepristone specifically, and other medication regimens are discussed. FDA 536. Defendants respectfully refer the Court to the cited documents for a full and accurate statement of their contents.
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.	13. Not disputed.
14. Mifepristone's FDA-approved	14. Disputed in part.

labeling identifies two potential risks: "[s]erious and sometimes fatal infections or bleeding." 2023SUPP1471-72; Stips. ¶¶19, 46.	Mifepristone's labeling discloses additional risks. Evidence: 2023 SUPP 001471-1489 (section 5).
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.	15. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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.	16. Not disputed.
17. FDA concluded that "the critical risk factor" for certain rare serious infections following mifepristone "[wa]s pregnancy itself." FDA880-81 n.69 (2016).	17. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants note that the quoted material states that "data from the medical literature and findings by the CDC suggest that the critical

	risk factor *in the reported cases of sepsis* is pregnancy itself." FDA 0880-81 n.69 (emphasis added).
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.	18. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants note that the quoted material discusses "surgical procedure," not "follow-up procedure." 2019 CP 664-65.
19. The follow-up procedure is identical to that used in procedural abortion or to treat an incomplete miscarriage. 2021ED199.	19. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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	20. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited documents for a full and accurate statement of their contents.

"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.	
21. All drugs have risks. Stips. ¶2.	21. Not disputed.
22. FDA typically manages those risks through "labeling," FDA-approved prescribing information provided with the medication. Stips. ¶2.	22. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). The parties did not renew the cited stipulations for purposes of the pending cross-motions for summary judgment. Defendants also note that the stipulation cited to FDA's website, which paraphrases the relevant statutory requirements.
23. There are over 20,000 FDA-approved prescription drugs. Stips. ¶59.	23. Accuracy of fact is not disputed, but dispute that the fact is material to this case.
24. Only 611 (3%) of those are	24. Objection. Because the

subjected to a REMS as of September 2024, according to FDA's website. *See Approved REMS*, FDA, http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm [http://perma.cc/9APR-EHQS] (sum of individual drugs in each REMS program, divided by 20,000).	role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited webpage for a full and complete statement of its contents. Defendants dispute that the alleged fact is material to this case.
25. Sixty-four percent of drugs with REMS are opioids. *Id.*	25. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited webpage for a full and complete statement of its contents. Defendants dispute that the alleged fact is material to this case.
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.	26. Not disputed that in 2000, FDA approved mifepristone (brand name Mifeprex) for use, in a regimen with the drug misoprostol, for the medical termination of intrauterine pregnancy through 49 days' gestation, subject to certain restrictions.

27. After enactment of the REMS statute in 2007, mifepristone was "deemed" to have a REMS encompassing the restrictions imposed in 2000. Stips. ¶23.	27. Not disputed that, pursuant to Section 909(b)(1) of the newly enacted Food and Drug Administration Amendments Act of 2007 (FDAAA), Mifeprex was "deemed to have in effect an approved risk evaluation and mitigation strategy" (*i.e.*, REMS) because FDA previously had approved it with certain restrictions under its "Subpart H" regulations. Defendants note that this provision took effect in 2008.
28. FDA retained the same restrictions after REMS reviews in 2011 and 2013. Stips. ¶¶24, 42; FDA232-243; FDA342-60.	28. Not disputed.
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.	29. Disputed to the extent it is suggested that FDA retains the prescriber certification solely because of a "possible rationale." Defendants respectfully refer the Court to the cited document for a full and accurate statement of its contents. Evidence: FDA 0342-0360; 2021 REMS 001561-1609.
30. FDA reviewed mifepristone's REMS in 2015-16. Stips. ¶¶25-26.	30. Not disputed.
31. In 2016, FDA reauthorized the Mifepristone REMS, including three Elements to Assure Safe Use ("ETASU"): (1) Prescriber Certification, requiring prescribers	31. Disputed in part. FDA did not "reauthorize" the Mifeprex REMS, but approved a supplemental application proposing a

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.	REMS modification for Mifeprex. Evidence: 21 U.S.C. § 355-1(g); *id.* § 355-1(h); FDA 0371-381.
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.	32. Disputed. In 2016, FDA approved modifications to the conditions for use for Mifeprex, including the REMS, to, among other changes, (1) lower the dose of mifepristone, (2) increase the gestational age limit from 49 to 70 days, (3) reduce the number of required in-person clinic visits from three to one, (4) remove the requirement that mifepristone be taken at a clinic, and (5) allow mifepristone to be prescribed by non-physician healthcare providers licensed under state law to prescribe drug. With respect to the Medication Guide, Defendants note that it has always been part of the labeling; in 2016, FDA removed the requirement relating to the Medication Guide from the REMS. Evidence: FDA 412-439; 21 U.S.C. § 321(m); 21 C.F.R. § 208.3(h)

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.	33. Not disputed.
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.	34. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited document for a full and accurate statement of its contents.
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:	35. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

"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.	Defendants respectfully refer the Court to the cited documents for a full and accurate statement of their contents.
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.	36. Not disputed, but Defendants respectfully refer the Court to the cited document for the full context of this statement.
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).	37. Not disputed.
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"):	38. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed.

"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.	R. Civ. P. 56(c)(2).
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), http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/20895s039s0421bl.pdf [http://perma.cc/Q5WP-CNN3] ("Patients should seek emergency treatment if an erection lasts >4 hours.").	39. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited document for the full context of this statement. Evidence: 2019 CP 000640.
40. In 2016, FDA's scientific review team recommended eliminating the Patient Agreement, concluding it is	40. Not disputed.

"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.	41. Disputed in part. Not disputed that the Commissioner is appointed by the President and confirmed by the Senate. Disputed that cited evidence shows that the Commissioner "overrule[d] the scientific review team," and disputed in that the alleged fact is not material to this case. Evidence: 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.	42. Disputed in that the alleged fact is not material to this case, and in that Plaintiffs' characterization is inaccurate, incomplete, and omits context. Evidence: FDA 0673-709.
43. In 2019, FDA approved a generic version of mifepristone, subject to the same labeling and REMS as Mifeprex (the "Mifepristone REMS"). Stips. ¶46;	43. Disputed in part. The generic version of mifepristone has the same labeling except for certain permissible differences.

2023SUPP1466-1509.	Evidence: 2023 SUPP 001466-1509.
44. In 2020-2021, In-Person Dispensing was enjoined by court order for approximately six months. 2021REMS1567.	44. Disputed in that the court order did not enjoin in-person dispensing, but rather temporarily barred enforcement of the Mifepristone REMS Program in-person dispensing requirement during the COVID-19 public health emergency. Evidence: 2021 REMS 001567.
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.	45. Disputed in that FDA announced it would exercise enforcement discretion during the COVID-19 public health emergency regarding the requirement in the Mifepristone REMS Program that mifepristone be dispensed to patients only in certain healthcare settings. Evidence: 2021 ED 512-14; 2021 ED 515-17.
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.	46. Disputed. FDA determined that there did not "appear" to be an increase in adverse safety events. Evidence: 2021 REMS 001598.
47. In connection with this litigation, FDA "agree[d] to undertake a full	47. Not disputed.

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.	48. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Not disputed that Defendants received the cited letters in 2021. Disputed that the letters "explain[ed] why the REMS is medically unjustified and burdensome." The phrase "explain why" implies that the REMS is in fact medically unjustified and burdensome, and FDA did not reach that conclusion. Evidence: 2021 REMS 001561-1609; 2021 REMS 000950-955; 2021 REMS 1159-1167.
49. In 2023, FDA reauthorized the	49. Disputed in part. FDA did

REMS, permanently eliminating In-Person Dispensing, retaining the Prescriber Certification and Patient Agreement ETASU, and adding a Pharmacy Certification ETASU. 2023SUPP1120-27; 2023SUPP1134-38.	not "reauthorize" the REMS, but approved supplemental applications that proposed a modified REMS, which included eliminating the requirement for in-person dispensing. Evidence: 21 U.S.C. § 355-1(g); *id.* § 355-1(h); 2023 SUPP 001448-1460, 1461-1465.
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	50. This alleged fact fails to comply with Local Rule 56.1, which provides that "[e]ach factual assertion shall be a single sentence." Not disputed that the documents associated with the REMS modification that FDA approved on January 3, 2023 are found at 2023 SUPP 001466-1517. Defendants respectfully refer the Court to the cited document for a full and accurate statement of its contents.

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.	51. Disputed in part. Not disputed that the two cited documents are among those in the administrative record that set out FDA's rationale for approving modification but not elimination of the Mifepristone REMS Program on January 3, 2023. Disputed that FDA "reauthorized" the REMS or that other documents in the record fail to provide evidence of FDA's rationale. Evidence: 21 U.S.C. § 355-1(g); *id.* § 355-1(h); 2021 REMS 1505-08; 2021 REMS 1509-1532; 2021 REMS 1390-1401; 2023 SUPP 1040-51; 2023 SUPP 1054-55; 2023 SUPP 001448-1460, 1461-1465.
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.	52. Disputed. In its 2021 review of the Mifepristone REMS Program, FDA carefully examined hundreds of publications to determine whether evidence since the 2016 REMS modification supported modifications to the REMS that would continue to assure safe use of the drug. The agency also reviewed information from a

	wide variety of other sources, including healthcare providers, advocacy groups, and plaintiffs. In addition to literature, letters, and submissions from Plaintiffs and others, FDA considered safety information from time periods in which the in-person dispensing requirement was not being enforced during the COVID-19 public health emergency, including information from the sponsors and adverse event reports. Additionally, in assessing whether to maintain the Patient Agreement Form, FDA considered the National Abortion Federation's 2020 Clinical Policy Guidelines for Abortion Care, as well as Practice Bulletins from the American College of Obstetricians and Gynecologists and the Society of Family Planning, and data relating to an increase in new providers for this care obtained from well-conducted surveys. Evidence: 2021 REMS 001561-1609.
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.	53. Disputed in part. Not disputed that FDA stated: "Our review of the literature did not identify any studies comparing providers who met

2021REMS1573-74.	these qualifications with providers who did not. In the absence of such studies, there is no evidence to contradict our previous finding that prescribers' ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide surgical intervention or arrange for such care through others if needed, is necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol." Disputed that this captures the entirety of FDA's rationale for retaining the prescriber certification requirement. Evidence: 2021 REMS 001561-1609.
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.	54. Disputed. FDA determined that the Pharmacy Certification requirement incorporates pharmacies into the REMS, ensures that pharmacies are aware of and agree to follow applicable REMS requirements, and ensures that mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers. Evidence: 2023 SUPP 1124-25; 2021 REMS 001561-

	1609.
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.	55. Disputed. Based on several publications, FDA concluded that "removal of the in-person dispensing requirement from the Mifepristone REMS Program . . . could significantly increase the number of providers to a larger group of practitioners." 2021 REMS 001578. Separately, FDA found that "[t]he requirement to counsel the patient, to provide the patient with the Patient Agreement Form, and to have the healthcare provider and patient sign the Patient Agreement Form, ensures that each provider, including new providers, informs each patient of the appropriate use of mifepristone, risks associated with treatment, and what to do if the patient experiences symptoms that may require emergency care." *Id.* Evidence: 2021 REMS 001578.
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.	56. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

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.	57. Disputed. FDA reviewed the abstract, but determined that "it was not possible to conduct a full review of the methods or results." 2021 REMS 001571; *see also* 2021 REMS 001604. FDA did not "refuse[]" to consider the full study, which was published after FDA completed its 2021 REMS review and directed the sponsors of mifepristone to propose a modified REMS. Evidence: 2021 REMS 001561-1609.
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.	58. Disputed in part. Not disputed that FDA's literature review "focused on publications containing safety data related to outcomes of medical abortion (objective safety data)" that FDA determined was relevant to the particular modifications being considered. 2021 REMS 001571. Disputed that FDA refused to consider other evidence, including practice guidelines and survey data as relevant. Also disputed that the literature review was the only source of evidence considered for the 2021 REMS review.

	Evidence: 2021 REMS 001561-1609.
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), http://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").	59. Disputed. FDA reviewed all relevant evidence before it. Evidence: 2021 REMS 001561-1609; 2021 REMS 1505-08; 2021 REMS 1509-1532; 2021 REMS 1390-1401; 2023 SUPP 1040-51; 2023 SUPP 1054-55; 2023 SUPP 001448-1460, 1461-1465.
60. FDA routinely relies on such evidence in other REMS reviews. *E.g.*, FDA, *REMSModification Notification (Isotretinoin)*, https://www.fda.gov/media/174325/download [http://perma.cc/6RF4-XFA&] (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").	60. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Disputed that the alleged fact is material to this case.
61. FDA has never explained in *any* REMS review how the mifepristone	61. Disputed. FDA explained its conclusions that ETASU

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.	are necessary to assure that the benefits of mifepristone outweigh the risks and that the burden of these requirements had been minimized to the extent possible. Evidence: 21 U.S.C. § 355-1(g)(4)(B); 2021 REMS 001561-1609; 2023 SUPP 1112-1150.
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.	62. Disputed. FDA may require ETASU if the drug "can be approved only if, or would be withdrawn unless, such elements are required." 21 U.S.C. § 355-1(f)(1)(A). FDA determined that the ETASU are "necessary" to assure mifepristone's safety, a requirement for FDA approval. 21 U.S.C. § 355(d). Evidence: 2021 REMS 001561-1609.
63. FDA "has removed REMS requirements ... based on the integration of the REMS safe use condition into clinical practice." FDA465 (FDA, 2016).	63. Not disputed as to accuracy, but disputed that the alleged fact is material to this case.
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	64. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

"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.	Defendants respectfully refer the Court to the cited documents for a full and accurate statement of their contents.
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.	65. Disputed in part. While Korlym—which is contraindicated in pregnancy—contains mifepristone as its active ingredient, its inactive ingredients are not "identical" to those of Mifeprex and its generic. Evidence: FDA 0269, 280.
66. "[T]he rate of adverse events with Mifeprex is much lower" than with Korlym. FDA537 (FDA, 2016).	66. Not disputed.
67. FDA noted that a Korlym REMS would "reduce[] access" and	67. Disputed in part.

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).	Not disputed that, in considering "whether or not a REMS is necessary for Korlym to maintain the integrity of the Mifeprex REMS," FDA considered "[t]he burden (reduced access, treatment delays) of a restrictive REMS to the Cushing's population without any benefit from the REMS for this population." FDA 0304. Not disputed that, when considering a new drug application for the use of Korlym to treat patients with endogenous Cushing's syndrome who have failed surgery or are not candidates for surgery, FDA 0308, FDA noted that "[t]he regulatory and legal challenge of this application is because of the more controversial use of [mifepristone] for medical termination of pregnancy in the approved formulation," FDA 0310. Disputed that Plaintiffs' summary fairly captures the context of these quotes. Evidence: FDA 0307-330.
68. Misoprostol alone is another evidence-based protocol for abortion and miscarriage care, carries the same rare risks	68. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the

associated with mifepristone (or any process that empties the uterus), and has no REMS. 2021REMS751; 2022CP531; 2022CP534-35; 2019CP409-10; Stips. ¶62.	evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants dispute that the alleged fact is material to this case.
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).	69. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited webpage for a full and complete statement of its contents. Defendants dispute that the alleged fact is material to this case.
70. Only 0.65% of FDA-approved prescription drugs have a REMS that includes a patient agreement ETASU. *Id.* (same for "ETASU D").	70. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants respectfully refer the Court to the cited webpage for a full and complete statement of its contents. Defendants dispute that the alleged fact is material to this case.

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).	71. Accuracy of statement is not disputed but disputed in that the fact is not material to this case.
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/Opiod_Analgesic_2021_04_09 REMS_Document.pdf [http:perma.cc/X9HE-GJNF]; FDA, Opiod Anagesic REMS, https://www.accessdata.gov/fda.gov/scripts/cder/rems/index.cfm?event=REMSDetails.pageREMS=17 [https://perma.cc/ZRA4-VYGA] (last updated Apr. 9, 2021) ("Products" tab).	72. Accuracy of statement is not disputed but disputed in that the fact is not material to this case.
73. Mifepristone carries no risk of dependency. Stips. ¶¶20, 46.	73. Not disputed.
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).	74. Accuracy of statement is not disputed but disputed in that the fact is not material to this case.
75. Prescriber Certification and the Patient Agreement may require health centers to develop special systems to track certifications and store signed forms, necessitating	75. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is

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.	inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). To the extent this alleged fact purports to describe legal requirements, disputed. Although health centers may develop such systems, neither the prescriber certification requirement nor Patient Agreement Form impose any such requirement. Evidence: 2023 SUPP 001466-70; 2023 SUPP 1510, 1514-1515, 1516-1517
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").	76. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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	77. Not disputed, except note that FDA did not redact the name of the Commissioner of Food and Drugs or the Director of the Center for

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).	Drug Evaluation and Research.
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.	78. Disputed in part. FDA did not rely on the finding specifically mentioned. Evidence: 2021 REMS 001577-78.
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.	79. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Not disputed that certified pharmacies must receive and maintain prescriber certification forms.
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…."	80. Disputed in part in that Defendants do not agree with Plaintiffs' characterization of the first two quotes and respectfully refer the Court to 2023SUPP 904 and 556, respectively, for a full and complete statement of their contents. Evidence: 2023 SUPP 000447, 556, 904.

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.	81. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). To the extent the alleged fact purports to characterize an agency finding, Defendants dispute that the characterization is accurate. Defendants respectfully refer the Court to the cited document for a full and accurate statement of their contents. Evidence: 2023 SUPP 001125.
82. The REMS exacerbates abortion-related stigma by classifying mifepristone as presenting safety risks comparable to opioids. 2022CP776; 2021REMS995; 2021REMS979-80.	82. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
83. Stigma stemming from the REMS complicates, delays, and derails clinicians' efforts to provide mifepristone. 2022CP1124-25; 2022CP776; 2021REMS995; 2021REMS1963-64.	83. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

84. There is a dearth of abortion providers in the U.S., particularly in rural areas. 2022CP84; FDA540; 2021REMS2024-25; 2021REMS1163; 2021REMS678.	84. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Defendants dispute that the alleged fact is material to this case
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.	85. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
86. Being denied a wanted abortion negatively impacts patients' health, well- being, and families. 2019CP591; 2023SUPP237; 2023SUPP34-35.	86. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2). Not disputed that obtaining an abortion may be medically

	appropriate. FDA 0859-60.
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).	87. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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.	88. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).
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	89. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

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.	90. Objection. Because the role of the district court in an APA case is to review the agency's findings of fact, the evidence Plaintiffs cite is inadmissible to establish facts not found by FDA. *See* Fed. R. Civ. P. 56(c)(2).

Dated: December 3, 2024

Respectfully submitted,

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