No. 26-30203

United States Court of Appeals
for the
Fifth Circuit

STATE OF LOUISIANA, *by & through its Attorney General, Liz Murrill*; ROSALIE MARKEZICH,

Plaintiffs–Appellants,

– v. –

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, C*ommissioner, U.S. Food and Drug Administration*; RICHARD PAZDUR, *in his official capacity as Director, Center for Drug Evaluation & Research, U.S. Food & Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,

Defendants–Appellees,

– v. –

GENBIOPRO, INCORPORATED,

Intervenor–Appellee.

– v. –

DANCO LABORATORIES, L.L.C.,

Intervenor–Appellee.

On Appeal from the United States District Court
for the Western District of Louisiana (Lafayette)
No. 6:25-CV-1491

BRIEF FOR *AMICI CURIAE* 322 REPRODUCTIVE HEALTH RESEARCHERS IN SUPPORT OF INTERVENORS-APPELLEES DANCO AND GENBIOPRO

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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Please refer to attached Appendix.

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Amici 322 Reproductive Health Researchers each state that they do not have a parent corporation and that no publicly held company owns 10% or more of their stock.

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INTEREST OF *AMICI CURIAE*

Amici curiae[1] are 322 leading reproductive health researchers in the United States and worldwide. Amici[2] are trained and experienced in conducting or evaluating clinical and social science studies on reproductive health issues and the safety and effectiveness of mifepristone. Amici share a significant interest in evidence-based reproductive health care and submit this brief to explain the ample scientific evidence of mifepristone's safety and effectiveness—including when prescribed via telehealth—supporting the Food and Drug Administration's 2021 decision, formalized in 2023, to lift the in-person dispensing requirement for mifepristone.

SUMMARY OF ARGUMENT

FDA's decision to remove the in-person dispensing requirement from the mifepristone Risk Evaluation and Mitigation Strategy ("REMS")—first announced in 2021 following a period of non-enforcement during the COVID-19 pandemic and then formalized in 2023—was supported by overwhelming scientific evidence. Across multiple rounds of review, FDA considered high-quality studies encompassing more than 50,000 patient experiences, all of which demonstrated that the in-person dispensing requirement is not necessary to ensure the safety and effectiveness

[1] This brief is filed with the consent of all parties. No party or party's counsel authored this brief in whole or part; no party or party's counsel contributed money to fund this brief's preparation or submission; and no person or entity, other than Amici or their counsel, contributed money to fund this brief's preparation or submission.

[2] A complete list of amici is provided in Appendix A. Amici's affiliations are noted for informational purposes only, and amici join this brief in their individual capacities only.

of mifepristone for medication abortion. These studies adhered to rigorous standards of reliability and validity, as demonstrated by their selection for publication in reputable scientific journals, subject to the academic peer-review process. FDA's review far exceeded the statutory threshold, which requires FDA to review only one adequate and well-controlled study to approve a drug and only an "adequate rationale" to remove a REMS requirement. FDA also properly determined that the in-person dispensing requirement for mifepristone ran counter to the statutory mandate that REMS elements not unduly burden patient access, particularly for patients who have difficulty accessing health care, including those in rural or medically underserved areas.

The scientific evidence published since 2023 has further confirmed the soundness of FDA's decision. A rigorous 2025 Cochrane Review—widely recognized as the gold standard for evidence-based medicine—concluded that telehealth abortion using mifepristone is "generally safe, effective, and acceptable." And a 2024 study comparing telemedicine and in-person outcomes for concurrently recruited individuals found no differences between the two groups in effectiveness or number of serious adverse events. Despite minor variations in results attributable to study design and available data, the scientific research consistently demonstrates that telehealth provision of mifepristone is extremely safe and effective, with rates comparable to those observed in studies assessing safety and effectiveness of medication abortion care under the in-person dispensing requirement.

Plaintiffs have not identified any sound or reputable peer-reviewed scientific studies that would provide any basis for a court to second-guess FDA's expert judgment in deciding to remove the in-person mifepristone dispensing requirement. Plaintiffs rely on a self-published report by the Ethics and Public Policy Center ("EPPC"), but this report is riddled with methodological flaws that render its conclusions unreliable. Indeed, EPPC has refused to disclose its underlying dataset, its methodology for identifying medication abortions, or the codes used to identify serious adverse events—preventing any independent verification of its conclusions. EPPC also inflated its serious-adverse-event figures by misclassifying as "serious adverse events" expected outcomes such as emergency-room visits not requiring treatment or intervention and normal post-abortion bleeding.

EPPC's claims that the removal of the in-person dispensing requirement caused an increase in "serious adverse events" and prescriptions to people with ectopic pregnancies also suffer from fundamental errors. EPPC impermissibly argues causation from correlation, fails to consider alternative explanations or limitations of its data, and draws conclusions based on incorrect assumptions about telehealth abortion care and the in-person dispensing requirement. This methodologically flawed report provides no basis for this Court to displace FDA's expert judgment to remove the in-person dispensing requirement.

The vast body of scientifically sound studies leaves no doubt as to the safety and effectiveness of mifepristone, including when provided by telehealth. Consistent with this overwhelming evidence, this Court should affirm the district court's decision denying Plaintiffs' motion.

ARGUMENT

I. FDA's 2021 Decision to Remove the In-Person Dispensing Requirement from the REMS, Formalized in 2023, Was Supported by More Than Ample Scientific Evidence.

FDA's decision to remove the REMS requirement that mifepristone be dispensed only in-person in clinics, medical offices, and hospitals (the "in-person dispensing requirement") was the product of a measured, multi-stage agency review grounded in rigorous scientific evidence. FDA first issued a nonenforcement decision in April 2021, then lifted the in-person dispensing requirement in December 2021, and then finalized that decision in 2023. At each stage, FDA considered and cited rigorous scientific studies supporting the determination that the in-person dispensing requirement was not necessary to ensure the safety and effectiveness of mifepristone for medication abortion, and therefore did not meet the statutory standard needed for a REMS element to assure safe use.

The review process that led to FDA's removal of the in-person dispensing requirement far surpassed the statutory requirements. Under the governing statute, FDA may approve a drug based on "data from *one* adequate and well-controlled

clinical investigation and confirmatory evidence." *See* 21 U.S.C. § 355 (d) (emphasis added). Removing a REMS requirement need only be supported by an assessment and an "adequate rationale." 21 U.S.C. § 355-1(g)(4)(A). Pursuant to these statutory requirements, FDA regularly approves drugs supported by only one clinical study.[3] Here, by contrast, FDA's multiple analyses encompassed 25 high-quality scientific studies, which together covered more than 50,000 patient experiences, that overwhelmingly supported the conclusion that mifepristone is extremely safe and effective without the in-person dispensing requirement. Plaintiffs' attempts to identify limitations of some of these studies mischaracterize FDA's analysis and the studies themselves. Br. at 57-62.

Moreover, FDA properly determined that the in-person dispensing requirement was inconsistent with statutory requirements. The statute provides that elements to assure safe use within a REMS must be "commensurate with [a] specific serious risk listed in the labeling of the drug," and cannot be "unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)." 21 U.S.C. § 355-1(f)(2). FDA correctly concluded that the REMS unduly burdened

[3] *See* Kaplan et al., Review of Evidence Supporting 2022 US Food and Drug Administration Drug Approvals, 6 JAMA NETWORK OPEN e2327650 (2023) (finding that 65% of approved novel drugs in 2022 were supported by one clinical study).

patients based on studies demonstrating that the in-person dispensing requirement reduced access to mifepristone.

As set forth below, FDA acted in accordance with the statutory requirements and ample conclusive scientific evidence in removing the in-person dispensing requirement.

A. The April 2021 Decision to Not Enforce the In-Person Dispensing Requirement Was Supported by Substantial Scientific Evidence.

To support its 2021 nonenforcement decision, FDA relied on studies that included clinical outcome data for more than 50,000 patients who obtained medication abortion care.[4] This literature studied the safety and effectiveness of care delivered in person, via telehealth, and through hybrid options—where some but not all stages of care were provided in person.[5] FDA determined that the "overall findings from these studies do not appear to show increases in safety concerns" when the medication is dispensed through telehealth.[6] Each study considered by FDA identified high effectiveness and safety rates, with patient outcomes consistent with those associated with in-person dispensing of mifepristone. Thus, FDA relied upon robust scientific evidence in concluding that the in-person dispensing requirement was not necessary to ensure the safe and effective use of mifepristone.

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[4] Letter from Janet Woodcock, Acting Commissioner of Food & Drugs, to Maureen Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021), at 1 (hereinafter "April 2021 FDA Letter").
[5] *Id.*
[6] *Id.* at 2.

One such study evaluated the TelAbortion Project, a pilot program through which patients could obtain mifepristone by mail.[7] The study found a 95% abortion completion rate across the 1,157 patients for whom it obtained pregnancy outcome information.[8] This success rate is comparable to that established for in-person care in prior scientific research.[9] Only 0.9% of telehealth patients experienced serious adverse events, which is consistent with the rate of serious adverse events reported when mifepristone is dispensed in person.[10] The authors concluded that their "data disprove[d] the notion that medication abortion must be dispensed in-person" to ensure safe use.[11]

Another study directly compared effectiveness and safety rates for 334 patients obtaining medication abortion via three methods: telehealth consultation with pills sent by mail, telehealth consultation with in-person medication pick-up, and in-

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[7] *Id.* at 1 (citing Chong et al., *Expansion of direct-to-patient tele-medicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 CONTRACEPTION 43 (2021)).
[8] Chong et al., *supra* note 7.
[9] *Id.* (citing Chen et al., *Mifepristone with Buccal Misoprostol for Medical Abortion, a Systematic Review*, 126 OBSTET. & GYNECOL. 12 (2015)).
[10] *Id.*
[11] *Id.* at 48. Plaintiffs argue, incorrectly, that this study does not support the safety of mifepristone by mail because "the vast majority of study participants . . . had either a pelvic exam or ultrasound prior to taking the drugs[.]" Br. at 60-61. As FDA noted, although this study's protocol included a screening ultrasound, in 52% (346 of 669) of the study's abortions that occurred during the COVID-19 pandemic—during which FDA permitted the entire medication abortion process to be completed remotely—participants were not screened via ultrasound. This allowed the authors to conclude that "direct-to-patient services that mail the pills to patients are safe, effective and feasible, even without a screening ultrasound." ROA.1032-33 (Center for Drug Evaluation and Research, Application Numbers: 020687 and 91178 Rationale Review (Dec. 16, 2021) (hereinafter "FDA 2021 Rationale Review") at 29-30); Chong et al., *supra* note 7, at 46, 48.

person care consultation and medication pick-up.[12] The study found that the fully remote group experienced "similar, low rates of adverse events" as the other two demographically similar cohorts and also reported the highest effectiveness rate (97.1%).[13]

In addition to this robust body of evidence collected in the United States, FDA considered two international studies. The first study included data from 52,142 patients obtaining abortions in England and Wales during the two months before and after COVID-related guidelines shifted medication abortion care to a telehealth framework.[14] The study included data on 85% of all patients obtaining medication abortion in England and Wales during this period. The authors concluded that treatment success was similar before and after the change in guidelines: for the post-COVID cohort, 99.2% of telemedicine patients and 98.1% of in-person patients had

[12] April 2021 FDA Letter at 1 (citing Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 CONTRACEPTION 49 (2021)). Plaintiffs argue, incorrectly, that this study does not support the safety of mifepristone by mail because some participants received in-person screening. Br. at 60-61. Yet, 33.2% of participants did not have a screening ultrasound, thus demonstrating the safety of no-test provision of mifepristone, as FDA acknowledged. ROA.1034-35 (FDA 2021 Rationale Review at 31-32).

[13] Kerestes et al., *supra* note 12.

[14] April 2021 FDA Letter at 1 (citing Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, 128 BJOG 1464 (2021)). Plaintiffs claim that FDA concluded this and other studies, including *infra* note 18, "were of limited usefulness or had limited certainty of results." Br. at 60. Plaintiffs mischaracterize FDA's reasoning, which discussed some limitations of the studies but concluded that they, along with all the evidence, supported the safety and effectiveness of mail dispensing of mifepristone. ROA.1037 (FDA 2021 Rationale Review at 34) ("[D]espite the limitations noted, these studies support that dispensing by mail is safe and effective.").

complete abortions, compared with 98.2% pre-COVID.[15] Both the pre- and post-COVID cohorts experienced extremely low rates of serious adverse events (.02% telehealth compared to .04% in clinic).[16] The study also found that telehealth increased access to care with significant reductions in waiting times and pregnancy duration at the time of termination.[17] The second international study examined 663 Scottish patients and found a 98% completion rate for patients who obtained an at-home medication abortion after a telephone consultation.[18] The patients' low rate of serious adverse events (with only 2 patients total admitted to the hospital) was "similar to those after abortion care in a clinical setting."[19]

B. FDA Relied on and Discussed Additional Evidence in Its December 2021 Analysis Supporting the Safety and Effectiveness of Removing the In-Person Dispensing Requirement.

In December 2021, FDA reviewed additional studies that included more than 3,000 patients, and further reviewed certain studies it examined in April 2021, all supporting the removal of the in-person dispensing requirement. All the studies found comparably high effectiveness rates and very low rates of serious adverse

[15] Aiken et al., *supra* note 14.
[16] *Id.*
[17] *Id.*
[18] April 2021 FDA Letter at 1 (citing Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, 47 BMJ SEX. REPROD. HEALTH 246 (2021)).
[19] Reynolds-Wright et al., *supra* note 18, at 247.

events between medication abortions dispensed in person and those obtained remotely.[20]

Two of the newly reviewed studies were additional publications evaluating the TelAbortion Project (*see supra* Section I.A), which again found very low rates of serious adverse events and high completion rates.[21] One identified a 94% completion rate with only two serious adverse events across 217 patients who received abortion medication by mail.[22] The other identified a 95.6% completion rate and only three serious adverse events across 412 patients who obtained abortion medication by mail.[23] The latter study also compared groups of patients who obtained a pretreatment ultrasound or pelvic exam to those who did not and identified no statistically significant differences in serious adverse events.

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[20] *See* FDA 2021 Rationale Review; *see also* Letter from Patrizia A. Cavazzoni, M.D., Director Center for Drug Evaluation and Research to Donna J. Harrison, M.D., Executive Director Am. Ass'n of Pro-Life Obstetricians & Gynecologists and Quentin L. Van Meter, President, Am. Coll. of Pediatricians denying in part and granting in part 2019 Citizen Petition at 25-36 (Dec. 16, 2021).

[21] FDA 2021 Rationale Review at 24, 28-29, 32, 34, 39 (discussing Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 CONTRACEPTION 173 (2019)); *id.* at 24, 28-30, 34, 39 (discussing Anger et al., *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the US*, 104 CONTRACEPTION 659 (2021)).

[22] Raymond et al. (2019), *supra* note 21.

[23] Anger et al., *supra* note 21. Plaintiffs argue that this study does not support safety of mifepristone by mail because FDA stated its findings should "be interpreted carefully." Br. at 60. But FDA did subsequently undertake that careful interpretation and concluded that the study "support[s] dispensing mifepristone and misoprostol by mail after a telemedicine visit" because "[e]fficacy was maintained" and "SAE frequencies [were] comparable to labeled rates." ROA.1035 (FDA 2021 Rationale Review at 32).

Three additional studies considered by FDA provided further evidence of the safety and effectiveness of remote provision of mifepristone. A U.S.-based study that did not require a pre-abortion ultrasound collected outcomes for 110 patients who obtained medication abortion through a mail-order pharmacy after a telehealth evaluation of medical history and pregnancy.[24] 95% of participants experienced a complete abortion without need for follow-up care, and no serious adverse events were reported.[25] A second study provided outcome data for 224 patients who were assessed in person before receiving medication through a mail-order pharmacy.[26] The study identified a 96.9% completion rate and only two serious adverse events—a rate comparable to the serious-adverse-event rate reported in connection with in-clinic care.[27] The third study focused on Australia's first nationwide telehealth abortion program to not require an in-person provider visit.[28] This study included data for 754 patients who received medication abortion through a mail-order pharmacy and showed a 96% completion rate. While the study found that 3% of patients were

[24] FDA 2021 Rationale Review at 24, 27-28 (discussing Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic*, 4 JAMA NETWORK OPEN e2122320 (2021)).
[25] Upadhyay et al. (2021), *supra* note 24.
[26] FDA 2021 Rationale Review at 24, 26, 28, 39 (discussing Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 CONTRACEPTION 36 (2022)). This study is the interim analysis of the larger study cited *infra* note 47.
[27] Grossman et al., *supra* note 26.
[28] FDA 2021 Rationale Review at 24, 27-28, 39 (discussing Hyland et al., *A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months*, 58 AUSTL. & N.Z. J. OBSTET. & GYNECOL. 335 (2018)).

admitted to the hospital, the reasons for hospitalization are not discussed by the authors and there were no increases in other serious adverse events. The study authors do note that the majority of telehealth patients (60%) lived outside of major cities.[29]

Based on the record of scientific evidence considered by FDA for its April 2021 nonenforcement decision and its December 2021 analysis, FDA reasonably concluded that removing the in-person dispensing requirement would not reduce the safety or effectiveness of mifepristone for use in medication abortion.

C. Additional Evidence Issued Before FDA's 2023 Final Decision Supports the Safety and Effectiveness of Removing the In-Person Dispensing Requirement.

FDA's 2021 decision to remove the in-person dispensing requirement was formalized in 2023. Before the agency's final decision, additional studies were published that demonstrated medication abortion via telehealth continued to be safe and effective, with low rates of serious adverse events similar to those arising from in-person dispensing.

One such study examined a cohort of 3,779 patients across 24 states who received medication abortion in outpatient and online clinics.[30] This study highlighted high rates of effectiveness and low rates of serious adverse events, regardless of whether the medication was dispensed in person or mailed to the patient.[31] A study

[29] Hyland et al., *supra* note 28, at 335.
[30] Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA INTERNAL MED. 482 (2022).
[31] *Id.*

of nearly 280,000 patients in Canada conducted before and after that country eliminated its REMS-like restrictions on mifepristone to make it available by prescription like other medications identified no material changes in rates of serious adverse events compared to the period before the restrictions were lifted.[32]

D. Plaintiffs Incorrectly Suggest That FDA Ignored Studies Showing Remote Dispensing Might Lead to More Emergency-Room Follow-Up Visits.

Plaintiffs argue incorrectly that the studies showed "an *increase* in risk," based on FDA's observation related to a *subset* of the studies reviewed that "there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail." Br. at 59 (quoting ROA.1088) (alteration in Plaintiffs' Brief).

This argument both selectively quotes FDA's analysis, which ultimately concluded "there are no apparent increases in other serious adverse events related to mifepristone use," (ROA.1088), and conflates emergency-room visits with serious adverse events. While FDA reviews information about emergency-room visits related to medication abortion, it considers whether those visits are accompanied by other serious adverse events when evaluating real-world safety and effectiveness.[33]

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[32] Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 NEJM 57 (2022).

[33] U.S. FOOD AND DRUG ADMINISTRATION, *What is a Serious Adverse Event?* (May 18, 2023), https://www.fda.gov/safety/report-ing-serious-problems-fda/what-serious-adverse-event (hereinafter "FDA, *What is a Serious Adverse Event?*") ("Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event)."); *see also* ROA.1088 (FDA 2021 Rationale Review at 34) ("One reason

Research shows that patients go to an emergency room after a medication abortion for reassurance, for symptom evaluation, to ask questions, or to confirm they are no longer pregnant, without receiving any treatment, and that the farther a patient lives from their abortion provider, the more likely they are to use an ER for follow-up care.[34] As many as half of all emergency room visits receive observation care without treatment.[35] Emergency-room-visit rates, which reflect patient behavior rather than clinical harm, therefore are not a reliable proxy for the safety or effectiveness of mifepristone.

E. FDA Properly Relied on Adverse-Event Reporting to Conclude That Removing the In-Person Dispensing Requirement Would Not Compromise Patient Safety.

FDA's reliance on adverse-event-reporting data was both appropriate and consistent with its statutory authority and standard agency practice. FDA reviewed the FDA Adverse Event Reporting System ("FAERS") data for January 27, 2020, through September 30, 2021—a period that included intervals when the in-person dispensing requirement both was and was not enforced. FDA's analysis, along with

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for the increase in frequent ED/urgent care visits in the Raymond publication, according to its authors, may have been that a substantial proportion of participants lived significant distances from their providers . . .").

[34] *See, e.g.*, Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175 (2015); Upadhyay et al., *Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample*, 16 BMC MED. 88 (2018); Br. at 52; Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 OBSTET. & GYNECOL. 616 (2017).

[35] Upadhyay et al., *Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample*, 16 BMC MED. 88 (2018).

its continuous monitoring of real-world adverse-event data, identified no safety concerns.[36] FDA analyzed seven instances of adverse events. While five of the seven were reported when the in-person dispensing requirement was not enforced, three of those five cases involved circumstances where mifepristone was dispensed in person.[37] FDA analyzed this data to determine whether there was any difference in adverse events between the two periods and found none, concluding that "mifepristone may be safely used without an in-person dispensing requirement."[38]

Although Plaintiffs argue that FDA's reliance on FAERS data was inappropriate because FDA lifted a reporting requirement in 2016, Br. at 54-57, Plaintiffs misunderstand the 2016 reporting modification. The change eliminated only an unusual requirement that prescribers separately report certain non-fatal adverse events to manufacturers. Absent the requirement, manufacturers must still review, collect, and submit all adverse-drug-experience information received from prescribers in periodic reports to FDA. 21 C.F.R. § 314.80. Critically, FDA determined that serious adverse events other than death would still be captured through these periodic safety reports—the same reporting mechanism FDA relies on for virtually all other

[36] FDA 2021 Rationale Review at 22-23; ROA.1026-27 (FDA 2023 Rationale Review at 23-24).
[37] *Id.*
[38] *Id.* at 23.

prescription drugs.[39] What's more, FDA still maintains a heightened reporting requirement that prescribers report any potentially associated fatalities.[40]

Moreover, FAERS data was only one component of FDA's analysis. The peer-reviewed studies that FDA considered—covering tens of thousands of patient outcomes, with data collected through rigorous study designs—provided an independently sufficient evidentiary basis for FDA's conclusion. *See supra* Section I.A. Plaintiffs' focus on the FAERS data ignores the overwhelming body of clinical evidence supporting the safety of removing the in-person dispensing requirement.

II. The Body of Scientific Evidence Published Since 2023 Further Confirms the Safety and Effectiveness of Medication Abortion Without an In-Person Dispensing Requirement.

A. Additional Scientific Evidence Further Supports Removing the In-Person Dispensing Requirement.

The scientific evidence published since 2023 has only further confirmed the safety and effectiveness of removing the in-person dispensing requirement. A large-scale study of over 6,000 patients obtaining medication abortions via telehealth found 97.7% effectiveness and a serious-adverse-event rate of only 0.25%, with no

[39] *Id.*; *see also* FAERS Public Dashboard – FAQ, FDA https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html (FAERS "supports the FDA's post-marketing safety surveillance program" for all marketed drug products).

[40] *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Jan. 17, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medi-cal-termination-pregnancy-through-ten-weeks-gestation (providing mifepristone's current REMS and prescriber agreement form).

significant differences between synchronous and asynchronous models of care.[41] Another 2024 study that examined outcomes for patients obtaining telehealth medication abortion with a concurrently recruited cohort of patients who obtained in-person care found no difference between the two groups in the effectiveness of the abortion care or rates of serious adverse events.[42] The overall effectiveness rate was 94.4% for the no-test-and-mail group and 93.3% for the in-person-with-ultrasonography group.[43] Further, a June 2025 Cochrane Review found that "the use of telemedicine for medical abortion in early pregnancy is generally safe, effective, and acceptable"; the review's findings were "consistent with the conclusions of previous work on the topic," including "more recent non-comparative studies."[44] The report concluded that "serious adverse events are rare" when medication abortions are obtained without an in-person dispensing requirement.[45]

Another study with 184 medication abortion patients compared in-clinic care to telehealth-care-with-medication-mailing and concluded that telehealth is "as

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[41] Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA,* 30 NATURE MED. 1191 (2024). Synchronous telehealth abortion care involves real-time interaction between a patient and clinician (by video or phone) before medication is prescribed. Asynchronous care relies on patients completing an online medical history and other screening that a clinician reviews later, with any additional communication needed before prescribing medication done through secure messaging.

[42] Ralph et al*., Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898 (2024).

[43] *Id.*

[44] Cleeve et al., *The use of telemedicine services for medical abortion*, 4 COCHRANE DATABASE SYSTEMATIC REVS. 1, 25 (2025).

[45] *Id.* at 10.

effective, timelier, and potentially more accessible than in-clinic" care.[46] Similarly, a study of 510 medication abortions where eligibility was assessed through an in-person visit but patients received medication through a mail-order pharmacy identified 97.8% effectiveness and only three serious adverse events.[47] Yet another study showed that "medication abortion care provided without screening ultrasonography or pelvic examination is comparably safe and effective to care with these screening tests."[48] And a pilot project of 156 patients in Colorado and Minnesota studying the feasibility and safety of a self-administered, programmed questionnaire to screen for medication abortion eligibility showed a 95% abortion completion rate and few adverse events.[49]

Telehealth dispensing is also critical for patient access. A recent study found that telehealth averted significant travel time—saving one hour and twenty-five minutes for public-transportation users—and particularly benefitted younger

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[46] Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. AM. BOARD FAM. MED. 295, 295 (2024).
[47] Grossman et al., *Mail-Order Pharmacy Dispensing of Mifepristone for Medication Abortion After In-Person Screening*, 184 JAMA INTERNAL MED. 873 (2024).
[48] Koenig et al., *Effectiveness and safety of medication abortion with vs without screening ultrasonography or pelvic examination*, 233 AM. J. OBSTET. & GYNECOL. 453 (2025); *see also* Hunter et al., *Test or No-Test: Comparison of Medication Abortion Outcomes and Adverse Events When Forgoing Ultrasound, Laboratory Testing, and Physical Examination*, 47 J. OBSTET. & GYNECOL. CAN. 102730 (2024) (showing similar results in Canada).
[49] Raymond et al., *Evaluation of a "smart" screening tool for asynchronous assessment of medication abortion eligibility: A pilot study*, 131 CONTRACEPTION 110340 (2024); *see also* Smith, *The Safety and Efficacy of a "No Touch" Abortion Program Implemented in the Greater Toronto Area During the COVID-19 Pan-demic,* 46 J. OBSTET. & GYNECOL. CAN. 102429 (2024) (assessing results for a similar program in the Toronto area).

patients, those living in rural areas, those experiencing food insecurity, and those living far from an abortion facility.[50] Patients also report widespread satisfaction with remote dispensing: a recent study showed that 98% of patients trusted their telehealth provider, and 96% felt telehealth was the right decision.[51] Patients most commonly cited privacy and expediency as primary benefits.[52]

These studies confirm what FDA knew to be true in 2021 and 2023: telehealth dispensing of mifepristone is safe, effective, and reduces burdens to accessing care.

B. Plaintiffs Have Not Identified Any Sound Science Undercutting the Decision to Remove the In-Person Dispensing Requirement.

Against the overwhelming scientific and medical consensus that informed FDA's reasoned decision-making, Plaintiffs lean on a self-published report by the Ethics and Public Policy Center ("EPPC"). Br. at 15; ROA.425-31. But this report does not cast doubt on FDA's decision to remove the in-person dispensing requirement because it is riddled with methodological flaws and is scientifically unsound.

As an initial matter, EPPC has refused to disclose the specific insurance claims database it utilized, the methodology for identifying medication abortions, or the coding it used to identify serious adverse events.[53] This lack of transparency

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[50] Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis*, 9 JMIR PUB. HEALTH AND SURVEILLANCE e45671 (2023).
[51] Koenig et al., *Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study*, 114 AM. J. PUB. HEALTH 241 (Feb. 2024).
[52] *Id.*
[53] EPPC repeatedly told journalists it could not reveal the dataset or even its source. *See, e.g.*, Kessler, *Digging Into the math of a study attacking the safety of the abortion pill*, WASH. POST

precludes any independent verification or reproducibility. Indeed, the report falls far short of the gold-standard science requirements defined by recent Executive Orders and White House Office of Science and Technology Policy guidance, which require that data and methods be "reproducible," "transparent," "communicative of error and uncertainty," "skeptical of its findings and assumptions," and "subject to unbiased peer review."[54] EPPC's report satisfies none of these criteria.

Beyond these transparency failures, EPPC's report systematically overestimates the number of serious adverse events associated with medication abortions obtained without an in-person dispensing requirement through a series of fundamental classification errors:

First, EPPC's largest category of serious adverse events is a vague catch-all category of "[o]ther abortion complications," which is likely where EPPC included

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(May 12, 2025), https://www.washingtonpost.com/poli-tics/2025/05/12/abortion-pill-medication-abortion-study-mifepristone. EPPC argues that it need not disclose its database because "substantially similar databases are widely available," making an analogy to baseball statisticians' use of different databases drawn from the same major league team box scores. EPPC Amicus Br. at 7. Yet, gold-standard science calls for reproducibility, which requires use of the same, not only similar, data and codes. Executive Order, *Restoring Gold Standard Science* (May 23, 2025), https://www.whitehouse.gov/presidential-ac-tions/2025/05/restoring-gold-standard-science. Additionally, EPPC has obstructed replicability, another standard for good science, by concealing the methodological details of its coding, including, for example, the parameters of its vague catch-all "serious adverse event" category of "other abortion complications." *See* Hall et al., *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, ETHICS & PUB. POL'Y CTR. (2025) at 2, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event (hereinafter "EPPC Report on Serious Adverse Event").The analogy to baseball statistics based on reproducible and replicable metrics of the game is thus inapt.

[54] Executive Order, *Restoring Gold Standard Science*, *supra* note 53.

unidentified "codes suggested by our doctors."[55] However, EPPC provides no information about the training or expertise of the individuals who did the coding, or what they relied upon to designate complications for this category. EPPC also does not disclose the codes that it counted in this "Other" category.[56]

Second, hemorrhage accounts for a significant number of EPPC's claimed "serious adverse events" and the term is inadequately defined by EPPC.[57] Because a successful medication abortion always involves bleeding, EPPC more likely than not misclassified cases of normal, expected bleeding as serious adverse events.[58]

Third, EPPC included emergency-room visits as serious adverse events,[59] even though—as discussed above—research consistently shows that many emergency-room visits following medication abortion are for routine symptom assessment and do not result in any treatment. FDA has also determined that an emergency-room visit alone is not a serious adverse event.[60]

Fourth, EPPC counted circumstances where patients sought treatment to complete a medication abortion as a serious adverse event. That approach is inconsistent with published literature and FDA guidance. The need for additional medications or

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[55] EPPC Report on Serious Adverse Event at 2, 5.
[56] *See id.*
[57] *Id.* at 2.
[58] *See* Arey, *Self-diagnosing the end of pregnancy after medication abortion*, 26 CULT. HEALTH SEX. 405 (2024).
[59] EPPC Report on Serious Adverse Event at 5.
[60] FDA, *What is a Serious Adverse Event?*, *supra* note 33.

a procedure to complete an abortion is an expected outcome in 3-5% of patients.[61] Any additional medications can be dispensed remotely and the procedure to complete the abortion can be administered in a doctor's office or outpatient clinic.

Fifth, EPPC purported to identify instances of medication abortions by identifying prescriptions for mifepristone with or without misoprostol within the next three days. But mifepristone and misoprostol are also used for miscarriage management, which is associated with a slightly higher complication rate than for abortion. EPPC's method of identifying abortions therefore artificially inflates the serious-adverse-event rate.[62]

Sixth, insurance-claims databases overrepresent patients more likely to have pregnancy complications, because some insurance plans—particularly Medicaid—provide coverage for abortion care only when the pregnancy endangers the life of the pregnant person or in instances of rape or incest, meaning patients with higher risk profiles are disproportionately captured in the data.[63]

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[61] Chen et al., *supra* note 9; Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: A systematic review*, 87 CONTRACEPTION 26 (2013); Upadhyay et al. (2015), *supra* note 34.

[62] EPPC Report on Serious Adverse Event at 4; *see, e.g.*, Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, 330 JAMA 766 (2023); Tarleton et al., *Society of Family Planning Clinical Recommendation: Medication management for early pregnancy loss*, 144 CONTRACEPTION 110805 (2025); Nobles et al., *Abortion Restrictions Threaten Miscarriage Management In The United States*, 43 HEALTH AFFAIRS (MILLWOOD) 1219 (2024); Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEJM 2161 (2018).

[63] EPPC argues that "[i]nsurance-claims data is a cornerstone of public health and safety monitoring" (EPPC Amicus Br. at 7), without acknowledging such data's limitations related to abortion

Even setting aside these pervasive methodological flaws, EPPC's sweeping conclusions and policy recommendations are not even supported by its own supposed evidence. In its report, EPPC argues that in-person dispensing would reduce serious adverse events.[64] Yet, the report does not differentiate its alleged serious adverse events by the dispensing location or by year, so there is no support for its claim that removing the in-person dispensing requirement has increased serious-adverse-event rates.[65]

EPPC's attempt to salvage its conclusions in a hastily written "Fact Sheet" fares no better. In that document, EPPC compared the alleged serious-adverse-event rate before and after July 2020—when FDA's in-person dispensing requirement was temporarily paused by court order—claiming that the data show a statistically significant higher serious-adverse-event rate in the second time period.[66]

EPPC itself concedes that it lacks the necessary data to separate patients based on whether they received care through telehealth.[67] Instead, EPPC erroneously infers

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care. *See, e.g.,* Frederiksen et al., *The limitations of using Medicaid administrative data in abortion research*, 142 CONTRACEPTION 110704 (2025).

[64] EPPC Report on Serious Adverse Event at 2.

[65] Similarly, although EPPC's analysis does not examine adverse events by pregnancy duration or whether mifepristone was provided by a physician or an advanced practice clinician, EPPC opines on gestational limits and recommends that only physicians provide mifepristone. EPPC Report on Serious Adverse Event at 2.

[66] *See* Hall et al., *Fact Sheet: Data Reveals the FDA's Removal of In-Person Dispensing Requirement Increased the Dangers of the Abortion Pill*, ETHICS & PUB. POL'Y CTR. (2026), https://media.eppc.org/2026/03/FACT-SHEET-Data-on-FDA-Removal-of-In-person-dispensing-requirement-2.pdf (hereinafter, "EPPC Fact Sheet").

[67] EPPC Fact Sheet at 1-2.

a causal relationship between the claimed change in "serious adverse events" and the removal of the in-person dispensing requirement simply because they occurred during the same time period. Remote dispensing was not even available during this entire period—the in-person dispensing requirement was in effect for several months of EPPC's second time period—but EPPC still attributes all outcomes during this period to the requirement's removal.

The difference EPPC claims occurred could be attributable to anything that happened during the second time period, a combination of factors, or limitations of EPPC's data, but EPPC fails to consider *any* alternative explanations, as would be proper for a high-quality study. Indeed, telehealth is likely not the cause of any such increase. Because most telehealth providers did not accept insurance during this period, the vast majority of telehealth abortions would not even be captured in EPPC's dataset.[68]

EPPC's claim that the removal of the in-person dispensing requirement caused an increase in prescriptions to people with ectopic pregnancies—based *only* on an alleged increase in ectopic-pregnancy rate during a period in which remote

[68] *See* Koenig et al., *Virtual Clinic Telehealth Abortion Services in the United States One Year After Dobbs: Landscape Review*, 26 J. MED. INTERNET RES. e50749 (2024) (of 20 virtual clinics providing telehealth abortion care in 26 states and Washington D.C. in June 2023, only two accepted private insurance and one accepted Medicaid); Upadhyay et al., *Pricing of medication abortion in the United States, 2021-2023*, 56 PERSPECTIVES ON SEX. AND REPROD. HEALTH 282 (2024) ("Most virtual clinics did not accept Medicaid. In 2021, none of the 31 (0%) virtual clinics accepted Medicaid, increasing to 16 out of 226 (7%) in 2023.").

dispensing was permitted—is also plagued by fundamental analytical errors.[69] In addition to erroneously implying causation from correlation, EPPC's claim assumes incorrectly that the in-person dispensing requirement, which controlled *where* someone picked up their medication, would necessarily determine *whether* or *how* patients were screened for ectopic pregnancies before being determined eligible for medication. However, the standard protocol for telehealth abortion care screens patients for medical eligibility, including evaluating any risk factors and symptoms of ectopic pregnancy before patients are approved to receive medication abortion.[70] According to the protocol, anyone screened out would be referred to in-person care.

Ultimately, the fundamental flaws in EPPC's methodology fatally undercut its claims. EPPC's report does not constitute the kind of rigorous, transparent, peer-reviewed science on which regulatory decisions should be based, and it provides no basis whatsoever for this Court to second-guess FDA's expert judgment to remove the in-person dispensing requirement.

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[69] *See* EPPC Amicus Br. at 5 (citing EPPC Fact Sheet).

[70] Raymond et al., *Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond*, 101 CONTRACEPTION 361 (2020); Biggs et al., *Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care*, 134 CONTRACEPTION 110405 (2024) ("Findings suggest that no-test telehealth abortion care does not delay and sometimes facilitates earlier detection and treatment of ectopic pregnancy.").

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's decision denying Plaintiffs' motion.

Dated: July 22, 2026

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CERTIFICATE OF SERVICE

I certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,436 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman font size 14.

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APPENDIX

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