No. 25A1207, 25A1208

IN THE

Supreme Court of the United States

DANCO LABORATORIES, LLC, *et al.*,

Applicants,

v.

THE STATE OF LOUISIANA, *et al.*,

Respondents.

GENBIOPRO, LLC, *et al.*,

Applicant,

v.

THE STATE OF LOUISIANA, *et al.*,

Respondents.

BRIEF OF AMICI CURIAE 360 REPRODUCTIVE HEALTH RESEARCHERS IN SUPPORT OF APPLICATIONS BY DANCO AND GENBIOPRO TO STAY OR VACATE THE FIFTH CIRCUIT'S STAY PENDING APPEAL

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae[2] are 360 leading reproductive health researchers in the United States and worldwide. Amici are trained and experienced in conducting or evaluating clinical and social-science studies on reproductive health issues, including studies on 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. A complete list of amici can be found in the Appendix.

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

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and no entity or person, other than *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

[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.

demonstrated that the in-person dispensing requirement is not necessary to ensure the safety and effectiveness 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 rigorous 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 difficultly accessing health care, including those in rural or medically underserved areas.

The scientific evidence published since 2023 has only 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 the 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 extremely 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 generate the study cohort and analyze the data—preventing any independent verification of its conclusions. EPPC also inflated its serious adverse event figures by misclassifying outcomes such as follow-up treatment in cases where the medication was not fully effective, emergency room visits not requiring treatment or intervention, and normal post-abortion bleeding as "serious adverse events." This methodologically flawed study 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 reverse the Fifth Circuit's decision.

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.

FDA's review to support the removal of the in-person dispensing requirement 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 confirmed 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, 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.

Moreover, FDA properly determined that the in-person dispensing requirement was not only unnecessary but also inconsistent with the statutory requirements for maintaining REMS elements. 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 patients in light of 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.

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[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% percent of approved novel drugs in 2022 were supported by one clinical study).

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 for the provision of medication abortion care via telehealth, with patient outcomes consistent with those associated with in-person dispensing of mifepristone. Thus, FDA relied upon ample evidence that the in-person dispensing requirement was not necessary to ensure the safety and effectiveness of mifepristone.

One such study evaluated the TelAbortion Project, a pilot program through which patients could

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[4] Letter from Janet Woodcock, Acting Commissioner of Food & Drugs, to Mauren Phipps, Chief Executive Official, 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.

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[.]"[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-person care consultation and medication pick-up.[12] The study found consistent effectiveness and "low rates of adverse events" across all three cohorts, with fully remote

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[7] *Id.* at 1 (citing Chong et al., *Expansion of direct-to-patient telemedicine 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.
[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)).

patients reporting the highest rate of effectiveness (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 local 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 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

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[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)).

[15] Aiken et al., *supra* note 14.

[16] *Id*.

[17] *Id.*

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 events between medication abortions dispensed in person and those obtained without an in-person visit.[20]

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[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.

[20] *See* Center for Drug Evaluation and Research, Application Numbers: 020687 and 91178 Rationale Review (Dec. 16, 2021) (hereinafter "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).

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 without the need for follow-up care.[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 medications 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.

Three additional studies provided further evidence of the safety and effectiveness of the provision of mifepristone without in-person dispensing at a hospital, clinic, or medical office. A U.S.-based study that did not require a pre-abortion ultrasound collected abortion outcomes for 110 patients who obtained medication abortion delivered by a mail-order pharmacy after a telehealth evaluation of medical history and

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[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.

pregnancy.[24] The study concluded that 95% of participants experienced a complete abortion with no 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 visit to a provider.[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 admitted to the hospital, the reasons for hospitalization are not discussed by the authors. The study authors do note that the

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[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 48.

[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)).

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 out of 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 of nearly 280,000 patients in

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[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.*

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 the incidence 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.

The Fifth Circuit incorrectly concluded that "FDA's 'own documents' show that 'emergency room care is statistically certain' in mifepristone cases." App. 11a (quoting *All. for Hippocratic Med.*, 2023 WL 2913725, at *10 (5th Cir. Apr. 12, 2023)).[33] This argument conflates emergency room visits with serious adverse events and obfuscates research into the reasons underlying emergency room visits after a medication abortion. 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.[34] Research

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

[33] "App." refers to the Appendix to the Application by Danco to Stay or Vacate the Fifth Circuit's Stay Pending Appeal.

[34] U.S. FOOD AND DRUG ADMINISTRATION, *What is a Serious Adverse Event?* (May 18, 2023), https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event (hereinafter "FDA, *What is a Serious Adverse Event?*") ("Emergency room

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.[35] As many as half of all emergency room visits receive observation care only without treatment.[36] Emergency room visit rates 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 with 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 its continuous monitoring of real-world adverse-event

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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.").

[35] *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).

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

data, identified no safety concerns.[37] 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.[38] 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."[39]

The Fifth Circuit concluded that Plaintiffs are likely to succeed on the merits because FDA's reliance on the FAERS data was inappropriate. App. at 13a. This argument misunderstands 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 prescription drugs.[40] What's more, FDA still maintains a heightened

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[37] FDA 2021 Rationale Review at 22-23; FDA 2023 Rationale Review.

[38] *Id.*

[39] *Id.* at 23.

[40] *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).

reporting requirement that prescribers report any potentially associated fatalities.[41]

In any event, the FAERS data was only one component of FDA's analysis. The peer-reviewed scientific studies that FDA reviewed—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 Lends Further Support for Removing the In-Person Dispensing Requirement.

The scientific evidence collected and published since 2023 has only further confirmed the safety and effectiveness of removing the in-person dispensing requirement. For example, a large-scale study of over

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[41] *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-medical-termination-pregnancy-through-ten-weeks-gestation (providing mifepristone's current REMS and prescriber agreement form).

6,000 patients obtaining medication abortions via telehealth found 97.7% effectiveness and a serious-adverse-effect rate of only 0.25%, with no significant differences between synchronous and asynchronous models of care.[42] Another 2024 study that examined outcomes for patients obtaining telehealth medication abortion with a concurrently recruited cohort of patients who obtained in-person care in the same clinic systems found no difference between the two groups in the effectiveness of the abortion care or rates of serious adverse events.[43] The overall effectiveness rate was 94.4% for the no-test-and-mail group and 93.3% for the in-person-with-ultrasonography group.[44] 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."[45] The report concluded that "serious adverse events are rare" when medication abortions are obtained without an in-person dispensing requirement.[46]

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[42] Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA.* 30 NATURE MED. 1191 (2024).

[43] Ralph et al.*, Comparison of No-Test Telehealth and In-Person Medication Abortion*, 322 JAMA 898 (2024). Synchronous care involves real-time video conferencing or telephone calls between a patient and provider; asynchronous care involves an intake form or app through which patients can submit information for the provider to view at a later time.

[44] *Id.*

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

[46] *Id.* at 10.

Another study with 184 medication abortion patients compared in-clinic care to telehealth-care-with-medication-mailing and concluded that telehealth is "as effective, timelier, and potentially more accessible than in-clinic" care.[47] 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.[48] 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."[49] And a pilot project in Colorado and Minnesota with 156 patients 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.[50]

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[47] 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).

[48] Grossman et al., *Mail-Order Pharmacy Dispensing of Mifepristone for Medication Abortion After In-Person Screening*, 184 JAMA INTERN. MED. 873 (2024).

[49] Koenig et al., *Effectiveness and safety of medication abortion with vs without screening ultrasonography or pelvic examination*, 233 AM. J. OBSTETRICS & GYNECOLOGY 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. & GY CAN. 102730 (2024) (showing similar results in Canada).

[50] 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*

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 patients, those living in rural areas, those experiencing food insecurity, and those living far from the nearest abortion facility.[51] 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.[52] Patients most commonly cited privacy and expediency as primary benefits.[53]

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.

Safety and Efficacy of a "No Touch" Abortion Program Implemented in the Greater Toronto Area During the COVID-19 Pandemic, 46 J. OBSTET. & GYN. CAN. 102429 (2024) (assessing results for a similar program in the Toronto area).

[51] 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); *see also* Koenig et al., *Mailing abortion pills does not delay care: A cohort study comparing mailed to in-person dispensing of abortion medications in the United States*, 121 CONTRACEPTION 109962 (2023) (finding that patients obtaining mifepristone via telehealth can access care just as quickly as patients obtaining mifepristone in person).

[52] 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).

[53] *Id.*

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"). 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 that render its conclusions unreliable.

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 generate the study cohort and analyze the data.[54] This fundamental lack of transparency precludes any independent verification or reproducibility—fatal deficiencies for any scientific analysis. 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

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[54] 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 (May 12, 2025), https://www.washingtonpost.com/politics/2025/05/12/abortion-pill-medication-abortion-study-mifepristone; Landman, *A Convenient Piece of Junk Science*, ATLANTIC, (May 24, 2025), https://www.theatlantic.com/health/archive/2025/05/mifepristone-abortion-rfk-fda/682939.

findings and assumptions," and "subject to unbiased peer review."[55] 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 event is a vague catch-all category of "[o]ther abortion complications," which is likely where EPPC included unidentified "codes suggested by our doctors."[56] However, EPPC provides no information whatsoever 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.[57]

Second, hemorrhage accounts for a significant number of EPPC's claimed "serious adverse events" and the term is inadequately defined by EPPC.[58]

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[55] Executive Order, *Restoring Gold Standard Science* (May 23, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science.

[56] 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), 2, 5, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event (hereinafter "EPPC Report on Serious Adverse Event").

[57] *See id.*

[58] *Id.* at 2.

Because a successful medication abortion always involves bleeding, EPPC more likely than not misclassified cases of normal, expected bleeding as serious adverse events.[59]

Third, EPPC included emergency room visits as serious adverse events,[60] 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, in and of itself, is not a serious adverse event.[61]

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 a procedure to complete an abortion is an expected outcome in 3-5% of patients.[62] 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

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[59] *See* Arey, *Self-diagnosing the end of pregnancy after medication abortion*, 26 CULT. HEALTH SEX. 405 (2024).
[60] EPPC Report on Serious Adverse Event at 5.
[61] FDA, *What is a Serious Adverse Event?*
[62] 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 35.

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.[63]

Sixth, insurance claims databases systematically 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.[64]

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.[65] Yet, the report does not differentiate its

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[63] 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 N. ENGL. J. MED. 2161 (2018).

[64] Frederiksen et al., *The limitations of using Medicaid administrative data in abortion research*. 142 CONTRACEPTION 110704 (2025).

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

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.[66]

EPPC's attempt to salvage its conclusions in a hastily written Q&A document posted days before filing its amicus brief at the district court—subsequently converted to a fact sheet—fares no better. In that document, EPPC compared the rate of alleged serious adverse events 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 rate of serious adverse events in the second time period.[67]

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 be captured in EPPC's dataset.[68] EPPC admits it does not even have data on

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[66] 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.

[67] *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.

[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

the number of medication abortions administered remotely after July 2020.[69]

Ultimately, the fundamental flaws in EPPC's methodology—particularly its expansive and scientifically unsupported classification of "serious adverse events"—fatally undercut any claims regarding an increase in adverse events. 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, based on a voluminous record of sound scientific studies, to remove the in-person dispensing requirement.

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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.").

[69] Society of Family Planning, *#WeCount Report April 2022 through June 2025*, (Dec. 9, 2025), https://societyfp.org/wecount-report-10-june-2025-data.

CONCLUSION

For the foregoing reasons, the Court should reverse the Fifth Circuit's decision.

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