United States Court of Appeals

for the

Fifth Circuit

Case No. 26-30203

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,

Plaintiffs-Appellants,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, 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.

DANCO LABORATORIES, L.L.C.; GENBIOPRO, INCORPORATED,

Intervenors-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA
NO. 6:25-CV-01491, HONORABLE DAVID C. JOSEPH, U.S. DISTRICT JUDGE

BRIEF OF *AMICUS CURIAE* HONEYBEE HEALTH, INC. IN SUPPORT OF APPELLEES' OPPOSITION TO PLAINTIFFS-APPELLANTS' MOTION

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record for *amicus curiae* certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

Amicus Curiae: Honeybee Health, Inc. ("Honeybee") is a privately held corporation. It does not have a parent corporation, and no publicly held company owns 10% or greater ownership in it.

Counsel for Amicus: Eugene M. Gelernter, Hilarie M. Meyers, Hadiya Williams, and Jillian F. Horowitz of Patterson Belknap Webb & Tyler LLP.

Date: April 23, 2026

Respectfully submitted,

/s/ *Eugene M. Gelernter*
Eugene M. Gelernter

TABLE OF CONTENTS

Page

INTEREST OF AMICUS CURIAE 1

ARGUMENT 1

I. Mail-Order Pharmacies Benefit Patients' Health and Autonomy 1

II. Obtaining Mifepristone by Telemedicine and Mail-Order Pharmacies Is Safe and Effective 5

III. Reinstating the In-Person Dispensing Requirement Would Seriously Harm Patients and Mail-Order Pharmacies 9

A. Eliminating access to mifepristone by mail would harm patients 9

B. Prohibiting mail-order dispensing of mifepristone would inflict serious harm on mail-order pharmacies 13

CONCLUSION 14

TABLE OF AUTHORITIES

Page(s)

Cases

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Rules

Fed. R. App. P. 32 16

INTEREST OF AMICUS CURIAE[1]

Honeybee is a mail-order pharmacy run by a board-certified pharmacist. Honeybee was the first mail-order pharmacy in the United States to dispense mifepristone after the FDA lifted the in-person dispensing requirement and dispenses the highest volume of mifepristone by mail of any U.S. pharmacy. Honeybee submits this brief to highlight: (1) the role that mail-order pharmacies play in providing patients with access to high-quality and low-cost medications; (2) the many studies showing that medication dispensed by mail-order pharmacies is safe and effective; and (3) the harms that reinstating the in-person dispensing requirement would impose.

ARGUMENT

I. Mail-Order Pharmacies Benefit Patients' Health and Autonomy.

Telemedicine and mail-order pharmacies play a vital role in ensuring patients have access to safe and effective healthcare and medication, including mifepristone. Research has shown that

[1] No counsel for any party authored this brief in whole or in part and no entity or person, other than *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

telemedicine is safe and effective, and provides patients with important benefits, including cost-savings and increased healthcare access.[2] Mail-order pharmacies like Honeybee play an integral role in the telemedicine ecosystem, delivering more than 200,000,000 prescriptions by mail annually.[3]

Substantial scientific evidence confirms the safety, efficacy, and benefits of using mail-order pharmacies.[4] A 2014 study found that using mail-order pharmacies "was not negatively associated with patient safety outcomes overall," and actually "may be associated with improved health

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[2] Shilpa N. Gajarawala & Jessica N. Pelkowski, *Telehealth Benefits and Barriers*, 17 J. Nurse Prac. 218 (2021); Victor C. Ezeamii et al., *Revolutionizing Healthcare: How Telemedicine Is Improving Patient Outcomes and Expanding Access to Care*, 16 Cureus e63881 (2024).

[3] Adam W. Gaffney et al., *Health Needs and Functional Disability Among Mail-Order Pharmacy Users in the US*, 181 JAMA Int'l Med. 554, 555 (2020).

[4] *E.g.*, Junyi Ma & Li Wang, *Characteristics of Mail-Order Pharmacy Users: Results from the Medical Expenditures Panel Survey*, 33 J. Pharmacy Prac. 293, 293 (2018).

outcomes."[5] Subsequent studies have confirmed these findings, including in the context of mifepristone.[6]

Research also has shown that patients who use mail-order pharmacies often exhibit better medication adherence, which leads to better health outcomes.[7] For example, studies have found that stroke patients and patients with type 2 diabetes who used mail-order pharmacies were more likely to adhere to their medication regimen than those using brick-and-mortar pharmacies.[8]

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[5] Julie A. Schmittdiel et al., *The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients*, 19 Am. J. Managed Care 882 (2014).

[6] Phil Schwab et al., *A Retrospective Database Study Comparing Diabetes-Related Medication Adherence and Health Outcomes for Mail-Order Versus Community Pharmacy*, 25 J. Managed Care & Specialty Pharm. 332 (2019); Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36 (2021).

[7] *E.g.*, Ma & Wang, *supra* note 4, at 293.

[8] *E.g.*, William P. Neil et al., *Mail order pharmacy use and adherence to secondary prevention drugs among stroke patients*, 390 J. Neurological Scis. 117 (2018); Schwab et al., *supra* note 6; Bharathi Ramachandran et al., *A Randomized Encouragement Trial to Increase Mail Order Pharmacy Use and Medication Adherence in Patients with Diabetes*, 36 J. Gen. Internal Med. 154 (2020).

Additionally, data show that using mail-order pharmacies results in significant cost savings.[9] For example, a 2020 study found that "the overall health-care costs including medication costs, inpatient costs, and outpatients costs, are . . . lower for mail-order pharmacy users."[10] These savings are particularly important at a time when many patients struggle with healthcare costs.[11]

Telemedicine and mail-order pharmacies also increase the availability of healthcare for many patients, particularly those who live in remote areas, lack access to transportation, or have disabilities that make travel difficult. For these patients, mail-order pharmacies make it possible to obtain medication that otherwise would be difficult, if not

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[9] *See* Ma & Wang, *supra* note 4, at 293; *see also* Julie A. Schmittdiel et al., *Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study*, 19 BMC Health Serv. Rsch. 422 (2019).

[10] Ma & Wang, *supra* note 4, at 293; *see also* Scott Devine et al., *A comparison of diabetes medication adherence and healthcare costs in patients using mail order pharmacy and retail pharmacy*, 13 J. Med. Econ. 2013 (2010).

[11] *See* Grace Sparks et al., *Americans' Challenges with Health Care* Costs, KFF (Apr. 16, 2026), https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/.

impossible, to obtain.[12] And patients who use telemedicine and mail-order pharmacies cite increased privacy as a further benefit.[13]

II. Obtaining Mifepristone by Telemedicine and Mail-Order Pharmacies Is Safe and Effective.

Mail-order pharmacies like Honeybee play a vital role in providing patients with safe and effective access to mifepristone by mail.[14] Medication abortions now account for nearly two-thirds of abortions

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[12] *See* Ezeamii et al., *supra* note 2; Natalie Lawson et al., *Disability and telehealth since the COVID-19 pandemic*, Ctr. Health & Rsch. Transformation (Aug. 29, 2022), at 5, https://chrt.org/wp-content/uploads/2022/08/RRTC-Telehealth-Aug-2022-1.pdf; Pankajkumar A. Anawade et al., *A Comprehensive Review on Exploring the Impact of Telemedicine on Healthcare Accessibility*, 16 Cureus e55996 (2024).

[13] *E.g.*, Leah R. 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, 248 (2024); *see also* Yam B. Limbu & Bruce A. Huhmann, *What influences consumers' online medication purchase intentions and behavior? A scoping review*, Frontiers in Pharmacology (Feb. 12, 2024), https://doi.org/10.3389/fphar.2024.1356059 ("Consumers' perceptions of privacy can influence their decision to buy some prescription medicines online . . . .").

[14] *See, e.g.*, Abigail Adams, *Meet the Pharmacist Expanding Access to Abortion Pills Across the U.S.*, TIME (June 13, 2022), https://time.com/6183395/abortion-pills-honeybee-health-online-pharmacy/.

provided nationwide.[15] Mifepristone is an essential part of a medication abortion regimen that is recommended[16] and most commonly used in this country.[17]

As countless studies have shown, prescribing medication abortion by telemedicine and dispensing that medication to patients by mail is safe and effective. For example:

- A 2024 study reviewing more than 6,000 medication abortions obtained via telehealth found that 97.7% of patients completed the abortion without further intervention, with a serious adverse event rate of only 0.25%. This study looked at both synchronous

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[15] *See* Isaac Maddow-Zimet et al., *Abortion in the United States*, Guttmacher Inst. (Mar. 2026), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states.

[16] Am. Coll. Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, Practice Bulletin No. 225 (Oct. 2020, reaff'd 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[17] *The Availability and Use of Medication Abortion*, KFF (March 20, 2024), https://www.kff.org/womens-health-policy/the-availability-and-use-of-medication-abortion/.

and asynchronous models of telemedicine care and found no difference in safety or effectiveness.[18]

- A study analyzing data for nearly 4,000 patients concluded that there was no statistically significant difference in the safety or efficacy of medication abortion when the patient received the medications by mail, rather than in person.[19]
- In a study of over 500 patients, researchers concluded that medication abortion through telehealth and mail-order dispensing has similar efficacy rates to in-person care, with "low rates of [adverse events] overall."[20]
- A 2024 study of 1600 abortion patients who obtained abortion care by telemedicine found that "nearly all patients were very satisfied with telehealth abortion," as telehealth abortion

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[18] Ushma D. Upadhyay et al., *Effectiveness and safety of telehealth medication abortion in the USA*, 30 Nature Med. 1191, 1192 (2024).

[19] *See* Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multi-center Cohort Study*, 182 JAMA Internal Med. 482, 487 (2022).

[20] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 901, 903 (2024).

ensures more privacy and is less expensive and faster than a clinic.[21]

Other research underscores that telehealth is a safe and effective way of providing patients with timely access to abortion care. For example, studies confirm that telehealth medication abortion "[is] as effective, timelier, and potentially more accessible than in-clinic care," with telehealth patients "receiv[ing] care more quickly" and seeking care earlier in pregnancy than for in-clinic visits.[22] Researchers have also found that mailing mifepristone for patients' in-home use "[does] not significantly prolong [the] time from patients' first contact with the clinic to mifepristone ingestion or increase pregnancy duration at mifepristone ingestion."[23]

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[21] Koenig et al., *supra* note 13, at 248.

[22] Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Uusual in-Clinic Care*, 37 J. Am. Bd. Fam. Med. 295, 299 (2024). *See also, e.g.*, Leonardo Cely-Andrade et al., *Telemedicine for the provision of medication abortion to pregnant people at up to twelve weeks of pregnancy: a systematic literature review and meta-analysis*, 21 Reprod. Health 136 (2024); Amanda Cleeve et al., *The use of telemedicine services for medical abortion*, 6 Cochrane Database of Syst. Revs. CD013764 (2025).

[23] Leah R. 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 (2023).

Even when patients obtain mifepristone and misoprostol in person at a clinic, they complete the two-drug regimen at home. Thus, even before the FDA lifted the in-person dispensing requirement, nearly all medication abortions "occur[red] largely in nonclinical settings."[24] In other words, "there is no medical reason for mifepristone to be dispensed in clinics."[25]

III. Reinstating the In-Person Dispensing Requirement Would Seriously Harm Patients and Mail-Order Pharmacies.

A. Eliminating access to mifepristone by mail would harm patients.

Reinstating the in-person dispensing requirement would eliminate access to mifepristone by mail, imposing severe harm on patients who rely on mail-order pharmacies for access to this medication. This harm would impact patients nationwide, but would fall hardest on patients who face barriers to accessing in-person healthcare and brick-and-mortar pharmacies, such as those who live in rural areas, are unable to travel,

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[24] Nat'l Acads. of Sci., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 56 (2018).

[25] Erica Chong et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 Contraception 43 (2021).

or have limited financial resources.[26] Reinstating the in-person dispensing requirement would also harm survivors of sexual violence or other trauma who may need the greater privacy and autonomy that mail-order pharmacies provide.[27] For all these patients, being able to obtain mifepristone from a mail-order pharmacy can mean the difference between obtaining desired medical care and having to forgo it.

Limiting access to mifepristone would have dire consequences for maternal and infant health. Medication abortion carries far less risk for

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[26] *See, e.g.*, Grossman, *supra* note 6 (noting that many patients access mail-order pharmacies because they "live far away from a local pharmacy or have difficulty making the trip"); Leah R. Koenig et al., *The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis,* 9 JMIR Pub. Health Surveillance e45671 (2023) (finding that telehealth reduced travel barriers and made it possible to obtain timely abortion care, particularly among patients who already face barriers to care); Nat'l Acads. of Sci., Eng'g & Med., *supra* note 24, at 78 ("Financial burdens and difficulty obtaining insurance are frequently cited by women as reasons for delay in obtaining an abortion.").

[27] *See* Elizabeth C. Romanis et al., *Safeguarding and Teleconsultation For Abortion*, 398 Lancet 555, 556 (2021), ("Many women in situations of intimate partner or family violence are prevented from attending a clinic in the first place."); *see also* Koenig et al., *supra* note 13 ("Most patients also reported choosing telehealth for greater privacy[.]"); Emily M. Godfrey et al., *Patient Perspectives Regarding Clinician Communication During Telemedicine Compared With In-Clinic Abortion*, 141 Obstetrics & Gynecology 1139, 1143 (2023) (noting that telemedicine allowed patients to "talk more freely and openly").

American women than childbirth. In 2017, the New England Journal of Medicine published a study finding that the maternal mortality rate for live births in the United States was 12 times higher than that associated with medication abortions using mifepristone.[28] More recent data establish that lifting the in-person dispensing requirement has not altered this disparity.[29] We also know that denying access to abortion threatens women's lives. Studies conducted both in the United States[30] and abroad[31] have demonstrated a strong correlation between abortion restrictions and maternal mortality. Additional studies demonstrate that

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[28] Mifeprex REMS Study Grp., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 N. Engl. J. Med. 790 (2017); Nat'l Acads. of Sci., Eng'g & Med., *supra* note 24.

[29] Upadhyay et al., *supra* note 18.

[30] *E.g.*, Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019 (2021); Dovile Vilda et al., *State Abortion Policies and Maternal Death in the United States, 2015–2018*, 111 Am. J. Pub. Health 1696 (2021).

[31] *E.g.*, Ngo Valery Ngo et al., *Reproductive Health Policy Saga, Restrictive Abortion Laws in Low- and Middle-Income Countries (LMICs), Unnecessary Cause of Maternal Mortality*, 45 Health Care for Women Int'l 5 (2021).

abortion restrictions are correlated with increased infant mortality rates.[32]

Furthermore, restricting access to mifepristone will exacerbate health disparities across racial and income lines. Due to structural inequalities, Black Americans, for instance, are more likely to seek abortions than white Americans, and are more likely to be denied access to abortion due to restrictions and bans.[33] Black Americans also face higher incidences of maternal mortality and pregnancy complications, creating greater risk of experiencing adverse health outcomes when access to abortion care is denied.[34]

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[32] *E.g.*, Parvati Singh & Maria F. Gallo, *National Trends in Infant Mortality in the US After* Dobbs, 178 JAMA Pediatrics 1364 (2024); Roman Pabayo et al., *Laws Restricting Access to Abortion Services and Infant Mortality Risk in the United States*, 17 Int'l J. Env't Rsch. Pub. Health 3773 (2020); Alison Gemmill et al., *US Abortion Bans and Infant Mortality*, 333 JAMA 1315 (2025).

[33] Latoya Hill et al., *What are the Implications of the* Dobbs *Ruling for Racial Disparities?*, KFF (Apr. 24, 2024), https://www.kff.org/womens-health-policy/what-are-the-implications-of-the-dobbs-ruling-for-racial-disparities.

[34] *E.g.*, Andreea A. Creanga et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity: A Multi-State Analysis, 2008-2010*, 210 Am. J. Obstetrics & Gynecology 435.e1 (2014); Anna Kheyfets et al., *The Impact of Hostile Abortion Legislation on the United States Maternal Mortality Crisis: A Call for Increased Abortion Education*, 11 Frontiers Pub. Health 1291668 (2023).

B. Prohibiting mail-order dispensing of mifepristone would inflict serious harm on mail-order pharmacies.

The Court should also consider the injury that mail-order pharmacies such as Honeybee would suffer if the in-person dispensing requirement is reinstated. The threat of *existential* harm to a company's business merits considerable weight. *Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.*, 875 F.2d 1174, 1179 (5th Cir. 1989).

Honeybee's business has relied heavily on the FDA's determination that dispensing mifepristone by mail is safe and effective. Every month, Honeybee delivers thousands of orders of mifepristone to patients, some of whom would not otherwise be able to access this medication at all. For example, people who do not live near clinics often turn to Honeybee for assistance, as do those who cannot afford the costs of in-person care and associated travel. Reinstating the in-person dispensing requirement would eliminate this aspect of Honeybee's business and prevent it from providing a safe, essential, and effective medication to patients.

Honeybee's business depends on its ability to dispense safe and effective medications, such as mifepristone, by mail in compliance with applicable federal and state laws. Honeybee is licensed by every board of pharmacy in each state to which it sends medication and only ships

mifepristone to states that permit it to do so. Reinstating the in-person dispensing requirement for mifepristone would jeopardize Honeybee's business and that of other mail-order pharmacies.

CONCLUSION

This Court should affirm the denial of Plaintiffs' motion.

Respectfully submitted,

/s/ *Eugene M. Gelernter*
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CERTIFICATE OF SERVICE

I hereby certify that on April 23, 2026, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which will send notification of such filing to all ECF participants.

/s/ Eugene M. Gelernter

CERTIFICATE OF COMPLIANCE

The undersigned counsel of record certifies pursuant to Fed. R. App. P. 32(g) that the Brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f), this document contains 2,599 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Century Schoolbook font in 14 point size.

/s/ Eugene M. Gelernter