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/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; MICHAEL DAVIS, IN HIS OFFICIAL CAPACITY AS ACTING 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,

GENBIOPRO, INCORPORATED,

Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellee/Cross-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA, LAFAYETTE

BRIEF OF *AMICUS CURIAE* HONEYBEE HEALTH, INC. IN SUPPORT OF INTERVENOR-APPELLEES/CROSS-APPELLANTS GENBIOPRO, INCORPORATED AND DANCO LABORATORIES, L.L.C.

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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: July 21, 2026

Respectfully submitted,

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

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae Honeybee Health, Inc. ("Honeybee") is a mail-order pharmacy run by a board-certified pharmacist with more than twenty years of experience. Honeybee was the first mail-order pharmacy in the United States to dispense mifepristone by mail after the U.S. Food and Drug Administration ("FDA") lifted the in-person dispensing requirement for mifepristone. Honeybee dispenses the highest volume of mifepristone by mail of any U.S. mail-order pharmacy. Honeybee only dispenses mifepristone by mail in jurisdictions whose laws permit it to do so (currently thirty-one states and the District of Columbia) and does not ship mifepristone to Louisiana. It has safely dispensed hundreds of thousands of orders of mifepristone to date.

Honeybee submits this brief to highlight: (1) the role that telehealth and mail-order pharmacies play in providing patients with access to high-quality and low-cost healthcare and medications; (2) the many studies showing the safety and efficacy of using medication, including mifepristone, dispensed by mail-order pharmacies; and (3) the harms

[1] No counsel for any party authored this brief in whole or in part or made any monetary contribution to its preparation and submission. All parties have consented to the filing of this brief.

that reinstating the in-person dispensing requirement would impose on patients and mail-order pharmacies.

SUMMARY OF ARGUMENT

Telehealth and mail-order pharmacies play a vital role in ensuring that patients have access to safe and effective healthcare and medication. Medications have been delivered to patients by mail for more than 100 years, and in recent years, use of mail-order pharmacies in the United States has increased dramatically. Research has shown that the use of telehealth and mail-order pharmacies is safe and effective and benefits patients by improving health outcomes, providing cost savings, and promoting patient privacy and autonomy.

Access to mail-order pharmacies promotes individual patients' ability to obtain high-quality and affordable healthcare in the manner that is most appropriate for them. That is true for mifepristone, which is an essential part of the recommended and most commonly used medication abortion regimen in the United States. Numerous studies have shown that prescribing mifepristone by telehealth and using mail-order pharmacies to dispense it is safe and effective, with an extraordinarily low rate of serious adverse outcomes. Research also

underscores that this model is a safe and effective way of providing patients with timely access to abortion care. Thus, substantial scientific evidence supports the FDA's decision to lift the in-person dispensing requirement for mifepristone. A stay of the 2023 REMS would disregard this scientific evidence.

Reinstating the in-person dispensing requirement would eliminate access to mifepristone by mail even in states where abortion is legal, which would impose severe harm on patients who rely on mail-order pharmacies to obtain this medication. This harm would fall hardest on patients who face difficulties accessing in-person healthcare and brick-and-mortar pharmacies. Reinstating the in-person dispensing requirement would also seriously harm mail-order pharmacies, like Honeybee, that have relied on the FDA's determination that dispensing mifepristone by mail is safe and effective. Requiring mifepristone to be dispensed in person would eliminate a significant portion of Honeybee's business and jeopardize the viability of mail-order pharmacies more broadly.

ARGUMENT

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

Telehealth, telemedicine, and mail-order pharmacies play a vital role in ensuring that patients have access to safe and effective healthcare and medication, including mifepristone.[2] Decades of experience have shown that telemedicine is safe and effective, and provides patients with important benefits, including cost-savings and increased healthcare access.[3] Research has also demonstrated that telehealth and telemedicine is as effective as in-person care,[4] and may be more effective in some circumstances.[5]

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[2] Although the terms "telehealth" and "telemedicine" are often used interchangeably, "telehealth" refers broadly to "the use of telecommunications technology in health care delivery, information, and education," including pharmacy services, whereas "telemedicine" "refers specifically to clinical services." Shilpa N. Gajarawala & Jessica N. Pelkowski, *Telehealth Benefits and Barriers*, 17 J. Nurse Prac. 218, 218 (2021).

[3] Victor C. Ezeamii et al., *Revolutionizing Healthcare: How Telemedicine Is Improving Patient Outcomes and Expanding Access to Care*, 16 Cureus e63881 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11298029/.

[4] *E.g.*, Carly McCord et al., C*omparison of in-person vs. telebehavioral health outcomes from rural populations across America*, 22 BMC Psychiatry 778 (2022); Joseph Ford & Markus Reuber, *Comparisons of Communication in Medical Face-To-Face and Teleconsultations: A Systemic Review and Narrative Synthesis*, 39 Health Commc'n 1012, 1012, 1017 (2023).

[5] *E.g.*, Derek J. Baughman et al., *Comparison of Quality Performance Measures for Patients Receiving In-Person vs Telemedicine Primary Care in a Large Integrated Health System*, 5 JAMA Network Open e223367 (2022), https:// pubmed.ncbi.nlm.nih.gov/36156147/; Christopher M. Jones et al., *Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic*, 79 JAMA Psychiatry 981, 981, 991 (2022).

Mail-order pharmacies like Honeybee play an integral role in the telehealth ecosystem. Between 1996 and 2018, use of mail-order pharmacies in the United States increased by approximately fifty percent.[6] An estimated 200,000,000 prescriptions are delivered by mail annually.[7] Like brick-and-mortar pharmacies, mail-order pharmacies are subject to regulation by state pharmacy boards and must comply with FDA regulations as to the medications that they dispense.[8]

Substantial scientific evidence confirms the safety, efficacy, and benefits of using mail-order pharmacies.[9] Research has shown that

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[6] Duy Do & Pascal Geldsetzer, *Trends in Mail-Order Pharmacy Use in the U.S. From 1996 to 2018: An Analysis of the Medical Expenditure Panel Survey*, 61 Am. J. Preventative Med. e63, e69 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8319048/.

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

[8] *See, e.g.*, 21 C.F.R. § 1304.40; *Locate a State-Licensed Online Pharmacy*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy (last visited July 17, 2026).

[9] *E.g.*, Junyi Ma & Li Wang, *Characteristics of Mail-Order Pharmacy Users: Results from the Medical Expenditures Panel Survey*, 33 J. Pharm. Prac. 293, 293 (2018); 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, 332, 337–39 (2019); Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36, 36 (2021). *See also* Julie A. Schmittdiel et al., *The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients*, 19 Am. J. Managed Care 882, 884, 886 (2013) (finding that use of mail-order pharmacies "may be associated with improved health outcomes").

patients who use mail-order pharmacies often exhibit better adherence to their medication regimens, which in turn can lead to better health outcomes.[10] For example, a 2018 study showed that stroke patients who had been prescribed anticoagulant, antiplatelet, anti-glycemic, antihypertensive, and/or lipid-lowering medications were more likely to adhere to their medication regimen if they used a mail-order pharmacy, rather than a brick-and-mortar pharmacy.[11] Similarly, a 2019 study found greater medication adherence among patients with type 2 diabetes mellitus who used mail-order pharmacies.[12]

Additionally, data show that using mail-order pharmacies provides significant cost savings.[13] For example, a study published in 2010 found

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[10] *E.g.*, Ma & Wang, *supra* note 9, at 293; Schmittdiel et al., *supra* note 9, at 882, 885.

[11] William P. Neil et al., *Mail order pharmacy use and adherence to secondary prevention drugs among stroke patients*, 390 J. Neurological Scis. 117, 118–19 (2018).

[12] Schwab et al., *supra* note 9, at 332, 339; *see also* 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, 154, 158–60 (2020) (finding that mail-order pharmacy use improved adherence to a key class of diabetes medications); Joan M. Neuner et al., *Medication delivery factors and adjuvant endocrine therapy adherence in breast cancer*, 197 Breast Cancer Rsch. Treatment 223, 223 (2023) ("Mail order users had higher adherence in both commercial and Medicare-insured cohorts [of breast cancer patients].").

[13] *See* Ma & Wang, *supra* note 9, 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).

that patients with diabetes who switched from brick-and-mortar retail pharmacies to mail-order pharmacies "trended toward lower total and diabetes-related medical costs over time."[14] And a 2020 study found that "overall health-care costs including medication costs, inpatient costs, and outpatients costs, are . . . lower for mail-order pharmacy users."[15] These cost savings are particularly important at a time when many patients find that healthcare costs are spiraling.[16]

Telehealth and mail-order pharmacies also increase the availability of healthcare for many patients, particularly those who live in remote areas, lack or have limited 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

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[14] 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. 203, 203 (2010).

[15] Ma & Wang, *supra* note 9, at 293.

[16] Recent polling shows that "[j]ust under half of U.S. adults say it is difficult to afford health care costs," with one-third saying "they have skipped or postponed getting health care they needed because of cost" in the past 12 months and one in four saying they "have not filled a prescription . . . because of the cost." Grace Sparks et al., *Americans' Challenges with Health Care Costs*, KFF (Apr. 30, 2026), https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/. Moreover, "[h]ealth care costs remain at the top of the list of people's financial worries, with nearly two-thirds (64%) saying they are at least somewhat worried about affording the cost of health care." *Id.*

not impossible, to obtain.[17] And patients who use telehealth and mail-order pharmacies cite increased privacy as a further benefit.[18]

II. Obtaining Mifepristone by Telehealth and from 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.[19] Medication abortions now account for nearly two-thirds of abortions

[17] *See* Ezeamii et al., *supra* note 3 ("Telemedicine can eliminate the need for long-distance travel for patients in rural or underserved areas, reducing the time and costs associated with accessing healthcare."); Natalie Lawson et al., *Disability and telehealth since the COVID-19 pandemic*, Ctr. Health & Rsch. Transformation (Aug. 29, 2022), https://chrt.org/wp-content/uploads/2022/08/RRTC-Telehealth-Aug-2022-1.pdf (explaining that telehealth can benefit people with disabilities by, inter alia, lessening the need to coordinate transportation, increasing access to specialists, and supporting independence); Pankajkumar A. Anawade et al., *A Comprehensive Review on Exploring the Impact of Telemedicine on Healthcare Accessibility*, 16 Cureus e55996 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11009553/ ("[T]elemedicine extends healthcare reach to remote and underserved areas while enhancing temporal accessibility with round-the-clock availability.").

[18] *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, 246 (2024) (reporting that 76% of patients who obtained abortion care through telehealth cited increased privacy as a benefit); *see also* Yam B. Limbu & Bruce A. Huhmann, *What influences consumers' online medication purchase intentions and behavior? A scoping review*, 15 Frontiers in Pharmacology 1356059 (2024), https://doi.org/10.3389/fphar.2024.1356059 ("[C]onsumers' perceptions of privacy can influence their decision to buy some prescription medicines online . . . .").

[19] *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.[20] Mifepristone is an essential part of the recommended[21] and most commonly used[22] medication abortion regimen.

An abundance of scientific evidence demonstrates that dispensing mifepristone by mail is safe, effective, and beneficial to patients. During the COVID-19 pandemic, the FDA determined that mifepristone can be safely dispensed by mail-order pharmacies in order to minimize burdens on patients, without jeopardizing patients' health.[23] As Intervenor-Appellees/Cross-Appellants Danco Laboratories, LLC and GenBioPro, Inc. have explained in their briefs to this Court, that initial nonenforcement determination was supported by scientific evidence, and additional compelling evidence supported the FDA's December 2021

[20] *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.

[21] 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.

[22] *The Availability and Use of Medication Abortion*, KFF (Mar. 20, 2024), https://www.kff.org/womens-health-policy/the-availability-and-use-of-medication-abortion/ ("The most common medication abortion regimen in the United States involves . . . mifepristone.").

[23] In implementing risk evaluation and mitigation strategies with respect to drugs like mifepristone, the FDA is required to "minimize the burden on the health care delivery system" and ensure that access to the drug is not "unduly burdensome on patient access to the drug." 21 U.S.C. § 355-1(f)(2)(C)– (D).

decision to lift the in-person dispensing requirement[24] and its 2023 formalization of that decision.[25] Thus, mifepristone has been available to patients through telehealth and mail-order pharmacies since the height of the COVID-19 pandemic.

Research from before and after the FDA's 2023 decision confirms the safety, efficacy, and benefits of dispensing mifepristone by mail. For example:

- A 2024 study reviewing over 4,500 medication abortions prescribed via telehealth and obtained by mail-order pharmacies found that 97.7% of patients completed the abortion without further intervention, with a serious adverse event rate of only 0.25%.[26] This study looked at both synchronous and asynchronous models of telehealth care and found no difference in safety or effectiveness.[27]

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[24] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, REMS Modification Rationale Review, at 4 (Dec. 16, 2021).

[25] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Application No. 020687Orig1s020 Summary Review (Jan. 3, 2023); *see also* Memorandum on Further Efforts To Protect Access to Reproductive Healthcare Services, 88 Fed. Reg. 4895 (Jan. 22, 2023).

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

[27] *Id.* at 1192.

- A study analyzing data for nearly 4,000 patients who visited either in-person or telehealth clinics and obtained abortion medication through either in-person or mail-order dispensing 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.[28]
- In a study comparing 500 patients who obtained telehealth abortion care and abortion medication dispensed by mail, telehealth abortion care and abortion medication dispensed in person, or in-person care, 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."[29]
- A 2024 study of 1600 patients who obtained abortion care by telehealth and obtained abortion medication from a mail-order pharmacy found that "nearly all [patients] were very satisfied

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

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

with telehealth abortion," including because this model ensures more privacy and is less expensive and faster than traveling to a clinic.[30]

- A meta-analysis of 21 studies published between 2011 and 2022 determined that there are no differences in the safety, effectiveness, and patient satisfaction between telemedicine medication abortion and in-person abortion care.[31] The study also found that the wait time to receive abortion medication was around 4.2 days shorter for those who used telemedicine as opposed to those who received in-person care.[32]

Other research underscores that telehealth is a safe and effective way for patients to obtain timely access to abortion care. For example, numerous 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

[30] Koenig et al., *supra* note 18, at 248.

[31] 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).

[32] *Id.* at 18.

earlier in pregnancy than patients who receive in-clinic care.[33] 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."[34] Moreover, pregnant persons who take mifepristone at home are no more likely than patients who take mifepristone at a health clinic to call a provider's office or make an unplanned medical visit than those who receive in-person care.[35]

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

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[33] 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.*, Cely-Andrade et al., *supra* note 31; Amanda Cleeve et al., *The use of telemedicine services for medical abortion*, 6 Cochrane Database of Systematic Revs. CD013764 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12135146/.

[34] 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 109962 (2023), https://doi.org/10.1016/j.contraception.2023.109962.

[35] Yael Swica et al., *Acceptability of home use of mifepristone for medical abortion*, 88 Contraception 122 (2012); *see also*, *e.g.*, Grossman et al., *supra* note 9, at 39 (finding that of the few adverse events reported by patients who had under-gone medication abortion at home, "none . . . would have been avoided by dispensing medications in person rather than with the mail-order pharmacy").

medication abortions "occur[red] largely in nonclinical settings."[36] In other words, "there is no medical reason for mifepristone to be dispensed in clinics."[37]

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

Reinstating the in-person dispensing requirement for mifepristone would seriously harm patients and mail-order pharmacies like Honeybee. If mifepristone is unavailable to patients by mail, it will effectively deny some pregnant persons access to this safe and effective abortion medication altogether, even in states where abortion is legal and protected by the state constitution. Reinstating the in-person dispensing requirement would also prevent mail-order pharmacies like Honeybee from dispensing this important medication in accordance with FDA regulations in states where it is permissible to do so under applicable state law. These realities should not be ignored.

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

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

[37] 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, 43 (2021).

Eliminating access to mifepristone by mail would impose severe harm on patients who rely on mail-order pharmacies for access to this medication, like the patients Honeybee serves.

The harms of restricted access to mifepristone 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, or have limited financial resources.[38] Requiring mifepristone to be dispensed in person also would harm survivors of sexual violence or other trauma who may need the greater privacy and autonomy that mail-order pharmacies provide.[39] For all these patients, being able to obtain

[38] *See, e.g.*, Ma & Wang, *supra* note 9, at 293 (noting that many patients use 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), https://pmc.ncbi.nlm.nih.gov/articles/PMC10664017/ (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 36, at 58, 78 ("Financial burdens and difficulty obtaining insurance are frequently cited by women as reasons for delay in obtaining an abortion."); Jill Barr-Walker et al., *Experiences Of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, 14 PLoS ONE. e0209991 (2019), https://doi.org/10.1371/journal.pone.0209991 (explaining that studies find burdens related to travel can negatively impact reproductive choices).

[39] *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 18, at 248 ("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

mifepristone from a mail-order pharmacy can mean the difference between obtaining desired medical care and having to forgo it. *Cf. Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) ("There is a general public interest in ensuring that all citizens have timely access to lawfully prescribed medications."); 21 U.S.C. § 355-1(f)(2)(C) (requiring REMS elements to "not be unduly burdensome on patient access to the drug").

Limiting access to abortion has dire consequences for maternal and infant health. As discussed *supra* in Section II, accessing mifepristone through telehealth and mail-order pharmacies is safe and effective. Indeed, medication abortion carries far less risk for American women than childbirth. In 2017, the New England Journal of Medicine published an expert commentary observing that the maternal mortality rate for women having live births in the United States was 14 times higher than the associated fatality rate for medication abortions using mifepristone.[40] More recent data establish that lifting the in-person dispensing

Obstetrics & Gynecology 1139, 1143 (2023) (noting that telemedicine allowed patients to "talk more freely and openly").

[40] Mifeprex REMS Study Grp., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 N. Engl. J. Med. 790, 791 (2017); *see also* Nat'l Acads. of Sci., Eng'g & Med., *supra* note 36, at 74–76.

requirement has not altered the safety of the mifepristone regimen, which remains significantly safer than continued pregnancy and birth; indeed, deaths among mifepristone users are virtually non-existent.[41] We also know that denying access to abortion threatens women's lives. Studies conducted both in the United States[42] and abroad[43] have demonstrated a strong correlation between abortion restrictions and maternal mortality. Additional studies demonstrate that abortion restrictions are correlated with increased infant mortality rates.[44]

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[41] Daniel Grossman & Sarah Raifman, *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2024"*, Advancing New Standards in Reprod. Health (May 15, 2025), https://www.ansirh.org/sites/default/files/2025-05/Issue%20Brief%20MAB%20SAEs-May2025%20Final_0.pdf; *see also* Upadhyay et al., *supra* note 26, at 1191; Nat'l Acads. of Sci., Eng'g & Med., *supra* note 36, at 74–76. *See generally supra* Section II (discussing safety of dispensing mifepristone by mail).

[42] *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, 2019, 2023 (2021) ("Overall, estimated pregnancy-related deaths would increase for the total population by 7% in the first year of a [total abortion] ban and by 21% in subsequent years."); Dovile Vilda et al., *State Abortion Policies and Maternal Death in the United States, 2015–2018*, 111 Am. J. Pub. Health 1696, 1699 (2021) (finding maternal mortality rates "were significantly higher . . . in states with the largest number of abortion restrictions").

[43] *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).

[44] *E.g.*, Alison Gemmill et al., *US Abortion Bans and Infant Mortality*, 333 JAMA 1315 (2025); 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).

Furthermore, restricting access to mifepristone would 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.[45] 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.[46] In short, the harms of restricting access to mifepristone would fall hardest on vulnerable communities who already face significant barriers to accessing healthcare.

Moreover, mifepristone has important medical uses in addition to its FDA-approved use as a part of a medication abortion regimen. For example, mifepristone has been effectively used for medical resolution of miscarriage, with a significantly higher success rate than other

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[45] 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.

[46] *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), https://doi.org/10.1016/j.ajog.2013.11.039; 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), https://doi.org/10.3389/fpubh.2023.1291668.

regimens.[47] Scientific studies also demonstrate that mifepristone is effective for managing and treating uterine leiomyomas,[48] for treating one type of brain tumor, and for treating endometriosis.[49] Depriving patients of access to mifepristone dispensed by mail would also harm patients who need mifepristone for reasons unrelated to abortion care.

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

This Court should also consider the injury that reinstating the in-person dispensing requirement would impose on mail-order pharmacies such as Honeybee. Honeybee has relied heavily on the FDA's determination that dispensing mifepristone by mail is safe and effective. Reinstating the in-person dispensing requirement would cause significant and irreparable harm to Honeybee's and other mail-order pharmacies' business. The threat of existential harm to a company's business merits considerable weight. *See, e.g.*, *Atwood Turnkey Drilling,*

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[47] Courtney Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Eng. J. Med. 2161, 2161, 2167–69 (2018); Lisa Wu et al., *ExPAND Mifepristone: Medical Management of Miscarriage and Abortion in FQHCs*, 21 Annals Fam. Med. 468 (2023).

[48] *See* Blake M. Autry & Roopma Wadhwa, *Mifepristone*, StatPearls (Feb. 28, 2024), https://www.ncbi.nlm.nih.gov/books/NBK557612.

[49] *See* Mifepristone (Mifeprex), Nat'l Libr. Med. (Feb. 15, 2026), https://medlineplus.gov/druginfo/meds/a600042.html#ho.

Inc. v. Petroleo Brasileiro, S.A., 875 F.2d 1174, 1179 (5th Cir. 1989); *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975); *hiQ Labs, Inc. v. LinkedIn Corp.*, 31 F.4th 1180, 1188 (9th Cir. 2022); *John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc.*, 588 F.2d 24, 28–29 (2nd Cir. 1978).

Dispensing mifepristone by mail accounts for about a quarter of Honeybee's overall business. Thus, Honeybee's business depends on its ability to dispense mifepristone to patients by mail in accordance with the FDA's evidence-based regulations that permit it to do so. Under the regulatory regime the FDA has created, Honeybee has dispensed hundreds of thousands of mifepristone prescriptions by mail to patients in jurisdictions that permit it to do so.[50] Honeybee has been able to dispense mifepristone at lower costs than other pharmacies, and it has serves some patients who may not otherwise be able to access the medication easily or at all. For example, Honeybee often serves patients who do not live near clinics or cannot afford the costs of in-person care

[50] 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. Honeybee has implemented a system whereby specific medications have "Shipping Rules," which define the states in which those medications are permitted to be shipped. In Honeybee's system, mifepristone is only shipped to states that have permitted the use of such medication via applicable state laws and regulations.

and associated travel. Reinstating the in-person dispensing requirement for mifepristone would eliminate a substantial portion of Honeybee's business and prevent it from providing a safe, essential, and effective medication to patients.

Honeybee has invested substantial time and resources to ensure that its dispensing of mifepristone complies with state and federal laws. Patients may utilize Honeybee's services only after they have received a prescription for mifepristone from a healthcare provider. And when filling prescriptions for mifepristone, the Honeybee team adheres to the FDA's REMS requirements,[51] e.g., by: completing a Pharmacy Agreement Form; confirming that Honeybee has the requisite Prescriber Agreement with the prescribing provider on file; recording the lot number for the medication, and sharing that information on the patient's dashboard; and ensuring each patient receives their mifepristone prescription within four days.[52] When Honeybee mails the medication, it provides the

[51] *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. Food & Drug Admin. (Apr. 8, 2026), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#TheMifepristoneREMSProgram.

[52] Through its relationship with GenBioPro, Honeybee also completes annual audit questionnaires to ensure REMS compliance.

tracking number to the patient and the patient's healthcare provider, and notifies the patient once the shipping carrier has marked the order as delivered. If a shipment is delayed, the Honeybee team works with the patient's healthcare provider to ensure the patient receives the medication within the timeframe required by applicable regulations. Thus, Honeybee has devoted significant resources to developing systems and processes that comply with the FDA's evidence-based regulations, and reinstating the in-person dispensing requirement would cause Honeybee substantial harm.

Critically, reinstating the in-person dispensing requirement would create instability and uncertainty for mail-order pharmacies even outside the context of mifepristone. As set forth above, mail-order pharmacies invest substantial time and resources and develop considerable business interests based on the FDA's evidence-based determination to eliminate a restriction on mail-order dispensing. If this Court stays the 2023 REMS, it will open the door to similar challenges to countless other medications that mail-order pharmacies dispense, thereby threatening to destabilize other aspects of mail-order pharmacies' business. When the FDA makes an evidence-based determination regarding the safety and

efficacy of dispensing a particular medication by mail, mail-order pharmacies need to be able to rely on the stability of that determination absent credible scientific evidence to the contrary. A stay of the 2023 REMS would create uncertainty that undermines the business model of mail-order pharmacies writ large. It would also undermine the legitimacy of the mail-order dispensing model overall, despite ample research that mail-order dispensing is safe, effective, and beneficial to patients.[53]

Like other mail-order pharmacies, 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. And Honeybee's practices present a paradigm for what mail-order pharmacies can offer: its technology and fulfillment processes ensure that the patients and their providers remain informed and connected, while its virtual services give patients the opportunity to realize greater privacy in receiving quality healthcare at a lower cost. Reinstating the in-person dispensing requirement for mifepristone would seriously jeopardize the viability of mail-order pharmacies like Honeybee and the benefits that they provide to patients.

[53] *See supra* Sections I, II.

CONCLUSION

For the foregoing reasons, Honeybee respectfully asks this Court deny Plaintiffs' request for a § 705 stay of the 2023 REMS.

Dated: July 21, 2026

Respectfully submitted,

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No. 26-30203 State of Louisiana v. FDA
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