

Nos. 23-235, 23-236

In The
Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

**On Writs Of Certiorari To The
United States Court Of Appeals
For The Fifth Circuit**

**BRIEF OF AMICUS CURIAE
HONEYBEE HEALTH, INC.
IN SUPPORT OF PETITIONERS**

STEPHANIE L. GUTWEIN
Counsel of Record
A. SCOTT CHINN
MATTHEW K. GIFFIN
ELIZABETH A. CHARLES
FAEGRE DRINKER BIDDLE
& REATH LLP
300 N. Meridian Street, Suite 2500
Indianapolis, IN 46204
(317) 237-0300
stephanie.gutwein@faegredrinker.com
scott.chinn@faegredrinker.com
matt.giffin@faegredrinker.com
elizabeth.charles@faegredrinker.com

LIBBY L. BANEY
FAEGRE DRINKER BIDDLE
& REATH LLP
1500 K Street NW,
Suite 1100
Washington, D.C. 20005
(202) 842-8800
libby.baney@
faegredrinker.com

TABLE OF CONTENTS

	Page
Interest of <i>Amicus Curiae</i>	1
Summary of Argument	3
Argument	5
I. Access to telemedicine and mail-order pharmacies advances individual liberties while preserving states' rights	6
II. Use of abortion medication at home is safe and effective.....	14
III. Prohibition of mail-order distribution of mifepristone will inflict serious harm on the public, patients, and businesses like Honeybee	22
A. The public interest and public policy weigh against enjoining the availability of mail-order mifepristone	23
B. Data show that eliminating access to mail-order mifepristone will inflict harm on many patients	24
C. Prohibiting mail-order delivery of mifepristone would inflict serious harm on Honeybee and other online pharmacies	29
Conclusion.....	30

TABLE OF AUTHORITIES

	Page
CASES	
<i>All. for Hippocratic Medicine v. U.S. Food & Drug Admin., No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023), appeal docketed, No. 23-10362 (5th Cir. Apr. 10, 2023)</i>	27
<i>Amoco Prod. Co. v. Vill. of Gambell, Alaska</i> , 480 U.S. 531 (1987)	23
<i>Atwood Turnkey Drilling, Inc. v. Petroleo Brasileiro, S.A.</i> , 875 F.2d 1174 (5th Cir. 1989).....	29
<i>Barsky v. Bd. of Regents of Univ.</i> , 347 U.S. 442 (1954)	11
<i>Fulgenzi v. PLIVA, Inc.</i> , 711 F.3d 578 (6th Cir. 2013).....	23
<i>Maryland v. King</i> , 567 U.S. 1301 (2012).....	23
<i>Mutual Pharm. Co., Inc. v. Barrett</i> , 570 U.S. 472 (2013)	23
<i>Nat’l Ass’n of Farmworkers’ Orgs. v. Marshall</i> , 628 F.2d 604 (D.C. Cir. 1980)	24
<i>Nat’l Propane Gas Ass’n v. U.S. Dep’t of Homeland Sec.</i> , 534 F. Supp. 2d 16 (D.D.C. 2008).....	23
<i>Nken v. Holder</i> , 556 U.S. 418 (2009)	23
<i>Pegram v. Herdrich</i> , 530 U.S. 211 (2000)	11

TABLE OF AUTHORITIES—Continued

	Page
<i>Pharmacia Corp. v. Alcon Labs., Inc.</i> , 201 F. Supp. 2d 335 (D.N.J. 2002).....	28
<i>Reedco, Inc. v. Hoffman-La Roche, Inc.</i> , 667 F. Supp. 1072 (D.N.J. 1987).....	28
<i>ViroPharma, Inc. v. Hamburg</i> , 898 F. Supp. 2d 1 (D.D.C. 2012).....	29
<i>Watson v. Maryland</i> , 218 U.S. 173 (1910)	11
<i>Weinberger v. Romero-Barcelo</i> , 456 U.S. 305 (1982)	23
 STATUTES, RULES, & REGULATIONS	
21 C.F.R. § 1304.40	10
 OTHER AUTHORITIES	
Abu-Farha, R., <i>et al.</i> , <i>Public Perceptions About Home Delivery of Medication Service and Factors Associated with the Utilization of This Service, Patient Preference and Adherence</i> (Aug. 22, 2022), available at: https://www.tandfonline.com/doi/abs/10.2147/PPA.S377558	10
Aiken, A.R.A., <i>et al.</i> , <i>Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study</i> , <i>BJOG</i> 2021 (Mar. 24, 2021), available at: https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/1471-0528.16668	9, 15, 19

TABLE OF AUTHORITIES—Continued

	Page
Autry, B.M., <i>et al.</i> , <i>Mifepristone</i> , StatPearls (last updated May 8, 2022), <i>available at</i> : https://www.ncbi.nlm.nih.gov/books/NBK557612/28	28
Chong, E., <i>et al.</i> , <i>Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic</i> , <i>Contraception</i> (Mar. 27, 2021), <i>available at</i> : https://pubmed.ncbi.nlm.nih.gov/33781762/ 16, 21	16, 21
Creanga, A., <i>et al.</i> , <i>Racial and Ethnic Disparities in Severe Maternal Morbidity: A Multi-State Analysis, 2008-2010</i> , <i>Am. J. Obstet. Gynecol.</i> , 2014 May (Dec. 1, 2013), <i>available at</i> : https://pubmed.ncbi.nlm.nih.gov/24295922/26	26
Dandy, K., <i>et al.</i> , <i>The Case for Telemedicine How Telehealth Solutions Can Reduce Legal Risk While Improving Patient Access and Lowering Health Care Costs</i> , <i>N.Y. St. B.J.</i> , Nov./Dec. 20186	6
Daniel, S., <i>et al.</i> , <i>Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone</i> , <i>Contraception</i> (Mar. 31, 2021), <i>available at</i> : https://www.contraceptionjournal.org/article/S0010-7824(21)00098-6/fulltext15	15

TABLE OF AUTHORITIES—Continued

	Page
Diamant, J., <i>et al.</i> , <i>What the data says about abortion in the U.S.</i> , Pew Research Center (Jan. 11, 2023), <i>available at</i> : https://www.pewresearch.org/short-reads/2023/01/11/what-the-data-says-about-abortion-in-the-u-s-2/	14
Disability Impacts All of Us Infographic, CDC, <i>available at</i> : https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html (last visited Jan. 23, 2024).....	9
Divya, J., <i>et al.</i> , <i>The Provision of Medication Abortion Care via Telehealth</i> , Women’s Health Issues, Jacobs Institute of Women’s Health (June 8, 2023), <i>available at</i> : https://www.whijournal.com/article/S1049-3867(23)00099-3/fulltext#articleInformation	15
Duy, D., <i>et al.</i> , <i>Trends in Mail-Order Prescription Use among U.S. Adults from 1996 to 2018: A Nationally Representative Repeated Cross-Sectional Study</i> , medRxiv (Sept. 23, 2020), <i>available at</i> : https://www.medrxiv.org/content/10.1101/2020.09.22.20199505v2	4
Endler M., <i>et al.</i> , <i>Telemedicine for medical abortion: a systematic review</i> , BJOG 2019 (Apr. 25, 2019), <i>available at</i> : https://pubmed.ncbi.nlm.nih.gov/30869829/	3, 25

TABLE OF AUTHORITIES—Continued

	Page
Gaffney, A.W., <i>et al.</i> , <i>Health Needs and Functional Disability Among Mail-Order Pharmacy Users in the US</i> , <i>JAMA Intern. Med.</i> (Dec. 14, 2020), <i>available at</i> : https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2774124?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamainternmed.2020.7254	3, 4, 8
Gajarawala, S., <i>Telehealth Benefits and Barriers</i> , <i>J. Nurse Pract.</i> , 2021 Feb. (Oct. 21, 2020), <i>available at</i> : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7577680/#bib6	6, 9
Grossman, D., <i>et al.</i> , <i>Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment</i> , <i>Contraception</i> (Sept. 20, 2021), <i>available at</i> : https://www.contraceptionjournal.org/article/S0010-7824(21)00384-X/fulltext	17, 20, 21, 27
Honeybee Health Trustpilot, <i>available at</i> : https://www.trustpilot.com/review/honeybeehealth.com (last visited Jan. 26, 2024)	1
Hyder, Maryam, <i>et al.</i> , <i>Telemedicine in the United States: An Introduction for Students and Residents</i> , <i>J. Med. Internet Res.</i> (Nov. 24, 2020), <i>available at</i> : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7690251/	6

TABLE OF AUTHORITIES—Continued

	Page
Kerestes, C., <i>et al.</i> , <i>Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models</i> , <i>Contraception</i> (Mar. 28, 2021), available at: https://www.contraceptionjournal.org/article/S0010-7824(21)00097-4/fulltext	18
Kheyfets, A., <i>et al.</i> , <i>The Impact of Hostile Abortion Legislation on the United States Maternal Mortality Crisis: A Call for Increased Abortion Education</i> , <i>Front. Pub. Health</i> (Dec. 5, 2023), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10728320/#ref14	26
Koenig, L., <i>et al.</i> , <i>Mailing abortion pills does not delay care: A cohort study comparing mailed to in-person dispensing of abortion medications in the United States</i> , <i>Contraception</i> (Feb. 1, 2023), available at: https://www.contraceptionjournal.org/article/S0010-7824(23)00015-X/fulltext#secsect0005	20, 21
Lawson, N., <i>et al.</i> , <i>Disability and telehealth since the COVID-19 pandemic</i> , <i>Center for Health & Research Transformation</i> (Aug. 29, 2022), available at: https://disabilityhealth.medicine.umich.edu/sites/default/files/downloads/RRTC%20Telehealth_final2.pdf	6, 9, 10
<i>Locate a State-Licensed Online Pharmacy</i> , FDA, available at: https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy (last visited Jan. 23, 2024)	10

TABLE OF AUTHORITIES—Continued

	Page
Ma, J., <i>et al.</i> , <i>Characteristics of Mail-Order Pharmacy Users: Results From the Medical Expenditures Panel Survey</i> , <i>J. of Pharm. Practice</i> (Oct. 2, 2018), <i>available at</i> : https://journals.sagepub.com/doi/10.1177/0897190018800188	4, 7, 9
Medication Abortion, Honeybee Health, Inc., <i>available at</i> : https://honeybeehealth.com/conditions/=medication-abortion (last visited Jan. 23, 2024)	13
<i>Meet the Pharmacist Expanding Access to Abortion Pills Across the U.S.</i> , <i>Time Magazine</i> (June 13, 2022), <i>available at</i> : https://time.com/6183395/abortion-pills-honeybee-health-online-pharmacy/	2, 15
Mifeprex REMS Study Group, <i>Sixteen Years of Overregulation: Time to Unburden Mifeprex</i> , <i>N. Engl. J. Med.</i> , Vol. 376 (Feb. 23, 2017), <i>available at</i> : https://www.nejm.org/doi/10.1056/NEJMs1612526	25
Mifepristone (Mifeprex), Nat'l Library of Medicine (last revised Mar. 15, 2023), <i>available at</i> : https://medlineplus.gov/druginfo/meds/a600042.html#how	28
Muellers, K., <i>Telemedicine decision-making in primary care during the COVID-19 pandemic: Balancing patient agency and provider expertise</i> , <i>Health Policy and Tech.</i> (Jan. 9, 2024), <i>available at</i> : https://www.sciencedirect.com/science/article/abs/pii/S2211883724000029	7

TABLE OF AUTHORITIES—Continued

	Page
Neil, W., <i>et al.</i> , <i>Mail order pharmacy use and adherence to secondary prevention drugs among stroke patients</i> , <i>J. Neurological Sci.</i> , Vol. 390 (Apr. 6, 2018), available at: https://www.jns-journal.com/article/S0022-510X(18)30170-9/fulltext#secst0005	8, 10
Ngo, N., <i>et al.</i> , <i>Reproductive Health Policy Saga, Restrictive Abortion Laws in Low- and Middle-Income Countries (LMICs), Unnecessary Cause of Maternal Mortality, Health Care for Women Int'l</i> , Vol. 45 (Nov. 2, 2021), available at: https://www.tandfonline.com/doi/full/10.1080/07399332.2021.1994971	26
Rafie S., <i>et al.</i> , <i>Pharmacist dispensing of mifepristone: An opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy</i> , <i>J. Am. Coll. Clin. Pharm.</i> 2024 (Dec. 13, 2023), available at: https://accpjournals.onlinelibrary.wiley.com/doi/full/10.1002/jac5.1909	15
Raymond, E., <i>et al.</i> , <i>TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States</i> , <i>Contraception</i> (June 3, 2019), available at: https://www.contraceptionjournal.org/article/S0010-7824(19)30176-3/fulltext	21
<i>Recent Guidance: FDA Lifts In-Person Dispensing Requirement for Mifepristone Abortion Pill</i> , 135 <i>Harv. L. Rev.</i> 2235 (June 2022)	27

TABLE OF AUTHORITIES—Continued

	Page
The Safety and Quality of Current Abortion Methods, <i>The Safety and Quality of Abortion Care in the United States</i> , Washington, D.C., Nat'l Academies of Sci., Engineering, and Med., The Nat'l Academies Press (2018), available at: https://doi.org/10.17226/24950	17, 20, 21, 25
Schmittdiel, J.A., et al., <i>Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study</i> , BMC Health Serv. Res. (June 25, 2019), available at: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4250-7#Abs1	7, 9
Schmittdiel, J., et al., <i>The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients</i> , Am. J. Manag. Care (Nov. 2013), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278640/pdf/nihms621271.pdf	8
Schreiber, C., et al., <i>Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss</i> , N. Eng. J. Med. Vol. 378 (June 7, 2018), available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1715726	28
Schummers, L., et al., <i>Abortion Safety and Use with Normally Prescribed Mifepristone in Canada</i> , N. Engl. J. Med. 2022 (Jan. 6, 2022) available at: https://www.nejm.org/doi/full/10.1056/NEJMsa2109779	18

TABLE OF AUTHORITIES—Continued

	Page
Shaver, J., <i>The State of Telehealth Before and After the COVID-19 Pandemic</i> , Prim. Care (Apr. 25, 2022), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9035352/	6
Stevenson, A., <i>The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant</i> , Demography (Dec. 1, 2021), available at: https://read.dukeupress.edu/demography/article/58/6/2019/265968/The-Pregnancy-Related-Mortality-Impact-of-a-Total	26
Swica, Y., et al., <i>Acceptability of home use of mifepristone for medical abortion</i> , Contraception (Nov. 21, 2012), available at: https://pubmed.ncbi.nlm.nih.gov/23177917/	20
<i>Telehealth Emerges as Preferred Channel for Routine Care While Increasing Access to Mental Health Treatment</i> , J.D. Power Finds, J.D. Power (Sept. 29, 2022), available at: https://www.jdpower.com/business/press-releases/2022-us-telehealth-satisfaction-study	2
Telehealth privacy for patients, HHS, available at: https://telehealth.hhs.gov/patients/telehealth-privacy-for-patients (last visited Jan. 15, 2024)	6

TABLE OF AUTHORITIES—Continued

	Page
The U.S. Generic and Biosimilar Medicines Savings Report (Sept. 2023), <i>available at</i> : https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf	24
Upadhyay, U.D., <i>et al.</i> , <i>Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study</i> , <i>JAMA Intern. Med.</i> (Mar. 21, 2022), <i>available at</i> : https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2790319	17
Upadhyay, U.D., <i>et al.</i> , <i>Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic</i> , <i>JAMA Netw. Open</i> (Aug. 24, 2021), <i>available at</i> : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8385590/	16, 25
Vaduganathan, M., <i>et al.</i> , <i>Prescription Filling Patterns of Evidence-Based Medical Therapies for Heart Failure During the COVID-19 Pandemic in the United States</i> , <i>J. of Cardiac Failure</i> , Vol. 27, Issue 11 (Nov. 2021), <i>available at</i> : https://www.sciencedirect.com/science/article/pii/S1071916421002608	10

INTEREST OF *AMICUS CURIAE*¹

Honeybee Health, Inc. (“Honeybee”) is a mail-order pharmacy run by board-certified pharmacists with more than 40 years’ combined experience. Honeybee has been using technology and transparency since 2018 to safely and effectively deliver medications approved by the federal Food and Drug Administration (“FDA”) to patients in the United States at costs almost always less than the patients’ local brick-and-mortar pharmacies. Honeybee patients obtain their medications directly from Honeybee, without having to work through insurance companies. Patients go online and have their medicine dispensed quickly and affordably via the mail. And they can and do connect in real-time with pharmacists who counsel them through questions or concerns with the FDA-approved medicine. Thousands of reviews confirm that patients who have counted on Honeybee to reliably deliver medications directly to them are overwhelmingly satisfied with their experiences.²

Forty-nine states and Washington D.C. have licensed Honeybee to ship to their residents prescribed medications; Honeybee also ships over-the-counter medications to patients across the country, where

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.

² See Honeybee Health Trustpilot, *available at*: <https://www.trustpilot.com/review/honeybeehealth.com> (last visited Jan. 26, 2024).

lawful to do so. Honeybee was one of the first, and is the largest, mail-order pharmacy in the United States to deliver mifepristone to patients—which it delivers in generic form, almost uniformly in conjunction with those patients’ receiving telehealth services.³ It also was the first pharmacy to distribute mifepristone on behalf of providers. And like the demand for telehealth services in the United States generally,⁴ demand for Honeybee’s services, and for mifepristone specifically, has only increased since Honeybee’s founding. Currently, Honeybee ships mifepristone to 24 states and the District of Columbia, all jurisdictions that permit Honeybee to lawfully deliver this vital medication to patients by mail. To date, Honeybee has dispensed more than 150,000 orders for mifepristone.

Honeybee submits this *amicus* brief to provide the Court the benefit of its experience in and knowledge of the market for mail-order medicine. In so doing, Honeybee explains the critical role telemedicine and mail-order pharmacies play in supporting patients’ individual freedom to access quality healthcare through the means most appropriate to them, while preserving states’ rights to ensure the healthcare their citizens

³ *Meet the Pharmacist Expanding Access to Abortion Pills Across the U.S.*, Time Magazine (June 13, 2022), available at: <https://time.com/6183395/abortion-pills-honeybee-health-online-pharmacy/>.

⁴ *Telehealth Emerges as Preferred Channel for Routine Care While Increasing Access to Mental Health Treatment*, J.D. Power Finds, J.D. Power (Sept. 29, 2022), available at: <https://www.jdpower.com/business/press-releases/2022-us-telehealth-satisfaction-study>.

receive is safe and effective. Honeybee emphasizes the wealth of clear and credible information demonstrating the safety and efficacy of mail-order pharmacies and the use of those pharmacies to obtain mifepristone for purposes of inducing abortions at home. And it offers additional considerations on the concrete harms the Court of Appeals' decision will inflict should it take effect.

◆

SUMMARY OF ARGUMENT

The role of telemedicine, and mail-order pharmacies in particular, in ensuring that all patients have access to safe and effective healthcare cannot be overstated.⁵ Mail carriers, including the United States Postal Service, have been delivering medications to patients for more than 100 years.⁶ Between 1990 and 2000, mail-order pharmacies' market-share of the outpatient prescription drug market nearly doubled, and use of mail-order pharmacies has continued to increase

⁵ "Telemedicine (TM) is the remote assessment and treatment of patients by means of telecommunications technology." Endler M., *et al.*, *Telemedicine for medical abortion: a systematic review*, *BJOG* 2019;126:1094-1102 (Apr. 25, 2019), *available at*: <https://pubmed.ncbi.nlm.nih.gov/30869829/>.

⁶ Gaffney, A.W., *et al.*, *Health Needs and Functional Disability Among Mail-Order Pharmacy Users in the US*, *JAMA Intern. Med.*, 2021;181(4):554-56 (Dec. 14, 2020), *available at*: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2774124?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamainternmed.2020.7254.

since.⁷ As of 2020, researchers estimate more than 200,000,000 prescriptions are delivered through the mail annually.⁸

The ability to use online telemedicine to provide abortion medications, including mifepristone, has steadily increased access to safe, effective, and essential reproductive healthcare.⁹ And, time and again, studies have shown that, much like other aspects of healthcare delivered through telemedicine, at-home medication abortion obtained through telemedicine in the United States is effective, acceptable to users, and has a very low rate of serious adverse outcomes.¹⁰

Honeybee, which was among the first and is the largest mail-order pharmacy in the United States to deliver mifepristone directly to patients for use in at-home abortions, offers this brief to reiterate the integral role that telemedicine and mail-order pharmacies play in ensuring that patients have access to safe, effective, and necessary abortion healthcare services by mail, and to further articulate the direct and, in some cases, irreversible harms that restrictions on these

⁷ See, e.g., Ma, J., *et al.*, *Characteristics of Mail-Order Pharmacy Users: Results From the Medical Expenditures Panel Survey*, *J. of Pharm. Practice*, 2020;33(3):293-98 (Oct. 2, 2018), available at: <https://journals.sagepub.com/doi/10.1177/0897190018800188>; Duy, D., *et al.*, *Trends in Mail-Order Prescription Use among U.S. Adults from 1996 to 2018: A Nationally Representative Repeated Cross-Sectional Study*, medRxiv (Sept. 23, 2020), available at: <https://www.medrxiv.org/content/10.1101/2020.09.22.20199505v2>.

⁸ Gaffney, *supra* note 6.

⁹ See *infra*, § I.

¹⁰ See *infra*, § II.

services will cause patients, pharmacies, and FDA-regulated industries more generally in the United States.



ARGUMENT

Telemedicine, and mail-order pharmacies specifically, represent a growing healthcare sector on which patients across the United States increasingly rely to meet their individual medical needs. Access to mail-order pharmacies promotes individual patients' freedom to obtain healthcare in the manner most appropriate for them, while preserving states' role in ensuring the care those patients receive is safe and effective. A wealth of scientific data confirms that, where legal to do so, using mail-order pharmacies to obtain mifepristone to induce an abortion at home, outside the presence of a provider, is a safe, effective, and necessary component of robust patient care in the United States. Yet, if permitted to stand, the Court of Appeals' decision, which eliminates access to this vital healthcare service, will immediately and irreparably harm the public interest, users of mail-order mifepristone in particular, and companies like Honeybee, whose business depends on distributing mail-order mifepristone. The lower court's order granting relief to the Respondents should be reversed.

I. Access to telemedicine and mail-order pharmacies advances individual liberties while preserving states' rights.

Telemedicine—the delivery of medical care and provision of general health service from a distance—has a decades-long history in the United States and is now widely used.¹¹ Recent studies show that 76% of U.S. hospitals connect with patients using some form of telemedicine.¹² This history has demonstrated that telemedicine is safe, effective, and can provide patients benefits over in-person healthcare, including, but not limited to cost-savings, increased access, and a level of privacy unachievable through in-person treatment.¹³ The availability of a telemedicine option also promotes

¹¹ Hyder, Maryam, *et al.*, *Telemedicine in the United States: An Introduction for Students and Residents*, *J. Med. Internet Res.* (Nov. 24, 2020), *available at*: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7690251/>.

¹² *Id.*; *see also, e.g.*, Shaver, J., *The State of Telehealth Before and After the COVID-19 Pandemic*, *Prim. Care*, 2022;Dec;49(4):517-30 (Apr. 25, 2022), *available at*: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9035352/>.

¹³ Dandy, K., *et al.*, *The Case for Telemedicine How Telehealth Solutions Can Reduce Legal Risk While Improving Patient Access and Lowering Health Care Costs*, *N.Y. St. B.J.*, Nov./Dec. 2018, at 39, 40; Lawson, N., *et al.*, *Disability and telehealth since the COVID-19 pandemic*, Center for Health & Research Transformation (Aug. 29, 2022), *available at*: https://disabilityhealth.medicine.umich.edu/sites/default/files/downloads/RRTC%20Telehealth_final2.pdf; Gajarawala, S., *Telehealth Benefits and Barriers*, *J. Nurse Pract.*, 2021 Feb. (Oct. 21, 2020), *available at*: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7577680/#bib6>; Telehealth privacy for patients, HHS, *available at*: <https://telehealth.hhs.gov/patients/telehealth-privacy-for-patients> (last visited Jan. 15, 2024).

patients' autonomy to decide the best format for their medical care based on their own individual needs.¹⁴ A promising body of evidence shows that telemedicine services increase patient knowledge and adherence to healthy behaviors.¹⁵

Mail-order pharmacies play an integral role in the larger telemedicine ecosystem. Recent research estimates that perhaps as many as one-quarter of pharmacy sales in the United States occur through use of mail-order pharmacies.¹⁶

Substantial scientific evidence also confirms the safety, efficacy, and benefits of mail-order pharmacies for patients across the United States.¹⁷ For example, nearly ten years ago, researchers demonstrated that patients' use of mail-order pharmacies "was not negatively associated with patient safety outcomes overall, suggesting mail order use [is not] a barrier to receiving primary and preventative care services for most patients."¹⁸ Other research shows that patients who

¹⁴ Muellers, K., *Telemedicine decision-making in primary care during the COVID-19 pandemic: Balancing patient agency and provider expertise*, Health Policy and Tech. (Jan. 9, 2024), available at: <https://www.sciencedirect.com/science/article/abs/pii/S2211883724000029>.

¹⁵ *Id.*

¹⁶ Schmittziel, J.A., *et al.*, *Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study*, BMC Health Serv. Res. 19, 422 (June 25, 2019), available at: <https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4250-7#Abs1>.

¹⁷ See, e.g., Ma, *supra* note 7.

¹⁸ Schmittziel, *supra* note 16.

receive medications by mail often demonstrate better medication adherence, and thus increase their odds of better health outcomes, than patients who receive their prescriptions through brick-and-mortar pharmacies.¹⁹ For example, research published in 2018 showed that stroke patients who had been prescribed a new anticoagulant, antiplatelet, anti-glycemic, antihypertensive, and/or lipid-lowering medication between January 1, 2007 and June 30, 2015 were more likely to adhere to their medications if they used mail-order pharmacies to receive them, as compared to those who used brick-and-mortar pharmacies.²⁰ And still other data confirms that use of mail-order pharmacies, like use of telemedicine more generally, also result in lower health-care costs overall: among other reasons for this

¹⁹ See, e.g., Gaffney, *supra* note 6; Ma, *supra* note 7 (“Studies show that using mail-order pharmacies results in higher medication adherence rate compared to retail pharmacies. Studies have consistently demonstrated that better medication adherence leads to better health outcomes; thus, the use of mail-order pharmacies may improve health[.]” (citations omitted)); Schmittdiel, J., *et al.*, *The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients*, *Am. J. Manag. Care*, 19(11):882-87 (Nov. 2013), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278640/pdf/nihms621271.pdf> (explaining that “[p]revious studies have shown mail order use is associated with greater medication adherence,” and “suggest mail order pharmacy services may *improve* [patient] outcomes” (emphasis added)).

²⁰ Neil, W., *et al.*, *Mail order pharmacy use and adherence to secondary prevention drugs among stroke patients*, *J. Neurological Sci.*, Vol. 390, 117-20 (Apr. 6, 2018), available at: [https://www.jns-journal.com/article/S0022-510X\(18\)30170-9/fulltext#secst0005](https://www.jns-journal.com/article/S0022-510X(18)30170-9/fulltext#secst0005).

cost-savings, mail-order pharmacies often coincide with lower in- and out-patient and medication costs.²¹

The benefits of mail-order pharmacies, and telemedicine generally, disproportionately abound to those with fewer advantages in our society. Telemedicine and mail-order pharmacies provide patients in remote areas and with disabilities increased access to healthcare.²² The CDC reports that up to one in four adults in the United States have some type of disability.²³ One in four adults with disabilities aged 18-44 years old do not have a regular healthcare provider.²⁴ Yet, adults with disabilities are six times more likely to have ten or more physician visits and five times more likely to be admitted to a hospital compared to people without disabilities.²⁵ Telemedicine, including

²¹ See Ma, *supra* note 7; Aiken, A.R.A., *et al.*, *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, *BJOG* 2021, 128: 1464-74 (Mar. 24, 2021), *available at*: <https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/1471-0528.16668>; *see also* Schmittiel, *supra* note 16 (“[M]ail order pharmacy use is correlated with better medication adherence . . . [and] is also associated with better health care outcomes and decreased health care utilization and costs.”).

²² Gajarawala, *supra* note 13 (reporting benefits of telemedicine for persons with disability including lower cost of care, lower transportation costs, and decreased need for paid personal assistance services).

²³ Disability Impacts All of Us Infographic, CDC, *available at*: <https://www.cdc.gov/ncbddd/disabilityandhealth/infographic-disability-impacts-all.html> (last visited Jan. 23, 2024).

²⁴ *Id.*

²⁵ Lawson, *supra* note 13.

mail-order pharmacies, helps to mitigate some of the disparities in care through improved access over in-person treatment.²⁶

And, just like brick-and-mortar pharmacies, mail-order pharmacies are subject to licensing requirements in each of the states in which they dispense medications, in addition to regulation by the FDA.²⁷ Pursuant to regulatory requirements, mail-order pharmacies may dispense a wide variety of essential therapeutics, including, for example, therapies for patients recovering from strokes, suffering from heart failure, and managing diabetes.²⁸ So while telemedicine, and mail-order pharmacies specifically, may offer individuals greater freedom to choose the mode of healthcare best for them, states continue to play an integral regulatory role.

More than a century of precedent confirms states' authority to regulate aspects of healthcare, including,

²⁶ *Id.*

²⁷ See, e.g., 21 C.F.R. § 1304.40; *Locate a State-Licensed Online Pharmacy*, FDA, available at: <https://www.fda.gov/drugs/besaferx-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy> (last visited Jan. 23, 2024).

²⁸ Vaduganathan, M., *et al.*, *Prescription Filling Patterns of Evidence-Based Medical Therapies for Heart Failure During the COVID-19 Pandemic in the United States*, *J. of Cardiac Failure*, Vol. 27, Issue 11, 1280-84 (Nov. 2021), available at: <https://www.sciencedirect.com/science/article/pii/S1071916421002608>; Neil, *supra* note 20; Abu-Farha, R., *et al.*, *Public Perceptions About Home Delivery of Medication Service and Factors Associated with the Utilization of This Service, Patient Preference and Adherence*, 16, 2259-69 (Aug. 22, 2022), available at: <https://www.tandfonline.com/doi/abs/10.2147/PPA.S377558>.

for example, by expanding delivery options and licensing professionals, to enhance health and well-being of their citizens. *See, e.g., Watson v. Maryland*, 218 U.S. 173, 176 (1910) (“It is too well settled to require discussion at this day that the police power of the states extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine.”); *Barsky v. Bd. of Regents of Univ.*, 347 U.S. 442, 449 (1954) (“It is elemental that a state has broad power to establish and enforce the standards of conduct within its borders relative to the health of everyone there.”); *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) (recognizing that “the field of health care” is “a subject of traditional state regulation”). Mail-order pharmacies that operate in compliance with each state’s laws and licensing requirements thus preserve states’ traditional role in regulating the provision of healthcare while promoting patients’ individual freedom to access the lawfully available healthcare of their choice.

The Court need look no further than Honeybee’s model to see these characteristics of telemedicine playing out in real time. Honeybee provides safe and legal access to myriad medications approved by the FDA, including but not limited to mifepristone. Its process for supporting patients’ healthcare needs ensures that patients realize all of the benefits telemedicine, and mail-order pharmacies in particular, have to offer, including increased privacy, cost-savings, greater access to

quality healthcare, and continuous support throughout a patient's healthcare journey.

Honeybee's rigorous processes promote safety and efficacy. Patients may utilize Honeybee's services only after they have consulted with a provider, and Honeybee offers patients resources to help them identify an appropriate provider, if they have not yet done so. And Honeybee assigns all its providers and organizations with which it partners an account manager to assist with onboarding and ongoing day-to-day operations. Once a provider has evaluated a patient and prescribed medication, the provider sends the patient's prescription to Honeybee electronically, and Honeybee creates an order for the patient in its system and notifies the patient that it has received the prescription. Acting as a bridge between the patient and the provider, Honeybee's dashboard permits the provider to view, cancel, and change the patient's prescription order and to update the patient's information as necessary.

Honeybee's pharmacists and technicians comply with all applicable laws when filling patients' prescriptions. Thus, when filling a mifepristone prescription, the Honeybee team adheres to the risk evaluation and mitigation strategy (REMS) requirements, including by confirming Honeybee has the requisite Prescriber Agreement with the prescribing provider on file, recording the lot number for the medication, which it also shares on the patient's dashboard, and ensuring each patient timely receives their mifepristone

prescription.²⁹ When it mails the medication (along with included supplies, supplemental materials from the patient’s provider, a GenBioPro treatment guide, and a postcard with Honeybee’s information) to the patient’s provided address, it provides the patient and the provider the tracking number, and then additionally notifies the patient once the shipping carrier has marked the order as delivered. And if a shipment is delayed, the Honeybee team works with the patient’s provider to ensure the patient receives a prescription within the timeframe regulations require.

Throughout the entirety of the process, Honeybee’s pharmacists and support team are available to answer questions and provide consultations via phone, email, and live chat. Honeybee also offers medication-abortion specific information to patients and providers on its website.³⁰ And always, Honeybee operates lawfully. Besides complying with federal law, Honeybee is licensed by every board of pharmacy in each state to which it sends medication, it monitors state laws surrounding the drugs it dispenses, including those related to its dispensation of mifepristone, and it ships mifepristone to only those states where it is legal to do so.

²⁹ Through its relationship with GenBioPro, Honeybee also completes annual audit questionnaires to ensure REMS compliance.

³⁰ See Medication Abortion, Honeybee Health, Inc., *available at*: <https://honeybeehealth.com/conditions/medication-abortion> (last visited Jan. 23, 2024).

Honeybee’s model represents the best that telemedicine, and mail-order pharmacies specifically, can be—for patients and states. Honeybee’s technology and fulfillment process ensure that the patients and their providers remain informed and connected, all while its virtual services give patients the opportunity to realize greater access and privacy in receiving quality healthcare. Honeybee’s dispensation of generic, rather than brand-name, drugs, including mifepristone, is just one example of the cost-savings Honeybee routinely helps patients realize. And Honeybee’s continuous efforts to comply with all applicable laws, and stay informed as to any changes to them, secures states’ place, alongside the federal government, in ensuring the healthcare Honeybee provides patients remains safe and effective.

II. Use of abortion medication at home is safe and effective.

Honeybee plays a vital role in allowing pregnant patients safe and effective mail-order access to medication abortion, with all the attendant benefits discussed above. Since the FDA approved mifepristone in 2000, the number of abortions in the United States has decreased.³¹ But, within that figure, the incidence of medication abortions has continued to increase, now constituting over half of the legal abortions being

³¹ See, e.g., Diamant, J., *et al.*, *What the data says about abortion in the U.S.*, Pew Research Center (Jan. 11, 2023), available at: <https://www.pewresearch.org/short-reads/2023/01/11/what-the-data-says-about-abortion-in-the-u-s-2/>.

performed in the United States.³² Honeybee plays a central role in this growing healthcare service as the largest mail-order pharmacy in the United States to deliver mifepristone to patients.³³

And study after study after study demonstrates that dispensation of abortion medication to patients by mail, and medication, rather than procedural, abortions via this mechanism, are safe, effective, and almost always result in positive patient outcomes.³⁴ For example:

³² See, e.g., Divya, J., et al., *The Provision of Medication Abortion Care via Telehealth*, Women's Health Issues, 33-4, 333-36, Jacobs Institute of Women's Health (June 8, 2023), available at: [https://www.whijournal.com/article/S1049-3867\(23\)00099-3/fulltext#articleInformation](https://www.whijournal.com/article/S1049-3867(23)00099-3/fulltext#articleInformation); Daniel, S., et al., *Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone*, Contraception, 2021Jul;104(1):73-76 (Mar. 31, 2021), available at: [https://www.contraceptionjournal.org/article/S0010-7824\(21\)00098-6/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(21)00098-6/fulltext).

³³ *Meet the Pharmacist*, supra note 3.

³⁴ "Medical" or "medication" abortions are defined as the use of medicines, rather than surgical procedures, to terminate a pregnancy. See, e.g., Aiken, supra note 21; Rafie S., et al., *Pharmacist dispensing of mifepristone: An opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy*, J. Am. Coll. Clin. Pharm. 2024; 1-9 (Dec. 13, 2023), available at: <https://accpjournals.onlinelibrary.wiley.com/doi/full/10.1002/jac5.1909> ("Medication abortion remains safe and effective when dispensed by pharmacists, including in mail-order pharmacies. Likewise, medication abortion provided through telemedicine has also been shown to be as safe as in-person care. Using telemedicine was effective and acceptable when compared with face-to-face visits, with similar overall satisfaction." (citations omitted)).

- Researchers in 2021 confirmed that out of more than 1,100 packages containing mifepristone and misoprostol delivered to patients by mail, in a study conducted between May 2016 and September 2020, 95% of patients completed the abortion without any further intervention.³⁵

- A separate study of among over 100 patients who relied on telehealth services to obtain a medication-abortion regimen by mail between October 2020 and January 2021 found 95% successfully completed their abortions without the need for follow-up care, and none reported any major adverse events.³⁶ This efficacy rate of medication abortion procedures through telehealth and mail-order means “is similar to in-person provision” and aligns with international studies on use of telehealth for medication abortions.³⁷

- Researchers analyzing 224 patients who underwent medication abortions at home between January 2020 and April 2021 found that nearly 97% had a complete abortion with medications alone, and the

³⁵ Chong, E., *et al.*, *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, *Contraception*, 2021Jul;104(1):43-48 (Mar. 27, 2021) available at: <https://pubmed.ncbi.nih.gov/33781762/>.

³⁶ Upadhyay, U.D., *et al.*, *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, *JAMA Netw. Open*, 2021Aug2;4(8):e2122320 (Aug. 24, 2021), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8385590/>.

³⁷ *Id.*

overwhelming majority reported being satisfied with receiving their medications by mail.³⁸

Research specifically aimed at comparing the outcomes of in-person administration of mifepristone with a provider versus self-administration of the medication obtained by mail after use of telehealth services is no less compelling.

- A recent retrospective, multicenter cohort study that analyzed data for nearly 4,000 diverse patients concluded that there was no statistically significant difference in the safety or efficacy of a patient’s medication abortion when the patient received the medications by mail, rather than in person.³⁹

- Scientific analysis of abortion outcomes in Canada after mifepristone became available via “normal prescription dispensed by pharmacists and taken at user discretion” showed that the change caused no material increase in the number of abortions or

³⁸ Grossman, D., *et al.*, *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, *Contraception* (Sept. 20, 2021), available at: [https://www.contraceptionjournal.org/article/S0010-7824\(21\)00384-X/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(21)00384-X/fulltext); see also, e.g., *The Safety and Quality of Current Abortion Methods, The Safety and Quality of Abortion Care in the United States*, Washington, D.C., Nat’l Academies of Sci., Engineering, and Med., The Nat’l Academies Press, 57-58 (2018), available at: <https://doi.org/10.17226/24950>.

³⁹ Upadhyay, U.D., *et al.*, *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, *JAMA Intern. Med.*, 2022;182(5):482-91 (Mar. 21, 2022), available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2790319>.

abortion-related adverse events, even while “the frequency of medical abortion rose substantially.”⁴⁰

- Research comparing outcomes of pregnant patients who underwent medication abortions in Hawaii between April and November 2020 after receiving the medications either in-person or through mail found that the “[r]ates of abortion success [were] similar for all methods of dispensing mifepristone and misoprostol” and that the success rate for completion of the abortion, greater than 93% across all forms of medication dispensation, also did not depend on whether the patient underwent an ultrasound before the abortion procedure.⁴¹

- Perhaps the largest study to date, analyzing over 52,000 medication abortions performed between January and June 2020, representing nearly 85% of all medication abortions performed in England and Wales during that time, found that medication abortions performed at home with no prefatory in-person treatment or dispensation requirement were at least as safe and effective as, and in some instances,

⁴⁰ Schummers, L., *et al.*, *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, *N. Engl. J. Med.* 2022; 386:57-67 (Jan. 6, 2022), *available at*: <https://www.nejm.org/doi/full/10.1056/NEJMsa2109779>.

⁴¹ Kerestes, C., *et al.*, *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, *Contraception*, 2021Jul;104(1):49-53 (Mar. 28, 2021), *available at*: [https://www.contraceptionjournal.org/article/S0010-7824\(21\)00097-4/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(21)00097-4/fulltext).

superior to, in-person medical abortion treatments.⁴² The pregnant patients who accessed medical abortion care through telehealth and mail-order services waited, on average, four fewer days for treatment and accessed the medical abortion services at an earlier gestation stage, than patients who received in-person treatment—two data points that support a *decreased* risk associated with medication abortions at home, rather than in a clinic setting.⁴³ Pregnant patients who obtained a medication abortion through telemedicine and mail-order services also successfully terminated their pregnancies 98.8% of the time, a rate akin to, but slightly *higher* than, those pregnant patients who received their medical services in person.⁴⁴ No data indicated that pregnant patients who accessed their care through telehealth and mail-order means experienced greater incidence of significant adverse events than those who accessed care in-person.⁴⁵

Still other research underscores the efficacy of telehealth in ensuring patients have access to abortion-related care. For example, studies confirm that mailing of medications for patients' use in at-home abortions “[does] not significantly prolong [the] time from patients' first contact with the clinic to mifepristone ingestion or increase pregnancy duration at

⁴² Aiken, *supra* note 21.

⁴³ *Id.*

⁴⁴ *Id.* (disclosing that the rate of successful medication abortions for in-person patients in the study was 98.2%).

⁴⁵ *Id.*

mifepristone ingestion,”⁴⁶ and pregnant persons who take mifepristone at home are no more likely to call a provider’s office or make an unplanned visit than those who opt for in-office administration.⁴⁷

This parity between patients’ experiences accessing abortion medication at home and in-person is unsurprising. As the National Academy of Sciences previously observed, even when pregnant persons in the United States obtain a medication abortion within the presence of a provider, they almost always “return home after taking mifepristone and take the misoprostol 28 to 48 hours later.”⁴⁸ As a result, nearly all of those medication abortions, like those patients self-administer after receipt of the prescribed medication by mail, “occur largely in nonclinical settings.”⁴⁹

The overwhelming evidence of the safety and efficacy of mail-order pharmacies for the provision of

⁴⁶ Koenig, L., *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*, *Contraception* (Feb. 1, 2023), available at: [https://www.contraceptionjournal.org/article/S0010-7824\(23\)00015-X/fulltext#secsect0005](https://www.contraceptionjournal.org/article/S0010-7824(23)00015-X/fulltext#secsect0005).

⁴⁷ Swica, Y., *et al.*, *Acceptability of home use of mifepristone for medical abortion*, *Contraception*, 2013;Jul;88(1):122-27 (Nov. 21, 2012), available at: <https://pubmed.ncbi.nlm.nih.gov/23177917/>; see also, e.g., Grossman, *supra* note 38 (finding that of the few adverse events reported during study by patients who had undergone medication abortion at home, “none . . . would have been avoided by dispensing medications in person rather than with the mail-order pharmacy”).

⁴⁸ *The Safety and Quality of Current Abortion Methods*, *supra* note 38, at 56.

⁴⁹ *Id.*

mifepristone to pregnant patients for abortions at home allows favorable comparison to other contexts. Specifically, the extremely low risk profile associated with self-administered medication abortions is comparable to “the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications,” such as NSAIDs and common antibiotics, which further supports that “no facility-specific factors are needed to ensure the safety of medication abortion, as there is no perceived need for facility-specific factors to ensure the safety of these other common pharmaceuticals.”⁵⁰ In other words, “there is no medical reason for mifepristone to be dispensed in clinics.”⁵¹

⁵⁰ *Id.* at 58.

⁵¹ Chong, *supra* note 35; *see also, e.g.*, Koenig, *supra* note 46 (explaining that several recent studies have demonstrated that abortion care through telehealth and mail-order services “is safe, effective, and highly satisfactory to patients”); Grossman, *supra* note 38 (“Preliminary findings from this study suggest that medication abortion with mail-order pharmacy dispensing of mifepristone was effective, feasible, and acceptable to patients seeking early abortion.”); Raymond, E., *et al.*, *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, *Contraception*, 2019Sep;100(3):173-77 (June 3, 2019), *available at*: [https://www.contraceptionjournal.org/article/S0010-7824\(19\)30176-3/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(19)30176-3/fulltext) (“This direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory.”).

III. Prohibition of mail-order distribution of mifepristone will inflict serious harm on the public, patients, and businesses like Honeybee

If the Court of Appeals' ruling is allowed to stand, neither brand-name nor generic mifepristone will be available to patients by mail. No mere inconvenience, such a result would deny some pregnant patients seeking to end pregnancies—and patients with other medical needs—access to a safe, effective medication altogether. Any consideration of the balance of hardships must account for the grave, irreparable harm that would befall the public interest, users of mail-order mifepristone in particular, and companies like Honeybee, whose business depends on distributing mail-order mifepristone.

As Danco and the FDA have demonstrated, the Respondents' theory of harm is speculative and attenuated. Mifepristone has been available to patients through telemedicine and mail-order pharmacies since the height of the COVID-19 pandemic, with no significant issues reported in the literature. By contrast, the harm that will befall pharmacies like Honeybee, patients, and the public interest should the Court of Appeals' decision be allowed to stand is certain, immediate, and irreparable. Even if the Respondents had standing and a reasonable prospect of success on the merits, equity does not favor the relief they seek.

A. The public interest and public policy weigh against enjoining the availability of mail-order mifepristone.

Courts must take “particular regard for the public consequences in employing the extraordinary remedy of injunction.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). When “the Government is the opposing party,” the assessment of “harm to the opposing party” and “the public interest” merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). And as courts have often recognized, a federal agency suffers inherent harm when prevented from implementing regulations that Congress has entrusted it with the authority to promulgate in the public interest. *See, e.g., Nat’l Propane Gas Ass’n v. U.S. Dep’t of Homeland Sec.*, 534 F. Supp. 2d 16, 20 (D.D.C. 2008). *See also Maryland v. King*, 567 U.S. 1301, 1303 (2012) (“[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.”). Here, the public interest weighs strongly against overriding the FDA’s judgment as to the drug’s safety and effectiveness.

Public interest analysis also accounts for the particular policy interests embodied in statute. *See, e.g., Amoco Prod. Co. v. Vill. of Gambell, Alaska*, 480 U.S. 531, 545-46 (1987). The 1984 amendments to the federal Food, Drug, and Cosmetic Act evinced a federal policy aim of reducing the cost of drugs and promoting the availability of generics, without compromising safety. *See Mutual Pharm. Co., Inc. v. Barrett*, 570 U.S. 472, 476-77 (2013); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d

578, 585 (6th Cir. 2013).⁵² Among its other impacts, implementation of the Fifth Circuit’s decision would deprive patients of an affordable, efficient way to obtain a generic medication that has been proven safe—a step backward from the policy Congress has charged the FDA with effectuating.

B. Data show that eliminating access to mail-order mifepristone will inflict harm on many patients.

Weighing the public interest means considering not only policy, but also the tangible consequences injunctive relief will have for other individuals or classes of non-parties. *See, e.g., Nat’l Ass’n of Farmworkers’ Orgs. v. Marshall*, 628 F.2d 604, 616 (D.C. Cir. 1980). The Fifth Circuit acknowledged the voices of several *amici* on this score, but it assigned little weight to the harm that would befall patients if the injunction were allowed to stand. The danger that “eliminating access to mifepristone, even temporarily, may pose health risks to certain women” was less material, it reasoned, because patients’ interest in access to the drug relates “primarily (if not wholly) to the challenge to the 2000 Approval,” rather than the 2016 REMS and the 2021

⁵² Wider availability of generic medications does, in fact, lower drug costs. The Association for Accessible Medicines estimates that generic drugs saved the U.S. Healthcare system approximately \$408 billion in 2022, and a total of \$2.9 trillion over the last ten years. *See* The U.S. Generic and Biosimilar Medicines Savings Report (Sept. 2023), *available at*: <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf> (last visited Jan. 18, 2024).

non-enforcement decision. Pet. App. 68a.⁵³ But the Fifth Circuit made no mention of the distinct interest of patients who rely on the mail-order mifepristone that has become available under those FDA actions—an interest that will suffer severe, immediate injury if its decision is affirmed. A thorough balancing of the interests at stake requires that the jeopardy to these patients be taken into account.

Medication abortion carries far less risk for American women than childbirth. An analysis by the New England Journal of Medicine in 2017 demonstrated that the mortality rate for mothers in live births in the United States was some 14 times higher than that associated with medication abortions using mifepristone.⁵⁴ Because, as discussed *supra* Section II, accessing mifepristone through a combination of telemedicine and mail-order pharmacies is safe and effective,⁵⁵ still more recent data establish that the 2016 and 2021 FDA policy changes have not altered this striking mortality disparity.⁵⁶

We also know that the inverse is true: denying access to abortion threatens women’s lives. Multiple

⁵³ “Pet. App.” refers to the FDA’s petition appendix in No. 23-235.

⁵⁴ Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, N. Engl. J. Med., Vol. 376, at 790-94 (Feb. 23, 2017), *available at*: <https://www.nejm.org/doi/10.1056/NEJMs1612526>; *see also* The Safety and Quality of Current Abortion Methods, *supra* note 38.

⁵⁵ Endler, *supra* note 5.

⁵⁶ Upadhyay, *supra* note 36.

studies, conducted in the United States⁵⁷ and globally⁵⁸ have demonstrated a strong correlation between restrictions on abortion and maternal mortality. Diminished access to abortion exacerbates underlying disparities in health outcomes for pregnant women across racial and income lines; due to structural inequalities, Black Americans, for instance, are more likely to seek abortions than white Americans, are thus more likely to be denied access to abortion where its availability is legally curtailed, and face far higher rates of serious complications or death in bringing a pregnancy to term.⁵⁹ And to the extent that enjoining mail-order mifepristone causes some patients to lose access to abortion altogether, who absent the injunction could access it legally via mail, the Fifth Circuit's

⁵⁷ Stevenson, A., *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, *Demography* 58 (6): 2019-28 (Dec. 1, 2021), available at: <https://read.dukeupress.edu/demography/article/58/6/2019/265968/The-Pregnancy-Related-Mortality-Impact-of-a-Total>.

⁵⁸ Ngo, N., et al., *Reproductive Health Policy Saga, Restrictive Abortion Laws in Low- and Middle-Income Countries (LMICs), Unnecessary Cause of Maternal Mortality, Health Care for Women Int'l*, Vol. 45 at 5-23 (Nov. 2, 2021), available at: <https://www.tandfonline.com/doi/full/10.1080/07399332.2021.1994971>.

⁵⁹ See Creanga, A., et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity: A Multi-State Analysis, 2008-2010*, *Am. J. Obstet. Gynecol.*, 2014 May (Dec. 1, 2013), available at: <https://pubmed.ncbi.nlm.nih.gov/24295922/>; Kheyfets, A., et al., *The Impact of Hostile Abortion Legislation on the United States Maternal Mortality Crisis: A Call for Increased Abortion Education*, *Front. Pub. Health* (Dec. 5, 2023), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10728320/#ref14>.

ruling could cause them to seek alternatives, some of which may be unsafe.

Moreover, as with access to a range of medicines and health treatments, for some who live in isolated rural areas, who have disabilities, or who have limited or no access to transportation, an in-person dispensing requirement may be an insuperable obstacle—or enough of a disincentive that many ultimately will not obtain abortion care.⁶⁰ And as *amici* before the Fifth Circuit explained and the district court record showed, survivors of sexual violence or other trauma may need the greater privacy and autonomy provided by obtaining medication abortion through telehealth and mail-order pharmacies.⁶¹ For these patients, or others for whom the marginal differences in cost, time, and convenience mean the difference between obtaining care and forgoing it, countermanding the FDA’s judgment and reinstating the in-person prescription

⁶⁰ Grossman, *supra* note 38 (noting that many patients access mail-order pharmacies because they “live far away from a local pharmacy or have difficulty making the trip”).

⁶¹ See Decl. of Katherine B. Glaser, M.D., Ex. 7, at 6, *All. for Hippocratic Medicine v. U.S. Food & Drug Admin.*, No. 2:22-cv-00223 (N.D. Tex. Jan. 13, 2023), appeal docketed, No. 23-10362 (5th Cir. Apr. 10, 2023), ECF No. 28; see also *Recent Guidance: FDA Lifts In-Person Dispensing Requirement for Mifepristone Abortion Pill*, 135 Harv. L. Rev. 2235, 2240-41 (June 2022) (noting that the REMS in effect for mifepristone, including the in-person prescription requirement, “disproportionately affect the most marginalized pregnant people seeking abortions,” and that “[r]acially marginalized, trans, and nonbinary pregnant individuals face prohibitive challenges,” including but not limited to travel to sites where in-person prescriptions can be obtained (asterisk omitted)).

requirement will curtail access to legal abortion care. This will inflict a cognizable harm on the women who are thereby denied a lawful means of medication abortion. *See, e.g., Pharmacia Corp. v. Alcon Labs., Inc.*, 201 F. Supp. 2d 335, 385 (D.N.J. 2002) (explaining that where an injunction would deprive the public of an FDA-approved medication, the public interest is paramount); *Reedco, Inc. v. Hoffman-La Roche, Inc.*, 667 F. Supp. 1072, 1080 (D.N.J. 1987) (finding that harm to patients from a three-month interruption in supply of a prescription drug weighed against issuance of an injunction).

And vital uses of mifepristone extend beyond abortion. Mifepristone has been shown to be an effective treatment for miscarriage management, reducing the incidence of serious complications from pregnancy loss.⁶² Scientific studies also reflect that mifepristone may be used for other non-abortion-related medical reasons, including managing and treating uterine leiomyomas,⁶³ at least one type of brain tumor, and endometriosis.⁶⁴ Depriving patients of mail-order access to mifepristone for these uses constitutes a harm

⁶² Schreiber, C., *et al.*, *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, N. Eng. J. Med. Vol. 378, at 2161-70 (June 7, 2018), *available at*: <https://www.nejm.org/doi/full/10.1056/NEJMoa1715726>.

⁶³ *See* Autry, B.M., *et al.*, *Mifepristone*, StatPearls (last updated May 8, 2022), *available at*: <https://www.ncbi.nlm.nih.gov/books/NBK557612/>.

⁶⁴ *See* Mifepristone (Mifeprex), Nat'l Library of Medicine (last revised Mar. 15, 2023), *available at*: <https://medlineplus.gov/druginfo/meds/a600042.html#how>.

independent of the evolving legal and policy landscape surrounding abortion.

C. Prohibiting mail-order delivery of mifepristone would inflict serious harm on Honeybee and other online pharmacies.

To the harms to patients must be added the injury that members of the pharmaceutical community, including Honeybee, will suffer if the injunction is allowed to go into effect. *See, e.g., ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 28-29 (D.D.C. 2012) (concluding that business harm to producers of a generic drug should its distribution be enjoined weighed against injunctive relief). While some forms of economic harm are discounted in the balancing of interests, 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).

Here, Honeybee's business, like that of many providers and pharmacies, depends on the FDA because, pursuant to the state Board of Pharmacy licenses necessary to operate its business, it may dispense only FDA-approved medications. Specifically with respect to mifepristone, Honeybee has relied heavily on the FDA's determination that dispensation of the drug through mail to facilitate medication abortions, is safe and effective. As noted above, under the regulatory regime the FDA has created, Honeybee has delivered thousands of doses of mifepristone to patients by mail

at costs lower than those patients could realize at their local brick-and-mortar providers, and it has served some patients who may not otherwise be able to access the medication easily or at all.

Honeybee has done so based on its appreciation for the robust scientific data demonstrating the soundness of the FDA's decision and its well-founded reliance on the congressionally mandated legal framework which designates the FDA as the federal government's foremost scientific expert on evaluating drugs' safety and efficacy. Honeybee's business model—and the service it provides to these patients—would be hamstrung if this Court overrides the FDA's assessment of the ample scientific evidence supporting the safety, effectiveness, and convenience of mail-order mifepristone.

◆

CONCLUSION

Mail-order pharmacies like Honeybee that operate in compliance with all applicable laws play an integral role in the growing telemedicine healthcare sector. They support patients' individual freedom to access the healthcare most appropriate for them, while preserving states' place to ensure, via regulation, that the healthcare all patients receive is both safe and effective. And the overwhelming evidence is that abortion through medication obtained by mail is not only safe and effective, but also often the only means by which a pregnant person in need of an abortion may be able to obtain that life-changing care. The theoretical harms

the Respondents have advanced do not outweigh the real, data-supported harm prohibiting this vital healthcare access will cause these patients and the businesses like Honeybee who support them. The Court of Appeals' order should be reversed to the extent it granted relief to the Respondents.

Respectfully submitted,

STEPHANIE L. GUTWEIN

Counsel of Record

A. SCOTT CHINN

MATTHEW K. GIFFIN

ELIZABETH A. CHARLES

FAEGRE DRINKER BIDDLE & REATH LLP

300 N. Meridian Street, Suite 2500

Indianapolis, IN 46204

(317) 237-0300

stephanie.gutwein@faegredrinker.com

scott.chinn@faegredrinker.com

matt.giffin@faegredrinker.com

elizabeth.charles@faegredrinker.com

LIBBY L. BANEY

FAEGRE DRINKER BIDDLE & REATH LLP

1500 K Street NW, Suite 1100

Washington, D.C. 20005

(202) 842-8800

libby.baney@faegredrinker.com

Counsel for Amicus Curiae

Honeybee Health, Inc.