No. 23-10362

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant-Appellant.

On Appeal from the United States District Court
for the Northern District of Texas, Amarillo, No. 2:22-cv-00223-Z
Hon. Matthew J. Kacsmaryk, U.S. District Judge

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

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2023

CERTIFICATE OF INTERESTED PERSONS AND DISCLOSURE STATEMENT

The undersigned counsel of record for *amicus curiae* certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1, in addition to those listed in the Appellants' Certificate of Interested Persons, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amicus Curiae:

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Culver City, CA 90232

Honeybee Health, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Honeybee Health, Inc.'s stock.

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Originally Submitted: April 27, 2023

Disclosure Information Updated: May 3, 2023

/s/ Stephanie L. Gutwein

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INTEREST OF *AMICUS CURIAE*

Run by board-certified pharmacists with over 40 years' combined experienced, Honeybee Health, Inc. ("Honeybee") has been using technology and transparency since 2018 to safely and effectively deliver only 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. Rather than contracting with insurance companies, Honeybee uses the Internet and mail carriers to work directly with patients to timely and inexpensively fill their prescriptions, with live pharmacists conveniently available to counsel patients through any questions or concerns. Thousands of reviews confirm that patients who have relied on Honeybee to reliably deliver medications directly to them are overwhelmingly satisfied with their experiences.[1]

Forty-six states and Washington D.C. have licensed Honeybee to ship their residents prescribed medications; Honeybee also ships over-the-counter medications to patients across the country. Honeybee was one of the first, and is the largest, mail-order pharmacy in the United States to deliver mifepristone to patients, almost uniformly upon those patients' receiving

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[1] *See Honeybee Health*, Trustpilot, *available at*: https://www.trustpilot.com/review/honeybeehealth.com (last visited Apr. 27, 2023).

telehealth services and, in every instance, the generic version of the drug.[2] It also was the first pharmacy to distribute mifepristone on behalf of providers. And like the demand for telehealth services in the United States,[3] demand for Honeybee's services, and for mifepristone specifically, has only increased since Honeybee's founding.

Honeybee submits this amicus brief to provide the Court with its experience in and knowledge of the market for mail-order medicine. In so doing, Honeybee emphasizes clear and credible information on the safety and efficacy of mail-order pharmacies and the use of those pharmacies to obtain mifepristone for purposes of inducing abortions at home. Honeybee also offers additional considerations on the concrete harms the District Court's injunction will inflict should it remain in place.

No fees have been paid or will be paid for the preparation and filing of this amicus brief.

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[2] *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/.

[3] *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.

SUMMARY OF ARGUMENT

Mail carriers, including the United States Postal Service, have been delivering medications to patients for over 100 years.[4] 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 since.[5] As of 2020, researchers estimate more than 200,000,000 prescriptions were delivered through mail annually.[6]

Pregnant persons in North America also have been inducing abortions outside the presence of providers for centuries, with data suggesting as many as 7% of women in the United States have attempted such an abortion.[7] In

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[4] Gaffney, A.W., et al., *Health Needs and Functional Disability Among Mail-Order Pharmacy Users in the US*, JAMA Intern Med., 2021;181(4):554–556, doi:10.1001/jamainternmed.2020.7254 (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.

[5] *See, e.g.*, Ma, J., et al., *Characteristics of Mail-Order Pharmacy Users: Results From the Medical Expenditures Panel Survey*, Journal of Pharmacy Practice, 2020;33(3):293-298, doi:10.1177/0897190018800188 (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, 2020.09.22.20199505, doi: https://doi.org/10.1101/2020.09.22.20199505 (Sept. 23, 2020), *available at*: https://www.medrxiv.org/content/10.1101/2020.09.22.20199505v2.

[6] Gaffney, *supra* note 4.

[7] Aiken, A.R.A., et al., *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, The Lancet Regional Health - Americas, 10:2022 100200, https://doi.org/10.1016/j.lana.2022.100200 (June 2022), *available at*: https://www.sciencedirect.com/science/article/pii/S2667193X22000175?via%3Dihub

recent years, however, patients' method for doing so has grown remarkably safer, as access to "the use of online telemedicine to provide the abortion medications mifepristone and misoprostol" has increased.[8] And, time and again, studies have shown that at-home "medication abortion provided through online telemedicine in the United States is effective, acceptable to users, and has a very low rate of serious adverse outcomes."[9]

Honeybee, which was among the first and is the largest mail-order pharmacy in the United States to deliver mifepristone to patients by mail for use in at-home abortions, offers this brief to reiterate the safety, efficacy, and necessity of mail-order pharmacies to deliver prescription medications, including mifepristone, to patients across the United States and to further articulate the incredible harm that restrictions on these services will cause patients, pharmacies, and FDA-regulated industries more generally in the United States.

(describing these abortions as those "that tak[e] place outside of the formal healthcare setting, and include[e] a spectrum of methods, such as the abortion pills mifepristone and/or misoprostol, menstrual extraction, botanicals, herbs, vitamins, beverages, and ingestion of toxic substances and physical injury").

[8] *Id.*

[9] *Id.*

ARGUMENT

A wealth of scientific data confirms that using mail-order pharmacies to obtain mifepristone for purposes of inducing an abortion at home, outside the presence of a provider, is a safe, effective, and a necessary component of robust patient care in the United States. If permitted to stand, the District Court's injunction, which eliminates access to medicated abortions throughout the United States, by mail or otherwise, will immediately and irreparably harm patients, the members of the pharmaceutical community, other medical providers, and a critical and relied-upon regulatory process of the federal government. The District Court's order should be reversed.

I. Delivery of mifepristone by mail is safe and effective.

A. Mail-order pharmacies are safe, effective, and essential to improved patient care.

Recent scientific research estimates that perhaps as much as one-quarter of pharmacy sales in the United States occur through use of mail-order pharmacies.[10] Substantial scientific evidence also confirms the safety,

[10] Schmittdiel, 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 (2019), https://doi.org/10.1186/s12913-019-4250-7 (June 25, 2019), *available at*: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-019-4250-7#Abs1.

efficacy, and benefits of mail-order pharmacies to the lives of patients across the United States.[11]

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."[12] In fact, research shows that patients who 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.[13] Mail-order pharmacies, like use of telemedicine, also result in lower health-care costs overall: among other reasons for this cost-savings, mail-order pharmacies often coincide with lower in- and out-patient

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[11] Ma, *supra* note 5.

[12] Schmittdiel, JA, et al., *Safety and effectiveness of mail order pharmacy use in diabetes*, Am J Manag Care, 2013 Nov;19(11):882-7, PMID: 24511986, PMCID: PMC4278640 (Nov. 20, 2013), *available at*: https://www.ajmc.com/view/safety-and-effectiveness-of-mail-order-pharmacy-use-in-diabetes.

[13] *See, e.g.*, Gaffney, *supra* note 4; Ma, *supra* note 5 ("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, *Safety and effectiveness of mail order pharmacy use in diabetes*, *supra* note 12 (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)).

and medication costs.[14] Honeybee's dispensation of only generic, rather than brand-name, mifepristone is just one example of these routinely attained cost-savings. And these favorable attributes of mail-order pharmacies, which reflect "improved access to medications with mail order pharmacy use, . . . may be of particular value to patients with disabilities, time constraints, or limited transportation."[15]

B. Medication abortions performed at home are safe and effective.

The number of pregnant patients pursuing abortions through medicated, rather than surgical, means also has continued to increase in recent years.[16] And numerous studies, analyzing data both before and after 2020, when the FDA requirement that mifepristone be dispensed in clinics initially was suspended, also confirm that mail delivery of mifepristone to

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[14] *See* Ma, *supra* note 5; 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: 1464-1474 (Mar. 24, 2021), *available at*: https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/1471-0528.16668; *see also* Schmittdiel, *Opportunities to encourage mail order pharmacy delivery service use for diabetes prescriptions: a qualitative study*, *supra* note 10 ("[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.").

[15] Schmittdiel, *Safety and effectiveness of mail order pharmacy use in diabetes*, *supra* note 12.

[16] Daniel, S., et al., *Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone*, Contraception, 2021 Jul;104(1):73-76, doi: 10.1016/j.contraception.2021.03.026 (Mar. 31, 2021), *available at*: https://www.contraceptionjournal.org/article/S0010-7824(21)00098-6/fulltext.

patients, and medicated, rather than surgical, abortions via this mechanism, are safe, effective, and almost always result in positive patient outcomes.[17] For example:

- Researchers in 2021 confirmed that out of more than 1,100 packages containing mifepristone and misoprostol delivered to patients by mail between May 2016 and September 2020, 95% of patients completed the abortion without any further procedure.[18]
- A study analyzing nearly 2,800 patients who confirmed undergoing an abortion with medications obtained through mail between March 2018 and March 2019 reflects that more than 96% ended their pregnancies successfully without any surgical intervention, while only 1% reported treatment for any serious adverse event.[19] And of the over 2,200 participants in that study who provided additional information about their experiences,

[17] "Medical" or "medicated" abortions are defined as the use of medicines, rather than surgical procedures, to terminate a pregnancy. *See, e.g.*, Aiken, *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, *supra* note 14.

[18] 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, 2021 Jul;104(1):43-48, doi: 10.1016/j.contraception.2021.03.019 (Mar. 27, 2021), *available at*: https://pubmed.ncbi.nlm.nih.gov/33781762/.

[19] Aiken, *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, *supra* note 7.

"98.4% were satisfied and 95.5% felt [performing the abortion with medication at home] was the right choice."[20]

- A separate study of among over 100 patients who relied on telehealth services to obtain a medicated-abortion regimen by mail between October 2020 and January 2021 found 95% completed their abortions without intervention, and none reported any major adverse events.[21] This efficacy rate of medicated abortion procedures through telehealth and mail-order means "is similar to in-person provision" and aligns with international studies on use of telehealth for medicated abortions.[22]
- Researchers analyzing 224 patients who underwent medicated abortions at home between January 2020 and April 2021 found that nearly 97% had a complete abortion with medications alone,

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[20] *Id.* (describing results as showing "[at-home] medication abortions provided through online telemedicine, outside the formal healthcare system, in the U.S. . . . were highly effective, with reported success rates comparing favorably with medication abortions carried out up to 10 weeks within the formal U.S. healthcare setting," "[a] reported prevalence of serious adverse events [that] was very low, and [that] users . . . reported high levels of satisfaction").

[21] Upadhyay, U.D., et al., *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, JAMA Netw Open, 2021 Aug 2;4(8):e2122320, doi: 10.1001/jamanetworkopen.2021.22320 (Aug. 24, 2021), *available at*: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8385590/.

[22] *Id.*

and the overwhelming majority reported being satisfied with receiving their medications by mail.[23]

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 underscores the safety and efficacy of the telehealth and mail-order model and its parity with in-person treatments. For example, when providers in Hawaii compared outcomes of pregnant patients who underwent medicated abortions between April and November 2020 after receiving the medications either in-person or through mail, they found that the "[r]ates of abortion success [were] similar for all methods of dispensing mifepristone and misprostol" and that 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.[24]

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[23] Grossman, D., et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, Contraception, doi:https://doi.org/10.1016/j.contraception.2021.09.008 (Sept. 20, 2021), *available at*: https://www.contraceptionjournal.org/article/S0010-7824(21)00384-X/fulltext.

[24] Kerestes, C., et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, Contraception, 2021 Jul;104(1):49-53, doi: 10.1016/j.contraception.2021.03.025 (Mar. 28, 2021), *available at*: https://www.contraceptionjournal.org/article/S0010-7824(21)00097-4/fulltext.

And in what might be the largest study to date to assess outcomes of in-person versus mail-order administration of abortion medications, researchers in Great Britain analyzed over 52,000 medicated abortions performed between January and June 2020, representing nearly 85% of all medicated abortions performed in England and Wales during that time.[25] Between January and March of 2020, pregnant patients in Britain seeking a medicated abortion were required to "attend in-person to receive an ultrasound scan and have mifepristone administered within the clinic."[26] With the onset of the COVID-19 pandemic in March 2020, the British government relaxed those requirements to permit pregnant patients seeking a medical abortion to rely on telehealth, forego an ultrasound except under limited circumstances, receive mifepristone and misprosotol directly by mail, and consume those medications outside the presence of a provider.[27] The study was designed specifically to compare outcomes and satisfaction levels for patients in the earlier cohort (those who received an assessment, ultrasound scan, and administration of mifepristone in-person with a

[25] Aiken, *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, *supra* note 14.

[26] *Id.*

[27] *Id.*

provider) with those in the latter (those who accessed the medicated abortion services through telehealth and mail-order means)—the latter cohort representing patients similarly situated to those who use Honeybee's services.[28]

The study's results were profound for the extent to which they demonstrated the safety, efficacy, and, in some instances, superiority of telehealth and mail-order medicated abortion services. For example, 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 medicated abortions performed at home, rather than in-person.[29] Pregnant patients who obtained a medicated 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.[30] No data indicated that pregnant patients who accessed their care

[28] *Id.*

[29] *Id.*

[30] *Id.* (disclosing that the rate of successful medicated abortions for in-person patients in the study was 98.2%).

through telehealth and mail-order means experienced greater incidence of significant adverse events than those who accessed care in-person.[31]

A study published just three months ago also has confirmed that mailing of medications for patients' use in at-home abortions "did not significantly prolong [the] time from patients' first contact with the clinic to mifepristone ingestion or increase pregnancy duration at mifepristone ingestion."[32] Research also shows that 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.[33] And this makes sense: even when pregnant patients receive mifepristone at a provider's office, their intake of the medication is no different from those

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[31] *Id.*

[32] 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, https://doi.org/10.1016/j.contraception.2023.109962 (Feb. 1, 2023), *available at*: https://www.contraceptionjournal.org/article/S0010-7824(23)00015-X/fulltext#secsect0005.

[33] Swica, Y., et al., *Acceptability of home use of mifepristone for medical abortion*, Contraception, 2013 Jul;88(1):122-7, doi: 10.1016/j.contraception.2012.10.021 (Nov. 21, 2012), *available at*: https://pubmed.ncbi.nlm.nih.gov/23177917/; *see also, e.g.*, Aiken, *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, *supra* note 7 (discussing "previous large randomized controlled trial[, which] showed that self-assessment of the outcome of medication abortion was non-inferior to clinical follow-up"); *see also, e.g.*, Grossman, *supra* note 23 (finding that of the few adverse events reported during study by patients who had undergone medicated abortion at home, "none . . . would have been avoided by dispensing medications in person rather than with the mail-order pharmacy").

who consume it at home following a telehealth visit and receipt of the medication in the mail—in either instance, the patient is ingesting the medication and then later navigating its effects outside of a provider's physical care absent a need to seek emergency treatment. Yet, as detailed above, the cost and access-enhancing benefits of mail-order medicines and telehealth services can be profound for many patients, even while safe and effective.

In other words, scientifically sound data demonstrates that mail-order dispensation of mifepristone for use in abortions performed at home results in outcomes at least as successful as those achieved through in-person dispensation. These results have led researchers consistently to conclude that "[m]edical abortion using telemedicine and mail is effective and can be safely provided without a pretreatment ultrasound," and "there is no medical reason for mifepristone to be dispensed in clinics."[34] And they have led a host

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[34] Chong, *supra* note 18; *see also, e.g.*, Aiken, *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, *supra* note 7 (concluding medication abortion performed at home after using online telemedicine "can be highly effective with low rates of serious adverse events," and "no-test medical abortion via telemedicine without routine ultrasound up to 10 weeks' gestation is an effective, safe and acceptable service model"); Koenig, *supra* note 32 (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 23 ("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*

of American obstetric and gynecological associations, including the American College of Obstetricians and Gynecologists and others, to endorse uninterrupted patient access to abortions, including through telehealth and mail-order services.[35]

C. Courts should not supplant their judgment for that of scientific experts.

This wealth of scientific data evidencing the safety and efficacy of mail-order pharmacies, including for the provision of mifepristone to pregnant patients for abortions performed at home, should not be easily forsaken by individual judges whose expertise lies in the law, not the laboratory. *See, e.g.*, *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020), Roberts, C.J., concurring (explaining that where "broad limits" of policymaking "are not exceeded, they should not subject to second-guessing" by judiciary, which "lacks expertise to access public health"); *League of*

United States, Contraception, 2019 Sep;100(3):173-177, doi: 10.1016/j.contraception.2019.05.013 (June 3, 2019), *available at*: https://www.contraceptionjournal.org/article/S0010-7824(19)30176-3/fulltext ("This direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory.").

[35] *See, e.g.*, *ACOG Releases Statement on FDA Announcement Regarding Changes to Restrictions on Provision of Mifepristone*, The American College of Obstetricians and Gynecologists (Jan. 3, 2023), *available at*: https://www.acog.org/news/news-releases/2023/01/statement-fda-announcement-regarding-changes-to-restrictions-on-provision-of-mifepristone; *Joint Statement on Abortion Access During the COVID-19 Outbreak*, The American College of Obstetricians and Gynecologists (Mar. 18, 2020), *available at*: https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.

Indep. Fitness Facilities & Trainers, Inc. v. Whitmer, 814 Fed. Appx. 125, 129 (6th Cir. 2020) ("Shaping the precise contours of public health measures entails some difficult line-drawing. Our Constitution wisely leaves that task to officials directly accountable to the people."); *Marshall v. U.S.*, 414 U.S. 417, 427 (1974) ("When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative opinions must be especially broad and courts should be cautious not to rewrite legislation, even assuming, arguendo, that judges with more direct exposure to the problem might make wiser choices.").

Courts must hold this truism particularly close when the FDA has exercised its scientific expertise to evaluate and adjudge medical drugs and their dispensation forms safe and effective. Congress, through its constitutional powers and the Federal Food, Drug, and Cosmetic Act (FFDCA), has established the FDA to promote and protect the public health. 21 U.S.C. §§ 393(b)(1) & (2). And it has tasked the FDA as the federal government's expert to evaluate the safety and efficacy of new drugs and changes to existing drug applications. *See* 21 U.S.C. §§ 355(d), 393(b)(2)(B) (directing the FDA to "protect the public health by ensuring that . . . drugs are safe and effective" by, among other things, reviewing clinical research

and taking appropriate action on the marketing of regulated products);[36] *see also, e.g.*, *Schering Corp. v. FDA*, 51 F. 3d 390, 399 (3d Cir. 1995) ("[J]udgments as to what is required to ascertain the safety and efficacy of drugs falls squarely within the ambit of the FDA's expertise and merit deference from us.").

Providers, pharmacists, manufacturers, and patients form their important, and in many cases life-altering, medical decisions around scientifically supported FDA determinations. Put simply, the FDA plays a pivotal role in the regulatory scheme enacted by Congress to ensure the safety and efficacy of drugs made available to the public. One court's renouncing those expert determinations absent the clearest of legal bases for doing so necessarily upends the administrative framework Congress (and the Constitution) has created to ensure that all pharmaceutical drugs that reach the market are both safe and effective.[37] Nearly fifty years ago, the United

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[36] The FDA also is tasked with approving generic medications. Generic medications are medications that are bioequivalents of an already approved "brand name" drug. *See, e.g.*, *Generic Drugs: Questions & Answers*, U.S. Food & Drug Admin., *available at*: https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#2 (last visited Apr. 24, 2023).

[37] *See also, e.g.*, *31 Patient and Provider Groups Warn that Mifepristone Ruling Threatens All FDA-approved Drugs* , *available at*: https://www.lls.org/sites/default/files/2023-04/Texas%20Hippocratic%20Medicine%20Ruling%20Statement%20041123_0.pdf (last visited Apr. 25, 2023).

States Supreme Court reiterated that this separation of powers, which the Constitution envisions and demands, has occasioned "the congressional determination that administrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the industry and the tasks of the agency involved." *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 525 (1978) (quoting *FCC v. Schreiber*, 381 U.S. 279, 290 (1965)). Consistent with these fundamental tenets of our divided government, courts should decline invitations, like the one Appellees offer in this action, to wade into a scientific debate with, and invade the province of, the FDA based on conjecture, their own interpretations of questionable studies, and, in some instances, anecdotal evidence. *See generally* Dkt. 7.

II. Suspension of delivery of mifepristone, by mail or otherwise, will inflict immense harm.

Contrary to the District Court's conclusion, substantial evidence also confirms that elimination of access to brand-name or generic mifepristone, entirely or by mail, will immediately, concretely, irreparably harm the federal government and the public—most importantly patients, but also members of the pharmaceutical community like Honeybee. These definitive harms

indisputably outweigh the hypothetical harms Appellees speculate they may suffer on some future occasion if mifepristone remains available.

A. Harm to the FDA is harm to the public interest.

Because the FDA is the federal governmental agency responsible for protecting the public from unsafe or ineffective drugs, the irreparable harm to the FDA and the public interest "merge" in this context. *Nken v. Holder*, 556 U.S. 418, 435 (2009). As this Court previously has recognized, when a statute is enjoined, the State suffers irreparable harm of denying the public interest in the enforcement of its laws. *See Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). Similarly, here, enjoining the FDA's regulatory approval process necessarily subverts the public interest in that process and, equally importantly, the interests of all those who stand to benefit from the regulation. Contrary to the District Court's assessment, the harm from its order enjoining the FDA's regulatory approvals certainly extends to the FDA but stretches even further—to the patients, providers, the pharmaceutical community, including Honeybee, and the public at large.

B. Potential harm to patients is immense.

There can be no question that the elimination of access to mifepristone, including through mail-order pharmacies, will cause acute and irreparable harm to patients across the United States.

Most generally, that outcome prevents patients from receiving medical care that has been deemed safe and effective by the FDA. *See 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); *Hybritech Inc. v. Abbott Labs.*, No. CV 86-7461/AK (PX), 1987 WL 123997, at *21 (C.D. Cal. July 14, 1987) (confirming that the public interest is served by the availability of safe and reliable medical supplies). This invades patient autonomy by intruding on patients' informed decisions about their preferred treatment. It also disallows providers from respecting patients' informed decisions.

More specifically, eliminating patients' access to mail-order mifepristone and its generics, increases patients' health risks.[38] Not all pregnant patients have access to in-person health services to terminate a pregnancy. As the District Court concedes, parts of the country are "maternity-care deserts." Dkt. 137 at 15.[39] Restricting access to mifepristone,

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[38] Generic medications increase competition in the marketplace and lower costs for patients, which is one of the FDA's top priorities. The Association for Accessible Medicines estimates that generic drugs saved the U.S. Healthcare system nearly $2.2 trillion between 2009 and 2019. *See 2020 Generic Drug & Biosimilars Access and Savings in the U.S. Report*, Association for Accessible Medicine, available at: https://accessiblemeds.org/resources/reports/2020-generic-drug-biosimilars-access-and-savings-us-report (last visited Apr. 24, 2023).

[39] *See also, e.g.*, Ma, *supra* note 5; Grossman, *supra* note 23 (explaining some patients access mail-order pharmacies because they "live far away from a local pharmacy or have

therefore, will not simply limit many patients' options for lawful abortion care, but it will effectively eliminate access to lawful abortion services as an option entirely. And "[t]here is clear evidence that restricting access to abortion does not reduce abortion rates, it simply makes the procedure less safe."[40]

Some pregnant persons who have no other meaningful access to health services necessary to end a pregnancy will revert to other forms of self-medicated abortion, demonstrably less safe and effective than abortions performed at home through telehealth and mail-order services. For example, "[b]etween 200,000 and 1.2 million unsafe abortions are estimated to have taken place per year in the U.S. in the 1950s and 1960s pre-*Roe*, with the resulting burden of morbidity and mortality falling disproportionately on

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difficulty making the trip" and observing "the declining number of abortion providers in the U.S." and that "[m]ail-order pharmac[ies] dispensing of mifepristone could further allow medication abortion patients to bypass geographical obstacles to the service and receive abortion care earlier in pregnancy"); Jerman, J., *Barriers to Abortion Care and Their Consequences For Patients Traveling for Services: Qualitative Findings from Two States*, Perspect Sex Repro H, 49: 95-102 https://doi.org/10.1363/psrh.12024 (June 2017), *available at*: https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12024 (reciting statistics on limited access to abortion services for vast majority of United States residents, including that, as of 2014, "some 90% of U.S. counties lacked an abortion clinic, and five states had only one").

[40] Aiken, *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, *supra* note 14 (observing that the telehealth, mail-order medicated abortion model serves the "advantages of improving access to care, especially in vulnerable groups and in resource-poor healthcare systems or where patients have to fund their own care").

racially minoritised people."[41] Others may be forced to carry to term pregnancies with potential fatality rates also much higher than those associated with abortions through a mail-order mifepristone and misoprostol regime, which data reflects never or almost never result in death to the pregnant person.[42]

Eliminating mail-order access to mifepristone also will harm patients whose interest in the drug is unrelated to an abortion procedure. Scientific studies reflect that mifepristone may be used for non-abortion-related medical reasons, including managing and treating Cushing's syndrome and uterine leiomyomas,[43] at least one type of brain tumor, endometriosis,[44] and miscarriages.[45]

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[41] Aiken, *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, *supra* note 7.

[42] *Id.* ("Rates of hemorrhage postpartum in the U.S. are over five times higher than those reported in this study, with Black women at disproportionately high risk. The trajectory of highly restricted access.").

[43] *See* Autry, B.M., et al., *Mifepristone*, In: StatPearls [Internet] Treasure Island (FL): StatPearls (last updated May 8, 2022), *available at*: https://www.ncbi.nlm.nih.gov/books/NBK557612/.

[44] *See* Mifepristone (Mifeprex), Nat'l Library of Med., (last revised Mar. 15, 2023), *available at*: https://medlineplus.gov/druginfo/meds/a600042.html#how.

[45] Barnhart, K., *Medical management of miscarriage with mifepristone*, The Lancet, doi: https://doi.org/10.1016/S0140-6736(20)31789-X (Aug. 24, 2020), *available at*: https://www.thelancet.com/article/S0140-6736(20)31789-X/fulltext#articleInformation.

And like pregnant patients who, without mail-order access to mifepristone, are likely to resort to less-safe and less-effective alternatives to medicated abortions at home, patients, pregnant or not, who *need* access to mifepristone, specifically, also are likely to look to less-safe and less-effective alternatives. Research confirms that, in the absence of lawfully available medications through lawfully regulated pharmacies, like Honeybee, patients will turn to unregulated online sellers supplying "substandard, counterfeit, misbranded, or diverted drugs."[46] In fact, data suggests that the vast majority of online sellers of prescription medications to United States patients operate without the types of regulatory approvals that online pharmacies like Honeybee work so hard to obtain and maintain, and, unlike Honeybee and other lawfully approved pharmacies, may "dispens[e] prescription drugs without a valid prescription," "offer foreign or unapproved drugs that may

[46] *Statement on Texas Northern District Court Decision Revoking FDA Approval of Mifepristone*, Alliance for Safe Online Pharmacies (ASOP Global) (Apr. 11, 2023), *available at*: https://buysaferx.pharmacy/wp-content/uploads/2023/04/ASOP-Global-statement-on-Texas-Court-decision-to-revoke-FDA-approval-of-mifepristone-_FINAL.pdf ("[W]hen access to FDA-approved medicine is limited – counterfeiters and illegal online drug sellers step up to fill the void at the expense of patient safety."); *see also, e.g.*, Poliak, A., et al., *Internet Searches for Abortion Medications Following the Leaked Supreme Court of the United States Draft Ruling*, JAMA Intern Med, 2022;182(9):1002–1004, doi:10.1001/jamainternmed.2022.2998 (June 29, 2022), *available at*: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2793813 (observing Internet searches for abortion medication in the United States reached their highest number then seen following the leak of the United States Supreme Court's draft opinion in *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022)).

be substandard or counterfeit," or otherwise sell drugs illegally.[47] This increased risk of consuming counterfeit, expired, or substandard mifepristone, or a drug illicitly marketed as its alternative, from unregulated online sellers inimical to licensed mail-order pharmacies like Honeybee tracks the pattern seen in nearly every instance where government has constrained access to medication proven scientifically safe and effective, and it is one more harm patients will suffer if the District Court's decision is upheld.

C. Enjoining mail-order delivery of mifepristone also will harm pharmacies like Honeybee.

In addition to harming patients, enjoining the FDA's regulations permitting mail-order delivery of mifepristone in both its branded and generic forms also will irreparably harm members of the pharmaceutical community, including Honeybee. 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. Honeybee, like other pharmacy industry stakeholders, is highly regulated and relies on both fair processes

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[47] *Internet Drug Outlet Identification Program, Progress Report for State and Federal Regulators: September 2018*, Nat'l Ass'n of Bds. of Pharmacy, *available at*: https://nabp.pharmacy/wp-content/uploads/2018/09/Internet-Drug-Outlet-Report-September-2018.pdf (last visited Apr. 26, 2023).

and reasonable certainty from the outcomes of those processes in conducting its business. Since its inception in 2018, Honeybee has built a successful business that depends on the FDA's expertise and the regulatory scheme in which it acts. As it relates to mifepristone, specifically, Honeybee has relied heavily on the FDA's 2019 and 2021 determinations, respectively, that the generic version of mifepristone, and its dispensation through mail to facilitate abortions outside the presence of a provider, are safe and effective to deliver thousands of doses of mifepristone to patients by mail at costs lower than those patients could realize at their local brick-and-mortar providers, assuming the drug even is within their geographic reach. And, as discussed above, Honeybee has done so based on its appreciation for the robust scientific data demonstrating the soundness of the FDA's decisions and its well-founded reliance on the legal framework which designates the FDA as the federal government's foremost scientific expert on evaluating drugs' safety and efficacy.

The District Court's disregard for the numerous protocols and precautions that the FDA undertook during its investigations culminating in these approvals, and the court's willingness to supplant its own assessments of the scientific evidence for that of the FDA, hamstrings Honeybee's business and undermines the entire regulatory framework on

which members of the pharmaceutical community, like Honeybee, necessarily rely.

D. These tangible harms indisputably outweigh the speculative harm Appellees assert.

The concrete harms to governmental integrity, patients, and pharmacy stakeholders like Honeybee that undoing scientifically sound FDA approvals and precluding access to mail-order mifepristone will wreak far outweigh the hypothetical, attenuated harm Appellees alleged and the District Court appears to have credited.

In order for Appellees' alleged injuries to occur, a series of distinct events must domino into place. First, a patient taking mifepristone must experience a rare serious event. *See* Dkt. 7 at 14. Second, a patient must seek out the care of one of the complaining physicians. *See id.* Third, the patient then must cause disproportionate burdens to a complaining physician such that their medical practice is "overwhelm[ed]." *See id.* Appellees' also fail to substantiate their alternative hypotheses, that the patient will expose them to increased malpractice liability exposure or that treatment of a patient will cause them distress, grief, and guilt. *See id.* at 14-15. Appellees' inability to identify any concrete, particularized injury is particularly telling, given that mifepristone has been approved and in use for over twenty years.

By contrast, the harm that will befall pharmacies like Honeybee, patients, and providers, in addition to the federal government, should the FDA's approval of mifepristone be enjoined, is certain, immediate, and irreparable. If the approval of mifepristone is enjoined, pharmacies must immediately stop dispensing it. For Honeybee, that means that a material part of its business will have been shut down overnight through no fault of Honeybee's by one court that substituted its judgment for the scientific experts at the FDA. Doctors will be forced to stop prescribing the drug, even when, in their judgment, doing so would be the best course of action for the patient. Patients will be deprived of a healthcare option that may be safer, less invasive, less costly, and more accessible, if not the only means available to them. And the FDA will be precluded from enforcing its own, scientifically founded regulations.

From the perspective of public trust in our systems of regulatory approval and judicial review, the comparison of harms in this case should transcend cabined legal characterization. The issue of whether Appellees may reasonably demonstrate injury sufficient to warrant standing in this case surely is one that deserves scrutiny. Separately, however, whether or not the Court chooses as a legal matter to embrace a broad notion of the balancing of harms among the constituencies represented by the parties in

this case, it is clear to all fair-minded observers that the harms Appellees strain to identify in order to pry open the door to the courthouse pale in comparison to those of the FDA's constituents. And that is not even to mention the problem of exalting the interests of a few against those of the many. It simply stretches credulity and tests the legitimacy of judicial review to see it otherwise.

CONCLUSION

For the reasons set forth above, the Court should reverse the District Court's order.

Originally Submitted: April 27, 2023 Respectfully submitted,

/s/ Stephanie L. Gutwein

CERTIFICATE OF SERVICE

I certify that on April 27, 2023, the foregoing Brief of Honeybee Health, Inc. as Amicus Curiae in support of Appellants' motion for stay pending appeal has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record and has been transmitted to the Clerk of the Court.

I further certify that on May 3, 2023, the foregoing Brief of Honeybee Health, Inc. as Amicus Curiae in support of Appellants' motion for stay pending appeal was re-submitted to the Clerk of the Court with Honeybee Health, Inc.'s Disclosure Statement updated.

/s/ Stephanie L. Gutwein
Counsel for Amicus Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5,983 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in Georgia 14-point font.

I further certify that (1) any required privacy redactions have been made, 5th Cir. R. 25.2.13; and (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1.

Originally Submitted: April 27, 2023

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