Nos. 25A1207 and 25A1208

In the Supreme Court of the United States

DANCO LABORATORIES, LLC,

Applicant,

v.

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, ET AL.,

Respondents

GENBIOPRO, INC.,

Applicant,

v.

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, ET AL.,

Respondents

BRIEF OF ETHICS AND PUBLIC POLICY CENTER AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS AND IN OPPOSITION TO APPLICANTS' EMERGENCY APPLICATIONS TO VACATE STAY

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INTEREST OF *AMICUS CURIAE*[1]

The Ethics and Public Policy Center (EPPC), based in Washington, D.C., is a nonprofit research institution dedicated to defending American ideals and to applying the Judeo-Christian moral tradition to issues of law, culture, and public policy. EPPC works to promote a culture of life in law and policy and to defend the dignity of the human being from conception to natural death. In their briefings, the parties and proposed intervenors have cited a study and report prepared and published by EPPC. Through this brief, EPPC seeks to add background and further information for the Court's use.

SUMMARY OF ARGUMENT

EPPC scholars conducted the largest-known study of the health effects of mifepristone-induced abortions. Drawing on an all-payer insurance claims database that includes 865,727 mifepristone abortions from 2017 to 2023, EPPC's study identified a serious adverse event rate of 10.93 percent, which is more than 22 times higher than the summary figure in clinical trials reported on the drug label. This same database reveals that the serious adverse event rate was significantly higher when the FDA's in-person dispensing requirement was not in effect.

GenBioPro has criticized EPPC's study, but its attacks are meritless. Despite the safety concerns raised by EPPC's study, GenBioPro continues to claim in its Emergency Application to this Court that the FDA can set aside mifepristone's in-person dispensing requirement without risking women's health and even their lives.

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[1] No counsel for a party authored this brief in whole or in part, and no person other than *Amicus*, its members, or its counsel made a monetary contribution to fund the brief's preparation or submission.

ARGUMENT

I. EPPC's study demonstrates that mifepristone-induced abortion presents severe health risks that are more than 22 times higher than the FDA has acknowledged, and the FDA's elimination of the in-person dispensing requirement makes those risks even higher.

In April 2025, EPPC scholars Jamie Bryan Hall and Ryan T. Anderson released a study on the adverse health effects of mifepristone abortions. Hall & Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Public Policy Center (Apr. 28, 2025) (EPPC Study), https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/ (filed as ECF No. 1-13 (W.D. La.)). Their study is based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions across the United States from 2017 to 2023. This analysis reveals that within 45 days following a mifepristone abortion 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious adverse event (as classified by a team of doctors following an FDA definition and NIH methodology). See U.S. Food & Drug Admin., *What is a Serious Adverse Event?* (May 18, 2023), https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event; U.S. Dep't of Health & Human Servs., *Common Terminology Criteria for Adverse Events (CTCAE), v. 5.0* (Nov. 27, 2017), https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v5-5x7.pdf. That real-world rate of serious adverse events following mifepristone abortions is more than 22 times higher than the summary figure of "less than 0.5 percent" in

clinical trials reported on the drug label. See U.S. Food & Drug Admin., *Mifeprex (mifepristone) Tablets, for Oral Use: Full Prescribing Information* 6-8 (rev. Jan. 2023) (FDA Label), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf (filed as ECF No. 1-9 (W.D. La.)).

In March 2026, Hall and Anderson published a follow-up analysis showing that the data also establish that the rate of serious adverse events was significantly higher when the FDA's in-person dispensing requirement was not in effect. Hall & Anderson, *Fact Sheet: Data Reveals the FDA's Removal of In-Person Dispensing Requirement Increased the Dangers of the Abortion Pill*, Ethics & Public Policy Center (Mar. 10, 2026), https://eppc.org/publication/fact-sheet-data-reveals-the-fdas-removal-of-in-person-dispensing-requirement-increased-the-dangers-of-the-abortion-pill/. Their analysis indicates that a serious adverse event was between 1.53 and 2.33 times more likely with remote dispensing than with in-person dispensing. The disparity was even greater for ectopic pregnancy, a life-threatening condition that can be diagnosed by a physician (or other medical professional) only with an in-person visit. The data indicate that the provision of mifepristone to a woman with an ectopic pregnancy was between three and six times more likely with remote dispensing as compared to in-person dispensing. *Ibid.*

The FDA-approved drug label requires that ectopic pregnancy be ruled out as a condition prior to using mifepristone. FDA Label 1. This is because the use of mifepristone by a woman with an ectopic pregnancy poses extraordinary, heightened risk to her life and health. Yet the FDA, implementing the Biden

administration's determination to nullify state restrictions on abortion, revised the REMS to eliminate the in-person dispensing requirement. The certain and predictable effect is a sharp increase in the provision of mifepristone to women with ectopic pregnancies in Louisiana (and elsewhere), a sharp increase in emergency care for these women, and a sharp increase in the Medicaid costs that Louisiana incurs for emergency care for complications caused by out-of-state mifepristone.

II. GenBioPro's criticisms of EPPC's study lack merit.

GenBioPro disregards the results and implications of EPPC's study showing that mifepristone-induced abortion presents severe health risks that are more than 22 times higher than the FDA has acknowledged, and the FDA's elimination of the in-person dispensing requirement makes those risks even higher. In the proceedings below, GenBioPro offered several criticisms of EPPC's analysis. But none of those criticisms has merit. And in its Emergency Application to this Court GenBioPro continues to insist that the FDA can set aside mifepristone's in-person dispensing requirement without risking patient safety. GenBioPro Emerg. Appl. 29.

A. Peer review is unnecessary as EPPC's study was prepared by a data scientist, was reviewed by a panel of physicians, and is fully replicable.

GenBioPro first complains that EPPC's study is a "self-published (i.e., non-peer reviewed) report authored by two non-physician, non-medical scientists." GenBioPro's Mem. in Opp'n to Pls.' Mot. for Prelim. Relief at 19, ECF No. 54-4, *Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA (W.D. La. Feb. 3, 2026) (GenBioPro Br.). As Hall and Anderson explain, this objection is a red herring. EPPC Study 6. They have made their study fully replicable for anyone who wants to analyze the

insurance claims data. Hall is a data scientist with an advanced degree in statistics from Harvard University. Their study was internally reviewed and adjudicated by a panel of board-certified obstetricians and gynecologists, who carefully evaluated the clinical classifications, coding, and outcome assessments to ensure medical accuracy and consistency. *Ibid.*; Hall & Anderson, *Frequently Asked Questions About the Largest Study on Chemical Abortion*, Ethics & Public Policy Center (May 7, 2026), https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/ (EPPC Study FAQ) (response to question 7).

B. The disclosure of the study's confidential database is unnecessary, as critics remain free to show that other databases yield different results.

GenBioPro next objects that EPPC "does not even disclose certain of the databases upon which it relies." GenBioPro Br. at 19. EPPC has entered into a confidentiality agreement with the particular vendor of the database that it is using, in order to protect the vendor from political backlash. See EPPC Study 5. But substantially similar databases are widely available. Insurance-claims data is a cornerstone of public health and safety monitoring. The FDA and countless peer-reviewed journals rely on such data precisely because they reflect real-world outcomes across massive populations. GenBioPro and other critics have had more than a year to try to show that other databases generate different results. It is telling that they have failed to do so.

A simple analogy illustrates the point: Different baseball statisticians could compile a season's worth of data from daily box scores of all major league teams. If you were to look to one statistician's database to compare, say, how lefthanded and

righthanded batters fared against lefthanded relief pitchers, someone who wanted to second-guess your conclusion wouldn't demand to know which database you used but could simply use another database. If that second database generated the same conclusion, it's a strong sign that the first database is sound.

C. The study's definition of "serious adverse event" was developed by a team of doctors following an FDA definition and NIH methodology.

GenBioPro also claims that "EPPC's report adopts a medically unsupported, overbroad definition of 'adverse events' that is inconsistent with established standards." GenBioPro Br. at 19. It contends in particular that "counting abortion-related emergency room visits by themselves as serious adverse events is contrary to the FDCA and FDA guidance." GenBioPro Br., Ex. B at 17 (GenBioPro Citizen Petition).

But, as Hall and Anderson explain, they did not at all do what GenBioPro charges. See EPPC Study FAQ (response to question 1). They included in their study only emergency-room visits related to mifepristone-induced abortion, based on the diagnosis and procedure codes in the insurance records. Further, such visits were counted only if the woman was treated for a serious complication related to the abortion. The only serious complications included were those classified as such by a team of doctors following an FDA definition and NIH methodology. GenBioPro Br., Ex. B at 5. Hall and Anderson excluded from their analysis a full 72 percent of emergency-room visits that took place within 45 days of abortion because they either were not serious enough or were not related to the abortion. EPPC Study FAQ (response to question 1); see also Hall & Anderson, *Fact Sheet: Excluded Adverse*

Events in Real-World Study of Mifepristone, Ethics & Public Policy Center (May 6, 2026), https://eppc.org/publication/fact-sheet-excluded-adverse-events-in-real-world-study-of-mifepristone/.

D. The study's inclusion of ectopic pregnancies is medically and legally appropriate.

Perhaps most bizarrely, GenBioPro objects that EPPC's study "captures events like ectopic pregnancies, which are not caused by mifepristone." GenBioPro Br. at 19. But Hall and Anderson have never claimed mifepristone *causes* ectopic pregnancies. Their study corresponds with the FDA's own reporting, which lists ectopic pregnancy as a relevant category of adverse events for mifepristone. U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024* (Dec. 31, 2024), https://www.fda.gov/media/185245/download. As Hall and Anderson have explained, the first page of the FDA-approved drug label requires that ectopic pregnancy be ruled out before using mifepristone, precisely because the use of mifepristone by a woman with an ectopic pregnancy poses extraordinary, heightened risk to her health. EPPC Study FAQ (response to question 3). The study reports 3,062 cases of ectopic pregnancy. EPPC Study at 2, Fig. 1. These are cases in which a woman was diagnosed with this condition only after she had already taken mifepristone. This failure to properly diagnose the ectopic pregnancy before the abortion attempt placed each of these women's lives at risk. The incidence of this life-threatening risk was between three and six times more likely with remote dispensing than with in-person dispensing. EPPC Study FAQ (response to question 9).

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EPPC's study of the health effects of mifepristone-induced abortions establishes that the serious adverse event rate is more than 22 times higher than the summary figure in clinical trials reported on the drug label. The data also reveal that the rate of serious adverse events—and particularly life-threatening missed ectopic pregnancies—was significantly higher when the FDA's in-person dispensing requirement for mifepristone was not in effect. These empirical findings reinforce Louisiana's showing that the FDA's removal of the in-person dispensing requirement was arbitrary, disregarded material safety information, and inflicts concrete and irreparable harms on Louisiana and its citizens.

CONCLUSION

For the foregoing reasons, this Court should deny the Applicants' request to vacate the Fifth Circuit's stay.

Respectfully submitted,

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