No. 26-30203

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; RICHARD PAZDUR, IN HIS OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH, U S FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

v.

GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
CIVIL ACTION NO. 6:25-CV-01491

BRIEF OF AMICUS CURIAE NAACP LEGAL DEFENSE AND EDUCATIONAL FUND, INC. IN SUPPORT OF DEFENDANTS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies, pursuant to Federal Rule of Appellate Procedure 26.1 and 5th Circuit Rule 28.2.1, amicus curiae NAACP Legal Defense and Educational Fund, Inc. ("LDF") is a nonprofit, non-partisan corporation. LDF has no parent corporation, and no publicly held corporation holds ten percent of its stock. The undersigned counsel of record certifies that, in addition to the persons and entities listed in the parties' Certificates of Interested Persons, the following persons and entities as described in the fourth sentence of 5th Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that judges of this Court may evaluate possible disqualification or recusal.

Amicus Curiae

NAACP Legal Defense and Educational Fund, Inc.

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Dated: July 22, 2026

Respectfully submitted,

/s/ Pilar Whitaker
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INTEREST OF AMICUS CURIAE[1]

The NAACP Legal Defense and Educational Fund, Inc. ("LDF") is the nation's first and foremost civil rights law organization. Through litigation, advocacy, public education, and outreach, LDF strives to secure equal justice under the law for all Americans and to break down barriers that prevent Black people from realizing their basic civil and human rights.

For decades, LDF has pursued litigation to secure the economic rights of Black families and individuals. Litigation to ensure nondiscriminatory delivery of babies, as well as the adequacy of healthcare and hospital services available to Black communities, has been a long-standing LDF concern. *See, e.g.*, *Bryan v. Koch*, 627 F.2d 612 (2d Cir. 1980) (challenging the closing of Sydenham public hospital in Harlem under Title VI of the Civil Rights Act of 1964). LDF has also worked on behalf of Black individuals struggling with the burden of discriminatory and inadequate healthcare services and the resulting health crises.

Black and low-income people rely on the right to abortion care at higher rates than other groups, and face profound inequities in accessing essential healthcare as a result of a long history of systemic racism and discrimination. LDF has supported

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[1] Counsel for all parties have consented to the filing of this brief. Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), amicus curiae states that no party's counsel authored this brief either in whole or in part, and further, that no party or party's counsel, or person or entity other than amicus curiae, amicus curiae's members, and their counsel, contributed money intended to fund preparing or submitting this brief.

efforts to promote equal rights and access to reproductive healthcare, emphasizing the impact of restrictions on abortion access on Black women[2] and other pregnant people living in poverty. *See, e.g.*, Br. for LDF & Other Orgs. as Amici Curiae in Supp. of Pet'rs, *Rust v. Sullivan*, Nos. 89-1391 & 89-1392, 1990 WL 10012645 (U.S. July 27, 1990); Br. of Amici Curiae of LDF & Other Orgs. in Supp. of Planned Parenthood of Se. Pa., *Planned Parenthood of Se. Pa. v. Casey*, Nos. 91-744 & 91-902, 1992 WL 12006401 (U.S. Mar. 6, 1992); Brief of Amicus Curiae LDF in Supp. of Pet'rs, *Whole Woman's Health v. Jackson*, No. 21-463, 2021 WL 5029029 (U.S. Oct. 27, 2021); Br. for Amici Laws.' Comm. for C.R. Under L., Leadership Conf. for Civ. & Hum Rts. & 16 C.R. Orgs. in Supp. of Resp'ts, *Dobbs v. Jackson Women's Health Org.*, No. 19-1392, 2021 WL 4594026 (U.S. Sep. 20, 2021); Br. of Amicus Curiae LDF in Supp. of Pet'rs, *U.S. Food & Drug Admin. v. All. for Hippocratic Med.*, Nos. 23–235 and 23–236, 2024 WL 400033 (U.S. Jan. 30, 2024).

LDF has a strong interest in this case and in ensuring continued access to safe abortion care.

SUMMARY OF ARGUMENT

This Court should affirm the district court's decision to deny Louisiana's requested injunction and grant the Food and Drug Administration ("FDA") the

[2] Amicus curiae's use of "woman" or "women" is not meant to exclude transgender men and nonbinary people that may be able to become pregnant and need to seek abortion services.

opportunity to complete its ongoing review of the 2023 Mifepristone Risk Evaluation and Mitigation Strategies ("REMS") and reverse the denial of Danco and GenBioPro's motions to dismiss. The district court reached this conclusion based on a number of factors including "the length of time the 2023 REMS has [sic] been in effect, reliance interests on that scheme throughout the nation, the sweeping effect any remedy would have across states with differing abortion laws," and the FDA's ongoing review of the REMS. ROA.9118. It did not abuse its discretion in reaching this conclusion.

As shown below, Black pregnant people must navigate economic, medical, and legal burdens that serve as barriers to abortion care. These include diminished economic resources, elevated health risks, and violations of their privacy rights stemming from increased surveillance. The availability of telehealth significantly eases these burdens. The critical interests of pregnant people who have relied upon expanded access to mifepristone via telehealth must be considered by the FDA in its ongoing review of the REMS, particularly for Black pregnant people who face heightened barriers in access to reproductive healthcare. The district court properly denied Louisiana's request to bypass this agency process, and this Court should affirm denial of the requested injunction.

ARGUMENT

I. The FDA's Current Regulatory Framework Has Generated Substantial Reliance Interests That Would Be Severely Harmed by a Return to In-Person Mandates, Particularly for Black Pregnant People.

The district court properly exercised its discretion in denying Louisiana's requested relief. "A district court abuses its discretion if it bases its decision on an erroneous view of the law or on a clearly erroneous assessment of the evidence." *Langiano v. City of Fort Worth*, 131 F.4th 285, 290 (5th Cir. 2025) (internal citations omitted).

Here, the district court properly stayed this litigation to enable the FDA to complete its review of the 2023 REMS, including its assessment of the significant reliance interests at stake. Indeed, under the Administrative Procedure Act ("APA"), an agency that changes an existing policy must supply a reasoned explanation for the change, and that obligation is heightened where the prior policy has "engendered serious reliance interests that must be taken into account." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Critically, that reliance-interest assessment "must be undertaken by the agency in the first instance, subject to normal APA review." *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 591 U.S. 1, 31 (2020). Here, Black women are likely to experience the economic, medical, and legal consequences of a

reinstatement of the in-person dispensing requirement, discussed *infra*, more harshly than other groups.

Courts have repeatedly declined to sustain the withdrawal of agency action where, as here, serious reliance interests are at stake. *See, e.g.*, *Encino Motorcars*, 579 U.S. at 222–23 (finding an agency's unexplained policy reversal arbitrary where regulated parties faced substantial costs and potential liability if required to conform to the agency's new position); *Texas v. Biden*, 10 F.4th 538, 553 (5th Cir. 2021) (holding that potential "fiscal harm" resulting from a change in agency policy constituted a reliance interest that the agency was required to consider).

These principles counsel strongly in favor of granting the FDA the opportunity to review the 2023 REMS, which would require an assessment of how doing so would affect the populations who have come to depend most heavily on telehealth and mail-order access. Specifically, the FDA must consider the reliance interests of people who have turned to telehealth in the face of significant access issues, rising healthcare costs, economic pressures, and legitimate privacy concerns. Louisiana asks this Court to bypass that process altogether and strike down the FDA's decision to lift the in-person dispensing requirement outright, without the agency's own determination of these critical issues. Doing so is contrary to the Supreme Court's clear directive that "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency."

Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). This Court should decline Louisiana's invitation and instead grant the FDA the time it has requested to conduct, in the first instance, the reliance-interest assessment that *Encino Motorcars* and *Regents* require.

A. Black Women Bear the Most Severe Impacts of Abortion Restrictions, Compounding Longstanding Economic and Societal Inequities.

Research has shown that restricting access to abortion care exacerbates racial and economic disparities faced by Black women in the United States. The denial of abortion access strongly correlates with lasting economic setbacks, including greater likelihood of poverty and increased risk of intimate partner violence.[3] One study found that women who were denied abortion access, and went on to give birth, experienced an increase in household poverty lasting at least four years relative to those who received an abortion.[4] In addition, such women are more likely to be unable to cover basic living expenses, like food, housing, and transportation years after being denied an abortion.[5] Women who were unable to access abortion care

[3] Zara Abrams, *Abortion Bans Cause Outsized Harms for People of Color*, Am. Psych. Ass'n (June 1, 2023), https://www.apa.org/monitor/2023/06/abortion-bans-harm-people-of-color.
[4] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions*, 108 Am. J. Pub. Health 407–13, https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304247.
[5] *Id.*

were thus more likely to experience poverty during the first years of their child's life, a time that is critical to the child's development.

Because nearly 60% of people who have abortions are already parents,[6] limiting access to abortion care causes increased financial burdens on Black families which can exacerbate the racial wealth gap.[7] For Black mothers, abortion access can be a decision made in service of the children they are already raising, preserving resources, stability, and parental capacity.[8]

When compelled to continue pregnancies against their will, women also face the risks of pregnancy and childbirth, which are statistically more dangerous for Black women.[9] Black women face disproportionately high maternal mortality rates, more than three times that of white women in the United States,[10] and these racial

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[6] Katherin Kortsmit et al., *Abortion Surveillance — United States, 2019*, 70 MMWR Surveillance Summaries No. 9, 1–29 (Nov. 26, 2021), https://www.cdc.gov/mmwr/volumes/70/ss/ss7009a1.htm#T8_down (59.8% of people who have an abortion have previously given live birth); Guttmacher Inst., *Abortion in the United States* (Mar. 2026), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states (approximately 55% of people who obtained an abortion had previously had at least one birth).

[7] Rakesh Kochhar et al., *Wealth Gaps Across Racial and Ethnic Groups*, Pew Rsch. Ctr. (Dec. 4, 2023), https://www.pewresearch.org/race-and-ethnicity/2023/12/04/wealth-gaps-across-racial-and-ethnic-groups/ (The wealth gap between white and Black households increased between 2019 and 2021. The typical white household had $250,400 in 2021, compared to $27,100 for Black households).

[8] *See* Foster et al., *supra* note 4 ("At the time of seeking an abortion, more than a quarter of all women in the study were living in a household as the only adult with children, and this increased significantly for women who were denied an abortion, indicating that the burden of raising a child often falls to women alone rather than to couples or an extended family.")

[9] Latoya Hill et al., *Racial Disparities in Maternal and Infant Health: Current Status and Key Issues*, KFF (Dec. 3, 2025), https://www.kff.org/racial-equity-and-health-policy/racial-disparities-in-maternal-and-infant-health-current-status-and-key-issues/.

[10] *Id.*

disparities persist regardless of Black women's social or economic status.[11] Black women are also more likely to experience race-based discrimination in their pregnancy-related care. For example, research demonstrates that anti-Black racial biases, specifically in pain perception, are associated with biased pain treatment and management, which result in negative maternal health outcomes for Black birthing people.[12]

Conversely, the benefits of increased access to reproductive healthcare are significant for Black women and reach beyond purely medical benefits. For example, Black women in places with greater access to abortion care are likely to see a near 7% increase in employment opportunities.[13] While abortion access increased women's participation in the workforce overall, the effects were particularly felt by Black women, whose labor market participation increased by 6.9 percentage points with increased abortion access.[14] Moreover, research indicates that

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[11] Emily E. Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths – United States, 2007-2016*, 68 Morbidity & Mortality Wkly. Rep. 762–65 (Sep. 6, 2019), https://pubmed.ncbi.nlm.nih.gov/31487273/.

[12] Nia Josiah et al., *Implicit Bias, Neuroscience and Reproductive Health amid Increasing Maternal Mortality Rates Among Black Birthing Women*, 10 Nursing Open 5780 (June 16, 2023), https://doi.org/10.1002/nop2.1759.

[13] Anna Bernstein & Kelly Jones, *The Economic Effects of Abortion Access: A Review of the Evidence*, Inst. for Women's Pol'y Rsch. (July 18, 2019), https://iwpr.org/articles/the-economic-effects-of-abortion-access-a-review-of-the-evidence/.

[14] *Id.*

eliminating barriers to abortion access would yield significant economic benefits for Black women specifically, with earnings projected to increase by as much as 9.6%.[15]

Taken together, comprehensive reproductive healthcare access for Black women is not a single-issue concern, but a thread running through maternal health equity, economic justice, and the broader right to self-determination. As shown below, restricting access to mifepristone would only add to the challenges Black people already face in accessing equitable, quality, and comprehensive healthcare, supporting existing families, and achieving economic security.

B. Federal Policy Changes Have Deepened an Already Existing Affordability Gap for Black Women.

1. Black Women Disproportionately Have Fewer Resources and Access to Reproductive Care.

Telehealth is significantly more affordable than in-person abortion services, *see infra* Section I.C.1., and is thus often the only realistic option for people who lack the financial cushion to absorb the cost of in-person care. This is especially true for women of color, who are less likely than white women to have enough cash on hand to cover an emergency expense, like abortion care.[16] Moreover, Black women

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[15] Melissa Mahoney, *State-Level Abortion Restrictions Cost the US Economy $133 Billion*, Inst. for Women's Pol'y Rsch. (June 23, 2025), https://iwpr.org/articles/state-level-abortion-restrictions-cost-the-us-economy-133-billion/.

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

face higher uninsurance rates than other groups, and this has only grown in recent years. In 2023, 9.8% of Black women ages 19 to 64 were uninsured.[17] In 2024, 10.3% of Black women ages 19 to 64 were uninsured, compared with 6.6% of white, non-Hispanic women in the same age group.[18] Lack of insurance access or restrictions on private health insurance services cause many people seeking abortion care to pay out-of-pocket, potentially forcing them to forego payment of bills and other necessary expenses in order to afford abortion care.[19] Moreover, studies demonstrate that the out-of-pocket costs for abortion care, coupled with travel expenses, pose significant barriers to accessing abortion care.[20]

Even among women who retain employer-sponsored coverage, the majority of covered workers now carry deductibles of $1,886 or more for single coverage,[21] and Black and Hispanic families have consistently paid a higher share of their earnings toward health insurance premiums than white families.[22] Thus, a lack of

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[17] Steven Ruggles et al., *IPUMS USA: Version 16.0* [dataset], IPUMS Ctr. for Data Integration (2025), https://doi.org/10.18128/D010.V16.0.

[18] Nat'l Women's L. Ctr., *Health Insurance Coverage by State* (2025), https://nwlc.org/resource/health-insurance-coverage-by-state/.

[19] Rachel K. Jones et al., *At What Cost? Payment for Abortion Care by U.S. Women*, 23 Women's Health Issues e173–78 (2013), https://www.whijournal.com/article/S1049-3867(13)00022-4/fulltext.

[20] Tracy A. Weitz, *Making Sense of the Economics of Abortion in the United States*, 56 Persps. on Sexual & Reprod. Health 199 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11606007/.

[21] Gary Claxton et al., *2025 Employer Health Benefits Survey*, KFF (Oct. 2025), https://www.kff.org/health-costs/2025-employer-health-benefits-survey/.

[22] Kurt Hager et al., *Employer-Sponsored Health Insurance Premium Cost Growth and Its Association with Earnings Inequality Among US Families*, 7 JAMA Network Open e2351644 (2024), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10792464/.

health insurance alone does not account for the full economic burden of accessing reproductive healthcare. Whether an individual has private or public insurance, most people need to come up with the out-of-pocket costs for abortion care. This is especially true for people on Medicaid because the Hyde Amendment prohibits federal funding of most abortions, and even those with private insurance may find themselves without coverage, as many states restrict private insurers from covering abortion services.[23] In addition to the cost of abortion care, pregnant people also need to cover the other associated costs, such as travel, lost wages, and childcare expenses.[24]

2. Recent Federal Actions Have Worsened Economic Conditions and Intensified Black Women's Reliance Upon Receipt of Mifepristone via Mail or Pharmacy.

Since the FDA lifted the in-person dispensing requirement for mifepristone, pregnant people's reliance interest in access to mifepristone via mail has grown. This is particularly so for Black women, for whom existing disparities in access to health insurance and increased economic pressures make in-person clinic visits more unaffordable. Increasing unemployment rates for Black women, and resulting decreased access to employer-sponsored insurance, have exacerbated these long-

[23] Ushma Upadhyay et al., *Trends in Self-Pay Charges and Insurance Acceptance for Abortion in The United States, 2017–20*, 41 Health Affs. 507 (Apr. 4, 2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01528.
[24] *Id*.

standing racial disparities in health insurance access. Moreover, recent federal policy changes have reduced access to both insurance and reproductive healthcare clinics, further adding to the economic necessity of affordable telehealth.

The loss of employer-sponsored healthcare, and/or less disposable income, generally, may render in-person reproductive care cost-prohibitive. Because employer-sponsored insurance is the primary source of health coverage for women, covering roughly 53% of Black women ages 19 to 64, the loss of a job frequently means the loss of that coverage entirely.[25]

Black women, in fact, suffered the largest employment loss of any group of women in 2025.[26] These losses were largely driven by the so-called Department of Government Efficiency ("DOGE")—a Trump Administration initiative that disparately impacted Black women, reducing their federal employment by 25%.[27] There were no statistically significant decreases in employment for any other demographic group.[28] In 2025, Black women's employment-to-population ratio fell

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[25] KFF, *Women's Health Insurance Coverage* (June 9, 2026), https://www.kff.org/womens-health-policy/womens-health-insurance-coverage/; Usha Ranji et al., *Health Policy 101: Health Policy Issues in Women's Health*, KFF (Oct. 8, 2025), https://www.kff.org/womens-health-policy/health-policy-101-health-policy-issues-in-womens-health/.

[26] Valerie Wilson, *Black Women Suffered Large Employment Losses in 2025—Particularly Among College Graduates and Public-Sector Workers*, Econ. Pol'y Inst. (Feb. 10, 2026), https://www.epi.org/blog/black-women-suffered-large-employment-losses-in-2025-particularly-among-college-graduates-and-public-sector-workers/.

[27] Brandon Enriquez, *When (Government) Work Disappears: Disparate Employment Effects of DOGE in the Short-Run*, 261 Econ. Letters 112793 (Mar. 2026), https://www.sciencedirect.com/science/article/abs/pii/S0165176525006305.

[28] *Id*.

by 1.4 percentage points to 55.7%, one of the sharpest one-year declines in the last 25 years, and more than double the decline experienced by Black men or white women.[29] That decline was driven almost entirely by a loss of 155,656 public-sector jobs, including 95,371 federal government jobs.[30] Those losses were only partially offset by private-sector gains of 76,419, and fell hardest on college-educated Black women, whose employment-to-population ratio dropped 3.5 percentage points, far more than any other college-educated group.[31]

Recent federal law and policy changes have also exacerbated disparities in healthcare access for Black people. The so-called One Big Beautiful Bill Act of 2025 (Public Law 119-21) ("OBBBA"), signed into law on July 4, 2025, included significant funding cuts and policy changes to Medicaid and health insurance marketplaces, among other healthcare related changes, which will worsen patient access to care.[32] These changes include new administrative requirements and conditions on Medicaid eligibility, including work requirements; restrictions on states' ability to use provider taxes to finance their Medicaid programs; and cutting

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[29] Wilson, *supra* note 26.
[30] *Id.*
[31] *Id*.
[32] Am. Med. Ass'n, *Changes to Medicaid, the ACA and Other Key Provisions of the One Big Beautiful Bill Act* (June 4, 2026), https://www.ama-assn.org/health-care-advocacy/federal-advocacy/changes-medicaid-aca-and-other-key-provisions-one-big.

Medicaid by $900 billion over 10 years.[33] The Congressional Budget Office estimated that all together, the OBBBA changes will result in 16 million more uninsured people by the year 2034 than would otherwise be the case.[34] These cuts will have significant detrimental effects on access to reproductive health services for low-income people.

Changes under both the OBBBA and to the Title X federal family planning program have also severely restricted funding for reproductive healthcare clinics, which has contributed to further clinic closures. In 2025, Title X family planning grants were withheld from a number of service providers, including 144 Planned Parenthood sites in 20 states.[35] The OBBBA then established a one-year prohibition on federal funding for Medicaid reimbursements to Planned Parenthood clinics for services provided to Medicaid enrollees.[36] While Planned Parenthood, states, and other healthcare providers like Maine Family Planning, have challenged these

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[33] *Id.*; Adam Sonfield & Amy Friedrich-Karnik, *New Federal Medicaid Cuts Will Devastate Coverage for Reproductive Health Care*, Guttmacher Inst. (Nov. 10, 2025), https://www.guttmacher.org/2025/11/new-federal-medicaid-cuts-will-devastate-coverage-reproductive-health-care.

[34] Jared Ortaliza et al., *How Will the One Big Beautiful Bill Act Affect the ACA, Medicaid, and the Uninsured Rate?*, KFF (June 18, 2025), https://www.kff.org/affordable-care-act/how-will-the-2025-budget-reconciliation-affect-the-aca-medicaid-and-the-uninsured-rate/.

[35] Brittni Frederiksen et al., *An Update on Medicaid, Title X and Planned Parenthood*, KFF (June 8, 2026), https://www.kff.org/womens-health-policy/an-update-on-medicaid-title-x-and-planned-parenthood/.

[36] *Id.*

actions in court,[37] these law and policy changes have already reduced access to reproductive healthcare. For example, between January 2025 and June 2026, 57 Planned Parenthood clinics across 20 states either closed or consolidated with other sites.[38]

Additionally, the enhanced tax credits that helped reduce the cost of health insurance plans under the Affordable Care Act ("ACA") expired in January 2026.[39] The loss of enhanced tax credits, which provided access to zero-premium coverage for those with incomes between 100% and 150% of the federal poverty line, may be particularly harmful for Black and Hispanic women who disproportionately live in states that did not expand Medicaid.[40] For these groups, the enhanced tax credits provided an affordable means to insurance coverage. A recent report indicated that there are approximately 3 million fewer people with ACA insurance plans as of February 2026, compared to the same time last year, likely because of the loss of enhanced tax credits.[41]

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[37] *Planned Parenthood Fed'n of Am. v. Kennedy*, No. 1:25-cv-111913 (D. Mass. 2025); *Fam. Plan. Ass'n of Me. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:25-cv-00364 (D. Me. 2025); *California v. U.S. Dep't of Health & Hum. Servs.*, No. 1:25-cv-12118 (D. Mass 2025).
[38] Frederiksen et al., *supra* note 35.
[39] Ali Swenson, *Millions Drop Obamacare Health Coverage After Subsidies Expire and Costs Rise*, Associated Press (June 27, 2026), https://apnews.com/article/affordable-care-act-obamacare-health-subsidies-premiums-3dc9a0cd249a7622ce31e8559bfff729.
[40] Nat'l Women's L. Ctr., *The Trump Republican New Tax and Budget Law Is Devastating for Women's Health, Including Reproductive Health* (Aug. 28, 2025), https://nwlc.org/resource/the-trump-republican-new-tax-and-budget-law-is-devastating-for-womens-health-including-reproductive-health/.
[41] Swenson, *supra* note 39.

Layered onto Black women's already high rates of uninsurance, the loss of employer-sponsored coverage and recent federal changes restricting access to reproductive healthcare clinics leave many Black women facing the full, unsubsidized cost of in-person reproductive care. Against that backdrop, the substantially lower cost of a telehealth medication abortion is not just a matter of convenience or preference; for many, it is the only economically accessible option.

C. Telehealth Mitigates Economic Burdens and the Risks of In-Person Care.

In the face of economic precariousness and weakened healthcare infrastructure, reliance on telehealth is documented, not speculative. Indeed, telehealth has become one of the most significant mechanisms of healthcare,[42] including abortion access, in the United States: in Quarter 2 of 2025, it accounted for roughly 27% of abortions across the United States, more than a fivefold increase from just three years earlier, when telehealth represented only 5% of all abortions in Quarter 2 of 2022.[43] In states without total bans, the proportion of abortion care provided through online-only clinics rose from 10% in 2023 to 15% in 2024, an

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[42] Tanya Albert Henry, *New Data Details How Telehealth Use Varies by Physician Specialty*, Am. Med. Ass'n (Dec. 8, 2025), https://www.ama-assn.org/practice-management/digital-health/new-data-details-how-telehealth-use-varies-physician-specialty (telehealth has nearly tripled since before COVID-19 pandemic).

[43] Soc'y of Fam. Plan., *#WeCount Report 10: April 2022 to June 2025* (Dec. 9, 2025), https://societyfp.org/wp-content/uploads/2025/12/WeCount-Report-10-June-2025-data.pdf.

increase of roughly 50,000 instances of care.[44] From January to June 2025, the share of abortions provided by telehealth in states that permit it ranged from a low of 8% in the District of Columbia to a high of 39% in Delaware,[45] reflecting how heavily some populations now depend on this method of care.

This growth in telehealth mirrors a broader, sustained shift toward medication abortion as the predominant method of abortion care generally: medication abortion use rose from 39% of all abortions in 2017 to 53% of all abortions in 2020,[46] making 2020 the first year in which medication abortion became the predominant method of abortion care in the United States, and by 2023 it accounted for 63% of all abortions nationally.[47]

1. Telehealth Reduces Cost Barriers to Accessing Care.

The need for access to telehealth and medication abortion is driven, in part, by the need to reduce the costs of accessing quality abortion care, which includes

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[44] Isaac Maddow-Zimet & Kimya Forouzan, *Stability in the Number of Abortions in US States Without Total Bans Masks Major Shifts in Access*, Guttmacher Inst. (Apr. 2025), https://www.guttmacher.org/report/stability-number-abortions-2023-2024-us-states-without-total-bans-masks-major-shifts-access.

[45] Soc'y of Fam. Plan, *supra* note 43.

[46] Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst., (Feb. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions (39% in 2017; 53% in 2020).

[47] Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Guttmacher Inst. (Mar. 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

the cost of the care itself as well as ancillary costs, including, *inter alia*, the time and expenses to travel to an in-person clinic. *See also supra* Section I.B.1. The median price of a medication abortion obtained through a brick-and-mortar clinic increased from $580 in 2021 to $600 in 2023, while the median price of a medication abortion obtained through a virtual clinic decreased from $239 in 2021 to $150 in 2023—75% less than the cost of in-person care.[48] These are just median prices—the actual costs associated with abortion care may vary significantly across states, as do the associated costs for each patient for travel, childcare, or time-off work. The expansion of lower-cost telehealth options is one way to reduce these barriers to quality abortion care for many pregnant people.

Access to medication abortion via mail and pharmacy dispensing also reduces the expenses associated with travel to in-person clinics. This is crucial when clinic closures have necessitated longer travel distances in the wake of *Dobbs*. Between 2020 and 2025, 54 brick-and-mortar abortion clinics closed, a figure that does not account for closures of other reproductive health center clinics that do not provide abortion.[49] These closures are not without consequence. Black women have

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[48] Karen Diep et al., *Abortion Trends Before and After Dobbs*, KFF (Jan. 7, 2026), https://www.kff.org/womens-health-policy/abortion-trends-before-and-after-dobbs/.

[49] Deidre McPhillips, *Abortion Clinics Are Closing, Even in States that Have Become Key Access Points*, CNN (Feb. 18, 2026), https://www.cnn.com/2026/02/18/health/abortion-clinic-closures-guttmacher; Rachel K. Jones et al., *Number of Brick-and-Mortar Abortion Clinics Declined Slightly Between 2024 and 2025*, Guttmacher Inst. (Feb. 2026), https://www.guttmacher.org/report/abortion-clinics-united-states-2024-2025.

historically faced, and continue to face, wage disparities, and are disproportionately represented in lower-paying jobs where they are less likely to have benefits such as paid sick days, which would allow them to travel for abortion care.[50] As Justice Breyer explained in the plurality opinion in *June Medical Services L.L.C. v. Russo*: "[B]oth experts and laypersons testified that the burdens of this increased travel would fall disproportionately on poor women, who are least able to absorb them." 591 U.S. 299, 302 (2020) (dictum).

All told, in-person requirements introduce unnecessary delay in obtaining abortion care. Black women already experience more delay in obtaining abortion care than women of other races. In the Centers for Disease Control and Prevention's most recent surveillance data, 77.1% of abortions obtained by Black women occurred at or before 9 weeks gestation, compared with 80.5% for white women and 81.8% for Hispanic women; Black women were also more likely than white women to obtain care after the first trimester.[51] Such delay in accessing care may deprive some people of access to medication abortion altogether.

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[50] Jasmine Tucker, *Black Women Have Been Undervalued and Underpaid for Far Too Long*, Nat'l Women's L. Ctr. (June 2024), https://nwlc.org/wp-content/uploads/2024/07/BWEPD-2024.6.28v4.pdf.

[51] Stephanie Ramer et al., *Abortion Surveillance — United States 2022*, 73 MMWR Surveillance Summaries No. 7, at 1 (Nov. 2024), https://www.cdc.gov/mmwr/volumes/73/ss/ss7307a1.htm.

2. In-Person Mandates Compound the Risks of Discriminatory Surveillance for Black Women.

For many Black patients, seeking in-person pregnancy-related care can quickly become an encounter with a healthcare system that functions as a gateway to the criminal legal system.[52] A comprehensive study of cases from 1973 to 2005 found that hospitals and medical professionals frequently disclosed confidential patient information and facilitated bedside interrogations by police, often relating to pregnancy outcomes not within control of the patient.[53] According to the study, healthcare providers were also more likely to report Black patients to police than white patients: among cases in which both race and reporting mechanism were

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[52] *See* Wendy A. Bach & Madalyn K. Wasilczuk, *Pregnancy as a Crime: A Preliminary Report on the First Year After Dobbs* 10–11, Pregnancy Just. (2024), https://www.pregnancyjusticeus.org/wp-content/uploads/2024/09/Pregnancy-as-a-Crime.pdf (tracing the continuity of criminal law's regulation of reproduction from slavery-era sexual assault, forced pregnancy, obstetric violence, and coerced sterilization through drug-war-era child abuse prosecutions and contemporary pregnancy-related enforcement practices that have consistently concentrated punishment on low-income women, particularly Black women and other women of color); Cynthia Conti-Cook, *Surveilling the Digital Abortion Diary*, 50 U. Balt. L. Rev. 1, 29–30 (2020) (tracing how slavery-era regimes of forced "breeding," sexual violence, and punishment of reproductive resistance constructed Black women's childbearing as a site of economic control and coercive regulation that prefigures contemporary surveillance and criminal enforcement of pregnancy outcomes); Sandhya Dirks, *Criminalization of Pregnancy Has Already Been Happening to the Poor and Women of Color*, NPR (Aug. 3, 2022), https://www.npr.org/2022/08/03/1114181472/criminalization-of-pregnancy-has-already-been-happening-to-the-poor-and-women-of (explaining that Black women have long been disproportionately targeted for pregnancy-related policing and criminalization, regardless of their pregnancy outcomes).

[53] Lynn M. Paltrow & Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973–2005: Implications for Women's Legal Status and Public Health Open* Access, 38 J. Health Pol., Pol'y, & L. 299, 310–13 (2013) (finding that Black women were nearly twice as likely as white women to enter the criminal legal system through reports by healthcare providers and were fourteen percentage points more likely to be charged with felonies), https://tinyurl.com/e7apksmx.

known, nearly half (48%) of Black women were reported by healthcare providers, compared to less than one-third (27%) of white women.[54] The risk has only grown. In the first year after *Dobbs*, at least 210 pregnancy-related prosecutions were documented, including in states where abortion remains legal—the highest annual total on record.[55] In more than half of those cases, information was obtained or disclosed in a medical setting.[56] Healthcare providers and institutions have thus become significant, and increasingly common, agents of state surveillance, investigation, and criminal enforcement against pregnant patients.

Telehealth can reduce the number of institutional contact points involved in a person's care, providing an additional way to protect the right to privacy regardless of a patient's state of residence or that state's abortion laws. That benefit has taken on a new urgency, however, as Black patients can no longer rely on the legal guardrails that once offered some privacy protection for pregnancy-related medical treatment. In the wake of *Dobbs*, the Department of Health and Human Services ("HHS") issued a rule that restricted the use or disclosure of protected health information to facilitate an investigation, prosecution, or impose liability for seeking

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[54] *Id*. at 326–31.
[55] Bach & Wasilczuk, supra note 52, at 2.
[56] *Id*.; *see also* Laura Huss et al., *Self-Care, Criminalized: August 2022 Preliminary Findings*, IfWhenHow (2022), https://ifwhenhow.org/wp-content/uploads/2023/06/22_08_SMA-Criminalization-Research-Preliminary-Release-Findings-Brief_FINAL.pdf (finding that 45% of cases investigated or prosecuted for suspicion of self-managed abortion were triggered by care providers or social workers).

reproductive healthcare that was lawfully provided.[57] In June 2025, a district court held that HHS's 2024 HIPAA Reproductive Health Privacy Rule violated the APA, vacating it nationwide.[58] At the same time, the federal government has signaled a retreat from enforcing long-standing protections for pregnancy-related health providers by reducing safeguards against harassment and intimidation at reproductive health facilities.[59]

Ultimately, as state and federal privacy protections recede and enforcement mechanisms weaken, Black patients face heightened risks that seeking reproductive healthcare will expose them to unjust surveillance, harassment, and criminal investigation. And, for Black communities already burdened by disproportionate

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[57] HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32976 (Apr. 26, 2024), *vacated*, *Purl v. U.S. Dep't of Health & Hum. Servs.*, 787 F. Supp. 3d 284 (N.D. Tex. 2025).

[58] *Purl v. U.S. Dep't of Health & Hum. Servs.*, 787 F. Supp. 3d 284, 331 (N.D. Tex. 2025).

[59] *See* Clemency Grants by President Donald J. Trump (2025-Present), Off. of the Pardon Att'y, U.S. Dep't of Just., https://www.justice.gov/pardon/clemency-grants-president-donald-j-trump-2025-present (last visited July 7, 2026) (pardoning 23 individuals convicted of FACE Act violations for offenses ranging from physically blocking patients from accessing their doctors, breaking into clinics, stealing fetal tissue, and harassing pregnant patients); Letter from Chief of Staff to the Att'y Gen. to Kathleen Wolfe, Supervisory Official of the C.R. Div. (Jan. 24, 2025), https://www.justice.gov/media/1386461/dl?inline (instructing that future abortion-related FACE Act prosecutions and civil actions may proceed only in extraordinary circumstances or cases involving significant aggravating factors, such as death, serious bodily harm, or serious property damage, and requiring authorization from the Assistant Attorney General for the Civil Rights Division before initiating new actions). *See also* Fatima Hussein et al., *Justice Department Announces a $1.7 Billion 'Anti-Weaponization' Fund to Compensate Trump Allies*, PBS (May 18, 2026), https://www.pbs.org/newshour/politics/justice-department-announces-a-1-7-billion-anti-weaponization-fund-fund-to-compensate-trump-allies (discussing announcement of a $1.7 billion fund for individuals claiming politically motivated prosecutions by prior administrations and identifying individuals convicted of violating the FACE Act—including anti-abortion extremists pardoned by President Trump—as potential recipients of unrestricted payments).

policing, surveillance, and intervention by child protective services, this climate only deepens longstanding distrust of the healthcare system—a distrust rooted in a history of reproductive exploitation,[60] nonconsensual sterilization,[61] discriminatory medical treatment,[62] and persistent racial disparities in maternal health outcomes.[63]

Taken together, these economic, medical, and legal burdens fall disproportionately on Black women, and the fact they have come to rely on telehealth to mitigate them is precisely the kind of serious reliance interest that the APA requires be assessed before unwinding a policy. In light of these stakes, the Court should grant the FDA the time it has requested to conduct, in the first instance, the reliance-interest assessment that *Encino Motorcars* and *Regents* require.

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[60] *See* Toluwani E. Adekunle, *Reproductive Coercion, Medical Mistrust, and Black Women's Health from the Antebellum Period to the 21st Century*, 24 Int'l J. Equity Health 1, 2–4 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12587519/ (discussing enslaved Black women's forced reproduction and subjection to invasive gynecological experimentation and medical practices that extracted knowledge from their bodies while denying their autonomy and consent).

[61] *Id*. at 4.

[62] *See generally* Elizabeth Dayo et al., *Health in Colour: Black Women, Racism, and Maternal Health*, 17 Lancet Reg'l Health Am. 1 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9735204/ (discussing how medical racism—from biased pain assessments and discriminatory treatment to obstetric mistreatment—impacts Black women's healthcare experiences).

[63] *Id*. at 1 ("Black mothers in the United States (U.S.) die at three-to-four times the rate of [w]hite mothers," and even when controlling for educational and socioeconomic factors, a "college-educated Black woman is three times more likely to experience severe maternal complications than a [w]hite woman without a high school education.").

CONCLUSION

For these reasons, this Court should affirm the district court's denial of Louisiana's request to vacate the 2023 REMS and reverse the denial of Danco and GenBioPro's motions to dismiss.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify on this 22nd day of July, 2026, that I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF filing system. I further certify that all counsel of record are registered CM/ECF users and that all service will be accomplished by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), I certify that this brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5), as it contains 5,697 words. This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font, and all footnotes are in 12-point Times New Roman font.

Dated: July 22, 2026

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