No. 26-30203

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH, PLAINTIFFS-APPELLANTS/CROSS-APPELLEES,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, U.S. FOOD & 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, INC., 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 NO. 25-CV-1491, HON. DAVID C. JOSEPH

BRIEF OF THE NATIONAL INSTITUTE OF FAMILY AND LIFE ADVOCATES AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS/CROSS-APPELLEES AND FOR REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

NIFLA is a charitable entity with a 501(c)(3) exemption letter from the IRS and is incorporated in Virginia. There are no shareholders, and it is governed by a board of Directors under state law.

Allan E. Parker is the Lead Counsel for *Amicus Curiae.*

R. Clayton Trotter is Counsel for *Amicus Curiae.*

Mary J. Browning is Counsel for *Amicus Curiae*.

Date: June 22, 2026

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INTEREST OF *AMICUS*

The National Institute of Family and Life Advocates (NIFLA) is a national legal network for pro-life pregnancy resource centers and medical clinics. Its purpose is to provide legal training, consultation, and education to its membership of pro-life centers, which number approximately 1,800. Of these members, over 1,300 operate as medical clinics providing medical services, such as ultrasound confirmation of pregnancy to mothers contemplating abortion, and STI testing and treatment. It is the mission of NIFLA and its members to provide life-saving alternatives to abortion for women considering abortion through the provision of life-affirming services. NIFLA also helps prevent women from being coerced, forced or unduly pressured into having an abortion. The legal status of abortion impacts the direction and programs offered in by NIFLA and its members. Thus, NIFLA has a unique interest and perspective helpful to this Court in protecting and helping women.[1]

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[1] Pursuant to FRAP 29(a)(2), counsel for Amici certify that all parties have consented to the filing of this brief. Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for *amicus curiae* states that: 1. No party's counsel authored this brief in whole or in part; 2. No party or party's counsel contributed money intended to fund preparing or submitting this brief; and 3. No person—other than *amicus curiae*, its members, or its counsel—contributed money intended to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

The Food and Drug Administration (FDA) has substantial but not unlimited authority. Congress authorized the FDA to protect public health by ensuring that drugs and medicines are "safe" and effective for humans. 21 U.S.C. §§ 355, 393. That statutory framework clearly does not authorize the FDA to approve drugs whose intended effect is to terminate human life at any stage, before or after birth.

Supreme Court and other federal appellate precedent recognize that abortion is categorically different from ordinary medical treatment because it involves the destruction of developing human life and seriously injures women's health. *See, Dobbs v. Jackson Women's Health Org.,* 597 U.S. 215 (2022); *Gonzales v. Carhart*, 550 U.S. 124 at 159 (2007) (". . .Some women come to regret aborting the infant life they once created and sustained . . ." "severe depression and loss of esteem can follow"), *See also*, *Planned Parenthood of SE. Pa. v. Casey*, 505 U.S. 833, 846, 882 (1992) where the Court recognized that abortion and can cause *"devastating psychological consequences . . ." See, Rounds*, at 735 (8th

Cir. 2008) (en banc) upholding a statutory definition that "abortion will terminate the life of a whole, separate, unique, living human being."

The historical record and the record below confirm the same point. As *Dobbs* explains, the federal government and the States long criminalized abortion, including abortion procured by "drugs, medicines, poisons, and any other noxious substances" intended to cause a woman to miscarry her child. *Dobbs*, at 302, 303; *See,* fn. 5, *infra.*

The legal history defeats any presumption that Congress somehow silently authorized the FDA to approve abortion-inducing drugs which kill "infant life," per *Gonzales*, 550 U.S. 124 at 150 (2007), under a legislative command to approve only "safe and effective" drugs. To uphold this erroneous interpretive aberration which occurred under "*Roe*" would perpetuate "the distortion of many important … legal doctrines" as cautioned against by the Court in Dobbs. *Dobbs* at 220. The Court explicitly stated that *Roe* and *Casey* had a "disruptive effect on other areas of the law." *Id.* at 268.

Finally, this case is not a setting for normal agency deference. Under *Dobbs* and *West Virginia v. EPA*, 597 U.S. 697 (2022), agencies must point to clear congressional authorization before asserting power

over questions of deep economic, political, and moral significance. Abortion is such a question. The FDA cannot continue to do so here even though it did so in the past before *Dobbs* and *West Virginia v. EPA, supra.* The Constitution and the Comstock Act also forbid approval of drugs that intentionally kill human life in the womb.

ARGUMENT

I. The FDA Lacks Authority to Approve Drugs or Medicines Intended to End Human Life. Instead, Approved Drugs Must Be "Safe" for Humans, Including Mothers and Their Children

The Federal Food, Drug, and Cosmetic Act ("FDCA") permits approval of a new drug only when the application contains "full reports of investigations" showing "whether such drug is "safe" for use and whether such drug is 'effective' in use." 21 U.S.C. § 355(b)(1)(A)(i). The FDA's mission is to "protect the public health by ensuring that . . . human . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). The FDA mandate is to execute the stated purpose for the benefit of all humans, including pregnant women and their children in the womb. The FDA has required or approved multitudes of applications for drugs and medicine which are clearly labeled – Do Not Take This Medicine If You Are Pregnant.

The FDA has always been bound to protect pregnant mothers and their children in the womb as all humans deserve legal protection. All human life, including "infant life," in the womb per *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) is entitled to protection under the FDCA, the Comstock Act, and the U.S. Constitution.

That FDCA framework presupposes that a "drug" is intended to treat disease, prevent illness, alleviate symptoms, or otherwise promote human health. Drugs are presumed to be remedies against disease. The definition does not logically extend to a product whose intended purpose is to end human life at any stage. This case therefore presents not a "moral" dispute, as the District Court below suggested (Opinion at 28) but a simple legal question of statutory authority. Of course, killing human beings without legal authority would be immoral as well. Because the statutory text is directed to the protection of human health, not the authorization of lethal ends, the FDA must point to a clear congressional grant before claiming authority to approve a drug regimen whose intended result is fetal death. The FDA has a duty to protect pregnant women and their children, and they normally do so, demonstrated by millions of warning labels. Why does the FDA demand disclosure that a

drug may be harmful to pregnant women? Because it has a duty under the law to protect pregnant women and their children from life-threatening consequences. The drug in this case, which is effective at producing abortion, is not safe for children in the womb.

II. Violating the Constitution and the Comstock Act

Protecting life is the legal and Constitutional duty of federal and state governments, and judges. Under the Fifth Amendment, human life from our founding was protected at the federal level, first, through the federal common law, which made abortion a common law crime, see Wilson quote below, and then through the Comstock Act, enacted shortly after the Fourteenth Amendment. The Fourteenth Amendment in 1868 imposed a similar Constitutional duty to protect life on the states and stated:

> Nor shall any **state** deprive any person of life . . . without due process of law, nor the equal protection thereof.

A founding signer of the Declaration, the Constitution, and a George Washington appointee to the U.S. Supreme Court, - James Wilson, - stated:

> With consistency, beautiful and undeviating, human life, from its commencement to its close, is protected by the common law. In the contemplation of law, life begins when the infant

> is first able to stir in the womb. By the law, life is protected not only from immediate destruction, but from every degree of actual violence, and in some cases, from every degree of danger.[2]

This was the law in America for 200 years (from the 1770s to 1973) until the erroneous and now repudiated decision in *Roe v. Wade* grievously purported to create a right to abortion, reversed in *Dobbs v. Jackson Women's Health Org.,* 142 S. Ct. 2228 (2022).

Until the latter part of the 20th Century, such a right was entirely unknown in America law. Indeed, when the 14th Amendment was adopted, three quarters of the States made abortion a crime at all stages of pregnancy. The abortion right is also critically different from any other right that the Supreme Court has held to fall within the Fourteenth Amendment's protection of "liberty." Id. The Court also stated that *Roe*'s defenders characterize the abortion right as similar to the rights recognized in past decisions involving matters such as intimate sexual relations, contraception, and marriage, but abortion is fundamentally different, as both *Roe* and *Casey* acknowledged, because it destroys what

[2] James Wilson, Collected Works of James Wilson, (1790-91), ed. by Kermit L. Hall and Mark David Hall, (Indianapolis: Liberty Fund, Inc. 2007) Volume II, Lectures on Law, Chapter XII, "Of the Natural Rights of Individuals, p. 1068 (emphasis added).

those decisions call "fetal life" and what the law in *Roe* described as an "unborn human being. *Id*. at 2243.

Another major founder, John Witherspoon stated, in his Lectures on Moral Philosophy delivered at what is now Princeton University that:

> [in America] we have denied the power of life and death to parents.[3]

Abortion as legalized by the FDA creates a legal problem because abortion is incompatible with the tenets of the Constitution. Indeed, the Constitution forbids it, which is why Congress passed the Comstock Act to prohibit abortifacients – the killing of a human "life" – through the U.S. Postal Service and interstate commerce, its areas of federal responsibility at the time.

James Kent, an early American jurist and legal scholar, echoed common-law and statutory principles regarding the legal status of children in the womb:

> Wherever such consideration would be for his benefit, a child en ventre sa mere (in the mother's womb) is considered as

[3] John Witherspoon, D.D., LL.D., President of the College of New Jersey (later called Princeton), Lectures on Moral Philosophy, (Princeton University Press, 1912), Lecture XI, p. 85.

absolutely born.[4]

There is a reason the Comstock Act was passed. It is the only federal law directly expressing Congress' view on abortion pills, and explicitly criminalizing mailing or delivery of drugs "for producing abortion" 18 U.S.C. § 1461. An abortion-producing drug is not medicine according to the Constitution and Congress; it destroys human life. The FDA's 2023 REMS, in effect, invites and even sanctions, law violators bringing abortion within the borders of states who have protections in place for their women, minor girls and babies. This is an improper usurpation of the state's sovereign powers.

Originalism is a "just powers" concept because it follows the original common and accepted meaning of the words of the people who adopted those words. Protecting life is thus the duty of the United States government and is expressed in the FDA's required protection of human life. Both the Fifth and the Fourteenth Amendments together bind all levels of government, federal and state. Originalism protects human life,

[4] Kent, James, Commentaries on American Law. 4 vols. New York: O. Halsted, 1826-1830.

which the Supreme Court and science admit exists in the womb. Originalism is the only reasonable and just way to decide this dispute.

The issue in this case therefore is not simply one of "scientific risk assessment." It is a legal question for courts concerning statutory authority, which is judges' area of expertise, not the province of the FDA. Whether Congress has expressly empowered the FDA to approve drugs whose intended function is to terminate living human life is a legal issue. Nothing in the FDCA clearly grants such authority. And if Congress had wished to confer authority of that kind, one would expect it to have done so expressly. *See, West Virginia v. EPA*, 597 U.S. 697 (2022).

This question is sharpened by the Supreme Court's decision in *Dobbs,* which held that the Constitution "does not confer a right to abortion," overruling *Roe* and *Casey*. *Dobbs* at 231, 292. The Court also emphasized that, "[u]ntil the latter part of the 20th century, there was no support in American law for a constitutional right to obtain an abortion," and that by the time of the Fourteenth Amendment, "three-

quarters of the States had made abortion a crime at any stage of pregnancy." *Id.* at 257.[5]

Now that abortion is no longer insulated by a purported constitutional right, ordinary principles of statutory interpretation regain their full force. This is the legal doctrine of revival. *Frost v. Corporation Commission*, 278 U.S. 515 (1929). Under this doctrine many state laws which criminalized abortion were revived once *Dobbs* reversed *Roe*.

America's long history of criminalization of abortion drugs defeats any suggestion that federal courts should casually presume congressional authorization for the FDA to approve abortion-inducing drugs under a

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[5] For example, the Missouri statute reproduced in Appendix A punished any person who "willfully and maliciously administer[ed]" "any **poison, or other noxious, poisonous or destructive substance** or liquid" with intent "**to cause or procure the miscarriage of any woman then being with child**." Likewise, the Illinois statute criminalized administering "any poison, or other noxious or destructive substance or liquid" with intent "to procure the miscarriage of any woman, then **being with child**." And the New York statute made it a crime to administer "any medicine, drug or substance whatever" or use "any instrument or other means whatever" **with intent "to procure the miscarriage of any such woman**," unless necessary to preserve her life.
The same pattern appears throughout the appendix. On a later page of Appendix A, the Delaware and Tennessee statutes criminalize administering "any poison, drug, medicine, or other noxious thing," or "any medicine, drug or substance whatever," **with intent to procure miscarriage or destroy the child**, absent a life-of-the-mother justification. These enactments are directly relevant here because they show that, as a matter of American legal tradition, drugs intended to produce abortions, which they called miscarriages, were historically criminalized—not treated as ordinary therapeutic products. (emphasis added throughout.)

general "safe and effective" statute intended to protect human life, including children in the womb. When historical practice treated such "miscarriage of a child" "medicines" as instruments of criminal abortion, any court should require a clear statement from Congress before finding that FDA possesses that authority. *Dobbs*, 597 U.S. at 248–57; See *West Virginia v. EPA*, 597 U.S. 697, (2022).

III. The Supreme Court, the Eighth Circuit and The Scientific Community Recognize Abortion Terminates Human Life

A. ***Gonzales v. Carhart,*** 550 U.S. 124, 159 (2007)

This drug regimen is intentionally designed to kill what the Supreme Court has called an "infant life" in the womb per *Gonzalez v.* Carhart:

> …it seems unexceptionable to conclude some women come to regret their choice to abort the **infant life** they once created and sustained. See Brief for Sandra Cano et al. as Amici Curiae in No. 05-380, pp. 22-24. Severe depression and loss of esteem can follow." Gonzales v. Carhart 550 U.S. 124, 159 (2007) . . . Severe depression and loss of esteem can follow. (emphasis added).

Even Justice Ginsburg said: "The Court is surely correct that, for most women, abortion is a difficult and painful decision." *Gonzales* at 183, *fn*. 7 (Ginsburg, J., dissenting).

The only reason this abortion-producing drug was approved in 2000 was because there was an admittedly erroneous Supreme Court opinion in *Roe v. Wade* with extremely distortive and destructive consequences for Americans, especially mothers and "infant life" at the time of the abortion. *Gonzales* at 159. Allowing a drug to be approved that kills a human being because there was an illegitimate creation of a purported Constitutional right was and still is a "serious distortion" of American law. This is a grave distortion in the law of America which made abortion a crime for almost 200 years, from our inception in 1776 until 1973 when *Roe* stopped protecting life in the womb. It was an "egregious" error that was created by the Supreme Court and has now been corrected by it.

It is the duty of the federal judiciary to correct its own mistakes in this area. Just as *Brown v. Board of Education of Topeka,* 347 U.S. 483, (1954) reversed the Supreme Court's egregious error in *Plessy v. Ferguson*, 163 U.S. 537 (1866), the court justly followed that up by uprooting segregation and telling America and state governors that the Court was serious and committed to removing all the "distortions," injustices and serious errors caused by the Court's own erroneous segregation decision.

It is the duty of the Supreme Court and all federal courts to protect human life. That is the purpose of government. That is why the Declaration of Independence, which under the doctrine of originalism sheds its light on the Constitution's Fifth and Fourteenth Amendment "life" clauses stated that the "right to life" is God-given, and inalienable. To secure these inalienable rights, including the right to life, governments are instituted among men, "deriving their just powers from the consent of the governed.[6]

B. *Planned Parenthood v. Rounds*, 530 F3d. 724, 737-38 (Eighth Circuit 2008) (en banc) - "Terminates the Life of a Whole, Separate Unique, Living Human Being"

The Eighth Circuit's en banc decision in *Planned Parenthood v. Rounds, supra*, is particularly significant because it addressed, as a factual and legal matter, the truthfulness of a state-required disclosure that "abortion will terminate the life of a whole, separate, unique, living human being," defined as a member of the species homo sapiens. 530 F.3d at 730, 735–38. The Court held that this disclosure was "truthful, non-

[6] "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable rights, that among these are life, liberty, and the pursuit of happiness - That, to secure these rights, governments are instituted among men, deriving their just powers from the consent of the governed. . ." U.S. Declaration of Independence.

misleading and relevant to the patient's decision to have an abortion." *Id.* at 737–38.

The court also rejected the argument that the statement was impermissibly ideological or scientifically unsound. The court explained that the disclosure reflected "the biological characteristics of a human organism at the embryonic or fetal stage of development" and concluded that the State had produced substantial evidence supporting the proposition. *Rounds*, at 735–36. That matters here because it refutes the suggestion that describing abortion as the termination of a living human being is merely moral, theological, political, or metaphysical rather than a biological fact. The Eighth Circuit upheld as "truthful, non-misleading and relevant" to a woman's decision a statutory disclosure requiring physicians to inform patients that abortion will "terminate the life of a whole, separate, unique, living human being." *Rounds* at 737–38.The court treated that proposition as grounded in biological fact, not ideology. See id. at 735–38.

C. Scientific Literature Documents the Overwhelming Scientific Consensus that Human Life Begins at Fertilization

Scientific literature confirms the overwhelming biological consensus that human life begins at fertilization. Steven Andrew

Jacobs's article, *The Scientific Consensus on When a Human's Life Begins*, reports that over 5,000 biologists from 1,058 academic institutions "assessed survey items on when a human's life begins and, overall, 96% (5337 out of 5577) affirmed the fertilization view." 36 Issues L. & Med. 221, 221 (2021). The article describes fertilization as the "leading biological perspective on when a human's life begins." *Id.* The same article explains that peer-reviewed biological and life-science journals have published articles representing "the biological view that a human's life begins at fertilization," and that this view "stands alone as the leading biological perspective on when a human's life begins." *Id.*

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment below and grant Plaintiffs-Appellants/Cross-Appellees requested relief.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 3,263 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) [or current applicable exclusion rule].

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 in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

/s/ Allan E. Parker
Allan E. Parker

CERTIFICATE OF SERVICE

I certify that on June 22, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished through the appellate CM/ECF system.

/s/ Allan E. Parker
Allan E. Parker

ECF CERTIFICATIONS

I certify that the required privacy redactions have been made pursuant to 5th Cir. R. 25.2.13, the electronic submission is an exact copy of the paper submission, and the document has been scanned for viruses and is free of viruses.

/s/ Allan E. Parker
Allan E. Parker