No. 23-2194

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,
Plaintiff-Appellant,
v.
KRISTINA D. RAYNES, in her official capacity as Prosecuting Attorney of Putnam County, and Patrick Morrisey, in his official capacity as Attorney General of West Virginia,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of West Virginia (Huntington),
No. 3:23-cv-00058-MGL, Hon. Robert C. Chambers

BRIEF OF *AMICUS CURIAE*, THE AMERICAN CENTER FOR LAW AND JUSTICE, SUPPORTING DEFENDANTS-APPELLEES ON THE MERITS AND URGING AFFIRMANCE. BRIEF FILED WITH THE CONSENT OF THE PARTIES.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 29(a)(4)(A) and Circuit Rule 26.1(b), *amicus curiae* the American Center for Law and Justice ("ACLJ") makes the following disclosures:

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2. No publicly held corporation or other publicly held entity owns any portion of the ACLJ.

3. The ACLJ is unaware of any publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of this litigation.

4. This case does not arise out of a bankruptcy proceeding or criminal case.

Dated: April 15, 2024

Respectfully submitted,

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The ACLJ is an organization dedicated to the defense of constitutional liberties secured by law. Counsel for the ACLJ have presented oral argument, represented parties, and submitted *amicus curiae* briefs before the Supreme Court of the United States, this Court, and other courts around the country in cases involving a variety of issues, including the right to life. *See, e.g.*, *Pleasant Grove City v. Summum*, 555 U.S. 460 (2009); *June Medical Servs. v. Russo*, 140 S. Ct. 2103 (2020); *Int'l Refugee Assistance Project v. Trump*, 857 F.3d 554 (4th Cir. 2017). The ACLJ is dedicated, *inter alia*, to combating the injustice of denying human rights to unborn children and has filed as amicus in previous abortion cases. The ACLJ is particularly concerned in this case with the specious arguments which amicus ACOG presents. The parties have filed blanket consents to the submission of amicus briefs.

CERTIFICATION PURSUANT TO FED. R. APP. P. 29(a)(4)(E)

Pursuant to Fed. R. App. P. 29(a)(4)(E), the American Center for Law and Justice ("ACLJ") affirms that no counsel for a party authored this brief in whole or in part and that no person other than the *amicus curiae*, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief.

SUMMARY OF THE ARGUMENT

This brief makes several points. First, that the FDA regulates a drug does not mean its use is somehow shielded from state law restriction. Homicide committed with fentanyl, for example, is still homicide, and states can ban it. Second, mifepristone is by no means safe. By design, it aims to cause pregnancy loss, an adverse effect. The claim – which amicus ACOG repeats – that abortion is safer than childbirth is debunked by scientific analysis of the relevant studies. The reliance by amicus ACOG upon pregnancy complications that manifest themselves *later* in pregnancy, moreover, is completely irrelevant to any supposed need for mifepristone, which is only approved for use in the first ten weeks of gestation.

ARGUMENT

I. FDA REGULATION OF A DRUG DOES NOT PREEMPT STATE PROHIBITION OF ACTS USING THAT DRUG.

GenBioPro makes the astonishing argument that FDA regulation of a drug preempts state restriction of acts involving that drug. *See* Appellant's Br. at 22 (federal statutory scheme "leaves no room for state restrictions"); Am'd Cplt. ¶¶ 15 (JA303) ("Congress authorized FDA, and only FDA, to impose restrictions on access to mifepristone."), 82 (JA323) ("The elements FDA determined are necessary to ensure mifepristone's safety are the *only* restrictions that may be imposed on a patient's access to, and the healthcare delivery system's distribution of, mifepristone") (emphasis in original). GenBioPro's contention is patently absurd.

That fentanyl is FDA-approved for pain relief, for example, does not mean a state is preempted from outlawing homicide because – or when – the killing was effectuated by use of fentanyl. *See Man Convicted of Killing Roseville Teen after Fentanyl Overdose Death*, ABC10 (July 7, 2023), https://tinyurl.com/FentanylMurder.

GenBioPro asserts, "Just as a state may not pass a law purporting to remove one of the REMS requirements (such as waiving the requirement of a Patient Agreement Form), it also may not impose any other elements restricting access." Am'd Cplt. ¶82 (JA 323-324). But it does not follow that because a state may not *remove* a federal limit (and thus override FDA's limits) that therefore a state may not *add* an additional limit. The FDA rules set a federal *floor* of restrictions. States are free to add further limits on use so long as there are no conflicting obligations. *See Wyeth v. Levine*, 555 U.S. 555, 573-74 (2009) (rejecting drug manufacturer's argument that federal law "establishes both a floor and a ceiling for drug regulation"). That the FDA might approve a drug does not mean a state cannot forbid its use to harm others. *See* Charles Graber, *How a Serial-Killing Night Nurse Hacked Hospital Drug Protocol*, Wired (Apr. 29, 2013), https://tinyurl.com/CullenMurder (Charles Cullen used digoxin and insulin to lethally overdose patients). Here, West Virginia generally restricts killing human beings before birth. The prohibition applies whether the killing is done with an FDA-approved drug, *e.g., Texas Man Sentenced to 180 Days in Jail for Drugging Wife's Drinks to Induce an Abortion*,

AP (Feb. 8, 2024), or a shish kabob skewer, *e.g., UCCS Student Accused of Using Skewer to Force an Abortion, Report says*, Denver7ABC (Oct. 7, 2016) https://tinyurl.com/SkewerAbortion.

II. MEDICATION ABORTION IS NOT SAFE.

A. Abortion Pills Induce Pregnancy Loss and Thus Inherently Cause Harm.

Abortion pills by their very design cause an adverse event: pregnancy loss.

Pregnancy loss is a dreaded complication. Consequently, medical authorities make efforts to warn pregnant women which drugs to avoid during pregnancy. *See*, *e.g.*, *Medicines to Avoid When Pregnant*, WebMD (June 8, 2023), https://www.webmd.com/baby/medicines-avoid-pregnant ("Some drugs can harm a developing baby or cause a miscarriage or stillbirth."); *Medicine and Pregnancy*, CDC, http://tinyurl.com/4zahm7hr (Apr. 10, 2023) ("Some medicines may cause birth defects, pregnancy loss, prematurity, infant death, or developmental disabilities."); Chaunie Brusie, *Medications You Should Avoid During Pregnancy*, Healthline (May 7, 2019), https://tinyurl.com/HlthLnMeds. The whole point of abortion pills, however, is to *cause* that adverse event. As the FDA concedes: "Mifepristone, when used together with another medicine called misoprostol, *is used to end a pregnancy . . . .*" *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Sept. 1, 2023), https://tinyurl.com/FDAMifeQA (emphasis added).

It is therefore flatly misleading to claim that mifepristone is "exceedingly safe." ACOG Amicus at 3.[1] To the contrary, except when the drug does not work, *every single woman* who takes mifepristone undergoes an adverse event: pregnancy loss. Diana Cuenca, *Pregnancy Loss: Consequences for Mental Health*, Frontiers

[1] ACOG describes itself as "a leading provider of authoritative scientific data regarding childbirth and abortion." ACOG Amicus at 1. What ACOG remarkably fails to mention is that it holds a strong advocacy position on abortion, namely, ACOG "is committed to protecting and increasing access to abortion." *Abortion Policy*, ACOG, https://tinyurl.com/ACOGAbPol. *See also* Carole Novielli, *The American College of Obstetricians and Gynecologist isn't neutral. It's pro-abortion*, Live Action (Aug. 9, 2018), https://www.liveaction.org/news/american-college-obstetricians-gynecologists-pro-abortion/ (with documentation).

Moreover, ACOG is more than willing to alter its official statements to serve political goals. It did exactly that when it added wording to its official statement on partial birth abortion. Slate covered the shocking story. *See* William Saletan, *When Kagan Played Doctor*, Slate (July 3, 2010) https://slate.com/technology/2010/07/elena-kagan-s-partial-birth-abortion-scandal.html. Some excerpts:

> Fourteen years ago, to protect President Clinton's position on partial-birth abortions, Elena Kagan doctored a statement by the American College of Obstetricians and Gynecologists. Conservatives . . . understate the scandal. It isn't Kagan we should worry about. It's the whole judiciary.
>
> Kagan, who was then an associate White House counsel, was doing her job: advancing the president's interests. The real culprit was ACOG, which adopted Kagan's spin without acknowledgment. But the larger problem is the credence subsequently given to ACOG's statement by courts, including the Supreme Court. Judges have put too much faith in statements from scientific organizations. This credulity must stop.
>
> . . .
>
> All of us should be embarrassed that a sentence written by a White House aide now stands enshrined in the jurisprudence of the Supreme Court, erroneously credited with scientific authorship and rigor.

Glob. Women's Health, Jan. 23, 2023 (Abstract) ("Pregnancy loss, in all its forms (miscarriage, abortion, and fetal death), is one of the most common adverse pregnancy outcomes . . ."). That the loss may have been *sought* by someone (not necessarily the woman) for nonmedical reasons (financial, relational, etc.) does not alter the reality of the loss. A woman who blinds herself suffers an adverse event even if she desires the outcome. Char Adams, *Woman Claims She Blinded Herself with Drain Cleaner to Fulfill Her Life-Long Dream of Being Disabled: 'I Should Have Been Blind from Birth,'* People (Oct. 1, 2015), https://tinyurl.com/PeopleSelfBlind.

The question whether, or under what conditions, people should be able to cause self-harm – or, in this case, harm to innocent third parties (prenatal humans) – should not be distorted by pretending that the physical harm is not physical harm.

B. Abortion Is Not Safer than Childbirth.

Amicus ACOG et al. repeat the claim that "'[t]he risk of death associated with childbirth is approximately 14 times higher than that with abortion.'" ACOG Amicus at 10 n.20. The inevitable source for this recurrent claim is the article (cited by ACOG in footnote 20 of its amicus brief), Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childhood in the United States*, 119 Obstet. & Gynecol. 215 (2012). But this claim – that continuing pregnancy is more deadly than abortion – is *unsupported and false*. *See* Amicus Brief

of the Elliot Institute in Support of Petitioners, *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022) (U.S. No. 19-1392) [hereinafter Elliot *Dobbs* Amicus], http://tinyurl.com/27u2tdh3. Not only is the statistical comparison underlying the claim flawed in multiple ways, Elliot *Dobbs* Amicus § II, but peer-reviewed medical research strongly indicates that in fact *abortion is more dangerous* than childbirth, Elliot *Dobbs* Amicus § III (citing multiple studies). Following is a brief review of the flaws underlying the claim that abortion is safer than childbirth.

The faulty claim rests upon a comparison of pregnancy mortality (formerly called "maternal mortality") and abortion mortality statistics published by the federal Centers for Disease Control and Prevention (CDC). *See, e.g.*, Raymond & Grimes, *supra*, at 215-16. The comparison is fundamentally flawed for multiple reasons.

First, abortion deaths also count as "pregnancy deaths," thereby misleadingly inflating the measure of deaths supposedly from childbirth. Elliot *Dobbs* Amicus at 16 n.17. This point bears emphasis: when a woman dies from abortion, that death counts *both* as an abortion mortality *and* as a pregnancy mortality. With such an approach, the results are mathematically stacked against childbirth ever being deemed safer than abortion. Consider: *even if every single woman in a single year who had an abortion died from the procedure, and only one woman that year died from a miscarriage or complication of childbirth, the total number of deaths in the "pregnancy mortality" category for that year would still*

exceed the total deaths in the "abortion mortality" category. This makes comparison of the two figures absurd.

Second, pregnancy mortality is measured per childbirth, not per pregnancy, Elliot *Dobbs* Amicus at 17 n.14, and thus pregnancy mortality is artificially inflated. That is, the relevant maternal population excludes those who experience miscarriages and stillbirths, but *if such women die, their deaths are nevertheless included in the pregnancy mortality total*. Thus, the relevant baseline population is reduced by excluding cases of pregnancy losses (no live birth), yet the total deaths still include those maternal deaths resulting from these very same excluded – uncounted – pregnancies. For example, even though many women survive ectopic pregnancies, the supposed pregnancy mortality rate for the subset of all ectopic pregnancies will be infinitely high. There will be *some maternal deaths* in the numerator but *no live births* in the denominator, yielding an infinitely large fraction. Obviously, this is a misleading, useless statistic. But this error will in turn infect and distort the overall pregnancy mortality rate by adding to the numerator (deaths) while not adding to the denominator (live births). Hence, the pregnancy mortality figure, contrary to its title, does *not* accurately depict the mortality risk of pregnancy. Instead, the statistic *overstates* the risk.

Third, the overall pregnancy mortality figures do not account for the stage of gestation. A high percentage of maternal deaths are associated with

miscarriages early in pregnancy. This matters. For example, a woman entering her second trimester faces zero risk of a first-trimester death from ectopic pregnancy. But the undifferentiated pregnancy mortality rate incorporates those first-trimester deaths, and thus does not reflect the actual risk going forward. For a woman who is beyond any given stage of pregnancy and considering the relative risks of continued pregnancy versus abortion, it makes no sense to compare abortion mortality with pregnancy mortality *throughout* pregnancy; the figures would have to be adjusted to subtract out deaths occurring at stages of pregnancy that have already passed. Yet pregnancy mortality statistics do not make this adjustment and thus are not properly comparable to abortion mortality statistics.

Fourth, abortion deaths are underreported. One simply cannot make a fair assessment of abortion deaths without knowing how many have occurred. Yet one published study found that, in Finland, *an astounding 94% of abortion-associated deaths were not identified from death certificates or cause-of-death registries alone.* Mika Gissler et al., *Methods for Identifying Pregnancy-associated Deaths: Population-based Data from Finland 1987-2000*, Paediatric & Perinatal Epidemiology 448, 451, tbl. 2 (2004). This problem infects the United States as well. *See* Elliot *Dobbs* Amicus at 13-15 (citing sources).

Fifth, abortion mortality statistics likely will not include many delayed deaths that result from abortion, Elliot *Dobbs* Amicus at 15 n.11, such as those

reflected in an increased rates of suicide or other longer-term fatal post-abortion outcomes, even though studies show a greater risk of death from these and other causes after abortion (as opposed to childbirth). A fair comparison of abortion with continued pregnancy, like a fair comparison of smoking with nonsmoking, would have to take into account not just immediate consequences, but also all other statistically significant increased death risks.

In short, the claim that abortion is 14 times safer (or, indeed, safer at all) than continuing pregnancy is embarrassingly unsupported and inaccurate. No serious advocate should make that assertion.

C. Abortion Pills Are Not Remedies for Later-Term Pregnancy Complications.

It is bad enough that ACOG repeats the debunked mantra that abortion is safer than childbirth. But ACOG does not stop there. In its tirade against pregnancy, ACOG cites a list of five "dangerous" conditions facing pregnant women. ACOG Amicus at 11-13.[2] Yet each of the five conditions manifests itself *after* the 70-day (10-week) window for taking mifepristone has already closed:

- **Pre-labor rupture of the membranes:** this term applies to gestations *at or after 37 weeks* of gestation, Antonette T. Dulay, MD, *Prelabor*

[2] ACOG cannot bring itself to say "pregnant women." Instead, it refers to "pregnant patients." *Id.*

Rupture of Membranes (PROM), MSD Manual (Professional Version, reviewed/revised Mar. 2024), https://tinyurl.com/MSDPROM. Prior to that, the rupture is called preterm PROM, *id.* Listed treatments for the latter condition address pregnancies down to 23 weeks of pregnancy. *Id.* Indeed, the very source ACOG cites for this condition, ACOG Practice Bulletin No. 217, *Prelabor Rupture of Membranes* 135 Obstetrics & Gynecology e80 (Mar. 2020), https://tinyurl.com/ACOG PROM, only cites studies that address *later* gestational stages or go as early as 14-24 weeks gestation, *id.* at e81, and gives no management recommendations other that for very late term pregnancy down to "less than 23-24 weeks of gestation," *id.* at e84.

- **Excessive bleeding/placenta accreta:** ACOG itself acknowledges that "most women are diagnosed in the second and third trimesters." *Placenta Accreta Spectrum*, ACOG (Dec. 2018), https://tinyurl.com/ ACOGPlacAccr. *See also Placenta Accreta*, Cleveland Clinic (last reviewed Sept. 26, 2022), https://tinyurl.com/ClevClPlacAccr ("There are usually no symptoms of placenta accreta. In some cases, you may experience bleeding in the third trimester of pregnancy (weeks 28 to 40) or pelvic pain (from the placenta pressing on your bladder or other organs).") .

- **Gestational hypertension and preeclampsia (high blood pressure):** gestational hypertension is "typically diagnosed after 20 weeks of pregnancy or close to delivery," and preeclampsia occurs "after 20 weeks of pregnancy," *High Blood Pressure During Pregnancy*, CDC (last reviewed June 19, 2023), https://tinyurl.com/CDCPreeclamp.
- **Placental abruption:** this condition "can occur at any time after 20 weeks of pregnancy, but it's most common in the third trimester," *Placental Abruption (Abruptio Placentae)*, WebMD (reviewed Aug. 9, 2022), https://www.webmd.com/baby/what-is-placental-abruption.
- **Gestational diabetes mellitus:** "Gestational diabetes usually develops around the 24th week of pregnancy, so you'll probably be tested between 24 and 28 weeks," *Gestational Diabetes*, CDC (reviewed Dec. 30, 2022), https://www.cdc.gov/diabetes/basics/gestational.html.

It makes no sense to tout mifepristone as a remedy to complications that do not become apparent until after the time for taking mifepristone has already passed. Yet ACOG, "the nation's leading group of physicians providing evidence-based obstetric and gynecologic care," ACOG Amicus at 1, does precisely that. ACOG does not seem concerned with the mismatch between, and hence the irrelevancy of, the conditions it lists and the unavailable "remedy" (mifepristone) that ACOG

defends. *See, e.g.,* ACOG Amicus at 15 (citing example of woman, Amanda Eid, whose complication manifested at 18 weeks, well past the window for approved use of mifepristone).[3] While ACOG concludes that "mifepristone is an important tool in [clinicians'] toolbox for responding to medical emergencies that can arise during pregnancy," ACOG Amicus at 18, its brief actually serves only falsely[4] to depict pregnancy and childbirth, as such, as frighteningly hazardous. The availability of mifepristone will have no effect on the conditions ACOG lists, and hence those conditions have no bearing on this case.

[3] ACOG then cites a "nearly identical experience" for Amanda Zurawski. ACOG Amicus at 16-17. The situations were not just "nearly identical" but *exactly* so: Amanda Eid and Amanda Zurawski are the same woman. *See* Elizabeth Cohen & John Bonifield, *Texas Woman Almost Dies Because She Couldn't Get an Abortion*, CNN (Nov. 16, 2022), https://bit.ly/3HOY20H. ACOG cited this very source, ACOG Amicus at 15 n.39, but apparently did not notice its own double-counting of the same incident – an incident which arose at 18 weeks of gestation and thus was in any event wholly irrelevant to mifepristone, which is only approved for use up to 10 weeks.

[4] According to the CDC, the maternal mortality rate for 2021 was 32.9 deaths per 100,000 live births. Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, CDC (last reviewed Mar. 16, 2023), https://tinyurl.com/CDCMMR 2021. This figure inflates the death rate, as noted *supra* p. 8. But even taking the CDC's number as a given, that translates to odds of roughly 1 in 3040. That is *lower* than the risks of dying from choking on food (1 in 2659), drowning (1 in 1006), and dying in a motor vehicle crash (1 in 93). *Odds of Dying*, National Safety Council (2021 data), https://tinyurl.com/NSC2021Odds. ACOG does not raise a similar alarm about eating, swimming, or riding in a car, each of which is more likely to cause death than pregnancy and childbirth.

CONCLUSION

This Court should affirm the judgment below.

Respectfully submitted,

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Date: April 15, 2024

CERTIFICATION PURSUANT TO FED. R. APP. P. 29 AND 32

This *amicus curiae* brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and 32(a)(7) because it contains 3,043 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: April 15, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on April 15, 2024, I caused a true and correct copy of the foregoing to be electronically filed with the Clerk of Court for the United States Court of Appeals for the Fourth Circuit using CM/ECF, which will send notification of such filing to counsel of record.

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