No. 23-2194

United States Court of Appeals
for the Fourth Circuit

GENBIOPRO, INC.

Plaintiff-Appellant,

v.

KRISTINA 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
No. 23-cv-58, Hon. Robert C. Chambers

BRIEF OF LIFE LEGAL DEFENSE FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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STATEMENT OF *AMICUS CURIAE*[1]

Amicus Life Legal Defense Foundation ("Life Legal") is a California non-profit 501(c)(3) public interest legal and educational organization that works to assist and support those who advocate in defense of life. Its mission is to give innocent and helpless human beings of any age, particularly unborn children, a trained and committed defense against the threat of death, and to support their advocates in the nation's courtrooms. Life Legal believes that human life begins at the moment of conception and does not end until natural death. It litigates cases to protect human life, from preborn babies targeted by a billion-dollar abortion industry to the elderly, disabled, and medically vulnerable denied life-sustaining care.

Pursuant to Federal Rule of Civil Procedure 29(a)(2), all parties have consented to the filing of *amicus* briefs.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Supreme Court ruled in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 302 (2022) ("*Dobbs*") that each state has the power to decide the issue of abortion for itself. ("The Constitution does not prohibit the citizens of each state from regulating or prohibiting abortion. *Roe* and *Casey* arrogated that authority. We

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), counsel for amici represent that no counsel for a party authored this brief in whole or in part and that no person or entity, other than amici or their counsel, made a monetary contribution to the preparation or submission of this brief.

now overrule those decisions and return that authority to the people and their elected representatives."). GenBioPro would have us believe that Congress, through the Food, Drug, and Cosmetic Act ("FDCA") and the Food and Drug Administration Amendments Act ("FDAAA"), delegated to unelected federal bureaucrats the authority to set abortion policy nationwide through regulation of abortion-inducing drugs. No such intent is evident from either statute, which purport only to regulate the *safety* and *effectiveness* of drugs and say nothing about guaranteeing a nationwide right of access to any drug or preempting the states' power to regulate abortion. GenBioPro's case should be rejected as a bald attempt to circumvent a Supreme Court ruling that threatens GenBioPro's business.

ARGUMENT

I. The Purpose of the FDCA and the FDAAA is to Ensure the Safety and Efficacy of Drugs, Not to Guarantee a Right to Drug Access or to Regulate Abortion.

"[T]he purpose of congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("*Wyeth*") (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("*Lohr*")). That purpose can be determined from the language of the relevant federal statutes, their statutory framework, and the structure and purpose of the statutes as a whole. *Lohr*, 518 U.S. at 485-86. From the beginning of the federal government's involvement in the regulation of drugs, the

overriding intent of Congress has always been "protecting the public health by ensuring the safety, efficacy, and security of human and veterinary food and drugs."[2]

In response to public uproar over Upton Sinclair's revelations of unsanitary practices in the meat packing industry in the novel *The Jungle*, Congress enacted the Pure Food and Drug Act in 1906 to prevent the manufacture, sale, or transportation of adulterated or misbranded food and drugs in interstate commerce.[3] Before this enactment, food and drug quality standards were left to the manufacturers and the states.[4] Congress increased the power of the federal government to regulate drugs in 1938 with the passage of the Food, Drug, and Cosmetic Act ("FDCA"), for the first time requiring drug manufacturers to demonstrate new drugs' safety and effectiveness to the newly created FDA before marketing and distribution to the general public. The FDCA also authorized the FDA to issue and enforce drug

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[2] *10 Facts About What FDA Does and Does not Approve,* U.S Food and Drug Administration, https://www.fda.gov/consumers/consumer-updates/10-facts-about-what-fda-does-and-does-not-approve. ("10 Facts").

[3] Pub. L. No. 59-384, ch. 3915, 34 Stat. 768 (1906); *The Pure Food and Drug Act*, U.S. Capitol Visitor Center, https://www.visitthecapitol.gov/exhibitions/congress-and-progressive-era/pure-food-and-drug-act.

[4] *The Food and Drug Administration: the Continued History of Drug Advertising*, Weill Cornell Medicine, https://library.weill.cornell.edu/about-us/snake%C2%A0oil%C2%A0-social%C2%A0media-drug-advertising-your-health/food-and-drug-administration-continued.

standards, inspect facilities, recall or seize unsafe products, and regulate advertising and labeling of drugs.[5]

In 1962, Congress amended the FDCA to shift the burden of proof for drug safety from the FDA to the drug manufacturer to demonstrate that the drug was "safe for use under the conditions prescribed, recommended, or suggested." 21 U.S.C. §§ 355(a) and (d). The amendments provided that "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law . . . *unless there is a direct and positive conflict* between such amendments and such provision of State law" ("Saving Clause").[6] Whereas in 1976, Congress enacted an express preemption provision for medical devices, it declined to do so for prescription drugs. *Wyeth*, 555 U.S. at 567. Together, the Saving Clause and the failure to enact an express preemption for prescription drugs evidence Congress's intent to preserve state law except in cases of "direct and positive conflict" between the two.

[5] Clinton Lam, Preeti Patel, *Food, Drug, and Cosmetic Act*, National Institutes of Health (July 31, 2023), https://www.ncbi.nlm.nih.gov/books/NBK585046/#:~:text=Under%20the%20drug%20regulations%20at,for%20modern%2Dday%20consumer%20protections.

[6] Drug Amendments to Assure Safety, Effectiveness, and Reliability, Pub. L. No. 87-781, § 202, 76 Stat. 793 (1962); https://www.govinfo.gov/content/pkg/STATUTE-76/pdf/STATUTE-76-Pg780.pdf#page=2.

In 1992, Congress added a section to the Code of Federal Regulations which allowed the FDA to restrict the "distribution or use" of drugs which treat "serious or life-threatening illnesses" in order to "assure safe use." 21 C.F.R. §§ 314.500, 314.520 ("Subpart H"); Joint Appendix ("JA") 97. Notably, drugs approved under Subpart H are subject to *restrictions in distribution*, for the purposes of safety. Mifeprex, the name-brand mifepristone, was approved in 2000 under Subpart H and was therefore subjected to such restrictions. *Id*.

In 2007, Congress enhanced the post-marketing authorities of the FDA with respect to the safety of drugs through its passage of the FDAAA.[7] As part of its new powers, the FDA required that drugs formerly approved under Subpart H be reapproved under a Risk Evaluation and Mitigation Strategy ("REMS") in order to ensure that the benefits of the drug outweigh the risks. Manufacturers are required to submit a proposed REMS when they submit applications for drug approval to the FDA. 21 U.S.C. § 355-1(a). In order to determine whether a REMS is necessary, the Secretary of Health and Human Services will consider, among other things "adverse drug experiences" associated with the use of the drug. § 355-1(a), (b)(1). In addition to the REMS proposed by the drug manufacturers, drugs that are associated with a "serious adverse drug experience" can be required by the Secretary to be subjected

[7] FDAAA pmbl., Pub. L. No. 110-85, 121 Stat. 823 ("FDAAA Preamble") https://www.govinfo.gov/content/pkg/PLAW-110publ85/html/PLAW-110publ85.htm.

to "additional elements" to "assure safe use of the drug." These elements required by the Secretary must "not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." §§ 355-1(c)(2), (f)(2).

In 2011, the FDA approved a REMS with "additional elements" to "assure safe use" for the name-brand drug Mifeprex.[8] The FDA approved GenBioPro's generic mifepristone in 2019 and applied the REMS to it as well.[9] The current REMS for mifepristone states:

> **I. GOAL**
> The goal of the REMS for mifepristone is *to mitigate the risk of serious complications associated with mifepristone* by:
> a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.
> b) Ensuring that mifepristone is only dispensed by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions issued by certified prescribers.
> c) Informing patients about the risk of serious complications associated with mifepristone. (emphasis added). Mifepristone REMS, at fn. 9.

The stated goal of mitigating serious complications from the use of mifepristone comports with the purpose of the FDA to ensure drug safety, recognized in the FDCA

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[8] *Risk Evaluation and Mitigation Strategy (REMS) for Mifeprex,* Food and Drug Administration (June 2011), https://www.fda.gov/media/164649/download.

[9] *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG,* Food and Drug Administration (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf. ("Mifepristone REMS").

and the FDAAA. Nothing in the Mifepristone REMS, the Prescriber Agreement Forms, the Pharmacy Agreement Form or the Patient Agreement Form discusses the abortion decision itself. They only discuss safety protocols and procedures for dispensing the drug *after* the decision has been made.

GenBioPro mischaracterizes Congress's intent in enacting the REMS regulatory scheme as a desire to vest the FDA with *sole authority* to restrict access to mifepristone. GenBioPro Opening Brief ("GOB") at 3. This intent is absent from the language of the FDAAA and the Mifepristone REMS. The FDAAA indicates that Congress wanted to ensure that "elements" imposed *by the Secretary* under the REMS would not be "unduly burdensome" to access. It says nothing about limiting state power.[10] The only places in the Mifepristone REMS that mention access are referring to patient access to medical facilities in cases of incomplete abortion or severe bleeding, which is a safety issue (para. II.A.1.a.) and limiting access to patient and prescriber identity (para II.A.2.a.), which is a privacy issue. GenBioPro's assertion that the placement of limitations on the Secretary's power to impose restrictions on the use of drugs necessarily preempts the power of the states to

[10] JA267-268; § 355-1 (f)(1) ("*The Secretary*, . . . may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug."); § 355-1 (f)(2) ("Such elements to assure safe use *under paragraph (1)* shall . . . not be unduly burdensome to patient access to the drug") (emphases added).

regulate abortion is a classic example of assuming what one is trying to prove. Such intent is absent from the statutory language.

GenBioPro also claims that the intent of Congress was to "expand" access to the drug mifepristone and that this was stated in the preamble to the FDAAA. GOB 45. But GenBioPro has inserted its own wording regarding expanding access to drugs; the preamble says nothing about access to drugs at all, only drug safety.[11] Contrary to GenBioPro's assertions, nothing in the REMS regulatory scheme of § 355-1 suggests that Congress intended that the imposition of REMS elements would expand access to drugs. Implicit in the scheme is the acknowledgment that REMS, which apply to drugs approved under Subpart H, tend to *limit*, rather than *expand* access.[12] Congress's concern is obvious – a REMS program that excessively restricted or eliminated access would be self-defeating. Thus, Congress was concerned not with the expansion of drug access, but rather with ensuring drug safety while not excessively limiting access.[13]

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[11] The preamble states: "An Act To amend the Federal Food, Drug, and Cosmetic Act. . . to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes." *See* FDAAA Preamble, fn. 7.

[12] "If FDA concludes that a drug product shown to be effective can be safely used *only if distribution or use is restricted, FDA will require such postmarketing restrictions* as are needed to assure safe use of the drug product." Subpart H.

[13] In fact, the only place in the FDCA or the FDAAA that explicitly mentions expanded access to drugs is in reference to the FDA's power to approve the use of "investigational drugs" (i.e. unapproved drugs) for the treatment of a serious disease or condition in emergency situations. §§ 360bbb, 355-1(f)(6).

Further undermining GenBioPro's argument is the FDA's own disclaimer that it "does not regulate the practice of medicine, medical services, the price or availability of medical products and whether they are reimbursed by health insurance or Medicare."[14] If the FDA does not regulate the practice of medicine or medical services, it cannot regulate abortion, which is a medical service within the practice of medicine. *Simopoulos v. Va.*, 462 U.S. 506, 512 (1983) (upholding state statute requiring physicians licensed in the practice of medicine perform second-trimester abortions in a hospital). Also, the FDA has stated, "The FDA does not endorse any drug product."[15] If the FDA does not regulate the availability of or endorse any drug products, then logically it cannot possess the power to mandate the availability of any drug over the objections of state lawmakers.

Furthermore, the assumption that Congress intended to preempt state abortion laws is undercut by the historical background against which the FDAAA was passed, namely *Roe v. Wade,* 410 U.S. 113 (1973) ("*Roe*") and *Planned Parenthood v. Casey*,

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The FDA's limited power to expand access to certain unapproved drugs does not help GenBioPro's case.

[14] *About FDA: Patient Q&A*, U.S. Food and Drug Administration, https://www.fda.gov/media/151975/download#:~:text=No.,by%20health%20insurance%20or%20Medicare.

[15] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation Quest. 9*, U.S. Food and Drug Administration ("Mifespristone Q & A"), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

505 U.S. 833 (1992) ("*Casey*"), both of which invalidated state laws and drastically limited the states' ability to regulate abortion. It would not have been necessary for Congress to even consider the issue of preemption of state laws such as the Unborn Child Protection Act ("UCPA"), which, under *Roe* and *Casey*, could not have existed at the time. *See* JA268-269.

The language of the federal statutes, the statutory framework surrounding them, and the structure and purpose of the statute as a whole (*Lohr*, 518 U.S. at 485-86) clearly demonstrate that the overriding purpose of Congress was to ensure drug safety, not guarantee a right to or expand drug access under any and all circumstances. Furthermore, nothing in the statutory history demonstrates, in the absence of a "direct and positive conflict," Congress's intention to preempt state laws on abortion, or to regulate the abortion decision at all.

II. The Purpose of West Virginia's Unborn Child Protection Act is the Protection of Unborn Life and Not the Regulation of Drug Safety.

The UCPA states, "The Legislature finds that the State of West Virginia has a legitimate interest in protecting unborn lives and prohibiting abortions in West Virginia except in the circumstances set forth in this article." W. Va. Code § 16-2R-1. "'Abortion' means the use of any instrument, *medicine*, *drug,* or any other substance or device with intent to terminate the pregnancy of a patient known to be pregnant and with intent to cause the death and expulsion or removal of an embryo

or a fetus." W. Va. Code § 16-2R-2 (emphasis added). The UCPA limits the performance or attempted performance of an abortion to cases where "(1) The embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists" or the pregnancy is the result of sexual assault or incest, up to specified points in the pregnancy. W. Va. Code § 16-2R-3. None of the provisions of the UCPA directly address drug safety or protocols for the administering of abortion drugs. Therefore, the UCPA limits the availability of abortions by any means, including by the use of drugs such as mifepristone, in order to protect unborn lives.

As the *Dobbs* Court noted, the history of pro-life laws in America goes back to colonial times and was grounded in the common law, dating back to the thirteenth century. *Dobbs*, 597 U.S. at 242-50 ("The inescapable conclusion is that a right to abortion is not deeply rooted in the Nation's history and traditions. On the contrary, an unbroken tradition of prohibiting abortion on pain of criminal punishment persisted from the earliest days of the common law until 1973"). This longstanding tradition undergirded the Court's decision to disclaim the authority to "decide how abortion may be regulated in the States" and instead to "return the power . . . to the people and their elected representatives." *Id.* at 259. The history of West Virginia's abortion law is no exception. Prior to *Roe*, West Virginia banned abortion, including by the use of a drug, except when a woman's life was in danger. This statute was

inherited from Virginia when West Virginia became a state in 1863. *Dobbs, 597 U.S.* at 314-15. A month after the Supreme Court decided *Dobbs*, a West Virginia County court invalidated the nineteenth century abortion law.[16] West Virginia then promptly passed the UCPA. JA255. Therefore, from the very beginning of its existence as a state, West Virginia law has included strong protections for the life of unborn children from the point of fertilization.

III. The UCPA Is not Preempted by Congress's Grant of Power to the FDA to Regulate Drug Safety.

Federal preemption is guided by two principles. First, "the purpose of Congress is the ultimate touch-stone in every preemption case." *Wyeth*, 555 U.S. at 565. Second, there is a presumption against preemption with respect to a field historically occupied by the states "unless that was the clear and manifest purpose of Congress." *Wyeth*, 555 U.S. at 565.

Neither the language of the FDCA and the FDAAA, nor their statutory frameworks, nor their structure and purpose evidence any intent on the part of Congress to preempt the long-recognized state police power to regulate abortion. *See* Secs. I and II. Since Congress has not adopted an express preemption clause with respect to prescription drugs (*Wyeth*, 555 U.S. at 574), GenBioPro instead relies

[16] Nate Raymond, *West Virginia Judge Blocks Pre-Roe v. Wade Abortion Ban*, Reuters (July 28, 2022, 12:57 PM PDT), https://www.reuters.com/world/us/west-virginia-judge-blocks-pre-roe-v-wade-abortion-ban-2022-07-18/

upon implied preemption, namely field preemption and conflict preemption, to argue that the UCPA must be set aside. GOB at 25-52. However, GenBioPro's implied preemption arguments fall short.

A. Congress Has Not Occupied the Field of Abortion Regulation by the States.

1. In the Area of Public Health and Safety, the Supreme Court Does Not Infer Preemption Solely Because Congress Has Legislated Comprehensively.

GenBioPro's first field preemption argument is that Congress has legislated comprehensively with respect to drugs subject to REMS with safe use elements so that there is no room left for the states to supplement federal law. GOB at 27.

GenBioPro's argument fails because, in the context of health and safety regulations, the Supreme Court has declined to infer preemption "solely from the comprehensiveness of federal regulations," because of the "presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations." *Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.*, 471 U.S. 707, 718 (1985) (rejecting preemption challenge against county regulations on blood plasma centers that were more restrictive than the FDA's). In *Hillsborough*, the Court found that inferring preemption solely from the comprehensiveness of federal regulations "is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." This result "would be inconsistent with the federal-state balance embodied in our Supremacy

Clause jurisprudence." *Id*. at 716-717. The nature of "modern social and regulatory legislation . . . require[s] intricate and complex responses from Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *Id.* at 717.

The same principle holds true in this case. The FDA has promulgated detailed regulations for the use of mifepristone. These regulations are in the area of health and safety, which has traditionally been occupied by the states. *Dobbs,* 597 U.S. at 250. The necessity of regulating comprehensively results from the need to provide an "intricate and complex response" to a potentially dangerous drug, not from a desire to preempt state laws that do not address drug safety. The Saving Clause that limits preemption to "direct and positive conflicts" only confirms Congress's lack of intent to preempt the field of abortion regulation.

2. The Fields of Federal Drug Safety Regulation and State Abortion Regulation Can Coexist.

The UCPA and the REMS can coexist. The FDA's purpose is to ensure drug safety and, solely with respect to "additional elements" imposed by the Secretary, to ensure that *those elements* are not unduly burdensome on access or on the healthcare delivery system. *See* Sec. I, *supra*. This narrow purpose falls far short of imposing the FDA's will over state health and safety laws that might limit abortion but still allow the FDA's regulations on mifepristone to operate.

In *Kelly v. Wash.*, 302 U.S. 1 (1937), the Court denied a preemption challenge against a state law regulating the inspection of the hull and machinery of tugboats. Although the tugboats were subject to federal regulations as boats engaged in interstate commerce, there was no federal regulation for the inspection of hulls and machinery. The Court stated that, where Congress had occupied only a "limited field," "state regulation outside that limited field and otherwise admissible is not forbidden or displaced." *Id*. at 10. Here, the FDA has occupied a "limited field" of ensuring that the safe use elements imposed by the Secretary do not excessively burden access to mifepristone. Even if its occupation of that limited field is comprehensive, it cannot displace abortion laws, like the UCPA, which lie outside the field, especially in the absence of any express Congressional intention to do so.

The UCPA's purpose is not to regulate drug safety at all but rather to restrict access to abortion for the purpose of protecting unborn lives. *See* Sec. II. §§16-2R-1; 16-2R-3. It is just as valid as state laws regulating the licensure of doctors and prescribers of medication, which directly implicate drug safety, unlike the UCPA. *Dent v. W. Va.,* 129 U.S. 114, 122 (1889) ("Dent") (holding that states have the power to license medical practitioners pursuant to their power to provide for the general welfare). Contrary to GenBioPro's assertion (GOB at 30), the FDA does not regulate which patients may receive the drug, apart from some minimal requirements that a woman has to have a normal pregnancy of less than 70 days gestation and that

she has signed the Patient Agreement Form. Mifepristone REMS. The Patient Agreement Form instructs healthcare providers to "Counsel the patient on the risks of mifepristone,"[17] not on the decision as to whether to have an abortion at all.

The latter counseling would fall within the realm of the practice of medicine, which the FDA cannot regulate. *Dent,* 129 U.S. at 122; *Hillsborough,* 471 U.S. at 719 ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."); *Buckman Co. v. Plaintiffs Legal Comm*., 531 U.S. 341, 350 (2001) ("off-label" usage of medical devices is a corollary of the FDA's mission to regulate *without directly interfering with the practice of medicine*) (emphasis added); Steven A. Engel, Assistant Att'y. Gen. Off. of Legal Couns., *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions* (May 3, 2019) ("FDA does not regulate the practice of medicine, which includes "off-label" prescribing.").

The FDA itself acknowledges the relationship between its regulations and the power of the states over the practice of medicine, even when state law would have the effect of restricting access to mifepristone. Currently, the FDA allows non-physician healthcare providers to prescribe mifepristone. JA33. However, even though the REMS specify the qualifications certified prescribers must meet (REMS

[17] *Mifepristone Patient Agreement Form*, U.S. Food and Drug Administration (Jan. 2023). Mifepristone REMS, *supra* fn. 9.

Para. II.A.1.a.), the FDA defers to state law on the question of which health care providers are allowed to prescribe medications in a particular state. "Some states allow health care providers other than physicians to prescribe medications. Health care providers should check their individual state laws." *Mifepristone Q & A,* No. 15, fn. 15. By GenBioPro's logic, such licensing laws should be invalidated because the REMS have occupied the field of who may prescribe mifepristone, and state licensing laws that limit prescribers to physicians necessarily restrict access to it. The FDA itself disagrees with GenBioPro's argument.

3. Congress's Federal Interest in Regulation of Mifepristone Does Not Support Preemption of the UCPA

GenBioPro asserts that Congress has a dominant federal interest in regulation of mifepristone because "it must maintain uniform regulatory standards to create workable policy." GOB at 31. However, GenBioPro relies on cases involving state or local legislation in areas that have traditionally been under the exclusive control of the federal government. *Campbell v. Hussey*, 368 U.S. 297 (1961) (state law requiring label on tobacco products sold in interstate commerce identifying geographic origin preempted by Federal Tobacco Inspection Act mandating national standards for classifying tobacco "regardless of any factors of . . . geographical nature"); *City of Burbank v. Lockheed Air Terminal, Inc.,* 411 U.S. 624, 626 (1973) (federal aviation laws, enacted pursuant to federal government's "complete and exclusive national sovereignty in the airspace of the United States" preempted local

law placing a curfew on flights from the local airport); *United States v. Ariz.*, 567 U.S. 387 (2012) ("Arizona") (*federal immigration law* preempted state immigration laws because the former is rooted in the Constitution and is not an area of traditional police power); *United States v. Locke*, 529 U.S. 89, 108 (2000) (state regulations for oil tankers were preempted by federal laws where "*Congress has legislated in the field from the earliest days of the Republic*"); *Ray v. Atl. Richfield Co.,* 435 U.S. 151 (1978) (same federal regulatory scheme as *Locke*); *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 474 (4th Cir. 2014) *aff'd sub nom. Hughes v. Talen Energy Mktg., LLC,* 578 U.S. 150 (2016) (holding that Maryland's program to subsidize the participation of a new power plant in the federal wholesale energy market was preempted by the exclusive power of the Federal Energy Regulatory Commission to regulate wholesale sales of energy in *interstate commerce*).[18] In these cases where states are legislating in a field traditionally reserved to the federal government, no presumption against preemption exists. *Wyeth,* 555 U.S. at 565.

This case involves the opposite. Congress has legislated in a field (health and safety) which is traditionally within state power. *See* Sec. I. Even if the FDA's "system" of drug regulation is a national federal function (GOB at 32-33), abortion regulation is not. *Dobbs* has decided this issue definitively. *Id.* at 302. GenBioPro's

[18] The District Court rejected GenBioPro's Commerce Clause claims, and GenBioPro has not appealed this ruling. JA278-288.

claim that Congress intended that the FDA, an agency comprised of unelected bureaucrats, could arrogate the authority of the states to regulate abortion, therefore, must fail.

This case is similar to *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894 (2019), in which the Court declined to invalidate a state law banning uranium mining, despite the "significant authority over the milling, transfer, use, and disposal of uranium" granted to the Nuclear Regulatory Commission ("NRC") by the Atomic Energy Act ("AEA"). Because "Congress conspicuously chose to leave untouched the *States' historic authority* over the regulation of mining activities on private lands within their borders" (emphasis added), the Court declined to find that the AEA preempted the state ban on uranium mining. *Id*. at 1900. Significantly, the Court stated that a litigant could not invoke "some brooding federal interest" but must point to "a constitutional text or federal statute that does the displacing or conflicts with state law." *Id.* at 1901. The AEA specifically stated that the NRC's regulatory powers arose only *after* the uranium was removed by mining. In this case, the Saving Clause specifically disavows field preemption and allows preemption only in the case of a "direct and positive conflict." The Saving Clause, coupled with the absence of any regulations regarding the abortion decision itself in the federal regulatory scheme, vitiates GenBioPro's field preemption claim.

GenBioPro's textual arguments for dominant federal interest are misguided. The requirement that the FDA must consider the impact of its "additional elements" on access to the drug by certain people groups (GOB at 33) does not mean that the FDA must guarantee that those groups, or any group, be able to access the drug for any reason anywhere in the country, regardless of state law. The use of the mandatory word "shall" throughout § 355-1 (GOB at 35) by its own terms imposes obligations only on the Secretary, not on the states, and does not indicate that the latter has exclusive control over anything but the REMS. The limited nature of the Secretary's authority is obvious since the Mifepristone REMS are silent as to the reasons underlying the abortion decision, and the FDA does not endorse or guarantee the availability of any drug. *See* Sec. I *supra*. Congress did not order the "FDA to consider the burden on the *national* 'health care delivery system' in calibrating restrictions on access." GOB at 33. The word "national" does not occur in § 355-1(f)(2)(D). This assertion is either an implicit attempt to import a Commerce Clause claim, which the District Court rejected (JA278-288), into GenBioPro's preemption claim, or it is an attempt to once again make the assumption that the federal regulations sought to preempt state law. But the latter intent appears nowhere in the regulatory scheme. Furthermore, the requirement in terms of burden on the system was that the elements to assure safe use for mifepristone should conform to those for other similar drugs and that they be "compatible with established distribution,

procurement, and dispensing systems for drugs." *Id*. The UCPA does not address or affect either of these two concerns, so it does not impose any burdens on the healthcare system at all, national or otherwise. In fact, by limiting abortion, the UCPA *reduces* the burden on the healthcare system in West Virginia.

Finally, the FDAAA legislative history that GenBioPro cites is also unhelpful to its case (GOB at 38). The word "alone" does not appear in Rep. Barton's comment.[19] Rep. Pitts' comment, taken in context, was made not with respect to drugs, but with respect to medical devices for which there is an express preemption provision. *Wyeth*, 555 U.S. at 567.[20] Rep. Sullivan's comments were concerned only with conflicting state labeling requirements for prescription drugs and were not general statements regarding preemption of state laws.[21]

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[19] "The legislation before us today strives to ensure *that the FDA has the authority* to monitor drugs to ensure that the balance between the benefit and the risk remains in equilibrium." 153 Cong. Rec. H10595 (daily ed. Sept. 19, 2007) (statement of Rep. Barton)(emphasis added)

[20] "Can you please explain what issues make UDI [unique device identifier] for devices more complicated along with the steps that you are proposing to address those concerns? . . . Would it not be counterproductive to public health for States to impose different REMS requirements than those imposed by the FDA ?" *Discussion Drafts Concerning Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and Certain Pediatric Pharmaceutical and Device Legislation: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 50 (2007) (statement of Rep. Joseph R. Pitts).

[21] Id. at 54 ((statement of Rep. John Sullivan).

Abortion regulation is a field traditionally occupied by the states, and Congress has not clearly manifested its intent to preempt state law. *Wyeth*, 555 U.S. at 565. Therefore, the presumption against preemption applies and GenBioPro's field preemption argument fails.

B. There is no "Direct and Positive Conflict" Between the Federal Regulatory Scheme and the UCPA.

A state statute can also be impliedly preempted if it conflicts with federal law. Conflicts include cases involving the physical impossibility of complying with both federal and state regulations, as well as cases where the state law stands as an obstacle to the accomplishment and execution of the purposes and objectives of Congress. *Arizona*, 567 U.S. at 399-400. However, as a corollary to the general rule, "[t]he teaching of this Court's decisions . . . enjoins seeking out conflicts between state and federal regulation where none clearly exists." *Huron Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960) ("Huron") (holding that federal ship inspection laws for ships operating in interstate commerce did not preempt Detroit Smoke Abatement Code which protected the health and cleanliness of the local community). GenBioPro fails to show a clear conflict between the UCPA and the REMS.

1. It Is Not Impossible for GenBioPro to Comply with Both Federal Law and the UCPA.

GenBioPro's claim that it is "impossible" for it to comply both with the REMS and the UCPA is untenable. GOB at 42-44. Impossibility has been found when state

and federal law conflict so directly that it is literally impossible to comply with both. In *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013), the Court found that a state law design-defect claim that turned on the adequacy of a drug's warning was preempted by the FDCA's prohibition on a manufacturer making any unilateral changes to a drug label once it was approved by the FDA. Therefore, it was literally impossible for the manufacturer to strengthen the drug label to comply with state law without violating federal law. *See Fla. Lime & Avocado Growers, Inc. v. Paul,* 373 U.S.132, 143 (1963) (noting that physical impossibility would exist if a federal law forbade the picking and marketing of any avocado testing more than 7% oil and a state law excluded from the state any avocado measuring less than 8% oil).

In *Wyeth,* the Court rejected impossibility preemption of a state damages action based on inadequate warning on a drug label because it found that the FDA's regulation permitted the drug manufacturer to unilaterally strengthen its warning. *Id*. at 573. Furthermore, where there is "no federal standard" that conflicts with state law, there is no impossibility of complying with both. *See Freightliner Corp. v. Myrick,* 514 U.S. 280, 289 (1995) (holding no preemption of state common-law negligent design defect lawsuit where nothing in the federal act regulated the use of antilock braking systems in tractor-trailers).

GenBioPro does not point to any direct conflict between the state and federal regulatory schemes that would make it physically impossible to comply with both.

Since there is "no federal standard" in the FDAAA or in the Mifepristone REMS that regulates abortion, and the UCPA regulates abortion not drug safety, there is no conflict based on impossibility of complying with both. The REMS do not require GenBioPro to conduct business in West Virginia, or in any state at all (JA270-271), and the UCPA does not prohibit it from doing so. Licensed medical professionals can comply with the abortion regulations and then, where an abortion is allowed under the UCPA, fully comply with the FDA's Mifepristone REMS regulations. GenBioPro's argument is not a physical impossibility argument, but rather is one of *economic* "impossibility," because it speculates that reduced demand for mifepristone will make it infeasible to continue doing business in the state. GOB at 44. GenBioPro has cited to no case that based impossibility preemption on less favorable economies of scale for a business.

2. The UCPA Does Not Stand as an Obstacle to the Purposes and Objectives of Congress

A state law can also be conflict preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (holding that a state law requiring alien registration was preempted by the Federal Alien Registration Act of 1940). However, even in conflict preemption, the presumption against preemption applies. *Wyeth*, 555 U.S. at 565. GenBioPro ignores the presumption and, at every turn, assumes the

opposite, namely that Congress intended to preempt state abortion laws, even though nothing in the language of the REMS statutes supports its position.

To support its argument that the UCPA stands as an obstacle to Congress's objectives, GenBioPro first claims that the intent of Congress was to "expand" access to the drug mifepristone and that this was stated in the preamble to the FDAAA. GOB 45. GenBioPro then claims that the UCPA's restriction on access conflicts with Congress's purpose. *Id*. However, the intent of Congress was not to "expand access" to drugs, but rather to ensure drug safety without unduly burdening access (*See* Sec. I, *supra*). The UCPA's abortion restrictions thus do not stand as an obstacle to Congress's purposes and objectives because the purpose and effect of the UCPA do not interfere with and have nothing to do with drug safety.

GenBioPro's next argument is that the UCPA impermissibly upset the FDA's balance between "access and burden" (GOB 47) and so stands as an obstacle to Congress's purpose. This is incorrect because the balance struck by the FDA is between *safety* (not access) and burden, the balance only applies to the Secretary's actions, not the states, and the UCPA does not regulate the safety of the drug mifepristone. Therefore, the UCPA cannot upset any balance struck by Congress between safety and access. *See* Secs. I and II, *supra*. The UCPA's restrictions are in addition to, not contradictory to, the REMS requirements. Once a licensed medical professional determines that an abortion is permissible under W. Va. Code § 16-2R-

3, a woman's access to mifepristone and the procedures set in place by the FDA come into play and are not affected by any other provision of the UCPA.

GenBioPro further argues that the UCPA conflicts with the REMS by imposing additional requirements that the FDA did not deem necessary. GOB at 48-50. The UCPA's "threshold requirements" are not presumptively preempted because they do not "clearly" contradict the REMS requirements but are in addition to them. *Huron,* 362 U.S. at 446. In *Wyeth* the "minimal standards" for drug labels served as a "floor upon which States could build." The Court found that the FDA's labeling rules did not preempt a state law duty to provide a stronger warning. The FDA has long acknowledged that state tort law could coexist with federal labeling standards. *Id*. at 577-78. Similarly, in *Eng. v. Gen. Elec. Co*., 496 U.S. 72 (1990) the Court allowed a state law claim based on whistleblower retaliation because the prohibition of whistleblower retaliatory lawsuits in the federal Energy Reorganization Act of 1974 was limited to the remedy provide by the Act itself and did not suggest that it supplanted state-law causes of action. *Id.* at 87-88.

There is no reason to come to a different conclusion with respect to the UCPA's abortion restrictions. Because the FDA does not address the availability or circumstances under which an abortion can be obtained, additional state regulations that do not directly conflict with the FDA's drug safety regulations are not

impermissible. This conclusion is underscored by the longstanding state power to regulate abortion and the existence of the presumption against preemption.

CONCLUSION

For the foregoing reasons, the District Court's decision to grant Appellees' motion to dismiss should be upheld.

Respectfully submitted,

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RULE 32 (g) CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE

I certify that this brief complies with the length limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B), the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5)(A), and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6).

This brief was prepared using a proportionally spaced typeface (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f), this brief contains 6,391 words. This certificate was prepared in reliance on the word-count function of the word-processing system (Microsoft Word 365) used to prepare this brief.

/s/ Catherine W. Short

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes and Patrick Morrissey

Pursuant to FRAP 26.1 and Local Rule 26.1,

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(name of party/amicus)

who is amicus curiae, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
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If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

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If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Catherine W. Short Date: April 12, 2024

Counsel for: Life Legal Defense Foundation

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