No. 23-2194

United States Court of Appeals for the Fourth Circuit

GENBIOPRO, INC.,
PLAINTIFF-APPELLANT,

v.

KRISTINA D. RAYNES, ET AL.,
DEFENDANTS-APPELLEES.

APPEAL FROM THE U.S. DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA, NO. 23-CV-58, HON. ROBERT C. CHAMBERS, PRESIDING

BRIEF OF FAMILY RESEARCH COUNCIL AND CONCERNED WOMEN FOR AMERICA AS *AMICI CURIAE* SUPPORTING APPELLEES AND AFFIRMANCE

CHRISTOPHER MILLS
Spero Law LLC
557 East Bay Street #22251
Charleston, SC 29413
(843) 606-0640
cmills@spero.law

Counsel for *Amici Curiae*

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. Raynes, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Family Research Counsel
(name of party/amicus)

who is amicus, 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
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES☑NO
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:

6. Does this case arise out of a bankruptcy proceeding? ☐YES☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES☑NO
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/ Christopher Mills Date: Apr. 15, 2024

Counsel for: Amicus Family Research Council

Print to PDF for Filing

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. Raynes, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Concerned Women for America
(name of party/amicus)

who is amicus, 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
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES☑NO
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:

6. Does this case arise out of a bankruptcy proceeding? ☐YES☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES☑NO
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/ Christopher Mills Date: Apr. 15, 2024

Counsel for: Concerned Women for America

Print to PDF for Filing

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICI CURIAE*

Family Research Council (FRC) is a Washington, D.C.-based nonprofit research and educational organization that seeks to advance faith, family, and freedom in public policy from a biblical worldview. FRC recognizes and respects the inherent dignity of every human life from conception until death and believes that the life of every human being is an intrinsic good, not something whose value is conditional based on its usefulness to others or to the state. We believe that all human life has been made in the likeness and image of God (Genesis 1:26). Accordingly, FRC recognizes the inherent dignity of every woman, and supports the creation and use of proper medical ethics and standards designed to protect their health and well-being.

Concerned Women for America (CWA) is the largest public policy organization for women in the United States, with about half a million supporters in all 50 states. CWA advocates for traditional values that are central to America's cultural health and welfare. CWA is made up of people whose voices are often overlooked—average American women whose views are not represented by the powerful or the elite. Because the Appellant's arguments would lead to harm against women and their families, CWA has a substantial interest in this case.[1]

[1] The parties have given blanket consent to *amicus* briefs. Pursuant to Fed. R. App. P. 29(a)(4)(E), no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and, no person—other than *amici curiae*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief.

INTRODUCTION

"There is no federal pre-emption *in vacuo*, without a constitutional text or a federal statute to assert it." *Puerto Rico Dep't of Consumer Affs. v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988). Yet neither GenBioPro nor its *amici* point to any federal law that preempts West Virginia's regulation of abortion. As GenBioPro's lead counsel has elsewhere explained, "[a]lthough legislation and FDA regulations have evolved over the past eight decades," one "feature[] of the regulatory regime" has "remained constant": "even as Congress has 'enlarged the FDA's powers,'" it has 'taken care to preserve state law.'" Brief for Respondents 3, *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, 2018 WL 6012388 (U.S. Nov. 14, 2018) (brackets omitted) (quoting *Wyeth v. Levine*, 555 U.S. 555, 567 (2009)) ("*Merck* Br."). As counsel has explained, "Congress has never enacted a prescription-drug preemption provision, despite numerous opportunities to do so." Brief for Respondent 27, *Wyeth*, No. 06-1249, 2008 WL 3285388 (U.S. Aug. 7, 2008).

Finding no preemption provision to guarantee its desired sales, GenBioPro turns to implied preemption. But "[i]mplied preemption analysis does not justify" GenBioPro's endeavor, which amounts to a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (cleaned up). Even implied preemption must "begin" "with the relevant text," and the preemption threshold is "high." *Id.* at

607–08. "Invoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law." *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1901 (2019) (plurality opinion).

Lacking any footing in statutory text, GenBioPro and its *amici* rely mostly on policy arguments, with sprinkles of statutory history. Statutory context and history are relevant to "divining meaning." *Abramski v. United States*, 573 U.S. 169, 179 (2014). But here, context and history only confirm what the absence of a preemption provision suggests: that Congress has never thought that state law "posed an obstacle to its objectives" here. *Wyeth*, 555 U.S. at 574. If it had, "it surely would have enacted an express pre-emption provision at some point during the FDCA's [8]0-year history." *Id.* As the Supreme Court said in agreeing with GenBioPro's counsel, Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state [regulation], is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. "[A]ll evidence of Congress' purposes is to the contrary." *Id.* at 574.

Finding no help in the original Federal Food, Drug, and Cosmetic Act (FDCA), GenBioPro puts all its eggs in the 2007 Food and Drug Administration Amendments Act (FDAAA). But once again, take it from GenBioPro's counsel: "As [*Wyeth*] recognized, the FDAAA did not change the preemption analysis." *Merck* Br. 24; *see Wyeth*, 555 U.S. at 567–68. It too lacks a broad preemption provision.

Now, GenBioPro insists that Congress's restrictions *on the FDA* via the FDAAA implicitly preempts state laws that would not have been preempted before. West Virginia shows why this theory is wrong, the simplest reason being that the FDCA, including after the FDAAA, merely provides a regulatory floor. Federal law does not give GenBioPro "an unconditional right to market [its] federally approved drug at all times" no matter what state law says. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 319 (2019) (Thomas, J., concurring) (cleaned up). Instead, federal law "provides a federal floor that can be supplemented by different state standards." *Id.* at 320. Thus, federal law does not occupy this field, and West Virginia law does not otherwise conflict with federal law.

This brief elaborates on the FDAAA's statutory history, which confirms the unsoundness of GenBioPro's preemption theories. The statutory history shows that Congress intended no changes in preemptive effect via the FDAAA. That amendment simply placed restrictions on FDA's approval of certain drugs—codifying regulations that the FDA was using for drugs like mifepristone, which had already been approved. The legislative history, to the extent relevant, confirms the point: the FDAAA had nothing to do with preemption of state law, and it was not focused simply on "accessibility." Federal law does not confer an unfettered right to sell mifepristone for any use. The district court's decision should be affirmed.

ARGUMENT

I. The statutory history does not support a preemption claim.

The statutory history of the FDCA, including the FDAAA, shows that Congress wanted to impose federal safety restrictions on prescription drugs—not strip states of their power to add health and safety regulations as well.

A. The FDA's development has complemented state law requirements.

Prescription-drug policy in the United States and the FDA's regulatory power has gradually "developed through a process of punctuated evolution." Jerry Avorn et al., *The FDA Amendment Act of 2007—Assessing Its Effects a Decade Later*, 379 N. Engl. J. Med. 1097, 1097 (2018). But its evolution does not stem from a desire to expand federal power or to displace states' efforts to protect its citizens. Instead, the FDA's transformation has been driven by crises. *See id.*

National concerns about "patent medicines" with "primarily alcohol or opium" ingredients led to the initial 1906 Pure Food and Drug Act, *see id.*, which "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs." *Wyeth*, 555 U.S. at 566. The statute "focused on postmarketing remedies only." Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 152 (2007). So only when a drug was already on the market and proven to be dangerous could it be seized. *Id.*

The early 20th century saw a flood of ineffective and dangerous drugs entering the market. *Wyeth*, 555 U.S. at 566. After over 100 people died from a toxic formulation of sulfanilamide in 1937, Congress approved a "stronger form of regulation" through the Federal Food, Drug, and Cosmetic Act (FDCA). Institute of Medicine, *supra*, at 152. The new statute's "most substantial innovation was its provision of *premarket* approval of new drugs." *Wyeth*, 555 U.S. at 566 (emphasis added). Congress required every drug manufacturer "to submit a new drug application, including reports of investigations and specimens of proposed labelling, to the FDA for review." *Id*. The statute prohibited a manufacturer from distributing a drug until its new application became effective. *Id*. All applications, however, would become effective 60 days after filing unless the FDA could show "that the drug was not safe for use as labeled." *Id*.

The burden of proof shifted from the FDA to the drug manufacturer after Congress's 1962 amendments to the FDCA. *Id*. at 567. The amendment required manufacturers to show that its drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." *Id*. The manufacturer needed to prove both safety *and* effectiveness by introducing "substantial evidence that the drug will have the effect it" suggests in the proposed labeling. *Id*.

As the FDA's powers enlarged "to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state

law." *Id*. After all, the FDCA was "nonetheless still somewhat weak," Institute of Medicine, *supra*, at 152, and the FDA had limited resources. Thus, "[t]he 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Wyeth*, 555 U.S. at 567 (quoting Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 781, 793). "Consistent with that provision, state common-law suits continued unabated." *Id.* (cleaned up). Congress reiterated this position on drug regulation preemption in 1976, when it "enacted an express pre-emption provision for medical devices" but "declined to enact such a provision for prescription drugs." *Id.*

Dangerous drugs continued to get FDA approval—and harm consumers. Specifically, rofecoxib (Vioxx) became "an important trigger for changes in how the Food and Drug Administration collects, analyzes, and acts on evidence of drug risks." Avorn et al., *supra*, at 1097. After Vioxx entered the market in 1999, several studies and large trials showed that the drug increased the risk of cardiovascular events—potentially doubling the incidence of heart attacks and strokes. *Id*. By 2006, Congress and the public demanded "to know how one of the country's best-selling drugs could carry such important risks without the FDA's being aware of their magnitude and importance." *Id*. At that time, the FDA only relied on "spontaneous, individual case reports of possible adverse reactions as its main source of postapproval

surveillance information"—a "notoriously limited way" of identifying problems with the drugs and determining their severity. *Id*.

Congress sought to respond to these deficiencies through the FDAAA. *Id*. at 1098; *see* Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). The FDAAA "instructed the FDA to build a population-based surveillance system to harness the enormous reservoir of data on medication use and clinical events generated automatically during routine electronic recording of filled prescriptions and virtually all other medical encounters." Avorn et al., *supra*, at 1098. The FDAAA also required that information on all clinical trials be recorded on a public database soon after a trial's inception. *Id*. Thus, the FDAAA "introduced important improvements in the FDA's capacity to track medication effects and mitigate risk." *Id*.

Further, in the provision focused on by GenBioPro here, the FDAAA gave FDA discretion to implement risk evaluation and mitigation strategies that "require physician certification, mandatory risk communications, or laboratory testing when specific high-risk medications are used." *Id*.

B. Congress has always left state law intact.

In the years before the FDAAA's enactment, the agency had changed its position on FDCA preemption and started "argu[ing] that [the statute] impliedly preempts many" state law requirements. David A. Kessler & David C. Vladeck, *A*

Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 Geo. L.J. 461, 464 (2008); *see* 72 Fed. Reg. 3,922, 3,935 (Jan. 24, 2006) ("FDA interprets the act to establish both a 'floor' and a 'ceiling.'"). The Supreme Court in *Wyeth* rejected the FDA's new position. *See* 555 U.S. at 580–81 ("[T]he complex and extensive regulatory history and background relevant to this case undercut the FDA's recent pronouncements of pre-emption, as they reveal the longstanding co-existence of state and federal law and the FDA's traditional recognition of state-law remedies." (cleaned up)).

Congress itself rejected that position in the FDAAA. First, "the infusion of resources that [would] come as a result of the enactment of the [FDAAA] suggests that Congress did not share the FDA's view that it is capable of adequately safe-guarding the public health on its own." Kessler & Vladeck, *supra*, at 468. Second, when Congress enacted the FDAAA, "it again chose not to enact a generally applicable express preemption provision, despite efforts by the pharmaceutical industry to obtain such a provision." Brief of Public Law Scholars as *Amici Curiae* in Support of Respondents 6–7, *Merck*, No. 17-290, 2018 WL 6168776 (U.S. Nov. 21, 2018). "The legislative record indicates that Congress considered the amendments' preemption implications and that, ultimately, Congress decided to expressly preempt only a very narrow category of state regulation." *Id.* at 7 (footnote omitted) (citing § 282(d),

121 Stat. 922 (preempting state registering requirements for certain clinical trials)). Thus, the FDAAA did not "broaden[] the FDCA's preemptive effect." *Id.* at 8 n.4.

GenBioPro emphasizes the FDAAA's REMS protocol, but that protocol simply codified existing approval processes—and still left the relevant FDCA provisions without any preemption provision. Though the REMS statutory structure was new, the underlying type of regulation was not. As the FDA's chief counsel explained just after the FDAAA was enacted, "plans that are intended to address and mitigate risk for certain drugs are nothing new." Gerald F. Masoudi, *Legal Developments in the Enforcement of Food and Drug Law*, 63 Food & Drug L.J. 585, 586 (2008). He continued: "FDA has for decades worked with sponsors to develop and implement plans to mitigate risks," including through "risk management plans" ("RiskMAPs") that "covered many well know[n] drugs" (including thalidomide). *Id.* The FDAAA simply gave FDA "authority to *mandate* these plans when certain statutory triggers are met." *Id.* at 587 (emphasis added); *see also* Kessler & Vladeck, *supra*, at 491 ("the agency has been imposing these sorts of requirements for some time").

Thus, REMS added a potential prerequisite to approval (or continued approval) of a drug. As explained, FDA approval had not been understood to preempt state law under the FDCA. And nothing in the FDAAA expresses any intent to change that federal-state balance. So no matter how detailed the REMS requirements

might be, the ultimate issue—whether a drug is approved—still has no bearing on whether states may place additional regulations on top of the federal floor. And the discretionary REMS option does not change the need for state regulations. "For example, REMS programs covering the use of extended-release and long-acting opioids often focus on how to use these products more than on how to avoid prescribing them." Avorn et al., *supra*, at 1099.

GenBioPro never explains why Congress would intend for an approval with REMS to be preemptive while an outright approval—demonstrating the agency's view that no REMS was necessary (*see* 21 U.S.C. § 355-1(a))—would *not* be preemptive. Nothing in the statutory text or history supports this strange understanding of congressional intent.

Any assertion that the FDAAA simply wanted to make drugs available that would otherwise not be is also belied by the history. Put aside that "it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law." *Norfolk Southern R. Co. v. Sorrell*, 549 U.S. 158, 171 (2007). Put aside too that if the goal of the FDCA process were simply "accessibility," the statutory scheme makes little sense. *See* Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 Mich. St. L. Rev. 1, 12 (2016) ("[A]pproval of a new drug application represents a necessary but hardly sufficient condition for patient access.").

Even focusing on drug availability, the history shows that many REMS drugs already had similar RiskMAPs in place. And the FDAAA specified that any "drug that was approved before the effective date of this Act is" "deemed to have" a REMS plan "in effect" already if those agreements were in place. § 909(b), 121 Stat. 950–51. An FDA rule after the FDAAA confirmed the applicability of the REMS protocol to those preexisting, already-approved drugs—specifically including mifepristone. 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008).

So before the FDAAA was ever enacted, mifepristone had been approved for use by the FDA. GenBioPro never claims that its pre-FDAAA approval was preemptive. And nothing in the FDAAA changed that preemption analysis: a drug that had already been approved with a voluntary safety protocol remained approved with a mandatory safety protocol. At both times, the drug was approved for use. As *Wyeth* (and GenBioPro's counsel) pointed out, nothing in the FDAAA changed the non-preemptive effect of that approval. The "enhance[d]" "postmarket authorit[y]" emphasized by GenBioPro has nothing to do with the question of federal preemption of state law. Br. 45 (quoting FDAAA pmbl., 121 Stat. 823). The FDA's use of mandatory rather than voluntary protocols for approved drugs does not alter the nature of federal approval as a floor for regulation, not a ceiling. The statutory history thus refutes GenBioPro's preemption argument.

II. The legislative history does not support a preemption claim.

In cursory fashion, GenBioPro argues that "[t]he FDAAA's legislative history confirms Congress's intent to grant FDA alone authority 'to ensure that the balance between the benefit and the risk remains in equilibrium.'" Br. 38 (quoting 153 Cong. Rec. H10595 (daily ed. Sept. 19, 2007) (statement of Rep. Barton)). Presumably recognizing that says nothing about preemption, GenBioPro then notes statements from two representatives from a subcommittee hearing about bill discussion drafts. One representative expressed broad concerns about "conflicting State labeling requirements for drugs" generally.[2] The other representative simply questioned whether states should "impose different REMS requirements than those imposed by the FDA."[3] GenBioPro does not explain how those statements connect to any statutory language enacted, much less how they are relevant here, given that West Virginia has not "impose[d] different REMS requirements" or other labeling.

This embarrassing use of legislative history—two representatives at most advocating for an absent preemption provision desired by the pharmaceutical industry, as discussed above—reveals the weakness of GenBioPro's statutory history

[2] *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. 54 (2007) (statement of Rep. Sullivan).

[3] *Id.* at 50 (statement of Rep. Pitts).

argument. It epitomizes why the Supreme Court has cautioned that "legislative history is itself often murky, ambiguous, and contradictory." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005). "Judicial investigation of legislative history has a tendency to become . . . an exercise in looking over a crowd and picking out your friends." *Id.* (cleaned up). That the Supreme Court has cautioned against using even "legislative materials like committee reports" (*id.*) underscores that GenBioPro's edited quotations of two representatives' questions during a subcommittee hearing on *discussion drafts* of future legislation has nothing to do with any proper statutory interpretation inquiry.

To the extent it matters, the legislative history about the bills that became the FDAAA provides far better direct evidence that most representatives understood the legislation to continue the FDCA's policy of non-preemption of state law. *See, e.g.*, 153 Cong. Rec. S25038 (Sept. 20, 2007) (statement of Sen. Kennedy, the chief sponsor of the FDAAA in the Senate) ("By enacting this legislation, we do not intend to alter existing state law duties . . . We do not believe that the regulatory scheme embodied in this act is comprehensive enough to preempt the field or every aspect of state law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum."); *id.* at S25039 (statement of Sen. Kennedy)

("Legislation designed to protect consumers from dangerous drugs must not be distorted into a shield protecting drug companies from accountability"); *id.* at S25042 (statement of Sen. Durbin) (criticizing "a creeping trend in recent years toward implied and agency preemption of state laws" and noting that "Congress does not intend to preempt state requirements" but instead "recognizes that State liability laws . . . play an essential role in ensuring that drug products remain safe and effective for all Americans"); *id.* at H10598 (statement of Rep. Green) (explaining that "one thing is clear: the Congress in no way intends to limit the ability of a patient injured by a drug to seek redress from" state legal remedies: "the conference agreement makes this perfectly clear."); H.R. Rep. No. 110-225, at 197 (2007) (additional views of Rep. Green and others) ("The additional regulation of pharmaceutical products proposed in this legislation is an effort to provide consumers with increased protection, not an effort to provide pharmaceutical manufacturers with immunity," and "[i]n no way do we intend to occupy this regulatory field.").

Thus, while the discussion about the FDAAA "provides ample opportunity to search the legislative history and find some support somewhere for almost any construction," *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 296 n.15 (2010) (cleaned up), GenBioPro's one-sided account is contrary to the weight of the legislative history expressly addressing preemption. And GenBioPro's selected quotations have no relationship to what matters for the

preemption analysis: the meaning of the statutory language in context. That language does not support preemption.

III. GenBioPro's supporting *amici*'s statutory history arguments are flawed.

Two sets of GenBioPro's *amici* try to use the FDAAA's history to advocate for preemption. Both accounts are unpersuasive.

A. The Historian *Amici*'s account is one-sided and irrelevant to preemption.

Start with the Historian *Amici*, who claim that "states have not traditionally regulated the drugs that doctors may prescribe, and the federal government has." Br. 5. That factual claim is dubious: on the same page of their brief, these *amici* concede that "[i]n the 18th century, some states implemented limited direct regulations of pharmaceuticals." *Id.*; *see also id.* at 23 ("23 states had laws against the adulteration of drugs by 1889"). These *amici* suggest that the laws were "limited" because they focused on "reducing fraud and deception," penalized "the distribution of poisonous substances," included "consumer protection-focused regulations," and "prohibited drug adulteration." *Id.* at 5. All this sounds rather like the FDCA. And the *amici* do not explain why they consider these laws "limited," except to note the irrelevant fact that states did not generally have the same bureaucratic drug approval process.

Regardless, the point is that states always had the power to regulate drugs for health and safety reasons—and they used that power. Even if states had *not* used that

power—or had used it "ineffective[ly]" (*id.* at 9)—that would not give rise to preemption untethered from statutory text. Regardless of whether the federal government appropriately exercises certain power under the Commerce Clause, states retain the general police power to legislate on all subjects unless forbidden by the Constitution or valid federal law. *See Bond v. United States*, 572 U.S. 844, 854 (2014). And these *amici* point to nothing in federal law that suggests an intent to nullify state laws like West Virginia's that (at most) supplement the federal drug regulations.

The Historian *Amici* claim that the FDCA was intended to provide a "[a] uniform, national regime in pharmaceutical regulation." Br. 18. But again, that simply elides the question: did it intend to *preempt* state law regulations or set a floor? And the Supreme Court has repeatedly answered that question, agreeing with GenBioPro's counsel that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's [8]0-year history." *Wyeth*, 555 U.S. at 574 (citation omitted). "Its silence on the issue, coupled with its certain awareness of the prevalence of state [regulation], is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. Congress evidently "recognized that state-law remedies further consumer protection

by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 574.

Next, the Historian *Amici* claim that "the past deficiencies of state regulation became dangerously apparent in the wake of several tragedies caused by unregulated medicines." Br. 18. They fail to address several tragedies that still happened under the FDA's regulations—tragedies that have long been remedied by states' protections. For instance, state laws provide far more extensive "information-gathering tools" than the FDCA gives the FDA, which generally cannot obtain "records of internal discussions or evaluations by company physicians and scientists." Kessler & Vladeck, *supra*, at 491.

A few examples illustrate this point. State law claims revealed that Merck, the manufacturer of Vioxx, "was acutely concerned about the heart attack risk associated with Vioxx before the FDA understood the risk" and before the manufacturer alerted the agency to the risk. *Id*. State law litigation also uncovered risks associated with the sleeping medication Halcion, the arthritis medication Zomax, and the weight loss medication ephedra, which led the FDA to take these three medications off the market. *Id*. at 493. States have stepped in to regulate opioid prescriptions, given the laxity of their REMS protocols. *See* Centers for Disease Control and Prevention, *State Successes*, https://www.cdc.gov/drugoverdose/policy/successes.html (last visited Apr. 13, 2024); Avorn et al., *supra*, at 1099. And state laws have provided redress

to consumers harmed by FDA-approved drugs. *E.g.*, *Wyeth*, 555 U.S. at 559 (state law redressing inadequate labeling of drug resulting in the amputation of a professional musician's arm and the loss of her livelihood). These state remedies are possible precisely because the FDCA does not preempt them—because Congress has repeatedly refused to add preemption to the FDCA.

So when the Historian *Amici* speak of an "assurance that the FDA, and not individual states, would control from end to end how medications were manufactured, processed, controlled, distributed, and advertised" (Br. 26), it is no wonder that they cite nothing to support this atextual "assurance"—it does not exist. Likewise, when they claim that Congress's "goal was to create regular and uniform standards for drugs that would supersede the vagaries of existing state regulations across the nation," they cite nothing to support that claim. *Id.* at 28. And they provide not one iota of evidence—no statement by a legislator, no congressional report, not even a claim by an advocacy group—in support of that claim.

Their final, extravagant assertion of "the inherent dangers of patchwork state regulation of pharmaceuticals" (*id.*) again has no citation, and disregards the long history of states protecting their citizens when federal regulations fail to ensure adequate safety standards. How could state safety regulations on top of federal regulations be "inherently dangerous"? "[S]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth*, 555 U.S.

at 579. These *amici* venture no "reasoned explanation . . . of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence." *Id.* at 577. Nor do they explain how "Congress [could] have 'left no room for supplementary state regulation' when the statute le[aves] open the precise type of state regulation at issue." Note, *Preemption As Purposivism's Last Refuge*, 126 Harv. L. Rev. 1056, 1068 (2013).

Preemption is fundamentally a question of congressional purpose tied to "the text and structure of the" statute, *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993), and the Historian *Amici* present nothing suggesting any congressional intent to preempt state laws like West Virginia's. Their historical account is both unbalanced and irrelevant to the question before the Court.

B. The Food and Drug Law and Health Law Scholar *Amici* ignore the regulatory history.

The Food, Drug, and Health Scholar *Amici*'s brief shares many of these problems. Their overarching argument is that "Congress intended for FDA to strike a precise balance" in the FDAAA: "A REMS drug with ETASU must be subject to patient access restrictions that allow it to reach the national market in the first instance, but cannot be subject to restrictions that render obtaining the drug impracticable." Br. 4. But the only "restrictions" Congress was concerned with were those imposed by the FDA. That makes sense: the entire REMS protocol is a discretionary decision left up to the FDA. The sub-provision continually referenced by GenBioPro

and its *amici* about FDA not imposing protocols "unduly burdensome on patient access to the drug" (21 U.S.C. § 355-1(f)(2)(C)) simply guides the FDA's use of discretion. *Accord* Scholar Br. 16 ("FDAAA mandates that FDA engage in a balancing exercise."). The REMS/ETASU provisions do not alter the underlying import of FDA approval, which continues to lack preemptive effect against state laws that supplement the federal floor.

The Scholar *Amici* acknowledge that "Congress's focus on patient safety . . . animates the statutory text and legislative history of the REMS with ETASU regime." Br. 3. They do not dispute that state legal requirements have been widely regarded as supplementing the FDA's safety regulations. Yet they claim that "another thread that motivated Congress to expand FDA's authority" was "that the REMS with ETASU regime would allow more drugs to enter the national market, drugs that would not have been approved *but for* such elements being in place." *Id.* The Scholar *Amici* cite nothing for this latter, other purpose. *Cf. Wyeth*, 555 U.S. at 574 ("Congress enacted the FDCA to bolster consumer protection against harmful products.").

Even if drug accessibility were one purpose of the FDAAA—or even its main purpose—the Scholar *Amici*'s "simplistic[]," atextual, purpose-based speculation underscores why the preemption analysis focuses on the text. *Sorrell*, 549 U.S. at 171; *see Foster v. Love*, 522 U.S. 67, 71 (1997) (focusing the preemption question

"on the meaning of the state and federal statutes" at issue). Again, that FDA could choose to approve some drugs using REMS does not change the underlying fact that FDA approval of a drug under the FDCA lacks preemptive effect. And as shown above, mifepristone is *not* a "drug[] that would not have been approved *but for* such elements being in place," for it had already been approved. So the REMS requirements only *restricted* mifepristone's continued FDA approval; it did not guarantee that approval, much less provide its manufacturers with a federal guarantee that they could sell the drug as they desired regardless of any state law. *Cf. Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 678 (2003) (Thomas, J., concurring in judgment) (emphasizing "the impossibility of defining 'purposes' in complex statutes at such a high level of abstraction and the concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others"); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting) (emphasizing the dangers of "running amok with our potentially boundless . . . doctrine of implied conflict pre-emption based on frustration of purposes").

The Scholar *Amici* speak of the "the exceptionality of the expanded authority that Congress granted to FDA in FDAAA." Br. 5. But as discussed (and as the *amici* eventually concede, *id.* at 11–12), the REMS protocol was not exceptional. It already existed in substantially similar fashion. The FDAAA simply gave the FDA authority to mandate a REMS protocol as a condition of approval (or continued approval).

Similar protocols had already been "voluntarily" agreed to by many manufacturers desirous of FDA approval. And this narrow, mandatory REMS authority is nested within the FDA's overall decision whether to approve a drug, which (as the Scholar *Amici* do not dispute) is not preemptive.

The Scholar *Amici* make no effort to explain as a matter of law or logic why *only* drug approvals with REMs would provide a guarantee to the manufacturer that it could sell its product in disregard of state law requirements. Again, why wouldn't the FDA's outright approval of a drug—with the implicit finding that the drug is so safe and effective that no REMS is needed—be preemptive, if an approval with REMS can be? For that matter, why would Congress want to preempt state requirements for a drug only while the lack of safety or efficacy data requires REMS, while permitting added state safety regulations once the evidence solidifies and any REMS is "removed" (Scholar Br. 16 n.9)?

Like the Historian *Amici*, the Scholar *Amici* have no answers, which is presumably why their brief instead offers a vision of the *original* FDCA as guaranteeing "national uniformity" and "a national market." Br. 7–8. But that was the vision rejected by the Supreme Court. *See Wyeth*, 555 U.S. at 575 ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."). And these *amici* simply ignore the existence of the narrow express preemption added by the FDAAA on a clinical trial issue, *see* § 801(d)(1), 121 Stat. 922,

even though it shows that Congress knew how to preempt state law when it wanted to and specifically did not do so for drugs approved with REMs.

In a footnote, the Scholar *Amici* claim that "the only way [health care providers] could abide with both sets of restrictions is to stop prescribing, i.e., 'stop selling,' the drug in nearly every circumstance," which they say is a "solution" that "has been rejected by the Supreme Court." Br. 26 n.16 (citing *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013)); *see also* GenBioPro Br. 42–43 (same). Not so. One cannot determine whether "stop selling" is a permissible solution until one makes the determination of whether the state law contradicts federal law and is thus preempted. If the federal statute leaves room for added state regulations, that a person may be able to comply with federal law yet still be restricted by the added state regulation is unremarkable.

Consider this scenario, using the underlying facts of *Wyeth*: a drugmaker selling Phenergan, which was FDA approved, could either comply with added state law requirements or stop selling in that state. "Stop selling" is a permissible solution precisely because the FDCA (including the FDAAA) does not preempt those state requirements. To make "stop selling" an *im*permissible solution, the drugmaker would have to show that the federal regime preempts the relevant state laws to begin with—*i.e.*, that federal law gives the drugmaker an absolute *right* to sell its product as-is. But neither GenBioPro nor the *amici*'s brief points to any preemptive language

or adequately explains how the FDAAA changes the underlying FDCA preemption calculus. The Court should reject GenBioPro's and the *amici*'s effort to use the "stop selling" canard as a circular device to avoid their heavy burden of showing preemption. *See Merck*, 587 U.S. at 314 ("[W]e have refused to find clear evidence of such impossibility where the laws of one sovereign permit an activity that the laws of the other sovereign restrict *or even prohibit*." (emphasis added)); *see also Geier*, 529 U.S. at 873 (describing impossibility as "state law penalizes what federal law *requires*" (emphasis added)).

Finally, the Scholar *Amici* pretend that their only interest here stems from their "expertise," as they "have published extensively and have been quoted widely on topics related to the U.S. Food and Drug Administration." Br. 1. Courts are "not required to exhibit a naiveté from which ordinary citizens are free." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019) (cleaned up). Several of these scholars have elsewhere written that the very argument that they make here—that FDAAA preemption should "partially invalidate general abortion bans" and "force states to allow the sale and use of medication abortion"—is "uncertain." David S. Cohen, Greer Donley, & Rachel Rebouché, *The New Abortion Battleground*, 123 Colum. L. Rev. 1, 56 (2023). But they eagerly desired such challenges, despite the threat "that preemption for abortion-inducing drugs could have effects that impact other state regulation of health products," undermining "[c]onsumer safety." *Id.* at 64–65. After

all, the scholars reasoned, "the [pharmaceutical] industry already is bringing these lawsuits," so "[i]t would be a missed opportunity to not take advantage of these cases to . . . expand[] abortion access." *Id.* at 65.

Another Scholar *Amicus* explained just last year that "FDA traditionally regulates drug products and their labeling and marketing, *not the circumstances of their prescription, administration, and use*": "These elements have been traditionally viewed as part of the practice of medicine, an area left to state regulation."[4] This *amicus* went on to explain that the "FDA's REMS authority" is "limited," making it "essential that state licensing boards be brought into the regulatory ecosystem"—because they "can impose further requirements."[5]

In their brief here, the scholars omit any citation to these 2023 writings, but their change of tune makes their actual interest clear: "expanding abortion access." Indeed, a couple weeks ago, these scholars were exulting over their "[l]ong term strategy" that "begins today": "*Dobbs* must be overturned."[6] These individuals can pursue "expand[ed] abortion," as harmful to unborn children as it is. But no one should pretend that their interest in this case stems from any other goal, including

[4] I. Glenn Cohen et al., *Pressing regulatory challenges for psychedelic medicine*, 380 Sci. 347, 348 (2023) (emphasis added).
[5] *Id.*
[6] Greer Donley (@GreerDonley), X (Mar. 29, 2024, 11:10 A.M.), https://twitter.com/GreerDonley/status/1773729325600178259.

some neutral "expertise." The Scholar *Amici*'s recitation of the REMS statutory scheme does not support GenBioPro's novel, "uncertain" preemption argument.[7]

CONCLUSION

For these reasons, the Court should affirm.

Respectfully submitted,

s/ Christopher Mills
CHRISTOPHER MILLS
Spero Law LLC
557 East Bay Street #22251
Charleston, SC 29413
(843) 606-0640
cmills@spero.law

Counsel for *Amici Curiae*

APRIL 15, 2024

[7] Incidentally, their Columbia Law Review article also explains that GenBioPro voluntarily dismissed a similar suit it had filed in Mississippi—while "signaling that it will likely file in a more favorable jurisdiction." Cohen et al., *supra*, at 71. If an abortion pill challenger had done the same, these scholars (and many more) would be caterwauling about forum shopping—and impugning the impartiality of Article III judges. *E.g.*, Carrie N. Baker, *Texas Judge Doesn't Have Power to Ban Abortion Pills Nationwide, Say Legal Experts*, Ms. Magazine (Mar. 3, 2023), https://tinyurl.com/36pym5e3 (Cohen: "[W]e don't need to pre-comply with fascism.").

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this brief contains 6,372 words.

2. This document 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 this document has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

Dated: April 15, 2024

/s Christopher Mills
Christopher Mills

CERTIFICATE OF SERVICE

I, Christopher Mills, an attorney, certify that on this day the foregoing Brief was served electronically on all parties via CM/ECF.

Dated: April 15, 2024

s/ Christopher Mills
Christopher Mills

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

APPEARANCE OF COUNSEL FORM

BAR ADMISSION & ECF REGISTRATION: If you have not been admitted to practice before the Fourth Circuit, you must complete and return an Application for Admission before filing this form. If you were admitted to practice under a different name than you are now using, you must include your former name when completing this form so that we can locate you on the attorney roll. Electronic filing by counsel is required in all Fourth Circuit cases. If you have not registered as a Fourth Circuit ECF Filer, please complete the required steps at Register for eFiling.

THE CLERK WILL ENTER MY APPEARANCE IN APPEAL NO. 23-2194 as

☑ Retained ☐ Court-appointed(CJA) ☐ CJA associate ☐ Court-assigned(non-CJA) ☐ Federal Defender

☐ Pro Bono ☐ Government

COUNSEL FOR: Family Research Council and Concerned Women for America

_____ as the
(party name)

☐ appellant(s) ☐ appellee(s) ☐ petitioner(s) ☐ respondent(s) ☑ amicus curiae ☐ intervenor(s) ☐ movant(s)

s/ Christopher Mills
(signature)

Please compare your information below with your information on PACER. Any updates or changes must be made through PACER's Manage My Account.

Christopher Mills Name (printed or typed)	843-606-0640 Voice Phone
Spero Law LLC Firm Name (if applicable)	_____ Fax Number
557 East Bay St. #22251 Charleston, SC 29413 Address	cmills@spero.law E-mail address (print or type)

CERTIFICATE OF SERVICE *(required for parties served outside CM/ECF)*: I certify that this document was served on _____ by ☐ personal delivery; ☐ mail; ☐ third-party commercial carrier; or ☐ email (with written consent) on the following persons at the addresses or email addresses shown:

_____ _____
Signature Date

1/28/2020 SCC