No. 24-1576(L), 24-1600, 24-1617

United States Court of Appeals for the Fourth Circuit

AMY BRYANT,
PLAINTIFF-APPELLEE,

v.

TIMOTHY K. MOORE, ET AL.,
INTERVENORS/DEFENDANTS-APPELLANTS

AND

JOSHUA H. STEIN, ET AL.,
DEFENDANTS-APPELLEES.

APPEAL FROM THE U.S. DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA, NO. 23-CV-77, HON. CATHERINE G. EAGLES, PRESIDING

BRIEF OF FAMILY RESEARCH COUNCIL AND CONCERNED WOMEN FOR AMERICA AS *AMICI CURIAE* SUPPORTING INTERVENORS AND REVERSAL

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. 24-1576 Caption: Bryant v. Moore, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Family Research Council
(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: 8/19/24

Counsel for: 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. 24-1576 Caption: Bryant v. Moore, 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: 8/19/24

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 to protect women's 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 Plaintiff's arguments would lead to harm against women and their families, CWA has a substantial interest in this case.[1]

---

[1] 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 no one has been able to point to any federal law that preempts North Carolina's regulation of abortion. As the lead counsel for the abortion pill manufacturer challenging West Virginia's abortion regulation on preemption grounds has 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.'" Br. 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 explained, "Congress has never enacted a prescription-drug preemption provision, despite numerous opportunities." Br. for Respondent 27, *Wyeth*, 2008 WL 3285388 (U.S. Aug. 7, 2008).

Finding no preemption provision to guarantee her desired sales, the Plaintiff here turned to implied obstacle preemption, and the district court adopted that theory. But "[i]mplied preemption analysis does not justify" the decision below, 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, the district court relied 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.* 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. "[L]anguage, history, and purpose all indicate that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 311 (2019) (cleaned up) .

Finding no help in the original Federal Food, Drug, and Cosmetic Act (FDCA), the district court put all its eggs in the 2007 Food and Drug Administration

Amendments Act (FDAAA). But again, take it from the abortion pill manufacturer's counsel: "As [*Wyeth*] recognized, the FDAAA did not change the preemption analysis." *Merck* Br. 24; *Wyeth*, 555 U.S. at 567–68. It too has no preemption provision.

The district court believed that Congress's restrictions *on the FDA* via the FDAAA implicitly preempts state laws that would not have been preempted before. Intervenors show 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 a manufacturer "an unconditional right to market [its] federally approved drug at all times" no matter what state law says. *Merck Sharp*, 587 U.S. at 319 (Thomas, J., concurring) (cleaned up). Instead, federal law "provides a federal floor that can be supplemented by different state standards." *Id.* at 320. Thus, North Carolina law *could* not conflict with federal law.

This brief elaborates on the FDAAA's statutory history, which confirms the unsoundness of the Plaintiff'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 prescribe mifepristone. The district court's decision should be reversed.

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.

A. The FDA's development has always 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.*

"State drug regulation . . . dates back to the colonies." Patricia J. Zettler, *Pharmaceutical Federalism*, 92 Ind. L.J. 845, 886–87 (2017). In 1906, national concerns about "patent medicines" with "primarily alcohol or opium" ingredients led to the initial federal 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*. Importantly, this act "supplemented the protection for consumers already provided by state regulation." *Wyeth*, 555 U.S. at 566.

The early 20th century saw a flood of ineffective and dangerous drugs entering the market. *Id.* 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*. 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." *Id.* (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 the district court 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.'"). Distinguishing the Plaintiff's lead case here, *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Supreme Court in *Wyeth* rejected the FDA's new position. According to the Court, "the 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 coexistence of state and federal law and the FDA's traditional recognition of state-law remedies." 555 U.S. at 580–81 (cleaned up).

Congress itself rejected the preemption 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 safeguarding 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. As the Supreme Court has explained, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone v. Liggett Grp.*, 505 U.S. 504, 518 (1992) (cleaned up). Here, Congress expressly considered the preemption issue and included a very limited preemption provision that does not help the Plaintiff. § 801(d)(1), 121 Stat. 922.

The district court emphasized the FDAAA's REMS protocol, asserting that it "significantly increased the FDA's regulatory role and responsibilities." JA 627. 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.

The district court never explained 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 accessible 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 "all evidence of Congress' purposes" shows that the statute's *primary* objective is "to bolster consumer protection against harmful products" (*Wyeth*, 555 U.S. at 574)—meaning that the Plaintiff is simplistically elevating a *secondary* objective. Ignore 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 accessibility, 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 with mandatory distribution restrictions. JA 107. The district court never suggested that this pre-FDAAA approval was preemptive. After the FDAAA,

a drug that had already been approved with a mandatory safety protocol remained approved with a mandatory safety protocol. At both times, the drug was approved for use. As *Wyeth* pointed out, nothing in the FDAAA changed the non-preemptive effect of approval.

The district court found it significant that the FDA had *not* imposed certain REMS requirements on mifepristone. Citing (but not quoting) *Geier*, the district court declared that state law is preempted if it "imposes a restriction on the sale or distribution of an FDA-approved drug that is designed to reduce the risks associated with the drug even though the FDA explicitly considered and rejected that restriction." JA 640–41.

There are at least three problems with this rule.

First, the Plaintiff's and district court's rule depends on courts discovering and elevating broad purposes from *both* state and federal law. The district court decided whether specific North Carolina regulations were preempted based on what purposes it ascertained for those regulations. *See id.* ("regulating or addressing potential health issues arising out of pregnancy" ok, "reduc[ing] risks" not ok). But this simply stacks one arbitrary judicial choice on another: if the concern is an "obstacle" to "accessibility," why do the potential purposes behind the state law matter? *See Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 107 (1992). And if not state "purposes," what is the logical stopping point for the "obstacle" to "accessibility":

Is a state's refusal to subsidize a drug enough? How about raising standards for prescriber certification? Prohibiting all telemedicine? Plaintiff embraced this absurdity below, distinguishing "general prescribing privileges under state law" (ok) from prescribing privileges for REMS drugs (not ok)—even though changing either privilege would have the same effect on a REMS drug's "accessibility." ECF No. 99, at 9. Neither the district court nor the Plaintiff had any coherent preemption explanation.

Second, the district court's rule would impermissibly "defer[] to an agency's conclusion that state law is pre-empted." *Wyeth*, 555 U.S. at 576 (emphasis omitted). The district court (and the Plaintiff's) repeated reliance on footnote 14 from *Wyeth* is misplaced. There, the Court rejected the drug company's "more specific contention" analogizing to *Geier*, because "the FDA did not consider and reject a stronger warning." 555 U.S. at 581 n.14. But that was simply icing on the cake. *Geier* held that a state tort suit was preempted where the plaintiff would have held all car manufacturers to a duty to install a *particular type* of safety device, given the federal objective to "bring about a *mix* of different devices introduced *gradually* over time." 529 U.S. at 875 (emphases added). The key decision point was the *obstacle* to federal law, not whether a federal agency had declined to adopt certain rules. *See Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 330 (2011) (*Geier*'s author explaining that "[a]t the heart of *Geier* lies our determination that giving auto manufacturers a

choice among different kinds of passive restraint devices was a *significant objective* of the federal regulation").

In *Wyeth*, the Court had already rejected a comparison between the FDCA and *Geier* before it got to footnote 14, broadly emphasizing "the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law" prerogatives. 555 U.S. at 581. The district court's analysis (and Plaintiff's argument) is no more than a rehashing of the dissenting opinion in *Wyeth*. *See id.* at 604–28 (Alito, J., dissenting); *see also* ECF No. 85, at 29 n.9 (Plaintiff below finding this dissent "notable"). And even focusing on footnote 14's reference to specific agency actions, when it comes to FDA actions about mifepristone, there is ample reason to question the FDA's "thoroughness, consistency, and persuasiveness." *Wyeth*, 555 U.S. at 577; *see, e.g.*, Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 Wake Forest L. Rev. 571, 573–74 (2001) (surveying the FDA's mifepristone actions and "conclud[ing] that the FDA's decisionmaking process was and probably will continue to be distorted by an inappropriate preoccupation with achieving a politically predetermined outcome").

Third and most fundamentally, the district court's rule makes little sense, because it does not address the antecedent question of whether Congress intended to let States regulate on a federal floor. If so, that an agency decides that the federal

regulatory goals do not require regulation says nothing about whether the *broader* federal purpose—including preserving two layers of regulations—would be impeded by state regulation. And even if the FDA thinks that States *should not* impose additional regulations, the relevant statutory provisions do not give the agency's hopes and dreams preemptive force. "[A]gencies have no special authority to pronounce on pre-emption absent delegation by Congress," *Wyeth*, 555 U.S. at 577, and if "abstract and unenacted legislative desires" are not enough for preemption, neither are abstract and unenacted desires by unelected bureaucrats. *Virginia Uranium*, 587 U.S. at 778 (plurality opinion).

In sum, the FDA's use of expanded mandatory 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 the district court's preemption analysis.

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

To the extent the Court finds any ambiguity in the statutory scheme so considers legislative history, it leads to the same result. The legislative history about the bills that became the FDAAA shows 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. . . . 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 law); 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.").

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), the weight of the legislative history

expressly addressing preemption refutes it. The Plaintiff here relied on a statement by a witness (ECF No. 85, at 30 n.10)—a particularly embarrassing use of legislative history. In other cases, preemption proponents have highlighted statements from two representatives from that same subcommittee hearing about discussion drafts, one expressing concerns about "conflicting State labeling requirements for drugs" generally and the other questioning whether states should "impose different REMS requirements than those imposed by the FDA."[2] These statements advocating for an absent preemption provision desired by the pharmaceutical industry have no relationship to the statute's meaning. That legislative history does not support preemption.

III. *Amici* supporting preemption present flawed statutory history arguments.

In the case involving West Virginia's law brought by the abortion pill manufacturer GenBioPro, two sets of *amici* used the FDAAA's history to advocate for preemption. Both accounts are unpersuasive. *See* Br. of *Amici Curiae* Historians, *GenBioPro, Inc. v. Raynes*, No. 23-2194, Doc. 122 (4th Cir. Aug. 6, 2024); Br. of Food and Drug Law and Health Law Scholars as Amici Curiae, *GenBioPro*, Doc.

[2] *Discussion Drafts: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 54 (2007) (statement of Rep. Sullivan); *id.* at 50 (statement of Rep. Pitts).

37-1 (4th Cir. Feb. 14, 2024). Because their accounts mirror the district court's, *amici* correct them here.

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 North Carolina'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). Congress instead "recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.*

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.

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 North Carolina'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 below 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.

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 broader REMS protocol as a condition of approval (or continued approval). Though the Scholar *Amici* say that similar protocols had already been "voluntarily" agreed to by some manufacturers, *id.* at 12, mifepristone's distribution restrictions were mandatory, as noted above. Either way, nothing fundamentally changed with REMS. And this narrow 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 Plaintiff and 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 repeatedly rejected by the Supreme Court. *See Merck Sharp*, 587 U.S. at 311 ("[L]anguage, history, and purpose all indicate that 'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.'" (quoting *Wyeth*, 555 U.S. at 575)). 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.

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*, 588 U.S. 752, 785 (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."[3] 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."[4]

In their brief in *GenBioPro*, the scholars omit any citation to these 2023 writings, but their change of tune makes their actual interest clear: "expanding abortion access." Indeed, a few months ago, these scholars were exulting over their "[l]ong term strategy" that "begins today": "*Dobbs* must be overturned."[5] No one should

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

pretend that their interest in this case stems from any other goal, including some neutral "expertise."

CONCLUSION

For these reasons, the Court should reverse.

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*

AUGUST 19, 2024

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 6,498 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: August 19, 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: August 19, 2024

s/ Christopher Mills
Christopher Mills