No. 25-1745

IN THE
United States Court of Appeals for the Fourth Circuit

VAPOR TECHNOLOGY ASSOCIATION; *et al.*,

Plaintiffs-Appellants,

v.

MCKINLEY WOOTEN, JR., in his official capacity as Director of the North Carolina Department of Revenue; *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of North Carolina
Case No. 4:25-cv-00076-M-RJ
(The Honorable Richard E. Myers, II)

BRIEF OF AMICI CURIAE IOWA AND 27 ADDITIONAL STATES IN SUPPORT OF APPELLEE AND AFFIRMANCE

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INTEREST OF AMICI CURIAE STATES

More than a century ago, the Supreme Court recognized that the Constitution preserved States' police power to promote public health by regulating cigarette sales. Today, that power extends to sales of electronic nicotine delivery systems ("ENDS" or "vapor products" or "vapes"). As tobacco regulations evolved, Congress imposed requirements on tobacco manufacturing, advertising, and labeling, while preserving the States' role in regulating sales. Indeed, the 2009 Tobacco Control Act ("TCA") expressly preserved the States' longstanding historical role in regulating in-State sales of tobacco products.

But Plaintiffs, vape retailers and consumers, seek to rewrite that law, disrupt that tradition, and depart from the district court and at least four federal courts of appeals that have affirmed the States' role in regulating tobacco products sales.

Plaintiffs challenge North Carolina's law that regulates vape sales. That law regulates North Carolina vape sales by, among other regulations, (1) requiring a directory of compliant vapes and (2) prohibiting the sale in North Carolina of any vapes not included in the directory. Plaintiffs argued that federal law preempts North Carolina's

law—despite Congress's express preservation of States' police powers in this area.

BACKGROUND

A. The 2009 Family Smoking Prevention and Tobacco Control Act.

Responding to "growing concerns about adolescent tobacco use," Congress amended the Food, Drug, and Cosmetic Act ("FDCA") by enacting the TCA. *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1173 (8th Cir. 2023) (citing Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009)). The law authorized the U.S. Food and Drug Administration to regulate tobacco products, including advertising, labeling, and manufacturing practices. Congress balanced the federal interest in national uniformity with respect for States' police power, enacting Preservation, Preemption, and Savings clauses. 21 U.S.C. § 387p(a). Those clauses mean that States remain free to regulate tobacco product sales. *See Edina*, 60 F.4th at 1175.

Since 2016, FDA has classified vapes containing tobacco-derived nicotine as "tobacco products" under the TCA. *See* 81 Fed. Reg. 28974, 28975 (May 10, 2016). In 2022, Congress amended the "tobacco products" definition to include products containing nicotine "from any source,"

including those containing synthetic, *i.e.*, non-tobacco-derived, nicotine. *See* Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, § 111(a).

So, before manufacturers may sell new ENDS interstate, they must follow the same federal requirements as other tobacco-product manufacturers: They must submit a Premarket Tobacco Product Application ("PMTA"); if FDA grants their PMTA, they may sell their products; if FDA denies their PMTA, they may not sell their products. *See* 21 C.F.R. § 1114.5; FDA, *Tobacco Products Marketing Orders*, perma.cc/GB97-PD3D (last visited Sept. 22, 2025) ("To legally market a new tobacco product in the United States, a company must receive a written marketing order from FDA."). Without authorization, federal law does not permit tobacco product sales in interstate commerce.

FDA authorized sale of only 39 vapor products as of July 2025. *See* FDA, *E-Cigarettes Authorized by the FDA*, perma.cc/VP8X-2HRK (last visited Sept. 22, 2025). But many more than 39 are marketed and sold because FDA has applied a series of ever-changing policies that began as deferred enforcement and is now case-by-case enforcement.

FDA's decision to engage in case-by-case enforcement is a resource-limitation issue. FDA recognizes "that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product," and since September 2021 has made best use of its resources via that policy. FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* at 31 ("2020 Guidance"), perma.cc/V2QA-QEDZ. That results in many federally illegal vapor products being sold. *See, e.g.*, 2020 Guidance at 27.

But FDA's prudent husbanding of resources has not meant no enforcement. Between July 2020 and November 2023, federal regulators issued over 630 warning letters and civil money penalty complaints against at least 57 manufacturers and retailers for manufacturing or selling unauthorized vapor products. *See Iowans for Alternatives to Smoking & Tobacco v. Mosiman*, No. 24-cv-448-SMR (S.D. Iowa), Dkt. 32-8 at 6–9. And customs officials have seized unauthorized vapor products upon arrival in the United States. *See id.* at 6–7; FDA News Release, *HHS, CBP Seize $86.5 Million Worth of Illegal E-Cigarettes in Largest-Ever Operation* (Sept. 10, 2025) perma.cc/4SQK-AF9T (last

visited Sept. 22, 2025) (detailing FDA's continued case-by-case enforcement against unauthorized vapor products and highlighting how few vapor products may "be legally marketed and sold in the U.S.").

B. North Carolina's Law.

Against that federal backdrop, 15 States have passed (and 25 other States are considering) vape registry laws. Public Health Law Center, *State E-Cigarette Registry Bill Map*, perma.cc/W39V-PK53?type=image (last visited Sept. 22, 2025). For example, Iowa enacted its own law in May 2024. 2024 Iowa Acts 694–698. Wisconsin enacted its law in 2023, with an effective date of July 1, 2025 and a registry publication date of September 1, 2025. Wis. Stat. Ann. § 995.15. And Kentucky enacted its law in 2024, too. *See Vapor Tech. Assoc. v. Taylor*, 2025 WL 348684, at *1 (E.D.K.Y. Jan. 30, 2025) (citing 2024 Ky. Acts ch. 111). North Carolina's law went into effect March 1, 2025.

Under these laws, manufacturers may only sell vapor products if their product is included in the directory. *See* SL2024-31, sec. 2.(a)(g); SL2024-31, sec. 2.(b) § 143B-245.12. The sales directory excludes certain products from eligibility for sale, including when a manufacturer fails to make a certification related to FDA approval, but also for previously

selling without a required certification, submitting false information, or failing to make a required payment. *Id.* If a manufacturer's products are not included in the sales directory, those products are prohibited from retail sale in North Carolina. *See* SL2024-31, sec. 2.(b) §143B-245.13.

The law establishes a regulatory system by which the North Carolina Department of Revenue certifies which vape products are eligible for sale in North Carolina. *See* SL2024-31, sec. 2.(a)(g). Beginning on March 1, 2025, e-cigarette manufacturers wishing to sell their products in North Carolina must certify to the Department one of the following:

(1) the FDA has issued a marketing granted order for the product,

(2) the product was on the market by August 8, 2016 (i.e. the effective date of the 2016 Deeming Rule) and the manufacturer submitted a PMTA for the product by September 9, 2020, which has not been denied or whose denial remains stayed, or

(3) the product is exempt from this process because it is a superficial change to an existing product.

Id., sec. 2.(b). And beginning on May 1, 2025, the Department must publish on its website a public directory listing products eligible for sale. *Id.*

To ensure that prohibited products that do not appear on the sales directory are not offered for retail sales, the Department conducts unannounced compliance checks. *See* SL2024-31, sec. 2.(b) § 143B-245.15. Liability turns on illegal sales. Fines and civil penalties apply for violations of SL 2024-31, sec. 2.(b) § 143B-245.13. *See* SL2024-31, sec. 2.(a)(h).

SUMMARY OF THE ARGUMENT

I. Plaintiffs lack standing.

II. Congress preserved and saved from preemption North Carolina's historical authority to regulate sales of tobacco products. Separately Congress authorized the federal government to exclusively enforce violations of the FDCA. So if a state law seeks to enforce or restrain violations of the FDCA, then the FDCA preempts that state law. But if a state law relates to sales of tobacco products, it falls within the TCA's Preservation and Savings clauses.

This Court should affirm the district court denying a preliminary facial injunction.

ARGUMENT

"[A] preliminary injunction is an extraordinary remedy *never awarded as of right*." *Henderson for Nat'l Lab. Rels. Bd. v. Bluefield Hosp. Co., LLC*, 902 F.3d 432, 440 (4th Cir. 2018) (quoting *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 22 (2008)). Plaintiffs must show: (1) likely success on the merits; (2) threat of irreparable harm; (3) balance of equities; and (4) that the injunction is in the public interest. *Centro Tepeyac v. Montgomery Cnty.*, 722 F.3d 184, 188 (4th Cir. 2013) (en banc).

And facial challenges are "hard to win." *Moody v. NetChoice, LLC*, 603 U.S. 707, 723 (2024). They "raise the risk of premature interpretation of statutes on the basis of factually barebones records." *Id.* at 777 (Alito, J., concurring) (cleaned up). "Invalidating a law on this basis should only be done as a last resort." *GLBT Youth in Iowa Schs. Task Force v. Reynolds*, 114 F.4th 660, 669 (8th Cir. 2024) (quotation marks omitted).

I. Standard Of Review.

This Court reviews a preliminary injunction for abuse of discretion, reviewing legal conclusions de novo and factual findings for clear error. *Centro Tepeyac*, 722 F.3d at 188. A district court abuses its discretion when it disregards "a relevant factor that should have been given significant weight." *Dixon v. City of St. Louis*, 950 F.3d 1052, 1055 (8th Cir. 2020) (quotation marks omitted).

II. Plaintiffs Lack Standing.

The FDCA bans the sale of new tobacco products—including vapor products—until FDA has issued a marketing granted order for the product. 21 C.F.R. § 1114.5; *see Taylor*, 2025 WL 348684, at *2 ("Put simply: [unauthorized products] are illegal products.").

No retailer Plaintiff alleges it has received a written marketing order from FDA. *See* Dkt. 27, at 27. And Plaintiffs do not allege that they sell their products exclusively in North Carolina—or otherwise outside the stream of interstate commerce. Federal law thus prohibits the sale, distribution, and, effectively, the purchase of Plaintiffs' products. *See* 21 C.F.R. § 1114.5; Dkt. 27 at 10. Plaintiffs essentially complain that North Carolina's law prevents them from violating federal law.

Indeed, at least one other district court found that failure to comply led to a lack of standing. *See Taylor*, 2025 WL 348684, at *2. That decision follows multiple federal appeals courts recognizing that Plaintiffs lack standing to make that complaint because no one has a right to violate the law. *See, e.g.*, *Citizen Ctr. v. Gessler*, 770 F.3d 900, 910 (10th Cir. 2024); *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 764 (9th Cir. 2018); *Bell v. Am. Traffic Sols. Inc.*, 371 F. App'x 488, 490 (5th Cir. 2010); *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006) (en banc); *see also Animal Legal Def. Fund v. Reynolds*, 89 F.4th 1071, 1082 (8th Cir. 2024). Although Plaintiffs quibble with the precise terminology, the result is the same—Plaintiffs' injuries are neither legally protected nor cognizable. That precludes preliminary injunctive relief.

A. Plaintiffs lack injury-in-fact.

"Standing is the 'irreducible constitutional minimum' required to make 'Cases' or 'Controversies' justiciable under Article III, § 2 of the Constitution." *Indus. Servs. Grp., Inc. v. Dobson*, 68 F.4th 155, 167 (4th Cir. 2023). Plaintiffs must establish that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant,

and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

An injury-in-fact is "'an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.'" *Laufer v. Naranda Hotels, LLC*, 60 F.4th 156, 161 (4th Cir. 2023) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). "Plaintiffs who do not have a legally cognizable injury lack standing to bring suit in federal court." *Garey v. James S. Farrin, P.C.*, 35 F.4th 917, 921 (4th Cir. 2022). That requires "that the dispute is traditionally thought to be capable of resolution through the judicial process." *United States v. Texas*, 599 U.S. 670, 676 (2023).

But to determine whether plaintiff has "an invasion of a legally protected interest" or a "legally and judicially cognizable" interest, a court must "consider whether the plaintiffs have a legal right to do what is allegedly being impeded." *See, e.g.*, *Gessler*, 770 F.3d at 910 (citation omitted); *Aurora Loan Servs. v. Craddieth*, 442 F.3d 1018, 1024 (7th Cir. 2006); *cf. Animal*, 89 F.4th at 1082.

That makes sense because a dispute is not "capable of resolution through the judicial process" if the law prevents plaintiffs from pursuing

their desired course of action apart from the litigation. *Pratt v. Helms*, 73 F.4th 592, 594 (8th Cir. 2023). A court does not have the power to "provide a remedy for actions that are unequivocally illegal." *Shulman v. Kaplan*, 2020 WL 7094063, at *2 (C.D. Cal. Oct. 29, 2020). An "interest in evading the law cannot create standing—a plaintiff's complaint that defendant's actions will make his criminal activity more difficult lacks standing." *Bell*, 371 F. App'x at 490 (citation and quotation marks omitted).

1. Plaintiffs allege injury because the law forces them to stop selling their federally unauthorized ENDS products. *See* Dkt. 27 at 9; *see also Food & Drug Admin. v. Wages & White Lion Investments, L.L.C.*, 145 S. Ct. 898, 910 (2025) ("because those products had not received premarket authorization, the effect of the [FDA Deeming] rule was to make their continued sale illegal").

As another federal court recently held in a nearly identical case, "'[u]nauthorized vapor products' . . . are illegal products," and "[t]he Court cannot, and will not, find that anyone has a legally protected interest in violating unambiguous federal law." *Taylor*, 2025 WL 348684, at *2–3. "A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until the FDA has

issued a marketing granted order." 21 C.F.R. § 1114.5. So "a company must receive a written marketing order from the FDA" to "legally market a new tobacco product in the United States." FDA, *Tobacco Products Marketing Orders*, perma.cc/GB97-PD3D; *see also* FDA, *Premarket Tobacco Product Marketing Orders*, perma.cc/525Y-H6TX (same). "[I]f vapor products do not comply with the FDCA and are not authorized by the FDA, § 1114.5 forbids them from being introduced into interstate commerce. Put simply: they are illegal products." *Taylor*, 2025 WL 348684, at *2.

Plaintiffs' claims are likewise "simply an attempt to evade enforcement against their selling of illegal products, and this interest in evading the law cannot create standing." *Id.* (citation modified).

2. Although federal law does not ban mere use of unauthorized vapor products, consumer Plaintiffs similarly lack standing. Courts lack power to force a private retailer to stock and sell an illegal product simply because a consumer wants to buy it. *See Hunafa v. Silwad*, 2012 WL 1945982, at *2 (M.D. Fla. May 10, 2012) (dismissing because plaintiff lacked legal right to purchase cigarette); *cf. Ga. Atlas, Inc. v. Turnage*, 594 F. Supp. 3d 1339, 1344 (N.D. Ga. 2022) (no standing because

plaintiffs "have no federal constitutional or statutory right" to possess marijuana). Even if consumer Plaintiffs had a legal right to purchase unauthorized vapor products, that injury is not judicially cognizable.

3. Defendants here are not arguing that Plaintiffs lack standing because they lack express legal permission to sell or purchase unauthorized but legal vapor products. Instead, Plaintiffs lack standing because federal law expressly prohibits selling those products. That distinction is critical.

For example, "[i]f customs officials were to institute a new and rigorous policy for inspecting packages brought in from other countries," "[s]tanding would not be recognized for a smuggler who asserted that his drug traffic was disrupted." 13A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 3531.4 (3d ed. 2025). That is not because the smuggler improperly filled out required customs forms or lacked a valid sales contract for his product, nor would it have anything to do with the legality of the underlying customs policy. The smuggler would lack standing because federal law independently bans the sale of his products. *Id.*

Here, federal law prohibited the sale of unauthorized tobacco products before North Carolina enacted its law, still prohibits those sales today, and, absent congressional action, will continue to prohibit those sales regardless of the outcome here. This Court cannot grant Plaintiffs the authority to flout a valid federal law that exists unchallenged in this litigation.

To be sure, like the smuggler, Plaintiffs might be able to show concrete economic harm. But those "paradigmatic examples of concrete harm," *id.*, do not support standing when "the asserted interest is not one the courts will protect." *See* Wright & Miller, *supra*, § 3531.4; *Just. 360 v. Stirling*, 42 F.4th 450, 459 (4th Cir. 2022); *see also E. Bay Sanctuary*, 932 F.3d at 764; *Bell*, 371 F. App'x at 490; *Walker*, 450 F.3d at 1093; *cf. ALDF*, 89 F.4th at 1082.

Plaintiffs' "true interest" in distributing, selling, and using "unlawful vapor products . . . is not one that federal courts will protect." *Taylor*, 2025 WL 348684, at *3; *see also E. Bay Sanctuary*, 932 F.3d at 764 (no standing to "assert a right to cross the border illegally"); *Turnage*, 594 F. Supp. 3d at 1344 (no standing because "no federal constitutional or statutory right to manufacture, distribute, or possess marijuana");

Kaplan, 2020 WL 7094063, at *2 (no legally cognizable injury because "any potential remedy" for damages to their "cannabis cultivation operation" would "provide a remedy for actions that are unequivocally illegal under federal law" and would "necessitate that a federal court contravene a federal statute"); *cf. ALDF*, 89 F.4th at 1082. Plaintiffs lack standing. Their claims should be dismissed.

B. The Vapor Tech Association lacks organizational standing.

To establish representational standing, an organization must "make specific allegations establishing that at least one *identified member* had suffered or would suffer harm." *S. Walk at Broadlands Homeowner's Ass'n, Inc. v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488 (2009)). Failing to identify "a single *specific member*" injured forecloses standing. *Id.* So the organization's standing rises (or falls) by its members. Because member retailer Plaintiffs lack a legally cognizable interest in selling federally unauthorized vapor products, they lack standing. So too with the organization Plaintiff.

III. North Carolina's Tobacco Registry is Not Preempted by Federal Law.

The touchstone of any preemption analysis is Congress's purpose as shown by the text and structure of the federal law at issue. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). "There is no federal preemption *in vacuo*." *Kansas v. Garcia*, 589 U.S. 191, 202 (2020) (quotation omitted). The "Laws of the United States" preempt conflicting state law. U.S. Const., art. VI, cl. 2. So federal enforcement priorities do not preempt state law. *See Kansas*, 589 U.S. at 212. "Invoking some brooding federal interest or appealing to a judicial policy preference should never be enough to win preemption of a state law." *Va. Uranium, Inc. v. Warren*, 587 U.S. 761, 767 (2019).

Federal preemption may be express or implied. *See Kansas*, 589 U.S. at 202–203. Only implied preemption is at issue here. Implied preemption has two types: field and conflict. *Id.* at 208–211. Of those, only conflict preemption is raised here. And conflict preemption also has two types: impossibility preemption, "where a party's compliance with both federal and state law would be impossible," and obstacles-and-purposes preemption, where state law poses "an obstacle to the accomplishment of congressional objectives." *Pet Quarters, Inc. v.*

Depository Tr. & Clearing Corp., 559 F.3d 772, 780 (8th Cir. 2009). Plaintiffs asserted only obstacles-and-purposes preemption here.

Preemption must be narrowly construed. *See Arizona v. United States*, 567 U.S. 387, 398–401 (2012). "Among the areas of traditional state authority to which the presumption against preemption applies is the 'regulation of matters related to health and safety.'" *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 271 (4th Cir. 2025) (quoting *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715 (1985)). "[A]ny analysis of preemption begins 'with the basic assumption that Congress did not intend to displace state law.'" *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336 (4th Cir. 2023), *cert. denied*, 144 S. Ct. 1458, 218 L. Ed. 2d 689 (2024) (quoting *S. Blasting Servs. Inc. v. Wilkes Cnty.*, 288 F.3d 584, 589 (4th Cir. 2002)).

More, the conflict preemption analysis begins with a presumption against preemption. *GenBioPro*, 144 F.4th at 273. That presumption is strongest when "Congress has legislated . . . in a field which the States have traditionally occupied." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quotation marks omitted). "[T]he historic police powers of the States [are] not to be superseded by the Federal Act unless that was the

clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good,* 555 U.S. 70, 77 (2008).

"State governments historically possess police power to protect public health and safety." *Edina*, 60 F.4th 1170, 1176 (8th Cir. 2023). That includes regulating tobacco products sales. *See R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 548–549 (9th Cir. 2022) (citing *Austin v. State of Tennessee*, 179 U.S. 343, 348–349 (1900)). Although Congress enacted cigarette advertising and labeling requirements, it "never preempted state and localities' traditional power to restrict or ban sales of tobacco products." *Id.* at 548–549 (citations omitted).

The TCA "implicates the States' traditional use of its police power." *See Edina*, 60 F.4th at 1178. Viewed against the historic backdrop, Congress's intent was to preserve States' primacy in regulating tobacco sales. *Id.* at 1179. The TCA thus preserves state laws like North Carolina's that relate to tobacco and thus vapor product sales.

A. Federal law does not preempt North Carolina's broad authority to regulate tobacco product sales.

The text of the FDCA and, more specifically, the TCA, shows that Congress sought to balance national uniformity in tobacco product

standards, which include things like manufacturing and marketing rules, with the States' historic role in regulating tobacco product sales.

The FDCA gives the federal government an exclusive cause of action to enforce the FDCA. 21 U.S.C. § 337(a). That section "implicates only enforcement of federal law." *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 850 (9th Cir. 2024). If state-law tort liability turns "solely by virtue" on a state court's adjudication of FDCA compliance, then section 337(a) preempts that law. *Buckman Co. v. Plaintiffs' Leg. Comm.*, 531 U.S. 341, 353 (2001). So if a State created a cause of action based solely on fraud against the FDA, the FDCA would preempt that law. *Id.* And that makes sense, because "policing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347 (citation modified). Indeed, such state-law "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351.

But if a state law relates to sales of tobacco products, Congress has made a different choice. Congress preserved the States' longstanding historical role in regulating in-State sales of tobacco products by

expressly preserving State regulatory power and expressly allowing States to continue regulating tobacco sales. *See* 21 U.S.C. § 387p(a).

1. The States' longstanding role in regulating tobacco shaped the TCA's preemption clauses. *See Edina*, 60 F.4th at 1173. TCA preemption "can be properly understood only against [this] historical backdrop." *Los Angeles*, 29 F.4th at 548 (citations omitted).

One of the TCA's goals was "'to set national standards controlling the manufacture of tobacco products.'" *Edina*, 60 F. 4th at 1173 (quoting 21 U.S.C. § 387 note). "[T]he TCA itself demonstrates" that Congress did not "broadly jettison[] the longstanding tradition of states and localities' role in the regulation of sales of tobacco when it enacted the TCA in 2009." *Los Angeles*, 29 F.4th at 549–550. To balance federal uniformity with historical State authority, "the Act has three sections relating to preemption: the Preservation Clause, the Preemption Clause, and the Savings Clause." *Edina*, 60 F.4th at 1173.

The Preservation Clause preserves State authority to enact restrictions "relating to or prohibiting the sale [or] distribution . . . of tobacco products" that are "in addition to, or more stringent than" the TCA. 21 U.S.C. § 387p(a)(1). It "tells us that there is no 'field preemption'

for the TCA"—States may regulate "above and beyond" the TCA. *Edina*, 60 F.4th at 1173–74.

The Preemption Clause then "limits that general principle" and "says that states and cities cannot create any rule 'which is different from or in addition to' the TCA's requirements 'relating to tobacco product standards' and tobacco 'adulteration.'" *Id.* at 1174 (quoting 21 U.S.C. § 387p(a)(2)(A)). The Preservation Clause provides a "general rule" that States can regulate beyond the TCA, then "the Preemption Clause carves out a few areas where they cannot." *Id.*

"The Savings Clause then qualifies the Preemption Clause's scope" by explaining that the Preemption Clause "does not apply to requirements relating to the sale, distribution, . . . or use of, tobacco products by individuals of any age.'" *Id.* (quoting 21 U.S.C. § 387p(a)(2)(B)). States thus remain free to regulate tobacco product sales. *Id.* at 1175.

2. "Congress thought smoking kills. Against this backdrop, it enacted § 387p, expressly preserving state authority to regulate sales of tobacco products." *Id.* at 1179. According to Congress, "[t]obacco use is the foremost preventable cause of premature death in America," it is

"inherently dangerous," and "Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight." TCA §§ 2(2), (8), (13).

So the TCA preserved States' power to enact laws relating to tobacco sales. *See* 21 U.S.C. § 387p(a)(2)(A). State sales regulations do not encroach on FDA's enforcement discretion; they operate within Congress's enforcement scheme and so are not impliedly preempted. *See Edina*, 60 F.4th at 1178. Congress did not intend "to give tobacco companies an unqualified right to sell each and every tobacco product not banned on a federal level. Nothing in the text of the statute supports that claim." *Id.* Indeed, removing State power to determine which products may be sold in the State would nullify the TCA's Preservation and Savings clauses.

3. That preemption structure contrasts with other parts of the FDCA that lack similar anti-preemption provisions and do not "legislate[] in a field which the States have traditionally occupied." *Medtronic, Inc.*, 518 U.S. at 485. For example, Congress swept back state medical device regulations and "imposed a regime of detailed federal oversight." *Riegel*

v. Medtronic, Inc., 552 U.S. 312, 316 (2008). That is opposite of what Congress did in the TCA, where it "effectively *carves out* federal power from a historical body of state and local authority." *Los Angeles*, 29 F.4th at 555.

It was therefore Congress's "clear and manifest purpose" to retain the States' historical primacy in regulating tobacco sales. *See id.* at 548. State laws that relate to tobacco sales—even if they also relate to manufacturing standards—are not preempted. *Edina*, 60 F.4th at 1175–78.

B. Any overlap North Carolina's law shares with FDCA premarket-review standards does not warrant obstacles-and-purposes preemption.

Applying ordinary principles of preemption, the conflict preemption analysis begins with a presumption against preemption. *See Edina*, 60 F.4th at 1176. "[T]he historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Grp.*, 555 U.S. at 77. And here, Congress's purpose is clear: The TCA's Preservation and Savings clause was a deliberate choice not to "broadly jettison[] the longstanding tradition of states and localities' role in the regulation of sales of tobacco products."

Los Angeles, 29 F.4th at 549–550). Thus, even if a state law overlaps with federal law, if it relates to sales of tobacco products but does not present an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," then preemption on that ground is improper. *See Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, 134 F.4th 326, 329 (5th Cir. 2025) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

After all, conflict preemption requires a conflict between state and federal law. And mere overlap between federal and state law does not necessitate conflict. *California v. Zook*, 336 U.S. 725, 733 (1949). "[T]here is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own." *Zyla Life*, 134 F.4th at 328 (quoting *Zook*, 336 U.S. at 735).

Federal law conflict-preempts state law only when the two conflict. And State laws do not "somehow conflict with [federal law] by incorporating it." *Zyla Life*, 134 F.4th at 331. Indeed, nothing in federal law prohibits States from regulating the same conduct via state law. *See id.* at 338. And federal law seldom bars States from adopting federal law for state purposes. *See, e.g., Gilbert v. Minnesota*, 254 U.S. 325, 330–331

(1920). "[T]here are now many instances in which a prosecution for a particular course of conduct could be brought by either federal or state prosecutors." *Kansas*, 589 U.S. at 212. "[I]n the vast majority of cases where federal and state laws overlap, allowing the States to prosecute is entirely consistent with federal interests." *Id.*

"[W]hen state law mirrors federal law, it 'recognizes the supremacy of the national law' by 'conform[ing] to it.'" *Zyla Life*, 134 F.4th at 332 (quoting *Asbell v. Kansas*, 209 U.S. 251, 258 (1908)). And "States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so." *Id.*

States often regulate the same conduct that federal law already regulates—especially in areas where States exercise their historic police powers to, "under their own parallel laws," regulate conduct similarly to how federal law regulates it. *Zyla Life*, 134 F.4th at 334. A discretion-based obstacle preemption analysis risks invalidating enforcement of "many state statutes [that] incorporate federal" requirements. *Id.* at 334–335 & nn.5–7 (collecting statutes).

An example illustrates the point. Both North Carolina and the federal government make it a crime for a convicted felon to own a

firearm—including persons convicted of a felony in federal court. *See* N.C. Gen. Stat. Ann. § 14-415.1; 18 U.S.C. § 922(g)(1). Enforcement-discretion obstacle preemption suggests that any North Carolina prosecution for such a violation necessarily infringes on the federal government's supposed decision not to prosecute. But that cannot be.

Nor could that be so with the federal Controlled Substances Act. Mere fact of identity between federal and state drug laws, coupled with federal nonenforcement against any one individual, cannot mean that North Carolina's drug law is preempted as applied to that individual's continued violation of federal and state drug laws.

Concerns over intruding on "federal enforcement discretion" would result in preempting "everything federal law touches." *Zyla Life*, 134 F.4th at 335. And that is why enforcement priorities are "not enough to provide a basis for preemption." *Kansas*, 589 U.S. at 212. Indeed, in *Kansas v. Garcia*, the Court emphasized that "[t]he Supremacy Clause gives priority to 'the Laws of the United States,' not the criminal law enforcement priorities or preferences of federal officers." *Id.* And it noted that preemption cannot be based on "a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives.'" *Id.* at 202

(quoting *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (plurality)).

Rather, the Supreme Court has said States may regulate the same conduct as the federal government relating to drug safety and effectiveness—even differently than the federal government—without interfering with FDA's enforcement priorities. *Wyeth*, 555 U.S. at 573–581. In short, absent true conflict between state and federal laws, mere overlap cannot establish obstacles-and-purposes preemption.

CONCLUSION

For these reasons, this Court should affirm the preliminary injunction denial.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g) and Local R. 29(b), I certify the following:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(4) because it contains 5,250 words, excluding those parts exempted by Fed. R. App. P. 32.

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September 22, 2025

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CERTIFICATE OF SERVICE

I certify that the foregoing was filed with the Clerk using the appellate CM/ECF system on September 22, 2025. All counsel of record are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

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