PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 25-1745

VAPOR TECHNOLOGY ASSOCIATION; AMV HOLDINGS, LLC, d/b/a Kure CBD and Vape; WAGES AND WHITE LION INVESTMENTS, LLC, d/b/a Triton Distribution; BRIGHT LEAF VENDORS, INC.; REAGAN MURPHY,

Plaintiffs - Appellants,

v.

MCKINLEY WOOTEN, JR., in his official capacity as the North Carolina Secretary of Revenue; PHILIP E. BERGER, in his official capacity as President Pro Tempore of the North Carolina Senate; DESTIN HALL, in his official capacity as Speaker of the North Carolina House of Representatives,

Defendants - Appellees,

STATE OF IOWA; STATE OF ARKANSAS; STATE OF GEORGIA; STATE OF IDAHO; STATE OF INDIANA; STATE OF KANSAS; STATE OF KENTUCKY; STATE OF LOUISIANA; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEBRASKA; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF PENNSYLVANIA; STATE OF SOUTH CAROLINA; STATE OF SOUTH DAKOTA; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF VIRGINIA; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA,

Amici Supporting Appellee.

Appeal from the United States District Court for the Eastern District of North Carolina, at Greenville. Richard E. Myers, II, Chief District Judge. (4:25-cv-00076-M-RJ)

Argued: January 29, 2026 Decided: July 30, 2026

Before AGEE, THACKER and QUATTLEBAUM, Circuit Judges.

Affirmed by published opinion. Judge Thacker wrote the opinion in which Judge Agee joined. Judge Agee wrote a concurring opinion. Judge Quattlebaum wrote a dissenting opinion.

ARGUED: James Christopher Fraser, THOMPSON HINE LLP, Washington, D.C., for Appellants. Stephanie A. Brennan, NORTH CAROLINA DEPARTMENT OF JUSTICE, Raleigh, North Carolina, for Appellee. **ON BRIEF:** Eric N. Heyer, Anna Stressenger, THOMPSON HINE LLP, Washington, D.C., for Appellants. Jeff Jackson, Attorney General, Olga E. Vysotskaya de Brito, Senior Deputy Attorney General, Terence Steed, Special Deputy Attorney General, Daniel T. Wilkes, Assistant Deputy Attorney General, NORTH CAROLINA DEPARTMENT OF JUSTICE, Raleigh, North Carolina, for Appellees. Brenna Bird, Attorney General, Eric Wessan, Solicitor General, Patrick C. Valencia, Deputy Solicitor General, OFFICE OF THE ATTORNEY GENERAL OF IOWA, Des Moines, Iowa, for Amicus State of Iowa. Tim Griffin, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF ARKANSAS, Little Rock, Arkansas, for Amicus State of Arkansas. Chris Carr, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF GEORGIA, Atlanta, Georgia, for Amicus State of Georgia. Raúl R. Labrador, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF IDAHO, Boise, Idaho, for Amicus State of Idaho. Theodore E. Rokita, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF INDIANA, Indianapolis, Indiana, for Amicus State of Indiana. Kris Kobach, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF KANSAS, Topeka, Kansas, for Amicus State of Kansas. Russell M. Coleman, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF KENTUCKY, Frankfort, Kentucky, for Amicus Commonwealth of Kentucky. Liz Murrill, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF LOUISIANA, Baton Rouge, Louisiana, for Amicus State of Louisiana. Aaron Frey, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MAINE, Augusta, Maine, for Amicus State of Maine. Anthony G. Brown, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, Baltimore, Maryland, for Amicus State of Maryland. Keith Ellison, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MINNESOTA, St. Paul, Minnesota, for Amicus State of Minnesota. Austin Knudsen, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MONTANA, Helena, Montana, for Amicus State of Montana. Michael T. Hilgers, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF NEBRASKA, Lincoln, Nebraska, for Amicus State of Nebraska. Aaron D. Ford, Attorney General, OFFICE OF THE ATTORNEY GENERAL

OF NEVADA, Carson City, Nevada, for Amicus State of Nevada. Raúl Torrez, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF NEW MEXICO, Santa Fe, New Mexico, for Amicus State of New Mexico. Drew Wrigley, Attorney General, OFFICE OF ATTORNEY GENERAL OF NORTH DAKOTA, Bismarck, North Dakota, for Amicus State of North Dakota. Dave Yost, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF OHIO, Columbus, Ohio, for Amicus State of Ohio. Dave Sunday, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF PENNSYLVANIA, Harrisburg, Pennsylvania, for Amicus Commonwealth of Pennsylvania. Alan Wilson, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF SOUTH CAROLINA, Columbia, South Carolina, for Amicus State of South Carolina. Marty Jackley, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF SOUTH DAKOTA, Pierre, South Dakota, for Amicus State of South Dakota. Jonathan Skrmetti, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF TENNESSEE, Nashville, Tennessee, for Amicus State of Tennessee. Ken Paxton, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF TEXAS, Austin, Texas, for Amicus State of Texas. Derek E. Brown, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF UTAH, Salt Lake City, Utah, for Amicus State of Utah. Charity R. Clark, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF VERMONT, Montpelier, Vermont, for Amicus State of Vermont. Jason S. Miyares, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF VIRGINIA, Richmond, Virginia, for Amicus Commonwealth of Virginia. Nicholas W. Brown, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF WASHINGTON, Olympia, Washington, for Amicus State of Washington. Joshua L. Kaul, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF WISCONSIN, Madison, Wisconsin, for Amicus State of Wisconsin. John B. McCuskey, Attorney General, OFFICE OF THE ATTORNEY GENERAL OF WEST VIRGINIA, Charleston, West Virginia, for Amicus State of West Virginia.

THACKER, Circuit Judge:

For almost a decade, the Food and Drug Administration ("FDA") has said that electronic nicotine delivery systems, more commonly known as "e-cigarettes" or "vapes," are tobacco products that require FDA approval before being sold. But the FDA has been slow to enforce that requirement. Trying to curb the influx of potentially harmful products within its borders, the State of North Carolina has recently enacted legislation that sharply curtails the ability of vape manufacturers and retailers to sell vapes that lack FDA approval within North Carolina's borders.

Vapor Technology Association; Wages and White Lion Investments, LLC; Bright Leaf Vendors, Inc.; AMV Holdings, LLC; and Reagan Murphy (collectively, "Appellants") are a coalition consisting of a vape trade group, a vape manufacturer, two vape retailers, and a vape user. They have filed suit in an attempt to set aside the North Carolina law. Appellants contend the North Carolina law is preempted by federal law. As a result, they moved the district court to enjoin the state law. The district court denied the motion, concluding that Appellants were unlikely to prevail on their preemption theory.

Finding no error, we affirm.

I.

A.

Federal Statutory Background

In 1938, Congress enacted the Food, Drug, and Cosmetic Act ("FDCA"), which requires covered products to first obtain approval from the FDA before they can be placed on the market. For 70 years, the FDCA did not cover tobacco products, and tobacco

regulation remained a task left largely to the States. *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 547 (9th Cir. 2022) ("Until just over a decade ago, tobacco products were regulated almost exclusively by the states and local governments, with little federal involvement.").

But, in 2009, Congress amended the FDCA by enacting the Family Smoking Prevention and Tobacco Control Act ("TCA"). Pub. L. No. 111-31, 123 Stat. 1776 (2009). The TCA gave the FDA, for the first time, regulatory authority over "new tobacco products." *Id.* The TCA did not, however, classify modern e-cigarettes or vape products as tobacco products. As a result, vape manufacturers could continue to sell their products without first obtaining FDA approval. That changed in 2016, when the FDA announced that vape products dispensing tobacco-derived nicotine were tobacco products subject to the TCA. And in 2022, Congress amended the TCA to clarify that all vape products -- including those dispensing synthetic nicotine -- were tobacco products covered by the TCA. Pub. L. No. 117-103, 136 Stat. 789 (2022).

By the time vape products came within the FDA's regulatory purview, the vape market in the United States had grown to a considerable size. Recognizing that it would be disruptive to pull these unapproved tobacco products off the shelves while the manufacturers sought the newly required FDA approval, the FDA adopted a more lenient enforcement policy. This policy, beginning in 2017, afforded the FDA a grace period wherein it deferred enforcement of the FDCA's pre-market review requirement for vape products so long as the vape product had been on the market by August 8, 2016, and the

FDA approval paperwork had been submitted and was under review. J.A. 21.[1] But, in 2020, the FDA shifted to a "case-by-case" enforcement policy, in which the FDA allows vape products that lack FDA approval to be placed on the market. J.A. 165. As a result, the FDA is currently allowing vape products that lack FDA approval to be sold in the United States and then picking and choosing which vapes it will insist receive FDA approval.

B.

State Statutory Background

In 2024, the North Carolina General Assembly passed House Bill 900, now known as Session Law 2024-31 ("S.L. 2024-31"). S.L. 2024-31 creates a regulatory framework through which the North Carolina Department of Revenue ("the Department" or "NCDOR") determines which vape products are eligible for sale in North Carolina.

To be eligible for sale in North Carolina, the manufacturer of a vape product must certify to the NCDOR Secretary, on an annual basis, that the vape product meets one of the following three criteria:

1. The vape product has received FDA approval;

2. The vape product was on the market by August 8, 2016, and an application seeking approval was submitted to the FDA by September 9, 2020;[2] or

[1] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal.

[2] This exception applies only to vapes dispensing tobacco derived nicotine. N.C. Gen. Stat. § 14-313(a)(3c).

3. The vape product is exempt from the two above listed requirements because it is only a superficial change to an existing product, such as the name, brand style, or packaging.

N.C. Gen. Stat. § 143B-245.11(a)(1)–(3). The manufacturer must also submit a $2,000.00 payment with its initial certification, and another $500.00 payment with each annual renewal. N.C. Gen. Stat. § 143B-245.11(b)(2).

From there, the NCDOR Secretary must assemble a directory listing each vape product, and its manufacturer, that has been certified eligible for sale in North Carolina. N.C. Gen. Stat. § 143B-245.12(a). The Secretary must exclude from the directory any vape product made by a manufacturer the Secretary determines:

1. Failed to provide a complete and accurate certification;
2. Submitted a certification that does not comply with the statutory requirements;
3. Failed to include the required payment with the certification;
4. Previously sold vape products in North Carolina that were required to be certified eligible for sale and placed on the directory but were not; or
5. Provided in its certification either false information or information that contained a material misrepresentation or omission.

N.C. Gen. Stat. § 143B-245.12(b).

The NCDOR Secretary was then charged with publishing the directory by May 1, 2025, and maintaining it moving forward. *See* N.C. Gen. Stat. § 143B-245.13(a). The directory publication triggered a 60 day grace period, after which vape products not listed in the directory are forbidden from being sold in North Carolina. *Id.*

The NCDOR Secretary is responsible for enforcing S.L. 2024-31. *See* N.C. Gen. Stat. § 143B-245.15(a). Should a manufacturer or retailer sell a vape product in North

Carolina that is not listed on the directory, the Secretary is authorized to impose a variety of penalties. N.C. Gen. Stat. § 14-313(h). These include monetary fines and seizure of the unlisted vape product. *Id.* But North Carolina has also deemed selling vapes not included in the directory a deceptive trade practice. N.C. Gen. Stat. § 14-313(j). As a result, any manufacturer or retailer that sells an unlisted vape in North Carolina can be sued for deceptive trade practices by a competitor. *See* N.C. Gen. Stat. § 75-16.

C.

The Lawsuit

Appellants filed this lawsuit on April 30, 2025, one day before the directory became public. They sued three North Carolina officials -- McKinley Wooten Jr., the North Carolina Secretary of Revenue; Philip E. Berger, the President Pro Tempore of the North Carolina Senate; and Destin Hall, the Speaker of the North Carolina House of Representatives ("Appellees") -- in their official capacities, in an attempt to block enforcement of S.L. 2024-31.

Appellants bring two claims in support of their suit. First, they allege that S.L. 2024-31 is impliedly preempted by the FDCA and TCA and thus inoperative. Second, they allege that S.L. 2024-31 violates the Equal Protection Clause of the Fourteenth Amendment by discriminating against similarly situated vape manufacturers, retailers, and consumers without a rational basis.

On May 16, 2025, Appellants moved for a preliminary injunction in an attempt to stop Appellee Wooten, the NCDOR Secretary, from enforcing S.L. 2024-31. In doing so,

Appellants pressed only their preemption argument. The Equal Protection theory was never raised in their motion for a preliminary injunction.

In support of their motion, two of the vape retailers -- Appellants AMV Holdings, LLC and Bright Leaf Vendors, Inc. (the "Commercial Appellants") -- proffered evidence that S.L. 2024-31 will irreparably harm them. For example, Sameh Salaymeh, the President and CEO of Appellant AMV Holdings, LLC, submitted a declaration as to the financial hardship his stores will suffer.[3] Salaymeh averred that, in 2024, 58% of the gross revenues for his stores came from vape products that will no longer be eligible for sale in North Carolina if S.L. 2024-31 is enforced. He thus reasoned that Appellant AMV Holdings, LLC will stand to lose a little over half of its gross revenue if S.L. 2024-31 is enforced. That sharp reduction in revenue, he submitted, could force the stores to close their doors.

Justin Shupe, the manager of Appellant Bright Leaf Vendors, Inc., another vape retailer, submitted a similar declaration. He averred that Appellant Bright Leaf Vendors, Inc. operates three vape retail stores in North Carolina -- stores in Greenville, Morehead City, and Havelock. Shupe explained that the stores in Havelock and Morehead City generate 71.0% and 67.4% of their revenue, respectively, from vape sales, the majority of which will no longer be permitted pursuant to S.L. 2024-31. Shupe thus submitted that these "two stores are certain to close their doors if S.L. 2024-31" takes effect. J.A. 224.

[3] Appellant AMV Holdings, LLC has 24 brick and mortar vape shops throughout North Carolina.

Appellees opposed the motion on two grounds. First, Appellees argued that Appellants lacked standing because S.L. 2024-31 only stops them from selling vapes that lack FDA approval, which is an act that already violates federal law. In other words, Appellees contended that Appellants' inability to sell illegal vape products was not an injury that confers Article III standing. Second, and on the merits, Appellees argued Appellants could not demonstrate their entitlement to injunctive relief.

The district court denied the motion. The court first held that Appellants had standing because enforcement of S.L. 2024-31 threatened them with "substantial economic harm, including the loss of sales revenue and the incursion of civil fines." J.A. 502. But, after turning to the merits, the district court held that Appellants were unlikely to prevail on their preemption claim. This was so, the court reasoned, because the TCA specifically saved from preemption state laws regulating the sale of tobacco products, such as S.L. 2024-31. The court also found preemption unlikely because Appellants could not establish that North Carolina was using S.L. 2024-31 to deputize itself to enforce the FDCA's premarket authorization requirement, which the FDCA prohibits. The court instead found that North Carolina was merely using S.L. 2024-31 to regulate which vape products can be sold within its borders.

This appeal followed.

II.

"Whether a plaintiff has Article III standing is an issue of law that we review de novo." *Fernandez v. RentGrow, Inc.*, 116 F.4th 288, 294 (4th Cir. 2024). "We review the decision to grant or deny a preliminary injunction," by contrast, "for an abuse of

discretion." *Platt v. Mansfield*, 162 F.4th 430, 438 (4th Cir. 2025) (quoting *Roe v. Dep't of Def.*, 947 F.3d 207, 219 (4th Cir. 2020)). "A district court abuses its discretion when it applies an incorrect preliminary injunction standard, rests its decision on a clearly erroneous finding of material fact or misapprehends the law with respect to the underlying issues in litigation." *N. Va. Hemp & Agric., LLC v. Virginia*, 125 F.4th 472, 492 (4th Cir. 2025).

III.

We face two questions here. First, do Appellants have standing? Second, and if so, should the district court have granted them injunctive relief? We answer these questions in turn.

A.

Standing

1.

"Article III of the Constitution limits the jurisdiction of the federal courts to 'Cases' and 'Controversies.'" *John & Jane Parents 1 v. Montgomery Cnty. Bd. of Educ.*, 78 F.4th 622, 628 (4th Cir. 2023) (quoting U.S. Const. art. III, § 2). "For there to be a case or controversy under Article III, the plaintiff must have a 'personal stake' in the case—in other words, standing." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021) (some internal quotation marks omitted) (quoting *Raines v. Byrd*, 521 U.S. 811, 819 (1997)). A plaintiff has standing to sue when she can "demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial

relief." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024); s*ee also Menders v. Loudoun Cnty. Sch. Bd.*, 65 F.4th 157, 162–63 (4th Cir. 2023) ("To establish standing, a plaintiff must 'show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief.'" (quoting *TransUnion*, 594 U.S. at 423)).

Here, the district court held that the Commercial Appellants satisfy this three part test and, therefore, have standing. We agree.[4]

First, S.L. 2024-31 puts the Commercial Appellants in a Catch-22: either stop selling their most popular products and lose revenue, or carry on business as usual and face fines and civil suits from competitors for deceptive trade practices. No matter which path they take, S.L. 2024-31 threatens the Commercial Appellants with financial harm. That "pocketbook injury" is the "classic" injury in fact for the purpose of Article III. *Tyler v. Hennepin County*, 598 U.S. 631, 636 (2023); *United States v. Texas*, 599 U.S. 670, 676 (2023) ("Monetary costs are of course an injury."); *TransUnion*, 594 U.S. at 425 ("If a defendant has caused physical or monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *see also Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 163 (3d Cir. 2017) ("[W]here a plaintiff alleges financial harm, standing 'is often

[4] Because we hold that the Commercial Appellants have standing, we need not decide whether any other Appellant has standing. *Biden v. Nebraska*, 600 U.S. 477, 489 (2023) ("If at least one plaintiff has standing, the suit may proceed.").

assumed without discussion.'" (quoting *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 293 (3d Cir. 2005))).

Second, this threatened financial harm is traceable to Appellee Wooten's enforcement of S.L. 2024-31. Appellee Wooten is the NCDOR Secretary. As such, he is responsible for compiling the registry of approved vapes, publishing the directory, and enforcing S.L. 2024-31. Appellee Wooten enforces S.L. 2024-31 by fining any store that sells vapes not included in the registry. Therefore, the Commercial Appellants easily satisfy the Article III traceability requirement. *See Hierholzer v. Guzman*, 125 F.4th 104, 116 (4th Cir. 2025) ("To be fairly traceable, there must be a causal connection between the injury and the conduct complained of." (internal quotation marks omitted) (quoting *Laufer v. Naranda Hotels, LLC*, 60 F.4th 156, 161 (4th Cir. 2023)).

Third, and finally, the Commercial Appellants' injuries are redressable. If Appellants prevail here -- and they can prove that S.L. 2024-31 violates federal law -- then the law will be struck down and thus will be inoperative. If that occurs, the Commercial Appellants will no longer face fines, nor civil suits from their competitors at least with regard to S.L. 2024-31. Because a favorable judicial decision in this case will insulate the Commercial Appellants from the financial harm S.L. 2024-31 threatens, their injury is redressable. *Frank Krasner Enters., Ltd. v. Montgomery County*, 401 F.3d 230, 234 (4th Cir. 2005) (explaining that Article III requires only "a non-speculative likelihood that the injury would be redressed by a favorable judicial decision").

Therefore, we hold that the Commercial Appellants have standing to challenge S.L. 2024-31. In doing so, we join the Seventh Circuit, which recently held that vape

retailers that sold non-FDA approved vapes had standing to challenge a Wisconsin statutory scheme that was functionally identical to S.L. 2024-31. *Wisconsinites for Alts. to Smoking & Tobacco, Inc. v. Casey*, 172 F.4th 976, 982–83 (7th Cir. 2026).

2.

Appellees see things differently. In arguing that the Commercial Appellants lack standing, Appellees begin by pointing to *Lujan v. Defenders of Wildlife*, in which the Supreme Court stated that Article III's injury in fact element requires "an invasion of a legally protected interest." 504 U.S. 555, 560 (1992). From there, Appellees note that federal law already makes it illegal to sell vape products that lack FDA approval. And because nobody has a right to violate federal law, Appellees conclude that the Commercial Appellants have no legally protected interest in selling their vape products and, as a result, will suffer no injury by way of the enforcement of S.L. 2024-31.

But this argument rests on a faulty premise as to whether the Commercial Appellants have suffered an injury in fact. *Lujan* did not, as Appellees contend, graft onto Article III a novel requirement that the plaintiff have a *legal right* to engage in the regulated conduct. Instead, *Lujan*'s statement that there must be "an invasion of a legally protected interest" was nothing more than a reformulation of the Supreme Court's longstanding requirement that the claimed injury be *judicially cognizable*. *See Jud. Watch, Inc. v. U.S. Senate*, 432 F.3d 359, 363 (D.C. Cir. 2005) (Williams, J., concurring) ("*Lujan* itself did not purport to announce a new rule but rather appeared aimed at restating the Article III standing triad.").

A number of factors compel this conclusion. To start, *Lujan* never signaled that it was tacking a new requirement onto Article III's injury in fact element; *Lujan* instead gave

every indication that it was summarizing the Court's existing standing doctrine. *See Lujan*, 504 U.S. at 560 ("Over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements."). And when summarizing the existing doctrine, *Lujan* cited three cases to support the notion that Article III standing requires the "invasion of a legally protected interest" -- and each of those cases explain that the injured interest must be "cognizable," not "legally protected." *Allen v. Wright*, 468 U.S. 737, 752, 754–56 (1984) (dismissing a claim for lack of Article III standing because the "injury [wa]s not judicially cognizable"); *Warth v. Seldin*, 422 U.S. 490, 514 (1975) (observing that "Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of statute"); *Sierra Club v. Morton*, 405 U.S. 727, 734–35 (1972) ("[T]he 'injury in fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured."). Perhaps most telling, *Lujan* used the phrase "legally protected interest" just once, and that was at the outset when providing an overview of the established standing doctrine. *Lujan*, 504 U.S. at 560. When it came time to determine whether the plaintiffs had suffered an injury that conferred standing, *Lujan* measured the injury against a familiar yardstick: whether it was cognizable. *Id.* at 562–63, 564 (explaining that "the desire to use or observe an animal species, even for purely esthetic purposes, is undeniably a cognizable interest for purpose of standing," but ultimately concluding that the plaintiffs had not established an imminent injury to that interest because they had only an "inten[t]" to "some day" travel to the affected area and view the animals).

The Supreme Court's post-*Lujan* cases confirm that a "legally protected interest" is just another way of saying a "cognizable interest." In *Bennett v. Spear*, for instance, the Court repeated verbatim *Lujan*'s articulation of the three elements of standing, save for one exception: the Court used the phrase "judicially cognizable interest" in place of "legally protected interest." 520 U.S. 154, 167 (1997) ("Th[e] irreducible constitutional minimum of standing requires: (1) *that the plaintiff have suffered an injury in fact—an invasion of a judicially cognizable interest* which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that there be a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." (emphasis supplied) (internal quotation marks omitted) (citing *Lujan*, 504 U.S. at 560–61)). And in *Raines v. Byrd*, the Court explained that Article III requires "the alleged injury [to] be legally and judicially cognizable." 521 U.S. 811, 819 (1997). This, the Court said, requires "that the plaintiff have suffered an invasion of a legally protected interest which is . . . concrete and particularized, and that the dispute is traditionally thought to be capable of resolution through the judicial process." *Id.* (internal quotation marks and citations omitted).

We thus reject the notion that *Lujan* changed Article III's well established test and imposed an additional requirement that the plaintiff have a legal right to engage in the regulated conduct. The injured interest need only be cognizable, and a financial injury is easily cognizable. *Cottrell*, 874 F.3d at 164 ("[T]he Supreme Court has repeatedly

recognized that financial or economic interests are 'legally protected interests' for purposes of the standing doctrine." (collecting cases)).

3.

Our dissenting colleague says that our decision in *Pender v. Bank of America Corporation*, 788 F.3d 354 (4th Cir. 2015), precludes us from reaching this conclusion. In the dissent's view, *Pender* "already recognized [a plaintiff having a] 'legally protected interest' as an independent requirement [of Article III] and supplied meaning to it." *Post* at 56.

In *Pender*, we considered whether a pair of plaintiffs had standing to bring a disgorgement claim pursuant to the Employee Retirement Income Security Act of 1974 ("ERISA") against their employer. *Pender*, 788 F.3d at 358. The employer had used the employees' retirement contributions to make money in excess of what the plaintiffs expected to make from their defined benefit retirement accounts, and the employer pocketed that additional profit. *Id.* at 358–60. The employer moved to dismiss for lack of standing, arguing that the employees had not suffered an injury because they had not lost any money. *Id.* at 361, 365. We rejected that simplistic analysis. "[I]t goes without saying," we began, "that the Supreme Court has never limited the injury-in-fact requirement to financial losses." *Id.* at 366. We explained that, "[i]nstead, an injury refers to the invasion of some 'legally protected interest' arising from constitutional, statutory, or common law." *Id.* (quoting *Lujan*, 504 U.S. at 578). And because ERISA gives employees an interest in the profits generated using their contributions, we held that the employees had standing to bring a disgorgement claim to recoup those profits. *Id.* at 366–67.

The dissent posits that *Pender*'s singular statement that "an injury refers to the invasion of some 'legally protected interest' arising from constitutional, statutory, or common law" means the plaintiff's conduct itself must be only "rooted in a recognized legal source." *Post* at 58. Or, put differently, the dissent would insist that a plaintiff identify some piece of positive law that gives them the specific right to engage in the regulated activity before a court will hear their challenge to a State regulation of that activity. *C.f. Beck v. McDonald*, 848 F.3d 262, 269 (4th Cir. 2017) (holding that "a plaintiff bears the burden of establishing . . . Article III standing").

But the dissent misreads *Pender* at least when viewed in full context. Rather, *Pender* instructs courts to focus on *the injury that results* from the defendant's conduct. *See Pender*, 788 F.3d at 367 (holding that plaintiffs had suffered "an invasion of a legally protected interest" because they "suffered an individual loss, measured as the spread or difference between the profit" the employer kept and the money the employees received (internal quotation marks and citation omitted)). If the plaintiff's resulting injury has a basis in "constitutional, statutory, or common law" then it is a cognizable one (although not the only cognizable one) and suffices for Article III purposes. *Id.* at 366. And *Pender* itself acknowledged that financial losses, such as those the Commercial Appellants claim here, are cognizable injuries for Article III purposes. *Id.* Small wonder, then, that no party to this appeal -- including the 28 State coalition that dedicated their amici brief to arguing there is no standing -- bothered to cite *Pender* a single time in the 170 pages of briefing before us.

Our dissenting colleague further criticizes our holding because it allows parties to file suit and challenge additional government regulation of their already prohibited conduct. But we discern no issue, in large part because it is a dubious reading of *Lujan* to condition a plaintiff's standing to challenge one law on their compliance with every other applicable law.[5] And, as we have explained, it is such reasoning on the part of the dissent that is untethered from the purpose of Article III's standing requirement: ensuring the plaintiff is the proper party to bring suit. *See, e.g.*, *White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 460 (4th Cir. 2005) ("The standing doctrine, of course, depends not upon the merits, . . . but on whether the plaintiff is the proper party to bring [the] suit." (internal quotations marks and citations omitted)).

Article III standing is "a bedrock constitutional requirement" that is "built on a single basic idea—the idea of separation of powers." *All. for Hippocratic Med.*, 602 U.S. at 378 (quoting *Texas*, 599 U.S. at 675). In our tripartite system of government, the federal courts do not "operate as an open forum for citizens 'to press general complaints about the

[5] The dissent repeatedly uses the phrase "undisputedly valid federal law" when explaining that the Commercial Appellants' conduct violates the FDCA. *Post* at 53, 62, 63. But what difference should it make whether another unchallenged law that also prohibits the plaintiff's conduct was passed by the federal or a state government, or whether the law is valid beyond dispute or subject to reasonable debate? After all, if the law has been enacted by a legislative body and signed by the executive, then the law is valid unless and until it is either struck down or repealed. And if that valid, democratically enacted law covers and prohibits the plaintiff's conduct, then, following the dissent's logic, there is but one conclusion: the plaintiff has no legally protected interest in that prohibited conduct. Perhaps the dissent's conclusion would change if the separate statute that already prohibits the plaintiff's conduct was doomed from the start and destined to be struck down. But, as we understand the dissent's position, there is no basis to find any cognizable interest in conduct that a valid, democratically enacted statute prohibits.

way in which government goes about its business.'" *Id.* at 379 (quoting *Allen*, 468 U.S. at 760). Instead, the federal courts exercise their "proper . . . role in our constitutional system" by deciding only live disputes between adversaries. *Texas*, 599 U.S. at 675–76. Doing so furthers certain commonsense interests, such as "assur[ing] that the legal questions presented to the court will be resolved, not in the rarefied atmosphere of a debating society, but in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action." *Piney Run Pres. Ass'n v. Cnty. Cmm'rs of Carroll Cnty.*, 268 F.3d 255, 262 (4th Cir. 2001) (quoting *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982)). But Article III's standing requirement serves interests even more fundamental to our system of self government, such as "prevent[ing] the judicial process from being used to usurp the powers of the political branches." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013)).

Thus, to ensure that we remain in our constitutionally prescribed lane, we ask "a basic question" to every plaintiff that knocks on the courthouse door: "What's it to you?" *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 110 (2025) (quoting *All. for Hippocratic Med.*, 602 U.S. at 379). If the plaintiff cannot demonstrate that the defendant's conduct affects them in an individualized, personal way, then we must send them away and await a party that is actually affected by the challenged conduct, a party that will be able to "properly . . . frame the issues and present them with the necessary adversarial zeal" to amount to a case or controversy. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 215 (4th Cir. 2020) (quoting *Sec. of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 956

(1984)). If, on the other hand, a prospective plaintiff can demonstrate that a defendant's conduct adversely affects them in an individualized way, then they have a sufficient "personal stake in the case" to unlock the courthouse doors, *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 269 (4th Cir. 2025) (internal quotation marks omitted) (quoting *Biden*, 600 U.S. at 489), and we have a duty to hear them out, *Sonda v. W. Va. Oil & Gas Conservation Comm'n*, 92 F.4th 213, 219 (4th Cir. 2024).

That is all Article III's injury-in-fact requirement is -- a way to "screen[] out [bystanders] who might have only a general legal, moral, ideological, or policy objection to a particular government action" from those individuals that are actually living with the effects of a policy or piece of legislation. *All. for Hippocratic Med.*, 602 U.S. at 381; *see also United States v. Students Challenging Regul. Agency Procs.*, 412 U.S. 669, 689 n.14 (1973) (explaining that Article III's injury-in-fact requirement "distinguish[es] a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem"); *Ansley v. Warren*, 861 F.3d 512, 517 (4th Cir. 2017) ("[C]oncerned bystanders may not marshal the judiciary as a vehicle for the vindication of value interests—the exercise of judicial power is restricted to litigants who seek to rectify a personal and discrete harm." (internal quotation marks omitted) (quoting *Hollingsworth v. Perry*, 570 U.S. 693, 707 (2013))).

Thus, a plaintiff need not be in perfect compliance with every applicable law in order for there to be a case or controversy sufficient to invoke our jurisdiction under Article III. They need only be adversely affected by the law they challenge. Because the Commercial Appellants here will suffer adverse financial consequences from Appellee

Wooten's enforcement of S.L. 2024-31, they have demonstrated an injury-in-fact and, with it, established standing. Therefore, we proceed to the merits.

B.

Merits

Appellants appeal the district court's denial of their motion for a preliminary injunction. As they see it, S.L. 2024-31 is preempted by the TCA and the FDCA. To properly frame the parties' arguments, we first review our standard for granting a preliminary injunction, the preemption doctrine, and the pertinent portions of the TCA and FDCA.

1.

Preliminary Injunction Standard

"A preliminary injunction," we have said, "is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *Mountain Valley Pipeline, LLC v. W. Pocahontas Props. Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). An injunction "may never be awarded 'as of right.'" *Id.* (quoting *Winter*, 555 U.S. at 24).

To obtain a preliminary injunction, "a plaintiff must establish that [1] they are likely to succeed on the merits; [2] they are likely to suffer irreparable harm absent preliminary relief; [3] the balance of the equities favors relief; and [4] the relief is in the public interest." *Nat'l Ass'n of Diversity Officers in Higher Educ. v. Trump*, 167 F.4th 86, 96 (4th Cir. 2026) (quoting *Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 339 (4th Cir. 2021) (en banc)). Importantly, the party seeking injunctive relief must prove by a clear

showing that each factor favors an injunction. *Frazier v. Prince George's County*, 86 F.4th 537, 544 (4th Cir. 2023) ("[A] preliminary injunction can be granted only if every [*Winter*] factor is met," "[y]et *denying* a preliminary injunction only takes the rejection of a single factor." (emphasis in original)); *see also Henderson ex rel. NLRB v. Bluefield Hosp. Co.*, 902 F.3d 432, 439 (4th Cir. 2018) ("*Winter* made clear that each of these four factors must be satisfied to obtain preliminary injunctive relief." (emphasis omitted)).

2.

Preemption Doctrine

"The Supremacy Clause of the Constitution dictates that 'the Laws of the United States' are 'the supreme Law of the Land.'" *Guthrie v. PHH Mortg. Corp.*, 79 F.4th 328, 336 (4th Cir. 2023) (quoting U.S. Const. art. VI). Put simply, that means "a state law which conflicts with federal law is preempted" and thus has no effect. *Cox v. Shalala*, 112 F.3d 151, 154 (4th Cir. 1997).

But preemption raises significant federalism concerns. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see also Arizona v. United States*, 567 U.S. 387, 398 (2012) ("Federalism, central to the constitutional design, adopts the principle that both the National and State Governments have elements of sovereignty the other is bound to respect."). For that reason, every preemption analysis "begins 'with the basic assumption that Congress did not intend to displace state law.'" *Guthrie*, 79 F.4th at 336 (quoting *S. Blasting Servs., Inc. v. Wilkes County*, 288 F.3d 584, 589 (4th Cir. 2002)). This presumption applies with full force where, as here, federal law ventures into an area traditionally occupied by the States. *Medtronic, Inc.*, 518 U.S. at 485; *see also S. Blasting*

Servs., Inc., 288 F.3d at 590 (explaining that the presumption against preemption "is strongest when Congress legislates in a field which the States have traditionally occupied" (internal quotation marks and citation omitted)).

There are a few ways in which Congress can overcome this presumption when enacting legislation. *Just Puppies, Inc. v. Brown*, 123 F.4th 652, 661 (4th Cir. 2024). The first is through express preemption, which occurs when federal law "explicitly state[s] an intention to preempt certain state laws." *Guthrie*, 79 F.4th at 336. The second method is through field preemption. Field preemption occurs when "federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *S. Blasting Servs, Inc.*, 288 F.3d at 590 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992)). Conflict preemption is Congress' third option, and it has two subsets. *Id.* The first subset is known as impossibility preemption, which, as its name suggests, exists when "compliance with both federal and state regulations is a physical impossibility." *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 713 (1985) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)). The second subset of conflict preemption is known as obstacle preemption. Obstacle preemption arises "when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *S. Blasting Servs., Inc.*, 288 F.3d at 590 (quoting *Hillsborough*, 471 U.S. at 713).

3.

TCA Overview

Regulating tobacco has historically been a task left largely to the States. *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 548–49 (9th Cir. 2022). Indeed, it was not until 2009 that Congress enacted the TCA and gave the federal government, via the FDA, significant regulatory authority over tobacco products. Pub. L. No. 111-31, 123 Stat. 1778 (2009).

One of the stated goals of the TCA was to "authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products." Pub. L. No. 111-31, 123 Stat. 1778 (2009). Because setting national uniformity standards required taking some regulatory authority away from the States, Congress realized that it needed to delineate what territory it claimed as exclusively federal and what territory it intended to share with the States. *County of Los Angeles*, 29 F.4th at 550 (explaining that the "TCA balances state and federal power over tobacco regulation"). Congress marked these boundaries using a three part preemption provision. *See* 21 U.S.C. § 387p.

First is the "Preservation Clause." It reads:

> Except as provided in [the Preemption Clause (discussed below)], nothing in [the TCA], shall be construed to limit the authority of . . . a State or political subdivision of a State . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion

> of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

21 U.S.C. § 387p(a)(1). The effect of the Preservation Clause is straightforward: Congress merely disclaimed any intent to preempt the tobacco field. *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1174 (8th Cir. 2023) (per curiam) ("Essentially, the Preservation Clause tells us that there is no 'field preemption' for the TCA—states and cities are free to go above and beyond the requirements of the TCA to curb tobacco use.").

The second clause in this preemption provision is the "Preemption Clause." That clause provides:

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter *relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products*.

21 U.S.C. § 387p(a)(2)(A) (emphasis supplied). Thus, although Congress disclaimed any intent to preempt the field, Congress used the Preemption Clause to remove a few areas of the tobacco industry from State regulation. *City of Edina*, 60 F.4th at 1174 ("So if the Preservation Clause is a general rule that [States] can regulate beyond the TCA, the Preemption Clause carves out a few areas where they cannot regulate beyond the TCA.").

The third and final clause in this tripartite preemption provision is the "Savings Clause." It provides:

> [The Preemption Clause] does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.

21 U.S.C. § 387p(a)(2)(B). The Savings Clause, therefore, removes some matters from the Preemption Clause's scope, and it makes clear that States can continue regulating those matters. *County of Los Angeles*, 29 F.4th at 549–50 (recognizing that "Congress [did not intend to] broadly jettison[] the longstanding tradition of states and localities' role in the regulation of sales of tobacco products when it enacted the TCA in 2009").

To recap: in the TCA, Congress disclaimed any intent to occupy the field, but it did reserve a few areas -- tobacco product standards, pre-market review, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified risk tobacco products -- where States cannot legislate. But Congress also made clear that States maintain the ability to regulate the sale of tobacco products.

Having worked through the TCA's unique preemption provision, we now have a second preemption provision to discuss. As explained above, when Congress enacted the TCA, it placed the TCA within the FDCA. *See* Pub. L. No. 111-31, 123 Stat. 1778 (2009). And the FDCA has its own unique preemption provision. Pursuant to 21 U.S.C. § 337(a), the FDA has exclusive enforcement authority when it comes to FDCA violations: "all . . . proceedings for the enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." This includes the requirement that tobacco

products -- including vape products -- first receive FDA approval before being placed on the market. *See* 21 C.F.R. § 1114.5.

4.

North Carolina S.L. 2024-31

Having worked through the necessary table setting, we now return to the case at hand. At the outset, we note that S.L. 2024-31 appears to fit comfortably in the Savings Clause as a sales regulation. In enacting S.L. 2024-31, North Carolina has passed legislation that sets certain criteria that vape products must meet before they can be legally sold in the State. In other words, S.L. 2024-31 acts as a sales restriction that conditions market access on a manufacturer certifying the vape product meets certain discrete criteria.

Despite this, Appellants argue that S.L. 2024-31 is impliedly preempted by the FDCA and TCA. Appellants make two arguments in support of this proposition. First, they argue that S.L. 2024-31 is preempted by § 337(a) because, in enforcing S.L. 2024-31, the State is, in effect, enforcing the FDCA premarket approval requirement, which § 337(a) forbids. Second, and in the alternative, Appellants contend that S.L. 2024-31 will greatly reduce the amount of vape products on the market, which will stand as an obstacle to the TCA's objective of helping tobacco users quit traditional cigarettes.[6] We address each argument in turn.

[6] Appellants also argue that S.L. 2024-31 is expressly preempted by the TCA. But because Appellants did not raise that theory of preemption below (or even include it in their complaint), we deem the argument waived. *Mountain Valley Pipeline, LLC v. 8.37 Acres of Land by Terry*, 101 F.4th 350, 360 (4th Cir. 2024) ("Absent exceptional (Continued)

a.

North Carolina Is Not Enforcing Federal Law

Appellants' first argument is straightforward. They argue that, because S.L. 2024-31 requires new vape products to have FDA approval before they can be placed on the directory and sold in the State, North Carolina is, in effect, using S.L. 2024-31 to enforce the FDCA's pre-market approval requirement. That State enforcement, Appellants contend, runs afoul of § 337(a). *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.").

To resolve this issue, we must determine what it means to "enforce" the FDCA. The Supreme Court has addressed the matter only once, in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). There, a medical device company had difficulty obtaining FDA approval for surgical screws it made. After a failed attempt, the company hired a consulting company, which helped the medical device company navigate the regulatory framework and get the screws approved. But those screws later proved defective, and they injured several patients. The patients filed a class action against the screw manufacturer and consulting company. The class brought state law fraud claims, alleging that the two defendants had made false representations to the FDA in order to get the screws approved, which led to their injuries.

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circumstances, parties may not raise new arguments on appeal that were not first presented to the district court.").

The Supreme Court held that these common law claims were preempted. In doing so, the Court first explained that regulating fraud against the FDA is anything but a traditional state function, which meant the presumption against preemption did not apply. *Buckman*, 531 U.S. at 347 ("Policing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." (internal citation and quotation marks omitted)). The Court then observed that Congress had given the FDA "a variety of enforcement options . . . that allow it to make a measured response to suspected fraud," ranging from fines and injunctions to criminal prosecution. *Id.* at 348–49. Allowing private plaintiffs to also police fraud against the FDA via state law fraud claims, the Court reasoned, would "would exert an extraneous pull on the scheme established by Congress," *id.* at 353, and "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives," *id.* at 350.

Trying to avoid this conclusion, the class members argued that the Court had already established in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), that state law "claims arising from violations of FDCA requirements" were not preempted by the FDCA. *Buckman*, 531 U.S. at 352. The Court disagreed. The Court explained that *Medtronic* involved a state law claim predicated on "the manufacturer's alleged failure to use reasonable care in the production of the product," as opposed to a "violation of FDCA requirements," which meant the plaintiff there was not enforcing the FDCA. *Id.* at 352. The *Buckman* class, by contrast, had brought "fraud claims [that] exist[ed] solely by virtue of the FDCA disclosure requirements," which meant the class members would have to prove "a[] violation of the

FDCA" in order to make out their claims. *Id.* at 353. Because "the existence of the[] [FDCA] [wa]s a critical element [of] their case," the Court held that the class members' fraud claims were attempts to enforce the FDCA and thus preempted by § 337(a). *Id.* at 349 n.4, 353.

Here, Appellants latch onto the "critical element" language from *Buckman*. As Appellants read it, *Buckman* stands for the proposition that a state law claim enforces federal law, and is therefore preempted, if it incorporates a portion of the FDCA and would not exist but for the FDCA. In support, Appellants cite *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403 (D. Del. 2014), an out of circuit district court case.

But *Scanlon* is of no moment here. Not only is it of no precedential value to us, it is wholly irrelevant. As Appellants concede, *Scanlon* dealt with a different preemption clause (21 U.S.C. § 360k) and discussed the tightrope that plaintiffs must walk to escape *that* preemption clause's unique requirements. *Scanlon*, 61 F. Supp. 3d at 411; *see also* Appellants' Opening Br. at 32 (discussing how "state law claim[s] survive[] preemption under section 360k"). *Buckman*, by contrast, dealt with § 337(a) alone and specifically avoided discussing § 360k's peculiar preemption requirements. *Buckman*, 531 U.S. at 348 n.2 ("[W]e express no view on whether these claims are subject to express pre-emption under 21 U.S.C. § 360k.").

Scanlon aside, Appellants read *Buckman* too broadly. *Buckman* does not, as Appellants suggest, mean a state law claim is preempted if the state law claim would not exist but for the FDCA's existence. Instead, *Buckman* instructs that a state law claim is

preempted if, but only if, the plaintiff needs to *establish an FDCA violation* to prevail on the claim.

The Ninth Circuit's decision in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), illustrates this point. There, the FDCA prohibited compounding[7] pharmacies from selling drugs that were "essentially a copy" of FDA-approved drugs. *Id.* at 1043. In other words, compounding pharmacies lacked FDA approval to sell generic versions of trademarked drugs; they could only sell compounded or altered versions of trademarked drugs. Nevertheless, a compounding pharmacy sold what was "essentially a copy" or an unapproved generic of a drug manufacturer's trademarked, FDA-approved drug. *Id.* The manufacturer sued the compounding pharmacy, alleging that these sales violated various States' laws that "prohibit[ed] the sale of drugs not approved by the FDA." *Id.* at 1044.

The Ninth Circuit held that these claims were preempted. In doing so, the court explained that the pharmacy was not bringing a traditional state tort suit premised on a violation of a common law duty that existed independent of the FDCA. *Nexus*, 48 F.4th at 1047–48. Instead, the court found that "a necessary element of [the plaintiff's] claim [was proving] *the alleged violation of the FDCA*." *Id.* at 1048 (emphasis supplied). That meant the plaintiff's claim "would require litigation of the alleged underlying FDCA violation in

[7] Compounding is the process by which pharmacies "alter[] ingredients in medicines to tailor them to individual patients." *Nexus*, 48 F.4th at 1042. This is done for any number of reasons. Sometimes, the patient is allergic to a mass produced, FDA approved version and they need an altered medication free of the allergen. *Id.* Other times, a prescription drug may be compounded to make the taste more palatable for children. *Id.*

a circumstance where the FDA has not itself concluded that there was a violation." *Id.* (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924, 930–31 (9th Cir. 2010)). In effect, that would result in the plaintiff "assum[ing] enforcement power [of the FDCA and] require the finder of fact to make a decision that the FDA itself did not make." *Id.* at 1049 (quoting *PhotoMedex, Inc.*, 601 F.3d at 930). Because § 337(a) forbids private plaintiffs from doing exactly that, the court held that the claims were preempted.

This case is worlds apart from *Buckman* and *Nexus*. Unlike those cases, enforcing S.L. 2024-31 does not require North Carolina to establish an underlying violation of the FDCA -- much less a violation that the FDA has yet to adjudicate. Instead, to enforce S.L. 2024-31, North Carolina officials need only show that a vape product was sold in the State, despite it not being listed on North Carolina's registry. That showing does not require State officials to establish a violation of the FDCA.

Indeed, a manufacturer may disagree with the decision of the NCDOR Secretary to remove them from the registry for any number of reasons, such as non-payment of the annual fee or for having made a material misstatement in the certification process, and continue to sell their FDA approved vape in North Carolina notwithstanding the Secretary's action. In either circumstance, the manufacturer will have complied with federal law but violated S.L. 2024-31. Because North Carolina can enforce S.L. 2024-31 without establishing an FDCA violation, S.L. 2024-31 does not run afoul of § 337(a).

Appellants argue in the alternative that S.L. 2024-31 is a backdoor means of enforcing the FDCA. This is so, Appellants contend, because S.L. 2024-31 "compels at least partial compliance with the FDCA's premarket review requirements" (presumably

because any new vape that has entered the market after August 8, 2016, can be sold in North Carolina only if it has FDA approval). Appellants' Opening Br. at 24.

This argument is irreconcilable with § 337(a)'s text and *Buckman*'s holding. Section 337(a), for its part, preempts only those "proceedings for the enforcement, or to restrain violations, of" the FDCA. 21 U.S.C. § 337(a). And *Buckman* made clear that a State proceeding "enforces" the FDCA if, but only if, the State must establish a "violation of [the] FDCA['s] requirements" to make its case. *Buckman*, 531 U.S. at 352–53. Section 337(a) does not prohibit a State, like North Carolina, from setting certain criteria that prospective sellers must meet before they can sell their tobacco products in the State. That is a valid exercise of a State's traditional police powers specifically reserved to the States by the TCA's Saving Clause.[8]

[8] Appellants also posit that construing the Savings Clause to permit the sort of sales regulation here will render the Preemption Clause a "nullity." Appellants' Opening Br. at 34. This is so, Appellants argue, because States could begin legislating on matters preempted by § 387p(a)(2)(A) so long as they couch the preempted laws as sales restrictions. We have yet to address whether a sales restriction can have the effect of regulating matters preempted by § 387p(a)(2)(A)'s Preemption Clause, and our sister circuits have expressed some disagreement on the matter. *Compare U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 434 (2d Cir. 2013) ("Certainly, any purported sales ban that in fact functions as a command to tobacco manufacturers to structure their operations in accordance with locally prescribed standards would not escape preemption simply because the City 'fram[ed] it as a ban on the sale of [tobacco] produced in whatever way [it] disapproved.'" (citation and some internal quotation marks omitted)), *with Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 83 n.11 (1st Cir. 2013) (disagreeing with *U.S. Smokeless*' "reasoning to the extent it suggests that, under some circumstances, a sales regulation may be an effective regulation on manufacturing" because "[g]iven Congress' decision to exempt sales regulations from preemption, whether those regulations have an impact on manufacturing is irrelevant"). We need not enter that fray today because, even if Appellants are correct and some sales restrictions may (Continued)

b.

North Carolina S.L. 2024-31 Does Not Frustrate Federal Objectives

We now turn to Appellants' second preemption argument, in which they argue that S.L. 2024-31 stands as an obstacle to the TCA and is therefore preempted. In support, Appellants first note that Congress enacted the TCA to give the FDA "flexible enforcement authority" over "less harmful tobacco products." Appellants' Opening Br. at 40. This was done, Appellants say, because Congress wanted the FDA to use the TCA to "reduc[e] serious tobacco-related disease and death, which is primarily caused by" traditional cigarettes. *Id.* From there, Appellants argue that the FDA has adopted its selective enforcement policy on vapes in order to carry out that command, recognizing that vapes, even if unapproved, are a safer option than traditional cigarettes. But Appellants contend that S.L. 2024-31 will limit consumers' options of vape products, including the most popular ones. And, Appellants posit, if vape users are left without their preferred products, they will revert to traditional cigarettes and risk contracting the tobacco related diseases Congress enacted the TCA to curtail. Appellants thus ask us to hold that S.L. 2024-31 stands as an obstacle to the TCA. We decline to do so.

As explained above, a state statute is obstacle preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Columbia Venture, LLC v. Dewberry & Davis, LLC*, 604 F.3d 824, 829–30 (4th Cir. 2010)

impermissibly intrude into matters immune from state regulation, the sales restrictions under review here do no such thing. So, we leave that issue for another day.

(quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). Making that determination "is a two-step process." *Guthrie*, 79 F.4th at 338 (quoting *Va. Uranium, Inc. v. Warren*, 848 F.3d 590, 599 (4th Cir. 2017)). We must first "determine Congress's 'significant objectives' in passing the federal law." *Id.* (quoting *Va. Uranium, Inc.*, 848 F.3d at 599). "We then turn to whether the state law stands 'as an obstacle to the accomplishment of a significant federal regulatory objective.'" *Id.* (quoting *Va. Uranium, Inc.*, 848 F.3d at 599).

Congress enacted the TCA to give the FDA "authority . . . to regulate tobacco products under [the FDCA], by recognizing [the FDA] as the primary [f]ederal regulatory authority *with respect to the manufacture, marketing, and distribution of tobacco products*." Pub. L. No. 111-31, 123 Stat. 1778 (2009) (emphasis supplied). In other words, Congress enacted the TCA to "authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products." *Id.*

These congressional pronouncements make clear that Congress intended the FDA to be the primary player in regulating the manufacture, marketing, and distribution of tobacco products. And Congress made that intention a reality when it preempted States -- via the TCA's Preemption Clause -- from regulating those specific areas of the tobacco industry.

But Congress never said that it intended the TCA to strip States of their traditional police power to regulate the sale of tobacco products within their borders. More to the point, we have no indication that Congress intended the TCA to force States to allow every

available tobacco product -- even those that lack FDA approval -- to be sold in their borders, simply because the FDA has yet to crack down on those tobacco products.

Yet Appellants ask us to find that Congress intended just that when it enacted the TCA. In making that argument, however, Appellants misconstrue the stated congressional purpose on which they purport to rely. In the TCA, Congress also declared that it was enacting the statute "to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to *develop, introduce, and promote less harmful tobacco products*." Pub. L. No. 111-31, 123 Stat. 1778 (2009) (emphasis supplied). That meant only that Congress intended the FDA to have some flexibility to work with tobacco companies as they developed new products and got them on the market. That stated purpose did not, as Appellants believe, demonstrate any "[c]ongress[ional] objective . . . to give tobacco companies an unqualified right to sell each and every tobacco product" to which the FDA turns a blind eye. *City of Edina*, 60 F.4th at 1178. To the contrary, Congress disclaimed that intent when it enacted the TCA's Savings Clause, which explicitly states the TCA does not preempt any state laws that "relat[e] to the sale [of] tobacco products." 21 U.S.C. § 387p(a)(2)(B).

This understanding matches Congress' intended operation of the TCA. The TCA gives the FDA exclusive regulatory authority when it comes to the manufacture and development of tobacco products. As a result, the FDA alone decides which tobacco products can go on the market. But the TCA also allows the States to use their longstanding police powers to pick and choose what available tobacco products can be sold within their borders. States remain free to follow the lead of the FDA and allow the sale of every

available tobacco product. But States also remain free to ban the sale of any tobacco product they choose -- or even entire classes of tobacco products, if they so desire. *County of Los Angeles*, 29 F.4th at 560 ("Congress intended to allow the federal government the sole authority to set tobacco product standards, while retaining for states and localities their longstanding authority to say: 'not here.'"); *see also Austin v. Tennessee*, 179 U.S. 343, 348–49 (1900) (upholding state law that bans cigarette sales, stating, "we think it within the province of the legislature to say how far [cigarettes] may be sold, or to prohibit their sale entirely [because] there [can] be no reason to doubt that the act in question is designed for the protection of the public health").

We do not see how S.L. 2024-31 stands as an obstacle to this two-tiered statutory scheme. The FDA is allowing unapproved vape products to enter the market -- that is the FDA's prerogative. But North Carolina remains free to prohibit the sale of those products within its borders. That is a valid exercise of North Carolina's police powers, and it is entirely consistent with the Savings Clause found in the TCA. Therefore, S.L. 2024-31 does not impede any congressional purpose enshrined in the TCA.

Appellants also point out, and we recognize, that S.L. 2024-31 may conflict with the FDA's case-by-case enforcement method for vapes that lack FDA approval. But that is immaterial to the obstacle preemption analysis. As the Supreme Court has made clear, "the possibility that federal enforcement priorities might be upset [by a State's co-regulation of that same activity] is not enough to provide a basis for preemption." *Kansas v. Garcia*, 589 U.S. 191, 212 (2020). And that makes good sense: obstacle preemption inquires into Congress' objectives, not the Executive's. *City of Edina*, 60 F.4th at 1178

("[C]onflict preemption requires the state law to stand in the way of the objectives of Congress, not the FDA.").

* * *

In sum, there is no indication that S.L. 2024-31 is preempted by federal law. Appellants have thus failed to demonstrate that they are likely to succeed on the merits, and the district court properly denied their motion for a preliminary injunction on that basis.

IV.

For the foregoing reasons, we affirm the district court's denial of Appellants' motion for a preliminary injunction.

AFFIRMED

AGEE, Circuit Judge, concurring:

This case is about whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts North Carolina's statutory scheme regulating electronic nicotine delivery system ("ENDS") products, SL 2024-31. Judge Thacker's opinion explains why it does not, and why, as a threshold matter, Plaintiffs—North Carolina retailers of ENDS products—have standing to bring this challenge. I am pleased to join it in full.

I write separately to respond to my good friend in dissent to discuss more directly the application of standing principles in this case.[1] In Judge Quattlebaum's view, Plaintiffs haven't suffered an Article III injury in fact because the FDCA, an unchallenged federal statute, also prohibits the sale of the products they wish to sell. In my view, the dissent reads too much into *Lujan*'s[2] lone reference to a "legally protected interest" for standing purposes. That said, the Supreme Court's stray language in *Lujan* has led to a degree of uncertainty that it ought to clarify.

* * *

Standing is a foundational constitutional principle. Under Article III, if a party doesn't have standing then it has no right to access a federal courthouse to present its claim. Just as important, without standing, the court is without authority to act on a claim.

As my colleagues have recounted, the oft-repeated elements of standing that a plaintiff must establish to come through the courthouse door are (1) injury in fact, (2)

[1] I use "Plaintiffs" to refer to what Judge Thacker has defined to be the "Commercial Appellants." *See* Maj. Op. at 9.

[2] *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

traceability (causation), and (3) redressability. *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024).

It's important to keep in mind that, in this case, we are primarily concerned with the first element: have Plaintiffs suffered a cognizable injury for Article III purposes? If not, then the remaining elements, traceability (causation) and redressability, are moot. That said, even if there is a cognizable injury, Plaintiffs still lack standing if their injury is not traceable to the defendant (i.e., the defendant wasn't the likely cause) or the court cannot provide a remedy for the injury.[3]

What qualifies as an injury in fact? At the most basic level, the injury requirement seeks "to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem." *United States v. Students Challenging Regul. Agency Procs. (SCRAP)*, 412 U.S. 669, 689 n.14 (1973); *see also Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 156 (4th Cir. 2000) (en banc) ("The injury in fact requirement precludes those with merely generalized grievances from bringing suit to vindicate an interest common to the entire public.").

Putting those purposes into focus, the injury in fact requirement requires a plaintiff to plead "an injury in fact that is concrete, particularized, and actual or imminent[.]" *Thole v. U.S. Bank N.A.*, 590 U.S. 538, 540 (2020). As Justice Kavanaugh recently put it: "An

[3] As discussed later, in a case with different facts, some of the concerns raised by Judge Quattlebaum could be resolved if a plaintiff cannot meet its burden to establish the traceability or redressability prongs of standing.

injury in fact can be a physical injury, a monetary injury, an injury to one's property, or an injury to one's constitutional rights, to take just a few common examples." *All. for Hippocratic Med.*, 602 U.S. at 381.

I agree with Judge Thacker that Plaintiffs clear the injury in fact bar in this case. They allege that North Carolina's enforcement of SL 2024-31 will prevent them from selling ENDS products in the State and force them to close their stores, which will lead to lost profits. *See, e.g.*, J.A. 28 ¶ 79. Those alleged economic harms are the interests at issue and are a paradigmatic judicially cognizable injury in fact: "classic pocketbook injury." Maj. Op. at 12; *see also Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018) (holding that "financial harm is a classic and paradigmatic form of injury in fact"). Enforcement of SL 2024-31 will, as alleged, "affect the plaintiff[s] in a personal and individual way." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016). And North Carolina has made clear it intends to enforce SL 2024-31, so the injury is sufficiently imminent. All this suffices, at this stage of the litigation, to adequately demonstrate Plaintiffs have alleged a sufficient injury in fact.

Concluding otherwise, the dissent focuses on the "legally protected interest" language from *Lujan* to conclude that Plaintiffs don't have an injury in fact. In support, the dissent zeros in on one line in *Pender v. Bank of America Corp.*, where we said that a "'legally protected interest' aris[es] from constitutional, statutory, or common law." 788 F.3d 354, 366 (4th Cir. 2015) (quoting *Lujan*, 504 U.S. at 578). From that singular dictum, the dissent asserts that we've already "recognized the importance" of, and "supplied meaning to" *Lujan*'s use of "legally protected interest" in the standing context. Diss. Op.

at 56. And because "neither the Constitution nor any statute nor the common law gives the plaintiffs a legally protected interest in conduct that violates unchallenged federal law," the dissent proffers that Plaintiffs have not alleged an injury in fact and thus do not have standing. *Id.* at 59.

Respectfully, I disagree. In my view, the dissent's analysis fails for at least two reasons. First, properly understood, *Lujan* requires only an injury to a judicially cognizable interest. The weight of authority demonstrates that, when the Supreme Court referred to a "legally protected interest," it meant only a judicially cognizable one. *See, e.g.*, *Sierra Club v. Jewell*, 764 F.3d 1, 6 (D.C. Cir. 2014) ("When the *Lujan* Court used the phrase 'legally protected interest' as an element of injury-in-fact, it was referring only to a cognizable interest." (cleaned up)). And, as explained below, an interest is judicially cognizable if it's "traditionally thought to be capable of resolution through the judicial process." *Flast v. Cohen*, 392 U.S. 83, 97 (1968). The Supreme Court, in *Lujan* or elsewhere, has never circumscribed a judicially cognizable interest, even by implication, to be limited to an interest solely derived from constitutional, statutory, or common law.

Second, the dissent's construction of "legally protected interest" unnecessarily conflates standing with the merits and confuses concerns ordinarily raised in assessing traceability and redressability with whether there's been an injury in fact.

Admittedly our discussion here is a bit academic. After all, it's hard to conceive of a valid injury that doesn't flow from a constitutional, statutory or common-law claim. But for standing purposes, the query is as whether the injury is initially "cognizable," that is, a recognized injury as alleged that gets you through the courthouse door to plead your case.

It's not whether your claim is ultimately valid from its inception as a matter of constitutional, statutory, or common law. If that were true, then every standing decision would be resolved at the first step on the merits, and the courthouse door would be closed before the plaintiff could enter.

Let's begin with *Lujan*. There is no indication in that decision that the Supreme Court altered the standing doctrine when it referred to an injury in fact as the "invasion of a legally protected interest." If it did introduce a new requirement for standing—"a bedrock constitutional requirement that [the Supreme Court] has applied to all manner of important disputes," *All. for Hippocratic Med.*, 602 U.S. at 378 (cleaned up)—one would expect the Court to have said so and explained how it operates. It did neither. *Lujan* did not define the phrase, nor did it independently analyze it when applying the alleged test it had just articulated. Further, the Supreme Court has rarely mentioned the phrase since.

To the contrary, *Lujan* cited cases establishing the "irreducible constitutional minimum of standing" that had developed "[o]ver the years." 504 U.S. at 560. Those decisions asked only whether the asserted injury was judicially cognizable, not whether it was barred by constitutional, statutory, or common law *ab initio*. *See Allen v. Wright*, 468 U.S. 737, 763 (1984) ("The interest acquired was judicially cognizable because it was a personal interest, created by law, in having the State refrain from taking specific actions."); *Warth v. Seldin*, 422 U.S. 490, 514 (1975) ("Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of statute."); *Sierra Club v. Morton*, 405 U.S. 727, 740 (1972).

Indeed, *Lujan* itself described "the desire to use or observe an animal species, even for purely esthetic purposes" as "undeniably *a cognizable interest* for purpose of standing." 504 U.S. at 562–63 (emphasis added) (citing *Morton*, 405 U.S. at 734). The plaintiffs' injury did not turn on whether that interest was "legally protected," but whether the plaintiffs were "among the injured," and "directly affected" by the challenged actions. *Id.* at 563 (cleaned up).

Lujan says nothing about the particular source of a plaintiff's alleged injury, nor did it establish a new requirement, since unmentioned, that every injury trace back to a circumscribed "legally protected interest." So, when *Pender* cited *Lujan*, there would have been no precedential basis by which to establish that only interests conclusively established "from constitutional, statutory, or common law" would be valid for standing purposes. *See* 788 F.3d at 366 (citing *Lujan*, 504 U.S. at 578). *Pender* merely identified a subset of injuries that are judicially cognizable. The critical requirement remains that the injury "affect 'the plaintiff in a personal and individual way'" rather than amount to a mere "generalized grievance." *All. for Hippocratic Med.*, 602 U.S. at 381 (quoting *Lujan*, 504 U.S. at 560 n.1); *cf. Cantrell v. City of Long Beach*, 241 F.3d 674, 681 (9th Cir. 2001) ("That the litigant's interest must be greater than that of the public at large does not imply that the interest must be a substantive right sounding in property or contract.").

Nor am I persuaded by the dissent's reliance on our prior isolated use of the phrase "legally protected interest." *See* Diss. Op. at 54. Consider *White Tail Park*, *Inc. v. Stroube*, 413 F.3d 451 (4th Cir. 2005), which provides no reason to think that a "legally protected

interest" differs from a judicially cognizable one.[4] There, we observed that "[a] regulation that reduces the size of a speaker's audience [could] constitute an invasion of a legally protected interest" because the speaker had a First Amendment interest in maintaining its audience size. *Id.* at 461. The point wasn't that the plaintiff had identified a freestanding source of positive law protecting audience size. It was that the asserted injury was the sort traditionally regarded as capable of judicial resolution.

That understanding accords with the consistent reading of *Lujan*. As the D.C. Circuit recently explained, the phrase "'legally protected interest' in *Lujan* is best understood as referring to a cognizable interest rather than imposing a new requirement that the invaded interest be affirmatively protected by positive law." *Tanner-Brown v. Haaland*, 105 F.4th 437, 446 (D.C. Cir. 2024) (citing *Jud. Watch, Inc. v. U.S. Senate*, 432 F.3d 359, 363 (D.C. Cir. 2005) (Williams, J., concurring)); *see also* Maj. Op. at 14 ("*Lujan* did not . . . graft onto Article III a novel requirement that the plaintiff have a *legal right* to engage in the regulated conduct."); *ABF Freight Sys., Inc. v. Int'l Bhd. of Teamsters*, 645 F.3d 954, 959 (8th Cir. 2011) ("A 'legally protected interest' requires only a 'judicially cognizable interest.'").

[4] The same is true of the out-of-circuit cases that Judge Quattlebaum indicates "agree" that "legally protected interest" does independent work in the standing analysis. *See* Diss. Op. at 55. For example, in *Ruiz v. Bally Total Fitness Holding Corp.*, the First Circuit found that if a contract "violate[s] the plaintiff's rights under" Massachusetts law, "that violation would necessarily constitute an invasion of a legally protected interest." 496 F.3d 1, 6 (1st Cir. 2007). But *Ruiz* never undertook to limit a "legally protected interest" to the exclusive box of constitutional, statutory, or common law. One can simply swap "legally protected interest" with "judicially cognizable interest"—and I conclude the two are interchangeable—and get to the same place.

In my view, *Lujan* only requires a plaintiff to allege an injury to a judicially cognizable interest that is (1) concrete and particularized and (2) actual or imminent. And an interest is judicially cognizable when it is "traditionally thought to be capable of resolution through the judicial process." *Flast*, 392 U.S. at 97; *see also Friends of the Earth, Inc.*, 204 F.3d at 154 ("Is the injury too abstract, or otherwise not appropriate, to be considered judicially cognizable?"). The question, for standing purposes, is whether the asserted injury is the sort courts can recognize, not whether the plaintiff can identify a constitutional provision, statute, or common-law rule that affirmatively and conclusively protects the precise conduct at issue *ab initio*.

The dissent acknowledges Plaintiffs' alleged injury from the challenged provision but concludes that this injury is insufficient to demonstrate an injury in fact. Put differently, the dissent would accept that SL 2024-31 forces Plaintiffs to either not sell ENDS products and lose profits or be subject to the statute's extensive enforcement scheme. Diss. Op. at 62. Despite acknowledging this economic injury—a "classic and paradigmatic form of injury in fact," *Air Evac EMS, Inc.*, 910 F.3d at 760—the dissent concludes that no injury in fact exists because "neither the Constitution nor any statute nor the common law gives the plaintiffs a legally protected interest in conduct that violates unchallenged federal law," Diss. Op. at 59.

But that conclusion answers a query ancillary to the determination of whether a plaintiff has an injury for standing purposes. Instead, standing asks whether the challenged action injures the plaintiff. *See, e.g.*, *White Tail Park, Inc.*, 413 F.3d at 461 ("A regulation that reduces the size of a speaker's audience can constitute an invasion of a legally

protected interest."). In that regard, Plaintiffs challenge North Carolina's enforcement of SL 2024-31, which they allege prevents them from selling ENDS products and causes them to lose profits. Those allegations describe a concrete and particularized injury. Yet under the dissent's approach, none of that matters and whether their injury is to a legally protected interest turns on whether Plaintiffs also separately challenge the FDCA.

The Supreme Court has repeatedly instructed that "standing in no way depends on the merits of the plaintiff's contention that particular conduct is illegal." *Warth*, 422 U.S. at 500. Accordingly, courts assessing standing must initially assume the validity of the plaintiff's legal theory rather than resolve it at a nascent stage. *See Laufer v. Naranda Hotels, LLC*, 60 F.4th 156, 161 (4th Cir. 2023). For the same reason, we "may not dismiss for lack of standing on the theory that the underlying interest is not legally protected." *Cooksey v. Futrell*, 721 F.3d 226, 239 (4th Cir. 2013). Yet that's effectively what the dissent's analysis requires. To determine whether Plaintiffs have suffered an injury to a legally protected interest, the dissent would first determine whether they have a lawful entitlement to engage in the regulated conduct. Under that approach, the standing inquiry becomes dependent on the very legal question a plaintiff would seek to litigate.

Whether Plaintiffs have suffered an injury in fact can't depend on the addition of another claim to the complaint. If it did, standing would turn not on the injury alleged but on the legal theories pleaded. Article III demands something different. Simply put, whether Plaintiffs also challenge the FDCA is beside the point. The injury they allege does not vanish simply because they seek relief from one source of the alleged harm—the inability

to sell ENDS products in North Carolina and the lost profits therefrom—rather than another.[5]

To be sure, courts—including our own—have repeatedly confronted the problem posed by an unchallenged law that may independently prohibit the conduct that a plaintiff has alleged is infringed. But they've addressed that potential problem through traceability and redressability—not injury in fact. *See, e.g.*, *Doe v. Va. Dept. of State Police*, 713 F.3d 745, 756 (4th Cir. 2013) ("A plaintiff faces a related obstacle to establishing traceability and redressability when there exists an unchallenged, independent rule, policy, or decision that would prevent relief even if the court were to render a favorable decision."); *WBY, Inc. v. City of Chamblee, Ga.*, 155 F.4th 1242, 1259 (11th Cir. 2025).

The Sixth Circuit's decision in *White v. United States* illustrates the point. 601 F.3d 545 (6th Cir. 2010). There, gamefowl breeders and sellers challenged provisions of the federal Animal Welfare Act restricting cockfighting activities, and the court determined

[5] The dissent relies on a handful of out-of-circuit cases that have "found no standing," Diss. Op. at 60, but those offer nothing more than dicta. *See, e.g.*, *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 764 (9th Cir. 2018) (mentioning in assessing third-party standing that the plaintiff-organizations' "clients, of course, would not have standing to assert a right to cross the border illegally, to seek asylum or otherwise" when no party sought to protect such a "right" (citing *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006) (en banc))); *Citizen Ctr. v. Gessler*, 770 F.3d 900, 910 (10th Cir. 2014) (mentioning that "a plaintiff lacks standing to complain about his inability to commit crimes because no one has a right to commit a crime" even though none of the plaintiffs sought to protect an interest in committing crimes (citing *Walker*, 450 F.3d at 1903)); *Levine v. Kling*, 123 F.3d 580, 582 (7th Cir. 1997) (holding, with no discussion of standing, that a criminal defendant doesn't have a legal malpractice *tort* cause of action if the plaintiff can't establish "that he was innocent of the crime with which he was charged" because, among other things, "[t]ort law provides damages only for harms to the plaintiff's legally protected interests, and the liberty of a guilty criminal is not one of them" (citation omitted)).

they lacked standing to do so based on the existence of unchallenged laws that restricted the identical conduct. But as the court acknowledged, the plaintiffs' alleged "economic injuries may constitute an injury-in-fact." *Id.* at 552. The problem thus wasn't the plaintiffs' lack of injury; it was an inability to show traceability and redressability. Because cockfighting was already prohibited "to a greater or lesser degree in all fifty states and the District of Columbia," the plaintiffs couldn't show that their alleged injuries were traceable to the federal statute or that invalidating it would redress them. *Id.* Their alleged lost profits remained economic injuries; they simply could not establish the remaining elements of standing.

The Ninth Circuit's decision in *San Diego County Gun Rights Committee v. Reno* points in the same direction. 98 F.3d 1121 (9th Cir. 1996), *abrogated in part on other grounds by District of Columbia v. Heller*, 554 U.S. 570 (2008). *Reno* involved a challenge to the Violent Crime Control and Law Enforcement Act provisions that prohibited the manufacture, transfer, or possession of new semiautomatic weapons. *Id.* at 1124. The plaintiffs pleaded an economic injury: "the Crime Control Act has caused the price of banned devices and grandfathered arms to increase 'from 40% to 100%,' thus hindering their ability to exercise their constitutional rights." *Id.* at 1130. As the court recognized, "[e]conomic injury is clearly a sufficient basis for standing[,]" but the "plaintiffs' asserted financial injury here fails the second prong of the *Lujan* test; plaintiffs fail to demonstrate that their alleged economic injury is fairly traceable to the Crime Control Act." *Id.* That was so because California also banned the same activity, so "any finding that the Crime

Control Act had a significant impact on the increase in prices of weapons would be tantamount to sheer speculation." *Id.*

The lesson of these cases is straightforward. When an independent, unchallenged law would prevent the plaintiff from achieving the desired result, the obstacle ordinarily arises at the traceability and redressability stages of the standing inquiry. Put differently, another law may defeat standing because it establishes lack of causation or prevents redress. But it doesn't erase an otherwise concrete and particularized injury in fact.[6]

[6] Considering the issues raised by the dissent in their proper framework, I conclude that Plaintiffs' alleged injury here is traceable and redressable. Traceability is established if it is "*likely* that the injury was caused by the conduct complained of and not by the independent action of some third party not before the court." *Doe*, 713 F.3d at 755 (emphasis added). An injury is redressable if it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* Traceability and redressability "are often flip sides of the same coin." *All. for Hippocratic Med.*, 602 U.S. at 380 (cleaned up). Here, Plaintiffs' theory is that only the FDA may enforce the FDCA and that, as a matter of enforcement discretion, the FDA has chosen not to require the immediate removal of the ENDS products at issue from the market. Accepting those allegations as true, plaintiffs have alleged that their inability to sell those products in North Carolina is traceable to SL 2024-31 rather than a separate federal barrier. And for the same reason, they have plausibly alleged that an injunction against SL 2024-31 would redress their injury.

To be sure, the FDA has emphasized that its enforcement guidance "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." J.A. 137. But the question for standing purposes is not whether plaintiffs' conduct is ultimately lawful under federal law. The question is whether plaintiffs have plausibly alleged that North Carolina's law, rather than possible federal enforcement, is preventing them from selling the products at issue. They have. Indeed, Plaintiffs allege that the FDA has deliberately exercised enforcement discretion in this area to avoid forcing certain ENDS products off the market while "it strike[s] a balance between the serious risk [those products] pose to youth [against] their potential benefit in helping adult smokers transition completely away from or significantly reduce smoking combustible cigarettes." J.A. 20 ¶ 56. At this stage, those allegations are sufficient to establish traceability and redressability so that Plaintiffs have standing to challenge SL 2024-31.

* * *

"Standing has been called one of the most amorphous (concepts) in the entire domain of public law[,]" *Flast*, 392 U.S. at 99 (citation omitted), and this case is obviously no exception. Indeed, Judge Quattlebaum is not alone in his construction of injury in fact for standing purposes.[7]

In short, this difference of opinion all flows from the Supreme Court's peculiar use of the phrase "legally protected interest" in *Lujan*. *See Jud. Watch, Inc.*, 432 F.3d at 363 (Williams, J., concurring) (expressing "puzzlement over the meaning of . . . 'legally protected interest'" (quoting *Lujan*, 504 U.S. at 560)). The resulting confusion, as witnessed by the multiple opinions in this case, can and should be resolved once and for all by the Supreme Court upon its next occasion to address standing.

[7] *See, e.g.*, *Vapor Tech. Ass'n v. Graham*, No. 1:25cv336, 2025 WL 3731013, at *4 (S.D. Miss. Dec. 15, 2025); *Vapor Tech. Ass'n v. Taylor*, No. 3:24cv74, 2025 WL 348684, at *2–3 (E.D. Ky. Jan. 30, 2025); *cf. Jud. Watch, Inc.*, 432 F.3d at 363–66 (Williams, J., concurring).

QUATTLEBAUM, Circuit Judge, dissenting:

Is lost revenue from illegal activity an "injury in fact" for purposes of Article III standing? *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). The plaintiffs say yes, and the majority agrees. According to them, North Carolina's regulatory scheme for electronic nicotine delivery system (ENDS) products—which makes it illegal to sell certain products in North Carolina—has cost the plaintiffs revenue. But selling these products is illegal under the Federal Food, Drug, and Cosmetic Act (FDCA), too. And the plaintiffs don't challenge the FDCA. In fact, they say it preempts the North Carolina scheme. In my view, the plaintiffs don't have standing to challenge a state law that prohibits what is already prohibited under an undisputedly valid federal law. So, while I agree with the majority that the FDCA doesn't preempt the North Carolina scheme, before we even get there, I'd remand this case with instructions to dismiss for lack of standing.

I.

I begin with standing. Our precedent seems to require that we apply *Lujan*'s "legally protected interest" language. Doing so, I conclude that it cannot encompass lost revenue from undeniably illegal activity. Then, I explain why the plaintiffs' backup arguments, which don't rely on there being a legally protected interest in undisputedly illegal conduct, should fail.

A.

A plaintiff must satisfy three elements to establish standing—injury in fact, traceability and redressability. *Lujan*, 504 U.S. at 560–61. This appeal involves the injury requirement. *Lujan* defined "injury in fact" as "an invasion of a legally protected interest

which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (citation modified). But *Lujan* didn't define "legally protected interest." While subsequent Supreme Court cases have elaborated on the other *Lujan* requirements, *see, e.g.*, *Gill v. Whitford*, 585 U.S. 48, 65–69 (2018) (particularity); *TransUnion LLC v. Ramirez*, 594 U.S. 413, 424 (2021) (concreteness), "[t]he Supreme Court has not defined the term 'legally protected interest' as it pertains to Article III standing, nor has it clarified whether the term does any independent work in the standing analysis," *Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 163 (3d Cir. 2017).

Our circuit has cited the *Lujan* standard on many occasions. *See, e.g.*, *Opiotennione v. Bozzuto Mgmt. Co.*, 130 F.4th 149, 153 (4th Cir. 2025); *Hierholzer v. Guzman*, 125 F.4th 104, 113 (4th Cir. 2025); *Laufer v. Naranda Hotels, LLC*, 60 F.4th 156, 161 (4th Cir. 2023). More than that, we have said that a "'legally protected interest' aris[es] from constitutional, statutory, or common law." *Pender v. Bank of Am. Corp.*, 788 F.3d 354, 366 (4th Cir. 2015) (quoting *Lujan*, 504 U.S. at 578); *see White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 461 (4th Cir. 2005) (finding that "[a] regulation that reduces the size of a speaker's audience [could] constitute an invasion of a legally protected interest" because the speaker had a First Amendment interest in maintaining its audience size); *Wikimedia Found. v. Nat'l Sec. Agency*, 857 F.3d 193, 209 (4th Cir. 2017) ("The allegation that the NSA is intercepting and copying communications suffices to show an invasion of a legally protected interest—the 'Fourth Amendment right to be free from unreasonable searches and seizures.'" (quoting *Schuchardt v. President of the U.S.*, 839 F.3d 336, 353 (3d Cir. 2016))).

Some of our sister circuits agree. *See, e.g.*, *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 6 (1st Cir. 2007) (finding that if a contract "violate[s] the plaintiff's rights under" Massachusetts law, "that violation would necessarily constitute an invasion of a legally protected interest"); *Donoghue v. Bulldog Invs. Gen. P'ship*, 696 F.3d 170, 176 (2d Cir. 2012) (finding that a section of the Securities Exchange Act provided the plaintiff with a legally protected interest); *E.T. v. Paxton*, 41 F.4th 709, 717 (5th Cir. 2022) (determining that "[n]either the ADA nor [the Rehabilitation Act] creates a legally protected interest in equality *simpliciter*"); *Aurora Loan Servs., Inc. v. Craddieth*, 442 F.3d 1018, 1023–24 (7th Cir. 2006) (noting that a legally protected interest "must be . . . the sort of interest that the law protects when it is *wrongfully* invaded" and deeming a plaintiff's foreclosure-sale certificate to confer a "solid legally protected interest" under Illinois law); *Shulman v. Kaplan*, 58 F.4th 404, 408 (9th Cir. 2023) (observing that a legally protected interest "may be 'one of property, one arising out of contract, one protected against tortious invasion, or one founded on a statute which confers a privilege'" (quoting *Tenn. Elec. Power Co. v. Tenn. Valley Auth.*, 306 U.S. 118, 137 (1939), *overruled in part on other grounds*, *Bond v. United States*, 564 U.S. 211, 216 (2011))).

Others do not. *See, e.g.*, *Jud. Watch, Inc. v. U.S. Senate*, 432 F.3d 359, 363 (D.C. Cir. 2005) (Williams, J., concurring) (expressing "puzzlement over" *Lujan*'s inclusion of a "legally protected interest" requirement and suggesting that the Court simply meant "that the interest affected be a *cognizable* one" (emphasis in original)); *see Parker v. District of Columbia*, 478 F.3d 370, 377 (D.C. Cir. 2007) (citing Judge Williams' concurrence approvingly); *ABF Freight Sys., Inc. v. Int'l Bhd. of Teamsters*, 645 F.3d 954, 959 (8th Cir.

2011) (citing *Parker* approvingly). Indeed, 20 years before *Lujan*, the Court rejected a "legal interest" test as "go[ing] to the merits" rather than to standing. *Ass'n of Data Processing Servs. v. Camp*, 397 U.S. 150, 153 (1970); *see Jud. Watch*, 432 F.3d at 364 (Williams, J., concurring) ("[I]t would seem strange to bring in through the backdoor what *Data Processing* threw out by the front.").

In a thoughtful order, the district court sided with the latter camp. And by affirming that decision, the majority does the same. It adopts Judge Williams' reasoning in *Judicial Watch*, declaring that even after *Lujan*, "[t]he injured interest need only be cognizable, and a financial injury is easily cognizable." Maj. Op. at 16. And like the district court's order, the majority and concurring opinions raise some good points. It's true, for example, that the Court "used the phrase 'legally protected interest' just once" in *Lujan* and that it hasn't always used that phrase in its post-*Lujan* injury-in-fact rule statements. *See id.* at 15–16; Conc. Op. at 44.

But it seems to me that in *Pender*, our circuit already recognized the importance of *Lujan*'s "legally protected interest" language and supplied meaning to it. *See Pender*, 788 F.3d at 366. There, we said that a "'legally protected interest' aris[es] from constitutional, statutory, or common law." *Id*. (quoting *Lujan*, 504 U.S. at 578). In my view, we must apply that precedent. *See McMellon v. United States*, 387 F.3d 329, 332 (4th Cir. 2004) (en banc) ("[O]ne panel cannot overrule a decision issued by another panel.").[1]

[1] Judge Agee regards *Pender*'s discussion of "legally protected interest" as "dictum." Conc. Op. at 42. I disagree. After saying that legally protected interests arise from constitutional, statutory or common law, we "examine[d] the principles that (Continued)

B.

How, then, does the requirement that the plaintiffs' injury arise from constitutional, statutory[2] or common law apply in this case? Let's begin with how not to apply it. Courts that are skeptical of taking "legally protected interest" seriously worry that doing so would conflate standing and the merits. *See, e.g.*, *Jud. Watch*, 432 F.3d at 364 (Williams, J., concurring) ("[T]he use of the phrase 'legally protected' to require showing of a substantive right would thwart a major function of standing doctrine—to avoid premature judicial involvement in resolution of issues on the merits."). The district court made the same point, observing that "[t]he standing doctrine does not presume upon the merits [of] a party's claim." J.A. 501 (citing *White Tail Park*, 413 F.3d at 460).

That's fair. It can't be that "every unsuccessful plaintiff [on the merits] . . . lack[s] standing in the first place." *White Tail Park*, 413 F.3d at 461 (quoting *Claybrook v. Slater*, 111 F.3d 904, 907 (D.C. Cir. 1997)). And on a different standing requirement, I have expressed a similar concern. *Lowy v. Daniel Def., LLC*, 167 F.4th 175, 213 (4th Cir. 2026) (Quattlebaum, J., dissenting) (discussing the overlap between traceability and tort

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underl[ay] [the plaintiffs'] claim . . . to discern whether there exist[ed] a legally protected interest." *Pender*, 788 F.3d at 366. Looking to the common law of restitution and trusts, as well as the "overall tenor of ERISA," we found that there was one. *Id.* at 366–67. So, our analysis of the term "legally protected interest" was necessary to our holding that the plaintiffs had standing.

[2] Identifying a statute as a source of an interest does not mean that a statutory violation automatically creates an injury in fact. *TransUnion*, 594 U.S. at 426. A plaintiff must still show that he has suffered a concrete harm, assessed by whether he has "identified a close historical or common-law analogue for [his] asserted injury." *Id.* at 424.

causation). So, I agree we should be careful not to interpret "legally protected interest" in a way that conflates standing and the merits.

But the fact that a legally protected interest must arise from constitutional, statutory or common law doesn't mean that the plaintiffs' claim must be valid under those sources of law.[3] A plaintiff may have a lousy claim on the merits but still allege an injury rooted in constitutional, statutory or common law. *See, e.g.*, *White Tail Park*, 413 F.3d at 461 (finding that the plaintiff had demonstrated a legally protected interest arising from the First Amendment "[a]lthough the First Amendment challenge . . . may ultimately prove unsuccessful" on the merits). If so, that plaintiff has standing to pursue that claim in federal court.

Rather than requiring ultimate success on the merits, asking whether an injury arises from constitutional, statutory or common law merely requires that a plaintiff's interest be rooted in a recognized legal source. Analyzed that way, the plaintiffs' alleged interest falls short. Two laws prohibit the plaintiffs from selling unauthorized ENDS products—the North Carolina scheme and the FDCA. The plaintiffs have only challenged the North Carolina scheme. So, even if the plaintiffs are right that the North Carolina scheme is

[3] Nor does it mean, as the majority says, that a plaintiff must "identify some piece of positive law" protecting his conduct. Maj. Op. at 18. Take a robber who slips and falls during a heist and sues the homeowner. The robber's conduct certainly isn't legally protected. But as the majority says, the operative question is whether the robber's *injury* is to a legally protected interest. So, if the robber's alleged injury is that he broke his leg and incurred hospital bills, he probably has standing, since his injury isn't the inability to engage in illegal conduct. On the other hand, if his alleged injury is that he wasn't able to finish the profitable string of robberies he had planned for the evening, I think he lacks standing.

invalid, the FDCA renders lost revenue from unauthorized ENDS products—the asserted injury in fact—illegal. And neither the Constitution nor any statute nor the common law gives the plaintiffs a legally protected interest in revenue from conduct that violates unchallenged federal law.

Judge Thacker and Judge Agee read *Pender* differently. They say *Pender* merely provided a few examples of sources of legally protected interests. *See* Maj. Op. at 18 ("If the plaintiff's resulting injury has a basis in 'constitutional, statutory, or common law' then it is a cognizable one (although not the only cognizable one) and suffices for Article III purposes." (quoting *Pender*, 788 F.3d at 366)); Conc. Op. at 45 ("*Pender* merely identified a subset of injuries that are judicially cognizable."). But *Pender* didn't say that. It said, "[A]n injury refers to the invasion of some 'legally protected interest' arising from constitutional, statutory, or common law." *Pender*, 788 F.3d at 366 (quoting *Lujan*, 504 U.S. at 578). Nothing about that language suggests that constitutional, statutory and common law interests are a subset of some larger set.

In fact, my colleagues do not identify sources of judicially cognizable injuries other than constitutional, statutory and common law. *See* Conc. Op. at 43 ("[I]t's hard to conceive of a valid injury that doesn't flow from a constitutional, statutory or common-law claim."). If the Constitution, statutes and common law are a subset of a larger group of sources, you'd think we'd know at least one of the other items from the larger set.

Judge Agee also points out that *Lujan* didn't provide a "precedential basis by which to establish that only interests conclusively established 'from constitutional, statutory, or common law' would be valid for standing purposes." Conc. Op. at 45 (quoting *Pender*, 788

F.3d at 366). I agree. But *Lujan* likewise didn't describe legally protected interest in a way that precludes that understanding. That's why we must rely on *Pender*.

It's true that our circuit hasn't addressed standing in a fact pattern similar to this one. But when our sister circuits have, they've largely found no standing. *See E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 764 (9th Cir. 2018) (noting that foreign nationals "would not have standing to assert a right to cross the border illegally, to seek asylum or otherwise"); *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006) ("[A] person complaining that government action will make his criminal activity more difficult lacks standing because his interest is not 'legally protected.'"); *Citizen Ctr. v. Gessler*, 770 F.3d 900, 910 (10th Cir. 2014) ("Though we do not consider the merits in connection with standing, we do consider whether the plaintiffs have a legal right to do what is allegedly being impeded. For example, a plaintiff lacks standing to complain about his inability to commit crimes because no one has a right to commit a crime."); *Hotel & Rest. Emps. Union*, *Loc. 25 v. Smith*, 846 F.2d 1499, 1518 (D.C. Cir. 1988) (en banc) (Silberman, J., separate opinion) ("Surely it cannot be argued that an [undocumented immigrant] who has violated American law by securing illegal entry has a legally protected interest in remaining undetected."); *see also Levine v. Kling*, 123 F.3d 580, 582 (7th Cir. 1997) ("Tort law provides damages only for harms to the plaintiff's legally protected interests, and the liberty of a guilty criminal is not one of them." (citation modified)); 13A Wright & Miller's Federal Practice and Procedure § 3531.4 (3d ed. 2026) ("If 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. Although the smuggler had been injured in fact, and the inspection procedures might indeed be unlawful, the asserted interest is not one the courts will protect. Thus the test of injury in fact leaves it necessary to identify what interests deserve protection against injury." (footnote omitted)).

To be sure, the majority points out that in *Wisconsinites for Alternatives to Smoking & Tobacco, Inc. v. Casey*, 172 F.4th 976 (7th Cir. 2026), the Seventh Circuit found standing in a similar circumstance. There, the court held similarly situated plaintiffs had standing to challenge a Wisconsin scheme almost identical to North Carolina's. *Id.* at 982–83. It noted that injuries in fact must be concrete and that "[c]oncrete injuries include tangible injuries such as monetary harms," found that the plaintiffs would "lose sales and business" and ended its injury-in-fact analysis there. *Id*. at 982. But the issue here is not whether the plaintiffs have suffered a concrete harm; it's whether they have suffered an invasion of a legally protected interest.[4] *Wisconsinites for Alternatives* didn't grapple with that question. The closest it got was in its causation analysis, where it said that the plaintiffs had "a legitimate basis to believe they [were] engaged in legal economic activities." *Id.* That would be news to the FDA, which has told companies that "[m]anufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns," J.A. 161, and said that its industry guidance on its enforcement priorities "does not in any way alter the fact that it is illegal to market any new tobacco product

[4] These are separate requirements. *See Biden v. Nebraska*, 600 U.S. 477, 489 (2023) (defining "injury in fact" as "a concrete and imminent harm to a legally protected interest").

without premarket authorization," J.A. 137. The executive branch doesn't render illegal conduct legal simply by policing it leniently.

Considering these decisions from our sister circuits, I'm not convinced that North Carolina's regulatory scheme, as the majority concludes, causes the plaintiffs a "classic" "pocketbook injury." Maj. Op. at 12 (quoting *Tyler v. Hennepin Cnty.*, 598 U.S. 631, 636 (2023)). While I agree that the North Carolina scheme causes these plaintiffs to "either stop selling their most popular products and lose revenue, or carry on business as usual and face fines and civil suits from competitors for deceptive trade practices," *id.*, they still haven't suffered an injury in fact. Why? Because those same sales are prohibited by an undisputedly valid federal law. A party has no legally protected interest in lost revenue that it concedes it could not legally obtain. And without the invasion of a legally protected interest, there is no injury in fact.

C.

The plaintiffs make two other arguments claiming they have shown injury in fact. But neither engages with the weight of authority I've just described. In fact, both are policy arguments.

1.

First, the plaintiffs contend that they must have standing because if they don't, states will be immunized from preemption challenges. *See NOVA Distro, Inc. v. Miyares*, No. 3:25-cv-857 (DJN), 2025 WL 3680321, at *5 (E.D. Va. Dec. 18, 2025) ("If standing turned on a plaintiff's perfect adherence to the federal requirements, states could sidestep preemption review simply by pointing to an alleged violation of the very federal standards

they may be forbidden to enforce." (citing *Iowans for Alts. to Smoking & Tobacco, Inc. v. Iowa Dep't of Revenue*, 781 F. Supp. 3d 724, 734 (S.D. Iowa 2025))). I disagree. We must follow the law wherever it takes us, whether we like the consequences or not. For that reason, "[t]he assumption that if [the plaintiffs] have no standing to sue, no one would have standing, is not a reason to find standing." *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 227 (1974).

Besides, that premise—if these plaintiffs don't have standing, then nobody does—seems wrong here. A plaintiff who undisputedly violates an undisputedly valid federal law lacks standing to challenge the state's enforcement of that law. But a plaintiff challenging a state's erroneous enforcement of an undisputedly valid federal law would seem to have standing because, unlike this case, his suit isn't premised on a violation of federal law. So would a plaintiff whose conduct violates federal and state law and who disputes the legality of the federal law and challenges the state law on preemption grounds.

What's more, if we're judging theories of standing by their consequences, the plaintiffs' theory has negative consequences of its own. Consider these hypotheticals:

- An agency promulgates a customs regulation. The smuggler described in Wright & Miller doesn't challenge the separate federal law prohibiting smuggling. But he challenges the customs regulation, asserting an injury in fact traceable to the regulation and redressable by its invalidation—lost revenue because the regulation has made it harder for him to smuggle.

- A city enacts a curfew on minors. A bar owner doesn't challenge the separate municipal law prohibiting alcohol sales to minors. But he challenges the curfew, asserting an injury in fact traceable to the curfew and redressable by its invalidation—lost revenue because he can't sell as much alcohol to minors as he did before.

- Congress imposes import tariffs on raw materials used in the production of ballistic missiles. An arms dealer doesn't challenge the separate federal prohibition against providing material support to designated terrorist organizations. But he challenges the tariffs, asserting an injury in fact traceable to the tariffs and redressable by their invalidation—lost revenue from decreased sales of ballistic missiles to designated terrorist organizations.

The smuggler, the bar owner and the arms dealer claim the kind of injury the majority finds today—lost revenue from conduct that's already prohibited by a separate law of unquestioned validity. That means that after today's decision, all three of these hypothetical plaintiffs have an injury in fact in our circuit.

2.

Second, the plaintiffs argue that the North Carolina scheme "will force [the plaintiffs] to close their doors, causing them to suffer lost revenue and profits from sales of other products that they sell," including products that are "legal to sell under federal law." Reply Br. at 8. But that's just a downstream effect of being unable to sell ENDS products in violation of federal law. *See* J.A. 92 (declaration from AMV Holdings, LLC noting that "at least 98.7%" of revenue from sales of ENDS products in North Carolina stores came from products "not eligible for inclusion on the North Carolina directory"); J.A. 223 (declaration from Bright Leaf Vendors, Inc. that while they "currently carry several lines of bottled e-liquids found on the [North Carolina] directory, these e-liquids only accounted for 4.3%" of a North Carolina location's revenue). A company that earns a lot of illegal revenue and a little legal revenue doesn't have a legally protected interest in maintaining its illegal revenue just because that revenue keeps the whole operation—illegal and legal revenue streams alike—afloat.

Thus, to wrap up, because I don't think lost illegal revenue is an injury in fact, I conclude that the plaintiffs lack Article III standing.[5]

II.

Since the majority finds the plaintiffs have standing, it addresses the likelihood that the plaintiffs would succeed on their preemption claim. Despite my view on standing, I agree that the FDCA doesn't preempt the North Carolina scheme. And while I agree with much of the majority's reasoning, I write separately to identify a few other points supporting that conclusion.

First, the plain text of 21 U.S.C. § 337(a) doesn't seem to pose any conflict with the North Carolina scheme. That provision provides that, with an exception not relevant here, "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The majority correctly points out that it's possible to violate the North Carolina scheme without also violating the FDCA. *See* Maj. Op. at 33. But even if North Carolina prosecutes an ENDS retailer for selling a product that the FDA didn't approve in advance, and thus wasn't included on the North Carolina directory, that doesn't violate the text of § 337(a). Section 337(a) prohibits a state attorney general from bringing an FDCA claim. But North Carolina is not doing that. It is

[5] If the plaintiffs who retail ENDS products lack standing, so do the remaining plaintiffs. On appeal, the plaintiffs don't argue that the Vapor Technology Association has any better claim to standing than the retailer plaintiffs. They do argue that the individual plaintiff, Reagan Murphy, has standing since "the FDCA does not prohibit the mere possession (or use) of unauthorized ENDS." Reply Br. at 9. But I'm unconvinced that a consumer has a legally protected interest in buying a product whose sale an unchallenged federal law prohibits.

enforcing its own law, and that law partially measures compliance against the FDCA. What if North Carolina had simply copied and pasted requirements listed in the FDCA into its own scheme instead of explicitly referencing the FDCA? The plaintiffs conceded at oral argument that this wouldn't have created a preemption problem under § 337(a). If that's right, I don't see how referencing an FDCA provision does either.

Second, the plaintiffs rely too heavily on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in arguing that the North Carolina scheme is impliedly preempted by § 337(a). The North Carolina scheme is a health-and-safety regulation, meaning that we start our analysis with a presumption against preemption. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (describing a presumption against preemption as "consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety"). That presumption did not apply in *Buckman* because the state action in that case addressed an "inherently federal" issue—"the relationship between a federal agency and the entity it regulates." 531 U.S. at 347. So, here, unlike in *Buckman*, we start with a thumb on the scale in favor of the state scheme.

Also, in *Buckman*, the Supreme Court expressed concern that state and federal authorities would interpret FDA regulations differently from one another. *See id.* at 351 (observing that regulated entities might "fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court"); *accord Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1048 (9th Cir. 2022) (finding implied preemption where a state claim "would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself

concluded that there was a violation" (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010))). There's no such concern here. To sell an ENDS product in North Carolina, a distributor or retailer simply needs to make sure the product is on North Carolina's directory. To the extent North Carolina uses the FDA's list of pre-approved products to determine what products are on its directory, there is no state interpretation of a federal rule or standard. So, there is no risk of inconsistent and conflicting interpretations of federal law.

In my view, these points bolster the majority's conclusion that the plaintiffs are unlikely to succeed on the merits of their preemption claim.

III.

I agree with the majority that the plaintiffs are unlikely to succeed on the merits of their preemption claim. But as a matter of law, the plaintiffs lack Article III standing to assert that claim.[6] So, rather than affirming the district court's denial of a preliminary injunction, I would remand with instructions to dismiss. *See Elec. Priv. Info. Ctr. v. U.S. Dep't of Com.*, 928 F.3d 95, 104 (D.C. Cir. 2019) ("[I]f, in reviewing the denial of a preliminary injunction, we determine that a litigant cannot establish standing *as a matter of law*, the proper course is to remand the case for dismissal." (emphasis in original));

[6] For the same reasons, the plaintiffs lack standing to pursue their Equal Protection Clause claim. *See* J.A. 31 (plaintiffs' complaint describing the harm from the alleged equal protection violation as "forcing [the plaintiffs] to stop selling [their] unauthorized ENDS products containing non-tobacco-derived nicotine").

Delmarva Fisheries Ass'n v. Atl. States Marine Fisheries Comm'n, 127 F.4th 509, 515 (4th Cir. 2025) (citing *Elec. Priv. Info. Ctr.*, 928 F.3d at 104).