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Appellate Vape Rulings May Expand State Regulation Powers

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On July 30, two federal appeals courts permitted the enforcement of state laws in Iowa and North Carolina conditioning the sale of electronic nicotine delivery systems, or ENDS, on a manufacturer's certification of compliance with U.S. Food and Drug Administration premarket review requirements.[1]

In Vapor Technology Association v. Wooten and Iowans for Alternatives to Smoking & Tobacco Inc. v. Mosiman, the U.S. Courts of Appeals for the Fourth and Eighth Circuits, respectively, held that the challengers were unlikely to succeed on preemption claims, finding that Congress intended to preserve states' authority to restrict tobacco product sales. The courts also found that there was no implied conflict with federal law.

They reached this conclusion even though enforcement of the state laws may conflict with the FDA's stated enforcement priorities.

If these decisions stand, we may see more states enact laws that incorporate federal tobacco product requirements as state sales restrictions where they deem federal enforcement efforts to be inadequate.

REGULATORY BACKGROUND

Each case involves the same regulatory scheme and nearly identical state laws.

ENDS products are regulated by the FDA as tobacco products under the Federal Food, Drug and Cosmetic Act, or FDCA, as amended by the Family Smoking Prevention and Tobacco Control Act, or TCA, which requires FDA premarket authorization before an ENDS product may be lawfully sold, manufactured or marketed.

Yet, to date, the FDA has authorized only 45 ENDS products from five companies,[2] and most ENDS sold in the U.S. market today lack FDA premarket authorization.

This is due to a number of factors, including the FDA's delay in reviewing premarket tobacco product applications, sometimes taking five years or more in excess of the statutory deadline of 180 days; high consumer demand; and FDA enforcement practices that favor a case-by-case, discretionary approach rather than a sweeping removal of all unauthorized ENDS products.

State ENDS Directory Laws

State ENDS directory laws have emerged as an effort to clear store shelves of ENDS products that are not in compliance with FDA premarket review requirements in the absence of more robust federal enforcement.

The directory laws follow a similar pattern. In order to sell an ENDS product in a state, these laws typically require manufacturers to annually certify that the products either: (1) have received a marketing granted order from the FDA; or (2) were on the market as of Aug. 8, 2016, and are subject to a premarket tobacco product application that was submitted to the FDA on or before Sept. 9, 2020, where the premarket tobacco product application either remains under FDA review or has received a marketing denial order that has been stayed, rescinded or vacated by the FDA or a court.

This latter option is consistent with the FDA's original enforcement guidance for ENDS[3] — a policy that has since been superseded and clarified to accommodate more products that have met the filing review stage of the premarket tobacco product application process.[4]

North Carolina's and Iowa's directory laws — S.L. 2024-31 and H.F. 2677, respectively — are examples of this approach. Both were challenged by industry plaintiffs on the theory that the FDCA's grant of exclusive enforcement authority to the FDA under Title 21 of the U.S. Code, Section 337(a), and the TCA's express preemption clause under Section 387p preempt the state directory requirements.

Key Provisions in the FDCA

A key question the courts resolved concerned the interplay of these two provisions: Section 337 of the FDCA and Section 387p of the TCA.

Section 337(a) of the FDCA provides that, with limited exceptions, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States," reflecting Congress' general intent that only the federal government may enforce the FDCA.

The TCA's preservation of authority provision at Section 387p, in turn, establishes a tripartite framework for allocating authority between the federal government and the states.

The preservation clause generally permits state and local authorities to adopt tobacco product measures that are "in addition to, or more stringent than" federal requirements relating to the sale, distribution or use of tobacco products by individuals of any age.

The preemption clause then carves out an exception, barring states from imposing requirements "different from, or in addition to" federal requirements relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards or modified risk tobacco products.

Finally, the savings clause narrows the preemption clause's reach, providing that it does not apply to state requirements relating to the sale, distribution, possession, information reporting to the state, advertising and promotion, or use of tobacco products of any age.

This statutory framework — Section 337(a)'s allocation of enforcement authority to the federal government, together with the preservation, preemption and savings clauses of Section 387p — is central to both the Fourth and Eighth Circuits' analyses below.

THE DECISIONS

The Fourth Circuit

In Vapor Technology Association v. Wooten, the Fourth Circuit, in an opinion by U.S. Circuit Judge Stephanie D. Thacker, held that North Carolina's directory law is not preempted.

The court first rejected the argument that North Carolina, by enforcing the directory law, was effectively enforcing the FDCA's premarket authorization requirement in violation of the FDCA's exclusive enforcement provision.[5]

The court reasoned that a state law enforces the FDCA only if a plaintiff or the state must establish an underlying FDCA violation to prevail, and that North Carolina officials need only show that a vape product was sold in the state without being listed on the state registry — a showing that does not require proving an FDCA violation.

The court also rejected the argument that the law is preempted because it frustrates the FDA's objective of preserving consumer access to less harmful, noncombustible alternatives to cigarettes, explaining that the TCA's savings clause preserves the states' traditional police power to regulate the sale of tobacco products within their borders, and that the possibility a state law might upset federal enforcement priorities — as opposed to the purposes of Congress — does not support preemption.

The Eighth Circuit

In Iowans for Alternatives to Smoking & Tobacco v. Mosiman, the Eighth Circuit, in an opinion by U.S. Circuit Judge L. Steven Grasz, applied the presumption against preemption to Iowa's directory law, given the state's historic police power to regulate matters of public health.

Working through the TCA's tripartite preservation, preemption and savings clauses, the court concluded that the TCA's preservation clause permits Iowa to add more stringent provisions, so long as — under the preemption clause — such restrictions do not involve, among other things, premarket review.

The court then determined that the savings clause permitted H.F. 2677 because it imposed a sales and distribution requirement.

On implied obstacle preemption, the court held that a state law mirroring federal premarket authorization requirements does not conflict with, or create an obstacle to, those requirements, because the state law "recognizes the supremacy of the national law and conforms to it," rather than displacing it.

The Eighth Circuit further explained that the possibility Iowa's law might upset the FDA's discretionary, case-by-case enforcement priorities does not establish preemption, because the supremacy clause gives priority to federal law, not federal enforcement preferences.

U.S. Circuit Judge James B. Loken concurred in the judgment, but would not have resolved the obstacle preemption question on the existing record, reasoning that a fuller record regarding how Iowa intends to enforce the statute — and how that enforcement would affect the FDA's exclusive enforcement authority — is needed.

POINTS OF AGREEMENT AND DIVERGENCE

The two decisions agreed on the result but framed the import of state law differently.

The decisions align with the U.S. Court of Appeals for the Seventh Circuit's April decision upholding Wisconsin's directory law in Wisconsinites for Alternatives to Smoking & Tobacco v. Casey, and apply a presumption against preemption.

The courts concluded that the TCA's savings clause preserves the states' authority to condition the sale of ENDS products on compliance-related criteria, notwithstanding the products' relationship to the FDA's premarket authorization regime.

Both decisions also rejected the argument that implied preemption blocks a state law because the state law disagrees with the FDA's discretionary enforcement priorities, reasoning that obstacle preemption looks to the objectives of Congress rather than the enforcement preferences of the executive branch.

The two majority opinions differ in how they frame the exclusive enforcement analysis. The Fourth Circuit focused on whether the state must prove an FDCA violation to enforce its own law, drawing on the U.S. Supreme Court's 2001 ruling in Buckman Co. v. Plaintiffs' Legal Committee. The Eighth Circuit emphasized that a state law that mirrors — rather than deviates from — federal requirements does not create a conflict, relying on the Supreme Court's 1949 decision in California v. Zook.

Judge Loken's separate opinion in Iowans for Alternatives to Smoking & Tobacco v. Mosiman also signals that the obstacle preemption question may be a closer and more record-dependent determination.

SIGNIFICANCE FOR INDUSTRY STAKEHOLDERS AND ONGOING LITIGATION

Rather than producing a circuit split, the current landscape reflects an emerging trend among the federal courts of appeals toward finding state ENDS directory laws not preempted, including in the Fourth, Seventh and Eighth Circuits. This means that ENDS manufacturers, distributors and retailers — at least in these circuits — can expect such laws to remain in effect in the near term.

Nevertheless, the preemption question is not entirely settled. The appellate rulings so far have come at the preliminary injunction stage, without the benefit of a full record, leaving open the possibility that the ultimate merits determinations could differ.

In addition, petitions for en banc review or outstanding preemption challenges, including in the U.S. Courts of Appeals for the Fifth, Ninth and Tenth Circuits, could still produce a disagreement.

Should the trend continue, however, such decisions may give states greater power to step in where they perceive federal enforcement to be lax. By holding that laws requiring compliance with federal requirements simply mirror

those requirements rather than enforce them, the Fourth and Eighth Circuits' decisions give states considerable latitude to backstop underenforced federal regimes and displace the federal enforcement priorities.

The distinction each court drew between congressional purpose and agency enforcement priorities is analytically sound in the abstract, but arguably avoids a harder question: Congress specified that only the FDA may enforce the FDCA's requirements under Section 337(a), and that allocation of enforcement authority is itself among the TCA's objectives.

By characterizing North Carolina's and Iowa's directory laws as sales restrictions rather than licensing or regulatory schemes, the Fourth and Eighth Circuits arguably allow each state to make its own determination of whether a manufacturer has complied with the TCA's premarket review requirements — a determination that, in the challengers' view, only the FDA is meant to make.

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[1] See *Vapor Technology Association v. Wooten*, No. 25-1745 (4th Cir. July 30, 2026); Iowans for Alternatives to Smoking & Tobacco, Inc. v. Mosiman, No. 25-2087 (8th Cir. July 30, 2026).

[2] E-Cigarettes, "Vapes" and Other Electronic Nicotine Delivery Systems (ENDS) Authorized by the FDA, Food & Drug Admin. (May 5, 2026), https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends-authorized-fda.

[3] Food & Drug Admin., Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) (April 2020), https://www.fda.gov/media/133880/download.

[4] Bryan Haynes et al., New FDA Guidance Clarifies Enforcement Discretion Policy for Certain ENDS and Nicotine Pouch Products, Regulatory Oversight, Troutman Pepper Locke LLP (May 15, 2026), https://www.regulatoryoversight.com/2026/05/new-fda-guidance-clarifies-enforcement-discretion-policy-for-certain-ends-and-nicotine-pouch-products/.

[5] 21 U.S.C. § 337(a).

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