In the

United States Court of Appeals

For the Seventh Circuit

No. 25-2565

WISCONSINITES FOR ALTERNATIVES TO SMOKING & TOBACCO, INC., *et al.*,

Plaintiffs-Appellants,

v.

DAVID CASEY, Secretary of the Wisconsin Department of Revenue, in his official capacity,

Defendant-Appellee.

Appeal from the United States District Court for the Western District of Wisconsin.
No. 3:25-cv-00552 — **William M. Conley**, *Judge*.

ARGUED DECEMBER 10, 2025 — DECIDED APRIL 21, 2026

Before BRENNAN, *Chief Judge*, and LEE and KOLAR, *Circuit Judges*.

BRENNAN, *Chief Judge*. The Food and Drug Administration regulates electronic products that deliver nicotine to the user, like electronic vaping devices and e-cigarettes. That authority includes review and approval of those products before they are marketed and sold. *See* 21 U.S.C. § 387j.

Wisconsin enacted a statute in 2023 that requires FDA authorization before electronic nicotine delivery systems may be sold. Wis. Stat. § 995.15. Manufacturers, distributors, retailers, and users of vapes and e-cigarettes sued to enjoin enforcement of that statute. In their view, the federal statutes granting the FDA exclusive authority over premarket authorization preempt the Wisconsin statute. The district court disagreed and denied a preliminary injunction.

The text of the applicable federal laws—the Federal Food, Drug, and Cosmetic Act, as well as the Tobacco Control Act—does not preempt the states' authority to regulate the sale and marketing of tobacco and tobacco-related products, so we affirm.

I.

A. Background

Electronic nicotine delivery systems (ENDS) products include "[v]apes, vaporizers, vape pens, hookah pens, electronic cigarettes (e-cigarettes or e-cigs), e-cigars, and e-pipes."[1] These products typically use a liquid containing tobacco-derived nicotine "heated to create an aerosol that is inhaled" by the user. *Id.* Wisconsin Statute § 995.15 requires the state's Department of Revenue to create a directory of ENDS products that may lawfully be sold in the state. Wis. Stat. § 995.15(6).

[1] E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems (ENDS) (March 12, 2026), https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends.

A product may qualify for the directory in any of three ways: (1) its manufacturer has received an FDA premarket authorization order; (2) it was marketed in the U.S. as of August 8, 2016, it has a pending FDA premarket authorization application submitted by September 9, 2020, and that application remains under review or the final decision has not taken effect; or (3) it contains hemp but not nicotine. Wis. Stat. § 995.15(2). As of September 1, 2025, retailers and manufacturers are prohibited from selling any ENDS products not listed in the directory. Wis. Stat. § 995.15(9)(a)–(b).

Businesses that sell such unlisted ENDS products are subject to forfeiture penalties of $1,000 per day per product and the seizure of the unauthorized products as "contraband." Wis. Stat. § 995.15(9)(a)–(b), (11)(a). Further, the sale of unlisted vaping products constitutes "an unfair and deceptive trade practice in violation of" Wis. Stat. § 100.20. *Id.* at 995.15(9)(c). So "[a]ny person" financially harmed may commence a civil suit to recover twice that "pecuniary loss, together with costs, including a reasonable attorney fee." Wis. Stat. § 100.20(5).

Two months before enforcement was set to begin under § 995.15, Wisconsinites[2] sued the Department, arguing that federal statutes preempted the state statute. They also contended that § 995.15 violates the Equal Protection Clause of the Fourteenth Amendment. Seeking preliminary and permanent injunctions against enforcement of the statute, Wisconsinites claimed § 995.15 would require them "to either run the

[2] Plaintiffs-Appellants Wisconsinites for Alternatives to Smoking are a Wisconsin non-profit corporation and its members, who are manufacturers, distributors, wholesalers, retailers, and users of ENDS products.

risk of incurring substantial fines and forfeitures for sales of [unlisted] ENDS products … or shut down because they cannot maintain a profitable business with the limited range of ENDS products that would be eligible for sale under the statute." They also asserted that the law would deprive consumers, including plaintiffs Kurt Wylie and Germaine Carmody, "of the ability to purchase and consume their preferred ENDS products because those products will not be eligible for sale."

Wisconsinites moved for a preliminary injunction on preemption grounds. Four days after § 995.15 went into effect, the district court denied Wisconsinites' motion. The court concluded that the Wisconsin statute was not preempted by the Federal Food, Drug, and Cosmetic Act, and therefore Wisconsinites had not shown a reasonable likelihood of success on the merits. They also failed to establish that the equities weighed in favor of enjoining the statute's enforcement. Wisconsinites timely appeal.[3]

II.

A. Jurisdiction

Before addressing the denial of the preliminary injunction, the parties debate the grounds for subject-matter jurisdiction. To Wisconsinites, the implied preemption and equal protection claims raise federal questions on which jurisdiction can rest. 28 U.S.C. § 1331. The Department contends that jurisdiction exists only through the equal protection claim.

[3] After the district court denied the preliminary injunction, Wisconsinites moved for an injunction pending appeal, which was denied on similar grounds.

Federal preemption is often raised as a defense against claims in a plaintiff's complaint. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). Federal-law defenses do not supply federal question jurisdiction, "even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." *Id.* at 393. Field, or complete, preemption does confer federal question jurisdiction, but conflict preemption "is merely a defense to the merits of a claim," and thus does not confer jurisdiction under 28 U.S.C. § 1331. *Vorhees v. Naper Aero Club, Inc.*, 272 F.3d 398, 403 (7th Cir. 2001); *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). Because field preemption is not implicated here, *see infra* III.B.1., Wisconsinites must advance a non-preemption basis to assert federal question jurisdiction.

There is no dispute that an equal protection claim is sufficient to supply federal-question jurisdiction. *See K.C. v. Individual Members of Med. Licensing Bd. of Ind.*, 121 F.4th 604, 614–15 (7th Cir. 2024). So, we agree that Wisconsinites have properly alleged a cause of action sufficient "to open the federal courthouse doors." *Braid v. Stilley*, 142 F.4th 956, 962 (7th Cir. 2025). Their preemption challenges follow along with their constitutional claim.

B. Standing

The Department also contests whether Wisconsinites have standing. "Article III of the Constitution confines the federal judicial power to 'Cases' and 'Controversies.'" *United States v. Texas*, 599 U.S. 670, 675 (2023). Plaintiffs who claim Article III standing must establish they (1) "suffered an injury in fact," that (2) was "likely caused by the defendant," and (3) is "likely [to] be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021).

An injury in fact must be "concrete, particularized, and actual or imminent." *Id.* Concrete injuries include tangible injuries such as monetary harms. *Wisconsin Voter All. v. Millis*, 166 F.4th 627, 632 (7th Cir. 2026) (per curiam). Section 995.15, Wisconsinites allege, will cause them to lose sales and business. That suffices as a concrete injury in fact, *see In re Recalled Abbott Infant Formula Prods. Liab. Litig.*, 97 F.4th 525, 529 (7th Cir. 2024), which the district court correctly found.

Next is causation. The Department asserts that Wisconsinites lack standing because their conduct would be illegal, regardless of this case's outcome. But this case is not similar to decisions the Department cites involving drivers running red lights or traffickers of illegal narcotics. Rather, as the district court found, Wisconsinites have a legitimate basis to believe they are engaged in legal economic activities. If the FDA had been taking enforcement action against unapproved tobacco products, Wisconsinites could not sell those products regardless of any state enforcement. But the FDA has opted for limited case-by-case enforcement.[4] Neither the actual nor realized threat of federal enforcement prevents Wisconsinites from selling their e-cigarettes. So, the state enforcement of § 995.15 would cause financial harm to Wisconsinites. They have thus shown causation for purposes of this standing analysis. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 385 (2024).

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[4] Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization 9 (April 2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.

Last is redressability. Courts redress injuries by providing the plaintiff a remedy against the defendant because remedies "operate with respect to specific parties." *California v. Texas*, 593 U.S. 659, 672 (2021) (quoting *Murphy v. NCAA*, 584 U.S. 453, 489 (2018) (Thomas, J., concurring)); *see also* William Baude & Samuel L. Bray, *Proper Parties, Proper Relief*, 137 HARV. L. REV. 153, 182 (2023). The relief must be "likely" and "not 'merely speculative'" to remedy the injury. *Soc'y of Divine Word v. U.S. Citizenship & Immigr. Servs.*, 129 F.4th 437, 447 (7th Cir. 2025) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). When analyzing redressability, courts "consider the relationship between the judicial relief requested and the injury suffered." *California*, 593 U.S. at 671 (citation modified). Redressability depends on the relief requested, not the relief to which a plaintiff can prove it is entitled on the merits. *Lac Du Flambeau Band v. Norton*, 422 F.3d 490, 502 (7th Cir. 2005). Put simply, when we enjoin the enforcement of a statute, the injunction runs against "the acts of the official," rather than "the execution of the statute." *Massachusetts v. Mellon*, 262 U.S. 447, 488 (1923).

The harms Wisconsinites allege "flow[] directly from" the enforcement of Wis. Stat. § 995.15. *Collins v. Yellen*, 594 U.S. 220, 244 (2021). This case is not like *Haaland v. Brackeen*, in which the Court held that plaintiffs lacked standing because they sued federal parties even though the state officials implemented the statute. *See* 599 U.S. 255, 292–93 (2023). It is also distinguishable from *Harp Advertising Illinois, Inc. v. Village of Chicago Ridge*, which involved two overlapping ordinances. 9 F.3d 1290, 1291 (7th Cir. 1993). That meant the plaintiff's injury was not redressable "even if it achieved total victory in th[e] litigation." *Id.* A decision for Wisconsinites would provide a remedy because they could sell and access ENDS

products without fear of adverse action. Because the alleged harms would flow directly from enforcing § 995.15, and are redressable by the requested relief, Wisconsinites have alleged and established a concrete harm sufficient for Article III standing.

III.

With jurisdiction secure and satisfied that Wisconsinites have standing, we review the district court's denial of a preliminary injunction.

A preliminary injunction is "an exercise of a very far-reaching power, never to be indulged in except in a case clearly demanding it." *Lukaszczyk v. Cook County*, 47 F.4th 587, 598 (7th Cir. 2022) (citation omitted). A party seeking a preliminary injunction must establish that (1) it is likely to succeed on the merits; (2) it will suffer irreparable harm without preliminary relief; (3) the balance of equities is in its favor; and (4) an injunction would be in the public interest. *Id.* (citing *Winter v. Nat. Res. Def. Council*, Inc., 555 U.S. 7, 20 (2008)).

When reviewing a denial of a preliminary injunction, "we review the district court's findings of fact for clear error, its legal conclusions *de novo*, and its balancing of the factors for a preliminary injunction for abuse of discretion." *Proft v. Raoul*, 944 F.3d 686, 693 (7th Cir. 2019) (citation omitted).

This case focuses on Wisconsinites' likelihood of success on the merits of its claims. Before considering that factor, we review the applicable law of implied conflict preemption and how it interacts with federal law regulating tobacco products. Then, we evaluate the district court's denial of a preliminary injunction based on Wisconsinites' failure to demonstrate a reasonable likelihood of success on the merits, applying the

law of implied conflict preemption, and specifically the Tobacco Control Act's tripartite preemption structure.

A. Statutory Background

The parties' arguments implicate the Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938), as well as the Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

Enacted in 1938, the FDCA gives the Food and Drug Administration vast power to regulate consumer products related to health and welfare. *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 549 (2025). The FDCA provides that all proceedings to enforce or restrain violations of the Act "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In 2009, the TCA extended the FDA's regulatory authority to "new tobacco product[s]," requiring manufacturers to receive approval from the FDA before marketing those products. 21 U.S.C. § 387j. A "new tobacco product" is one not commercially marketed in the United States as of February 15, 2007, or modified after that date. 21 U.S.C. § 387j(a)(1).

E-cigarettes were not initially considered "new tobacco products" under the TCA. *FDA v. R. J. Reynolds Vapor Co.*, 606 U.S. 226, 230 (2025) (citation omitted). But in 2016, the FDA changed course and determined e-cigarettes were "tobacco products," requiring FDA premarket authorization. *Id.*; 81 Fed. Reg. 29028–44 (2016). Congress later amended the TCA to define "tobacco product[s]" as those containing nicotine "from any source," such as synthetic (non-tobacco-derived) nicotine. 21 U.S.C. § 321(rr)(1). To mitigate any disruption to the market, the FDA deferred TCA enforcement against e-

cigarette manufacturers while they sought premarket approval. *See R.J. Reynolds*, 606 U.S. at 230; 81 Fed. Reg. 29009–15 (2016).

A manufacturer seeking FDA approval must first submit a premarket tobacco product application. 21 C.F.R. § 1114.1(a); 31 U.S.C. § 387j. If the application is approved, the FDA issues a "marketing granted order." 21 C.F.R. § 1114.5, 1114.31. The sale of e-cigarette products in interstate commerce without FDA premarket authorization is prohibited and violators are subject to fines and imprisonment. 21 U.S.C. §§ 331(a), 333(a), 387b(6)(A); *Wages & White Lion Invs.*, 604 U.S. at 555 ("[B]ecause those products had not received premarket authorization, the effect of the [FDA] rule was to make their continued sale illegal.").

Against the backdrop of federal regulation, the TCA's text shows Congress's "explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products.'' *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 550 (9th Cir. 2022) (quoting *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013)); *see also* 21 U.S.C. § 387p.

Three separate clauses of the TCA, taken together, make this plain. First, the TCA preserves a state's power to create regulations "in addition to, or more stringent" than the statute's requirements. 21 U.S.C. § 387p(a)(1) (the "preservation clause"). Second, it carves out several exceptions to its general preemption provisions, allowing states to regulate on several aspects of tobacco product control. 21 U.S.C. § 387p(a)(2)(A) (the "preemption clause"). And third, it contains a savings clause excepting more categories from preemption. 21 U.S.C. § 387p(a)(2)(B) (the "savings clause").

This tripartite preemption framework balances the states' power to regulate tobacco against the FDA's "sole authority to set tobacco product standards." *County of Los Angeles*, 29 F.4th at 560. The power to regulate includes the power to prohibit. *See id.* Although we acknowledge the FDA's regulatory authority, we must also respect the areas Congress excepted from preemption.

B. Likelihood of Success on the Merits

Wisconsinites submit that the district court erred in interpreting the preservation clause. To them, § 995.15, by requiring strict compliance with the TCA's premarket review requirements, denies the FDA the "flexible enforcement authority" provided by that Act. They submit that this obstacle to the "balancing and accomplish[ing]" of Congress's purposes means the TCA preempted § 995.15. But the district court properly concluded that Wisconsinites were unlikely to succeed on the merits of their claim.

We start with the law of implied conflict preemption. Then we apply this law to the TCA's tripartite preemption framework to conclude that the Act's text makes it unlikely that Congress intended to preempt state laws that rely on that Act's requirements to regulate the sale of tobacco products.

1. *Implied Conflict Preemption*

Federal statues preempt state law through the Supremacy Clause. *Ye v. GlobalTranz Enters., Inc.*, 74 F.4th 453, 457 (7th Cir. 2023); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 234 (2000). "There is no federal preemption *in vacuo*." *Kansas v. Garcia*, 589 U.S. 191, 202 (2020). Instead, a federal restriction of a state law "must stem from either the Constitution itself" or a congressional statute. *Id.* As a result, the Supremacy Clause

empowers federal statutes to preempt or nullify a state law that "prevent[s] or frustrate[s]" Congress's objective. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (citation modified).

As with all preemption arguments, the analysis of implied preemption claims "must be grounded 'in the text and structure of the statute at issue.'" *Kansas*, 589 U.S. at 208 (citing *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). An "[i]mplied preemption analysis does not justify a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation modified).

There are two forms of implied preemption: field and conflict. *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Nelson v. Great Lakes Educ. Loan Servs., Inc.*, 928 F.3d 639, 646–47 (7th Cir. 2019). Field preemption occurs when "Congress has so completely preempted a particular area that no room remains for any state regulation and the complaint would be necessarily federal in character." *Rogers v. Tyson Foods, Inc.*, 308 F.3d 785, 787 (7th Cir. 2002) (citation modified). Two provisions in the TCA provide that field preemption is not implicated here. "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." *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1174 (8th Cir. 2023); 21 U.S.C. § 387p(a)(1). And the savings clause excepts certain tobacco product regulations from preemption. 21 U.S.C. § 387p(a)(2)(B).

When Congress first enacted the FDCA, it included a provision specifying that all enforcement of the Act's violations "shall be by and in the name of the United States." 21 U.S.C.

§ 337(a). The Court has interpreted § 337(a) as preempting the states' authority to enforce the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). But when Congress amended the FDCA through the TCA, it expressly reserved enforcement authority for the states. *See* 21 U.S.C. § 387p. Thus, there is no field preemption here because the TCA reserves some authority for the states to regulate tobacco. *See* 21 U.S.C. § 387p(a)(2)(B); *City of Edina*, 60 F.4th at 1174.

By contrast, conflict preemption exists when either (1) "compliance with both federal and state regulations is a physical impossibility" or (2) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 984 (7th Cir. 2012) (quoting *Arizona*, 567 U.S. at 399). So, we are to answer whether the text and structure of 21 U.S.C. §§ 337(a) and 387p conflict preempt § 995.15.

2. *Preemption under the TCA*

As described above, the TCA creates a tripartite preemption structure. *See* 21 U.S.C. § 387p(a)(1)–(a)(2)(B). The preservation clause's text shows Congress's decision to reserve the states' power to regulate tobacco "in addition to, or more stringent than" the Act's requirements "[e]xcept as provided in [the preemption clause]." 21 U.S.C. § 387p(a)(1); *see also City of Edina*, 60 F.4th at 1174.

In turn, the preemption clause limits the reach of the preservation clause by prohibiting states from enacting regulations "different from or in addition to," the TCA's requirements in certain categories. 21 U.S.C. § 387p(a)(2)(A). The

preemption clause "carves out eight limited exceptions to the preservation clause, each of which relates most obviously to the production or marketing stages—and not the retail sale—of tobacco products[.]" *County of Los Angeles*, 29 F.4th at 553–54 (citing 21 U.S.C. § 387p(a)(2)(A)). But the savings clause excepts certain categories from preemption, including "requirements relating to the sale, distribution, … or use of … tobacco products[.]" 21 U.S.C. § 387p(a)(2)(B).

Therefore, the district court correctly reasoned that the preservation clause's text suggests "at minimum, Congress intended that States use the TCA as a floor for further restrictions on tobacco product manufacturers from accessing their markets." And "[t]he language of the Savings Clause also suggests Congress's apparent intent that States retain the ultimate authority to prohibit the sale of a tobacco product altogether, regardless of its compliance with TCA provisions." The court concluded that "the power to enact and enforce the same or *additional* sales requirements is expressly preserved to the States after adopting the TCA, at least so far as tobacco product requirements are created by state law[.]" Further, "the full text of the TCA and FDCA" make it "unlikely that Congress intended to preempt the States' authority to enact and enforce laws restricting the sale of tobacco products that rely in part on TCA requirements, such as Wis. Stat. § 995.15[.]" Thus, the court found that Wisconsinites failed to demonstrate a reasonable likelihood of prevailing on the merits.

To counter this application of the tripartite preemption structure, Wisconsinites argue that only the federal government can enforce the TCA. They invoke *Buckman* to support that proposition. 531 U.S. at 348. There, the Court considered

whether state law claims for fraud on the FDA conflicted with the FDA's responsibility to police fraud. *Id.* at 350. It ruled that Congress did not intend to force medical device manufacturers to comply "with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes." *Id.* So, the state law claims were impliedly preempted by the Medical Device Amendments to the FDCA. *Id.* at 353. The Court concluded the claims were preempted because of explicit evidence, not the FDA's nebulous enforcement power. *See id.*

But *Buckman* involved non-federal enforcement of fraud-on-the-FDA claims, which caused over-disclosure of information to the FDA in medical device applications. *Id.* at 351. There is no such issue here. And as the district court ruled, relying on the FDCA to provide a standard is different from enforcing the statute.

Wisconsinites also contend the federal government has exclusive FDCA enforcement authority. After all, the TCA is an amendment to the FDCA. That means the Acts share the same enforcement mechanisms. Yet, *Buckman* held that the FDCA preempted state-law fraud-on-the-FDA claims, not because the FDA had discretionary enforcement, but because the claims "exist[ed] solely by virtue of the FDCA disclosure requirements," and that Act showed Congress's intent to provide exclusive federal jurisdiction to regulate the products. *Id.* at 352–53.

The Court in *Buckman* was also concerned the state-law claims could "exert an extraneous pull on the scheme established by Congress," creating tension between FDA determinations (favoring more minimal disclosures) and state court adjudications (incentivizing greater disclosures). *Id.* at 351, 353. This issue does not arise here because adjudication is not

needed. *See Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 966 (6th Cir. 2004) (no concerns of "inter-branch meddling … when the FDA itself determines that a fraud has been committed on the agency") (citation modified). So, there is not a possible problem with Wisconsin infringing upon the FDA's enforcement authority.

The district court found Wisconsinites' reliance on *Buckman* unpersuasive. Most of the cases they cited did not "involve tobacco products or the TCA's Preservation and Savings Clauses." The few cases that did involve tobacco products "simply appl[ied] *Buckman* without analysis of the effect of the Preservation and Savings Clauses." On appeal, Wisconsinites fare no better, as they continue to cite non-tobacco cases to support their *Buckman*-preemption theory.[5]

In their principal brief to us, Wisconsinites also argue that "the text, structure, and legislative history of the FDCA suggest that Congress did not intend the TCA's preservation and savings clauses … to allow States to enact and enforce requirements that cross-reference, and thus are parasitic on, the TCA's requirements."

This is incorrect. The preemption clause has certain carveouts, none of which apply to the sale of tobacco products. And the savings clause expressly safeguards the regulation of tobacco "sale[s]" and "distribution" from preemption. Thus,

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[5] *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (medical devices); *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F. 4th 1040 (9th Cir. 2022) (drugs); *Anthony v. Country Life Mfg., L.L.C.*, No. 02 C 1601, 2002 WL 31269621 (N.D. Ill. Oct. 9, 2002) (food); *Vanzant v. Hill's Pet Nutrition Inc.*, No. 17 C 2535, 2025 WL 296062 (N.D. Ill. Jan. 24, 2025) (pet food).

state regulations "relating to the sale [or] distribution" are not preempted by the TCA. *See* § 21 U.S.C. 387p(a)(2)(B).

In the alternative, Wisconsinites argue that states cannot enforce federal requirements. Even if the TCA sets a federal "floor" for regulation which states can exceed, they argue, that does not mean states can enact the federal requirements as state law and subsume the FDA's enforcement authority. Wisconsinites submit that Congress has "a long history" of explicitly providing that states may enforce requirements identical to federal statutes. But the TCA does not include any such reference to state authority. States can enforce requirements "in addition to, or more stringent than" the FDCA requirements through the preservation clause. 21 U.S.C. § 387p(a)(1). And the preemption clause prohibits states from enacting regulations "different from or in addition to," the TCA's requirements. 21 U.S.C. § 387p(a)(2)(A). But neither clause references requirements identical to FDCA requirements. Thus, Wisconsinites claim, Congress only intended to allow state tobacco regulations that differed from federal regulations.

But this argument misconstrues preemption. Implied preemption asks whether state law conflicts with federal law. *See Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). A state law that mirrors a federal standard does not create a conflict; rather, they impose the same standards. *Id.* at 76–77. There is no implied conflict preemption if there is no conflict. *See Wyeth v. Levine*, 555 U.S. 555, 581 (2009). Accordingly, the TCA permits identical regulations as well regulations "in addition to, or more stringent than" the FDA's requirements. *See* 21 U.S.C. § 387p(a)(1).

Wisconsinites also overread § 337(a),[6] which limits only lawsuits that implicate adjudications of FDCA violations. *Buckman*, 531 U.S. at 348; *see also Garcia*, 385 F.3d at 966 (holding that concerns over state court encroachment on the FDA's authority "do not arise" when "the FDA *itself*" determines the violation). Section 995.15 asks whether a product has FDA approval. It does not involve an adjudication of a violation. Therefore, § 995.15 does not seek to enforce the FDCA, either indirectly or directly. Indeed, noncompliance with the FDCA is not even a basis for the Department to start proceedings. And cross-referencing to FDA approval orders is not equivalent to enforcing the FDCA itself. *But cf. Iowans for Alts. to Smoking & Tobacco, Inc. v. Iowa Dep't of Revenue*, 781 F. Supp. 3d 724, 741 (S.D. Iowa 2025).

Finally, Wisconsinites fail to recognize that in the FDCA-enforcement context, tobacco products are distinct. Unlike drugs, food products, and medical devices, states have long regulated tobacco. *See Austin v. Tennessee*, 179 U.S. 343, 348–49 (1900) (cigarettes are "within the province of the legislature to say how far they may be sold, or to prohibit their sale entirely…"); *see also Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1191 (11th Cir. 2017). At both the district court and on appeal, Wisconsinites have not identified any tobacco cases to support their unsuccessful *Buckman*-preemption theory.

3. *Other courts*

Four other circuits have concluded that the TCA does not preempt similar tobacco sales laws because such bans are not

[6] "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a).

efforts to set tobacco product standards. *City of Edina*, 60 F.4th at 1179 (Eighth Circuit holding that states and cities are free to regulate tobacco above the Act's floor); *County of Los Angeles*, 29 F.4th at 561 (Ninth Circuit concluding similarly); *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 436 (Second Circuit ruling that city ordinance was not preempted because it regulated sales rather than setting standards); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82–83 (1st Cir. 2013) (recognizing that the Act allows regulations relating to the sale of tobacco products).

True, one published district court decision has concluded otherwise. *See Iowans for Alts. to Smoking & Tobacco, Inc.*, 781 F. Supp. 3d at 741. But this decision, which Wisconsinites rely on, overreads *Buckman*. There, the Court concluded that exclusive federal enforcement in the FDCA forecloses non-federal enforcement to maintain the balance of statutory objectives and the FDA's responsibilities. *Buckman*, 531 U.S. at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."). As analyzed above, relying on the FDCA to provide a standard is different from enforcing the statute. *See supra* at III.B.2.

Not every sales ban is "a backdoor 'requirement … relating to tobacco product standards.'" *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434 (quoting 21 U.S.C. § 387p(a)(2)(A)). A preempted tobacco product standard "must be something more than an incentive or motivator … it must require manufacturers to alter the construction, components, ingredients, additives, constituents ... and properties of their products." *Id.* (citation modified); *see also City of Edina*, 60 F.4th at 1175. Section 995.15 is another such tobacco sales ban. The preservation

clause expressly authorizes states to enact and enforce the same or additional sales requirements. 21 U.S.C. § 387p(a)(1). And the savings clause states the preemption clause "does not apply to requirements relating to the sale … of tobacco products," thereby removing any limitation on the states' authority to enact tobacco sales bans. 21 U.S.C. § 387p(a)(2)(B). Together, these clauses show that Congress did not intend to preempt states' authority to regulate the sale of tobacco products.

The text of the TCA reveals where Congress decided to preempt state law, *see* 21 U.S.C. § 387p(a)(2)(A), and where Congress expressly preserved state authority and limited preemption, *see* 21 U.S.C. § 387p(a)(1), (a)(2)(B). We need not ignore this mandate providing states the final authority on which tobacco products may be sold in their respective marketplaces. Accordingly, Wisconsinites have failed to meet their burden to demonstrate a reasonable likelihood of prevailing on the merits of their claims.

C. Irreparable Harm

In addition to establishing a reasonable likelihood of success on the merits, a party seeking a preliminary injunction must show it is "likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest." *K.C.*, 121 F.4th at 613 (quoting *Winter*, 555 U.S. at 20). A preliminary injunction analysis operates on a sliding scale: the greater the likelihood of success on the merits, the less the equities need to favor the moving party. *Id.* at 633.

Irreparable harm occurs when the "legal remedies available to the movant are inadequate, meaning they are seriously

deficient as compared to the harm suffered." *DM Trans, LLC v. Scott*, 38 F.4th 608, 618 (7th Cir. 2022). A modification to the movant's business can constitute irreparable harm if it forces the movant to shut down its business while litigation is pending. *See Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 386 (7th Cir. 1984). Here, the district court's conclusion of irreparable harm is supported by the record.

Quantifiable harm is typically not irreparable. *Life Spine, Inc. v. Aegis Spine, Inc.*, 8 F.4th 531, 546 (7th Cir. 2021) (concluding that "harm stemming from lost customers or contracts may be quantifiable if the lost customers or contracts are identifiable"). Wisconsinites submit that the sales of products subject to § 995.15 "represent between 83% and 91.5% of the[ir] revenues and profits." But plaintiffs also anticipate that the revenue from eligible ENDS products would not cover their operating costs. And Wisconsinites also risked incurring substantial financial penalties if they sold ENDS products not listed in the directory after September 1, 2025. This combination of lost revenue from ENDS products and the substantial financial penalties incurred for selling those products means plaintiffs would be forced to shut down while awaiting trial. For preliminary injunction purposes, then, such harms are irreparable. *See Roland Mach. Co.*, 749 F.2d at 386.

D. Balance of Equities and Public Interest

The equities and public interest factors tilt against Wisconsinites. The injunction of a state's duly enacted law causes significant harm to the state and the public interest. *K.C.*, 121 F.4th at 633; *see also Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers).

Plaintiffs point to a First Amendment challenge in *ACLU of Illinois v. Alvarez*, 679 F.3d 583 (7th Cir. 2012). There, this court ruled that "if the moving party establishes a likelihood of success on the merits, the balance of harms normally favors granting preliminary injunctive relief." *Id.* at 589–90. In that context, the injunction of a likely unconstitutional statute was in the public interest because it furthered the public's First Amendment rights. *See id.* at 590 (citing *Christian Legal Soc'y v. Walker*, 453 F.3d 853, 859 (7th Cir. 2006)). But here, Wisconsinites bring an equal protection challenge to the government's attempt to "effectuat[e] statutes enacted by representatives" of the people of Wisconsin. *Maryland*, 567 U.S. at 1303 (Roberts, C.J., in chambers). And such an effort to enjoin enforcement when the government is likely to succeed on the merits weighs in favor of the Department. *See Trump v. CASA, Inc.*, 606 U.S. 831, 860–61 (2025); *cf. Alvarez*, 679 F.3d at 589–90.

We must also consider Wisconsinites' delay in bringing the suit, more than 19 months after § 995.15 enactment and only two months before the directory was to go into effect. These balance of equities and public interest factors weigh in favor of the Department.

IV.

Wisconsinites have failed to demonstrate a reasonable likelihood of success on the merits of their claim that Wisconsin Statute § 995.15 is preempted by federal law. Although they have shown they would suffer irreparable harm under the state statute, the balance of harms and the public interest do not weigh in favor of enjoining enforcement of the state law. For these reasons, the district court correctly denied Wisconsinites' motion for a preliminary injunction.

AFFIRMED