No. 25-2087

IN THE
United States Court of Appeals for the Eighth Circuit

IOWANS FOR ALTERNATIVES TO SMOKING & TOBACCO; *et al.*,

Plaintiffs-Appellees,

v.

MARY MOSIMAN, in her official capacity as Director of the Iowa Department of Revenue,

Defendant-Appellant.

On Appeal from the United States District Court
for the Southern District of Iowa
Case No. 4:24-cv-448
(The Honorable Stephanie M. Rose)

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July 22, 2025

SUMMARY OF CASE AND STATEMENT ON ORAL ARGUMENT

This appeal raises significant issues of standing and federal preemption. Plaintiffs—vapor product retailers, consumers, and an advocacy group for vapor retailers—challenge an Iowa law, House File 2677, regulating vapor products sales in Iowa. This Court has held that States are free to enact laws regulating sales of tobacco products (which, under federal law, include vapor products), because the federal Tobacco Control Act expressly saves those laws from preemption. *See R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170 (8th Cir. 2023).

The district court nevertheless preliminarily enjoined Defendant's enforcement of HF2677 as preempted. But 1) Plaintiffs lack standing to challenge a state law that they allege inhibits their ability to continue violating federal law; 2) Plaintiffs are not likely to succeed on the merits because the TCA saves HF2677 from preemption as a state law related to tobacco products sales; and 3) the remaining injunction factors weigh against relief. Adopting Plaintiffs' theory of standing, the district court then reasoned that HF2677 must be preempted as encroaching on federal enforcement discretion because it incorporates federal standards, despite also imposing unique state law duties as a condition of legal sales in Iowa.

Defendant requests 15 minutes per side for oral argument.

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STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331 and issued its order granting Plaintiffs' renewed motion for preliminary injunction on May 2, 2025. R.Doc.49. Defendant timely appealed on May 30. R.Doc.54. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1) to review an interlocutory order granting a preliminary injunction. *Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds*, 530 F.3d 724, 730 (8th Cir. 2008).

STATEMENT OF THE ISSUES FOR REVIEW

1. Whether Plaintiffs have standing to challenge a state law that they allege inhibits their ability to continue violating federal law.

Cases: *Vapor Tech. Ass'n v. Taylor*, 2025 WL 348684 (E.D. Ky. Jan. 30, 2025)

Animal Legal Def. Fund v. Reynolds, 89 F.4th 1071 (8th Cir. 2024)

2. Whether the Tobacco Control Act, which broadly preserves and saves from preemption state laws relating to sales of tobacco products, preserves and saves HF2677 from preemption because HF2677 creates unique state law requirements before certain tobacco products may be sold in Iowa.

Cases: *California v. Zook*, 336 U.S. 725, (1949)

R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170 (8th Cir. 2023)

Zyla Life Sci., L.L.C. v. Wells Pharma of Houston, L.L.C., 134 F.4th 326 (5th Cir. 2025)

Vapor Tech. Ass'n v. Wooten, 2025 WL 1787420, (E.D.N.C. June 27, 2025)

Statutes: 21 U.S.C. § 387p(a)

21 U.S.C. § 337(a)

Iowa Code § 4.4(1)

Iowa Code § 4.7

3. Whether the district court abused its discretion in granting injunctive relief where the court failed to assess the non-merits factors and waived the mandatory injunction-bond requirement.

Cases: *Ng v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992 (8th Cir. 2023)

Dixon v. City of St. Louis, 950 F.3d 1052 (8th Cir. 2020)

Sessler v. City of Davenport, 990 F.3d 1150 (8th Cir. 2021)

INTRODUCTION

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

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

Plaintiffs challenge Iowa House File 2677, which regulates vape sales. That law regulates Iowa vape sales by (1) requiring a directory of HF2677-compliant vapes and (2) prohibiting the sale in Iowa of any vapes not included in the directory. Plaintiffs argued that federal law preempts

HF2677—despite Congress's express preservation of States' police powers in this area.

The district court agreed. The district court enjoined Defendant's enforcement of HF2677 after finding the law was "parasitic" of federal law, reasoning that Iowa's law in part, but not in whole, incorporated federal law to determine the scope of a state law tobacco-product-sales violation. Not only is that a novel conclusion in federal courts, but it conflicts with this Court's precedent.

Worse yet, the district court granted a preliminary facial injunction even though Plaintiffs not only lack injury-in-fact but lack irreparable harm—shown by their seven-month delay in suing. Applying Eighth Circuit and Supreme Court precedent, this Court should reverse the district court and allow Defendant to enforce HF2677 to the benefit of Iowa's public health.

STATEMENT OF THE CASE

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

Responding to "growing concerns about adolescent tobacco use," Congress amended the Food, Drug, and Cosmetic Act ("FDCA") by enacting the TCA. *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th

1170, 1173 (8th Cir. 2023) (citing Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009)). The law authorized the U.S. Food and Drug Administration to regulate tobacco products, including advertising, labeling, and manufacturing practices. Congress balanced the federal interest in national uniformity with respect for States' police power, enacting Preservation, Preemption, and Savings clauses. 21 U.S.C. § 387p(a). Those clauses mean that States remain free to regulate tobacco product sales. *See Edina*, 60 F.4th at 1175.

Since 2016, FDA has classified vapes containing tobacco-derived nicotine as "tobacco products" under the TCA. *See* 81 Fed. Reg. 28974, 28975 (May 10, 2016). In 2022, Congress amended the "tobacco products" definition to include products containing nicotine "from any source," including those containing synthetic, *i.e.*, non-tobacco-derived, nicotine. *See* Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, § 111(a).

So before manufacturers may sell new ENDS interstate, they must follow the same federal requirements as other tobacco-product manufacturers: They must submit a Premarket Tobacco Product Application ("PMTA"); if FDA grants their PMTA, they may sell their

products; if FDA denies their PMTA, they may not sell their products. *See* 21 C.F.R. § 1114.5; FDA, *Tobacco Products Marketing Orders*, perma.cc/GB97-PD3D (last visited Jul. 22, 2025) ("To legally market a new tobacco product in the United States, a company must receive a written marketing order from FDA."). Without authorization, federal law does not permit tobacco product sales in interstate commerce.

FDA has authorized sale of only 34 vapor products to date. *See* FDA, *E-Cigarettes Authorized by the FDA*, perma.cc/VP8X-2HRK (last visited Jul. 22, 2025). But many more than 34 are marketed and sold because FDA has applied a series of ever-changing policies that began as "deferred enforcement" and is now case-by-case enforcement. App.Vol.I.19–20, R.Doc.27 at 15–16; App.Vol.I.289, R.Doc.32-8 at 3.

FDA's decision to engage in case-by-case enforcement is a resource-limitation issue. FDA recognizes "that it is unable, as a practical matter, to take enforcement action against every illegally marketed tobacco product," and since September 2021 has made best use of its resources via that policy. App.Vol.I.253, R.Doc.32-5 at 33. That results in many federally illegal vapor products being sold. *See, e.g.*, FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other*

Deemed Products on the Market Without Premarket Authorization (Revised) at 27 ("2020 Guidance"), perma.cc/V2QA-QEDZ.

But FDA's prudent husbanding of resources has not meant no enforcement. Between July 2020 and November 2023, federal regulators issued over 630 warning letters and civil money penalty complaints against at least 57 manufacturers and retailers for manufacturing or selling unauthorized vapor products. App.Vol.I.292–295, R.Doc.32-8 at 6–9. And customs officials have seized unauthorized vapor products upon arrival in the United States. App.Vol.I.292–293, R.Doc.32-8 at 6–7.

B. House File 2677.

Against that federal backdrop, 15 States have passed (and 25 other States are considering) e-registry laws. Public Health Law Center, *State E-Cigarette Registry Bill Map*, perma.cc/W39V-PK53?type=image (last visited Jul. 22, 2025). Iowa enacted HF2677 in May 2024. 2024 Iowa Acts 694–698. HF2677 amended chapter 453A to regulate the sale of vapor products in Iowa. *Id*.

Beginning on the date the Director first makes the vapor products directory publicly available, manufacturers may only sell vapor products in Iowa, "either directly or through a distributor, wholesaler, retailer, or

similar intermediary or intermediaries," if their product is included in the directory. Iowa Code § 453A.52A. To be included, the manufacturer must certify under penalty of perjury to the Department that one of the following applies to their vapor product:

> *a.* That the vapor products manufacturer has received a marketing authorization or similar order for the vapor product from the [FDA under] 21 U.S.C. § 387j. [Or]
> *b.* That the vapor product was marketed in the United States as of August 8, 2016, the vapor products manufacturer submitted a premarket tobacco product application for the vapor product to the [FDA] pursuant to 21 U.S.C. § 387j on or before September 9, 2020, and the application either remains under review by the [FDA] or a final decision on the application has not otherwise taken effect.

Id. § 453A.52(1). Manufacturers must submit separate applications for each vapor product to be included in the directory along with the required supporting documents establishing section 453A.52(1) compliance, plus a $100 per-product fee. *Id.* § 453A.52(3). Manufacturers must also appoint and engage an agent for service of process in Iowa. *Id.* § 453A.52D.

Department staff may approve, deny, or request more information about the application. App.Vol.II.331–332, R.Doc.39-2 at ¶ 6.

Department staff may later audit directory-approved vapor products to ensure the application's accuracy. Iowa Code § 453A.52C. If a product is not included in the directory, HF2677 prohibits selling it in the State. *Id.* § 453A.52A(1).

Manufacturers must annually recertify their vapor products. *Id.* § 453A.52(1). Failure to recertify or maintain compliance may result in removal from the directory. *Id.* §§ 453A.52(6)–(8).

The Department must "maintain and make publicly available a vapor products directory that lists all vapor products manufacturers and vapor products for which certification forms have been submitted." *Id.* § 453A.52(5)(*a*). Products not included in the directory may not be sold in Iowa and are considered "contraband and are subject to seizure, forfeiture, and destruction." *Id.* § 453A.52(8).

Liability under HF2677 turns on illegal sales. Retailers who sell vapor products in Iowa that are not included in the directory are subject to fines and their retailer license may be affected. After the Department publishes the directory—and after any later removal of a vapor product from the directory—businesses in Iowa will have 21 business days to

come into compliance. App.Vol.II.333–334, R.Doc.39-2 ¶ 14; Iowa Code § 453A.52(8).

Once the Department begins enforcing the directory, a retailer, distributor, or wholesaler will be subject to a $300 per/day civil penalty for each vapor product sold or offered for sale in Iowa that is not included in the directory, plus suspension or revocation of a retailer's permit for repeat violations. Iowa Code § 453A.52B(1). Manufacturers will be subject to a $1,000 per/day civil penalty for each vapor product sold or offered for sale in Iowa that is not included in the directory. *Id.* § 453A.52B(2).

HF2677 took effect on July 1, 2024. On July 29, the Department announced that directory applications would open November 12, the directory would be first published January 2, 2025, and enforcement would begin February 3. *See* App.Vol.II.332–333, R.Doc.39-2 ¶ 10.

C. Plaintiffs Sue to Enjoin Defendant's Enforcement of HF2677.

Five vapor retailers and an advocacy group for retailers in the vapor industry sued on December 17, 2024, seeking to enjoin the Department and Director's implementation and enforcement of HF2677 in its entirety. App.Vol.II.407–408, R.Doc.4–5. The Department voluntarily

stayed enforcement during the district court proceedings. App.Vol.II.405, R.Doc.49 at 2.

On February 19, 2025, Plaintiffs amended their complaint to add two plaintiff-consumers who seek to use unauthorized ENDS products. App.Vol.I.5–36. R.Doc.27. Two days later, Plaintiffs renewed their motion seeking the same preliminary injunctive relief. App.Vol.I.178–181, R.Doc.32; App.Vol.II.407–408, R.Doc.4–5.

Retailer Plaintiffs do not allege that they have received a written marketing order from FDA. *See* App.Vol.I.8–10, R.Doc.27 ¶¶ 12–17. Nor do they allege that any of their products falls outside FDA jurisdiction such that a marketing order is not required. Rather, multiple retailer Plaintiffs allege they are distributors, wholesalers, or retailers of "unauthorized ENDS products." App.Vol.I.9–10, R.Doc.27 ¶¶ 13–17. Another alleges the FDA application for its products is pending. App.Vol.I.9, R.Doc.27 ¶ 14.

Retailer Plaintiffs allege HF2677 "forces" them "to stop selling [their] [federally] unauthorized ENDS products." *See, e.g.*, App.Vol.I.27–28, R.Doc.27 ¶¶ 85–90; App.Vol.I.30–31, R.Doc.27 ¶¶ 100–104; App.Vol.I.33–34, R.Doc.27 ¶¶ 114–118. Consumer Plaintiffs allege

HF2677 may "deprive" them of the "ability to purchase and consume their preferred," "unauthorized ENDS products." App.Vol.I.8, R.Doc.27 ¶ 11; App.Vol.I.10–11, R.Doc.27 ¶¶ 18–19; App.Vol.I.28, R.Doc.27 ¶ 90.

D. District Court Grants Preliminary Injunction.

After a hearing, the district court enjoined Defendant Mary Mosiman, Director of the Iowa Department of Revenue "from implementing and enforcing the provisions to HF2677 relating to the establishment and enforcement of a vapor products directory." App.Vol.II.434–435, R.Doc.49 at 31–32.[1] The district court held that Defendant Mosiman could enforce HF2677's requirement that nonresident vapor product manufacturers not registered to do business in the State appoint and continually engage an agent for service of process. App.Vol.II.435, R.Doc.49 at 32. But the court did not explain how Defendant could separate that requirement, which is part of directory enforcement itself.

The district court determined that all Plaintiffs had standing to challenge HF2677, even though federal law unequivocally bans the sale

[1] The district court dismissed the Department based on Eleventh Amendment immunity. App.Vol.II.414, R.Doc.49 at 11.

of unauthorized ENDS products, because "FDA has deliberately exercised enforcement discretion in this field, creating a regulatory environment where market participants have developed legitimate reliance interests despite the absence of formal authorization." App.Vol.II.416, R.Doc.49 at 13. The court did not address a recent contrary federal ruling regarding a nearly identical law. That court concluded that because "'[u]nauthorized vapor products' . . . are illegal products," "[t]he Court cannot, and will not, find that anyone has a legally protected interest in violating unambiguous federal law." *Vapor Tech. Ass'n v. Taylor*, 2025 WL 348684, at *2–3 (E.D. Ky. Jan. 30, 2025).

The court concluded Plaintiffs' implied preemption claim was likely to succeed on the merits because, while "states retain broad police power over tobacco sales" and could "permissibly ban all ENDS products," they "cannot create a scheme that is parasitic on the FDCA." App.Vol.II.428–429, R.Doc.49 at 25–26.[2] The court relied on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). App.Vol.II.425–429, R.Doc.49 at 22–26.

[2] The district court rejected Plaintiffs' equal protection challenge. App.Vol.II.429–433, R.Doc.49 at 26–30.

The district court did not make any findings on: (1) Plaintiffs' likelihood of suffering irreparable harm; (2) whether the balance of equities favored an injunction; or (3) whether an injunction served the public interest. App.Vol.II.404–435, R.Doc.49 at 1–32.

Defendant Mosiman's appeal followed.

SUMMARY OF THE ARGUMENT

I. The district court erred in concluding that Plaintiffs had standing to challenge HF2677. Plaintiffs allege harm because HF2677 prevents them from continuing to violate federal law. Such injury is neither legally protected nor legally or judicially cognizable. Plaintiffs do not allege that they have received any written marketing order from FDA. And it is uncontested that federal law prohibits sale of Plaintiffs' federally unauthorized ENDS products. Because no Plaintiff has a legally cognizable interest in continuing to violate federal law, Plaintiffs lack injury-in-fact. And the only members the organization Plaintiff names are already named Plaintiffs. The organization's standing thus falls with the other Plaintiffs' lack of standing.

II. Congress preserved and saved from preemption Iowa's historical authority to regulate sales of tobacco products. Separately

Congress authorized the federal government to exclusively enforce violations of the FDCA. So if a state law seeks to enforce or restrain violations of the FDCA, then the FDCA preempts that state law. But if a state law relates to sales of tobacco products, it falls within the TCA's Preservation and Savings clauses.

HF2677 regulates which vapor products may be sold in Iowa. It does not create any obstacle to the federal government's role in enforcing the FDCA. Though it incorporates some FDCA standards, any Iowa-law liability arises only from violation of unique Iowa-law requirements coupled with impermissible sale in Iowa. That distinguishes HF2677 from state laws or claims held to be preempted where state law liability existed solely by virtue of FDCA requirements.

The district court applied an overbroad standard. Instead of applying this Court's precedent and determining whether HF2677 is preserved by the TCA, the district court asked a different question: whether HF2677 is related to FDCA standards and thus preempted under section 337(a). That novel approach is incorrect. State laws that incorporate, but do not rely solely on, federal standards do not create an obstacle to federal law.

At a minimum, the injunction is overbroad because the district court failed to apply Iowa's statutory severability requirement and severed only one of the law's many constitutional applications. This Court should vacate or narrow the injunction and clarify that any relief Plaintiffs receive does not also apply to nonparties.

III. The district court failed to assess the non-merits injunction factors. That alone warrants reversal. In all events, the preliminary-injunction factors weigh against an injunction. Plaintiffs lack any irreparable harm by a law that makes their already-illegal conduct further illegal. And any alleged harm does not outweigh the substantial irreparable harm imposed on the State when its law is enjoined, particularly when that law protects Iowans' health.

This Court should vacate the preliminary facial injunction.

ARGUMENT

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Plaintiffs must show: (1) likely success on the merits; (2) threat of irreparable harm; (3) balance of equities; and (4) that the injunction is in the public interest. *Rounds*, 530 F.3d at 729 n.3.

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

I. Standard Of Review.

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

When interpreting Iowa statutes, this Court applies Iowa's codified rules of construction. *See GLBT Youth*, 114 F.4th at 670–671 (applying Iowa Code ch. 4). "In enacting a statute, it is presumed that . . . [c]ompliance with the Constitutions of the state and of the United States is intended." Iowa Code § 4.4(1).

II. Plaintiffs Lack Standing.

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

No retailer Plaintiff alleges it has received a written marketing order from FDA. *See* App.Vol.I.8–10, R.Doc.27 ¶¶ 12–17. And Plaintiffs do not allege that they sell their products exclusively in Iowa—or otherwise outside the stream of interstate commerce. Federal law thus prohibits the sale, distribution, and, effectively, the purchase of Plaintiffs' products. *See* 21 C.F.R. § 1114.5. Plaintiffs essentially complain that HF2677 prevents them from violating federal law. *See, e.g.*, App.Vol.I.8, R.Doc.27 ¶ 11; App.Vol.I.10–11, R.Doc.27 ¶¶ 18–19; App.Vol.I.27–28, R.Doc.27 ¶¶ 84–90; App.Vol.I.30–31, R.Doc.27 ¶¶ 99–104; App.Vol.I.33–34, R.Doc.27 ¶¶ 113–118.

But Plaintiffs lack standing to make that complaint because, as multiple federal appeals courts have recognized, no one has a right to violate the law. *See, e.g.*, *Citizen Ctr. v. Gessler*, 770 F.3d 900, 910 (10th Cir. 2024); *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 764 (9th

Cir. 2018); *Bell v. Am. Traffic Sols. Inc.*, 371 F. App'x 488, 490 (5th Cir. 2010); *Initiative & Referendum Inst. v. Walker*, 450 F.3d 1082, 1093 (10th Cir. 2006) (en banc); *see also Animal Legal Def. Fund v. Reynolds*, 89 F.4th 1071, 1082 (8th Cir. 2024). Although Plaintiffs quibble with the precise terminology, the result is the same—Plaintiffs' injuries are neither legally protected nor cognizable. Those errors warrant reversal.

A. Plaintiffs lack injury-in-fact.

"[S]tanding is a jurisdictional prerequisite." *City of Clarkson Valley v. Mineta*, 495 F.3d 567, 569 (8th Cir. 2007). Plaintiffs must establish that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see also Pratt v. Helms*, 73 F.4th 592, 594 (8th Cir. 2023).

"An 'injury-in-fact' is 'an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.'" *ABF Freight Sys., Inc. v. Int'l Bhd. of Teamsters*, 645 F.3d 954, 959 (8th Cir. 2011) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). "To support standing, an injury must be legally and judicially cognizable." *Pratt*, 73 F.4th at 594 (quoting *Va.*

House of Delegates v. Bethune-Hill, 587 U.S. 658, 666 (2019)). That requires "that the dispute is traditionally thought to be capable of resolution through the judicial process." *Id.* (quoting *United States v. Texas*, 599 U.S. 670, 676 (2023)).

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

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

1. Retailer Plaintiffs allege injury because HF2677 "forces" them "to stop selling [their] [federally] unauthorized ENDS products." *See, e.g.*, App.Vol.I.27–28, R.Doc.27 ¶¶ 85–90; App.Vol.I.30–31, R.Doc.27 ¶¶ 100–104; App.Vol.I.33–34, R.Doc.27 ¶¶ 114–118. Consumer Plaintiffs allege HF2677 injures them because it may "deprive" them of the "ability to purchase and consume their preferred ENDS products," which they specify are "certain unauthorized ENDS products." App.Vol.I.8, R.Doc.27 ¶ 11; App.Vol.I.10–11, R.Doc.27 ¶¶ 18–19; App.Vol.I.28, R.Doc.27 ¶ 90. And Iowans for Alternatives to Smoking & Tobacco, an advocacy organization, alleges it suffers harm through one or more of its members "in that it forces them to stop selling certain [federally] unauthorized ENDS." App.Vol.I.27, R.Doc.27 ¶ 84; App. Vol.I.30, R.Doc.27 ¶ 99; App.Vol.I.33, R.Doc.27 ¶ 113.

But no retailer Plaintiff alleges it has received a written marketing order from FDA, making their products "unauthorized ENDS products." *See* App.Vol.I.8–10, R.Doc.27 ¶¶ 12–17. Nor does any allege that their products fall outside FDA jurisdiction or the stream of interstate commerce. One alleges it has a pending FDA application for its products. App.Vol.I.9, R.Doc.27 ¶ 14. And Iowans for Alternatives to Smoking &

Tobacco does not allege that any of its retailer members have received written FDA marketing orders. App.Vol.I.8–9, R.Doc.27 ¶ 12.

As another federal court recently held in a nearly identical case, "'[u]nauthorized vapor products' . . . are illegal products," and "[t]he Court cannot, and will not, find that anyone has a legally protected interest in violating unambiguous federal law." *Taylor*, 2025 WL 348684, at *2–3. "A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until the FDA has issued a marketing granted order." 21 C.F.R. § 1114.5. So "a company must receive a written marketing order from the FDA" to "legally market a new tobacco product in the United States." FDA, *Tobacco Products Marketing Orders*, perma.cc/GB97-PD3D; *see also* FDA, *Premarket Tobacco Product Marketing Orders*, perma.cc/525Y-H6TX (same). "[I]f vapor products do not comply with the FDCA and are not authorized by the FDA, § 1114.5 forbids them from being introduced into interstate commerce. Put simply: they are illegal products." *Taylor*, 2025 WL 348684, at *2.

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

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

3. The "legal right" theory that Plaintiffs and the district court incorrectly accused Defendant of "resurrect[ing]" is a red herring. App.Vol.II.415, R.Doc.49 at 132 (citing *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153–154 (1970)); *see also* R.Doc.40-1 at 1–2. The "legal rights" theory required plaintiffs to have a "legal right" protected by the law of property, contract, tort, or statute to suffer an

injury-in-fact. *See Ass'n of Data Processing*, 397 U.S. at 153–154. But Defendant is not arguing that Plaintiffs lack standing because they lack express legal permission to sell or purchase unauthorized but legal vapor products. Plaintiffs lack standing because federal law expressly prohibits selling those products. That distinction is critical.

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

Here, federal law prohibited the sale of unauthorized tobacco products before the Legislature enacted HF2677, still prohibits those sales today, and, absent congressional action, will continue to prohibit those sales regardless of the outcome here. This Court cannot grant

Plaintiffs the authority to flout a valid federal law that exists unchallenged in this litigation.

To be sure, like the smuggler, Plaintiffs might be able to "demonstrate concrete injuries" like "substantial economic harm—including lost sales, customers, and goodwill." *See* App.Vol.II.416, R.Doc.49 at 13. But these "paradigmatic examples of concrete harm," App.Vol.II.416, R.Doc.49 at 13, do not support standing when "the asserted interest is not one the courts will protect." *See* Wright & Miller, *supra*, § 3531.4. In finding otherwise, the district court is at odds with decisions from the Fifth, Ninth, and Tenth circuits. *See E. Bay Sanctuary*, 932 F.3d at 764; *Bell*, 371 F. App'x at 490; *Walker*, 450 F.3d at 1093; *cf. ALDF*, 89 F.4th at 1082.

4. The district court found standing here because "[t]he FDA has repeatedly exercised enforcement discretion to allow the continued marketing of certain unauthorized ENDS products." App.Vol.II.417–418, R.Doc.49 at 14–15. Beyond contradicting this Court's precedent, that approach is logically and factually flawed.

FDA statements about enforcement priorities do not impose rights or obligations. "Policy statements are not binding, either as a legal or

practical matter." *Iowa League of Cities v. EPA*, 711 F.3d 844, 873 n.17 (8th Cir. 2013) (citing *NRDC v. EPA*, 643 F.3d 311, 321 (D.C. Cir. 2011)). Indeed, "[t]he hallmark of a[] . . . policy statement is that [it] cannot be independently legally enforced." *Id.* at 874. Rather, "[i]t is the underlying legislative rules that drive compliance." *Id.*

Here, binding federal law is unequivocal: "A new tobacco product may not be introduced or delivered for introduction into interstate commerce . . . until [the] FDA has issued a marketing granted order for the product." 21 C.F.R. § 1114.5. Under this Court's precedent this prohibition is binding; FDA enforcement discretion is not. *See Iowa League of Cities*, 711 F.3d at 873–874 & n.17.

The header on every page of FDA's April 2020 Guidance states: "Contains Nonbinding Recommendations." App.Vol.I.222–273, R.Doc.32-6 at 1–53. And this Guidance states: "This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." App.Vol.I.225, R.Doc.32-5 at 5. That Guidance further recognizes that FDA's resource constraints—not any implied authorization via deferred enforcement—require FDA's case-by-case enforcement, because FDA "is unable, as a practical matter, to take

enforcement action against every illegally marketed tobacco product." App.Vol.I.253, R.Doc.32-5 at 33. Yet the district court still concluded that those "nonbinding recommendations" override the FDCA. App.Vol.II.418, R.Doc.49 at 15.

Even putting precedent aside, as a practical matter, case-by-case enforcement discretion does not distinguish the FDCA's ban on unauthorized ENDS products from any other criminal or regulatory prohibition. Prosecutorial discretion is inherent in any enforcement regime, "[a]fter all the Executive Branch must prioritize its enforcement efforts." *Texas*, 599 U.S. at 679–680 (citing *Wayte v. United States*, 470 U.S. 598, 607–608 (1985)). "[T]he Executive Branch (i) invariably lacks the resources to arrest and prosecute every violator of every law and (ii) must constantly react and adjust to the ever-shifting public-safety and public-welfare needs of the American people." *Id.* at 680. But that necessary enforcement discretion does not change federal law.

"For example, the Department of Justice has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property." DOJ, *Guidance Regarding Marijuana Enforcement*, at 2 (Aug.

29, 2013) perma.cc/B52P-7SU9 (last visited Jul. 22, 2025) ("2013 Guidance"). Rather, "[i]n deciding which marijuana activities to prosecute . . . with the Department's finite resources, prosecutors . . . follow the well-established principles that govern all federal prosecutions." DOJ, *Marijuana Enforcement* (Jan. 4, 2018) perma.cc/RPG4-KME2 (last visited Jul. 22, 2025). As with FDCA enforcement, prosecutors weigh federal enforcement priorities, the seriousness of the conduct, the deterrent effect of enforcement, and the cumulative impact of conduct on local communities. *Id.* But that discretion "does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law." 2013 Guidance at 4. Thus, these enforcement priorities do not create a legally protected right or judicially cognizable interest in selling marijuana. *See Kaplan*, 2020 WL 7094063, at *2.

This is not a matter of standing "based solely on imperfect compliance with federal law." App.Vol.II.416, R.Doc.49 at 13. Regardless of FDA enforcement priorities, federal law categorically bans the sale of new tobacco products that lack FDA authorization. *Compare* 2013 Guidance at 4, *with* App.Vol.I.232, R.Doc.32-5 at 13 (FDA's "case-by-case"

enforcement necessitated by "resource[]" constraints "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization"). FDA's enforcement discretion is not a blanket non-enforcement policy, "creating a regulatory environment where market participants have developed a reliance interest despite the absence of formal authorization." App.Vol.II.416, R.Doc.49 at 13.

As FDA's Guidance explains, "[t]he Agency retains discretion to pursue enforcement action at any time against any new deemed new tobacco product marketed without premarket authorization." App.Vol.I.233, R.Doc.32-5 at 13. Thus, "[w]hile some deemed new tobacco products have remained on the market in light of FDA's deferred enforcement policy, such policies are subject to change. Manufacturers cannot have settled expectations to market unlawful products, especially in the face of evolving public health concerns." App.Vol.I.249, R.Doc.32-5 at 29.

Even before FDA's deferred enforcement policy ended in September 2021, "FDA retained the ability to take enforcement action at its discretion." App.Vol.I.289–290, R.Doc.32-8 at 3–4. Indeed, since July 2020, federal regulators have issued warning letters, civil money penalty

complaints, and import alerts to companies manufacturing and selling unauthorized vapor products. App.Vol.I.292–295, R.Doc.32-8 at 6–9. In January 2021 alone, U.S. Customs and Border Protection at the Dallas Fort Worth International Airport seized 33,681 units of e-cigarettes. App.Vol.I.292–293, R.Doc.32-8 at 6–7.

Plaintiffs' "true interest" in distributing, selling, and using "unlawful vapor products . . . is not one that federal courts will protect." *Taylor*, 2025 WL 348684, at *3; *see also E. Bay Sanctuary*, 932 F.3d at 764 (no standing to "assert a right to cross the border illegally"); *Turnage*, 594 F. Supp. 3d at 1344 (no standing because "no federal constitutional or statutory right to manufacture, distribute, or possess marijuana"); *Kaplan*, 2020 WL 7094063, at *2 (no legally cognizable injury because "any potential remedy" for damages to their "cannabis cultivation operation" would "provide a remedy for actions that are unequivocally illegal under federal law" and would "necessitate that a federal court contravene a federal statute"); *cf. ALDF*, 89 F.4th at 1082. Plaintiffs lack standing. Their claims should be dismissed.

B. Iowans for Alternatives to Smoking & Tobacco lack organizational standing.

Iowans for Alternatives to Smoking & Tobacco has not alleged direct standing. It asserts only organizational standing. App.Vol.I.27, R.Doc.27 ¶ 84; App.Vol.I.30, R.Doc.27 ¶ 99; App.Vol.I.33, R.Doc.27 ¶ 113.

A membership organization may sue on behalf of its members if "(a) its members would otherwise have standing to sue in their own right; [and] (b) the interests it seeks to protect are germane to the organization's purpose." *Missouri Prot. & Advoc. Servs., Inc. v. Carnahan*, 499 F.3d 803, 809 (8th Cir. 2007). It must specifically identify at least one member who has suffered the harm. *See Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 601–602 & n.12 (8th Cir. 2022). The only members named are also Plaintiffs. App.Vol.I.9–10, R.Doc.27 ¶¶ 13–17. So the organization's standing rises (or falls) by its members. Because those Plaintiffs lack a legally cognizable interest in selling federally unauthorized vapor products, they lack standing. Iowans for Alternatives to Smoking & Tobacco therefore lacks standing too.

III. HF2677 Does Not Create an Obstacle to the Federal Government's Exclusive Role In Enforcing The FDCA.

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

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

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

Preemption must be narrowly construed. *See Arizona v. United States*, 567 U.S. 387, 398–401 (2012). "'[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading,' [courts] must 'accept the reading that disfavors preemption.'" *Edina*, 60 F.4th at 1176 (quoting *Altria Grp., Inc., v. Good*, 555 U.S. 70, 77 (2008)); *see also* Iowa Code § 4.4(1) (presume "that [c]ompliance with the Constitutions of the state and of the United States is intended"); *GLBT Youth*, 114 F.4th at 670–671.

More, the conflict preemption analysis begins with a presumption against preemption. *Edina*, 60 F.4th at 1176. That presumption is strongest when "Congress has legislated . . . in a field which the States have traditionally occupied." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quotation marks omitted). "[T]he historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Grp.,* 555 U.S. at 77; *see also MIMG CLXXII Retreat on 6th, LLC v. Miller*, 16 N.W.3d 489, 500

(Iowa 2025) (applying presumption against preemption "when federal law would intrude on an area of traditional state responsibility").

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

The TCA "implicates the States' traditional use of its police power." *See Edina*, 60 F.4th at 1178. Viewed against the historic backdrop, Congress's intent was to preserve States' primacy in regulating tobacco sales. *Id.* at 1179. The TCA thus preserves state laws like HF2677 that relate to tobacco and thus vapor product sales.

HF2677 conditions eligibility for in-State sales on several requirements, some of which incorporate federal standards. But HF2677 violations do not exist solely by virtue of federal law violations. Consider two tobacco products: Product A has received federal premarket approval

but Product B has not. Under the TCA, the sale of Product B in interstate commerce violates federal law and the sale of Product A does not. But that information alone is not enough to assess HF2677 compliance. The manufacturer of Product A still must submit the required documentation and application fee and register for service of process in Iowa. App.Vol.331–332, R.Doc.39-1 at ¶¶ 5–6. Selling Product A in Iowa before doing so violates HF2677, even though it would not violate federal law. In contrast, Product B, which lacks federal authorization, may still comply with HF2677 if it has an HF2677-compliant pending FDA application and its manufacturer submits the necessary certifications and fee prior to any sale in Iowa.

Even though liability under HF2677 is triggered by impermissible sales in Iowa, the district court determined the FDCA's enforcement section preempted HF2677. Relying on a Supreme Court case, which held preempted state laws that "exist solely by virtue of" FDCA violations, the district court reasoned that HF2677 is impermissibly "parasitic on the FDCA." App.Vol.II.428, R.Doc.49 at 25. But it did so despite recognizing part of HF2677 had nothing to do with FDCA standards. App.Vol.II.435, R.Doc.49 at 32. The district court's novel approach warrants reversal.

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

The text of the FDCA and, more specifically, the TCA, shows that Congress sought to balance national uniformity in tobacco product standards, which include things like manufacturing and marketing rules, with the States' historic role in regulating tobacco product sales.

The FDCA gives the federal government an exclusive cause of action to enforce the FDCA. 21 U.S.C. § 337(a). That section "implicates only enforcement of federal law." *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 850 (9th Cir. 2024). So if a State sought to criminalize fraud against FDA, the FDCA would preempt that law. *Buckman*, 531 U.S. at 353. And that makes sense, because "policing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id*. at 347 (citation modified).

But if a state law relates to sales of tobacco products, a narrower preemption scheme applies. Congress preserved the States' longstanding historical role in regulating in-State sales of tobacco products by expressly preserving State regulatory power and expressly allowing States to continue regulating tobacco sales. *See* 21 U.S.C. § 387p(a).

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

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

The Preservation Clause preserves State authority to enact restrictions "relating to or prohibiting the sale [or] distribution . . . of tobacco products" that are "in addition to, or more stringent than" the TCA. 21 U.S.C. § 387p(a)(1). It "tells us that there is no 'field preemption' for the TCA"—States may regulate "above and beyond" the TCA. *Edina*, 60 F.4th at 1173–74.

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

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

2. "Congress thought smoking kills. Against this backdrop, it enacted § 387p, expressly preserving state authority to regulate sales of tobacco products." *Id.* at 1179. According to Congress, "[t]obacco use is the foremost preventable cause of premature death in America," it is "inherently dangerous," and "Federal and State public health officials, the public health community, and the public at large recognize that the

tobacco industry should be subject to ongoing oversight." TCA §§ 2(2), (8), (13).

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

3. This preemption structure contrasts with other parts of the FDCA that lack similar anti-preemption provisions and do not "legislate[] in a field which the States have traditionally occupied." *Medtronic, Inc.*, 518 U.S. at 485. For example, Congress swept back state medical device regulations and "imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). That is opposite what Congress did in the TCA, where it "effectively *carves out* federal power

from a historical body of state and local authority." *Los Angeles*, 29 F.4th at 555.

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

B. HF2677 is a state regulation of tobacco product sales.

HF2677 regulates which vapor products may be sold in Iowa. App.Vol.330–331, R.Doc.39-1 at ¶¶ 1–3. It creates a directory of all HF2677-compliant vapor products. Iowa Code § 453A.52. And it prohibits selling or offering for sale "a vapor product in this state that is not included in the vapor products directory." *Id.* § 453A.52A(1).

1. HF2677 falls squarely within the TCA's Preservation and Savings clauses. The Eighth, First, Second, and Ninth Circuits have all held that sales regulations are not tobacco product standards under the Preemption Clause. *See Edina*, 60 F.4th at 1175; *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 82–83 & n.11 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d

428, 435 (2d Cir. 2013); *Los Angeles*, 29 F.4th at 558. HF2677, like the sales regulations at issue in those cases, "does not tell tobacco companies how to manufacture tobacco or what additives they can include in tobacco." *Edina*, 60 F.4th at 1175. Nor does it alter the premarket review process the FDCA requires. All it does is restrict sales of certain tobacco products in Iowa. *See id.*

That alone is enough to end the obstacles-and-purposes preemption inquiry. But even if sales restrictions "constitute [] tobacco product standard[s]," "the Savings Clause allows [those restrictions] because [they] relate[] to the sale of tobacco products." *Id.* at 1175, 1177; *see also Los Angeles*, 29 F.4th at 558; *Providence*, 731 F.3d at 82–83 & n.11; *New York*, 708 F.3d at 435. So "[n]o matter how [Plaintiffs] [try] to frame this case, the end result is the same[:] A plausible reading of the TCA allows state prohibitions . . . on the sale of . . . tobacco products." *Edina*, 60 F.4th at 1177.

2. Section 337(a) does not change the analysis. The district court's theory was that section 337(a) preempts HF2677 because HF2677 adopts in part FDCA's premarket-review standards and thus is a state law seeking to enforce the FDCA. App.Vol.II.424–425, R.Doc.49 at 21–22

(detailing HF2677's overlap with FDCA's PMTA requirements). But that theory renders the TCA's clauses meaningless. And it is a theory this Court rejected in *Edina*.

In *Edina*, Plaintiffs challenged a city ordinance banning the sale of flavored tobacco products. 60 F.4th at 1173. Plaintiffs argued the ordinance was preempted in part because it was a regulation of tobacco product standards masquerading as a sales regulation. *Id.* at 1177. This Court disagreed. Though the ordinance related to tobacco products standards and might create an incentive for manufacturers to change their production decisions, it did not "require manufacturers to alter the construction or components of their products." *Id.* at 1175 (cleaned up).

In the alternative, this Court reasoned that even if such a sales regulation can be considered a "tobacco product standard," it falls within the Savings Clause's broad protection of state law "relating to the sale" of tobacco products. *Id.* at 1175–78. Though there was a plausible reading that the TCA's clauses preempted the ordinance, the Court applied the presumption against preemption because the TCA and the ordinance implicate traditional State "police power to protect public health and safety." *Id.* at 1176–77.

That analysis dictates a similar result here, even if HF2677 sought to enforce FDCA's premarket-review standards.

The TCA prohibits state laws from imposing "any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards [or] premarket review." 21 U.S.C. § 387p(a)(2)(A). Laws imposing different or additional "tobacco product standards" are treated similarly as laws imposing different or additional "premarket review" standards.

HF2677 regulates sales of tobacco products in Iowa. Congress's clear and manifest purpose in enacting the TCA was to "expressly preserv[e] state authority to regulate sales of tobacco products." *Edina*, 60 F.4th at 1179.

Even if such a sales regulation has an "effect on" tobacco product standards, like in *Edina*, or on premarket review standards, like alleged here, it remains a state regulation relating to tobacco products sales expressly Preserved or Saved by the TCA. Like in *Edina*, the Court should "accept the reading that disfavors preemption.'" *Id.* at 1176 (quoting *Altria Grp.*, 555 U.S. at 77); *see also* Iowa Code § 4.4(1).

That result makes further sense because, to the extent there is any conflict between the more general section 337(a) and the more specific TCA, the specific statute controls. *See Hughes v. Canadian Nat'l Ry. Co.*, 105 F.4th 1060, 1067 (8th Cir. 2024) (specific controls when broad law is "supplemented or superseded throughout by more specific provisions to control in specific situations"); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 183 (2012) (same). That is black-letter Iowa law. Iowa Code § 4.7; *State v. Hess*, 983 N.W.2d 279, 287 (Iowa 2022) (collecting cases).

And here, section 337(a) generally provides the federal government an exclusive cause of action to enforce or restrain violations of the FDCA. The TCA applies more specifically to laws regulating tobacco products. The specific statute, the TCA, controls.

3. A recent federal district court decision confirms this result. That court concluded a North Carolina law materially similar to HF2677 was not preempted. *See Vapor Tech. Ass'n v. Wooten*, 2025 WL 1787420, (E.D.N.C. June 27, 2025). Plaintiffs there challenged a state law that "partially conditions the sale of e-cigarettes on compliance with the [FDCA]." *Id.* at *1. The state law created a vapor products directory,

through which the State certified vapor products as eligible for sale in the State. *Id.* at *2. To be included in the directory, and thus to be sold in the State, a manufacturer must certify on an annual basis that the vapor product:

> (1) received a marketing granted order from the FDA;
>
> (2) was on the market as of August 8, 2016, and an associated PMTA was submitted to the FDA on or before September 9, 2020; or
>
> (3) the product is exempt from both previous subsections because its existence reflects only a change to its name, brand style, or packaging. § 143B-245.11(a)(1)–(3).

Id. at *2. The law then subjected manufacturers and retailers who sell products not listed in the directory to liability. *Id.* at *2. Plaintiffs argued the state law was preempted because it "improperly seeks to enforce the provisions of the FDCA, in violation of § 337(a)" by "referenc[ing] the FDCA's premarket authorization requirements." *Id.* at *4–*5.

The district court rejected a request for preliminary injunction, reasoning in part that Plaintiffs' theory "would render the Preservation and Savings Clauses a nullity." *Id.* at *5. Though section 337(a) gave the United States exclusive authority to enforce the FDCA, the TCA specifically and expressly preserved the State's authority to "enact and

enforce laws with respect to the sale of tobacco products." *Id.* at *5. HF2677 requires the same result here.

C. Any overlap HF2677 shares with FDCA premarket-review standards does not warrant obstacles-and-purposes preemption.

Overlap between federal and state law does not necessitate conflict preemption. *California v. Zook*, 336 U.S. 725, 733 (1949). As the Supreme Court held, "'there is no conflict in terms, and no possibility of such conflict, for the state statute makes federal law its own.'" *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston, L.L.C.*, 134 F.4th 326, 328 (5th Cir. 2025) (quoting *Zook*, 336 U.S. at 735).

Yet the district court concluded that HF2677 is obstacles-and-purposes preempted because it "directly incorporates" FDA compliance "as a condition of lawful sale in Iowa." App.Vol.II.426–428, R.Doc.49 at 23–25. That was wrong. Both as a matter of preemption (overlap does not mean conflict) and as a matter of interpretation (HF2677 liability is not triggered solely by virtue of an FDCA violation).

1. Overlapping state and federal laws do not necessarily conflict.

Federal law conflict-preempts state law only when the two conflict. And State laws do not "somehow conflict with [federal law] by

incorporating it." *Zyla Life*, 134 F.4th at 331. Indeed, nothing in federal law prohibits States from regulating the same conduct via state law. *See id.* at 338. And federal law seldom bars States from adopting federal law for state purposes. *See, e.g., Gilbert v. Minnesota*, 254 U.S. 325, 330–331 (1920). "[T]here are now many instances in which a prosecution for a particular course of conduct could be brought by either federal or state prosecutors." *Kansas*, 589 U.S. at 212. "[I]n the vast majority of cases where federal and state laws overlap, allowing the States to prosecute is entirely consistent with federal interests." *Id.*

This makes sense. The "fact of identity" between laws does "not mean the automatic invalidity of State measures." *Zook*, 336 U.S. at 730. "[W]hen state law mirrors federal law, it 'recognizes the supremacy of the national law' by 'conform[ing] to it.'" *Zyla Life*, 134 F.4th at 332 (quoting *Asbell v. Kansas*, 209 U.S. 251, 258 (1908)). And "States may have a legitimate interest in punishing or providing redress for wrongs even if federal law already does so." *Id.*

States often regulate the same conduct that federal law already regulates—especially in areas where States exercise their historic police powers to, "under their own parallel laws," regulate conduct similarly to

how federal law regulates it. *Id.* at 334. A discretion-based obstacle preemption analysis risks invalidating enforcement of "many state statutes [that] incorporate federal" requirements. *Id.* at 334–335 & nn.5–7 (collecting statutes). Indeed, violation of federal law often constitutes negligence *per se* in Iowa state courts. *See Wiersgalla v. Garrett*, 486 N.W.2d 290, 292–293 (Iowa 1992).

An example illustrates the point. Both Iowa and the federal government make it a crime for a convicted felon to own a firearm—including persons convicted of a felony in federal court. *See* Iowa Code § 724.26; 18 U.S.C. § 922(g)(1). Enforcement-discretion obstacle preemption suggests that any Iowa prosecution for such a violation necessarily infringes on the federal government's supposed decision not to prosecute. But that cannot be.

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

Concerns over intruding on "federal enforcement discretion" would result in preempting "everything federal law touches." *Zyla Life*, 134 F.4th at 335. And that is why enforcement priorities are "not enough to provide a basis for preemption." *Kansas*, 589 U.S. at 212.

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

2. State laws incorporating FDCA standards are not preempted.

The district court effectively transformed the operative question from whether HF2677 relates to tobacco sales, and is thus Preserved or Saved under the TCA, to whether HF2677 is related to FDCA standards and is thus preempted under section 337(a). That novel approach is incorrect.

1. Plaintiffs invoked cases outside the TCA context. Dkt. 36 at 13–17 (citing *Buckman*, 531 U.S. at 349 n.4; *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *Brown v. Medtronic, Inc.*, 2021 WL 9682170

(S.D. Iowa March 10, 2021)). The district court adopted that reasoning and applied *Buckman*. App.Vol.II.426–428, R.Doc.49 at 23–25. But *Buckman* and the FDCA's enforcement section are inapposite here.

Buckman arose under the FDCA's more restrictive preemption regime that applies to non-tobacco sales regulations. Other products regulated by the FDCA, like medical devices, have no Preservation or Savings clause. Instead, Congress swept back historical state regulations. *Riegel*, 552 U.S. at 316. And it expressly preempted States from "establish[ing] . . . any requirement . . . which is different from, or in addition to, any requirement applicable . . . to the device" that "relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). That preemption "is significantly broader" than the TCA. *Greene v. Five Pawns, Inc.*, 2016 WL 11750182, at *10 (C.D. Cal. Aug. 30, 2016).

And the material distinctions from *Buckman* do not end there. In *Buckman*, plaintiffs brought state fraud claims, arguing that defendant Buckman had made fraudulent representations to FDA that induced FDA to approve the medical device which ultimately caused plaintiff injury. 531 U.S. at 343. The Supreme Court held that the FDCA preempted those "state-law fraud-on-the-FDA claims." *Id.* at 348. The

federal government "has at its disposal a variety of enforcement options" to "respon[d] to suspected fraud upon the [FDA]," including section 337(a). *Id.* at 349 & n.4. Those claims conflicted with FDA's responsibility to police fraud against FDA. *Id.* at 350. And "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347 (quotation marks omitted).

Buckman had nothing to do with whether a state law improperly mirrored FDCA requirements. *Zyla Life*, 134 F.4th at 337–338 (detailing *Buckman*'s limiting principles). Rather, *Buckman* held preempted state-law claims used to police "a wrong committed against the Federal Government." *Id.* at 337.

Indeed, *Buckman* even recognized that state laws paralleling federal requirements might not be preempted, even under the harsher medical-devices preemption regime. 531 U.S. at 353. "*Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements." *Id.*; *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013).

2. The district court reasoned that, even if the state law relates to tobacco sales, it is preempted as "parasitic on the FDCA" because it

"condition[s] sales on FDA requirements." App.Vol.II.426–428, R.Doc.49 at 23–25. That wrongly extends *Buckman* to craft novel requirements on tobacco sales regulations.

In the district court, Defendant emphasized that no case applied *Buckman* and section 337(a) preemption to state laws regulating tobacco sales. R.Doc.39 at 14–15; App.Vol.II.479–489, R.Doc.51 at 43–53. The district court instead reasoned that it was applying *Buckman*'s "clear instruction." App.Vol.II.426, R.Doc.49 at 23.

Yet neither Plaintiffs nor the district court identified precedent applying *Buckman* to a state law regulating tobacco sales. The district court cited "one court [that] has specifically applied *Buckman* preemption to state law claims based upon FDA compliance for products governed by the TCA." App.Vol.II.423, R.Doc.49 at 20 (citing *Yimam v. Myle Vape, Inc.*, 2020 WL 13614925, at *2–4 (D.C. Super. Jun. 11, 2020)). That D.C. Superior Court decision considered District of Columbia law consumer-protection claims where liability turned on FDA authorization; that court did not consider any state law regulating tobacco products sales. App.Vol.II.423, R.Doc.49 at 20.

Plaintiffs relied on *Yimam* and several Ohio cases that said Ohio could not bring unfair and deceptive practices claims relating to violations of FDCA labeling requirements. R.Doc.36 at 16. But as the state court there noted, the result in those cases "would be different" if the state were enforcing its own "more restrictive requirements on the sale of tobacco products." *State v. Cent. Tobacco and Stuff Inc.*, 2024 WL 4626167, at *4 (Ohio Com.Pl. Oct. 29, 2024). Instead, the State was using its preexisting consumer protection laws to enforce FDCA violations.

In each of Plaintiffs' state court cases, unlike HF2677, an FDCA violation automatically violated state law. In other words, the claims there "exist[ed] solely by virtue of" FDCA violations and were thus preempted. *Buckman*, 531 U.S. at 352–353.

3. Yet many cases clarify that *Buckman* does not preempt state laws even if the state law violation is based in part on the FDCA or FDA regulations.

Recently the Fifth Circuit considered state laws that expressly mirrored the FDCA. *Zyla Life*, 134 F.4th at 331. The court held the FDCA did not conflict-preempt those laws: "*Buckman* holds that the FDCA's allocation of enforcement to the Federal Government forecloses non-

federal actors from policing *wrongdoing against the Federal Government*." *Id.* at 338.

Any broader reading conflicts with Supreme Court precedent and risks extreme jurisprudential consequences. *Id.* The Fifth Circuit understood that interpreting *Buckman* to preempt state laws that incorporate FDCA standards would be reading *Buckman* without its context; after all, "*Buckman* itself" did not go as far as Plaintiffs want. *Id.* at 339. *Buckman* plaintiffs sued under generally applicable state tort law; the issues there had nothing to do with state laws that incorporate federal standards.

Other courts have similarly held that state laws that "borrow" federal definitions or that are premised on FDCA violations are not preempted. *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040 (9th Cir. 2015); *Bausch v. Stryker Corp.,* 630 F.3d 546, 556–558 (7th Cir. 2010); *Hughes v. Boston Sci. Corp.,* 631 F.3d 762, 774–76 (5th Cir. 2011). Whereas *Buckman* concerned an area not historically left to the States and thus saw no presumption against preemption, these other cases concerned areas "left largely to the States" before the FDCA and thus

applied the presumption against preemption. *McClellan*, 776 F.3d at 1040.

This Court too should decline to extend *Buckman*. *Buckman* held preempted a plaintiff's attempt to use ordinary tort law to regulate fraud on FDA. That is not this case. HF2677 does not "polic[e any] wrongdoing against the Federal Government." *Zyla Life*, 134 F.4th at 338. It creates independent state law requirements as a condition of sales of tobacco products in Iowa. It incorporates PMTA standards, in addition to unique state-law requirements. And it does not even go as far as the state law held not preempted in *Zyla Life*, which adopted an FDCA violation as an actionable state law violation.

Crucially, unlike the law in *Buckman,* HF2677 is an exercise of Iowa's historic role in regulating tobacco sales. *See Edina*, 60 F.4th at 1178; *Los Angeles*, 29 F.4th at 548. So the presumption against preemption should apply here.

In the end, no cases extend *Buckman* to state tobacco sales regulations. And for good reason: state laws regulating tobacco product sales are preserved. This Court need not split from several sister circuits declining to apply *Buckman* to the circumstances present here.

4. In all events, the district court should have adopted this Court's approach in *Edina*, where this Court explained that when presented with two plausible readings of a preemption clause, the court "must accept the reading . . . that disfavors pre-emption." *Edina*, 60 F.4th at 1176–78.

If this Court determines that the district court's reading of section 337(a)'s enforcement section is plausible, but also concludes that, under *Edina*, the TCA's "relating to the sale" of tobacco requirement is broad enough to include HF2677, then it should accept the latter reading and disfavor preemption here.

D. Liability under HF2677 arises from selling products in Iowa before satisfying independent state-law duties.

Even applying *Buckman* here, preemption is unwarranted because liability under HF2677 does not arise "solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352.

Buckman held that the FDCA preempted state-law fraud claims that "exist[ed] solely by virtue of the FDCA disclosure requirements." 531 U.S. at 353. There, if there was no FDCA violation, there would be no state law liability; but if there was fraud on FDA, then state law liability would follow. *Id.* at 347–350. The Supreme Court reasoned that state law

liability may "parallel" federal requirements, but it cannot turn "solely by virtue" on a federal violation. *Id.* at 353.

But here, HF2677 does not arise "solely from the violation of FDCA requirements." *Id.* at 352. HF2677 is a sales regulation that, in part, incorporates but does not turn solely on federal law. HF2677 creates non-FDCA related duties owed to Iowa before a vapor product is eligible for inclusion in the vapor products directory and thus before the product is eligible for sale in Iowa.

1. HF2677 violations therefore do not exist solely by virtue of federal law violations, so *Buckman* would not preempt them even absent the TCA. HF2677 liability arises from failure to comply with requirements to be included in the directory, coupled with illegal sale in Iowa. Though HF2677 incorporates some federal language, it exists independently from the FDCA. Mere noncompliance with the FDCA does not trigger state law liability. Some vapor products that comply with the FDCA may not be sold in Iowa. And some vapor products that violate the FDCA may still comply with HF2677. Any HF2677 liability is conditioned on sale in Iowa prior to satisfying unique state-law duties.

That is no different than North Carolina's law—which remains enforceable after a challenge. *Vapor Tech. Ass'n v. Wooten*, 2025 WL 1787420, at *5. That law was "not a premarket review regulatory scheme disguised as a sales prohibition" because mere noncompliance with the FDCA "is not itself an actionable basis" for a state law violation. *Id.* at *5. Rather, the state law "tied violations of state law with the retail sale of tobacco products," and thus a lawful exercise of the State's preserved police power. *Id.* That aptly describes HF2677 too.

2. The district court recognized that HF2677 had requirements apart from the FDCA. But rather than conclude that those unique requirements distinguish Iowa's law from the law in *Buckman*, the court set aside the law's non-FDCA requirements as "ancillary" features that "do not alter the core mechanism of the statute." App.Vol.II. 425–426, R.Doc.49 at 22–23.

The court reasoned that any law that includes federal premarket standards as part of its own state-law duties is impermissibly "parasitic on the FDCA." App.Vol.II.426, R.Doc.49 at 23. But such a caveat finds no basis in *Buckman* nor section 337(a). Ancillary or not, they are requirements separate from the FDCA that one must satisfy as a

condition of tobacco product sales in Iowa. That means that HF2677 liability does not arise "solely from the violation of FDCA requirements." *Buckman,* 531 U.S. at 352–353. So even if *Buckman* could apply to state tobacco sales regulations, it does not fit here.

3. The district court further misapplied the federal PMTA standards. The court described HF2677's standards as "fundamentally dependent on federal authorization status, permitting some products that the FDA currently allows through its enforcement discretion while excluding others." App.Vol.II.428, R.Doc.49 at 25. But that conflates federal enforcement discretion with federal authorization under the FDCA. And federal enforcement priorities do not preempt state law. *Kansas*, 589 U.S. at 212. Even worse, it is a wrong interpretation of FDA's present policy.

Until 2020, FDA had a deferred enforcement policy that Plaintiffs construe as giving temporary approval to products if the manufacturer had submitted a PMTA by a certain date and that application remained pending. App.Vol.I.19–20, R.Doc.27 at 15–16 (detailing FDA's deferred enforcement policy). But since at least September 2021, FDA has adopted a case-by-case policy. Now, FDA recognizes that due to resource

constraints it cannot "take enforcement action against every illegally marketed tobacco product." App.Vol.I.253, R.Doc.32-5 at 33. And that "does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization." App.Vol.I.232, R.Doc.32-5 at 13.

HF2677 requires that, for a product to be included in the directory, and thus lawfully sold in Iowa, (a) the product must have received written marketing authorization from FDA or (b) the manufacturer must have submitted a PMTA by a certain date and that remains under review. Iowa Code § 453A.52(1). To the extent that second path to eligibility for Iowa's directory incorporates any FDA nonbinding policy, it incorporates one that has not been in place since at least September 2021. That second path is now uniquely a creature of Iowa law and cannot be "parasitic" on any active FDA deferred enforcement policy. And that is just another way of saying that liability under HF2677 does not arise "solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352.

E. The district court improperly relieved plaintiffs of their burden at this preliminary stage.

The district court erred by granting Plaintiffs relief different from anything they pleaded or briefed. "Litigants mounting a facial challenge

to a statute normally must establish that no set of circumstances exists under which the [law] would be valid." *United States v. Hansen*, 599 U.S. 762, 769 (2023) (cleaned up); *see NetChoice*, 603 U.S. at 723 (The decision to litigate as a facial challenge "comes at a cost."). It is not a court's job at this preliminary stage to narrow Plaintiffs' pleaded relief. *See United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020).

Plaintiffs requested a pre-enforcement, preliminary facial injunction of the entire law. App.Vol.I.35, R.Doc.27 at ¶ 120 (complaint requesting court enjoin Defendant "from implementing and enforcing HF2677"); R.Doc.36 at 21 (preliminary-injunction brief requesting same). At no point did Plaintiffs plead, even in the alternative, a facial or as-applied injunction as to a narrowed portion of HF2677.

Only after Plaintiffs realized there were constitutional applications of HF2677 did they say in rebuttal at the hearing on the preliminary injunction that they would accept a facial injunction as to anything less than the entire law. App.Vol.II.497, R.Doc.51 at 61:16–25. That led the district court to take up Plaintiffs' invitation and sever from the injunction certain "ancillary" features that "do not alter the core mechanism of the statute." App.Vol.II. 425–426, R.Doc.49 at 22–23.

That is an abuse of discretion for at least two reasons. *First*, it proves correct Defendant's argument that liability under HF2677 does not arise "solely by virtue" from the FDCA, but also from purportedly ancillary, yet nevertheless independent, state law requirements.

Second, that reasoning lessens the cost Plaintiffs must pay for their strategic litigation choice to seek facial relief. It negates the need to ever plead narrowed facial or as-applied relief. If a plaintiff can plead facial relief as to every part of a new law, thus avoiding the burden of narrowing their request to certain sections of the law—or, worse yet, avoiding the fact-intensive as-applied inquiry—yet still receive whatever narrowed relief a district court determines proper, why would a plaintiff ever go through the trouble of pleading narrowed relief? Holding plaintiffs to account is even more important when there are undisputedly legal applications of a law—which defeat a facial challenge.

This Court should hold Plaintiffs to their choice. Plaintiffs asked for a facial injunction of HF2677. But there are constitutional applications of the law—no matter that the district court thinks them ancillary. Plaintiffs cannot show that they are entitled to their pleaded facial relief. The district court should have ended its analysis there.

F. The district court's injunction is overbroad.

Even if this Court determines a preliminary injunction is warranted, the district court's injunction is overbroad for two reasons.

First, as the Supreme Court recently clarified, preliminary injunctions should not grant universal relief to nonparties. *Trump v. CASA, Inc.*, 145 S.Ct. 2540, 2556–58 (2025). The district court did not limit its relief to Plaintiffs and instead granted universal relief. That is error.

Second, Iowa's laws are presumed severable. *See* Iowa Code § 4.12. Plaintiffs seeking to enjoin enforcement of Iowa laws must meet their burden to show that each part of the law they challenge is independently facially unenforceable. Else, their facial challenges must fail.

The district court severed and preserved section 453A.52D's requirement that manufacturers appoint and engage an agent for service of process in Iowa before their products may be included in the directory. App.Vol.II.435, R.Doc.49 at 32. But other parts of the law are similarly independent from any FDCA requirement and should be severed. For example, HF2677's second path for establishing eligibility for the directory, *see* Iowa Code § 453A.52(1)(*b*), does not incorporate any current

FDCA standard. That part of the law, like the agent requirement, is an independent state law standard.

This Court should vacate the injunction or, alternatively, should vacate all parts of the injunction that this Court agrees are not preempted by federal law.

IV. The District Court Abused Its Discretion by Failing to Consider the Non-Merits Injunction Factors and by Waiving the Injunction Bond.

A. The remaining factors weigh against preliminary injunctive relief.

Plaintiffs' failure to show they are "likely to prevail on the merits" is fatal. *Rounds*, 530 F.3d at 732. Even if Plaintiffs are likely to succeed on the merits, "a preliminary injunction does not follow as a matter of course." *Benisek v. Lamone*, 585 U.S. 155, 158 (2018) (citing *Winter* , 555 U.S. at 32). "The likelihood that plaintiff ultimately will prevail is meaningless in isolation." *Dataphase Sys., Inc. v. C.L. Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981). Courts must also consider the other factors. *Id.* ("In every case, [the likelihood of success on the merits] must be examined in the context of the relative injuries to the parties and the public."). "No single factor in itself is dispositive; in each case all the factors must be

considered." *Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc.*, 815 F.2d 500, 503 (8th Cir. 1987) (citing *Dataphase*, 640 F.2d at 113).

But here, the district court did not make any findings on: (1) Plaintiffs' likelihood of suffering irreparable harm; (2) whether the balance of equities favored an injunction; or (3) whether an injunction served the public interest. App.Vol.II.404–435, R.Doc.49 at 1–32. That alone is reversible error. *See Dixon*, 950 F.3d at 1055–1057.

The remaining preliminary injunction factors weigh against an injunction. Plaintiffs have not shown irreparable harm. That deficiency presents "independently sufficient" reason "to deny a preliminary injunction." *Sessler v. City of Davenport*, 990 F.3d 1150, 1156 (8th Cir. 2021) (citation omitted).

Retailer Plaintiffs allege harm from lost sales and consumer Plaintiffs allege an inability to purchase their preferred unauthorized ENDS. *See, e.g.*, App.Vol.I.27–28, R.Doc.27 ¶¶ 84–90 (alleging harm relating to "unauthorized ENDS products"). No Plaintiff alleges that they wish to sell or use any FDA-authorized vapes.

So any irreparable harm argument suffers from the same flaw as Plaintiffs' standing—an injunction would not allow them to sell or

purchase their products in Iowa, because those products cannot be sold under federal law. Plaintiffs thus fail to show why they need an injunction to address any irreparable harm.

Plaintiffs' delay in seeking relief further undercuts any irreparable-harm argument. *See Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, 182 F.3d 598, 603 (8th Cir. 1999). The Governor signed HF2677 into law on May 17, 2024. The Department announced its enforcement schedule on July 29. App.Vol.II.332–333, R.Doc.39-2 ¶ 10. Yet Plaintiffs waited seven months from enactment and five from the Department's announcement to sue. And consumer Plaintiffs waited two months more. Such delays "undermine a showing of irreparable harm and [are] a sufficient ground to deny a preliminary injunction." *Ng v. Board of Regents of Univ. of Minn.*, 64 F.4th 992, 997 (8th Cir. 2023) (quotation marks omitted).

Nor does the balance of harms support a preliminary injunction. An injunction irreparably harms the State. The Department has a unique interest in enforcing HF2677 to address nicotine addiction and abuse, particularly among Iowa's youth. *See, e.g.*, *Nebbia v. People of New York*, 291 U.S. 502, 523–524 (1934). And HF2677 is a valid exercise of the

State's historic police power. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (States have "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."); *Edina*, 60 F.4th at 1176–77 (banning sales of tobacco products falls within the historic state police power to protect public health and safety). Restricting Iowa from exercising this power risks Iowans' health, outweighing any alleged harm to Plaintiffs.

And an injunction is not in the public interest. Enjoining enforcement of a state law "clearly inflicts irreparable harm on the State." *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018); *CASA*, 145 S. Ct. at 2562. Statutes are to be "presumed constitutional and all doubts are resolved in favor of constitutionality." *Arkansas Times LP v. Waldrip as Tr. of Univ. of Ark. Bd. of Trs.*, 37 F.4th 1386, 1393 (8th Cir. 2022). That is black letter Iowa law. *See* Iowa Code §§ 4.4(1), (3), (5). A pre-enforcement injunction that presumes constitutional flaws "thwart[s] [Iowa's] presumptively reasonable democratic process." *Rounds*, 530 F.3d at 732–733.

B. The district court should have required injunction bond under Rule 65(c).

Facial injunctions impose serious costs on States. Yet district courts continue to refuse to impose meaningful bonds when asked. Defendant requested the Court require an injunction bond under Federal Rule of Civil Procedure 65(c) before any injunction could take effect. App.Vol.II.490–492, R.Doc.51 at 54:25–56:15. That rule says the "court may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). The Rule includes one exception: "The United States, its officers, and its agencies are not required to give security." *Id.*

The district court "waive[d] the bond requirement." App.Vol.II.434, R.Doc.49 at 31. This violates the rule's mandatory language. The Rule provides one exception, which means that the Rules allow for no other exception. To be sure, the district court cited a case from this Court reasoning that an "important public interest in the enforcement of NEPA" allows district courts discretion to waive the bond requirement. App.Vol.II.433, R.Doc.49 at 30 (citing *Richland/Wilkin Joint Powers*

Auth. v. United States Army Corps of Eng'rs, 826 F.3d 1030, 1043 (8th Cir. 2016)). But this is not a NEPA case, nor did the district court evaluate the public interest. The district court thus erred in not requiring any security to issue before the injunction could take effect.

If the Court finds an injunction proper, Defendant renews her request for bond in the amount as detailed in the district court, based off HF2677's penalty scheme. App.Vol.II.491–492, R.Doc.51 at 55:11–56:15.

CONCLUSION

For these reasons, this Court should vacate the preliminary injunction.

July 22, 2025

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g) and Local R. 25A, I certify the following:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,993 words, excluding those parts exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and Fed. R. App. P. 32(a)(6) because the brief has been prepared in Century Schoolbook 14-point font using Microsoft Word for Microsoft Office 365.

3. This brief complies with the electronic filing requirements of Local R. 25A because the text of the electronic brief is identical to the text of the paper copies and because the electronic version of this brief has been scanned for viruses and no viruses were detected.

July 22, 2025

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CERTIFICATE OF SERVICE

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

July 22, 2025

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