IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

IOWANS FOR ALTERNATIVES TO SMOKING & TOBACCO, INC., GLOBAL SOURCE DISTRIBUTION LLC, WAGES AND WHITE LION INVESTMENTS, LLC, doing business as Triton Distribution, SMOKIN HOT LLC, CENTRAL IOWA VAPORS WDM, LLC, TASTE THE VAPE LLC, doing business as Route 69 Vapor, MARTINA PAGANO, and JAMES COLE, Plaintiffs, v. IOWA DEPARTMENT OF REVENUE, and MARY MOSIMAN, Defendants.	)	Case No. 4:24-cv-00448-SMR-HCA ORDER ON MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs are a coalition of manufacturers, retailers, and consumers of electronic cigarettes, who challenge a recently enacted Iowa law that conditions the lawful sale of these products on federal regulatory compliance. At issue is whether Iowa's regulatory scheme impermissibly encroaches upon the federal government's exclusive authority to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA"), or whether it represents a valid exercise of the state's traditional police powers to regulate sales of potentially harmful products within its borders. The Court must determine not only the proper boundary between state and federal authority in this domain, but also whether the statute's differential treatment of tobacco-derived and synthetic nicotine products comports with constitutional guarantees of equal protection. After careful consideration of the arguments presented, the Court concludes that portions of Iowa's regulatory scheme cannot withstand scrutiny.

I. BACKGROUND

A. Factual Background

This case involves a challenge to an Iowa statute regulating electronic nicotine delivery systems ("ENDS"), commonly known as e-cigarettes or vapor products. The facts, as alleged in the Amended Complaint, are as follows.

In 2024, the Iowa Legislature enacted House File 2677. That law directs the Iowa Department of Revenue ("Department") to take enforcement actions—including imposing monetary penalties—against manufacturers and sellers of ENDS products that have not received marketing authorization from the United States Food and Drug Administration ("FDA").

The statutory scheme contemplates the creation of a registry of permissible ENDS products. Under House File 2677, ENDS manufacturers whose products are sold in Iowa must certify to the Department that their products either: (1) have received FDA marketing authorization, or (2) were on the market as of August 8, 2016—the date ENDS containing tobacco-derived nicotine became subject to the FDCA—and had a premarket tobacco product application ("PMTA") filed with FDA by September 9, 2020, that remains under FDA review or is the subject of ongoing litigation. Once the Department publishes its registry, the sale of ENDS products not listed in the registry becomes unlawful in Iowa.

House File 2677 contains no comparable exception for ENDS products containing non-tobacco-derived nicotine, even when manufacturers filed timely PMTAs for such products after non-tobacco-derived nicotine products became subject to the FDCA in April 2022. The Department announced that it would publish the vapor products registry on January 2, 2025, and begin enforcement on February 3, 2025. This deadline has subsequently been delayed pending the resolution of Plaintiffs' request for injunctive relief.

Most ENDS products on the market today lack FDA marketing authorization. Since 2016, when ENDS products first became subject to FDA regulation, the FDA has exercised enforcement discretion regarding unauthorized ENDS products, adjusting its enforcement policies at least seven times. As the FDA has recognized, immediately forcing all unauthorized ENDS products off the market could result in ENDS users reverting to more harmful traditional cigarettes. Accordingly, the FDA has sought to "strike a balance between the serious risk that e-cigarettes pose to youth and their potential benefit in helping adult smokers completely transition from or significantly reduce smoking combustible cigarettes." [ECF No. 27 ¶ 57].

Since September 2021, the FDA has exercised its enforcement discretion with respect to unauthorized ENDS products on a "case-by-case" basis. The FDA continues to evaluate new information and adjust its enforcement priorities "in light of the best available data," taking into account youth usage rates and other risk factors. *Id*. ¶ 58.

Before the Iowa Legislature enacted House File 2677, R.J. Reynolds Tobacco Company had sought similar restrictions through other channels. In February 2023, R.J. Reynolds filed a Citizen Petition with the FDA requesting that the agency adopt a new enforcement policy against unauthorized ENDS products. The proposed policy would have excluded its own unauthorized Vuse brand ENDS products from enforcement because they were on the market by August 8, 2016, and R.J. Reynolds had submitted PMTAs for those products by September 9, 2020. The proposed policy offered no safe harbor for ENDS products with non-tobacco-derived nicotine, even if timely PMTAs were filed for such products. The FDA denied the petition in November 2023. *Id*. ¶ 63.

R.J. Reynolds also filed a complaint with the United States International Trade Commission ("ITC") seeking to bar importation of many unauthorized ENDS products. The FDA urged the ITC to reject R.J. Reynolds' attempt, emphasizing that Congress intended "decisions

about the regulatory or compliance status of tobacco products and what products should be prioritized for enforcement [to] reflect the view of the agency charged with administering the FDCA." *Id*. ¶ 66 (alteration in original). The ITC ultimately dismissed R.J. Reynolds' claim, reasoning that "it would usurp the FDA's authority to enforce the FDCA and impermissibly grant a private right of action to enforce the FDCA if the Commission were to institute an investigation based on the Reynolds complaint." *Id*. ¶ 67.

On March 27, 2024, House File 2677 was introduced in the Iowa Legislature. Lobbyists for R.J. Reynolds and Altria (maker of Marlboro and Virginia Slims cigarettes) immediately declared their support for the bill. The Iowa House passed House File 2677 on April 3, 2024; the Iowa Senate passed it on April 19, 2024; and the Governor signed it into law on May 17, 2024.

Plaintiffs in this case include Iowans for Alternatives to Smoking & Tobacco, Inc. ("IFAST"), a non-profit corporation whose members include manufacturers and sellers of ENDS products; several manufacturers, distributors, and retailers of ENDS products; and individual consumers who rely on ENDS products to avoid reverting to traditional cigarette smoking. Defendants are the Department and its Director Mary Mosiman.

Plaintiffs allege that House File 2677 violates the Supremacy Clause of the United States Constitution because the FDCA impliedly preempts state law that seeks to enforce the Act when Congress has given the Federal Government exclusive authority to do so. Plaintiffs further contend that House File 2677 violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and the Equal Protection Clause of the Iowa Constitution because it treats manufacturers, sellers, and consumers of ENDS containing tobacco-derived nicotine differently than manufacturers, sellers, and consumers of ENDS containing non-tobacco-derived

nicotine, without a rational basis for such differential treatment. Plaintiffs now seek preliminary and permanent injunctions against enforcement of House File 2677.

B. Procedural Background

Plaintiffs initiated this action on December 17, 2024, simultaneously filing their Complaint and a motion for preliminary injunction. [ECF Nos. 1, 2]. The parties subsequently filed a joint motion for a modified briefing schedule, recognizing both the fundamental constitutional questions at stake and the practical need to address Plaintiffs' concerns before the Department's enforcement deadline. [ECF No. 9].

Following additional procedural developments, including the filing of an Amended Complaint, the Court held a hearing on April 3, 2025. [ECF No. 45]. At the hearing, counsel for both Plaintiffs and Defendants presented arguments addressing the statute's constitutional validity, the standards governing preliminary relief, and the public health implications of the regulatory framework. The parties submitted supplemental authority and briefing on the evolving regulatory landscape for ENDS products at both state and federal levels. Having carefully considered the parties' written and oral presentations, the Court now addresses Plaintiffs' request for preliminary injunctive relief.

II. DISCUSSION

A. Legal Standard

1. Preliminary Injunction Standard

A preliminary injunction is an "extraordinary remedy" that should be granted "only upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat'l Res. Def. Council, Inc*., 555 U.S. 7, 22 (2008). The purpose of preliminary injunctive relief is not to conclusively

determine the rights of parties, but to preserve the relative positions of the parties until the court can hold a trial on the merits. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).

To secure a preliminary injunction, a plaintiff must establish four requirements: (1) likelihood of success on the merits; (2) likelihood of suffering irreparable harm absent preliminary relief; (3) that the balance of equities tips in the plaintiff's favor; and (4) that an injunction serves the public interest. *Winter*, 555 U.S. at 20. Although all four factors must be analyzed, the United States Court of Appeals for the Eighth Circuit has consistently held that likelihood of success on the merits is "the most significant" factor. *Sleep Number Corp. v. Young*, 33 F.4th 1012, 1016 (8th Cir. 2022) (citing *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013)); *accord Barrett v. Claycomb*, 705 F.3d 315, 320 (8th Cir. 2013).

The already demanding standard for preliminary relief is further heightened when a plaintiff seeks to enjoin the enforcement of a duly enacted statute. In such cases, the plaintiff must make "a clear showing" that it is "likely to prevail on the merits." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024). This heightened standard reflects the judiciary's appropriate respect for the democratic processes that produce state legislation. *D.M. by Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1000 (8th Cir. 2019).

For the irreparable harm requirement, a plaintiff need not prove with absolute certainty that injury will occur, but must demonstrate that irreparable harm is "likely" without an injunction. *Winter*, 555 U.S. at 22. The absence of likely irreparable harm is an "independently sufficient" basis to deny preliminary relief. *Sessler v. City of Davenport*, 990 F.3d 1150, 1156 (8th Cir. 2021) (citation omitted).

The balance of equities analysis requires the Court to weigh the threat of irreparable harm to the moving party against the potential injury that granting the injunction would inflict on the

non-moving party. *MPAY Inc. v. Erie Custom Comp. Applications, Inc*., 970 F.3d 1010, 1020 (8th Cir. 2020). Similarly, the public interest factor requires consideration of how an injunction—or its denial—would affect non-parties to the litigation. *Id*.

2. Federal Preemption Framework

The Supremacy Clause provides that the Constitution, federal laws, and treaties "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. From this constitutional command flows the principle that state laws that interfere with or are contrary to federal law must yield. *La. Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 368 (1986).

Federal preemption takes several forms. Congress may expressly preempt state law through clear statutory language. Alternatively, preemption may be implied when Congress enacts a regulatory scheme "sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (citation omitted).

Implied preemption also encompasses conflict preemption, which occurs in two circumstances: when compliance with both state and federal law is physically impossible, or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citation omitted). This latter form—obstacle preemption—requires careful assessment of both the federal regulatory scheme and the challenged state law to determine whether the state law frustrates federal purposes.

Congressional intent remains the touchstone of all preemption analyses. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Courts must examine the statutory text, structure, and purpose to discern this intent. Where Congress includes an express preemption clause, the analysis properly

begins with the plain language of that provision. *CSX Transp. Inc. v. Easterwood*, 507 U.S. 658, 664 (1993).

Courts approaching preemption questions must also account for our federalist structure. When Congress legislates in areas traditionally occupied by the states, courts presume that federal law does not supersede the historic police powers of the states unless Congress has made such intention clear. *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Lohr*, 518 U.S. at 485).

In this case, Plaintiffs contend that the FDCA impliedly preempts House File 2677 through obstacle preemption. Specifically, they argue that Iowa's law stands as an obstacle to the accomplishment of federal objectives by interfering with the FDA's authority and discretion to enforce the FDCA according to its own prioritization and timeline.

B. Analysis

Plaintiffs advance three primary arguments for why House File 2677 is unlawful and should be enjoined. First, they assert that the statute is impliedly preempted by the FDCA. Specifically, they contend that 21 U.S.C. § 337(a)—which provides that enforcement proceedings under the FDCA "shall be by and in the name of the United States"—reflects Congress's intent to give the federal government exclusive enforcement authority over the Act. According to Plaintiffs, House File 2677 effectively seeks to enforce federal requirements by prohibiting the sale of unauthorized ENDS products, thereby usurping FDA's enforcement discretion and creating an obstacle to the achievement of federal objectives.

Second, Plaintiffs argue that House File 2677 violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution. They maintain that the statute irrationally distinguishes between manufacturers, sellers, and users of ENDS products containing tobacco-derived nicotine and those containing non-tobacco-derived (synthetic) nicotine.

Specifically, they highlight that House File 2677 creates a "safe harbor" for certain unauthorized tobacco-derived nicotine products that were on the market as of August 8, 2016, and for which PMTAs were filed by September 9, 2020, but provides no comparable exception for synthetic nicotine products, even when timely PMTAs were filed for such products after they became subject to FDA regulation in April 2022.

Third, Plaintiffs assert a violation of equal protection guarantees under the Iowa Constitution, advancing substantially similar arguments about the allegedly irrational differential treatment of tobacco-derived versus synthetic nicotine products.

Defendants vigorously contest each of these theories. With respect to preemption, Defendants argue that the FDCA contains preservation and savings clauses which expressly preserve state authority to regulate tobacco product sales. They emphasize that the statute's text, structure, and purpose demonstrate Congress's intent to preserve the states' historical police power to regulate tobacco product sales within their borders. Defendants further contend that House File 2677 does not enforce federal law, but rather creates an independent state regulatory scheme that merely references FDA authorization status as a criterion for determining which products may be sold in Iowa.

Regarding the equal protection claims, Defendants maintain that the distinction between tobacco-derived and synthetic nicotine products easily satisfies rational basis review. They assert that the Iowa Legislature had ample reason to conclude that synthetic nicotine products uniquely foster addiction and abuse, particularly among youth, due to consumer misconceptions about their health risks. Drawing on research showing that products marketed as "tobacco-free" may be particularly appealing to young adults, Defendants argue that Iowa's regulatory scheme serves the legitimate governmental interest in protecting public health.

Defendants also raise several threshold objections. They contend that Plaintiffs lack standing because they seek to sell products that federal law prohibits, and thus have no legally protected interest. Defendants further assert that the balance of equities and public interest favor denying the injunction, given Iowa's strong interest in protecting its citizens' health through exercise of its traditional police powers. The Court will address each of these arguments in turn.

1. Proper Parties Before the Court

Before reaching the substantive questions presented by Plaintiffs' motion, the Court must address a threshold jurisdictional matter concerning the proper defendants in this action. This inquiry reflects the foundational principle that federal courts possess only limited jurisdiction, carefully circumscribed by both constitutional constraints and prudential considerations. The sovereign immunity doctrine—a bedrock feature of our constitutional structure—significantly impacts which governmental entities may properly appear before this Court. Plaintiffs have named both the Iowa Department of Revenue and its Director, Mary Mosiman, as defendants. The Court must therefore determine whether these parties fall within its jurisdictional reach and, if so, the nature and scope of any potential relief that might be awarded against them.

A fundamental principle of our constitutional structure is that the Eleventh Amendment shields states and their agencies from suit in federal court. *Hans v. Louisiana*, 134 U.S. 1, 15 (1890). This immunity extends to state departments and agencies that function as arms of the state. *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 100 (1984). The Department, as an executive agency of Iowa, clearly falls within this protected category.

The Supreme Court recognized an important exception to sovereign immunity in *Ex parte Young*, 209 U.S. 123 (1908), which permits suits against state officials in their official capacities for prospective injunctive relief to prevent ongoing violations of federal law. This doctrine rests

on the legal fiction that when a state official acts in violation of the Constitution or federal law, the official is "stripped of his official or representative character." *Id*. at 160. The doctrine is carefully circumscribed, however, and applies only to officials who have "some connection with the enforcement" of the challenged law. *Id*. at 157.

Applying these principles, Plaintiffs' claims against the Department must be dismissed. The Department, as an arm of the state, is entitled to Eleventh Amendment immunity. *Armstrong v. Exceptional Child Ctr., Inc*., 575 U.S. 320, 326–27 (2015). Federal courts lack jurisdiction to award injunctive relief against state agencies, regardless of the merits of the underlying claims.

With respect to Director Mosiman, however, the analysis is different. The Supreme Court has recently reaffirmed that federal courts have the power to enjoin individuals tasked with enforcing laws, not the "laws themselves." *Whole Woman's Health v. Jackson*, 595 U.S. 30, 44 (2021). Director Mosiman, as the official charged with implementing and enforcing House File 2677, falls squarely within the *Ex parte Young* exception. The Amended Complaint alleges that Director Mosiman, in her official capacity, is planning to enforce a state law that purportedly conflicts with federal law, thereby violating the Supremacy Clause.

Consequently, although the Court cannot enjoin the Department or House File 2677 itself, it may—if the requirements for preliminary injunctive relief are otherwise satisfied—enjoin Director Mosiman from taking specific enforcement actions that would violate federal law. *See Armstrong*, 575 U.S. at 326–27 (recognizing the "ability to sue to enjoin unconstitutional actions by state and federal officers" as "a judge-made remedy" inherent in courts' equitable powers).

Therefore, the Court will consider Plaintiffs' Motion for Preliminary Injunction as it pertains to Director Mosiman in her official capacity, but will dismiss the Department as an improper party to this action.

2. Article III Standing Requirements

The Court must also address Defendants' contention that Plaintiffs lack Article III standing to bring this action. They argue that because Plaintiffs seek to sell or purchase ENDS products that allegedly violate federal law, they have no "legally protected interest" that could give rise to a cognizable injury. This argument misstates the nature of standing doctrine.

Article III standing requires three elements: (1) an injury in fact, (2) causation, and (3) redressability. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). An injury in fact requires the invasion of a legally cognizable interest that is concrete, particularized, and actual or imminent. The standing inquiry serves as a threshold jurisdictional question, ensuring that parties seeking judicial review possess "a personal stake in the outcome" of the case. *Gill v. Whitford*, 585 U.S. 48, 54 (2018) (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)).

Defendants' argument hinges entirely on the "legally protected interest" language from *Lujan*, suggesting that because unauthorized ENDS products cannot lawfully be introduced into interstate commerce under the FDCA, Plaintiffs have no legally protected interest in selling or purchasing such products. This reading distorts the Supreme Court's standing jurisprudence. When the Court referred to a "legally protected interest" in *Lujan*, it was describing the need for a "judicially cognizable interest," not imposing a requirement that a plaintiff's conduct comply with all aspects of federal law. The phrase does not resurrect the discarded "legal right" theory of standing that the Supreme Court rejected decades ago. *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153–54 (1970).

Multiple circuit courts have correctly recognized this distinction. The Eighth Circuit has held that a "legally protected interest" requires only a "judicially cognizable interest." *Carlsen v. GameStop*, Inc., 833 F.3d 903, 908 (8th Cir. 2016). As the Sixth Circuit explained, "a plaintiff

need not have a 'legal right,' or a right protected by the law of property, contract, tort, or statute, to suffer injury-in-fact." *Christian Cnty. Clerk ex rel. Kem v. Mortg. Elec. Registration Sys., Inc*., 515 Fed. App'x 451, 454 (6th Cir. 2013) (citation omitted). The appropriate inquiry focuses not on whether Plaintiffs' activities fully comply with federal law, but on whether they have alleged a concrete injury that could be redressed by a favorable decision.

This issue is particularly relevant in the context of Supremacy Clause challenges. Congress has the authority to limit states' regulatory discretion, which it did through Section 337(a) by reserving FDCA enforcement authority to the federal government. A rule that denies standing to Plaintiffs based solely on imperfect compliance with federal law would create an anomalous result: states could evade preemption challenges by simply asserting a plaintiff's noncompliance with the very federal standards at issue. Such circularity finds no support in our federalist structure.

The regulatory context here further illuminates why Defendants' standing argument fails. Unlike statutes criminalizing possession of contraband, the FDCA does not prohibit mere possession or use of unauthorized ENDS products. Rather, it regulates their distribution in interstate commerce. 21 U.S.C. § 331(a)–(c). More significantly, the 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.

Plaintiffs have demonstrated concrete injuries that readily satisfy the injury-in-fact requirement. The manufacturer and retailer Plaintiffs face substantial economic harm—including lost sales, customers, and goodwill—if House File 2677 takes effect. Such economic injuries represent paradigmatic examples of concrete harm sufficient to support standing. *United States v. Texas*, 599 U.S. 670, 676 (2023). The individual consumer Plaintiffs face imminent loss of access

to products they rely upon to avoid combustible cigarettes, presenting direct health risks. These injuries are not speculative, but flow directly from House File 2677's enforcement.

The economic impact on the retailer Plaintiffs is particularly concrete and immediate. They attest that the law's enforcement would require them to close their businesses entirely, causing lost revenues not only from unauthorized ENDS products but also from numerous other product lines, including FDA-authorized ENDS products, FDA-authorized nicotine pouch products, federally legal hemp products, and other non-ENDS merchandise. This broader economic impact demonstrates the concrete nature of Plaintiffs' injuries regardless of whether certain products in their inventory lack FDA authorization.

Defendants' position, if accepted, would effectively immunize state laws from preemption challenges whenever a plaintiff's underlying conduct fails to comply perfectly with all federal requirements. Such a rule cannot be reconciled with our constitutional structure, which relies on the Supremacy Clause to resolve conflicts between state and federal law. *Armstrong*, 575 U.S. at 324–25.

As Plaintiffs correctly observe, Congress deliberately centralized FDCA enforcement authority in the FDA through Section 337(a), recognizing that inconsistent state enforcement regimes would undermine the federal regulatory approach. Iowa's acknowledged purpose in enacting House File 2677—to address "federal non-enforcement"—precisely illustrates why Congress vested enforcement authority exclusively with the federal government.

The distinction between this case and those cited by Defendants is significant. Defendants rely on cases involving plaintiffs seeking to engage in clearly illegal activities, such as narcotics trafficking or evading traffic citations. The circumstances here are markedly different. The FDA has repeatedly exercised enforcement discretion to allow the continued marketing of certain

unauthorized ENDS products, recognizing that "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001). In fact, if House File 2677 were to go into effect, even products which are unauthorized by the FDA would be permitted for sale in Iowa.

This case presents precisely the type of federalism dispute that Article III standing exists to resolve. At its core, Plaintiffs contend that House File 2677 impermissibly intrudes upon a field regulated by federal law. Whether their underlying conduct complies with that federal regulatory regime is a separate question that goes to the merits, not to standing. For these reasons, the Court concludes that Plaintiffs have established Article III standing to challenge House File 2677.

3. Implied Preemption Claim

Plaintiffs argue that House File 2677 is impliedly preempted by the FDCA. The Court's analysis of this claim requires careful consideration of both the statutory framework that Congress has established and the historical relationship between federal and state regulation of tobacco products.

The doctrine of implied conflict preemption recognizes that federal law supersedes state law when "it is impossible for a private party to comply with both state and federal law," or "when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of [Congress].'" *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (citation omitted). It is not sufficient to observe "'the ultimate goal of both federal and state law' is the same," for conflict preemption purposes. *Forest Park II v. Hadley*, 336 F.3d 724, 733 (8th Cir. 2003) (citation omitted). Rather, state law is preempted when "it interferes with the methods

by which the federal statute was designed to reach that goal." *Id*. (cleaned up) (quoting *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987)).

The polestar of any preemption analysis is congressional intent. When Congress legislates in a field traditionally occupied by the States—as is the case with tobacco regulation—a court begins its analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (alteration in original) (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)).

This inquiry is "a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). The Supreme Court has cautioned that implied preemption analysis should not become "a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives," as this would "undercut the principle that it is Congress rather than the courts that pre-empts state law." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted). With these principles in mind, the Court turns to the specific regulatory scheme governing tobacco products.

a. The Federal Regulatory Scheme for ENDS Products

The FDCA contains a critical enforcement provision in Section 337(a) of Title 21. This provision states unambiguously that all proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has recognized this language as "clear evidence that Congress intended" the FDCA to be "enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Courts have consistently applied this principle across various contexts within the FDCA's regulatory framework. The

United States Court of Appeals for the First Circuit has held that state-law claims existing "solely by virtue" of an FDCA violation are impliedly preempted because Congress reserved enforcement authority to the federal government alone. *Plourde v. Sorin Grp. USA, Inc*., 23 F.4th 29, 33 (1st Cir. 2022). Similarly, the Ninth Circuit has affirmed that proceedings addressing FDCA violations "must be by and in the name of the United States, not a private party." *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc*., 48 F.4th 1040, 1049 (9th Cir. 2022). This consistent interpretation reflects Congress's deliberate choice to centralize enforcement authority in the federal government.

Unlike many other areas regulated by the FDCA, Congress has preserved a significant role for state and local regulation of tobacco products. The Family Smoking Prevention and Tobacco Control Act ("TCA"), which brought tobacco products within the FDA's jurisdiction, includes a carefully structured preemption scheme containing both a Preservation Clause and a Savings Clause. *See* 21 U.S.C. § 387p. This provision reflects congressional recognition of the "extensive background of state and local tobacco regulation" and a deliberate choice not to "broadly jettison[] the longstanding tradition of states and localities' role in the regulation of sales of tobacco products when it enacted the TCA in 2009." *R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, 29 F.4th 542, 549–50 (9th Cir. 2022).

The Preservation Clause explicitly reserves to states and localities the authority to enact requirements "relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products." 21 U.S.C. § 387p(a)(1). This reservation of authority allows states to regulate tobacco sales in ways that might exceed federal requirements. The statute also contains a Preemption Clause that prohibits states from establishing requirements that are "different from, or in addition to," federal requirements relating to certain

aspects of tobacco product regulation, including product standards, premarket review, and manufacturing practices. *Id*. § 387p(a)(2)(A). Finally, the Savings Clause creates an exception to this preemption provision, allowing states to adopt measures relating to the sale of tobacco products even when such measures might indirectly affect areas otherwise preempted. *Id*. § 387p(a)(2)(B).

This tripartite structure establishes an intricate framework for federal-state regulatory spheres, preserving traditional state authority over sales regulations while ensuring federal primacy in technical aspects of product regulation. The question presented here is whether House File 2677—despite being characterized as a sales regulation—effectively encroaches upon the federal government's exclusive enforcement authority under Section 337(a) by conditioning market access on compliance with federal authorization standards.

Section 337(a)'s reservation of enforcement authority to the federal government applies with equal force to tobacco products regulated under the TCA as it does to other FDCA-regulated products. When Congress intends to permit states to enforce provisions of the FDCA, it does so explicitly, as demonstrated by the exceptions enumerated in Section 337(b). No such exception exists for enforcement of the TCA's premarket authorization requirements, suggesting Congress intended to maintain exclusive federal enforcement in this domain.

The Court must therefore determine whether House File 2677 functions as a permissible sales regulation within the state's preserved authority or impermissibly seeks to enforce federal premarket authorization requirements in contravention of Section 337(a)'s reservation of enforcement authority to the federal government.

Defendants argue that Plaintiffs are invoking "an inapplicable FDCA preemption regime" because Section 337(a) concerns the Medical Device Amendments ("MDA") rather than the TCA.

[ECF No. 39 at 20]. At the preliminary injunction hearing, Defendants asserted that by seeking application of Section 337(a)'s preemptive effects to the TCA, Plaintiffs are asking the Court to extend *Buckman*. They reason that there are no cases where *Buckman* has been applied to state regulations on tobacco sales because of the preservation and savings clauses included in the TCA.

This argument, however, puts the cart before the horse. The question is not whether the preemptive principles in *Buckman* apply to the TCA. It is whether: (1) House File 2677 allows for the enforcement of regulations in the FDCA by a party other than the Federal Government and (2) whether the specific preemption provisions in the TCA—Section 387p—carve out an exception permitting House File 2677 to do so despite the restrictions of Section 337(a).

The application of Section 337(a) to the TCA does not represent an extension of *Buckman*, but rather a straightforward application of established principles to a different subject matter within the same statutory framework. Congress enacted the TCA in 2009, well after the Supreme Court's decision in *Buckman*, and deliberately chose to place tobacco regulation within the FDCA rather than creating a standalone regulatory regime. The preemption provisions in Section 387p indicate that nothing in Chapter 9 on tobacco shall be construed to limit federal agencies, states, or other political entities from enacting and enforcing rules more stringent than the requirements laid out in that chapter. 21 U.S.C. § 387p(a)(1). Notable, these provisions refer specifically to "this subchapter" (Chapter 9 on tobacco), not more broadly to Section 337(a) in Chapter 3. This textual distinction is significant, as it suggests that Congress could have expressly authorized states to enforce FDCA provisions for tobacco products but declined to do so.

Defendants have identified no substantive reason why the Supreme Court's interpretation of Section 337(a) would not apply with equal force to the TCA. The TCA exists on the same plane as the MDA within the FDCA's regulatory framework. This conclusion finds support in cases

applying Section 337(a) and its preemptive effect against state laws that incorporate FDCA standards, even when those laws pertain to provisions without express preemption clauses. *Nexus Pharms.,* 48 F.4th at 1046 (holding that when claims rely "on a state statute which itself relies on the federal statute," they violate implied preemption principles by standing as an obstacle to the FDA's enforcement discretion); *Novo Nordisk Inc. v. WELLHealth Inc*., --- F. Supp. 3d ----, ----, 2025 WL 699769, at *5 (M.D. Fla. Jan. 30, 2025) (applying *Buckman* to prescription drugs and noting that to succeed on a claim that the product at issue is unlawful under Florida state law, "non-compliance with the FDCA is required because the pre-market approval requirement under the Florida DCA relies on the FDCA").

At least one court has specifically applied *Buckman* preemption to state law claims based upon FDA compliance for products governed by the TCA. *See Yimam v. Myle Vape, Inc.*, No. 2019 CA 008050 B, 2020 WL 13614925, at *5 (D.C. Super. June 11, 2020) (explaining that "if the state law claim would not exist in the absence of the FDCA, 'then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*'") (quoting *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 173 (D. D.C. 2018)). The FDA itself has recognized Section 337(a)'s applicability to tobacco regulation, recently explaining to the International Trade Commission that this provision ensures "decisions about the regulatory or compliance status of tobacco products and what products should be prioritized for enforcement reflect the views of the agency charged with administering the FDCA." [ECF No. 27 ¶ 66]. This underscores the central role of enforcement discretion in the FDA's comprehensive regulatory approach.

While Section 387p's unique structure unquestionably applies to tobacco product regulation in addition to Section 337(a), the fundamental principle remains that "Congress

intended that the [TCA] be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. As the Supreme Court has explained, "neither an express pre-emption provision nor a saving clause 'bars the ordinary working of conflict pre-emption principles.'" *Id*. (cleaned up) (quoting *Geier v. Am. Honda Motor Co*., 529 U.S. 861, 869 (2000)). With this framework in mind, the Court turns to whether House File 2677 impermissibly conflicts with the federal statutory scheme.

b. Iowa's House File 2677

House File 2677 establishes a "Vapor products directory" and imposes comprehensive requirements on manufacturers who sell ENDS products in Iowa. Under the statutory scheme, every vapor product manufacturer selling products in Iowa must certify to the Department its products either: (1) have received marketing authorization from the FDA pursuant to federal law, or (2) were on the market as of August 8, 2016, and had a premarket tobacco product application ("PMTA") filed with the FDA on or before September 9, 2020, that remains under FDA review or is subject to ongoing litigation. Iowa Code § 453A.52(1). Only products meeting one of these criteria may be lawfully sold in Iowa after the directory is published.

The law mandates that manufacturers submit initial and annual certification forms listing all vapor products sold in the state, accompanied by copies of FDA marketing authorizations, orders, or records demonstrating compliant submission, along with a payment for each product. Manufacturers must also maintain ongoing compliance with notification requirements, promptly informing the Director of any changes regarding their products' authorization status, including the issuance of denial orders or other FDA actions affecting product status.

Beyond these certification requirements, House File 2677 creates a comprehensive enforcement regime. The law makes it unlawful for any person to sell vapor products in Iowa that

are not listed on the vapor products directory. *Id*. § 453A.52A. Violations trigger escalating civil penalties and can result in suspension of a retailer's permit. *Id*. § 453A.52B. The statute designates the knowing shipment or receipt of non-compliant vapor products as an unfair practice and a violation of Iowa's consumer fraud law, authorizes unannounced compliance checks of distributors, and requires the appointment of an agent for service of process.

The structure of House File 2677 reveals that it does more than establish general requirements for tobacco product sales. Rather, it creates a registration regime that explicitly incorporates federal premarket review standards as the determinative factor for market access. The statutory scheme effectively allows Iowa to bring enforcement actions in its own name against manufacturers and retailers based on compliance with the TCA's PMTA process—a federal requirement that Congress entrusted exclusively to FDA enforcement.

While the law includes provisions unrelated to federal authorization status, such as requiring the designation of an agent for service of process, these ancillary requirements do not alter the core mechanism of the statute: conditioning market participation on federal authorization status or safe harbor provisions that mirror federal deadlines. The law's operative effect is to create a state-level enforcement regime for federal premarket authorization requirements, with Iowa substituting its enforcement discretion for that of the FDA.

c. House File 2677 Is Impliedly Preempted by the FDCA

Section 387p establishes a carefully balanced framework governing the relationship between federal and state tobacco regulation. The Preemption Clause prohibits states from establishing requirements "different from, or in addition to," federal standards relating to tobacco product standards, premarket review, registration, and manufacturing practices. 21 U.S.C. § 387p(a)(2)(A). The Preservation and Savings Clauses together maintain states' authority to

regulate tobacco product sales, allowing them to impose more stringent sales restrictions than federal law requires. 21 U.S.C. § 387p(a)(1), (a)(2)(B).

House File 2677, however, extends beyond a mere sales regulation by creating an extensive state-level regulatory scheme that directly incorporates federal premarket authorization status as a condition of lawful sale in Iowa. Unlike the ordinance upheld in *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170 (8th Cir. 2023), which implemented a straightforward ban on flavored tobacco products, House File 2677 establishes a directory with requirements contingent on manufacturers' compliance with federal premarket authorization processes.

Plaintiffs aptly characterize House File 2677 as "parasitic on the FDCA," observing that the law would be nonsensical without the extensive cross-referencing of federal law. Unlike permissible state regulations such as the *City of Edina*'s outright flavor ban, House File 2677 creates a scheme that conditions sales eligibility on FDA authorization status. Defendants counter that Iowa's law is not parasitic on the FDCA because the three-step framework of the TCA (Preservation, Preemption, and Savings Clauses) preserves states' robust authority in tobacco regulation. This argument overlooks the Supreme Court's clear instruction in both *Geier* and *Buckman* that "savings clauses do not affect the ordinary working of conflict preemption principles." *Buckman*, 531 U.S. at 352.

Courts have drawn an important distinction between permissible sales restrictions and impermissible attempts to regulate product standards. States may implement sales bans that have incidental effects on product manufacturing, but they may not structure legislation that functions as requirements on manufacturers to "structure their operations" in accordance with locally prescribed standards. *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 434 (2d Cir. 2013). House File 2677 crosses this line by conditioning market access on compliance

with federal authorization standards rather than imposing a direct prohibition on defined product characteristics.

Defendants maintain that House File 2677 serves legitimate state interests independent of federal enforcement concerns. They specifically highlight the requirement that manufacturers designate an agent for service of process, arguing this provision ensures Iowa consumers have legal recourse against foreign companies selling harmful products within the state. Although this consumer protection measure undoubtedly falls within Iowa's traditional police powers, it represents merely an ancillary feature of the statutory scheme. Such peripheral provisions cannot redeem a regulatory framework whose central organizing principle—conditioning market access on federal authorization status—fundamentally encroaches upon the FDA's exclusive enforcement authority.

Significantly, House File 2677 violates Section 337(a)'s reservation of enforcement authority to the federal government. The statute explicitly designates the "[k]nowingly shipping or receiving vapor products in violation of this subchapter" as "an unfair practice and a violation of section 714.16." Iowa Code § 453A.52B(4). It further provides that the state may recover costs for bringing enforcement actions. *Id*. § 453A.52B(5). This enforcement mechanism directly contravenes the principle that enforcement of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

By expressly incorporating the PMTA process into the statutory framework and using it as the foundation for determining which products may be lawfully sold in Iowa, House File 2677 effectively transfers the FDA's enforcement discretion to the state. This approach conflicts with Section 337(a)'s reservation of enforcement authority to the federal government. *Buckman*,

531 U.S. at 352. The Preservation and Savings Clauses cannot salvage this encroachment on federal authority. *Id*.

Section 387p allows states to establish requirements identical to federal standards regarding tobacco product standards, premarket review, registration, and manufacturing practices. It also permits states to impose more stringent requirements relating to sales. House File 2677, however, neither establishes identical standards nor imposes straightforward sales requirements. Rather, it creates a regulatory scheme that is fundamentally dependent on federal authorization status, permitting some products that the FDA currently allows through its enforcement discretion while excluding others.

This selective enforcement approach places Iowa in the position of making its own judgments about which federal requirements to enforce and how stringently to enforce them—precisely the role Congress reserved exclusively to the FDA. By doing so, Iowa interferes with "the methods by which the federal statute was designed to reach [its] goal." *Forest Park II*, 336 F.3d at 733 (citation omitted).

Plaintiffs have correctly identified the fundamental principle that governs this case. The Court holds that while states retain broad police powers over tobacco sales, they cannot enforce the FDCA. States may permissibly ban all ENDS products or ban all flavored products, as California and New York have done through proper exercise of their police powers. *See U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434 (upholding city ordinance prohibiting flavored tobacco products as a permissible sales restriction rather than a manufacturing standard). However, states cannot create a scheme that is parasitic on the FDCA by conditioning sales based on FDA authorization status. Such a regulatory approach impermissibly intrudes upon federal

enforcement authority and contravenes congressional intent to centralize FDCA enforcement in the federal government.

The Court acknowledges Iowa's legitimate interest in protecting its citizens' health through exercises of its traditional police powers. However, House File 2677's regulatory approach stands as an obstacle to the accomplishment of Congress's objective in centralizing FDCA enforcement authority in the federal government. Accordingly, the Court concludes that House File 2677 is impliedly preempted by federal law.

4. Equal Protection Claim

a. Standard of Review

Plaintiffs also contend that House File 2677 violates the equal protection guarantees under both the United States and Iowa Constitutions. They argue that the statute impermissibly discriminates between manufacturers, sellers, and users of ENDS products containing tobacco-derived nicotine and those containing non-tobacco-derived (synthetic) nicotine. Specifically, they challenge the provision creating a "safe harbor" for unauthorized tobacco-derived nicotine products that were on the market as of August 8, 2016, and for which PMTAs were filed by September 9, 2020, while providing no comparable exception for synthetic nicotine products.

The Equal Protection Clause of the Fourteenth Amendment prohibits states from "deny[ing] to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. The Iowa Constitution similarly provides that "[a]ll laws of a general nature shall have a uniform operation; the general assembly shall not grant to any citizen, or class of citizens, privileges or immunities, which, upon the same terms shall not equally belong to all citizens." Iowa Const. art. I, § 6. Although these provisions are textually distinct, Iowa courts generally treat them as functionally identical for analytical purposes. *In re Morrow*, 616 N.W.2d

544, 548 (Iowa 2000) (applying "the same analysis in considering the state equal protection claim as . . . in considering the federal equal protection claim") (quoting *State v. Ceaser*, 585 N.W.2d 192, 196 (Iowa 1998)).

Because House File 2677 does not burden a suspect class or implicate a fundamental right, the parties correctly agree that rational basis review applies. *Pennell v. City of San Jose*, 485 U.S. 1, 14 (1988) (citing *New Orleans v. Dukes*, 427 U.S. 297, 303 (1976)). Under this deferential standard, a classification will be upheld "if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *FCC v. Beach Commc'ns, Inc*., 508 U.S. 307, 313 (1993). The law carries "a strong presumption of validity," and those challenging its rationality bear the burden "to negative every conceivable basis which might support it." *Id*. at 315 (quoting *Lehnhausen v. Lake Shore Auto Parts Co*., 410 U.S. 356, 364 (1973)). This presumption is particularly strong in Iowa, where it is codified by statute. *See* Iowa Code § 4.4(1) (requiring courts to presume "that [c]ompliance with the Constitutions of the state and of the United States is intended").

b. Rational Basis for Classification

The Court finds that Plaintiffs have not met their heavy burden of demonstrating that House File 2677's differential treatment fails rational basis review. The Iowa Legislature could have rationally concluded that synthetic nicotine products pose unique risks to public health, particularly among youth, that justify more stringent regulation. Several legitimate bases support this conclusion.

First, Defendants cite to research suggesting that nicotine products labeled "tobacco-free" may increase consumption among young adults due to misconceptions about health risks. *See* Morean et al., *"Tobacco-free" Nicotine Pouches: Risk Perceptions, Awareness, Susceptibility, and*

Use Among Young Adults in the United States, 25 Nicotine & Tobacco Rsch. 143 (Aug. 24, 2022), https://pubmed.ncbi.nlm.nih.gov/36000776/ [https://perma.cc/GAJ9-FEVB]. Studies indicate that "describing synthetic nicotine as 'tobacco-free nicotine' increased intentions to purchase e-cigarettes among youth who use e-cigarettes" because the terminology "may be misleading to youth in ways that increase the appeal of these addictive products." Reid Johnson, *Study Finds Youth Have Misperceptions About Synthetic Nicotine in E-Cigarettes*, UNC Lineberger Comprehensive Cancer Center (May 15, 2023), https://unclineberger.org/news/study-finds-youth-have-misperceptions-about-synthetic-nicotine-in-e-cigarettes/ [https://perma.cc/9LHW-BTN8]. This concern is particularly acute given ENDS products' already documented appeal to youth. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019) (noting that "E-cigarettes are indisputably highly addictive and pose health risks, especially to youth").

Second, synthetic nicotine products often employ marketing approaches—such as labels proclaiming "clean nicotine" or "putting the flavor back in vaping"—that may create misleading impressions about relative safety compared to tobacco-derived nicotine. Ramamurthi et. al., *Marketing of "Tobacco-Free" and "Synthetic Nicotine" Products*, 17–18 (2022), https://tobacco-img.stanford.edu/wp-content/uploads/2022/03/13161808/Synthetic-Nicotine-White-Paper-3-8-2022F.pdf [https://perma.cc/4ULG-LJER]. The Iowa Legislature could reasonably have determined that such marketing warranted greater caution in regulating these products. Studies also show that flavored nicotine products have growing popularity, especially among young Americans, with synthetic nicotine products often marketed specifically to highlight their flavor profiles. *See* Hassan Z. Sheikh, Cong. Rsch. Serv., *Synthetic Nicotine: Frequently Asked Questions* 1 (Feb. 28, 2022), https://www.congress.gov/crs-product/R47043 [https://perma.cc/WKU5-

62T3]. Risk perception and flavor are important drivers in nicotine abuse by young Americans, making the Legislature's caution toward synthetic products entirely rational.

Third, the timing of FDA regulatory coverage provides a rational explanation for the differing treatment. Tobacco-derived nicotine products became subject to FDA regulation in 2016, with manufacturers facing a 2020 PMTA filing deadline. By contrast, synthetic nicotine products were not brought under FDA jurisdiction until 2022. Given this regulatory history, the Iowa Legislature could rationally have chosen to align its safe harbor provision with the established federal timeline for tobacco-derived products while taking a more cautious approach toward the more recently regulated synthetic alternatives. This approach is consistent with the gradual development of federal regulation in this area.

Although Plaintiffs argue that the distinction is irrational because synthetic nicotine "is likely to contain lower levels of organic impurities than tobacco-derived nicotine," [ECF No. 36 at 24 n.8], this single assertion, even if true, fails to negate every conceivable basis for the classification. Moreover, it ignores the reality that the Iowa Legislature's concern may reasonably have focused not on the chemical purity of synthetic nicotine itself, but rather on consumer perception and the potential for synthetic products to attract youthful users through misleading marketing or palatability.

Plaintiffs also suggest that House File 2677's distinction mirrors a proposal that R.J. Reynolds previously advocated before the FDA, implying some improper purpose. But rational basis review does not permit judicial inquiry into legislative motive. As the Supreme Court has emphasized, "it is entirely irrelevant for constitutional purposes whether the conceived reason for the challenged distinction actually motivated the legislature." *Beach Commc'ns*, 508 U.S. at 315 (citation omitted). So long as the classification furthers a legitimate governmental interest—here,

protecting public health, particularly among youth—the Court must uphold it regardless of what may have prompted its enactment.

The Court's role is not to second-guess the wisdom of a legislature's policy choices or to substitute its judgment for that of elected representatives. As the Supreme Court has cautioned, rational basis review is not "a license for courts to judge the wisdom, fairness, or logic of legislative choices." *Id*. at 313.

Iowa has a legitimate government interest in protecting the health and welfare of its citizens, especially its youth. This interest falls squarely within the State's traditional police powers. *See Nebbia v. People of New York*, 291 U.S. 502, 524 (1934) (holding that a state's "authority to make regulations of commerce is as absolute as its power to pass health laws"); *Borlin v. Civil Serv. Comm'n of City of Council Bluffs*, 338 N.W.2d 146, 150 (Iowa 1983) (recognizing that individual rights are subject to reasonable "regulation[s] . . . necessary to protect public health"). House File 2677's differential treatment of tobacco-derived and synthetic nicotine products is rationally related to this purpose. The Court therefore concludes that Plaintiffs have not demonstrated a likelihood of success on their equal protection claims under either the United States or Iowa Constitutions.

c. No Bond Required

The Court must also consider whether to require Plaintiffs to post a security bond pursuant to Rule 65(c) of the Federal Rules of Civil Procedure. Although Rule 65(c) states that a preliminary injunction may issue "only if the movant gives security," the Eighth Circuit has recognized that district courts possess substantial discretion in this determination. *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Engr's*, 826 F.3d 1030, 1043 (8th Cir. 2016).

Defendants' proposed bond calculation is fundamentally flawed. Their calculation—$36,000 per product for retailers and $129,000 per product for manufacturers—presupposes that Plaintiffs would violate House File 2677 and incur daily penalties over a projected 120-day enforcement period. This approach improperly conflates regulatory penalties with actual damages, effectively seeking security against Plaintiffs' hypothetical future violations rather than against harm to Defendants from an improvidently granted injunction. As Plaintiffs persuasively argued at the preliminary injunction hearing, many would face business closure rather than continued operation in violation of the statute, making the penalty-based calculation particularly inappropriate. The Court finds that no security is warranted where, as here, Plaintiffs have demonstrated a strong likelihood of success on their constitutional claims and Defendants have identified no concrete, non-speculative damages they would suffer if wrongfully enjoined. The Court therefore exercises its discretion to waive the bond requirement.

III. CONCLUSION

For the reasons discussed above, the Court concludes that House File 2677 impermissibly intrudes upon the federal government's exclusive authority to enforce the FDCA. Although Iowa retains broad police powers to regulate the sale of tobacco products within its borders, it may not condition market access on compliance with federal authorization standards in a manner that effectively transfers the FDA's enforcement discretion to state authorities. The Court finds, however, that Plaintiffs have not demonstrated a likelihood of success on their equal protection claims, as the statute's differential treatment of tobacco-derived and synthetic nicotine products satisfies rational basis review. Accordingly, Plaintiffs' Motion for Preliminary Injunction is GRANTED. [ECF No. 32]. IT IS HEREBY ORDERED that:

1. Defendant Mary Mosiman, in her official capacity as the Director of the Iowa Department of Revenue is ENJOINED from implementing and enforcing the provisions of House

File 2677 relating to the establishment and enforcement of a vapor products directory. Defendant may continue to enforce the provisions of House File 2677 requiring nonresident vapor product manufacturers not registered to do business in the state as a foreign corporation or business entity to appoint and continually engage an agent for service of process and to provide notice as required by Iowa Code § 453A.52D(2).

IT IS SO ORDERED.

Dated this 2nd day of May, 2025.

STEPHANIE M. ROSE, CHIEF JUDGE
UNITED STATES DISTRICT COURT