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

IOWANS FOR ALTERNATIVES TO SMOKING & TOBACCO, INC.; GLOBAL SOURCE DISTRIBUTION, LLC; WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION; SMOKIN HOT LLC; CENTRAL IOWA VAPORS WDM, LLC; AND TASTE THE VAPE LLC d/b/a ROUTE 69 VAPOR, Plaintiffs, v. THE IOWA DEPARTMENT OF REVENUE AND MARY MOSIMAN, DIRECTOR OF THE IOWA DEPARTMENT OF REVENUE, Defendants.	Case No.: 24-cv-448-SMR-HCA **PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** **Oral Argument Requested**

Pursuant to Federal Rule of Civil Procedure 65 and Local Rule 65, Plaintiffs Iowans for Alternatives to Smoking & Tobacco, Inc., Global Source Distribution, LLC, Wages and White Lion Investments, LLC d/b/a Triton Distribution, Smokin Hot, L.L.C., Central Iowa Vapors WDM, LLC, and Taste the Vape d/b/a Route 69 Vapor (collectively "Plaintiffs") file this motion for a preliminary injunction against Defendants the Iowa Department of Revenue and Mary Mosiman, the Director of the Iowa Department of Revenue (collectively "Defendants"), and in support thereof state as follows:

1. On May 17, 2024, Governor Kim Reynolds signed House File 2677—a statute that regulates the distribution and sale of vapor products (electronic cigarettes)—into law.

2. The Iowa Department of Revenue ("IDR") has announced that it will begin enforcing HF 2677 on February 3, 2025.

3. Pursuant to 28 U.S.C. § 2201, Plaintiffs' Verified Complaint asks this Court to enter an order declaring that HF 2677 violates: (1) the Supremacy Clause of the United States Constitution; (2) the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution; and (3) the Equal Protection Clause of the Iowa Constitution.

4. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C §§ 301 et seq. ("FDCA"), gives the Food and Drug Administration ("FDA") exclusive authority to enforce the FDCA, including authority over "tobacco products," which include electronic nicotine delivery systems ("ENDS") containing tobacco-derived nicotine and ENDS containing non-tobacco-derived nicotine.

5. The FDCA impliedly preempts HF 2677 because it encroaches on the FDA's enforcement discretion.

6. Further, HF 2677's different treatment of manufacturers and sellers of unauthorized ENDS containing tobacco-derived nicotine compared to manufacturers and sellers of unauthorized ENDS containing non-tobacco-derived nicotine is arbitrary and irrational, and lacks a rational basis in violation of the Equal Protection Clause of the Fourteenth Amendment and the Equal Protection Clause of the Iowa Constitution.

7. As explained in more detail in the attached brief in support of this motion, Plaintiffs respectfully request that the Court enter an order that preliminarily enjoins Defendants the Iowa Department of Revenue and Mary Mosiman, the Director of the Iowa Department of Revenue, from enforcing House File 2677 because: (1) Plaintiffs are likely to succeed on the merits of their claims; (2) Plaintiffs will suffer immediate, irreparable harm in the absence of preliminary relief; (3) the balance of the equities favors Plaintiffs; and (4) preliminary relief will be in the public interest.

8. Given the complexities of the Federal Food, Drug and Cosmetic Act, the FDA's discretionary enforcement thereunder, and the interplay of the same with HF 2677, Plaintiffs respectfully request oral argument on their motion, to be heard as soon as practical, given Defendant Iowa Department of Revenue's announcement that it will begin enforcing HF 2677 on February 3, 2025.

Dated: December 17, 2024

Respectfully submitted,

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IOWANS FOR ALTERNATIVES TO SMOKING & TOBACCO, INC.; GLOBAL SOURCE DISTRIBUTION, LLC; WAGES AND WHITE LION INVESTMENTS, LLC d/b/a TRITON DISTRIBUTION; SMOKIN HOT LLC; CENTRAL IOWA VAPORS WDM, LLC; AND TASTE THE VAPE LLC d/b/a ROUTE 69 VAPOR, Plaintiffs, v. THE IOWA DEPARTMENT OF REVENUE AND MARY MOSIMAN, DIRECTOR OF THE IOWA DEPARTMENT OF REVENUE, Defendants.	Case No.: 24-cv-448-SMR-HCA **BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** **Oral Argument Requested**

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INTRODUCTION

Plaintiffs Iowans for Alternatives to Smoking & Tobacco, Inc., Global Source Distribution, LLC, Wages and White Lion Investments, LLC d/b/a Triton Distribution, Smokin Hot, L.L.C., Central Iowa Vapors WDM, LLC, and Taste the Vape d/b/a Route 69 Vapor (collectively "Plaintiffs") are a non-profit corporation and its members that are manufacturers, distributors, wholesalers, and retailers of electronic nicotine delivery systems (also known as "ENDS," "e-cigarettes," and "vapor products"). Among the vapor products that Plaintiffs sell are ENDS that contain *non-tobacco-derived* nicotine, as opposed to ENDS that contain *tobacco-derived* nicotine.

House File 2677, "an Act Relating to the Regulation of Vapor Products and Providing Penalties" (hereinafter "HF 2677"), was signed into law on May 17, 2024, and directs the Iowa Department of Revenue ("IDR") to take enforcement actions (including the issuance of monetary penalties) against the manufacturers and sellers of ENDS that have not received marketing authorization from the Food and Drug Administration ("FDA"). HF 2677 contains an exception for ENDS that were on the market as of August 8, 2016—the date ENDS containing *tobacco-derived nicotine* became subject to the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act")—and that had a premarket tobacco product application ("PMTA") filed with FDA by September 9, 2020, that is still undergoing FDA review or is the subject of ongoing litigation. However, HF 2677 contains no such exception for ENDS containing *non-tobacco-derived nicotine* for which PMTAs were timely filed when ENDS containing non-tobacco-derived nicotine became subject to the FDCA in 2022. Plaintiffs seek a preliminary injunction that enjoins Defendants from enforcing HF 2677, which the IDR has announced it will begin enforcing on February 3, 2025.

The Court should grant Plaintiffs' motion for preliminary relief because each factor that courts analyze for such motions—likelihood of success on the merits, irreparable harm, balance of the equities, and the public interest—weighs in Plaintiffs' favor.

First, Plaintiffs are likely to succeed on the merits of one or more of their claims.

Plaintiffs are likely to succeed on their first claim—that HF 2677 violates the Supremacy Clause of the United States Constitution. Because the FDCA provides that only the federal government can enforce the Act, the Supreme Court and lower federal courts have held that the FDCA impliedly preempts state laws that seek to enforce the Act. Such implied preemption occurs where the existence of the FDCA is a critical element of the State law. That is the situation here—the existence of the FDCA's marketing authorization process is a critical element of HF 2677.

Plaintiffs are also likely to succeed on their second claim—that HF 2677 violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution. A State violates the Equal Protection Clause when it treats similarly situated persons differently and there is no rational basis for that differential treatment. HF 2677 treats manufacturers and sellers of unauthorized ENDS containing tobacco-derived nicotine differently than manufacturers and sellers of unauthorized ENDS containing non-tobacco-derived nicotine. Specifically, HF 2677 provides a safe harbor for the sale of some unauthorized ENDS containing tobacco-derived nicotine while it offers no safe harbor for any unauthorized ENDS containing non-tobacco-derived nicotine. There is no rational basis for this differential treatment. Indeed, the FDCA makes no distinction between tobacco-derived nicotine and non-tobacco-derived nicotine.

Plaintiffs are also likely to succeed on their third claim—that HF 2677 violates the Equal Protection Clause of the Iowa Constitution. The Equal Protection Clause prohibits the State from treating similarly situated persons differently when there is no valid reason for such differential treatment. There is no valid reason for HF 2677's differential treatment of unauthorized ENDS with non-tobacco-derived nicotine.

Second, Plaintiffs will suffer irreparable harm in the absence of preliminary relief. Constitutional violations create irreparable harm in general. And in the absence of preliminary relief, manufacturers and sellers of unauthorized ENDS that do not fall within HF 2677's safe harbor provision (including Plaintiffs in this case) will suffer irreparable injuries in the form of lost sales of such products that are not compensable in damages because of sovereign immunity. Indeed, absent an injunction, the retailer Plaintiffs will be forced to close their doors when Defendants start enforcement of HF 2677 on February 3, 2025.

Third, the balance of the equities and the public interest factors weigh in Plaintiffs' favor. Those factors merge when the government is the defendant. And when a plaintiff establishes a likelihood that a defendant's action is unconstitutional, the plaintiff has also established that both the balance of the equities and the public interest favor preliminary relief.

FACTUAL AND LEGAL BACKGROUND

A. The FDCA gives FDA regulatory authority over tobacco products.

Congress enacted the FDCA in 1938 "to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, [medical] devices, and cosmetics." 75 P.L. 717, 52 Stat. 1040 (1938). The FDCA defines the terms "adulterated" and "misbranded." For example, a drug or medical device is "adulterated" if it is manufactured in a facility that does not fully comply with FDA's current good manufacturing practice ("CGMP") regulations, even if the failure to comply with those regulations has no adverse effect on the product.[1]

[1] *See* 21 U.S.C. § 351(a)(1)(B) & (h), 21 C.F.R. Parts 210, 211, and 820; *see also United States v. Lit Drug Co.*, 333 F. Supp. 990, 998 (D.N.J. 1971) (observing that "a drug may be pharmaceutically perfect in content but still be regarded as adulterated under law" where "any manufacturing, packing or holding method does not conform to current good manufacturing practice").

Congress amended the FDCA in 2009 to prohibit the movement in interstate commerce of certain adulterated and misbranded tobacco products, including traditional (combustible) cigarettes. *See* 21 U.S.C. § 331 (prohibiting the "introduction into interstate commerce of any food, drug, device, *tobacco product*, or cosmetic that is adulterated or misbranded") (emphasis added); 21 U.S.C. § 387a(b) (limiting FDA's authority over tobacco products to, *inter alia*, cigarettes).

In 2016, FDA adopted a regulation that extended the agency's authority over tobacco products to electronic nicotine delivery systems ("ENDS") containing tobacco-derived nicotine. *See* 81 Fed. Reg. 28974 (May 10, 2016). In April 2022, Congress extended this authority to ENDS containing non-tobacco-derived nicotine.[2]

ENDS heat a solution containing nicotine (called "e-liquid") into an aerosol that the user inhales. (Verified Complaint, ¶ 49.) Unlike traditional cigarettes, ENDS do not contain any tobacco leaf, do not rely on combustion, and do not generate smoke. (*Id.*)

As the top officials from the National Institutes of Health ("NIH") and FDA recently noted, "Many adults who smoke have used e-cigarettes to quit smoking." (*Id*. at ¶ 50.) And according to FDA, "ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents" than cigarettes and "biomarker studies demonstrate significantly lower exposure to [those harmful constituents] among current exclusive ENDS users than current smokers." (*Id.*) Thus, "smokers who switch completely to ENDS will have reduced toxic exposures and this likely leads to less risk of tobacco-related diseases." (*Id.*)

A "new" tobacco product, including a new ENDS product, is "adulterated" if FDA has not authorized the marketing of the product through FDA's premarket tobacco product application

[2] *See* Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) (amending the definition of "tobacco product" in 21 U.S.C. § 321(rr)(1) to include products containing nicotine "from any source").

process. *See* 21 U.S.C. § 387b(6)(A). To date, FDA has authorized a very limited number of ENDS products, most of which are sold by subsidiaries of "Big Tobacco" companies—*e.g.*, R.J. Reynolds (maker of Camel and Lucky Strike brand cigarettes) and Altria (maker of Marlboro and Virginia Slims brand cigarettes).[3]

B. The FDCA gives the Federal Government the exclusive authority to enforce the Act.

The FDCA provides various enforcement tools to address the distribution of "adulterated" and "misbranded" products, including "adulterated" and "misbranded" tobacco products. Those enforcement tools include criminal prosecutions, civil injunctions, and seizures. *See* 21 U.S.C. §§ 332, 333, 334. The FDCA also provides that (with limited exceptions not relevant here) *only* the Federal Government can enforce the Act. *See* 21 U.S.C. § 337(a) (stating, "all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States").[4]

Because the FDCA gives the Federal Government the exclusive authority to enforce the Act, the Supreme Court and other federal courts have rejected attempts by other parties to challenge an FDA decision to *not* enforce provisions of the Act. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (stating that the FDCA's enforcement provisions "commit complete discretion to [FDA] to decide how and when they should be exercised"). And the Supreme Court and other courts have held that 21 U.S.C. § 337(a) impliedly preempts any state law that seeks to enforce the Act. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

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[3] *See* https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last accessed Dec. 7, 2024).

[4] The FDCA allows a State, in limited circumstances, to bring a civil action to enforce some of the Act's food provisions. *See* 21 U.S.C. § 337(b).

C. FDA exercises enforcement discretion over unauthorized ENDS.

When ENDS containing tobacco-derived nicotine became subject to the FDCA in August 2016, they became "adulterated" tobacco products until the manufacturer obtained an FDA marketing authorization through the PMTA process. 21 U.S.C. §§ 387b(6)(A), 387j(a)(2)(A). Similarly, when ENDS containing non-tobacco-derived nicotine became subject to the FDCA in April 2022, they became "adulterated" tobacco products until the manufacturer obtained FDA marketing authorization through the PMTA process. 21 U.S.C. §§ 387b(6)(A), 387j(a)(2)(A).

However, there were already countless ENDS with tobacco-derived nicotine on the market by August 2016; and there were countless ENDS with non-tobacco-derived nicotine on the market by April 2022. (Verified Complaint, ¶ 54.) FDA has recognized that immediately forcing all unauthorized ENDS off the market while manufacturers go through the PMTA process could result in many ENDS users reverting to traditional cigarettes. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 498 (6th Cir. 2020) (noting FDA's view that removing all unauthorized ENDS from the market too quickly "creates a genuine risk of migration from potentially less harmful [e-cigarette] products back to combustible products," and that this would be a "public health outcome that should be avoided if at all possible").

Therefore, "[t]hrough enforcement [discretion] policies that FDA has revised over time, the agency 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." (Exhibit B; Verified Complaint, ¶ 56.)

Indeed, since ENDS became subject to the FDCA in 2016, FDA has revised its enforcement discretion policy no less than seven times. Those revisions were as follows:

- **May 2016**: When FDA announced the finalization of its rule "deeming" ENDS products with tobacco-derived nicotine to be subject to the FDCA, FDA also announced that its policy would be to exercise enforcement discretion for those unauthorized

products until August 2019 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by August 9, 2018). (Verified Complaint, ¶ 57-a.)

- **May 2017**: Approximately four months after President Trump first took office, and less than a week after President Trump's first FDA Commissioner was sworn in, FDA extended its enforcement discretion period for unauthorized ENDS until November 2019 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by November 9, 2018). (Exhibit C; Verified Complaint, ¶ 57-b.)

- **July 2017**: As part of FDA's new "comprehensive regulatory plan to shift [the] trajectory of tobacco-related disease [and] death," the agency announced that the enforcement discretion period for unauthorized ENDS would be extended until August 2023 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by August 9, 2022). (Exhibits D and E; Verified Complaint, ¶ 57-c.)

- **July 2019**: In response to a court ruling, FDA shortened the enforcement discretion period for unauthorized ENDS to May 2021 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by May 9, 2020). (Verified Complaint, ¶ 57-d.)

- **January 2020**: Largely in response to the popularity among youth of JUUL brand ENDS—an unauthorized "cartridge-based" ENDS that looked like a USB drive and was easy for youth to conceal from their teachers at school and from their parents at home—FDA revised its enforcement discretion policy to target unauthorized cartridge-based ENDS that came in flavors other than tobacco or menthol. (Exhibit F; Verified Complaint, ¶ 57-e.)

- **April 2020**: As a result of the COVID-19 pandemic, the enforcement discretion period for other unauthorized ENDS was extended to September 2021 (so long as the product was on the market by August 8, 2016, and the manufacturer submitted a PMTA by September 9, 2020) (Exhibit F; Verified Complaint, ¶ 57-f.)

- **September 2021**: Since September 2021, FDA has exercised its enforcement discretion with respect to unauthorized ENDS on a "case-by-case" basis, citing its authority to do so under the Supreme Court's *Heckler v. Chaney* decision. (Verified Complaint, ¶ 57-g.) In exercising its enforcement discretion, FDA says it "is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data," and that it "will take appropriate action regarding [ENDS] that are marketed without premarket authorization as warranted based on changed circumstances, new information, or to better address minors' use of those products." (*Id.*)

D. R.J. Reynolds tries, but fails, to convince FDA to revise its enforcement discretion policy.

The major cigarette manufacturers sell approximately 170 billion cigarettes in the United States every year. (Verified Complaint, ¶ 47.) So, they have every incentive to limit the number of ENDS available on the market.

To that end, R.J. Reynolds filed a Citizen Petition with FDA in February 2023 requesting that the agency "adopt a new enforcement" policy because FDA "was not [doing] enough" to prevent underage use of unauthorized ENDS. (Exhibit G; Verified Complaint, ¶ 58.) However, Reynolds' proposed policy excluded the company's own unauthorized ENDS from enforcement even though the latest CDC data showed that those ENDS were the second most popular ENDS among high school students and the third most popular ENDS among middle school students. (Exhibit H; Verified Complaint at ¶ 59.)

Reynolds justified its proposal to exclude its own unauthorized ENDS from enforcement on the grounds that the products were on the market by August 8, 2016, the company submitted PMTAs for those products by September 9, 2020, and those PMTAs were still under review or were the subject of ongoing litigation against FDA. (Verified Complaint, ¶ 60.)

But Reynolds' justification for excluding its unauthorized ENDS from enforcement was pretextual in that Reynolds' proposed policy would have offered no safe harbor for ENDS with non-tobacco-derived nicotine even if the product had a pending PMTA that had been timely filed when Congress made those products subject to the FDCA in April 2022. (Verified Complaint, ¶ 61.) In other words, Reynolds' proposed enforcement policy was aimed at protecting the company's sales of its own cigarettes and unauthorized ENDS; it was not aimed at reducing youth usage of ENDS.

FDA denied Reynolds' Citizen Petition in November 2023. (Exhibit I; Verified Complaint, ¶ 62.) In doing so, FDA told Reynolds:

> [W]e do not agree that FDA has taken insufficient compliance and enforcement action against illegally marketed ENDS products . . . To the contrary, we believe that FDA's comprehensive approach to this matter demonstrates the Agency's robust commitment to implementing and enforcing the law with respect to such products (including restricting such unauthorized products from the lawful marketplace) and preventing their access to and promotion of use by youth. (*Id.*)

FDA also provided Reynolds with a three-page summary of the various actions the agency had taken to prevent youth usage of ENDS. (Exhibit I; Verified Complaint ¶ 63.) FDA concluded that "[g]iven all of [those] regulatory and enforcement actions," it was "clear that FDA has been taking critical compliance and enforcement efforts targeting [unauthorized] ENDS products." (*Id.*) FDA also stated that it "is continuously evaluating new information and, in making enforcement decisions, taking into account data on youth use and other risk factors." (*Id.*)

E. R.J. Reynolds tries, but fails, to convince the United States International Trade Commission to bar the importation of products identified in its Citizen Petition.

While its Citizen Petition was pending, Reynolds also filed a complaint at the United States International Trade Commission ("ITC") asking the Commission to, *inter alia*, bar the importation of many of the same products that Reynolds asked FDA to target via its Citizen Petition. (Verified Complaint, ¶ 64.)

FDA sent a letter to the ITC urging it to reject Reynolds' attempt to use the ITC to enforce the FDCA. (Exhibit B; Verified Complaint, ¶ 65.) Citing 21 U.S.C. § 337(a), FDA noted that Congress wants "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.*) FDA also noted that 21 U.S.C. § 337(a) reflects congressional intent to have "uniform administration of the FDCA." (*Id.*)

Based in part on FDA's letter, the ITC dismissed Reynolds' claim seeking to bar the importation of unauthorized ENDS. (Verified Complaint, ¶ 66.) The ITC reasoned 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.*)

F. The Iowa Legislature adopts R.J. Reynolds' proposed enforcement policy for unauthorized ENDS.

On March 27, 2024, HF 2677 was introduced in the Iowa Legislature. (Exhibit J; Verified Complaint, ¶ 67.) That same day, lobbyists for Reynolds and Altria declared their support for HF 2677. (Exhibit K; Verified Complaint ¶ 68.) Other lobbyists for Reynolds and Altria declared their support for HF 2677 within a week. (*Id.*) Lobbyists for the American Cancer Society Action Network declared their *opposition* to HF 2677 within two days. (*Id.*)

The Iowa House passed HF 2677 on April 3, 2024; the Iowa Senate passed HF 2677 on April 19, 2024; and the Governor signed HF 2677 into law on May 17, 2024. (Exhibit J; Verified Complaint, ¶ 69.) HF 2677 directs the Iowa Department of Revenue to do, in effect, what Reynolds asked FDA to do via it March 2023 Citizen Petition and what Reynolds asked the ITC to do via its October 2023 complaint—*i.e.*, take enforcement action against persons selling ENDS that have not been authorized by FDA unless the product was on the market by August 8, 2016, and the product has a pending PMTA that was filed by September 9, 2020.

HF 2677 (Exhibit A) establishes the following procedures by which the IDR will step into FDA's role with respect to the enforcement of the FDCA's tobacco provisions:

- An ENDS manufacturer whose products are sold in Iowa shall, on an annual basis, certify to the IDR in writing and under penalty of perjury that it agrees to comply with HF 2677 and either (1) that the manufacturer's product "has received a marketing authorization or similar order for the vapor product from [FDA] pursuant to 21 U.S.C. § 387j," or (2) that the manufacturer's product was marketed in the United States by August 2016, the manufacturer submitted a PMTA for the product by September 2020,

"and the application remains under review by [FDA] or a final decision on the application has not otherwise taken effect." HF 2677, § 4-1 (to be codified at Iowa Code § 453A.52).

- Each initial and annual certification shall be accompanied by "a copy of the marketing authorization or other order for each vapor product issued by [FDA] pursuant to 21 U.S.C. § 387j, or evidence that the [PMTA] for each vapor product was submitted to [FDA] and a final authorization or order has not taken effect." HF 2677, § 4-3 (to be codified at Iowa Code § 453A.52).

- Manufacturers shall notify IDR of any material change to the facts contained in its most recent certification within thirty days of such material change; a material change includes "the issuance of a denial of a marketing authorization or other order by [FDA] pursuant to 21 U.S.C. § 387j, or any other order or action by [FDA] that affects the authorization of the vapor product." HF 2677, § 4-4 (to be codified at Iowa Code § 453A.52).

- The IDR shall publish a publicly available directory that lists all the ENDS products for which certifications have been submitted and shall make changes to that directory as necessary. HF 2677, § 4-5 (to be codified at Iowa Code § 453A.52).

- Once the IDR's directory becomes public, it shall be unlawful for a person to sell an ENDS product in Iowa that is not listed in the directory. HF 2677, § 5-1 (to be codified at Iowa Code § 453A.52A).

- Any person who sells an ENDS product in Iowa that is not in the IDR directory is subject to monetary penalties and suspension of his State permit to sell ENDS products. HF 2677, § 6-1 (to be codified at Iowa Code § 453A.52B).

- Any ENDS manufacturer whose ENDS are not listed in the IDR's directory and are sold in Iowa, whether directly or through a third party, is subject to monetary penalties. HF 2677, § 6-2 (to be codified at Iowa Code § 453A.52B).

The IDR has announced that it will publish the directory on January 2, 2025, and that it will begin enforcement of the directory on February 3, 2025. (Verified Complaint, ¶ 72.)

G. FDA announces that youth vaping has dropped to its lowest levels in ten years.

On September 5, 2024, FDA announced that the latest CDC data shows that 500,000 "fewer U.S. youth reported current use of [ENDS] in 2024 compared to 2023." (Exhibit L; Verified Complaint, ¶ 73.) This represented a drop to approximately one-third of the number of youth who reported using ENDS during the "peak" of youth usage in 2019. (*Id.*)

H. Donald Trump is elected the 47th President of the United States.

On November 5, 2024, the Republican Party's nominee for President, Donald J. Trump, was elected the 47th President of the United States. (Verified Complaint, ¶ 74.) He will be sworn into office on January 20, 2025—exactly two weeks before the IDR intends to begin enforcing the vapor products registry. (*Id.*)

President Trump will replace President Joseph R. Biden, a Democrat. (Verified Complaint, ¶ 75.) Executive Branch agencies often shift their enforcement policies when there is a change in administrations from one political party to another political party. (*Id.* at ¶ 76.) Plaintiffs anticipate the new administration may change FDA's enforcement policies with respect to ENDS products in a manner that allows more ENDS products to continue to be marketed while premarket applications are pending. (*Id.*)

STANDARD OF REVIEW

Courts in the Eighth Circuit consider four factors when determining whether to grant a motion for a preliminary injunction: (1) "plaintiff's likelihood of success on the merits of his claim," (2) "the threat of irreparable harm" to plaintiff "without preliminary relief," (3) "the balance of equities" between the parties, "weighing the harm suffered by plaintiff versus the harm to other parties because of an injunction," and (4) "the public interest." *Miljas v. Greg Cohen Promotions, LLC*, 536 F. Supp. 3d 409, 425-26 (S.D. Iowa 2021) (citing *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc)). None of these "factor[s] in itself is dispositive." *Miljas*, 536 F. Supp. 3d at 426 (quoting *Dataphase*, 640 F.2d at 113). But the "likelihood of success on the merits is most significant." *Id.* (quoting *Minn. Ass'n of Nurse Anesthetists v. Univ. Hosp.*, 59 F.3d 80, 83 (8th Cir. 1995)).

ARGUMENT

A. Plaintiffs are likely to succeed on the merits.

Plaintiffs have a strong likelihood of proving that: (1) the FDCA impliedly preempts HF 2677; (2) HF 2677 violates the Fourteenth Amendment's Equal Protection Clause; and (3) HF 2677 violates the Equal Protection Clause of the Iowa Constitution.

1. The FDCA impliedly preempts HF 2677.

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citing U.S. Const., Art. VI, cl. 2). As relevant to this action, "state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby*, 530 U.S. at 372. This "implied conflict preemption" occurs where, *inter alia*, "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Congress intends for the Federal Government to have the sole authority to enforce the FDCA's tobacco, drug, medical device, and cosmetic provisions. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act, shall be by and in the name of the United States."). In other words, the FDCA's enforcement provisions "commit complete discretion to [FDA] to decide how and when they should be exercised." *Heckler*, 470 U.S. at 835 (1985); *accord National Milk Producers Fed. v. Harris*, 663 F.2d 339, 344 (8th Cir. 1981) (stating there is "no provision [in the FDCA] which narrows or limits the discretion of the FDA to investigate, enforce, or prosecute alleged violations of the Act or its regulations").

Because the Federal Government has the exclusive authority to enforce the FDCA, the Supreme Court and lower courts have held that state law may not encroach on FDA's enforcement

discretion. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001) (stating "the FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [Act]") (citing 21 U.S.C. § 337(a)).

In *Buckman*, plaintiffs alleged they suffered personal injuries caused by defective FDA-cleared medical devices. The plaintiffs' claims included state-law fraud claims based on an allegation that defendant had obtained FDA-clearance of the devices by submitting false reports to FDA.[5] The Court held that the plaintiffs' state-law claims "conflict[ed] with" and were "therefore impliedly preempted by" the FDCA. 531 U.S. at 348.

The Court noted that the "conflict stem[med] from the fact that the federal statutory scheme amply empowers FDA to punish and deter fraud against the agency," that "this authority is used by the agency to achieve a somewhat delicate balance of statutory objectives," and that such a balance could "be skewed by" the plaintiff's claims. *Id.* In other words, FDA "has at its disposal a variety of enforcement options," including "seeking injunctive relief and civil penalties, seizing the [products], and pursuing criminal prosecutions," that "allow the agency to make a measured response to suspected" violations of the FDCA. *Id.* at 349 (cleaned up).

The Court also explained why plaintiffs could not circumvent implied preemption by styling their claims as state-law claims. Unlike "traditional state tort law [claims] which had predated the federal enactments in question," plaintiffs' "claims exist[ed] solely by virtue of the FDCA." 531 U.S. at 353. In short, "the existence of [the FDCA]" was "a critical element in [plaintiffs'] case." *Id*. Finally, the Court concluded that for "the reasons stated above," plaintiffs'

[5] The FDCA prohibits the submission of such false reports. *See* 21 U.S.C. § 331(q)(2); *see also* 21 U.S.C. § 360(k) (discussing required reports for devices).

claims "would exert an extraneous pull on the scheme established by Congress, and [those claims were] therefore preempted by that scheme." 531 U.S. at 353.

In *Bryant v. Medtronic, Inc. (In re: Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.),* 623 F.3d 1200 (8th Cir. 2010), the court recognized that *Buckman* is not limited to state-law *fraud* claims. The plaintiffs in *Bryant* alleged they suffered personal injuries caused by defendant's medical devices, and they asserted state-law failure-to-warn claims based on a theory that defendant "failed to provide FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations." *Id.* at 1205. The Eighth Circuit held "these claims are simply an attempt by private parties to enforce the [FDCA], claims foreclosed by § 337(a) as construed in *Buckman*." *Id.*

In *Brown v. Medtronic, Inc.*, No. 20-cv-00295, 2021 U.S. Dist. LEXIS 262681 (S.D. Iowa 2021), this Court (Jarvey, C.J.) held that *Buckman* is not limited to state *common law* claims, and that *Buckman* extends to claims relying on a state *statute* if that statute did not pre-date the relevant FDCA requirement. *Brown* involved a personal injury plaintiff who brought a state-law negligence *per se* claim based on an allegation that defendant's medical device violated Iowa's statutory prohibition on selling "adulterated" medical devices. *Id.* at *13-14; *see* Iowa Code § 155A.23(1)(f) (prohibiting the "sale [of] any drug or device that is adulterated [or] misbranded").

In dismissing plaintiff's claim as impliedly preempted, the court stated that "plaintiff [had] not cited, and the Court [had] not found, any authority holding or plausibly suggesting that the provisions of [Iowa Code § 155A.23] are merely codifications of traditional state tort law that 'predated' the FDCA." 2021 U.S. Dist. LEXIS 262681, *15. Because plaintiff's "negligence *per se* claim boil[ed] down to no more than an attempt to enforce the quality, control, inspection, and investigation requirements of the [FDCA]," the claim was "'foreclosed,' that is impliedly

preempted, 'by § 337(a) as construed in *Buckman*.'" *Id.* at *16 (quoting *In re: Medtronic*, 623 F.3d at 1206-07).

* * *

Based on the case law discussed above, 21 U.S.C. § 337(a) impliedly preempts HF 2677. The Iowa statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp.*, 514 U.S. at 287. Congress made clear that only the Federal Government can enforce the FDCA's tobacco provisions. But HF 2677 attempts to deputize the Iowa Department of Revenue to enforce those provisions.

Just like the preempted state law in *Buckman*, "the existence of [the FDCA]" is a "critical element" of HF 2677. *Buckman*, 531 U.S. at 353. Just like the preempted state law in *In re: Medtronic*, HF 2677 is triggered when a product manufacturer has not submitted certain documentation to the FDA. And just like the preempted state law in *Brown*, HF 2677 is not a codification of traditional state law that predated the FDCA (or the FDCA's tobacco provisions).

Finally, it bears noting that the FDCA includes a savings clause that preserves the right of states to adopt and enforce laws with respect to tobacco products that are "in addition to, or more stringent than, the requirements established under [Chapter 10 of the FDCA]. 21 U.S.C. § 387p(a)(1). The savings clause is limited by an express preemption clause that preempts certain types of state laws. 21 U.S.C. § 387p(a)(2). But neither the savings clause nor the express preemption clause affects Plaintiffs' claim that 21 U.S.C. § 337(a) preempts HF 2677 under the doctrine of implied conflict preemption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (stating that a "savings clause (like [an] express preemption provision) does *not* bar the ordinary working of conflict preemption principles") (emphasis in original); *Buckman*, 531 U.S. at 353 (stating that "neither an express preemption provision nor a savings clause bars the ordinary

working of conflict preemption principles") (cleaned up); *see also id.* at 348 n.2 (stating there was no need for the Court to decide whether the FDCA's express preemption provision for medical devices preempted plaintiff's state law claim because section 337(a) impliedly preempted the claim).

Because the FDCA preempts HF 2677, Plaintiffs are likely to succeed on the merits.

2. HF 2677 violates the Equal Protection Clause of the Fourteenth Amendment.

The Equal Protection Clause of the Fourteenth Amendment provides that no State shall "deny any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. A State violates the Equal Protection Clause when it treats similarly situated persons differently and there is no "rational basis" for the differential treatment. *Nordlinger v. Hahn*, 505 U.S. 1, 11 (1992). A State's action fails this "rational basis test" when there is no "plausible policy reason for" the differential treatment or the differential treatment is "arbitrary" or "irrational." *Id.*

HF 2677 treats manufacturers and sellers of unauthorized ENDS containing tobacco-derived nicotine differently than it treats manufacturers and sellers of unauthorized ENDS containing non-tobacco-derived nicotine. Specifically, HF 2677 allows for the sale of some unauthorized ENDS containing tobacco-derived nicotine—those that were on the market as of August 2016 and for which a still-pending PMTA was filed by September 9, 2020—whereas HF 2677 does not allow for the sale of any unauthorized ENDS containing non-tobacco-derived nicotine, including those for which a timely filed PMTA is still pending.

HF 2677's differential treatment of manufacturers and sellers of unauthorized ENDS with non-tobacco-derived nicotine fails the rational basis test. There is no plausible policy reason for treating the manufacturers and sellers of ENDS containing non-tobacco-derived nicotine less

favorably than the manufacturers and sellers of ENDS containing tobacco-derived nicotine.[6] The differential treatment of the two products is arbitrary and irrational. Indeed, the FDCA makes no distinction between tobacco products containing tobacco-derived nicotine and tobacco products containing non-tobacco-derived nicotine. *See* 21 U.S.C. § 321(rr)(1) (defining "tobacco product" as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption").[7]

3. HF 2677 violates the Equal Protection Clause of the Iowa Constitution.

The Equal Protection Clause of the Iowa Constitution states: "All 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. 6, § 1. A statute that passes muster under the Fourteenth Amendment's Equal Protection Clause may still violate the Equal Protection Clause of the Iowa Constitution. *Racing Ass'n of Cent. Iowa v. Fitzgerald*, 675 N.W.2d 1, 4-7 (2004). A statute that treats similarly situated persons differently violates the Equal Protection Clause where the Iowa Legislature had no "valid reason to treat [the similarly situated persons] differently." *Id.* at 7.

For the same reasons noted with respect to the Fourteenth Amendment's Equal Protection Clause, HF 2677's differential treatment of manufacturers and sellers of unauthorized ENDS with non-tobacco-derived nicotine violates the Equal Protection Clause of the Iowa Constitution.

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[6] Indeed, manufactured, non-tobacco-derived nicotine is likely to contain *lower* levels of organic impurities than tobacco-derived nicotine. (Verified Complaint, ¶ 95.)

[7] The legislative history of HF 2677 gives no indication that the Legislature was aware that no PMTAs for ENDS containing non-tobacco-derived nicotine were filed by September 9, 2020, because such ENDS did not become subject to the FDCA until 2022. Therefore, it is likely that the Legislature did not know that it was depriving ENDS with non-tobacco-derived nicotine with timely-filed PMTAs of a safe harbor under HF 2677.

B. Plaintiffs will suffer irreparable harm in the absence of preliminary relief.

Because HF 2677 violates the United States Constitution and/or the Iowa Constitution, Defendants' enforcement of HF 2677 results in irreparable harm to Plaintiffs. *See Morehouse Enters., LLC v. BATFE*, 78 F.4th 1011, 1017 (8th Cir. 2023) ("In most instances, constitutional violations constitute irreparable harm."); *de Jesus Ortega Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) ("It is well established that the deprivation of constitutional rights 'unquestionably constitutes irreparable injury.'") (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)).

In any event, Defendants' enforcement of HF 2677 will cause Plaintiff IFAST's members—including Plaintiffs Global Source Distribution, LLC, Wages and White Lion Investments, LLC, Smokin Hot, L.L.C., Central Iowa Vapors WDM, LLC, and Taste the Vape LLC—to suffer injuries in the form of lost sales of unauthorized ENDS products that do not fall within HF 2677's safe harbor provision. (*See* Verified Complaint, ¶¶ 83-88, 96-101, 108-113.) Indeed, given the substantial monetary penalties imposed for selling ENDS products not listed on the registry, absent injunctive relief, Plaintiffs Smokin Hot, L.L.C., Central Iowa Vapors WDM, LLC, and Taste the Vape LLC, as well as other Iowa specialty vapor product retailers, will be forced to close their doors once the State starts enforcement of HF 2677 on March 3, 2025.[8]

Defendants are likely immune from liability for monetary damages for such injuries.[9] Therefore, those injuries would be irreparable. *Alabama Ass'n of Realtors v. Dep't of Health &*

[8] (*See* Declaration of Heather Glenn, Exhibit M hereto, at ¶¶ 8-10; Declaration of Corey Halfhill, Exhibit N hereto, at ¶¶ 8-11; Declaration of Don Gier, Exhibit O hereto, at ¶¶ 8-10.)

[9] The Eleventh Amendment prohibits federal courts from adjudicating claims "against one of the United States by Citizens of another State" and extends to claims brought against a State by one of its own citizens. *See Hans v. Louisiana*, 134 U.S. 1 (1890). State officials have qualified immunity from federal constitutional tort claims brought under 42 U.S.C. § 1983. *See, e.g.*, *Wood v. Moss*, 572 U.S. 744, 757-58 (2014). Absent a statutory waiver of sovereign immunity, the State of Iowa is immune from claims for money damages for state constitutional claims. *Burnett v. Smith*, 990 N.W.2d 289 (Iowa 2023). The Iowa Legislature has explicitly stated that it has not waived

Hum. Servs., 594 U.S. 758, 765 (2021) (observing that pandemic-era eviction moratorium "has put applicants . . . at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery"); *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) (finding irreparable harm because movant "would not be able to bring a lawsuit to recover their undue economic losses if the FCC's rules are eventually overturned"); *Johnson v. Bayens*, No. 4:20-cv-00306-RGE-CFB, 2020 U.S. Dist. LEXIS 260374, at *28-29 (S.D. Iowa Dec. 10, 2020) ("Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages.").

C. The balance of equities and public interest factors weigh in favor of preliminary relief.

When the government is a defendant, the balance of equities and public interest factors "merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009); *see also, e.g.*, *Eggers v. Evnen*, 28 F.4th 561, 564-65 (8th Cir. 2022). And when a plaintiff establishes "a likelihood that" a defendant's action "violates the U.S. Constitution," the plaintiff has "also established that both the public interest and the balance of the equities favor a preliminary injunction." *Arizona Dream Act Coalition v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014); *see also Brandt v. Rutledge*, 47 F.4th 661, 672 (8th Cir. 2022) ("It is always in the public interest to prevent the violation of a party's constitutional rights.") (cleaned-up).

CONCLUSION

For the reasons discussed above, Plaintiffs respectfully request that this Court grant their motion for a preliminary injunction to enjoin Defendants from enforcing HF 2677.

Plaintiffs respectfully request oral argument on their motion.

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sovereign immunity for such claims. Iowa Code§ 669.26. State officials have qualified immunity for tort claims. Iowa Code § 669.14A.

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Respectfully submitted,

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