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

CLIMBING KITES LLC and FIELD DAY BREWING COMPANY LLC, Plaintiffs, v. THE STATE OF IOWA; KELLY GARCIA, in her official capacity as Director of the Iowa Department of Health and Human Services; and THE IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	)	CASE NO. 4:24-cv-202 **BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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PRELIMINARY STATEMENT

In 2020, Iowa legalized the manufacture, distribution, and sale of consumable hemp products within the state. Plaintiffs—who lawfully manufacture and sell canned beverages containing tetrahydrocannabinol (or "THC")—are two participants within this quickly emerging market. House File 2605, enacted on May 17, 2024, caps the amount of THC contained within any consumable product at "four milligrams [of THC] per serving and ten milligrams per container." It also requires manufacturers to provide certain health-related claims on the labels of consumable hemp products, as determined by the Defendant Department of Health and Human Services (the "Department"). The law goes into effect on July 1.

Despite a conscious legislative effort to prevent the Department from defining potency limits for hemp products, the Department is set to do just that, according to "guidance" issued on June 7. The Department's guidance is unlawful and interprets the potency limits of House File 2605 in an unreasonable manner. The stakes are high: beginning July 1—according to the Department's guidance—Plaintiffs will face felony criminal charges for selling products containing "ten milligrams per container" based on a statute that permits the sale of products containing "ten milligrams per container." The Department must be stopped.

Fortunately, there is a clearer route to resolve this dispute. Although Plaintiffs manufacture and sell products regulated by Iowa's consumable hemp statutes, their products are also "food" as defined by the Federal Food, Drug, and Cosmetic Act (the "FDCA"). The legislature's potency

limits and labeling requirements are not identical to requirements under the FDCA, and therefore, Congress expressly preempted them. 21 U.S.C. § 343-1. For the reasons set forth herein, injunctive relief is required to declare the rights and status of Plaintiffs' businesses prior to the Department's enforcement of House File 2605.

FACTUAL BACKGROUND

Congress legalized production of hemp as a commodity in the Agriculture Improvement Act of 2018, commonly known as the 2018 "Farm Bill." P.L. 115-334 (2018). The Iowa legislature followed suit shortly thereafter by passing the Iowa Hemp Act. 2019 Iowa Acts ch. 130 (codified at Iowa Code chapter 204). Those laws recognize an increasingly important legal distinction between "marijuana" and "hemp": while both plants derive from the "cannabis sativa" species, the difference is the concentration of tetrahydrocannabinol, or "THC". (Declaration of Scott Selix ¶ 4 (hereinafter "Selix Decl."); Declaration of Dan Caraher ¶ 4 (hereinafter "Caraher Decl.")). Marijuana plants, by definition, contain more than 0.3% THC on a dry weight basis while hemp plants contain 0.3% or less THC by the same measure. (Selix Decl. ¶ 5; Caraher Decl. ¶ 5). For that reason (and presumably others), Congress and the Iowa legislature made the policy decision to exclude hemp from state and federal definitions of "marijuana," thereby legalizing hemp production across the state. P.L. 115-334, § 12619; 2019 Iowa Acts ch. 130, § 23.

The 2019 Iowa Hemp Act permitted not only producing *hemp* within Iowa, but also contemplated production and sale of hemp-based *products* within the state, such as textiles, paper, and consumables. *Id.* § 2 (defining "hemp product"); *id.* § 7 (permitting retail sale of hemp products). Thus began Iowa's nascent market of "consumable hemp:" i.e., production, manufacture, and sale of products, intended for human consumption, that contain lawful cannabis- or hemp-derived THC. (Selix Decl. ¶ 3; Caraher Decl. ¶ 3).

The following year, industry stakeholders worked alongside state policymakers to build a statewide regulatory framework for consumable hemp products. Those discussions resulted in a second hemp bill, passed by near-unanimous margins, formally establishing the state's consumable hemp program. 2020 Iowa Acts ch. 1065. The legislation maintained the definition of "hemp" as a plant or any derivatives thereof with a maximum THC concentration of 0.3%, which mirrors federal law. *Id.* § 2. It defined "consumable hemp product" as a product that could be consumed through digestion, internal absorption, or absorption through the skin. *Id.* § 2. It required any person manufacturing or selling consumable hemp products to register with the state prior to conducting business. *Id.* § 11. It also required compliance with state "packaging and labeling requirements," to be established by administrative rule, and confirmed that any hemp product manufactured, distributed, sold, or consumed in compliance with state law was not a controlled substance and therefore legal under state law. *Id.* § 11.

Plaintiffs are two participants in Iowa's consumable hemp market. Climbing Kites, LLC, was formed in 2023 and is headquartered in Des Moines, Iowa. (Selix Decl. ¶ 2). Climbing Kites produces and sells canned beverages (also called "Climbing Kites") that contain carbonated water, citric acid, natural flavors, and hemp-derived cannabis oil. (Selix Decl. ¶ 6). Climbing Kites offers beverage "versions," which differ in terms of flavor and amount of total THC. (Selix Decl. ¶ 7). Climbing Kites currently offers canned beverages containing 5, 10, and 20 milligrams of cannabidiol ("CBD") and 2.5, 5, and 10 milligrams of total THC per beverage. (Selix Decl. ¶ 8). While current law requires Climbing Kites' products to contain 0.3% or less THC, its products actually contain between 0.001% and 0.003%. (Selix Decl. ¶ 9). Climbing Kites is fully licensed and registered with the State of Iowa, has had all products reviewed and approved by the Department of Health and Human Services, and complies with all federal guidance relating to

hemp-derived CBD and THC. (Selix Decl. ¶ 10; *see* Ex. A). Climbing Kites sells its beverages within Iowa. (Selix Decl. ¶ 11).[1]

Plaintiff Field Day Brewing Company, LLC ("Field Day Brewing") was formed in 2023 and is headquartered in North Liberty, Iowa. (Caraher Decl. ¶ 2). Field Day Brewing manufactures and sells consumable hemp products; namely, canned beverages (called "Day Dreamers") that contain carbonated water, citric acid, natural flavors, and hemp-derived cannabis oil. (Caraher Decl. ¶ 6). Field Day Brewing also offers different versions of the beverage in terms of flavor and number of milligrams of total THC contained within the beverage. (Caraher Decl. ¶ 7). Field Day Brewing currently offers canned beverages containing 2, 7, and 15 milligrams of CBD and 2, 7, and 15 milligrams of total THC per beverage. (Caraher Decl. ¶ 8). While current law requires Field Day Brewing's products to contain 0.3% or less THC, its products actually contain between .001% and .003%. (Caraher Decl. ¶ 9). Field Day Brewing is fully licensed and registered with the State of Iowa, has had all products reviewed and approved by the Department of Health and Human Services, and complies with all federal guidance relating to hemp-derived CBD and THC. (Caraher Decl. ¶ 10). Field Day Brewing manufactures and sells its beverages within Iowa. (Caraher Decl. ¶ 11).

Notably, nothing in the 2018 Farm Bill affected the Federal Food, Drug, and Cosmetic Act (the "FDCA") or the authority of the U.S. Food and Drug Administration (the "FDA") to promulgate regulations that "relate to the production of hemp under the Act." P.L. 115-334, § 10113 (now codified at 7 U.S.C. § 1639r). An accurate summary of the FDA's public statements

[1] Although the Department of Inspections and Appeals ("DIA") was initially responsible for administering the state's consumable hemp program, unrelated legislation shifted those responsibilities to the Defendant, Department of Health and Human Services. 2023 Iowa Acts ch. 19, §§ 281-82. Climbing Kites' and Field Day Brewing's products have been reviewed and approved by the Department or DIA, as appropriate. (Selix Decl. ¶ 10; Caraher Decl. ¶ 10).

on the status and regulation of cannabis-derived products since the passage of the 2018 Farm Bill could fill numerous volumes of a treatise. *See generally* U.S. Food & Drug Ass'n, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (Feb. 6, 2024), Hyperlink.

At bottom, the FDA maintains its authority to regulate food products that contain cannabis-derived ingredients but vaguely acknowledges that whether it is legal to sell such products depends on the product's intended use and how it is labeled and marketed. *Id.* (Questions and Answers 8 & 10) ("We are aware that state and local authorities are fielding numerous questions about the legality of CBD."). Whether and to what extent the FDA should provide further clarification for product manufacturers has become a political football and the subject of numerous Congressional hearings. *See, e.g.*, U.S. House Committee on Oversight & Accountability, Hearing Wrap Up: FDA's Failure to Regulate CBD Threatens Consumer Access to Safe Products (July 28, 2023), Hyperlink. As recently as April 2024, the FDA Commissioner testified the FDA would not implement further regulation without Congressional action. *See* U.S. House Committee on Oversight & Accountability, Oversight of the U.S. Food and Drug Administration (April 11, 2024), Hyperlink.

By late 2023, state policymakers wished to address several emerging issues related to the consumable hemp market. The Iowa Department of Public Safety, for example, believed the "cap" on THC for consumables (less than or equal to 0.3% THC on a dry weight basis) should be restricted to consider products that contain heavy or wet ingredients, common in consumables. Iowa Dep't of Pub. Safety, Consumable Hemp Pre-File Bill Request (November 27, 2023), Hyperlink. State officials therefore introduced a bill to place potency restrictions on consumable hemp products: i.e., the maximum amount of THC within a food product. H.S.B. 665,

90th G.A., 2d Sess. (Iowa 2024); S.S.B. 3159, 90th G.A., 2d Sess. (Iowa 2024). Initial legislation gave the Department of Health and Human Services authority to "determine dose and volume/serving size limitations via administrative rule." *Id.* § 7. The introduced bill also modified the Department's preexisting authority to issue rules on packaging and labeling for hemp products. *Id.* § 6.

As is common, the legislation was amended significantly during the legislative process. Importantly, the legislature removed the Department's authority over serving and potency limits and instead incorporated potency limits ("Potency Limits") directly into the legislation. Amendment H-8193 to Amendment H8134 to H.F. 2605, 90th G.A., 2d Sess. (Iowa 2024). Floor statements from multiple legislators confirm the change was intended to remove any discretion of the Department to set potency and serving limits. In the House, the bill's floor manager stated the agreed-upon potency limits represented a compromise to move the bill forward. *See House Video HF2605: H-8193 to H-8134 by Holt of Crawford*, Iowa Legislature, at 4:53:25-4:53:55 PM (March 12, 2024), Hyperlink. Another representative stated:

> Like many bills and amendments in this building, we quite often do not get what we want, rather we get what we can get done. And that is this amendment. This amendment strikes two milligrams of THC and raises it to four milligrams per serving, and with a ten milligram max per container.

House Video HF2605: H-8193 to H-8134 by Sorenson of Adair, Iowa Legislature, at 4:52:35 to 4:52:55 PM (March 12, 2024), Hyperlink. "And ultimately," that legislator continued, "this [amendment] keeps us in the driver's seat on setting limits, *instead of faceless bureaucrats*." *Id.* at 4:53:15 to 4:53:23 PM (emphasis added). Likewise, in the Senate, the bill's floor manager stated:

> The previous THC allotment was supposed to be done through rules. There was a sense of vagueness inside of that rulemaking authority of what the boundaries

> would be, and therefore this amendment would put those boundaries on there as to four milligrams per serving and ten milligrams per container.

Senate Video SF2352: S-5116 by Dawson of Pottawattamie, Iowa Legislature, at 12:39:30 to 12:40:20 PM (April 2, 2024), Hyperlink.

House File 2605 passed both chambers and was signed into law on May 17, 2024. 2024 Iowa Acts ch. 1176. As amended by House File 2605, Iowa Code § 204.2(*c*) will now provide in relevant part:

> *c*. A hemp product is deemed to be a consumable hemp product if all of the following apply:
>
> …
>
> (2) Its maximum total tetrahydrocannabinol concentration is less than or equal to the lesser of the following:
>
> (a) Three-tenths of one percent on a dry weight basis.
>
> (b) *Four milligrams per serving and ten milligrams per container on a dry weight basis*.

Id. § 2 (emphasis added). As amended, Iowa Code § 204.7(8)(*a*)(3) will now provide:

> (3) The consumable hemp product complies with packaging and labeling requirements, which shall be established by rules adopted by the department of health and human services. Each container storing consumable hemp shall be affixed with a notice advising consumers regarding the risks associated with its use. The department of health and human services shall adopt rules regarding the language of the notice and its display on the container.

Id. § 4. The Potency Limit in § 204.2(2)(*c*)(2)(b)—four milligrams per serving and ten milligrams per container—and the Department's packaging and labeling authority in Iowa Code § 204.7(8)(*a*)(3) ("Packaging and Labeling Authority") are this litigation's focus. HF2605 will take effect on July 1—two weeks from now. *See* Iowa Code § 3.7(1).

After the bill's approval, the Department issued two versions of guidance for current manufacturers and retail sellers to help "understand regulatory changes to the program that will be in effect on July 1, 2024." (Selix Decl. ¶ 12; Caraher Decl. ¶ 12). The Department's initial

guidance, issued May 24, effectively merged the per-serving and per-container Potency Limits together, claiming that "a closed-container beverage shall be defined as one serving per container, regardless of its ability to be re-sealed or the total fluid ounces it contains." (Selix Decl. ¶ 13; Caraher Decl. ¶ 13). The second, more recent Department guidance issued on June 7. Iowa Dep't of Health & Human Servs., Consumable Hemp: HF2605 FAQ – What it Means, Draft Rules, Townhall Info (June 7, 2024) (hereinafter "Department Guidance"), Hyperlink.

According to the most recent Guidance, the Department intends to implement Potency Limits by defining "serving" as established in FDA regulations. *Id.* p. 1; *see* 21 C.F.R. § 101.12. That means, for example, that despite the statute providing a hemp product may contain up to "ten milligrams per container," the Department has determined one 12-ounce can of Climbing Kites or Day Dreamer may only include up to four milligrams of THC, because the FDA's "serving size" for some beverages is 12 fluid ounces. (Selix Decl. ¶ 15; Caraher Decl. ¶ 15). Curiously, the Department's guidance defines *all* beverages as containing a serving size of 12 fluid ounces, despite the FDA establishing a smaller serving size for some beverages, such as 8 fluid ounces for fruit juices. *See* 21 C.F.R. § 101.12 (heading "Fruits and Fruit Juices"). Moreover, even though neither Iowa's hemp statutes nor the FDA's serving size rules include a *minimum* container size, the Department will criminalize all beverage containers smaller than 12 fluid ounces. *See* Department Guidance p. 1.[2]

According to the Department, any products that do not conform to its proposed potency limits, labeling requirements, or size restrictions will be a controlled substance beginning July 1. *Id.* at 3. There will be no "grace period" for on-hand products not meeting its interpretation of the

[2] Many beverage companies, such as Coca-Cola or Pepsi, sell 8-ounce cans of soda. The FDA's recommended serving size is adjusted downward when a container contains less than the full amount of a suggested serving size. (Selix Decl. ¶ 16; Caraher Decl. ¶ 16).

new Potency Limits, and the Department noted that penalties "may range from a serious misdemeanor to a class B felony, depending on the amount of product in [a registrant's] possession." *Id.* at 3-4. Registrants "should be aware that the penalties for non-compliance … are severe and HHS intends to enforce these new regulations when they become effective on July 1. *Registrants should expect enforcement activities on and on behalf of HHS*." *Id.* at 6 (emphasis added). Regarding Packaging and Labeling Authority, the Department proposed the following warning label information:

> *This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product may cause the consumer to fail a drug test for THC. Products containing THC may cause impairment and a consumer's ability to operate a vehicle. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.*

Id. at 2 (emphasis in original).

On June 12, the Department filed a Notice of Intended Action, consistent with rulemaking requirements under the Iowa Administrative Procedure Act, in an effort to implement the Potency Limits *and* Packaging and Labeling Authority. ARC8064C (June 12, 2024), Hyperlink. Plaintiffs filed this lawsuit following issuance of the Department's Guidance and request temporary relief prior to the effective date of HF2605 on July 1.

ARGUMENT

This dispute's crux lies at the intersection of consumable hemp law and food labeling regulation. Though relatively complex, the overlay of these areas of law confirms the Potency Limits and Packaging and Labeling Authority within HF2605, to be codified at Iowa Code § 204.2(2)(*c*)(2)(b) and § 204.7(8)(a)(3), are preempted by the FDCA and, therefore, are void and unenforceable. Even if these provisions are not preempted, this Court should enjoin both provisions under the doctrine of primary jurisdiction until the FDA issues regulatory guidance for

consumable hemp products. And assuming those provisions *are* constitutional, the Department's interpretation of the Potency Limits is unreasonable and unlawful. The Court should grant injunctive relief to prevent irreparable harm to Plaintiffs that will no doubt occur once HF2605 goes into effect.[3]

I. LEGAL STANDARD

The Eighth Circuit evaluates preliminary injunctions under the *Dataphase* factors. *Dataphase Sys., Inc. v. C L Sys. Inc.*, 640 F.2d 109, 114 (8th Cir. 1981). These factors include:

> (1) the movant's probability of success on the merits, (2) the threat of irreparable harm to the movant absent the injunction, (3) the balance between the harm and the injury that the injunction's issuance would inflict on other interested parties, and (4) the public interest.

Pro Edge, L.P. v. Gue, 374 F. Supp. 2d 711, 734 (N.D. Iowa 2005), *modified*, 411 F. Supp. 2d 1080 (N.D. Iowa 2006); *see also PFS Dist. Co. v. Radeuchel*, 332 F. Supp. 2d 1236, 1244 (S.D. Iowa 2004). As described in greater detail below, each of these factors is met here. Thus, an injunction is appropriate.

II. PLAINTIFFS ARE LIKELY TO SUCCEED IN THEIR CLAIMS.

Although 'no single factor is determinative,' likelihood of success on the merits is 'the most significant.'" *Katecho, Inc. v. Cont'l Mfg. Chemist, Inc.*, No. 4:18-cv-00314, 2018 WL 9814656, at *5 (S.D. Iowa Oct. 16, 2018) (quoting *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013)). A party need not demonstrate at this stage that it will win the case, nor must it even demonstrate "it has a 'greater than fifty percent'" chance of prevailing. *Sleep Number Corp. v. Young*, 33 F.4th 1012, 1016 (8th Cir. 2022) (quoting *D.M. ex rel. Bao Xiong v. Minn.*

[3] Plaintiffs *only* challenge the newly enacted potency limits and the Department's packaging and labeling authority, which will be codified at Iowa Code § 204.2(2)(*c*)(2)(b) and § 204.7(8)(*a*)(3). Any other provision of HF2605 can be severed from the unconstitutional provisions and take effect on July 1. *See* Iowa Code § 4.12.

State High Sch. League, 917 F.3d 994, 999 (8th Cir. 2019)). It simply must show it has a "fair chance of prevailing." *Id.* "To show a "fair chance of prevailing," a party must show that its claims provide "fair ground for litigation." *Id.* at 1016-17 (quoting *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003)). Put differently, "to weigh in the movant's favor, the movant's success on the merits must be 'at least … sufficiently likely to support the kind of relief it requests.'" *Pro Edge*, 374 F. Supp. 2d at 748 (quoting *Curtis 1000, Inc. v. Youngblade*, 878 F. Supp. 1224, 1247 (N.D. Iowa 1995)).

A. The Law's Potency Limits and Packaging and Labeling Authority Are Not Identical to Those Promulgated By the Food and Drug Administration for Consumable Hemp Products and Are Therefore Preempted.

Under the United States Constitution's Supremacy Clause, "state laws that conflict with federal law are without effect." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008). This includes state laws enacted under traditional police powers, so long as it was "the clear and manifest purpose of Congress" to preempt such a law. *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 157 (1978) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The FDCA is a comprehensive statutory scheme requiring uniform treatment of all food products. *See* 21 U.S.C. § 343(q). For all food intended for human consumption and offered for sale, the food's label must include:

> the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or…if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food….

Id. § 343(q)(A)(i)-(ii); *see* 21 C.F.R. § 101.9 (requiring that "all nutrient and food component quantities *shall be declared* in relation to a serving as defined in this section" (emphasis added)). A food's "serving," in turn, is defined by the FDA's "Reference amounts customarily consumed" per eating occasion, or "RACCs" for short. *See* 21 C.F.R. § 101.12. The FDA's RACCs—the

same referenced by the Department in its June 7 guidance—account for nearly every type or category of food imaginable. *Id.*

Separately, the FDCA defines a "food additive" as any substance that, once combined with food, "affect[s] the characteristics" of that food. 21 U.S.C. § 321(s). Once added, a "food additive" becomes one component of the "food" regulated under the FDCA. *See id.* § 321(f)(3). According to the FDA, food additives are deemed presumptively unsafe unless approved by the FDA or "generally recognized as safe" (or "GRAS"). *Id.* § 321(s); *id.* § 348(a). However, "Counsel who wishes to write an opinion or brief on 'food additive' status must be extremely careful. The reader, client, or judge will need to be told that this term of art does not mean what the simple terms mean." Katharine A. Van Tassel, *Definitions – Food additive*, 1 Food and Drug Admin. § 11:3 (2023-2) (West, Westlaw updated Nov. 2023). In other words, food additive or GRAS determinations are highly technical and specialized. *See id.* § 11:4 ("This metaphysical question is difficult to answer even after the author's four decades in this field."); *see generally* U.S. Food & Drug Ass'n, Understanding How the FDA Regulates Food Additives and GRAS Ingredients (June 6, 2024), Hyperlink. Suffice it to say, for purposes of this dispute, any direct or non-incidental food additives, contained within a food, are required to appear on the food's label as an ingredient consistent with FDA regulations. 21 C.F.R. § 101.4(a)(1).

The FDCA's uniform labeling requirements also apply to all "health-related claims" included on labels that "characterize[] the relationship of any nutrient…of the food to a disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B). Those claims must meet "the requirements of the regulations of the Secretary" promulgated under federal rules after the FDA determines there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." *Id.* § 343(r)(3)(A)-(B).

To ensure uniformity in the FDCA's comprehensive framework, Congress included an express preemption provision to clearly occupy the entire field of food labeling and ingredient requirements—to the exclusion of any inconsistent state regulation. 21 U.S.C. § 343-1. In fact, Congress could not have made clearer which state regulations are preempted under the FDCA: "[*A*]*ny requirement* for nutrition labeling of food that is not identical to the requirement of section 343q of this title." 21 U.S.C. § 343-1(a)(4) (emphasis added). "Not identical to" means the state requirement:

> directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that … [a]re not imposed by or contained in the applicable provision … or … [d]iffer from those specifically imposed by or contained in the applicable provision.

21 C.F.R. § 100.1(c)(4). Similarly, Congress preempted "*any requirement* respecting "*any claim* of the type described in section 343(r)(1) of [the FDCA] made in the label or labeling of food that is not identical to the requirement of section 343(r) of [the FDCA]." 21 U.S.C. § 343-1(a)(5) (emphases added).

The preemption provisions of the FDCA clearly indicate Congress's intent, and it is "well established" that the FDCA preempts state laws or state-law claims to the extent they impose requirements different than those prescribed by federal law—including serving size. *Pardini v. Unilever United States, Inc.*, 65 F.4th 1081 (9th Cir. 2023); *see also Hi-Tech Pharm., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1196 (11th Cir. 2018); *Yonan v. Walmart, Inc.*, 591 F. Supp. 3d 1291, 1301–02 (S.D. Fla. 2022) ("Section 343(q) empowers the FDA to promulgate regulations for 'the number of servings … per container.'" (quoting 21 U.S.C. § 343(q)(1)(B))).

Despite having authority to do so, the FDA has *not* imposed or otherwise offered any definitive labeling or ingredient guidance related to food products that contain cannabis-derived ingredients, including any required dosage or serving size. The FDA's decision to *not* act on this

threshold issue (i.e., food additive or not), is critical. It is unknowable whether the FDA will characterize cannabis-derived ingredients in food as (1) an additive, (2) a standalone "type" of food for purposes of RACCs, (3) similar to any other ingredient in a food item (and therefore dependent upon another food's RACC), (4) excluded from the FDCA, (5) similar to alcohol, tobacco, or caffeine (with no RACC), or (6) something else entirely. Yet by enacting HF2605, the legislature usurped the federal role by choosing an option (probably Option #1 or #3) to set limits on the amount of total THC per serving and per container. The Potency Limits regulate "the number of servings or other units of measure per container," an area reserved for exclusive federal regulation, 21 U.S.C. § 343(q)(1)(B), and are therefore preempted. *See* 21 C.F.R. § 100.1(c)(4) (preempting any state requirement "concerning the composition or labeling of food, or concerning a food container" when "not imposed by" the FDA).

By the same token, the FDA has not issued conclusive determinations on the health and safety labeling statements now required under Iowa law via HF2605. Rather, the FDA's position is there is *not yet* enough information to determine what health-related claims, if any, should definitively appear on packaging for consumable hemp products. *See* U.S. Food & Drug Ass'n, FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward (Jan. 26, 2023), Hyperlink ("Given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives."). State-specific labeling requirements are problematic when different states require *substantially* the same warnings but with slight differences in language.[4] Such requirements make it practically impossible for manufacturers to

[4] For example, the Department's health-claims requirement differs from that of Tennessee. *See, e.g.*, Tenn. Admin. Code § 0080-10-02-.06(2)(a) (Notice of Rulemaking Authority submitted Dec. 14, 2023), Hyperlink.

comply with each state's idiosyncratic labeling requirements. Imagine the impossibility faced by brewers or winemakers if all fifty states required a substantially identical (but distinct) surgeon general's warning on a case of beer or wine.

Because Plaintiffs' beverages are characterized as "food" "intended for human consumption and … offered for sale," there is no question Plaintiffs must comply with the FDA's content, packaging, and labeling requirements. 21 U.S.C. §§ 343(q), 343(r). But to comply with *state* law, Plaintiffs must necessarily place content on its beverage labels that is "not identical to" the composition, nutrition, or health-related information imposed by the FDCA. 21 U.S.C. §§ 343-1(a)(4), 343-1(a)(5). Consequently, Plaintiffs will face liability for a misbranding claim under federal law by complying with obligations under state law. And Plaintiffs will face liability far into the foreseeable future: if and when the FDA issues guidance on cannabis-derived ingredients in food products, Plaintiffs must comply with two regulatory frameworks for food labeling unless and until the FDA's requirements are "identical" to those enacted in HF2605. This is precisely why Congress expressly gave the FDA sole authority to decide these issues. *Hi-Tech Pharm.*, Inc., 910 F.3d at 1195 ("Hi-Tech's state-law claim is preempted because it would impose liability for labeling that does not violate the Food, Drug, and Cosmetic Act or the regulations that carry it into effect.").

The Court is particularly justified in striking down the state's Potency Limits given what we *can* glean from the FDA on this important issue. Although the FDA deliberately has not imposed regulations for consumable hemp products in this space, if anything, the FDA indicated it would do so by treating cannabis-derived ingredients as a *food additive* (subject to approval through its additive or GRAS processes) and *not* as any other ingredient contained in a traditional food product (which are subject to serving sizes or common units of measurement). U.S. Food &

Drug Ass'n, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (Feb. 6, 2024), Hyperlink (Question & Answer 10). Accordingly, the FDA would consider the appropriate measure of an acceptable intake of THC as an "acceptable daily intake," (or "ADI")—not subject to the RACCs, as contemplated by state law. *See* U.S. Food & Drug Ass'n, Understanding How the FDA Regulates Food Additives and GRAS Ingredients (June 6, 2024), Hyperlink. Put differently, even if not preempted, the Department's reliance on RACCs is misplaced because it is contrary to the FDA's indications on how hemp and THC likely will be handled. HF2605's Potency Limits characterize the issue as a serving of hemp based on milligrams of THC consumed (i.e., a dosage), not based on the size or characteristics of the vehicle carrying that dosage. This discrepancy makes it all the more important that the FDA, with its recognized expertise, be responsible for setting such regulation as Congress intended. 21 U.S.C. § 343-1.

The bottom line is that, while the FDA has clear authority to set the required or recommended dosage of THC in food products, the information appearing on food labels, and what health-related claims or warnings must appear on those same products, it has not done so. HF2605 establishes a Potency Limit of "four milligrams per serving and ten milligrams per container" and requires health-related labeling on consumable products. These limitations "directly or indirectly establish" requirements not identical to the FDCA, and those limitations "[a]re not imposed by or contained in" the applicable provisions of the FDCA. 21 U.S.C. § 343-1(a)(4)–(5); 21 C.F.R. § 100.1(c)(4). Consequently, the Potency Limits and Packaging and Labeling Authority in HF2605 are preempted by the FDCA.

B. The Law's Potency Limits and Packaging and Labeling Authority Should Be Enjoined Until the FDA Issues Further Guidance on Consumable Hemp Products.

Even if the state's Potency Limits and Packaging and Labeling Authority were not preempted, the Court should enjoin both provisions, at least temporarily, based on the doctrine of

primary jurisdiction. The doctrine applies "where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed with the special competence of an administrative body." *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005). In other words, primary jurisdiction is used to coordinate judicial and administrative decision making. *Access Telecomm. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998); *see also Ravreby v. United Airlines, Inc.*, 293 N.W.2d 260, 262 (Iowa 1980). "No fixed formula exists for applying the doctrine of primary jurisdiction." *Chase v. Andeavor Logistics, L.P.*, 12 F.4th 864, 870 (8th Cir. 2021) (quoting *United States v. W. Pac. R.R.*, 352 U.S. 59, 63 (1956)).

Several courts across the country have stayed cases, citing the primary jurisdiction doctrine, until the FDA provides formal guidance on food labeling requirements for products containing cannabis-derived ingredients. In 2020, Florida enacted a law regulating CBD products, including labeling requirements specifying the number of milligrams of hemp extract within a product. *Snyder v. Green Roads of Fla LLC*, 430 F. Supp. 3d 1297, 1306 (S.D. Fla. 2020). A local CBD manufacturer was sued by purchasers on a label-misrepresentation claim, alleging they were overcharged for products. *Id.* at 1300. The district court, however, stayed the case pending outcome of the FDA's then-current rulemaking regarding regulatory oversight of CBD "ingestible" products, noting the FDA had not yet promulgated CBD labeling regulations. *Id.* at 1306-07, 1309. The court relied on the primary jurisdiction doctrine, which defers judicial decision-making on an issue that Congress placed within the jurisdiction of an administrative body, pursuant to a statute that subjects an industry activity to a comprehensive regulatory scheme, and requires expertise or uniformity in administration. *Id.* at 1308.

> The FDA regulations currently provide little guidance with respect to whether CBD ingestibles, in all their variations are food supplements, nutrients or additives and

> what labelling standards are applicable to each iteration. Although the newly-enacted Florida Rule 5K-4.034 addresses CBD product labelling, the Court would benefit greatly from the FDA's regulatory framework. Accordingly, the case will be stayed until the FDA completes its rulemaking regarding the marketing, including labelling, of hemp-derived ingestible products.

Id. at 1309 (citation omitted); *see Ahumada v. Global Widget, LLC*, No. 19-cv-12005, 2020 WL 5669032, at *2 (D. Mass. Aug. 11, 2020) (applying primary jurisdiction doctrine under similar circumstances); *Glass v. Global Widget, LLC*, No. 2:19-cv-01906, 2020 WL 3174688, at *3 (E.D. Cal. June 15, 2020) (same); *Colette v. CV Sciences, Inc.*, No. 2:19-cv-10227, 2020 WL 2739861, at *5 (C.D. Cal. May 22, 2020) (same); *see also Ivie v. Kraft Foods Global, Inc.*, No. C-12-02554, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013) (invoking the primary jurisdiction doctrine "where the FDA has yet to speak on whether a particular label or claim on a consumer product is unlawful or misleading").

To be sure, Plaintiffs believe the Potency Limits and Packaging and Labeling Authority are preempted outright. But should the Court disagree, this Court should enjoin any enforcement of those provisions until, at a minimum, the FDA provides this Court its specialized expertise on appropriate or required potency limits of consumable hemp products and other required health-related claims. Congress vested the FDA with exclusive authority to define and regulate those areas for *all* food products, including those containing food additives such as hemp-derived THC. This Court should temporarily restrain implementation of any state-law measures until technical guidance issues from the FDA.

Plaintiffs understand the decisions cited above stay the enforcement of a *case*—not a statute—pending administrative review. But the doctrine does not depend on procedural posture: "In every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation." *Western Pac. R. Co.*, 352 U.S. at 64. The stakes of *this* litigation are high: if Plaintiffs are correct and the

statute misapplies applicable serving size, consumption, or labeling requirements, Plaintiffs will face severe consequences including but not limited to being charged with felony crimes for possessing "noncompliant" consumable hemp products. *See* Department Guidance at 3-4. Invoking the doctrine may add expense and delay, *see Access Telecommunications*, 137 F.3d at 608; however, under these circumstances it would ensure the state has not misapplied or misinterpreted federal law at the expense of Plaintiffs' basic constitutional freedoms. *See Webster v. Westlake*, 587 F. Supp. 3d 846, 862-63 (S.D. Iowa 2021) (recognizing that the Fourth Amendment protects an individual's right to be free from unlawful arrest).

C. Even If Those Laws Are Constitutional, the Department's Guidance Ignores the Potency Limits Chosen By the Legislature.

Effective July 1, the Department will administer Iowa's hemp laws according to its Guidance. It will enforce its own interpretation of the Potency Limits, *up to and including criminal referrals*, despite having no authority to interpret the law and having made no attempt to follow the necessary rulemaking process. What was legal one day becomes illegal the next. The Department will interpret "container" as any holder of beverage—unless the container is less than 12 fluid ounces. It will interpret "serving" according to its own misguided understanding of FDA RACCs. The Department appears to fundamentally disregard the legislature's directive that *any* single-serving beverage container may contain "ten milligrams [of total THC] per container." The Department's action must be stopped.

Pursuant to the plain language of the statute, this Court must interpret the Potency Limits as establishing an upper limit of "ten milligrams per container" regardless of the number of servings—however defined—within that container. Despite defining the FDCA elsewhere in the hemp statute, the legislature did not define "serving" according to FDA definitions. Even if it had defined "serving," the Potency Limits resemble an average daily intake amount akin to a *dosage*,

not an amount dependent on the underlying food product's RACC. If the FDA's deliberate inaction creates ambiguity in the term "serving" as to hemp products, so be it: a ten-milligram per-container limit on consumable hemp products is unambiguous, reasonable, applies to *all* consumable hemp products regardless of the means of consumption (i.e., ingestion *or* absorption), and gives effect to the entire statute as enacted by the legislature.

1. As a Threshold Matter, the Department Lacks Authority to Interpret the Potency Limits Through "Guidance" Posted On Its Website.

If you give an agency a statute, it's going to issue some guidance. *See* Laura Numeroff, *If You Give a Mouse a Cookie* (1985). Here, the Department strayed too far. "'[T]he legislative authority of this state shall be vested in a general assembly…'—not the executive branch." *City of Des Moines v. Iowa Dep't of Transp.*, 911 N.W.2d 431, 434 (Iowa 2018) (quoting Iowa Const. art. III, § 1). In other words, executive branch agencies lack authority to set policy any further than the legislature permitted. *Id.* at 439; *see Brakke v. Iowa Dep't of Nat. Res.*, 897 N.W.2d 522, 533–34 (Iowa 2017) ("The power of the agency is limited to the power granted by statute."); *see also* Iowa Code § 17A.23(3). And even when such authority is delegated, the agency cannot declare its own policy through bare "guidance"—it must follow the well-established rulemaking process contained within the Iowa Administrative Procedure Act. *See* Iowa Code §§ 17A.3(2); 17A.4(5).

First, to constitute lawful agency action, the Department must convince this Court it was delegated authority to interpret the Potency Limits through rulemaking or otherwise. *Brakke*, 897 N.W.2d at 530-31. Delegation is not taken lightly, and any grant of rulemaking authority "shall be construed narrowly." Iowa Code § 17A.23. Here, the Department—quite clearly—does not

have authority. The Hemp Act *does* delegate interpretative and rulemaking authority within the Iowa Hemp Act in five narrow ways:

- Packaging and labeling requirements. HF2605, § 4 (to be codified at Iowa Code § 204.7(8)(*a*)(3)).
- Restrictions upon the sale or other distribution of a product. HF2605, § 5 (to be codified at Iowa Code § 204.7(8)(*a*)(4)).
- Registration and revocation of a registration for product manufacturers. Iowa Code § 204.7(8)(*b*).
- Registration and revocation of a registration for product sellers. Iowa Code § 204.7(8)(*c*).
- Defining a "synthetic consumable hemp product." HF2605, § 8 (to be codified at Iowa Code § 204.14A(1B)).

None of these items provide the Department authority to interpret the Potency Limits.

We *know* the Department's packaging and labeling authority does not encompass the authority to set potency limits. Legislative history of HF2605 confirms setting potency limits was a legislative decision, not an administrative one. The introduced version of HF2605 expressly delegated the issue to the Department, *in addition to* amendments to the packaging and labeling authority. HSB 665 §§ 6 & 7; SSB3159 §§ 6 & 7. The authority to set potency and serving limits was expressly removed through subsequent amendments to HF2605. Amendment H-8193 to Amendment H8134 to H.F. 2605, 90th G.A., 2d Sess. (Iowa 2024). The legislature knew *how* to delegate authority on potency and serving limits to the Department; in the end, it simply—and deliberately—decided not to. *See Abbas v. Iowa Ins. Div.*, 893 N.W.2d 879, 889–890 (Iowa 2017) (using prior bill versions and legislative amendments to determine legislative intent). Stated intent from individual legislators confirms as much. *See LS Power Midcontinent, LLC v. State*, 988 N.W.2d 316, 337 (Iowa 2023) (using floor statements to determine the circumstances of a bill's passage).

Second, the Department's action is unlawful because it did not even attempt to follow proper rulemaking procedures prior to enforcing its interpretation of the Potency Limits. *City of Des Moines*, 911 N.W.2d at 439-440. Compliance with Chapter 17A is required to ensure agency action is "lawful, fully responsive to the popular will, and adequately coordinated to avoid conflict and inconsistency." *Iowa Fed. of Labor, AFL-CIO v. Iowa Dep't of Job Serv.*, 427 N.W.2d 443, 446 (Iowa 1988) (quoting A.E. Bonfield, *State Administrative Rule Making* §§ 8.4, at 550 (1986)). As a result, agency action that does not substantially comply with the rulemaking process in 17A is "not valid." Iowa Code § 17A.4(5); *see also id.* § 17A.2(11) (defining a "rule" as including an agency statement that "implements, interprets, or prescribes law or policy").

The Department's guidance does not comply with Chapter 17A in any regard. Agencies are not entitled to interpret new legislation on a whim, even if the agency must move promptly to implement a law's quickly approaching effective date. The legislature knows how to provide an agency "emergency" rulemaking authority, and regularly does so through an express grant of emergency rulemaking authority. *See, e.g.*, 2024 Iowa Acts ch. 1090, § 14 ("EMERGENCY RULES"). None was given here. Alternatively, the Department may seek the approval of the legislature's Administrative Rules Review Committee (or "ARRC") to speed up the rulemaking process. Iowa Code § 17A.4(2); *id.* § 17A.5(2)(*b*). Tellingly, the Department filed a notice of intended action—the *first* step in any required rulemaking, if it were allowed—on June 12. ARC8064C (June 12, 2024), Hyperlink. This indicates the Department knows *how* to promulgate valid rules; it also confirms the Department's rules—which implement its Guidance—will not be in effect by July 1. *See* Iowa Code §§ 17A.4, 17A.5.

The Department *cannot* circumvent Chapter 17A entirely, especially considering the magnitude of the Department's guidance in this case. Any other interpretation raises significant

due process concerns, especially considering the severe civil and criminal penalties at stake. *Cf. Iowa Fed. of Labor, AFL-CIO*, 427 N.W.2d at 447 (recognizing "serious due process questions" when agency action is not judicially reviewable). Even if rulemaking were allowed, the Court should stay the Department's Guidance and enjoin any enforcement of HF2605 by the Department until it engages in the appropriate rulemaking process for agency action. Iowa Code § 17A.19(5).

2. The Department's Interpretation of the Potency Limits Is Unreasonable. The Statute Unambiguously States a Container Can Hold Up to 10 Milligrams of THC.

The Department's guidance also is an unreasonable, unworkable interpretation of the statute. At the outset, the Department is not entitled to deference in its interpretation—for the same reason it has no rulemaking authority. The legislature did not "clearly vest" the Department with the authority to interpret the statute. *See NextEra Energy Res. LLC v. Iowa Utilities Bd.*, 815 N.W.2d 30, 37 (Iowa 2012). To the contrary, legislative history establishes the Potency Limits were incorporated into the statute because the legislature *did not* want the Department creating its own interpretation of the law. The Department has no "special expertise" to interpret or explain what "serving" or "container" means. *Id.* at 37 (quoting *Renda v. Iowa Civil Rts. Comm'n*, 784 N.W.2d 8, 14 (Iowa 2010)). The Department does not establish serving sizes or container sizes in the normal course and lacks the knowledge and expertise required to do so for these products.

The Department's Guidance criminalizes any consumable beverage in a container of less than 12 fluid ounces. On what basis? House File 2605 is wholly silent on the container size in which a product may be sold. The FDA does not mandate minimum container sizes. The Department is attempting to add words to the statute—through unlawful guidance—that it wishes the legislature would have included. Such an interpretation is unreasonable, especially when the legislature expressly demonstrated a desire to chart its own course. *See Auen v. Alcoholic Bev. Div.*, 679 N.W.2d 586, 591 (Iowa 2004) (rejecting interpretation of a statute requiring a court to

"read something into the law that is not apparent from the words chosen by the legislature" (quoting *State v. Guzman-Juarez*, 591 N.W.2d 1, 2 (Iowa 1999))).

The Department prohibits smaller beverage containers because it misreads federal regulations. By the Department's flawed logic, because *all* beverages have a recommended serving size of 12 fluid ounces, *no* beverages can be sold in a container of less than 12 fluid ounces. But not all beverages have a recommended serving size of 12 fluid ounces. Juice beverages, for example, have a recommended serving size of *eight* fluid ounces. 21 C.F.R. § 101.12(b). Has the legislature outlawed consumable hemp juices without saying so? There is no lawful authority for this restriction. Similarly, manufacturers regularly package soft drinks in containers holding less than 12 fluid ounces. Can manufacturers no longer do so for hemp-based products? What portion of HF2605 makes an 8-ounce container a felony? The Department's lack of specialized knowledge related to food serving sizes, packaging, and labeling shows.

In fact, the Department's approach is categorically different than the FDA's current consideration of hemp- or cannabis-derived ingredients within consumables. The FDA—unlike the Department—*does* have specialized knowledge of serving sizes, packaging, and labeling. A "serving" of THC is not based on quantity of the underlying food product, such as a beverage or solid food; rather, it should be considered a food additive—or a dosage—added to that product. *See* U.S. Food & Drug Ass'n, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (Feb. 6, 2024), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (Questions and Answers 10). The appropriate "serving" of THC, then, is based upon an

"acceptable daily intake," *not* the common household measure (RACC) for a soda, chocolate bar, or a candy.[5]

The legislature knew the foregoing when it passed HF2605. For example, many consumable food products are manufactured and packaged in a single-serving container. Yet in those circumstances, it is difficult to reconcile the language "four milligrams per serving and ten milligrams per container" with an interpretation that a "container" holding one serving cannot—as it turns out—hold "ten milligrams per container." Under the Department's flawed interpretation, the term "ten milligrams per container" would be entirely read out of the statute, which is disfavored. *Cox v. Iowa Dep't of Hum. Servs.*, 920 N.W.2d 545, 553 (Iowa 2018) ("When interpreting the meaning of the statute, we give effect to all the words in the statute unless no other construction is reasonably possible." (quoting *Oyens Feed & Supply, Inc. v. Primebank*, 808 N.W.2d 186, 193 (Iowa 2011))); *First State Bank v. Clark*, 635 N.W.2d 29, 32 (Iowa 2001) (recognizing that courts "do not interpret statutes to render any part superfluous").

The legislature knows how to reference federal law in the Hemp Act; indeed, the FDCA is a defined term within Chapter 204. *See* Iowa Code § 204.2(7). Yet it did not choose federal "serving size" definitions when setting the Potency Limits. Viewing THC as an additive—or a dosage—was clearly the legislature's intent. Louisiana, for example, defines "serving" as the "amount of individual units or amount of liquid of a product *recommended by the manufacturer* to

[5] The FDA (quite obviously) does not issue a RACC for lotions and salves because those products are not food. 21 C.F.R. § 101.12(b). However, those products *are* consumable hemp products. *See* Iowa Code § 204(2)(*d*)(1) (defining "consumable hemp product" to include those "absorbed through the skin, such as a topical application"). Because it is nonsensical to apply RACCs to those consumables, and because there is no distinction in Iowa's hemp statute among edible or non-edible consumable hemp products, it is nonsensical to apply RACCs to *any* consumable hemp product. Similarly, the amount of alcohol, tobacco, or caffeine in a product does not depend on the serving size of the vehicle in which those substances are consumed. The *dosage* consumed is the appropriate measure.

be consumed at a single time." La. Rev. Stat. 3:1481(11) (emphasis added). Other legislatures have considered a serving definition dependent on an amount "reasonably suitable for a person's use in a single day." H.B. 563, Part I (N.C. Gen. Assemb. 2023 Sess.). Those definitions, like the language enacted in HF2605, resemble an average-daily-intake amount, not an amount dependent on the underlying food product's RACC. And until federal regulators set an established average daily intake amount, the legislature could have conceivably intended that the product may contain an amount "recommended by the manufacturer." La. Rev. Stat. 3:1481(11). But in any event, the legislature was clear that a product may contain up to ten milligrams per container.

The FDA's view that THC is a food additive creates some ambiguity in Iowa's statute, but only as to the meaning of "serving." That's the problem with the Department's unlawful interpretation: "serving" is the tail wagging the proverbial dog. *See State v. Iowa Dist. Ct. for Scott Cnty.*, 889 N.W.2d 467, 472 (Iowa 2017). By defining "serving" in a way that necessarily affects the meaning of "container," the Department keeps itself in the driver's seat to establish potency limits—a role the legislature did not intend the agency to play. The Department's interpretation might be reasonable with a statute that provides a limit of "ten milligrams per container, *so long as the container holds a minimum of 30 fluid ounces in the case of a beverage*." No such language exists, and the Department may not add it.

"Container," on the other hand, is an unambiguous term. It means a "receptacle (as a box or jar) or a formed … covering for the packing or shipment of articles, goods, or commodities." receptacle or a flexible covering for the shipment of goods." *Webster's Third New Int'l Dictionary* 490 (3d ed. unabridged 1976). A beverage can defined as a "container." *See id.* The per-container limit of HF2605 is easily applied and has reasonable limits. Indeed, in Minnesota, a consumable beverage can contain up to two five-milligram servings of THC "per container," i.e., *ten*

milligrams per container. Minn. Stat. § 151.72(5a)(f); *see Iowa Ins. Institute v. Core Grp. of Iowa Ass'n for Justice*, 867 N.W.2d 58, 77 (Iowa 2015) (considering the rule in other jurisdictions when interpreting a statute).

The rule of lenity must also be considered because any difference of opinion is the difference between lawful business and potential imprisonment. *State v. Middlekauff*, 974 N.W.2d 781, 793 (Iowa 2022); *cf. State v. Mathias*, 936 N.W.2d 222, 238 (Iowa 2019) (Mansfield, J., dissenting) ("Criminal statutes ought to give fair notice to the public of the conduct that is prohibited; we enforce that concept through the rule of lenity."). Relatedly, Plaintiffs have a constitutional right to fair warning of conduct that is prohibited by this statute. *Planned Parenthood of Greater Iowa, Inc. v. Miller*, 1 F. Supp. 2d 958, 961-62 (S.D. Iowa 1998). A statute is void for vagueness "if people of 'ordinary intelligence' are forced to guess at the meaning of the statute and differ as to its application." *Id.* at 962 (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972)). Here, the Department purports to make *and* enforce criminal law via "guidance" posted to its website. It presents a problem of constitutional magnitude for Plaintiffs to face felony charges for selling products containing "ten milligrams per container" based on a statute that permits the sale of products containing "ten milligrams per container."

At bottom, the Department impermissibly interpreted the legislature's Potency Limits to cause something the legislature did not say. The legislature could have delegated authority to the Department to define "serving" or "container," but it did not. The legislature could have referenced federal RACC regulations to define "serving" or "potency," but it did not. What it *did* provide—unambiguously—is a statement that a consumable hemp container may include "ten milligrams per container"—notwithstanding any uncertainty, ambiguity, or shadow of a doubt as to the meaning of "serving." As applied to Plaintiffs' sale of products, and considering the stakes

involved, if preemption is not found, this Court must interpret the Potency Limits of HF2605 as establishing an upper limit of ten milligrams per "container" regardless of the number of servings—however defined—within that container.

III. THE POSSIBILITY OF CRIMINAL LIABILITY IS SIGNIFICANT AND IRREPARABLE HARM.

Effective July 1, the Department will begin to administer and enforce the provisions of HF2605. Pursuant to the Department's Guidance, between 72% and 77% of Plaintiffs' current inventory will become illegal and subject Plaintiffs to potential criminal liability on July 1. (Selix Decl. ¶ 17; Caraher Decl. ¶ 17). Products that account for between 89% to 90% of Plaintiffs' revenue will become illegal. (Selix Decl. ¶ 18; Caraher Decl. ¶ 18). 83.33% of Climbing Kites' previously planned production for July are no longer cancellable and set to become illegal. (Selix Decl. ¶ 19). Absent Court intervention, the Department's guidance indicates it may pursue civil or criminal penalties immediately, including felony charges. Indeed, the Department stated the penalty for noncompliance with its Guidance will be "severe." Department Guidance p. 6.

Under these circumstances, Plaintiffs demonstrate irreparable harm. *See Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986) (requiring proof that irreparable harm is imminent and there is a clear and present need for equitable relief); *Mga Susu, Inc. v. County of Benton*, 853 F. Supp. 1147, 1154 (D. Minn. 1994) (granting injunctive relief in part because nothing prevented the defendants from civil enforcement or criminal prosecution absent such relief); *Bio Gen, LLC v. Sanders*, No. 4:23-cv-00718, 2023 WL 5804185, at *8 (E.D. Ark. Sept. 7, 2023) (finding irreparable harm in not enjoining hemp regulations argued to be preempted by federal law where substantial lost profits and criminal liability could ensue).

IV. PLAINTIFFS WILL BE GREATLY HARMED IF AN INJUNCTION IS NOT ISSUED, BUT THE DEPARTMENT WILL MERELY NEED TO ENFORCE THE LAW—AS CURRENTLY ENACTED—WHICH IS CONSISTENT WITH FEDERAL LAW.

A significant portion of the Department's Guidance focuses on its application of the Potency Limits. However, should an injunction issue, the Department will simply be asked to regulate at the same level at which it currently regulates—and has, for the past four years—related to potency levels and label requirements for consumable hemp products. There is no "harm" to the Department, in this respect.

To the extent the Department's harm sounds in "public safety," Plaintiffs note that Congress expressly preempted the state's Potency Limits and Packaging and Labeling Authority. In our constitutional order, and consistent with the U.S. Constitution's Supremacy Clause, Congress is entitled to do so under these circumstances. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (recognizing that the "'purpose of Congress is the ultimate touchstone' in every pre-emption case" (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992))). At times, the rule of law requires a state regulation—even enacted under a state's police powers—be superseded by federal law when it was the clear and manifest intent of Congress to do so. *Altria Grp., Inc.*, 555 U.S. at 77.

V. INJUNCTIVE RELIEF UNDER THESE CIRCUMSTANCES RESPECTS PUBLIC POLICY BY PROVIDING CONSISTENT REGULATION IN A COMPLEX REGULATORY ENVIRONMENT.

Plaintiffs understand one purpose of enacting the state's Potency Limits and amending the Department's Packaging and Labeling Authority was to add clarity to Iowa's consumable hemp laws. But considering the intent of Congress and the FDA in enacting a comprehensive regulatory scheme related to food labeling and ingredient requirements, in effect, the disputed provisions begin the state down a path of patchwork and idiosyncratic regulation in that same regulatory

environment. That is the precise purpose for Congress expressly preempting such regulation. Public interest favors certainty and reliability in this area.

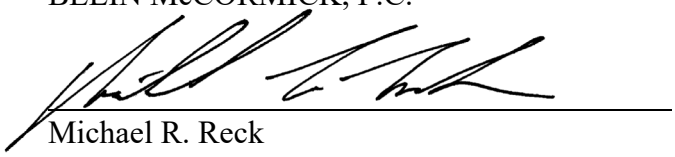
CONCLUSION

Beginning July 1, 2024, the Department is set to interpret, enforce, and otherwise administer Iowa's consumable hemp laws to include a Potency Limit as enacted in Section 2 of House File 2605, to be codified at Iowa Code § 204.2(2)(*c*)(2)(b), and Packaging and Labeling Authority as enacted in Section 4 of House File 2605, to be codified at Iowa Code § 204.7(8)(*a*)(3). Both provisions violate the Supremacy Clause of the United States Constitution, or otherwise conflict with an area of federal regulation in which the FDA should decide—as a matter of first impression—the technical or specialized components of such regulation prior to judicial intervention. The statute, as written and interpreted by the Department, will irreparably harm Plaintiffs. Accordingly, Plaintiffs respectfully request the Court issue a preliminary injunction striking down the identified provisions of House 2605, or alternatively, preventing the Department from interpreting, enforcing, or otherwise administering Iowa's consumable hemp laws to include a Potency Limit or Packaging and Labeling Authority not identical to federal requirements or otherwise consistent with the plain language of House File 2605.

Dated this 17th day of June 2024.

Respectfully submitted,

BELIN McCORMICK, P.C.



Michael R. Reck
Christopher J. Jessen
666 Walnut Street, Suite 2000
Des Moines, IA 50309-3989
Telephone: (515) 283-4645
Facsimile: (515) 558-0645
mrreck@belinmccormick.com
cjessen@belinmccormick.com
ATTORNEYS FOR PLAINTIFFS