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

CLIMBING KITES LLC, *et al.*, *Plaintiffs*, v. STATE OF IOWA, *et al.*, *Defendants*.	Case No. 4:24-cv-00202-SMR-SBJ

DEFENDANTS' RESISTANCE TO PLAINTIFFS'

MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Congress recently legalized hemp, a plant like marijuana but with a lower level of marijuana's active drug—THC. *See* 7 U.S.C. § 1639*o*(1); 21 U.S.C. § 802(16)(B)(i). After Congress legalized hemp, Iowa legalized the sale of consumable hemp products. Hemp-derived beverages soon hit the Iowa market. But federal law relies on States as the main regulators of hemp and hemp-derived products; and it expressly permits States to regulate hemp more stringently than federal law. 7 U.S.C. § 1639p(a)(3)(A). With limited State regulations in place governing Iowa's newly-created THC-consumables market, concerns over the products' safety took hold.

Responding to those concerns—particularly that THC beverages sold in Iowa contained potentially dangerous levels of THC and, crucially, lacked adequate safety warnings—the Legislature passed House File 2605 in April 2024. Two of HF2605's sections are relevant here: the Potency Provision, which establishes per-serving and per-container limits on how much THC can be in a beverage, and the Warning Provision, which requires that THC beverages contain a label warning consumers of the risks of THC. The law gives Iowa's Department of Health and Human Services authority to promulgate rules to carry these provisions into effect.

Plaintiffs manufacture the THC beverages that prompted the safety concerns driving the Legislature's enactment of HF 2605. Plaintiffs seek an injunction allowing them to avoid putting warning labels on their THC beverages and to avoid the new potency limits. They argue both provisions are preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"), which does preempt some state laws about the familiar "Nutrition Facts" label on all foods. 21 U.S.C. § 343–1(a). But they fail to mention that the FDCA says it "shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides a warning concerning the safety of the food or a component of the food." National Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6(c)(2), 104 Stat. 2353, 2364 (1990) (codified at 21 U.S.C. § 343–1 Note

(Construction of Pub. L. No. 101-535)). HF 2605's Warning Provision falls squarely within this exclusion, so it is not preempted. And because the Potency Provision has no labeling requirement, it is not preempted by federal labeling laws.

Although about one month and two townhall meetings remain in the Department's notice-and-comment period for its rules implementing HF 2605, Plaintiffs challenge a set of Frequently Asked Questions the Department published to help explain the draft rules. R. Doc. 1 ¶ 56. And they assert this claim under the Iowa Administrative Procedure Act ("IAPA"). But Iowa's state courts have exclusive jurisdiction over IAPA claims. So this Court lacks jurisdiction over any IAPA claim. In any event, the FAQs and draft rules are far from a "final agency action" ripe for judicial review.

This Court should deny Plaintiffs' motion for a preliminary injunction.

BACKGROUND

A. Iowa's Regulation of Hemp

Hemp and marijuana are varieties of the cannabis plant. Both contain the psychoactive chemical delta-9-tetrahydrocannabinol, or "THC." Selix Decl. ¶ 4.

In 2018, Congress passed the Agriculture Improvement Act of 2018, also known as the "2018 Farm Bill," which legalized hemp by excluding it from the federal definition of marijuana. Pub. L. No. 115-334, 132 Stat. 4490 (2018). Under federal law, "hemp" is simply a cannabis plant with a concentration of THC "not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639*o*(1).

The 2018 Farm Bill explicitly allows States to regulate the production and distribution of hemp products—including products made from hemp, like beverages that contain THC. The law says States retain the authority to "regulate[] the production of hemp . . . more stringent[ly]" than federal standards. 7 U.S.C. § 1639p(a)(3)(A) ("Nothing in this subsection preempts or limits any

law of a State that . . . regulates the production of hemp and is more stringent than this subchapter."). In response, many States have regulated hemp-based products more stringently than federal law. *See, e.g.*, Ind. Code § 35-48-4-10.1 (criminalizing smokable hemp); Minn. Stat. § 151.72, subd. 5a(f) (setting a five-milligram THC limit for "edible cannabinoid product[s]"); 49 La. Admin. Code Pt. I, § 501(A) (imposing a 0.5 milligram per-package limit on "Adult-Use Consumable Hemp Product[s]"). And courts have dismissed challenges to these laws. *See, e.g.*, *AK Indus. Hemp Ass'n, Inc. v. Alaska Dep't of Nat. Res.*, 2023 WL 8935020, at *2 (D. Alaska Dec. 27, 2023) (rejecting a preemption challenge to an Alaska law that "effectively prohibits the in-state sale of hemp products intended for human or animal consumption that contain any delta-9-THC or other non-naturally occurring cannabinoid"); *N. Virginia Hemp & Agric. LLC v. Virginia*, 2023 WL 7130853, at *7 (E.D. Va. Oct. 30, 2023) (holding that Virginia's two-milligram-per-package restriction on THC was not preempted).

Iowa is one of those States. In 2020, Iowa enacted a regulatory framework for consumable hemp products. *See* Iowa Code ch. 204. Although the law set up basic labeling requirements that would be later promulgated via rulemaking, it did not impose potency limits on hemp consumables beyond the federal requirements. *See id.*

Iowa's Department of Public Safety raised concerns over the potency and dangers of foods under the federal THC limit. *See* Consumable Hemp Pre-File Bill Request, HF 2605, 2024 Sess. (Iowa Nov. 27, 2023), https://perma.cc/62U7-TM6F (Iowa DPS recognizing that "[i]n foods and beverages that contain heavy and dense ingredients, 0.3% can contain sufficiently high levels of THC that can lead to intoxication"). So the Legislature passed House File 2605. *See* An Act Providing for the Regulation of Hemp and Hemp Products, Providing Penalties, and making Penalties Applicable, 2024 Iowa Acts ch. 1176 (to be codified at scattered sections of Iowa Code

chs. 123, 204, and 805). The bill was introduced in February 2024, passed both houses by April 2, and was signed by the Governor on May 17. It makes two changes relevant here.

First, HF 2605's Potency Provision sets the maximum THC concentration for hemp consumables at a level lower than the federal 0.3% maximum:

> 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.

HF 2605 § 2. This means that, for carbonated beverages, the law reduces the THC concentration limit from 0.3% on a dry weight basis to 4 milligrams per serving and 10 milligrams per container on a dry weight basis.

Second, the law's Warning Provision establishes packaging and labeling requirements, and it delegates power to the Iowa Department of Health and Human Services to establish rules. It reads:

> 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 by rule. 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.

HF 2605 § 4. This is not a unique requirement. Many other States have similar laws. *See, e.g.*, Minn. Stat. § 151.72, subd. 5a(e)(4); Tenn. Code Ann. § 43-27-209(a)(2)(B); N.Y. Cannabis Law § 103(1); 27 Cal. Code Regs. §§ 27001(c), 25603(a)(2)(B).

HF 2605 tasks the Department with carrying out its enactments. *See* HF 2605 §§ 2–4. As a result, the Department has issued a series of draft rules and responses to FAQs, which are far from

final and have already evolved significantly. *See* Selix Decl. ¶ 13; Caraher Decl. ¶ 13 (discussing initial May 2024 guidance and FAQ).

To comply with its obligations under the Iowa Administrative Procedure Act, the Department issued an informal Notice of Intended Action on June 7, 2024, which included proposed rules to give effect to HF 2605. Iowa Dep't of Health and Human Servs., Notice of Intended Action for HF 2605 (June 7, 2024), https://perma.cc/6589-N6XF. A few days later, the Department released a formal Notice of Intended Action. Notice of Intended Action, ARC 8064C, 46 Iowa Admin. Bull. 10015, 10074–83 (June 12, 2024). The notice includes the current version of the proposed rules and informs the public that those rules are in the notice and comment period. The notice also provides Zoom links to the July 2 and July 8 hearings and invites the public's participation and input. *Id.* at 10075.

To implement HF 2605's Potency Provision, the Department proposes defining "serving" in accordance with federal law: "serving" means "the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12." *Id.* at 10077. And it would define "container" as an "object that holds one or more servings of a consumable hemp product." *Id*.

To implement the Warning Provision, the Department proposed a label that says:

> 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 10080. Finally, as part of its authority to promulgate packaging requirements, HF 2605 § 4, the Department proposes requiring liquid consumable hemp products be packaged in containers no smaller than 12 oz, 46 Iowa Admin. Bull. at 10077.

The same day the Department released the draft rules, June 7, it also released a document explaining the draft rules to help the public "understand [the] regulatory changes." Iowa Dep't of Health and Human Servs., *Consumable Help: HF 2605 FAQ – What it Means, Draft Rules, Townhall Info*, at 1 (June 7, 2024) ("FAQ Guidance"), https://perma.cc/2EUV-LAY2. The FAQ Guidance neither prescribes additional rules nor sets out additional policy. It does, however, explain that the proposed rules remain in the notice and comment period, and it provides dates for the remaining public hearings, which the Department will hold on July 2 and July 8, 2024. *Id.* at 6. Finally, the FAQ Guidance explains that the Department's rules will not be adopted until July 17, 2024, at the earliest, or published until August 7, 2024. *Id.*

On June 17, 2024—over a month after the Governor signed HF 2605 into law—Plaintiffs, who produce and sell THC beverages, sued the State and the Department, alleging that HF 2605 is preempted by federal law and that the Department's FAQ Guidance violated the Iowa Administrative Procedure Act. R. Doc. 1. Plaintiffs moved for a preliminary injunction of HF 2605's Potency and Warning Provisions and of the Department's FAQ Guidance. R. Doc. 11.

B. The Federal Food, Drug, and Cosmetic Act and Its Exception for State Warning Labels

The federal FDCA is designed to protect the health and safety of the public at large. *See 62 Cases of Jam v. United States*, 340 U.S. 593, 596 (1951). In 1990, Congress passed the Nutrition Labeling and Education Act ("NLEA"), which amended the FDCA and established the Food and Drug Administration's authority to require nutrition labeling on foods. NLEA, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

The FDCA's structure recognizes that "the regulation of food and beverage labeling" has "traditionally fallen within the province of state regulation." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009). Though it gives FDA exclusive authority to regulate some aspects of

labeling by preempting certain state laws, the FDCA expressly preserves the States' historic role of requiring safety warnings on food labels. That structure is expressed in two parts of the FDCA, which, although they do not appear in the text of the Code, carry the force of law.

First, Section 6(c)(1) of the NLEA says the FDCA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343–1(a)] of the Federal Food, Drug, and Cosmetic Act." Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (1990) (codified at 21 U.S.C. § 343–1 Note (Construction of Pub. L. No. 101-535)). By adding this limitation—which excludes any implied preemption of State laws—"Congress . . . explicitly stated that it does not intend to occupy the field of food and beverage nutritional labeling." *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

Second, Section 6(c)(2) preserves States' historic role in protecting their citizens by requiring certain food safety warnings be placed on food labels. It explains that any FDCA express preemption provision "shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides a warning concerning the safety of the food or a component of the food." NLEA § 6(c)(2). That warning exclusion "carves out an exemption from its express preemption clause where warnings concerning the safety of food or component of food are at issue." *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 801 (N.D. Cal. 2015). It is broadly construed. *See Lavoie-Fern v. Hershey Co.*, 610 F. Supp. 3d 661, 665 (M.D. Pa. 2022) (describing it as "broadly worded"); *Sciortino*, 108 F. Supp. 3d at 803 (explaining that Congress intended a "broad construction").

While the FDCA thus preserves the States' role in promulgating food safety laws, two other provisions of the FDCA expressly preempt state laws in other areas:

Section 343–1(a)(4). This provision concerns the familiar "Nutrition Facts" label on all foods. Federal law mandates certain nutritional information be included in his part of the label. *See* 21 U.S.C. § 343–1(a). States may not intrude on that function. *Id.* § 343–1(a)(4); *see also New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 118 (2d Cir. 2009) ("*NYSRA*") (describing this section in plain English). This express preemption provision means States may not pass laws that create "any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title." 21 U.S.C. § 343–1(a)(4). And Section 343(q) is the part of the FDCA that lays out the requirements for what nutrients must be on the "Nutrition Facts" label on all foods. The label must include: "the serving size," 21 U.S.C. § 343(q)(1)(A)(i), the number of servings per container, *id.* § 343(q)(1)(B), and the "amount of . . . nutrients" such as cholesterol, sodium, carbohydrates, and sugars, *id.* § 343(q)(1)(D), among other requirements. The Secretary of Agriculture can add required nutrients, too. *Id.* § 343(q)(2)(A). In short, the preemption provision in section 343–1(a)(4) establishes that the FDCA controls the mandatory "Nutrition Facts" on all foods, and States cannot change it.

Section 343–1(a)(5). This preemption provision relates to "*voluntary* information, that is, those claims a food purveyor may *choose* to add to its product label about the nutrient content (for example, 'low sodium') or health benefits (for example, 'fiber reduces cholesterol') of its product." *NYSRA*, 556 F.3d at 119; *see also Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1117 (N.D. Cal. 2010) (explaining that this section "governs all voluntary statements about nutrient content or health information a manufacturer chooses to include on a food label or packaging"). It prevents States from passing laws that create "any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title." 21 U.S.C. § 343–1(a)(5). And Section 343(r)

governs two types of voluntary characterizations made by manufacturers. First, characterizations of "the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food"—that is, claims about the level of nutrients required on the "Nutrition Facts." 21 U.S.C. § 343(r)(1)(A). An example would be "low sodium." *NYSRA*, 556 F.3d at 119. Second, characterizations of "the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition"—that is, claims about the health benefits or risks of the nutrients required on the "Nutrition Facts." 21 U.S.C. § 343(r)(1)(B). An example would be "fiber reduces cholesterol." *NYSRA*, 556 F.3d at 119.

Putting section 343–1(a)(5)'s cross references together, it prevents States from passing laws that require manufacturers to make claims about the level of any nutrients required on the "Nutrition Facts" label, 21 U.S.C. § 343(r)(1)(A), or the health benefits or risks of those nutrients, *id.* § 343(r)(1)(B).

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). The power to grant a preliminary injunction is "an awesome power" that "necessarily requires the Court to analyze the record carefully to determine whether Plaintiff has shown that it will be irreparably harmed absent the issuance of the requested relief." *Mediacom Comms. Corp. v. Sinclair Broad. Group, Inc.*, 460 F. Supp. 2d 1012, 1017 (S.D. Iowa 2006).

When determining whether to grant a preliminary injunction, courts consider, "(1) the probability of success on the merits; (2) the threat of irreparable harm to the movant; (3) the balance between this harm and the injury that granting the injunction will inflict on other interested

parties; and (4) whether the issuance of an injunction is in the public interest." *Sanborn Mfg. Co., v. Campbell Hausfeld/Scott Fetzer Co.*, 997 F.2d 484, 485–86 (8th Cir. 1993).

Plaintiffs fail to acknowledge the heightened bar they must clear: When a plaintiff seeks to "enjoin the implementation of a duly enacted state statute," a district court must "make a threshold finding that a party is likely to prevail on the merits." *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732–33 (8th Cir. 2008) (en banc). Only after that threshold showing may a court "then proceed to weigh the" other factors. *Id.* at 732. This "more rigorous standard" is intended to ensure that "a state's presumptively reasonable democratic processes" aren't thwarted without "an appropriately deferential analysis." *Id.* at 733.

And when reviewing Iowa statutes, certain canons of construction are black letter law. The Legislature adopted Chapter 4 to provide rules for the construction of Iowa statutes. "In enacting a statute, it is presumed that [c]ompliance with the Constitutions of the state and of the United States is intended." Iowa Code § 4.4(1). "It is presumed that . . . [a] just and reasonable result is intended." *Id.* § 4.4(3). And the "[p]ublic interest is favored over any private interest." *Id.* § 4.4(5). Iowa's laws are also presumed severable. *Id.* § 4.12.

ARGUMENT

I. PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS.

Plaintiffs must show there are no "circumstances" in which a state statute can be constitutionally applied to win on a facial challenge. *Furlow v. Belmar*, 52 F.4th 393, 400 (8th Cir. 2022); *see United States v. Salerno*, 481 U.S. 739, 745 (1987). This they cannot do. As for preemption, the FDCA explicitly allows state food-safety-warning laws such as the Warning Provision. And because the Potency Provision does not concern labeling, there cannot be a conflict with the FDCA. Plaintiffs also invoke the primary jurisdiction doctrine, but that doctrine has never been used to enjoin a state law. It is especially inapplicable here, where FDA has said it will not

promulgate rules on hemp without congressional action. Finally, this Court should not address Plaintiffs' IAPA claim because it lacks jurisdiction over an exclusively state-court matter.

A. House File 2605 Is Not Preempted By The FDCA.

Plaintiffs argue that the FDCA's food-labeling provisions "expressly preempt[]" two parts of HF 2605: the Warning Provision and the Potency Provision. R. Doc. 11 at 3. They are wrong. The Warning Provision is not preempted because the FDCA's preemption provision "shall not be construed to apply to any requirement . . . that provides a warning concerning the safety of the food or a component of the food." NLEA § 6(c)(2). And the Potency Provision says nothing about labeling, so it is not preempted by federal laws regulating labeling, either.

i. Courts start with the assumption that laws like the FDCA do not preempt state law.

When analyzing whether a federal act expressly preempts State law, courts "begin [their] analysis with the assumption that the historic police powers of the States are not to be superseded by the Federal Act." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quotation marks omitted). Only when it is the "clear and manifest purpose of Congress" will state police powers be preempted. *Id.* (citation omitted); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." (quotation marks omitted)).

This presumption against preemption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Grp.*, 555 U.S. at 77. So "'when the text of a pre-emption clause is susceptible of more than one plausible reading,' [courts] must 'accept the reading that disfavors pre-emption.'" *R. J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170, 1176 (8th Cir. 2023) (quoting *Altria Grp.*, 555 U.S. at 77). The same goes under Iowa

law, which codifies the interpretative presumption that "[c]ompliance with the Constitutions of the state and of the United States is intended." Iowa Code § 4.4(1); *State v. Carter*, 733 N.W.2d 333, 335 (Iowa 2007) ("[I]f the statute may be construed in more than one way, we adopt the construction that does not violate the constitution.").

The FDCA regulates health and safety issues that "have traditionally fallen within the province of state regulation," so the assumption that it does not preempt State laws applies here. *Holk*, 575 F.3d at 334–35 (discussing the FDCA's preemption provision); *see also Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people against fraud and deception in the sale of food products."); *Lavoie-Fern*, 610 F. Supp. 3d at 665 ("Matters of safety and public health, and specifically the regulation of food and beverage labeling and branding, have traditionally fallen within the province of state regulation." (quotation marks omitted)); *Sciortino*, 108 F. Supp. 3d at 796 ("The states' historic police powers included laws regulating the proper marketing of food." (quotation marks and alteration omitted)).

ii. The FDCA's preemption provision explicitly carves out state food-safety-warning laws.

Plaintiffs rely on two specific subsections of the FDCA's preemption provision, 21 U.S.C. sections 343–1(a)(4) and (a)(5). R. Doc. 11 at 14. The first subsection, section 343–1(a)(4), preempts State laws that impose requirements that differ from the mandatory nutrients and statistics that the FDCA requires on the "Nutrition Facts" panel on all foods. 21 U.S.C. §§ 343–1(a)(4), 343(q). For example, a State could not ban disclosing a covered product's sodium content. *NYSRA*, 556 F.3d at 118. The second subsection, section 343–1(a)(5), preempts State laws that require labels contain characterizations about the levels of any nutrient required by the "Nutrition Facts" label, 21 U.S.C. §§ 343–1(a)(5), 343(r)(1)(A), or characterizations about the health benefits

or risks of any nutrient, *id.* § 343(r)(1)(B). For example, a State could not require a label to say, "low in sodium" or "fiber reduces cholesterol." *NYSRA*, 556 F.3d at 119.

But Plaintiffs fail to mention the significant statutory limits on those preemption sections. First, a State law is preempted only when "such provision is expressly preempted" under section 343–1(a). NLEA § 6(c)(1). In other words, there is no implied or field preemption. *See Lockwood*, 597 F. Supp. 2d at 1032. And more importantly, section 6(c)(2) states that the FDCA's preemption provision "shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides a warning concerning the safety of the food or a component of the food." NLEA § 6(c)(2). This "broadly worded" exclusion, *Lavoie-Fern*, 610 F. Supp. 3d at 665, is dispositive here.

iii. The Warning Provision is not preempted because it is a warning concerning the safety of the food.

HF 2605's Warning Provision requires that a consumable hemp container "be affixed with a notice advising consumers regarding the risks associated with its use." HF 2605 § 4. That falls squarely within the FDCA's exclusion for "warning[s] concerning the safety of the food." NLEA § 6(c)(2). And although the text of HF 2605 is what matters for preemption analysis, the agency's not-yet-final rule also accomplishes that goal by warning consumers of risks such as unpredictable psychoactive effects, medication interactions, and harm to babies in the womb. *See* Dani Blum, *Weed Drinks Are a Buzzy Alcohol Substitute. But Are They Safe?*, N.Y. Times (Aug. 19, 2022), https://perma.cc/AZ2T-3UV8 (warning that "weed drinks might induce more psychoactive effects than cannabis products that you smoke" and that "you can go from a pleasant experience to a really unpleasant, dysphoric experience really quickly"); Tony Antoniou, *Drug Interactions with Cannabinoids*, 192 Can. Med. Ass'n J. 206 (2020) (listing the side effects of drug interactions); Zeinab Breijyeh, et al., *Cannabis: A Toxin-Producing Plant with Potential Therapeutic Uses*, 13

Toxins 117, 134 (2021) (explaining that "THC and other cannabinoids cross the placenta rapidly" and that "studies have linked maternal cannabis use to impaired memory, impulse control, quantitative reasoning, problem-solving, and verbal development in children aged 1–11 years old").

Courts across the country have held that preemption does not apply to similar warning laws because of the FDCA's broad warning exclusion. Take California's Proposition 65, which requires the following warning on certain food products: "**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov." 27 Cal. Code Regs. § 25603(a)(2)(A). In *Sciortino v. Pepsico, Inc.*, the district court, in a thorough opinion, held that the FDCA did not preempt Proposition 65 because the "the plain language of the NLEA, which is uncontradicted by its legislative history, excludes state law safety warning requirements from the scope of the NLEA's express preemption provision." 108 F. Supp.3d at 795–811.

Proposition 65 applies to consumable hemp products because they contain THC and thus carry the risk of "reproductive toxicity." 27 Cal. Code Regs. § 27001(c). So, if sold in California, Plaintiffs' beverages must contain a label stating: "**WARNING:** This product can expose you to chemicals including Delta-9-tetrahydrocannabinol, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov." *See* 27 Cal. Code Regs. § 25603(a)(2)(B). Other States have similar warning-label laws for hemp consumables. *See, e.g.*, Tenn. Code Ann. § 43-27-209(a)(2)(B) (requiring "[a] warning statement concerning the risk of impairment from consumption of the product, keeping the product out of the reach of children, and other warning information as

required by rule of the department of agriculture"); Minn. Stat. § 151.72, subd. 5a(e)(4) (similar); N.Y. Cannabis Law § 103(1) (similar).

Other courts have reached similar conclusions when addressing warnings involving caffeine consumption, *Fisher v. Monster Beverage Corp.*, 656 F. App'x 819, 823 (9th Cir. 2016), the risks associated with consuming a chemical found in black licorice, *Lavoie-Fern*, 610 F. Supp. at 665, and the risks of consuming high-sodium foods, *Nat'l Rest. Ass'n v. New York City Dep't of Health & Mental Hygiene*, 148 A.D.3d 169, 179–80 (N.Y. App. Div. 2017). There is no meaningful distinction between HF 2605's Warning Provision and those warning provisions.

More to the point, the Warning Provision does not violate the plain text of either of the two preemption provisions Plaintiffs invoke. *First*, the Warning Provision does not violate section 343–1(a)(4), which preempts State laws that impose "requirement[s] for *nutrition labeling* of food that [are] not identical to" the mandatory nutrient disclosures in section 343(q), because it does not impose any requirement relating to the required nutrient disclosures described in section 343(q). 21 U.S.C. § 343–1(a)(4) (emphasis added).

Second, the Warning Provision does not violate section 343–1(a)(5), which preempts State laws that require characterizations of "the level of any *nutrient required*" in the mandatory "Nutrition Facts," section 343(r)(1)(A) (emphasis added), or characterizations of "the relationship of *any nutrient which is of the type required*" to appear in the "Nutrition Facts" to "a disease or a health-related condition," section 343(r)(1)(B) (emphasis added). THC is not a "nutrient" that is required or of the type that is required in the "Nutrition Facts." And Plaintiffs do not point to any regulation classifying it as such. The Fifth Circuit put it well: "a state law requiring warning labels concerning an ingredient *not addressed by the FDCA* would not be preempted." *Spano ex rel. C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 263 (5th Cir. 2023) (emphasis added); *see also* 136 Cong. Rec.

H5842 (July 30, 1990) (statement of Rep. Waxman) (Congressional statement of intent noting that the warning exclusion "may be unnecessary" because the FDCA "does not require health warnings," and thus its preemption provision does not apply to "state laws requiring health warnings"). The warning required by HF 2605 therefore falls outside the scope of this preemption provision.

Plaintiffs completely ignore the NLEA's warning exclusion. As a result, none of the cases they cite are relevant to the issue here because none addresses State-mandated safety warnings. *See Pardini v. Unilever U.S., Inc.*, 65 F.4th 1081, 1083 (9th Cir. 2023) (involving a labeling issue that turned on whether "I Can't Believe It's Not Butter! Spray" is a butter or a spray); *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1189 (11th Cir. 2018) (whether a protein powder correctly listed its nutrients); *Yonan v. Walmart, Inc.*, 591 F. Supp. 3d 1291, 1295 (S.D. Fla. 2022) (whether a Coffee Mate product accurately reported the number of servings).

The FDCA's preemption exclusions thus show that Plaintiffs' claim that "Congress included an express preemption provision to clearly occupy *the entire field of food labeling*," R. Doc. 11 at 14 (emphasis added), is inaccurate. *See Lockwood*, 597 F. Supp. 2d at 1032 (explaining that "Congress . . . explicitly stated that it does not intend to occupy the field of food and beverage nutritional labeling").

Even cases in which courts held the warning exclusion did not apply do not help Plaintiffs' case here. *See, e.g.*, *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104, 109 (D.D.C. 2006) (involving a warning that milk could cause gastric effects to the lactose intolerant); *In re Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.*, 2009 WL 3762965, at *6 (W.D. Mo. Nov. 9, 2009) (involving a warning about a chemical in plastic). In each case FDA had made a safety determination. *See Mills*, 441 F. Supp. 2d at 109 (FDA concluding that "the risk of gastrointestinal

irritations . . . does not implicate 'safety' concerns"); *In re BPA*, 2009 WL 3762965, at *6 (FDA concluding that "the use of BPA in epoxy liners is 'safe'"). FDA has made no such determination here. To the contrary, Plaintiffs predict FDA would "treat[] cannabis-derived ingredients as a food additive." R. Doc. 11 at 17. That means, under the FDCA, that it would be considered presumptively unsafe. *See* 21 U.S.C. § 348(a) (establishing that "[a] food additive shall . . . be deemed to be unsafe" unless certain conditions are met); R. Doc. 11 at 13 (Plaintiffs agreeing).

Even so, *Mills* and *In re BPA* were wrongly decided. The FDCA's warning exclusion—a statute—trumps FDA's rulemaking, and an FDA rule that a product is "safe" despite potential risks establishes a regulatory minimum that States can supplement with additional warnings. *See Sciortino*, 108 F. Supp. 3d at 802 (disagreeing with *In re BPA* for this reason).

Congress intended that federal law would not preempt provisions such as HF 2605's Warning Provision. At a minimum, there is no such clear and manifest purpose of Congress. *See, e.g.*, 136 Cong. Rec. H5840 (July 30, 1990) (statement of Rep. Waxman) (sponsor of the NLEA explaining the preemption provision "explicitly permit[s] the States to adopt requirements for warning about the ingredients or components of food").

iv. The Potency Provision is not preempted because it says nothing about labeling.

Plaintiffs' challenge to the Potency Provision fares no better. The only federal preemption that Plaintiffs invoke to challenge the Potency Provision relates to labeling. But the Potency Provision is not about labeling. Consider its text:

> 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.

HF 2605 § 2. Rather, the Potency Provision limits the amount of THC in consumable hemp products—a regulation that the federal Farm Bill expressly permits. *See N. Virginia Hemp & Agric.*, 2023 WL 7130853, at *1 (explaining that the Farm Bill allows "state regulation of . . . the growth, production, sale, and use of industrial hemp and hemp products" (citing 7 U.S.C. § 1639p)); 7 U.S.C. § 1639p(a)(3) (allowing States to regulate hemp "more stringent[ly]" than federal law). Plaintiffs do not argue that States cannot set limits of this type.

The Court should end its preemption analysis here, at the statute's text, because the Department's rule is not yet final and could change before it goes into effect. After all, in a pre-enforcement, facial challenge like this, Plaintiffs must establish it is likely that there is no constitutional application of the state statute. *Salerno*, 481 U.S. at 745. Courts do not assume a State's future unconstitutional interpretation or enforcement of a law, nor do they preempt state laws based on "'hypothetical' or 'imaginary' cases." *Wash. State Grange v. Wash. State Rep. Party*, 552 U.S. 442, 449–50 (2008).

Even if the Court were to trudge on and address the Department's not-yet-final rule that may very well change, there would be no preemption issue. The current draft of the Department's proposed rule would require two things.

First, that products be "packaged in a container that holds a minimum of 12 fluid ounces." 46 Iowa Admin. Bull. at 10077. This would be a permissible regulation of the amount of THC in hemp consumables, which is not preempted by the Farm Bill. Nor does it require any particular labeling.

Second, that "[i]f a liquid consumable hemp product is packaged in a manner that includes more than a single serving, the number of servings must be conspicuously labeled." *Id.* This

provision simply tracks the FDCA's requirement that "the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food" and "the number of servings or other units of measure per container." 21 U.S.C. § 343(q)(1)(A)(i), (1)(B). And how would the Department's not-yet-final rule measure what counts as a serving for these beverages? By adopting FDA's regulations on serving sizes. 46 Iowa Admin. Bull. at 10077 ("'Serving' means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12."). Here, because Plaintiffs' beverages primarily consist of carbonated water, Selix Decl. ¶ 6; Caraher Decl. ¶ 6, FDA's required label statement for serving size would be 12 oz, 21 CFR § 101.12, Table 2—the size in which Plaintiffs currently serve their beverages.

Plaintiffs instead emphasize that FDA's required label statement for serving size of fruit juice is 8 oz, but they do not allege that their companies offer any fruit juices; they allege instead that they provide only carbonated beverages. And even if they did, the draft rule would merely require Plaintiffs to disclose that their 12-oz containers contain one-and-a-half servings, in accordance with federal regulations. Plaintiffs thus fail to show any conflict between state and federal law: The not-yet-final rule would not require Plaintiffs to label their beverages contrary to any federal requirement.

Plaintiffs therefore cannot show they are likely to succeed on the merits of either of their preemption arguments. The Court should deny their request for a preliminary injunction.

B. The Primary Jurisdiction Doctrine Does Not Apply Here.

Primary jurisdiction is a common-law doctrine "utilized to coordinate judicial and administrative decision making." *Access Telecommunications v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998). It is "invoked sparingly," because it "results in added expense and delay." *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 477 (8th Cir.1988). The main reasons to

apply the doctrine include when an issue of fact is not within the "conventional experience of judges" and instead requires agency expertise, or to promote uniformity within a particular field of regulation. *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938–939 (8th Cir. 2005). "The advisability of invoking primary jurisdiction is greatest when the issue is already before the agency." *Chase v. Andeavor Logistics, L.P.*, 12 F.4th 864, 870 (8th Cir. 2021) (quotation marks omitted). At bottom, the point of the doctrine is to delay issuing a judicial decision when an agency will soon issue final rules on point to the question before the court.

This is not such a case. Iowa, in enacting HF 2605, invokes its traditional role—preserved under the FDCA—to require food safety warnings on labels. A federal agency's expertise is not needed to evaluate a law in a field that has "traditionally fallen within the province of state regulation." *Holk*, 575 F.3d at 334.

Moreover, Plaintiffs cite no case where a court invoked the doctrine to stay enforcement of a statute. Instead, as Plaintiffs recognize, the primary jurisdiction doctrine allows courts to defensively "stay the enforcement of a *case*–not a statute–pending administrative review." R. Doc. 11 at 18–19 (emphasis in original) (collecting cases).

Finally, Plaintiffs rely on cases where the agency was already in the process of rulemaking, so a court agreed to apply the doctrine and stay the case "until the [agency] completes its rulemaking" and elaborates on an area requiring the agency's factual expertise. *Snyder v. Green Roads of Fla. LLC*, 430 F. Supp. 3d 1297, 1307 (S.D. Fla. 2020); *see, e.g.*, *Ahumada v. Glob. Widget, LLC*, 2020 WL 5669032, at *2 (D. Mass. Aug. 11, 2020) (applying doctrine and staying case "[g]iven the imminence of FDA's rulemaking in this area"); *Colette v. CV Scis., Inc.*, 2020 WL 2739861, at *5 (C.D. Cal. May 22, 2020) (staying case because FDA "is working feverishly" to develop rules); *Glass v. Glob. Widget, LLC*, 2020 WL 3174688, at *4 (E.D. Cal. June 15, 2020)

(same, citing *Colette*); *Ivie v. Kraft Foods Glob., Inc.*, 2013 WL 685372, at *7 (N.D. Cal. Feb. 25, 2013) (doctrine applied because "FDA is currently engaged in rulemaking procedures"). But here there is nothing for this Court to wait for because, as Plaintiffs well recognize, FDA "would not implement further regulation" in this area "without Congressional action." R. Doc. 11 at 6. So not only is there no ongoing, on-point federal rulemaking, but FDA has said it will not even begin any such rulemaking absent further action by Congress. The doctrine does not apply.

C. Plaintiffs' Iowa Administrative Procedure Act Claim Fails

Plaintiffs seek judicial review under the IAPA of the Department's June 7 FAQ Guidance. R. Doc. 1 ¶ 57. But because Iowa state courts have exclusive jurisdiction over IAPA claims, Iowa Code § 17A.19(2), this Court lacks jurisdiction.

1. State court is the sole avenue for judicial review of an Iowa agency's action. *Id.* § 17A.19. The IAPA provides that "[p]roceedings for judicial review shall be instituted by filing a petition either in Polk county district court or in the district court for the county in which the petitioner resides or has its principal place of business." *Id*. § 17A.19(2). That section of the IAPA is the "exclusive means by which a person or party . . . may seek judicial review of such agency action." *Id*. § 17A.19. But if a plaintiff brought a federal constitutional challenge to an Iowa statute or final rule, then this Court could have jurisdiction to hear those constitutional claims. *See Lunde v. Schultz*, 221 F. Supp. 3d 1095, 1099–1100 (S.D. Iowa 2014) (holding that while an IAPA claim would not be proper in federal court, a request for a declaratory judgment that an Iowa statute was unconstitutional was). That is because "[a] federal court does not have jurisdiction . . . to award relief against a State based only on State law where violation of State law does not amount to a constitutional violation." *Harmon v. Auger*, 768 F.2d 270, 275 (8th Cir. 1985). The IAPA is a "is a comprehensive procedural plan established by State law. Violation of the Act is a violation of

State law and not of due process. Jurisdiction to construe the State statute is in the State Courts of Iowa." *Id*.

Plaintiffs' attempt to seek "Judicial Review of Agency Action" in federal district court is thus improper. R. Doc. 1 at 9. Plaintiffs' IAPA claim is not a federal constitutional challenge but relies solely on the IAPA. *See id.* ¶¶ 54–58 (count two; exclusively citing Iowa law in support of IAPA claim). They admit their claim "seek[s] judicial review of the Department's June 7 Guidance," *id.* ¶ 57, a far cry from bringing a constitutional challenge to a state agency action. Plaintiffs' only federal constitutional claim is their preemption count, and that fails for the reasons explained above. *See id.* ¶¶ 45–53 (count one). Plaintiffs' third and fourth counts—for injunctive and declaratory relief—rely only on the first two substantive counts and thus do not remedy the IAPA claim's pleading deficiency. *Id.* at 11–12.

This Court should not go beyond Plaintiffs' Complaint to find a federal hook. *Cf. Lunde*, 221 F. Supp. 3d at 1100 (finding federal jurisdiction where a pro se plaintiff's requests were "somewhat difficult to discern," because the complaint stated "a request for a declaratory judgment that the challenged state statutes are unconstitutional *and not as a request solely to review the Secretary of State's decision*" (emphasis added)). Because the petition for judicial review was not filed in State court and is not constitutional, this Court lacks jurisdiction.

2. Even if this Court had jurisdiction, judicial review would still be improper for two reasons.

First, despite their contention otherwise, Plaintiffs do not challenge a "final agency action" as required by Iowa Code § 17A.19(1). *See* R. Doc. 1 at ¶¶ 56–58. An agency action is final if "the agency has completed its decisionmaking process" and "the result of that process is one that will directly affect the parties." *Dunn v. City Dev. Bd. of Iowa*, 623 N.W.2d 820, 825 (Iowa 2001).

The agency action challenged here is not final because the Department has not yet completed its decisionmaking process. Plaintiffs do not challenge the Department's Draft Rules, but an FAQ sheet explaining those draft rules, which Plaintiffs opt to call "formal guidance." R. Doc. 1 ¶¶ 55, 58. But "formal" does not mean "final." As the FAQ notes, there are two remaining hearings—on July 2 and July 8—where the public can comment on the proposed rules. *See* FAQ Guidance at 6 ("Standard administrative rule adoption procedures will apply and Registrants will be able to provide comments on proposed and noticed rules throughout the process and before the rules become effective."). And the rules will not be final until, at the earliest, July 17. *Id*.

Because final administrative rules often differ from proposed rules, the Department seemingly would issue updated guidance explaining any changes. Indeed, as Plaintiffs acknowledge, the Department issued an initial FAQ on May 24, 2024, only to issue a revised FAQ on June 7. R. Doc. 11 at 8–9. Just like the May 24 FAQ, the June 7 FAQ can be revised any time. This challenged FAQ—like the draft rules—is thus not a "final agency action." *Dunn*, 623 N.W.2d at 825.

Second, Plaintiffs have not exhausted their administrative remedies. Under the IAPA, a party challenging a final agency action must exhaust "all adequate administrative" remedies before seeking judicial review. *See* Iowa Code § 17A.19(1). Here, exhaustion requires Plaintiffs to first present their objections to the Department under Iowa Code section 17A.7, which allows "an interested person [to] petition an agency requesting the promulgation, amendment, or repeal of a rule." *See Schmitt v. Iowa Dep't of Soc. Servs.*, 263 N.W.2d 739, 742 (Iowa 1978); *Sierra Club Iowa Chapter v. Iowa Dep't of Transp.*, 832 N.W.2d 636, 648 (Iowa 2013) (stating this rule after an in-depth statutory analysis). Only after the Department issues a decision on that petition can Plaintiffs seek judicial review in state court. *Id*. That is because the state "court sits as an *appellate*

court in judicial review of a final agency action,*"* not as the initial adjudicator. *IES Utilities Inc. v. Iowa Dep't of Revenue & Fin.*, 545 N.W.2d 536, 539 (Iowa 1996). Plaintiffs have not done so.

None of the exceptions to the exhaustion requirement apply here. *See id*. at 538 (describing exceptions to the exhaustion requirement). For example, there is an exception for when a plaintiff claims a final agency action violates the rulemaking procedures set forth in the IAPA. *Lundy v. Iowa Dep't of Hum. Servs.*, 376 N.W.2d 893, 896 (Iowa 1985). But Plaintiffs present both substantive and procedural challenges to the FAQ, *see* R. Doc. 11 at 21–28, so that exception does not apply. *Lundy*, 376 N.W.2d at 896.

Even if this Court had jurisdiction (it does not), and even if Plaintiffs had exhausted their administrative remedies (they have not), Plaintiffs' IAPA claims would still fail on the merits. Plaintiffs first argue that the Department impermissibly created policy through guidance instead of through rulemaking. R. Doc. 11 at 21. Not so. The Department followed the proper rulemaking process under the IAPA by proposing rules under its statutory authority, helping explain the proposed rules, and opening the proposed rules to a notice and comment period. *See* FAQ Guidance at 1, 5, 6. The Department did not purport to make rules or policy through its June 7 FAQ guidance; it sought to explain the proposed rules implementing HF 2605. *See id*. at 1. That is well within the Department's authority. *See* HF 2605 §§ 4, 6, 8.

Plaintiffs' argument that the Department unreasonably interpreted certain terms in HF 2605 also fails. The Legislature gave the Department rulemaking authority under HF 2605, and that authority requires the Department to interpret the law's provisions. When a term is not defined in a statute, an agency must interpret the term to carry out its duties. *Burton v. Hilltop Care Ctr.*, 813 N.W.2d 250, 257 (Iowa 2012); *see also Renda v. Iowa C.R. Comm'n,* 784 N.W.2d 8, 12 (Iowa 2010) (holding that when an agency "must necessarily interpret [an undefined term] in order

to carry out its duties, the power to interpret the term [is] clearly vested in the department and deference [is] therefore given").

HF 2605 has two potency limitations: "four milligrams per serving or ten milligrams per container on a dry weight basis." HF 2605 § 2. As Plaintiffs recognize, the law does not define "serving" or "container," so the Department must define those terms. *See Renda,* 784 N.W.2d at 12. In doing so, the Department must give effect to both the per-serving limitation and the per-container limitation—it cannot define one term in a way that would render another superfluous. *See* Iowa Code § 4.4(2).

Starting with "serving," it is entirely reasonable to define "serving" based on federal law: "'Serving' means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12." FAQ Guidance at 1. Tellingly, Plaintiffs offer no alternative definition of "serving."

And to avoid nullifying the per-serving limitation, it is reasonable to define "container" in this context to mean an "object that holds one or more servings of a consumable hemp product." 46 Iowa Admin. Bull. at 10077. Defining "container" as expansively as Plaintiffs suggest would render the per-serving limitation practically meaningless. Plaintiffs argue "container" means any receptacle. R. Doc. 11 at 27. But that would allow a 1-serving (12-oz) container to contain 10 mg of THC, and it would even allow a 1-oz container to contain 10 mg of THC. In other words, Plaintiffs prefer a definition that would read out of the statute the per-serving limitation. That is contrary to black letter Iowa law, and ordinary tools of interpretation. *See* Iowa Code § 4.4(2); *Bribriesco-Ledger v. Klipsch*, 957 N.W.2d 646, 650–651 (Iowa 2021) (courts "interpret every word and every provision of a statute to give it effect" and avoid making a section "superfluous").

Just because the per-serving standard is more limiting than the per-container standard does not mean the Department's interpretation is unreasonable. Relatedly, the requirement that beverages be a minimum of 12 oz is a reasonable exercise of the Department's authority to promulgate "packaging . . . requirements," which ensure that beverages with THC are sold in familiar quantities. HF 2605 § 4.

For these reasons, this Court lacks jurisdiction over Plaintiffs' IAPA claims. Should the Court conclude it has jurisdiction, Plaintiffs' claims likely fail on the merits.

II. THE OTHER FACTORS WEIGH AGAINST A PRELIMINARY INJUNCTION

Because Plaintiffs are unlikely to succeed, the Court need not proceed to the other preliminary injunction factors. *See Rounds*, 530 F.3d at 732. But those factors also weigh against an injunction.

Plaintiffs have not shown irreparable harm. They must show the alleged "harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Powell v. Noble*, 798 F.3d 690, 702 (8th Cir. 2015). But uncertainty stemming from a new regulation, even paired with the cost of complying with that new regulation, is "typically insufficient to constitute irreparable harm." *Morehouse Enterprises, LLC v. ATF*, 2022 WL 3597299, at *12 (D.N.D. Aug. 23, 2022), *aff'd,* 78 F.4th 1011 (8th Cir. 2023). Nor is the threat of criminal prosecution enough to justify a preliminary injunction—indeed, the Eighth Circuit has rejected claims that a risk of prosecution, without more, is an irreparable harm. *See, e.g.*, *Munson v. Gilliam*, 543 F.2d 48, 54 (8th Cir. 1976); *Bacon v. Neer*, 631 F.3d 875, 879 (8th Cir. 2011).

Plaintiffs' delay in bringing this suit underscores their inability to show imminent harm. After a lengthy and highly-publicized legislative process—of which Plaintiffs were well aware, *see* Galen Bacharier, *Iowa House Passes Consumable Hemp Regulations, Including Age Threshold and Potency Limit*, Des Moines Register (Mar. 12, 2024), perma.cc/WA2Y-KMNW (Climbing

Kites CEO commenting on the proposed bill in March 2024)—the Legislature passed HF 2605 on April 2, 2024, and Governor Reynolds signed it on May 17, 2024. But Plaintiffs waited to sue until 14 days before the law was set to take effect. Such a delay "vitiates much of the force of" any "allegations of irreparable harm." *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 895 (8th Cir. 2013). It is no excuse that Plaintiffs were waiting for the agency to issue guidance or rules, because the exclusive way to object to final agency action, of course, is in state court under Iowa Code Chapter 17A, and not via federal suit.

Once Plaintiffs did finally sue, they did not seek an expedited briefing schedule, even though the default briefing schedule under the Local Rules would mean their motion would not be decided until after HF 2605 took effect. *Cf. Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016) (The "very idea of a preliminary injunction is premised on the need for speedy and urgent action," so a "delay in seeking a preliminary injunction of even only a few months—though not necessarily fatal—militates against a finding of irreparable harm.").

No one has the right to be a civil plaintiff in federal court. *See Whole Woman's Health v. Jackson*, 595 U.S. 30, 48–50 (2021). Plaintiffs could assert any constitutional claims as an as-applied defense to state prosecution, and the Iowa courts would be constitutionally obligated to entertain them. *See, e.g.*, *Testa v. Katt*, 330 U.S. 386, 392–93 (1947). In cases like this, a plaintiff needs to show there is reason to "doubt [] the capacity of the [Iowa] state courts to adequately protect [the plaintiff's] constitutional rights." *Munson*, 543 F.2d at 54. Plaintiffs cannot make that showing here, so they lack any plausible claim of irreparable harm.

To the extent irreparable harm does exist, it is borne by the State. "[A]ny time a State is enjoined by a court from effectuating statutes . . . it suffers a form of irreparable injury." *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers);

see Org. for Black Struggle v. Ashcroft, 978 F.3d 603, 609 (8th Cir. 2020) (similar). Indeed, statutes are supposed to be "presumed constitutional and all doubts are resolved in favor of constitutionality." *Arkansas Times LP v. Waldrip as Tr. Of Univ. of Ark. Bd. of Trustees*, 37 F.4th 1386, 1393 (8th Cir. 2022). That is not just a principle or canon of construction in Iowa; that is black letter Iowa law. *See* Iowa Code § 4.4.

Moreover, "the State's interest in the enforcement of its criminal laws" is among the most important interests. *Juidice v. Vail*, 430 U.S. 327, 335 (1977). And the Supreme Court has long recognized that States have a unique interest in the health and well-being of their people. *See, e.g.*, *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 602 (1982). Here, an injunction risks exposing Iowans to health risks. THC is, most generously, an understudied substance. "[W]eed drinks might induce more psychoactive effects than cannabis products that you smoke," and a user "can go from a pleasant experience to a really unpleasant, dysphoric experience really quickly." Blum, *supra*. At worst, it can cause severe birth defects, can make driving while intoxicated even more dangerous than it already is, and is addictive. Breijyeh, et al., *supra*, at 134; Antoniou, *supra*, at 206. There is a strong public interest in protecting Iowans, especially the vulnerable population like children, from such risks. Meanwhile, the risks Plaintiffs face include (1) having to sell a drink containing a substance (that has been legal for only a few years) at lower concentrations and (2) having to warn their consumers of the well-documented health risks posed by the THC Plaintiffs put in their drinks. The balance of this harm compared to exposing Iowans—without warning—to health risks weighs against an injunction.

CONCLUSION

For these reasons, the Court should deny the preliminary injunction.

Respectfully submitted,

BRENNA BIRD
Attorney General of Iowa

/s/ *Eric Wessan*
Eric Wessan
Solicitor General

/s/ *Patrick C. Valencia*
Patrick C. Valencia
Deputy Solicitor General

/s/ *William C. Admussen*
William C. Admussen*
Assistant Solicitor General
*Admitted *Pro Hac Vice*

/s/ *Alexa S. Den Herder*
Alexa S. Den Herder
Assistant Solicitor General

Iowa Department of Justice
Hoover State Office Building
Des Moines, Iowa 50319
(515) 823-9117 / (515) 281-5191
(515) 281-4209 (fax)
eric.wessan@ag.iowa.gov
patrick.valencia@ag.iowa.gov
william.admussen@ag.iowa.gov
alexa.denherder@ag.iowa.gov

ATTORNEYS FOR DEFENDANTS

Original filed electronically.
Copy electronically served on all parties of record.

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served on counsel for all parties of record by delivery in the following manner on June 26, 2024:

☐ U.S. Mail ☐ FAX
☐ Hand Delivery ☐ Overnight Courier
☐ Federal Express ☐ Other
☒ CM/ECF

Signature: /s/*Patrick C. Valencia*