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. STATE OF IOWA, KELLY GARCIA, in her official capacity as Director of Iowa Department of Health and Human Services, IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	)	Case No. 4:24-cv-00202-SMR-SBJ ORDER ON PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Plaintiffs Climbing Kites, LLC ("Climbing Kites") and Field Day Brewing Company, LLC ("Field Day") manufacture and sell beverages infused with THC derived from hemp. Their products are legal under federal and state law after Congress and then the Iowa legislature passed bills legalizing the production and consumption of hemp products. Earlier this year, the Iowa legislature changed the permissible THC content in these beverages and added a required warning label. Shortly thereafter, the Iowa Department of Health and Human Services (the "Department") proposed regulations pursuant to the new law.

Plaintiffs claim that law, House File 2605 ("HF 2605"), is preempted by federal law. They maintain that their products are "food" governed by the Food, Drug, and Cosmetic Act ("FDCA") but the HF 2605 imposes potency limits and labeling requirements that are not identical to the FDCA. Plaintiffs assert that the Food and Drug Administration ("FDA") has authority in this realm but has not acted on these products, so state legislatures may not either. Furthermore, they argue that the Department's guidance regarding the minimum container and serving size under HF 2605

is unreasonable and transgresses the goal of the legislature in enacting the law. Plaintiffs seek a preliminary injunction that prohibits the enforcement of its provisions before it goes into effect on July 1, 2024. The Court denied the Motion for Preliminary Injunction on June 28, 2024—this Order sets forth the reasons for the disposition. [1] [ECF No. 25].

I. BACKGROUND

A. Factual Background[2]

Marijuana is a drug that is comprised from the cannabis sativa plant. *The Federal Status of Marijuana and the Policy Gap with States*, Congressional Research Service (2024) ("Cong. Rsch. Serv."). While there are currently legislative proposals to change marijuana's scheduled status as a controlled substance, it is still classified as a Schedule I drug under the Controlled Substances Act ("CSA") and is strictly regulated. *Id*.; Cannabis Administration and Opportunity Act, S. 4226, 118th Cong. (2024) (as introduced May 1, 2024). Before 2018, the definition of marijuana in the CSA included hemp. *Id.* However, in 2018, Congress passed the Farm Bill and defined hemp as any part of the cannabis sativa plant with a delta-9 THC that does not exceed 0.3% based on a dry weight.[3] 7 U.S.C. § 1639o.

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[1] On that same day, shortly after the Court issued its denial of the Motion for Preliminary Injunction, Plaintiffs filed an amended complaint adding a claim that HF 2605 was unconstitutionally vague, and sought a temporary restraining order pursuant to the amended pleading. [ECF Nos. 24; 26]. The Court denied the motion for a temporary restraining order and set an expedited hearing on Plaintiffs' newly-raised claim for July 11, 2024. [ECF No. 27].

[2] "[F]indings of fact and conclusions of law made by a court granting a preliminary injunction are not binding." *Patterson v. Masem*, 774 F.2d 251, 254 (8th Cir. 1985). "Affidavits submitted at the preliminary injunction phase need not meet the requirements of affidavits under Rule 56(c)(4), but courts may consider the competence, personal knowledge and credibility of the affiant in determining the weight to give the evidence." *Wymore v. City of Cedar Rapids, Iowa*, 635 F. Supp. 3d 706, 710 (N.D. Iowa 2022) (cleaned up) (citation omitted).

[3] THC is the psychoactive compound in marijuana. Cong. Rsch. Serv.

Pursuant to the Farm Bill, hemp was removed as a controlled substance under the CSA and its production was permitted under federal law. 21 U.S.C. § 802. While Congress's intent may have been to deregulate hemp to facilitate its use in agriculture and the production of commodities, one consequence of the Farm Bill was that THC could now be added to consumable products.[4] First, the Farm Bill only limits the potency of delta-9 THC. However, there are other types of THC, such as delta-8 and delta-10, which can be derived from hemp and used as an intoxicant. *Id*. Second, although a 0.3% limit on a dry weight basis for THC would preclude its intoxicating effects if it were consumed as inhalant, when infused into beverages and other food, these products may be very intoxicating even under the statutory potency limit.[5]

Regardless of Congress's intent, the legalization of hemp in the Farm Bill opened wide the gates for production of intoxicating products containing THC, which soon found its way into consumable products and became the subject of extensive litigation. *See AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682 (9th Cir. 2022); *C.Y. Wholesale, Inc. v. Holcomb*, 965 F.3d 541 (7th Cir. 2020); *Bio Gen, LLC v. Sanders*, 690 F. Supp. 3d 927 (E.D. Ark. 2023); *N. Virginia Hemp & Agric. LLC v. Virginia,* No. 123CV1177LMBIDD, 2023 WL 7130853 (E.D. Va. Oct. 30, 2023);

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[4] Meghan Thompson, Travis Yuille, *ANALYSIS: How Congress Created a Legal Market for THC- By Mistake,* Bloomberg Law, (April 23, 2024), https://www.bloomberglaw.com/bloomberglawnews/bloomberg-law-analysis.

[5] Andrew Kline, *Hemp-Derived Intoxicants Need Better Cannabis Law Guardrails,* Bloomberg Law (Feb. 12, 2024), https://www.bloomberglaw.com/product/blaw/bloomberglawnews/cannabis/X26IA2BC000000?bc.

At the preliminary injunction hearing, Plaintiffs admitted the impracticality of the 0.3% potency limit in consumable hemp beverages when they explained that their products could contain a gram of THC and still comply with that regulation.

AK Indus. Hemp Ass'n, Inc. v. Alaska Dep't of Nat. Res., No. 3:23-CV-00253-SLG, 2023 WL 8935020, at *1 (D. Alaska Dec. 27, 2023).

The Farm Bill gave the Secretary of the United States Department of Agriculture the "sole authority to issue Federal regulations and guidelines that relate to the production of hemp," but it also set up a framework for state plan approval which would allow them to have "primary regulatory authority over production of hemp" in their state. 7 U.S.C. § 1639p. The Farm Bill explicitly held that it was not preempting or limiting states from regulating the production of hemp as long as state laws were consistent with the federal provisions.[6] *Id*. However, it also states that nothing in the Farm Bill affects or modifies the FDCA or the authority of the Commissioner of the FDA and the Secretary of the United States Department of Health and Human Services "to promulgate Federal regulations and guidelines that relate to the production of hemp under the Act described in [the FDCA] or [the Regulation of biological products]." 7 U.S.C. § 1639r.

In 2019, Iowa passed the Iowa Hemp Act ("IHA"), which required the Iowa Department of Agriculture to prepare a plan to be submitted to the United States Secretary of Agriculture pursuant to the 2018 Farm Bill. Iowa Code § 204.3.[7] The IHA defined hemp in accordance with the Farm Bill and explicitly stated that a hemp product does not include "[a]n item or part of an item with a maximum tetrahydrocannabinol concentration that exceeds three-tenths of one percent on a dry weight basis." Iowa Code § 204.2. The IHA removed hemp products that complied with

[6] The bill makes clear that it would be a violation of an approved state plan for a hemp producer to produce cannabis with a THC level of more than 0.3% on the dry weight basis. *Id.*

[7] The IHA was amended in 2020. These amendments, among other changes, set a definition for a "consumable hemp product." Iowa Code § 204.2.

the statute from the definition of a controlled substance under Iowa law and set out regulations for the production and sale of hemp in Iowa. It specifically states:

> [A] consumable hemp product shall not be manufactured, sold, or consumed in this state unless all of the following conditions are met:
>
> (1) The consumable hemp product is manufactured in this state in compliance with this chapter.
>
> (2) The hemp contained in the consumable hemp product was produced exclusively in this state in compliance with this chapter.
>
> (3) The consumable hemp product complies with packaging and labeling requirements, which shall be established by the department of health and human services by rule.

Iowa Code § 204.7.[8]

The Department promulgated rules and regulations as provided by the IHA. In pertinent part, those regulations stated that a consumable hemp product may only be sold or distributed if it has the proper documentation identifying the jurisdiction of origin and a certificate of analysis which states that (1) the product was tested by an independent accredited laboratory, (2) the presence and concentration of cannabinoids as is marketed, (3) that the product came from a batch with THC that did not exceed the 0.3% dry weight calculation, and (4) that it had been tested for pesticides and other toxicants and is compliant with the limits in the rule. Iowa Admin. Code r. 481-32.3 (2021); Iowa Admin. Code r. 641-156.3 (2023). Notably, neither the statute, nor the Department's rule, placed restrictions on THC content.

The Department's regulations did, however, specify requirements for packaging and labeling of products. It required that individual sale hemp products must be plainly identified as a consumable hemp product and must include:

> a. Lot number;

[8] There are exceptions to the requirement that the hemp product be manufactured in the state as well as other registration and licensing requirements under the IHA. Iowa Code § 204.7(8).

> b. Expiration date;
>
> c. Product name;
>
> d. Name, telephone number, and email address of the product manufacturer;
>
> If specific cannabinoids are contained within or marketed for the product, the number of milligrams of each cannabinoid per serving and serving size;
>
> a. A certificate of analysis that the batch contained a total delta-9 tetrahydrocannabinol concentration that did not exceed .3 percent on a dry weight basis as calculated pursuant to an official test as provided in Iowa Code section 204.8.[9]

Iowa Admin. Code r. 481-32.4 (2021); Iowa Admin. Code r. 641-156.4 (2023). Under this backdrop of Iowa law, companies like Plaintiffs began producing THC products. [ECF No. 11 at 4].

Climbing Kites sells beverages that differ in flavor and THC content. The company offers canned beverages with 5, 10, and 20 milligrams of cannabidiol ("CBD") and 2.5, 5, and 10 milligrams of total THC per beverage. [ECF No. 2-1 ¶ 8]. Field Day currently sells canned beverages containing 2, 7, and 15 milligrams of CBD and 2, 7, and 15 milligrams of total THC per beverage. [ECF No. 2-2 ¶ 8]. Iowa law requires that these products contain 0.3% or less THC, but both companies aver that their products contain a fraction of that limit. [ECF Nos. 2-1 ¶ 9; 2-2 ¶ 9].

On May 17, 2024, the Iowa legislature passed HF 2605, which set limits on lawful THC content for consumable hemp products. H.F. 2605, 90th Gen. Assemb., 2nd Reg. Sess. (Iowa 2024). The provision which the Court will refer to as the "Potency Limit" provides in relevant part:

[9] The rules allow this information to be presented in the form of website link, a QR code, or a bar code on the label. Iowa Admin. Code r. 481-32.4(2) (2021); Iowa Admin. Code r. 641-156.4(2) (2023).

> *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. The Potency Limit will be codified at Iowa Code § 204.2(*c*). HF 2605 also empowered the Department to establish rules for packaging and labeling of consumable hemp products. That section, to be codified at Iowa Code § 204.7(8)(*a*)(3), states:

> (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.

Pursuant to the authority delegated by HF 2605, the Department promulgated proposed rules regarding consumable hemp products on June 7, 2024 which, in accordance with rulemaking requirements under the Iowa Administrative Procedures Act ("APA"), were then republished in a Notice of Intended Action on June 12, 2024 ("Guidance"). 46 Iowa Admin. Bull. at 10074. Plaintiffs challenge two specific provisions in the Guidance.

First, the Guidance states that a "serving" of a liquid consumable hemp product must be a minimum of 12 fluid ounces. *Id*. The Guidance reflects that this standard is derived from FDA regulations which designate a "serving" for carbonated and noncarbonated beverages, wine coolers, and water as 12 fluid ounces. *See* 21 C.F.R. § 101.12(a) (explaining that a serving size is the amount "customarily consumed per eating occasion").

Second, the Guidance also proposes warning label information regarding the risks of the consumable hemp products. This will be referred to as the Warning Provision:

> 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 [impact][10] 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.

46 Iowa Admin. Bull. at 10074.

On June 17, 2024, only five days after the Department filed the Notice of Intended Action to implement the Potency Limits and Warning Provision, Plaintiffs filed this lawsuit. They sought a preliminary injunction prohibiting the enforcement of HF 2605 and the Department's Guidance on the grounds that it is preempted by the FDCA. They alternatively argue that HF 2605 and the Guidance should be stayed pending a regulatory decision by the FDA on serving and labeling requirements, and that the Department exceeded its interpretive authority granted by the IHA and HF 2605.

B. Procedural Background

Plaintiffs filed their Complaint and Motion for Preliminary Injunction on June 17, 2024. [ECF No. 2]. Plaintiffs sought expedited relief prior to July 1, 2024 when HF 2605 goes into effect. The Court ordered an expedited briefing schedule from the parties, granting Defendants an extension until June 26, 2024 to respond, and setting an evidentiary hearing for June 28, 2024. [ECF No. 9–10]. Notwithstanding the tight schedule, the parties thoroughly and ably presented the legal issues in a clear manner. Their efforts are commendable and appreciated.

[10] As noted by the Court during the June 28, 2024 hearing, the proposed Warning Provision contains a typographical error. The Court assumes the missing word is either "impact" or "affect."

Serious questions about the clarity and constitutionality of HF 2605 came to light at the hearing. Defendants acknowledged that possible interpretive issues would be remedied with final rules from the Department. After the hearing, Plaintiffs filed an amended complaint, challenging the law as a violation of due process on the grounds that it is unconstitutionally vague. [ECF No. 24]. An order was issued denying injunctive relief on the claims which were pled in Plaintiffs' initial complaint and argued at the hearing. [ECF No. 25]. This Order expounds on the reasons for that denial. Plaintiffs then filed a motion for a temporary restraining order ("TRO") and a renewed motion for preliminary injunction on the grounds indicated in their amended complaint. [ECF No. 26]. Plaintiffs' motion for a TRO was denied and a hearing for their renewed motion for preliminary injunction was set for July 11, 2024. [ECF No. 27].

II. DISCUSSION

A. Legal Standards

1) Preliminary Injunction Standard

Preliminary injunctive relief is an extraordinary remedy that is not issued routinely or "as a matter of right." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (quoting *Munaf v. Green*, 553 U.S. 674, 689–90 (2008)). The main purpose of a preliminary injunction is to preserve the status quo and prevent irreparable harm until the court can make a final decision on the merits. *Ferry-Morse Seed Co. v. Food Corn, Inc.*, 729 F.2d 589, 593 (8th Cir. 1984). "A plaintiff seeking a preliminary injunction bears the burden of showing that such extraordinary relief is warranted." *H&R Block, Inc. v. Block, Inc.*, 58 F.4th 939, 946 (8th Cir. 2023) (citation omitted).

At this early stage of the case, the Court weighs four factors in determining whether to issue a preliminary injunction: (1) Plaintiffs' probability or likelihood of success on the merits of

the claim; (2) the threat of irreparable harm or injury to Plaintiffs absent preliminary relief; (3) the balance of equities, weighing the harm suffered by Plaintiffs against the harm to Defendants that would result from issuing an injunction; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc).

Although no individual factor is dispositive, the Eighth Circuit has held that probability of success "is the most significant." *Sleep Number Corp. v. Young*, 33 F.4th 1012, 1016 (8th Cir. 2022) (citation omitted). When a party seeks to enjoin the enforcement of a duly enacted statute, they must show that they are "likely to prevail on the merits" on the claims. *Eggers v. Evnen*, 48 F.4th 561, 565 (8th Cir. 2022) (citation omitted). Courts apply a heightened standard in that circumstance "because the duly enacted state statute constitutes government action based on presumptively reasoned democratic processes, and such action is entitled to a higher degree of deference and should not be enjoined lightly." *D.M. by Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1000 (8th Cir. 2019) (cleaned up) (citation omitted). The heightened standard is applied not only to statutes but also regulations. *Sleep Number Corp.*, 33 F.4th at 1016 ("[T]he more-likely-than-not standard is reserved for injunctions against the enforcement of statutes and regulations[.]") (citation omitted). The Eighth Circuit has held that the likely to prevail on the merits standard applies when "a preliminary injunction is sought to enjoin the *implementation* of a duly enacted state statute." *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732 (8th Cir. 2008) (en banc) (emphasis added).

A plaintiff is not required to establish with absolute certainty that irreparable harm will occur, but it must show that "irreparable injury is likely in absence of an injunction." *Winter*, 555 U.S. at 22. Failure to show irreparable harm is an "independently sufficient basis upon which to deny a preliminary injunction." *Sessler v. City of Davenport*, 990 F.3d 1150, 1156 (8th

Cir. 2021) (citation omitted). When balancing the equities of a preliminary injunction courts weigh "the threat of irreparable harm shown by the movant against the injury that granting the injunction" will cause to the other party's litigant. *MPAY Inc. v. Erie Custom Comp. Applications, Inc.*, 970 F.3d 1010, 1020 (8th Cir. 2020) (cleaned up) (citation omitted).

2) Federal Preemption

Plaintiffs challenge two provisions of HF 2605 on the grounds that they are preempted by federal law. Federal preemption of state statutes and regulations is grounded in the Supremacy Clause. U.S. Const. art. VI, cl. 2 (providing that federal law is "the supreme Law of the Land"). For more than 200 years, the United States Supreme Court has recognized for that state laws that interfere with or are contrary to the laws of Congress must yield to federal law. *See Gibbons v. Ogden*, 22 U.S. 1, 9 (1824). However, there is a presumption against preemption when the law in question touches on the police power of the States. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992). In that situation, Congress must clearly state its intent when it passes a law to preempt state law. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (holding that "the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress"). On the other hand, the presumption against preemption is "not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000). Congressional intent is the ultimate touchstone when assessing the preemptive effect of a statute. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990).

Federal preemption comes is three different varieties. The first way that Congress may preempt state law is by expressly saying so. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Aside from express language in a statute, "Congress may indicate pre-emptive intent through a

statute's . . . structure and purpose." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (citing *Rath Packing*, 430 U.S. at 525). When Congress has expressly preempted state law, "[t]here should be no presumption against pre-emption." *Id*.

In the absence of express preemptive language, courts have recognized versions of implied preemption, such as conflict preemption. Conflict preemption "occurs when it is impossible for a private party to comply with both state and federal law, and when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives'" of federal law. *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000)) (cleaned up).

The other form of implied preemption is what is known as field preemption. Field preemption is when "federal law occupies a 'field' of regulation so comprehensively that it has left no room for supplementary state legislation." *Murphy v. NCAA,* 584 U.S. 453, 479 (2018) (citation omitted). Where federal law occupies an entire field in this manner, "even complementary state regulation is impermissible." *Arizona v. United States*, 567 U.S. 387, 401 (2012) ("Field preemption reflects a congressional decision to foreclose any state regulation in an area, even if it is parallel to federal standards.").

The Supreme Court has admonished that the "[i]mplied preemption analysis does not justify a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives; such an endeavor would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (citation omitted).

B. Jurisdiction

1) Sovereign Immunity

The Eleventh Amendment to the United States Constitution provides that, "[t]he judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. Const. amend. XI. The Supreme Court has long held that suits against a state by its own citizens in federal court is generally prohibited. *Hans v. Louisiana*, 134 U.S. 1, 18 (1890). Sovereign immunity is not only for money damages but also equitable relief. *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 58 (1996) ("[T]he relief sought by a plaintiff suing a State is irrelevant to the question whether the suit is barred by the Eleventh Amendment.").

In this case, Plaintiffs name as Defendants the State of Iowa, the Iowa Department of Health and Human Services, and Kelly Garcia, the Director of the Iowa Department of Health and Human Services. The State of Iowa, as the sovereign by name, is entitled to immunity. Sovereign immunity also extends to the Department of Health and Human Services. *P.R. Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.,* 506 U.S. 139, 146 (1993) (holding that pursuant to the Eleventh Amendment, a state's sovereign immunity in federal court extends to private suits against state agencies, state departments, and other arms of the state.).

This leaves Garcia as the remaining possible Defendant. A "narrow exception" to sovereign immunity, is the *Ex parte Young* exception, which is aimed at "preventing state executive officials from enforcing state laws that are contrary to federal law." *Whole Woman's Health v. Jackson*, 595 U.S. 30, 39 (2021). Under the *Ex parte Young* exception, the Eleventh Amendment does not bar a suit that "alleges an ongoing violation of federal law and seeks relief properly characterized as prospective." *Va. Off. for Prot. & Advocacy v. Stewart*, 563 U.S. 247, 268 (2001).

The Supreme Court has limited the *Ex parte Young* exception to "cases in which a violation of federal law by a state official is ongoing as opposed to cases in which federal law has been violated at one time or over a period of time in the past." *Papasan v. Allain*, 478 U.S. 265, 277−78 (1986).

The *Ex parte Young* analysis entails "a straightforward inquiry into whether the complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective." *Verizon Md., Inc. v. Pub. Serv. Comm'n of Md.*, 535 U.S. 635, 645 (2002) (cleaned up). To invoke the *Ex parte Young* exception, the named official(s) must have a sufficiently close relationship to the enforcement of the challenged law. *See Ex parte Young*, 209 U.S. at 157 (requiring that the named state official "must have some connection with the enforcement" of the challenged law, or else the lawsuit is "merely making [the official] a party as a representative of the state" which is an impermissible "attempt[] to make the state a party").

Although this issue was not raised by the parties in their written briefs, the Court inquired about this point at the hearing. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006) (observing that subject matter jurisdiction "can never be forfeited or waived" and courts "have an independent obligation to determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party"); *Jones v. United States*, 255 F.3d 507, 511 (8th Cir. 2001) (concluding "it is axiomatic that . . . sovereign immunity implicates subject matter jurisdiction and the government may raise it at any stage.").

At the hearing, Plaintiffs admitted that Kelly Garcia as Director of the Department was the only legally proper defendant. Likewise, Defendants conceded the application of *Ex parte Young* and did not challenge Plaintiffs' cause of action. Defendants further indicated that Garcia, as director, was a proper party and did not contest her enforcement authority in that role.

C. Analysis

Plaintiffs offer three bases that entitle them to a preliminary injunction. First, they contend that the HF 2605's potency limits and packaging/labeling requirements are preempted by the FDCA. Plaintiffs argue that Congress expressly preempted state laws that are not identical to federal requirements for food labeling and ingredients. Since the FDA has not issued specific regulations for consumable hemp products, they contend that Iowa's attempt to regulate in this area conflicts with federal law.

Second, even if HF 2605 is not preempted, Plaintiffs maintain that the Court should enjoin its enforcement under the doctrine of primary jurisdiction until the FDA issues guidance on consumable hemp products. They point to other cases where courts have stayed pending cases to await agency rulemaking.

Finally, Plaintiffs challenge the Department's interpretation of the law's potency limits as set forth in Guidance documents. They contend that the Department lacks authority to interpret the statute through informal guidance rather than proper rulemaking procedures. Moreover, they argue the Department's interpretation is unreasonable and conflicts with the plain language of the statute, which allows up to 10 mg per container regardless of serving size.

1. Likelihood of Success on the Merits

a. FDCA Preemption

The FDCA is a consumer protection statute with the goal of ensuring "the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014). This includes prohibiting "the misbranding of food and drink." *Id*. The FDA's authority over nutrition labels was clarified and strengthened by the Nutrition Labeling and Education Act ("NLEA")

which amended the FDCA. *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 796 (N.D. Cal. 2015) (quoting *Nat'l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997)).

The FDCA imposes rules for nutrition labels on food products. 21 U.S.C. § 301 *et. seq.* It also preempts any law which imposes requirements that are "not identical" to those required by the FDCA. 21 U.S.C. §§ 343-1(a)(4), (a)(5). The Code of Federal Regulations provide that "[n]ot identical to" is when 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).

Plaintiffs argue that HF 2605 is preempted by two separate labeling provisions, each of which set forth grounds for misbranding under the FDCA. The first provides, in relevant part:

> A food shall be deemed to be misbranded—
>
> **(q) Nutrition information**
>
> **(1)** Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides--
>
> **(A)(i)** 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
>
> **(ii)** 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,
>
> **(B)** the number of servings or other units of measure per container,
>
> **(C)** the total number of calories—
>
> **(i)** derived from any source, and

> **(ii)** derived from the total fat[.]

21 U.S.C. § 343(q). This will be referred to as the "Serving Size" provision. The other provision of the FDCA governs nutrient levels and other health-related claims:

> A food shall be deemed to be misbranded—
>
> **(r) Nutrition levels and health-related claims**
>
> **(1)** Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—
>
> **(A)** characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or
>
> **(B)** characterizes 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 unless the claim is made in accordance with subparagraph (3) or (5)(D).

Id. § 343(r). This provision will be referred to as the "Health Claims" provision.

Plaintiffs maintain that they must comply with the FDA's requirements on content, packaging, and labeling. However, they argue that HF 2605 will require them to "place content on its beverage labels that is 'not identical to' the composition, nutrition, or health-related information imposed by the FDCA." [ECF No. 3-1 at 16]. At the same time, they emphasize that the FDA has the authority to promulgate labeling and ingredient guidance for cannabis-derived products but has declined to do so.

Accordingly, Plaintiffs argue that the FDCA preempts the Potency Limits and the Warning Provision because the FDA has the sole power to promulgate guidance on the content of nutrition labels. They characterize the FDCA's framework as "comprehensive" which "clearly occup[ies]

the entire field of food labeling and ingredient requirements—to the exclusion of any inconsistent state regulation."[11] [ECF No. 3-1 at 14]. According to Plaintiffs, congressional intent to preempt inconsistent state laws is plain by the text of the statute, which preempts: "any 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). Section 343-1(a)(5) contains the same language, preempting "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]." *Id*. § 343-1(a)(5).

Plaintiffs insist that these provisions cover the portions of HF 2605 challenged in this case. Although the FDA has the authority to impose labeling and ingredient guidance, the agency has not yet issued any. Plaintiffs characterize this as an affirmative decision to not act. Without action by the FDA, they urge that it is unknown whether the agency will treat cannabis-derived components of food as additives, standalone foods, ingredients within other foods, or some other regulatory decision. As such, Plaintiffs assert that Iowa's attempt to establish its own limits on potency and impose labeling requirements for consumable hemp products improperly encroaches on this federal regulatory domain and that the states are preempted from usurping this authority from the federal government.

Defendants reject Plaintiffs' position on FDCA preemption. They argue that Plaintiffs are incorrect that the Warning Provision is preempted because a separate portion of the law, not cited by Plaintiffs, exempts warnings that concern the safety of food. Additionally, Defendants point out that the Potency Limit imposes no labeling requirements, therefore federal laws regulating

[11] Plaintiffs clarified at the hearing that their claim is that the referenced provisions in HF 2605 are *expressly* preempted by the FDCA.

labeling cannot preempt it. Furthermore, Defendants urge that there is a presumption against preemption for laws like the FDCA because its provisions invade the traditional police power of states. When federal laws concern this area of law, courts require a clear indication from Congress that it intends to preempt state police power.

The two provisions that Plaintiffs rely on for FDCA preemption are inapplicable. The first provision, section 343-1(a)(4), relates to state laws which impose requirements contrary to the mandatory nutrient information required by the FDCA. 21 U.S.C. §§ 343-1(a)(4), 343(q). This is the nutrition label that would likely be familiar to nearly every American food consumer. The nutrition label provides information on a food's calories, fat, sodium, carbohydrates, protein, etc. *Id*. § 343(q)(C)–(D). It must be "express[ed] in a common household measure that is appropriate to the food." *Id*.

The second provision is section 343-1(a)(5), which preempts state laws that differ from requirements under the FDCA regarding "characterizations" about nutrient levels in a food product or health-related claims. *Id*. §§ 343-1(a)(5), 343(r)(1)(A)–(B). For this provision, think "zero fat" or "low sodium" claims on a food package. In essence, the FDCA prohibits a food manufacturer from complying with the nutrient disclosures in section 343(q), but then contradicting that information elsewhere on the product in an effort to mislead a consumer.

i. Potency Limit

As Defendants point out, neither of these provisions are transgressed by the Potency Limits in HF 2605. The Potency Limits do not address labeling requirements at all:

> 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.

H.F. 2605, 90th Gen. Assemb., 2nd Reg. Sess. (Iowa 2024). Nowhere in this language does HF 2605 impose a "requirement for nutrition labeling of food that is not identical to" the FDCA requirements for the content of nutrition labels. *See* 21 U.S.C § 343-1(a)(4). It does not obligate the manufacturer to characterize the level of any nutrient in a different manner than required by the FDCA. *Id*. § 343-1(a)(5). It also does not alter the characterization of the relationship of any nutrient to "a disease or health-related condition." *Id*. § 343(r)(1)(B).

Furthermore, regulating the amount of permissible THC in a consumable hemp product is expressly permitted by the Farm Bill. *N. Va. Hemp & Agric. LLC*,2023 WL 7130853, at *1 (noting that the Farm Bill permitted "state regulation of . . . the growth, production, sale, and use of industrial hemp and hemp products") (citing 7 U.S.C. § 1639p). In fact, the Farm Bill expressly provides, "[n]othing in this subsection preempts or limits any law of a State or Indian tribe that i) regulates the production of hemp; and ii) is more stringent than this subchapter." 7 U.S.C. § 1639p(a)(3)(A).

Plaintiffs also offer that the proposed Guidelines are preempted due to the Department's designation of a 12-ounce serving size. This argument poses similar difficulties for Plaintiffs. First, the Guidelines are not final, and are subject to revision before going into effect. Because Plaintiffs bring a facial challenge to HF 2605, they must establish there is no constitutional application of the law. *See United States v. Salerno*, 481 U.S. 739, 745 (1987). This argument runs aground because federal courts do not have authority to enjoin enforcement of a state law according to uncertain and fanciful applications. *Wash. State Grange v. Wash. State Rep. Party*, 552 U.S. 442, 449–50 (2008) ("In determining whether a law is facially invalid, we must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary'

cases."). Here, the Guidance does not even have a "face" to judge for its constitutionality. Notwithstanding the lack of authority to do so, it would also be imprudent to enjoin a state law on the basis of proposed regulations before they have been finalized. This would only invite more litigation of the constitutionality of state laws, a task frequently asked of judicial officers in this District already. *See, e.g., United States v. Iowa*, --- F. Supp. 3d ---- (S.D. Iowa 2024); *GLBT Youth in Iowa Schs. Task Force v. Reynolds*, --- F. Supp. 3d ---- (S.D. Iowa 2023); *Animal Legal Defense Fund v. Reynolds*, 630 F. Supp. 3d 1105 (S.D. Iowa 2022).

Moreover, Plaintiffs' complaints regarding the 12-ounce serving size ring hollow for two reasons. First, the FDCA requires that a label must reflect "the serving size which is an amount customarily consumer 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). Notably, the language in the statute itself only references how many milligrams are permitted per "serving;" it does not set a serving size. The serving size in the proposed Guidance is drawn from the FDCA's own regulations for carbonated beverages. *See* 21 C.F.R. § 101.12.

Plaintiffs insist that if they are required to comply with the provisions of HF 2605, they "*will* face liability for a misbranding claim under federal law by complying with obligations under state law." [ECF No. 3-1 at 16] (emphasis added). This claim is surprising, given the fact that they have currently set a 12-ounce serving size for their products. At the hearing on the Motion for Preliminary Injunction, the Court asked Plaintiffs what would change on the label of their product. While initially unresponsive to this question, they eventually indicated that their product labels would remain substantially the same. However, without final rules from the Department on this issue, logistically producers and manufacturers of consumable hemp products are free to set

their own serving sizes because these products are not specifically regulated by the FDA. Defendants have indicated an assumption that FDCA standard serving sizes would apply to the statute in the interim, but Defendants also acknowledge the language in the statute does not incorporate FDA standards. While this implicates other constitutional issues, it does not demonstrate that HF 2605 or the Guidelines are preempted by the FDA as there are no specifications for the state law and regulations to be "not identical to." 21 C.F.R. § 100.1(c)(4).

In summary, Plaintiffs' have not established a likelihood of success on the merits regarding the Potency Limit's preemption by the FDCA.

ii. Warning Provision

Plaintiffs also argue that the Warning Provision of HF 2605 is preempted because "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." [ECF No. 3-1 at 15]. They urge that divergent state-specific label requirements "make it practically impossible for manufacturers to comply" with them. *Id*. at 15–16. Similar to the Potency Limits, Plaintiffs contend that they may only comply with state law by placing content on their packages that is "not identical to" the FDCA requirements.

The Warning Provision requires that a consumable hemp container "be affixed with a notice advising consumers regarding the risks associated with its use." Notwithstanding Plaintiffs' protestations, the FDCA expressly permits states to issue warning labels for regulated food products. *See* Pub. L. 101-535, § 6, 104 Stat. 2343 (1990) (providing that the 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"); *See also*

Sciortino v. Pepsico, Inc., 108 F. Supp. 3d 780, 801 (N.D. Cal. 2015); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1033 (N.D. Cal. 2009).

The plain text of the Warning Provision advises the consumer about potential health effects. Similar warning laws required by other states have been upheld on FDCA challenges. California has a notable warning which consumers may have encountered advising that certain chemicals in a product are "known to the State of California to cause cancer." 27 Cal. Code Regs. § 25603(a)(2)(A). A preemption challenge to this warning, known as Proposition 65, was rejected by a district court in the Northern District of California. *See Sciortino*, 108 F. Supp. 3d at 811. The court concluded that "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." *Id*. In fact, California applies Proposition 65 to consumable hemp products as well. *See* Cal. Code Regs. § 27001(c). California is not the only state that has warning labels for consumable hemp products. *See, e.g.,* Tenn. Code Ann. § 43-27-209(a)(2)(B); Minn. Stat. § 151.72, subd. 5a(e)(4); N.Y. Cannabis Law § 103(1).

Aside from preemption provision issue, which is expressly exempted, there is nothing in the Warning Provision that violates either of the FDCA provisions. THC is almost certainly not a "nutrient" and, by their own admission, Plaintiffs are unsure how the FDA would characterize consumable hemp products at all. *See* [ECF No. 3-1 at 15] (speculating that it could be treated as a food additive, a standalone food, a food ingredient, among other possibilities). Plaintiffs have presented no basis on which to conclude that the Warning Provision of HF 2605 is preempted by the FDCA.

In summary, Plaintiffs have failed to establish a likelihood of success on the merits that HF 2605 violates the Supremacy Clause. They point to no provision in the FDCA which preempts—

expressly or impliedly—the Potency Limits or the Warning Provision of the law. The Farm Bill expressly contemplated that states could impose more stringent regulations on hemp products. Nothing in the Iowa legislature's most recent attempt to regulate the industry contradicts federal law.

b. Primary Jurisdiction Doctrine

Plaintiffs argue in the alternative that, even if the HF 2605 is not preempted by federal law, the Court should enjoin its enforcement pending a decision by the FDA on labeling requirements. Under a doctrine known as primary jurisdiction, courts will occasionally stay a case if the disposition of a claim depends on resolution of regulatory issues that fall within "the special competence of an administrative body." *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (quoting *Atlantis Exp., Inc. v. Standard Transp. Servs., Inc.*, 955 F.2d 529, 532 (8th Cir. 1992)). Primary jurisdiction is a procedural mechanism to promote consistent and uniform application of the law in areas of regulation, particularly in cases concerning "issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion." *Access Telecomm. v. Sw. Bell Tel. Co.*, 137 F.3d 605, 608 (8th Cir. 1998) (quoting *Far East Conf. v. United States*, 342 U.S. 570, 574 (1952)).

There is not a "fixed formula" for application 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)). Invocation of primary jurisdiction is most advisable "'when the issue is already before the agency,' and the agency's 'informed opinion will be of material aid to the district court in the resolution of'" the issues. *Id*. (quoting *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 532 F.2d 412, 420 (5th Cir. 1976)).

The primary jurisdiction doctrine has been applied in cases concerning misbranding of CBD products. *Snyder v. Green Roads of Fla. LLC*, 430 F. Supp. 3d 1297, 1306 (S.D. Fla. 2020). In *Snyder*, a manufacturer of CBD products was sued by consumers who alleged they were overcharged for products due to misrepresentation on the product label. *Id*. at 1300. The district court stayed the case to await the FDA's final disposition on rulemaking for ingestible CBD products, which was already underway. *Id*. at 1306–07. The stay was predicated on the primary jurisdiction doctrine, after the district court determined that it would "benefit greatly" from guidance from the FDA. *Id*. at 1309. Plaintiffs cite to other district courts who applied the primary jurisdiction doctrine under similar circumstances. *See Ahumada v. Glob. Widget, LLC*, Case No. 19-cv-12005-ADB, 2020 WL 5669032, at *2 (D. Mass. Aug. 11, 2020) (citing to *Snyder* when applying primary jurisdiction doctrine under similar circumstances); *Glass v. Glob. Widget, LLC*, No. 2:19-cv-01906-MCE-KJN, 2020 WL 3174688, at *3 (E.D. Cal. June 15, 2020) (invoking the primary jurisdiction doctrine for CBD products); *Colette v. CV Scis., Inc.*, 2:19-cv-10227-VAP-JEM(x), 2020 WL 2739861, at *5 (C.D. Cal. May 22, 2020) (issuing a stay pending FDA guidance which the agency was "working feverishly" to devise).

However, those cases applied the primary jurisdiction doctrine to stay a pending *case*. Plaintiffs do not ask for this case to be stayed—they ask for a state law to be enjoined. Although a court has inherent power to stay a case, no similar authority exists for enjoining a state law. *See Landis v. N. Am. Water Works & Elec. Co.*, 299 U.S. 248, 254 (1936) (explaining that "the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort").

Plaintiffs acknowledge this point but contend that "the doctrine does not depend on procedure posture" because the doctrine only asks whether the purpose of the doctrine is present,

and whether the purposes are served by its application. [ECF No. 3-1 at 19] (quoting *W. Pac. R. Co.*, 352 U.S. at 64). But the issue with application of primary jurisdiction here is not the procedural posture, it is the exercise of federal judicial power. Plaintiffs' argument for a stay pursuant to the primary jurisdiction doctrine, is a watered-down version of their preemption argument.

They maintain that the stakes of this case are high because, if their interpretation regarding HF 2605 is correct, they will face potential criminal consequences for possession of noncompliant consumable hemp products. Notwithstanding the importance to Plaintiffs, there is no authority for a federal court to enjoin a duly-enacted state law, and governing regulations, without a showing that it is more likely than not that the law violates the Constitution. Plaintiffs have not made that showing and the Court cannot enjoin the implementation of the law under the primary jurisdiction doctrine.

c. Iowa Administrative Procedures Act

Plaintiffs' final argument is that the Department's Guidance ignores the Potency Limits selected by the legislature. They claim that the Department is poised to enforce its own interpretation of the Potency Limits without the authority to do so. Plaintiffs allege that the Department "made no attempt to follow the necessary rulemaking process." [ECF No. 3-1 at 20]. Furthermore, the Department allegedly disregarded the directive in the statute that permits any single-serving beverage container to contain 10 mg of THC per container. The 10 mg standard in HF 2605 is unambiguous, reasonable, and applies to all consumable hemp products, according to Plaintiffs.

Judicial review of state agency action is governed by the Iowa Administrative Procedures Act ("Iowa APA"). *See* Iowa Code § 17A.19(10); *Brakke v. Iowa Dep't of Nat. Res.*, 897 N.W.2d

522, 530 (Iowa 2017) (citation omitted). An agency may not promulgate administrative rules if its action is "[b]eyond the authority delegated to the agency by any provision of law or in violation of any provision of law." Iowa Code § 17A.19(10)(*b*). The Iowa Supreme Court has held that an agency rule is presumptively valid "unless the party challenging the rule proves a rational agency could not conclude the rule was within its delegated authority." *Meredith Outdoor Advert., Inc. v. Iowa Dep't of Transp.*, 648 N.W.2d 109, 117 (Iowa 2002) (cleaned up) (citation omitted). The authority for agency rulemaking "is limited to the power granted by statute." *City of Des Moines v. Iowa Dep't of Transp.*, 911 N.W.2d 431, 439 (Iowa 2018) (quoting *Brakke*, 897 N.W.2d at 533). An agency's interpretation and construction of a statute is not entitled to deference unless "the legislature has clearly vested that interpretation in the agency." *Brakke*, 897 N.W.2d at 533.

Iowa Code 17A.19 makes clear that after a party has exhausted *all* adequate administrative remedies for *final* agency action, they may proceed with a petition for judicial review 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." Iowa Code § 17A.19(2). While there are certainly issues regarding whether Plaintiffs have exhausted their remedies and whether the Department's "intended action" would constitute final agency action, the Court need not address those subjects because any challenge to an action by a state agency under Iowa law must be brought in state court. *Id*.

The Iowa statute gives *exclusive* jurisdiction on this issue to its state courts. Iowa Code § 17A.19. Further, "a federal suit against state officials on the basis of state law contravenes the Eleventh Amendment when—as here—the relief sought and ordered has an impact directly on the State itself." *Pennhurst State Sch. & Hosp. v. Halderman,* 465 U.S. 89, 117 (1984); *See also Grand River Enterprises Six Nations, Ltd. v. Beebe,* 467 F.3d 698, 701 (8th Cir. 2006) (holding that when seeking to enjoin a state officials' action in federal court, plaintiffs must seek vindication

of a *federal* right). The Plaintiffs have not presented, nor is the Court aware of, any reason that it should exercise jurisdiction over this state claim between citizens of the state of Iowa, especially when there is an administrative procedure codified in Iowa law to address precisely the claims that Plaintiffs allege, including their argument that the agency's action is unconstitutional. Iowa Code § 17A.19(2). Given this jurisdictional hurdle that Plaintiffs seemingly cannot overcome, they are unlikely to succeed on the merits of their Iowa APA claim.

2. Remaining Injunction Factors

Plaintiffs assert they will suffer irreparable harm absent an injunction, as a significant portion of their inventory and revenue would become illegal on July 1 when the law takes effect. They face potential criminal liability, including felony charges, for non-compliance. As discussed above, the Court concludes that Plaintiffs have failed to make a sufficient showing for success on the merits. Therefore, the degree of irreparable harm, the balance of the equities, and the public interest cannot overcome this failure to establish their underlying legal claim.

III. CONCLUSION

Based upon the claims in Plaintiffs' initial complaint which were argued at the hearing, they have not met the requirements for a preliminary injunction. It is for these reasons that their Motion for Injunctive Relief was DENIED. [ECF No. 3]. Plaintiffs' renewed motion for a preliminary injunction based on the claims in their amended complaint will proceed as indicated by the Court in its prior order. [ECF No. 27].

IT IS SO ORDERED.

Dated this 2nd day of July 2024.

Stephanie M. Rose

STEPHANIE M. ROSE, CHIEF JUDGE
UNITED STATES DISTRICT COURT