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

CLIMBING KITES LLC and FIELD DAY BREWING COMPANY LLC, Plaintiffs, v. THE STATE OF IOWA; KELLY GARCIA, in her official capacity as Director of the Iowa Department of Health and Human Services; and THE IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 4:24-cv-202 PLAINTIFFS' REPLY TO DEFENDANTS' RESISTANCE TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

On June 17, 2024, Plaintiffs sought a preliminary injunction focusing on the fact the State of Iowa is taking actions preempted by federal law. On June 26, 2024, the State Defendants resisted.

ARGUMENT

I. THE DEPARTMENT'S LATEST POSITION MAKES UNCLEAR WHAT IT WILL ENFORCE ON MONDAY, JULY 1, 2024.

The Department issued interpretation of House File 2605 on June 7, 2024, which included its interpretation of "serving size," "container," and the consequences of non-compliance beginning July 1. This was Department "action"—no matter what the document is called. *See* Iowa Code § 17A.2(2). There also is no ambiguity about what happens if a business owner does not comply with the Department's interpretation on July 1:

> **What products are prohibited for sale in Iowa on July 1?**
>
> Consumable hemp products containing more than 4 mg total tetrahydrocannabinol (THC) per serving and more than 10 mg total THC per container *will be prohibited* from sale in Iowa on July 1. As of July 1, products in excess of these THC limits *are considered a controlled substance under Iowa law* and not legal for sale in the state.
>
> **Will there be a "grace period" for on-hand products that do not meet the new serving and container limits?**
>
> No, products that contain >4 mg total THC per serving or >10 mg THC per container *must not be available for sale on July 1*. Registrants should ensure that they are not in possession of these products on July 1. HHS is not responsible for the facilitation or the destruction of non-compliant products.
>
> Products not compliant with HF2605 *are considered controlled substances pursuant to Iowa Code section 124.401*. Penalties may range from a serious misdemeanor to a class B felony, depending on the amount of product in their possession.
>
> **What are the penalties if I sell non-conforming or illegal products?**
>
> *Selling non-conforming or illegal products in Iowa may result in civil and criminal penalties*. Products which contain tetrahydrocannabinols and do not conform with Iowa's Consumable Hemp law are "controlled substances" pursuant to Iowa Code sections 124.101(20), 124.202, and 124.204(4)(m). Those possessing, manufacturing, or distributing controlled substances in Iowa may be criminally prosecuted.
>
> Additionally, HHS may order confiscation and disposal of any non-conforming hemp product or product sold by a person who is not registered with HHS. Reasonable costs incurred for destroying non-conforming products may be assessed to the Registrant or unregistered individual.

> **What should Registrants expect from HHS regarding inspection and enforcement?**
>
> Registrants should be aware that the penalties for non-compliance implemented by HF 2605 are severe and ***HHS intends to enforce these new regulations when they become effective on July 1***. Registrants should expect enforcement activities on and on behalf of HHS.

Iowa Dep't of Health & Human Servs., Consumable Hemp: HF2605 FAQ – What it Means, Draft Rules, Townhall Info (June 7, 2024) (non-heading emphases added).

Now—five days before July 1—the Department seems to suggest it did not mean what it said. It says the Department's interpretation of HF2605:

- "[is] far from final and [has] already evolved significantly."
- "will not be adopted until July 17, 2024, at the earliest, or published until August 7, 2024."
- "may very well change."
- "can be revised any time."

Deft. Br. pp. 4–5; 6; 18; 19; 23. The Department promises it is following the proper administrative rulemaking process—which permits a September 11 effective date, at the earliest—and claims (wrongly) that the Department has rulemaking authority to interpret the law in the manner it did on June 7. *Id.* at 24.[1] Yet, its Guidance, telling the world Plaintiffs' products are illegal, remains posted publicly telling every supplier, "Don't sell Plaintiffs' products or you'll be prosecuted."

Put simply, the Department either intends to enforce its interpretation of House File 2605 on July 1, or it doesn't. The June 7 Guidance tells everyone who deals with Plaintiffs that it will. Either way, Plaintiffs have already suffered irreparable harm as a result of the Department's Guidance. When the Department speaks, market participants are obliged to listen: inventory has been pulled from warehouses; products have been removed from shelves; distributors have

[1] The September 11 *effective date* for any such rules is conspicuously absent from the Department's resistance. Deft. Br. at 6; *see also* Administrative Rules 2024 Schedule for Rulemaking (for rules noticed on or before June 12, 2024), *available at* https://www.legis.iowa.gov/docs/publications/ACOD/1386483.pdf.

cancelled orders and shifted routes; market shares have diminished; and Plaintiffs have incurred costs to move inventory out of state. (Second Decl. of Scott Selix ¶ 3; Second Decl. of Dan Caraher ¶ 3). All because the Department—for three weeks now—has broadcast its interpretation of the law and made clear it intends to enforce that interpretation on July 1, 2024. Its action continues to cause market disruption and—now—significant regulatory confusion. If, as it now claims, it did not intend its harmful words to be taken seriously, surely the Department will have no objection to the Court granting preliminary injunctive relief ordering the Department to remove the June 7 Guidance from its website, and prohibiting the Department from administering or enforcing its interpretation of the Potency Limits or the Packaging and Labeling Authority until the Department properly completes its purportedly valid, ongoing rulemaking process. Plaintiffs maintain those provisions of state law are preempted and the Department has no rulemaking authority to set potency limits. However, in the interest of resolving "Who gets charged with a felony on Monday?", Plaintiffs do not object to temporary injunctive relief to provide the Court additional time to resolve the important issues presented in this case.

II. CONGRESS DECIDED THE FDA—NOT INDIVIDUAL STATES—MUST DEFINE HOW THC IN FOOD PRODUCTS IS CHARACTERIZED.

Who decides how consumable hemp products are regulated? The Department suggests federal law expressly permits states to regulate hemp more stringently than federal law, citing 7 U.S.C. § 1639p(a)(3)(A).[2] But of course, these Plaintiffs do not produce bales of hemp; they produce "food" within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"). For food products containing hemp-derived THC, Congress was clear that the FDA—*not* states—

[2] That statute allows for states to regulate the "production of hemp." 7 U.S.C. § 1639p(a)(3)(A). The United States Department of Agriculture, for purposes of its Domestic Hemp Production Program, defines "produce" as "[t]o grow hemp plants for market, or for cultivation for market, in the United States." 7 C.F.R. § 990.1.

retains authority to regulate such products and determine any applicable "potency limit," "serving size," "concentration," or whatever other characterization it chooses:

> Nothing in [the 2018 Farm Bill] shall affect or modify…the [FDCA]…or the authority of the Commissioner of Food and Drugs…under…the [FDCA]…to promulgate federal regulations and guidelines that relate to the production of hemp under the [FDCA].

7 U.S.C. § 1639r(c).

Congress's 2018 delegation of authority is critical because, as the Department acknowledges, the FDCA contains a variety of express preemption provisions. *See* 21 U.S.C. § 343-1(a). But it also negates the Department's insistence that this Court should disfavor preemption because it is somehow unclear who Congress intended to regulate food products containing hemp-derived THC. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485–86 (1996) (recognizing that, even when legislating in a field which states traditionally occupied, "any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose*'" (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504 at 530 n.27 (1992) (emphasis in original))). For better or worse—fast or slow—FDA remains the authority to determine serving and potency limits for THC food products.

The FDA has not provided guidance or issued regulations on how food products containing hemp-derived THC should be characterized. There is no dispute this creates confusion. For example, the FDA could simply characterize THC as any other component in a food product. *See* 21 U.S.C. § 321(f) (defining "food"). That designation requires food products containing THC to be classified, branded, labeled, and packaged based on—in part—"serving size" or another common household unit of measure. *See* 21 U.S.C. § 343(q)(1)(A). HF2605 characterizes THC as a traditional component in food products, and accordingly, the Department concedes it defined

the "serving size" for those products. Deft. Br. at 25. The Department will require the following information on the label of Plaintiffs' products:

> A declaration of the net quantity of contents indicating the number of servings and total THC per serving and per container in compliance with Iowa Code section 204.2.

ARC8064C (June 12, 2024) (amending Iowa Admin. Code rule 641–156.4(1)), *available at* https://www.legis.iowa.gov/docs/aco/arc/8064C.pdf.

But the FDA has *not* characterized THC as a traditional food component. Indeed, it indicated it is more likely to characterize THC as a "food additive," as it did with other hemp seed ingredients. *See* 21 U.S.C. § 321(s); *see also* U.S. Food & Drug Ass'n, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (Feb. 6, 2024) (Question & Answer 10), *available at* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd. If characterized as a recognized food additive, THC is characterized and limited according to the quantity of the substance that "does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food," *an amount set by the FDA*. 21 C.F.R. § 172.5(a); *id.* § 182.1(b)(1). Accordingly, THC would *not* be labeled according to "serving size," but, rather, by the amount of THC permitted as an ingredient within the food product. 21 U.S.C. § 343(i) (requiring a food product to list common names of all ingredients). Perhaps the FDA could characterize THC as a "drug" for purposes of the FDCA, like caffeine. 21 C.F.R. § 340.50 (regulating labeling of "stimulant drug products"). Or are THC products a "dietary supplement"? *See* 21 U.S.C. § 321(ff); 21 U.S.C. § 343(r)(6) (regulating labeling claims regarding dietary supplements). Is THC a "nutrient"? *See* 21 U.S.C. § 343(q)(1) & (2) (requiring the amount of nutrients on a label if the FDA Secretary deems it necessary).

Bottom line: Congress gave the FDA jurisdiction and authority to decide these areas, *see* 7 U.S.C. § 1639r(c), and importantly, all resulting packaging and labeling requirements for THC food products are driven by the FDA's threshold decision of how to characterize THC, *see Snyder v. Green Roads of Fla. LLC*, 430 F. Supp. 3d 1297, 1309 (S.D. Fla. 2020) ("The FDA regulations currently provide little guidance with respect to whether CBD ingestibles, in all their variations are food supplements, nutrients or additives and what labelling standards are applicable to each iteration.").

Even if Plaintiffs share frustration with the FDA's inaction, frustration does not allow the State to usurp the FDA's role to regulate in a space from which Congress excluded it. *See, e.g.*, *United States v. Iowa*, 4:24-cv-00162, 2024 WL 3035430, at *11–13 (S.D. Iowa June 17, 2024). The Department claims its interpretation "would not require Plaintiffs to label their beverages contrary to any federal requirement." Deft. Br. at 19. That's not true. FDA requirements do not require a declaration of the net quantity of THC in a food product per serving and per container. State law now requires it. ARC8064C (June 12, 2024) (amending Iowa Admin. Code rule 641–156.4(1)), *available at* https://www.legis.iowa.gov/docs/aco/arc/8064C.pdf. Those standards are not "identical" as the law requires. For preemption purposes, FDA's inaction *is* action. *See O'Connor v. Henkel Corp.*, No. 14-cv-5447, 2015 WL 5922183, at *6 (E.D. N.Y. 2015) (holding plaintiffs' claims preempted by the FDCA because of the FDA's "silence on slack-fill cosmetics and nonprescription drugs," an area where the FDA is "charged…with promulgating regulations"); *Bimont v. Unilever U.S., Inc.*, No. 14-cv-7749, 2015 WL 5256988, at *6 (S.D. N.Y. 2015) ("A state rule forbidding non-functional slack-fill in drugs and cosmetics would impose a requirement that is in addition to or not identical with federal law, and it would do so on a subject matter that clearly could be regulated by the FDA.").

Congress expressly preempted nutrition information and nutrition-level state regulation "not identical to" FDA requirements. 21 U.S.C. § 343-1(a)(4)–(5); *see* 21 C.F.R. § 100.1(c)(4) (state requirements "not identical to" federal regulation includes requirements "not imposed by or contained in" the FDCA). By usurping FDA's authority to make an initial determination of how THC is characterized in food products, the state's Potency Limits necessarily put Plaintiffs out of compliance with federal law and require them to characterize the level and amount of THC within their products according to a metric and an amount *wholly absent* and *not required* by federal law. 21 U.S.C. § 343(q)(1), (r)(1)(A).[3] It is "impossible for [Plaintiffs] to comply with both state and federal requirements," and the Potency Limits are therefore preempted. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

III. PACKAGING AND LABELING REQUIREMENTS ARE ALSO PREEMPTED DUE TO THE FDA'S INACTION.

The statute's Packaging and Labeling Authority is preempted by 21 U.S.C. § 343(r)—via 21 U.S.C. § 343-1(a)(5)—for the same fundamental reason its Potency Limits are preempted: the FDA's inaction to characterize THC within food products creates a federal standard "not identical to" state packaging and labeling requirements. Under the Department's logic, unless the FDA acts, Plaintiffs must face the risk of including up to fifty distinct health-related claims on its beverage containers depending on the policy preferences of individual state legislatures.

The FDA Secretary has broad authority to determine what nutrients or components of a food product must be included in the label or labeling of that food to assist consumers in "maintaining healthy dietary practices." *See* U.S.C. § 343(q)(2)(A). Despite having Congressional authority to do so, the FDA has not determined how THC must be characterized for

[3] Indeed, the Department concedes 21 U.S.C. § 343-1(a)(5) "prevents States from passing laws that require manufacturers to make claims about the level of any nutrients required on the 'Nutrition Facts' label." Deft. Br. at 9.

purposes of food regulation. Is it a component, a compound, a nutrient, an additive, a supplement, a dosage, or something entirely different? The FDA has not determined whether THC consumption has an effect on an individual's healthy dietary practices. Depending on those determinations, the FDCA's health-related claims regulations may or may not apply: a product that "characterizes the relationship of any nutrient which is 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" is not permitted under the FDCA, *unless* established by the FDA Secretary. 21 U.S.C. § 343(r)(1)(B). To be clear, no one knows whether FDA believes THC is a nutrient: it has not declared it one way or the other. But *here*, *the Department* chose, and it is adamant it must *not* be a nutrient, which ignores the FDCA's express preemption clause.

Once outside the express preemption provisions that dictate "health-related claims" on food products, the Department, of course, fares better, but the Department still reverses who decides the propriety or necessity of health-related claims: it reasons the statute's "warning exclusion" trumps FDA rulemaking. Deft. Br. at 17. The safe harbor upon which the Department relies is a rule of construction, codified as a note. *See* 21 U.S.C. § 343-1 (note 2). The statute itself—specifically, in 21 U.S.C. § 343(r)—provides the FDA Secretary broad discretion to determine *when* specific health-related claims are warranted or require preemptive effect. Congress certainly knew how to delegate authority over such areas, and did so here. The Packaging and Labeling Authority, and the resulting language the Department chose in its proposed rules, are expressly preempted.

IV. THIS COURT CAN—AND SHOULD—CONSIDER PLAINTIFFS' SUPPLEMENTAL STATE LAW CLAIMS.

This Court has jurisdiction to consider Plaintiffs' state-law judicial review claim. No one disputes the Court has subject matter jurisdiction over Plaintiffs' preemption claim—the Department can't argue otherwise. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.14 (1983)

("It is beyond dispute that federal courts have jurisdiction over suits to enjoin state officials from interfering with federal rights."); *see Ex parte Young*, 209 U.S. 123 (1908). Both the preemption challenges and the rule-making violations are part of the "same case or controversy," permitting the Court to exercise supplemental jurisdiction over related state claims. 28 U.S.C. § 1367(a). Supplemental jurisdiction arises from Article III, Section 2 and does not depend on whether a state statute requires a case be filed in state court. *See, e.g.*, *Brown v. City of Memphis*, 440 F. Supp. 2d 868, 878 (W.D. Tenn. 2006) (rejecting a similar argument raised by public officials).

Similarly, procedural hurdles the Department raises are unavailing. Based on the Department's logic, Plaintiffs may not question the Department's enforcement of HF2605 until formal rulemaking proceeds, in mid-July. Meanwhile, however, the Department continues to tell the world it will enforce HF2605 on July 1, with no "grace period." With a few keystrokes on the Internet, HHS made Plaintiffs' product unmarketable and injected terrible uncertainty into the market, creating the extreme likelihood of irreparable harm. How long should Plaintiffs wait before they seek a ruling on whether they are committing a criminal offense? *Cf. Sash v. Zenk*, 439 F.3d 61, 64 (2d Cir. 2005) ("[A]n agency cannot be given discretion to interpret the scope of a criminal law."). On June 7, the Department told every Iowa business, "don't do business with Plaintiffs on these products or we will throw you in jail," and then claims it did nothing. Guidance <u>*is*</u> a statement of law interpreting its understanding of HF2605, as it will be administered and enforced on July 1. It is "agency action." *See* Iowa Code § 17A.2(2). If that Guidance isn't "final" when posted and affecting the market, when *would* it be final? Because Plaintiffs challenge the rulemaking as violative of preemption principles, there is no need to exhaust administrative remedies. *Alberhasky v. City of Iowa City*, 433 N.W.2d 693, 695 (Iowa 1988) (recognizing the "emerging rule").

On the merits of the Department's interpretation, the legislature did not grant deference for the Department to further define Potency Limits as it chose. The Department spots the problem: "the law does not define 'serving.'" Deft. Br. at 25. From there, somehow, the Department concludes *it* then gets to step into the FDA's role, characterize THC in food products, and deem the appropriate "serving size" for purposes of our state and create criminal violations. Until the FDA exercises the authority granted to it under the 2018 Farm Bill, it is unclear whether "serving" is even the correct nomenclature or characterization of THC concentration limits. *See* 21 U.S.C. § 343(r) (requiring accurate claims of nutrition levels). In the meantime, and if the Potency Limits are not preempted, the definition of "serving" cannot read other terms out of the statute. It cannot reference federal food regulations for products that aren't even edible. And the definition of "serving" certainly cannot form the basis for criminalizing 8-ounce beverage containers because the Department believes that is an "unfamiliar" type of container. Deft. Br. at 26. The Department's interpretation is improper and unworkable, which is perhaps why the Iowa legislature did not want the Department controlling the meaning of serving, container, or potency.

V. ALL OTHER FACTORS FAVOR INJUNCTIVE RELIEF.

The Department's evolving stance on its July 1 enforcement date may alter the nature of Plaintiffs' irreparable harm, but it does not eliminate it. If the Department does not intend to enforce its interpretation of the law—despite clear representations in the June 7 Guidance—Plaintiffs continue to suffer irreparable harm by the Guidance merely existing on the Department's website. No partner will purchase its product under risk of imprisonment even if the Department suggests it does not mean what it says. Indeed, it is even harder to understand the basis for the Department creating such harm if what it posted is not its position. If the Department *does* intend to enforce its interpretation on July 1, the threat of "severe" civil and criminal penalties also constitutes irreparable harm. *Mga Susu, Inc. v. County of Benton*, 853 F. Supp. 1147, 1154 (D.

Minn. 1994). Until its discussion of irreparable harm, the Department claims Plaintiffs sued *too early*—the regulations aren't even final yet…. Deft. Br. at 23. But for purposes of irreparable harm, the Department claims Plaintiffs sued *too late*—the law was signed in May. It is June. Yet, the Department again argues Plaintiffs file *too soon*: they could wait to be criminally prosecuted, and then raise preemption and a state court would be "constitutionally obligated" to entertain those claims. Deft. Br. at 27. This approach is inconsistent with applicable federal law. *See Ex parte Young*, 209 U.S. at 150–51. Nor does it explain how Plaintiffs will get anyone to sell their products!

Once a party establishes likelihood of success on federal preemption grounds, the balance-of-harm and public-interest factors "drop from the case." *Bank One, Utah v. Guttau*, 190 F.3d 844, 847–48 (8th Cir. 1999). Nevertheless, it is worth pointing out the Department does believe HF2605 is a "criminal law." Deft. Br. at 28. To the extent conduct is criminal merely because an executive branch agency—and not the legislature—deems it such, the public interest certainly favors judicial resolution of that question. *See Sash*, 439 F.3d at 64.

Dated: June 27, 2024

Respectfully submitted,

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