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' SUPPLEMENTAL BRIEF IN OPPOSITION TO PRELIMINARY INJUNCTION**

ARGUMENT

The Department's interpretation and implementation of HF2605's per-serving potency limit leaves many questions unanswered. But the Department's post-hearing briefing also confirms further dissonance between what HF2605 requires, what the Department's rules purport to require, and what actually matters when the Department is approving or denying consumable hemp products. Given the unintelligible standard in the law and the Department's arbitrary enforcement of its interpretation of the law thus far, this Court should enjoin the per-serving potency limit until the legislature revisits the issue and provides needed clarity as to what "serving" really means.

Prior to July 1, 2024, the Department approved or denied products based on a "serving" of THC within a consumable, as set by the product's manufacturer. *See* ECF No. 43-4 p. 4. The underlying product's "serving size" did not matter because that was not the Department's chosen metric: it treated THC as an additive to that product. Approved products thus lawfully contained 10 milligrams total THC in one container. The legislature—as this Court knows—did not define "serving" in HF2605. But the Department now interprets "serving" as the FDA's recommended

"serving size" of the underlying food product, without any indication from the legislature to justify the shift. Most problematic? ***The Department's actual administration of the program has not reflected the same***. The only relevant difference between the Department's pre- and post-July 1 application process is apparently a change from the amount of *cannabinoids* (per-serving and per-container) to the amount of *THC* (per-serving and per-container). ECF No. 43-1 ¶¶ 14–15. Although the words "as provided by the manufacturer" are now conspicuously absent, the Department—tellingly—is <u>*not*</u> requesting a container size for beverages (or any product, for that matter). *Compare* ECF No. 43-4 p. 3 *with* ECF No. 43-5 p. 3. Why not? That information is necessary to determine whether a product should be approved, at least according to the Department's rules. It is also necessary to determine whether the product holds less than 12 fluid ounces. *See* ECF No. 43-6 p. 2. And a beverage may—under the Department's legal interpretation—contain 10 milligrams total THC if the beverage contains thirty fluid ounces. *See* ECF No. 43-7 p. 3. Yet, the Department does not find it useful to know that information in deciding whether a product complies with the law.[1]

The Department's response—as confirmed in its Resistance—is that Plaintiffs are required to follow the law <u>*and*</u> persuade the Department to approve the product on their Portals. ECF No. 43 p. 5. But what if products denied through the Department's Portal are lawful under the Department's regulations, or the actual face of the statute? The Department's rules require one baseline of information, and its administrative processes another. Plaintiffs are entitled to greater clarity before their economic interests are curtailed and the risk of criminal sanctions are imposed.

[1] Similarly, the Department states some hemp products simply are not subject to the per-serving limitation, such as lotions, creams, or salves. ECF No. 43-1 ¶ 45. But of course, the only reason the Department intends to regulate those products differently is because it interprets the statute as regulating *edible* hemp products, not *consumable* hemp products. Iowa law regulates all consumable hemp products—whether ingested or absorbed—and gives no authority for this distinction. *See* Iowa Code § 204.2(2)(*d*)(1). Thus, the Department's position contravenes the plain terms of the statute and shows just how untenable the Department's position is to unilaterally shift the definition of "serving" after the passage of HF2605.

Coincidentally, some of Plaintiffs' products were approved in the Portal *the day after* the Department enacted its rules on an emergency basis.[2] Only now Plaintiffs learn the Department had made an "operational decision" to require *any* registrant to submit an entirely new product list—all in the name of "administrative efficiency." ECF No. 43-1 ¶ 35. Of course, absent from the Department's brief is any indication that it informed industry participants or the public about its "operational decision" before its filing on July 19, 2024. Even when sitting face-to-face with these litigants and before members of the legislature just last week, the Department refused to explain this "operational decision" to stakeholders or members of the legislature. *See Administrative Rules Review Committee*, Iowa ARRC Committee, at 12:22:20 to 12:24:20 PM (July 16, 2024),*available at* https://www.legis.iowa.gov/committees/meetings/meetingsListComm?groupID=705&ga=90&session=2. Even now, Plaintiffs have been given no meaningful explanation why the Department shadow-banned products approved prior to July 1, in anticipation of conducting business after July 1, when other registrants were not treated similarly—right until after the Department's rules were finalized. The absence of a credible explanation further supports the notion that the Department chose to operate its consumable hemp program how it wanted, no matter the state of the law or regulations.[3] Any "administrative efficiency" was greatly outweighed by significant economic disruption and market confusion for all industry stakeholders.

[2] Significantly, and for purposes of an as-applied vagueness challenge, the Department also denied products from both Plaintiffs that contain less than 4 milligrams per serving (as defined by the manufacturer) and between 5 and 10 milligrams in a 12-fluid ounce container.

[3] The Department also confirmed at the legislative hearing that its purported authority to define "serving" and "container" resides in the statute's "packaging and labeling" rulemaking authority. *See Administrative Rules Review Committee*, Iowa ARRC Committee, at 12:16:00 to 12:17:05 PM (July 16, 2024), *available at* https://www.legis.iowa.gov/committees/meetings/meetingsListComm?groupID=705&ga=90&session=2.
Plaintiffs previously renewed their motion for preliminary injunction on the basis of federal preemption, and continue to maintain the statute's potency limits are preempted by federal law.

Similarly, no industry stakeholders were aware the Department intended to finalize its rules on an emergency basis (effective July 17) until July 16, just one day prior.[4] And even then, only legislators on the state's Administrative Rules Review Committee received a copy of the Department's "draft" rules (stakeholders were not provided a copy), which were apparently finalized sometime within the previous twenty-four hours. Legislators had to ask Department officials directly—on multiple occasions—to get clear answers on the rules' operative provisions and whether the effective date would, in fact, be July 17. *See id.* 12:53:10 to 1:00:45 PM. The Department's final guidance advises manufacturers to take "reasonable steps" to comply with the already-final labeling requirements. ECF No. 43-7 p. 1. What is a "reasonable step" under these circumstances? The Department's final guidance also states it is apparently retroactive, backdating enforcement to July 1. *Id.* p. 7. What was lawful one day became criminal *not* the next day, but sixteen days *prior*, with no notice and uncertain terms. All signs point toward the arbitrary enforcement of a statutory scheme in which vague terms of art were transformed into criminal conduct, two weeks ago. *See Sec. State Bank v. Ziegeldorf*, 554 N.W.2d 884, 894 (Iowa 1996) ("'[A]rbitrary' means an unreasoned decision made without regard to law or facts."); *cf. Matter of Robintech, Inc.*, 863 F.2d 393, 396 (5th Cir. 1989) ("In general, due process requires that reasonable notice is that which is reasonably calculated to reach all interested parties, reasonably conveys all of the required information, and permits a reasonable amount of time for response." (citing *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950))).

It is ultimately unclear what the legislature intended when it enacted the per-serving limit on consumable hemp products. But under no circumstances did it intend for the Department to

[4] Indeed, attorneys for the Department in this matter have assured the Court its final rules would not go into effect "for some time." June 28, 2024 Hearing Tr. 44:7–16. It is unclear why the Department did not alert the Court at the July 11 hearing that it intended on finalizing rules on July 17.

implement the per-serving limit of HF2605 in the manner it has. If the legislature wanted the Department to define potency limits, it would have granted the Department that authority. If it desired the Department to implement emergency rules, it would have granted that authority, too. If it chose to define "serving" according to the standard serving sizes of the underlying food product, it would have said so. And if it wanted the Department to bring the entire consumable hemp market to a grinding halt while the Department decided how to implement the law moving forward, it would have provided as much. Instead, the Department continues to inject market uncertainty into an industry based on vagaries, incomplete information, and non-responsive decisionmakers. Due process requires more.

CONCLUSION

For the reasons previously stated, Plaintiffs respectfully request this Court enter an order enjoining the Department, through Director Kelly Garcia, from any enforcement of the per-serving potency limit in HF2605 because it is unconstitutionally vague and until such time as the legislature can provide further guidance through a subsequent enactment of law.

Dated July 22, 2024.

Respectfully submitted,

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