

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

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CLIMBING KITES LLC and FIELD DAY BREWING COMPANY LLC,	)	CASE NO. <u>4:24-CV-202</u>
	)	
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,	)	<b>AMENDED COMPLAINT AND REQUEST FOR INJUNCTIVE RELIEF</b>
	)	
Defendants.	)	

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Plaintiffs Climbing Kites LLC and Field Day Brewing Company LLC, by and through the undersigned counsel, hereby and for their Amended Complaint and Request for Injunctive Relief against Defendants State of Iowa, Director Kelly Garcia, and the Iowa Department of Health and Human Services (together the “Department”), state as follows.

**PARTIES**

1. Plaintiff Climbing Kites LLC is an Iowa limited liability company with a principal place of business in Polk County, Iowa. Climbing Kites LLC is an Iowa citizen within the meaning of 28 U.S.C. § 1332(c).

2. Plaintiff Field Day Brewing Company LLC is an Iowa limited liability company with a principal place of business in Johnson County, Iowa. Field Day Brewing Company LLC is an Iowa citizen within the meaning of 28 U.S.C. § 1332(c).

3. Defendant State of Iowa is a state of the United States.

4. Defendant Kelly Garcia serves as the Director of the Iowa Department of Health and Human Services and based on information and belief, is an Iowa citizen within the meaning

and intent of 28 U.S.C. § 1332. Director Garcia is sued in her official capacity and is responsible for interpreting, enforcing, and otherwise administering Iowa’s consumable hemp program.

5. Defendant Iowa Department of Health and Human Services is a principal central department within the state executive branch. The Department is an Iowa citizen within the meaning and intent of 28 U.S.C. § 1332.

### **JURISDICTION AND VENUE**

6. The Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331 because this is a civil action in which Plaintiffs raise a claim for relief against the Department arising under article VI, clause 2 of the United States Constitution, the Fourteenth Amendment to the United States Constitution, and the Federal Food, Drug, and Cosmetic Act. The Court has jurisdiction over Plaintiffs’ related state-law claims because they form part of the same case or controversy within the meaning of 28 U.S.C. § 1367(a).

7. Venue is proper in the United States District Court for the Southern District of Iowa under 28 U.S.C. § 1391(b) because a substantial part of events giving rise to Plaintiffs’ claims occurred in this district and because all Defendants reside in this district. For purposes of Plaintiffs’ state-law claims, venue is appropriate in this district as it includes Polk County, Iowa, within the meaning of Iowa Code § 17A.19(2).

### **FACTUAL BACKGROUND**

8. Congress legalized production of hemp as a commodity in the Agriculture Improvement Act of 2018, commonly known as the 2018 “Farm Bill.” The Iowa legislature followed suit shortly thereafter by passing the Iowa Hemp Act in 2019. Those laws signify a policy decision at the state and federal level to exclude hemp from state and federal definitions of “marijuana,” thereby legalizing hemp production across the country and State of Iowa.

9. The 2019 Iowa Hemp Act permitted not only producing hemp within Iowa, but also contemplated production and sale of hemp-based products within the state, such as textiles, paper, and consumables.

10. Thus began Iowa's nascent market of "consumable hemp:" i.e., production, manufacture, and sale of products, intended for human consumption, that contain lawful cannabis- or hemp-derived THC.

11. In 2020, a second hemp bill was passed in Iowa by near-unanimous margins. That law formally established the state's consumable hemp program; maintained the definition of "hemp" as a plant or any derivatives thereof with a maximum THC concentration of 0.3% or less, which mirrored federal law; defined "consumable hemp product" as a product that could be consumed through digestion, internal absorption, or absorption through the skin; required any person manufacturing or selling consumable hemp products to register with the State prior to conducting business; required compliance with State "packaging and labeling requirements," to be established by administrative rule; and confirmed that any hemp product manufactured, distributed, sold, or consumed in compliance with state law was not a controlled substance and therefore legal under state law.

12. Plaintiff Climbing Kites LLC ("Climbing Kites") was formed in 2023 and is headquartered in Des Moines, Iowa.

13. Climbing Kites produces and sells canned beverages (also called Climbing Kites) that contain carbonated water, citric acid, natural flavors, and hemp-derived cannabis oil.

14. Climbing Kites offers beverage "versions," which differ in terms of flavor and amount of total THC.

15. Climbing Kites currently offers canned beverages containing 2.5, 5, and 10 milligrams of total THC per beverage.

16. While current law requires Climbing Kites' products to contain 0.3% or less THC, its products actually contain between 0.001% and 0.003%.

17. Climbing Kites is fully licensed and registered with the State of Iowa, has had all products reviewed and approved by the Department, and complies with all federal guidance relating to hemp-derived CBD and THC.

18. Climbing Kites sells its beverages within Iowa.

19. Plaintiff Field Day Brewing Company, LLC ("Field Day Brewing") was formed in 2023 and is headquartered in North Liberty, Iowa.

20. Field Day Brewing manufactures and sells consumable hemp products; namely, canned beverages (called "Day Dreamers") that contain carbonated water, citric acid, natural flavors, and hemp-derived cannabis oil.

21. Field Day Brewing offers different versions of the beverage in terms of flavor and number of milligrams of total THC contained within the beverage.

22. Field Day Brewing currently offers canned beverages containing 2, 7, and 15 milligrams of total THC per beverage.

23. While current law requires Field Day Brewing's products to contain 0.3% or less THC, its products actually contain between .001% and .003%.

24. Field Day Brewing is fully licensed and registered with the State of Iowa, has had all products reviewed and approved by the Department, and complies with all federal guidance relating to hemp-derived CBD and THC.

25. Field Day Brewing manufactures and sells its beverages within Iowa.

26. Nothing in the 2018 Farm Bill affected the Federal Food, Drug, and Cosmetic Act (the “FDCA”) or the authority of the U.S. Food and Drug Administration (the “FDA”) to promulgate regulations that “relate to the production of hemp under the Act.” The FDA maintains its authority to regulate consumable hemp products, has concluded it is unlawful to introduce such products into interstate commerce, and has acknowledged that whether it is legal to sell such products depends on the product’s intended use and how it is labeled and marketed.

27. Whether and to what extent the FDA should provide further clarification for product manufacturers has become a political football and the subject of numerous Congressional hearings. As recently as April 2024, the FDA Commissioner testified the FDA would not implement further regulation without Congressional action.

28. By late 2023, state policymakers wished to address several emerging issues related to the consumable hemp market, including a “cap” on THC for food products to better consider products that contain heavy or wet ingredients common in consumable hemp products.

29. State officials therefore introduced legislation to place potency restrictions on consumable hemp products: i.e., the maximum amount of THC within a food product.

30. Initial legislation gave the Department authority to “determine dose and volume/serving size limitations via administrative rule.” The introduced bill also modified the Department’s preexisting authority to issue rules on packaging and labeling for hemp products. The bill was subsequently amended throughout the legislative process.

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

*c.* A hemp product is deemed to be a consumable hemp product if all of the following apply:

...

(2) Its maximum total tetrahydrocannabinol concentration is less than or equal to the lesser of the following:

(a) Three-tenths of one percent on a dry weight basis.

(b) Four milligrams per serving and ten milligrams per container on a dry weight basis.

As amended, Iowa Code § 204.7(8)(a)(3) will now provide:

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

32. HF2605 will take effect on July 1, 2024.

33. After HF2605's approval, the Department issued two versions of guidance for current manufacturers and retail sellers to help "understand regulatory changes to the program that will be in effect on July 1, 2024." The second, more recent Department guidance issued on June 7.

34. According to that June 7 Guidance, the Department intends to implement potency limits by defining "serving" as those established in FDA regulations.

35. The Department's Guidance means, for example, that despite the statute providing a hemp product may contain up to "ten milligrams per container," the Department has determined one 12-ounce can of Climbing Kites or Day Dreamer may only include up to four milligrams of THC, because the FDA's "serving size" for some beverages is 12 fluid ounces.

36. The Department's guidance defines all beverages as containing a serving size of 12 fluid ounces, despite the FDA establishing a smaller serving size for some beverages, such as 8 fluid ounces for fruit juices.

37. Even though neither Iowa’s hemp statutes nor the FDA’s serving size rules include a minimum container size, the Department will criminalize all beverage containers smaller than 12 fluid ounces.

38. According to the Department, any products that do not conform to its proposed potency limits, labeling requirements, or size restrictions will be a controlled substance beginning July 1.

39. There will be no “grace period” for on-hand products not meeting the new limits, and the Department noted that penalties “may range from a serious misdemeanor to a class B felony, depending on the amount of product in [a registrant’s] possession.”

40. Regarding Packaging and Labeling Authority, the Department proposed the following warning label information:

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

41. On June 12, 2024, the Department filed a Notice of Intended Action, consistent with rulemaking requirements under the Iowa Administrative Procedure Act, in an effort to implement the potency limits and Packaging and Labeling Authority.

42. Pursuant to the Department’s Guidance, approximately 80% of Plaintiffs’ current inventory will become illegal because of the Department’s interpretation of the potency limits and subject Plaintiffs to potential criminal liability on July 1.

43. Products that account for approximately 85% of Plaintiffs’ revenue will become illegal because of the Department’s interpretation of the potency limits.

44. HF2605, as enacted and as interpreted by the Department, has and will continue to harm Plaintiffs.

**COUNT I**  
**Preemption**

45. Plaintiffs restate and reallege paragraphs 1 through 44 of this Complaint as if fully set forth herein.

46. Under the Supremacy Clause, federal law is “the supreme law of the Land,” preempting any contrary state laws. U.S. Const. art. VI, Cl. 2.

47. Federal law preempts state laws, even if enacted pursuant to a state’s police powers, especially when evidenced by the clear and manifest purpose of Congress.

48. Congress has regulated the field of adulterated or misbranded food and drugs since the enactment of the Pure Food and Drugs Act in 1906. Congress gave authority to the United FDA to oversee food safety upon the passage of the FDCA of 1938. In 1990, Congress passed the Nutrition Labeling and Education Act, which created a national uniform nutritional labeling scheme. Through these laws and others, including, but not limited to, 21 U.S.C. § 343-1, Congress has expressly preempted any state-law requirement for composition, serving sizes, labeling, and packaging of food that is not “identical to” federal requirements.

49. Section 2 of House File 2605 amends Iowa’s consumable hemp laws to include a potency limit of “[f]our milligrams per serving and ten milligrams per container on a dry weight basis.” (To be codified at Iowa Code § 204.2(2)(c)(2)(b)).

50. This state-law potency limit violates the Supremacy Clause because it attempts to regulate matters exclusively reserved to the federal government as evidenced by Congress’s express preemption provisions.



51. Section 4 of House File 2605 amends Iowa’s consumable hemp laws to include authority for the Department to adopt packaging and labeling requirements, specifically relating to health-related claims on consumable hemp products. (To be codified at Iowa Code § 204.7(8)(a)(3)).

52. This state law packaging and labeling requirement violates the Supremacy Clause because it attempts to regulate matters exclusively reserved to the federal government as evidenced by Congress’s express preemption provisions.

53. Plaintiffs have been and will continue to be harmed by the enactment of the potency limit in Section 2 and the packaging and labeling requirement of Section 4 of House File 2605.

WHEREFORE, Plaintiffs respectfully request the Court enter an order declaring that a potency limit of “[f]our milligrams per serving and ten milligrams per container on a dry weight basis,” as enacted in Section 2 of House File 2605 (to be codified at Iowa Code § 204.2(2)(c)(2)(b)) and the packaging and labeling authority related to health-related claims, as enacted in Section 4 of House File 2605 (to be codified at Iowa Code § 204.7(8)(a)(3)), violate the Supremacy Clause of the United States Constitution, and awarding the costs of this action and any other relief the Court deems just and proper.

**COUNT II**  
**Judicial Review of Agency Action**

54. Plaintiffs restate and reallege paragraphs 1 through 53 of this Complaint as if fully set forth herein.

55. House File 2605 was lawfully enacted on May 17, 2024, and takes effect on July 1, 2024. On June 7, 2024, and to purportedly implement HF2605, the Department issued formal guidance on regulatory changes to the state’s consumable hemp laws based on the Department’s reading of House File 2605.

56. The Department has no authority to interpret, administer, or otherwise enforce the provisions in HF2605 in the manner described by the Department's June 7 Guidance. Nonetheless, the formal and finalized guidance constitutes final agency action under Iowa Code §§ 17A.2(2) and 17A.19(1).

57. Plaintiffs seek judicial review of the Department's June 7 Guidance, which constitutes final agency action, related to the Department's interpretation of HF2605's Potency Limits and Packaging and Labeling Authority.

58. Plaintiffs have been prejudiced by the Department's formal guidance because the final agency action is:

- a. Beyond 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).
- b. Based upon an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency. Iowa Code § 17A.19(10)(c).
- c. The product of reasoning that is so illogical as to render it wholly irrational. Iowa Code § 17A.19(10)(i).
- d. Otherwise unreasonable, arbitrary, capricious, or an abuse of discretion. Iowa Code § 17A.19(10)(n).

WHEREFORE, Plaintiffs respectfully request the Court enter an order declaring the Department has no authority to interpret or otherwise administer the provisions of HF2605 in any manner beyond the plain language of the statute, through rulemaking or otherwise, and prohibiting the Department from interpreting, enforcing, or otherwise administering Iowa's consumable hemp laws in a manner that prohibits the manufacture, distribution, or sale of a consumable hemp product that contain ten or less milligrams total THC per container, and for such other relief as the Court may deem equitable and appropriate.

**COUNT III**  
**Violation of Due Process Clause (Facial and As Applied)**

59. Plaintiffs restate and reallege paragraphs X through X of this Complaint as if fully set forth herein.

60. The Due Process Clause of the United States Constitution prohibits the State of Iowa and its state agencies and officials from depriving any person of life, liberty, or property without due process of law.

61. The Potency Limits enacted in HF2605 provide that a consumable hemp product cannot contain more than “four milligrams per serving and ten milligrams per container” of total THC.

62. Any consumable hemp product manufactured, distributed, or otherwise maintained by a retailer within the State of Iowa that exceeds the Potency Limits constitutes a criminal offense.

63. House File 2605 does not define, explain, or otherwise shed any light on what constitutes a “serving” of total THC in a consumable hemp product.

64. On its face, and as applied to the Plaintiffs, the Potency Limits in HF2605 violate the U.S. Constitution’s Due Process Clause because they are unconstitutionally vague.

65. The Department has issued guidance and has begun to promulgate rules attempting to define “serving” and “container” within the meaning of the Potency Limits.

66. In addition to having no legal authority to issue such guidance or promulgate such rules, the Department’s interpretation of the Potency Limits also violates the U.S. Constitution’s Due Process Clause because they, too, are unconstitutionally vague.

67. Plaintiffs are subject to criminal and civil penalties if deemed to manufacture, distribute, or otherwise maintain non-complaint consumable hemp products.

68. For Plaintiffs, the difference between lawful business and criminal conduct is an unintelligible, unreasonable, and unworkable potency limit standard for consumable hemp products.

69. The Department intends to enforce the Potency Limits of HF2605 and its interpretation of those Potency Limits beginning July 1, 2024.

70. The Department's enforcement of the Potency Limits will cause irreparable and severe harm to Plaintiffs in violation of their rights under the U.S. Constitution's Due Process Clause.

WHEREFORE, Plaintiffs respectfully request the Court enter an order declaring that a potency limit of "[f]our milligrams per serving and ten milligrams per container on a dry weight basis," as enacted in Section 2 of House File 2605 (to be codified at Iowa Code § 204.2(2)(c)(2)(b)) Violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution, and further ordering the Department or its officials from interpreting, enforcing, or otherwise administering Iowa's consumable hemp laws to include the Potency Limit enacted in HF2605, and for such other relief as the Court may deem equitable and appropriate.

**COUNT III**  
**Temporary and Permanent Injunctive Relief**

71. Plaintiffs restate and reallege paragraphs 1 through 58 of this Complaint as if fully set forth herein.

72. Effective July 1, 2024, the Department intends to implement the newly enacted Potency Limit and Labeling and Packaging Authority contained in House File 2605 consistent with its June 7 Guidance. The Department's actions are unlawful.

73. Plaintiffs are likely to prevail on the merits in this matter.

74. The actions of the Department have and will continue to cause irreparable harm to Plaintiffs for which monetary damages alone will be an inadequate remedy.

75. Requiring the Department to administer and enforce Iowa’s consumable hemp laws *without* the newly enacted Potency Limit or Packaging and Labeling Authority—as is the law currently and has been for years—will not cause the Department harm, and the balance of harms is substantially greater to Plaintiffs.

76. Public policy favors the enactment of constitutional legislation and does not favor state regulation when Congress has expressly concluded otherwise.

WHEREFORE, Plaintiffs respectfully request the Court enter an order granting temporary and permanent injunctive relief in its favor and against the Department by: (1) enjoining the enactment or enforcement of House File 2605’s Potency Limits and Packaging and Labeling Authority based on federal preemption and/or the doctrine of primary jurisdiction, or the Due Process Clause of the Fourteenth Amendment to the United States Constitution, or alternatively, (2) enjoining the Department from interpreting or otherwise administering the provisions of HF2605 in any manner beyond the plain language of the statute, through rulemaking or otherwise, and (3) enjoining the Department from interpreting, enforcing, or otherwise administering Iowa’s consumable hemp laws in a manner that prohibits the manufacture, distribution, or sale of a consumable hemp product that contains ten or less milligrams total THC per container, and awarding the costs of this action and any other relief the Court deems just and proper.

**COUNT IV**  
**Declaratory Action**

77. Plaintiffs restate and reallege paragraphs 1 through 64 of this Complaint as if fully set forth herein.

78. This Court may determine the legal rights of Plaintiffs effective July 1, 2024, in this matter within the meaning of Federal Rule of Civil Procedure and Iowa Code § 17A.19(5)(d).

79. House File 2605 violates the U.S. Constitution's Supremacy Clause and the Due Process Clause of the Fourteenth Amendment, and the Department's interpretation of HF2605 in its June 7 Guidance is unlawful, unreasonable, and fails to administer House File 2605 according to the plain language of the statute.

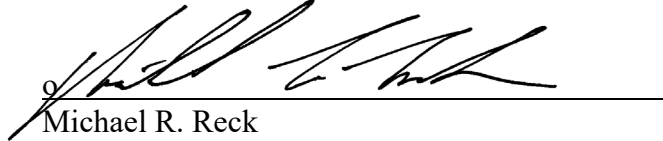
80. Considering the significant consequences of noncompliance with Iowa's consumable hemp laws effective July 1, 2024, this Court should declare the rights, status, and other legal relations of Plaintiffs' ability to sell or otherwise possess consumable hemp products the Department claims will be unlawful effective July 1.

WHEREFORE, Plaintiffs respectfully request the Court enter an order declaring (1) the Potency Limits and Packaging and Labeling Authority of House File 2605 unconstitutional as a violation of the Supremacy Clause of the United States Constitution and/or the Due Process Clause of the Fourteenth Amendment, (2) the Department has no authority to interpret or otherwise administer the provisions of HF2605 in any manner beyond the plain language of the statute, through rulemaking or otherwise, (3) if HF2605 is constitutional, the rights, status, and other legal relations of Plaintiffs' ability to manufacture, sell, or otherwise possess consumable hemp beverages that contain ten or less milligrams per container of THC consistent with the plain language of HF2605, and awarding the costs of this action and any other relief the Court deems just and proper.

Dated this 28<sup>th</sup> day of June, 2024.

Respectfully submitted,

BELIN McCORMICK, P.C.

A handwritten signature in black ink, appearing to read "Michael R. Reck", is written over a horizontal line.

Michael R. Reck

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