EXHIBIT
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
WESTERN DIVISION

HW PREMIUM CBD, LLC, AJ's HEALTH AND WELLNESS d/b/a AMERICAN SHAMAN, E. KRIEGER LAND, LLC d/b/a GREENE GOODS MARKET & GREENHOUSES, GREEN ONYX INC. d/b/a YOUR CBD STORE, BEYOND CBD, LLC dba BEYOND CBD, CAMPBELL'S NUTRITION CENTERS, INC., TCI ENTERPRISE, INC. d/b/a SKY HIGH, ICANNA, LLC, YOUR CBD STORES FRANCHISING, LLC,

Plaintiffs,

v.

GOVERNOR KIM REYNOLDS in her official capacity, DIRECTOR OF IOWA DEPARTMENT OF HEALTH AND HUMAN SERVICES KELLY GARCIA in her official capacity, COMMISSIONER OF IOWA DEPARTMENT OF PUBLIC SAFETY STEPHAN BAYES in his official capacity, and IOWA SECRETARY OF AGRICULTURE MIKE NAIG in his official capacity,

Defendants.

Case No. 4:24-cv-00210-SHL-HCA

PLAINTIFFS' SUPPLEMENTAL REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Now that Final Rules have been adopted on an emergency basis, Defendants attempt to wash their hands of the irreparable harm their unconstitutional actions have caused. But it is not that simple. Defendants failed to provide proper notice as to what conduct is prohibited: regulations were not adopted until nearly *three weeks* after the vague law went into effect, the portal was not operational, and DHHS refused to review products before July 1. Beginning the same day Defendants filed their opposition brief, DHHS began haphazardly approving or denying Plaintiffs' products based on Final Rules and non-binding FAQs. The Final Rules and FAQs do not cure constitutional defects for undefined Potency Provision terms within the statute because DHHS has no authority to do so thereunder. And this lack of deference was intended, as DHHS concedes it *cannot define those terms without being preempted by federal law*. Yet, DHHS has denied products based upon definitions it subjectively interprets from "recommended" servings within a sampling of Plaintiffs' products and based on DHHS' interpretation of what is a "synthetic" or semi-synthetic cannabinoid. This has left Plaintiffs in regulatory limbo today and overwhelmingly confused as to what DHHS considers compliant. An injunction is necessary to prevent imminent, arbitrary enforcement.

ARGUMENT

I. The Vagueness of the Potency Provision is Properly Before the Court.[1]

Defendants' fleeting attempt to avoid the vagueness of the Potency Provision on the merits should be denied by the Court. Plaintiffs challenged the Potency Provision (ECF No. 30 at 10) and provided sufficient notice to Defendants such that Defendants cannot argue prejudice. And frankly, Defendants do not argue prejudice, leaving this issue ripe for consideration by this Court. Even if

[1] Plaintiffs incorporate their previous briefing in response to Defendants' arguments concerning the facial vagueness of the Hemp Amendments. *See* ECF Nos. 10, 30, 35.

the Court considers Plaintiffs not to have addressed the Potency Provision's vagueness before their Reply Brief, *Martin v. Am. Airlines, Inc.*, 390 F.3d 601, 609 n.4 (8th Cir. 2004) fails to support Defendants' argument that Plaintiffs are barred from raising arguments for the first time in a reply and/or supplemental brief at the district court level. *Martin* addressed a rule applied to *appellate* briefing, and Defendants cite no opinion from this district or the Eighth Circuit as support for their argument while a motion remains pending.[2] Accordingly, this issue is properly before the Court.

II. The Final Rules Do Not Cure the Vagueness of the 2605 Requirements.[3]

The Final Rules, conveniently adopted during this supplemental briefing schedule and over objection of at least four legislators on the Administrative Rules Committee,[4] do *not* cure the vagueness within the 2605 Requirements. Notwithstanding the unconstitutional statutory and regulatory scheme under the Supremacy Clause, dormant Commerce Clause, and Takings Clause, the due process violations persist despite the emergency adoption of the Final Rules.

A. The Potency Provision Remains Vague.

The definition of "serving" within the Final Rules mirrors the draft regulations. This is not surprising, as Defendants admitted during the Preliminary Injunction Hearing ("PI Hearing") that they could not provide a statutory or regulatory definition of "serving" other than incorporating the Reference Amounts Customarily Consumed ("RACC") in table 2 of 21 CFR 101.12, because

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[2] Even the non-binding case Defendants cite in support of this claim, *Lukis v. Whitepages Inc.*, 542 F. Supp. 3d 831, 843 (N.D. Ill. 2020), does not prohibit a party from raising an argument for the first time in briefing at the district court, but instead gives the Court discretion regarding such briefing. Here, Defendants were not prejudiced in addressing the Potency Provision, as similar due process arguments were raised by Climbing Kites. *See* Tr. at 68-69. Further, new arguments may be raised and considered prior to the closure of briefing on a motion. *See Johnson v. Land O' Lakes, Inc.*, 18 F. Supp. 2d 985, 997–98 (N.D. Iowa 1998) ("[t]he court is reluctant to disregard potentially relevant authorities and arguments on a question of law, however belatedly proffered, when the ultimate goal of judicial proceedings is a just disposition of the issues presented.").

[3] Because the Court ordered supplemental briefing as to the Plaintiffs' due process challenges only, this briefing does *not* address the impact the Final Rules have (if any) on Plaintiffs' remaining constitutional claims. In the event the Court determines such briefing is required prior to ruling on Plaintiffs' pending Motion for Preliminary Injunction, Plaintiffs reserve the right to do the same.

[4] Senators Nielson, Olson, Boulton, and Winkler voted to suspend the rules. *See* July 16, 2024 Administrative Rules Committee Meeting, https://www.legis.iowa.gov/committees/meetings/meetingsListComm?groupID=705&ga=90.

to do otherwise would violate federal law. Tr. at 72-73. What Defendants actually argue is that the Final FAQs issued by DHHS on July 17, 2024, resolve the Potency Provision's vagueness. (ECF No. 37 at 18) (citing to the Final FAQs explanation that the serving limit in the definition of "serving" does not apply to non-food consumable hemp products). Defendants' attempt to remedy the unconstitutional vagueness of the "serving" limitation, by explaining:

> HHS' confirmation of table 2 of 21 CFR 101.12 for the definition of "serving" relates only to products intended to be ingested ("eaten") or contain food. As topically applied products … are not contained in table 2 of 21 CFR 101.12, they will not be held to a standard for serving, but any individual topical product cannot contain > 10 mg Total THC per container.

ECF No. 37-1, Ex. 6.

But Defendants are incorrect that the Final FAQs document carries the force of law that can remedy the rote unconstitutional vagueness in the Potency Provision. While it may be an "agency statement of general applicability that…interprets…law or policy," ICA § 17A.2(11), it did not go through notice and comment rulemaking required by ch. 17A to be given the force and effect of law. The Final FAQs have no legal effect and are not binding on DHHS or, just as importantly, *other* agencies tasked with enforcing the 2605 Requirements such as local law enforcement, county prosecutors and the Department of Public Safety. *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015) (stating that interpretive rules issued by federal agencies do not have the force and effect of law under the APA). The FAQs are a moving target based on how DHHS begins to enforce the Hemp Amendments. Further, even if the FAQs carried the force of law, they still fail to remedy vagueness about the full range of products Plaintiffs sell, such as cosmetics and liquid hemp products. (ECF No. 35 at 5).[5] The Plaintiffs are no better off than they

[5] Defendants are wrong that Plaintiffs' vagueness claim is defeated because the plaintiffs in *Climbing Kites et al. v. Iowa* understand serving and container requirements. That lawsuit exclusively addresses carbonated beverages, which is only one of many products sold by Plaintiffs. In addition, what Climbing Kites understands is distinct from what the Plaintiffs understand, demonstrating on its face the heightened risk for arbitrary enforcement here.

were at the beginning of this litigation regarding uncertainty as to whether selling their products will be criminalized.[6] The *only* clarity provided is that topical creams – at least *today* – will not require "per serving" input on the DHHS portal. But that could change tomorrow.

Additionally, the FAQs are nothing more than DHHS' interpretation of an ambiguous statute it concedes it has no authority to expand upon without running afoul of preemption principles. Tr. at 72-73. DHHS's interpretation of the Potency Provision should not be entitled to any deference, as the Hemp Amendments do not vest in DHHS the discretion to define, construe, or interpret the Potency Provision. *See Loper Bright Enterprises v. Raimondo*, -- S. Ct. ----, 2024 WL 3208360 (June 28, 2024) ("courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."); ICA § 17A.19(11)(b). Moreover, agency interpretation within the FAQs *and* the Final Rules should not be given deference because the Final Rules go far beyond what is included in the 2605 Requirements. *See, e.g., California Cosmetology Coal. v. Riley*, 110 F.3d 1454, 1460 (9th Cir. 1997) ("A regulation may not serve to amend a statute, nor add to the statute something which is not there." (cleaned up)). Here, the Potency Provision did not define "serving" or "container." 2605 did not define "synthetic," or provide clarity on what warning was necessary.[7] DHHS says it *can't* define serving, but yet it is enforcing what constitutes a serving based on its own subjective interpretation within expanded Final Rules and non-binding FAQs. Ex. 1, Powell Decl. ¶ 234. *See also* ECF No. 37 at 11-12.

[6] The Revised Consumable Hemp Product List Upload Guide (the "Revised Guide"), ECF No. 37-1, Ex. 4 provides no clarity either. It fails to even incorporate the Final FAQ guidance regarding topical products, and does not address what a "serving" is for tinctures, topicals, gummies, etc.

[7] This lack of authority was recognized by legislators during the adoption of the emergency rules and calls into question the constitutionality of the Final Rules. July 16, 2024 Administrative Rules Committee Meeting, https://www.legis.iowa.gov/committees/meetings/meetingsListComm?groupID=705&ga=90 at 2:05:15 pm.

The Final Rules also leave the definition of "container" unchanged. ECF No. 37-1, Ex. 7. Defendants' reliance on the Final FAQs to provide clarity as applied to Plaintiffs' products falls short for the same reasons detailed above regarding "serving" guidance. Ex. 1, Powell Decl. ¶ 21. The Final FAQs state *as an example*, "Edibles | Compliant – A 10-pack of gummies at 1mg THC per gummy." (ECF No. 37-1, Ex. 6). This does *nothing* to explain how, for example, a sheet of 10 gummies that are in individual blisters (*i.e.,* 10 individual packages) is considered a container or whether the blister itself is a container. ECF No. 35-2 ¶ 21.

The 2605 Requirements impose a *statutory* requirement to meet *both* the serving and container requirements distinct from federal requirements. Tr. at 74.[8] And this requirement leaves the manufacturer, retailer and those enforcing the law to guess how DHHS interprets a "serving," when these products are manufactured to be sold in multiple states.[9] Due to the risk of criminal enforcement, Plaintiffs must be given fair notice of what conduct is prohibited, *see F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 258 (2012), and neither the statute nor any rule or informal guidance published by Defendants does this.[10] Plaintiffs submit that the "serving" and "container" requirements are plainly and textually read together, and thus a finding of vagueness as to one requirement dooms the Potency Provision in its entirety. *See* HF 2605 § 2 ("Four milligrams per serving *and* ten milligrams per container…"). Nevertheless, DHHS has arbitrarily applied these

[8] It is irrelevant to the determination of whether the Potency Provision is unconstitutional that Plaintiffs may have had to enter a product's total cannabinoids per serving and container when submitting a product to the portal before July 1. DHHS did not deny products based on any information provided regarding total cannabinoid servings or containers because they could not do so. Tr. at 74. DHHS itself was also previously charged with calculating whether the product met the THC limitation based on the certificate of analysis ("COA"). ECF No. 37-1 ¶ 25. Now, licensees are tasked with gleaning this information from the COA and making their own calculations at the risk of criminal penalties. What's more, COAs do not show the amount of milligrams of THC per container because this is not an industry standard. ECF No. 35-5 ¶ 11.

[9] See e.g., ECF Nos. 35-1 ¶8-9; 35-3 ¶ 12; 35-5 ¶12-13; 35-9 ¶ 9-10. In addition, manufacturers are now being held to have a COA no older than one year old, contrary to industry standard and the shelf life of the products. Ex. 1, Powell Decl. ¶ 10.

requirements as dependent in some instances but independent in others, compounding confusion surrounding these terms and rendering it nearly impossible to understand what products are compliant or not. *See* FAQs (topical products will not be held to the 4 mg "per serving" requirement but will be held to the 10 mg "per container" requirement).[11] Accordingly, even in the event the Court finds serving vague but not container, or vice versa, their interconnectedness mandates that the Potency Provision be enjoined in its entirety and allow a return of the status quo that existed in Iowa under the 2018 Farm Bill before July 1, 2024.

B. The Synthetic Prohibition Remains Unconstitutionally Vague.

Defendants grossly oversimply the vagueness problems with the Synthetic Prohibition. The "text, context, and the industry's well-known understanding of the term" is what renders this provision so vague and at risk for arbitrary enforcement. (ECF No. 37 at 19). Further, *United States v. Sims*, 849 F.3d 1259, 1260 (9th Cir. 2017) does not save the provision. The straightforward condition given to the defendant for supervised release in *Sims* was to avoid *all* marijuana products including synthetic cannabinoids. The same is not true for Plaintiffs here, where they must be able to understand the difference between non-synthetic and "synthetic or semi-synthetic consumable hemp products." The provision and Final Rules do not achieve this, and imminent enforcement is here, as products are being denied which do *not* have Delta 8 in them. Ex. 1, Powell Decl. ¶ 7.

C. The Final Rules did not give fair notice of the Warning Label Requirement.

The Final Rules were revised, passed and deemed instantly effective within a 24-hour period. This is not fair notice. The Final Rules invite arbitrary enforcement, leaving considerable discretion with enforcing authorities to determine what meets the requirements. (ECF No. 37-1, Ex. 5 ("A warning label containing the following or *substantially similar languag*e, in addition to

[11] *See generally* Ex. 1, Powell Decl. Exs. A-D (confirming the potency terms are intermingled because they are denied on an "and/or" basis and the denials fail to detail whether the serving or container terms are implicated.).

any other warning language necessitated by the specific product.") (emphasis added)). The Court should, at minimum, enjoin the enforcement of this provision for a period of at *least* six months to allow new manufacturers to comply with the Warning Label Requirement and provide clarity as to whether it applies to non-THC products, too.[12]

III. DHHS's Arbitrary Enforcement Shows an Injunction Is Needed.

The 2605 Requirements are already being arbitrarily applied to Plaintiffs. DHHS has only recently denied Plaintiffs' products, including for reasons not provided for or permitted in the Hemp Amendments, and for products containing *no* THC. Ex. 1, Powell Dec. ¶ 17; *See also* Ex. 2, Decl. of Mathew Miller. Without an injunction, this haphazard and inconsistent enforcement, illustrating the underlying unconstitutional vagueness, will only worsen.

CONCLUSION AND PRAYER FOR RELIEF

Plaintiffs are continuing to gamble with their freedom to operate their businesses. The Final Rules and FAQs do not "fix" the vagueness inherent in the Potency Provision, the Synthetic Prohibition or the Warning Label Provision. Plaintiffs request the Court enjoin the entire Hemp Amendments and Final Rules, which should be enjoined because they are intertwined with and enforce the 2605 Requirements. *See Salazar v. Buono*, 559 U.S. 700 (2010) ("A court must find prospective relief that fits the remedy to the wrong or injury that has been established."). Alternatively, Plaintiffs request the Court sever and enjoin the enforcement of the 2605 Requirements and the Final Regulations as applied to those industry participants and consumers who possess, manufacture, transport, distribute, and sell hemp-derived products and sever the 2605 Requirements from the Hemp Amendments.

[12] *See generally* Ex. 3, Krieger Decl.; Ex. 1, Powell Decl. ¶ 19. And this is assuming the Court does not find it facially vague for violating the Due Process Clause, and inhibiting a fundamental right under the U.S. Constitution.

Dated this 22nd day of July 2024.

HW PREMIUM CBD, LLC, AJ's HEALTH AND WELLNESS d/b/a AMERICAN SHAMAN, E. KRIEGER LAND, LLC d/b/a GREENE GOODS MARKET & GREENHOUSES, GREEN ONYX INC. d/b/a YOUR CBD STORE, BEYOND CBD, LLC dba BEYOND CBD, CAMPBELL'S NUTRITION CENTERS, INC., TCI ENTERPRISE, INC. d/b/a SKY HIGH, ICANNA, LLC, YOUR CBD STORES FRANCHISING LLC, Plaintiffs,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 22nd day of July 2024, the foregoing was electronically served by the court via EDMS on all counsel of record.

/s/ *Ryann A. Glenn*