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

HW PREMIUM CBD, LLC, *et al.*, *Plaintiffs*, v. KIM REYNOLDS, Governor of Iowa in her official capacity, *et al.*, *Defendants*.	Case No. 4:24-cv-00210-SMR-SBJ

DEFENDANTS' SUPPLEMENTAL BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

INTRODUCTION 1

BACKGROUND 2

A. The Consumable Hemp Registrant Portal 2

B. The Department Updates the Portal Then Processes All Registrants' Post-July 1 Product Submissions. 5

C. The Department's Final Rules Became Effective On July 17, 2024. 8

ARGUMENT 9

I. The Court Need Not Consider Plaintiffs' Facial Vagueness Challenges. 9

II. HF2605's Challenged Provisions Are Not Unconstitutionally Vague. 12

III. The Hemp Amendments Have Not Resulted in Arbitrary Enforcement. 18

CONCLUSION 19

TABLE OF AUTHORITIES

Page(s)

Cases

City of Chicago v. Morales,
527 U.S. 41 (1999) 10
Gallagher v. City of Clayton,
699 F.3d 1013 (8th Cir. 2012) 9
Gonzales v. Carhart,
550 U.S. 124 (2007) 15
Guedes v. ATF,
920 F.3d 1 (D.C. Cir. 2019) 12
Johnson v. United States,
576 U.S. 591 (2015) 9
Lukis v. Whitepages Inc.,
542 F. Supp. 3d 831 (N.D. Ill. 2020) 10
Martin v. Am. Airlines, Inc.,
390 F.3d 601 (8th Cir. 2004) 10, 11, 13
Moody v. NetChoice, LLC,
144 S. Ct. 2383 (2024) 13
Sanimax USA, LLC v. City of S. St. Paul,
95 F.4th 551 (8th Cir. 2024) 9, 10
Sessions v. Dimaya,
584 U.S. 148 (2018) 9
United States v. Burgee,
988 F.3d 1054 (8th Cir. 2021) 9
United States v. Ghane,
673 F.3d 771 (8th Cir. 2012) 9, 10
United States v. Rybicki,
354 F.3d 124 (2d Cir. 2003) 10
United States v. Sims,
849 F.3d 1259 (9th Cir. 2017) 15
United States v. Veasely,
98 F.4th 906 (8th Cir. 2024) 10
Vill. of Hoffman Estates v. Flipside, Hoffman Ests., Inc.,
455 U.S. 489 (1982) 12, 13, 15, 16

Statutes

7 U.S.C. § 6502(22) 16
Iowa Code § 4.4 12
Iowa Code § 4.6 12
Iowa Code § 17A.4 ..... 8, 12
Iowa Code § 17A.5 ..... 8, 12

Regulations

21 CFR 101.12 13
Iowa Admin. Code r. 641—156.1 ..... 2, 8, 14, 16
Iowa Admin. Code r. 641—156.2 3
Iowa Admin. Code r. 641—156.4 17

INTRODUCTION

Plaintiffs claim three parts of HF2605 are unconstitutionally vague. Though each challenged section's plain language gives a person of ordinary intelligence notice of what conduct HF2605 prohibits, Plaintiffs claim that they do not know what conduct is proscribed. Plaintiffs' argument revolves around a concern that, until the Department of Health and Human Services issues a final rule, Plaintiffs are subject to unacceptable uncertainty. And that such a final rule may not issue for two months. But the Department, under its emergency authority, completed rule-making, and the Final Rules took effect on July 17, 2024. The Final Rules, and the Department's accompanying Final FAQ Guidance, provide definitions, examples, and descriptions of the terms Plaintiffs challenge, curing any alleged ambiguity or confusion.

Meanwhile, Department employees have been tirelessly working to rollout a new online tool to assist the Department in its enforcement of Iowa's Hemp Amendments. As of today, the Department has processed all consumable hemp products submitted between July 1 and July 17, 2024, for the Department's review. Each Plaintiff that submitted new products for approval since July 1, has, by now, received notice that their product was either approved or denied.

Plaintiffs now have their answers. Any claim that the challenged parts of HF2605 are unconstitutionally vague as applied to Plaintiffs thus fails. As does any facial vagueness challenge, because such challenges are unavailable when, as here, Plaintiffs do not bring First Amendment claims.

Plaintiffs attempt to amend their claims via supplemental briefing, raising vagueness claims they did not plead. That attempt at shoehorning in last-minute claims does not satisfy minimum notice pleading standards. In all events, these belated vagueness claims fail just like Plaintiffs' actually-pleaded vagueness claims.

More, these recent developments do not affect Plaintiffs' other constitutional claims, including their preemption, commerce clause, and takings claims.

Preliminarily enjoining enforcement of a state statute requires a rigorous threshold showing that the movant is likely to prevail on the merits. Plaintiffs fall well short of that necessary showing. The Court should deny Plaintiffs' renewed motion for preliminary injunction.

BACKGROUND

A. The Consumable Hemp Registrant Portal.

When Iowa's consumable hemp industry began a few years ago, the Department understood it needed infrastructure to enforce the program, which required each consumable hemp manufacturer, establishment, or distributor in Iowa, as defined by Iowa Admin. Code r. 641—156.1, to obtain (1) a consumable hemp registration from the Department and (2) approval of their product as compliant by the Department. Parker Decl. ¶¶ 4, 11. The Department reviewed more than 46,000 products submitted by 1,200 Registrants. Given that influx, the Department needed a useful tool to help it approve products for retail sale. *Id.* ¶¶ 5, 7, 8, 18.

So the Department, and its Bureau of Cannabis Regulation, with the help of a third-party developer, built and maintained a "Consumable Hemp Registrant Portal" to support registration and product approvals. *Id.* ¶¶ 5, 7. When registering with the Department on the Portal, each Registrant signs an attestation stating its understanding of the Iowa Hemp Act and agreeing to comply with State and federal law when selling their consumable hemp products. *Id.* ¶ 9. Approval of a product for sale does not alleviate each Registrant's responsibility to ensure their product continues to comply with state and federal law. *Id.* ¶ 10.

Registrants looking to have their products approved for sale in Iowa use the Portal and its included resources. Before July 1, 2024, the Department's primary criteria for approval was complying with the 2018 Farm Bill's less-than 0.3% THC threshold. *Id.* ¶ 25. Rules required

Registrants to disclose the "cannabinoids per serving" and "cannabinoids per container" somewhere on their product. *Id.* ¶¶ 14–15. So the Department gave Registrants an Excel template that laid out that required information. *Id.* No Registrant ever complained that they did not know what this "per serving" disclosure requirement meant; they knew that "cannabinoids per serving" meant cannabinoids per serving of the product you put the cannabinoid in. *Id.* ¶ 16. Registrants were also required to submit a Certificate of Analysis, which would include the information necessary to allow the Department to calculate whether the product complied with the federal <0.3% THC threshold. *Id.* ¶¶ 25–28.

Once new or revised products are submitted for the Department's review, the Department has 30 days to review and act on the submission. *Id.* ¶ 6; Iowa Admin. Code r. 641—156.2(1)(*c*) and 2(2)(*c*). While the product is pending approval, Registrants cannot begin selling it; they may only sell consumable hemp products in Iowa that are approved by the Department. *Id.* ¶ 11. If registrants sell noncompliant or unapproved products, the Department can enforce in a few different ways, including civil penalties. *Id.* ¶ 13. But such penalties are usually issued after repeated violations. *Id.*

After receiving Registrants' submissions, the Department provides emails receipt of the submission, confirming that the product is under review and, per the Department's obligation, will be acted on within 30 days. *Id.* ¶ 19. Though instantaneous review is not possible, because of how thorough the Department's process is, the Department was still able to maintain an average decision time of four days between July 1, 2023, and June 30, 2024. *Id.* ¶ 20.

No products are approved or denied without the Department providing notice to the Registrant. *Id.* ¶ 21. If a product is approved, the Registrant receives a receipt of the approval instantaneously and may view the product in its "approved product list" on the Portal. *Id.* ¶ 22.

When a Registrant submits a product list update during the registration's effective period, only newly submitted products are reviewed, while previously approved products on the list are maintained. *Id.* ¶ 23. But if the product is denied, the Registrant receives an email communication explaining which specific products were denied and why. *Id.* ¶ 24. The Department does not issue denials without also issuing express notice and explanation to the Registrant. *Id.*

HF2605's Potency Provision required the Department to build and implement substantive, and technical, updates to the Portal ahead of the law's July 1 effective date. *Id.* ¶ 30. That required extensive work by the Department and third-party web developers. *Id.* ¶¶ 7, 29, 30. To ensure a timely rollout, the Department began the work in April 2024, even before the Governor signed the law in May. *Id.* The Department timely completed the necessary updates and rolled out the updated Portal at midnight on July 1, 2024. *Id.* ¶ 30.

The key update to the Portal was that Registrants must now disclose "Total THC per Serving" and "Total THC per Container," instead of total *cannabinoids*, for any products submitted after July 1, 2024. *Id.* ¶ 31. The Department made related necessary changes to the Excel template. *Id.* ¶ 33. And it revised the "Consumable Hemp Product List Upload Guide" to outline the changes for Registrants' per-serving and per-container THC declarations and explaining why products may be denied by the Department. *Id.* ¶¶ 33–34.

But the Department did not begin reviewing products' compliance with HF2605 until after the law took effect. It had no authority to approve or deny products submitted for review under HF2605's new standards before the law's July 1, 2024, effective date. *Id.* ¶ 29. Meanwhile, until July 1, 2024, the Department still had the responsibility to continue approving products meeting the pre-HF2605 standards. *Id.* Processing products based on HF2605 before July 1 would have risked sending the signal to the public that the Department was enforcing the law before it was

even in effect. *Id.* ¶ 42. And from a practical standpoint, as a matter of resources and staffing, the Department could not double its Portal-derived workload—having to review the same product under both the pre- and post- July 1 standards—all while working hard to ensure a clean rollout of the amended hemp program at midnight on July 1, 2024. *Id.* ¶ 43.

Instead, the Department made an operational decision to require any Registrant entering the Portal on or after July 1, 2024, whether seeking to renew a registration or make a product list update, to submit a new product list in accordance with the portal updates and newly effective law. *Id.* ¶ 35. At that time, the Department had more than 46,000 products on file; instead of *sua sponte* re-approving or de-approving all those products, the Department pursued administrative efficiency and it expected Registrants—consistent with Registrants' continuing obligation under their Portal attestations to comply with state and federal law—to sift out any products that did not comply with the new law *Id.*

On July 1, 2024, Registrants with up-to-date registrations could still sell their products in Iowa, so long as (1) the Department had approved the product and (2) it complied with the new requirements set forth in HF2605 *Id.* ¶ 39. Otherwise, Registrants were expected to submit their product for the Department's review. *Id.* ¶ 35.

B. The Department Updates the Portal Then Processes All Registrants' Post-July 1 Product Submissions.

Once the Department rolled out the updated Portal on July 1, thus allowing it to enforce HF2605's updated THC potency standards, it immediately began accepting new or updated products submissions. Registrants entering the Portal after the July 1 rollout would have seen a banner atop the homepage flagging the substantial changes under HF2605, highlighting that the changes "will be in effect on July 1, 2024," and providing various resources for Registrants. *Id.* ¶ 32. Included in those resources was the revised Upload Guide outlining the changes for

Registrants' per-serving and per-container THC declarations and explaining why products may be denied by the Department. *Id.* ¶¶ 33–34. Another of those resources was the new template Excel spreadsheet Registrants were expected to use when submitting new and revised product lists for approval. *Id.* Because THC potency was newly regulated post-July 1, the template now requires Registrants to declare the "Total THC per serving" and "Total THC per container" for their product. *Id.* ¶¶ 15, 33.

Registrants could then submit their new product list updates for the Department's review if they declared the amount of THC per serving and THC per container for their products complied with HF2605. ¶¶ 36, 40. Once Registrants submitted new or updated products list post-July 1, their list of products approved pre-July 1 were archived from Registrants view, though the Department maintained access to those still-approved products. *Id.* ¶¶ 36–38. Those earlier approved products were not "denied"—no communications were sent to any Registrant *sua sponte* "de-approving" any products. *Id.* ¶ 38 After all, the Department does not issue denials without giving Registrants notice. *Id.* ¶¶ 24, 38. Instead, the Department would have 30 days from the date of the product's submission to act on the submission.

So, starting July 1, many Registrants began submitting their products for approval. And between July 1 and July 17, 2024, Registrants have submitted via the Portal 186 product list updates, 8 new applications for registrations, and 14 renewal applications for the Department's review under the new standards. *Id.* ¶ 46. And as of today, the Department has processed all such submissions—written notices of approval or denial have issued. *Id.* In the case of a denial, the Department explained to registrants why it determined their product did not comply with HF2605 and administrative rules, per the Department's standard practice as detailed above. *Id.*

Before and after July 1, the Department followed its standard operating procedures, reviewing each Registrant and product submission in accordance with its standard procedures. *Id.* ¶ 51. And it did so while maintaining compliance with the 30-day period it is given, by regulation, to review new or updated products. *Id.* ¶¶ 41–42.

This includes all products Plaintiffs have submitted since July 1, including, for example, products submitted by Climbing Kites and Field Day Brewing—plaintiffs in the companion case, Case No. 4:24-cv-202. *Id.* ¶¶ 47–51.

Some products Plaintiffs submitted have already been approved. Climbing Kites submitted a new product list on July 9, 2024, and received instantaneous confirmation that the Department had received its submission, which was then under review. *Id.* ¶¶ 22, 48. A copy of that email receipt is attached to the Parker Declaration as Exhibit 7. That email receipt was opened by Climbing Kites on July 11. *Id.* ¶ 48. On July 18, Climbing Kites received notice that the Department approved several of its products as compliant with HF2605. *Id.* ¶ 49. That approval notice is attached to the Parker Declaration as Exhibit 8. For example, one approved product was the Climbing Kites "4MG - Pineapple Passion Fruit," which is a 12-oz carbonated beverage that includes 4 mg of THC per serving and 4 mg of THC per container. *Id.* The Department approved the 12-oz can because it contains 4 mg or less of THC in the one, 12-oz serving of carbonated beverage, and it therefore complies with HF2605. *Id.*

Other products Plaintiffs submitted have already been denied. Plaintiff Field Day Brewing received notice and explanation of several product denials on July 18 and 19, 2024. *Id.* ¶ 50. That notice and Excel explanation are attached to the Parker Declaration as Exhibits 9 and 10, respectively. The first product denial detailed in the Excel sheet—the Day Dreamer Classic Raspberry Hibiscus, a 12-oz can of carbonated beverage—was denied because it contained more

than 4 mg of THC in the 12-oz can, which violates the definition of serving. *See* Exhibit 6 to the Parker Declaration (Final FAQ Guidance), at 3 ("Not Compliant – A 12 fl oz can containing >4 mg THC"). It did not matter that Field Day reported to the Department that the product contained 4 mg of THC per serving, because the 12-oz container held 8 mg of THC. Parker Decl. ¶ 50. But a 12-oz can of carbonated beverage is one serving of carbonated beverage, so it cannot contain more than 4 mg of THC. *Id.* Yet this product contained 8 mg of THC, so it was denied. *Id.* Another Field Day Brewing product—the Day Dreamer Low Key Raspberry Hibiscus—was denied because, although it was reported on the Excel template that the 12-oz carbonated beverage product contained 4 mg of THC per serving, and 4 mg of THC per container, the testing did not match that reporting. *Id.* The Certificate of Analysis revealed that the product contained 4.62 mg of THC per serving, thus exceeding the per-serving limit. So the Department denied the product. *Id.*

Because the Department is following its standard review process, and treating all Registrants similarly, the above examples are also how all Plaintiffs'—indeed, all Registrants'—products submissions have been processed since July 1. *Id.* ¶¶ 38–41, 46–52.

C. The Department's Final Rules Became Effective On July 17, 2024.

Since Defendants last briefed this case and appeared in court for the hearing, the Department invoked its emergency authority to finalize the Rules and make them effective as of July 17, 2024. *See* Iowa Code §§ 17A.4(3)(a); 17A.5(2)(b). The Rules are materially like the draft Rules noticed on June 12. The Final Rules are attached as Exhibit 5 to the Parker Declaration. *See also* Iowa Admin. Code. r. 641-156.1–156.11 (2024), available at https://perma.cc/8UKU-BTXT. The Department has also issued Final FAQ guidance document (attached as Exhibit 6 to the Parker Declaration), which explains the final Rules and addresses concerns raised by community members during the public comment period. *See* Iowa Dep't of Health and Human Servs.,

Consumable Help: HF 2605 FAQ – What it Means, Rules Effective July 17 (July 17, 2024) ("Final FAQ Guidance"), https://perma.cc/CE8J-C9ME.

ARGUMENT

Defendants do not intend to re-brief all legal issues and instead incorporate prior briefing on all claims. *See* Dkt. 27. Defendants address only the claims Plaintiffs elaborate on in their supplemental briefing, as well as the implications for Plaintiffs' remaining claims of the Rules taking effect on July 17. For the reasons detailed in Defendants' prior briefing, this Court should deny Plaintiffs' request for injunctive relief.

I. The Court Need Not Consider Plaintiffs' Facial Vagueness Challenges.

Facial challenges to criminal statutes for vagueness are unavailable on non-First Amendment grounds. *See* Hr'g Tr. 5:17-24; *see also United States v. Ghane*, 673 F.3d 771, 777 (8th Cir. 2012). When a vagueness challenge to a statute does not involve First Amendment freedoms, courts evaluate the challenge on an "as-applied basis." *Sanimax USA, LLC v. City of S. St. Paul*, 95 F.4th 551, 569 (8th Cir. 2024); *see Gallagher v. City of Clayton*, 699 F.3d 1013, 1021 (8th Cir. 2012) ("It is well established that vagueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." (quotation marks omitted)).

That standard remains notwithstanding cases cited by Plaintiffs. *Sanimax*, 95 F.4th at 569. Plaintiffs point to both *Johnson v. United States*, 576 U.S. 591 (2015) and *Sessions v. Dimaya*, 584 U.S. 148 (2018) to argue that their facial vagueness claim may proceed without a First Amendment challenge. But those cases required the Supreme Court to determine whether a conviction was considered a predicate offense. That type of challenge is analyzed using the categorical approach, which examines "the elements and the nature of the offense of conviction, rather than [ ] the particular facts relating to petitioner's crime." *United States v. Burgee*, 988 F.3d 1054, 1058–59

(8th Cir. 2021) (internal quotation omitted). Plaintiffs' claims here do not call for a categorical approach, so their reliance on *Johnson* and *Dimaya* is unavailing.

Plaintiffs' reliance on *City of Chicago v. Morales*, 527 U.S. 41, 52–53 (1999) and *United States v. Veasely*, 98 F.4th 906 (8th Cir. 2024) fares no better. Plaintiffs cite *Morales* to support the proposition that a facial challenge to a vague criminal statute may proceed even outside the context of First Amendment concerns. But *Morales* was a plurality opinion. And the Eighth Circuit has declined to apply the plurality's approach. *See, e.g., Ghane*, 673 F.3d 771, 777; *Sanimax*, 95 F.4th 551, 569; *see also United States v. Rybicki*, 354 F.3d 124, 131 (2d Cir. 2003) (refusing to adopt *Morales*'s non-majority approach). And *Veasely* did not involve a facial *vagueness* challenge, but a facial challenge to constitutionality of a gun statute under the Second Amendment. *Veasley*, 98 F.4th at 909. That difference matters.

Recognizing that their facial vagueness claims face stiff precedential headwinds, Plaintiffs, via supplemental briefing, now attempt to raise a First Amendment challenge for the first time. Dkt. 35 at 14. Plaintiffs say the Warning Provision implicates commercially protected speech and thus violates the First Amendment. But Plaintiffs did not raise this issue in their pleadings nor in their briefs in support of their motion for a preliminary injunction.

A supplemental brief may not raise arguments for the first time that could have been timely raised before the close of briefing. When it does, those arguments are forfeited. *See Martin v. Am. Airlines, Inc.*, 390 F.3d 601, 608, n.4 (8th Cir. 2004) ("We will not consider an issue first raised in a reply brief, absent some reason given by the appellant for failing to raise and brief the issue in his opening brief."); *Lukis v. Whitepages Inc.*, 542 F. Supp. 3d 831, 843 (N.D. Ill. 2020) (noting that a "district court is entitled to find that an argument raised for the first time in a reply brief is forfeited . . . and that is doubly true of an argument raised for the first time in a supplemental

brief"). This Court should not consider the claim for the first time now, after the parties have completed briefing and conducted a full hearing on the issues that Plaintiffs pleaded and briefed. Worse, Plaintiffs do not explain their failure to raise this First Amendment challenge in their earlier briefs, though it appears they raise the claim only in response to this Court's skepticism at the hearing of their non-First Amendment vagueness challenges.

So too for Plaintiffs' belated claim that the Potency Provision is unconstitutionally vague. As Defendants and this Court highlighted at the hearing, Hr'g Tr. 9, 68–69, Plaintiffs did not plead that claim nor did they brief it in their opening brief in support of their motion for preliminary injunction. Instead, Plaintiffs first raised the issue in their reply brief, and only after it came up in the companion case. *Cf. Martin*, 390 F.3d at 608, n.4.

In that reply, Plaintiffs claimed they pleaded vagueness as to the Potency Provision. Their cites to their complaint, however, reveal significant notice pleading deficiencies. Dkt. 30 at 8 (collecting cites). None of their cites discuss any vagueness or confusion as to the Potency Provision; Plaintiffs instead rely on broad statements in their complaint like "[c]ritical phrases are not defined" or, even more simply, "[t]he Hemp Amendments" are "vague." Dkt. 1, ¶¶ 18, 128, 138, 139. But the surrounding paragraphs make clear that the only "critical phrases" Plaintiffs thought vague were the Warning Provision and Synthetics Prohibition. Dkt. 1, ¶¶ 129–135, 159. Plaintiffs' brief in support of their motion confirms as much. Dkt. 10. If Plaintiffs thought the Potency Provision was one of the unconstitutionally vague "[c]ritical phrases," Dkt. 1, ¶ 18, one would think they would reference it in their brief asking for injunctive relief. But they did not.

Because Plaintiffs' vagueness claim must be considered as-applied, Defendants' opportunity to brief the as-applied vagueness claim as to "serving" in the companion case does not cure Plaintiffs' failure to give Defendants' notice of the claim as to Plaintiffs here. Given these

pleading and notice deficiencies, this Court need not consider Plaintiffs' delayed, revised vagueness claim.

II. HF2605's Challenged Provisions Are Not Unconstitutionally Vague.

HF2605 is not unconstitutionally vague as applied to Plaintiffs. The law provides notice to a person of ordinary intelligence of what is prohibited and gives sufficient standards to law enforcement to prevent arbitrary and discriminatory enforcement. Dkt. 27 at 5-10.

More, the Department's Rules are now final and took effect on July 17, under the Department's emergency rulemaking authority. *See* Exhibit 5 to the Parker Declaration (Final Rules); Iowa Code §§ 17A.4(3)(a); 17A.5(2)(b). So to the extent there was any ambiguity in the statute's text (there is not), the now-final Rules provide Plaintiffs with their desired answers. *See Guedes v. ATF*, 920 F.3d 1, 28 (D.C. Cir. 2019) (promulgation of rules through notice-and-comment procedures can afford fair notice of prohibited conduct to avoid unconstitutional vagueness); *Vill. of Hoffman Estates v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 503–04 (1982) (Courts do not "assume that the [government] will take no further steps to minimize the dangers of arbitrary enforcement. The [government] may adopt administrative regulations that will sufficiently narrow potentially vague or arbitrary interpretations of the ordinance."); *see also* Iowa Code §§ 4.4, 4.6.

Indeed, much of what Plaintiffs argued in support of their vagueness claim focused on the delay in the forthcoming Rules' effective date. *E.g*, Dkt. 28-1 at 7 ("These provisions are not readily ascertainable because they are subject to definitions within rules that will be adopted by DHHS in the future, likely not until the end of August once effective."). The Rules are final, and the Department has continued in its regular, timely course of issuing approvals and denials—which are always issued in writing, with an explanation of the grounds for denial—of consumable hemp products that may be sold in Iowa. Parker Decl. ¶ 46. In fact, the Department has processed every

product Plaintiffs submitted for approval between July 1 and July 17; some have been approved for sale, some denied, but all have been processed. *Id.* ¶¶ 46–52. Because the statute is not ambiguous, the Rules are final, and the Department is timely processing approvals on the Portal, Plaintiffs now have the answers they sought, now three times over.

The standards are clear. Plaintiffs' as-applied vagueness claim fails. So even if the Court considers Plaintiffs' facial vagueness challenges, Plaintiffs' facial challenge would be doomed because they cannot establish that they are likely to succeed on the as-applied front. *See Moody v. NetChoice, LLC*, 144 S. Ct. 2383, 2397 (2024) ("[A] plaintiff cannot succeed on a facial challenge unless he "establish[es] that no set of circumstances exists under which the [law] would be valid.").

a. The Potency Provision provides adequate notice of proscribed conduct.

Plaintiffs for the first time challenge the Potency Provision as unconstitutionally vague. Hr'g Trans. 9:14-19. Plaintiffs did not challenge the Potency Provision in their pleadings nor in their brief in support of their motion for a preliminary injunction. *Id*. So this Court should not consider it as a part of this case. *Martin*, 390 F.3d at 608, n.4. Even if this Court considers this claim as applied to these Plaintiffs, the Potency Provision is not unconstitutionally vague.

Plaintiffs challenge the terms "serving" and "container" as unconstitutionally vague. Both arguments fail. Defendants incorporate the argument made in the companion case, that the terms "serving" and "container" carry their plain meaning and that no person of ordinary intelligence could fail to understand what they meaning in this context. *See Climbing Kites v. Iowa*, No. 4:24-cv-202 (S.D. Iowa) ("CK Dkt.") Dkt 35 at 10–17.

Yet even if there is any potential ambiguity, the Rules implementing HF2605 took effect on July 17 and provide even more clarity. The Final Rules "sufficiently narrow potentially vague or arbitrary interpretations of the [statute]." *Vill. of Hoffman Ests.*, 455 U.S. at 504.

Starting with "serving," the Final Rules say a serving is:

> the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12 (as amended to July 17, 2024). If a solid consumable hemp product is packaged in a manner that includes more than a single serving, each serving must be clearly identified and severable from the other servings in the container. If a liquid consumable hemp product is packaged in a manner that includes more than a single serving, the number of servings must be conspicuously labeled. Liquid consumable hemp products shall be packaged in a container that holds a minimum of 12 fluid ounces.

Iowa Admin. Code r. 641–156.1. That puts Plaintiffs on notice about what constitutes a serving for edible consumable hemp products. Plaintiffs are directed to federal regulations covering serving sizes for food. That approach follows the term's plain meaning. CK Dkt. 35 at 10–17.

Plaintiffs also allege the term "serving" is too broad because it applies to "hemp-derived creams, ointments, oils, and beauty products," consumable hemp products that Plaintiffs sell but which are not considered food. Dkt. 35 at 4. And because these are not food, the "serving" size is not apparent in Table 2 of the federal regulations. But the Final Rules and accompanying Final FAQ guidance directly address that. Exhibit 6 to the Parker Declaration (Final FAQ Guidance), at 2. "Serving" relates only to "products intended to be ingested ('eaten') or contain food." Because topical products—like Plaintiffs' creams, ointments, oils, and beauty products—are not eaten, the Final FAQ guidance document explains that the serving limit does not apply. Only the per-container limit applies, so these topical products must not "contain >10 mg Total THC per container." *Id.*; Parker Decl. ¶ 45. So Plaintiffs' argument also fails.

The term "container" also carries a readily ascertainable meaning. Indeed, Plaintiffs in the companion case concede that the "per container" limit "is an unambiguous term." CK Dkt. 11 at 27. But even if it were not, the Final Rules define the term and provide clarity. Under the Final Rules, "container" means "the object which holds one or more servings of a consumable hemp

product." Iowa Admin. Code r. 641–156.1(204). And rules can "sufficiently narrow potentially vague or arbitrary interpretations of [a statute]." *Vill. of Hoffman Ests.*, 455 U.S. at 504.

Plaintiffs argue they are unsure of what "container" means based on this definition and the plain meaning. They claim they do not know whether a 10-count blister pack of gummies would be 1 or 10 containers. But the Department explained this in its July 17 and June 7 FAQ guidance documents explaining the draft and final rules: a 10-pack is one container, so each individual gummy in a 10-pack must include 1 mg or less of THC. *See* Exhibit 6 to the Parker Declaration (Final FAQ Guidance) at 3; Iowa Dep't of Health and Human Servs., Consumable Help: HF 2605 FAQ – What it Means, Draft Rules, Townhall Info, at 1 (June 7, 2024), https://perma.cc/2EUV-LAY2.

Plaintiffs Climbing Kites and Field Day Brewing, in the companion case, understand what "per container" means. They do not challenge that limit. Hr'g Tr. 102:22–103:1. Because those plaintiffs "can understand what conduct is prohibited" by the per-container limit, it cannot be unconstitutionally vague. *Gonzales v. Carhart*, 550 U.S. 124, 148–149 (2007).

The terms "serving" and "container" are not unconstitutionally vague. They put a person of ordinary intelligence on notice of what conduct is prohibited when given their plain meaning. But even if there is ambiguity, the Final Rules provide sufficient clarification.

b. The Synthetics Prohibition & the Warning Provision

Plaintiffs insist that the Synthetics Prohibition and the Warning Provision are also unconstitutionally vague. But these arguments likewise fail.

As Defendants explained in opposition to Plaintiffs' motion, Dkt. 27 at 17–21, the meaning of "synthetic consumable hemp products" is "readily ascertainable" by looking to the provision's text, context, and the industry's well-known understanding of the term. *See United States v. Sims*,

849 F.3d 1259, 1260 (9th Cir. 2017) (rejecting a vagueness challenge to the term "synthetic cannabinoid"). Dkt. 27 at 17–21. Plaintiffs have now had two briefs and a hearing to respond to *Sims*'s instructive approach to analyzing the vagueness claim here, yet each time they fail to do so. Their silence speaks volumes.

Even if there is any ambiguity as to the Synthetics Prohibition, the Final Rules provide enough clarity. The Rules define "synthetic consumable hemp products" and provide examples of what those products may be:

> products containing synthetic or semisynthetic cannabinoids. Synthetic and semisynthetic cannabinoids refer to a class of cannabinoids that are created through a chemical process and are structurally similar to naturally occurring cannabinoids or cannabinoids that may occur in very small amounts naturally. Examples of synthetic consumable hemp products include but may not be limited to delta-8 tetrahydrocannabinol, delta-10 tetrahydrocannabinol, hexahydrocannabinol (HHC), tetrahydrocannabiphorol (THC-P), and tetrahydrocannabinol-O-acetate (THC-O).

Iowa Admin. Code r. 641–156.1. That definition reflects the Iowa and federal definitions of "synthetic." Dkt. 27 at 17–21. Indeed, federal controlled substances law similarly defines "synthetic" as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring . . . sources." 7 U.S.C. § 6502(22). If Plaintiffs find the term ambiguous despite its plain meaning and common usage in the industry, the Rules "sufficiently narrow potentially vague or arbitrary interpretations of the [statute]." *Vill. of Hoffman Ests., Inc.*, 455 U.S. at 504.

The industry understanding of the term "synthetic," coupled with the definition in the Final Rules and the federal law definition, gives Plaintiffs notice about what constitutes a "synthetic consumable hemp product." The term is thus not unconstitutionally vague.

Nor is the Warning Provision vague. Plaintiffs complained in their opening brief that the Warning Provision is vague because the Department had not yet finished the requisite rules for its

enforcement. Dkt. 10 at 16; *see also* Dkt. 35 at 8 ("[T]he question remains as to how Plaintiffs are supposed to sell any consumable hemp product in Iowa without an adopted and effective regulation prescribing the language required to be in the warning."). But now the Rules are final and give notice as to what the Warning Provision requires. According to the Final Rules, a warning notice must include the "following or substantially similar language" on the product "in a prominent and conspicuous manner," even if the below language is "divided into multiple sections" across the product:

> (1) A statement that the product has not been evaluated or approved by the United States Food and Drug Administration (unless such approval has been secured); (2) The potential for the product to cause the consumer to fail a drug test for THC; (3) A statement that products containing THC may cause impairment and impact a consumer's ability to operate a vehicle; (4) A statement that the product is not recommended for use by pregnant or breastfeeding women; (5) A statement that product use may result in health risks and medication interactions; and (6) A statement in capital letters to KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

Iowa Admin. Code r. 641—156.4(1)(*j*). Plaintiffs can no longer argue that they do not know what warning notice is required for their products. Beginning July 17, 2024, Registrants must "take reasonable steps to comply" with this provision." Exhibit 6 to the Parker Declaration (Final FAQ Guidance), at 1. "The Department's enforcement of the Warning Provision "will occur through inspection and investigation of complaints as they are received. Repeated violations of labeling regulations will be addressed through the imposition of civil penalties." *Id.* That aligns with the Department's standard spectrum of enforcement, which usually begins with cease and desist orders and ends with civil penalties. Parker Decl. ¶ 13. None of the challenged sections—the Potency Provision, the Synthetic Prohibition, and the Warning Provision—are unconstitutionally vague.

To the extent Plaintiffs object to the Final Rules, they can challenge them under the Iowa Administrative Procedure Act in the proper State-court venue after they have exhausted the requisite remedies—a point this Court made in the companion case. CK Dkt. 29, at 26–28.

If Plaintiffs continue to challenge the Final Rule's constitutionality in federal court, such challenges are not likely to succeed. The Final Rules implementing HF2605 give clear explanations and examples of what conduct is prohibited, thus clarifying beyond the statute's already-clear plain text. These Rules, and the terms' usages in the industry and under federal law, confirm the plain meaning of the terms and provisions Plaintiffs seek to enjoin.

More, the Final Rules have no impact on Plaintiffs' pending preemption, dormant commerce clause, or takings claims. Those separate constitutional claims fail for the reasons stated in Defendants' prior brief. *See* Dkt. 27.

* * *

Plaintiffs submitted several products for the Department's review under the post-July 1 standards. Parker Decl. ¶¶ 46–52. And the Department has since approved every compliant product, and denied—with written explanation for the denial—every noncompliant product. *Id.* There is no further notice or indication of compliant products that the Department could provide Plaintiffs. Considering the statute's plain text, the Final Rules, and the Department's processing of Plaintiffs' product submissions, Plaintiffs' as-applied vagueness challenges fail across the board.

III. The Hemp Amendments Have Not Resulted in Arbitrary Enforcement.

The Department followed its standard operating procedures, reviewing each Registrant and product submission similarly. Parker Decl. ¶ 51. Contrary to Plaintiffs' assertions, the Department did not remove any of Plaintiffs'—or any other Registrants'—products from the approved list. *Id.* ¶¶ 35–40. Instead, the Department reviewed each newly submitted product for compliance, applying each challenged provision's plain meaning, as confirmed by the common meaning in the industry and the now-Final Rules. And it did so while complying with the 30-day period it is allowed, by regulation, to review new or updated products. *See id.* ¶¶ 41–42. There has been no arbitrary enforcement of the Hemp Amendments.

CONCLUSION

For these reasons, and those in Defendants' prior briefing, Dkt. 27, the Court should deny Plaintiffs' motion.

Respectfully submitted,

BRENNA BIRD
Attorney General of Iowa

/s/ *Eric Wessan*
Eric Wessan
Solicitor General

/s/ *Patrick C. Valencia*
Patrick C. Valencia
Deputy Solicitor General

/s/ *William C. Admussen*
William C. Admussen*
Assistant Solicitor General
*Admitted *Pro Hac Vice*

/s/ *Alexa S. Den Herder*
Alexa S. Den Herder
Assistant Solicitor General

Iowa Department of Justice
Hoover State Office Building
Des Moines, Iowa 50319
(515) 823-9117 / (515) 281-5191
(515) 281-4209 (fax)
eric.wessan@ag.iowa.gov
patrick.valencia@ag.iowa.gov
william.admussen@ag.iowa.gov
alexa.denherder@ag.iowa.gov

ATTORNEYS FOR DEFENDANTS

Original filed electronically.
Copy electronically served on all parties of record.

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served on counsel for all parties of record by delivery in the following manner on July 19, 2024:

☐ U.S. Mail ☐ FAX
☐ Hand Delivery ☐ Overnight Courier
☐ Federal Express ☐ Other
☒ CM/ECF

Signature: */s/Patrick C. Valencia*