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“Hemp in the Modern World: The Yearslong Wait for FDA Action”

Chairwoman McClain, Ranking Member Porter, and Members of the Subcommittee, thank you for inviting me to testify today. My name is Gillian Schauer, and I am the Executive Director of the Cannabis Regulators Association (referred to as CANNRA). CANNRA is a non-partisan association of government agencies that regulate cannabis and hemp across 45 states and U.S. territories. We are an association comprised entirely of current government officials who are in the trenches implementing cannabis and hemp policy in their states and territories. We convene and support governments so they can learn from each other, identify best practices in policy, and troubleshoot challenges. Prior to serving as the first Executive Director of CANNRA, I spent more than a decade working with federal agencies – including CDC and the National Institutes of Health – on cannabis-related policy, research, and public health. I went on to consult directly with state and municipal regulatory agencies. I have a PhD in Behavioral Science and a master’s in public health.

Because of a broad definition of hemp in the 2018 Farm Bill, we have seen an explosion of hemp-derived products that are intoxicating, that are not safe for consumers, and that can appeal to and be accessed by youth. This is one of the biggest issues facing cannabis and hemp regulators today. Red states, blue states – every state is grappling with the public health and safety risks that come from unregulated intoxicating hemp-derived cannabinoid products. We commend you on holding a hearing on “hemp in the modern world” and for including a regulatory perspective at this hearing. Given their unique experience implementing policy, state, territorial, municipal, and tribal regulators must have a seat at the table for any regulatory discussions about hemp or cannabinoid products.

The Issue

1. Modern hemp products extend well beyond fiber, grain, and feed. **Today, a significant portion of the marketplace is consumable hemp-derived products that contain THC and other intoxicating cannabinoids found in the *Cannabis sativa L.* plant – which is the same plant species for hemp as for marijuana or cannabis.** These hemp-derived compounds extend well beyond CBD, though CBD is commonly used as a source material for manufacturing hemp-derived intoxicating products.

- **Hemp-derived products on the market today often contain THC levels that meet or exceed the levels permitted in state marijuana or cannabis marketplaces**, including products with high levels of delta-9 THC^{1,2} – the primary component in the cannabis plant that gets you high, and THCA³ – which readily converts to delta-9 THC when heated or combusted. Other intoxicating cannabinoids - like delta-8 THC, THC-O-Acetate, H4-CBD, THCP, and HHC, which are often prohibited in state-regulated marijuana markets due to safety, are also widely available in the hemp marketplace.
- **The current hemp marketplace also includes cannabinoid products that are expressly prohibited by state marijuana regulators because they appeal to youth or have dangerously high levels of THC or other intoxicating cannabinoids.** For example, in Minnesota, a hemp-derived product called “Death by Gummy Bears”⁴ contained 100 mg delta-9 THC per serving and 2500 mg per package. Servings sizes and package limits in state-regulated marijuana markets are typically 10mg/serving, 100mg per package.⁵ Another online hemp-derived edible product is being marketed as the “largest legal THC gummy in history” and contains - in a single gummy - 3,000 mg of delta-9 THC per serving and 20,000 mg per package,⁶ 200 times more than would be allowed in an adult use marijuana market. Other products mimic commercially available food products and appeal to youth.^{7,8,9}
- **Some of the cannabinoids found in so-called “hemp” products are not found in nature and have never been studied for human consumption or safety.** Some of these products are made synthetically and contain nothing that came from a hemp or marijuana plant. These newly developed, unstudied products are widely available across the country online, and in gas stations and grocery stores, with no federally required testing for contaminants, no required packaging and labeling to tell consumers what is in the products or how they were manufactured, and no federal age-gating to ensure that intoxicating products are only sold to adults. This is in direct contrast to state-regulated marijuana or cannabis markets, which are regulated with consumer safety and youth prevention at the forefront.

2. Unregulated and often intoxicating hemp-derived cannabinoid products can pose serious risk to consumers, including:

- **A lack of testing and tracking for consumer safety:** Products – whether intoxicating or not – may have contaminants that can be harmful to human health. Some of these contaminants result from the chemical manufacturing process required to convert CBD into intoxicating compounds and are known to be toxic or are unidentified and unstudied in humans. Some of these contaminants may be present on or in the plant (e.g., heavy metals, microbials, pesticides). Unlike products in state-regulated marijuana markets that are subjected to contaminants testing and track and trace systems to facilitate quick recalls in the case of adverse events, no required testing or system to recall products or notify consumers in the case of adverse events exist federally for cannabinoid hemp products.

- ***A dangerous lack of consumer awareness and education:*** Consumers may not know that the hemp products they are purchasing can have an intoxicating effect or result in a positive drug test. In states like Oklahoma and Texas, where adult-use or recreational cannabis consumption is not legal, consumers can purchase untested, unregulated hemp-derived intoxicants that mimic the effects of high potency THC products at CBD shops and gas stations. These types of products are also available in states with regulated adult-use markets but are sold outside of the regulatory structure due to their designation as “hemp” and are available for purchase online and delivered through the mail. Consumers are not only being misled intentionally, they can experience potential health risks from consuming and inhaling products that have not been properly tested or regulated.
- ***Product packaging and forms that appeal to children and mimic existing commercial food and candy products.*** Whereas state marijuana markets are highly regulated in terms of product form and packaging to prevent accidental consumption of products by children, intoxicating hemp products exist in a range of forms (some that mimic commercially available food and candy items) and are sold with packaging that may appeal to children. The national poison centers documented more than 2,000 cases of exposure to hemp-derived delta-8 THC between January 2021 and February 2022: 40% of those cases involved unintentional exposure to delta-8 THC and 82% of those cases were in pediatric patients. 70% of all cases required a healthcare facility evaluation and 8% of those resulted in admission to a critical care unit.^{10,11,12}
- ***Inaccurate and incomplete product labeling.*** Hemp-derived products are not subject to federal packaging and labeling requirements and often do not include accurate and complete ingredient and labeling information, or information about how the product was manufactured. For example, the State of Maryland conducted a study of hemp-derived products available at retail establishments in the state in 2022.¹³ Only 3 out of 25 (12 percent) of the hemp-derived products purchased across the state included warning statements that the product may be impairing or intoxicating, despite every product containing high levels of THC. In addition, THC potency levels for all hemp-derived products tested fell outside the standard 10 percent variance that is acceptable in all regulated marijuana and cannabis markets, meaning what was in the product was not what was on the label. A study by researchers at Johns Hopkins tested 105 topical CBD products and found that only 24% were accurately labeled for CBD, and many products contained THC and did not advise consumers on the label.¹⁴

3. The federally unregulated hemp-derived cannabinoid marketplace undermines state-regulated marijuana markets which have been set up to protect consumers and prevent youth access. Counter to state-regulated marijuana markets, intoxicating hemp-derived products cost less to produce and sell because there are no manufacturing or testing standards, or product quality and safety requirements in place to protect consumers. Intoxicating hemp-derived products are available without added state-excise taxes, in mainstream locations where consumers - including minors - can purchase other goods and services. Consumers can purchase these products using credit cards (vs. the cash-based state-marijuana markets) and can have them delivered through the mail across state lines. When compared to state-regulated marijuana markets, the current cannabinoid hemp market is effectively an alternative unregulated market for intoxicating cannabinoids, with lower barriers to entry and access due to a complete lack of consumer safety and public health regulations.

Regulatory Considerations

- 1. States and territories face significant challenges regulating or restricting the sale of intoxicating hemp-derived products.** Absent federal regulation of hemp-derived products, or even clarification on the legality of these products under federal law, states are limited in their ability to protect consumers and prevent youth access. States cannot easily regulate interstate commerce of hemp or online markets without federal intervention and enforcement. The overly broad federal definition of “hemp” in the farm bill has led to the exploitation of a seemingly endless permutation of loopholes.¹⁵ The resulting intoxicating so-called “hemp” products can be naturally occurring, partially synthetic, or totally synthetic and are produced under the guise of federal legality, making it extremely difficult for states to protect public health and maintain safe, well-regulated medical and adult-use marijuana markets.
- 2. Hemp-derived cannabinoid products are not just one thing. They exist in many forms with many different active ingredients.** Cannabinoids function the same whether they come from “hemp” or “marijuana”. State regulations often take a holistic view and classify and regulate intoxicating hemp products in the same manner as marijuana. In some states, Attorney General’s offices have been engaged in trying to protect consumers. Low-THC hemp products are often left available to the general public under these regulatory frameworks. **But how low-THC is defined matters greatly.** Unless Congress intends to legalize marijuana under the guise of “hemp,” low THC thresholds should be nonintoxicating to a majority of people, and substantially lower than what we see in marijuana markets (which range from 5-10 mg THC/serving and 50-100 mg THC/package). The state of Oregon published a review of the science to help guide these levels.¹⁶
- 3. The current landscape of hemp-derived cannabinoid products warrants urgent federal action and regulation.** Despite what many consumers may assume when purchasing a commercial product, **the production and sale of hemp-derived cannabinoid products is not regulated federally.** Federal hemp regulation stops at the border of the farm. Finished hemp products are not regulated federally for contaminants, ingredients, cannabinoid content, mode of consumption or product type, packaging and labeling, or serving size. **This is in stark contrast to the state-regulated cannabis frameworks,** which aim to prioritize public and consumer safety by requiring product testing, ingredient disclosure and compliance, adherence with accepted product types, inclusion of specific packaging and labeling – including warnings and child resistant packaging and serving size and package limits for intoxicating cannabinoids.
- 4. A comprehensive federal regulatory framework that addresses all hemp-derived cannabinoids is urgently needed.** This framework cannot just focus on CBD. It must be a framework that includes the cannabinoid hemp products we see in the field today – including intoxicating products being converted from CBD, and products being manufactured from whole-plant CBD products that contain many other cannabinoids (some potentially intoxicating, some not) that must be regulated. A federal regulatory framework must account for the many ways cannabinoid hemp products are consumed – as foods, beverages, vaped products, and smoked products. It must acknowledge that many of the same compounds from the *Cannabis sativa L.* plant are being regulated in states as state legal – but federally illegal marijuana. A narrow regulatory focus only on specific cannabinoids (e.g., CBD alone) will leave gaps that will most certainly be exploited and continue to pose risks to consumers and public health.

5. A federal regulator with a background in public health and consumer safety (like FDA) is urgently needed for hemp-derived cannabinoid products, *including but not limited to* CBD. The 2018 Farm bill did not clearly name a regulator for finished cannabinoid hemp products. A regulator should be promptly identified, authorized, and funded, with a short and specified timeframe to:

- Provide clear boundaries and definitions for the products that will be regulated, including combusted and aerosolized products, which do not fit into existing federal food, dietary supplement, or cosmetics regulatory pathways.
- Set minimum requirements for processing and manufacturing, ingredients, modes of consumption and product types, testing, packaging and labeling, and serving size (among other elements).
- Establish and implement an education and enforcement approach to ensure compliance.
- Conduct consumer education about legal products.

As an association of state regulators, **CANNRA is not encouraging the re-criminalization of cannabinoid hemp products, but rather comprehensive regulation that accounts for the potential product risks and the existing markets that states have carefully architected for marijuana.** States have demonstrated that thoughtful regulatory frameworks can protect consumers and public health and move us away from the harms of prohibition. As state regulators know well, these are complex regulatory questions that will require a regulator to be nimble and course correct as more scientific information comes out.

Conclusion

Whether through the Farm Bill or another priority piece of legislation, a broad regulatory framework is urgently needed to address hemp-derived cannabinoid products. **Congress has an opportunity to learn from the approaches that states have taken to set a thoughtful and comprehensive federal regulatory framework.** The regulation of hemp-derived products is complex and nuanced, and state regulators understand those nuances better than anyone. CANNRA's state cannabis and hemp regulators, who work every day regulating cannabinoids and implementing frameworks that protect consumers, public health, and markets, stand ready to engage with members of Congress to provide valuable insight from members' states and jurisdictions and to inform a federal regulatory framework that does the same.

I want to thank members of the committee who have reached out to speak directly with their hemp and cannabis regulator, and I want to extend an invitation to connect any of you with your state cannabis and hemp regulator, if you do not already know them. We look forward to being a resource to Congress on this important topic. Thank you for inviting me to speak on behalf of CANNRA to share a state regulatory perspective.

Respectfully,



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