CANNRA

CANNABIS REGULATORS ASSOCIATION

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August 18, 2023

RE: Cannabis Regulators Association (CANNRA) Response to: Bicameral Congressional Request for Information on the Regulation of CBD and Hemp-Derived Cannabinoid Products

Thank you for the opportunity to provide insight on a potential regulatory pathway for hemp-derived cannabinoid products, including CBD. The Cannabis Regulators Association (CANNRA) is a nonpartisan association of government agencies engaged in cannabis and hemp regulation across 45 states and U.S. territories. The regulation of hemp-derived cannabinoid products is complex and nuanced, and state regulators understand those nuances better than anyone. Our detailed responses to the thoughtful questions included in the bicameral congressional request for information are included as an attachment to this letter. To summarize key points from CANNRA's response:

- **The current hemp marketplace is much broader than CBD.** The broad definition of "hemp" in the 2018 Farm Bill has resulted in a marketplace that includes a wide array of products that contain the range of cannabinoids that can be derived directly or chemically from the *Cannabis sativa* L. plant, including intoxicating cannabinoids like delta-9 THC, delta-8 THC, delta-10 THC, THCP, THCB, THCjd, hexahydrocannabinol (HHC), H4-CBD, and THC-O-acetate. The language in the 2018 Farm Bill effectively legalized marijuana federally, without product regulation, and called it "hemp." Hemp-derived products on the market today can be ingested, applied topically, aerosolized, inhaled or combusted, applied transdermally or transmucosally, or used in other ways. Many of these products and forms extend beyond anything that would be allowed in state-regulated "marijuana" marketplaces.
- **A comprehensive regulatory approach that accounts for all cannabinoid hemp products is urgently needed.** A federal regulatory approach must have a broad focus with regulatory authority to address the products that are available on the market today and the products

that may be available in the future. A focus on CBD alone is insufficient, in part because many CBD products contain other cannabinoids which also need to be regulated for consumer safety and public health. In addition, CBD is being used as a source material to chemically manufacture other intoxicating cannabinoids. Failure to provide regulatory authority for a federal agency to address all of the cannabinoid hemp products on the market will result in regulatory gaps that will be exploited at the risk of public health and consumer safety.

- **Current FDA regulatory pathways are insufficient to address the types of cannabinoid hemp products on the market.** Existing pathways do not address aerosolized, inhaled, or combusted products. They also do not include sufficient authorities for testing, regulation of packaging and labeling across modes of use and products, regulation of additives and ingredients that could pose risk, and authority to limit the potential appeal and consumption of products by youth. Current state regulatory frameworks for cannabinoids derived from marijuana extend well beyond any of the current FDA pathways.

- **Consumer safety and public health are at risk if a federal regulatory agency is not named**, funded, and given the authority to regulate cannabinoid hemp products. FDA is the primary federal agency with experience regulating finished products for consumer safety and public health. That said, FDA needs specific authorities and defined, short timelines under which to issue regulations. Those regulations should include clear boundaries and definitions for products that will be regulated as "cannabinoid hemp," minimum requirements for safety, and an education and enforcement framework. In following the approach states have taken, regulations should be based on the science we have today, but ongoing review of and adjustments to regulations will be essential as additional science emerges. Coordination with state and U.S. territories, and tribal nations will be vital as well.

- **Federal regulations should set a floor, not a ceiling.** Federal regulations should create minimum standards for cannabinoid hemp products to ensure that consumer safety and public health are protected. However, states should be able to enact regulations that extend beyond federal minimums to further protect their communities and consumers.

- **Regulation does not mean recriminalization.** State-regulated marijuana programs across the country are focused on regulation for consumer safety. Part of a regulatory agency's job is to determine whether a product can be manufactured safely or consumed safely and what regulatory policies are needed to safeguard against potential adverse effects. A determination that a product is unsafe for a commercial marketplace is **not** synonymous with recriminalizing or criminalizing use of that product. Enforcement actions across states often focus on progressive civil penalties or impacts on licenses as a way to deter production of unapproved products.

We appreciate and value the opportunity to share our insight on cannabinoid hemp regulation. 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.

Please do not hesitate to reach out if we can provide any additional context related to our responses.

Respectfully,

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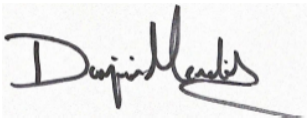

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DETAILED CANNRA RESPONSE TO CONGRESSIONAL RFI ON CANNABINOID HEMP REGULATION[a]

Current Market Dynamics

1. What does the current market for CBD products look like? Please describe the types and forms of products available, manufacturing practices within the industry, market supply chain, how products are marketed and sold, the types of cannabinoids used in products, the marketed effects of CBD products, and the range of CBD doses currently found in the market.

RESPONSE: The current definition of hemp in the 2018 Farm Bill[1] is extremely broad and extends far beyond CBD isolate. The definition includes "the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers" from a *Cannabis sativa* L. plant with not more than 0.3% delta-9 THC on dry weight basis. Hemp and marijuana are the same plant – *Cannabis sativa* L. - and contain the same substances.[2] Whether those substances come from what we call "hemp" or "marijuana"[b] – they work the same in the body – yet they are regulated differently. This is confusing for consumers, challenging for operators in the market, and has major public health and consumer safety risks. The 2018 Farm Bill language also left gaps in this definition that have been exploited at the risk of consumers and communities.[3] These gaps include:

(1) the 0.3% delta-9 THC by weight definition – which has resulted in high amounts of delta-9 THC being present in heavier products that still meet the weight-based definition of "hemp."
(2) The THCA issue – which has resulted from a narrow definition of hemp that included delta-9 THC, but not its acid form, THCA, which is naturally occurring in cannabis plant material and readily converts to delta-9 THC when heated or combusted.
(3) The derivatives issue – which has resulted from a broad definition of hemp that legalized anything to come from the plant, including intoxicating cannabinoids derived chemically from CBD, many of which have not been well studied for human consumption or safety.

Because of the broad definition of hemp and the existing gaps in the 2018 Farm Bill language, the current hemp market extends well beyond CBD isolate. Regardless of their state-regulated policy for marijuana, state officials are seeing the following cannabinoid and CBD products that purport to meet the current definition as "hemp." Many of these products are marketed as "hemp," "CBD," "farm bill compliant," or "legal THC". Please see **Appendix A** for pictorial examples of these products from state and online markets.

Table 1: Types of cannabinoid products appearing on the current hemp marketplace

Product type	***Description***
CBD isolate products	These products contain *only* CBD. CBD alone is non-intoxicating.
Broad spectrum CBD products	These products are marketed as CBD, but also contain other active, non-THC cannabinoids from the hemp plant.
Whole-plant or full spectrum CBD products	These products are marketed as CBD but contain all of the cannabinoids from the hemp plant, including delta-9 THC, typically extracted and in a concentrated form. These products can contain sufficient delta-9 THC to be intoxicating.

[a] Note that we did not respond to every question. If a question is skipped, it is because we did not provide a response.

[b] Because both "hemp" and "marijuana" come from the cannabis plant (both are technically "cannabis"), we use the term "marijuana" in this document instead of "cannabis" when we are talking about products regulated by state medical and non-medical programs.

THCA products	The 2018 Farm Bill defined hemp **solely** based on having no more than 0.3% delta-9 THC by dry weight. However, cannabis plants produce THCA, not THC.[4] When THCA is heated or combusted (i.e. when the plant is smoked), the THCA converts (decarboxylates) into delta-9 THC.[4] This is the reason every state medical or adult use/recreational marijuana regulation defines THC in terms of both THCA and delta-9 THC.[5–8] THCA products – including flower, vape cartridges, and concentrates – that contain up to 99% THCA (equivalent to around 87% delta-9 THC) are being sold as "hemp." These products are indistinguishable from marijuana products sold in state-regulated adult use/recreational or medical use programs.
Products with high doses of delta-9 THC	The 2018 Farm Bill defined hemp based on having no more than 0.3% delta-9 THC **by dry weight**.[1] While this may be an appropriate agricultural definition for hemp plant material, a 0.3% by weight in a heavier item – like a chocolate bar or a package of gummies can yield hundreds of milligrams of delta-9 THC and still be "farm bill compliant." In fact – hemp derived edibles can have more legal delta-9 THC in them than marijuana products in state-regulated markets – which are typically limited to 10 mg/serving, 100 mg/package and many nonmedical ("recreational") marijuana products have 5 mg/serving or less.[9]
Products with intoxicating cannabinoids other than delta-9 THC	The 2018 Farm Bill legalized virtually any compound that comes from or can be derived from *Cannabis sativa* L. plants that meet the definition of "hemp." This has resulted in people taking CBD extract from the plant and using chemistry (heat, solvents, acids, etc.) to turn that CBD extract into other cannabinoids, including intoxicating compounds like delta-8 THC, hexahydrocannabinol (HHC), THC-O-acetate, and H4-CBD. Some of these compounds are not naturally occurring in the cannabis plant in any amount, and others may be found in the plant, but only in very small amounts (and often post-harvest). Little to no research has been performed to date on the safety to humans of these non-delta-9 intoxicating cannabinoids

**See Appendix A for examples of products from the current marketplace*

In addition to the cannabinoids contained in products on the current hemp marketplace, products can be consumed in a wide variety of ways, including ingested (e.g., drinks, drink mix-ins, candies, gummies, cookies, ice creams, chocolates, tinctures, pills), aerosolized, combusted, or inhaled (e.g., cigarettes, vape cartridges, concentrates and dabs), topically (e.g., lotions, oils), and transmucosally or transdermally (e.g., lubes, bath bombs, patches) (see appendix A). Some of these product forms (e.g., perishable foods, transmucosal products) are not allowed on some state-regulated marijuana marketplaces due to increased consumer risks.

This marketplace continues to evolve rapidly, and products that were not prevalent on the marketplace a year ago now dominate. Regulation needs to address not only what is on the market today, but what might be marketed tomorrow. In addition, the current marketplace includes cannabinoid products purporting to be "hemp" that may not have been derived from a cannabis plant at all. Some cannabinoids are being manufactured by traditional organic chemistry (synthesized from off-the-shelf chemicals) or biosynthesized (created using genetic engineering in yeast, algae, or another living material). Determining whether a particular substance was derived from hemp or manufactured in another manner is challenging and establishing different legal statuses for the same substances depending on how they are made creates confusion and perverse incentives in the industry.

Given the federal illegality of marijuana, states have established regulatory structures to protect marijuana consumers and satisfy the expectations of the Cole memorandum.[10] In contrast, the Farm Bill legalized hemp at the federal level, yet there are no federal regulatory structures to protect consumers, and no federal

requirements or licensing for hemp processing. This has led to the proliferation of an industry that operates largely outside of any regulatory structure or oversight. The processes used to manufacture different hemp-derived cannabinoids are typically not made clear to the consumer and require differing levels of regulation to ensure that they yield the intended substance with acceptable purity for consumer safety.

2. How has the market changed since the passage of the 2018 Farm Bill?

RESPONSE: Prior to the passage of the 2018 Farm Bill, state-regulated medical and non-medical marijuana marketplaces were the primary sources of intoxicating cannabinoid products and were being carefully regulated to prevent diversion, to prevent access to youth, and to meet consumer safety standards.[9] Following the 2018 Farm Bill, which contained a broad definition of "hemp" legalizing virtually anything that comes from the cannabis plant and contains less than 0.3% delta-9 THC,[1] states have seen a surge of intoxicating cannabinoid products that purport to be federally legal, have no federal regulation, and fall outside of their state-regulatory purview as medical or non-medical marijuana.

The definition of hemp in the 2018 Farm Bill effectively legalized "marijuana" federally – with no product regulation – and called it "hemp." States and U.S. territories have been working to implement regulations for cannabinoids in state-legal marijuana markets to protect consumers and public health, including (among many other policies) product testing for contaminants, adult-only sales environments, excise taxes to fund a range of related externalities and restorative justice initiatives, packaging and labeling to educate consumers and avoid youth appeal and access, and serving size and package limits to avoid over consumption. Conversely, in the "hemp" market, the same cannabinoids can now be sold anywhere, without age-gating, without required testing for contaminants, without added taxes, with packaging that appeals to children and is not regulated for accuracy, and in serving sizes and package amounts that exceed what is allowed in state-regulated marijuana programs (see appendix A). And consumers can buy these products with a credit card and have them mailed directly to them. This alternative, unregulated market for cannabinoid hemp undermines the regulated system that states have so carefully developed with public health, consumer safety, and equity in mind.

3. How is the lack of national standards for CBD products affecting the market?

RESPONSE: With no federal regulation in place, state legislatures are enacting policy state-by-state. These laws do not focus on CBD in isolation, but rather seek to address the range of products coming from hemp, including CBD. State-enacted policies vary and include policies that:

- prohibit certain novel and unknown or understudied intoxicating cannabinoids (e.g., MT, ND, MD)
- provide limited standalone regulation (i.e., outside of the current marijuana regulatory framework) for the many cannabinoids coming from hemp (e.g., KY, CA, VA)
- regulate specific intoxicating cannabinoids coming from hemp as part of the state-regulated adult use or medical marijuana marketplace (e.g. CT, HI, NV, MD, UT)
- place limits on the amount of THC than can be in hemp products (e.g., CO, CT, MD, NY, OR)
- regulate all hemp-derived cannabinoids under the same regulatory agency as marijuana-derived cannabinoids (e.g., IA, MD, MI, NY, RI, UT, WA)

Policy differs, but states are increasingly bringing intoxicating hemp products under the purview of the marijuana regulator, where the same cannabinoids – but derived from marijuana – are being regulated. Without federal minimum standards, we are creating a patchwork of regulation that creates consumer safety and market challenges and leaves regulatory gaps that cannot be covered by states alone, including in online markets and through interstate commerce. This also results in inconsistencies in product quality, potency, and safety, potentially jeopardizing public health and consumer trust.

Pathway

4. Please comment on the concerns FDA has raised with regard to regulating most CBD products through existing pathways (i.e., conventional foods, dietary supplements, and cosmetics), and FDA's view that there is a need for a new regulatory pathway for CBD products. If existing regulatory pathways are sufficient for regulating CBD products, please explain how these existing pathways can be used to address the concerns raised by FDA, as appropriate.

RESPONSE: Because only a small subset of products on today's hemp market contain *only* CBD, regulation must be broader than CBD. Furthermore, virtually all states that regulate cannabinoids within a state system regulate them in a manner that extends well beyond the regulatory approaches provided for through a food or dietary supplement pathway. Even states that claim to have based their regulation of hemp-derived cannabinoid products on a food or dietary supplement approach (e.g., CO, CA) are regulating well beyond the regulatory frameworks associated with those pathways.[11,12] This is because food and dietary supplement pathways are not comprehensive enough for hemp-derived cannabinoids, including CBD products (which typically contain cannabinoids beyond CBD).

Table 2: Reasons food and dietary supplement pathways are insufficient for CBD and cannabinoids

Reason food/dietary pathway inadequate	***Rationale and state experiences to date***
Does not account for aerosolization, inhalation, transdermal systems, nasal sprays, suppositories, injectables, and other non-food and dietary methods of consumption.	State regulatory agencies have seen all of these types of products marketed (and more) on state-regulated marijuana cannabinoid marketplaces. Many of these modes of consumption have special regulatory considerations and/or may be determined to be unsafe for certain cannabinoids or product formulations. For example, the state of Colorado created a category of "audited products" for particular marijuana-derived cannabinoid products that mirror medical devices (e.g., metered dose inhalers, suppositories, and nasal sprays).[7] Some states (e.g., NY, OR) prohibit injectable marijuana-derived cannabinoid products.
Does not limit active ingredients across products. The Food, Drug, & Cosmetics Act allows FDA to limit an active ingredient in a specific formulation, but not across products.	This means as new products come onto the market with new and unknown cannabinoids, terpenes, or other active ingredients that may have safety risks (but meet the current definition of "hemp"), FDA would not be able to ban them across products. They would only be able to ban them in a specific formulation. Following the Vaping Lung Injury outbreak (VALI, or EVALI) that sickened people across the country and killed previously healthy young people,[13–15] states took a closer look at potentially concerning additives in marijuana vape products. Some states, like Oregon, found certain additives – like Vitamin E acetate, squalene, and squalane – may have been linked to their VALI cases and were able to ban them across all products.[16] Colorado, for example, banned PEG, Vitamin E acetate, and MCT oil as marijuana vaping additives.[7]
Does not prevent packaging or product forms that appeal to youth.	Food and dietary supplement pathways at FDA do not allow for specific packaging regulations to limit the appeal of a product to underage consumers. They also do not allow for the regulation of certain product forms (e.g. cake pops, cotton candy, gummies shaped like unicorns) that inherently appeal to kids. State-regulated marijuana markets frequently include language prohibiting product

	packaging from containing elements that can appeal to kids – or mimicking commercial products targeted at kids.[9] State marijuana markets also frequently prohibit the manufacture of certain types of products that appeal to children.[9]
Does not allow for specific warnings by form or function.	State-regulated marijuana markets often contain specific warnings for certain product types (e.g., a warning that the onset of effects may be delayed for edibles, a warning that smoking can be hazardous to health, a warning that certain types of products – like concentrates – can be associated with schizophrenia).[9,17] These warnings are important communication for consumers because cannabinoids are consumed in many different forms that have different considerations and risks.
Does not require testing of products.	Dietary supplement and food pathways rely on current Good Manufacturing Practices (cGMP) as opposed to product testing. cGMP provides standards for processing/manufacturing facilities to adhere to that result in a higher quality final product. However, all states with established state-regulated marijuana/cannabis markets have taken the additional step for consumer safety of mandating compliance testing of marijuana products in their final form for contaminants (e.g., pesticides, heavy metals, residual solvents, mycotoxins, microbials).[9] Several states, such as California, require both cGMP and regulatory testing. Compliance testing is extremely important and necessary for both "hemp" as well as "marijuana" or "cannabis" products, even with cGMP requirements, as there are potential contamination issues unique to *Cannabis sativa* L. plants, and specific to certain hemp and marijuana manufacturing processes that regulatory testing identifies.
Does not require comprehensive review of ingredients for each product formulation.	FDA's dietary supplement pathway uses a "New Dietary Ingredient Notice" (NDIN) – but does not require review of ingredients by product formulation. Cannabinoids can interact with certain drug components or other dietary supplements that may be combined in products, and the current dietary supplement pathway would be insufficient to identify those potential interactions. Furthermore, additives in products that may be safe as food can be harmful to health if aerosolized or combusted and require additional review.[15]
Does not account for the source or derivation of an ingredient.	Cannabinoids can be extracted from the plant, synthesized, or otherwise chemically derived from materials in the plant or from other non-plant chemicals, or derived biosynthetically (e.g., from yeast or algae). Some processes for deriving cannabinoids can result in byproducts and residual chemicals that need to be removed. Furthermore, certain processing methods can result in the creation of the mirror image of a molecule or other "stereoisomers" of a molecule. These different configurations of the molecule are not identical and can have dramatically different effects in the body.[18] These processes must be regulated differently to ensure safety.

5. How should CBD and/or cannabinoid-containing hemp products be defined? What compounds should be included and excluded from a regulatory framework?

RESPONSE: Cannabinoid-hemp products are broad and encompass products with hundreds of cannabinoids. Regulatory authority should be sufficiently broad to address all the cannabinoids that can be derived from hemp – whether directly derived from the plant or manufactured, and to determine appropriate regulatory requirements based on the manner in which the product is derived. The risk of adopting a regulatory framework that is too narrow is that it will leave gaps that will inevitably be exploited by some at the risk of consumer safety and public health. Adoption of standard nomenclature at the federal level that will include newly discovered or created cannabinoids is paramount for regulatory consistency.[19]

a. Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced by *Cannabis sativa* L. in food and dietary supplements? Which substances, if any, warrant greater concern? How should these substances of concern be addressed? What products, if any, should not be allowed on the market?

RESPONSE: Yes – regulatory authority should be granted to set limits for intoxicating cannabinoids. Limits should be based on the best available science. Because science is rapidly evolving, regulatory authority should also be granted to revisit and reset limits based on additional data, and to set limits that may differ based on individual cannabinoids and product forms. These should include the ability to set thresholds for and regulate synthetic and semi-synthetic hemp-derived cannabinoids that are intoxicating (i.e., compounds made synthetically that also occur naturally, compounds that are not naturally occurring, and compounds that are not hemp derived and not naturally occurring and being sold as hemp).

Hemp-derived cannabinoid products that can be intoxicating and are sold on a general marketplace pose specific concerns, given that consumers may not understand that they are purchasing an intoxicating cannabinoid, and youth may have increased access to them. Products that remain on a general marketplace (versus moving into an adult-only marketplace) should be products that are non-intoxicating to a majority of consumers. A number of states have suggested that serving size is likely to be something around or less than 0.5mg THC/serving, with less than 1-2 mg/package.[20,21] 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 (see Appendix A). For example, in Minnesota, a hemp-derived product called "Death by Gummy Bears" contained 100 mg delta-9 THC per serving and 2,500 mg per package.[22] Serving sizes and package limits in state-regulated marijuana markets are typically 10 mg/serving, 100 mg /package.[9] 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, 200 times more than would be allowed in an adult use marijuana market.[23] Other products mimic commercially available food products and appeal to youth (see Appendix A).

Cannabinoids found in so-called "hemp" products that are not found in nature and/or that have never been studied for human consumption or safety also pose specific concerns.[24–26] Some of these products are made synthetically and contain nothing that came from a hemp or marijuana plant. They can contain unknown byproducts and contaminants that are known to be harmful to humans, such as unidentified cannabinoids, triethyl aluminum, boron trifluoride etherate, dichloromethane, PTSA, and iodine. 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. Consumers are literally the test case for the safety of these products. Impurities of these chemical compounds by way of creation make them

difficult to predict in comparison to naturally occurring compounds. This is in direct contrast to state-regulated marijuana or cannabis markets, which are regulated with consumer safety and youth prevention at the forefront.

b. How should Congress or FDA identify appropriate limits for THC and other cannabinoids in finished products? Relatedly, how should a framework account for "total THC," including tetrahydrocannabinol acid (THCA), in FDA's regulation of intermediate and finished products?

RESPONSE: Congress should grant authority to a federal regulatory agency that has a focus on regulating for public health and consumer safety (i.e., the Food and Drug Administration) to set appropriate limits for THC and other cannabinoids in hemp products. Some science exists to begin to set these thresholds,[20] which – for products sold to the general public – should be low enough that a majority of people will not become intoxicated. Authority should be granted for a regulatory body to revisit these limits based on emerging science. Setting these limits in statute prevents a regulatory body from being able to respond to the rapidly evolving scientific landscape that should inform policy and makes it inherently more difficult to respond to public health or safety issues that might arise from setting the wrong limit. These federal limits should establish a foundation and should not preempt states and territories from setting different, more stringent limits to protect consumers in their jurisdiction.

Congress should define total THC broadly, including tetrahydrocannabinolic acid (THCA), which is abundant in the plants, and converts to delta-9 THC when heated. All state-regulated marijuana regulations across the United States include a definition of THC that accounts for THCA. Other THC isomers, like delta-8 THC, have been included in some state definitions for total THC as well.[27] Limits for allowable total THC in the field and in plants should differ from thresholds set for finished products. The current definition of hemp that allows for no more than 0.3% delta-9 THC by dry weight is an agricultural definition that does not translate well to finished products and has resulted in many consumable hemp products that contain more "legal" delta-9 THC than is allowed in state-regulated marijuana markets (which is typically no more than 10 mg/serving and 100 mg/package) (see appendix A). For example, a chocolate bar or a beverage could yield a product that contains hundreds of milligrams of THC and still be considered compliant with the 2018 Farm Bill.

Congress should grant a federal regulatory agency authority to age-gate products based on their concentration of THC, similar to the way that alcoholic beverages are age-gated above 0.5% alcohol by volume. However, THC is approximately 3000 times more potent by weight than alcohol, so a concentration threshold for THC would need to be correspondingly lower. A standard unit of alcohol, equivalent to a 12 oz beer or 5 oz glass of wine, is 14 grams (14,000 mg).[28] A standard unit of THC, established by NIDA, is 5 mg.[29] Based on these numbers, a THC concentration threshold of 0.0002% (2 parts per million) would be roughly equivalent to the 0.5% abv threshold for alcohol.[20]

Congress must also recognize that delta-9 THC is not the only intoxicating cannabinoid found in the hemp plant. Other naturally occurring cannabinoids, including CBN and THC-V, can potentially be intoxicating. CBD is also used to manufacture an increasing number of intoxicating cannabinoids, including delta-8 THC, delta-10 THC, HHC, HHC-O-acetate, THC-B, and THC-O-acetate. Compounds like THCP – thought to be more than 30 times as potent as delta-9 THC[30] – are also being manufactured and sold as "hemp" (see appendix A).

c. Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?

RESPONSE: FDA should have regulatory authority over semisynthetic derivatives and biosynthetic cannabinoids and should be able to set requirements that ensure consumer safety of these products,

including whether safety standards can be met to allow them to be marketed. Failure to regulate these with other cannabinoid products would leave loopholes that would be exploited at the risk of consumer safety and public health. Identifying whether a substance was derived from hemp, biosynthesized, or made synthetically is difficult, especially when manufacturers are not regulated in a way that requires transparent recordkeeping. These products need rigorous regulation, given that the chemical compounds used in the processes employed to create these semi-synthetic derivatives and biosynthetic cannabinoids are a significant chemical contamination risk, and that these processes can create unwanted byproducts that pose risk to consumer health and safety. They should only be allowed when safety data indicates they are safe for human consumption. Regulatory authority needs to be broad enough to allow for the determination of appropriate pathways and the regulations needed to comply with those pathways for consumer safety.

7. How has the absence of federal regulation over CBD created a market for intoxicating, synthetically-produced compounds, such as Delta-8 THC, THC-O, THC-B, HHC-P, and others?

a. What is the public health impact of these novel compounds?

RESPONSE: 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 or other starting materials 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).[31] 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,[9] no required testing or system to recall products or notify consumers in the case of adverse events exists 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 North Carolina, Georgia, Oklahoma, and Texas, where adult-use or recreational marijuana 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 (whereas state-regulated marijuana is not). Consumers are not only being misled intentionally, but they can also experience potential health risks from consuming and inhaling products that have not been properly tested or regulated.

- **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.[32] 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.[33]

- **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,[9] 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 (see appendix A). 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.[34] In one specific case, two pediatric patients ages 2 and 4 were admitted to a pediatric intensive care unit with abnormally slow breathing after allegedly ingesting 500 mg delta-8 THC in a gummy rope candy designed to resemble a popular candy brand.[35] Clinicians across states have reported increases in emergency visits related to delta-8 THC. For example, an emergency physician in South Carolina reported seeing patients suffering from delta-8 THC overdoses multiple times per month, including effects requiring ICU level care.[36]

- **Intoxicating products that are widely available to youth.** Novel, intoxicating cannabinoids, as well as other intoxicating hemp-derived cannabinoids are widely available online with no age-gating, and in commercial stores that youth frequent like gas stations, grocery stores, and convenience stores.[37] For example, at least seven students were sickened at a middle school in Virginia after eating delta-8 THC gummies.[38] In another similar incident, five students at a high school in Iowa became ill after consuming delta-8 THC and two of them had to be taken to the hospital with high heart rate and severe paranoia.[39]

b. How have FDA and state regulators enforced against products containing these compounds?

RESPONSE:

a. **Federal regulatory approach to date:** There is an urgent need for efficient regulatory compliance and enforcement mechanisms to address new and potentially dangerous cannabinoids. To date, FDA has issued warnings – both to the general public and in the form of letters to a limited number of specific companies. They have also referred certain adverse effects or violations to state regulatory agencies, but they do not have current authority to protect consumers of inhalable or combusted products (which fall outside of the Food, Drug, & Cosmetics Act) in the same manner as administered over traditional foods, drugs, and cosmetics.

b. **State and territorial regulatory approaches to date:**

   i. **Most states do not have the authority for enforcement and compliance over these products**. State enforcement agents are also hesitant to enforce FDA regulations more stringently than FDA has enforced those regulations. Many states have established regulatory pathways for hemp-derived products with upper limits of CBD and/or THC in terms of serving sizes and package limits and limited pathways for how products are manufactured. The challenge is that because hemp-derived cannabinoids are not currently federally regulated and have unclear federal legality, state enforcement actions are often limited to businesses that are licensed within the state. Businesses that operate in one state and sell to another state typically fall outside of the purview of state enforcement and the state regulatory authority. Law enforcement in a number of

states has been hesitant to engage because of a lack of DEA clarity on the federal legality of certain compounds (like delta-8 THC or THCA).

ii. **Some states have regulations that prohibit or restrict different cannabinoids derived from hemp** (e.g., delta-8 THC), which has resulted in some voluntary compliance, and often impacts where online marketers are willing to ship those products. However, these state regulations are typically unable to impact the interstate marketplace in substantial ways, and products still find their way into these states as "hemp."

iii. **Federal support for enforcement and compliance of these products is urgently needed,** including clear guidance from DEA on the legality of certain cannabinoids, and guidance from FDA on federal thresholds or parameters for licit vs. illicit products. Federal support is also warranted for enforcement actions against multi-state violations, and to bolster resources for in-state violations.

iv. **Education, enforcement, and compliance approaches are needed across the range of cannabinoid hemp products,** regardless of mode of consumption. A regulatory framework that focuses on enforcement and compliance for only dietary supplement-like or food-like cannabinoid hemp products would leave substantial gaps.

c. How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?

RESPONSE: These novel cannabinoid hemp products must be included in a regulatory framework and must be explicitly addressed. Regulations are needed to clarify what conditions (i.e., cannabinoids, other ingredients, product types, packages, doses or serving sizes) are appropriate for sale, if permitted. A failure to address semi-synthetic, synthetic, and biosynthetic novel cannabinoids under a federal regulatory agency's authority will result in regulatory loopholes that will be exploited at the expense of consumer safety and public health.

8. CBD products are not limited to just ingestible routes of administration—some are interested in products with alternative routes of administration (e.g., inhalable, topical, ophthalmic drops, etc.).

a. For which non-ingestible routes of administration are consumers interested in consuming CBD products?

RESPONSE: State and territorial cannabis and hemp regulators have seen a wide array of product types – both on the market currently, and that have been proposed. For example, regulators have seen manufacturers and retailers interested in making (and in many cases actually selling) hemp-derived cannabinoid suppositories, transdermal patches, injectables, nasal sprays, metered-dose inhalers, cigarettes, vape cartridges, concentrates and dabs, pills, lotions, tinctures, oils, eye-drops, lubricants, and consumable food products of all types (including perishable food products that require specific food inspection for safety).

Failure to account for any potential form of consumable cannabinoids would result in a gap that would be exploited at the risk of consumer safety and public health. Based on initial interest in manufacturing virtually any product into a cannabinoid product, state marijuana regulators in most states have established accepted product forms and routes, and anything outside of those routes is not legal in those states.[9]

b. How should a regulatory framework for cannabinoid products account for non-ingestible routes of administration?

RESPONSE:

A regulatory framework for hemp-derived cannabinoid products should extend to <u>all</u> products that are intended for human use, regardless of whether they are ingested, inhaled, applied to the skin, or consumed or used in some other way. Any standards put in place should be based on the route of administration and should be specific to the product type to account for how different routes of administration impact consumption of cannabinoids.

Specific standards and regulations will be needed for certain routes of administration that can pose additional risks or harms. For example, many states have implemented specific regulations for vaped or aerosolized marijuana cannabinoid products in the wake of the Vaping-Associated Lung Injury outbreak (VALI or EVALI) that sickened people across the country and resulted in at least 70 deaths.[13,14] States have also enacted specific policies for consumable marijuana cannabinoid products, including specific consumable forms and formulations, and limiting THC per serving size for consumer safety.[9] At least one state (CO) has enacted a policy requiring products with forms that are medical in nature (e.g., metered-dose inhalers, nasal sprays, suppositories) to adhere to more rigorous product safety standards to protect consumers.[7] Other states (e.g., NV) have prohibited marijuana product forms that require a medical device to administer or are medical in nature (e.g., eye drops, inhalers, nasal sprays). With regard to cannabinoid hemp products, a number of states (e.g., CA, HI, IN, LA, TX) have banned or attempted to ban smokeable hemp as part of efforts to avoid renormalizing smoking following the Master Settlement against the tobacco industry and state clean indoor air policies.[40] Other states have language that smokeable hemp products can only be used in places where tobacco or nicotine products can be consumed.[41]

<u>Federal-State Interaction</u>

9. In the absence of federal regulation or enforcement over CBD products, many states have established state regulatory programs to safeguard public health and create market certainty for industry participants.

a. Which product standards relating to warning labels, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting, and others, have states adopted to protect consumer safety?

RESPONSE: States are in the process of adopting a range of standards for cannabinoid hemp products, with several states adopting manufacturing requirements (e.g., HI, MI, NV), minimum age of sale (e.g., AK, FL, HI, KY, MD, NV, NY, OR), required packaging and labeling standards (e.g., CO, CT, FL, HI, KY, MD, VA), and required testing standards (e.g., CA, HI, KY, OH, MD, NY, OR).[c] However, state regulations are being determined largely by state legislatures. This is a complex topic, and this is one of a myriad of issues that state lawmakers are dealing with. Accordingly, there can be gaps in education that impact the type of policies state legislatures enact.

Given that the cannabinoids coming from hemp are the same cannabinoids (and in some cases extend beyond those) legalized in state-regulated marijuana programs, it is important to look at how states and territories are regulating marijuana for consumer safety and public health. All state-regulated marijuana programs require contaminant testing for things like pesticides, residual solvents, molds, mycotoxins,

[c] Examples are not comprehensive and do not include a full listing of states with specific policies in place.

heavy metals, and microbials. Many states prohibit certain additives or ingredients (e.g., certain diluents, excipients, or added flavors, and any nicotine, tobacco, or alcohol). Some states (e.g., NV) limit the total amount of non-cannabinoid ingredients that can be in certain products like vape cartridges to no more than 10% to avoid having excess quantities of any additive.[9]

Regulations in all states require packaging that does not appeal to children (including prohibitions on cartoons or certain images, and in some cases, bright colors and fonts).[9] Packaging in most states must contain specific health warnings, a serving size or dose, and a universal symbol to denote that the product contains cannabinoids, THC, or can be intoxicating. In nearly all states, products must be sold in adult-only stores that only sell marijuana and do not sell other goods or services.[9] An increasing number of states (e.g., CO, MA, MI, MT, UT) have requirements for the people working in those retail environments to complete certain training and adhere to certain standards in terms of the information they provide to consumers.

In terms of adverse events – state-regulated marijuana frameworks typically require seed to sale tracking of products, allowing the regulator to quickly and easily identify and recall any products that have potential concerns to prevent additional sale. There is no such tracking required of cannabinoid hemp products. In the event of a concerning adverse effect, public health and epidemiologic work would be needed to identify the product, and the state would not have the ability to quickly quarantine or recall those products.

States have put these regulatory frameworks in place for marijuana-derived cannabinoids because of the safety profiles of these products. As outlined in question 4, these approaches to protect consumer safety and public health are not available under the existing foods and supplement pathways.

b. Which such standards, if any, should Congress look to as models?

RESPONSE: No state has landed on a perfect approach for protecting consumers of cannabinoid hemp products. State approaches to date have varied, and have come largely from state legislatures, which may be influenced by lobbyists from existing and potential businesses. State approaches have also been limited by the confusing federal legality of these hemp-derived cannabinoid products, and the non-existent federal regulatory guidelines. States that have the most robust and established markets for medical and adult use marijuana products historically have the most comprehensive approaches to protect public health and safety for cannabinoid hemp products. They have learned from cannabinoid regulation in marijuana. Examples of various state approaches to regulating hemp-derived cannabinoids include:

- **California:** Last year, California passed Assembly Bill 45 - Industrial Hemp Products, which focused on allowable uses of non-intoxicating CBD.[11]
    - AB 45 requires manufacturers of dietary supplements and food that includes industrial hemp to register with the State Department of Public Health and demonstrate that all parts of the plant used come from a state or county that has an established, approved industrial hemp program that conducts safety inspections and ensures that the hemp cultivator is in good standing and in compliance with applicable laws.
    - The bill also defines "THC or comparable cannabinoid" as: (1) tetrahydrocannabinolic acid, (2) any tetrahydrocannabinol, including, but not limited to, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, and delta-10-tetrahydrocannabinol, however derived, and (3) any other cannabinoid, except cannabidiol, that the State Department of Public Health determines to cause intoxication.
    - The bill requires product testing by an independent laboratory and a certificate of analysis from the lab to accompany the final product.

- The authorized a state regulatory body to prohibit the inclusion of hemp in products through regulation when it poses as risk to human or animal health. It also granted the state regulator authority to set limits on serving size of active cannabinoid(s) in a product and the allowable number of servings per package.
- Hemp products are prohibited from including untrue health-related statements in labels or advertising with regard to the effects of industrial hemp, cannabinoids, extracts, or hemp derivatives.
- The bill requires specific packaging and labeling and prohibits advertising or marketing to children and people who are pregnant or breastfeeding.
- The bill set specific regulations for inhalable products including prohibitions on added flavors, and certain excipients and diluents.

- **Colorado:** Colorado's most recent legislative session culminated in Senate Bill 23-271 - Intoxicating Cannabinoid Hemp and Marijuana.[12] The primary focus of this bill was to address regulatory and statutory loopholes that had been identified and exploited by some operators marketing hemp products with high THC content that closely mirrored or exceeded reasonable allowances in Colorado's regulated marijuana market.
  - To address the potential health threat these unregulated intoxicating hemp products pose, Colorado developed several limitations specific for these products entering the market, to include limitations on THC content, serving size allowance, purchase age restrictions, and package container limits.
  - Additionally, the bill expanded the definition of THC beyond the most known "Delta 9" THC (to include THCs D10, D9, D8, D7, and their isomers). This expansion provides clarity regarding the agencies' regulatory oversight authority and allows the agencies to better keep pace with industry innovation to protect public health and safety and support consumer awareness and education of the content of products they purchase.
  - In addition to these established requirements, SB 23-271 provided comprehensive and broad rulemaking authority to the Colorado Department of Public Health and Environment and Marijuana Enforcement Division to be responsive to hemp industry changes as products evolve and to prevent future attempts to circumvent regulatory oversight.

- **Maryland:** Maryland's recent Cannabis Reform Act, which authorized adult-use sales of cannabis and cannabis products, established a maximum amount of THC allowable in any finished product sold *outside* of the regulated market.[21]
  - The state now requires that any product intended for human consumption must contain less than 0.5 milligrams of THC per serving and 2.5 milligrams of THC per package to be sold at any unlicensed retailer. This allows for CBD-isolate products, as well as topical products to be sold at unlicensed establishments. Any product above this THC threshold may cause intoxication and must be sold through the state's licensed and regulated marijuana market, which has strict age-gating and identification checks at retail establishments.[21] Further, any product above these THC thresholds is subjected to the same packaging, labeling, and testing restrictions of any other licensed product in the state.
  - The legislation also defines "THC" broadly, using a definition that includes Delta-8, Delta-9, or Delta-10-THC, or any other compound that the State's regulatory body determines to cause intoxication.
  - Lastly, the state prohibited the sale or distribution of "a cannabinoid product that is not derived from naturally occurring biologically active chemical constituents." This provision prohibits the sales of products that contain compounds that have not been

isolated or identified within the plant itself. Maryland's provisions only pertain to finished products, and still allow for the cultivation of hemp plants under the Maryland Department of Agriculture, and in accordance with the USDA's Hemp Farming Program. Businesses that continue to sell hemp-products outside of the licensed market with either THC concentrations above the statutory restrictions or containing not-naturally occurring cannabinoids are subjected to fines and misdemeanors.

- **New York:** New York regulates cannabinoid hemp under the Office of Cannabis Management which has oversight over the Adult-Use Cannabis, Medical Cannabis and Cannabinoid Hemp Programs.[41] The primary goal of the Cannabinoid Hemp Program is to establish consumer protection and quality control standards for the manufacturing, packaging and labeling and laboratory testing of cannabinoid products grounded in public health best practices.
    - The state licenses the manufacturers of cannabinoid hemp products requiring all manufacturers to receive a qualified third-party GMP audit of their manufacturing facility.
    - The state also licenses any business that sells cannabinoid hemp products to consumers. To date, the state has licensed over 3,000 Cannabinoid Hemp Retail licenses.
    - All cannabinoid hemp products sold must be laboratory tested by a third-party laboratory accredited by ISO 17025 for common contaminants similar to testing in state marijuana programs (heavy metals, pesticides, mold, etc.).
    - Recently, the state passed emergency regulations implementing total THC milligram limits on certain forms of cannabinoid hemp products and establishing a 15:1 CBD to THC ratio that those products must adhere to. The goal of the emergency regulations is to keep intoxicating cannabinoid hemp products out of the state's Cannabinoid Hemp Program and leave those intoxicating products, which are more appropriately regulated for sale in the Adult-Use Program.

- **Oregon:** Oregon was one of the first states to act in terms of passing specific legislation (HB 3000 in 2021) to address consumer safety risks of cannabinoid hemp products on the market.[42]
    - Oregon age-gates the sale of hemp products containing any significant amount of THC (more than 0.5 mg per package) to adults age 21 and over. Cannabinoid hemp products sold to adults also have limits on the amount of THC per serving and per package so hemp products are less potent than adult-use marijuana products.
    - Cannabinoid hemp products are required to undergo compliance testing for potency and contaminants, just like adult use marijuana in the state, prior to sale.
    - Synthetic hemp derivatives are prohibited for sale to consumers except in the state-licensed marijuana marketplace, where regulations allow a narrow path for some of these semisynthetic derivatives that are able to establish a baseline expectation of safety.
    - In Oregon regulations, hemp is defined based on total THC rather than delta-9 THC alone.
    - Manufacturing cannabinoid hemp products in Oregon requires licensure from the state Department of Agriculture.

- **Hawaii:** A bill passed in the 2023 legislative session to address hemp regulation.[43] That bill requires:
    - Anyone making a manufactured hemp product (limited to edible forms and topicals) to obtain a permit from the Hawaii Department of Health if they are processing hemp plant material, hemp crude extract or using a hemp product as an ingredient to manufacture another hemp product.

- Permitted hemp processors must comply with GMP rules for producing manufactured hemp products.
- Finished hemp products must undergo compliance testing for cannabinoid content and contaminants prior to sale in Hawaii.
- The prohibition of artificially and synthetically derived cannabinoids in manufactured hemp products.
- Establishment of a Task Force convened by the Hawaii Department of Health and the Hawaii Department of Agriculture to gather data and make recommendations for future regulatory actions.

10. How should Congress consider federal preemption as it works towards a regulatory pathway? Should states be able to continue to build upon federal regulation of CBD products?

RESPONSE: Federal regulations should set minimum standards but should not preempt states or territories from enacting additional measures to protect consumers or public health in their jurisdiction. Federal standards are needed, given the current patchwork of cannabinoid hemp regulations across states. However, these standards should set a floor, not a ceiling. The current landscape of legal, unregulated intoxicating hemp products that pose risks to public health and consumer safety was created by federal regulations. Assigning clear, broad federal regulatory authority over this market should alleviate some of these issues, but if regulatory gaps remain, states have a significant interest in being able to address any potential gaps at the state level.

Safety

12. What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?

RESPONSE: Given the wide availability of these products and the array of routes of administration, the federal government should invest in research to help states and the public understand the products on the market today, and any products that might be marketed in the future. Research should focus on the benefits and potential risks of specific cannabinoids, including how those benefits and risks might vary based on the dose or method of exposure. Research is also warranted to identify how different additives and ingredients might interact with cannabinoids to impact consumer safety, given an increase in products that combine approved dietary supplements with hemp-derived cannabinoids.

13. How should a new framework for CBD products balance consumer safety with consumer access?

RESPONSE: A regulatory framework should work to protect those most vulnerable and at risk (i.e., youth, pregnant people, older individuals, medical patients). If there is insufficient knowledge of the safety profile of a product, the precautionary principle[44] should be considered (i.e., the introduction of certain new products whose ultimate effects are disputed or unknown should be resisted) and at a minimum, consumers should be made clearly aware of the gap in scientific knowledge so they can make the best decision for themselves. In state-legal medical marijuana programs, often advisory boards or commissions of clinicians and scientific experts weigh in to advise regulatory agencies on whether a particular condition is recommended for medical marijuana use. A similar approach could be adopted at the federal level to assess the safety and appropriateness of different hemp-derived cannabinoids or product formulations, with regulatory authority being granted to a federal regulator to determine the necessary regulatory pathways to manufacture products safely and make them available through the appropriate retail channel.

State-regulated marijuana programs across the country are focused on regulation for consumer safety. Part of a regulatory agency's job is to determine whether a product can be manufactured safely or consumed safely and what regulatory policies are needed to safeguard against intended and unintended effects. A determination that

a product is unsafe for a commercial marketplace is **not** synonymous with recriminalizing or criminalizing use of that product. CANNRA is suggesting that it is important for a regulatory agency to have authority to determine whether and how products can be manufactured safely and sold in ways that minimize potential externalities. We are not suggesting the recriminalization of components of the hemp plant. Enforcement actions across states often focus on progressive civil penalties or impacts on licenses to deter production of unapproved products. These could be applied at the federal level as part of an enforcement program focused on the production and sale of unapproved products deemed unsafe or inappropriate for sale.

16. Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics?

RESPONSE: Yes, thresholds and limits for cannabinoids in products are imperative. Tobacco and nicotine products should be prohibited from containing CBD or any other cannabinoid. Currently, all state-regulated marijuana programs prohibit cannabinoid products from being mixed with tobacco/nicotine and alcoholic beverages;[9] however, in the hemp market, we are seeing these products be infused with various hemp-derived and synthetic cannabinoids and other additives. Regulatory authority should be granted to determine, based on scientific evidence, the level of CBD or other hemp-derived cannabinoids that can be included in certain products and how those levels should vary based on the method of consumption (e.g., ingested, topical, inhaled, etc.). Regulatory authority should also include the ability to determine retail parameters for products based on certain limits and thresholds in those products (e.g., for sale to the general population vs. for sale in adult-only environments).

If so:

a. Should Congress or FDA set such limits, recognizing the time it can take to complete the legislative process and the regulatory process at FDA?

RESPONSE: Congress should **not** set limits, as the science – and the types of available CBD and hemp-derived cannabinoid products – continue to evolve rapidly. **Setting limits in statute would require statute to be reopened to make course corrections.** Rather, Congress should call on FDA to set limits within a specified timeframe, based on current science and current market considerations. Those limits should set a minimum standard for states.

b. How should that amount be determined? What should the amount be?

RESPONSE: The thresholds for various cannabinoids in hemp products should be set by the designated federal regulatory body and should be based on the current science. They should address all of the hemp-derived cannabinoid products on the market, but thresholds may vary based on the end market and consumer population (e.g., some products may have different thresholds if bound for an adult-only retail sales environment, such as state-legal marijuana retail stores).

In terms of setting a THC limit in CBD products, a significant portion of the market consists of "full spectrum" products that contain CBD, THC, other cannabinoids, and other naturally occurring substances from hemp.[20] CBD and THC in hemp exist in proportion to one another. Even high-CBD low-THC plants may produce THC in proportion to CBD at approximately a 1:20 ratio.[45] That means full-spectrum hemp products that contain large concentrations of CBD will also have elevated levels of THC. It is therefore impossible to set a THC limit that prohibits the sale of intoxicating hemp products without also effectively prohibiting the sale of full spectrum hemp products. However, state regulators hear concerns that minors should not be able to purchase products with THC. Regulatory authority must be granted for a federal regulator to work with stakeholders to strike a balance between not allowing intoxicating hemp products, especially to youth, and acknowledging the types of products for which there is demand among adults.

A THC threshold in hemp cannot be zero, as that is impossible to enforce. Due to the nature of product testing, laboratories tests can only show that a substance is not present above a specified concentration; they cannot show that the substance is completely absent from the sample. Even hemp seed-based food products like hemp milk have a nonzero threshold. The FDA has accepted GRAS notices for hulled hemp seeds and hemp seed protein powder containing up to 4 parts per million (ppm) THC, and for hemp seed oil containing up to 10 ppm THC. However, **a threshold for THC in hemp must be substantially lower than the cannabinoid products sold on state-regulated medical and adult-use markets.** For marijuana edibles, state markets have generally set limits of 5 to 10 mg per serving size and 50 to 100 mg per package.[9] **An ideal threshold for THC in hemp-derived products should be nonintoxicating for most adult consumers.**

Increasingly, states (e.g., OR, MD, MT) are proposing a threshold at or around 0.5 mg total THC per serving, 2 mg per package. The state of Oregon Liquor and Cannabis Commission (the marijuana regulatory body in the state) outlined a rationale for this based on how thresholds are set for alcohol in products labeled "non alcoholic."[20] An excerpt from that rationale is included below:

> "Alcohol may be present in small quantities in foods and beverages other than alcoholic beverages. In order to be considered "non-alcoholic," a food or beverage can contain no more than 0.5% alcohol by volume. A minor may purchase non-alcoholic foods and beverages that contain this small amount of alcohol.
>
> This 0.5% threshold for alcohol is not at all comparable with the 0.3% threshold for THC in hemp products because alcohol is much less potent than THC on a weight-to-weight basis. One standard unit of alcohol – a typical 12 fl oz beer, 5 fl oz glass of wine, or 1.5 fl oz portion of distilled spirits – contains 14 g or 14000 mg of alcohol (National Institute on Alcohol Abuse and Alcoholism [NIAAA] 2021). By contrast, a standard unit of THC is only 5 mg (National Institute on Drug Abuse [NIDA] 2021). There is nearly a 3000-fold difference between the weights of these standard units.
>
> The relevant limiting factor with consumption of alcohol from non-alcoholic beverages is the amount of liquid that a person can reasonably drink at one time. A person would have to consume approximately one gallon of liquid at 0.5% to consume one standard unit of alcohol. By contrast, a person would only have to drink one-third of a teaspoon (1.7 ml) of liquid at 0.3% to consume one standard unit of THC.
>
> A threshold for THC equivalent to the non-alcoholic threshold can be derived on a percentage basis, or on a per-container basis by comparison to a typical unit of a non-alcoholic beverage:
>
> · Percentage equivalence: 0.5% alcohol × (5 mg THC ÷ 14000 mg alcohol) = 0.0002% THC.
>
> · Per-container equivalence: Taking 12 fl oz to be a typical container size for a non-alcoholic beverage, 12 fl oz × 0.5% alcohol × 29.5735 ml/fl oz × 0.789 g/ml = 1.4 g alcohol. Since a standard unit of alcohol is 14 g, this means a typical container of a non-alcoholic beverage can contain one-tenth of a unit of alcohol. A standard unit of THC is 5 mg, so one-tenth of a standard unit of THC would be 0.5 mg THC."

The proposed 0.5 mg THC/serving is consistent with values proposed by a number of international bodies that have focused on identifying the "lowest observed adverse effect level" (LOAEL) or the "no observed adverse effect level" (NOAEL) (see OLCC Report for detailed information by country).[20]

c. Should such limits be applied on the amount per serving, and/or per package?

RESPONSE: It is essential that the limits be set both per serving and by package. Failure to do so will result in regulatory gaps whereby manufacturers may comply with a serving size limit, but produce a package with many servings (e.g., a gummy bear that complies with the 0.5 mg THC limit, but is in a standard gas station sized bag – which contains about 60 gummy bears – would yield a package that would be expected to be eaten in one sitting and contains 30 mg of THC). Package limits are needed to avoid accidental overconsumption. Package limits can also help prevent accidental consumption by children, should they get their hands on a package.

d. No CANNRA response provided.

e. How should the experience of states inform the setting of limits on amounts of CBD in products?

RESPONSE: See our response to 16b above. State cannabis and hemp regulators have unique insight about the products in the marketplace and the potential consumer safety risks. They have experience regulating the same cannabinoids within state-legal marijuana markets, and they understand the rationale behind serving sizes and package limits that have been set in adult-only marijuana markets. As mentioned above, states have also carefully considered the literature, and have assessed regulation from other substances (e.g., alcohol) that could be translated to cannabinoids to help inform a limit in the absence of perfect and complete science. Being able to implement thoughtful policy based on the science we have now (versus science that will take years to develop) is an essential component for any agency regulating cannabinoids.

The largest focus in state policy has been on intoxicating cannabinoids and setting limits for THC in hemp-derived products. Importantly, many current state thresholds for THC in hemp-derived products have been set by state legislatures (not the regulatory agency) and have been influenced by the broader political process. Thus, not all state thresholds for THC in hemp are based on current science or practical applications from other domains. States that have reviewed the science and existing markets have generally proposed a serving size of 0.5 to 1 mg THC, with a limit of 2 to 10 mg per package (e.g., CT, MD, MT, NY, OR, VT, VA). Some states (e.g., NY, OR, MD) have prohibited retailers from selling any product with more than a certain threshold (e.g., 0.5 mg total THC) to anyone under 21 years of age. State legislatures have also increasingly passed policies that require a specific CBD:THC ratio (usually between 15:1 and 25:1), though these ratios are not based on science. They are often proposed to allow for full spectrum tinctures with high quantities of CBD to continue to exist in the general market, but the consumer safety and public health implications of these ratio requirements are unclear.

Learnings from state cannabis and hemp regulators suggest that the best regulations for protecting consumers and enforcing compliance in the market are those that account for both hemp and marijuana. Cannabinoids are the same molecules whether they come from what we call "hemp" or what we call "marijuana." It is both challenging and confusing to consumers for states to have two different regulatory approaches to products that are essentially the same. Regulations for hemp must account for regulations that may be in place in a state for medical or non-medical cannabis.

19. What functional ingredients combined with cannabinoids raise safety concerns?

RESPONSE: State cannabis and hemp regulators have been concerned with the combination of certain existing dietary supplements and cannabinoids. Research is needed to assess possible interactions and avoid combinations that may be unsafe. In the wake of the Vaping-Associated Lung Injury outbreak (VALI or EVALI),[13,14] state regulators have also put much greater focus on additives in products – especially additives in products that are aerosolized or combusted. Because cannabinoids are non-polar, they do not readily dissolve in water or water-based solvents, and instead are most commonly dissolved in non-polar substances such as lipids or fats. For example, diluents used in vape cartridges are typically oil or lipid-based. Some of these lipid-based diluents can change when aerosolized or heated and become harmful compounds that should not be inhaled into the body. A number of state marijuana regulations ban certain additives – both diluents (e.g., polyethylene glycol, MCT oil, vitamin E acetate, mineral oil, squalane) and in some cases terpenes that can be extracted from the cannabis plant (phytol, squalene) that may be harmful to human health when aerosolized.[6,7] Flavoring agents have also been increasingly assessed by regulators. Importantly, these additives are different from additives in nicotine vape cartridges, since nicotine is water soluble, so the regulatory science from nicotine additives does not apply here. Finally, state-regulated marijuana frameworks prohibit the combination of nicotine/tobacco or alcohol with cannabinoids due to potential synergistic and compounding effects in terms of intoxication and abuse liability.[46]

Quality

20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls?

1. **How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements, and cosmetics?**

   RESPONSE: Both GMP and product testing are needed to ensure consumer safety. GMP focuses on standards for processing and manufacturing facilities. But even in a GMP facility, there can be potential issues with contaminants that are concerning for consumer safety. Final product testing is a critical component of consumer safety, particularly with cannabinoids, since products can be so different based on the inputs (flower, genetics, cultivation practices/conditions) and outputs for processing (e.g., whether the processing is creating a high concentration distillate vs. a low concentration product). While some testing occurs as part of the GMP process, final product testing is still needed both to ensure consumer safety and to ensure transparency in reporting. Consumers should be able to know what is in the final product they are getting. In addition, because many consumers are using cannabinoids for medical purposes, it is even more imperative to make sure contaminants are not present in their product.

2. **Are those food, dietary supplement, and cosmetics GMP frameworks adequate for regulating quality in CBD? Why or why not?**

   RESPONSE: No, they are not adequate. GMP requirements for food products are not appropriate to use on products that contain psychoactive substances that work on the brain (which includes CBD). Similarly, dietary supplement GMP approaches do not address all the issues relevant to food-like products. For example, dietary supplements do not have requirements for expiration, shelf life, or best if used by dates. They also do not have associated stability testing. Additionally, cannabinoids including CBD are often contaminated with adulterants other than pesticides and microbials, which regulatory frameworks for dietary supplements and food do not require testing to detect. In summary, GMP requirements that are adapted for cannabinoid products will be an important component of product safety, but final product testing is also essential, given the current market.

21. What are alternative quality approaches that Congress should consider for CBD products? For example, how should third parties be leveraged for the creation and auditing of manufacturing and testing requirements?

RESPONSE: Product testing is an important component of quality control and product safety. State regulatory agencies overseeing cannabinoids derived from marijuana have put in place testing schemes that seek to test products for a range of contaminants (e.g., molds, microbials, mycotoxins, heavy metals, pesticides) at critical stages in the product development.[9] These testing schemes vary based on product form (i.e., are different for flower vs. ingestible products vs. combusted products). Because of the Schedule 1 designation of marijuana, states have had to leverage third party entities that are licensed by the state to conduct the testing. There has been a hesitancy among laboratories with federal funding to engage in testing a Schedule 1 substance. Importantly, states have learned that it is vital to have a state reference lab – a lab that works directly for the state and can assist in development of testing methodology, proficiency testing among third party labs, and third-party lab audits. State regulatory agencies employ inspectors who regularly inspect laboratories testing marijuana. Most state regulatory agencies require testing labs to share Certificates of Analysis that are linked to product tests for review as well. These lab testing systems are essential in terms of identifying contaminants, and states regularly detect issues with products. State regulations for marijuana typically outline processes for retesting, remediation, or – if necessary – destruction of product that does not meet standards to ensure that product is not diverted onto an illicit market.

Form, Packaging, Accessibility, and Labeling

22. What types of claims should product manufacturers be permitted to make about CBD products? Please reference how such permitted claims compare to the types of claims that may be made about drugs, foods, dietary supplements, and cosmetics.

RESPONSE: All state-regulated marijuana programs have language in statute or rule prohibiting false and misleading claims, in accordance with the Federal Trade Commission (FTC). Many states also prohibit health or medical claims or set high standards for limited instances where those can be made.

23. What is the evidence regarding the potential benefits of including a symbol or other marking on product labeling to provide clarity for consumers who would purchase products that contain CBD?

RESPONSE: In state-regulated marijuana markets, statues and regulatory agencies have required a universal symbol that denotes that the product contains THC, cannabis, or cannabinoids.[9] The purpose of those symbols has been to alert potential consumers in a visual manner that does not require literacy or proficiency in the English language that the product contains an ingredient they need to be aware of – and in this case, an ingredient that could cause intoxication. These symbols were first introduced in response to overconsumption reports to poison centers that were the result of someone seeing an item – usually a food item – and consuming it without knowledge that it was not "just a brownie" or "just a cookie." In most states with non-medical marijuana regulations, a universal symbol is required to be on the package (with specific requirements around placement and size to ensure that it is visible). Some states (e.g., CO, NV, RI, CT) also require the symbol to be stamped on the product directly to ensure that even if the product is detached from its original packaging, a consumer will still know that it contains THC or cannabis. In addition to making consumers aware of the components of the product, CBD products that contain THC should contain a visual symbol to denote that the product contains THC because – even in smaller quantities – THC can be intoxicating for some people and can result in a positive drug test. Products that contain CBD *only,* without other cannabinoids, should also include a visual symbol denoting that the product contains CBD, since CBD is a psychoactive drug that works on the brain. This will help differentiate a food item that may contain CBD from a potentially similar looking food item that does not contain CBD.

26. Some suggest requiring labels for CBD products to include "potential THC content." Would THC content be unknown in a particular product? Is there precedent for such a labeling requirement?

RESPONSE: In state-regulated marijuana markets, the THC content of cannabinoid products is never unknown. States require finished product testing to ensure that the consumer knows the number of milligrams of delta-9 THC in the product they purchase and consume. However, the THC content in most cannabinoid hemp products labeled as "CBD" or "hemp" or "Farm Bill compliant" is unknown to consumers because there are no current federal requirements for finished product testing of total THC and related labeling on packaging. Consumers must be made aware of products that have THC or other intoxicating cannabinoids in them. **Labeling products as having "potential THC content" is insufficient.** Consumers need to be made aware of the amount of total THC in milligrams by serving size and in the package - including for CBD products currently labeled "full spectrum" or "whole plant." Labeling that a product is "Farm Bill compliant" or "<0.3% THC" does not convey to consumers that the product may contain a cannabinoid that can be intoxicating and may result in a positive drug test. It also does not allow a consumer to make a decision for themselves about whether the amount of THC in the product or serving size could be intoxicating for them. Failure to provide consumers with explicit information about how much THC is in a serving size or product could lead to accidental impairment in situations where impairment could be high risk (e.g., driving, operating heavy machinery, etc.). It could also result in consumers failing to recognize that certain products need to be stored out of reach of children and pets. There are also consumers who may not want to consume a product with THC (for any range of reasons) and who do not know

that the “CBD” or “hemp” product they are consuming actually contains THC. See also our response to question 23.

28. What specific additional restrictions should apply to CBD products regarding their appeal to or use by children with regard to marketing, packaging, and labeling? Is there precedent in the food, dietary supplement, tobacco, or cosmetics space for restricting certain product features that would make products appealing to children? Please describe.

RESPONSE: There are precedents that federal regulators can look to and learn from to prevent the appeal of products to children. Tobacco control literature is extensive in this regard. State statutes and regulations for medical and nonmedical marijuana have borrowed from this literature and have sought to craft policies to prevent against youth appeal of products.[40,47–49]

These policies typically include:

- Broad language that product cannot advertise, market, or be packaged in a manner that is appealing to persons under the age of 21.
- Specific language prohibiting content that includes: pictures of minors, cartoons, likeness to images, characters or phrases popularly used to advertise to children, imitation of candy packaging, use of the terms “candy” or “candies”, cartoon-like fonts, or caricatures. Some states also have prohibitions on bright colors on packaging.

However, state regulators have reported challenges in enforcing these policies, as they can be subjective in some instances. A number of states have implemented uniform or standard packaging, and instead of defining in statute the elements that *cannot* be included, they define the only elements that *can* be included on the package.[9] This facilitates enforcement and further reduces the appeal of the product to minors. Some states have mandatory (e.g, NV, WA, OR) or optional (e.g., MA) product or package review programs to ensure compliance.[9]

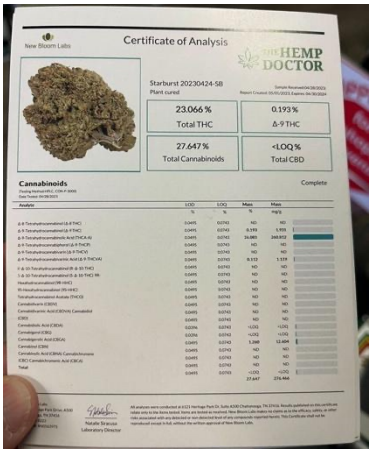
29. Some suggest requiring packages with multiple servings to be easily divisible into single servings. Does a framework like this exist today for any other product or substance?

RESPONSE: Yes. A number of state-regulated marijuana markets require easily divisible servings to ensure that consumers know what a serving size of the product is and can easily demarcate that serving and consume the desired dose.[9] Early experiences in states that legalized medical and nonmedical marijuana suggested that consumers had difficulty taking one bite of a cookie or just eating the arm of a gummy bear, and that clearer demarcations for servings were needed to assist with appropriate dosing and avoid overconsumption. Today, many states (e.g., AK, CA, CO, CT, HI, MA, NV, OR, WA, MD, HI) now include detailed language in statute or rule that edible products must either be single serving products or must be scored or physically demarcated and readily separable to enable a reasonable person to determine how much of the product is a single serving. In instances where a product cannot be demarcated, typically it must be a single serving. Many states require beverages to either be a single serving or include a clear measuring device. These regulatory approaches have assisted consumers in determining how much they consume, and for products that contain intoxicating cannabinoids, have helped to decrease incidents of accidental overconsumption.

APPENDIX A: Examples of hemp-derived products from state marketplaces*

*** All products below are from the hemp marketplace in states and online. Photos were provided by our member states and territories.**

Examples of high THCA hemp-derived products: *The 2018 Farm Bill definition did not define total THC in terms of both THCA and delta-9 THC (as state-regulated marijuana markets do). This has resulted in a surge of THCA products. Products with THCA – which the acid form that is a precursor to delta-9 THC, convert to delta-9 THC when heated.*

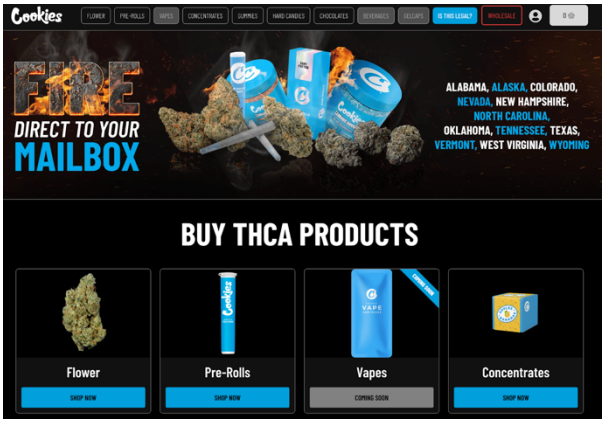


Certificate of Analysis from a lab test of hemp-derived flower that is 23.66% total THC (due to high THCA content). This is indistinguishable from flower in state-regulated marijuana marketplaces - from Minnesota

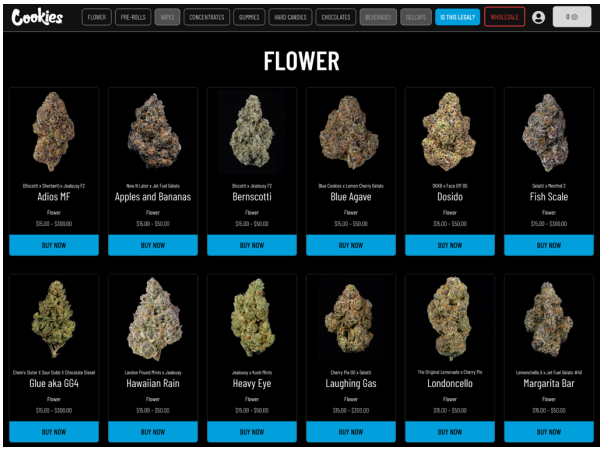
THCA pre-roll infused flower - from Minnesota

Example of hemp-derived THCA (and delta-9 THCP) vape cartridge pod with 1 gram per pod, available online.

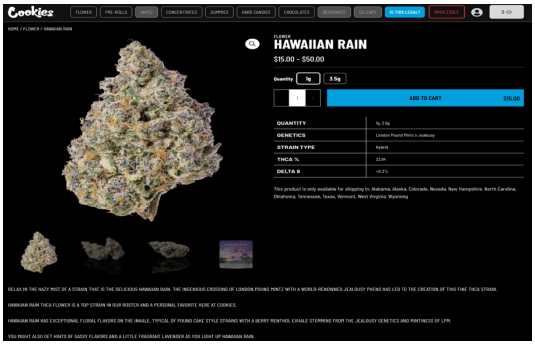
Example of THCA Live Rosin Diamond Wax dabs, using 99% THCA distillate and live rosin, with 2500 mg THCA (which converts to delta-9 THC when heated) - available online.



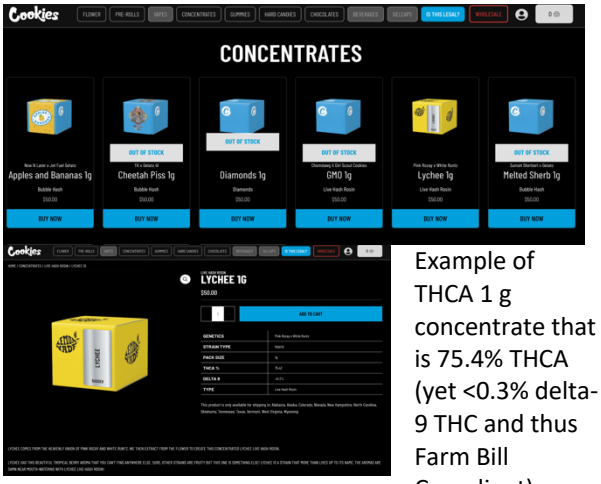
This is a marijuana brand that now offers hemp derived THCA products in the online marketplace.



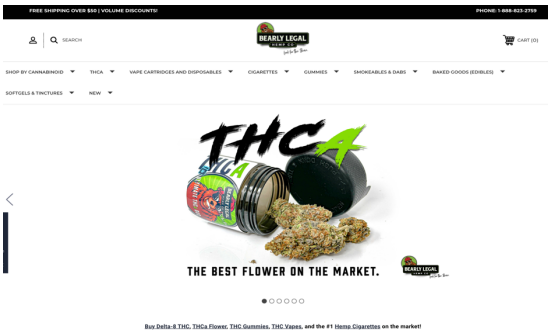
Examples of hemp derived THCA flower/bud for sale in the online marketplace.



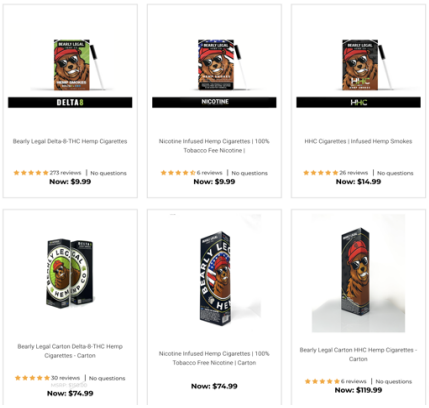
Example of a THCA flower/bud for sale online. This image shows that the product is "farm bill compliant" with <0.3% delta-9 THC, but it contains 22.9% THCA – which will be converted (decarboxylate) into delta-9 THC when smoked.



Example of THCA 1 g concentrate that is 75.4% THCA (yet <0.3% delta-9 THC and thus Farm Bill Compliant).



Example of THCA marketing online.



Example of smokeable THCA products, including some that combine hemp or cannabinoids with nicotine, which is prohibited in state-legalized marijuana markets.

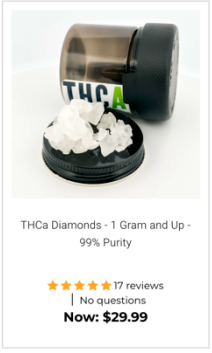
Our THCA Disposable Vapes Live Rosin are the first THCA disposable vapes on the market. This innovative disposable vape uses premium 99% THCA distillate, paired with live rosin cannabis terpene strains to give a superior experience than regular vapes. Comes in Sour Pebbles and Unicorn Berry strains.

THCA is extremely potent, compared equally to Delta 9. Live Rosin vapes are brand new, and has an amazing terpene flavor and taste. If you like the highest quality vape carts you can find, these are for you.

Binoid THCA Live Rosin Disposable Vapes are taking the world by storm, and are getting extremely popular with these awesome live terpene flavors. Users may feel an extraordinary buzz and experience. Don't let the sizing fool you, this THCA disposable is the real deal.

- Live Rosin Terpenes
- Hemp-derived
- Premium 99% THCA Distillate
- Half Gram Sizing

Example of THCA disposable vape pen with 99% THCA distillate from hemp, available online. Note the detail provided on the website about the potency of THCA.

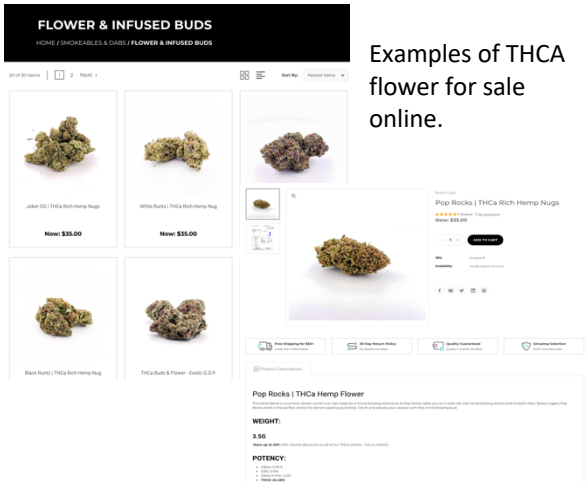


Example of a THCA "diamonds" with 99% THCA from hemp, available online. As stated in the description below, *"These dazzling diamonds are made from pure, hemp-derived THCa, giving you the royal treatment your highnesss. But don't be fooled by their non-psychoactive facade, these diamonds pack a punch. Heat them up and watch them transform into psychoactive THC, the "King of cannabinoids." …. Federally legal and fit for royalty."*

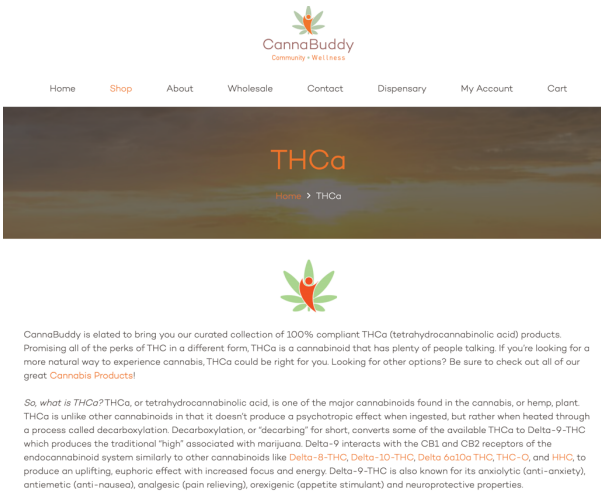
New from Bearly Legal… the "crown jewels" of Hemp concentrates.

These dazzling diamonds are made from pure, hemp-derived THCa, giving you the royal treatment your highnesss. But don't be fooled by their non-psychoactive facade, these diamonds pack a punch. Heat them up and watch them transform into psychoactive THC, the "King of cannabinoids."

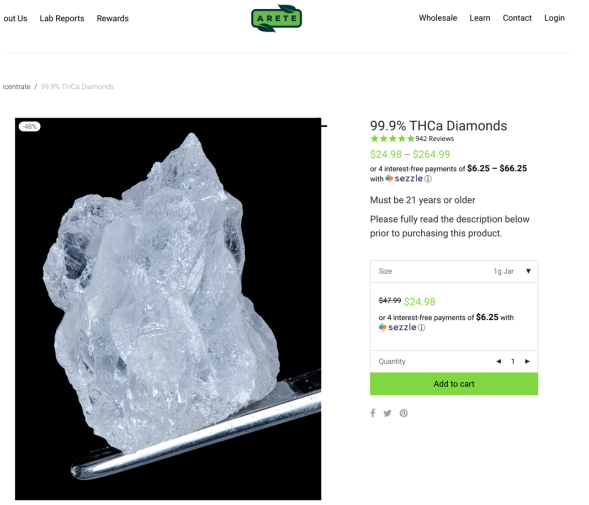
Our THCa Diamonds are made from the highest quality hemp, carefully extracted and purified to ensure maximum potency. They are perfect for those looking for a cannabis experience fit for a king or queen. Add them to your favorite vape or use them as a tincture, and "heat to seat" the King or Queen in you. Experience the difference with Bearly Legal Hemp's THCa Diamonds, Federally legal and fit for royalty.



Examples of THCA flower for sale online.

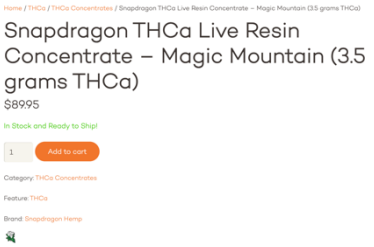


Example of online marketing of THCA product categories.



Example of hemp-derived THCa diamonds for sale online. Diamonds are a form of THC concentrate.

Example of THCa concentrate available online with 3.5 grams of THCa.



Examples of hemp-derived products that are high in delta-9 THC. *The farm bill defined "hemp" as having no more than %0.3 delta-9 THC by weight. This is an agricultural definition that does not translate well to finished products, which typically weigh much more than dried flower, and can therefore contain intoxicating amounts of delta-9 THC and still be "farm bill compliant".*

<table>
<tr>
<td> 

Example of hemp-derived delta-9 THC-infused sweetened and sugars being sold at a store in Minnesota. Most states would not approve this edible product due to potential for accidental consumption.</td>
<td> 

Single-serve, 50 mg hemp-derived delta-9 THC ice cream being sold at a store in Minnesota. A number of state-regulated marijuana markets prohibit perishable foods because they require specific food inspection that does not occur.</td>
</tr>
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<td> 

Example of hemp-derived gummies that contain 120 mg delta-9 /package, which is greater than the 100mg / package limit in this state's regulated marijuana marketplace.</td>
<td> 

Example of a "hemp gummy candy" that contains 15 mg THC and 15 mg CBD per piece – from Maryland.</td>
</tr>
<tr>
<td> 

Example of a hemp-derived chocolate bar that contains 150 mg delta-9 THC – from Maryland. The maximum package limit in most state-regulated marijuana markets is 100 mg.</td>
<td> 

Example of hemp-derived delta-9 gummies with "<0.3% delta-9 THC" – from Maryland. The maximum package limit in most state-regulated marijuana markets is 100 mg.</td>
</tr>
<tr>
<td> 

Example of a package of "Cotton Candy Canna Gummies" that are "Full Spectrum" hemp and contain 3000 mg THC (and are still under the 0.3% delta-9 THC limit).</td>
<td> 

Delta-9 and THCA beverage with 400 mg THC (4 times the limit allowed in any state-regulated non-medical marketplace – from Minnesota</td>
</tr>
</table>

Example of a hemp-derived delta-9 edible that claims to be the "largest legal THC Gummy in History" with 3,000 mg delta-9 THC (200 times the serving size limit in state-regulated marijuana markets) – available online.

Example of hemp-derived delta-9 edible that has 2.5 times the serving size limit of total THC allowed in a regulated medical marijuana edible in Hawaii.

Example of a "Full Spectrum CBD" Party Mix Gummies that appear to be marketed for their delta-9 THC content – from a smoke shop in Oregon. Contains "1500 mg" but it's not clear what portion of that dose is THC.

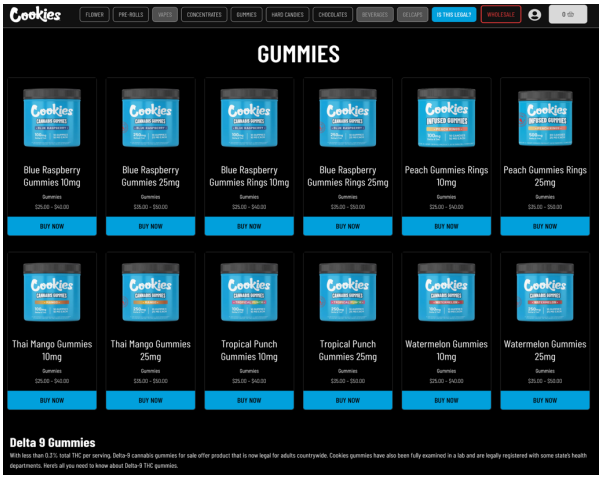
Gummies with 200 mg delta-9 THC – from a smoke shop in Oregon.

Example of delta-9 hemp lollypops – for sale in Alaska. Each lollypop has twice the serving size of delta-9 THC allowed in the Alaska's state-regualted marijuana marketplace.

Example of a "hemp supplement" with delta-9 THC and CBD. The package does not tell the consumer how much delta-9 is in a serving (or the package) – for sale in Alaska.

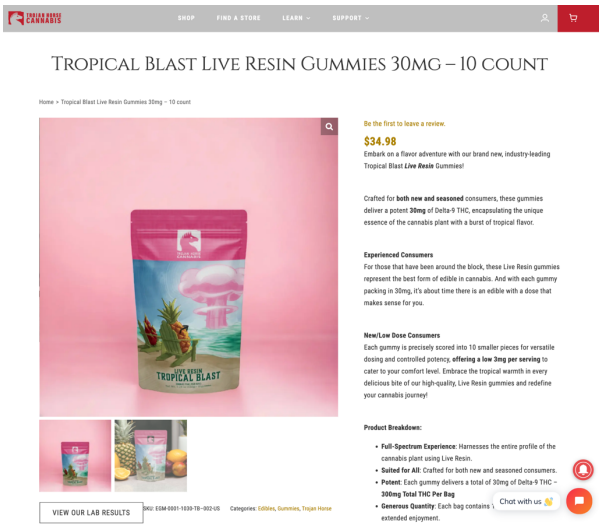
Example of a "hemp-derived" delta-9 pre-roll – for sale in Alaska.

Example of a hemp-derived delta-9 "ice cream cake" vape cartridge – for sale in Alaska.

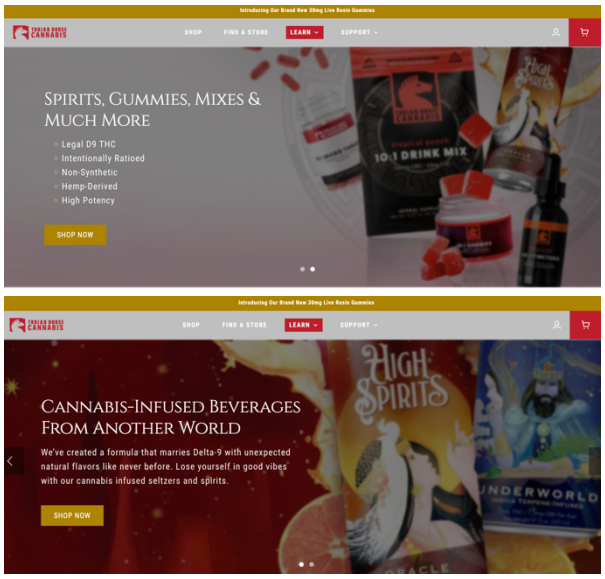


Examples of hemp-derived gummies that contain between 10-25 mg of “farm bill compliant” delta-9 THC per gummy. Most state-regulated marijuana markets have a required serving size of between 5-10 mg total THC for edible products.

Example of a hemp-derived gummies that contain between 25 mg of “farm bill compliant” delta-9 THC per gummy, between 2.5 and 5 times the dose limits for delta-9 THC set in most state-regulated marijuana markets. Note the product states that it is <0.3% Delta-9 THC by weight.



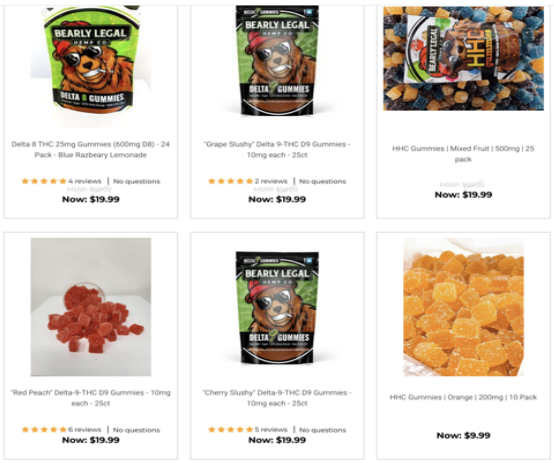
Example of “Live Resin” gummies that are advertised as being “full spectrum” and “suited for all” and contain 30 mg delta-9 THC per serving and 300 mg per bag – three times the legal limit of delta-9 THC in any state-regulated marijuana market. Available online.



Example of online marketing – advertising high delta-9 products as “legal D9 THC” and “Hemp-Derived” and “high potency”.

Example of hemp-derived delta-9 syrup – for sale online.

Example of hemp-derived high potency cookies with delta-9 and other intoxicating cannabinoids. For sale online.



Examples of hemp-derived delta-9 gummies (and some delta-8 and HHC gummies) from the online marketplace.

Examples of hemp-derived edible products with high doses of delta-9 THC being sold at a store in Minnesota.

Examples of Products with Intoxicating Derivatives. These products purport to be legal because the broad definition of hemp in the 2018 Farm Bill legalized "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers." These products are often manufactured using CBD as a starting material. Frequently marketed "hemp-derived" cannabinoid derivatives include HHC, delta-8, delta-10, THC-O-acetate, and THC-P.

Hemp-derived HHC gummies, mixed with Lions Mane mushrooms – for sale in Minnesota.

Example of a "tincture oil" with 3,000 mg of delta-8 THC per bottle, for sale in Minnesota.

Example of the back of a package of hemp-derived gummies that contain 50 mg delta-9 THC, 50 mg of CBD, and an undisclosed amount of THC-P per package. THC-P is thought to be between 10-30 times more potent than delta-9 THC.

Examples of hemp-derived products with hexahydrocannbinol (HHC) and delta-8 THC.

Examples of vape cartridges that contain THC-M, THC-A, and THC-P.

Examples of gummies that contain delta-8 THC.

Example of hemp-derived delta-8 pretzels with 35 mg/serving. Serving size limits in this state regulated marijuana marketplace are 10 mg total THC/serving.

Example of an edible that contains hemp-derived delta-9 THC, PHC, delta-10 THC, THC-X, THC-B, and THC-P – from Minnesota.

Example of hemp-derived gummies that contain 500 mg THC-V (25 mg/piece) and 2500 mg delta-8 THC (125 mg/piece) – from Maryland.

Example of "root beer float" hemp gummies that contain delta-9 THC, THC-H, THC-JD, THC-P, and delta-8 – from Maryland.

Example of delta-8 infused cigarettes with "100% Organic Hemp Flower" available for sale in Washington State.

Example of delta-8 dabs for sale in Washington State.

Example of a Delta-8-THC cartridge from a smoke shop in Oregon.

Example of Candy similar to “Pop Rocks” containing delta-9 THC and THC-O – from a smoke shop in Oregon.

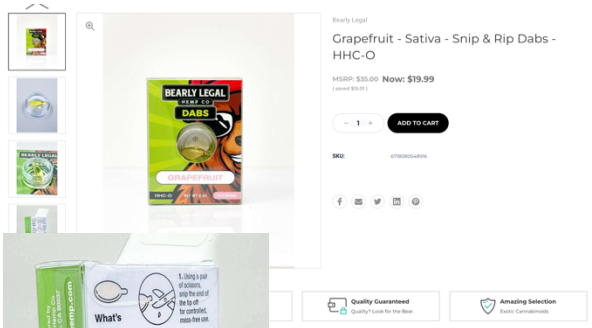
Example of hemp-derived “gummy ropes” with delta-9 THC, OH-THC, delta-8 THC, and THC-P – for sale in Connecticut.

Example of hemp-derived “sour belts” that contain HHC, THC-O, THC-P, and delta-8 THC – for sale in Connecticut.

THC-O hemp vape carts available for sale in Connecticut.

Hemp-derived delta-8 infused pre-roll joints for sale in Connecticut.

Example of hemp-derived THC-O infused “hemp smokes” with 750 mg THC-O per pack – for sale in Texas. Note that they claim to contain 100% organic hemp flower and are <0.3% THC.



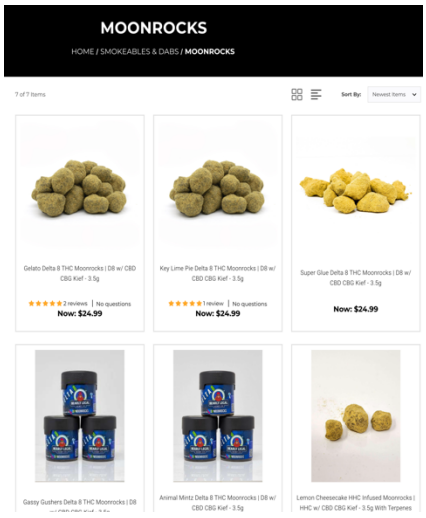
Example of an HHC-O hemp dab, including instructions about how to consume a dab, available online.

Vape cartridges with 1,000 mg HHC, 900mg delta-8 THC or delta-10 THC, Minnesota

Examples of combusted and aerosolized products with delta-8 THC, delta-9 THC, and THC-O found in a popular market in Oklahoma City, OK.

Example of hemp product intended to be heated and inhaled and containing synthetic cannabinoid HHC.

Examples of delta-8 concentrates for sale in Minnesota.



Example of hemp-derived delta-8 and HHC infused “moon rocks” – available online. Moon rocks mix hemp flower, THC, and sometimes CBD concentrate with hemp kief.

Examples of delta-8 and THC seltzers. From Texas.

Examples of intoxicating hemp-derived products that appeal to kids. *These products would not be allowed in most state-regulated marijuana markets because they mimic existing commercial products and/or have marketing elements that have been deemed in state statute or rule to be potentially appealing to kids.*

A product that advertises hemp-derived delta-8, delta-9, delta-10, "PHC," THC-P, THC, THC-B, and "THC-X" - with 7,000 mg per package. This package would be unlikely to be allowed in current state-regulated marijuana markets, because it has bright colors and could appeal to kids.

A product that claims to have 1,000 mg "legal THC" (with 100 mg per serving and 10 gummies per container). A single gummy contains the package limit in most state-regulated non-medical marijuana markets. This product imitates a commercial brand (NRds vs Nerds) that appeals to kids.

"Hemp-derived" delta-8 "Sticky Charms" cereal bars that claim to have 500 mg. This product imitates a commercial brand ("Sicky charms" vs "Lucky Charms") that appeals to kids. For sale in Minnesota.

"Hemp-derived" delta-8 gummy rope with 500 mg per rope. This product would likely not be allowed in state-regulated marijuana markets because it could appeal to kids. For sale in Minnesota.

Delta-8 sour gummies, airheads, and nerds, with packaging that directly imitates commercial products targeted at kids – for sale in Washington State.

Delta-8 mini cereal pouches, with packaging that directly imitates commercial products targeted at kids – for sale in Washington State.

Examples of hemp-derived delta-8 THC products that imitate commercial products and/or appeal to kids - for sale in Minnesota.

Example of hemp-derived HHC vape-cartridges that imitate a commercial product designed to appeal to kids – for sale in Washington State.

Example of a package of "Golden Grahamz" treats with 500 mg of THC per treat, for sale in Maryland. This package imitates a commercial product designed to appeal to kids.

Examples of edible THC products that imitate commercially available products and brands – for sale at a smoke shop in Washington State.

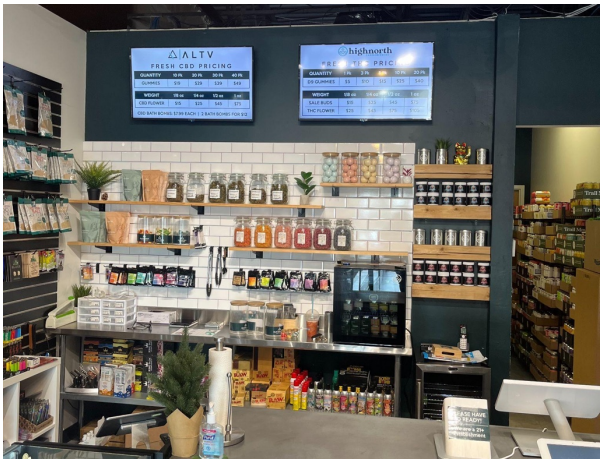
Example of hemp-derived THC "Wonka Bars" with 500 mg THC. This package imitates a commercial product that is designed to appeal to kids. Available for sale in Connecticut.

Peanut Butter nugget containing undeclared amount of delta-9 THC. Available for sale in Hawaii.

Examples of the hemp retail environment for hemp-derived cannabinoid products in states

Examples of high delta-9 THC chocolate bars (and some delta-8 "crispy blunt" candies and "candy rings" being sold at a consumer goods store alongside regular, non-cannabinoid candy - in Minnesota

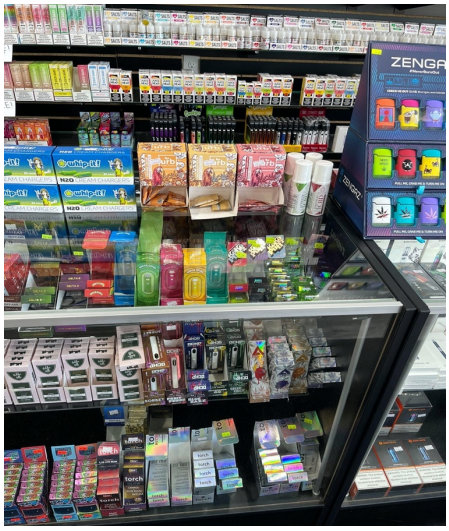
Examples of hemp-derived smokeable/ inhalable products with high doses of delta-9 THC being sold at a store in Minnesota.



Example of a CBD/Hemp store in Minnesota

Example of a CBD/Hemp store in Minnesota

Example of a smoke shop with intoxicating hemp-derived products.

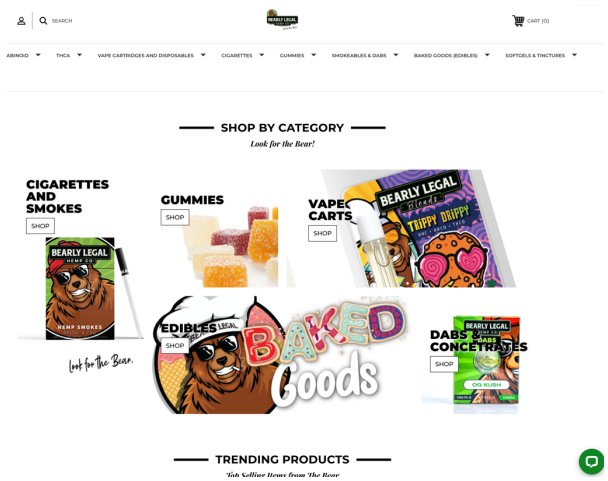


Example of a vape store with intoxicating hemp-derived products.

Example of a store with “Buy one get one” deals (which are prohibited in many state-regulated marijuana markets).

Hemp-derived HHC, THCA, delta-9, and CBD products on display at a hemp store in Minnesota.

Hemp-derived delta-10, delta-8, delta-9, and THC-O edibles, vape carts, and resins for sale at a hemp store in Minnesota. Note many of the packages state, “Legal THC,” and “hemp derived.”



Example of online retail store.

Examples of other hemp products:

Example of a nicotine/CBD cigarette that uses “50 mg natural CBD” and 7.5 mg synthetic nicotine. The product claims to have *“pure unadulterated synthetic nicotine that is not sourced from tobacco, so you can enjoy each hit as if it were a real cigarette. And because they’re Hemp cigarettes, they don’t contain the laundry list of harmful toxins or pollutants typically found in real cigarettes.”* – available online.

Tobacco-Free Nicotine Infused Hemp Cigarettes

Volume discounts from 1-10 packs(carton). Pricing as low at $7.50 a pack!

The functional equivalent of a real cigarette, Bearly Legal is pleased to announce the world's first Tobacco-Free Nicotine Infused Hemp Smokes. We didn't have to compromise on quality, and the result is a smooth, satisfying smoke. Our Nicotine-Free Hemp Cigarettes are made with pure, unadulterated synthetic nicotine that is not sourced from tobacco, so you can enjoy each hit as if it were a real cigarette. And because they're Hemp cigarettes, they don't contain the laundry list of harmful toxins or pollutants typically found in real cigarettes (Who knows what they contain).

Simple is Better. Just 2 Ingredients:

1. Raw A+ Quality Cali Grown Hemp
2. Tobacco-Free Nicotine

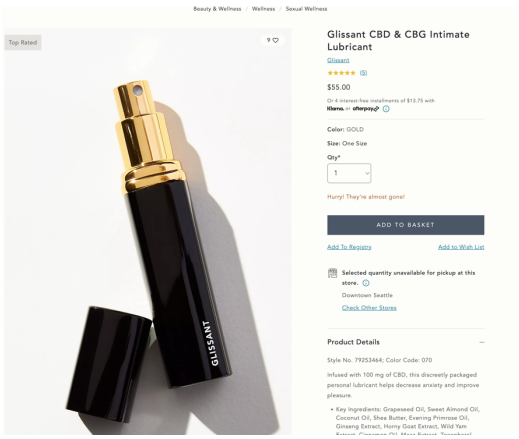
Included:

- 1 Pack of Bearly Legal Nic Smokes (Tobacco-Free)
- 20 cigarettes per pack
- Each cigarette is approximately 0.8g of fine hemp.
- 7.5mg of Nicotine
- 50mg of Natural CBD

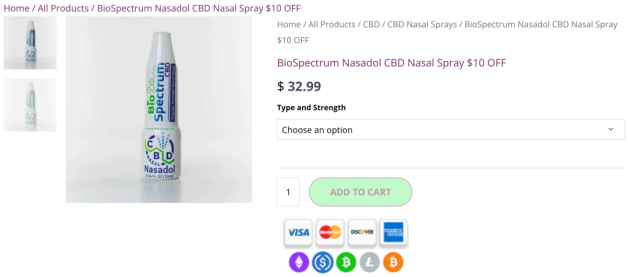
Contains less than .3% Delta-9-THC

Example of hemp-derived CBD “beer” (the beer has <0.5% alcohol, which is under the threshold to be considered alcoholic).

Example of CBD suppositories – for sale at a large department store and online.



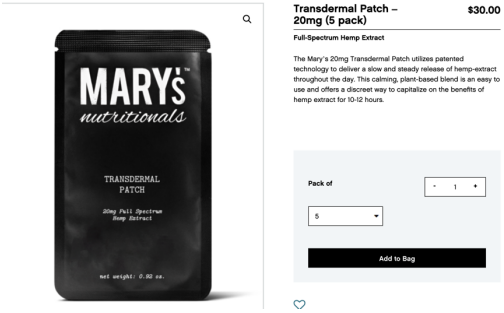
Example of CBD and CBG lubricant



Example of CBD nasal spray – available online.

Example of CBD lube for sale online.

Examples of “hemp” transdermal patches (cannabinoids not specified). These products combined cannabinoids with dietary supplements, like melatonin, valerian root, and ashwagandha.



Example of “full spectrum” hemp transdermal patch – for sale online.

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