**U.S. Hemp Roundtable Response to United States Congress**
**Request for Information Regarding the Regulation of Cannabidiol Products**

The U.S. Hemp Roundtable and its members – listed on the final (50th) page of this document – appreciate the opportunity to submit responses to the U.S. Congress regarding its Request for Information regarding the regulation of cannabidiol (CBD) products. The Roundtable is the hemp industry's leading national advocacy organization. For nearly a decade, the Roundtable's more-than-100 members have stood at the forefront of ensuring a fair regulatory environment for the safe and responsible manufacture and sale of hemp cannabinoid products.

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.

   *Hemp cannabinoids products including CBD products are sold in a wide range of formats, from ingestible products including food, beverages and dietary supplements, cosmetics (e.g., topically applied products and personal care products), and inhalable/smokable products. Manufacturing practices will vary depending on the product type; for products marketed as conventional foods or dietary supplements, it is expected that manufacturers adhere to the appropriate FDA current Good Manufacturing Practices (cGMPs), i.e., 21 CFR Part 117 for foods and 21 CFR Part 111 for dietary supplements, as well as applicable Food Safety Modernization Act (FSMA) requirements. Several states also require products marketed as food and dietary supplements to follow federal cGMP requirements; however, some states (e.g., Colorado) prescribe specific cGMPs for hemp-derived CBD products, which may cover cosmetics and inhalable or smokable products. As cosmetics are not currently subject to mandatory federal cGMPs, manufacturing practices with respect to CBD cosmetics vary, although as noted some states impose their own cGMPs for hemp/CBD cosmetics. It is expected that following the implementation of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), companies manufacturing hemp/CBD cosmetics will adhere to the FDA's cGMP framework for cosmetics. For OTC products that contain CBD as an inactive or cosmetic ingredient, it is expected that manufacturers adhere to federal cGMPs applicable to drug products.*

   *CBD products are marketed and sold through a variety of channels, including brick-and-mortar retail, e-commerce, and through multi-level marketing companies. A recent economic study estimated the market for CBD products to have hit $5 billion in 2022, but there are two very different scenarios for future revenues. If a federal regulatory framework is in place by the end of 2024, the study projects the*

*market will top $11 billion by 2027. In the absence of a framework, however, CBD sales are expected to only reach $7 billion in five years.*[1]

*While CBD has been the most popular marketed cannabinoid, in recent years consumer interest in other cannabinoids such as CBN (cannabinol) and CBG (cannabigerol) has increased. Due to the negative market and economic conditions surrounding CBD (described below), the market for chemically converted cannabinoids such as Delta-8 THC has grown as well. Unlike CBD, CBN, CBG, and similar cannabinoids that are marketed for structure/function type benefits such as relief from occasional stress or sleeplessness, Delta-8 THC products and other chemically converted cannabinoid products may be marketed for their intoxicating effects.*

*Thus, a framework for the regulation of CBD products should encompass other cannabinoid products, and as described below, should regulate products that are scientifically shown to have impairing effects separately from non-impairing products. Further, the existing frameworks for dietary supplements, foods, and cosmetics provide appropriate guardrails with respect to marketing claims as well as ingredient and safety requirements that limit the types of cannabinoids that can be used in products. With respect to dosages, these currently vary across products. However, the typical serving size of CBD foods and dietary supplements amongst U.S. Hemp Roundtable members ranges between 25 and 100 mg/serving. The current regulatory environment is a disincentive for companies to invest the substantial amounts of money required for safety studies, yet many Roundtable members have expended millions of dollars to conduct extensive toxicity studies to establish a safe serving size for their individual ingredients, as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Proper regulation of hemp cannabinoids as food and dietary supplements under the current authorities in the FD&C Act and its implementing regulations would require all companies to ensure the safety of their products by conducting safety studies when appropriate and help ensure that CBD and other cannabinoid products sold as food or dietary supplements do not exceed levels that may be unsafe; and importantly, that such products are only marketed to healthy adults and those who are not pregnant or nursing. We note that this is not only the opinion of the U.S. Hemp Roundtable, but represents the consensus position of the hemp industry, as indicated by the support of 31 leading hemp industry organizations who advocate for an approach that relies on existing frameworks to regulate non-impairing hemp and CBD products as well as impairing products, without criminalizing the latter category. See* ***Appendix C****.*

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

*Regulatory uncertainty has persisted since the 2018 Farm Bill, causing the negative market and economic conditions described below. This is because on the same day the 2018 Farm Bill became effective, FDA reasserted its opinion that it is illegal to market CBD as a dietary supplement or to use CBD as a food additive. The FDA's comments, and its failure to develop a regulatory regime, cast a cloud over the industry, causing big box stores and major food and beverage brands to abandon plans to market CBD and other hemp extracts.*

*While some states have enacted favorable laws and regulations for hemp cannabinoid products, which has created some intrastate market opportunities, confusion and uncertainty remains at the federal level with respect to hemp cannabinoid products in interstate commercial markets.*

[1] Brightfield Group, CBD: FDA Impact & the Path Forward, 2022 Mid-Year US CBD Report, available at: https://content.brightfieldgroup.com/cbd-fda-impact-the-path-forward.

*Chilled and stagnant CBD commerce has resulted in a continuing oversupply of hemp biomass and derivative products, such as crude oil, with hemp commodity prices dropping sharply, adversely impacting hemp farmers. In addition, many farmers – in particular minority farmers – who were negatively impacted by declining demand for their other crops (e.g., tobacco) turned to hemp as a lifeline to save their livelihood. Thus, declining demand for hemp has had a disproportionate impact on minority farmers as well. This has been a deeply unfortunate but recurring pattern in U.S. agriculture that the hemp industry aims to reverse. According to independent reporting agency Hemp Benchmarks, aggregate prices for hemp CBD biomass, crude oil, full spectrum distillate, and CBD isolate declined more than 90% between April 2019 and April 2023. While prices stabilized somewhat in late 2021, any significant and sustained price increases are not expected in the foreseeable future, barring regulatory clarity.*[2]

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

   *Lack of national standards has led to the proliferation of unregulated products, some of which raise significant quality, safety, and other consumer protection concerns. Adding to these issues, surplus hemp CBD biomass is being chemically converted into impairing products, such as Delta-8 THC, which are being sold unregulated, sometimes to minors. These products serve as a lifeline to U.S. farmers, and when manufactured properly, can be of considerable value to adult consumers. Accordingly, we oppose their ban or criminalization. However, they must be strictly regulated for safety and kept out of the hands of children.*

   *The lack of national standards, along with FDA's reassertion of its opinion that it is illegal to market CBD as a dietary supplement or to use CBD as a food additive, has had serious economic impacts in other ways as well. In addition to a severe downturn in U.S. hemp production, major banks and payment processing services, including Chase and PayPal, are refusing to onboard hemp and CBD companies, citing regulatory uncertainty. And as mentioned above, consumer packaged-goods giants and major retailers have been reluctant to embrace CBD products, referring to FDA's opinion and the absence of clarifying regulations as a key concern.*

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.

   *FDA's conclusion that CBD and other hemp-derived cannabinoids cannot be regulated under existing frameworks, and therefore should be subject to a novel regulatory pathway based on "harm reduction," is flawed. With respect to CBD, widely available science from around the world demonstrates its safety in the low milligram serving size formats typically found in the retail marketplace. In addition, the existing frameworks for dietary supplements and food/beverage, as well as FDA's current authorities under the FD&C Act, provide the Agency with the tools to effectively regulate these products, just as they do for the many thousands of other botanically-derived products currently on the market. Indeed, nearly the entire FDA "wish list" for regulatory authority could be*

[2] See **Appendix B**, "Written Testimony of Jonathan Miller Before the House Oversight Committee," July 27, 2023, Figures 1-3

*achieved without the development of new pathway specific to hemp cannabinoid products. We again note that this is not only the opinion of the U.S. Hemp Roundtable, but represents the consensus position of the hemp industry, as indicated by the support of 31 leading hemp industry organizations. See **Appendix C**.*

*While we disagree with FDA's opinion that a new regulatory regime is needed for food, dietary supplements, or cosmetics, especially given the length of time this would require, we are certainly open to stricter regulation of CBD and other ingestible or topically applied cannabinoid products on top of the existing frameworks for similar product categories. For example, we agree that FDA needs new authorities for combustible/inhalable products which would not be considered food, dietary supplements, or cosmetics.*

Scope

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

   *Although we believe ingestible and topical hemp cannabinoid products can be effectively regulated under existing frameworks for food, dietary supplements, or cosmetics, the creation of a new product category, such as "cannabinoid hemp products," within those categories seems largely acceptable and non-controversial. We also support maintaining the federal illegality of purely synthetic cannabinoids that have no origin from the cannabis plant and products that contain dangerous ingredients as determined by notice-and-comment rulemaking. Notably, cosmetics will soon be subject to increased regulation by FDA due to the passage of the Modernization of Cosmetics Regulation Act (MoCRA), and issues such as THC and CBD limits, child-proof packaging and the like, are not applicable to topical products where there has been no real-world evidence of unsafe usage or misuse by ingestion. Drug products, as defined in the FD&C Act, and inhalable/combustible products are not considered food, dietary supplements, or cosmetics and should remain outside the scope of these regulatory frameworks.*

   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?

      *There should be two separate categories within existing regulatory frameworks that distinguish products by their potential to cause impairment. This currently exists with regard to alcohol and the 0.5% ABV limit under which a product like kombucha can be considered food. FDA would regulate non-intoxicating hemp products, while those that may be impairing should be strictly regulated and controlled in an adult-only framework by a separate agency such as the Alcohol and Tobacco Tax and Trade Bureau (TTB), rather than prohibited or criminalized. Topical products containing CBD and other hemp-derived cannabinoids should not be part of any new framework and should continue to be regulated under the current comprehensive framework for cosmetics.*

      *We strongly object to banning products that are potentially intoxicating merely due to that potential. We share FDA's concerns—and have been publicly outspoken—about the recent development of an unregulated multi-billion-dollar market for impairing products (such as*

*Delta-8 THC), particularly those products that are poorly manufactured and/or easily confused with ordinary foods, and that are attractive to children (e.g., candies, cereal). The answer, however, is not prohibition. Unregulated products would continue to proliferate in gray or black markets, continuing to pose harm to children and other consumers. Indeed, when manufactured in compliance with regulatory standards and sold only to adults, these products provide value to consumers and a lifeline for the livelihood of U.S. farmers who have struggled in recent years. Compared to the price collapse of other hemp commodities since 2019, prices for hemp flower significantly recovered due to the opportunity of converting that flower to Delta- 8 THC.*[3]

*The correct answer was found in unanimous votes of the Kentucky legislature, which created a new legal framework for impairing cannabinoids such as Delta-8 THC, providing strict regulation for public health and safety and ensuring these products are kept out of the hands of children. Other states such as Florida and Tennessee have followed Kentucky's lead, and so should Congress. We also note that this position is shared by the leading hemp industry organizations that all agree that impairing or intoxicating cannabinoids should not be criminalized but regulated. See* ***Appendix C.***

*We believe FDA is not the appropriate agency to regulate these products. Rather, TTB has the appropriate expertise to regulate products intended for adult use, such as alcohol and tobacco, and should be directed to regulate impairing cannabinoids.*

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?

*To distinguish between non-intoxicating hemp products and impairing cannabinoids, we agree in setting a specified threshold, but it should be set in regulation (similar to the ABV limit mentioned above), with FDA having the authority to update or refine the limit (to a degree) through notice-and-comment rulemaking.*

*In order to provide policymakers with a survey of studies on intoxication, the U.S. Hemp Roundtable has developed a white paper sharing the current evidence which is attached hereto as* ***Appendix A****. The white paper demonstrates that current science supports a limit of a maximum of 5 milligrams of THC per serving for edible or ingestible products. Products exceeding this limit of THC and other potentially intoxicating cannabinoids would be regulated by TTB and available to adults only.*

*Ultimately, Congress, the states, and/or FDA should use scientific studies and evidence to determine intoxication benchmarks. Too often, these levels have been set by states using arbitrary numbers, often much lower than the science suggests due to a misunderstanding of full-spectrum hemp products and lobbying by competing industries.*

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

*As noted above, we support maintaining the federal illegality of purely synthetic cannabinoids that have no origin from the cannabis plant. With respect to "semisynthetic derivatives," this*

[3] See Appendix B, Figure 4

*term should be clearly defined, and a federal definition and regulation would be helpful as state regulation and terminology vary widely. For example, several states (e.g., Minnesota and Oregon) refer to such products as "artificially derived cannabinoids," which are typically defined as cannabinoids created by a chemical reaction that changes the molecular structure of any chemical substances derived from the cannabis plant, but excluding: (1) a naturally occurring chemical substance that is separated from the cannabis plant by a chemical or mechanical extraction process; or (2) cannabinoids that are produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst. Further some states (e.g., Oregon) prohibit these substances, while others (e.g., Minnesota) permit and regulate them under a hemp cannabinoid regulatory framework. FDA should regulate non-scheduled semi-synthetic derivatives, and the framework we have proposed would allow the Agency to do this effectively, with mandatory cGMPs, labeling requirements, and safety evaluations required as appropriate. Impairing products, including semisynthetic derivatives, would be regulated by an agency such as TTB and reserved for adult use only.*

6. Other non-cannabinoid products are available on the market that have raised safety concerns among some individuals, which FDA has regulated without a substance-specific regulatory framework (e.g. kratom, caffeine, etc.). How has FDA dealt with products containing those substances? How might these products be implicated by a CBD-specific product framework?

   *We have not fully considered the extent to which our proposed framework for hemp cannabinoid products could apply to non-cannabinoid products as our focus has been limited to establishing a regulatory framework for hemp cannabinoid products. We are aware of the challenges posed by substances such as pure powdered caffeine, including the potential challenges faced by FDA in regulating these substances. However, based on the safety data available to date, we do not believe CBD and other non-impairing hemp-derived cannabinoids pose the same challenges or health risks, and therefore should not be regulated in the same manner. We believe the existing frameworks provide adequate safeguards for non-impairing hemp-derived cannabinoids, and a separate analysis and evaluation of potential pathways for the regulation of other non-cannabinoid substances is warranted.*

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?

   *As noted above, lack of national standards has led to the proliferation of unregulated products, some of which raise significant quality, safety, and other consumer protection concerns.*

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

      *Intoxicating compounds like Delta-8 THC, which are typically produced by chemically converting hemp-derived CBD biomass, are—for the most part—being sold unregulated at retail. Some of these products pose public health risks because of their high concentrations of THC and marketing and labeling in ways that are appealing to children or that may confuse consumers because of similarities to traditional foods.*

      *However, we are unaware of evidence indicating that Delta-8 THC alone has a detrimental effect on healthy adults when manufactured appropriately. In addition, there is considerable anecdotal evidence that adults find wellness value in these products. The challenge is that the*

*lack of regulation of these products has resulted in products that are improperly manufactured and/or marketed in ways that are dangerous and/or appealing to children.*

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

*Apart from the "5 Things to Know" consumer update issued by FDA regarding Delta-8 THC and Warning Letters issued to manufacturers and distributors of Delta-8 THC products,[4] we are not aware of any regulation of Delta-8 THC or enforcement against such products by FDA. We are not aware that FDA has issued Warning Letters, public statements, or taken other action against similar impairing products such as Delta-10 THC, HHC, THC-O, etc.*

*However, some states have chosen to regulate impairing products like Delta-8 THC on their own. Regulations vary and range from legalization to restriction to adult-use markets, to complete prohibition.*

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

*As described above, we propose two categories within the existing frameworks by which non-intoxicating hemp products would be regulated by FDA, while products that may be impairing should be strictly regulated in an adult-only framework by a separate agency such as TTB.*

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?

*We are aware of consumer interest in non-ingestible inhalable, topical, ophthalmic drops, and injectable products.*

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

*We do not object, in concept, to the addition of most non-ingestible products to a regulatory framework for hemp cannabinoid products, but urge Congress to look to existing authorities such as those in place for drugs, alcohol, tobacco and cosmetics. Cosmetics will soon be subject to increased regulation by FDA due to the passage of MoCRA, and issues such as THC and CBD limits, child-proof packaging and the like, are not necessary or warranted for topical products given there has been no real-world evidence of unsafe usage or misuse by ingestion.*

*We support a regulatory framework for inhalable products and believe this can be done through FDA's Center for Tobacco Products (CTP). It is important, however, that ingredients used in inhalable products be considered separately from those used in ingestible products. In addition, different categories of inhalable products require different considerations and tolerances, separate and apart from food, dietary supplements, or cosmetics.*

[4] FDA, 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC (May 2022), available at: https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc.

Federal-State Interaction

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?

    *States have enacted various requirements for hemp cannabinoid products, including manufacturing and testing standards, registration and product listing, product approval, age limits, adverse event reporting, cannabinoid and THC limits per serving and per package, ingredient prohibitions, warning labels, child-proof and tamper-evident packaging, and storage restrictions. The various requirements exist in a non-uniform patchwork of regulations.*

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

    *Florida provides a strong model for Congress to follow both in its treatment of non-intoxicating hemp products, as well as those products that are impairing, such as Delta-8 THC. Unfortunately, a growing number of states have enacted laws or adopted regulations that have created burdensome and unworkable requirements for the hemp industry. For example, Colorado and Utah require manufacturers to utilize state-certified labs to test hemp-based products, and Iowa has imposed an onerous product registration system that has led to delays in bringing products to market within the state. We expect this trend to continue, which further emphasizes the need for a uniform federal framework that preempts these burdensome and often unnecessary requirements.*

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?

    *Given the disruptive and conflicting patchwork of state laws that have emerged in recent years due to FDA inaction, the new federal law should preempt state laws, particularly when it comes to labeling, packaging, and the criminal prohibition of certain hemp products. We oppose legislation that sets a "federal floor" of standards, allowing states to be more prescriptive, particularly as it relates to cGMPs, testing, packaging, and labeling. The current patchwork of state requirements has left both consumers and industry confused, and therefore preemption is necessary to establish comprehensive, uniform requirements that help ensure consumer health, safety, and transparency in labeling.*

Safety

11. What is currently known about the safety and risk-benefit profile of CBD and other hemp derived cannabinoids? What safety and toxicity data are available to support this knowledge. Please include in your answer any relevant information about safety with regard to specific populations, such as children and pregnant individuals.

    *There is a growing body of scientific evidence demonstrating the safety of orally consumed CBD at lower milligram amounts, such as the amounts typically found in CBD food and dietary supplement products sold at retail. As outlined below, there are multiple toxicity studies published between 2020 and 2023 demonstrating the safety of CBD at these lower amounts, as well as other studies we expect*

*to be published soon. Of note, one study focused on male and female reproductive toxicity. However, most of the studies described below were intended to establish safe intake levels of CBD for healthy adults who are not pregnant or nursing. Additional studies are needed to establish safe consumption levels of CBD as a dietary supplement or food for vulnerable populations such as children and pregnant individuals, but clear warning labels can be used until such time as those studies are conducted.*

- *Three published toxicity studies on three different types of hemp extract, conducted as part of independent GRAS affirmations, have consistently demonstrated the safety of CBD at serving sizes typically found in products sold at retail.*[5]
- *A fourth toxicity study published in 2023 on CBD isolate and a fifth toxicity study on a high-CBD hemp extract also reported positive findings with respect to CBD's safety.*[6]
- *A sixth toxicity study published in 2023 evaluating the effects CBD isolate provides the relevant data needed to establish safe intake levels related to male and female developmental and reproductive toxicity, which addresses an important data gap identified by FDA.*[7]
- *A genotoxicity evaluation, also published in 2023, concluded that CBD is unlikely to pose a genotoxic hazard.*[8]
- *Multiple unpublished studies presented confidentially to the FDA yielded additional positive safety findings, with two studies using hemp extract and two using CBD isolate. Most of these studies are expected to be published in 2023-2024.*
- *Another toxicity study with additional safety was data submitted to the FDA in conjunction with a Citizen Petition, further demonstrating the safety of another CBD product containing hemp extract.*[9]
- *A further study, based on Phase II and Phase III clinical trials utilizing full and broad-spectrum hemp extracts with up to 150 mg of hemp extract daily, was not associated with elevated liver tests, notable drug interactions, or adverse events.*[10]
- *Observational data and the results of another study provide additional evidence of CBD's safety in over 4,000 participants collectively:*

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[5] Tennille K. Marx *et al.*, "An Assessment of the Genotoxicity and Subchronic Toxicity of a Supercritical Fluid Extract of the Aerial Parts of Hemp" (2018) (available at https://doi.org/10.1155/2018/8143582); Margitta Dziwenka *et al.*, "Safety Assessment of a Hemp Extract using Genotoxicity and Oral Repeat-Dose Toxicity Studies in Sprague-Dawley Rats" (2020) (available at https://doi.org/10.1016/j.toxrep.2020.02.014); Margitta Dziwenka *et al.*, "Toxicological safety of VOHO Hemp Oil; a supercritical fluid extract from the aerial parts of hemp" (2022) (available at https://doi.org/10.1371/journal.pone.0261900).

[6] Rayetta G. Henderson *et al*., "Oral toxicity evaluation of cannabidiol" (2023) (available at https://doi.org/10.1016/j.fct.2023.113778); Toxicological safety assessment of HempChoice® hemp oil extract; a proprietary extract consisting of a high concentration of cannabidiol (CBD) in addition to other phytocannabinoids and terpenes derived from Cannabis sativa L (2023), https://doi.org/10.1016/j.heliyon.2023.e16913; Reproductive and developmental toxicity evaluation of cannabidiol (2023), https://doi.org/10.1016/j.fct.2023.113786.

[7] Rayetta G. Henderson *et al*., "Reproductive and developmental toxicity evaluation of cannabidiol" (2023), https://doi.org/10.1016/j.fct.2023.113786).

[8] Genotoxicity evaluation of cannabidiol (2023), https://doi.org/10.1016/j.yrtph.2023.105425.

[9] U.S. Food and Drug Administration, "Citizen Petition from Daniel Fabricant, Ph.D., on behalf of Natural Products Association, Docket No. FDA-2022- P-0600" (Feb. 21, 2022), https://www.npanational.org/wp-content/uploads/2022/02/CBD-CP-on-CBD.pdf).

[10] Presented confidentially to the FDA. Pregnant women were excluded from the studies.

- *A 2021 observational study conducted by Validcare in over 800 participants using CBD products showed no increase in the prevalence of elevated liver function tests when compared to a population with a similar incidence of medical conditions.*[11]
- *Another Validcare study of over 1,000 participants, completed in March 2022, showed that CBD is not associated with elevated liver tests, low testosterone levels, or daytime drowsiness.*[12]
- *The results of a Radicle Sciences study published in November 2022 and using 2,800 participants reported only minor unwanted effects (e.g., gas, headache) in less than 10% of participants, with no severe adverse effects.*[13]

*The testimony of Dr. Rayetta Henderson, a toxicologist and Senior Managing Scientist in the Foods & Consumer Products Practice at ToxStrategies LLC, before the House Committee on Oversight and Accountability Subcommittee on Health Care and Financial Services further confirms that CBD can be regulated as a dietary supplement under the existing framework.*[14] *Based on her experience performing toxicological evaluation, Dr. Henderson concluded that "the data available are sufficient for conducting a safety assessment of CBD following the same principles that we would apply for any ingredient proposed for use in foods or supplements," and that safe levels of consumptions can be determined based on the existing data – contrary to the FDA's assertions that CBD cannot be regulated under the current regulatory framework.*

*Notably, international regulatory bodies have reviewed the same publicly available evidence and determined that CBD products can be safely marketed to healthy adults who are not pregnant or nursing. The World Health Organization determined that pure CBD is "generally well tolerated with a good safety profile" and presents little risk of abuse or dependency potential, recreational use, or public health-related problems.*[15] *Australia's Therapeutic Goods Administration concluded that CBD "presents a good safety and tolerability profile" and approved CBD products, up to a maximum of 150 mg/day, for use in adults, to be supplied over-the-counter by a pharmacist, without a prescription.*[16] *The United Kingdom's Food Standards Agency determined that CBD products can be regulated and marketed as novel foods, provided they meet standards for safety and content, recommending a 70 mg daily limit for healthy adults.*[17]

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[11] Robert Kaufman *et al*., "Observed Impact of Long-term Consumption of Oral Cannabidiol on Liver Function in Healthy Adults" (2021) (available at https://www.liebertpub.com/doi/10.1089/can.2021.0114).

[12] U.S. Hemp Roundtable, "New Study Demonstrates CBD's Strong Safety Profile, Amplifies Calls for FDA Regulation," HEMPSUPPORTER.COM (May 17, 2022), https://hempsupporter.com/news/new-study-demonstrates-cbds-strong-safety-profile-amplifies-calls-for-fda-regulation/.

[13] Jessica Londeree Saleska *et al.*, "The Safety and Effectiveness of Commercially Available Cannabidiol Products for Health and Well-Being: A Randomized, Multi-Arm, Open-Label Waitlist-Controlled Trial" (2022) (available at https://doi.org/10.1089/imr.2022.0081).

[14] Written Testimony of Rayetta G. Henderson, Ph.D. before the House Committee on Oversight and Accountability, Subcommittee on Health Care and Financial Services, Hemp in the Modern World: The Years-Long Wait for FDA Action (July 27, 2023), available at https://oversight.house.gov/wp-content/uploads/2023/07/R-Henderson_Written-Statement-for-27Jul2023.pdf.

[15] World Health Organization, CANNABIDIOL (CBD) Critical Review Report, Expert Committee on Drug Dependence Fortieth Meeting, Geneva, 4-7 June 2018, available at: https://www.who.int/docs/default-source/controlled-substances/whocbdreportmay2018-2.pdf.

[16] Australia Therapeutic Goods Administration, Over-the-counter access to low dose cannabidiol (December 2020), available at: https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol.

[17] United Kingdom Food Standards Agency, Food Standards Agency sets deadline for the CBD industry and provides safety advice to consumers (May 2022), available at: https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers.

*Taken together, these toxicity studies covering a range of CBD-containing ingredients, combined with the safety data in humans reflected in clinical trials, observational studies, and the compelling testimony from Dr. Henderson, provide ample evidence that CBD can be safely consumed at the serving sizes found in most CBD dietary supplements and foods sold at retail, i.e., lower milligram dosage CBD products not intended for use as drugs, and regulated under the existing regulatory frameworks for dietary supplements and food.*

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

    *Although existing data provide sufficient evidence to establish safe usage levels of CBD, we support continued research on the safety of CBD at the federal level. We also understand safety data on other cannabinoids is ongoing, and we fully support continued research in this area. While our responses have focused primarily on CBD, as noted by Dr. Henderson in her testimony, the safety of other hemp-derived products can be evaluated using the same approaches already in place for other dietary ingredients, i.e., under existing frameworks.*

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

    *We do not support a new framework for ingestible or topical CBD products classified as food, dietary supplements, or cosmetics. The federal framework we support currently exists within the FD&C Act and already effectively balances consumer safety with consumer access. Rather than criminalize or prohibit any products, utilizing the existing framework would make all hemp cannabinoid products accessible to consumers through appropriate channels. FDA would regulate non-intoxicating hemp products and apply the same robust manufacturing, labeling, and safety standards applicable to food, dietary supplements, and cosmetics. Products that may be impairing would be strictly regulated in an adult-only framework by a separate agency such as TTB. This approach helps ensure consumers have access to safe, quality products while also keeping potentially impairing products out of the hands of children.*

14. Some stakeholders have raised concerns that CBD products have inherent risks. What are those inherent risks, and at what levels of CBD do those risks present themselves? What data and other evidence support the existence of such risks, and from which products are such data and evidence derived?

    *Please see response to Question 11.*

    *In addition, we are aware that CBD can present risks (e.g., liver and reproductive toxicity) at higher amounts such as those indicated to treat serious disease, e.g., the drug Epidiolex® is an FDA-approved prescription medication containing high dosages of purified CBD intended to treat certain seizure disorders. However, as noted in our response above, recommended levels for safe use can be derived based on the available data, and these levels are much lower than the high dosages indicated to treat disease. The typical dosage of Epidiolex® can range from several hundred milligrams to over 1500 milligrams. By contrast the typical serving size of most CBD foods and supplements sold at retail is 25-100 milligrams, and a range of data clearly demonstrate these lower levels present a different risk profile.*

15. FDA approved Epidiolex, a drug containing CBD, based in part on a data package that included preclinical data from rodent safety models, as well as clinical trials. FDA has received safety data on CBD products from several manufacturers also based on rodent models. How should FDA consider data

submitted for a CBD-containing drug as evidence to support that CBD is safe for human consumption in non-drug products, recognizing the inherent differences in the intended uses of such products?

*As noted by Dr. Henderson, in her testimony, the data package for Epidiolex® is the most comprehensive available and provides "important information that can be incorporated into an assessment of CBD consumer safety." We agree this data is relevant to the extent it indicates that the risk of adverse events (e.g., liver toxicity) increases as the dosage of CBD increases, which is consistent with other safety and toxicological data on CBD. Dr. Henderson also notes that "human clinical trials conducted with CBD for other indications are available in the public domain; while most involve patients of various disease states, more recent studies also include healthy populations." As discussed in detail in our response to Question 11, there is a growing body of scientific evidence demonstrating the safety of CBD at lower milligram amounts, such as the amounts typically found in CBD food and dietary supplement products sold at retail. Thus, the entire range of data on CBD – preclinical data from rodent safety models and other toxicological data, human clinical trials, observational data, and adverse event reports – should be considered in its entirety, as well as the intended use and target population of a given product. However, we believe the data on CBD supports its safety at lower amounts is more relevant than the data on drug-level dosages of CBD.*

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

*We are open to the possibility of reasonable, science-based limits on CBD per serving in foods and dietary supplements. We do not believe limits are warranted for CBD in cosmetics. We take no position on CBD limits for tobacco products. Limits for ingestible hemp cannabinoids used in food or dietary supplements can be established using the available body of evidence and, under current authorities, each manufacturer of a hemp cannabinoid ingredient would be required to demonstrate safety in accordance with the requirements of the FD&C Act and its implementing regulations.*

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?

*As the regulatory agency with the appropriate scientific expertise, we believe FDA is in the best position to set such limits via standard notice-and-comment rulemaking. We are also not aware of any precedent for Congress setting limits for a specific food or dietary ingredient via legislation. We recognize rulemaking could take considerable time, and therefore we would be open to a reasonable interim (i.e., temporary) limit set via legislation, or through a policy of enforcement discretion issued by FDA. However, setting a serving size or daily limit for CBD is not necessary given the existing frameworks for food and dietary supplements. The ingredient safety standards and requirements for dietary supplements and food under the FD&C Act and FDA regulations (e.g., NDI and adulteration provision for supplements, GRAS and food additive requirements for food) contemplate serving size limits based on the intended use of the product and target population. For example, the FD&C Act provides that a dietary supplement is adulterated if the product or its ingredients present "a significant or unreasonable risk of illness or injury under…conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."[18] Thus,*

[18] 21 U.S.C. § 342(f).

*dietary supplements that contain levels of CBD that pose a significant safety risk are deemed adulterated and are already prohibited under the current regulatory framework.*

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

*Stakeholder input should be sought for the development of regulatory standards and for any refinements made to the regulatory framework in the future, i.e., any permanent limits, if necessary, should be established through standard notice-and-comment rulemaking procedures. Moreover, scientific data and empirical evidence should drive the regulatory standards.*

*From our review of the studies outlined in our answer to Question 11, we believe that the limits could be higher than the standard products found in the marketplace that range from 25 to 100 mg/serving. In fact, published data from clinical studies supports a higher dose of 150 to 160 mg/serving from a safety and efficacy perspective.*

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

*If limits are deemed necessary, we suggest a maximum amount of CBD per serving. New York provides an example with 25 mg of CBD/serving in food and beverages, and 100 mg of CBD per serving in supplement products like tinctures and caplets.*

*We do not believe package limits are warranted and oppose the efforts of some states that have mandated package limits. Hemp and CBD products are often packaged to provide a 30-, 60-, or 90-day supply of the product, and include instructions for use that direct users not to consume more than the recommended serving per day. We are also not aware that consumers are misusing these products by consuming the entire package at once. State package limits have forced a significant number of companies to reformulate and repackage products in order to achieve compliance. Not only does this come at a great expense for these companies, but consumers are also forced to purchase multiple products at once, and the additional packaging will create unnecessary waste and negative environmental impact. And, as demonstrated in our response to Question 11, there is ample and growing evidence supporting the safety of CBD.*

*FDA has previously addressed a situation where it opted for serving limits, rather than package limits, for dietary supplements containing highly concentrated caffeine in a form that prevented reasonable consumers from measuring a single serving. In response to this issue, in 2018 FDA published a guidance document, "Highly Concentrated Caffeine in Dietary Supplements: Guidance for Industry."[19] The Guidance was drafted in a manner to give consumers access to a product that was safe and effective below the set serving limit but could present serious risk for injury if an amount above the Agency's serving limit is consumed. The Agency recognized that consumers should be allowed to make a reasonable choice about their health and wellness without creating unnecessary regulations pertaining to packing limits. Although CBD products clearly do not pose the same safety risks as pure powdered caffeine, if serving size guidance is deemed necessary, we suggest that the Agency be directed to follow a similar process for hemp cannabinoid products and not impose package limits.*

[19] FDA, Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements (Apr. 2018), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-highly-concentrated-caffeine-dietary-supplements.

d. Could FDA set such limits under its current statutory regulatory authorities for foods and dietary supplements to potentially address safety concerns, notwithstanding exclusionary clause issues?

*FDA's current authorities under the FD&C Act provide the Agency with the tools to effectively regulate hemp cannabinoid products, including abundant consumer safeguards. For example, the law precludes manufacturers and distributors of dietary supplements, food, and cosmetics from selling mislabeled or adulterated products. Both food and dietary supplement manufacturers must comply with cGMPs, as well as application provisions of the Food Safety Modernization Act. Soon, cosmetics will also be subject to mandatory cGMPs, product listing, and other requirements due to the passage of MoCRA. Reporting of serious adverse events and adverse event recordkeeping is also required for dietary supplements, and detailed labeling requirements are applicable to all products categories. FDA also has authority to require warnings against the use of products by children or other vulnerable populations, and currently many CBD companies already include such warnings on their product labels. Finally, the FDA with the Consumer Product Safety Commission could require child-proof packaging via regulation, as is already the case for certain iron-containing dietary supplements.*[20]

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

*Few states have set limits for hemp-derived cannabinoids. For example, currently, New York imposes a limit of 3,000 milligrams of total cannabinoids per package for orally consumed products, with no more than 100 milligrams of total cannabinoids per individual serving (exclusive of THC).*[21] *In general, state requirements for CBD products vary widely, and as noted in our response to Question 10 above, the current patchwork of state requirements has left both consumers and industry confused and uniform requirements are needed to help ensure consumer health, safety, and transparency in labeling, including, if deemed necessary, a federal limit on the amount of CBD in dietary supplements and foods.*

17. How should a regulatory framework account for CBD products marketed in combination with other substances that may alter or enhance the effects of CBD (e.g., caffeine, melatonin, etc.)?

*The existing frameworks for food, dietary supplements, and cosmetics already account for the safety of combination products through the applicable adulteration provisions under the FD&C Act. Thus, CBD products should not be subject to additional regulatory requirements concerning combination products.*

18. What precedent is there for FDA restricting certain otherwise allowable ingredients in legally marketed products? What amount and type of evidence has been required/demonstrated to support any such restrictions?

*See our response to 16 (c) above. This precedent was set when ingredients presenting serious risk of illness and injury after their consumption were linked to several consumer deaths in 2018. Hemp cannabinoid products do not present a risk for serious illness or injury when formulated and marketed responsibly, as we have outlined in this document.*

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[20] 21 C.F.R. § 101.17, available at: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.17.
[21] N.Y. Comp. Codes R. & Regs. tit. 9 § 114, available at: https://cannabis.ny.gov/system/files/documents/2021/11/part_114_cannabinoid_hemp_regulation_11-10-21.pdf.

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

*As described above, existing frameworks for food, dietary supplements, and cosmetics already address adulterated products, including combination products. For example, the FD&C Act provides that a dietary supplement is adulterated if the product or its ingredients present "a significant or unreasonable risk of illness or injury under…conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use."*[22]

Quality

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

*Congress does not need to create a new manufacturing framework for dietary supplements, food, or cosmetics, as the existing cGMPs for dietary supplements and food and future cGMPs to be developed by FDA for cosmetics will provide appropriate consumer safety standards and quality controls. We also recommend preempting state requirements in favor of a uniform, national framework.*

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

*A new framework is unnecessary given cGMPs for food and dietary supplements are already in place. We support several pieces of legislation in the House and Senate that would require compliance with the entire existing comprehensive regulatory frameworks for dietary supplements and food and would ensure that hemp cannabinoid products are safe, properly labeled, and produced under Good Manufacturing Practices. These bills include H.R. 1628, H.R. 1629, and S. 2451 and are also supported by many other hemp organizations. See* ***Appendix C.*** *Once MoCRA is implemented, cGMPs will also apply to cosmetics and can easily incorporate CBD-containing cosmetics.*

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

*Yes, the cGMP frameworks for food and supplements cover a range of mandatory compliance areas including appropriate personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the manufacturing process. We anticipate that the cGMPs for cosmetics, once established, will cover similar areas. In addition, federal law already precludes manufacturers and distributors from selling mislabeled or adulterated products, including products that fail to comply with cGMP requirements for food and supplements.*

*Existing frameworks also provide for FDA facility inspections to ensure compliance with cGMPs and prevent adulterated products from entering the marketplace, and to issue Warning Letters*

[22] 21 U.S.C. § 342(f).

*in cases of non-compliance. Where there are instances of repeated violations, FDA can seek an injunction, which the Agency has done on several occasions.*[23]

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?

*We believe that industry self-regulation can complement federal and state regulation. More than 50 hemp/CBD companies have achieved certification through the U.S. Hemp Authority (USHA) since it was established in 2018, and other companies have used other reputable certifying bodies to audit and certify cGMP for food and dietary supplements under ANSI standards. USHA is the hemp industry's initiative to provide high standards, best practices and self-regulation, giving consumers and retailers confidence in hemp and CBD products. USHA creates and upholds stringent regulatory standards, developed by a diverse collaboration of industry leaders, through independent third-party auditing, certifying hemp and CBD growers and products. In 2019, USHA was recognized by Prevention magazine, a leading provider of trustworthy health information for over six decades, with more than two million readers, for one of its 2019 Health Breakthrough Awards, billed as ten major medical innovations of the past year. USHA would be pleased to work with Congress and FDA to supplement government oversight with industry self-regulation.*

*In 2019, NSF began certifying CBD and hemp products. NSF certifies products to NSF/ANSI 173 (Dietary Supplements Contents Certified), NSF 229 (Functional Foods), NSF 306 (NSF Certified for Sport®), and NSF 527 (Personal Care Contents Certified).*[24] *NSF's certification program helps ensure products do not contain unacceptable levels of contaminants, including those specific to hemp, like THC and certain solvents, and verifies the validity of label claims. Finished products seeking NSF Certified for Sport® certification must meet the additional strict THC requirements of NSF 306 in addition to the over 280 banned substances banned by professional sports leagues and anti-doping organizations. In addition, NSF GMP certification (for dietary supplement, functional foods or cosmetic and personal care manufacturers or packers) or registration (for dietary ingredient manufacturing) provides consumers and retailers, as well as regulators, with assurance that products produced are consistent with GMPs, appropriate quality-control procedures and industry best practices.*

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.

*Our proposal would incorporate CBD into the existing frameworks for foods, dietary supplements, and cosmetics. In particular, CBD-containing dietary supplements should be permitted to make structure/function claims in accordance with 21 C.F.R. § 101.93. We do not believe claims should be*

[23] *See*, e.g., Federal judge enters permanent injunction against New York-based dietary supplement manufacturer (Mar. 2021), available at: https://www.fda.gov/news-events/press-announcements/federal-judge-enters-permanent-injunction-against-new-york-based-dietary-supplement-manufacturer; Federal judge enters consent decree against Tennessee drug, dietary supplement and device distributors, Basic Reset and Biogenyx, for drug, device and dietary supplement violations (Sept. 2019), available at: https://www.fda.gov/news-events/press-announcements/federal-judge-enters-consent-decree-against-tennessee-drug-dietary-supplement-and-device.

[24] NSF, CBD and Hemp Product Certification, available at: https://www.nsf.org/health/dietary-nutrition-supplements-personal-care-products/nutritional-supplements-cosmetics-personal-care-products/hemp-and-hemp-derived-cbd-product-certification.

*restricted or limited because a product contains CBD. Further, the FD&C Act and laws enforced by the Federal Trade Commission prohibit the labeling and marketing of products with unlawful claims and untruthful, misleading claims.*

*However, we note that labeling is perhaps the most urgent area to require federal preemption of state laws. Manufacturers currently are forced to navigate a scattered and conflicting patchwork of state labeling laws which impose unnecessary costs and burdens. A strong, preemptive federal standard would be embraced by the industry.*

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?

*There is no evidence or reasonable need for any special symbol or other marking on a non-intoxicating hemp cannabinoid product. We are aware of a handful of states that require a symbol or marking on certain hemp cannabinoid products. They are in the large minority. We are also not aware of any evidence regarding the efficacy or potential benefits of requiring such a symbol or marking. We support the certification seal provided by the U.S. Hemp Authority, a self-regulatory organization established in the absence of FDA regulatory action.*

24. What are the potential benefits or drawbacks of an additional or substitute standardized label panel for CBD products, compared to the current Nutrition Facts Label and Supplements Label?

*We find this unnecessary. The existing labeling regimes for food and dietary supplements are sufficient, and consumers are already familiar with the current Nutrition and Supplement Facts formats.*

25. What precedent exists in foods, dietary supplements, tobacco, and cosmetics for requirements of labeling to present risks to special populations in labeling (e.g., children, pregnant and lactating women, consumers taking certain drugs, etc.)? What amount and type of evidence has been required to support such requirements?

*As discussed above, the FD&C Act prohibits the distribution of adulterated food, dietary supplements, and cosmetics, and products are considered misbranded if their labeling is "false or misleading in any particular" – which is a broad prohibition that covers labeling that omits warnings that are necessary to ensure safe use, including by vulnerable populations.[25] In addition, responsible companies are already utilizing several of the tools FDA has referred to as necessary for the regulation of CBD and other cannabinoid products, either on a voluntary basis or to comply with state mandates. For example, many of our members have taken the following steps:*

- *Restricting sales of CBD and other cannabinoids products to consumers 18 and older;*
- *Restricting sales of THC-containing products to consumers 21 and older;*
- *Use of child-resistant and tamper-evident packaging on products containing THC;*
- *Clear and consistent labeling with marketed cannabinoids and THC milligrams disclosed;*

[25] 21 U.S.C. § 343 (Misbranded food including dietary supplements); 21 U.S.C. § 362 (Misbranded cosmetics).

- *Including QR codes or similar scannable codes on labels that provide access to a product's Certificate of Analysis (COA) that includes the levels of cannabinoids and THC, as well as levels of pesticides, residual solvents, microbials, mycotoxins, and heavy metals;*

- *Use of product warnings, e.g., advising consumers who have a medical condition or are pregnant, nursing, under 18, or taking medication not to consume the product or to consult a healthcare practitioner prior to use, and for products containing THC, that consumption of the product may lead to a positive drug test.*

*Ensuring product packaging, labeling, and marketing is not attractive to children, and that products are not marketed for their impairing or intoxicating effects. With respect to precedent, FDA currently requires the following warning statement (and as noted above, child-resistant packaging) for certain iron-containing dietary supplements:*

> *WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.*[26]

*In addition, the following warning is required for certain protein products:*

> *WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women.*[27]

*And the following warning is required for juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens:*

> *WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.*[28]

*For cosmetics packaged in a self-pressurized container and intended to be expelled from the package under pressure, the following warning is required:*

> *Warning—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.*[29]

*And for foaming detergent bath products, the following warning is required:*

> *Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.*[30]

*In addition, in the case of a cosmetic for which adequate substantiation of safety has not been obtained, the product is considered misbranded unless it contains the following conspicuous statement on the principal display panel:*

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[26] 21 C.F. R. § 101.17(e).
[27] *Id* at § 101.17(d).
[28] *Id* at § 101.17(g).
[29] 21 C.F.R. § 740.11
[30] 21 C.F. F § 740.17.

*Warning—The safety of this product has not been determined.*[31]

*The regulations also prescribe the format and placement of the warnings, e.g., requiring a warning to appear prominently and conspicuously on the principal display panel of the package label and any other labeling. Thus, it is abundantly clear that FDA has ample authority under existing frameworks to require warnings for vulnerable populations where necessary, and a new framework is not required.*

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?

    *Standard testing available from ISO 17025 certified labs across the United States provide adequate testing to determine if there is any THC contained in a hemp cannabinoid product. There is no basis for claiming the amount of THC in any hemp cannabinoid product cannot be determined. We are not aware of any precedent for a labeling requirement regarding "potential THC content" and would oppose such a requirement due to its likelihood to cause confusion.*

27. How should access to CBD products by children be regulated? For example, would it be appropriate to have an age restriction on the purchase of CBD products? If so, what is an appropriate age limit?

    *We support requiring child-resistant packaging by adding cannabinoids derived from Cannabis sativa L. to the list of substances requiring special packaging.*[32] *We also support restrictions on product formats that resemble candy or snacks; labeling depicting characters, animals, vehicles, or fruit; and products in the shape of characters, animals, vehicles, or fruit.*

    *However, we oppose prohibitions such as a ban on the use of bright colors for products and packaging, as this would unnecessarily limit the formulation of flavored, non-intoxicating products. Importantly, gummies—which are a standard, safe, and widely used product format within the dietary supplement industry—should not be prohibited. Other measures such as child-resistant packaging, provide an effective way to reduce accidental consumption.*

    *As discussed above in our responses to Questions 5 (a) and 13, for impairing products, under our proposed TTB framework these products would be restricted to consumers 21 and older.*

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.

    *Please see our response to Question 27.*

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?

    *We are not aware of a precedent for this proposal. Packages where serving may not easily be determined, such as tinctures, should include an indicator or measuring device to help accurately determine a single serving size. For other ingestible products (e.g., gummies, capsules, etc.) packaging changes are not warranted. Further, as noted above, existing law already prohibits the distribution of adulterated food and dietary supplements, including dietary supplements that present a significant or*

[31] 21 C.F.R.§ 740.10
[32] 16 C.F.R. § 1700.14.

*unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, and prohibits the distribution of products with misleading labeling.*

*However, we believe that the use of scorelines on an individual gummy to indicate multiple servings, for example, may increase the risk of overconsumption and should not be permitted*.

**Recommended Upper Limit THC Levels:**
**Hemp-Based Extract Products**

## INTRODUCTION

The hemp industry has experienced significant growth in recent years, driven by the increasing popularity of orally ingestible hemp-based products. However, with this growth comes the need for robust regulations to ensure consumer safety and protect public health. This white paper addresses the specific issue of impairment caused by ingestion of hemp-based cannabinoids, and specifically Tetrahydrocannabinol or THC, the main cannabinoid associated with impairment. There are several identified isomers of THC found in the hemp plant, with Delta 9 Tetrahydrocannabinol (Delta 9 THC) and Delta 8 Tetrahydrocannabinol (Delta 8 THC) being the most well-known. This paper will generically refer to THC throughout to refer to all *naturally occurring* isomers and variants of THC collectively.

Orally ingestible products containing a full suite of hemp-based cannabinoids, including THC, have been demonstrated to promote health and wellness. As discussed below, when an average healthy adult orally ingests THC in small servings below 5 mg, the THC does not exhibit a significant risk of impairment. Dietary supplements have a long history of providing consumers with nonpharmaceutical options to address health and wellness. There is a place for cannabinoid products in human health and wellness if they promote endpoints relevant to the structure or function of the body. Impairment does not promote health or wellness and is mentioned in the preamble of the applicable regulations as being a disease endpoint. Therefore, it is imperative any regulation of hemp-based dietary supplement products apply a sensible upper limit for THC/serving that allows consumers access to safe and efficacious health and wellness products containing THC while at the same time protecting public health and welfare.[1]

By establishing a clear and evidence-based upper THC limit, lawmakers can strike a balance between providing safe and efficacious dietary supplement products and safeguarding public health. Advocating for the implementation of an upper serving limit of 5 mg of orally ingested THC is analogous to the .5% Alcohol by Volume limit on food products before they are classified as alcohol and considered adulterated food. Due to the inherent differences between foods and dietary supplements, namely the significantly smaller serving sizes for dietary supplements, we recommend a discrete upper limit cap rather than a percentage by weight or volume.

## THC: A NATURAL COMPONENT OF HEMP

THC is a naturally occurring component of hemp and the most well-known cannabinoid present in the plant. It is responsible for the psychoactive effects or “high” commonly associated with marijuana use. THC binds to cannabinoid receptors in the brain and central nervous system, leading to alterations in perception, mood,

[1] The upper limit described herein is intended to apply to healthy adults who are not pregnant or nursing.

and cognition. The potency of THC can vary across different plant varieties and products, highlighting the importance of regulating its consumption with a discrete upper limit per serving to ensure consistent and predictable effects across all products.

THC is found in a variety of product formats in the market, including smokable, orally ingestible, and topically applied. Each form has its own onset time, duration of effects, and potential benefit and risks associated with consumption. Understanding the characteristics and variability of THC across different sources and forms is crucial for establishing appropriate safety limits that address potential health concerns while still allowing for the responsible use of hemp-based products.

Research has shown THC can have a range of effects on the body and mind depending on the amount orally ingested. Low doses of orally ingested THC are often associated with relaxation, mood regulation, improved sleep, and pain relief, which can be beneficial for overall health and wellness. However, higher doses of orally ingested THC can lead to increased likelihood of psychoactive effects, impaired cognitive function, and a heightened risk of adverse reactions.

The potential for negative effects, particularly at higher dosages, underscores the importance of establishing a safety limit to protect consumers from potential harm. This white paper will focus on the orally ingestible formats which would be classified as dietary supplements, including but not limited to gummies, soft gels, capsules, and tinctures. All following discussions and references will be in reference to orally ingestible formats.

## EXISTING RESEARCH ON THC SAFETY LIMITS

A comprehensive review of multiple scientific studies provides evidence in support of instituting an upper limit of 5 mg of THC per serving in an orally ingested product as the threshold limit to prevent impairment. These studies encompass diverse methodologies, including randomized controlled trials, observational studies, and meta-analyses, and have been conducted by reputable researchers and institutions. The findings indicate a 5 mg upper THC limit on an orally ingestible product strikes the proper balance between allowing for the potential therapeutic benefits of THC and minimizing the risk of adverse effects.

The selected studies have examined a wide range of health considerations related to THC ingestion. They have investigated the short-term cognitive impairments which can occur with higher THC doses, including impaired memory, attention, and decision-making abilities. Furthermore, these studies have explored the psychiatric effects of THC, such as increased anxiety and psychosis-like symptoms, particularly among individuals with a predisposition to mental health disorders. The collective evidence from these studies strongly supports the need for an upper limit at 5 mg per serving to mitigate potential health risks associated with excessive THC consumption.

## THC LIMITS AND IMPAIRMENT

To ensure a science-based approach was utilized to determine the proper reasonable upper limit for THC in hemp products, particularly considering the potential for impairment, the authors reviewed the literature for information pertaining to law enforcement and clinical research on levels of THC consumption and serum data to confirm impairment. The first step was to examine pharmacokinetics of oral ingestion of THC to understand what doses of orally ingested THC would equate to when serum levels were quantified.

Oral testing for cannabinoids offers an advantage over urine as presence of THC in oral fluid is indicative of recent cannabis use[2]. This is important when considering the effects of THC on performance as described above. Oral administration of a brownie laced with 25 mg of Delta 9 THC resulted in peak oral concentration of THC at 3.4 to 4.8 ng/mL within the first hour after consumption[2]. A separate study explored serum measures of THC following consumption of brownies laced with 10, 25 or 50 mg of Delta 9 THC. The peak concentration measured for each dose were 1.0, 3.5 and 3.3 ng/mL[3,4]. Another group found that oral doses of 8.4 and 16.9 mg Delta 9 THC in brownies resulted in peak serum concentrations of THC at 5 and 9 ng/mL THC[5]. Studies have shown that there is an initial and significant shift toward impairment when THC was measured in serum concentrations between 2 and 5 ng/ml. When concentrations are measured between 5 and 10 ng/ml, 75-90% of participants demonstrated symptoms of impairment in every performance test. Serum concentrations greater than 30 ng/ml demonstrated unequivocally that participants were 100% impaired on every performance test.[6]

Based on review of the literature, particularly data pertaining to the level of orally ingested THC that would lead to impairment for most consumers, an upper limit of 5 mg THC/serving is recommended. The information discussed above indicates limiting oral ingestion to 5 mg THC/serving or less would yield serum or oral THC levels lower than those indicated as causing impairment. Many states have passed legislation around serum limits for THC with a per se 5 ng/ml threshold which correlates with the recommended serving limit of THC at 5 mg/serving to remain below that per se impairment threshold. Therefore, in summary, the clinical data and state legislation around THC serum levels support a federal standard that delineates a per serving limit for THC at 5 mg.

**HEALTH CONSIDERATIONS**

Chronic excessive THC consumption has been associated with a range of adverse health effects, emphasizing the importance of establishing an upper limit per serving. Psychiatric effects are another crucial aspect to consider. Certain individuals may experience increased anxiety, paranoia, or psychosis-like symptoms with higher THC doses. Vulnerable populations, such as adolescents and individuals with a history of mental health disorders, may be more susceptible to these effects. By implementing an upper limit of 5 mg THC per serving, lawmakers can prioritize the mental well-being of individuals and mitigate potential risks associated with excessive THC consumption.

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[2] Niedbala, R. S., Kardos, K. W., Fritch, D. F., Kardos, S., Fries, T., Waga, J., … Cone, E. J. (2001). *Detection of Marijuana Use by Oral Fluid and Urine Analysis Following Single-Dose Administration of Smoked and Oral Marijuana. Journal of Analytical Toxicology, 25(5), 289–303.* doi:10.1093/jat/25.5.289

[3] Vandrey R, Herrmann ES, Mitchell JM, Bigelow GE, Flegel R, LoDico C, Cone EJ. Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes. J Anal Toxicol. 2017 Mar 1;41(2):83-99. doi: 10.1093/jat/bkx012. PMID: 28158482; PMCID: PMC5890870.

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Long-term health considerations also warrant attention. Chronic, heavy THC use has been linked to an increased risk of cannabis dependence and addiction. By setting an upper limit, lawmakers can promote responsible use and minimize the likelihood of individuals developing problematic patterns of THC consumption. This is particularly relevant in regions where cannabis is legal for both recreational and medicinal purposes, as clear regulations help protect public health and reduce potential burdens on healthcare and law enforcement systems.

Establishing an upper limit of 5 mg of THC per serving accounts for various health considerations associated with THC consumption. By mitigating short-term cognitive impairments, psychiatric effects, and long-term risks of cannabis dependence, such a limit can promote public health and ensure responsible use of THC-containing products for health and wellness purposes. By combining scientific evidence and law enforcement limits which prioritize consumer safety, lawmakers can strike a balance that allows individuals to access the potential benefits of THC while minimizing the potential for impairment.

**PUBLIC SAFETY AND RESPONSIBLE USE**

One crucial aspect of THC regulation in dietary supplements is ensuring public safety, particularly in relation to activities such as driving. Research consistently demonstrates THC impairs psychomotor skills, reaction time, and coordination. Implementing an upper per serving limit for THC helps establish clear guidelines and label warnings for individuals regarding safe timeframes between THC consumption and engaging in activities that require alertness, such as driving. By promoting responsible use through proper labelling with adequate warnings and educating consumers about the potential impairment effects of THC, lawmakers can minimize the risks to public safety.

Preventing unintentional overconsumption is a key component of responsible use. Without a sensible upper per serving THC limit establishing a national standard, accurate dosing of hemp products is challenging, leading to unintentional ingestion of higher THC levels than intended. By implementing an upper limit for THC per serving, lawmakers can encourage product manufacturers to provide accurate and standardized labeling, enabling consumers to make informed decisions about their consumption. This approach helps protect individuals from unintended overconsumption, reduces the likelihood of adverse effects, and promotes responsible use of hemp products.

A per serving, upper limit for THC not only addresses public safety concerns related to impaired driving but also fosters responsible use by preventing unintentional overconsumption. By providing clear guidelines for consumers, product manufacturers, and retailers, lawmakers can contribute to the overall well-being of individuals and society. Establishing a balance between access to THC-based dietary supplement products and public safety is paramount, and a 5 mg per serving upper limit aligns with these goals while allowing for responsible use and informed decision-making.

**CONSIDERATIONS FOR REGULATING THC LEVELS**

When establishing THC limits for orally ingested hemp products, lawmakers must consider various factors to develop effective and feasible regulations. One crucial consideration is consumer demand and market dynamics. Understanding the preferences and patterns of hemp-based cannabinoid consumption among consumers is essential to ensure that regulations align with market realities. By engaging with industry stakeholders, lawmakers can gauge consumer expectations and tailor THC limits that strike a balance between meeting consumer needs and safeguarding public health.

Feasibility and enforceability are also vital aspects to address. Lawmakers should assess the practicality of implementing regulations around THC limits and the resources required for enforcement. Considerations include testing capabilities, labeling requirements, and monitoring compliance, all of which are currently authorized under the Dietary Supplement Health and Education Act and conducted by the FDA's Office of Dietary Supplement Programs, ensuring that the proposed limits can be effectively enforced and monitored.

The authors encourage lawmakers to take the guidance outlined in this white paper and further engage with a diverse range of stakeholders, including industry representatives, healthcare professionals, law enforcement and advocacy groups to consider different viewpoints and ensure the ultimate federally regulated per serving THC limit is informed by a broad range of expertise and science-based evidence. By incorporating stakeholder input, lawmakers can enhance the transparency, fairness, and legitimacy of the regulatory framework, fostering public trust and acceptance.

When regulating THC levels in products, lawmakers should consider consumer demand, market dynamics, feasibility, enforceability, and stakeholder perspectives. By taking a comprehensive approach that balances consumer needs, public health objectives, law enforcement/public safety concerns and practical implementation, policymakers can develop regulations that effectively manage THC consumption, promote responsible use, and protect public safety.

## CONCLUSION AND POLICY RECOMMENDATIONS

In conclusion, the evidence presented in this white paper supports the implementation of a limit of 5 mg per serving of THC in all hemp-based products. The reviewed studies demonstrate a 5 mg per serving size limit on orally ingested THC is non-impairing. Review of scientific literature on levels of THC/serving and serum or oral THC measures that were associated with impairment also supports a 5 mg per serving limit on orally ingested THC as non-impairing. By establishing a reasonable hemp-based THC limit for orally ingested products, lawmakers can prioritize consumer well-being, public safety, and responsible use of hemp-based products.

Based on the findings and analysis, the following policy recommendations are proposed:

- Establish a statutory THC safety limit of 5 mg per serving for all THC-containing hemp products.
- Utilize the mechanism of the Farm Bill to establish a safe and reasonable federal standard for THC limits in orally ingestion hemp-based agricultural products without over-reaching into the mandates and authorities of the FDA. This would not legalize any hemp-based products without the input and oversight of the FDA, but it would address the proliferating conflicts in state laws authorizing the manufacture and sale of hemp-based cannabinoid products as foods, dietary supplements and food additives.
- Develop comprehensive education and awareness campaigns to inform the public about the potential health risks associated with excessive THC ingestion and the importance of adhering to the suggested serving size. These campaigns should focus on promoting responsible use, clear serving size guidelines, and the implications of impaired driving.
- Implement robust regulatory frameworks to enforce hemp-based THC limits, ensuring accurate product labeling, standardized testing protocols, and strict compliance measures. Collaboration with industry stakeholders, regulatory agencies, and law enforcement authorities is crucial to ensure effective enforcement and monitoring of THC levels in products.

By adopting these policy recommendations, lawmakers can strike a balance between facilitating access to the potential health benefits of hemp-based THC while protecting public health and promoting responsible use. Implementing a 5 mg per serving size and per day THC safety limit is a proactive step toward ensuring consumer safety, mitigating health risks, and establishing a transparent and accountable hemp-based CBD and THC industry.

**REFERENCES – REVIEWED STUDIES**

The reviewed studies provide substantial evidence to support the establishment of a per serving limit of 5 mg of THC. Studies have shown that doses as low as 2.5 to 3 mg of THC can provide therapeutic benefits without significant psychoactivity. Clinical trials involving various populations, such as individuals with PTSD, multiple sclerosis, anorexia, dementia, and cancer, have demonstrated the safety and efficacy of THC at doses ranging from 1.5 to 10 mg per day. These trials reported minimal adverse effects, with some studies highlighting the well-tolerated nature of THC even at higher doses.

Furthermore, research on driving impairment has shown that THC has a different impact compared to alcohol. THC-positive drivers are not necessarily impaired or meaningfully impaired, challenging the current approach of stand-alone cannabis-presence driving offenses. Studies comparing the effects of alcohol and cannabis on driving performance have consistently shown that alcohol has a more detrimental effect.

Overall, the evidence supports a 5 mg per serving size THC limit and strikes a balance between enabling therapeutic benefits and minimizing the risk of adverse effects. It aligns with the findings of numerous studies, clinical trials, and governmental guidelines, emphasizing the need to establish a clear and scientifically informed regulatory framework for THC ingestion.

**CLINICAL TRIALS**

**2022: Using brain imaging, the average THC dose to cause impairment was 35.6 ± 11.5 mg**
*Identification of Δ9-tetrahydrocannabinol (THC) impairment using functional brain imaging*
https://pubmed.ncbi.nlm.nih.gov/34999737/
"The mean THC dose for these 80 participants considered to be impaired was 35.6 ± 11.5 mg. Likewise, 57 participants had concordant ratings of not clearly impaired on the CCR and HR/self-rated high algorithm (Fig. 2A); the mean dose of THC for these 57 participants rated as not clearly impaired was 34.8 ± 16.1 mg."

**2022: In humans with PTSD, 7.5 mg THC helped with emotional processing during an emotional regulation task**
*Cannabinoid modulation of brain activation during volitional regulation of negative affect in trauma-exposed adults*
https://pubmed.ncbi.nlm.nih.gov/35981598

**2021: A case series of patients with neuropathic itch using dronabinol (pharmaceutical THC) found low levels to only cause the transient side effect of lightheadedness**
*Neuropathic itch treated with oral cannabinoids: A case series*
https://pubmed.ncbi.nlm.nih.gov/34692966/
"All 3 patients reported improvement within their initial few doses and described a dose-dependent effect. Side effects included lightheadedness, which was mild and transient and resolved with persistent use. We found that initiating therapy at low doses divided throughout the day followed by gradual increases to be helpful in increasing tolerability."

**2020: In humans, 5 milligrams of dronabinol (synthetic THC) improved optic nerve had blood flow with no psychoactive or negative effects**
*The Effect of Orally Administered Dronabinol on Optic Nerve Head Blood Flow in Healthy Subjects-A Randomized Clinical Trial*
https://pubmed.ncbi.nlm.nih.gov/31977076/

**2020: In multiple sclerosis patients, an average dose of 4 mg of THC caused no impairment**
*Safety and efficacy of low-dose medical cannabis oils in multiple sclerosis*
https://pubmed.ncbi.nlm.nih.gov/33387864/
"No impairment in disability, ambulation, dexterity or processing speed was observed."

**2019: In humans, 5 to 10 mg of THC increased food consumption & altered hormones related to appetite & digestion**
*Effect of acute Δ9-tetrahydrocannabinol administration on subjective and metabolic hormone responses to food stimuli and food intake in healthy humans: a randomized, placebo-controlled study*
https://pubmed.ncbi.nlm.nih.gov/30949710/
"Dronabinol capsules containing 2.5 mg of Δ9-THC were orally administered to the participants, depending on their body weight (0.1 mg/kg, titrated to the nearest 2.5 mg, with a minimum of 5 mg and maximum of 10 mg). This dose was chosen based on previous research demonstrating that a single dose of 10 mg is well-tolerated and does not induce any nausea or vomiting"

**2019: In humans with PTSD, 5 mg of dronabinol (pharmaceutical THC) caused no serious adverse effects & a similar level of nonserious adverse effects to the placebo**
*Effects of Delta-9 Tetrahydrocannabinol (THC) on Retention of Memory for Fear Extinction Learning in PTSD: R61 Study*
https://clinicaltrials.gov/study/NCT03008005

**2018: In healthy humans, 10 mg of THC caused no changes to the brain's fronto-striatal resting-state connectivity while CBD increased it**
*Probing the endocannabinoid system in healthy volunteers: Cannabidiol alters fronto-striatal resting-state connectivity*
https://pubmed.ncbi.nlm.nih.gov/29887287/

**2018: In a test of THC on ocular dynamics, 5 mg of THC caused no serious adverse events & only one non-serious adverse event (skin rash)**
*The effect of Tetrahydrocannabinol on ocular hemodynamics in healthy subjects*
https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-004852-52/results

**2017: In humans with chest pain, 10 mg of dronabinol (pharmaceutical THC) increased pain thresholds & caused no significant adverse events**
*Dronabinol increases pain threshold in patients with functional chest pain: a pilot double-blind placebo-controlled trial*
https://pubmed.ncbi.nlm.nih.gov/26822791/

**2017: A study of the pharmacokinetics of THC in heathy humans finds a single dose of 5 mg to be well-tolerated**
*Effect of food on the pharmacokinetics of dronabinol oral solution versus dronabinol capsules in healthy volunteers*
https://pubmed.ncbi.nlm.nih.gov/28138268/

**2017: In humans with dementia, 3 mg of THC per day had "a benign adverse event profile regarding mobility and was well tolerated by community-dwelling dementia patients"**
*Effects of tetrahydrocannabinol on balance and gait in patients with dementia: A randomised controlled crossover trial*
https://www.ncbi.nlm.nih.gov/pubmed/27624148

**2017: In healthy humans given 10 mg of THC orally, they showed no impairment & a third of them did not even test positive for cannabinoids in their blood**
*Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes*
https://pubmed.ncbi.nlm.nih.gov/28158482/
"Also, for two participants, no blood cannabinoids were detected after administration of the 10 mg THC dose…. Significant correlations were also observed between psychoactive blood cannabinoids and DSST percent correct, but these correlations were highest at the 10 mg THC dose when there was no impairment relative to baseline task performance."

**2015: In humans with anorexia, 5 mg of dronabinol (pharmaceutical THC) per day did not change their insulin levels but did help with HPA axis activity with no mention of negative side effects**
*Changes in IGF-I, urinary free cortisol and adipokines during dronabinol therapy in anorexia nervosa: Results from a randomised, controlled trial*
https://pubmed.ncbi.nlm.nih.gov/26248813/

**2015: In humans, a month of 5 mg of dronabinol (pharmaceutical THC) twice per day did not alter metabolic parameters & mentions no negative side effects**
*A 4-week pilot study with the cannabinoid receptor agonist dronabinol and its effect on metabolic parameters in a randomized trial*
https://pubmed.ncbi.nlm.nih.gov/26283236/

**2015: In surgical patients, 5 mg before the surgery was well tolerated & helped with nausea**
*Prevention of Postoperative Nausea and Vomiting (PONV) in Surgical Patients (PONV)*
https://clinicaltrials.gov/study/NCT00757822?intr=THC%205&aggFilters=status:com&page=4&rank=40&tab=results

**2015: In humans with dementia, up to 3 mg THC was safe & well tolerated but did not reduce symptoms**
*Tetrahydrocannabinol in Behavioral Disturbances in Dementia: A Crossover Randomized Controlled Trial*
https://www.ncbi.nlm.nih.gov/pubmed/26560511

**2015: In humans with dementia, 4.5 mg of THC caused a similar number of adverse events in the placebo group as the active ingredient group**
*Tetrahydrocannabinol for neuropsychiatric symptoms in dementia: A randomized controlled trial*
https://pubmed.ncbi.nlm.nih.gov/25972490/
"The number of patients experiencing mild or moderate adverse events was similar (THC, n = 16; placebo, n = 14, p = 0.36). No effects on vital signs, weight, or episodic memory were observed."

**2015: In older humans with dementia, 1.5 mg of THC for 2 months caused no significant impairment & more adverse events were reported for the placebo group than the active ingredient group**
*Safety, pharmacodynamics, and pharmacokinetics of multiple oral doses of delta-9-tetrahydrocannabinol in older persons with dementia*
https://pubmed.ncbi.nlm.nih.gov/25752889/
"All participants completed the study as scheduled. In general, THC was safe and well tolerated by these older individuals with dementia. In total, 98 adverse events were reported during the study period. More adverse events were reported with placebo (55 adverse events) than with THC (43 adverse events) (period A, 0.75 mg THC 21 adverse events and placebo 30 adverse events, P = 0.290; period B, 1.5 mg THC 22 adverse events and placebo 25 adverse events, P = 0.435).
Thirteen (13 %) of the reported adverse events were considered to be possibly (n = 12) or probably (n = 1) related to study drugs (THC and placebo). Of these, only six adverse events (6 % of total adverse events) were considered to be (possibly) related to THC, two with 0.75 mg (dizziness and fatigue in one patient each), and four with 1.5 mg (agitation in three patients and fatigue in one patient). All were mild and transitory in nature. There were no THC-related serious adverse events. THC treatment was not associated with changes in the patients' physical state, laboratory test results (hematology and clinical chemistry), or ECG parameters (e.g., QT and RR intervals)."

**2014: In older adults, 5 mg THC safe & well tolerated**
*Safety and pharmacokinetics of oral delta-9-tetrahydrocannabinol in healthy older subjects: a randomized controlled trial*
https://pubmed.ncbi.nlm.nih.gov/25035121/

**2013: In multiple sclerosis patients, 1.5 or 5 mg caused no significant deleterious effects**
*A two-phased, randomized, double blind, placebo-controlled study of ECP002A (Δ9-THC) to determine safety, tolerability and efficacy in Multiple Sclerosis patients suffering from spasticity and pain*
https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-022033-28/results

**2012: In cancer patients, those using Sativex at the 2.5 mg to 25 mg THC dosage range showed little difference in adverse effects or patient discontinuation from the placebo**
*Nabiximols for opioid-treated cancer patients with poorly-controlled chronic pain: a randomized, placebo-controlled, graded-dose trial*
https://pubmed.ncbi.nlm.nih.gov/22483680/
"There was a dose related incidence of AEs, with the high-dose group comparing unfavorably with placebo and the 2 lower dose groups showing little difference from placebo."

**2011: In 2 patients with dementia, 2.5 mg of dronabinol before bed helped with nighttime agitation & was well tolerated**
*Randomized, controlled crossover trial of dronabinol, 2.5 mg, for agitation in 2 patients with dementia*
https://pubmed.ncbi.nlm.nih.gov/21364345/

**2011: Double-blind placebo trial finds 2.5 mg THC to be a threshold dose**
*Combined effects of acute, very-low-dose ethanol and delta(9)-tetrahydrocannabinol in healthy human volunteers*
https://pubmed.ncbi.nlm.nih.gov/21110996/
"When given alone, 2.5mg THC produced modest effects on subjective ratings, measures of cognitive performance, and physiological measures. Although participants did not report feeling any drug effects, THC significantly reduced POMS 'vigor' scale scores (Table 3) and increased sedation as measured by the ARCI PCAG scale. THC altered POMS 'friendliness' scale scores (THC × Time: $F[2,9] = 4.99$; $p = 0.035$) but none of the individual time points differed significantly in post hoc tests. Additionally, THC slightly impaired performance on the DSST overall ($F[1,10] = 4.60$; $p = 0.058$), and visual inspection and a follow-up post hoc test indicated that THC significantly impaired performance on this task at 100 min (Table 3). THC also significantly reduced diastolic blood pressure overall (Table 3). No other significant effects were seen on behavioral or physiological measures."

**2010: In patients with ALS, 2.5 to 10 mg of THC did not help their cramps but it was well tolerated**
*Tetrahydrocannabinol (THC) for cramps in amyotrophic lateral sclerosis: a randomised, double-blind crossover trial*
https://pubmed.ncbi.nlm.nih.gov/20498181/
"Oral doses from 2.5 to 10 mg were well tolerated… Two serious adverse events occurred. Both patients were admitted to hospital. One patient developed pneumonia during the wash-out period (after THC period) and later died; the other developed deep venous thrombosis before the THC period. These adverse events were felt not to be study-related. None of the remaining patients withdrew from the study. One patient experienced mild dizziness while on THC (sequence 0/1). The patient continued the study with half the dosage. Otherwise, none of the patients reported any side effects."

**2009: In patients with schizophrenia, 5 to 10 mg a day of THC improved symptoms & "all subjects made the point that the medication did not feel like real marijuana and did not give them a high"**
*Synthetic delta-9-tetrahydrocannabinol (dronabinol) can improve the symptoms of schizophrenia*
https://pubmed.ncbi.nlm.nih.gov/19440079/

**2006: In humans with severe dementia, 2.5 mg dronabinol helped for agitation at night with no negative side effects (6 patients in an open-label pilot study)**
*Delta-9-tetrahydrocannabinol for nighttime agitation in severe dementia*
https://www.ncbi.nlm.nih.gov/pubmed/16521031

**2006: In patients with cancer, 2.5 mg twice daily for two weeks was well tolerated**
*Comparison of orally administered cannabis extract and delta-9-tetrahydrocannabinol in treating patients with cancer-related anorexia-cachexia syndrome: a multicenter, phase III, randomized, double-blind, placebo-controlled clinical trial from the Cannabis-In-Cachexia-Study-Group*
https://pubmed.ncbi.nlm.nih.gov/16849753/

**2003: In women who underwent a hysterectomy, 5 mg of oral THC caused no significant adverse effects compared to the placebo besides an increased awareness of surroundings**

*Lack of analgesic efficacy of oral delta-9-tetrahydrocannabinol in postoperative pain*
https://pubmed.ncbi.nlm.nih.gov/14581124/
"Increased awareness of surroundings was reported more frequently in patients receiving delta-9-THC (40 vs 5%, P=0.04). There were no other significant differences with respect to adverse events."

**1995: Patients with anorexia receiving 5 mg of dronabinol (pharmaceutical THC) per day caused no serious side effects**
*Dronabinol as a treatment for anorexia associated with weight loss in patients with AIDS*
https://pubmed.ncbi.nlm.nih.gov/7730690/
"Dronabinol was well tolerated. The majority of side effects reported were central nervous system disturbances that are commonly associated with cannabinoids. In most cases, they were not severe enough to warrant intervention. There was no significant difference between both treatment groups in the patient dropout rates due to adverse reactions. Six dronabinol versus three placebo recipients discontinued therapy due to any adverse effect thought to be possibly or probably related to treatment. These numbers are small and attest to the safety and tolerance of treatment."

## DRIVING

**2022: A deep dive into the uneven science of cannabis & impaired driving: a call for a new paradigm**
*How to read a paper on the short-term impairing effects of cannabis: A selective and critical review of the literature*
https://journals.sagepub.com/doi/pdf/10.1177/20503245221119046
"The recent use of cannabis is indicated toxicologically by the presence of delta-9-tetrahydrocannabinol (THC) in blood or oral fluid. Evidence is provided that most THC-positive drivers are not impaired, and certainly not meaningfully impaired. It follows that the justice of stand-alone cannabis-presence driving offences must be questioned."

**2022: In a review about policy guidelines, they recommend a "per se limit" with a quantitative THC cut-off between 3.5 and 5 ng/ml in the bloodstream to "currently be considered the most balanced [policy] choice"**
*Cannabis and Driving: Developing Guidelines for Safety Policies*
https://pubmed.ncbi.nlm.nih.gov/35713145

**2022: In a comparison of alcohol & cannabis for driving, only alcohol caused worse driving**
*Comparison of the effects of alcohol and cannabis on visual function and driving performance. Does the visual impairment affect driving?*
https://pubmed.ncbi.nlm.nih.gov/35717788

**2012: 10 mg of dronabinol (pharmaceutical THC) caused only moderate changes to driving performance in occasional users & no change in habitual users**
*Medicinal Δ(9) -tetrahydrocannabinol (dronabinol) impairs on-the-road driving performance of occasional and heavy cannabis users but is not detected in Standard Field Sobriety Tests*
https://pubmed.ncbi.nlm.nih.gov/22553980/

**Written Testimony of Jonathan Miller**

General Counsel of the U.S. Hemp Roundtable

Before the Subcommittee on Health Care and Financial Services of the

House Committee on Oversight and Accountability

July 27, 2023

Madame Chairwoman, Congresswoman Porter, I am grateful for the opportunity to testify before your committee today. The subject of today's hearing is a matter of urgency for the U.S. hemp industry, for which the U.S. Hemp Roundtable, serves as the national advocacy organization.

Chairman Comer, I am grateful for your presence today, but more importantly for your decade-long leadership on behalf of Kentucky and U.S. hemp farmers. You and I started on this journey in 2012 and worked across the aisle to secure hemp's legalization in the Bluegrass State. Indeed, hemp's policy success has always been a bipartisan hallmark.

Unfortunately, the U.S. hemp industry has been struggling considerably in the last few years. And this turmoil is due in large part to decisions made by the U.S. Food & Drug Administration, the FDA.

When Congress passed the 2018 Farm Bill, it explicitly legalized the sale of hemp and its derivatives such as CBD by removing them from the Controlled Substances Act. Farmers across the nation relied on this government action, and invested considerable time and resources to plant, grow, and market commercial hemp crops, and particularly for the market for which there was immediate processing infrastructure and consumer demand: hemp-derived CBD and cannabinoids.

But just a few hours after the Farm Bill was signed into law, the FDA reasserted its opinion that it was illegal to market CBD as a dietary supplement or to use as a food additive. Beyond warning letters targeting illegal disease claims, such as that CBD cures cancer or COVID, the agency has not engaged in meaningful enforcement. But its inconsistent position, coupled with lack of action, has cast a cloud over the industry.

We've watched in bewilderment as FDA has jerked back and forth with contradictory opinions. First, the agency affirmed its ability to regulate CBD under current law.[1] So far, so good. But then, in the intervening four years, FDA stalled, even ignoring congressional appropriations report directives to take expedited action. Meanwhile, federal regulatory uncertainty severely impacted the hemp and CBD market, with reduced manufacturing demand resulting in a more than 90% commodity price decline, crushing opportunities for U.S. farmers. Please refer to Figures 1-6 below.

Then finally, this January, the agency stated that it cannot regulate CBD under existing regulatory pathways because of its concern over the substance's safety, essentially punting this responsibility to Congress. But in so doing, the FDA relied on a narrow set of research mainly focused on high-dosage CBD isolate formulations often using drug-level dosages that exceed 1000 milligrams – while refusing to acknowledge a range of studies that demonstrate the safety of various CBD formulations at much lower amounts – 30, 40, 50 milligrams/serving -- such as those typically found in CBD dietary supplements and foods sold at retail. Please see the "summary of studies" section below.

Lack of a federal framework has led to the proliferation of unregulated products, some of which raise significant quality, safety, and other consumer protection concerns. Adding to these issues, surplus hemp CBD biomass is being chemically

converted into impairing products, such as Delta-8 THC, which are being sold unregulated, sometimes to minors. These products served as a lifeline to U.S. farmers, and when manufactured properly, can be of considerable value to adult consumers. Accordingly, we oppose their ban or criminalization. However, they need to be strictly regulated for safety and kept out of the hands of children. Kentucky's General Assembly recently passed unanimously legislation to this effect – HB 544 -- it should be a model for the nation. A copy of this bill is included below.

Given that it has been over five years since enactment of the 2018 Farm Bill, and the agency has refused to act, punting the ball now to Congress, we agree that it is the time for Congress to act. We support House legislation that's been introduced by a bi-partisan coalition led by Congressmen Morgan Griffith (R-VA) and Angie Craig (D-MN): HR 1628 would provide a regulatory pathway for CBD as food and beverage additives. H.R. 1629 would ensure that hemp-derived CBD, and other hemp ingredients, could be lawfully marketed as dietary supplements. In the upper chamber, Senators Ron Wyden (D-OR), Rand Paul (R-KY), and Jeff Merkley (D-OR) have introduced S. 2451, which would provide both regulatory paths. Rep. Earl Blumenauer (D-OR) has filed the companion bill to S. 2451 in this chamber. All of these bills would require compliance with the entire existing comprehensive regulatory frameworks for dietary supplements and food, which help ensure products are safe, properly labeled and produced under Good Manufacturing Practices.

There are abundant consumer safeguards encompassed in the Federal Food, Drug and Cosmetic Act that would be applied to CBD products sold as dietary supplements. For example, the law precludes manufacturers and distributors from selling mislabeled or adulterated products; and it requires manufacture and sale of products consistent with good manufacturing product standards. The law also requires reporting of serious adverse events, and it mandates strict labeling, including if FDA desires, warnings against the use of products by children. Finally, the FDA with the Consumer Product Safety Commission could require child-proof packaging.

While we disagree with FDA's opinion that a new regulatory regime is needed, especially given the length of time this would require, we are certainly open to stricter regulation of CBD and other cannabinoid products on top of the existing frameworks.

We understand that the agency has provided technical assistance to some in Congress suggesting it has now concluded that the existing regulatory framework is insufficient to regulate CBD products; instead, the agency has suggested a "harm reduction" framework. We have serious doubts about the ability of such a framework to be implemented expeditiously, given the breadth of the proposal and the current jammed congressional schedule. Further, we take exception to the idea of couching CBD products in terms of harm, given that consumers look to these products to help them lead healthier lifestyles. Hemp farmers know first-hand the implications of a government harm reduction program given the experience with tobacco – a product that does not provide a good parallel.

In the absence of FDA action, the hemp industry has established the US Hemp Authority, a self-regulatory organization that provides a certification seal to good actor farmers and manufacturers, to provide high standards and promote best practices. But without a federal regulatory pathway for hemp-derived CBD requiring such standards, economic opportunities for U.S. hemp farmers will be diminished, and consumers will not have access to safe, quality products. In fact, progress made in the hemp fiber markets – a multi-billion-dollar opportunity for U.S. farmers – has also been stymied by this dynamic. Legislation is necessary to help stabilize the hemp markets, open up a promising economic opportunity for U.S. agriculture and honor the commitment made to growers in the 2018 Farm Bill.

The hemp industry may be unique in that we are coming to Congress to ask: Please, regulate us! A rational, sensible regulatory framework for the hemp industry can also provide a needed financial jolt to a nation emerging through economic recovery. Regulatory relief for the hemp-derived CBD industry constitutes an economic stimulus package for the nation's farmers and small businesses without requiring one dime from the American taxpayer. Independent studies predict that if FDA issues regulatory guidance by the end of 2024, the market will top $11 billion by 2027, but will fall $4 billion short if there's no FDA action.

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## Expanded Testimony and Supportive Data

In passing the 2018 Farm Bill, Congress made clear its intent to support the production and sale of hemp and hemp derivatives such as CBD.[2] Thousands of U.S. growers planted hemp in response, with farming for CBD representing the overwhelming majority of all hemp acreage.[3] (Even as of 2021, floral hemp production for cannabinoid-based products still accounted for approximately 75% of total hemp production.)[4] However, public statements by FDA officials indicating that it is illegal to sell ingestible hemp-derived CBD products have taken their toll on the industry. While the agency has primarily taken action against companies that have made improper disease claims, and while FDA officials have announced that they are investigating a potential regulatory pathway for CBD products, CBD commerce and investment have been chilled due to the absence of federal regulation, impairing economic opportunity for farmers and small businesses:

- The current regulatory gray area has stifled significant hemp market opportunities for farmers and businesses. State and local agencies have threatened and/or taken enforcement actions against the sale of CBD products, citing FDA guidance. Many big-box retailers are reluctant to carry CBD products due to FDA's position, while the nation's top food companies have delayed efforts to introduce new CBD products into the marketplace.[5]
- Chilled and stagnant CBD commerce has resulted in a continuing oversupply of hemp biomass and derivative products, such as crude oil, with hemp commodity prices dropping sharply, adversely impacting hemp farmers. According to independent reporting agency Hemp Benchmarks, aggregate prices for hemp CBD biomass, crude oil, full spectrum distillate, and CBD isolate declined more than 90% between April 2019 and October 2022. (See Figures 1-4). While prices stabilized somewhat in late 2021, any significant and sustained price increases are not expected in the foreseeable future, barring regulatory clarity.
- Regulatory uncertainty has resulted in a severe downturn in US hemp production. In 2021, roughly 200,000 acres were registered with state hemp programs, down more than 50% compared to 430,000 acres registered in 2020.[6] Of those registered, only 54,200 acres were grown across the country in 2021, representing a 50-75% decline in acreage dedicated to hemp production from 2019-2020.[7] And of the hemp grown, a much smaller portion was actually harvested: Colorado, for example, planted more than 10,000 acres of hemp, but only harvested 31 percent of it.[8] 2022 brought further declines; as of October, only 21,172 acres had been planted *nationally*, with only 7485 acres grown for CBD. (See Figure 5). And just because a farmer managed to harvest hemp doesn't mean the hemp was successfully sold: Despite significantly less supply coming to the market, observed wholesale prices remain depressed. (See Figures 1-4).
- The COVID-19 crisis also weighed heavily on hemp farmers. The pandemic led to significant increases in shipping costs; for example, Hemp Benchmarks reported that average costs to ship bulk hemp products increased between 22-94% during 2021.[9] While hemp farmers were finally deemed eligible by the USDA for Coronavirus Food Assistance Program funds in September 2020, the benefits were much less generous than most other crops, paying only $15/acre of 2020 crops.[10] Unlike other segments of the economy, the hemp extract market did not bounce back from a 2020 COVID-related sales slump: one economic study pegs the growth of U.S. CBD sales at only 2.5% in 2021, barely recouping an estimated 2.0% downturn in 2020, and a far cry from the meteoric annual growth observed pre-pandemic.[11]
- Plummeting hemp and CBD prices, COVID disruptions and an oversupply of biomass have led to another challenge: Struggling farmers and businesses have pivoted to selling compounds, such as Delta-8 THC, which are produced by chemically converting hemp-derived CBD biomass. These products, sold unregulated at retail and sometimes marketed in ways that are appealing to children, can raise serious health and safety concerns for minors.[12] Indeed, as an October 2022 Hemp Benchmarks study demonstrates, prices for hemp flower had declined only 37% since their 2019 peak; the relative stability due to its use in the manufacturing of intoxicating products. (See Figure 6).
- At least three major hemp companies have filed for bankruptcy, including Atalo Holdings[13], GenCanna Global[14], and Elemental Processing.[15] In each instance, regulatory uncertainties were cited as a leading cause of bankruptcy. Atalo

and GenCanna specifically attributed their bankruptcies to declining sales, closing markets, and frozen investment in the time since the release of FDA's public comments.[16]

- At the same time, major banks and payment processing services, including Chase and PayPal, are refusing to onboard hemp and CBD companies, citing regulatory uncertainty. Some, like Visa, are even levying significant penalties against financial services providers that process hemp and CBD transactions, which has caused merchants' accounts to be suspended. As a result, farmers and hemp companies are being left without critical financial and merchant services, further compromising their farms and businesses. Impacts are not limited to the hemp CBD industry, but are also being felt by hemp fiber and grain companies, and even hemp non-profit organizations and ancillary hemp industry service providers. Further, private investment in the industry has dried up; there's been a "precipitous decline" in M&A deals.[17]
- There are becoming fewer outlets for hemp companies to advertise their products, providing an additional barrier to entry into consumer markets. Facebook, for example, has prohibited ads marketing ingestible CBD products, citing FDA's pronouncements. Facebook even prohibits the marketing of non-CBD hemp products if ingestible CBD is mentioned anywhere on a company's website.[18]
- Across the country, the industry has also been the target of litigation. More than a dozen class action lawsuits regarding CBD have been threatened or filed, citing FDA's public statements as grounds for injury.[19] Even more cases have been brought by farmers against processors for non-payment and breaching hemp contracts.[20] These lawsuits are tying up cash and disrupting business operations and supply chains.
- Federal and state political leaders of all stripes have repeatedly called on FDA to issue formal regulations for CBD in dietary supplements and food. U.S. Senate Majority Leader Mitch McConnell (R-KY) and Senator Ron Wyden (D-OR) have each urged FDA to take expedited action,[21] U.S. Congressmen Andy Harris (R-MD) and Mark Pocan (D-WI) have declared that public confidence in the FDA is being challenged by its lack of action on CBD,[22] while Kentucky Commissioner of Agriculture Ryan Quarles witnesses FDA's inaction as "preventing growth in the hemp marketplace…Promising potential markets remain closed while crop production has increased. When there is a surplus of crop and it begins to pile up, the result is obvious: crop prices will fall."[23]
- FDA is acutely aware of the broad public support for a regulatory framework for CBD, but has been unwilling to act. Former FDA Commissioner Scott Gottlieb testified that "[FDA] heard Congress loud and clear...Congress wants there to be a pathway for CBD to be available."[24] Former FDA Commissioner Stephen Hahn stated it would be a "fool's game" to try to completely shut down the CBD marketplace.[25] Former Acting Administrator Janet Woodcock has tried to combat the perception that FDA is opposed to CBD in dietary supplements as a matter of policy. However, she argues that the "law is very clear about this, and so it puts us in a stalemate position."[26] At a May 2022 congressional hearing, current FDA Commissioner Robert Califf testified to his disappointment in the lack of agency action on CBD, and expressed his interest in developing a regulatory path, asking Congress for broader regulatory powers: "I don't think the current authorities we have on the food side or the drug side necessarily give us what we need to have to get the right pathways forward…We're going to have to come up with something new. I'm very committed to that."[27] And while FDA recently announced plans to establish a new regulatory pathway for CBD and other cannabis products,[28] FDA staff has informed congressional staff that the regulatory process could take five years to implement, requiring the funding of a new center at the agency.

**REGULATION MEANS SAFETY**: FDA also argues it is hesitant to act because it has not yet accumulated sufficient safety data on CBD. However, public safety data is compelling, and regulation is the only approach to ensuring public health and safety:

- There's a growing body of evidence, including data published by the industry, demonstrating that hemp-derived CBD, especially at the levels found in many dietary supplements and food, is safe.[29] While FDA has listed liver injury as a concern, a published 2021 observational study, updated with more compelling evidence in 2022, demonstrated that CBD does not pose significant safety concerns at the levels typically found in many dietary supplements and food and

that also addresses specific safety concerns raised by FDA ( "no evidence" of liver toxicity).[30] Scientific experts have recognized that data already exists to determine that hemp extracts containing CBD can be Generally Recognized as Safe (GRAS).[31] And despite a notable increase in the use of these products, the number of reported adverse events continues to be remarkably low.[32] **For full details, see "*Summary of Studies Supporting the Safety of CBD as Hemp Extract and Isolate*" attached hereto**.

- Other international regulatory bodies have reviewed the same publicly available evidence and determined that CBD products can be safely marketed. The World Health Organization determined that pure CBD is "generally well tolerated with a good safety profile" and presents little risk of abuse or dependency potential, recreational use, or public health-related problems.[33] Australia's Therapeutic Goods Administration concluded that CBD "presents a good safety and tolerability profile,"[34] and approved CBD products, up to a maximum of 150 mg/day, for use in adults, to be supplied over-the-counter by a pharmacist, without a prescription.[35] United Kingdom's Food Standards Agency determined that CBD products can be regulated and marketed as novel foods, provided they meet standards for safety and content, recommending a 70mg daily limit for healthy adults.[36]
- Recognizing CBD's safety as well as the need for consumer protection, a majority of U.S. states now provide explicit legal protection for the sale of ingestible hemp-derived CBD products, and new regulatory regimes have emerged in the nation's largest wellness markets, such as California, New York, Florida and Texas.[37] While this is good news for farmers and consumers in these states, the cloud of federal legal uncertainty looms over interstate commerce. Worse, according to a recent Consumer Brands Association study a contradictory state patchwork of laws and regulations have led to deep public confusion and impose significant compliance burdens on farmers and manufacturers.[38]
- The most pressing safety problem is, as independent studies demonstrate,[39] and as FDA recently reported to Congress,[40] without a clear regulatory framework, bad actors are selling products without appropriate safeguards and misleading consumers with false label claims. Further, as discussed above, regulatory uncertainty for CBD has led many struggling farmers and businesses to pivot to market intoxicating products such as Delta-8 THC, prompting FDA warnings that they pose consumer health and safety risks, particularly for minors.[41]

**REGULATION PORTENDS A BRIGHT FUTURE**: Once FDA does legally recognize and regulate CBD products, the hemp industry can partner with the agency to provide a needed financial jolt to a nation emerging through economic recovery. Regulatory relief for the hemp-derived CBD industry constitutes an economic stimulus package for the nation's farmers and small businesses without requiring one dime from the American taxpayer:

- A recent economic study estimates the market for CBD products to have hit $5 billion in 2022, but there are two very different scenarios for future revenues. If FDA issues regulatory guidance by the end of 2024, the study projects the market will top $11 billion by 2027. But if there's no FDA action, CBD sales are expected to be more than $4 billion lower in five years.[42] An earlier analysis projected a CBD sales range of $4 billion to $16.5 billion by 2025, the higher end dependent on favorable FDA regulations.[43] A third study projects CBD sales to reach $19.5 billion by 2025, with mainstream retail exceeding $15 billion annually, but that's based on a prediction that FDA will regulate CBD as a food additive in 2022.[44] Other hemp constituents, such as CBG and CBN, are also providing new economic opportunities for U.S. farmers and could flourish in a regulated system.[45]
- Wider availability through additional retail venues and product manufacturers would address consumer demand and help stabilize hemp prices, posing tremendous economic opportunity to U.S. farmers that struggled through the pandemic. One economic study forecasted that hemp sown for CBD could potentially generate substantially more revenue per acre than corn.[46] Clear laws and regulations would also empower farmers to get out of the court system and into the hemp fields, with more secure access to banking, merchant services, and marketing opportunities.
- Unlike many existing industries that will have to rebuild over the next few years to achieve their previous stature, the hemp industry needs no ramp-up period; sales would surge once regulations are in place. Unlike existing industries that will struggle to return workers to their jobs, the hemp industry will offer brand new jobs immediately in agriculture, manufacturing, distribution, retail, testing and other fields that serve the hemp supply chain.

- Limiting CBD to a drug-only path remains a deeply anti-consumer approach. CBD is only FDA-approved for very rare medical conditions, and costs patients up to $35,000/year.[47] A drug-only path would block access for the millions of Americans want to use non-prescription hemp-derived CBD to help manage their everyday health and wellness. CBD can coexist as an ingredient in both drugs and supplements, but under different regulatory frameworks just like fish oil, niacin, caffeine, menthol, and many other natural ingredients do today. Dietary supplement regulations are intended to strike a balance between consumer safety and consumer access. If vitamins, minerals, and botanicals were regulated like drugs then they would be too expensive for the millions of people that use them for good health.[48] CBD regulated as a dietary supplement provides appropriate consumer protections, quality control and transparency. Supplement regulations require manufacturers to conduct pre-market safety evaluations when necessary and to follow FDA's guidelines for manufacturing and testing, as well as maintain post-market surveillance for adverse events.
- A partnership in which FDA regulation is complemented by industry initiatives such as U.S. Hemp Authority self-regulation[49] also helps ensure that consumers can purchase safe, transparent, quality-assured products.

# Hemp Pricing Data

**Figure 1: CBD Biomass (Aggregate)**

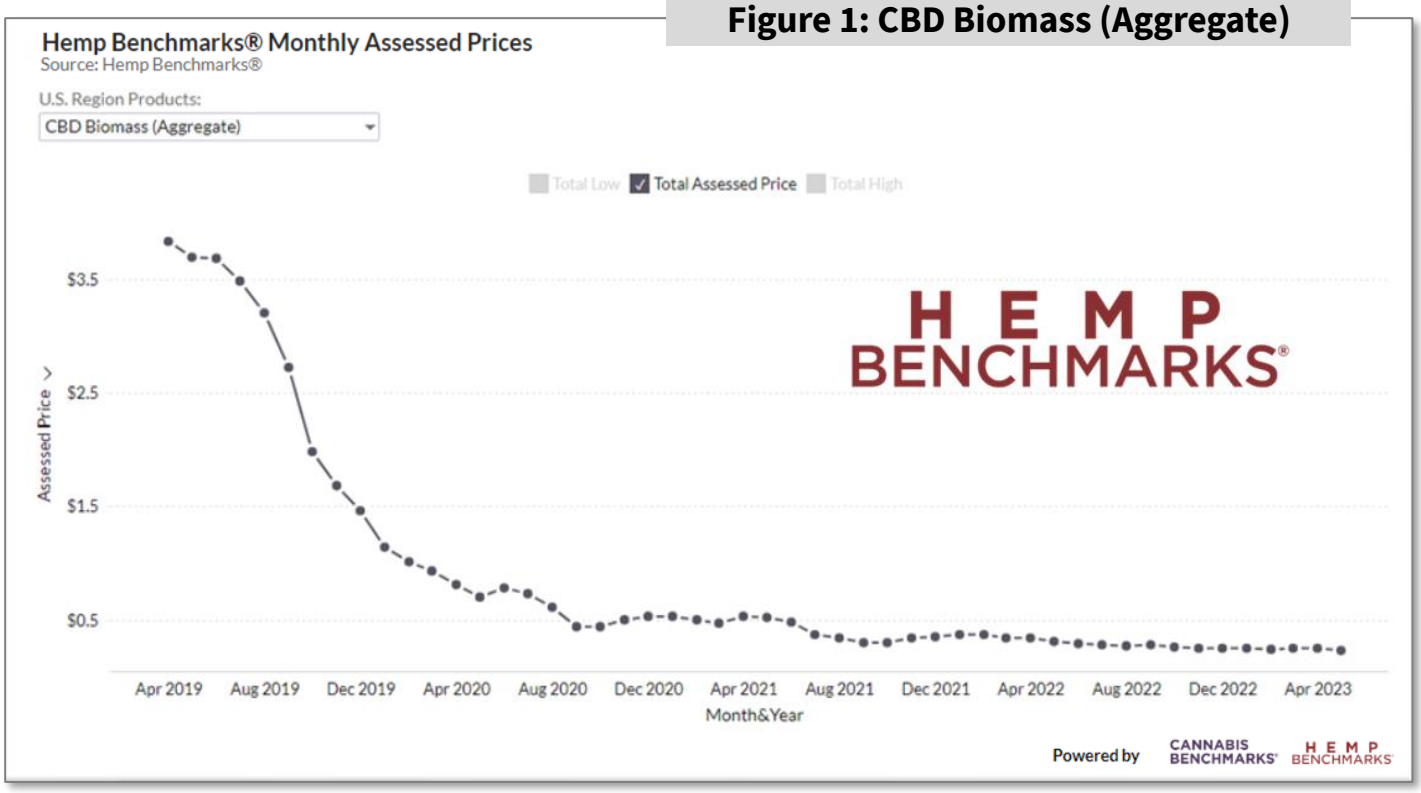
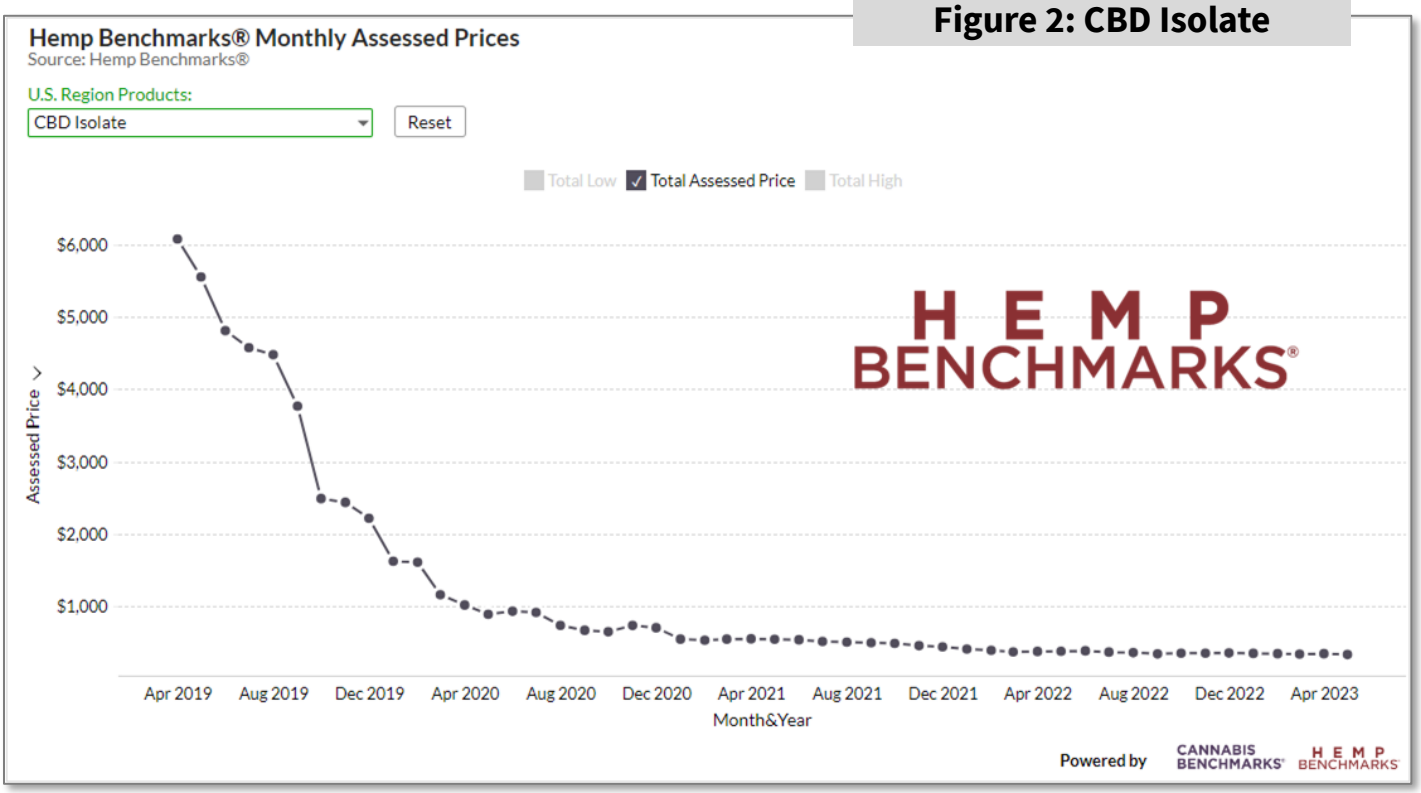



**Figure 2: CBD Isolate**



# Hemp Pricing Data

**Figure 3: Distillate – Full Spectrum**

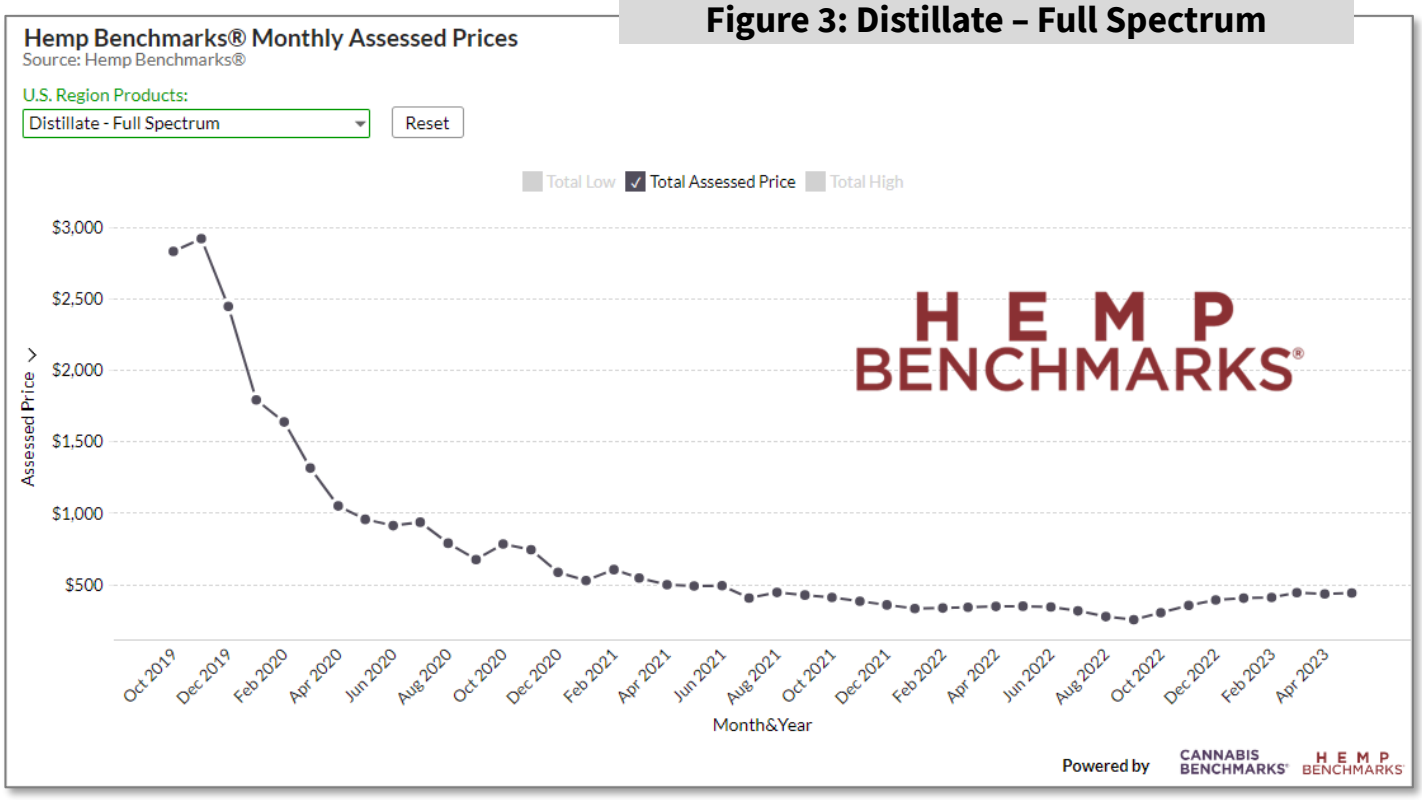
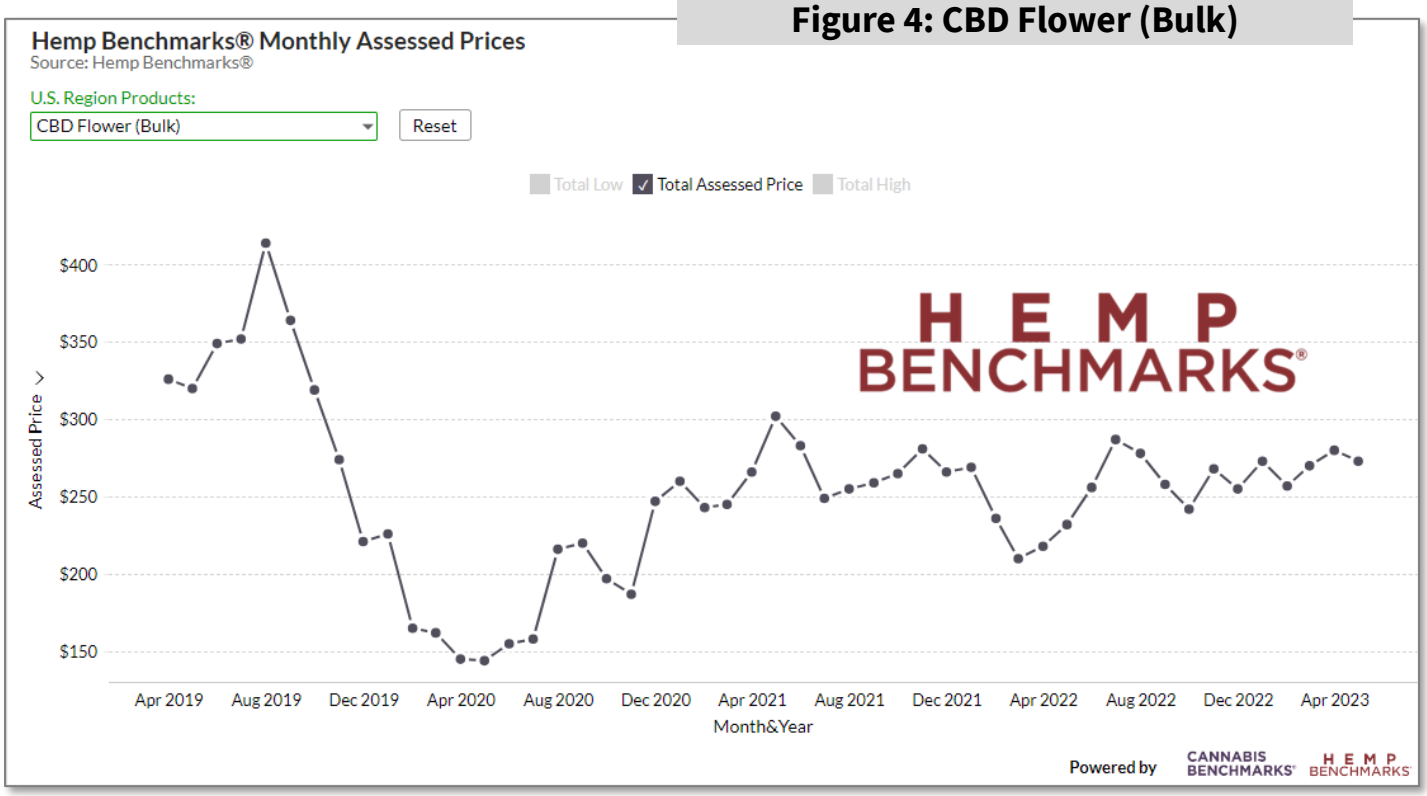



**Figure 4: CBD Flower (Bulk)**



# Hemp Pricing Data

**Figure 5: Total US Hemp Acres (2019-2022)**

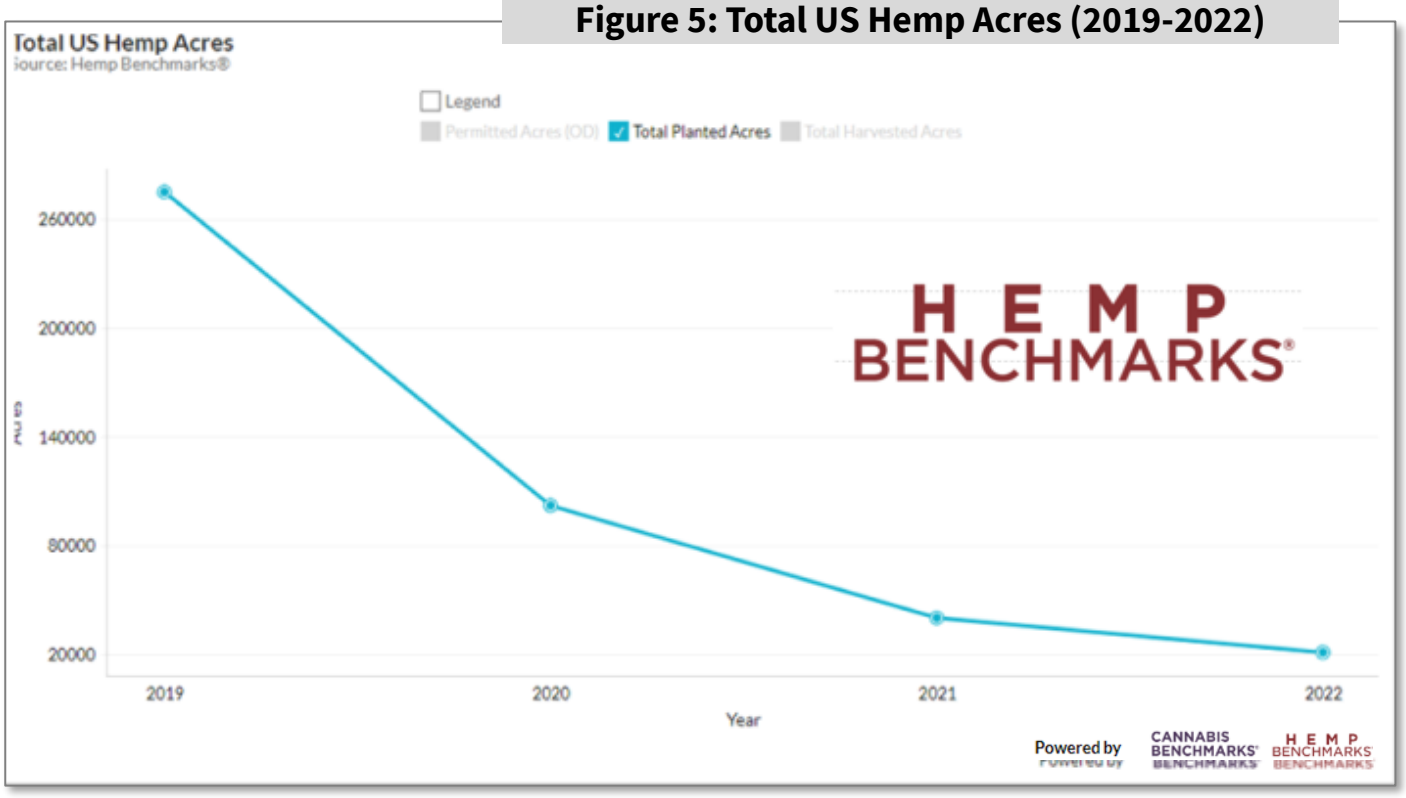
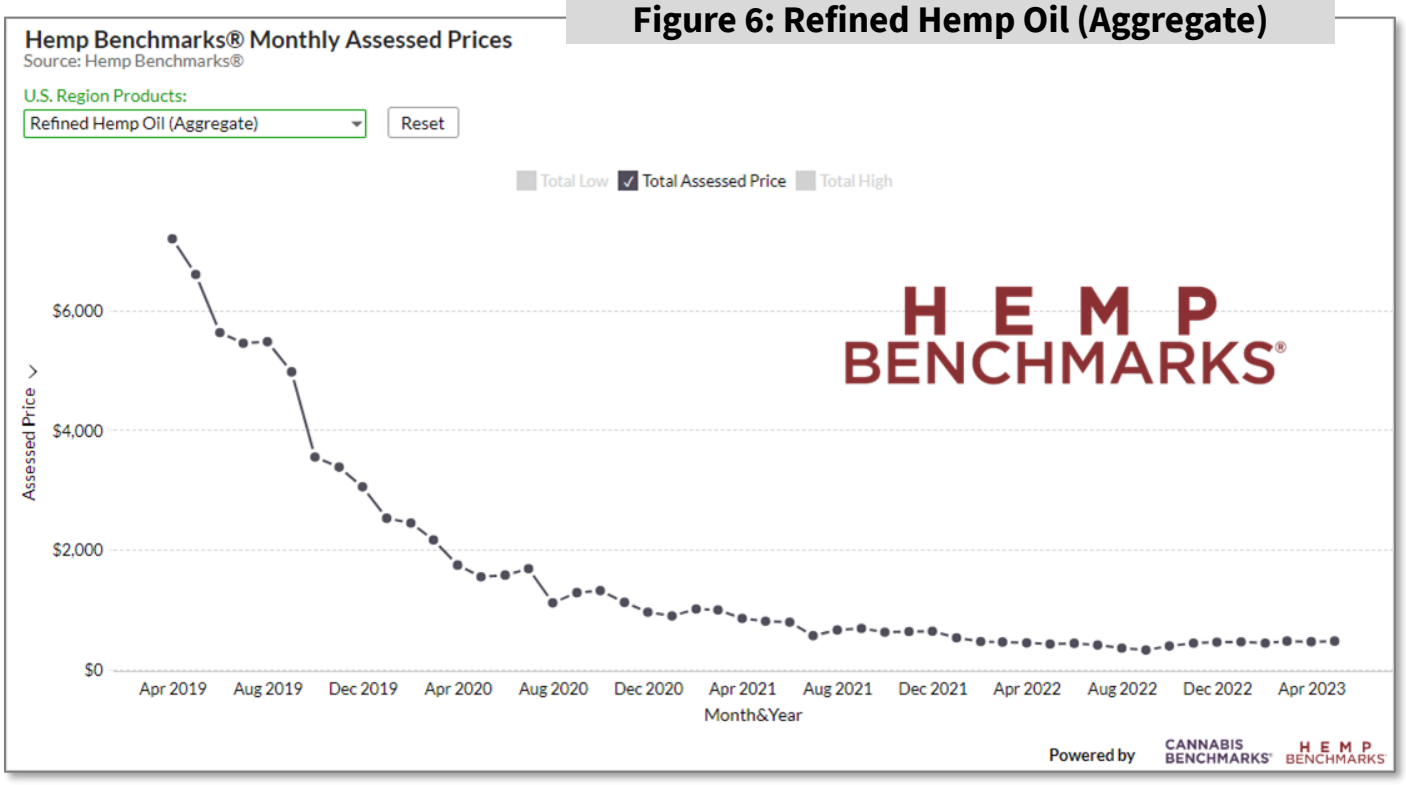



**Figure 6: Refined Hemp Oil (Aggregate)**



## Summary of Studies Supporting the Safety of CBD as Hemp Extract and Isolate

FDA's repeated claims that CBD poses safety risks is directly contradicted by a growing body of scientific evidence. While FDA relies on studies based on high-dosage, pharmaceutical-grade CBD formulations, more than a dozen studies demonstrate the safety of CBD at much lower amounts – such as those typically found in CBD dietary supplements and foods sold at retail – and belies the agency's safety concerns about the compound.

Three 90-day toxicity studies in animals, conducted in accordance with established scientific protocols and following FDA procedures for ingredients that are Generally Recognized as Safe (GRAS), demonstrate that CBD-containing hemp extracts studied thus far are safe. Two toxicity studies published in 2023 provide useful data regarding the safety of CBD isolate, including addressing developmental and reproductive toxicity concerns. Another study published in 2023 on a proprietary, high-CBD hemp extract found that the extract was well-tolerated. Six additional 90-day toxicity studies in animals that have not yet been published reported similar positive safety findings and include studies on both hemp extract and CBD isolate. Recently conducted human clinical trials on hemp extract reinforce these conclusions and reported zero serious adverse events.

This science is also backed up by several years of adverse event data maintained by the industry, as required by federal law for dietary supplements. This data indicates an extremely low number of adverse events associated with CBD, with an even lower number of serious adverse events, and correlates with observational data demonstrating the safety of CBD.

Taken together, these toxicity studies covering a range of CBD-containing ingredients, combined with the safety data in humans reflected in clinical trials, observational studies, and low number adverse event reports, demonstrate that CBD can be safely consumed at the serving sizes found in most CBD dietary supplements and foods sold at retail.

References:

- Three published toxicity studies on three different types of hemp extract, conducted as part of independent GRAS affirmations, have consistently demonstrated the safety of CBD at serving sizes typically found in products sold at retail.[50]
- A fourth toxicity study published in 2023 on CBD isolate and a fifth toxicity study on a high-CBD hemp extract also reported positive findings with respect to CBD's safety.
- A sixth toxicity study published in 2023 evaluating the effects CBD isolate provides the relevant data needed to establish safe intake levels related to male and female developmental and reproductive toxicity, which addresses an important data gap identified by FDA.[51]
- A genotoxicity evaluation, also published in 2023, concluded that CBD is unlikely to pose a genotoxic hazard[52]
- Unpublished studies presented confidentially to FDA yielded additional positive safety findings, with two studies using hemp extract and two using CBD isolate. Most of these studies are expected to be published in 2023-2024.
- Another toxicity study with additional safety was data submitted to FDA in conjunction with a Citizen Petition, further demonstrating the safety of another CBD-containing hemp extract.[53]
- A further study, based on Phase II and phase III clinical trials utilizing full and broad-spectrum hemp extracts, up to 150 mg of hemp extract daily was not associated with elevated liver tests, notable drug interactions, or adverse events.[54]
- Observational data and the results of another study provide additional evidence of CBD's safety in over 4,000 participants collectively:
    - A 2021 observational study conducted by Validcare in over 800 participants using CBD products showed no increase in the prevalence of elevated liver function tests when compared to a population with a similar incidence of medical conditions.[55]
    - Another Validcare study of over 1,000 participants, completed in March 2022, showed that CBD is not associated with elevated liver tests, low testosterone levels, or daytime drowsiness.[56]
    - The results of a Radicle Sciences study published in November 2022 and using 2,800 participants reported only minor side effects (e.g., gas, headache) in less than 10% of participants, with no severe side effects.[57]

[1] Commissioner Scott Gottlieb stated the day the Farm Bill was signed into law, "Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds." (Statement of FDA Commissioner Scott Gottlieb, M.D. on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis, cannabis-derived compounds" December 20, 2018); In April of 2019, Dr. Gottlieb announced a May public hearing as well as a high-level internal agency working group that would study potential pathways for marketing of CBD-containing products as dietary supplements and also as conventional foods. At that time, Dr. Gottlieb reiterated the language above about the agency's current authority and the agency titled his statement in terms of "potential regulatory changes." (Statement from FDA Commissioner Scott Gottlieb, M.D. on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products." April 2, 2019.)

[2] https://www.mcconnell.senate.gov/public/index.cfm/pressreleases?ID=0B71B14E-5F77-4283-9084-561F67EFBC70 (Senate Majority Leader Mitch McConnell: "Congress' intent was clear with the passage of the Farm Bill that these products should be legal, and our farmers, producers and manufacturers need clarity as well as a workable pathway forward regarding the Agency's enforcement and potential regulatory plans for certain CBD products"); https://www.wyden.senate.gov/download/062519-wyden-letter-to-fda-hhs-on-hemp-cbd- (Senator Ron Wyden: "The passage of the 2018 Farm Bill is Congress's clear intent to further advance and support the domestic production and sale of hemp and hemp derivatives like CBD.")

[3] https://www.reporterherald.com/2020/05/18/enthusiasm-leads-to-oversupply-of-hemp-in-colorado/ (Colorado: 79% of acreage in 2020 dedicated to hemp grown for CBD products.); https://www.kyagr.com/marketing/hemp-overview.html (Kentucky: 92% of hemp acreage grown for CBD in 2019.)

[4] National Hemp Report 02/17/2022 (usda.gov)

[5] https://www.barrons.com/articles/hemp-cbd-demand-is-poor-prices-are-falling-in-a-blow-to-farmers-51580482811 ("Consumer packaged-goods giants like PepsiCo (PEP) and big retailers like Walmart (WMT) haven't committed to CBD-laced products. A big reason is concerns voiced by the U.S. Food and Drug Administration, which says it can't permit the biologically-active ingredient in food and drink without tests of CBD's safety.")

[6] Hemp Benchmarks, Hemp Spot Price Index Report, Dec 2021

[7] National Hemp Report 02/17/2022 (usda.gov); compare to: VH_2020_Crop_Report_final (votehemp.com)

[8] National Hemp Report 02/17/2022 (usda.gov)

[9] Hemp Benchmarks, Hemp Spot Price Index Report, Dec 2021

[10] https://www.farmers.gov/cfap; *See also* https://hempindustrydaily.com/hemp-industry-daily-taking-stock-of-how-coronavirus-has-affected-farmers-businesses/ (54% of hemp companies have reported that applications for COVID-19 relief funds have gone unanswered, and another 29% report their applications being denied outright or relief loans going unfulfilled.)

[11] Brightfield Group, US CBD Market Industry Update, October 2021.

[12] What Is Delta-8-THC?: The Hemp Derivative That's a Hot Seller - The New York Times (nytimes.com); https://www.politico.com/news/2021/03/27/rise-of-delta-8-thc-478215

[13] https://www.forbes.com/sites/davidcarpenter/2020/03/18/hemp-company-files-for-bankruptcy-as-confounding-regulatory-guidelines-hamper-growth/#417b60955794

[14] https://www.winchestersun.com/2020/02/06/gencanna-files-for-chapter-11-bankruptcy/

[15] https://hempindustrydaily.com/kentucky-extractor-elemental-processing-files-for-bankruptcy-protection/

[16] https://www.thefencepost.com/news/gencanna-exec-blames-fda-for-hemp-industry-troubles/; (GenCanna: FDA's "uncertainty over how to regulate hemp…has diminished the interest of big companies in hemp food products and 'frozen' processors access to capital."); https://www.forbes.com/sites/davidcarpenter/2020/03/18/hemp-company-files-

for-bankruptcy-as-confounding-regulatory-guidelines-hamper-growth/#417b60955794 (Atalo: "The path to growth has been impeded by confounding guidance from regulatory agencies.")

[17] https://www.forbes.com/sites/mergermarket/2020/04/27/precipitous-decline-in-hemp-and-cannabis-ma-continuing-amid-covid-19-pandemic/#2d8825375c05

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[21] https://www.marijuanamoment.net/mitch-mcconnell-talks-cbd-regulations-with-fda-head/

[22] GOP Congressman Says FDA's Lack Of CBD Regulations Is 'Disrupting Public Confidence' In The Agency - Marijuana Moment; FDA Head Admits Agency Has Been Slow To Regulate CBD, But Suggests Congress Needs To Do More - Marijuana Moment

[23] https://www.kyagr.com/ky-agnews/press-releases/2020/Quarles-Urges-FDA-End-Bureaucratic-Paralysis-Hemp-Regulatory-Decisions.html

[24] https://www.naturalproductsinsider.com/ingredients/fda-commissioner-deeply-focused-cbd-issues

[25] https://www.nutraingredients-usa.com/Article/2020/02/28/FDA-chief-Hahn-says-it-would-be-fool-s-game-to-try-to-shut-down-CBD-markets

[26] Acting FDA chief suggests no quick solution to CBD 'stalemate' (naturalproductsinsider.com)

[27] FDA Head Admits Agency Has Been Slow To Regulate CBD, But Suggests Congress Needs To Do More - Marijuana Moment

[28] FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward | FDA

[29] *See e.g.*, https://www.sciencedirect.com/science/article/pii/S2214750019305207; https://www.hindawi.com/journals/jt/2018/8143582/;https://pubmed.ncbi.nlm.nih.gov/32268347/; https://www.tandfonline.com/doi/abs/10.1080/19390211.2020.1767255

[30] Kaufmann R, Aqua K, Lombardo J, Lee M (2021*) Observed impact of long-term consumption of oral cannabidiol on liver function in healthy adults*, Cannabis and Cannabinoid Research X:X, 1–7, DOI: 10.1089/can.2021.0114: Observed Impact of Long-term Consumption of Oral Cannabidiol on Liver Function in Healthy Adults (hempsupporter.com) (The study "calls into question the claim that CBD can cause liver injury." Observational data gathered from 839 participants — ages 18–75 from across the U.S. and known to be taking hemp-derived CBD products orally for a minimum of 30 days — showed that CBD at the doses consumed in the study is not associated with clinical liver toxicity.); Kauffmann R, Bozer A, Aqua K, Lombardo J (2022) *Observed Effects of Daily consumption of Hemp-derived CBD on liver function, testosterone, and daytime drowsiness,* Abstract; New Study Demonstrates CBD'S Strong Safety Profile, Amplifies Calls… (hempsupporter.com).

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[32] https://hempsupporter.com/assets/uploads/2019.07.16-US-Hemp-Roundtable-FDA-Comments.pdf (Industry study showed percentage of adverse effects reported between .01 and .1%)

[33] https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf<https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>

[34] https://www.tga.gov.au/alert/review-safety-low-dose-cannabidiol

[35] https://www.tga.gov.au/media-release/over-counter-access-low-dose-cannabidiol

[36] https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers;

[37] See e.g., Bill Text - AB-45 Industrial hemp products. (ca.gov); https://regs.health.ny.gov/sites/default/files/proposed-regulations/20-21hemp.pdf; New Hemp Rules in Effect January 1 / 2020 Press Releases / Press Releases / News & Events / Home - Florida Department of Agriculture & Consumer Services (fdacs.gov); Texas Administrative Code (state.tx.us)
[38] Unregulated and Exploding: How the CBD Market Is Growing Amid a Labyrinth of State Approaches and Rampant Consumer Confusion - Consumer Brands Association
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[40] https://hempsupporter.com/assets/uploads/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf; *See also*, https://www.fda.gov/news-events/speeches-fda-officials/remarks-lowell-schiller-jd-council-responsible-nutrition-conference-1172019-11072019 (FDA's Lowell Schiller: "Many of the manufacturers entering this space lack experience with FDA or DSHEA, and we have serious concerns about issues like harmful contaminants such as pesticides, heavy metals, or other drugs like THC.")
[41] 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC | FDA
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AN ACT relating to the regulation of hemp-derived products.

WHEREAS, on August 3, 2022, the Boone Circuit Court entered a permanent injunction prohibiting the Kentucky State Police from instituting or continuing any criminal enforcement action against a person in possession of certain products containing delta-8 tetrahydrocannabinol (THC); and

WHEREAS, on November 15, 2022, Governor Andy Beshear issued Executive Order 2022-799, stating that delta-8 is a form of THC, delta-8 can be derived from cannabidiol (CBD) through further processing, and products containing delta-8 are sold at retail businesses in Kentucky and surrounding states; and

WHEREAS, Executive Order 2022-799 further stated that there are no requirements currently applied to delta-8 products sold in Kentucky for their packaging and labeling or for their use as ingestible cannabinoid products, and that certain requirements that exist for the packaging and labeling of CBD products sold in Kentucky should also apply to delta-8 products to ensure the public's protection; and

WHEREAS, Executive Order 2022-799 further stated that under KRS 217.125(1) of the Food, Drug, and Cosmetic Act, the Cabinet for Health and Family Services has the authority to promulgate administrative regulations for the administration and enforcement of KRS 217.005 to 217.215; and

WHEREAS, the cabinet promulgated 902 KAR 45:190 to regulate hemp-derived CBD products and establish packaging and labeling requirements for such products; and

WHEREAS, since delta-8 THC is a cannabinoid, 902 KAR 45:190 applies to delta-8 THC products and application of this administrative regulation to delta-8 THC products will ensure the safety of those purchasing and consuming those products and establish a regulatory framework that in the future may be applied to medical cannabis if approved by the Kentucky General Assembly; and

WHEREAS, in Executive Order 2022-799, the Governor ordered and directed that the secretary of the Cabinet for Health and Family Services include delta-8 THC products

sold in Kentucky under 902 KAR 45:190; and

WHEREAS, by virtue of Executive Order 2022-799, the Governor also ordered and directed the Cabinet for Health and Family Services to take all necessary steps to implement and enforce 902 KAR 45:190 as applied to delta-8 THC products sold in Kentucky, including but not limited to designating any other state agency as its duly authorized agent to assist with implementation and enforcement of the administrative regulation under KRS 217.155; and

WHEREAS, the General Assembly and this Commonwealth have an interest in limiting the ability of minor children to obtain delta-8 THC products and other products that have intoxicating effects on consumers, and in ensuring that adult consumers of such products have access to accurate information about their contents;

NOW, THEREFORE,

***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

➔Section 1. (1) The General Assembly directs the Cabinet for Health and Family Services to immediately begin the process of regulating delta-8 tetrahydrocannabinol and any other hemp-derived substances.

(2) As used in this section:

(a) "Covered product" means any product containing delta-8 tetrahydrocannabinol or any other hemp-derived substance identified by the Cabinet for Health and Family Services as having intoxicating effects on consumers; and

(b) "Production" has the same meaning as in KRS 218A.010.

(3) Not later than August 1, 2023, the Cabinet for Health and Family Services shall promulgate an emergency administrative regulation with applicability to covered products that:

(a) Implements measures called for in Executive Order 2022-799;

(b) Prohibits the sale, gift, or other transfer of possession of covered products to a person who has not reached the age of 21 years;

(c) Prohibits the possession of covered products by a person who has not reached the age of 21 years;

(d) Requires retailers to keep covered products behind the counter in order to prevent theft or easy access by children;

(e) Establishes a laboratory testing and approval process for contaminants and phytochemicals of a covered product;

(f) Prohibits a covered product to be sold or distributed in the Commonwealth unless it has been approved under paragraph (e) of this subsection;

(g) Requires each covered product manufactured, marketed, sold, or distributed in the Commonwealth to be packaged and labeled in accordance with KRS 217.037;

(h) Except as established in paragraph (i) of this section, requires that a covered product's label include, in a print no less than six point font, the following information:

1. A statement of identity or common product name on the principal display panel of the label;

2. The net quantity of contents expressed in both standard English and metric units of measurement, located in the lower 30 percent of the principal display panel of the label parallel to the base of the container;

3. The ingredients of the product, in descending order of predominance by weight;

4. The name of the manufacturer or distributor;

5. The total amount of each cannabinoid per serving for ingestible products, or the total amount per container for cosmetic products;

6. Suggested use instructions or directions, including serving sizes; and

7. An expiration date, if any;

(i) Requires an ingestible or cosmetic covered product that has a total area of 12 square inches or less to bear labeling in accordance with paragraph (h) of this subsection, except the print may be smaller than six point font but not less than 1/32 of an inch in

height;

(j) Requires each covered product container have a tamper evident seal;

(k) Prohibits covered product packaging, labeling, or advertising material from bearing any implicit or explicit health claims stating that the covered product can diagnose, treat, cure, or prevent any disease; and

(l) 1. Permits a Kentucky production facility that is shipping a covered product to a state with testing requirements for the covered product, to defer to that state's requirements; and

2. Requires a Kentucky production facility that is shipping a covered product to a state without testing requirements for the covered product, to abide by Kentucky's requirements.

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