



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 Holdings¹³, GenCanna Global¹⁴, 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-regulation⁴⁹ also helps ensure that consumers can purchase safe, transparent, quality-assured products.

Hemp Pricing Data

Figure 1: CBD Biomass (Aggregate)

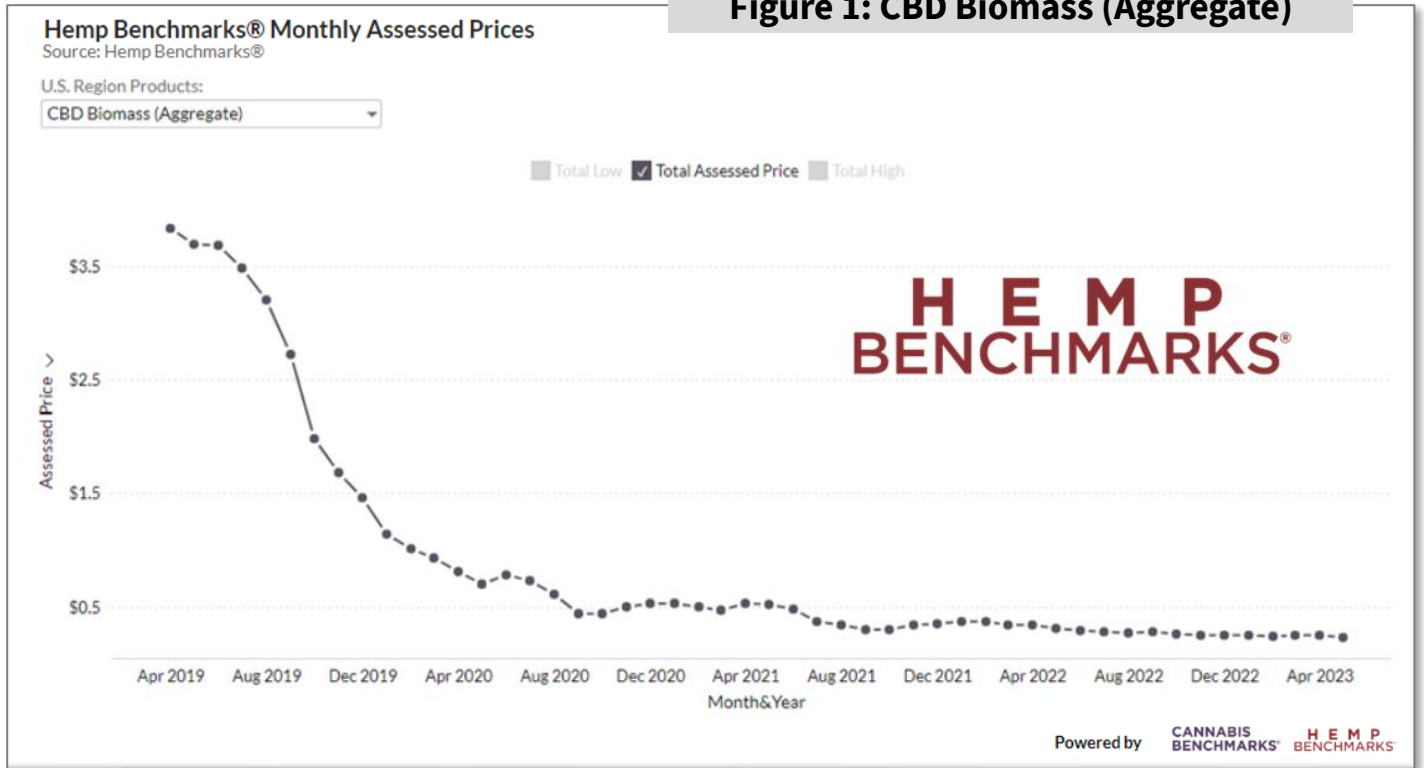
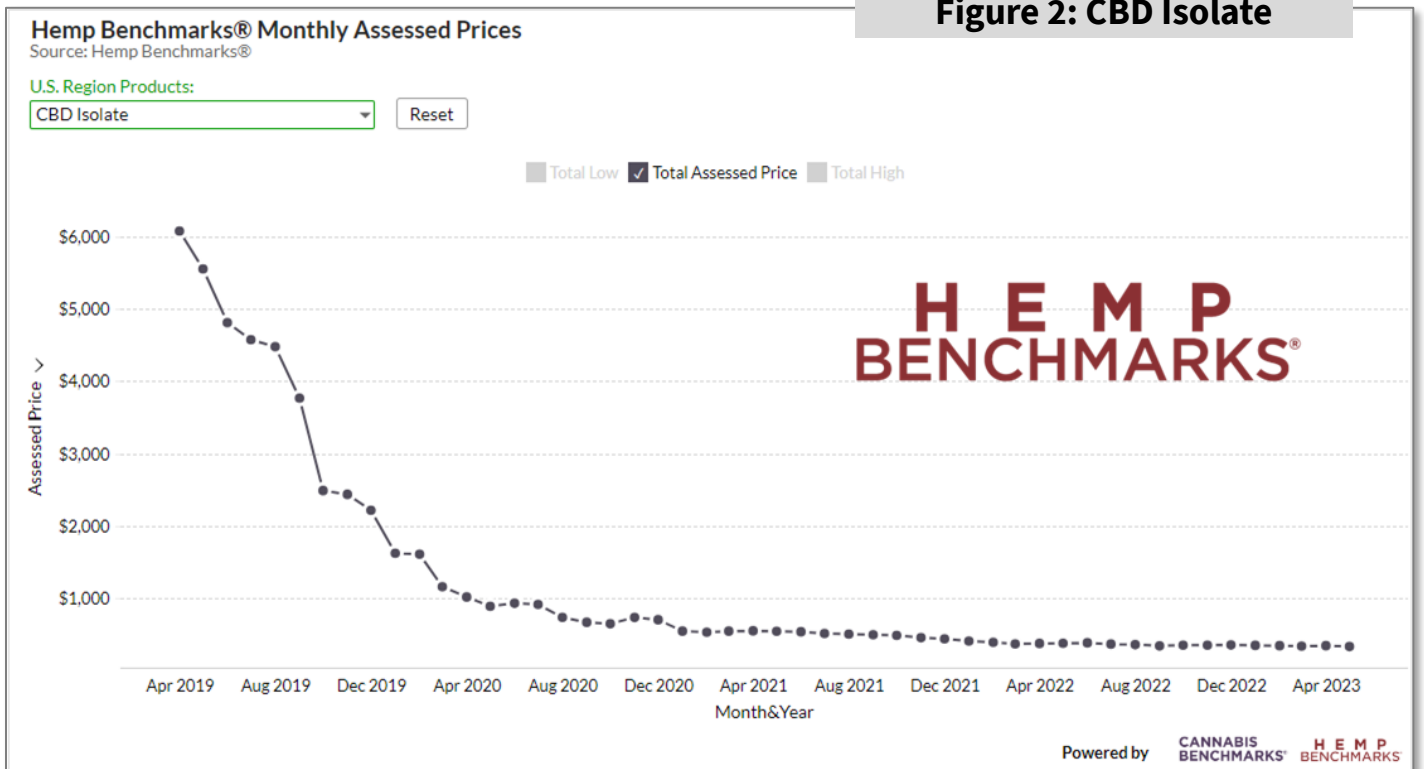


Figure 2: CBD Isolate



Hemp Pricing Data

Figure 3: Distillate – Full Spectrum

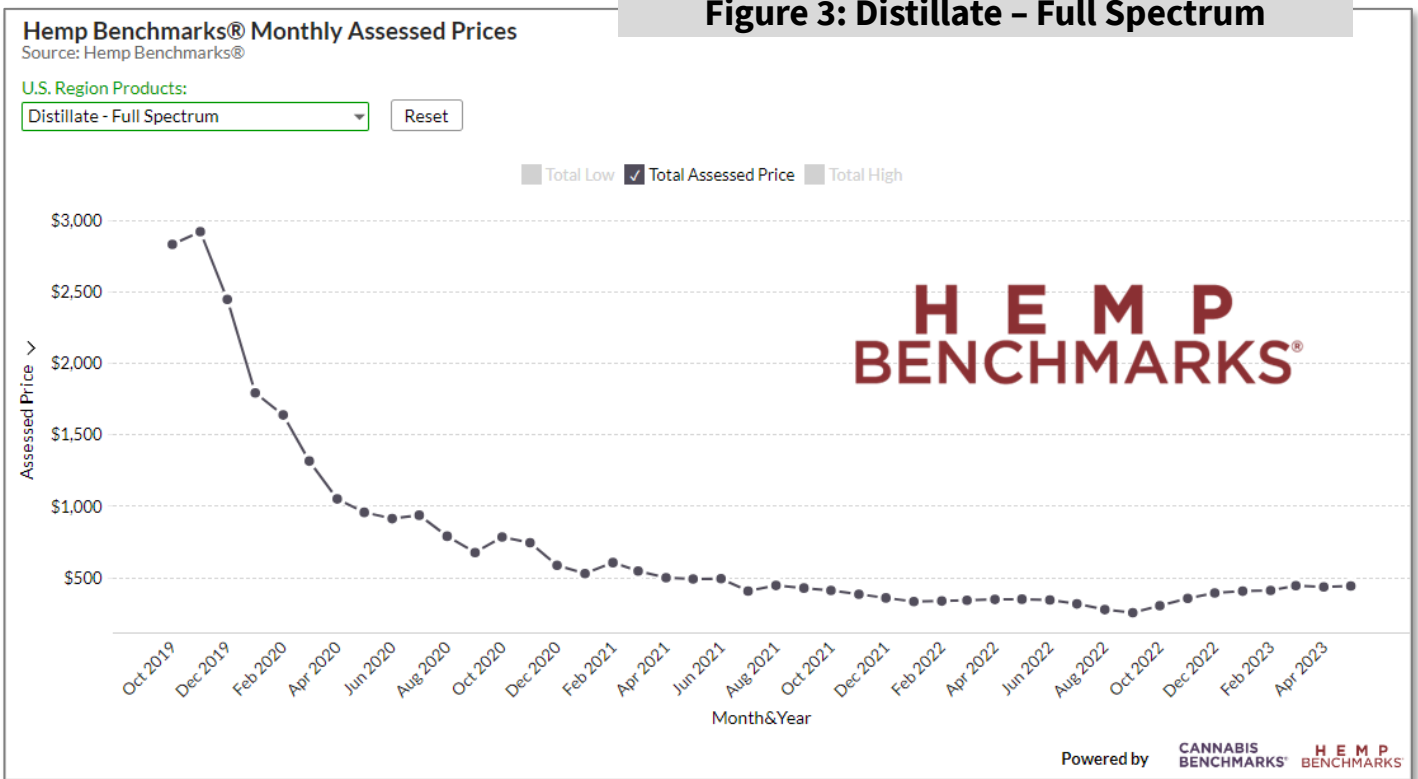
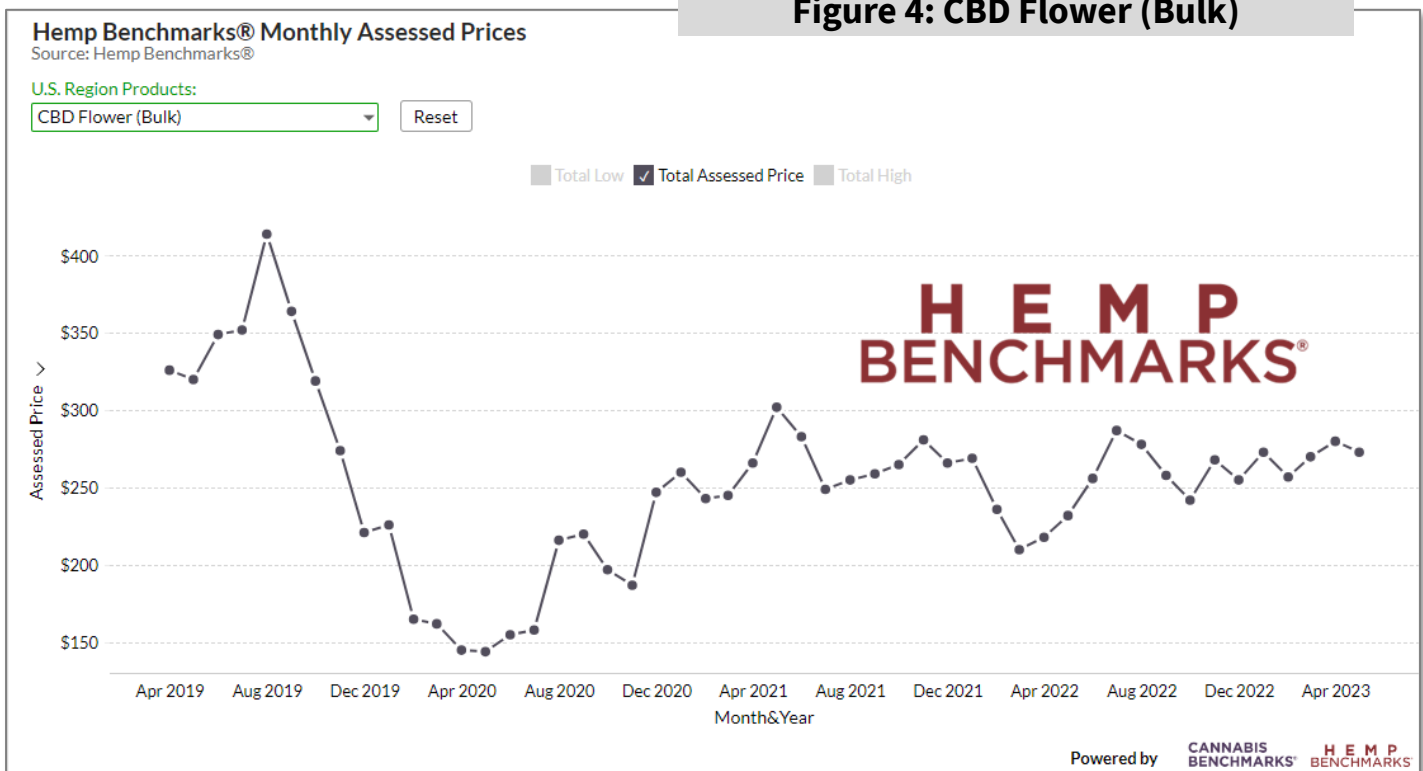


Figure 4: CBD Flower (Bulk)



Hemp Pricing Data

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

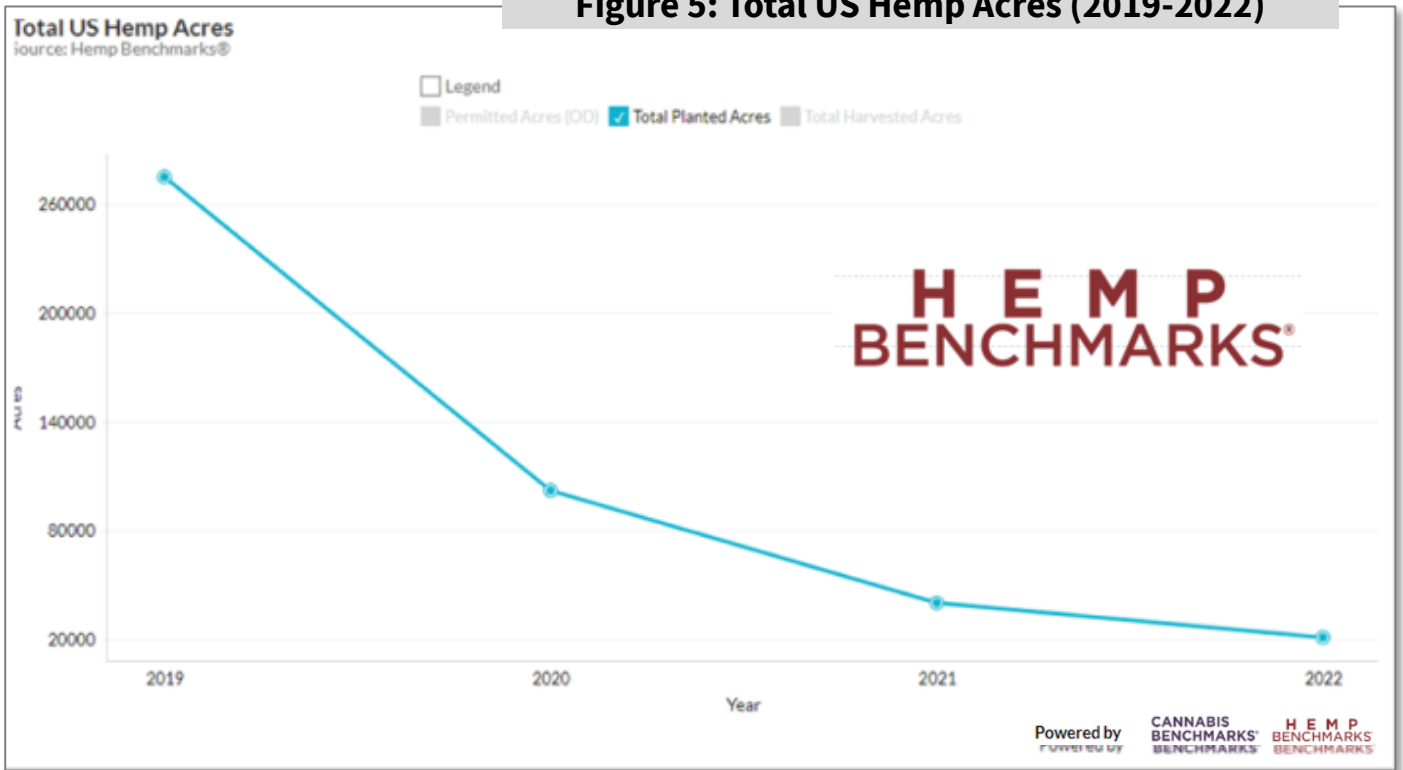
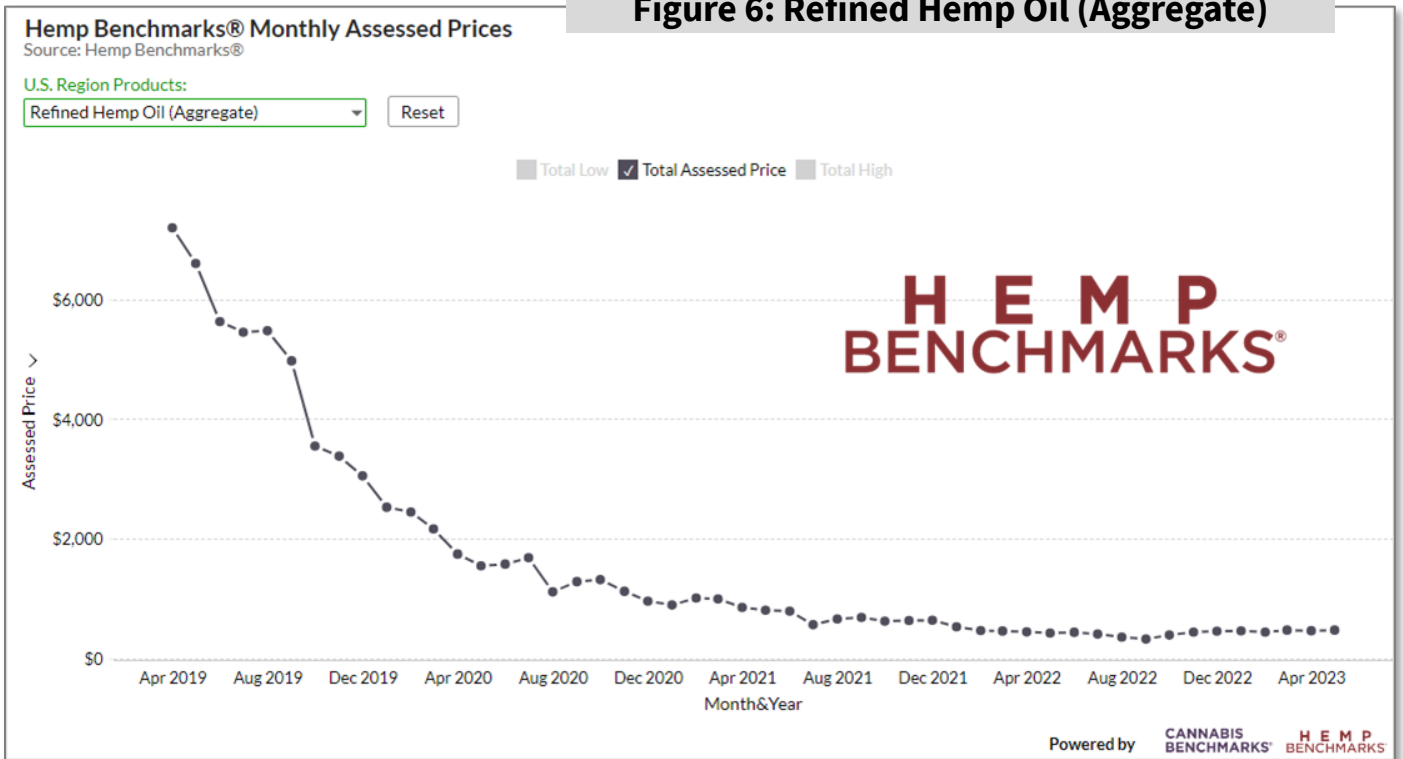


Figure 6: Refined Hemp Oil (Aggregate)



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 hazard⁵²
- 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 \(usda.gov\)](https://www.usda.gov/national-hemp-report-02-17-2022)

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 \(usda.gov\)](https://www.usda.gov/national-hemp-report-02-17-2022); compare to: [VH 2020 Crop Report final \(votehemp.com\)](https://www.votehemp.com/vh-2020-crop-report-final)

⁸ [National Hemp Report 02/17/2022 \(usda.gov\)](https://www.usda.gov/national-hemp-report-02-17-2022)

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.nytimes.com/2021/03/27/health/cannabis/delta-8-thc.html);
<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>

¹⁸ <https://mobylyft.com/blog/how-to-advertise-cbd-on-facebook-and-instagram/>

¹⁹ <https://www.classaction.org/media/fausett-et-al-v-koi-cbd-llc.pdf>; <https://www.classaction.org/media/dasilva-v-infinite-product-company-llc.pdf>

²⁰ <https://www.courtlistener.com/docket/17027232/third-wave-farms-llc-v-pure-valley-solutions-llc/>

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... \(hempsupporter.com\)](#).

³¹ See e.g., self-GRAS affirmations from Charlotte’s Web (<https://www.prnewswire.com/news-releases/charlottes-web-achieves-self-affirmed-gras-status-301025721.html>); CV Sciences (<https://ir.cvsciences.com/press-releases/detail/85/cv-science-inc-achieves-industrys-first-hemp-extract>); and Manitoba Harvest ([https://www.prnewswire.com/news-releases/manitoba-harvest-announces-broad-spectrum-hemp-extract-self-affirmed-gras-status-300858631.html#:~:text=MINNEAPOLIS%2C%20May%2031%2C%202019%20%2F,Recognized%20as%20Safe%20\(GRAS\)](https://www.prnewswire.com/news-releases/manitoba-harvest-announces-broad-spectrum-hemp-extract-self-affirmed-gras-status-300858631.html#:~:text=MINNEAPOLIS%2C%20May%2031%2C%202019%20%2F,Recognized%20as%20Safe%20(GRAS)))

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](#)
- ³⁹ <https://jamanetwork.com/journals/jama/fullarticle/2661569>; (Only 30% of tested CBD products accurately labeled.); <https://www.marijuanamoment.net/fda-notifies-public-about-recall-of-cbd-product-that-tested-high-for-lead/> (Florida regulators prompt national recall of CBD product that tested high for lead.)
- 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](#)
- ⁴² [CBD: FDA Impact & the Path Forward \(brightfieldgroup.com\)](#)
- ⁴³ <https://hempsupporter.com/assets/uploads/cowen2020report.pdf>; See also <https://www.marketsandmarkets.com/Market-Reports/industrial-hemp-market-84188417.html> (“The industrial hemp market is projected to grow from USD 4.6 billion in 2019 to USD 26.6 billion by 2025...The food segment is projected to account for the largest market share in the industrial hemp market during the forecast period.”); <https://bdsa.com/u-s-cbd-market-anticipated-to-reach-20-billion-in-sales-by-2024/> (US sales of “CBD products to surge from \$1.9 billion in 2018 to \$20 billion by 2024...majority of CBD product sales will soon occur in general retail stores.”)
- ⁴⁴ [POLITICO Pro | Newsletter](#)
- ⁴⁵ <https://www.forbes.com/sites/janellelassalle/2019/09/11/why-cbg-cannabigerol-expensive-produce/#2881d972f771>
- ⁴⁶ <https://www.cannabisbusinesstimes.com/article/projections-us-leads-in-global-hemp-cultivation/>
- ⁴⁷ [How Much Does Epidiolex Cost? \(The Cost May Shock You\) - Nature by Science](#)
- ⁴⁸ [History and overview of DSHEA - PubMed \(nih.gov\)](#)
- ⁴⁹ <https://ushempauthority.org/>
- ⁵⁰ An Assessment of the Genotoxicity and Subchronic Toxicity of a Supercritical Fluid Extract of the Aerial Parts of Hemp (2018), <https://doi.org/10.1155/2018/8143582>; Safety Assessment of a Hemp Extract using Genotoxicity and Oral Repeat-Dose Toxicity Studies in Sprague-Dawley Rats (2020), <https://doi.org/10.1016/j.toxrep.2020.02.014>; Toxicological safety of VOHO Hemp Oil; a supercritical fluid extract from the aerial parts of hemp (2022), <https://doi.org/10.1371/journal.pone.0261900>
- ⁵¹ Oral toxicity evaluation of cannabidiol (2023), <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>.
- ⁵² Genotoxicity evaluation of cannabidiol (2023), <https://doi.org/10.1016/j.yrtph.2023.105425>.
- ⁵³ Citizen Petition from Daniel Fabricant, Ph.D. on behalf of Natural Products Association, Docket No. FDA-2022-P-0600, <https://www.npanational.org/wp-content/uploads/2022/02/CBD-CP-on-CBD.pdf>.
- ⁵⁴ Presented confidentially to FDA. Pregnant women were excluded from the studies.
- ⁵⁵ Observed Impact of Long-term Consumption of Oral Cannabidiol on Liver Function in Healthy Adults (2021), <https://www.liebertpub.com/doi/10.1089/can.2021.0114>.
- ⁵⁶ <https://hempsupporter.com/news/new-study-demonstrates-cbds-strong-safety-profile-amplifies-calls-for-fda-regulation>.
- ⁵⁷ The Safety and Effectiveness of Commercially Available Cannabidiol Products for Health and Well-Being: A Randomized, Multi-Arm, Open-Label Waitlist-Controlled Trial (2022), <https://doi.org/10.1089/imr.2022.0081>.

1 AN ACT relating to the regulation of hemp-derived products.

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

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

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

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

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

21 WHEREAS, since delta-8 THC is a cannabinoid, 902 KAR 45:190 applies to delta-
22 8 THC products and application of this administrative regulation to delta-8 THC products
23 will ensure the safety of those purchasing and consuming those products and establish a
24 regulatory framework that in the future may be applied to medical cannabis if approved
25 by the Kentucky General Assembly; and

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

1 sold in Kentucky under 902 KAR 45:190; and

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

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

12 NOW, THEREFORE,

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

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

17 (2) As used in this section:

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

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

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

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

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

- 1 (c) Prohibits the possession of covered products by a person who has not reached
2 the age of 21 years;
- 3 (d) Requires retailers to keep covered products behind the counter in order to
4 prevent theft or easy access by children;
- 5 (e) Establishes a laboratory testing and approval process for contaminants and
6 phytochemicals of a covered product;
- 7 (f) Prohibits a covered product to be sold or distributed in the Commonwealth
8 unless it has been approved under paragraph (e) of this subsection;
- 9 (g) Requires each covered product manufactured, marketed, sold, or distributed in
10 the Commonwealth to be packaged and labeled in accordance with KRS 217.037;
- 11 (h) Except as established in paragraph (i) of this section, requires that a covered
12 product's label include, in a print no less than six point font, the following information:
- 13 1. A statement of identity or common product name on the principal display
14 panel of the label;
- 15 2. The net quantity of contents expressed in both standard English and metric
16 units of measurement, located in the lower 30 percent of the principal display panel of the
17 label parallel to the base of the container;
- 18 3. The ingredients of the product, in descending order of predominance by
19 weight;
- 20 4. The name of the manufacturer or distributor;
- 21 5. The total amount of each cannabinoid per serving for ingestible products, or
22 the total amount per container for cosmetic products;
- 23 6. Suggested use instructions or directions, including serving sizes; and
- 24 7. An expiration date, if any;
- 25 (i) Requires an ingestible or cosmetic covered product that has a total area of 12
26 square inches or less to bear labeling in accordance with paragraph (h) of this subsection,
27 except the print may be smaller than six point font but not less than 1/32 of an inch in

1 height;

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

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

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

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

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