

ENDORSED BY INDUSTRY LEADERS:



H.R. 8179: THE HEMP AND HEMP-DERIVED CBD CONSUMER PROTECTION AND MARKET STABILIZATION ACT OF 2020

When Congress passed the 2018 Farm Bill, it explicitly legalized the sale of hemp and its derivatives such as CBD. 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 is immediate processing infrastructure and consumer demand: hemp-derived CBD and cannabinoids.

Unfortunately, **regulatory uncertainty** regarding the legality of hemp-derived CBD has started to dismantle the up-and-coming market, limiting demand from the manufacturing sector, and resulting in a sharp decline in hemp prices and economic hardship for hemp farmers. While the FDA has recognized the significant public interest in CBD, the agency has not yet established a legal pathway for its sale.

At the same time, a multitude of CBD products continue to be sold, some of which raise significant **quality, safety and other consumer protection concerns**, since FDA is not, for the most part, ensuring these products' compliance with the federal regulations that apply to dietary supplements.

H. R. 8179 would ensure that hemp-derived CBD, and other non-intoxicating hemp ingredients, could be lawfully marketed as dietary supplements. This would also require CBD products and hemp extract product manufacturers to comply with the entire existing comprehensive regulatory framework for dietary supplements, which ensures that the products are deemed safe, properly labeled and prepared utilizing Good Manufacturing Practices.

Failing to establish a regulatory pathway for legalizing hemp-derived CBD will continue to reduce economic opportunity for U.S. hemp farmers and deny consumers access to safe, quality products. H.R. 8179 would **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.

Once FDA does legally recognize and regulate CBD products, the hemp industry can 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 surveys predict that with a regulatory

pathway, sales of CBD products would grow from approximately \$1.2 billion in 2019 to anywhere from \$10.3 billion to \$16.8 billion market by 2025.

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Congress of the United States
Washington, DC 20515

COSPONSOR HR 8179, The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020

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Dear Colleague:

We are writing to ask for your support of HR 8179, *The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020*.

When we passed the 2018 Farm Bill, Congress explicitly legalized the sale of hemp and its derivatives such as cannabidiol (CBD).

Farmers across the nation relied on this government action, and invested considerable time and resources to plant, grow, and market commercial hemp crops, particularly where there is immediate processing infrastructure and consumer demand for hemp-derived CBD and cannabinoids.

Unfortunately, regulatory uncertainty about the legality of hemp-derived CBD has limited demand from the manufacturing sector, resulting in a sharp decline in hemp prices, economic hardship for hemp farmers, and job loss.

Specifically, while the FDA has recognized the significant public interest in CBD, the agency has not yet acted to establish a legal pathway for its sale. Meanwhile, a multitude of products continue to be sold, some of which raise significant quality, safety and other consumer protection concerns, since FDA is not, for the most part, ensuring these products' compliance with the federal regulations that apply to dietary supplements.

Congress must take action to allow American consumers the ability to purchase safe, legal dietary supplements containing hemp and hemp-derived CBD. In so doing, we would help stabilize the hemp markets, open up a promising economic opportunity for U.S. agriculture and workers, and honor our commitment made to farmers in the 2018 Farm Bill.

The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020 would ensure that hemp-derived CBD, and other hemp ingredients – that necessarily contain less

than 0.3% THC, the psychoactive compound found in cannabis -- could be lawfully marketed as dietary supplements. Significantly, it would also require CBD and hemp extract product manufacturers to comply with the entire existing comprehensive regulatory framework for dietary supplements, so that consumers would be assured that the products they consume are safe, properly labeled and prepared with Good Manufacturing Practices.

Today's regulatory uncertainty has both impaired economic opportunity for U.S. hemp farmers and their employees and denied access to safe, quality products to U.S. consumers. The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020 would represent a boon for American agriculture and jobs and the provision of trusted products to the CBD marketplace.

We would appreciate your cosponsorship and your support for this important legislation. For more information, or to sign on as a cosponsor, please contact Chris Huckleberry with Rep. Schrader at huck@mail.house.gov or Emily Mace with Rep. Griffith at Emily.Mace@mail.house.gov.

Sincerely,



KURT SCHRADER
Member of Congress



MORGAN GRIFFITH
Member of Congress

U.S. HEMP ROUNDTABLE'S REPORT TO CONGRESS: FEDERAL REGULATION NEEDED URGENTLY TO HONOR COMMITMENT TO U.S. HEMP FARMERS

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.¹ Thousands of U.S. growers planted hemp in response, with farming for CBD representing the overwhelming majority of all hemp acreage.² However, public statements by FDA officials arguing 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 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 Big Food companies have delayed efforts to introduce new CBD-infused products into the marketplace.³
- Chilled CBD commerce has resulted in an oversupply of hemp biomass and derivative products, such as crude oil, with hemp commodity prices dropping sharply, adversely impacting hemp farmers. Data from three independent reporting agencies reveals that aggregate prices for hemp CBD biomass, crude oil and seeds have declined between 75-125% since June 2019.⁴ (See Figures 1-4). This is happening at the same time as a surge in farm bankruptcies.⁵ Many farmers who plan to add hemp into their crop rotation are suffering greatly from the coronavirus pandemic's damage wrought on other commodities.
- The COVID-19 crisis also looms heavy on farmers producing hemp. From January to August, during the height of pandemic disruption, aggregate prices for hemp CBD biomass, crude oil and seeds have dropped between 45-94%. (See Figure 3). While hemp farmers recently were finally deemed eligible by the USDA for Coronavirus Food Assistance Program funds in September, the benefits are much less generous than most other crops, paying only \$15/acre of 2020 crops.⁶ Though online sales of CBD appear to have ticked upwards, total sales have declined due to the pandemic, and disruptions in labor and transportation are expected to exacerbate this trend.⁷
- At least three major hemp companies have filed for bankruptcy, including Atalo Holdings⁸, GenCanna Global⁹, and Elemental Processing.¹⁰ 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.¹¹
- 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 significantly; there has been a "precipitous decline" in hemp-related M&A deals.¹²
- 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.¹³
- There is also a disturbing trend in hemp-related litigation across the country. More than a dozen class action lawsuits regarding CBD have been filed, citing FDA's public statements as grounds for injury.¹⁴ Even more cases have been brought by farmers against processors for non-payment and breaching hemp contracts.¹⁵ These lawsuits are tying up cash, disrupting business operations and supply chains, and unduly burdening the civil legal system.

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- 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 and Senator Ron Wyden have each urged FDA to take expedited action,¹⁶ while Kentucky Commissioner of Agriculture Ryan Quarles has insisted that FDA end its “bureaucratic paralysis.” 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.”¹⁷ FDA is acutely aware. 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.”¹⁸ Current FDA Commissioner Stephen Hahn stated it would be a “fool’s game” to try to completely shut down the CBD marketplace.¹⁹

REGULATION MEANS SAFETY: FDA 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 generally safe.²⁰ Scientific experts have recognized that data already exists to determine that hemp extracts containing CBD can be Generally Recognized as Safe (GRAS).²¹ And despite a notable increase in the use of these products, the number of reported adverse events continues to be remarkably low.²²
- 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.²³ Australia’s Therapeutic Goods Administration concluded that CBD “presents a good safety and tolerability profile at the low dose range of under 60mg/day.”²⁴ 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.²⁵
- The most pressing safety problem is, as independent studies demonstrate,²⁶ and as FDA recently reported to Congress,²⁷ without a clear regulatory framework, bad actors are selling products without appropriate safeguards, and misleading consumers with false label claims.

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:

- One economic survey predicts that “widespread, easy access to CBD products at traditional retail outlets will drive a surge in CBD sales,” projecting sales to grow from approximately \$1.2 billion in 2019 to \$10.3 billion by 2024.²⁸ Another study estimates a \$16.8 billion market by 2025, should FDA create a regulatory pathway for ingestible CBD, lowering previous projections because “inaction by US FDA is constraining the growth of the US CBD market.”²⁹ A third analysis projected a CBD sales range of \$4 billion to \$16.5 billion by 2025, the higher end dependent on favorable FDA regulations.³⁰ 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.³¹
- 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 struggling through the pandemic. One economic study forecasted that hemp sown for CBD could potentially generate substantially more revenue per acre than corn.³² 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.

- A partnership in which FDA regulation is complemented by industry initiatives such as U.S. Hemp Authority self-regulation³³ also helps ensure that consumers can purchase safe, transparent, quality-assured products.

2020 HEMP PRICING DATA

HEMP BENCHMARKS®

U.S Wholesale Hemp Price Benchmarks

May 2020

June 2020

Year on Year Price % Change: May 2019 to May 2020

June 2019 to June 2020

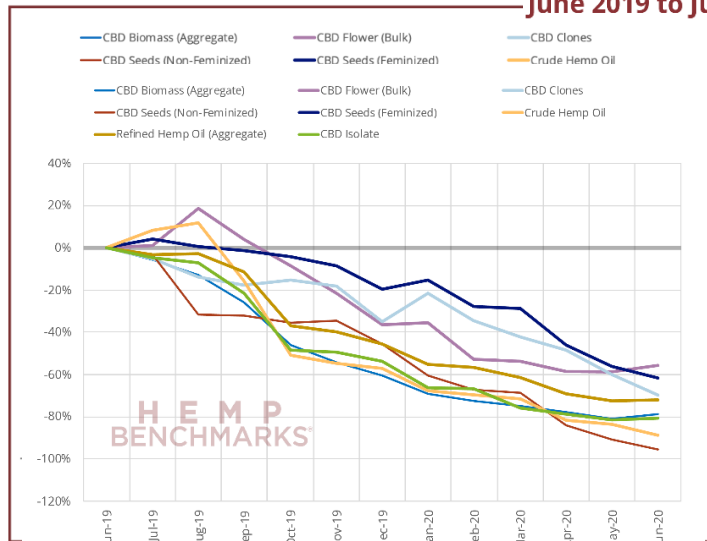


Figure 1 : Hemp Benchmarks®

This chart illustrates the dramatic erosion in wholesale prices in the U.S. hemp market over the past year. It also reinforces the data illustrated in the Correlation Matrix, on page 6, which has consistently shown that price movement in the hemp-CBD supply chain is strongly correlated. The major exception is the price for smokable CBD Flower, which rose through last summer as demand manifested amongst consumers. However, with plentiful supply in the wake of the harvest, rates for high-CBD Flower have plunged after peaking in August 2019.

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www.hempbenchmarks.com
May 27, 2020

Hemp Biomass Pricing July 2019 to April 2020

Hemp Biomass (% CBD/lb) - West - Weekly Average



Figure 2 : The Jacobsen Publishing

2020 HEMP PRICING DATA

Hemp CBD Supply Chain: Price Change from Dec 25 2019 to August 26 2020

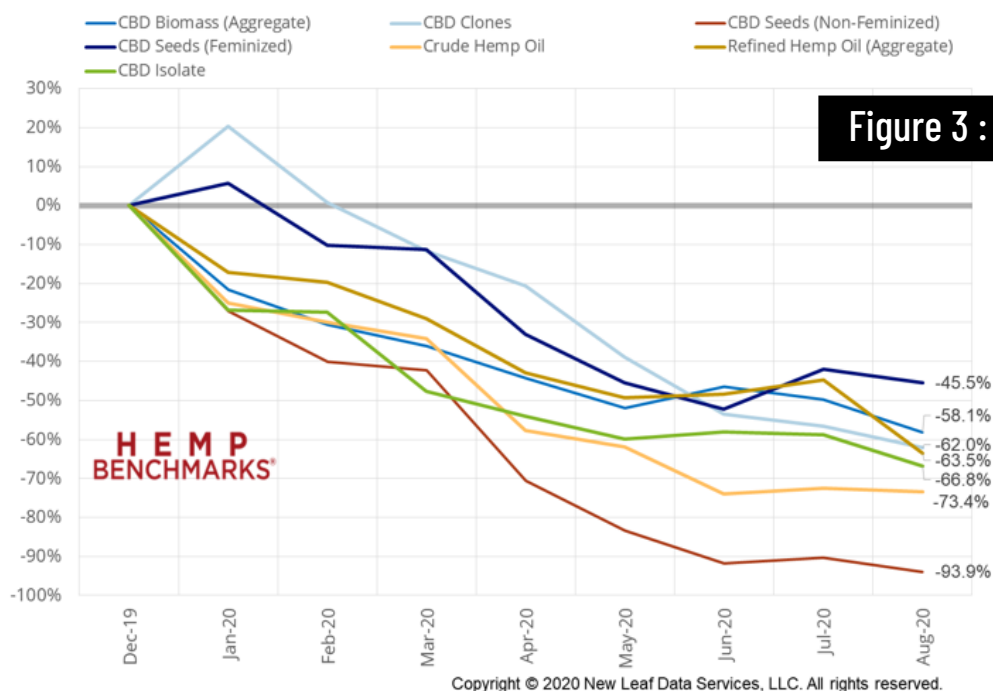
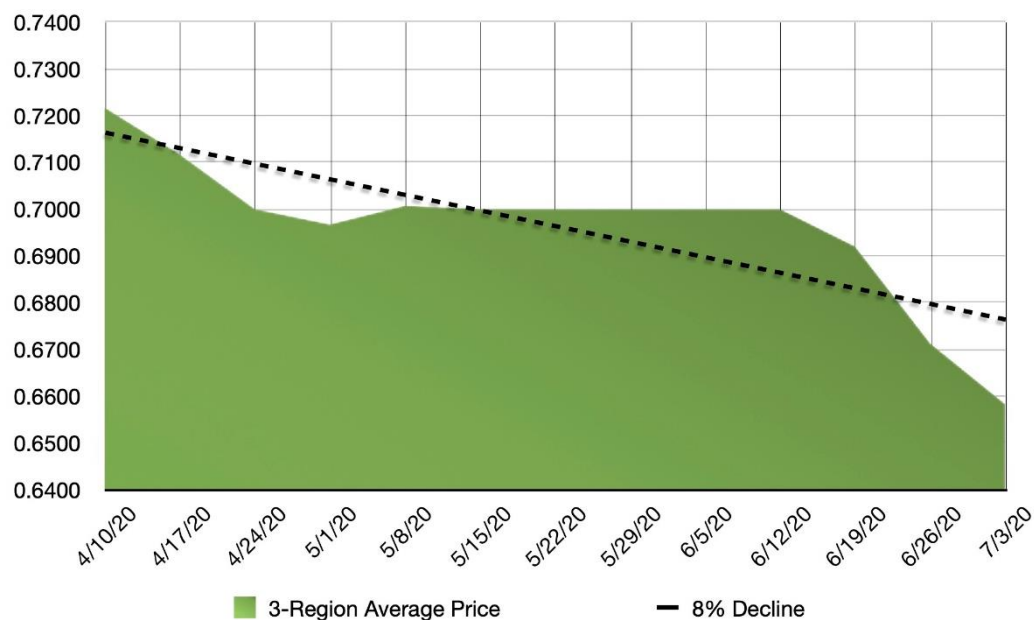


Figure 4 : The Jacobsen Publishing

CBD Biomass %CBD/lb
Averaged for All Regions



¹ <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.")

² <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.)

³ <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.")

⁴ <https://hempsupporter.com/assets/uploads/USHRHempPricingData.pdf>; <https://wfpl.org/hemp-prices-crash-leaving-ohio-valley-farmers-feeling-burned/> ("The price of CBD-rich hemp has crashed, dropping more than 75% in 6 months."); <https://www.barrons.com/articles/hemp-cbd-demand-is-poor-prices-are-falling-in-a-blow-to-farmers-51580482811> ("Piles of hemp 'biomass' sit unsold, and the price of what did sell fell 30% from December to January."); <https://www.reporterherald.com/2020/05/18/enthusiasm-leads-to-oversupply-of-hemp-in-colorado/> (Prices on hemp in Colorado have dropped from \$40/pound in Summer 2019 to \$10/pound; "The current oversupply means that there is a 'significant volume of biomass that's still in storage,' which could help keep prices down as older hemp is less valuable than a freshly harvested crop.")

⁵ <https://www.cnn.com/2019/11/02/trade-wars-climate-change-plunge-the-family-farm-into-crisis.html> ("Farm bankruptcies through September surged 24% versus the prior year...the suicide rate for farmers is 1.5 times higher than the national average.")

⁶ <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.)

⁷ <https://hempindustrydaily.com/cbd-companies-see-online-sales-spike-as-coronavirus-shuts-down-retails-shops/> (While online sales spike, major CBD manufacturers experience significant losses from 2019 to 2020); <https://www.hempbenchmarks.com/hemp-market-insider/expectations-for-2020-hemp-growing-season-shift-covid-19-impacts/> (70% of survey respondents reported April sales were "below expectations due specifically to COVID-19.")

⁸ <https://www.forbes.com/sites/davidcarpenter/2020/03/18/hemp-company-files-for-bankruptcy-as-confounding-regulatory-guidelines-hamper-growth/#417b60955794>

⁹ <https://www.winchestersun.com/2020/02/06/gencanna-files-for-chapter-11-bankruptcy/>

¹⁰ <https://hempindustrydaily.com/kentucky-extractor-elemental-processing-files-for-bankruptcy-protection/>

¹¹ <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.")

¹² <https://www.forbes.com/sites/mergermarket/2020/04/27/precipitous-decline-in-hemp-and-cannabis-ma-continuing-amid-covid-19-pandemic/#2d8825375c05>

¹³ <https://moblyft.com/blog/how-to-advertise-cbd-on-facebook-and-instagram/>

¹⁴ <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>

¹⁵ <https://www.courtlistener.com/docket/17027232/third-wave-farms-llc-v-pure-valley-solutions-llc/>

¹⁶ <https://www.marijuanamoment.net/mitch-mcconnell-talks-cbd-regulations-with-fda-head/>

¹⁷ <https://www.kyagr.com/ky-agnews/press-releases/2020/Quarles-Urges-FDA-End-Bureaucratic-Paralysis-Hemp-Regulatory-Decisions.html>

¹⁸ <https://www.naturalproductsinsider.com/ingredients/fda-commissioner-deeply-focused-cbd-issues>

¹⁹ <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>

²⁰ 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>

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- ²¹ 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-sciences-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)))
- ²² <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%).
- ²³ <https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf> <<https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>>
- ²⁴ <https://www.tga.gov.au/alert/review-safety-low-dose-cannabidiol>
- ²⁵ <https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers>;
- ²⁶ <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.)
- ²⁷ 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.")
- ²⁸ https://hempindustrydaily.com/wp-content/uploads/2019/10/Hemp-CBD-Factbook-2019-executive-summary_FINAL.pdf
- ²⁹ <https://www.foodnavigator-usa.com/Article/2020/07/28/What-s-the-size-of-the-hemp-derived-CBD-prize-Brightfield-Group-releases-new-report>
- ³⁰ <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.")
- ³¹ <https://www.forbes.com/sites/janellelassalle/2019/09/11/why-cbg-cannabigerol-expensive-produce/#2881d972f771>
- ³² <https://www.cannabisbusinesstimes.com/article/projections-us-leads-in-global-hemp-cultivation/>
- ³³ <https://ushempauthority.org/>

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