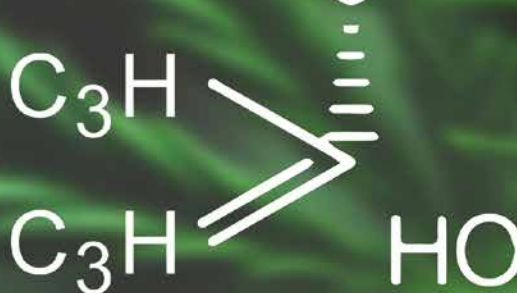




# CBD opportunity:

*Smart brands capitalize on market expansion*

2018 Farm Bill, consumer demand, safe products and product innovation



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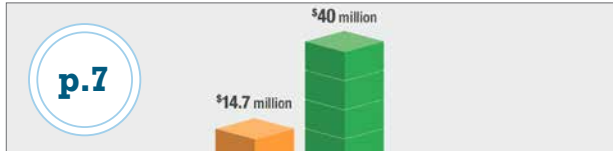






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## Charlotte's Web, Elixinol offerings reflect growing success of CBD market

**Josh Long** examines the initial public offering by Charlotte's Web and Elixinol, sales in the broader market for hemp-derived CBD and the impact of the 2018 Farm Bill.



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## CBD product trends: Market plagued with ambiguity, driven by opportunity

**Rachel Adams** breaks down product trends in the CBD market, and discovers one trend is clear: innovation is sparse.



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## CBD brands managing risk in uncertain times

One of the biggest unknowns since the passage of the 2018 Farm Bill is how states will regulate CBD and other hemp products.

**Rend Al-Mondhry** of Amin Talati Upadhye LLP offers insights into how states might react.



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## CBD and hemp products: A regulatory and marketplace analysis

FDA has maintained its position that CBD is an impermissible ingredient in food and supplements, even after the 2018 Farm Bill. Attorneys **Garrett Graff** and **Bridget Hill-Zayat** of Hoban Law Group share how FDA may change its viewpoint.



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## CBD: Why, why now and how to take advantage of market opportunity

CBD product introductions grew more than 250 percent in the past year. **Perteet Spencer**, SPINS, reviews CBD's potential to scale in mainstream channels.



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## Cannabidiol: Regulations, research & where to go next

Marijuana is recreationally legal in ten states and Washington, D.C., but CBD is legal in 43 states. **Suzy Badaracco**, Culinary Tides Inc., sheds light on market trends, clinical health research and new products.



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## CBD set to disrupt the fast-moving consumer goods market

Globally, CBD products are present in a growing variety of consumer health categories, including dietary supplements and topical analgesics. **Zora Milenkovic**, Euromonitor International, explores how manufacturers can look to add CBD to their ingredients list.



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## Hemp oil, CBD, THC regulations and sport drug testing considerations

While CBD isn't prohibited by the World Anti-Doping Agency (WADA), **Oliver Catlin** notes that other cannabinoids are, effectively banning hemp oil for many professional athletes.



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## On CBD, parachutes and more

**Blake Ebersole**, NaturPro Scientific, details how cannabis products, whether classified as marijuana or industrial hemp, are being recognized as effective front-line treatments for a range of health issues rooted in pain and inflammation.



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## Takeaways for your business

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A woman in a black tank top and blue pants is kneeling in a field of tall grass, smiling. A young child in a yellow shirt and grey pants is walking away from her. A dog is lying down in the grass. The background shows a blue sky with white clouds and a line of trees in the distance.

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## I was wrong about CBD and the ‘hemp revolution’



**Four and a half years ago, I was standing on a beach in San Diego with an impeccably dressed Chicagoan from a company then known as CannaVest.**

Stuart Tomc was convinced that cannabidiol (CBD)—at the time a little-known compound in cannabis—was going to proliferate in health food stores across the United States alongside fish oil and other natural products.

“We are standing here at the forefront of a revolution,” Tomc, currently vice president of human nutrition with CV Sciences, told me in 2014. “I’m calling it the hemp revolution.”

At the time, his spiel seemed to me unrealistic, if not downright ludicrous.

Now, consider the facts.

- In the 52 weeks that ended Sept. 9, 2018, CBD functional ingredient sales in vitamins and supplements in the natural channel grew to nearly US\$32.5 million, according to SPINS.
- The figure is up from just \$1.2 million two years earlier.
- In 2018, the market for hemp-derived CBD generated \$390 million in the United States, *Hemp Business Journal* reported.

And in 2018 alone, two prominent industry players raised tens of millions of dollars in funds from investors.

What’s more, the regulatory and legal hurdles that have plagued the industry are quickly dissipating. President Donald Trump in December signed into law the 2018 Farm Bill, which removed hemp from the Controlled Substances Act (CSA).

The same day the ink was drying on the president’s signature, FDA’s top official signaled a willingness to find a legal path to market for CBD in conventional food and dietary supplements. On Jan. 15, [U.S. senators from Oregon urged FDA to act](#), so CBD-containing food, beverage and supplement products can be sold in interstate commerce.

Hundreds of brands have emerged in response to voracious consumer demand for CBD. Brightfield Group forecasted the U.S. market for CBD will reach a whopping \$22 billion by 2022.

“CBD phytocannabinoid products are like a tsunami,” Twinlab CEO Anthony Zolezzi said in an [article](#) in this digital magazine written by my colleague, Rachel Adams, INSIDER managing editor. “They’re going to be one of the biggest opportunities the natural health space/alternative health care has ever seen.”

Turns out, we’re in the middle of a “hemp revolution.”



**Josh Long**

**Legal and Regulatory Editor**

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# Charlotte's Web: Elixinol offerings reflect growing success of CBD market

by Josh Long

## INSIDER's Take

- In 2018, two marketers of CBD-containing supplements raised tens of millions of dollars, proving institutional investors have a healthy appetite for the hemp industry.
- Revenues in the CBD industry are soaring as more U.S. retailers embrace an ingredient sourced from hemp.
- The passage of the 2018 Farm Bill adds to the industry's momentum, making it easier for hemp companies to increase business without the fear of prosecution from the federal government.



**Charlotte's Web Holdings Inc. became a public company in 2018, highlighting a milestone event in the rapidly growing cannabidiol (CBD) or "hemp extracts" market in North America.**

The company completed an initial public offering (IPO) in Canada that raised net proceeds of US\$71.5 million. The funds will support the distributor's growth in the hemp-based CBD sector, including its planned international expansion.

The "Stanley Brothers"—a group of brothers behind Charlotte's Web—first ventured into "marijuana when they began researching alternative cancer treatments after their uncle was diagnosed with pancreatic cancer in 2008," according to their website. In 2011, the Stanley Brothers met Paige Figi, whose young daughter Charlotte suffered from a rare and severe form of epilepsy called Dravet syndrome. Charlotte found relief through the use of a strain of medical cannabis developed by the men—one high in CBD and low in tetrahydrocannabinol (THC), the psychoactive compound in marijuana.

Charlotte's story was recounted by the American neurosurgeon and journalist Sanjay Gupta in a 2013 CNN documentary that raised consumer awareness of CBD.

Charlotte's Web (CSE: CWEB) is considered a market leader in the CBD space whose sales in recent years highlight the industry's rapid growth. The Boulder, Colorado-based business reported \$40 million in 2017 revenues, year-over-year growth of 172 percent from 2016 (\$14.7 million).

Its momentum carried into 2018. Through the first nine months of 2018, Charlotte's Web posted net income of \$8.7 million on revenues of \$48 million. Those figures are up from net income of \$5.1 million on revenues of \$27.5 million in the nine months that ended Sept. 30, 2017.



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Charlotte's Web has global ambitions. In its prospectus filed with securities authorities in Canada prior to its IPO, Charlotte's Web described global distribution as "paramount to its growth in the next 24 months, with near-term focus on the European Union, South America and Asia.

"To achieve this international reach, [Charlotte's Web] ... is planning to either partner with distributors and/or manufacturers in these international locations or create its own foreign licensed subsidiaries to transact business in these regions," the company disclosed. Charlotte's Web said it anticipates making final decisions regarding "its proposed international expansion once its regulatory review of potential jurisdictions is complete."

Charlotte's Web isn't the only CBD-based company that attracted investors in 2018. Enter Elixinol Global Limited (ASX: EXL). In September, the Sydney-based company announced raising 40 million Australian dollars (US\$28.7 million) in a secondary offering.

Todd Harrison, founding partner and chief investment officer of the hedge fund CB1 Capital, suggested Australia is among the countries where cannabis sales will proliferate.

"Australia is going to be a monster in the southern hemisphere," the Wall Street veteran said in an interview. "It's just early."

Elixinol also has a foothold in the United States. Its businesses include Elixinol USA, a Broomfield, Colorado-based manufacturer and global distributor of hemp-based dietary supplement and skin care products founded in 2014.

**"Hemp CBD-based supplements are now more popular than ever as people from all walks of life are experiencing the benefits."**

— Paul Benhaim, CEO, Elixinol Global



Part of the funds raised by Elixinol will be applied toward boosting the capacity of its hemp-derived CBD U.S. production facility to prepare for growing demand. The company also said it would increase its sales force and marketing efforts in Europe and the United States. And in Australia, Elixinol plans to use funds from the investment offering to build a medical cannabis facility following receipt of a license from a government agency.

"Hemp CBD-based supplements are now more popular than ever as people from all walks of life are experiencing the benefits and positive effects these products offer," Elixinol Global CEO Paul Benhaim said in an email through a spokesperson. "With supportive legislation being implemented both in the [United States] and globally, consumers are more easily able to access these products."



Alan Brochstein is a financial analyst who tracks the cannabis industry and he founded 420 Investor, an online resource that describes itself as “the go-to community for investors to learn, explore and profit from the marijuana companies.” He has been closely following public companies that sell CBD, including Charlotte’s Web, CV Sciences Inc. (OTCQB: CVSI) and Elixinol.

Commenting on the funds raised by Charlotte’s Web and Elixinol Global, Brochstein said, “It ... tells you the investment mindset about the space and the maturation of it. Nobody was raising money like that a few years ago.”

### Increasing distribution

In an interview, Brochstein described as “extremely impressive” various metrics reported by CBD companies that he’s tracked, including revenues and the number of stores where CBD products are sold.

Consider CBD’s increasing presence on retail store shelves. In the 52 weeks that ended Sept. 9, 2018, CBD functional ingredient sales in vitamins and supplements in the natural channel grew to nearly \$32.5 million, according to SPINS, a Chicago-based provider of retail consumer insights, analytics reporting and consulting services for the natural, organic and specialty products industry.

Sales for the latter 52-week period were up 433.5 percent from the previous year (roughly \$6.1 million), according to SPINS data obtained by INSIDER. For the 52 weeks that ended Sept. 11, 2016, sales only totaled \$1.2 million, the data showed.

Kimberly Kawa, retail reporting analyst with SPINS, said many factors likely have contributed to the strong demand for CBD and hemp extracts in the United States, and the retail market specifically, including potentially “an increased consumer interest in personalized nutrition and self-care.”

In an email, the analyst wrote, “CBD and cannabinoids have been highly publicized.” She added, “There is abundant research on potential benefits, and it’s all at our fingertips in this digital age.”

In October, Charlotte’s Web divulged its products are sold in more than 3,000 retail locations across the United States. That’s up from around 2,000 locations at the end of 2017. As of Sep. 30, 2018, CV Sciences increased its retail channel distribution to 2,093 stores, a 6 percent quarterly sequential increase over its retail count in the second quarter of 2018 (1,968).

### Blazing sales and the Farm Bill

CV Sciences’ increasing retail presence has contributed to its skyrocketing sales. Through the first nine months of 2018, the company generated net income of \$7.1 million on product sales of \$34 million. During the same period in 2017, CV Sciences posted a net loss of roughly \$5.4 million on sales of \$13.4 million.

The broader market for hemp-derived CBD sales has flourished. It increased from \$174 million in 2016 to an estimated \$590 million in 2018, Bethany Gomez, research director for the Chicago-based Brightfield Group, a market research firm, told the *Atlanta Journal-Constitution* in an article the newspaper published in August.

Sean Murphy, founder of *Hemp Business Journal*, reported more conservative figures than Brightfield Group. In an email, he stated the hemp-derived CBD market generated \$390 million for 2018 in the United States. *Hemp Business Journal* is projecting \$1.4 billion in sales in 2022, just a fraction of Brightfield Group's forecast: a whopping \$22 billion.

### The hemp-derived CBD market U.S. projected sales, 2022



Murphy said one could reasonably argue the market will generate between \$1.5 billion and \$3 billion by 2022 depending on various factors, including what happens with FDA.

The government agency has opined CBD cannot be sold in dietary supplements and conventional food because, in a nutshell, it was first studied as a drug. However, FDA is considering whether to pursue issuance of a regulation that would authorize the use of CBD in food and supplements, its commissioner disclosed in December.

Adding to the industry's momentum: the 2018 Farm Bill, which removed hemp from the Controlled Substances Act (CSA). President Donald Trump signed the bill in December.

*(Editor's note: For more information on FDA regulations and the Farm Bill, read the article (page 21) in INSIDER's CBD digital magazine written by Rend Al-Mondhiry, "CBD brands managing risks in uncertain times.")*

The new law is expected to attract institutional investors and make it easier for businesses like credit card merchants and advertisers to forge relationships with the hemp industry without the fear of prosecution from the federal government.



## Adding to the industry's momentum: the 2018 Farm Bill, which removed hemp from the Controlled Substances Act (CSA).

"Charlotte's Web can now pursue relationships with federally regulated institutions such as banks, credit card companies, e-commerce marketplaces and advertising platforms in ways not previously accessible," Hess Moallem, president and CEO of Charlotte's Web, said in a statement commenting on the Farm Bill.



Patrick Rea is co-founder and CEO of CanopyBoulder, a seed-stage business accelerator and venture fund for ancillary cannabis start-ups. He suggested the 2018 Farm Bill has the potential to be a “game-changing event for the hemp and the CBD space,” spurring an influx of investment like what occurred following the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA).

In a late October interview before the Farm Bill was passed, when asked what might result from passage of the Farm Bill, Rea replied, “Institutional capital that has stayed away from hemp, CBD and cannabis would be unleashed.”

“Hemp’s removal from the CSA has been a core legal requirement for many national retailers wanting to carry whole-plant hemp extracts,” Moallem added in his statement on the Farm Bill. “Removing the social stigma linked with being a ‘controlled substance’ and having the ability to attain organic certification under the USDA will help to grow consumer acceptance.”


### **‘Phenomenal branding’**

Murphy credited Charlotte’s Web with “phenomenal branding and capitalizing on really being the first to market.” The company did not respond to a request for comment for this article.

Since Charlotte’s Web’s inception, hundreds of brands have entered the market. An estimated 750 brands are in the hemp-derived CBD business, according to a market assessment by Boulder, Colorado-based brand Functional Remedies.

In its prospectus, Charlotte’s Web described the hemp-derived supplements category as “extremely fragmented, with more than 200 brands, each capturing insignificant market share in 2016.” Charlotte’s Web reported that was the year it commanded 8 percent of reported category sales, leading the market based on a report by Brightfield Group. Charlotte’s Web noted its share grew to 14 percent the next year based on its 2017 revenues in an estimated \$287 million hemp CBD market.

The company is hungry to capture additional market share in 2019. Eugenio Mendez, a former executive with The Coca-Cola Co., recently joined Charlotte’s Web in the newly created role of “chief growth officer.”

He will lead business development, marketing and sales functions as Charlotte’s Web eyes global expansion in a rapidly evolving industry filled with promise. 



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# CBD product trends: Market plagued with ambiguity, driven by opportunity

by Rachel Adams



## INSIDER's take

- Negligible-THC, high-CBD products derived from marijuana are not the same as those derived from hemp.
- CBD products may contain CBD isolates or full-spectrum hemp extracts, but the two are not equals.
- Some product innovations feature CBD derived from sources other than hemp.

**Looking to the market for cannabidiol (CBD)-related products, one thing stands out, per Anthony Zolezzi, CEO of Twinlab: Ingenuity is sparse.**

“I don’t see much innovation in the CBD category,” he said. “I see what’s easily done in a distillation facility, like oil. If you look, really, almost everything is tinctures of oil.”

What’s plentiful in this budding category (pun intended), however, is ambiguity.

What’s the best plant source of endocannabinoids like CBD? What’s the best (and legally compliant) ingredient form—a full-spectrum extract or an isolate? What’s the effective dose? Which delivery forms are most effective?

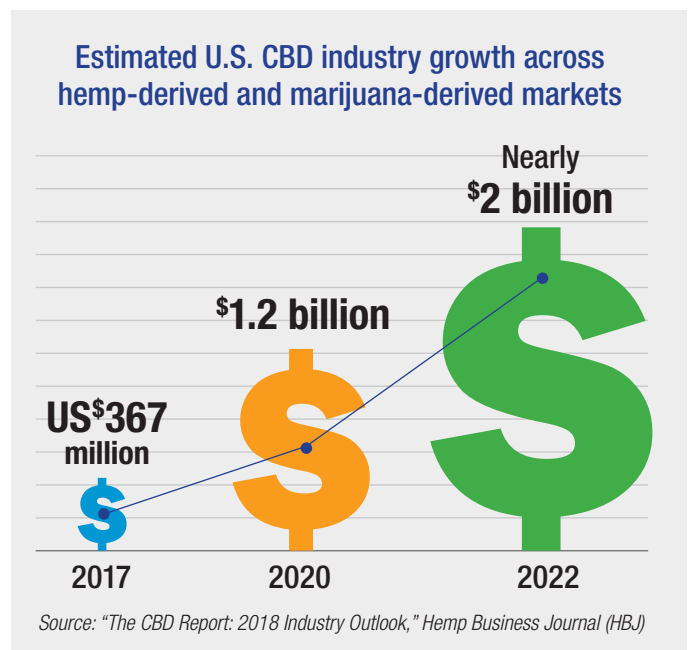
And, what about hemp versus marijuana? As long as the content of tetrahydrocannabinol (THC)—the psychoactive compound in cannabis—is low and CBD content is high, it’s all the same, right? (Hint: Wrong.)

Yet, the market for CBD-related products is booming.

Per “The CBD Report: 2018 Industry Outlook,” *Hemp Business Journal (HBJ)* estimated the U.S. CBD industry grew by nearly 40 percent in 2017 to reach a total market size of US\$367 million in sales across hemp-derived and marijuana-derived markets, and is predicted to grow to \$1.2 billion by 2020, and nearly \$2 billion by 2022.

2017 marked the first year, per *HBJ*, that sales of hemp-derived CBD products outpaced marijuana-derived CBD products, evidence of yet another plentiful component of the market for CBD-related products: opportunity.

“CBD phytocannabinoid products are like a tsunami,” Zolezzi said. “They’re going to be one of the biggest opportunities the natural




health space/alternative health care has ever seen.” But to realize the potential of such products, “we can’t do it cutting corners, sprinkling other ingredients in, [and] not doing dose-verified products.”

For this reason, Twinlab, along with other industry leaders, is allocating time and resources to develop a foundation of science, compliance and safety to not only seize the dynamic opportunity hitting the market today, but to answer the tough questions that can lead to market longevity and continued success.

### ‘Who’s your mama?’

The passage of the Farm Bill in 2018 legalized growth and production of hemp and paved the way for the natural products industry to legally produce and sell hemp-containing products, given the products contain not more than 0.3 percent THC.

However, the CBD category contains both hemp- and marijuana-derived CBD-containing products. In fact, some marijuana-derived CBD products contain high amounts of CBD with negligible amounts of THC, making these products similar to hemp-derived CBD products, and thus, creating confusion within the marketplace.



**Marijuana-derived products, unlike hemp-derived products, cannot be sold in mass market or natural retail channels, even when THC content does not exceed 0.3 percent.**

“With the marijuana-derived low- or negligible-THC products, if [THC content] is under 0.3 percent, it’s interesting because it would meet the legal definition of hemp, but because it’s grown as marijuana (licensed to grow as marijuana) and sold through a dispensary, it’s legally marijuana,” explained Sean Murphy, director of hemp analytics, New Frontier Data, and chief editor of *HBJ*. “It looks like hemp, meets the requirements of hemp, but it’s marijuana.”

Products derived from marijuana are sold in dispensaries and require a license to purchase or are subject to age restrictions. Marijuana-derived products, unlike hemp-derived products, cannot be sold in mass market or natural retail channels, even when THC content does not exceed 0.3 percent.

In the words of Stuart Tomc, vice president of human nutrition, CV Sciences: “The hemp farming bill is what passed ... not the low-THC, high-CBD marijuana bill—that didn’t pass.”

To determine whether a product is indeed hemp, Tomc advised using the “seed rule.” Quoting a colleague, he used another phrase: “Who’s your mama?” In other words, what seed did you use?



“Now that the Farm Bill has passed,” he said, “I want to ask everyone selling a CBD product, ‘What seed did you plant in the ground to get the CBD from?’ Because it makes a difference, right? If it’s AC/DC [strain], that’s a marijuana plant. That’s wrong,” he said.

Beyond regulatory classification, marijuana and hemp are genetically different, and the differences impact the plant’s naturally occurring amounts of THC. “In true agricultural hemp, there’s a polymorphism in that [single-nucleotide polymorphism] where it will not produce large amounts of THC,” Tomc explained. “It’s weight-limited genetically. It has different DNA.”

According to *HBJ*’s 2018 CBD report, sales of negligible-THC CBD products derived from marijuana amounted to nearly \$21 million in 2016 and grew to \$28 million in 2017, with nearly 60 percent sold through medical marijuana dispensaries. Marijuana-derived negligible-THC CBD product sales are on track to reach \$90 million by 2022, with growth remaining strong.

However, *HBJ* predicted hemp-derived CBD products will increasingly claim market share, especially as consumers turn to natural and specialty retailers for negligible-THC, high-CBD products.

“We’ve seen a bit of a shift that people aren’t going to their dispensary to get their high-CBD, low-THC or negligible-TCH product,” Murphy said, citing the term “consumer intent.”

“It’s not the consumer that’s going to the dispensary thinking, ‘I’m gonna get a no-THC product.’ That’s just not why they’re going to a dispensary,” he explained. “That’s been the trend that started to emerge, and we think, at New Frontier, that’s going to continue, that people are going to dispensaries for the most part to get a THC-based product.”

### CBD isolate vs. hemp extract

After differentiating between hemp and marijuana, “the next conversation is what’s the difference between isolated CBD and hemp extracts,” Tomc said.

Adding a layer to the regulatory complexity surrounding CBD, FDA approved in 2018 a prescription drug—Epidiolex®—containing CBD. FDA maintains its position that CBD is excluded from the definition of a dietary supplement.

“FDA has said ... that if you call out the CBD in your products, you’re making the claim that it’s the same as a prescription drug,” explained Cheryl Myers, R.N., integrative health expert and head of Terry Naturally’s Science and Education Advisory board.

Following the signing of the Farm Bill, FDA Commissioner Scott Gottlieb, M.D., issued a statement reiterating FDA’s stance that CBD is an active ingredient in FDA-approved drugs and, therefore, not permitted for use in dietary supplements.

Hemp oil derived from different parts of the hemp plant—the stalk, the leaves and the flower—contains naturally occurring cannabinoids including, but not limited to, CBD. In fact, Myers said more than 120 cannabinoids are found in hemp.

**More than 120  
cannabinoids  
are found  
in hemp.**

– Cheryl Myers, R.N., integrative health expert and head of Terry Naturally’s science and education advisory board





“We believe that full-spectrum hemp oil is a powerful and beneficial product, and so we have been scrupulously careful in making sure that we are developing a product that falls within all of the governmental guidelines as they currently stand,” Myers said. “So because FDA has said that making claims for CBD or developing a CBD-extracted product is not legal, we didn’t even pursue that route.”

Terry Naturally’s recently launched hemp line, called Hemp Select, contains non-genetically modified organism (GMO), CO<sub>2</sub>-extracted hemp stalk extract, “which gives us the richest spectrum of naturally occurring cannabinoids,” suspended with hemp seed oil, which is a source of omega-3 fatty acids and does not contain cannabinoids.

“There’s some really interesting research that shows that omega-3 fatty acids in the body play a role in modulating the attachment of the cannabinoid—whether it’s an endo- or phytocannabinoid—to the cannabinoid receptor,” Myers explained. “So it makes sense to deliver it in an omega-3-rich substance like hemp oil.”

The product is available in a 50 mg capsule. Other Hemp Select products include a 25 mg dose of hemp oil in combination with Terry Naturally’s clinically studied curcumin, and a liquid delivery that provides 100 mg of hemp oil per dropper.

The dose does not represent the amount of CBD in the products, but it represents the hemp oil.

“Contained within that is the full spectrum of cannabinoids,” Myers said.

CV Sciences, too, offers products containing full-spectrum hemp oil. Products include liquid and spray delivery, capsules and softgels containing hemp extract derived from hemp’s aerial plant parts, including the seed, stalk and stem.

Rad Extracts, manufacturer and supplier of full-spectrum hemp oils and broad-spectrum THC-free oils and white label and private label manufacturer of hemp-derived CBD products, strives to keep its products as close to their natural state as possible. “Every time you perform an additional process, you lose benefits that were in the crude oil,” said Clarence Bachmeier, COO, Rad Extracts. “For instance, when you take the full-spectrum oil and turn it into distillate, you have to use a lot of heat. Most of the time, especially when using a short path distillation, you burn off almost all of the terpenes,” he said, adding that terpenes offer benefits, as well, and help create the “entourage effect” that supports efficacy.

“After making a distillate and losing benefits in that process, then comes the process of making isolate,” Bachmeier said, explaining that isolates are made using high heat followed by a cooling process, and can also require use of certain chemicals to isolate the CBD. This process can affect the efficacy of a product, he said, because the product “does not contain any minor cannabinoids or terpenes.”

Known by some as the “Wild West,” the CBD market is no stranger to CBD isolate products, or products claiming high amounts of CBD.

According to Garrett Bain, chief sales officer at GenCanna, CBD isolate has become very popular for its purity and absence of THC. “Many brands that are entering mass-market retail have focused their product development on isolate-based formulations that remove THC from the consumer decision process,” he said.

GenCanna is a vertically integrated supplier of CBD ingredients and private label products including oil, softgels, symptom-specific capsules, cosmetics, fruit chews and pet products.

“There’s a huge customer demand [for CBD],” Myers said. “And there’s always willing people that are going to step in to that opportunity to give people what they want.”

Murphy, too, noted a prevalence of CBD isolates in the food and beverage category.

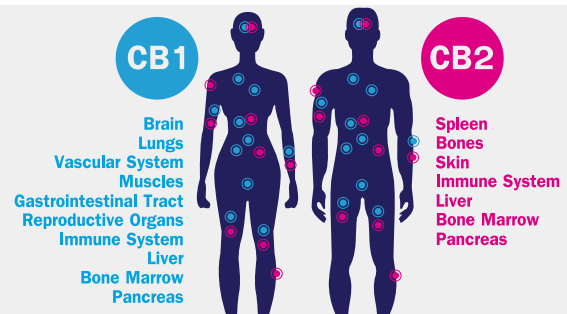
“People were putting CBD in everything,” he said, “but with FDA’s comments hours after the Farm Bill was signed, I think we’ll see a pull back on people putting isolates into food and doing that market-y jazz, that ‘Oh, our drinks have CBD in it because we put some isolate in it.’”

Myers, too, indicated a shift toward compliant practices on the part of manufacturers and retailers. Referencing CBD-only stores (stores that are similar in design and appeal to dispensaries, but carry high CBD-content products), she said, “When I looked at the CBD-only stores, in my opinion, everything in them is not labeled according to FDA guidelines. But, on the other hand, I’ve been to health food stores that are more interested in making sure they’re doing things the right way, and are starting to shift more toward making sure the products that they’re selling are the full-spectrum hemp that contains all the cannabinoids and don’t completely focus on CBD.”

Regarding manufacturers, she said, “I’ve noticed some companies that previously talked about CBD that are starting to move more toward talking about hemp in general.”

Does this mean there’s no room for isolated CBD in the natural products industry? Not necessarily, Tomc said.

## Researchers and product developers are looking into non-hemp sources for innovative products for endocannabinoid health.



“Would isolated CBD be better in a topical product, where you can get hundreds and hundreds of milligrams in there without any sticky black stuff to rub it into your skin for irritation and inflammation? Probably, right?”

As he explained it: “Different product, different market, different customer.”

Medical Mary, a supplier of hemp-based ingredients, a private label manufacturer of CBD products and a consumer packaged good (CPG) brand, offers a range of CPG topical and skin care products containing isolated CBD. Products include eye serum, massage oils, body lotions, face creams and a recently launched line of bath bombs.

According to Norman Bean, president and founder of Medical Mary, CBD isolate is often preferred in skin care applications opposed to full-spectrum hemp extract. “It’s easier to work with, and [in most cases] we don’t really see the necessity for a full-spectrum product,” he said.

### Sources galore?

Hemp is not the only source of cannabinoids, and researchers and product developers are looking into other sources for innovative products for endocannabinoid health.



“There is not just one way to get CBD and, as you’ve heard, [researchers are] suggesting that it can be derived from hops,” Tomc said. “There’s a lot of debate as to whether it can be derived from a combination of other ingredients, and there’s an argument that you can get it from wintergreen and orange.”

Twinlab has invested three to five years in the CBD and phytocannabinoid space, focusing on education, science and other facets of product development, Zolezzi said. Phytocannabinoid sources is just one area of focus for the company.

“We’ve got a whole team doing nothing but working on the endocannabinoid system [and] phytocannabinoid sources,” Zolezzi said. “We’re doing a lot of work because I believe if you really look at the whole endocannabinoid system, it’s much broader than just the hemp plant. There’s a reason why hops have phytocannabinoids, there’s a reason why echinacea has phytocannabinoids, so I really want to understand that, and I want to understand it better than I do now.”

Twinlab has yet to launch a product in the CBD category; it’s not a matter of if Twinlab will enter the CBD category, but when.

“We’re going to do product,” Zolezzi said. “There’s no doubt.”

In the meantime, Twinlab launched a consumer-facing podcast, “The Science of CBD,” to help educate consumers on CBD and phytocannabinoids.

Terry Naturally’s product AnxioCalm is an echinacea-based supplement for occasional anxiety. The product contains a single cannabinoid found in echinacea that is extracted and concentrated and has been “clinically proven to significantly reduce anxiety with the first day of use,” Myers said (*Phytotherapy Research*. 2012. DOI: 10.1002/ptr.4677).

“It’s interesting now that we’re starting to be more vigorous in our investigations of how the endocannabinoid system works that we’re finding more compounds in plants other than hemp that also have an important role to play,” she said. “The compound we use from echinacea is not found in hemp, so depending upon the plant source, they’re all quite different, and I think there’s a lot of interest and amazing pieces of information that we haven’t yet discovered.”

Emerald Health Bioceuticals offers a range of endocannabinoid products featuring non-cannabis cannabinoids. Its PhytoCann™ Complex is a formulation of cannabis-free cannabinoids and other ingredients to support the endocannabinoid system.



Emerald Health Bioceuticals was named Editors’ Choice Supplement for the Natural Products Expo East 2017 NEXTY Awards. [Click here](#) to see all the 2017 winners.



In 2018, the company’s Endo Brain supplement was named winner of the Brain Health category in the SupplySide West CPG Editor’s Choice Awards. To see all the supplement winners, [click here](#).



### The innovation hurdle

Consumer awareness and interest in CBD and CBD-related products is high. But regulations and science are still catching up.

“It always makes me have the visual of someone hitting the gas pedal and the brake at the same time,” Murphy said. “It’s like, ‘Are we going fast or slow?’ It’s a weird moment where you hit them both at the same time. That’s where we’re at right now.”

With regulations still stacked against CBD-containing supplements, mass-market retailers remain hesitant to stock such products on the shelves.

“With the conundrums and the clouds around the FDA position on this, I think you’re going to see major retailers and major brands walk a little bit slowly because they don’t want to become an FDA target,” said Jim Hamilton, CEO at Neptune Wellness Solutions. “You will see local brands, local health food brands, local retailers being active ... but that can change really quickly.”

According to Murphy, mass-market is the missing link to innovation and growth.

He noted if CBD product brand owners are able to enter mass-market retail, it will drive revenue for them, as well as research and development (R&D) and new product development. In addition, “It will give new companies the eye to say, ‘Wow, we could get a new innovative product into a place like that, why aren’t we trying to develop something new and innovative?’ as opposed to just another CBD capsule or tincture or oil,” Murphy said. “I think that’s the big moment.”

And industry is preparing for that moment.

“With the Farm Bill and with this trend toward legalization of CBD from hemp in the United States,” Hamilton said, “major retailers and major brands are putting strategies together to see how [they] can enter ... ‘Let’s get some formulation work going, let’s understand the regulatory [climate] more clearly, and let’s be ready to roll’ because—and my view is—it’s not a question of if, it’s a question of when,” he said.





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# CBD brands managing risk in uncertain times

by Rend Al-Mondhiry



## INSIDER's take

- The 2018 Farm Bill removed hemp from the definition of “marihuana,” confirming it—and CBD—is not a controlled substance.
- CBD regulation at the state level is inconsistent, and state lawmakers’ reactions to hemp’s new status remain unknown.
- FDA states CBD cannot be added to food or dietary supplements—regardless of whether it is derived from hemp or marijuana.

## 2018 proved to be a challenging but momentous year for the cannabidiol (CBD)

industry. Congress finally passed legislation legalizing hemp and hemp derivatives, including CBD. On the other hand, FDA reaffirmed its position against the use of CBD in food and dietary supplements, although following the passage of the 2018 Farm Bill, the agency hinted at a possible pathway forward for CBD as an ingredient in these products. Adding to the confusion was the varied regulation of CBD and inconsistent enforcement at the state level, which may continue despite the legalization of hemp at the federal level.



### 2018 Farm Bill

On Dec. 20, 2018, President Donald Trump signed into law the [Agriculture Improvement Act of 2018](#) (also known as the 2018 Farm Bill). The 2018 Farm Bill categorized hemp as an agricultural commodity under the regulatory purview of USDA and defined hemp as follows:

The plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3 percent on a dry weight basis.

The bill also removed “hemp” from the definition of “marihuana” in Schedule I of the Controlled Substances Act (CSA), provided the THC concentration is within the defined limit—confirming hemp and hemp derivatives, such as CBD, that meet the definition are not controlled substances. In doing so, the legislation ended years of back-and-forth between the hemp industry and Drug Enforcement Administration (DEA) regarding the legal status of hemp extracts such as CBD.

Prior to the passage of the 2018 Farm Bill, only products derived from exempted parts of the hemp plant or hemp grown and cultivated in compliance with the 2014 Farm Bill were not considered controlled substances. However, DEA and industry held conflicting interpretations about the legitimacy of these sources of CBD, leading to uncertainty about the enforcement risks at both the federal and state level, since several states chose to follow DEA’s lead on this issue.

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While the 2018 Farm Bill has cleared up the confusion regarding hemp as a legal source of CBD and other products, the legislation also allows states to be the primary regulators of hemp in their states and take a more restrictive approach to the sale of hemp and hemp-derived products. The only limitation is states cannot prohibit the transport and shipment across states—meaning hemp products must be able to move freely through the state, but states can still ban sales to consumers within their state.

### State regulation of CBD

One of the biggest unknowns is how states will regulate CBD and other hemp products, and this will have a significant impact on the CBD marketplace. Under the 2018 Farm Bill, states that opt to regulate hemp on their own must submit a plan to USDA for approval; USDA then has 60 days to approve or reject the plan. Kentucky recently submitted its plan, and other states that are already invested in hemp production and have robust industrial hemp pilot programs established under the 2014 Farm Bill, such as Colorado and Oregon, are likely to follow. In addition, states that previously prohibited CBD based on DEA's position, such as Alabama, have reversed course and [announced](#) hemp-derived CBD below 0.3 percent THC can be legally produced, sold and possessed in the states following passage of the 2018 Farm Bill. The industry is awaiting similar news from states such as Ohio and South Dakota that currently have in place prohibitions against CBD, although the federal legislation allows these states to continue to restrict access to CBD, or states could choose to limit CBD sales to licensed cannabis dispensaries.

In California—arguably one of the largest markets for CBD—the Department of Public Health issued an [FAQ document](#) in July 2018, stating CBD derived from hemp is prohibited for use in food or dietary supplements, while continuing to allow the sale of CBD derived from marijuana that is sourced from, produced and sold by those with commercial cannabis licenses. The passage of the 2018 Farm Bill is unlikely to change the state's position since it is based primarily on FDA's opinion regarding CBD, rather than whether hemp-derived CBD is a controlled substance.

### CBD and FDA

Importantly, the 2018 Farm Bill did not impact FDA's authority to regulate CBD under the Federal Food, Drug and Cosmetic Act (FD&C). FDA currently takes the position that CBD cannot be added to food or dietary supplements—regardless of whether it is derived from hemp or marijuana—because CBD is an active ingredient in an FDA-approved drug, and it was the subject of substantial clinical investigations before it was marketed as a food or dietary supplement.

The agency first asserted its view in 2015 with a series of [warning letters](#) to companies selling CBD-containing products, mainly dietary supplements. FDA cited several illegal disease claims used to promote the products, as well as manufacturing and quality issues. The warning letters also referenced a provision in the FD&C stating if an article (such as CBD) has been approved as a new drug or authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, then products containing that



substance cannot be added to a dietary supplement or food, unless the substance was marketed as a dietary supplement or food before the drug approval or the new drug investigations were authorized.

FDA issued two additional rounds of warning letters in 2016 and 2017, and it has maintained an [FAQ document](#) outlining its position regarding CBD and marijuana in general. Of note, FDA's opinion does not extend to CBD added to cosmetics or other topical products.

Despite FDA's view, the market for CBD-containing supplements and food has experienced massive growth over the past few years. Many in the industry dispute FDA's basis for its position. What's more, CBD is a relatively safe ingredient at the levels sold in dietary supplements and food products. As a federal agency with limited resources, FDA enforcement has targeted CBD products that make disease claims or otherwise pose a safety risk.

In a [statement](#) issued immediately after the passage of the 2018 Farm Bill, FDA's commissioner acknowledged "the proliferation of products containing cannabis or cannabis-derived substances" and the agency's intent to "continue [to] closely scrutinize products that could pose risks to consumers." While FDA reiterated its position that CBD is an unlawful dietary supplement and food ingredient, it also signaled a willingness to explore additional pathways for CBD, noting, "FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement." The timeline is uncertain, and of course, the details of such a regulation are expected to be the subject of intense discussions between FDA and interested stakeholders.

### Managing risk in uncertain times

In the face of regulatory uncertainty at both the federal and state levels, at a minimum, companies should ensure CBD ingredients are sourced exclusively from hemp and have THC levels at or below 0.3 percent, or undetectable if the product is sold in states with a zero-THC policy, such as Idaho and Kansas. Companies should also be familiar with FDA's requirements for manufacturing and labeling dietary supplements, food and cosmetics—including the specific ingredient and claims requirements for each of these categories. Finally, as state regulation continues to evolve following passage of the 2018 Farm Bill, companies should closely monitor state activity concerning the production and sale of hemp, as states may choose to regulate hemp-derived CBD as a controlled substance or impose other restrictions, either based on FDA's position or current policies in place. These state developments could happen at a quicker pace, but FDA's next move on CBD is likely to take longer.



*Rend Al-Mondhiry, senior counsel, [Amin Talati Upadhye LLP](#), advises the dietary supplement, food, cosmetic and over-the-counter (OTC) medicine industries on a broad range of regulatory and compliance matters. She is committed to helping companies responsibly develop and market products, drawing on her years of experience advising the nation's leading dietary supplement and food companies on complex ingredient and labeling issues. Al-Mondhiry reviews product labels, ingredients and advertising claims to determine compliance with federal and state regulations, and assists companies in matters before FDA, FTC and the National Advertising Division (NAD). She also advises clients on compliance with California's Proposition 65, U.S. Customs issues, class-action defense strategies, and FDA matters including warning letters, recalls, detentions, seizures and import alerts.*



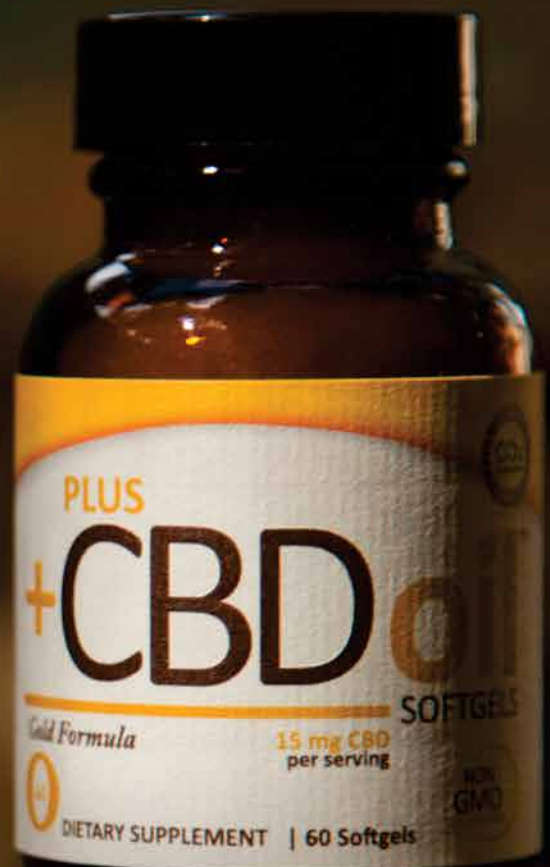


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# CBD and hemp products: A regulatory and marketplace analysis

by Garrett Graff and Bridget Hill-Zayat



## INSIDER's take

- The 2018 Farm Bill renders hemp and CBD products legal to sell, but FDA's position is CBD is not a legal dietary ingredient.
- However, in a recent statement, FDA acknowledged "pathways forward" to allowing hemp ingredients in foods and supplements.
- Whatever FDA determines, brands still need to ensure claims on CBD products are substantiated, truthful and not tied to diseases.

## In recent years, manufacturers and consumers are crazed about products

containing cannabinoids—such as cannabidiol (CBD)—derived from hemp. Cannabinoids are compounds naturally occurring in hemp, along with terpenes (which provide flavor and aroma profiles, just as those found in citrus) and other constituents. Notably, CBD, one of the most popular cannabinoids, is associated with therapeutic properties.

Hemp foods are nothing new in the United States. In the early 2000s, sterilized (hulled) hempseeds, cold-pressed hempseed oil and other similar products were widely available. Since then, Congress enacted laws in 2014 and, most recently, in late 2018 that more permissively allow for the use of all parts of a hemp plant as lawful, especially hemp flowers where cannabinoids such as CBD are most prevalent. Accordingly, the *Hemp Business Journal* and the Brightfield Group estimated the industry will eclipse US\$1 billion in sales in 2018, and grow to perhaps \$22 billion by 2022.

A wide variety of hemp and CBD products are marketed around the United States. Product types mimic many existing products in accordance with the product's intended use, along with other less traditional forms. For example, oral ingestibles, such as capsules, edibles and tinctures, are often marketed as supplements. Given many people prefer oral ingestion as a delivery method, ingestible products are rather popular, especially with trends toward athlete-focused products.

Similarly, balms, salves and other topicals are often marketed as cosmetics. Many cite topical application and absorption as an optimal method of consumption, increasing bioavailability (as opposed to ingestion, which travels through the body) of the cosmetic ingredients into the body.

Perhaps less traditional are many other products types, ranging from vaporizer cartridges; smokable hemp flowers; and novel applications, such as nasal and oral sprays, patches and other applications that appear to test FDA's distinctions between supplements and cosmetics, as opposed to devices intended to deliver a drug.



In December 2018, Congress enacted the Agriculture Improvement Act of 2018 (the Farm Bill), which specified hemp—including cannabinoids—may not be treated as a controlled substance. This policy makes sense, particularly given cannabinoids naturally occur in other sources, such as cacao, human breast milk and other types of botanicals, to name a few. However, the Farm Bill did not resolve whether these substances may be compliantly incorporated into products regulated by FDA.

To this end, for several years FDA has maintained its position that CBD is an impermissible ingredient in food and supplements, primarily because of investigational new drug applications submitted to explore CBD as a drug. FDA reiterated this position quickly after President Donald Trump signed the Farm Bill into law, causing uproar among hemp industry stakeholders who thought the Farm Bill also resolved these uncertainties with FDA. The hemp industry generally maintains FDA's conclusions are premature, flawed in citing certain preclusions contained in the Dietary Supplement Health and Education Act of 1994 (DSHEA), and ultimately, are not conclusive. These competing FDA and industry perspectives remain unresolved. Notwithstanding FDA's positions, hemp companies continue to manufacture and widely distribute products.



In December 2018,  
**Congress enacted**  
the **Agriculture**  
**Improvement**  
**Act of 2018**  
(the Farm Bill), which  
specified hemp—including  
cannabinoids—may not be  
treated as a controlled substance.

A large, stylized orange stamp with the letters 'FDA' in a bold, sans-serif font. The stamp has a distressed, ink-like texture and is tilted slightly to the right.

**Notwithstanding FDA's  
positions, hemp companies  
continue to manufacture and  
widely distribute products.**

In June 2018, FDA approved a drug—Epidiolex®—that contains an isolated form of CBD for the treatment of certain epileptic indications. The distinction between pharmaceutical formulations approved by FDA and formulations of dietary supplements and other products types must be considered, such as the making of medical claims, which are allowed for drugs and prohibited for supplements.

Interestingly, however, in its recent statement, FDA acknowledged “pathways forward” to resolving these uncertainties and for FDA to take the reins in regulating hemp-derived products. This acknowledgment is an encouraging development and consistent with FDA's exercise of discretion to date.

Over the past several years, FDA's enforcement of its position resulted in the issuance of warning letters to product manufacturers, which primarily addressed the making of impermissible medical claims—FDA's clear enforcement priority—rather than focusing on





the ingredient issue. In line with FDA's acknowledgment of such "pathways," sights are set on FDA changing its position and instead providing regulatory certainty to regulators and the industry alike.

Though, like any other supplement, manufacturers cannot make medical claims, anecdotal evidence substantiates the efficacy of hemp extracts and/or CBD. And, as cannabis policy evolves around the country and world, continued research is expected to accelerate. To that end, even the World Health Organization (WHO) acknowledged the therapeutic potential for CBD along with its good safety profile. The recent surge in available CBD products is a testament to the growing acceptance and interest in CBD as an alternative to traditional medications for various health issues.

However, as FDA's regulatory oversight on hemp products evolves, the ability to make otherwise allowable and substantiated claims (i.e., structure/function) will likely follow established FDA protocols. In considering such claims, FDA generally reflects on criteria and substantiation including: the meaning of the claim made, the relationship of the evidence to the claim, the quality of the evidence and the totality of the evidence presented.

The future appears bright for hemp-derived CBD products. Unprecedented legislation helps pave the way, but now, much power and responsibility lies with FDA in sensibly regulating these products going forward. Yet, with the industry's success to date, a raging opioid crisis and the quickly deteriorating stigmas toward hemp, these all point toward the "pathways forward" for hemp and CBD products that even FDA now seems set to acknowledge.



*Garrett Graff is an associate attorney at [Hoban Law Group](#), where he specializes in representation of both the marijuana and industrial hemp industries. For these clients, his practice involves corporate and transactional law, real estate law, regulatory/compliance law, FDA/FTC compliance, intellectual property (IP) law, and civil and commercial litigation. Graff counsels clients regarding corporate structuring and restructuring, acquisition and sale of real property and leasehold interests, drafting of transactional documents such as governing documents, resolving partnership disputes and litigating commercial disputes. Within the marijuana industry, he represents numerous companies seeking licensure, and maintaining ongoing compliance with the evolving regulatory schemes.*



*Bridget Hill-Zayat, counsel, Hoban Law Group, is active in the Pennsylvania cannabis industry. She was selected to participate in state Sen. Daylin Leach's "Regulatory-Palooza," convened to develop standards and methods for cannabis regulations in the Commonwealth. Hill-Zayat has testified in front of the Philadelphia City Council to advise on strategies the city can employ to increase energy efficiency, foster the cannabis market and help growers, processors and dispensaries thrive. She continues to engage the legal community on cannabis issues and hosts speaking events in coordination with Women Grow, the National Cannabis Bar Association and Cannavation.*

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# CBD: Why, why now and how to take advantage of market opportunity

by Perteet Spencer

## INSIDER's take

- Most CBD products are sold in the natural grocery chains, so mainstream channels offer large growth opportunity.
- CBD product introductions grew more than 250 percent in the past year, with supplements being the most common offering.
- Expansion into the CBD market requires a brand to build a solid foundation of its category and consumer dynamics.

**Cannabidiol (CBD) is one of several cannabinoid compounds found in both** cannabis and hemp. Beyond cannabinoids' connection to promoting overall wellness and resiliency, the compound's distinguishing factor is it lacks psychoactive effects. While the body of medical research is currently limited, CBD has been linked to improvement of a broad range of ailments, including pain management (*Pain*. 2017 Dec;158(12):2442-2451), anxiety (*Neurotherapeutics*. 2015 Oct;12(4):825-836), insomnia (*Perm J*. 2016 Fall;20(4):108-111) and even allergy symptoms (according to 2015 self-reported survey data from Bluebird Botanicals' CBD product consumers). Given consumer shifts toward more natural approaches to improving well-being and CBD's growing availability, CBD is well positioned in today's market.

Early indicators showed signs that CBD is much more than a fad. As consumers actively shift toward more natural remedies and legislation evolves in favor of cannabis, CBD and hemp, expansion potential is tremendous. Across the breadth of grocery retailers, about 95 percent of CBD's US\$48 million in sales are occurring in the natural channel, according to SPINScan natural and specialty gourmet channels, conventional multioutlet and convenience channels (powered by IRI), for the 52 weeks ending Nov. 4, 2018.

SPINScan often refers to the natural and specialty gourmet channels as incubator or innovation channels, but this high concentration of early-adopter natural





retailers may be an indicator of CBD's potential to scale in mainstream channels over time. As consumer awareness, retail availability and the assortment of products expand, the landscape for CBD will look quite different over the next few years.

CBD's already coming to market across several categories and formats, from body care to supplements to functional foods and beverages. It's no surprise so many brands are attracted to the prospect of bringing CBD on board; the market opportunity so far has been impressive. SPINS tracked nearly 160 new introductions in the last year. While nearly 98 percent of sales volume currently comes from supplements, expansion beyond extracted oils is creating new opportunities for brands to enter the market. As an ingredient added to other formats, these extracted oils are versatile in any number of segments and formulations, offering many possibilities for expanded market presence. In fact, this year food and beverage offerings were the fastest-growing segment of CBD products—an early predictor of what's to come.

Despite all the strong growth, brands entering the CBD market should consider if the ingredient aligns with their proposition and consumer base.



**As consumer awareness, retail availability and the assortment of products expand, the landscape for CBD will look quite different over the next few years.**

### Strategy for brands getting into CBD

Expansion into CBD requires a thoughtful approach that starts with building a solid foundation of a brand's category and consumer dynamics. Before a brand jumps on the CBD bandwagon, it should be prepared with the fact base to fully understand and maximize the specific opportunity for growth. A few key considerations:

**The CBD consumer**—Consider the demographics of CBD users, and how they align with the brand's current consumer base. Ensure the brand can uniquely deliver value to them. Leverage demographics and purchase-behavior data to support learning and develop a winning proposition.

**The competitive landscape**—In a rapidly evolving market, brands with a clear purpose, vision and superior product will win. Having a well-defined perspective on how a product is differentiated in the marketplace will inspire consumers and retailers.

**Expansion opportunities**—CBD shoppers spend 63 percent more at retail than the average shopper, according to SPINS (52 weeks ending May 27, 2018). Brands should partner with retailers to maximize






opportunity with this high-value shopper by helping retailers navigate the rapidly changing landscape to support their growth, too. With both assortment expansion and shared success with retail partners on the horizon, painting a vision for a category with each retailer will go a long way. Brands should review each retailer's current assortment, then make sure they are poised to convey the unique value that products bring to each retailer's shelves.

### **CBD opportunity for investors**

While the market is led by specialized companies like CV Sciences and Charlotte's Web, recent big investments from mega-companies like Constellation Brands (\$4 billion investment in Canopy Growth) and Altria (\$1.8 billion in Cronos) indicate the mainstream is soon to follow. This is further reinforced by the expansion of offerings beyond more developed formats like topicals and supplements. While these early indicators may prompt investors to act right away, strategic investors should keep a few things in mind:

- 1 Look beyond the numbers:** Data-driven due diligence is critical in identifying the right partnership opportunities. Beyond the numbers, given the potential for broad application for CBD, investors should seek partnership with brands that have mutually aligned vision for in-market activation.
- 2 Cautiously evaluate the supply chain:** While CBD's availability at retail is still limited, consumers will become more discriminating based on product quality as the market continues to scale. Choosing a brand partner with a sustainable, high-quality supply chain will be essential to long-term growth.
- 3 Play the long game:** Many regulatory hurdles must be addressed before CBD can fully scale. Investors in this space should enter knowing returns may not be immediate and should take a more forward-looking approach to growth. 



*As principal of [SPINS'](#) brand growth solutions, [Perteet Spencer](#) helps clients transform data into insights that fuel innovation.*

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COMPLIANCE

REGULATION

## Cannabidiol: Regulations, research & where to go next

by Suzy Badaracco

### INSIDER's take

- Market research firms vary on the specific numbers, but all show CBD and cannabis product sales are rising dramatically.
- New research showed CBD reduced pain and anxiety, and consumers are becoming aware of these benefits.
- New CBD food, beverage and supplement products span smoothies, coffee- and beer-like beverages, and oils.

### Marijuana is recreationally legal in ten states and Washington D.C., but

cannabidiol (CBD) is legal in 43 states—if it has been derived from hemp. New York Gov. Andrew Cuomo is looking to legalize recreational marijuana in 2019. Just two years ago, he said it was a gateway drug he could not support legalizing for recreational use, although he did support medical marijuana.

### Market

Market predictions vary on the strength of cannabis sales, but they all are on the upswing. According to Packaging Machinery Manufacturers Institute (PMMI), by the year 2020, the cannabis industry is expected to reach US\$24.5 billion, with \$11.2 billion for recreational products and \$13.3 billion for medical products. A report from Arcview Market Research and BDS Analytics found cannabis sales accounted for \$9.5 billion in consumer spending in 2017. The total size of the global cannabis market is estimated to reach \$32 billion by 2022 and \$57 billion by 2027. But according to Mordor Intelligence, the market is expected to grow to just \$22 billion by 2022. RBC Capital Markets reported the legal cannabis category is set to grow at a 17 percent compound annual growth rate (CAGR) during the next decade to \$47 billion in annual sales. And recreational cannabis is projected to increase more than 700 percent to \$50 billion in annual legal sales by 2026, according to Cowen and Co.

### Clinical health research

Research has linked CBD to potential use for pain, anxiety, insomnia and inflammatory relief. Researchers from Northwell Health presented a survey of patients suffering chronic



pain from osteoarthritis, spinal stenosis, hips and knees at the May 2018 meeting of the American Geriatrics Society in Orlando to gauge how effective medical marijuana was at managing chronic pain and reducing opioid use. The researchers found 27 percent of the patients completely stopped use of opioids and 91 percent of the patients said they would recommend medical marijuana to other patients. Scientists at McGill University pinpointed the effective dose of CBD for safe pain relief in rats (*Pain*. 2019 Jan;160(1):136-150). The study showed CBD acts through the mechanism that binds specific receptors involved in anxiety and pain. To examine its effects on anxiety, a 2016 pediatric study from the University of Colorado found CBD oil can be effective in reducing anxiety and insomnia (*Perm J*. 2016 Fall;20(4):108-111).

Consumers have been studied for their knowledge and acceptance of cannabis and its derivatives. AT Kearney reported more than 75 percent of consumers surveyed said they are aware cannabis has nonpsychoactive components that may offer health benefits, and consumers are most likely to try “therapeutic cannabis” in foods (55 percent), vitamins (50 percent) and skin care products (43 percent). Of those surveyed, 41 percent said food would be how they prefer to consume recreational cannabis, followed by smoking (39 percent), edible capsules (28 percent), nonalcoholic beverages (21 percent) and alcoholic beverages (15 percent). Cannabis consumption is directly competing with alcohol consumption, as well. According to a Yahoo News poll, the share of college students who drink alcohol daily fell from 4.3 percent in 2016 to 2.2 percent in 2017.



**AT Kearney reported more than 75 percent of consumers said they are aware cannabis has nonpsychoactive components that may offer health benefits.**


They reported they favor cannabis over alcohol because it is cheaper and calorie-free, and they experience no hangover the next day. Also, RaboResearch reported 72 percent of consumers said they believe cannabis is safer than alcohol.



### New products

New products range from beverages to food to supplements. Their uses mirror research findings:

- Diamond CBD launched Chill CBD-infused coffee capsules. These pods fit in almost all modern single-cup coffee makers, delivering 25 mg of CBD per serving.
- Heineken's Lagunitas introduced Hi-Fi Hops, an "IPA-inspired" sparkling water infused with cannabis that comes in two versions: a hybrid variety with 5 mg of tetrahydrocannabinol (THC) and 5 mg of CBD.
- Toast Holdings Inc. produced a new line of CBD oils: Toast CBD Oil Original and Toast CBD Oil Cold Pressed Orange, designed to help balance mood, relieve post-exercise pain and calm anxiety.
- Root Blends launched CBD smoothie kits that come in Protein, Mint Protein, Skin & Hair and Calm Blend.
- SNAAK Bar launched a hemp CBD sports bar with hemp CBD to improve athletic and workout performance, mood, inflammation, stress, restful sleep and pain management.

Now that cannabis legislation is moving forward state by state, it is likely just a matter of time before legislative approval passes at the federal level. Clinical health research will be both its ally and adversary going forward, and it will be the overriding factor governing its uses and limitation. While consumers may be divided generationally, the real fight is going to come from recreational competition from alcohol and prescription medication for long-term efficacy. 



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# CBD set to disrupt the fast-moving consumer goods market

by Zora Milenkovic

## INSIDER's take

- Globally, CBD, THC and the combination of both appear in dietary supplements, topical analgesics, beverages and skin care products.
- Sales of CBD products in packaged food is expected to double over the next two years, as consumer awareness and demand grows.
- As cannabis becomes legal in more regions, CBD will compete with THC and other cannabinoids in the consumer goods market.



## The cannabis plant contains just over 100 chemical compounds

called cannabinoids, of which cannabidiol (CBD) is one of the best known. In the United States, Euromonitor International expects CBD sales to push US\$1 billion in 2019, driven by the 2018 Farm Bill that legalized hemp production federally and will boost CBD production in the country.

CBD is currently the functional cannabis ingredient of choice, being free of the psychoactive cannabinoid tetrahydrocannabinol (THC) and thus legal, with applications spanning anti-anxiety<sup>1</sup>/stress relief,<sup>2</sup> pain relief (via anti-inflammatory properties),<sup>3</sup> anti-nausea<sup>4</sup> and anti-spasmodic.<sup>5</sup> Given the range of functional usages, it's little surprise CBD is on the commercial agenda of fast-moving consumer good (FMCG) corporations, from beauty and consumer health to packaged food and beverages. FMCGs are inexpensive products that people usually buy on a regular basis, such as supermarket foods or toiletries.



## Consumer health and beauty products

Globally, CBD products are present in a growing variety of consumer health categories, including dietary supplements, topical analgesics and sleep aids. Its anti-inflammatory properties are applicable for conditions such as psoriasis and eczema, while its pain relief properties are found in topical analgesics, digestive remedies and wound care. CBD's high antioxidant, omega oil and protein content are applicable to dietary supplements and sports nutrition, both of which will be spurred by CBD products into new sources of value growth. CBD's calming properties are also found in sleep aids—an area of interest for companies, especially in tandem with THC, a recognized analgesic. Canada's largest cannabis producer, Canopy Growth Corp., is reportedly developing a sleeping aid product.



The current opioid crisis in mature markets such as the United States, the U.K., Canada and Australia will drive demand for cannabis as a natural, homoeopathic alternative to pharmaceuticals for the relief of chronic pain and stress. Euromonitor International predicted vitamins and dietary supplements will be the largest cannabis-driven, over-the-counter (OTC) market globally by 2025, with 2 percent of total value sales to be CBD- or THC-based, followed by topical analgesics, sleep aids and sports nutrition.

Cannabis is also stimulating debate about its role as an adaptogen since it works in tandem with the body's own endocannabinoid system. Though cannabis does not alter in the body according to need as do true adaptogens, cannabis can be altered to achieve different mood-modulating effects in the body according to need. Different types of cannabinoids (specifically THC) and combinations thereof are also known to work on both ends of the mood spectrum, from energy boosting to relaxing.



## The endocannabinoid system exists in all mammals, so CBD pet care products are marketed for relief of anxiety, itching and joint mobility.

The endocannabinoid system exists in all mammals, so by the same token, CBD pet care products are marketed for relief of anxiety (in treats), itching (in shampoos and balms) and joint mobility (in treats and balms/gels). They are also cited as offering “neuroprotection,” as well as stimulating appetite in sick animals.

CBD-infused beauty launches have largely been prevalent in skin care, toiletries and cosmetics. Euromonitor International expects skin care—specifically brands operating in the therapeutic and dermocosmetics space—to be the main driver of cannabis beauty growth, aligning with current holistic and health-focused beauty trends of repair, protection and therapy. CBD finds a perfect fit with beauty's current consumer trends, including pampering, cleansing, invigorating (within toiletries), soothing, calming, reparative, therapeutic, preventive (within skin care and dermocosmetics), multifunctional, mood-altering, mental well-being (within fragrances) and neurocosmetics.

### Packaged food and beverages

Alcoholic drinks are, by far, the most embedded industry in the cannabis sector. At least three leading corporate players have a stake in cannabis producers, the most notable being U.S.-based Constellation Brands and its 38 percent share in leading Canadian cannabis producer Canopy Growth. With the spirits and beer categories already headed in a low- or nonalcoholic direction, a future where THC replaces alcohol





is on the horizon. Cannabis beverages, with specific THC dosing and controlled onset of effects, will become more common in places that have legalized recreational use, ultimately providing the equivalent effect of a glass of wine or beer. These would be calorie-free, alcoholic or nonalcoholic or recreational beverages with an intoxicating buzz.

Health and wellness trends are driving the global soft drinks industry, fueled by sugar reduction. The functional health and wellness trend is thus a natural bedfellow for CBD-infused products. In soft drinks, CBD launches have become prevalent over the last two to three years, particularly in bottled water, juices, ready-to-drink (RTD) tea, RTD coffee and energy drinks, as well as THC inclusions where recreational use of cannabis is legal.

Tea is currently the most popular application for CBD products in hot drinks, particularly green tea and herbal tea, related as they are to health and wellness. As low- and nonalcoholic beverages grow in popularity, and sugary soft drinks continue to decline, a consumer trend confluence occurs between alcoholic drinks and soft drinks. These blurring lines are creating a fertile ground for adult recreational soft drinks, where cannabis (more specifically THC in the long term) fits in as a social lubricant with a health and wellness halo.

Within packaged food, Euromonitor International expects sales of CBD products to double over the next two years as consumer awareness grows. CBD and THC are the superpower holistic food ingredients of the future—think turmeric (anti-inflammatory) crossed with coconut oil (essential fatty acids [EFAs]). CBD/THC falls within the naturally functional and mindful consumption trends, tapping into the vegan, plant-based and free-from movements. Given hemp is grown sustainably, it is also spurred by the ethical living megatrend and back-to-basics move. THC-combined CBD products are chiefly prevalent in sweet categories, such as confectionery (chocolate and sugar), protein bars and ice cream, with potential for savory snacks, pasta and soups, among others.

As CBD and THC become more mainstream, and manufacturers recognize their potential, the market will be dominated by outcome-based products: a specific dose, in a specific combination, carried in a specific format, to address a specific condition, potentially in microdoses, blurring the boundaries between food and consumer health. This outcome-based future for cannabis products means by 2030, most people will use a product containing cannabis, and the current \$10 billion global market for legal cannabis will have easily multiplied several times over.

### It's all about CBD ... for now

As consumers become educated on CBD's benefits and more CBD-infused products appear on shelves, conversations around cannabis in general are picking up.



The reality is medical cannabis legalization, a traditional precursor to stimulating debate around recreational legalization, has been developing and gaining traction for decades; in fact, California legalized medical cannabis in 1998. However, the pace of change has dramatically picked up in the last few years, and legalization is now on the political agenda of several countries. Euromonitor International expects the United States to federally legalize both medical and recreational use of cannabis within a decade.

Cannabis regulation is currently divided into medical and recreational (or “adult”) use; the former permits use with prescription only, and the latter permits cannabis products containing THC to be sold freely through licensed outlets at a taxable price. The regulatory distinction will eventually fade as recreational use becomes more widely legalized, leaving a cannabis product landscape spanning from a functional ingredient (with a range of cannabinoids) in foods, beverages and beauty; as well as a broad wellness positioning for the nonclinical treatment of health issues like pain, anxiety and sleep; to the development of powerful pharmaceutical drugs (many synthetically produced).

However, CBD is not the only cannabinoid. Many other cannabinoids work in concert with each other and will have their day once CBD becomes commonplace and consumers become more educated about cannabis. As scientific studies develop, a range of cannabinoids in specific combinations will be created for certain ailments and pave the way for attendant health claims to be legally utilized.



*Zora Milenkovic is head of drinks and tobacco at [Euromonitor International](#). Milenkovic is responsible for the company's global data and analysis on soft drinks, hot drinks, alcoholic drinks and tobacco, specializing in future trends impacting these industries, from cannabis to water scarcity, and linking them to the wider consumer space.*

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# Hemp oil, CBD, THC regulations and sport drug testing considerations

by Oliver Catlin

## INSIDER's take

- Recent research on CBD's potential benefits in reducing pain and inflammation may make it an attractive supplement for athletes.
- While CBD isn't prohibited by the World Anti-Doping Agency (WADA), other cannabinoids are, effectively banning hemp oil.
- One study showed most athletes could ingest 0.45 mg/d of THC without triggering a positive test for THC under WADA guidelines.

## The hemp oil industry continues to expand despite challenges with regulations.

The complications in large part stem from conflation of hemp oil, cannabidiol (CBD) and tetrahydrocannabinol (THC), all of which are derived from the cannabis plant. The intermingling of the terminology has made it difficult to deal with the regulations of the items both generally and within sport drug testing.

Hemp oil—and phytocannabinoids that are naturally present in the oil, like CBD—may have benefits to athletes, while too much THC can result in a doping violation or undesirable psychoactive effects.

The story starts with the cannabis plant itself: the source of hemp oil, CBD and THC. Over thousands of years, the cannabis plant has been bred both for the hemp form and the infamous marijuana form known to get people high. The marijuana form has been bred with a focus on the psychoactive chemical THC. Hemp has traditionally been grown for use as rope, paper, foodstuffs and other industrial purposes. Recently, the hemp form has been bred to be rich in the nonpsychoactive chemical CBD.

CBD has been the subject of much attention for a variety of potential health and medical benefits that continue to be studied and evaluated. Some of the possible benefits, like pain (*Nurs Outlook*. 2018 Dec 13. pii: S0029-6554[18]30563-3) or inflammation management (*Pain*. 2017 Dec;158[12]:2442-2451), could be attractive for athletes.

In the United States, FDA approved the first cannabis-derived medicine in the form of Epidiolex (from GW Pharmaceuticals), which is nearly pure CBD with trace amounts of other phytocannabinoids present. Epidiolex was demonstrated to be effective in the treatment of certain seizures, but its approval has complicated the regulatory perspective for supplements because CBD is now considered a drug.

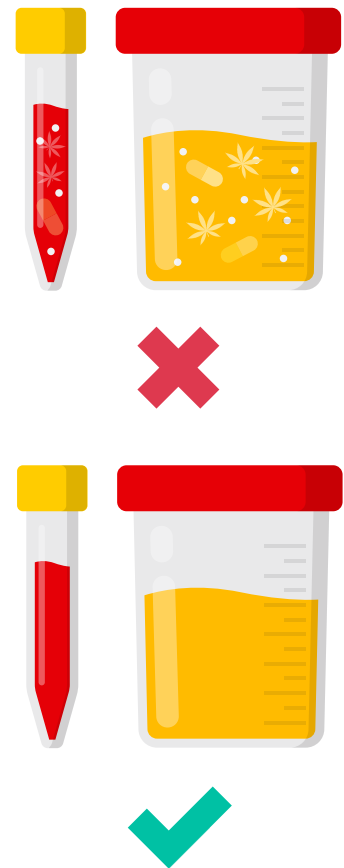
Hemp oil, which is rich in CBD, but usually differs in chemical makeup from the pharmaceutical drug Epidiolex, has been sold as a dietary supplement and is responsible for a burgeoning new industry. Hemp-derived products are required to have no more

than 0.3 percent THC content. Despite the passage of the [Agriculture Improvement Act of 2018](#), the hemp industry remains in regulatory limbo as the FDA position stands that hemp oil, and specifically CBD, are not legal supplement ingredients; however, the agency has agreed to consider regulatory pathways for such products in the future.

The primary concern for athletes is how much THC might remain in hemp oil or a CBD product. Is hemp oil legal for athletes? Will it cause a positive drug test?

The World Anti-Doping Agency (WADA) no longer prohibits CBD, but that does not mean hemp oil is legal and approved for athletes. Other naturally present cannabinoids in hemp oil remain prohibited by WADA, perhaps an oversight in its language adjustment. Other sports have yet to follow suit and remove CBD from the prohibited substance lists, so CBD technically remains prohibited by most other sporting groups, including the NFL, MLB and NCAA.

While CBD content is the focus of hemp oil products, it is the urine testing threshold for THC that matters to athletes or others subject to drug testing. In practice, THC metabolites and synthetic cannabinoids are the compounds of relevance in urine testing; most groups do not test for CBD.



### The primary concern for athletes is how much THC might remain in hemp oil or a CBD product.

Athletes subject to sport drug testing must consider how much THC they could ingest by consuming hemp oil products, as few are completely free of THC. Pure CBD isolate products would perhaps be acceptable under WADA regulations, but those would be considered a drug in the United States, so CBD isolate is not a legal option for the dietary supplement industry to pursue.

WADA drastically increased the threshold for [THC metabolites](#) in May 2013 to 150 ng/ml, up from 15 ng/ml. Some other sports have followed suit by increasing THC urine thresholds.

## Sports testing




Current [THC thresholds](#) are as follows: MLB—50 ng/ml, NFL—35 ng/ml, NBA—15 ng/ml and NHL—not banned. The NCAA, whose athletes are perhaps most at risk, has the lowest threshold at 5 ng/ml. An initial radioimmunoassay screening threshold is often higher than the confirmation threshold.

The [federal urine testing](#) THC initial screening threshold is 50 ng/ml with a confirmation threshold of 15 ng/ml. The U.S. military has zero-tolerance policies for THC, but also uses the federal urine testing thresholds. The military services each have their [own policy on hemp oil](#); it is prohibited in all but the Marine Corps.

If athletes, or other professionals subject to drug testing, are to consume hemp oil, they must consider the amount of THC they are ingesting to remain below relevant urine thresholds. A study published in the *Journal of Analytical Toxicology*, “Evaluating the Impact on Hemp Food Consumption on Workplace Drug Tests,” is useful in considering what amount of THC might be acceptable to consume for those subject to sport, federal or workplace drug testing (2001 Nov-Dec;25(8):691-8).

In the study, all subjects who consumed 0.45 mg/d of THC were below the 50 ng/ml radioimmunoassay screening threshold considered, and below a 5 ng/ml confirmation threshold by gas chromatography mass spectrometry (GCMS). At 0.6 mg/d of ingestion, only one subject broke the 50 ng/ml screening threshold and the 5 ng/ml confirmation threshold at 5.2 ng/ml.

Based on this study, most athletes or other professionals would not be in jeopardy of testing positive if they keep their ingestion of THC under 0.45 mg/d. However, this was only a limited study. The daily ingestion guidelines gleaned from it should be considered cautiously and conservatively and in no way represent a guarantee that consumption at such levels is acceptable. 



Oliver Catlin is president of the [Banned Substances Control Group \(BSCG\)](#), an international third-party certification and testing provider specializing in prohibited substance testing, label specification and quality verification, GMP (good manufacturing practice) compliance and more. Certifications include Certified Drug Free®, Certified Quality™, Certified GMP™ and Certified Hemp. Services are offered to finished product brands, ingredient providers, and manufacturing facilities in the dietary supplement and natural product industries.



# On CBD, parachutes and evidence

by Blake Ebersole

**INSIDER's take**

- Popular medical professionals and institutions are noting the health benefits of cannabis and CBD, giving credibility to the market.
- Brands have established safety protocols and have distributed CBD to a wide number of consumers without serious adverse events.
- As CBD products explode on the market, the nutrition industry must ensure products stay safe to avoid legal and reputational consequences.

**Cannabis products, whether classified as marijuana or industrial hemp, are** increasingly being recognized as effective front-line treatments for a range of health issues rooted in pain and inflammation. Physicians and medical experts such as [Sanjay Gupta, M.D., have weighed in](#), and the news so far is positive. Many in the health and medical world are accepting sincere and legitimate firsthand and anecdotal reports on cannabis as evidence. Just as people consider parachutes effective to prolong life in skydivers without well-designed clinical trials,<sup>1</sup> it may be the widespread use and perceived safety and efficacy for cannabidiol (CBD) that serve as the strongest type of evidence for its approval.

For those who need studies and expert medical opinions, they're available, too. It seems like ages ago, but in 2017, the Institutes of Medicine (IOM) report "[The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research](#)," stated in no uncertain terms that cannabis provides effective pain relief. The report also said the benefits of controlled and responsible use of cannabis to support pain and inflammatory conditions is likely to outweigh potential risks.

That was before 2018, when CBD really hit the market.

It's hard to believe that only a couple years ago, hemp was dominated mostly by people wearing clothes made of the plant. (Which is just fine; hemp is more sustainable than cotton).<sup>2</sup> But today the hemp industry includes farmers in jeans and businessmen in suits. And entering the market now, while it still requires all the hustle of before (maybe more), is a bit late to the game. Aided by state-run marijuana markets, marijuana-derived CBD grew to a US\$176 million market in 2017, while hemp-derived CBD contributed another \$291 million, according to the Brightfield Group. The CBD market is also estimated to increase another 40 times (yes, by 4,000 percent) by 2022.

What can explain this ridiculous amount of growth? Among other reasons, CBD appears to be one of the few ingredients in the category of safe, effective "anti-inflammatory adaptogens" that people can feel, and that can impact everyday life in a meaningful and positive way. Case in point: In a July 2017 consumer survey from the Brightfield Group, of 2,400 CBD users, 80 percent rated the substance "very effective" or "extremely effective" for anxiety, joint pain, insomnia and depression.

In a July 2017 consumer survey from the Brightfield Group, of 2,400 CBD users, **80%** rated it "very effective" or "extremely effective" for



**Anxiety**



**Joint pain**



**Insomnia**



**Depression**

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More great news is several brands appear to be producing high-quality, safe and effective hemp CBD products, in the absence of federal or state regulation. For a natural product that is so unregulated, serious safety issues have hardly been reported—a considerable “stress test” in real time. In 2018, at least one firm—CV Sciences—announced the determination that its hemp-based CBD products meet the [FDA requirement of GRAS](#) (generally recognized as safe), which is considered one of the last hurdles to full legalization.

In December 2018, FDA approved the GRAS assessment of hemp seeds, seed oil and protein, which coincidentally are permitted to contain trace levels of CBD. The findings of excellent safety for CBD are consistent with the published literature that includes more than 70 studies on various forms and sources of CBD, whether as a drug substance, purified chemical or a hemp extract.<sup>3</sup> CBD also appears to have none of the addictive, psychoactive side effects of tetrahydrocannabinol (THC)—in fact, it is known to counteract the “high” of THC.

Not everyone is so positive about the growth of CBD. A January 2019 [report](#) by the National Law Review stated some hurdles for the industry ahead, including an expected public meeting with FDA, and guidance from FDA, USDA and DOJ. It is likely firms that market CBD and can vouch for its safety and quality will have the upper hand in the soon-to-be-regulated CBD world.

**For a natural product that is so unregulated, serious safety issues have hardly been reported—a considerable “stress test” in real time.**

Another interesting finding from the Brightfield Group consumer survey is a sentiment echoed by many: Hemp CBD is not even the most effective type of cannabis. Many believe marijuana-derived CBD, typically with a small but measurable amount of THC, is often considered more effective than hemp-derived CBD, which typically contains only traces of THC. Years of studies on cannabis-derived drugs suggest a combination of CBD and THC may be more effective for some medical conditions than either compound on its own<sup>4</sup>—one of the first examples of the “entourage effect” considered more fact than myth. Yet for many people, hemp CBD, including more purified forms without measurable THC or terpenes, works fine, often better than nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotic painkillers. The power of cannabis, like the parachute, is self-evident to those who are sure of what they are feeling.



More observations and data must be generated, as always. [The Harvard Health Blog](#) noted CBD can cause nausea, fatigue and irritability. It may also theoretically interfere with drug metabolism in a similar fashion as grapefruit juice, but more studies need to be done to understand if animal study findings at mega-doses can be replicated in humans at human doses. Research also hasn't determined what dosages of CBD work for what health application and for whom. Despite many millions of servings of CBD being consumed, and a lot of anecdotal evidence, clinical study data is limited on the types commonly found on the market, such as crude extracts from hemp and marijuana containing CBD.

Just because parachutes are accepted as effective does not mean anyone should be allowed to make and use them as they want. One musn't forget the recent lessons of asbestos in baby powder and virulent *E. coli* in wheat flour—safe and effective products don't just happen. They require a lot of work that stands up to the closest scrutiny. But at least for now, CBD appears to be low on FDA's priority list of public health hazards. This could change if the continued lack of regulation coupled with industry growth permits a similar crisis in product safety.

Now is the time to develop the appropriate science, substantiation and regulations for CBD aligned with similar products, including dietary supplements. It is true the anticipation of economic growth and sustainable agriculture spurred by an integrated U.S.-based hemp industry is yet to be realized. But it's also true millions of Americans have now leaped to CBD with limited evidence, and they have landed on their feet. 🌀



*Blake Ebersole has led several botanical quality initiatives and formed collaborations with dozens of universities and research centers. As president of [NaturPro Scientific](#), Ebersole established quality compliance and product development services for supplements and ingredients such as ID Verified™. Follow him on Twitter at [@NaturalBlake](#).*

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## CBD players must differentiate themselves in evolving market

**US\$390 million. The figure should silence the critics who feel cannabidiol (CBD)** is nothing but hype. It represents 2018 revenues in the hemp-based CBD industry in the United States, according to *Hemp Business Journal*.

No doubt about it—the CBD market is growing like gangbusters. In 2018 alone, two prominent players whose shares are traded on foreign exchanges raised tens of millions of dollars in capital to help plan for expansion in the United States and abroad.

In an initial public offering (IPO) in Canada, Charlotte's Web generated net proceeds of \$71.5 million. Elixinol Global raised \$40 million Australian dollars (US\$28.7 million) in a secondary offering. Institutional investors are hungry to sit at the CBD table amid monumental changes in federal law.

Thanks to the 2018 Farm Bill, DEA no longer will interfere with hemp in interstate commerce. Retailers—both large and small—are carrying hemp extracts and reporting strong consumer demand. And FDA has signaled a willingness to identify a legal path for CBD in foods and supplements.

To be a winner, it's not enough to sell CBD or hemp extracts in a supplement or food. It's too late to be the first to market. Hundreds of brands are peddling hemp extracts.

The challenge? "I don't see much innovation in the CBD category," Twinlab CEO Anthony Zolezz observed.

A few key principles could help a business stay ahead of the competition:

**Companies must separate themselves from an increasingly cluttered pack.**

They can do so through product formulation, creative branding and other initiatives that carve out a specialized niche within the broader CBD/hemp extracts market.

"As CBD and THC become more mainstream, and manufacturers recognize their potential, the market will be dominated by outcome-based products," stated Zora Milenkovic of Euromonitor International.

**Legal and regulatory compliance is equally paramount.** Marketers and manufacturers of hemp-derived CBD must strictly adhere to local, state and federal laws and regulations. Institutional investors aren't keen to risk their capital on players who flout the rules, inviting government scrutiny.

In a statement the day the Farm Bill was signed into law, FDA's commissioner, Scott Gottlieb, M.D., asserted his agency would only consider a path to market for CBD in a food or supplement "if the agency were able to determine that all other requirements in the [Food, Drug and Cosmetic Act] are met, including those required for food additives or new dietary ingredients."

The future looks bright indeed for the hemp-based CBD industry—provided companies are willing to follow all the rules and create safe products that provide consumers with meaningful health benefits.





Do you think CBD should be legal for dietary supplements and why?



Yes. FDA may try to assert NDIs (new dietary ingredients) or GRAS (generally recognized as safe) with supplements, but it will settle for preventing drug disease claims.

Todd Runestad  
Senior Editor



Yes. The 2018 Farm Bill removed the restriction on hemp and the holdup to move ahead into dietary supplements is no longer warranted.

Danielle Dunlap  
Vice President of Marketing Services



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