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A Primer on CBD's Complex & Changing Landscape

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Companies in the CBD space are facing a regulatory and legal landscape that continues to be uncertain at best. In fact, the one certainty at present is the lack of concrete standards governing both the growing hemp production and commerce. As a result, companies selling CBD products face a range of risks. These risks include the threat of FDA enforcement, increasing consumer litigation, potential FTC enforcement, and a maze of contradictory state-level laws and regulations. These pressures present increased exposure in a market facing an ongoing downturn in market prices for CBD and other hemp derivatives.

This article briefly highlights the most prevalent risks in the current landscape facing CBD companies. It then offers practical steps that companies can take to mitigate those risks.

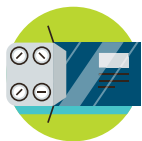


THE WILD WEST: A Snapshot of the Current CBD Regulatory Framework

CBD, the commonly used shorthand for cannabidiol, has seen a well-publicized boom since the 2018 Farm Bill removed from the Controlled Substances Act both hemp and its derivatives with less than 0.3% tetrahydrocannabinol, or THC, the psychoactive ingredient in cannabis.

Although it de-scheduled hemp, Congress also maintained the FDA's regulatory authority over products featuring hemp derivatives, including CBD and its cousin, CBG. But Congress gave the FDA little guidance on how to regulate CBD, and in the ensuing 15 months, the FDA has been slow to regulate the ingredient despite pressure from the industry, lawmakers, and other stakeholders for the FDA to provide formal guidance. In the meantime, the market is being flooded with a wave of new CBD products. As a result, everything from CBD jellybeans to CBD-infused lattes are being marketed and sold in a legal gray area.

Numerous companies and investors have not waited for the FDA to act but have instead moved forward to market while keeping a close eye on the FDA and other regulators, as well as an eye on nascent litigation. The following are the most prevalent areas in which companies face risk:



1. **FDA action** enforcing the FDA's position that **CBD is not legal as a food additive or dietary supplement**.
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2. **Civil litigation**, with industry-watchers predicting a coming wave of consumer litigation, including class actions alleging that CBD products did not live up to their lofty promises of anxiety reduction and chronic pain relief.
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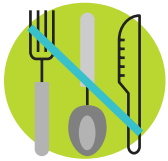
3. **State-level laws and regulations**, which are all over the place and often contradictory.
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4. **FTC action**, primarily **cracking down on CBD marketing** that contains treatment claims without scientific backing.



Companies have been long hoping for the FDA to give CBD products a **“generally recognized as safe”** designation.



FDA'S POSITION: Not Safe, Not Food

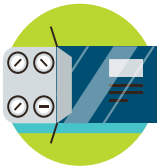
The FDA has yet to issue formal regulations for CBD products. But a Q&A document on the FDA website states that the agency has concluded that “CBD products are excluded from the dietary supplement definition.” The FDA’s conclusion stems from the fact—something of an accident of history—that CBD was first investigated and approved as a pharmaceutical drug (Epidiolex) before being put on the market as a dietary supplement.

In other words, virtually any ingestible product containing CBD is technically illegal. This may come as a surprise to observers who have seen CBD-infused products—ranging from gummies to lattes to protein powders—proliferating on Walgreens shelves, mall kiosks, Kroger grocery stores and online marketplaces. But availability does not equate to legality.

Nevertheless, CBD-infused vapes, edibles, and bottled water already are flooding the market. In late October 2019, the FDA sent warning letters to 15 companies marketing CBD products using scientifically unsupported health claims. Those letters represent the extent of the FDA’s enforcement so far, but industry watchers expect that the FDA’s enforcement efforts could escalate in coming months.

Companies have been long hoping for the FDA to give CBD products a “generally recognized as safe” designation. (The “generally recognized as safe”—or GRAS—designation permits a substance to be used as a food additive without undergoing the FDA approval process.) Instead, in a November 25, 2019 press release, the FDA expressly declined to give CBD food additives a GRAS designation, stating that at present the FDA “cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.”

The FDA’s November 25 statement assured the CBD market that the agency “continues to explore potential pathways for various types of CBD products to be lawfully marketed” and promised that the FDA would give a progress update regarding its CBD approach in the coming weeks. But many weeks later, the FDA has still provided no further guidance on the legality of CBD as a food additive or dietary supplement.



FTC'S POSITION: Cracking Down on Wonder Drug Promises

Like the FDA, the FTC has sent warning letters to a handful of companies marketing CBD to consumers as a cure-all for a wide variety of ailments and conditions. The first round of such letters were issued in September 2019 to three different companies that had advertised their CBD products with wholly unsubstantiated health claims. Subsequently, in October 2019, the FTC sent joint warning letters along with the FDA. The warning letters signaled that the FTC is prepared to move against sellers who are loosely marketing the additive as a cure-all remedy for everything from insomnia and inflammation to Alzheimer's and cancer.



CONSUMER LITIGATION: A Coming Wave of Class Actions and Other Civil Suits

The lack of a federal regulatory framework along with the dearth of concrete standards for CBD products create conditions that are ripe for civil litigation. Indeed, plaintiffs' lawyers have so far filed over half a dozen proposed class actions against CBD companies over their labeling practices.

The first round of these lawsuits was filed between August and October 2019. Two of the suits were filed against Just Brands USA Inc., with the suits including allegations that CBD products contained less than the advertised dosage of CBD and that consumers of edible gummies failed drug tests despite labeling that said that the gummies contained no THC.

Another class action, filed in September 2019, against Hemp Bombs, alleges that Hemp Bombs' product label and website systematically and grossly misrepresent the actual CBD content of Hemp Bombs' product. In yet another class action complaint filed in September, Diamond CBD was also accused of misleading advertising that inflated its products CBD content.

A more recent spate of class actions filed over the recent weeks allege that the companies, by marketing CBD products as dietary supplements, misled customers into the belief that they were buying FDA-approved products. These lawsuits claim that the companies thereby engaged in "false, fraudulent, unfair, deceptive, and misleading" marketing of their CBD products. The named defendants in the lawsuits include a couple of industry giants along with other known CBD manufacturers.

In most of the lawsuits, plaintiffs' lawyers are asking the court to require the companies to disgorge all of the profits they've made from their "misleading" advertising as well as pay other damages and punitive damages. But the main hurdle for all the cases will be the class certification stage; if a case is certified, the defendant company will face liability exposure that could bankrupt most players in the nascent industry.

In early February, two of the defendant CBD manufacturers—Colorado-based Elixinol and Koi CBD—filed motions asking the courts to dismiss the cases altogether on the ground that the "uncertain regulatory landscape" surrounding CBD as a dietary supplement does not make it illegal. The manufacturers argued that FDA's press release about CBD as a food ingredient

does not constitute formal guidance, much less binding law. The manufacturers urged the courts, at a minimum, to stay the class action proceedings pending the conclusion of formal rulemaking by the FDA, as at least one federal court in Florida did in early January of this year. (Shortly after the filing of Koid CBD's motion, the case against it was voluntarily dismissed.)

Experts believe that the lawsuits filed so far are just the tip of the iceberg and that CBD processors and retailers could face a floodtide of consumer litigation over the failure of CBD products to meet their often over-the-top claims or to contain the promised quantities of CBD.



STATE-LEVEL REGULATION: A Maze of Differing Laws

In the same 2018 Farm Bill that removed hemp from the Controlled Substance Act, Congress delegated broad authority to the states to regulate hemp cultivation, extraction, and distribution. As a result, companies selling CBD products face contradictory regulations within the same states and across borders. Even practitioners who specialize in the space are scrambling to keep up with who can sell what products where and how products can be labeled and transported.

For example, Mississippi, Idaho, New Hampshire and South Dakota continue to prohibit production of the crop within their borders. Meanwhile, Oklahoma requires labeling indicating whether the CBD additive is natural or synthetic and where the CBD ingredient originated, while Maryland prohibits the use of CBD as an additive to food or beverages. In other states, like Colorado, CBD is virtually unregulated aside from agricultural regulations governing its cultivation in order to prevent growers from exceeding the 0.3% THC limitation.

In a recent example of the complicated interplay between conflicting state laws (and federal laws), an Idaho judge ruled in a January 21, 2020 ruling that Idaho State Police had acted properly in impounding 6,701 pounds of industrial hemp that a Big Sky Scientific (a Colorado-based CBD company) was transporting from Oregon to Colorado. The hemp at issue had been grown in Oregon and was being transported to Colorado—both of which states have industrial hemp pilot programs. Even though the hemp crop complied with Oregon's and Colorado's laws, and tested below or at federal THC standards to qualify as industrial hemp, the judge found that its owner had forfeited all rights to the hemp by illegally transporting it through Idaho.

The Big Sky Scientific judge's ruling—which was set forth in a wide-ranging order discussing the present confusing interplay of federal and state regulation of various cannabis species—highlights the complicated legal and botanical issues facing the market. And the ultimate outcome underscores the labyrinth that must be navigated by CBD companies operating across state lines. The months ahead will bring an increasing number of rulings addressing that labyrinth, some of which may severely penalize unwary companies, as happened with Big Sky.

Companies selling CBD products **face contradictory regulations** within the same states and across borders.

Another problematic area involves interstate transportation of hemp-derived crude oil. According to Stuart Harrison, an Ernst & Young partner who works with clients in the industrial hemp and CBD space, “Concentrations of all cannabinoids—including THC—will increase during the extraction of crude oil from hemp. Thus, concentrations of THC will likely be above the 0.3% level prior to further refinement or dilution.” For this reason, Harrison advises his clients to avoid transporting crude oil across state lines. This includes avoiding sending crude oil samples to labs for testing in another state and transporting crude oil between extraction or processing facilities in different states.

IMPACT to the Investing Community

“The current climate is slowing the influx of new investors,” said Harlan Lyons, CEO of ASK Consulting Group LLC, a consultancy specializing in start-up and growth companies in the Hemp / CBD space. “Smart money is conducting even deeper due diligence than we’ve seen in the past,” added Lyons, “to ensure quality and testing can be verified and claims are validated and represented accurately and in alignment with local, state and platform requirements.”



YOUR COMPANY: How Can Your Company Stay Compliant and Minimize its Risk Exposure?

From a legal compliance standpoint, CBD companies should give particular attention to the following compliance areas:

1. **Packaging and marketing content:** Your company should examine its packaging and marketing materials—and those of your distributors—to ensure that you are not making any scientifically unsupported claims or inflated claims regarding CBD content and its purported benefits. As noted, the FDA, the FTC, and plaintiffs' lawyers have all shown a willingness to go after exaggerated or unsupported claims. Also, be careful what your company and any of its representatives say on website and blog posts.
2. **CBD as a dietary supplement:** Your company should be aware that the sale of any CBD-infused food or beverage is still, for the moment, not yet FDA approved. Although the FDA has not shown any indication that it will pursue companies on this basis alone, some class action lawyers have demonstrated such a willingness. Notably, topical CBD products have received far less scrutiny from regulators.
3. **State-by-state regulation:** Your company should have up-to-date information on the regulatory regime of any state in which you grow, extract, or sell hemp or its derivatives.
4. **Interstate transport:** As illustrated by the Big Sky Scientific ruling in Idaho, your company should be in the know regarding the legal status of CBD for any state that your CBD products will be passing through in transit. It's also important to understand what coverage may exist to protect your goods in transit and scenarios in which insurance can help protect.
5. **Policy response:** Given the nuances in class action litigation, coverage can respond differently than what you may expect. Your company needs to understand how various markets have structured their policies, where coverage gaps exist and if you truly have coverage for claims brought against the business.

Disclaimer: This article does not constitute legal advice.

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