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Retailers and Restaurants Shouldn't Rush to Enter the Budding CBD Market

A risk manager for a well-known retailer recently made a surprising discovery when visiting one of the company's stores. On sale on the shop's shelves was a lotion infused with cannabidiol (CBD), one of the key chemicals found in hemp and marijuana. The retailer had begun placing hemp-derived CBD-infused product in its stores, and, in the rush to meet booming demand, had neglected to inform its risk manager.

From edibles to cosmetics and skin care, the market for products containing CBD is surging. There is growing consumer interest in the unsubstantiated claims made by CBD advocates that it can boost health and wellness, including treating chronic conditions and relieving stress and anxiety.

Last year, Congress took the crucial step towards legalizing hemp-derived CBD. The Agricultural Improvement Act of 2018, better known as the federal farm bill, took hemp-derived CBD off the banned substances list identified in the federal Controlled Substances Act of 1971 (CSA), where it had sat for decades alongside tetrahydrocannabinol (THC). While it is not a

psychoactive substance, CBD occurs naturally in both marijuana and hemp along with the mind-altering THC, the compound that creates the feeling of a "high" experienced by marijuana users. CBD derived from marijuana remains a Schedule I controlled substance under the CSA.

And in a major step, during a May 31 hearing, the US Food and Drug Administration kicked off a review of the use of hemp-derived CBD in an array of products, from drugs to cosmetics.

So, case closed? Well, maybe not quite yet.

There is still no clear green light — or perhaps, for that matter, even a yellow one — from the federal government for the sale and use of hemp-derived CBD in consumer and health products. As retailers weigh consumer demand for CBD-infused products, there are several potential state and federal legal and regulatory issues for retailers to consider.

While the 2018 farm bill took a major step towards legalizing the use of hemp-derived CBD in products, the FDA will make the final determination in a review process that could take months to play out and whose final result is uncertain. And whether a CBD-infused product is legal "depends, among other things, on the intended use of the product and how it is labeled and marketed," wrote Dr. Scott Gottlieb, the FDA's commissioner, before he stepped down in April.



An Evolving Federal Regulatory Scene

The market for hemp-derived CBD products is expected to reach \$20 billion by 2024, up from \$1.9 billion in 2018, according to a study by BDS analytics and Arcview Market Research. And many retail and restaurant organizations have entered the fray this year. Two major national retail pharmacy chains, for example, announced in March 2019 that they plan to start selling hemp-derived CBD-infused creams, sprays, patches, and other products in a number of states. A national restaurant chain, meanwhile, rolled out a CBD-infused cheeseburger on April 20, a day when marijuana advocates typically highlight legalization efforts.

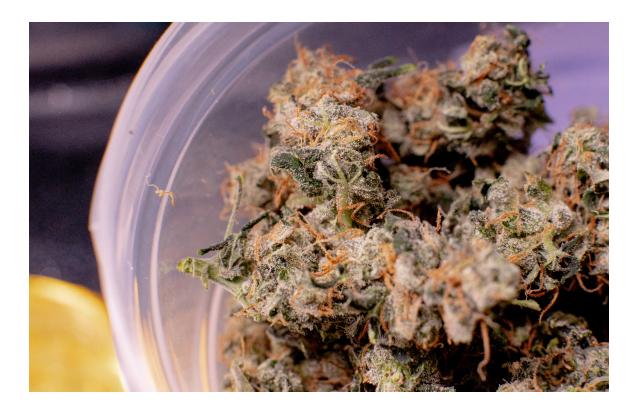
Federal regulators are scrambling to keep up. In addition to its federal ban under the CSA, many state governments had also long prohibited both THC and CBD. That's begun to change recently, with some states starting to draft regulations for hemp and hemp-derived CBD. Still, while hemp-derived CBD is no longer considered an illegal substance, regulators are miles away from giving their blessing to products with the substance in them.

At the May 31 public hearing in Washington, FDA officials heard testimony from business and industry groups eager to see a clear pathway to market for a broad array of products containing hemp-derived CBD. On the other side of the aisle were critics, including organizations opposed to the use and legalization of marijuana — and by extension, CBD — which argue that its health impacts and potential risks have not been sufficiently studied.

In comments made after the hearing, Dr. Amy Abernathy, the FDA's principal deputy commissioner, acknowledged "the need to further clarify the regulatory framework to reduce confusion in the market." She argued that extensive study of CBD is needed to address key questions and set safety thresholds.

While federal regulations regarding hemp-derived CBD products remain a work in progress, retailers and restaurants can find some guidance from the FDA itself, which posted an extensive Q&A on its website in April 2019.

CBD products meant to be consumed in edibles or ingested as medicine remain illegal as far as the FDA is concerned, and will stay that way until the agency is able to study their health impacts and come to a decision.



This includes dietary supplements or other drugs containing CBD that claim to treat various medical conditions. The one exception is Epidiolex, an anti-seizure drug containing CBD that was approved by the FDA in June 2018.

By contrast, marketing and use of CBD in products like cosmetics and lotions do not face such severe restrictions. Cosmetics are defined broadly by the agency as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance." Cosmetic products are not required to be pre-approved by the FDA, and cannabis and cannabis-derived ingredients are not on a list of substances the agency prohibits in the use of makeup, lotions, and similar products.

A Patchwork of State Regulations

Interest in CBD-infused products may be driven in part by shifting attitudes toward the legalization of marijuana for medical and recreational use. Roughly 70% of the US population lives in states where restrictions on marijuana use have been partially or completely lifted.

Retailers, determined to establish a strong foothold in the fast-growing market, have expressed interest in selling CBD products across the country. But they can't assume that legalization in several states is a green light to restock their shelves. That's because the regulatory situation in states that have legalized marijuana and/or CBD products may in fact be more complex and challenging to navigate.

Even in states that have legalized medical and recreational marijuana, a separate regulatory agency may be charged with overseeing the sale of hemp-derived CBD products. A prime example is California, where the Bureau of Cannabis Control oversees the sale of CBD-infused products through the regulated medical and recreational marijuana market. But the California Department of Public Health — the agency that oversees California's food and drug laws — has stated that hemp-derived CBD products may not be sold outside of the regulated marijuana market until such time as the FDA provides guidance on how these products may be lawfully sold. A proposed bill, AB 228, may pave the way for hemp-derived CBD products to be sold in the state before the FDA makes a determination on the federal level by permitting hemp-derived CBD products to be sold to the general public in California stores, and not only in regulated marijuana retail outlets.

Key Takeaways

With demand for hemp-derived CBD products rising, retailers and restaurants understandably face intense pressure to get in on the ground floor and establish market share, or face losing out to competitors. But in their efforts to steer clear of regulatory and legal hazards, there is much for corporate risk managers to consider.

The federal regulatory framework for overseeing hemp-derived CBD products remains very much a work in progress, with the FDA just beginning what is likely to be a lengthy review of the use of the cannabis extract in everything from medicines to hamburgers. But retailers must also look closely at the laws and regulations of the states in which they plan to sell CBD-based products. States that have legalized recreational and medical marijuana may have different regulatory requirements for the sale of hemp-derived CBD products, as is the case in California.

Thus, before stocking up on hemp-derived CBD-infused products, retailers must do their homework — not just on FDA rules, but also on the laws and regulations of the states in which they plan to sell their products.





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