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CANNABIS INTELLIGENCE BRIEFING

CBD: Cannabinoids Escape the Dispensary

EXECUTIVE SUMMARY

In the absence of clear guidance, some U.S. states have moved ahead individually on CBD, as many have also done on legalizing cannabis, circumventing federal regulation and allowing CBD as a food additive in their own statutes

CBD: Cannabinoids Escape the Dispensary

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Arcview Market Research in partnership with BDS Analytics

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Executive Summary

Cannabidiol, popularly known as CBD, has captured the imagination of businesses, consumers, regulators and cultivators. The compound is now experiencing attention on the same level that its sister compound, THC, has been receiving since the cannabis legalization movement began.

Driving the expectation—and the hype—is copious anecdotal evidence and emerging scientific proof that CBD may be able to address a laundry list of ailments and conditions. While the endocannabinoid system was identified decades ago, researchers are just beginning to understand the effects of CBD on that system, with studies being conducted on a wide array of ailments and conditions. With Epidiolex, the first plant-derived CBD drug approved by the U.S. Food and Drug Administration (FDA), now on the market for the treatment of Dravet and Lennox-Gastaut syndromes, CBD has received official government acknowledgement of its efficacy as medication.

But enthusiasm alone does not make a market. There are substantial complexities to CBD that will make the next few years a make-or-break situation at all levels of the industry.

Deregulation and re-regulation are happening at lightning speed. The Agricultural Act of 2014 opened up pilot programs for hemp growers and led to a proliferation of hemp and hemp-derived CBD products across the country. At the same time, legal cannabis dispensaries experienced an increase in demand for higher CBD products. That demand has established the legal cannabis dispensary channel as the biggest revenue generator for the CBD industry to date.

The Agriculture Improvement Act of 2018 specifically allowed for the legal commercialization of hemp cultivation, opening the doors for hemp-derived CBD products (hemp is legally defined as *Cannabis sativa* with less than 0.3% THC), but CBD as a food additive or supplement remains illegal at the federal level. While this regulatory shift cleared the air a bit, it has left confusion on the state level and put manufacturers of CBD edibles and supplements on the wrong side of federal law. States have a blueprint from the legal cannabis industry on how to navigate these issues, and many are pushing the boundaries by writing their own laws on hemp-derived CBD usage and distribution (see: "States Break Trail Again").

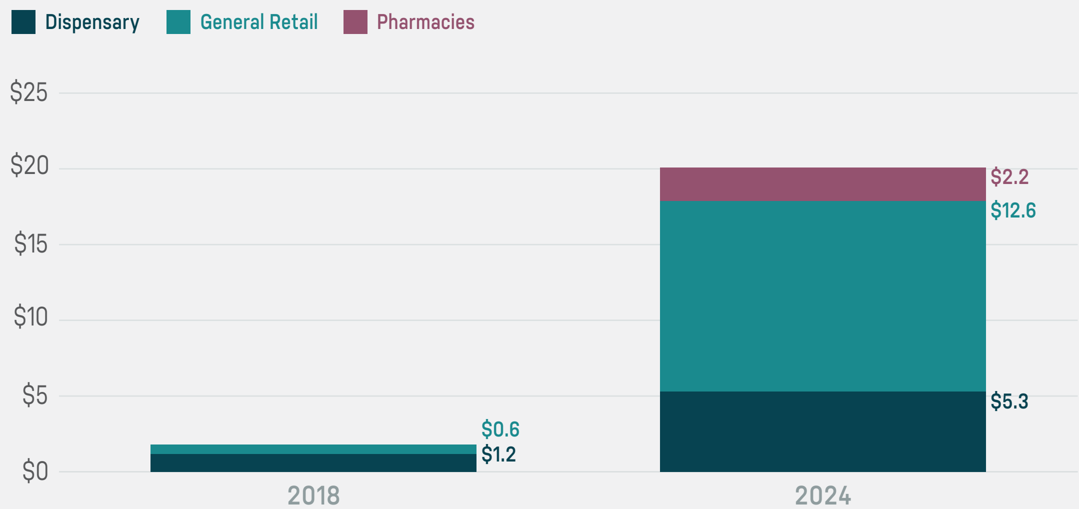
The FDA held hearings on May 31, 2019, to gather testimony from stakeholders on how it should regulate CBD. Recent statements from FDA officials echo pharmaceutical company testimony, leading to concern that regulators are leaning toward a highly restrictive federal regulatory scheme for the compound. This could hamper the growth of the CBD market in the U.S., at least in general retail channels. However, the likelihood that the FDA can rebottle the CBD genie is slim, given the long-standing history of medications having both pharmaceutical and over-the-counter versions, the existing structure of a vast legal nutraceutical market into which THC-free CBD products neatly fit and—most importantly—the existence of state-sanctioned dispensaries selling more than a billion of dollars' worth of CBD products already.

Even if the FDA were to adopt a highly restrictive model, it is more likely that states and the hemp industry will follow the precedent of the established legal cannabis market by asserting state authority. In any case, cannabis-based CBD likely will continue to enjoy broad legality and availability through dispensaries in legal states. Many states may allow hemp-based CBD to move quickly into general retail, while every state in the union already has an FDA-approved form available in pharmacies.

In this forecast, it is assumed that the FDA decides to approve hemp-based CBD as a food additive in products in general retail stores. That will change the market mix dramatically. Cannabis dispensaries currently lead the way, generating $1.2 billion in 2018 sales to general retail's $624 million—alongside a very small contribution from CBD pharmaceuticals. But, with the assumed cooperation of the FDA, dispensaries will generate $5.3 billion in CBD sales, general retail $12.6 billion and CBD pharmaceuticals $2.2 billion by 2024 (see: "How US CBD Sales Will Quintuple by 2024").

That kind of explosive growth in retail sales would reverberate up the supply chain, prompting a hemp-cultivation boom, especially in those states that are moving

US CBD Sales, 2018 vs. 2024 (In Billions)



Source: Arcview Market Research/BDS Analytics

Cannabis dispensaries currently lead the way, generating $1.2 billion in 2018 sales to general retail's $624 million—alongside a very small contribution from CBD pharmaceuticals

quickly to license growers now that the plant's cultivation is federally legal (see: "Hemp Versus Cannabis for CBD"). The cultivation of CBD-rich hemp is very different than growing industrial hemp for its fiber content. Even with this kind of growth in retail sales, demand for CBD-rich flower would still trail that for legal cannabis, but the gap would be closing by 2024.

The industry still has much to do to educate the consumer. As shown in studies by BDS Analytics' Consumer Insights, the consumer, while attracted to the CBD story, remains confused about CBD products (see: "Where, What and Why"). Cannabis dispensaries are in the best position to continue the education of consumers they've begun, which could prove pivotal in the coming battle between dispensaries, pharmacies and general retailers for the CBD consumer. This is essentially the cannabis dispensaries' battle to lose, and they have substantial advantages against mass-merchant competition that has decimated many specialty-store sectors in the past.

Much depends on the product mix that attracts the most consumer interest. Inhalables set the CBD ball rolling via dispensaries, but will not be widely available elsewhere. Other retail types have advantages specific to their markets, such as pet stores' ability to serve all pet owners' needs in one location.

Nobody would have predicted the CBD phenomenon when California legalized medical cannabis in 1996. Now it is simply the next stage in a market battle that will likely play out again and again as scientists and consumer products developers work on the 100-plus other cannabinoids in *C. sativa*. CBD is the first cannabinoid to escape the dispensary; it will not be the last, with some in the industry already moving on to other cannabinoids such cannabigerol (CBG) or cannabidivarin (CBDV).

Letter From the Editor

Humans have been consuming cannabis for several millennia; what if its popularity turns out to be at least as much about the relaxing effects of cannabidiol (CBD) as the psychoactive impact of tetrahydrocannabinol (THC)?

According to Dr. Jeff Chen, head of University of California at Los Angeles' Cannabis Research Initiative, the ratio of THC to CBD in commercially available cannabis soared from 10-to-1 in 2000 to 79-to-1 today. He speculates that "it might have only been 2-to-1 or 1-to-1" 20 years earlier." The '60s counterculture adopted cannabis as its recreational drug of choice and began to breed it with the goal of increasing its psychoactive properties. Now the exact opposite is happening with specialists such as Charlotte's Web breeding strains with the goal of lowering the psychoactive properties to negligible.

The importance of cannabinoids beyond THC, both in the plant's historic popularity and in the legal business now being built around it, is supported by:

- The clear evidence of an "entourage effect": reported and measurable differences between the consumption of flower or whole-plant extracts versus highly refined THC distillates.
- The growing popularity of products now being marketed based on their containing substantial amounts of CBD in the legal dispensary channel.
- The acknowledgement by the Food and Drug Administration (FDA) in its approval of the first cannabis-plant-derived pharmaceutical, Epidiolex, in June 2018, that CBD has efficacy in the treatment of central nervous system disorders.

This is a line of thinking that casts Congress' legalization of the growing of hemp (low-THC cannabis plants) in the December 2018 Farm Bill in a whole new light: CBD products in pharmacies and health and wellness channels might be a small fraction of what we view as the legal cannabis market of today, but they are likely to be a much bigger piece of tomorrow's Total Cannabinoid Market.

Forecasts of such future revenue streams, based largely on the just-now emerging science around cannabinoids, can only purport to be directionally correct. Just ponder what science—agricultural and medical—has done with other plants while the 100-plus cannabinoids in *C. sativa* were under lock and key for 80 years. The legalization of CBD is going to spark a profusion of product development and distribution channel innovations in the Total Cannabinoid Market for years to come.

Tom Adams
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