

Impact of CBD-Derived Products on State Boards of Pharmacy



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As states have begun legalizing marijuana for recreational use and attention to the potential medicinal benefits of marijuana and its derivatives has increased, states and the federal government are struggling to add a layer of regulation for new classes of products made from cannabis.

History of Federal and State Regulation

Cannabis is a species of plant with a long history of use for its numerous phytochemicals and fibers. Among the 104 identified biologically active chemical compounds, called cannabinoids, the two most commonly known are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

While both THC and CBD share similar properties, including molecular structure, a slight chemical difference accounts for how each affects the body's cannabinoid receptors. Cannabis' psychoactive effects are associated with THC, which is also responsible for the adverse effects reported from acute or regular cannabis use. On the other hand, CBD has a different chemical structure devoid of psychoactive effects.

Although marijuana has remained illegal under federal law for decades, states contradicted federal laws by creating state laws legalizing medical, and now recreational, use of marijuana. California first legalized medical marijuana in 1996 and 16 years later, Colorado voters approved recreational marijuana in 2012. All but four states (Idaho, Kansas, Nebraska,

and South Dakota) allow some form of medical marijuana or CBD with low THC content.

Federal Regulation of Cannabis Products: 2018 Farm Bill

The Agriculture Improvement Act of 2018, Pub. L. 115-334 (the 2018 Farm Bill) dramatically expanded prospective opportunities for hemp and hemp-derived products. Specifically, it expanded the industrial hemp definition to mean "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 concentration of not more than 0.3 percent on a dry weight basis."

Carving out the industrial hemp definition from the Controlled Substances Act Schedule I was a major change, but the 2018 Farm Bill did not outright legalize CBD or marijuana. Marijuana and hemp are both encompassed under the umbrella of "cannabis," but with hemp being distinguished as having less than 0.3% THC. Hemp is the only form of cannabis that can be legal under both federal and state law. On October 29, 2019, the United States Department of Agriculture (USDA) announced the establishment of the US Domestic Hemp Program to help states complete their hemp agriculture plans in time for the 2020 planting season. State agriculture plans will address record keeping, testing for THC, disposal procedures for plants having too much THC, and related inspections and certifications. The similarity in appearance between hemp and marijuana are going to be ongoing challenges for law enforcement authorities as they will increasingly need to rely on testing and certification schemes that will need to



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be developed. Regulation by USDA does not mean substances made from hemp can be used in food. As is the case for all substances used in food, Food and Drug Administration (FDA) has an essential role in regulating substances made from hemp that will be used in food or dietary supplements.

Federal Regulation of Cannabis and Cannabis-Derived Products: FDA

Excitement about substances made from cannabis does not change FDA responsibility to regulate all substances added to food. The FDA authority to regulate products containing hemp-derived substances presents more complex issues that will take longer to resolve. Certain hemp-related ingredients that are derived from plant parts lacking THC or CBD already may be lawfully added to food and dietary supplements (eg, hemp seed oil, which is the subject of a 2018 notification to FDA that the substance is generally recognized as safe).

Not all substances that may be derived from hemp can be used in food or dietary supplements. **It is unlawful to sell food or dietary supplements containing added CBD regardless of whether the substances are hemp-derived.** This is because CBD and THC are active ingredients in FDA-approved drugs and were the subject of clinical investigations before they were marketed as foods or dietary supplements. When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act, the exclusion applies unless FDA uses a “never-before-used option” to issue a regulation making it lawful to use a prior-approved active ingredient as a dietary supplement or food.

FDA has approved Epidiolex®, which contains a purified form of CBD. In addition, FDA has approved three cannabis-related drug products –

Marinol® and Syndros® that include the active ingredient dronabinol, a synthetic THC, and Cesamet™ that contains the synthetically derived active ingredient nabilone, which has a chemical structure similar to THC. These approved products are only available with a prescription from a licensed health care provider.

Before food and dietary supplements can lawfully contain hemp-derived ingredients like CBD, FDA must first resolve the complicated issues caused by the prior approval of CBD as a drug ingredient. FDA has sent mixed messages about whether this will be done through the regular rulemaking processes. Despite the typical regulatory process taking years, FDA has said consumer interest in cannabis-related products compels the agency to move quickly. FDA sought input from the scientific community and industry at a heavily attended public meeting in May 2019 and has promised to provide a framework for future regulatory activities before the end of 2019.

In the meantime, an increasing number of dietary supplement and food products are being marketed under the belief that FDA is exercising “enforcement discretion” by tacitly allowing dietary supplement or food products that contain CBD or related ingredients to be marketed as long as claims are not the type considered “over-the-line” by former FDA Commissioner Scott Gottlieb during a March 2019 subcommittee hearing before a US Senate Committee on Appropriations. Consistent with that approach, in 2019, FDA sent four warning letters to dietary supplement companies that focus on claims not allowed for supplements (eg, related to Alzheimer’s, cancer, depression, arthritis, etc), while making a relatively lighter mention about the illegality of the CBD ingredient. There have been no FDA enforcement actions based solely on the presence or use of CBD.

In the short term, regulatory developments for food and dietary supplements will continue to affect the operations of pharmacies that are already selling or intend to sell cannabis-derived products. Further, we anticipate that state boards of pharmacy will increasingly be looked to as a resource on issues of CBD sales and safety. As such, it will be important to actively track developments from FDA, USDA, and state governments. This includes confirming whether and how states are updating their own controlled substance laws to reflect the federal-level changes that already occurred in the 2018 Farm Bill.

In the long term, FDA’s policy decisions about possible CBD use in food and dietary supplements will have strategy implications for the research and development of FDA-approved prescription drugs. Once FDA provides a framework for cannabis products used in drugs, food, and dietary supplements, it is anticipated that FDA’s enforcement strategy for food and supplements will broaden beyond claims enforcement to more forcefully prevent food and supplement products from containing ingredients that FDA determines are for use only in drugs. This FDA enforcement and guidance will be useful for boards of pharmacy as they protect the health and safety of patients who encounter cannabis products in circumstances beyond the current use in drugs. NABP will continue to monitor policies that help state boards of pharmacy to fulfill their public health missions and will seek ways to work together with relevant stakeholders to benefit patient health and consumer safety.

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