Congressional Research Service
Informing the legislative debate since 1914

IN FOCUS

Updated February 10, 2020

FDA Regulation of Cannabidiol (CBD) Consumer Products

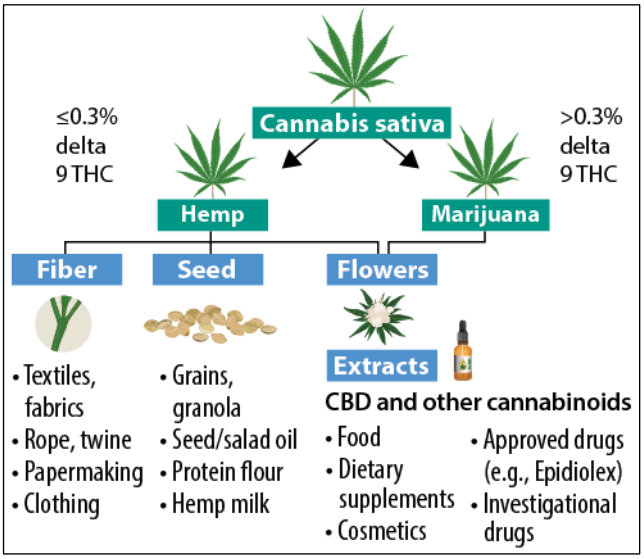
Cannabidiol (CBD) is promoted as treatment for a range of conditions, including anxiety, pain, inflammation, and post-traumatic stress disorder—despite limited scientific evidence to substantiate or disprove many of these claims. CBD is derived from the *Cannabis sativa* plant (commonly referred to as cannabis), which includes both marijuana and hemp. CBD and tetrahydrocannabinol (THC) are thought to be the most abundant cannabinoids in cannabis. CBD is considered to be nonpsychoactive and may be derived from either hemp or marijuana. THC—a psychoactive compound—is found at high levels in marijuana and low levels in hemp. For additional information, see CRS Reports R46189 and R44742.

Regulation of Cannabis: Overview

Botanically, marijuana and hemp are from the same species of plant, *Cannabis sativa*, but from different varieties or cultivars. Marijuana and hemp have separate definitions in U.S. law and are subject to different statutory and regulatory requirements. *Marijuana* (as defined in statute) generally refers to the cultivated plant used as a psychotropic drug, either for medicinal or recreational purposes. It is a Schedule I controlled substance under the Controlled Substances Act (CSA, 21 U.S.C. §§802 et seq.) and is regulated by the Drug Enforcement Administration (DEA). The unauthorized manufacture, distribution, dispensation, and possession of marijuana is prohibited. Despite the federal prohibition on growing, selling, or possessing the drug, marijuana and marijuana-derived CBD have been made available in states where medical and/or recreational cannabis is allowed under state law. *Hemp* (as defined in statute separately from marijuana) is generally grown for broader (nonpsychotropic) purposes, including for use in food, dietary supplements, fabrics and textiles, and other industrial goods (see **Figure 1**).

Until December 2018, hemp was included in the CSA definition of marijuana and was thus subject to the same restrictions as marijuana. The Agriculture Improvement Act of 2018 (2018 farm bill; P.L. 115-334) removed hemp and its derivatives (including hemp-derived CBD) from the CSA definition of marijuana. As a result, hemp is no longer subject to regulation and oversight as a controlled substance by DEA. Instead, hemp production is now subject to regulation as an agricultural commodity by the U.S. Department of Agriculture (USDA). The 2018 farm bill also expanded the statutory definition of what constitutes *hemp* to include "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers," as long as it contains no more than a 0.3% concentration of delta-9 THC (7 U.S.C. §1639o). CBD products that do not meet the statutory definition of hemp continue to be prohibited (aside from lawful use for research purposes) under the CSA and remain regulated by DEA.

Figure 1. Examples of Cannabis-Derived Products



Notes: This figure was created by CRS to provide a high-level illustration of the relationship between cannabis, marijuana, and hemp, per the statutory distinction. As the figure shows, it is difficult to discern between marijuana and hemp based on appearance.

Legislative changes related to hemp enacted as part of the 2018 farm bill were expected by many to generate market opportunities for hemp-derived consumer products such as hemp-derived CBD. However, the 2018 farm bill explicitly preserved the Food and Drug Administration's (FDA's) authority under the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.), including for hemp-derived products. Because the 2018 farm bill did not change FDA law, cannabis and cannabis-derived FDA-regulated products are subject to the same authorities and requirements as FDA-regulated products containing any other substance (whether cannabis-derived or otherwise).

FDA Regulation of CBD Products

FDA, under the FFDCA, regulates many of the products marketed as containing cannabis and cannabis-derived compounds, including CBD. CBD is marketed and sold as an ingredient in food, cosmetics, and dietary supplements. CBD is also the active ingredient in the drug Epidiolex—the first (and only) FDA-approved prescription drug formulation of highly purified, marijuana-derived CBD in the United States. As described below, FDA has determined that at this time CBD cannot be added to any food that is sold in interstate commerce and that CBD cannot be marketed as a dietary supplement. FDA has not made similar determinations for other FDA-regulated product categories (e.g., pharmaceutical drugs, cosmetics).

Food and Food Additives

There are several provisions of the FFDCA that FDA believes restrict the use of CBD in food and dietary supplements. Under the FFDCA, it is unlawful to introduce into interstate commerce a food (human or animal) to which a drug has been added—either an approved drug or a drug for which substantial clinical investigations have been instituted and made public (21 U.S.C. §331(ll)). There are several statutory exceptions to this (e.g., if the Secretary has issued a regulation approving the use of such drug in food). However, FDA has concluded, based on available evidence, that none of the statutory exceptions are the case for CBD, and because CBD is an active ingredient in an approved drug, FDA has taken the position that it is unlawful to introduce into interstate commerce food containing added CBD. In addition, independent of its status as a drug ingredient, CBD has not been approved as a food additive. Furthermore, according to FDA, based on a lack of scientific information supporting its safety in food, the agency cannot conclude that CBD is generally recognized as safe (GRAS) for use in food.

According to FDA, cannabis-derived ingredients that do not contain CBD (or THC) may fall outside the scope of this prohibition. More specifically, foods containing parts of the hemp plant that include only trace amounts of CBD (e.g., hemp seed and hemp-seed derived ingredients) may be lawfully marketed under certain circumstances—pursuant to FDA approval as a food additive (by regulation) or a determination that the substance is GRAS. FDA has not approved hemp as a food additive but has evaluated three GRAS notices related to hemp seed-derived ingredients (hulled hemp seeds, hemp seed protein, and hemp seed oil), allowing them to be added to human food under specified conditions.

Dietary Supplements

The FFDCA excludes from the definition of a dietary supplement an article that is an active ingredient in an approved drug, or that has been authorized for investigation as a new drug and for which the existence of such clinical investigations has been made public. An exception to this is if FDA issues a regulation finding that the use of such article in a dietary supplement is lawful. An article that is approved as a drug or being investigated as a drug may be marketed in or as a dietary supplement if it was marketed as a dietary supplement or as a food prior to its approval or clinical investigation (21 U.S.C. §321(ff)(3)). Because CBD is an active ingredient in an approved drug (i.e., Epidiolex) and was the subject of clinical investigations before it was marketed in food, FDA has determined that CBD may not be marketed in or as a dietary supplement.

Other FDA-Regulated Products

FDA has not determined that CBD may not be added to cosmetics, provided therapeutic claims are not made and that the product is not otherwise adulterated or misbranded. In addition, CBD may be lawfully marketed as a drug, pursuant to FDA approval and in compliance with applicable statutory and regulatory requirements. If a firm seeks to market CBD as a treatment or an otherwise therapeutic product, the firm generally would need to obtain premarket approval from FDA via the new drug approval pathway. To date, FDA has approved one CBD-containing drug—GW Pharmaceuticals' Epidiolex—which is available by prescription for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years old and older. In general, if a product claims that its intended use is to cure, mitigate, treat, or prevent a disease, FDA considers that product to be a drug and subject to premarket approval. Thus, for a CBD product to make therapeutic claims, whether hemp-derived or otherwise, it must be approved by FDA for that use.

CBD Market in the United States

From an industry perspective, there are three markets for CBD: hemp-derived CBD, marijuana-derived CBD (a Schedule I controlled substance), and pharmaceutical CBD (only Epidiolex). In 2014, total U.S. CBD sales were a reported $108 million. In 2018, more than 1,000 companies produced and marketed CBD for the U.S. market, and U.S. CBD sales were estimated at $534 million, according to the *Hemp Business Journal*. That dollar amount is projected to exceed $1 billion in 2020 and to reach nearly $2 billion in 2022. Although some industry analysts foresee a strong market for marijuana-derived CBD, it remains prohibited (aside for lawful research purposes) under the CSA if the product does not meet the statutory definition of *hemp* in 7 U.S.C. §1639o. At the retail level, consumer products labeled as containing CBD are being sold in food and beverages, dietary supplements, and other product categories—despite FDA's position that CBD may not be sold in food and beverages or dietary supplements.

Considerations for Congress

Some Members of Congress have expressed support for a regulatory framework for hemp-derived CBD in certain FDA-regulated products. Although FDA *could* issue a regulation allowing CBD to be added to food or allowing its use in dietary supplements, the agency has never issued such a regulation for any drug (whether cannabis-derived or not). In absence of such a framework, Congress has directed FDA to undertake various activities related to hemp-derived CBD, including to issue a policy of enforcement discretion with respect to CBD products that meet the statutory definition of hemp that also come under FDA jurisdiction. In addition, legislation has been introduced in the 116th Congress that would amend those FFDCA provisions that FDA has identified as restricting marketing of CBD in food and dietary supplements.

Questions remain regarding the therapeutic benefits of CBD. To date, FDA has approved one CBD drug product—Epidiolex—but the mechanism by which the drug exerts its anticonvulsant effects is not known. Clinical trials to support the approval of Epidiolex demonstrated the potential for liver injury at certain doses, and CBD may interact with other drugs or dietary supplements. Other concerns include the potential dosing and cumulative effects of exposure to CBD from multiple sources (e.g., supplements and cosmetics); whether there are populations for whom CBD is not appropriate (e.g., pregnant women); and whether allowing CBD to be marketed as a supplement or food could undermine incentives for conducting clinical trials and obtaining evidence to support drug approval.

Agata Dabrowska, Analyst in Health Policy

IF11250

Renée Johnson, Specialist in Agricultural Policy

Disclaimer