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Hemp-Derived Cannabidiol (CBD) and Related Hemp Extracts

Cannabidiol (CBD) is a plant-derived compound from *Cannabis sativa*, the species of plant that includes both hemp and marijuana, but from different plant varieties or cultivars. CBD is the primary nonpsychoactive compound in cannabis, whereas tetrahydrocannabinol (THC) is cannabis's primary psychoactive compound. CBD is promoted as treatment for a range of conditions—including epileptic seizures, post-traumatic stress disorder, anxiety, and inflammation—despite limited scientific evidence to substantiate many of these claims. In the United States, CBD is marketed in a range of consumer products—food and beverages, dietary supplements, personal care products, and cosmetics—subject to regulation by the Food and Drug Administration (FDA). Consumer products containing plant-based CBD are either hemp- or marijuana-derived.

Market for Hemp-Derived CBD

The 2018 farm bill (Agriculture Improvement Act of 2018, P.L. 115-334) included a number of provisions intended to facilitate the commercial cultivation, processing, marketing, and sale of hemp in the United States, expanding on policies enacted in the previous farm bill. It expanded the statutory definition of what constitutes *hemp* to include:

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 [delta-9 THC] concentration of not more than 0.3 percent on a dry weight basis. (7 U.S.C. §1639o)

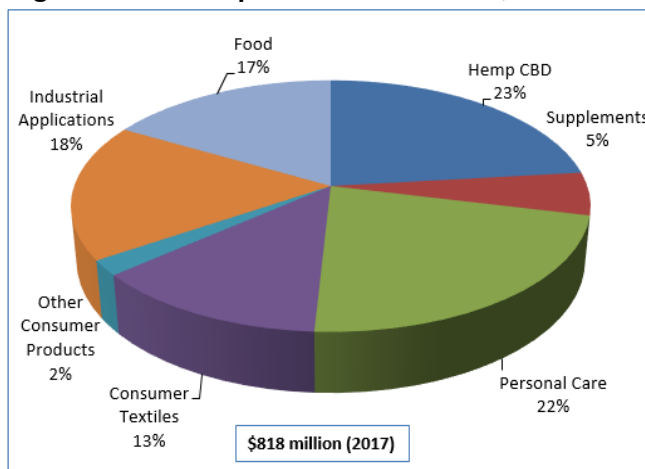
The 2018 farm bill also amended U.S. drug laws to remove longstanding federal restrictions on cultivation of hemp, excluding it from regulation and oversight as a controlled substance by the U.S. Drug Enforcement Administration (DEA). Hemp production is now subject to regulation and oversight as an agricultural commodity by the U.S. Department of Agriculture (USDA).

Cannabis not defined as hemp is considered to be *marijuana* under the Controlled Substances Act (CSA, 21 U.S.C. §§801 et seq.) and remains regulated by DEA.

Changes enacted in the 2018 farm bill related to hemp were widely expected to generate additional market opportunities for the U.S. hemp market. As an agricultural commodity, hemp is cultivated for use in the production of a wide range of consumer and industrial products, including food, personal care products, textiles, paper, and construction materials (**Figure 1**). Perhaps the fastest-growing market for hemp is for hemp-derived CBD and related hemp extracts. Following changes in the 2018 farm bill, hemp was widely expected to become the dominant means to source CBD for use in a range of consumer products, including foods, beverages, cosmetics, topical creams, and dietary supplements. Hemp-derived CBD supplements are marketed in a variety of products (**Figure 2**) and sold

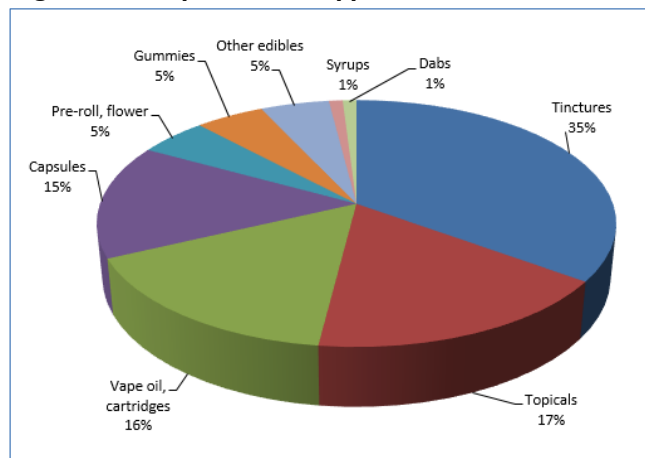
through a variety of channels, including specialty retailers (e.g., natural grocery stores, tobacco shops, yoga studios), direct-to-consumer online sales, farmers' markets, herbal practitioners, and large retailers.

Figure 1. U.S. Hemp-Based Product Sales, 2017



Source: *Hemp Business Journal* estimates. Percent of gross revenues.

Figure 2. Hemp-Derived Supplement Market, 2018



Source: Brightfield Group, *Hemp-Derived CBD*, September 2018. Percent of gross revenues.

Hemp-derived CBD sales account for about one-fourth of the total U.S. annual hemp market sales (**Figure 1**). The *Hemp Business Journal* reports that hemp-derived CBD sales in the United States totaled \$240 million in 2018, up from \$59 million in 2014. This same source projects the U.S. market for hemp-derived CBD products will reach \$647 million by 2022. Others project even higher sales. For example, the Nielsen Company predicts the U.S. hemp-derived CBD market (including sales of food and beverage products containing CBD) could reach \$6 billion annually by 2025, and the Brightfield Group predicts the hemp-derived CBD market could reach \$22 billion by 2022.

Continued Regulatory Uncertainty

Despite continued promotion and sales of CBD—whether hemp- or marijuana-derived—as treatment for a range of conditions, there remains regulatory uncertainty in the U.S. CBD market. The 2018 farm bill explicitly preserved FDA’s authority to regulate cannabis and cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.) and other FDA laws. FDA is responsible for oversight and regulation of certain consumer products containing CBD (e.g., food, dietary supplements, cosmetics). FDA has stated it is “unlawful” under the FFDCA to introduce food containing added CBD into interstate commerce, or to market CBD products as or in dietary supplements, regardless of whether derived from hemp, in part because CBD is an active ingredient in an approved drug (i.e., Epidiolex®). FDA is reviewing its CBD policy and related product safety issues. (See CRS In Focus IF11250, *FDA Regulation of Cannabidiol (CBD) Products*.)

Over the past few years, FDA has issued warning letters to numerous manufacturers of cannabis-derived CBD products marketed as dietary supplements. In the letters, the agency has cited several FFDCA violations, including that upon testing the chemical content of the products, several did not contain CBD levels claimed on the label. Studies by independent researchers have corroborated these concerns, with laboratory tests showing that CBD products in the U.S. market may contain CBD levels that differ from what is indicated on the label. For example, a study by researchers at the University of Pennsylvania found that nearly 70% of online CBD products tested contained CBD levels that were either lower or higher than indicated on the label. Tests also indicate that some CBD products contain harmful contaminants. A study by researchers at Virginia Commonwealth University found that some products contained such contaminants, including compounds found in illegal synthetic cannabis products.

Hemp’s Potential for Sourcing CBD

Within the CBD industry, some have raised quality and safety concerns about sourcing CBD from hemp. Some claim hemp-derived CBD is less preferable to deriving CBD from marijuana. Hemp flowers are often smaller in size and contain less resin than marijuana flowers, and may contain lower amounts of cannabinoids. Cannabinoids are the many chemical compounds produced in cannabis—including CBD and THC—that are associated with bringing about certain psychological and physiological effects. Some claim hemp’s statutory threshold requiring THC concentrations of no more than 0.3% may limit the presence of, and possible positive interactive effects between, CBD and other cannabinoids (including THC) that may be present in the cannabis plant. The hemp plant’s genetics and the presence of other plant compounds may influence cannabinoid volumes in the hemp flower. While illegal at the federal level, CBD products marketed and sold in states with legalized medical and/or recreational marijuana tend to be formulated from cannabis with THC concentrations generally ranging from 0.45% to 1.5%. Some CBD products in the market contain even greater THC levels.

Other industry concerns involve products marketed as hemp-derived CBD that are produced from pressed hemp seeds, and not the hemp flower, resulting in a product with low CBD levels. The cannabis plant’s cannabinoids are mostly concentrated in the flowering head of the plant, where the plant’s *trichomes* tend to be located. Trichomes are the small resin-like hairs/glands of the flowering buds, but may also cover the leaves, bracts, and stems of plants. Cannabinoids may be present in other parts of the plant, including the seeds, but in lower quantities.

Some claim there may be public health and safety risks associated with any cannabis extraction, given that cannabis tends to bioaccumulate toxins in the soil. Contamination also depends on how the plant is produced and the types of production inputs used. Contamination risks include the possible presence of metals, chemicals, pesticides, and other adulterants, as well as residual solvents depending on how compounds in the plant are extracted. CBD is extracted from the cannabis plant using a variety of methods, including lipid or alcohol/ethanol infusions, CO² extraction, and extractions using chemical solvents (such as hexane, butane), as well as solvent-free extractions. The lack of production and processing standards in the CBD industry heightens concerns about product safety and quality.

Considerations for Congress

To address safety and quality concerns, many commenters at FDA’s May 2019 public hearing on CBD expressed the need for the agency to actively regulate CBD and enforce relevant FFDCA violations. Some in the hemp industry are advocating for developing and implementing labeling and manufacturing standards specific to hemp-derived CBD, including product certification, operating procedures, and recordkeeping consistent with Current Good Manufacturing Practice regulations for dietary supplements that are enforced by FDA. Congress could also direct FDA to develop industry guidance for hemp-derived CBD, representing the agency’s current thinking on how the industry can best comply with applicable laws and regulations. In addition, most agriculture-based groups advocate for federally supported hemp research. Such actions could support the safe and orderly marketing of hemp-derived CBD and related hemp-derived products.

Many in the hemp industry advocate for relaxing the statutory threshold for hemp. Some consider the 0.3% THC threshold definition to be arbitrary and without a clear scientific basis, despite its established use. Amending the statutory definition for *hemp* could increase the types of CBD product formulations available to hemp producers, and allow them to compete with other CBD products formulated from cannabis strains with THC concentrations above 0.3%. Prior legislation has proposed alternative thresholds. For example, H.R. 3530 (115th Congress) proposed to define *research hemp* as having a delta-9 THC concentration of less than 0.6%. Raising hemp’s statutory threshold might also simplify enforcement, as it is difficult to measure THC concentrations at current regulated levels.

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