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Potential Use of Industrial Hemp in Cannabidiol Products

Industrial hemp refers to an agricultural commodity that is cultivated for use in the production of a wide range of products, including foods and beverages, cosmetics and personal care products, and nutritional supplements, as well as fabrics and textiles, and a range of other manufactured goods. Botanically, hemp is a variety of *Cannabis sativa* and is of the same plant species as marijuana and therefore subject to federal drug laws.

As part of the Agricultural Act of 2014 ("farm bill," P.L. 113-79; 7 U.S.C. §5940) Congress made changes to U.S. agricultural policies regarding industrial hemp, allowing for hemp production under certain circumstances. Under the law, certain research institutions and state departments of agriculture may grow hemp, as part of an agricultural pilot program, if allowed under state laws where the institution or state department of agriculture is located. The farm bill also established a statutory definition of "industrial hemp" as "the plant *Cannabis sativa* L. and any part of such plant with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis."

Bills in the House and Senate could further facilitate the use of industrial hemp to produce cannabidiol (CBD), which is considered to offer a wide scope of possible medical applications

With industrial hemp cultivation increasing under the farm bill, some are examining additional potential uses for hemp. One such potential application includes the use of hemp to produce cannabidiol (CBD). CBD refers to one of the primary non-psychoactive compounds in *Cannabis sativa*. In general, cannabis with high levels of CBD is generally low in psychoactive compounds, such as THC, marijuana's primary psychoactive chemical. Products containing CBD are increasingly being considered as offering a potentially wide scope of medicinal applications, which has garnered the attention of some in Congress. For example, in June 2015, the Senate Caucus on International Narcotics Control, led by Senators Chuck Grassley and Dianne Feinstein, held a hearing on the barriers to research and the potential medical benefits of CBD. The caucus leaders claimed that many leading medical organizations have called for further research into the potential medical use of CBD.

Products containing CBD are currently being produced and marketed using primarily marijuana-grade cannabis plants and their byproducts, generally as prescription drugs. Some companies, however, are producing and marketing products containing CBD as an herbal (dietary) supplement. Some companies are using industrial hemp as a source of CBD.

Many hemp stakeholders support the use of industrial hemp to produce CBD and related products. In the 114th Congress, bills in both the House and Senate would amend the Controlled Substances Act (CSA, 21 U.S.C. §§801 *et seq*.) "to exclude cannabidiol and cannabidiol-rich plants from the definition of marihuana, and for other purposes." Both bills would also amend the CSA to define a "cannabidiol-rich plant" to mean "the plant *Cannabis sativa* L. and any part of such plant" with a THC concentration of not more than 0.3% on a dry weight basis—a definition similar to the 2014 farm bill. The two bills are related but not identical. The House bill (Charlotte's Web Medical Access Act of 2015, H.R. 1635) would further exclude CBD and CBD-rich plants from being subject to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq*.). This provision is not part of the Senate bill (Therapeutic Hemp Medical Access Act of 2015, S. 1333). The "Charlotte's Web" reference in the House bill refers to a high-CBD (low THC) cannabis extract that has been sold as a dietary supplement and marketed as helping to address various ailments, including neuropathic pain, epilepsy, post-traumatic stress disorder, nausea from chemotherapy, and other disorders.

FDA Actions Regarding Products Containing CBD

Recently, the Food and Drug Administration (FDA) has taken a series of actions regarding the production and marketing of certain CBD products.

First, in February 2015, FDA issued warning letters to several companies selling products claiming to contain CBD that lab tests showed to contain little or no CBD. These companies allegedly also made unsubstantiated product claims (e.g., for use in treating cancer). (See partial listing of products in the text box on the next page). FDA claimed these products were "unapproved drugs" and "not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease, and often they do not even contain the ingredients found on the label." These products were reportedly pulled from the market. Reportedly, other companies producing products containing CBD with a much higher percentage weight per weight concentration did not receive FDA warning letters. This action involved concerns about product fraud and product claims, and was not related to the use of a cannabis-derived substance (i.e., FDA did not issue these warning because of concerns about a cannabis-containing substance that could be in violation of the Controlled Substances Act).

Press reports indicate that agency personnel claim FDA "has not approved any drug product containing CBD, for any indication" (i.e., no products containing CBD have been determined by FDA to be safe or effective for their intended indications). These same press reports indicate that FDA is concerned at the "proliferation of therapeutic claims made about an increasing number of products" containing CBD, which are for sale in all 50 states. Hemp industry activists have also expressed concerns about the potential misrepresentation of using industrial hemp to produce CBD and related products.

FDA Warning Letters and Test Results

Product	Lab Results (%CBD w/w)
Canna Companion Capsule Size 4:	0.1%
CBD Wedges-Canna-Biscuits (dogs):	None detected >0.1%
Canna-Pet for Cats:	0.5%
Canna-Pet MaxCBD Capsules (dogs):	2.6%
UltraCBD (multiple samples tested):	None detected >0.1%
UltraCBD (multiple samples tested):	0.02%
Hemp Pure Vape E-Drops (Peached):	Negative for cannabinoids
Cibaderm Hemp Salve:	0.2% (Cannabidiolic Acid)
Cibdex Hemp CBD Complex Drops:	0.3%
Hemp Honey 21% Cannabidiol Oil:	Negative for cannabinoids
Hemp Honey CBD Vape Oil :	Negative for cannabinoids
CBD Oil Extract Capsules:	Negative for cannabinoids
Real CBD Extract – CBD:	0.5%
21% CBD Hemp Oil Treatment:	Negative for cannabinoids
26% CBD Hemp Oil Treatment:	0.14%
Arisi-Tol:	0.2%

Source: Compiled by CRS from FDA information (some categories have been merged). "w/w" refers to percentage weight per weight concentration.

Second, FDA issued a factsheet, "FDA and Marijuana: Questions and Answers," primarily geared toward addressing stakeholder questions related to medical marijuana. In this factsheet, FDA states that the agency "has concluded that cannabidiol products are excluded from the dietary supplement definition" (Federal Food, Drug, and Cosmetic Act, §201(ff)(3)(B)(ii)). FDA's pronouncement could have important implications for companies seeking to produce and market products containing CBD. The laws and regulations governing prescription drugs differ significantly from those governing dietary supplements. In general, dietary supplements are regulated as a food, whereas drugs must undergo a more thorough review.

FDA claims that it is "not aware of any evidence that would call into question its current conclusion that cannabidiol products are excluded from the dietary supplement definition." FDA further notes that the agency could consider additional information that might further modify its position, namely: "Interested parties may present the agency with any evidence that they think has bearing on this issue." Such action could happen as part of FDA's drafting of final industry guidance regarding dietary supplements. Whether FDA will modify its current position remains unknown. It is also unclear whether FDA will consult with its federal and state partners to initiate a federal enforcement action against the manufacturers of products containing CBD that are marketed as dietary supplements. Products containing CBD continues to be produced and marketed as medical marijuana products but also as dietary supplements.

FDA's factsheet does not distinguish between industrial hemp (as defined by the 2014 farm bill, P.L. 113-79; 7 U.S.C. §5940) and drug-grade cannabis (marijuana).

Views on Hemp's Potential for Making CBD

The question remains whether industrial hemp might have potential application for use in making CBD products.

There is growing concern that hemp-based CBD products, derived from industrial hemp, are being marketed as being rich in CBD and as having comparable therapeutic uses to CBD extracts. However, CBD is not produced or pressed from hemp seeds. Hemp seed oil, marketed as "hemp oil," is made by pressing hemp seeds that contain low levels of CBD (typically less than 25 parts per million). In 2014, the hemp advocacy group Hemp Industries Association noted:

> CBD is not a product or component of hemp seeds, and labeling to that effect is misleading.... Hemp seed oil does not contain any significant quantity of CBD. Hemp fiber and seed cultivars contain relatively minimal CBD and CBD production from such plants should not be considered a primary product. Generally hemp cultivars available to American farmers are not suitable for producing CBD.

According to industry experts, most of the CBD extracts currently being marketed for certain therapeutic purposes (such as Charlotte's Web) are generally formulated from strains of cannabis with THC levels higher than 0.3%, but generally less than 1% THC. Furthermore, a 2016 report by Project CBD (a medical marijuana advocacy groups) is more critical of whether industrial hemp is suitable for producing CBD:

> If grown outdoors in tested soil and carefully processed, industrial hemp can be a viable source of CBD. But it is not an optimal source of CBD-rich oil for several reasons. Industrial hemp typically contains far less cannabidiol than high-resin, CBD-rich cannabis, and huge amounts of skimpy hemp foliage are required to extract a small amount of CBD. This raises the risk of contaminants as hemp is a bio-accumulator, meaning the plant draws toxins from the soil. That's an excellent property for phyto-remedial purposes, but it's not so great for making ingestible medicinal oil concentrates.

Despite these types of concern, research continues to be conducted in some states on the potential uses for industrial hemp-derived CBD. Most agriculture-based groups continue to advocate for the need for such research.

The 2016 Project CBD report, however, questions the seemingly arbitrary designation of the current statutory definition of industrial hemp based on a 0.3% THC limit. Other potential definitions based on higher THC limit, including limits up to 1% THC, would likely still fall below levels that might induce a narcotic effect. Modifying the current statutory definition for industrial hemp could raise the therapeutic potential of hemp for producing CBD and related products.

For more general information, see CRS Report RL32725, *Hemp as an Agricultural Commodity*.

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