SPECIAL REPORT

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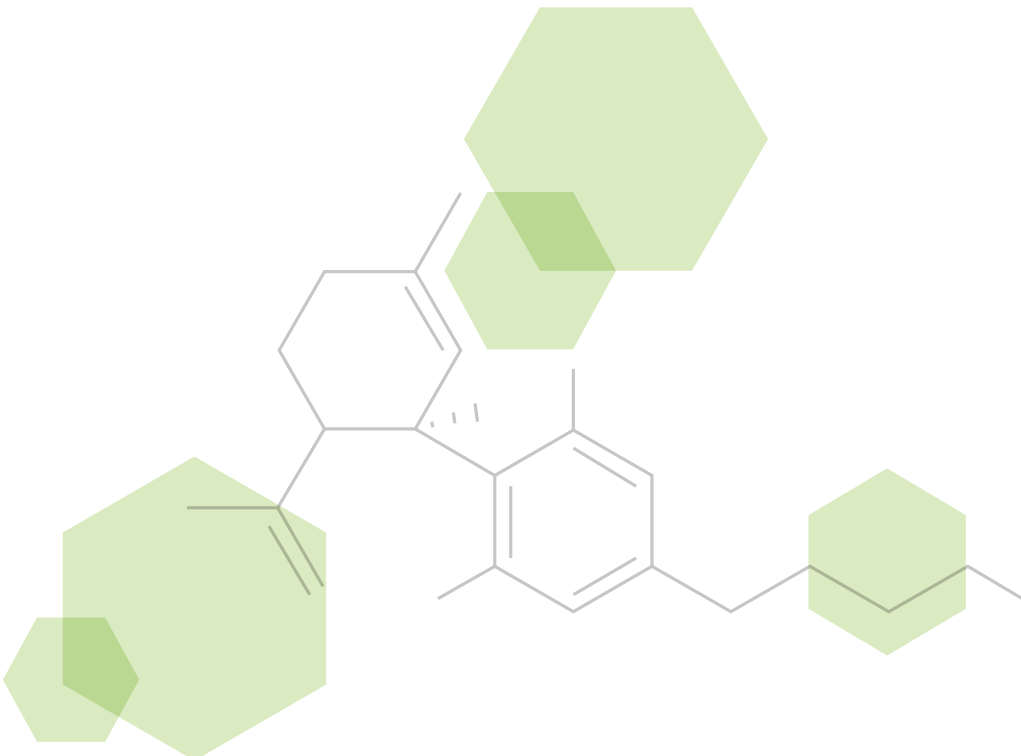
by Jim Prochnow, Esq.



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The industry is in turmoil and indecision regarding the U.S. manufacture, sale and distribution of cannabidiol (CBD) as a dietary ingredient in a dietary supplement or as a finished dietary supplement product. What we do know, clearly, is that CBD is subject to federal statutes and regulations, some of which are implemented and enforced by FDA and others by the Drug Enforcement Administration (DEA). Although state statutes and regulations must also be considered by those engaged in the CBD industry, the federal law and its enforcement is the focus of this report.

CBD oil can legally be sold in the United States if it (a) is derived from a part of the marijuana plant that Congress decided is not covered by or included in the Controlled Substances Act (CSA) definition of "marihuana" and (b) qualifies as a dietary ingredient pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA). Because compliance with both is problematic for companies in the CBD industry, the ability for a company or an individual to manufacture, sell or distribute CBD oil in the United States, for sale within the United States, depends on the exercise of enforcement discretion by DEA and FDA ("the government"), which, in turn, is dependent on the attitude of President Donald Trump, the U.S. attorney general and the agency heads with respect to the CBD industry.

Definitions are critical in the sometimes confusing regulatory world of CBD, hemp and marijuana (spelled "marihuana" in the federal law). There are important legal distinctions among those words; there is even a difference of opinion on basic definitions, as well as enforcement intention of DEA and FDA. Besides confusion caused by an absence of unanimity about the words, confusion also exists because of reasonable differences of opinion about the intent, scope and effect of DEA and FDA public statements about the applicable laws and the enforcement of those laws and regulations.

CBD is a compound (ingredient or article) derived from the *Cannabis sativa L.* plant. It is one of hundreds of constituents in that plant. This report uses the term "CBD oil" when discussing the regulatory landscape of CBD because the oil form is the most popular or common form of CBD. A related term is "hemp," which is not defined by either the Federal Food, Drug, and Cosmetic Act (FDCA) or by the CSA. Hemp is commonly used to mean a part (as contrasted with being a constituent) of the *Cannabis sativa L.* plant, which is not included in the definition of "marihuana" as set out in the federal CSA at 21 U.S.C.§ 802(16). Keep in mind, hemp is not synonymous with CBD. "Industrial Hemp" is defined in a special federal statute (Sec. 7606 of the 2014 Farm Bill: 7 U.S.C. § 5940): "Legitimacy of Industrial Hemp Research." It means "the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetra hydrocannbinol (THC) concentration of not more than 0.3 percent on a dry weight basis."

There is vigorous disagreement among those in the hemp and CBD industries—and between those industries and the government—about the several provisions of that law, including whether that definition in the Farm Bill was intended to modify or actually modifies the CSA, as well as whether it exclusively applies to universities and state departments of agriculture and their efforts to grow and cultivate industrial hemp for the exclusive purpose of studying the growth, cultivation or marketing of industrial hemp. DEA appears to be taking a conservative position on the scope of the Farm Bill.

CBD oil, when manufactured and sold as a dietary ingredient or dietary supplement, is subject to (a) the FDCA, which includes DSHEA, and (b) the CSA. CBD must be or qualify as a *dietary ingredient* within the definition of "dietary supplement," as found in Section 201(ff) of the FDCA, also commonly cited as 21 U. S. C.§321 (ff). A subsection of that law includes a provision that precludes the use of an ingredient (an "article") in a dietary supplement if, generally speaking, it was the subject of at least two FDA-authorized drug trials before that ingredient was first marketed (sold) as a dietary supplement or food in the United States. The critical words of that provision are these: an article cannot legally be in a dietary supplement if it "was authorized for investigation as a new drug ... to which substantial clinical investigations have been instituted and for which the existence of such investigations have been made public."

In early 2016, FDA issued a guidance document in which it concluded it could not find any evidence that CBD had been marketed in the United States as a dietary supplement or as a food before FDA's authorization of two specifically identified clinical trials that included the study of CBD as a possible drug. FDA then sent about a dozen warning letters to distributors of dietary supplements that confirmed the agency's position. FDA has been careful to point out that anyone may present to the agency evidence that would establish a prior sale of a dietary supplement or conventional food.

The crucial consideration

for a CBD company is whether its CBD oil is the same "article" as the CBD oil that was the subject of the relevant drug clinical trials.

Keep in mind there isn't any legal obligation for a company or individual to inform the government of its advance intention to sell any dietary supplement or to inform the government if that company believes its products comply with or don't comply with DSHEA, including this exclusionary provision. On the other hand, if a distributor of a CBD supplement does not have a good faith, substantial basis for believing the product or ingredient fully complies with DSHEA, including the exclusionary provision, that person is subject to significant criminal liability (felony) for selling or offering to sell an adulterated or misbranded product. Do not forget that every violation of the FDCA subjects a company and its principals to civil and misdemeanor (criminal) liability.

The crucial consideration for a CBD company is whether its CBD oil is the same "article" as the CBD oil that was the subject of the relevant drug clinical trials. If a company's CBD is not basically identical, that CBD oil is not subject to or precluded for use by the exclusionary provision. Therefore, it is incumbent on each CBD company or its supplier to determine and possess a precise, accurate and complete scientific assay of its CBD

composition and to obtain from the publicly available records the exact composition of the CBD administered in the two drug tests cited by FDA in its warning letter. For example, it is possible that the THC quantity or potency in the CBD of the products is different.

The sellers of CBD oil are in a hot seat because of FDA's recent history of pursuing criminal investigations with respect to companies that do not heed the agency's warnings of possible severe action if industry participants disregard the language of those warning letters, even if companies other than them received such a warning letter. Currently, FDA has not taken any public enforcement action against a CBD oil company due to a violation of the exclusionary provision. However, that could change tomorrow or whenever the company that undertook the drug trials actually obtains FDA approval for the marketing of new drugs that contain CBD oil—or if there is some major violation of the GMPs (good manufacturing practices) that is applicable to dietary supplements.

DEA's issuance of the Dec. 14, 2016, final rule, "Establishment of a New Drug Code for Marihuana Extract," has been the target of significant controversy since its release. This new regulation consists of an amendment to 21 C.F.R. 1308.11(d) by adding (including) a new sub-paragraph (58) which creates a new drug code number in Schedule I of the CSA. The regulation reads:

> *(58) Marihuana Extract – (7350): Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.*

DEA issued two pages of explanation to accompany the regulation. DEA's position is that (1) this amendment (a new drug tracking code) does not modify the CSA and is not intended to do so; (2) it will continue to regulate extracts of marihuana as Schedule 1 controlled substances; and (3) the amendment was only made to enable the United States to comply with UN treaty obligations about the separate tracking of marihuana, THC and marijuana extracts.

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taken any public enforcement action against a CBD oil company due to a violation of the exclusionary provision of the Federal Food, Drug, and Cosmetic Act.

It is worthwhile paying attention to the two lawsuits filed earlier this year by several entities, including, but not limited to, the Hemp Industries Association (HIA), against DEA and its acting administrator. The first was filed Jan. 13, 2017, in San Francisco with the U.S. Court of Appeals for the Ninth Circuit—a notoriously liberal court. It asked the court to declare the Dec. 14 DEA final rule (a federal regulation) to be invalid. The petition alleges, among other things, that the regulation wrongfully (a) "dictates that the mere presence of cannabinoids … is the determinative factor of whether a compound is a marihuana extract and (b) that the regulation is inconsistent with the Farm Bill." The petitioners filed their initial legal brief on April 3; DEA must file its legal brief no later than June 2.

The second lawsuit was filed by HIA and nine other entities on Feb. 6 with the same court. It is a much different action because it requests the court hold DEA in contempt of court

for continuing to violate a Feb. 6, 2004 order issued by this same court. In 2004, the court prohibited DEA from enforcing two of its 2003 regulations that, when read together, banned all food products for human consumption that contained even a miniscule amount of naturally occurring THC. A settlement conference has been ordered for May 18.

A question has been raised in the general news media and industry press about whether DEA is likely to refrain from more aggressive regulatory action against products containing hemp or CBD—or against companies that manufacture CBD or hemp—in light of the filing and pending of these two lawsuits. Industry press has highlighted a comment that Chuck Rosenberg, acting DEA administrator, made to a House subcommittee that held a hearing on "Oversight of the DEA." He reportedly remarked DEA "is not looking to harass farmers and processors as long as they abide by section 7606 of the Farm Bill." That informal comment should not provide any solace to the CBD or hemp industries for two reasons: First, it was an informal comment—his published formal statement to the subcommittee did not mention this topic; secondly, he cautioned the Farm Bill must be complied with by all concerned.

So, where does all of this leave the CBD industry? Presently, FDA and DEA appear to be exercising prosecutional discretion, similar to that which FDA does to "perhaps as many as several thousand drug products (that) are marketed illegally without required FDA approval." See FDA Guidance (Sept. 19, 2011) "Marketed Unapproved Drugs – Compliance Policy Guide: §440.100," which consists of 13 pages. There, FDA expressly stated it will give higher priority of enforcement to the following categories of drugs:

(A) Drugs with potential safety risks (e.g., significant violations of Good Manufacturing Practices)

(B) Drugs that lack evidence of effectiveness

(C) Health fraud drugs (false, misleading and deceptive labeling [both as to claims and the description of the ingredients] and advertising)

(D) Drugs that present direct challenges to the new drug approval and OTC drug monograph systems

(E) Unapproved new drugs that are also violative of the Act in other ways

(F) Drugs that are reformulated to evade an FDA enforcement action

The hemp and CBD oil industries are "growing" significantly from a commercial and economic standpoint. It is likely that the effect on the government of that growth will result in DEA, in particular, not pursuing aggressive enforcement action against CBD oil and hemp companies and products in the near future.

Jim Prochnow, Esq., is a shareholder at Greenberg Traurig LLP in Denver. His practice concentrates on FDA and FTC advice and related litigation, which includes import detentions, government inspections, investigations and defense of class actions. He also counsels clients about cosmetics, homeopathic drugs, OTC drugs, and MLM issues with an emphasis on FDA, the FTC and various federal and state courts and regulatory bodies.