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Will CBD land California business owners in hot water?

By Rebecca Stamey-White

As regulatory attorneys advising on licensing and compliance issues around producing cannabidiol — CBD — products, we often hear from clients that "everyone else is doing it, why can't I?" This mindset typically stems from enforcement efforts not being able to keep pace with the unlawful activity, the sheer size of the market for CBD products, and a very confusing compliance landscape.

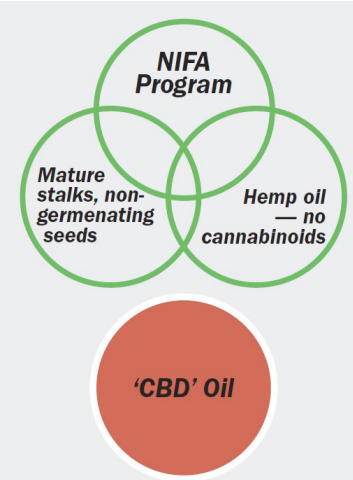
As CBD products have flooded grocery store shelves and online retailers trying to meet the demand of consumers, many websites and industry associations will claim that hemp-based CBD is "completely legal in 50-states" when the communications coming out from the regulators tell literally the opposite story. CBD entrepreneurs are stuck between the devil and the deep blue sea when it comes to legally-compliant options for producing CBD.

The first fork in the road for analyzing the issues is whether the CBD will be derived from hemp or from marijuana (used here instead of cannabis to distinguish how the federal government classifies the two products).

Hemp and marijuana are both derived from the cannabis sativa plant, but are distinct varieties with different uses and benefits. Section 7606 of the 2014 Farm Bill, which first permitted industrial hemp to be grown in the U.S. as part of research agricultural pilot programs in the states, but not for general commercial activity, defines industrial hemp as "the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a [THC] concentration of not more than 0.3 percent on a dry weight basis."

The Controlled Substances Act defines marijuana, on the other hand, as "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin" but excludes the mature stalks of the plant and the sterilized seed not capable of germination. 21 U.S.C. Section 802(16).

Where this gets confusing is that the hemp industry interpreted the 2014 Farm Bill as acknowledging the Controlled Substances Act, but placing industrial hemp outside of it, including CBD derived from hemp. *See, e.g.*, "Opinion on the Federal Legal Status of Hemp-Derived Cannabidiol (CBD)," U.S. Hemp Roundtable, Oct. 2, 2017. But the Drug Enforcement Agency has instead asserted jurisdiction of hemp-based CBD under the Controlled Substances Act, stating that "[f]or practical purposes, all extracts that contain CBD will also contain at least small amounts of other cannabinoids. However, if it were possible to produce from the cannabis plant an extract that contained only CBD and no other cannabinoids, such an extract would fall within" the act's definitions of controlled marihuana extracts. See Marihuana Extract Final Rule, 21 CFR Part 1308. The two sides went to court over this issue and the 9th Circuit resolved the case on procedural grounds in an unpublished opinion, and the DEA's rule stands.



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Essentially, this is how the DEA sees the legality of hemp-based oils on green-light, red-light terms. Thus, in order for marijuana-derived CBD to be produced and sold, it may only be done in conflict with federal law, pursuant to state laws regarding medical or adult use marijuana and under the authority of state-issued licenses. For hemp-derived CBD to be produced and sold, it must be done so pursuant to the state's hemp laws under the National Institute of Food and Agriculture authorization, but also in conflict with the federal regulators' own interpretation of federal law, either because it is produced from parts of the plant that are not the mature stalks, non-germinating seeds or because it contains cannabinoids like CBD (and if it doesn't contain CBD, then what's the point of producing it in the first place?). Producers are thus in risk of breaking federal law either way, and potentially subject to the federal sentencing guidelines. While there may appear to be little enforcement in comparison to the market size and number of retailers and suppliers entering the market, the DEA has been conducting raids, most recently last week in Texas.

Before you pick up your pitchfork, Congress does appear to be listening to CBD enthusiasts, patients and the burgeoning American hemp industry seeking to wrest control from the DEA and has passed the Hemp Farming Act of 2018 out of the Senate, moving on to the House for a vote this fall.

In the meantime, businesses making or selling CBD products that decide to accept the risks of violating federal law need to ensure compliance with state law. For marijuana- derived CBD, this means getting cannabis licenses, complying with local zoning and permitting restrictions, conducting mandatory testing, complying with packaging and advertising requirements, only selling from licensed retailers, paying required taxes, keeping detailed records, having good standard operating procedures, and complying with all the numerous laws and regulations. For hemp-derived CBD, this means making sure the products derive from lawful state operations from state ag or education departments or pilot program members in states that permit commercial use, conducting lab testing to ensure the products don't have unlawful ingredients or harmful chemicals, and thinking hard about how you want to package and advertise these products, lest the Food and Drug Administration comes calling over those disease and structure/function claims or the Federal Trade Commission challenges your advertising claims.

In California, where we're based, the CBD market just got a lot trickier. The California Department of Public Health just released guidance at the beginning of July that prohibits industrial hemp-derived products in food or as a dietary supplement, meaning CBD oil derived from hemp is a no go by itself or when added to other products. And the California Department of Alcoholic Beverage Control followed up promptly by updating their guidance on cannabis and alcoholic beverages to clarify that beers, wines and distilled spirits infused with hemp-derived CBD are still prohibited. We will see what the enforcement looks like, or if the industry will voluntarily comply with the regulators' interpretations of these laws, but for now, it looks like California is concerned about hemp-based CBD products being an end-run around the legal cannabis market and about the potential pesticide and chemical concentrations in hemp-based CBD products and wants to nip these products in the bud. The hemp industry again believes the regulators are in the wrong and some may choose to continue selling their products and take the regulators to court. See "Letter to CDPH from U.S. Hemp Roundtable," July 19, 2018.

The state of the law is certainly in flux in this space, and even if the regulators are wrong, their enforcement efforts could still lead to businesses losing their shirts and possibly paying big fines or going to prison, none of which we want for our clients. While practitioners encourage industry members to challenge the state of the law when practicable, we also want to keep our clients compliant and in the good graces of regulators who are working hard to get control of the black market.

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