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Managing the Risks of Hemp Products: 7 Questions About Hemp You're Too Afraid to Ask

Compliance and Ethics





CHEAT SHEET

- Hemp. Industrial hemp is a non-intoxicating variety of cannabis that can be used in everything
 from fabrics and textiles, foods and beverages, to cosmetic and medicinal products, and
 more.
- *Outliers.* Canada, the United States, and Uruguay are among the handful of countries to legalize cannabis for nonmedical use. Both Canada and the United States similarly regulate industrial hemp, requiring licenses for cultivation.
- *CBD.* Hemp-produced cannabidiol (CBD) products are subject to heavier production and sale restrictions in the United States and Canada than other hemp products.
- Transport. Changes are expected, but for now, industrial hemp itself cannot be transported

over US state lines — but some of its products can be.

If you live in North America, you've likely seen a myriad of products touting the benefits of "CBD," the non-intoxicating cannabinoid that pop culture claims can cure anything from anxiety to sleeplessness — claims that have gotten more than one company into trouble with federal regulators. For in-house counsel who work for companies that sell CBD products (which include candles, oils, beer, wine, tea, and lotions, just to name a few), or any industrial hemp product, it is important to know how the law has changed — and what is still unsettled.

This article addresses some frequently asked questions about the current state of industrial hemp. It seeks to provide practical answers to questions about an area of law that is both fascinating and in a state of flux.

Q: What is "industrial hemp"?

A: In short, it is nonintoxicating cannabis.

The slightly longer answer is that many people confuse industrial hemp and marijuana. They are both varieties of cannabis, but they are bred for different uses and distinguished based on their genetic make-up and chemical composition. Industrial hemp, under its current legal definition, is a variety of cannabis, specifically cannabis sativa L., which contains only trace amounts (less than 0.3 percent on a dry weight basis) of delta-9 tetrahydrocannabinol (THC), the "intoxicating" ingredient found in cannabis, and high levels of cannabidiol (CBD). THC and CBD are the two best-known compounds found in cannabis, with the latter considered non-intoxicating (and one of the major uses for hemp in the United States).

While much of the literature uses the terms "psychoactive" and "non-psychoactive" to describe the compounds, that is not technically correct, since CBD does actually interact with endocannabinoid receptors in the brain and the central nervous system. See "Is CBD Really Non-Psychoactive," Project CBD (May 17, 2016). ("If CBD can relieve anxiety or depression or psychosis, then obviously cannabidiol is a profound mood-altering substance, even if it doesn't deliver much by way of euphoria. Perhaps it would be better to say that CBD is 'not psychoactive like THC,' rather than repeating the familiar and somewhat misleading refrain that 'CBD is not psychoactive."). Thus, intoxicating and non-intoxicating is the preferred nomenclature.

Q: Is it legal to grow industrial hemp in the United States?

A: That's a complicated question with an equally complex answer. The best answer is yes, under certain conditions, and those conditions are in a state of flux.

Industrial hemp <u>used to be a major agricultural crop</u> in states like Kentucky in the 18th and 19th centuries, and its fiber was used to make rope and canvas during the Age of Sail. It fell out of favor with the US government and certain business interests in the early 20th century (culminating in the passage of the Marijuana Tax Act in 1937), and was ultimately swept up in the drug war as part of the US Federal Controlled Substances Act (CSA) in the 1970s. The CSA treated all marijuana (including

non-intoxicating industrial hemp) as a Schedule I controlled substance — no different than heroin, LSD, GHB, or MDMA (but not cocaine, which has an accepted medical use, and is therefore listed as Schedule II).

Because of federal prohibition, no industrial hemp was legally cultivated in the United States from the time of the CSA to 2014, though certain hemp byproducts were imported. In 2014, Congress passed the Agricultural Act of 2014 (2014 Farm Bill), which carved out industrial hemp from the general definition of marijuana based on THC content and allowed for its lawful cultivation in connection with industrial research programs. In December 2018, US President Trump signed the Agriculture Improvement Act of 2018 (2018 Farm Bill) into law, removing industrial hemp and its derivatives from Schedule I; laying out how industrial hemp may be legally cultivated in accordance with a plan adopted or approved by the US Department of Agriculture (USDA); and eventually permitting transportation of industrial hemp across state lines (notwithstanding any state-level prohibition on the cultivation or sale of hemp).

Federal law contained certain exceptions for categories of hemp derived products, which is why things like hulled hemp seeds, and articles of clothing manufactured from hemp fiber, were available on store shelves. See, generally, "Hemp as an Agricultural Commodity," Congressional Research Service (June 22, 2018); Horn v. Medical Marijuana, Inc., 15-CV-701, at *8 (W.D.N.Y. Apr. 17, 2019) (noting that the prior definition of marijuana, under 21 U.S.C. § 802(16), excluded "certain parts of the plant that are incapable of germination: (1) the mature stalks of the Cannabis sativa plant, (2) fiber produced from the stalks of the Cannabis sativa plant, (3) oil or cake made from the seeds of the Cannabis sativa plant, (4) any compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, fiber, oil, or cake (excluding resin extracts), and (5) the sterilized seed of the Cannabis sativa plant.").

2018 Farm Bill, §§7605, 10113, 10114, and 12619. See also, <u>USDA Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp (USDA Memo)</u>, May 28, 2019, (explaining the USDA's view that some provisions of the 2018 Farm Bill, like de scheduling, were self-executing, but others only apply to industrial hemp grown in accordance with plans approved in accordance with the 2018 Farm Bill or some other federal law, like the 2014 Farm Bill).

Although the <u>USDA takes the position</u> that the de-scheduling of industrial hemp was self-executing, it does not mean that industrial hemp can be freely grown. The 2018 Farm Bill only allows the cultivation of industrial hemp in accordance with rules developed by states or Native American tribes and approved by the USDA, or the USDA rules, where the state has opted to use those rules instead of developing its own. While there is some uncertainty as to whether industrial hemp grown in accordance with the 2014 Farm Bill (which was for research purposes only) qualifies for the protections afforded to "industrial hemp" under the 2018 Farm Bill, cultivating industrial hemp without a license issued by a state essentially means cultivating marijuana. The 2018 Farm Bill contains a sliding scale of penalties tied to the cultivation of marijuana that does not qualify as industrial hemp (ranging from "knowing" to "innocent" violations).

Q: Who can grow hemp in the United States?

A: This is a state-by-state question, but a license of some sort is required.

Those states that have participated in the 2014 Farm Bill Pilot Program have taken different approaches to the broadness of their licenses. Nevertheless, each had certain criteria that potential cultivators had to meet and, generally speaking, many more people applied for licenses than are

available. While more applications are likely to be accepted in coming years due to the expansion of the programs under the 2018 Farm Bill (for instance, Kentucky has approved over 1,000 applications to cultivate up to 42,000 acres of hemp in 2019), a licensing process will still be in place. It is useful to look at the rule Kentucky submitted to the USDA on Dec. 20, 2018 (the day the 2018 Farm Bill was signed into law) as an example, but each state's licensing process may vary.

Q: What about Canada, and beyond?

A: That depends on the country. Canada defines hemp in a way similar to the United States under its Cannabis Act. Other countries, which use the more general definition of cannabis under the Single Convention on Narcotic Drugs of 1961, do not distinguish between the two.

It is important to understand that industrial hemp is a legal definition for low-THC cannabis, not a specific plant. Canada regulates hemp under the Cannabis Act, which defines industrial hemp the same way the 2018 Farm Bill does, and <u>requires a license</u> to produce hemp. The Cannabis Act also has <u>specific regulations applicable</u> to the possession, production, distribution and sale of CBD. As Canada's regulator, Health Canada, warns: "Under the Cannabis Act, CBD products remain strictly regulated and are only legal when sold in compliance with the Act and its regulations." A processing license is required to manufacture products containing CBD for sale, no matter the source of the CBD.

Globally, cannabis and its derivatives (such as CBD) are governed by the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, under Articles 23 and 28. Cannabis is a scheduled drug, which can only be used for medical purposes. Therefore the production and transportation of cannabis and CBD across national lines is strictly controlled. The move toward broader legalization and recreational use, is a recent one. As the Report of the International Narcotics Control Board (the body charged with enforcing the convention) notes in its most recent report: "[u]niversal and full implementation of the treaties is put at serious risk because countries, such as Canada and Uruguay (as well as states in the United States), have legalized cannabis for nonmedical use." Canada, and to a lesser extent the United States, should be seen as the outlier and not the rule worldwide.

Q: Can you transport hemp/hemp products over state lines?

A: As it stands today, certain industrial hemp products can be transported over state lines, but others, including industrial hemp itself, need to wait until the USDA approves industrial hemp cultivation rules under the 2018 Farm Bill.

The 2018 Farm Bill does two things that allow people to transport industrial hemp and hemp products across state lines. Section 12619 amends the CSA to exclude industrial hemp (and its byproducts) from the definition of marijuana if they contain less than 0.3 percent THC dry weight. Section 10114 preempts states and Indian tribes from prohibiting the interstate transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the 2018 Farm Bill. Indeed, <u>USPS will ship</u> industrial hemp and hemp-derived CBD, provided the mailer complies with all applicable federal, state, and local laws pertaining to industrial hemp production, processing, distribution, and sales, and retains records establishing its compliance with such laws for "no less than two years after the date of mailing."

However, before shipping industrial hemp in its raw form (sometimes called biomass), one needs to be sure that the industrial hemp was actually grown in accordance with rules authorized by the 2018 Farm Bill or, at the very least, some other program authorized by federal law, such as the 2014 Farm Bill.

However, before shipping industrial hemp in its raw form (sometimes called biomass), one needs to be sure that the industrial hemp was actually grown in accordance with rules authorized by the 2018 Farm Bill or, at the very least, some other program authorized by federal law, such as the 2014 Farm Bill. This is not anecdotal, as Big Sky Scientific found out trying to transport industrial hemp through Idaho that, according to the Idaho state police, was not cultivated in accordance with the 2018 Farm Bill. Idaho does not distinguish between marijuana and industrial hemp. Without the preemption afforded by the 2018 Farm Bill, the Idaho state police seized a shipment of industrial hemp and criminally charged the driver of the truck. That case is winding its way through the federal courts, and the USDA has disagreed with Idaho's interpretation. However, this is a novel issue with which the courts — and Big Sky Scientfic — are grappling.

Q: What types of products use industrial hemp?

A: Potential uses seem to only be limited by one's imagination, but how commercially practical those uses are is a different matter, considering the costs associated with cultivating industrial hemp, the current processing capacity, and the availability of alternatives.

Beyond attempting to quench the United States' thirst for CBD, industrial hemp has a variety of uses. As noted by the <u>Congressional Research Service in 2018</u>, those uses include the following:

- Hemp fibers are used in fabrics and textiles, yarns and spun fibers, paper, carpeting, home furnishings, construction and insulation materials, auto parts, and composites.
- Hurds (the short woody fibers found in the stalk of the plant) are used in animal bedding, papermaking, and oil absorbents.
- Hemp seed and oilcake are used in a range of foods and beverages (e.g., salad and cooking oil and hemp dairy alternatives) and can be an alternative food and feed protein source.
- Oil from the crushed hemp seed is used in soap, shampoo, lotions, bath gels, and cosmetics.
- Hemp is also being used in nutritional supplements and in medicinal and therapeutic products, including pharmaceutical, as well as a range of composite products.
- Hempcrete (a mixture of hemp hurds and lime products) is being used as a building material.
- Hemp is used as a lightweight insulating material and in hemp plastics and related composites for use as a fiberglass alternative by the automotive and aviation sectors.
- Hemp is also promoted as a potential biodiesel feedstock and cover crop.

Different varieties of industrial hemp are cultivated for different uses. As North Carolina's State Bureau of Investigations explains in its memorandum directed at "Industrial Hemp/CBD Issues," there are broadly three kinds of industrial hemp currently:

- One variety is grown for seed oils. Oil is extracted from the seeds and used in various products such as bread, shampoos, and granola products.
- One variety looks like long stalks of bamboo and is grown for fiber for textiles and rope.
- One variety looks like marijuana and grows "buds" just like marijuana. CBD is extracted from

the buds.

One concern expressed by North Carolina's law enforcement community (and which is a concern common to other states that have not decriminalized marijuana) is that the third kind of hemp (which is the most profitable due to the proliferation of CBD) "looks just like marijuana, including the leaves and buds, and it smells the same as marijuana," and there is no way of distinguishing it from marijuana except through chemical analysis that would determine the level of THC in the plant. Still, as it stands today, the production of CBD appears to be one of the primary uses for industrial hemp at the moment, with that market alone expected to reach \$US20 billion by 2024.

Q: Is it safe to use hemp products and are they legal to buy and sell?

A. That depends on the product.

From a legal perspective, following de-classification of industrial hemp as a Schedule I drug, there is not anything particularly different with respect to industrial products made from industrial hemp, such as textiles or building materials. The US Food and Drug Administration (FDA) also has a hands-off approach with respect to certain categories of industrial hemp-derived consumables. Specifically, the FDA has evaluated hulled hemp seed, hemp seed protein powder, and hemp seed oil, and considers them to be generally recognized as safe for human consumption.

That is not the case, however, for products containing CBD. Currently, the industry and the FDA are at odds about the safety and efficacy of CBD. Companies marketing CBD products would like the FDA to take the view that CBD should generally be marketed as a dietary supplement under the Dietary Supplements Health and Education Act (DSHEA) provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which mainly governs the truthfulness of product labels, packaging, and inserts and promotional material accompanying a product.

The FDA takes the view that certain products containing CBD, including medicines, foods, and dietary supplements, are subject to wider regulation under the FD&C Act and section 351 of the Public Health Service Act (PHSA) because both THC and CBD are active drug ingredients in a medication (Epidiolex) approved by the FDA. The FDA's two primary areas of concern with respect to the marketing and sale of products containing CBD are: (1) that unsupported health claims are being made with respect to what CBD can be used to treat, including Alzheimer's Disease, cancer, and various other diseases; and (2) there are wider questions about the safety and efficacy of CBD itself. The FDA has undertaken a rulemaking process to address CBD marketing titled "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds." On its FAQ page, and in all of its press releases, the FDA is clear that the marketing and sale of products containing CBD that fall under the purview of the FD&C Act and the PHSA is prohibited until the FDA completes its rulemaking process.

The industry has taken the view that, as long as they stay away from consumables (e.g., food and drink "infused" with CBD) or "remedies," the FDA will not enforce its more general stated views while the rulemaking process is ongoing. In July 2019, this was thrown into doubt, when the FDA sent a <u>warning letter to Cureleaf Inc.</u> stating some of its products, including a CBD lotion and a CBD pain-relief patch, were unapproved human drug products. Whether that was the case of a seller overreaching with respect to the claims made in its advertising (both official and unofficial via social media), or whether it has larger implications, remains to be seen.

Beyond the usual contamination issues such products face, sellers need to be careful to

make sure that products they sell are in fact manufactured from "industrial hemp" (i.e., do not contain more than 0.3 percent THC dry weight).

There are several other issues to consider when it comes to CBD. First, certain states (and even some municipalities, like New York City), have rules governing the use of CBD in consumables. Those rules should be consulted if products are sold in those jurisdictions. Second, CBD (along with THC) has been caught up in the uproar about "vaping," and the lung illnesses potentially related to it, since CBD oils can be "vaped." As of the writing of this article, it is unclear as to whether CBD vaping products will be implicated by the rules the Trump administration charged the FDA with drafting, or by similar state action. Finally, consumers and resellers should be aware that consumable products that include CBD derived from industrial hemp (including CBD oils intended for vaping) may, in fact, be misbranded. Beyond the usual contamination issues such products face, sellers need to be careful to make sure that products they sell are in fact manufactured from "industrial hemp" (i.e., do not contain more than 0.3 percent THC dry weight). Otherwise, they may face consumer claims in addition to enforcement action by the government.

An example of this is the Horn v. Medical Marijuana, Inc., 15-CV-701 (W.D.N.Y. Apr. 17, 2019) case, where a truck driver was allowed to pursue claims concerning the marketing and sale of a CBD additive (the Dixie X Dew Drops) that was advertised as having no THC, but contained THC that allegedly showed up during a routine drug test and led to the truck driver's termination.

Conclusion

There are many legal and practical questions that remain concerning industrial hemp, and in-house counsel should monitor this area of law as companies across the country start planting, harvesting, processing, transporting, distributing, and making new products from industrial hemp.

ACC EXTRAS ON... Cannabis

ACC Docket

Cannabis Conundrum: Advising Clients Doing Business in the Cannabis Industry (March 2019).

Ask Aliya: How Canada's Legalization of Marijuana Impacts Employee Policies (March 2018).

Articles

Top Ten Ways Marijuana Legalization Affects Employers (July 2019).

Further Reading

21 U.S.C.A. § 812(b)(1). A Schedule I controlled substance is a drug which (a) has a high potential for abuse, (b) has no currently accepted medical use in treatment in the United States, and (c) lacks safety in use under medical supervision.

Pub. L. No. 113-79.

Pub. L. No. 115-334.

2018 Farm Bill § 10113, Sec. 297B, at (e) (Violations).

See Big Sky Scientific LLC v. Idaho State Police, 2019 WL 438336 (D. Idaho, Feb. 2, 2019).

See "Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp," supra, discussion of Big Sky Scientific in section titled "Recent Developments."

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