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Emerging Opportunities in the US Hemp and CBD Space

2018 Federal legislation removes obstacles to commercialization, controlled substance concerns

The 2018 Farm Bill, a comprehensive update of the United States' agricultural laws, has opened up a wealth of new opportunities in the rapidly growing Hemp and Cannabidiol (CBD) product space, but patience and diligence will be needed for companies hoping to take full advantage.

Hemp and Marijuana are close cousins, coming from different varieties of the same species of plant, *Cannabis sativa*. Marijuana typically refers to the psychotropic drug, while Hemp is cultivated for a wide variety of products, including textiles, foods and personal care products, to name a few.

substance that cannot be manufactured, possessed or distributed under the federal Controlled Substances Act (CSA).

Until passage of the 2018 Farm Bill, Hemp was also considered a controlled substance under the CSA's definition of Marijuana, hindering its production and limiting its market. The CSA makes it unlawful to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense" any controlled substance. The CSA also makes it a crime to possess any controlled substance except as authorized by the Act. The level of restriction depends on the schedule on which a substance is included, with Schedule 1 being the strictest.

Before passage of the 2018 Farm Bill, the CSA defined Marijuana in relevant part 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." This included Hemp.

HEMP REMOVED FROM LIST OF CONTROLLED SUBSTANCES

However, the Farm Bill expressly removed Hemp from the definition of Marijuana. This means Hemp is no longer a controlled substance under US law. As such, it is not subject to US Drug Enforcement Agency (DEA) regulation, and is instead treated like an agricultural product subject to US Department of Agriculture (USDA) oversight.

The majority of the changes promulgated by the 2018 Farm Bill are contained in amendments to the Agricultural Marketing Act of 1946, which was

The Farm Bill removed Hemp from the definition of Marijuana in the federal Controlled Substances Act. For regulatory purposes, it is now considered an agricultural crop.

CANNABIS LAW LANDSCAPE

In recent years, a growing number of US states have legalized Marijuana in various forms for medical or recreational use, but the overall legal landscape for Marijuana remains an uneven patchwork of laws and regulations. This is complicated by Marijuana's continued inclusion as a Schedule 1 controlled

enacted to provide a “sound, efficient, and privately operated system for distributing and marketing agricultural products.” The six major changes to the law involve:

- The definition of Hemp
- The creation and approval of and compliance with state Hemp plans
- The creation and approval of and compliance with a federal Hemp plan
- The regulatory authority of the US Secretary of Agriculture
- The transportation of Hemp products in interstate commerce
- The effect of the farm bill on other laws, in particular the Federal Food, Drug and Cosmetic Act (FD&C Act.)

COMPLIANCE POINT: THC CONCENTRATION

The 2018 Farm Bill defines Hemp as “the plant *Cannabis Sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, whether growing or not, with a [THC] concentration of not **more than 0.3 percent on a dry weight basis.**”

THC, or delta-9-tetrahydrocannabinol, is one of the two best-known compounds contained in the *Cannabis sativa* plant, and is responsible for the “high” feeling experienced by Marijuana users. The other primary compound is Cannabidiol or (CBD), which is not psychoactive and may have potential clinical effects on anxiety disorders, movement disorders, cognition and pain.

This means companies wishing to market Hemp or Hemp-derived CBD products must ensure they comply with the 0.3 percent THC concentration limit. This should not be difficult, because in general, Hemp contains only trace amounts of THC. However, companies should be on notice that they must be diligent in vetting suppliers of Hemp-based CBD containing products to confirm their source. We recommend including specific representations, warranties and indemnification provisions in each vendor agreement.

HEMP REGULATION: FOCUS ON THE STATES

The 2018 Farm Bill gives states the primary responsibility for monitoring and regulating Hemp production and requires them to produce a plan for doing so. State plans must include:



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- Practices for maintaining information on land where Hemp is produced.
- Procedures for testing THC levels in Hemp.
- A disposal process for non-compliant Hemp plants.
- Enforcement procedures for violations.
- Procedures for annual, random compliance sampling.
- Procedures for sharing information with the federal government.
- Certification that the state has the resources needed to carry out its plan.

States have a significant amount of leeway in crafting their plans, and are permitted to enact laws that are stricter than federal Hemp laws. The US Secretary of Agriculture must approve or reject state plans within 60 days of submission. In states without approved plans, Hemp producers must comply with a plan to be established by the US

Secretary of Agriculture. Penalties for violations under the state and federal plans are nearly identical. For negligent violations, the producer must correct the conduct and periodically report to the state for a period of two years. There are no criminal penalties for negligent violations, even if the violation involves producing Hemp with a THC content of more than 0.3 percent. However, repeat offenders will be referred to the state's chief law enforcement officer or the US Attorney General.

For now, until one year after the federal government establishes a federal plan, the 2014 Farm Bill remains in effect. That said, nothing in the 2018 Farm Bill suggests the 2014 Farm Bill prohibits selling Hemp-CBD. We recommend operating under existing state laws regarding Hemp-CBD where possible and modifying operations as state and federal plans are approved.

FDA TAKES OVER FROM DEA

The 2018 Farm Bill provides the US Secretary of

Finally, the bill does not affect the FD&C Act or the authority of the Commissioner of Food and Drugs to promulgate regulations under the Act. This means Congress explicitly preserved the FDA's current authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act.

KEY LAW: FOOD DRUG AND COSMETIC ACT

The FD&C Act establishes a comprehensive federal scheme for the regulation of food, drugs and cosmetics, among other products. Included in that scheme is a prohibition against introducing new drugs into interstate commerce without first meeting certain regulatory approvals. The act also prohibits the introduction of adulterated or misbranded drugs into interstate commerce. Following the passage of the 2018 Farm Bill, the FDA issued a statement clarifying its position on the regulation of products that contain cannabis and cannabis-derived products.

The statement starts by saying the FDA will treat "products containing cannabis or cannabis-derived compounds" as it does any other FDA-regulated product, regardless of the source of the substance. It goes on to recognize the "growing public interest" in cannabis and cannabis-derived products, including CBD, and the potential opportunities that presents. The FDA also promises it will "continue to take steps to make the pathways for the marketing of these products more efficient," but this may take as long as 18-24 months, according to a recent report.

WATCH HEALTH CLAIMS

It is worth noting that the statement asserts that "cannabis and cannabis-derived products claiming in their marketing and promotion materials that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the US" It also emphasizes that it is unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements ... because both are active ingredients in FDA-approved drugs

Companies wishing to market Hemp or Hemp-derived CBD products must ensure they contain no more than a 0.3 percent concentration of THC.

Agriculture with the sole authority to develop regulations and guidelines for the production of Hemp, and requires that such regulations be promulgated "as expeditiously as possible." This shifts enforcement and regulatory authority away from the DEA to the Food and Drug Administration (FDA). The bill also expressly states that it does not prohibit interstate Hemp commerce, and forbids states from prohibiting the transportation or shipment of Hemp or Hemp products, including Hemp-CBD, through the state if produced in accordance with the 2018 Farm Bill. This includes states that have not adopted their own plans.

(Epidiolex) that were the subject of substantial clinical investigations before being marketed as foods or dietary supplements. However, a careful reading of the statement suggests the FDA's enforcement priorities involve only the most serious health claims.

STATUS QUO: APPLICABLE STATE LAWS

From now until one year after the Secretary of Agriculture establishes the "federal plan," the 2014 Farm Bill remains in effect. Here's an overview of the status quo until then.

Before passage of the 2018 Farm Bill, many states enacted their own Hemp-related statutes in accordance with the 2014 Farm Bill, which permitted qualifying individuals and entities to grow, cultivate and market industrial Hemp for **research purposes only**, through state agriculture pilot programs. Because the 2014 Farm Bill provided so few details about its limitations and restrictions, including what qualifies as "market research," five federal agencies – USDA, The Department of Justice, DEA, FDA and Department of Health and Human Services – filed a Statement of Principles on Industrial Hemp in an effort to clarify the issue. In particular, the statement explained that the 2014 Farm Bill permits the sale of industrial Hemp in states with an agricultural pilot program for the purpose of market research, but **prohibits general commercial activity**, as well as interstate transportation of Hemp plants or seeds.

The upshot is that the 2014 Farm Bill and most state analogs provide for the growth and cultivation of industrial Hemp, but not the commercial sale or distribution of Hemp or Hemp products. This creates significant uncertainty for companies seeking to sell or distribute such products today, made even more so by the handful of states whose Hemp laws do contemplate the sale of Hemp or Hemp products. The 2018 Farm Bill makes it clear that it does not prohibit interstate commerce. At the very least, any company wishing to get into the Hemp space today should make certain that its suppliers comply with applicable state Hemp laws.

CBD CONTROLLED SUBSTANCE QUESTIONS

Hemp-derived CBD-containing products face a separate question, which is the applicability of state controlled substances laws. Can states classify

Hemp as a controlled substance despite the 2018 Farm Bill? Before the 2018 Farm Bill, many states carved out an exception to Marijuana drug laws for industrial Hemp produced in state programs run in accordance with the 2014 Farm Bill. They did this in four ways:

- Amended drug laws to specifically exclude industrial Hemp grown in accordance with state pilot programs from the definition of Marijuana.
- Included a provision in Hemp laws removing industrial Hemp grown in compliance with state pilot programs from the definition of Marijuana.
- Included a provision in Hemp laws that provided immunity from prosecution if the grower complied with state law.
- A combination of the three.

Despite the regulatory environment remaining very much in flux, the current state of the law has opened a path of opportunity for companies hoping to sell Hemp or CBD-infused products in the US.

States that have tied the definition of "Marijuana" to compliance with their state Hemp laws are in question because, under the 2018 Farm Bill, Hemp is not a controlled substance even if an entity does not comply with a state Hemp program.

All of this highlights the fact that despite the regulatory environment remaining very much in flux, the current state of the law has opened a path of opportunity for companies hoping to sell Hemp or CBD-infused products in the US. Until the federal government enacts its Hemp plan, and a year passes, it will be especially important to research the applicable state laws and proceed carefully.

CBD PRIMER

Hemp and Marijuana come from the same species of

plant, *Cannabis sativa*, but from different varieties or cultivars that have been bred for different uses. In fact, Hemp and Marijuana are genetically distinct forms of cannabis that differ by their use, chemical makeup and different cultivation practices.

There are 500 natural components found within the *Cannabis sativa* plant, of which over 100 have been classified as “cannabinoids,” or chemicals that are unique to the plant. The two most well-

known are delta-9-tetrahydrocannabinol (THC), the psychoactive cannabinoid that gives Marijuana users their “high,” and Cannabidiol (CBD), the plant’s main non-psychoactive cannabinoid.

CBD can be derived from both Hemp and Marijuana and may have therapeutic effects on certain conditions including anxiety disorders, movement disorders, cognition and pain. It can be ingested in multiple ways, including by inhalation of smoke or vapor, via an aerosol spray into the cheek, or by mouth. It may also be supplied by tinctures (essentially CBD-infused alcohol), CBD oil containing only CBD as the active ingredient, capsules or as a liquid solution. In 2017 and 2018, CBD products spread to natural food stores, beauty aisles and cafes. By one estimate, the CBD market alone is poised to hit \$22 billion by 2022.

FOX ROTHSCHILD CANNABIS LAW PRACTICE

Legalized cannabis is a rapidly expanding industry in the United States, with a growing list of jurisdictions now regulating its use for medical and/or recreational purposes. Fox has assembled a national team of skilled and experienced attorneys to assist cannabis businesses at every step.

Fox has experience working for highly regulated businesses and navigating the constantly evolving matrix of state compliance regulations. We also have deep experience in corporate and financing

work, including banking, entity formation and venture capital. Cannabis growers, distributors, processors, investors and others also turn to Fox for practical and efficient advice on tax issues, real estate, intellectual property and employment law. ■

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Bill represents clients in highly regulated industries, particularly gaming and cannabis. He is co-chair of Fox’s Cannabis Law practice and counsels clients in the medical and recreational cannabis space in multiple states across the US. Bill is a trusted adviser to both public and private cannabis companies. Bill is a member of the National Cannabis Bar Association and a member of the Editorial Board of the *Cannabis Law Journal*.

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Joshua understands the needs of businesses in the rapidly expanding and highly regulated market for legalized cannabis. He is part of a multidisciplinary team at Fox that provides comprehensive services and guidance to legal Marijuana businesses and is a sought-after authority on complex cannabis law issues. Joshua chairs the Employment Issues Subcommittee of the Philadelphia Bar Association’s Medical Marijuana and Hemp Committee, serves on the Editorial Board of the Cannabis Law Journal and is a member of the Pennsylvania Bar Association’s Medical Marijuana and Hemp Law Committee.

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