New York State Bar Association
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Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments; FDA Docket No. FDA-2019-N-1482

COMMITTEE ON CANNABIS LAW

Cannabis #2 July 5, 2019

On May 31, 2019, the U.S. Food and Drug Administration conducted a public hearing to learn more about cannabis and cannabis-derived products, soliciting comments on: health and safety risks, manufacturing and product quality, and marketing/labeling/sales. Below are written comments submitted by the New York State Bar Association's Committee on Cannabis Law.

NYSBA Committee on Cannabis Law

In late 2017, the New York Bar Association (NYSBA) formed a Committee on Cannabis Law with the following mission:

> *The Committee on Cannabis Law is charged with serving as the New York State Bar Association's focal point for the evolving legal status of Cannabis at both the state and federal level. Cannabis law is perhaps one of the fastest growing yet complex areas of the law that poses a broad spectrum of challenges. This Committee seeks to help NYSBA lawyers give their clients better advice through sharing educational resources, and otherwise helping New York set the highest possible legal and business (including advice to medical professionals) standards for legalized Cannabis products.*

The Committee is composed of subject matter experts in the key legal disciplines relevant to the developing area of cannabis law and includes an academic advisor, Professor Robert Mikos, Vanderbilt Law School, who wrote the first law school text book on cannabis law, *Marijuana Law, Policy, and Authority* in 2017.[1]

In 2018, the Committee kicked off its activities with an Annual Meeting program in New York City (NYC) focusing on the federal and state regulation of cannabis, including a panel discussing the history of cannabis regulation in New York, Cannabis Law in New York State and the U.S. 2018. Later that year, the Committee held three more programs in New York: (1) Legislative

[1] The Committee is Co-Chaired by Aleece Burgio and Brian Malkin and is composed of members from the following NYSBA Sections, as well as other legal disciplines: Business Law; Corporate Counsel; Commerical and Federal Litigation, Criminal Justice; Elder Law and Special Needs; Entertainment, Arts and Sports Law Section; Food, Drug and Cosmetic Law, General Practice; Health Law; Intellectual Property Law; International Law; Labor and Employment Law; Real Property Law; Tax Law; Trusts and Estates Law; and Young Lawyers.

Developments in Medical Marijuana in New York 2018 held in Albany, (2) Patient, Provider and Registered Organizations Perspectives on Medical Marijuana and Adult Use in New York held in Buffalo, and (3) Practical Implications of Decriminalized Marijuana for the Legal Practitioner: What Lawyers Need to Knows, held in NYC. In 2019, the Committee again held an Annual Meeting in NYC, Hot Topics in Cannabis Law and a subsequent meeting on May 6, 2019, Hot Topics in Cannabis Law: CBD Rulemaking, CRTA, Advertising Issues and Ethical Considerations. In addition, the Committee has been meeting regularly, discussing developments in cannabis law nationally and, in particular, New York, along with reflecting on its learning from these legal programs.

Through its ongoing meetings and legal programs, the Committee has developed in a short amount of time deep legal expertise in the regulated area of cannabis law both nationally and in New York State. We aim to be one of the key legal resources on cannabis law in the country and for lawyers conducting business with companies involved in the cannabis industry. With these comments and recommendations, the Committee wishes to provide its thoughts in response to the FDA's call for comments.

Background

Like many states, New York has had a history of regulating cannabis as a medical product, available only by prescription, with varying degrees of tolerance for adult use or possession. Currently, cannabis possession is illegal in New York, except for individuals with prescriptions from qualified medical providers under the Compassionate Care Act in 2014, for certain medical ailments under specified conditions. New York also launched its Industrial Hemp Agricultural Research Pilot Program in 2015, which permitted a limited number of educational institutions to grow and research industrial hemp. In 2017, the State eliminated the cap on the number of sites authorized to grow and research the plant and expanded the program to include farmers and businesses. Also, a new statute established industrial hemp as an agricultural commodity under the State's Agricultural and Markets Law.

On December 20, 2018, the Farm Bill was enacted into federal law, which changed the definition of "hemp" to contain any part of the cannabis plant as long as the THC was below 0.3 percent on a dry weight basis, and decontrolled hemp (but not marijuana, which is also a form of cannabis) from the Controlled Substances Act (CSA). The Farm Bill further empowered states to develop industrial hemp programs consistent with certain conditions in the Farm Bill (or to make it illegal within the state), but each state program would need to be approved by the U.S. Department of Agriculture (USDA), which would also develop a federal hemp program. At the same time, the Farm Bill stated that the FDA would regulate hemp products that fell within its jurisdiction, i.e., food, dietary supplements, drugs, and medical devices that are sold in interstate commerce.

At this point, many other states and New York's bordering country, Canada, have already legalized the use of cannabis, or are in the process of doing so. However, for federal law purposes, use of cannabis is still illegal, classified as a Schedule 1 controlled drug substance under the Controlled Substances Act ("CSA"), putting it in the same category as cocaine or heroin. This designation is for drugs perceived to show a high potential risk for abuse, contain minimal medical value, and that cannot be safely prescribed. Therefore, the transporting of cannabis interstate is still illegal, as is the advertisement of cannabis products.

However, without a federal hemp program or USDA timetable to regulate state hemp, states and industry were uncertain what would become of the current state hemp programs, some of which were only created legislatively in the state but had few or no registrants. On February 27, 2019,

the USDA reiterated in a new webpage that until the USDA issues its regulations under the Farm Bill (due Fall 2019), no state program will be authorized under the Farm Bill, and industry/hemp farmers and producers should follow the Farm Bill 2014 provisions and 2016 joint USDA/DEA/DOJ/HHS/FDA Statement. According to the 2014 Farm Bill, industrial hemp growing was essentially only for research to consider the feasibility of hemp products (including marketing research). Further, the 2016 Statement said that under state industrial hemp programs, marketing is only for research, not commercial purposes, and while industrial hemp could be sold in other states with similar industrial hemp programs, such hemp could not be sold in states where such sale would be prohibited.

On February 26, 2019, FDA's former Commissioner, Scott Gottlieb, M.D., began speaking about how the FDA planned to hold a public meeting to initiate a rulemaking procedure on the key non-psychoactive component in cannabis, cannabidiol or "CBD". Gottlieb stated that FDA's goal was to create "an appropriately efficient and predictable regulatory framework for regulating CBD products." Gottlieb added that at this moment, it is illegal to introduce food or supplement products into interstate commerce that contain added CBD. On the following day, Gottlieb testified before the House Appropriations Committee, where he noted that the FDA recognized that Congress intended there to be a pathway for CBD to be available, when Congress passed the Farm Bill in 2018. Gottlieb said he could "speculate" on a possible future framework where high-concentration, high-purity CBD would be regulated as a drug, whereas lower-concentration, lower-purity CBD products could be regulated as dietary supplements. But he cautioned that FDA's rulemaking process could take two to three years, so Congressional legislation may be necessary before then to address the CBD issue.

Cannabis Clients and Overlay with the FDA

- Since 2015 NYSBA, our members have taken on an increasing number of cannabis-related clients, including international and state medical marijuana growing and dispensary programs. Many of our clients have been frustrated with limited opportunities for clinical research regarding their products due to drug scheduling under the Controlled Substances Act. Following the 2018 Farm Bill, many of our clients hope to work with the FDA to conduct clinical research for hemp- and CBD-containing products, while navigating the myriad of conflicting federal and state laws, including the uncertainty concerning the ability to freely market their products.
- Also since the 2018 Farm Bill, we are seeing an increasing number of companies entering the cannabis product market, primarily regarding hemp-derived (foreign and domestic) products, often with a first goal to enter hemp-state-friendly markets and then interstate commerce following FDA review and development of guidance. And some companies have entered all markets, arguably within FDA's jurisdiction under the long-arm interpretations of interstate commerce.
- Many state hemp programs, however, are a patch work–some defer to the FDA or identify certain products that may not contain cannabis-derived products (e.g., food), whereas others are silent, some with seeming overlapping product authority including the FDA.

Law Firms with Cannabis Industry Groups

- Initially many smaller firms added a cannabis practice group, and some new cannabis "boutique" law firms formed, initially focusing on state program licenses and compliance, not FDA regulatory compliance.

- Then larger law firms began adding cannabis groups, offering a multidisciplinary approach, some building on tobacco or alcohol practice groups or other core strengths with ties to the cannabis industry.
- Many of the initial issues concerned cannabis company due diligence, including banking issues, but over time larger cannabis operations were able to locate banks willing to work with them and other banking options became available such as funding through mergers and acquisitions or newer cyber currencies and investment options (e.g., crowd-funding).
- Potential ethical issues, however, continue due to confusing and conflicting federal and state laws, sometimes limiting the possibility for firm engagement, e.g., only cash-paying clients who cannot obtain bank accounts.

Need for FDA Client Guidance Increasing

Given the ever-increasing number of cannabis-derived products, particularly for hemp-derived and CBD-related products, we wanted to identify specific areas where we saw FDA's regulation or guidance (hereafter "guidance" unless otherwise identified) would be particularly helpful when concerning products in interstate commerce.

- The December 2018 Farm Bill created more confusion concerning what is a "legal" hemp or CBD product. The FDA should work with state authorities to determine which regulatory body has primary authority over which cannabis-derived and CBD products and whether certain products may have overlapping authorities.
- The FDA can further help cannabis-derived companies (and states) struggling with:
    - Cannabis ingredient terminology such as:
        - Cannabidiol (CBD) – "CBD extract", "CBD oil"; "broad/full spectrum" CBD (e.g., the definition of CBD is distinguishable from full spectrum hemp since full spectrum hemp contains, among other things, naturally-occurring amounts of CBD akin to differentiating between over-the-counter versus prescription strength fish oil).[2]
        - "Hemp extract", "hemp oil" (e.g., hemp seed, flower, or plant?)
        - "THC free" (e.g., less than 0.3% or lower?)
    - Laboratory testing accreditation for cannabinoids (CBD/THC) and appropriate testing thresholds.
    - Intermediary processing and THC testing, e.g., cannabis/hemp biomass and the potential shipment of it in interstate commerce for further processing.
    - What cannabis- or hemp-derived products may be used in all FDA-regulated products including over-the-counter products such as cosmetics, drugs, and

[2] The Committee on Cannabis Law proposes that the FDA consider the following approach:

"Full spectrum hemp" is a whole-plant extract, which contains naturally occurring CBD, among other ingredients. "CBD" or "CBD isolate" is a crystalline powder that contains only CBD. CBD or CBD isolate contains none of the other cannabinoids, annabinoids, phytonutrients, chlorophyll, healthy fatty acids, terpenes, and flavonoids that commonly result from the whole-plant extraction process.

Accordingly, it is recommended that the FDA set limits on the percentage of full spectrum hemp contained in products sold to the general public and provide a pathway through over-the–counter drugs, or investigational new drug exemptions to provide for higher percentage levels of prescription strength, full spectrum hemp contained in products as is the case with prescription strength fish oil sold under the brand name, Lovaza.

medical devices, and whether cannabis ingredient terminology or CBD/THC threshold amounts matter.

- Discuss whether dosage forms change the product category e.g., vitamins may be gummies or inhaled (e.g., B-12) or oils (e.g., vitamin E) - does a particular dosage form, e.g., vaped CBD, automatically make "hemp extract" or CBD a "drug" or "dietary supplement"?
- Discuss whether there is a need for allergen testing for CBD (either for internal or external use) to determine safe levels or levels where adverse events may be observed - and does purity or "broad/full spectrum" matter?
- Develop guidelines for cGMPs for cannabis-derived products and CBD in particular or indicate that current guidelines would be sufficient.
- Expound on import/export implications for hemp and CBD used in FDA-regulated products, especially regarding documentation and labeling for the US Customs and Border Protection.
- Work with FTC to develop advertising guidelines for cannabis-containing products and help states with their own programs regarding advertising guidelines.
- Work with states to develop more uniform labeling and packaging and guidelines for what is a state-only versus interstate commerce cannabis-containing/derived product. We are currently seeing a trend where states are issuing new licensing, testing, labeling, and documentation requirements without any consistency to other states' standards. This patchwork of requirements will lead to consumer confusion.

Thank you for the opportunity to provide these comments.