REGULATION OF CBD IN THE UNITED STATES – BALANCING PUBLIC SAFETY AND SOCIAL CONSIDERATIONS WITH INDUSTRY EXPECTATIONS AND CONSUMER DEMAND

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CBD (cannabidiol) is currently an industry hot topic. While cannabis companies continue to jockey for position in this budding market, we are now seeing large household names – including CVS Pharmacy and Ben & Jerry's – enter into this space.[1]

In our previous article "*How Are CBD Products Regulated Under Canadian Cannabis Law*", we provide a general background on the different varieties of cannabis (including hemp[2]), the chemical differences between THC (Delta-9-tetrahydrocannabinol) and CBD, and the Canadian regulatory framework governing CBD and CBD products. We also highlight the United States' regulatory framework governing CBD and CBD products derived from hemp – emphasizing a key difference between the U.S. framework relative to Canadian law.

This article seeks to expand on the general regulatory landscape governing CBD and CBD products in the U.S. and to discuss the recent U.S. Food and Drug Administration ("**FDA**") public hearing concerning cannabis that took place on May 31, 2019.

1. 2018 *Farm Bill* – Federal Legalization of Hemp

Cannabis (including all parts and derivatives thereof, such as THC and CBD) remains generally illegal under U.S. federal law.[3] However, on December 20, 2018, President Donald Trump signed the *Agriculture Improvement Act of 2018* (commonly known as the "**2018 Farm Bill**")[4] into law, amending the *Agricultural Marketing Act of 1946*[5] (the "**Agricultural Marketing Act**") to allow for hemp production and removing hemp and certain cannabinoids extracted from hemp from the U.S. *Controlled Substances Act*.[6] CBD and CBD products that are derived from hemp are therefore no longer federally illegal, whereas CBD and CBD products derived from other varieties of cannabis remain federally illegal. Consequently, it is important to understand how hemp is legally distinguished from other varieties of cannabis.

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, acids, salts, and salts of isomers, whether growing or not, with a [THC] concentration of not more than 0.3 percent on a dry weight basis".[7] Any cannabis plant or derivative thereof containing more than 0.3% THC is therefore not categorized as hemp and is illegal under U.S federal law.

2. U.S. Federal and State Regulation

Under the *2018 Farm Bill*, the U.S. Department of Agriculture (the "**USDA**") must issue regulations governing the commercial production of hemp in the U.S. Until such time, the production of hemp will remain governed by the *2014 Farm Bill*. Details regarding these regulations and the federally run program remain undefined.[8] The USDA has expressed an intention to have its regulations finalized by fall 2019 in order to facilitate the 2020 planting season.[9]

In accordance with the *2018 Farm Bill* and the *Agricultural Marketing Act*, states have the authority to implement state-specific regulations governing the production of hemp for commercial uses.[10] However, the USDA must first review and pre-approve any state-promulgated regulations regarding hemp production (including any regulations implemented by a state prior to federal legalization under the *2018 Farm Bill*). Nevertheless, states are not required to implement their own hemp regulations.[11] In the absence of a state-specific plan, the USDA is empowered under the *2018 Farm Bill* to regulate the production of hemp in those states.[12]

3. The Food, Drug, and Cosmetic Act

Despite certain regulatory changes under the *2018 Farm Bill*, Congress has maintained the FDA's authority under the *Federal Food, Drug, and Cosmetic Act* (the "**FDCA**") and section 351 of the *Public Health Service Act* to regulate products containing cannabis or cannabis-derived compounds, including CBD.[13] While a comprehensive discussion of the FDA's authority under the *FDCA* goes beyond the scope of this article, the *FDCA's* expansive definitions of the terms "food additives", "dietary supplements", "drugs", and "cosmetics" appear to cover most consumer products capable of containing CBD:

a. *Food, Food Additives, and Dietary Supplements*

Generally, the FDA's role is to ensure that food and other products are safe for human and/or animal consumption. It does so by regulating dietary supplements, food additives, and other ingredients that are destined for interstate commerce.[14]

The FDA prohibits adulterated and misbranded food products from being manufactured, introduced, and sold into interstate commerce.[15] Food products may be deemed 'adultered' if they contain food additives not approved by the FDA.[16] The FDA must appropriately sanction the new food additive before it can be sold.[17]

The addition of an approved drug (or a drug in the process of substantial clinical investigations that are known to the public) to food products is also prohibited, subject to certain exceptions.[18]

b. *Drugs*

The FDA regulates the manufacturing, labelling, branding, and sale of drugs introduced into interstate commerce. Drugs are prohibited from being combined with food and sold as dietary supplements, unless approved by the FDA.[19] The FDA must also approve any products claiming to diagnose, cure, mitigate, treat, or prevent diseases prior to these drugs entering the public market.[20]

c. *Cosmetics*

The FDA does not regulate all ingredients added to cosmetics, but it does prohibit the adulteration or misbranding of cosmetics in general.[21] Adulteration occurs when ingredients contain poisonous or deleterious substances, or they have been prepared, packed, or stored in unsanitary conditions, that may prove injurious when used as intended.[22] If a cosmetic product claims to diagnose, cure, mitigate, treat, or prevent a disease, or it intends to affect the structure of the body, it is considered both a drug and a cosmetic. Consequently, applicable drug provisions would also apply.

4. What is the FDA's Stance on Hemp-Derived CBD and CBD Products?

CBD is categorized by the FDA as an active drug ingredient in the U.S.[23] The FDA has approved one CBD drug product – Epidiolex, a drug containing CBD that is used to treat seizures associated with two rare and severe forms of epilepsy.[24] Epidiolex underwent substantial testing prior to being released to the public and is strictly supplied by medical professionals only in appropriate circumstances. The agency is therefore particularly concerned about businesses marketing their CBD products for therapeutic or medical uses without first seeking FDA approval.

While the FDA acknowledges the potential therapeutic benefits of CBD and certain CBD products, they have yet to confirm their safety and effectiveness.[25] The agency views the "deceptive marketing of unproven treatments [to] raise significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases." [26] The FDA takes the position that any products making such therapeutic claims are both illegal and potentially harmful to public consumers.

Because CBD is currently an active ingredient in a drug product, the FDA prohibits this compound from being added to any food products or dietary supplements regulated under the *FDCA*.[27] The agency does have authority to issue regulations approving the use of active drug ingredients in food products but it has yet to do so in this case.[28] Absent further legislative action or reclassification, the only way CBD can be legally added to

food products or dietary supplements is if the FDA issues the appropriate regulations.

The FDA has not explicitly prohibited or restricted the use of cannabis and cannabis-derived compounds, such as CBD, in cosmetics.[29] However, the agency has expressed its general concerns related to the marketing and safety of these products. It is unclear at this time how the FDA intends to regulate cosmetics containing CBD.

Historically, the FDA has publically reprimanded certain companies that have marketed their CBD products for therapeutic uses, without having received the necessary regulatory approvals.[30] However – like most rapidly evolving industries – a gap continues to exist between industry knowledge/practice and regulatory enforcement. In light of current industry, social, and health considerations, the FDA is now considering the viewpoints of various stakeholders in an attempt to refine its position towards hemp-derived CBD and CBD products.

5. CBD and the FDA – A Bottleneck soon to be Widened?

On May 31, 2019, the FDA held a public hearing titled "*Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds*".[31] Over 100 stakeholders, including members of academia, agriculture, government, healthcare, manufacturing, retail and distribution, and members of the general public, came to express their views on the FDA's position towards cannabis, hemp, and compounds/products derived therefrom. Part of the discussion concerned the FDA's regulation of hemp-derived CBD and CBD products.

The hearing was generally balanced by two major themes: safety and consumer risk versus financial opportunity and economic growth. The number of CBD products already in the marketplace was a major point of discussion. Multiple stakeholders reported numerous instances where hemp products contained high levels of mold, pesticides, and heavy metals. Others drew attention to hemp products with misleading labels that make unsubstantiated claims. Conversely, industry representatives highlighted the economic potential for a properly regulated hemp industry, arguing that appropriate regulations would introduce a new cash crop to domestic farmers, create new jobs, and help ensure the health and safety of consumers. Certain stakeholders also stressed the importance of remaining globally competitive – both at the consumer level and in terms of research and development.

The FDA is treading on unprecedented territory in its efforts to appropriately regulate hemp-derived CBD and CBD products. Many attendees at the hearing stressed that such regulations are both necessary and urgent. As public interest in CBD continues to increase, illicit products will continue to flood the market to meet consumer demand. The FDA has established an online docket, which will remain open until July 2, 2019, allowing for comments on this matter. With further information, the FDA hopes to target and address areas of

uncertainty in their attempt to achieve a sound and science-based policy on hemp-derived CBD and CBD products.[32]

6. What Is in Store for the Future?

Relative to Canadian law, the U.S. federal government appears to have taken a different stance towards hemp-derived CBD and CBD products.[33] In a recent publication, the FDA stated:

We remain steadfast in our effort to obtain research, data, and other safety and public health input to inform our approach and to address consumer access in a way that protects public health, maintains incentives for cannabis drug development, and creates a robust administrative record needed to support the initiation of any rulemaking.[34]

The FDA seems to be moving towards a more free-flowing regulatory system that allows currently restricted hemp-derived CBD products to be sold to the public.[35] However, the details of this scheme remain unclear. Until such time, businesses may be left with a blurred regulatory landscape in which they must navigate. For example, CVS Pharmacy intends to sell over-the-counter topical hemp-derived CBD products, including creams, sprays, and roll-ons, as an "alternative source of relief". The pharmacy chain also hopes to avoid any association of its CBD products with therapeutic or medical claims by marketing its "creams and salves as over-the-counter medicinal products, merchandised in a dedicated display".[36] It is unclear at this time whether CVS Pharmacy's operations are offside of the FDA's stance towards hemp-derived CBD products. As more businesses (small and large) continue to enter into the cannabis space, greater pressure will be placed on the FDA to publish an update on hemp-derived CBD regulation.

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather it is recommended that companies in the industry seek local legal counsel to help them navigate the evolving cannabis industry in respect of legal issues they may face.

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[1] See Shamard Charles, "CVS to sell CBD products in 800 stores in 8 states" NBC News (March 21, 2019), [Charles] (CVS Pharmacy intends to begin selling over-the-counter CBD products in eight states. They plan to market topical products, like creams, sprays, and roll-ons, infused with CBD as "an alternative source of relief"); Sarah Min, "Ben & Jerry's plans to introduce a CBD-infused ice cream, pending FDA approval" (May 31, 2019), CBS News.
[2] Hemp is a variety of *Cannabis sativa* that it is often differentiated based on its chemical profile. For the

purposes of this article, the terms 'hemp' and 'industrial hemp' are treated as the same. For more details, see Section 1 of this article.

[3] The Federal *Controlled Substances Act* categorizes "marihuana" as a Schedule 1 "hallucinogenic substance": 21 USC § 812(1)(c)(10) [CSA]. It is defined 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": CSA, 21 USC § 802(16).

[4] US, Bill HR 2, *Agriculture Improvement Act of 2018*, 115th Cong, 2018 (enacted) [*2018 Farm Bill*].

[5] *Agricultural Marketing Act of 1946*, 7 USC § 1621 [*Agricultural Marketing Act*].

[6] *2018 Farm Bill*, *supra* note 4 at § 10113, 12619; *ibid*, § 1639o(1).

[7] *2018 Farm Bill*, *supra* note 4 at § 10113.

[8] USDA, "Hemp Production Program" (February 27, 2019), USDA.

[9] *Ibid* ("[t]he 2018 Farm Bill extension of the 2014 authority expires 12 months after [the] USDA has established the plan and regulations required under the 2018 Farm Bill).

[10] *2018 Farm Bill*, *supra* note 4 at § 10113; *Agricultural Marketing Act*, *supra* note 5 at § 1639p(1).

[11] *Agricultural Marketing Act, supra* note 5 at § 1639p(a)(3)(A).

[12] *Agricultural Marketing Act, supra* note 5 at § 1639q(a)(1).

[13] FDA, "Statement from FDA Commissioner Scott Gottlieb, MD, on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds" (December 20, 2018), FDA [Scott Gottlieb Statement].

[14] *CSA, supra* note 3 at § 321(f), (s) and (ff); FDA, "What does FDA regulate?" (2019). A thorough discussion of the FDA's jurisdiction over products that enter interstate commerce goes beyond the scope of this article. However, we note that the FDA's authority may be expansive should the definition of 'interstate commerce' be interpreted broadly.

[15] *CSA, supra* note 3 at § 331(a), (b) and (g).

[16] *CSA, supra* note 3 at § 342.

[17] *CSA, supra* note 3 at § 348(a) and 350b(a).

[18] *CSA, supra* note 3 at § 331(ll).

[19] *Ibid*.

[20] *CSA, supra* note 3 at § 355(a).

[21] *CSA, supra* note 3 at § 361 and 362.

[22] *CSA, supra* note 3 at § 361(a).

[23] *Ibid* at Question 11.

[24] FDA, Scott Gottlieb Statement, *supra* note 13; FDA, Cannabis Q&A, *supra* note 23 at Question 3.

[25] FDA, Cannabis Q&A, *supra* note 23 at Question 4.

[26] *Ibid*.
[27] FDA, Cannabis Q&A, *supra* note 23 at Questions 9 and 10.
[28] FDA, Cannabis Q&A, *supra* note 23 at Question 9.
[29] FDA, "FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers" (2019) at Question 13, *FDA* [Cannabis Q&A].
[30] FDA, "Warning Letters and Test Results for Cannabidiol-Related Products" (2019), *FDA*.
[31] For a webcast recording of this proceeding, see: FDA, "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing" (2019), FDA.
[32] Amy Abernethy & Lowell Schiller, "FDA is Committed to Sound, Science-based Policy on CBD" (June 14, 2019), *FDA*.
[33] See our previous article "*How Are CBD Products Regulated Under Canadian Cannabis Law*".
[34] Abernethy, *supra* note 31.
[35] FDA, "Remarks by Dr. Sharpless at the *FDA* Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds" (May 31, 2019), *FDA*.
[36] Charles, *supra* note 1.

A Cautionary Note