8 Scientific, Legal, and Regulatory Considerations for Cannabidiol

Jay Manfre, Esq., Rick Collins, Esq., Marielle Kahn Weintraub, and Robert E.C. Wildman

CONTENTS
8.1 Introduction .................................................................................................................. 147
8.2 Potential for Nutraceutical Benefit of Cannabidiol .......................................................... 147
8.3 Analytical Methods for Hemp and Cannabidiol ............................................................... 149
8.4 The Farm Bill ............................................................................................................... 150
8.5 The Food and Drug Administration and the Food, Drug, and Cosmetic Act .................. 152
8.6 Federal Legislation on the Horizon ................................................................................. 155
8.7 The Future of Cannabidiol ............................................................................................. 155
References ...................................................................................................................... 155

8.1 INTRODUCTION

Both marijuana and hemp are produced from the same species of plant, Cannabis sativa, though different varieties are cultivated for specific characteristics. Cannabidiol (CBD) is one of over 100 naturally occurring cannabinoids found in both marijuana and hemp. Although both marijuana and hemp come from Cannabis sativa, hemp typically has a much lower concentration of delta-9 tetrahydrocannabinol (THC), the psychoactive chemical found in marijuana that produces a “high” when consumed.1 The World Health Organization’s Expert Committee on Drug Dependence discussed CBD during its 39th meeting, which took place in November 2017 in Geneva, Switzerland. The World Health Organization reported that when consumed by humans, pure CBD does not exhibit the effects indicative of abuse, dependence potential, or any public health-related problems.2 Although pure CBD does not produce a “high” or cause dependence in users, the legal status of CBD in the United States has been mired in an intricate web of regulatory and legal considerations that are worthy of examination.

8.2 POTENTIAL FOR NUTRACEUTICAL BENEFIT OF CANNABIDIOL

Groundbreaking work by Dr. Ralph Mechoulam and his colleagues in 1963 discovered and defined the chemical structure of CBD (Figure 8.1), followed by the chemical structure of THC a year later.3 Alynn Howlett further defined the activation of delta-9-tetrahydrocannabinol on a specific cannabinoid receptor, CB1, found in areas of the brain involved in movement, stress, and cognitive function.4 These findings, in addition to identification of specific G-protein-coupled receptors for THC,5 and the discovery of two endogenous cannabinoids, arachidonoyl-ethanolamide (AEA), referred to as anandamide and arachidonoyl glyceride (2-AG),4–6 laid the substantial foundation for the discovery of the endocannabinoid system (ECS).7,8 The ECS was named after the Cannabis sativa plant and psychoactive ingredient THC that led to its discovery. This biological system is involved
in homeostatic and physiologic functions. The ECS has also been shown to play an important role in CNS development, neuroplasticity, and neuroprotective properties.

THC has a higher binding affinity for CB1 receptors, which are found in more abundance in the CNS in comparison to CB2 receptors, found throughout the peripheral nervous system (PNS). CB2 receptors were originally found in spleen cells but were later identified throughout the PNS. Although there are some similarities in composition to CB1 receptors, CB2 receptors are thought to be more involved in the modulation of immune function and inflammation. Interestingly, CBD has been discovered to indirectly impact both CB1 and CB2 receptors, by modulating the affinity of other cannabinoids, including THC, and compounds binding to these receptor types. Understanding this mechanism of action may help us better comprehend the positive effects CBD appears to have on various physiological processes, discussed further in this chapter.

Traditional synaptic signaling involves neurotransmitters being released from the presynaptic terminal, then diffusing to the postsynaptic terminal, where they bind and activate receptors. However, the CB1 receptor is theorized to use a less common form of signaling, called retrograde signaling. Retrograde signaling occurs when a diffusible messenger is released from the postsynaptic terminal and travels “backward” across the synaptic cleft, where it activates receptors on the presynaptic cell (Figure 8.2).

Several studies of both the endocannabinoid system and endogenous cannabinoids have revealed their involvement in numerous physiological processes, including appetite, pain sensation, control of chronic pain, and regulation of immune cell functions. Endocannabinoid compounds, such as cannabidiol, have been shown to modulate various disease pathology and movement disorders.

![FIGURE 8.1 Cannabidiol (CBD).](image1)

![FIGURE 8.2 Anandamide mediates retrograde synaptic signaling via cannabinoid receptors.](image2)
There is little research available on the direct effects of CBD supplementation in conjunction with exercise in human subjects; however, it has been suggested that the endocannabinoid system partakes in adaptive responses to exercise. One theory of this adaptation is evident by the activation of the endogenous cannabinoid, anandamide, during exercise. Anandamide acts as a vasodilator, leading to hypertension and facilitating blood flow. Additionally, studies have demonstrated that both endocannabinoids and exogenous cannabinoids can act as bronchodilators, affecting the respiratory system and therefore possibly facilitating breathing during exercise. The degree to which endocannabinoids and phytocannabinoids increase regenerative properties, such as “healthy bone, tendon, ligament, muscular and connective tissue integrity” is still being researched. However, Dr. Hector Lopez theorizes how hemp-derived CBD products may help balance and optimize ECS physiology. The addition of a CBD extract product may reduce anxiety levels, increase quality sleep, and contribute to an optimized diet.

Numerous studies have demonstrated both anti-inflammatory and analgesic properties of CBD. CBD has also been shown to have antioxidant properties and neuroprotective qualities. A study published by the American Medical Association (2017) found that 99% of deceased NFL players were found to have chronic traumatic encephalopathy (CTE). CTE is a neurodegenerative disorder characterized by a buildup of abnormal tau protein manifesting in memory loss, aggression, depression, and impaired judgment. Research suggests that the neuroprotective effects of CBD may offer preventative measures from concussions resulting from high-impact sports and exercise. Although the possible neuroprotective effects from CBD are intriguing, the anti-inflammatory effects may be another catalyst for the increase in popularity among athletes. Reduced inflammation in muscle and tissue following intense training and exercise, as well as reduced anxiety, may contribute to faster healing times and reduced performance anxiety during competitions. Although further studies are needed to better understand the impact CBD can have on both pre- and post-workout routines, there has been a clear shift in the attitude toward CBD in sports. The World Anti-Doping Agency (WADA) officially removed CBD from its 2018 list of prohibited substances, although THC remains a prohibited substance.

### 8.3 ANALYTICAL METHODS FOR HEMP AND CANNABIDIOL

Through the US Hemp Authority, the need to have relevant and defined testing regulations was voiced by the industry and made a priority. Numerous members of the industry have come together through these and other trade organizations, such as the Hemp Industries Association, National Hemp Association, and American Herbal Products Association, in an effort to assist in the writing of these self-regulation standards, until clear direction is developed at both the state and federal levels. The US Hemp Round Table’s mission to “Join citizens from across government, the agricultural industry, U.S. manufacturers, the small business community, and beyond, to support legislation (Senate Bill 2667 and House Bill 5485) that would establish hemp as an agricultural commodity, removing it completely and permanently from the purview of the Controlled Substances Act.” In addition, the US Hemp Authority, which developed “stringent self-regulatory standards and comprehensive guidance for hemp growers and processors,” is a part of the hemp industry’s objective to provide high standards, best practices, and self-regulation, giving confidence to consumers and law enforcement that hemp products are safe and legal.

CBD regulations continue to evolve at the state and federal level; meanwhile, third-party analytical testing laboratories are attempting to comply with these changes. This is accomplished by monitoring the state regulations passed and by closely setting internal testing standards to mimic dietary supplement testing and regulations that are more clearly defined by the FDA. For example, in July 2018, the State of Indiana passed a regulation, Engrossed Senate Bill No. 52 (ESB52), that all industrial hemp-derived CBD products must have a certificate of analysis from an ISO 17035:2005 accredited third-party analytical laboratory for the compound THC. This regulation was written to ensure compliance with the federal definition of hemp. Following this regulation, laboratories that
wished to be in compliance for their customers selling CBD products had to get their cannabinoid potency methods ISO accredited by an approved accreditor, suggested in ESB52. In addition to state testing regulations, there are very explicit labeling regulations that affect all products sold in CA listed under the Safe Drinking Water and Toxic Enforcement Act, better known as Prop 65, that CBD product retailers and manufacturers must also strictly follow.

Although the legal status of CBD as a dietary ingredient is still not on solid ground, new hemp companies and numerous “mainstream” food and dietary supplement companies are formulating new products with hemp extracts and launching these products on the US market. In response to these new products, globally recognized standard-developing organizations, such as AOAC International and ASTM, have launched programs to ensure the hemp and cannabis industries will have access to developed and published technical standards for test methods, materials, processes, and other consensus standards.

The following excerpt written by Johnathan S Miller and Nolan M Jackson, of Frost Brown Todd LLC, discusses the confusing landscape of industrial hemp-derived products. They explain how federal statements regarding CBD products have increased uncertainty of the legal status of those products. “While the Farm Bill and Omnibus Law provide protections for the sales of hemp-derived CBD—especially when the hemp is grown as part of a state-authorized pilot program—some federal agencies objected, and began to issue non-legally-binding statements that suggested that CBD was not permitted for sale under federal law. Most concerning to the hemp industry, the FDA concluded that CBD could not be marketed as a dietary supplement, and that the interstate sale of food products containing CBD was not legal. However, the FDA has left the question open to further input from the industry and did not signal that any enforcement actions were imminent.”

8.4 THE FARM BILL

When presented with the question, “Is CBD legal?” most supporters cite the Agricultural Improvement Act of 2018 (the 2018 Farm Bill) as the federal act that gives CBD the “green light” to be sold in the United States so long as the CBD comes from hemp. Although this argument “sounds good,” we must examine the text of the 2018 Farm Bill to determine what, in fact, it authorizes and what it does not. “Farm Bills” are typically passed about every 5 years to create or reauthorize certain federal programs. The Agriculture Act of 2014 (the 2014 Farm Bill) was signed into law by President Obama on February 7, 2014, and included Section 7606, entitled “Legitimacy of Industrial Hemp Research.” This was the first step along the journey of legalizing the growing and cultivating of hemp within the United States. Section 7606 of the 2014 Farm Bill allowed for an institution of higher education or a state department of agriculture to grow or cultivate industrial hemp if: “1. the industrial hemp [was] grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and 2. the growing or cultivating of industrial hemp [was] allowed under the laws of the state in which such institution of higher education or state department of agriculture [was] located and such research occur[ed].” The 2014 Farm Bill defined “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% on a dry weight basis.” Under the 2014 Farm Bill, if the legal requirements of Section 7606 were met, then growing and cultivating industrial hemp was permitted. As can be seen from the plain language of the Act, industrial hemp was only permitted to be grown by an institution of higher education or state department of agriculture for purposes of research. While the 2014 Farm Bill was a historical piece of legislature, the Act did not allow simply anyone who wanted to grow or cultivate industrial hemp to do so.

Due to the increased media attention and general confusion surrounding the sale of CBD, specifically the product sold by CW Hemp called Charlotte’s Web, the DEA released a statement to The Cannabist on CBD, hemp, and the 2014 Farm Bill. The DEA stated, “It is important to correct a misconception that some have about the effect of the Agricultural Act of 2014 (which some refer to as the ‘farm bill’) on the legal status of ‘Charlotte’s Web/CBD oil. Section 7606 of the Agricultural
Act of 2014 authorizes institutions of higher education (e.g., universities) and state Departments of Agriculture to grow and cultivate ‘industrial hemp’ (defined under the Act as marijuana with a THC content of 0.3% or less) for agricultural research purposes where permitted under state law. However, the Agricultural Act of 2014 does not permit such entities, or anyone else, to produce non-FDA-approved drug products made from cannabis. Thus, the CSA and FDCA restrictions remain in effect with respect to the production of ‘Charlotte’s Web’/CBD oil for human consumption.”

Contrary to widespread belief among those in the marijuana and hemp industries, the 2014 Farm Bill did not give the “green light” to those who sought to sell CBD derived from hemp for commercial purposes.

On December 20, 2019, President Trump signed the Agriculture Improvement Act of 2018 (the 2018 Farm Bill). Senate Majority Leader Mitch McConnell of Kentucky introduced the Hemp Farming Act, a standalone bill that sought to legalize hemp in April of 2018. The provisions of that bill were later included in the Farm Bill of 2018. There are several differences between the 2014 Farm Bill and the 2018 Farm Bill. The first major difference is the way that “hemp” is defined. As explained above, the 2014 Farm Bill allowed for the growing and cultivation, subject to limitations, of “industrial hemp,” which it defined as “the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.” The 2018 Farm Bill, on the other hand, more broadly defines the term “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 delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.” Notably, the 2014 Farm Bill used the term “industrial hemp,” while the 2018 Farm Bill simply states “hemp.” Additionally, the 2018 Farm Bill includes within its definition of hemp the specific chemical constituents of the plant, including CBD (Figure 8.3).

The second, and arguably most impactful, distinction between the 2014 Farm Bill and the 2018 Farm Bill is that the 2018 version amends the CSA. The very first line of the 2014 Farm Bill stated, “Notwithstanding the Controlled Substances Act…” As a result, under the 2014 Farm Bill, the only parts of the hemp plant that were not considered a controlled substance were those parts that were specifically excluded as a controlled substance from the CSA—“the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.” This meant that all chemical constituents and extracts of hemp, including CBD, were Schedule 1 controlled substances. The 2018 Farm Bill specifically amends the CSA to exempt “hemp” from the definition of “marijuana” and, as a result, “hemp” is no longer a controlled substance. That amendment removes hemp, including CBD derived from hemp, as defined in the 2018 Farm Bill, from the oversight authority of the Drug Enforcement Administration (DEA). Furthermore, the 2018 Farm Bill removes the THC contained in hemp (not more than 0.3%...
on a dry weight basis) from the CSA. However, at this time, marijuana is still federally illegal; thus, CBD and THC that are derived from the marijuana plant are still Schedule I controlled substances.

The third most significant change is how the two versions differ with respect to who is permitted to grow and cultivate hemp. The 2014 Farm Bill specifically stated that “an institution of higher education or a State department of agriculture may grow or cultivate industrial hemp if—(1) the industrial hemp [was] grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and (2) the growing or cultivating of industrial hemp [was] allowed under the laws of the State in which such institution of high education or State department of agriculture [was] located and such research occurs.” The 2018 Farm Bill removes the restriction on growing and cultivating “for purposes of research” and removes the ability of the individual states to restrict the growing and cultivation of hemp. The 2018 Farm Bill provides that if a state or Native American tribe wants to have primary regulatory authority over the production of hemp in their State or Tribal territory, they must submit a plan to the Secretary of Agriculture, under which the State or tribe will monitor and regulate the production. The Secretary has 60 days following the receipt of a State or Tribal plan to either approve or disapprove its plan. If a State or Tribal government does not submit a plan, or their plan is rejected by the Secretary, the production of hemp in that State or tribal territory will be subject to a plan established by the Secretary. Accordingly, the 2018 Farm Bill makes the growing and cultivation of hemp legal in all 50 US states and Native American territories.

8.5 THE FOOD AND DRUG ADMINISTRATION AND THE FOOD, DRUG, AND COSMETIC ACT

If a product is composed of or contains CBD that was extracted from hemp grown pursuant to the 2018 Farm Bill, can that product be lawfully marketed and sold as a dietary supplement? In order to answer that question, we must analyze the regulatory framework of the Food and Drug Administration. The FDA regulates foods, drugs, and cosmetics, among other consumer goods, under the Food Drug and Cosmetic Act (FDCA). Currently, President Donald Trump is seeking to consolidate federal food safety under a single agency under the US Department of Agriculture. President Barack Obama also sought to consolidate food safety; however, Congress would not extend President Obama the power to do so. If the Trump Administration’s plan ultimately comes to fruition, food safety would be removed from the FDA’s jurisdiction and the FDA would be renamed the “Federal Drug Administration.” Whether or not this change occurs, dietary supplements will continue to be regulated by the FDA.

Congress passed the Dietary Supplement Health and Education Act of 1994, which was signed by President Bill Clinton in October of 1994. Although still classifying dietary supplements as “food” under the FDCA, DSHEA established a clearer and more practical framework for the regulation of dietary supplements. Among other things, DSHEA created a legal definition for a “dietary supplement” as a product (other than tobacco) intended to supplement the diet that contains one or more “dietary ingredients.” By definition, “dietary ingredients” in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances for use by man to supplement the diet by increasing the total dietary intake. Dietary ingredients can also include extracts, metabolites, or concentrates of the preceding substances. As explained above, both hemp and marijuana come from the plant Cannabis sativa L. and therefore fit under the DSHEA definition of botanicals. Because dietary ingredients also include “extracts, metabolites, or concentrates” of botanicals, products containing CBD, which has been extracted from the cannabis plant, would also fall within the general definition of a dietary supplement.

Although CBD appears to qualify as a dietary supplement based on the general definitions set forth above, other provisions of the FDCA and DSHEA must be examined to determine the regulatory status of CBD as a dietary supplement. In addition to the categories of dietary
ingredients, DSHEA also distinguishes between those ingredients marketed and sold prior to the passage of DSHEA and those marketed and sold after DSHEA. A “new dietary ingredient”(NDI) is defined as a dietary ingredient that was not marketed in the United States before October 15, 1994.\textsuperscript{35} A product containing an NDI is deemed adulterated and subject to FDA enforcement sanctions unless it meets one of two exemption criteria: either (1) the supplement in question contains “only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered”, or (2) there is a “history of use or other evidence of safety” provided by the manufacturer or distributor to the FDA at least 75 days before introducing the product into interstate commerce.\textsuperscript{35} CBD that has been isolated from hemp, or hemp oil containing amounts of CBD in excess of those naturally contained in the plant, would not meet the first exemption under DSHEA because the “form has been chemically altered.” Certain companies have chosen to try to limit their exposure to risk by selling products containing “Full-Spectrum Hemp Extract.” The reasoning behind this is that “Full-Spectrum Hemp Extract” is purportedly extracted from hemp in a form that has not been chemically altered. On December 20, 2018 (the same date the 2018 Farm Bill was signed by President Trump), the FDA completed its evaluation of three Generally Recognized as Safe notices for food ingredients derived from hemp seed.\textsuperscript{36} The FDA reviewed the GRAS submissions and had no questions regarding the company’s conclusion that the ingredients are GRAS under their intended conditions of use.\textsuperscript{36} While this is a great step forward, it is important to note that the hemp ingredients contain only trace amounts of THC and CBD, which the seeds might pick up through contact with other parts of the plant during the harvesting and processing.\textsuperscript{36} At the time of this writing, no GRAS notice has been accepted by the FDA for hemp ingredients that have been derived from parts of the hemp plant that have more than a trace level of CBD.

As a result, in order to market and sell CBD as a dietary supplement, the manufacturer or distributor would need to submit an NDI notification to FDA demonstrating the safety of CBD.\textsuperscript{35} That information would include: (1) the name of the new dietary ingredient and the Latin binomial name, and (2) a description of the dietary supplement that contains the new dietary ingredient, including (a) the level of the new dietary ingredient in the product, (b) conditions of use of the product stated in the labeling, or if no conditions of use are stated, the ordinary conditions of use, and (c) a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, is reasonably expected to be safe.\textsuperscript{35}

Assuming that the manufacturer or distributor of a CBD supplement submitted an NDI notification to the FDA and sufficiently demonstrated the safety of the product, would that NDI notification ultimately be successful? At the current time, the answer is most likely no. In addition to the distinction between “old” and “new” dietary ingredients, DSHEA also defines what a dietary supplement does not include. DSHEA states that a dietary supplement does not include:

- an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or an article authorized for investigation as a new drug, an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary’s discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.\textsuperscript{35}

In 2007, GW Pharmaceuticals began conducting clinical investigations on its CBD drug Epidiolex. On June 25, 2018, the FDA approved Epidiolex for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome for patients 2 years of age and older.\textsuperscript{37} This means that,
under DSHEA, in order for CBD to potentially be considered a dietary supplement, CBD would have had to have been legally marketed as a dietary supplement or food prior to GW Pharmaceuticals’ clinical investigations in 2007. On the FDA website, there is a page entitled, “FDA and Marijuana: Questions and Answers.” Question 12 on this website asks, “Can products that contain THC or cannabidiol (CBD) be sold as dietary supplements?” In its answer, the FDA concludes that products containing CBD cannot be sold as dietary supplements because there is no evidence that CBD was lawfully marketed as a dietary supplement or food before the new drug investigation for CBD was authorized. The FDA does state that interested parties can present the agency with evidence that they believe has bearing on the issue, but “[FDA’s] continuing review of information that has been submitted thus far has not called [FDA’s] conclusions into question.” Based on the FDA’s position and subsequent approval of CBD as a pharmaceutical drug, it appears that unless the industry can come forth with evidence to support that CBD was lawfully marketed as a dietary supplement or food prior to 2007, CBD sold as a dietary supplement will continue to be an adulterated or misbranded drug and subject to enforcement. The Hemp Industries Association has publicly stated that it provided FDA with evidence that hemp extract and CBD was marketed prior to 2007, but the FDA has not offered its opinion on such.

Aside from the NDI notification and GRAS determinations explained above, there is another potential way for CBD to be a permissible dietary ingredient and supplement. The FDA is a regulatory agency within the US Department of Health and Human Services (HHS). The Secretary of HHS has the authority under the FDCA to issue a regulation, following notice and comment, finding CBD lawful in dietary supplements. The FDA released a statement on December 20, 2018 (the date the 2018 Farm Bill was signed), offering some potential hope for the future of CBD as a dietary supplement. In the press release, the current FDA Commissioner, Scott Gottlieb, M.D., stated, “pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process.” Prior to this statement, the FDA’s position on CBD as a dietary supplement seemed impervious to change. While there has been no change to the FDA’s formal position on the legality of CBD as a dietary supplement, this statement offers a glimmer of hope for the future of CBD as a supplement.

Putting aside for the moment the various hurdles facing CBD as a dietary ingredient, it is important to also understand that dietary supplements can never be marketed to diagnose, treat, cure, or prevent any disease state. Multiple companies that sell products that are, or contain, CBD have received warning letters from the FDA for making “disease claims” related to their CBD supplements. The FDA defines a disease as, “damage to an organ, part, structure or system of the body such that it does not function properly, or a state of health leading to such dysfunctioning.” Many companies selling CBD as dietary supplements tout the benefits of CBD on conditions like cancer, anxiety, dementia, arthritis, epilepsy, and inflammation. Based on the FDA’s definition of a disease, these types of claims about a dietary supplement cause that product to be deemed a misbranded or adulterated drug. These types of claims are “low-hanging fruit” for the FDA because rather than arguing over the regulatory status of CBD as a dietary supplement, the claims alone cause these CBD products to be considered adulterated and misbranded drugs under the FDA definition, subjecting the marketers to enforcement actions. Further, when companies make these disease claims, it only serves to increase the level of scrutiny surrounding the CBD market. In addition to the FDA, the Federal Trade Commission regulates the marketing and advertising of dietary supplements. Companies that make claims about their CBD products that are not substantiated risk enforcement actions from the FTC. In addition to the warning letters sent to companies making disease claims, the FDA has also issued warning letters because certain products containing CBD also contained high levels of THC.
8.6 FEDERAL LEGISLATION ON THE HORIZON

On June 27, 2018, Senate Democratic Leader Chuck Schumer introduced the Marijuana Freedom and Opportunity Act cosponsored by Senators Bernie Sanders, Tim Kaine, and Tammy Duckworth. The Marijuana Freedom and Opportunity Act would remove marijuana from the list of controlled substances under the CSA and allow states to decide how to treat marijuana possession. Although not directly mentioning CBD, by removing marijuana from the list of controlled substances, it would effectively remove marijuana extract from the CSA as well. This is due to the fact that the scheduling of marijuana extract is dependent upon marijuana itself being a Schedule I controlled substance. If ultimately signed into law, this Act would remove CBD derived from marijuana from the CSA and DEA jurisdiction—a significant win for CBD and the marijuana industry as a whole.

8.7 THE FUTURE OF CANNABIDIOL

Based on the laws and regulations as they currently exist in the United States, the FDA considers CBD to be an adulterated and misbranded drug if labeled and sold as a dietary supplement. Despite this, the CBD market continues to grow and expand, with individual states legalizing marijuana for medical and recreational purposes and creating state-specific CBD laws. Further, with the current “opioid epidemic” in the United States, it appears that the FDA and DEA have “bigger fish to fry” when determining the proper allocation of resources. While companies selling CBD are currently choosing to accept the risk of enforcement, the Farm Bill of 2018 removed hemp from the CSA, allowing farmers to grow and cultivate hemp for commercial purposes and taking enforcement away from the DEA. Additionally, if signed into law, the Marijuana Freedom and Opportunity Act would legalize marijuana and remove marijuana-derived CBD from the list of controlled substances where it is currently a Schedule I drug as marijuana extract. While all of these developments would benefit the marijuana and hemp industry, the regulatory status of CBD as a dietary supplement, the comments by former Commissioner Scott Gottlieb and the FDA’s actions related to the three GRAS notifications led to speculation suggesting a future reconsideration of the FDA’s position. On May 31, 2019, the FDA held a public hearing on CBD with over 100 speakers and 10 hours of testimony. The purpose of the hearing was to obtain scientific data and information about the safety, manufacturing, marketing, labeling, quality, and sale of products containing cannabis or cannabis-derived compounds. The FDA began the hearing by expressing safety concerns regarding side effects, drug interactions, dosing, and adolescent use. While those concerns may not have been fully addressed at that time, the hearing was a step forward in assessing how the FDA might establish a pathway to regulate CBD products.

REFERENCES

34. Controlled Substances Act, 21 U.S.C. 812(c).

37. U.S. Food & Drug Administration. 2018, June 25. FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm

