IN THE WEEDS: FDA ENFORCEMENT PRIORITIES, PUBLIC HEARING, AND LITIGATION CONSIDERATIONS FOR CANNABIS PRODUCTS

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FDA and Health Care Alert

CBD, or cannabidiol, is a compound in the cannabis plant that does not cause the psychoactive or hallucinogenic effect of tetrahydrocannabinol (THC).[1] It is being widely studied, marketed, and reported as having beneficial effects on numerous diseases and conditions, such as anxiety, pain, inflammation, nausea, seizures, and opioid use disorder. Simply put, the words “trending” or “buzzworthy” do aptly describe its current status on the market — based on its growing demand, the CBD market is predicted to be valued at more than $20 billion by 2020. Much of that is being driven by a movement in the food, beverage, dietary supplement, and personal care product industries to develop products containing CBD. Yet, countless companies jumping on the CBD bandwagon do not know or understand the federal and state regulatory status and implications of using CBD as a food or dietary supplement, and often worse, are not contemplating litigation risks posed by marketing and selling such products.

The Agriculture Improvement Act of 2018 (2018 Farm Bill),[2] which was signed into law on December 20, 2018, changes certain federal laws relating to the production and marketing of hemp, defined generally as any portion of the cannabis plant with up to 0.3 percent of THC on a dry weight basis. While the major change of the 2018 Farm Bill is the removal of hemp from the Federal Controlled Substances Act (CSA),[3] the law does not impact the U.S. Food and Drug Administration's (FDA's) authority to regulate cannabis and cannabis-derived products.

Current FDA laws prohibit the use of CBD and THC in food and dietary supplements, including hemp and hemp-derived products, because such compounds are active ingredients in approved drugs and have been the subject of substantial clinical investigations. To date, New York City's Department of Health [4] and several states, including California,[5] Maine,[6] and Ohio,[7] have instituted bans on and taken enforcement actions related to food products containing CBD. As of last December, FDA has favorably responded to Generally Recognized As Safe (GRAS) Notifications for certain uses of three hemp-seed derived ingredients — hulled hemp seeds, hemp seed protein, and hemp seed oil — in food products.[8]

On Thursday, March 28, outgoing FDA Commissioner Scott Gottlieb informed lawmakers that FDA is exercising “enforcement discretion” regarding the use of CBD in certain FDA-regulated products.[9] In his remarks, Commissioner Gottlieb noted that FDA's enforcement priorities will target marketers making unapproved drug claims for the use of such products to cure, treat, or prevent serious diseases and conditions, such as cancer or Alzheimer's. On that same day, FDA and FTC jointly issued warning letters to three CBD companies that focused on the unapproved drug claims related to their CBD products.[10] Specifically, the three 2019 warning letters noted that the CBD products involved, including infused gummies, isolate, oil, and products for dogs, claimed to treat Alzheimer's disease, anxiety, depression, skin conditions, and inflammation. In 2018, only one warning letter was issued regarding CBD. The 2018 warning letter was sent to a CBD manufacturer related to issues with their

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manufacturing process and their unapproved drug claims, which included statements on their website that CBD products could treat Alzheimer's disease, cancer, Crohn's disease, diabetes, and glaucoma, among others.[11]

From 2015 to 2017, FDA issued over 40 warning letters to manufacturers of CBD products, including oils, capsules, and gummies, for making such disease claims.[12] In some of these warning letters, FDA had tested the chemical content of CBD in the products and reported that many did not contain the levels claimed in product labeling.

In addition, on various occasions throughout 2018, the Agency reiterated its enforcement priorities regarding the marketing of such products for serious, unproven disease claims.[13] For example, in June of 2018, FDA stated, “[W]e are prepared to take action when we see the illegal marketing of CBD-containing products with serious, unproven medical claims. Marketing unapproved products, with uncertain dosages, and formulations can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.”[14]

Following the passage of the 2018 Farm Bill in December 2018, Commissioner Gottlieb stated that FDA would consider issuing a regulation, after notice and comment, approving the use of CBD to be marketed in food or as a dietary supplement.[15] In remarks to the House Appropriations Committee on February 27, 2019, Commissioner Gottlieb informed lawmakers that FDA would appoint a working group to consider the Agency's options for cannabis-derived ingredients, including hemp, in food and dietary supplements following a public meeting the Agency plans to conduct as early as this month.[16] In a recent interview, Commissioner Gottlieb separately noted that it would likely take several years for the Agency to devise rules that would legalize the use of hemp-derived CBD in food products unless Congress does, in fact, step in.

In light of the increasing interest in CBD and other cannabis-derived products, on April 3, 2019, FDA announced it will hold a public hearing on May 31, 2019 to obtain additional scientific data and other information to inform its regulatory oversight of such products.[17] FDA encourages public comments and presentations at the public hearing on the following considerations for such products: health and safety risks; manufacturing and product quality; and marketing, labeling, and sales. All requests to make presentations during the hearing must be submitted to FDA by the close of registration on May 10, 2019.

Companies currently selling or developing products containing CBD should continue to monitor FDA regulatory activity in relation to the compound, but an ambiguous state of regulation does not mean companies are free and clear of risk for manufacturing, marketing, or selling CBD products, even without unapproved drug claims. In fact, the lack of clear regulation typically creates a grey area that plaintiffs' attorneys love to exploit by way of civil litigation, either in the form of consumer class actions for false advertising or true product liability claims and lawsuits. Issues specific to CBD are ripe for these types of legal action, including sourcing and quality control, potency and dosing, and perhaps the most controversial of all — access and appeal to children.

K&L Gates will continue to monitor and provide updates on further developments in this area. Given our substantive experience in and knowledge of FDA-regulated industries, K&L Gates is well-positioned to facilitate engagement and help stakeholders assess regulatory and litigation risks in this area.

Notes:

[1] Cannabis contains more than 80 compounds. The most commonly known compounds are CBD and THC.

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[2] P.L. 115-334, H.R.2 — 115th Congress (2017-2018). Available at https://www.congress.gov/bill/115th-congress/house-bill/2/text.

[3] The Agricultural Act of 2014 (P.L. 113-79, H.R. 2642 – 113th Congress) defined "industrial hemp" as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 THC concentration of "not more than 0.3 percent on a dry weight basis" and legalized the growth of industrial hemp for research purposes in compliance with state agricultural pilot programs. The 2018 Farm Bill expands the definition of hemp and its legal status. Specifically, as provided by the 2018 Farm Bill, the term "hemp" is now defined under the Agricultural Act of 1946 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." The 2018 Farm Bill removes "hemp" from the federal definition of "marihuana" and, therefore, excludes hemp from the Controlled Substances Act.

[4] Cannabidiol (CBD) Prohibited in Food and Drink, New York City Department of Health and Mental Hygiene (2019) (available at https://www1.nyc.gov/site/doh/business/food-operators.page).

[5] FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products, California Department of Public Health (revised July 6, 2018) (available at https://hempsupporter.com/wp-content/uploads/2018/07/Web-template-for-FSS-Rounded-Final.pdf).

[6] State Official Apologizes as Chaos Reigns Over Sales of CBD Products, Press Herald (Feb. 22, 2019) (available at https://www.pressherald.com/2019/02/22/state-official-apologizes-for-confusion-over-cbd-policy/).

[7] Ohio Medical Marijuana Control Program CBD Oil FAQ, State of Ohio Board of Pharmacy (available at https://www.pharmacy.ohio.gov/Documents/Pubs/Special/MedicalMarijuanaControlProgram/CBD%20Oil%20FAQ.pdf)

[8] FDA Response Letter GRAS Notice No. GRN 000765 (Dec. 20, 2018) (available at https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM628945.pdf); FDA Response Letter GRAS Notice No. GRN 000771 (Dec. 20, 2018) (available at https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM628944.pdf); and FDA Response Letter GRAS Notice No. GRN 000778 (Dec. 20, 2018) (available at https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM628943.pdf).

[9] See Review of the FY2020 Budget Request for the FDA, Hearing Before the Subcomm on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the S. Comm. on Appropriations, 116th Cong. (2019) (statement of Scott Gottlieb, Comm'r, Food and Drug Admin.) (available at https://www.appropriations.senate.gov/hearings/review-of-the-fy2020-budget-request-for-the-fda).

[10] FDA Warning Letter to Advanced Spine and Pain, LLC (March 28, 2019) (available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm634781.htm); FDA Warning Letter to Nutra Pure LLC (March 29, 2019) (available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm634776.htm); FDA Warning Letter to PotNetwork Holdings, Inc. (March 28, 2019) (available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm634738.htm).

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[11] FDA Warning Letter to Signature Formulations (July 31, 2018) (available here https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm616278.htm).

[12] Warning Letters and Test Results for Cannabidiol-Related Products, FDA (available at https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm).

[13] See FDA, FDA News Release FDA Approves First Drug Comprised of An Active Ingredient Derived From Marijuana to Treat Rare, Severe Forms of Epilepsy, (June 25, 2018) (June 2018 FDA News Release) (available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm); See also, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds, (Dec. 20, 2018) (December 2018 FDA Statement) (available at https://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm628988.htm).

[14] June 2018 FDA News Release.

[15] December 2018 FDA Statement.

[16] See Food and Drug Administration – Status of Operations, Hearing Before the Subcomm. on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House Comm. on Appropriations, 116th Cong. (2019) (statement of Scott Gottlieb, Comm'r, Food and Drug Admin.) (available at https://appropriations.house.gov/legislation/hearings/food-and-drug-administration-status-of-operations).

[17] 84 FR 12969 (April 3, 2019).

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