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FDA Releases Progress Report Regarding Enforcement Discretion Policy on Hemp-Derived Cannabidiol (CBD)

Last week, FDA submitted a report to Congress detailing the Agency's progress on developing an enforcement discretion policy (i.e., a policy of not taking enforcement action) on hemp-derived cannabidiol (CBD). At the same time, FDA also issued a press announcement from Commissioner Hahn sharing much of the same information in the report with the public. FDA's report to Congress had been overdue. A joint explanatory statement from Congress, attached to the 2020 appropriations package, had directed FDA to submit the report by February 20, 2020.

FDA's report signaled that the Agency is exploring (1) issuing a risk-based enforcement discretion policy, in guidance, and (2) engaging in rulemaking that would allow *dietary supplements* containing CBD to be marketed lawfully. Notably, the report was silent regarding a similar rulemaking process for conventional food (e.g., beverages) containing CBD. These signals come on the heels of a statement by Dr. Hahn at a recent meeting held by the National Association of State Departments of Agriculture (NASDA). At that meeting, Dr. Hahn stated:

"We're not going to be able to say that you can't use these products. It's a fools errand to even approach that[.] We have to be open to the fact that there might be some value to these products and certainly Americans think that's the case. But we want to get them information to make the right decisions."

FDA's report to Congress—particularly when juxtaposed with Dr. Hahn's recent statement—suggests that FDA may soon loosen the reins on FDA-regulated CBD products. However, the report made clear that FDA still has concerns about safety issues potentially associated with CBD products (e.g., liver injury, drowsiness, and the potential for drug interactions). Moreover, FDA is also concerned that "[s]elling products with unsubstantiated therapeutic claims can put patients at risk, such as

by influencing them not to use proven, approved therapies to treat serious diseases." In keeping with those concerns, FDA telegraphed that its enforcement priorities will include:

- Products that are marketed with claims of therapeutic benefit, such as treating or curing serious diseases;
- Products that contain contaminants, including THC; and
- Products marketed with false or misleading claims or directed toward vulnerable populations (e.g., children or pregnant women).

FDA also used the report to announce that it is re-opening the docket that was established as part of the May 2019 public meeting, indefinitely, to allow researchers and stakeholders to continue to share new data and information as they emerge. In addition, FDA announced that it is developing an action plan for product sampling, to better understand the extent to which products on the market are mislabeled or adulterated.

To put FDA's recent report to Congress and its public statements into context, we have provided additional background on the recent evolution of federal CBD oversight, below. We have also provided our thoughts regarding the potential implications of FDA's report and recent public statements on the FDA-regulated industry and consumers.

BACKGROUND

There has been an extraordinary amount of interest in CBD products in the last 16 months—since the Farm Bill[1] was enacted in December 2018. Historically, both the federal Controlled Substances Act (CSA) and the federal Food, Drug, and Cosmetic Act (FDCA) provided regulatory hurdles to lawfully selling FDA-regulated consumer products (e.g., conventional food, dietary supplements, and cosmetics) containing CBD. The Farm Bill changed that by effectively carving "hemp" (i.e., all parts of the cannabis plant with no more than 0.3% THC on a dry weight basis) out of the definition of "marihuana." Since the Farm Bill was enacted, the CSA no longer provides a significant hurdle for products containing hemp-derived CBD, as opposed to marijuana-derived CBD.

However, the FDCA still poses hurdles for some hemp-derived CBD products. For example, Section 301(ll) of the FDCA prohibits the marketing of food (i.e., conventional food and dietary supplements) that contains substances that were first recognized in the marketplace as drugs—because they have been either approved or studied as drugs.[2] There is a similar clause in Section 201(ff)(3) of the FDCA that excludes from the definition of "dietary supplement" products that contain substances that have been approved or studied as drugs.[3]

Over the last several years, FDA has sent multiple warning letters citing "food products to which CBD had been added and CBD products marketed as dietary supplements."[4] The letters have been premised on violations of Sections 301(ll) and 201(ff)(3) of the FDCA because CBD first gained recognition in the marketplace by being studied and/or approved as a drug.[5] FDA explained that:

> "[a]llowing drug ingredients in foods can undermine the drug approval process and diminish commercial incentives for further clinical study of the relevant drug substance. It also raises questions about the safety to consumers of exposure from broader consumption of such ingredients."[6]

The prohibitions in Sections 301(ll) and 201(ff)(3) of the FDCA (collectively the "Exclusionary Rules"), however, can be overridden if FDA issues a regulation[7] or if Congress revises those sections in the statute to otherwise permit CBD in food and dietary supplements.

Despite the prohibitions in the statute, FDA has only issued Warning Letters to companies that are marketing the products with egregious "disease" claims that are likely to deceive the public, or where analytical results of content do not

match labeling claims.[8] As FDA conceded in its report to Congress last week, FDA simply does not have the resources to police all of the CBD products on the market subject to its oversight.

Moreover, there has been an enormous push to legalize dietary supplements and food containing CBD, such that as a practical matter, it may not make sense to shut the industry down now, only to legalize it in the near future. Notably, Dr. Hahn's recent statement to NASDA was not the first time that an FDA Commissioner has acknowledged the push for legalization and the need to find a path forward. Former FDA Commissioner Gottlieb (who stepped down in mid-2019) told Congress last March that he understood Congress' passage of the Farm Bill to be a signal: "We heard Congress loud and clear here. We know you want a pathway."[9] In addition, FDA held a public meeting in May 2019, to explore potential paths forward.[10]

IMPLICATIONS FOR INDUSTRY AND CONSUMERS

As mentioned above, FDA's report to Congress signaled that the Agency is exploring (1) issuing a risk-based enforcement discretion policy, in guidance, and (2) engaging in rulemaking that would allow *dietary supplements* containing CBD to be marketed lawfully. The rulemaking exercise would result in, among other things, a regulation that would override the Exclusionary Rules, at least as they apply to dietary supplements. FDA has predicted that it will take three-to-five years to legally authorize hemp-derived CBD in food and dietary supplements, through regulation.[11] FDA needs that time to collect data to support decisions on "dosing, nomenclature, product claims, and numerous other manufacturing and marketing issues."[12]

FDA's signal in its report to Congress—that it is contemplating issuing an enforcement discretion policy in guidance, as well as a regulation—suggests that industry stakeholders and consumers may not have to wait three-to-five years for a path forward. This suggestion is underscored by Dr. Hahn's statement that it would be a "fools errand" to prevent the use of CBD products and that there may be some value in them. And, FDA's report to Congress telegraphs what that guidance might look like. As mentioned, FDA clearly stated that its enforcement priorities included:

- Products that are marketed with claims of therapeutic benefit, such as treating or curing serious diseases;
- Products that contain contaminants, including THC; and
- Products marketed with false or misleading claims or directed toward vulnerable populations (e.g., children or pregnant women).

Thus, any enforcement discretion policy issued by FDA in guidance, at a minimum, is likely to provide an effective safe harbor for CBD products (1) marketed without therapeutic claims, (2) marketed without contaminants, such as THC, and (3) marketed for adult use only, with appropriate warnings for women who are pregnant or expecting to become pregnant. In addition, Dr. Hahn's statement suggesting that it will be important to ensure that consumers get "information to make the right decisions," hints that the guidance may also recommend disclaimers regarding potential safety issues (e.g., liver injury, drowsiness, and the potential for drug interactions).

For now, though, FDA's report to Congress, and Commissioner Hahn's recent statements provide nothing more than fodder for reading tea leaves. To know more, we will have to wait for FDA guidance, assuming FDA decides to issue it. However, it suddenly seems possible that we may have more direction, in the form of a guidance, sooner rather than later, potentially even by the end of the calendar year.

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involving all FDA-regulated products. We have been tracking developments related to CBD closely, and we would be happy to answer any questions that you may have.

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[1] See Agriculture Improvement Act of 2018, Pub. L. 115-334 (enacted Dec. 20, 2018) (hereinafter "2018 Farm Bill").
[2] *See* 21 U.S.C. § 331(ll).
[3] *Id.* § 321(ff)(3)(B).
[4] FDA, Notice of Public Hearing, *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds*, 84 Fed. Reg. 1,969, 12,970 (Apr. 3, 2019).
[5] *See id. See also* Warning Letter to Michigan Herbal Remedies (Feb. 4, 2016); Warning Letter to HealthyHempOil.com (Feb. 4, 2016).
[6] 84 Fed. Reg. at 12970.
[7] *See* 21 U.S.C. §§ 331(ll)(2), 321(ff)(3)(A).
[8] *See* FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns, Nov. 25, 2019, https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details; *see, e.g.*, FDA Warning Letter to KOI CBD LLC, Nov. 22, 2019 (citing Koi for marketing its CBD products with claims, including (among others): (1) "relieves pain and inflammation," (2) "lowers incidence of diabetes," (3) "CBD AND OPIOID ADDICTION," (4) "effective in fighting breast cancer cells," and (5) "Fibromyalgia, " "Schizophrenia," . . . "MS," "Crohn's Disease"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/koi-cbd-llc-593391-11222019
[9] *See* Josh Long, Gottlieb: FDA targeting CBD marketers of 'over-the-line claims,' Natural Products Insider (Mar. 28, 2019) (reporting on congressional hearing on "Review of the FY2020 Budget Request for the FDA" before the U.S. Senate Committee on Appropriations' Subcommittee on Department of Agriculture, Rural Development, Food and Drug Administration, and Related Agencies), https://www.naturalproductsinsider.com/ingredients/gottlieb-fda-targeting-cbd-marketers-over-line-claims
[10] FDA, Notice of Public Hearing, Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds, 84 Fed. Reg. 12,969, 12,970 (Apr. 3, 2019).
[11] Throckmorton: FDA Needs More Data, Not Authority, for CBD Regulation, InsideHealthPolicy, Jan. 21, 2020, https://insidehealthpolicy.com/daily-news/throckmorton-fda-needs-more-data-not-authority-cbd-regulation?s=em2
[12] *Id. See also* Testimony of Douglas Throckmorton, M.D., Deputy Director for Regulatory Programs, CDER, before the House Committee on Energy and Commerce, Subcommittee on Health, Cannabis Policies for the New Decade, Jan. 15, 2020, https://www.fda.gov/news-events/congressional-testimony/cannabis-policies-new-decade-01152020