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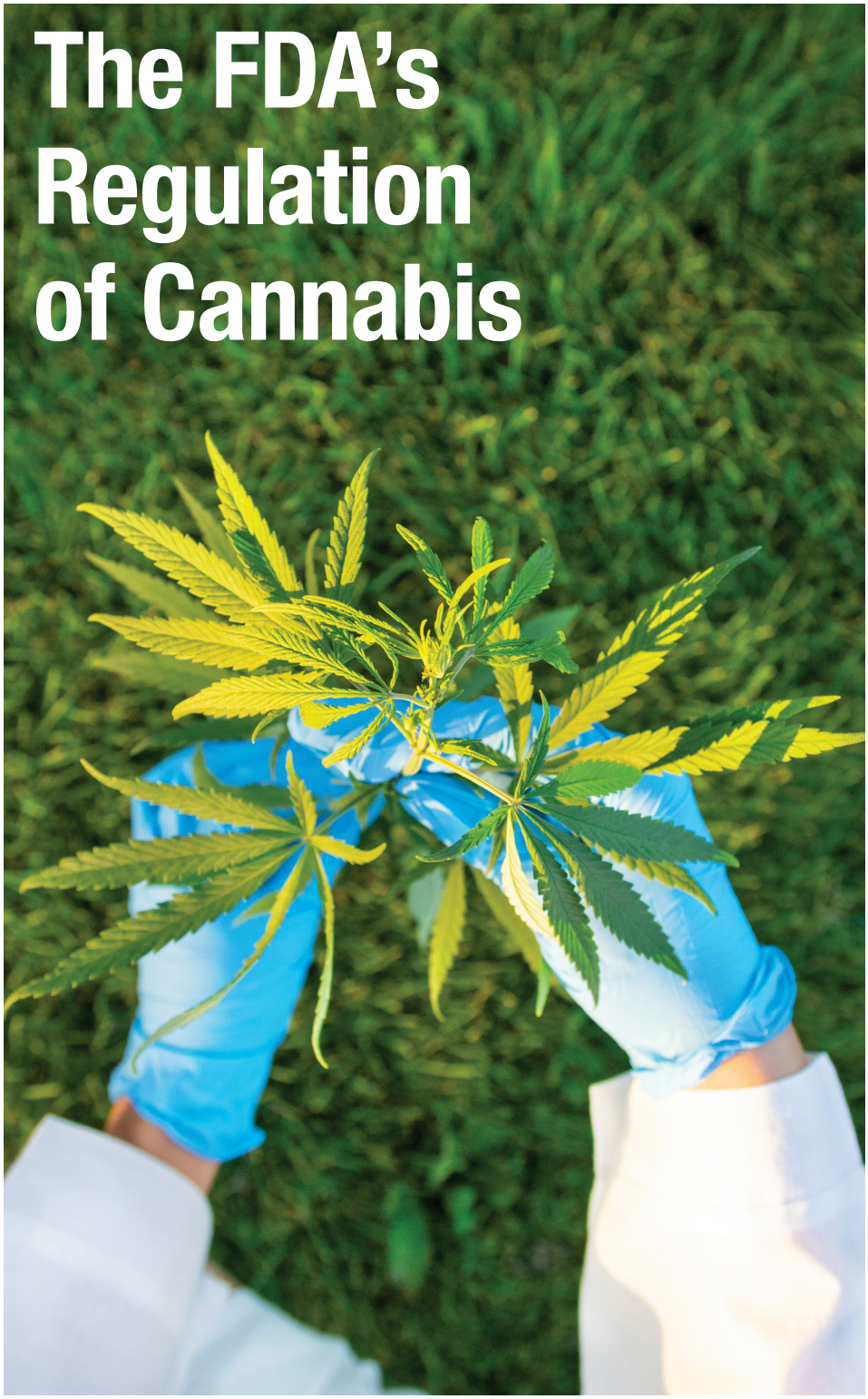

By Lisa M. Dwyer

Practitioners are hopeful that the much-anticipated FDA guidance will answer many thorny legal questions surrounding the regulation of food and dietary supplements containing cannabidiol.

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There has been an extraordinary amount of interest in cannabidiol (CBD) products in the last two years, since the Farm Bill was enacted in December 2018. *See* Agriculture Improvement Act of 2018, Pub. L. 115-334, Dec. 20, 2018

(hereinafter "Farm Bill"). Historically, both the federal Controlled Substances Act (CSA) and the federal Food, Drug, and Cosmetic Act (FDCA) provided regulatory hurdles to selling certain consumer products (e.g., 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 percent tetrahydrocannabidiol [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 CBD that meet the definition of "hemp."

With the CSA effectively out of the way, all eyes have turned to the Food and Drug Administration (the FDA or the "Agency") for guidance on how the Agency will regulate food, dietary supplements, and cosmetics containing CBD that meets the definition of "hemp," moving forward. The FDA has already shown its cards regarding *cosmetics* containing CBD. In an April 2019 Federal Register notice, the FDA clarified that cannabis-derived CBD (that meets the definition of "hemp") in cosmetics is lawful, so long as it does not render the product injurious to consumers. 84 Fed. Reg. 12969, 12974 (April 3, 2019). The FDA also cautioned that cosmetics containing CBD cannot be mislabeled. *See id.* In addition, under the FDCA, *cosmetics* cannot be marketed with promotional claims suggesting that the products are intended to (1) affect the structure or function of the body, or (2) affect disease—because doing so would trigger the definition of "drug" under the FDCA, 21 U.S.C. §321(g), and subject the products to the FDA's drug requirements, such as pre-market approval.

The FDA's regulation of *food* and *dietary supplements* containing cannabis-derived CBD, however, is thornier from a legal perspective, as explained in Section II below, and as such, the future of those products is less clear. That said, on July 22, 2020, the FDA submitted draft guidance titled, *Cannabidiol Enforcement Policy*, to the White House for review and approval, signaling that the FDA may be weeks away from issuing draft guidance that will provide additional clarity on how the FDA will regulate *food* and *dietary supplements* containing cannabis-derived CBD. *See* RIN 0910-ZA76, Cannabidiol Enforcement Policy, Draft Guidance for Industry, Office of Information and Regulatory Affairs, Office of Management and Budget, June 22, 2020. Until that time, we will have to continue to read the tea leaves.

Significantly, the last document that provided fodder for tea leaf reading was the March 2020 report that the FDA submitted to Congress, detailing the Agency's progress on developing guidance on products containing CBD. *See* Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Cannabidiol (CBD), Report in Response to Further Consolidated Appropriations Act, 2020, U.S. Food and Drug Administration ("March Report to Congress"). An FDA press release issued at the same time provided some additional color. *See* FDA Statement: FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity, March 5, 2020. Section III, below, describes the March Report to Congress in detail, and Section IV forecasts the potential implications of the FDA's coming guidance on companies planning to market *food* or *dietary supplements* containing CBD.

The FDA's Regulation of Food and Dietary Supplements Containing Cannabis-Derived CBD

As mentioned, since the Farm Bill was enacted, the CSA no longer provides a significant hurdle for products containing CBD that meet the definition of "hemp." However, the FDCA still poses hurdles for some 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. *See* 21 U.S.C. §331(ll). 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. *Id.* §321(ff)(3)(B).

Over the last several years, the FDA has sent multiple warning letters citing "food products to which CBD had been added and CBD products marketed as dietary supplements." *See* 84 Fed. Reg. at 12970. 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. *See id; see also* Warning Letter to Michigan Herbal Remedies (Feb. 4, 2016); Warning Letter to HealthyHempOil.com (Feb. 4, 2016). In the FDA's Federal Register notice, which discussed the warning letters, the 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." 84 Fed. Reg. at 12970. The prohibitions in Sections 301(ll) and 201(ff)(3) of the FDCA (collectively the "Exclusionary Rules"), however, can be overridden if the FDA issues a regulation, *see* 21 U.S.C. §§331(ll)(2), 321(ff)(3)(A), or if Congress revises those sections in the statute to otherwise permit CBD in food and dietary supplements.

Despite the prohibitions in the statute, the FDA has only issued warning letters to companies that are marketing the products with egregious "disease" claims that are likely to deceive the public (and trigger the definition of "drug" under the FDCA). *See* FDA Statement: FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns, Nov. 25, 2019; *see*, *e.g.*, FDA Warning Letter to KOI CBD LLC, Nov. 22, 2019 (citing Koi for marketing its CBD products with claims,

including: (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"). The FDA is likely focusing on these products because the marketing claims make them particularly risky. As the FDA conceded in its March Report to Congress, the Agency simply does not have the resources to police *all* of the CBD products on the market subject to its oversight. *See* March Report to Congress at 1.

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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. Significantly, at a February 2020 meeting held by the National Association of State Departments of Agriculture (NASDA), FDA Commissioner Hahn stated, "We're not going to be able to say that you can't use these products. It's a fool's game 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 Chief Hahn Says It Would Be a "Fool's Game" to Try to Shut Down CBD Markets*, NUTRAingredients-usa.com, Feb. 28, 2020.

Dr. Hahn's 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 in March 2019 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." *See* Josh Long, *Gottlieb: FDA targeting CBD marketers of "over-the-line claims,"* Natural Products Insider (Mar. 28, 2019). In addition, the FDA held a public meeting in May 2019 to explore potential paths forward. *See* 84 Fed. Reg. at 12970.

Overview of the FDA's March Report to Congress

The FDA's March Report to Congress telegraphed that the Agency is exploring issuing a risk-based enforcement discretion policy (i.e., a policy of not taking enforcement action), in guidance, that would cover FDA-regulated products containing CBD (e.g., food and dietary supplements), and engaging in rulemaking that would override the Exclusionary Rule regarding *dietary supplements*, in a manner that would affirmatively 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.

The FDA's March Report to Congress—particularly when juxtaposed with Dr. Hahn's February statement at the NASDA meeting—suggests that the FDA may soon loosen the reins on FDA-regulated CBD products. However, the report made clear that the FDA still has concerns about safety issues potentially associated with CBD products (e.g., liver injury, drowsiness, and the potential for drug interactions). Moreover, the 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." March Report to Congress, at 12. In keeping with those concerns, the FDA signaled 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).

See id. The FDA also used the report to announce that it is re-opening the docket that was established as part of the Agency's May 2019 public meeting, indefinitely, to allow researchers and stakeholders to continue to share new data and information as they emerge. *See id.* at 13. In addition, the FDA announced that it is developing an action plan for product sampling, to improve its understanding of the extent to which products on the market are mislabeled or adulterated. *See id.* at 14–15.

Implications for Industry and Consumers

Given that the FDA submitted a draft guidance to the White House on July 22, 2020, that is titled *Cannabidiol Enforcement Policy*, there may be a path forward for *food* and *dietary supplements* containing CBD soon. Assuming this prediction is correct, the FDA's March Report to Congress provides some idea of what that path may look like.

Based on that report, it is reasonable to expect that any enforcement policy issued by the FDA in guidance may provide an effective safe harbor for food and/or dietary supplements containing CBD that are (1) marketed without therapeutic claims, (2) marketed without contaminants, such as THC, and (3) marketed for adult use only. 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, the FDA's March 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 the FDA's draft guidance. Hopefully, the draft guidance will be issued in a matter of weeks, or at least before the end of the calendar year. FD