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FAST GROWING CBD MARKET CONTINUES TO CREATE REGULATORY CHALLENGES AND LITIGATION OPPORTUNITY

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CBD and CBD-containing products are ubiquitous, yet there is significant misunderstanding about their regulatory status. CBD is cannabidiol, one of more than a hundred different active compounds that can be derived from the hemp plant. The 2018 Farm Bill changed the legal status of hemp, separating it from the Schedule 1 substance known as "marihuana" under the Controlled Substances Act. The effect was to decriminalize the plant that meets the definition of hemp, as well as its derivatives. But, as the Food and Drug Administration (FDA) was quick to point out just hours after the President signed the bill, FDA's requirements relating to food, beverages, dietary supplements, cosmetics and other products regulated by the federal Food Drug and Cosmetic Act (FD&C Act) were not modified.

From a regulatory perspective, 2020 was "more of the same" from FDA. FDA continues to seek public input on the regulation of CBD, but has not taken any formal action regarding regulatory clearance for use as an ingredient in FDA-regulated products. FDA has, however, continued to issue Warning Letters companies making egregious claims or distributing contaminated product. FDA issued 21 Warning Letters, more than half of which were focused on impermissible COVID-19 claims. Other claims included those relating to cancer, pain relief, arthritis, artery blockage, heart disease, immune disorders, diabetes/blood sugar control, stress and anxiety, ADHD, depression, and more, and FDA continues to assert that use of CBD in foods or beverages constitutes impermissible addition of a drug to such products, in violation of the FD&C Act. FDA considers company websites, social media posts (including retweets), marketing materials and more to assess the claims made by a company.

The Federal Trade Commission (FTC) dove deeper into the CBD marketing claims action this year as well. It too issued Warning Letters to companies marketing CBD to address COVID-19, and in December, announced the "first law enforcement crackdown on deceptive claims" in the CBD market, part of its initiative entitled "Operation CBDeceit." Six companies, each of which was making false and misleading health claims, were the target of FTC enforcement actions that resulted in, among other things, monetary penalties of up to $85,000 each. One item to note in particular was that one of the Operation CBDeceit enforcement actions also involved claims relating

to cannabigerol (CBG), a different cannabinoid compound derived from hemp. The market is starting to see an increasing number of claims relating to these other cannabinoids, and regulatory and litigation scrutiny of these other derivatives is not expected to be any different from CBD. Of course, FDA and FTC Warning Letters and enforcement can be an invitation to private parties to initiate litigation. 2020 saw more than twenty new putative claims action claims filed against CBD companies in California, Florida, Illinois and Massachusetts, and substantive rulings in many of the cases filed toward the end of 2019. These cases center around consumer protection claims, alleging liability for actions such as selling product with less than the labeled CBD content, misleading the consumer about the legality of the product, and making false or misleading claims regarding the benefits of CBD.

These claims are generally met with motions to dismiss that pursue preemption, primary jurisdiction or standing arguments. Primary jurisdiction has largely been the most successful of these, leading multiple courts to stay the litigation while FDA continues to pursue rulemaking. See, e.g., Snyder v. Green Roads of Florida LLC, Case No. 0:19-cv-62342 (S.D.Fla.). Multiple courts have noted that "FDA is under considerable pressure from Congress and the industry to expedite the publication of regulations and policy guidance regarding CBD products." See, e.g., Colette et al v. CV Sciences, Inc., 2:19-cv-10227 (D.D.Cal.)(referencing Snyder). However, these primary jurisdiction arguments are not always successful, as one defendant in a Florida action discovered. In that case, the judge ruled that no matter the outcome of FDA rulemaking, it would not be expected to allow actual CBD content to differ from labeled CBD content, as the suit claimed. See Potter v. PotNetwork Holdings Inc. et al., Case No 1:19-cv-24017 (S.D.Fla.). Nonetheless, we cannot expect stays to last indefinitely, especially if FDA is not seen as making any progress. The experience with proposed FDA rulemaking in the "naturals" space will likely serve as a good guide here.

For further reading on this topic and others, please see our **2020 Food Litigation Round-Up**.
