CBD in Consumer Goods:

The Class Action Lawsuits Have Arrived

By Matthew Kaplan and Edward Racek

As industry's efforts to capitalize on the rapid growth and consumer demand of CBD-containing products has outpaced government regulation, it was only a matter of time before litigation reared its head. As companies fought to be on the cutting edge, they pushed products to market before rules and regulations could catch up.

Seizing on the opportunity to take a piece of the profits from the CBD market, plaintiffs' class action attorneys are rushing into courts across the county and claiming that products containing CBD, their marketing and use, violate various laws and, therefore, the industry is inducing consumers to purchase illegal goods, which they otherwise would not purchase if they knew the truth.

The current wave of lawsuits targets alleged false advertising and mislabeling of CBD products, many piggybacking off warning letters issued by the U.S. Food and Drug Administration (FDA). As the lawsuits pile up and the rate of filings accelerate, businesses need to consider their tolerance for risk and evaluate their practices to minimize the chance of being caught in the crosshairs of these plaintiffs' attorneys. For those companies that already have been or may get swept up in these lawsuits, it is important to be proactive and coordinated in defense of their products.

The Current State of CBD Regulation

CBD, or cannabidiol, is one of the many chemical compounds found in the cannabis plant. It can be derived from either marijuana (which remains illegal under federal law) or industrial hemp (which is on its way to being legalized).

Despite the 2018 Farm Bill's steps toward legalizing and regulating industrial hemp, including its derivatives like CBD, only recently has the U.S. Department of Agriculture (USDA) published interim regulations and is in the process of reviewing submitted state and tribal industrial hemp plans to promote this market; however, even once USDA approves such plans, the production of industrial hemp-based CBD products still will be subject to regulation and lawsuits.

Notwithstanding the 2018 Farm Bill, FDA is still the regulatory body that oversees all food, drug, cosmetic and dietary supplement products, and CBD-containing products must comply with all FDA rules and regulations. Thus, the recent crop of false claim lawsuits will be only the beginning of a trend as long as CBD-containing products make inaccurate or unsubstantiated claims on their labeling, advertising or marketing materials, or CBD is added to food or beverages.

FDA Cracks Down on Companies Selling CBD Products as Dietary Supplements

The FDA has strongly opposed the use of CBD as an ingredient in food, beverages or dietary supplements for human or animal consumption, whether derived from industrial hemp or marijuana; however, the FDA has not issued formal regulations. Therefore, there is a limited

understanding of FDA's enforcement position based largely on guidance opinions and warning letters.

On Nov. 22, 2019, the FDA issued 15 warning letters to different companies selling products containing CBD. The FDA warning letters claimed that the companies were using product webpages, online stores and social media to market CBD products in ways that violate the Federal Food, Drug and Cosmetic Act, including making unapproved heath claims, marketing CBD as a dietary supplement, or selling food or drink products containing CBD.

In the past, FDA's CBD warning letters focused on the impropriety of making health claims about CBD, which it has warned can turn the product into an illegal new drug. The Nov. 22, 2019 letters continued this focus, warning against health claims made about CBD's alleged ability to reduce symptoms of—or cure conditions such as—cancer, diabetes, chronic pain, opioid addiction, PTSD, schizophrenia, depression, anxiety, inflammation, alcoholism, autism, epilepsy, fibromyalgia, irritable bowel syndrome, migraines, Parkinson's and ADHD, among others. Further, FDA's position is that CBD products that are marketed as having such health effects are unapproved drugs because they have not gone through the rigorous FDA drug approval process and have not been proven to be safe and effective in treating these conditions based on appropriate scientific data. FDA also takes the position that these are misbranded drugs because they are promoted for health conditions that are not appropriate for self-diagnosis and treatment, and, thus, "adequate directions for use" cannot be written so that a layperson can use the CBD-containing products safely for their intended purpose (i.e., treating the claimed health condition).

Further, to the extent the products were being marketed as dietary supplements, the FDA reiterated its position that CBD products do not meet the legal definition of dietary supplements because CBD is the active ingredient in an approved prescription drug (Epidiolex). It is FDA's position that there is no evidence that CBD was marketed as a dietary supplement or conventional food ingredient before clinical investigations for Epidiolex were authorized or before the drug was approved, so it cannot meet the definition of a dietary supplement.

Somewhat new to the warning letters is FDA's heavier focus on CBD in human and animal food and beverage products. FDA warns that use of CBD as a food additive renders the food products adulterated. FDA's position on CBD in food is similar to its position on use of CBD as a dietary supplement. FDA asserts that CBD cannot be used in products sold as food because of FDA's approval of Epidiolex and the absence of any evidence that CBD was used as a food additive before Epidiolex's approval or substantial clinical investigations of the drug had begun. FDA also points out that there has been no premarket approval of CBD as a food additive, and it does not believe that CBD qualifies under the legal definition of items that are "generally recognized as safe" (GRAS) due to the lack of scientific proof of its safety or evidence of its use in food prior to 1958.

The CBD Class Actions

The class action lawsuits have focused largely on false advertising claims, paralleling what the FDA has claimed is illegal in its warning letters. Unsurprisingly, several of the companies sued in the recent class action lawsuits are the same companies that received FDA warning letters.

These lawsuits have focused on two different types of alleged false labeling: The first is that the amounts of THC and/or CBD did not conform to the amounts or levels claimed by the companies on their labels, and the second that CBD itself is an illegal ingredient thereby rendering the products illegal for sale and "worthless."

An example of the first type of claim is a recent filing involving Bhang Medicinal Chocolates.

In the Complaint filed Dec. 4, 2019, Charles Bard alleges that testing revealed that the amounts and levels of THC and CBD did not conform to the statements, representations and warranties set forth on the front and back labels, packaging or marketing materials of the Bhang products, with the actual amounts being substantially less than stated. Bard claims he was defrauded into buying the products and either would not have done so (or would have paid much less) had he known the true THC/CBD levels. Bard seeks recovery on behalf of a nationwide class of consumers under various consumer protection laws.

Three other lawsuits filed in California around Dec. 4, 2019 are examples of the other type of recent claim. In separate cases against Charlotte's Web Holdings, Inc.; Elixinol, LLC; and Koi CBD, LLC, a group of plaintiffs' lawyers have largely followed the road map of the FDA warning letters. Their client consumer plaintiffs allege that the manufacturer/sellers of CBD products knowingly made false representations about their CBD products and the putative benefits from use of CBD-containing supplements, tinctures, lotions, vaping oil, edibles, etc., rendering them valueless and causing economic injury to anyone who purchased them. The lawsuits claim the products are being sold as unapproved and misbranded drugs, unapproved dietary supplements, or food ingredients that do not have FDA's premarket approval and are not GRAS. Thus, they are allegedly illegal products with no value.

A Nov. 14, 2019 decision by one of

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Nutrition Organizations Unite to Form the American Nutrition Association

Five leading nutrition organizations have united to form the American Nutrition Association (ANA). They are the American College of Nutrition, Board for Certification of Nutrition Specialists, Center for Nutrition Advocacy, Accreditation Council for Nutrition Professional Education and American Nutrition Association Foundation.

"There is a profound nutrition gap, said Michael Stroka, CEO of the ANA. "Relative to its power, we vastly underutilize nutrition in our health system and culture. One key reason is that most health professionals are untrained in nutrition science and practice," he added. "As a unified professional association, the ANA addresses the chronic disease crisis by equipping health professionals with the science and practice of personalized nutrition."

Personalized nutrition is a field that leverages human individuality to drive nutrition strategies that prevent, manage and treat diseases and optimize health. According to the association, it is the most important lever for preventing and reversing chronic illness and obesity, as poor nutrition poses a greater threat than tobacco, inactivity or any other risk factor.

"We now have a deep body of science underscoring the impact of nutrition as the single most powerful and modifiable determinant of our health," said ANA Board Chair Jeffrey Blumberg, PhD, FACN, FASN, CNS-S. "Genetics represents only a very small portion of the risk for chronic disease, while the overwhelming majority of the risk comes from modifiable actions we take every day. And personalized nutrition interventions hold the potential to have a profound impact."

"Our group of forward-thinking nutrition scientists, health professionals and thought leaders realized that a comprehensive solution was required, targeting each root of the nutrition gap. So our organizations made a historic decision to unite. As one unified voice, we have a powerful platform to educate, certify, advocate and connect, to champion personalized nutrition," said Corinne Bush, board director of the ANA. "What especially excites me is that we are deeply steeped in science, not tied to a specific ideology. Science is our North Star."

For more information, visit www.theana.org.

Legalities

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the federal appeals courts paved the way for this new wave of lawsuits by issuing an opinion that undermines one of the major defenses to these types of claims that many companies successfully have used in the past. In Debernardis v. IQ Formulations, LLC, the United States Court of Appeals for the Eleventh Circuit ruled that a consumer should be allowed to let a jury decide if he/she has suffered an economic loss by purchasing a dietary supplement that was "worthless" because its sale was prohibited by FDA regulations and the Federal Food, Drug and Cosmetic Act due to its containing an ingredient (DMBA) that, like CBD, did not have FDA approval as a "new dietary ingredient."

Importantly, some of the lawyers involved in the Debernardis case are the very same lawyers that filed the recent cases against the CBD companies in California. They have recycled their successful arguments that because CBD is not a legal ingredient in food or dietary supplements, every person who bought CBD products was economically harmed by spending money on an illegal product. Whether the California courts will agree remains to be seen, but the Debernardis decision surely means that more cases are coming, especially in consumer-friendly states such as California and Florida. While thus far the lawsuits have focused on larger players in the CBD industry, every company that manufactures, sells or markets CBD-containing products is potentially at risk depending on how it promotes them.

Assess Your Risk Tolerance and Take Action to Protect Yourself From Litigation

In the current unsettled state of the law and regulation of CBD products, companies involved in or thinking about entering the CBD market need to assess their individual risk tolerance about the claims they make about their products and the source of their ingredients. Businesses should be sure to know who they are working with and understand their products and the meaning of what they say about them in this rapidly changing environment.

Despite the uncertainty caused by these early bumps on the road to growth, these early fights will eventually lead to a more stable legal environment in which businesses will thrive in the future. **NIE**

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