

# FDA SAYS CBD IS ILLEGAL TO MARKET AND POSSIBLY UNSAFE



By **KIM J. SVESKA, R.Ph., M.S., J.D., MPA** general counsel



By **(IAN) ERIC NORDAN, R.Ph, Pharm.D, J.D.,** attorneys at *Foley, Baron, Metzger & Juip Attorneys, PLLC, Livonia, Michigan*

**M**arijuana use in Michigan will likely increase as lawful accessibility increases.<sup>1</sup> The regulated marijuana market is controlled by Michigan’s Marijuana Regulatory Agency<sup>2</sup> and competes with an ongoing unregulated (black) market with safety concerns currently coming from black-market marijuana vape products and unregulated, non-Food and Drug Administration (FDA) approved cannabidiol (CBD) products.

CBD containing products are everywhere, due in part to confusion regarding the 2018 Farm Bill’s removal of hemp from the Controlled Substances Act and the FDA’s retained control over CBD regulation. Hemp, as distinguished from marijuana, contains no more than 0.3% THC—the psychoactive part of the cannabis plant—by dry weight.<sup>3</sup> Grocery, health food and party stores, gas stations, video stores and even some brave independent pharmacies sell consumable CBD products like gummies, tinctures and more.

dietary supplement. Finally, the FDA does not consider CBD to be Generally Recognized as Safe (GRAS) for use in human or animal food because more scientific information is needed. The FDA enforces its view regarding the illegality of CBD by sending warning letters to companies who violate its position.<sup>8</sup> These letters target companies that claim their CBD products are intended to prevent, diagnose, treat, mitigate or cure serious illness. Additional concerns around CBD products center around processing and manufacturing controls. Specifically, some CBD products do not contain the amount of CBD and other cannabinoids alleged on the labels. There are also reports of CBD products containing unsafe levels of contaminants (e.g., THC, pesticides, heavy metals and toxic solvents). CBD manufacturers do not typically provide certificates of analysis or other information showing what is contained in the products. And of course, there is little or no scientific research establishing CBD safety and efficacy.

**“It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.”**  
 – FDA Consumer Guidance, November 2019<sup>4</sup>

The FDA stated that limited safety data reveals potential health risks that must be considered before using CBD. There are identifiable CBD related drug interactions because CBD and other phytocannabinoids are metabolized by cP450 enzymes while functioning as “competitive inhibitors” of these liver enzymes.<sup>5</sup> CBD can increase blood levels of medications for cholesterol, allergies, blood pressure, mental health, pain and blood thinners by the exact same mechanism that grapefruit juice does.<sup>6</sup> CBD may cause liver injury and monitoring should be encouraged in patients who choose to use CBD.<sup>7</sup> Side effects of CBD may include diarrhea, drowsiness, somnolence and mood changes including irritability and agitation. Other general health and safety concerns are bio-accumulation, impacts on special populations (e.g., elderly, children, pregnant and lactating women) and animal safety profiles.

Since CBD is the active ingredient in an FDA approved drug product, Epidiolex™, and FDA considers CBD to be a drug, the FDA has continued to state that it is illegal to put CBD containing foods into interstate commerce. CBD also cannot be added to, or considered to be, a

So far, Michigan’s Licensing and Regulatory Affairs Department (LARA) and the Marijuana Regulatory Agency have not taken any action against CBD manufacturers or retailers. So while there is no clear answer as to whether a pharmacy could be subject to legal action if they sell CBD containing products, there is some risk and we are recommending that pharmacies just say no to CBD.

## REFERENCES

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