

## The Hazy Science of CBD

Dr. Christopher Spaeth and Dr. Scott Drouin, Rimkus Consulting, Division of Toxicology and Food Safety

As governments and regulatory bodies loosen their rules on hemp-related products, including the legalization of marijuana, the cannabidiol, or CBD, market has grown at remarkably high rates. One projection by BDS analytics and Arcview Market Research puts the overall CBD market at \$20 billion by 2024<sup>1</sup>. Combining the CBD market with the legal marijuana market, projections by BDS hit \$45 billion<sup>2</sup>. Industries affected by the legalization of cannabis-related products include cosmetics, food and beverage, and jewelry and pharmaceuticals, and with the rapid expansion of this market, a large section of the US economy will be involved in CBD use or production by 2024.

As of 2019, many channels of CBD distribution are untracked - driven by small dispensaries and independent cannabis farmers who are typically missed by USDA and USFDA regulations as a result of loopholes in the Farm Bill of 2014, thereby posing a potential threat to consumers. Legal CBD can be extracted or purified from hemp variations of *Cannabis sativa* plants, whereas marijuana variations of *Cannabis sativa*, which also produce CBD, are currently outlawed for consumer use by the Federal government. Legal hemp plants are not regulated federally and consumer products from these plants are often not regulated at any level, leading to potential safety issues for consumers. Based on USFDA tracing of products from 2015-2019, many CBD-based products do not contain the amount of CBD they claim (Bon Miller et al., 2017). That is, many CBD products may be of uncertain composition and origin due to potentially improper preparation. Furthermore, many of these products also contain measurable amounts of tetrahydrocannabinol (THC), which accounts for the psychoactive properties of marijuana (Bon Miller et al., 2017) and is currently outlawed by the US federal government.

In addition to not complying with the label composition guidelines as required by Federal Regulations under 21 CFR, many of these CBD products make unproven claims about the efficacy and potential uses of CBD. Under the FD&C Act (or 21 CFR), a cosmetic is defined as “(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting

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<sup>1</sup> BDS analytics report on CBD market. <https://bdsanalytics.com/u-s-cbd-market-anticipated-to-reach-20-billion-in-sales-by-2024/>. Visited 1/16/2020

<sup>2</sup> *Ibid.*

attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.”<sup>3</sup> Many of the claims for CBD seen on the market are not consistent with cosmetics and might fall under the category of a drug which is defined as: A product intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug (sometimes called a cosmeceutical). That is, many of these CBD products are not approved by the USFDA and the potential risk to consumers cannot be quantified by the authority of the USFDA.

CBD has only been approved by the USFDA in a highly purified form for the treatment of two rare epileptic disorders as the drug Epidiolex (Devinsky et al., 2018). Other uses of CBD are not approved due to lack of systematic testing and USFDA review, including double-blind placebo controls monitored by the USFDA. Despite the lack of scientific validation, claims for CBD range across the entire spectrum of human diseases. The scientific literature enumerates a number of different potential uses, ranging from an adjuvant to standard cancer therapy to decreasing inflammation, with dispensaries making additional claims not supported by the scientific evidence (see Russo, 2016 and Hildebrand, 2018). These studies are largely preliminary and preclinical and do not approach the necessary standard for approved use (Laprarie et al., 2015). Combined with the lack of monitoring of CBD products in terms of supply chain and composition, the consumer is exposed to multiple potential risks from CBD that have not been quantified. Our talk will focus on the CBD claims supported by scientific evidence versus the unproven claims from the CBD industry, and the potential hazards inherent from using unregulated CBD products.

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<sup>3</sup> US Code Title 21 Chapter 9: <https://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9&edition=prelim>. Visited 1/16/2020