

## Outside Counsel

# State of Cannabis Packaging and Labeling and NY Cannabis Development

This is a fascinating time for cannabis companies, their investors, employees, consumers and service providers. The “blue wave” of the 2020 elections ushered in real hope towards potential federal decriminalization efforts and, ultimately, interstate commerce. How did we get here and where are we going, at least in New York?

### Introduction

Marijuana is classified as a Schedule I controlled substance under the U.S. Controlled Substances Act of 1970, as amended (Controlled Substances Act or CSA), and is illegal under federal law for any purpose. Schedule I substances by definition have a high potential for abuse, have no currently “accepted medical use” in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold.

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Even in those states in which the use of marijuana has been legalized, its use remains a violation of federal law, and state and federal laws regarding marijuana often conflict. Following the 2020 elections, 35 states allow their citizens to use marijuana for medical purposes while 15 states allow adult-use (or recreational) marijuana. Although cannabis remains a Schedule I drug, the Rohrabacher-Farr amendment to the congressional budget process prohibits the use of federal funds in investigating and prosecuting persons and entities complying with state medical cannabis laws. In addition, various memoranda over the years from the U.S. Attorney General have stated that enforcing federal cannabis laws and regulations in jurisdictions that have enacted laws legalizing

medical cannabis and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, processing, distribution, sale and possession of cannabis, was not a priority for the U.S. Department of Justice.

Although the cultivation of industrial hemp was made legal in the United States in early 2019 with the enactment of The Farm Bill of 2018, the U.S. Food and Drug Administration (FDA) has since issued several statements declaring that despite the new status of hemp, the wildly popular cannabinoid known as CBD remains illegal to add to food or health products without the agency's approval. This is because the FDA does not view CBD as Generally Recognized as Safe (GRAS) as a result of approving CBD as the active ingredient in a prescription drug Epidiolex for adolescent seizures, after years and hundreds of millions of dollars of clinical trials. Conversely, there have been no widespread clinical trials of CBD as a dietary supplement or ingredient in food, beverages or cosmetics. Rules and regulations around hemp, which is derived from CBD, remain unclear

and the FDA had been expected to provide further guidance for over a year. To the industry's chagrin, a proposed FDA enforcement policy relating to CBD which had been submitted to the Trump Office of Management and Budget, the contents of which remain unknown, was withdrawn in the early days of the Biden administration.

### Cannabis Packaging And Labeling

While the FDA considers adding CBD to the food supply or for use in dietary supplements to be illegal, the federal enforcement against CBD companies to date has been solely limited to those making unproven health or disease claims on their packaging or in their advertising. The FDA has sent dozens of cease and desist letters to companies alleging their products alleviate pain, chronic fatigue or treat various diseases. The U.S. Federal Trade Commission recently completed Operation CBDceit in which it handed out fines from \$20,000 to \$85,000 for similar unproven assertions about CBD's efficacy on various human conditions.

Marijuana companies cannot register any U.S. federal trademarks for their cannabis products. Recent guidance has opened the door to CBD related trademarks however. As a result, cannabis companies, while able to secure state trademark protection in many instances, likely will be unable to protect their cannabis product trademarks beyond the geographic areas in which they conduct business, thus inhibiting the creation of true national brands.

Advertising is extremely challenging as §843 of the CSA prohibits persons



Cannabis seedlings. Photo: Mary Esch/AP

from using communications facilities (i.e., “any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other communications”) to market Schedule I drugs. Persons are similarly prohibited from knowingly or intentionally using the internet to “advertise the sale of, or to offer to sell, distribute, or dispense” controlled substances. Social media platforms, such as Facebook, Yelp and Twitter have routinely shut down any attempts at cannabis advertising. The U.S. Postal Service takes the position that “advertisements for the sale of marijuana are non-mailable.” Cannabis companies have resulted to using billboard advertising at a rate ten times that of other consumer packaged goods companies. Cannabis companies can gain a marketing edge by growing their hemp using certified organic practices or sustainable farming, or applying for one of the growing number or quality and purity certifications available from trade and testing groups.

Indiana in 2018 went to the forefront of CBD packaging and labeling standards by becoming the first state to require QR codes on all packages which links to a website showing batch numbers, licenses, dosage and serving size, quantity of cannabinoids, growing region, the lab where testing was conducted and good manufacturing information. Several other states have followed suit.

In the fall of 2020, New York proposed adding Part 1005 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations to set up a comprehensive framework for regulating CBD and effectively usurp the FDA's position that CBD cannot be added to the food supply, used in cosmetics or as a dietary supplement in New York. The comment period has expired and New York can be expected to enact final regulations shortly with respect to the processing and retail sale of cannabinoid hemp in the state. New York's proposed rules start with the FDA's regulations for dietary supplement packaging and labeling and adds to them. For instance, New York

will require a facts panel containing ingredients, quantity of servings and serving size and a warnings label. The warnings label needs to be in font, no smaller than eight point and include: keep out of reach of children; derived from hemp and may contain THC; has not been evaluated by the FDA for safety or efficacy; pregnancy warnings; and, if inhalable, may be hazardous to health. New York is proposing a “NY Hemp” certification for 100% locally grown and processed hemp in an effort to build a differentiating factor like Napa wine. In addition, New York is at the forefront in requiring a CBD content not in excess of 25mg in food and beverage per product container and not in excess of 3,000mg per product container for dietary supplements. There won’t be any Costco sized packages containing CBD.

Best practices for cannabis packaging and labeling include first deciding whether your product is most appropriately categorized as a food, dietary supplement or cosmetic and then trying to adhere as closely as possible to the FDA’s rules and regulations for those products. Then slavishly follow the state level rules for each state in which the product will be sold, which will often conflict with federal guidelines. Importantly, never make medical or disease claims either on packaging, websites or through social media.

### **New York’s Cannabis Regulatory Developments**

New York is well on its way to finalizing over 60 pages of statutes regulating the processing and retail sale of cannabinoid CBD in New York State and putting into place the regulatory

framework for further rulemaking. New York is also seemingly right behind its neighbor, New Jersey, in moving full speed ahead towards passing adult-use marijuana legislation.

After several years of failed efforts, partly due to quarrels over what to do with the tax windfall, Governor Cuomo announced in his January 2021 State of the State address a proposal to legalize and create a comprehensive system to oversee and regulate cannabis. Under the proposal, a new Office of Cannabis Management would be created to oversee the new adult-use program, as well as the State’s existing medical and

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cannabinoid hemp programs. Additionally, the adult-use proposal contemplates offering licensing opportunities and assistance to entrepreneurs in communities of color who have been disproportionately impacted by the war on drugs. Once fully implemented, the Governor’s office expects more than \$300 million in annual tax revenue. In the past, Governor Cuomo has sought to link legalization efforts to the state budgetary process. If that holds true this time, there is a deadline of April 1st to enact adult-use legislation. The Governor recently spearheaded a

multi-state regional summit with Connecticut, New Jersey, Pennsylvania and Rhode Island to encourage taking coordinated actions with respect to adult-use marijuana implementation, rules, taxes and regulation. Several lawmakers in Albany are critical of the Governor’s proposal and want to see an even greater emphasis on social equity and justice and righting the wrongs of the war on drugs, which is increasingly being viewed as racist and disproportional in its impact on communities of color and lower-income populations.

### **Conclusion**

Cannabis industry participants are encouraged to make decisions regarding packaging, labeling and regulatory compliance in consultation with experienced cannabis counsel. The industry remains a challenging minefield both for its operators and their legal counsel and other professional advisors. Companies must continue to monitor and seek guidance with respect to developments at the federal, state, and local levels, given the fast-changing and dynamic nature of the cannabis industry and conflicting federal and state regulations.