

Joint Comments

Barbara J. Brohl Principal & Founder B J Brohl Strategies, LLC 720-252-8423 Former Executive Director – Colorado Department of Revenue & State Licensing Authority for Marijuana Businesses	Ronald R. Kammerzell Regulatory & Government Affairs Consultant Kammerzell Consulting Services 720-220-2240 Former Senior Director of Enforcement – Colorado Department of Revenue with Direct Oversight of the Marijuana Enforcement Division
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Date: October 31, 2018

Re: Docket No. FDA-2018-N-3685 for “International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-FUBINACA; FUB-AMB(MMB-FUBINACA_ AMB-FUBINACA); ADB-CHMINACA; CUMYL-4CN-BINACA; Cyclopropyl Fentanyl; Methoxyacetyl Fentanyl; *Ortho*-Fluorofentanyl; *Para*-Fluoro Butyrfentanyl; *Para*-Methoxybutyrfentanyl; *N*-Ethylnorpentylone; Tramadol; Pregabalin; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; Request for Comments.

Thank you for the opportunity to provide comments regarding this important subject. As the top two regulators in the state of Colorado from 2011 through 2017, we bring a great deal of knowledge and experience in cannabis policy, cannabis regulation, and cannabis data.

It has been our experience that the only way to truly control and oversee the safe cultivation, production, sale, possession, and use of cannabis¹ is to regulate it legally.

Background

Medical marijuana became legal in Colorado in 2000 through the approval of Amendment 20 to the state’s Constitution. The first 10 years were largely focused on patient regulation. In 2010, through House Bill 10–1284, the General Assembly created the regulatory structure for medical marijuana; naming the Executive Director of the Department of Revenue as the State Licensing Authority, creating the Medical Marijuana Enforcement Division (“MMED”, now “MED”), and setting up a licensing construct for cultivations, products manufacturers, and centers – all of which were required to undergo financial and criminal background checks. Additionally, it required all employees in the industry to be licensed and undergo criminal background checks.

In November, 2012, Colorado voters made themselves heard again and approved Amendment 64, legalizing cannabis for adult use. Many of the same safeguards that had been developed for the medical side of cannabis were included in this amendment. Amendment 64, its enabling statutes, and resulting regulations allowed for persons over 21 to purchase, possess, and consume up to one ounce of cannabis lawfully. It established a system of licensed, regulated businesses to provide cannabis lawfully: cultivations, manufacturers, stores, and for the first time, independent labs. These cannabis businesses were the only establishments allowed to sell cannabis lawfully.

¹ Cannabis and marijuana will be used interchangeably in these comments.

Establishment of the Regulatory Program

The State Licensing Authority established the licensing program – rules, processes, and operations to grant, deny, revoke, and sanction licensees; and for renewal and transfer of licenses. In addition, the rules required the State Licensing Authority to establish licensing requirements. The business owners are required to undergo a fingerprint-based FBI criminal background check and an extensive financial background check with a complete disclosure of all persons with a financial interest to ensure there is no unlawful financial assistance. These requirements ensure that only those of good character are licensed.

Other regulations address Public Safety, Public Health, and Protection of Children. Regulations protecting Public Safety and Public Health include: requirements for video surveillance; alarm systems; seed-to-sale track and trace systems; restrictions on edible marijuana-infused products; and mandatory testing for potency, homogeneity, residual solvents, and contaminants. Regulations protecting Children include: child-resistant packaging; extensive labeling requirements; underage compliance checks; and advertising restrictions.

Results Regarding Effects on Youth

Colorado has not seen an increase in consumption, not even for underage use. The Colorado Department of Public Safety has recently issued its 2018 Report on the Impacts of Marijuana Legalization in Colorado - A Report Pursuant to Senate Bill 13-283,² compiling and analyzing data on marijuana-related topics that include crime, impaired driving, hospitalizations and ER visits, usage rates, effects on youth, and other topics of interest.

The report notes that overall the state is not seeing an impact of recreational marijuana use on high school graduation and drop-out rates. In fact, graduation rates are up – rising steadily from a 10-year low point of 72% in the 2009-2010 school year to 79% in the 2016-2017 school year. During this same time period, drop-out rates decreased from 3.1% to 2.3%. Youth Graduation rates are up and drop-out rates are down since 2012. The Graduation rate rose steadily from a 10-year low point of 72 percent in the 2009-2010 school year to 79 percent in the 2016-2017 school year. Over that same time period, the drop-out rate decreased from 3.1 percent.³

Equally as important, Colorado is not experiencing an increase in youth usage of marijuana. Both the National Survey on Drug Use and Health (NSDUH) and the Healthy Kids Colorado Survey (HKCS) report that youth usage is down. Specifically, the NSDUH reports that for the 2015-2016 school year (9.1%) was the lowest it has been since the 2007-2008 school year (9.1%). Additionally, the HKCS reports that the proportion of students trying marijuana before age 13 has dropped as well, from 9.2% in 2015 to 6.5% in 2017.⁴

² http://cdpsdocs.state.co.us/ors/docs/reports/2018-SB-13-283_report.pdf

³ *Id.* at pp 100 – 139.

⁴ *Id.*

Results Regarding Impacts on Crime

The report finds that generally crime has not increased. An area of major focus is that law enforcement and prosecutors are actively and aggressively pursuing cases against black market activity. While there have been increases in felony marijuana court case filings between 2015 and 2017, it is believed that the increase in filings might be in part because legislation changed the legal indoor plant count, providing law enforcement agencies with greater clarity and tools to increase their enforcement of black market activity. Nonetheless, it is important to note that felony filings in 2017 (907) were still below 2008 filings (1,431).⁵

Specific Comments

1. The legal regulation of cannabis has proven that it can work. A robust, regulatory program with focused attention on licensing requirements, compliance checks, and criminal investigations can ensure that those in the cannabis industry are compliant with regulations.
2. It is clear that it does not increase youth use. We believe that is due to extensive focus by state officials, including public education campaigns that raise awareness about the health and legal consequences of teen cannabis use.
3. Establishing a continuous improvement approach ensures that issues can be addressed quickly, and brings the regulated industry, law enforcement, the medical community, parents' groups, and government officials together to develop solutions.
4. As reported in Colorado, crime generally has not risen. Indeed, by providing law enforcement greater statutory clarity, tools, and increased resource funding from the Marijuana Tax Fund, they have been able to begin addressing black market activity with greater success.
5. If individuals are going to consume cannabis, government officials have an obligation to ensure its safety. In Colorado, all regulated cannabis must be tested.
 - It is tested for potency to ensure that consumers know the potency of the products they are consuming – this ensures that consumers do not overconsume or have negative effects. In addition, each serving can only contain a maximum of 10 mg. of THC, each edible product can only contain a maximum of 10 servings, and each serving must be marked with the Universal Symbol.
 - It is tested for homogeneity – this ensures that for those edible products that contain THC, it is evenly distributed across the edible product to ensure that one serving does not contain the majority of the THC in the product.
 - It is tested for residual solvents when solvents are used to extract the THC from the cannabis plant.
 - It is tested for contaminants. These contaminants include mold, microbials, pesticides, and other items that should not be resident in cannabis.
 - All of these safety precautions are even more significant when one considers that individuals with compromised immune systems and other medical conditions are consuming cannabis for medical use.

⁵ *Id* at pp 18 – 62.

6. At this point, prohibition is creating harm, for the following reasons:

- Without a legalized, regulated program, individuals will continue to purchase cannabis through the black market. The notion that individuals buy from their friends is a red herring – at some point, that cannabis originated in the black market and was simply distributed by those friends. In fact, when states or countries merely decriminalize minor possession and consumption without a legal way to obtain it, it creates an unintended consequence – it creates an opportunity for the black market to flourish.
- Without a legalized, regulated program, individuals will continue to consume cannabis that is not safe. It is not tested, and it is unclear if there are unsafe and dangerous ingredients contained within it.
- As more and more states continue to legalize medical and adult-use marijuana, it results in a patch work of different regulatory requirements and schemes from one state to another. States which have not legalized have an increased risk of diversion from legal markets in neighboring states, which undermines one of the key objectives: to significantly reduce or eliminate the illicit market for marijuana.
- A lack of participation by the federal government in legalization and regulatory oversight has contributed to a number of challenges at the state level including access to banking services, oversight on pesticides, efficacy and research for medical marijuana products and general regulatory inconsistencies from state to state.

7. A legalized, regulated program reduces those harms as mentioned above, in addition to:

- Providing a safe environment for the purchase of cannabis.
- By limiting sales to individuals over 21, it reduces consumption rates for teens.
- By requiring potency testing and extensive labeling, consumers know what they are consuming. In the event of accidental ingestion, the testing and labeling allows the medical community to know what they are dealing with.
- By requiring a seed-to-sale track and track system, if cannabis is contaminated, it can be easily identified and recalled.
- By requiring a taxing program, tax revenues can be raised to address the social costs related to cannabis: youth prevention, substance abuse treatment and prevention, public education campaigns, and law enforcement initiatives.

8. Other countries have begun the process of legalizing and regulating cannabis. By legalizing and regulating now, the United States can begin to work with them to ensure that national and international laws and treaties are addressed with the United States' interests represented.

9. Attached we are providing a link to the Global Commission on Drug Policy Report – 2018 Regulation – The Responsible Control of Drugs. It is a well-reasoned report and provides recommendations to many of the issues countries face when considering legalization and regulation of drugs.⁶

⁶ <http://www.globalcommissionondrugs.org/reports/regulation-the-responsible-control-of-drugs/>

Conclusion

We appreciate the opportunity to provide comments on this very important subject and thank the US Federal Drug Administration for requesting comments.

Sincerely,

Barbara J. Brohl

B J Brohl Strategies, LLC

Sincerely,

Ronald R. Kammerzell

Kammerzell Consulting Services