Comments to Docket No. DEA-1362 Proposed Rescheduling of Marijuana
Submitted: July 18, 2024

Recommendation: **No** - in defense of our nation's children and young people

<u>Who we are:</u> One Chance to Grow Up is a non-profit, non-partisan, citizen-led organization formed after Colorado became the first state in the nation to legalize the commercial production and sales of marijuana. We began our work as the voice for kids after public health and safety and protecting kids ranked as the LAST priority in the state's initial policy and regulatory proceedings.

Together with the support of our 11,000 members, including parents, educators, and community partners, we have advocated for over 30 critical pieces of legislation in the past twelve years improving outcomes for kids. We have engaged in every aspect of the policy and regulation-making processes at the local and state levels while educating the U.S. Congress and relevant U.S. agencies. We have been a trusted go-to source for elected officials, the media, and the public.

We do not accept any financial support from state or local taxes generated from marijuana sales or from the marijuana industry.

<u>Rescheduling would be dangerously short-sighted for four primary reasons:</u>

1) Rescheduling a plant with over 100 components versus an active component of the plant shown in controlled clinical studies to have medical use doesn't make sense and would result in unacceptable negative consequences.

2) A Schedule III classification requires evidence of moderate to low potential for physical and psychological dependence and abuse, but evidence already shows the potential for severe physical and psychological addiction and abuse from even casual marijuana use (especially with high potency THC products).

3) There are far more appropriate and better ways to meet the reasons offered for rescheduling.

4) A Schedule III classification recognizes the medical uses of marijuana; however, the realities of today's commercial markets and currently available research show such a designation would be dangerously premature based on the actual products being sold as "medical" marijuana today.

Supporting information for these primary reasons:

1)There is no scientific justification for rescheduling the marijuana plant when it is the amount of the psychoactive component (THC) in the finished product that should be determined and, based on that analysis, a decision on which schedule to place the individual product should be made.

DEA.gov/drug scheduling uses as examples, Heroin – Schedule I, Vicodin- Schedule II (less than 15 mg of hydrocodone per dosage unit), Tylenol -Schedule III (less than 90 mg of codeine per dosage unit), Robitussin -Schedule V (less than 200 mg of codeine per 100 ml.). While all are derived from the opium poppy plant and derivatives, these drugs are scheduled based on the amount of the active ingredient in the finished product.

The following are examples of the wide range of medical marijuana products currently available for sale in states where medical marijuana is legal. Which of these products would be rescheduled? **Rescheduling the plant without consideration of the final products is not consistent with the prior work of the DEA or FDA to protect public health and safety.**

Legal Medical Marijuana Products (FL,UT, PA,CO)		
Product Name	**Potency**	**Route**
Chocolate Chip Cookies	100 mg THC per package	Eaten
Malibu Blast - flavored vape	1g THC vape, 86% THC	Vaped
Rise Extracts - wax	83.4 % THC	Dabbed
Rasberry Chews	50 mg THC per chew	Eaten
Explore Suppository *	3:2 ratio THC, CBD	Vaginal
	thcphotos.org/photos/product-type	
	* legal recreational product	

The legalization of hemp in the Agricultural Improvement Act of 2018 (2018 U.S. Farm Bill) should serve as an instructive example that rescheduling the marijuana plant rather than the total psychoactive amount in the finished product leads to unacceptable risks, harms, and adverse outcomes for the public. The 2018 U.S. Farm Bill allowed for the sale of hemp with less than 0.3% delta 9 THC on a dry weight basis. And yet, without specificity as to the active ingredients allowed in the finished products and their intended use, a multi-billion industry has sprung up selling highly psychoactive/intoxicating products under the guise of "hemp" and "CBD" to include intoxicating delta 8, 10, 0 and other THC variants and derivatives nationwide.

Recently (Mar 20, 2024), 21 state attorneys general sent a letter to Congress urging them to address this loophole, stating that "hemp-derived intoxicants have proliferated across our states, posing a significant threat to public health and safety, and benefiting unregulated, untaxed, and unaccountable market actors." They reported that regardless of congressional intent, "the reality is that this law has unleashed on our states a flood of products that are

nothing less than a more potent form of cannabis, often in candy form that is made attractive to youth and children—with staggering levels of potency, no regulation, no oversight, and a limited capability for our offices to rein it in." Rescheduling marijuana is quite likely to lead to many similar outcomes.

2) A Schedule III classification requires evidence of moderate to low potential for physical and psychological dependence and abuse, when evidence shows high potential for physical and psychological dependence and abuse even from casual marijuana use (especially of high potency THC products).

The following evidence show that marijuana is addictive.

Evidence of Dependence	Source
1. 65% of industry sales from those using 26-31 days per month	2019 Colorado Marijuana Enforcement Division & NDSHU Longwoods Study
2. 6.1% of marijuana users in CO purchase 74.7% of the products	2019 Colorado Marijuana Enforcement Division & NDSHU Longwoods Study
3. 1 in 10 of users will become addicted, 1 in 6 under 18, 30% of current users meet the criteria for addiction	Yalemedicine.org/marijuana-use-disorder
4. 9% of all users experience addiction, of which nearly a fifth began use in adolescence	Volkow ND, New England Journal of Medicine, 2014, Jun 05;370
5. Cannabinoid Hyperemesis Syndrome is dramatically rising (unrelenting vomiting from daily use, even so users need intervention to quit)	CHS Recovery Group - over 27k members, grew over 600 last month
6. Daily use of cannabis 10% potency or higher increases risk of psychosis	US Senate International Narcotics Control Report, March 2021
7. Marijuana use before age 18 associated with future opioid use disorder	Johannes Thrul, et al, 12 yr longitudinal study, Addiction, March 2021
8. High THC can lead to:psychotic symptoms & disorders, including schizophrenia; mental health symptoms including anxiety, depression and suidical ideation; cannabis hyperemesis syndrome; cannabis use disorder/dependence including phsyical and psychological dependence	2020 Colorado Dept of Public Health and Environment, "THC Concentration in Colorado marijuana: Health Effects & Public Health Concerns." Mandated warnings at point of sale, House Bill 21-1317, passed into law in 2021
9. High potency THC linked with 3x risk of psychosis, daily use 5x risk of psychosis	DiForti, et al, Lancet Journal of Psychiatry, 2015
10. Harms associated with frequency of use, THC potency, amount of THC consumed	2020 Colorado Dept of Public Health and Environment, "THC Concentration in Colorado marijuana: Health Effects & Public Health Concerns."
11. Young adults who vape cannabis higher liklihood of using other substances	Addictive Behaviors Report, 2023
12. 22% of high school seniors report past 30 day use, 37% lifetime THC vaping rapidly increasing, including doubling for high school seniors	Monitoring the Future Youth Survey, 2019

Evidence from Colorado, the state with the longest experience with commercial sales, shows how costly the negative impacts have been, especially for children and young people.

Negative Consequence	Source
1. Fatal over dose deaths in Colorado are dramatically on the rise	Trends in Fatal and Non-Fatal Drug Overdoses in Colorado:
Total OD Deaths 2010 - 653 2023 - 1865	Substance Abuse Trend and Response Task Force June 21, 2024
Marijuana OD Deaths 2010 - 0 2023 - 62	Data SUDORS CDC, Vital Statistics Program, Colorado Department of Public
drug types not mutually exclusive	Health and Enivronment
2. 42.9% of 15-19 yr olds who died by suicide in CO had THC present	Colorado Dept of Health And Environment Violent Death Reporting System, 2023
THC is by far the most prevalent substance found	
For Hispanic Teens 49%, for Black Teens 67%	
3. Psychosis from Cannabis use is on a dramatic rise	The American Journal of Psychiatry - Rates and Predictors of Conversion to
One psychotic episode following cannibis use was associated with a	Schizopherina or Bipolor Disorder Following Substance-Induced Psychosis
47% probability of developing bipolar or schizophrenia disorder	28 Nov 2017
Every young adult diagnosed w/schizophrenia cost economy $92K per year	Schizophrenia & Psychosis Action Alliance
$3.8 million per lifetime	
4. Nationally a 1375% increase in pediatric edible cannabis accidental	American Academy of Pediatrics
consumption from 2017-2021, including death, hospitalization	Pediatric Edible Cannabis Exposures and Acute Toxicity 2017-2021, Jan 03 2023
5. Ages 18-25 the highest consuming population, our emerging workforce	2019 Behavioral Risk Factor Surveilance System, State of Colorado
1 in 3 regular users, 1-7 daily users	
6. 2008-2016 Self-reported pregnancy use increased 4% to 7% when harms	National Institue of Drug Abuse
include long-term brain development issues affecting cognition & behavior	Betsy Dickson, et al., Obstetrics and Gynecology, June 2018
2018 study found 69% of 400 CO dispensaries recommending marijuana	Univ of Colorado School of Pharmacy, 2018
to pregnant women	
7. 2020-2022 emergency visits increased by 88% & hospitalzations by	Colorado Department of Public Health and Environment, "Identifying cannabis-
268% of 13-17 year olds	attributed heatlh outcomes in Colorado: Assessment of hospital & emergency
	department data," January 2024
8. Marijuana has not decreased CO Opioid Overdose Deaths,2019 data	Wadeker AS, Drug and Alcohol Dependence 2020
shows: 24% increase in prescription overdose deaths, 115% increase in	
fentanyl deasths since 2000	

3)There are far less risky, more appropriate ways to meet the stated reasons for rescheduling

These include:

- Congress can establish baseline minimum product standards and youth safeguards while allowing states to prohibit commercial sales or enact additional safeguards, as it has done for tobacco and more recently the youth vaping crisis.
- Continue implementing high-priority decriminalization and criminal justice reforms at the state and national levels.
- Congress can continue to address any existing barriers to researching marijuana's medical uses.
- Potential and promising medicines derived from the marijuana plant can go through a similar FDA approval process as other medicines.
- Congress can close the psychoactive hemp/CBD loophole in the next Farm Bill.
- Congress can direct the FDA to establish a regulatory pathway for non-intoxicating hemp and CBD.

4.) A Schedule III classification recognizes the medical uses of marijuana; however, the realities of today's commercial markets and the current research show such a designation would be dangerously premature based on the actual products being sold as "medical" marijuana.

People are using marijuana for a range of reasons and ailments. A recent meta-analysis found the primary reason is to control pain and for pain management. These use-cases are not without adverse side effects and are based on experience with lower THC content products than what is found in today's 'medical' marijuana markets. The meta-analysis concludes that there is strong clinical support for avoiding cannabis in adolescence, early adulthood, for people struggling with mental health challenges and disorders, during pregnancy, and before driving.

There is consensus among many researchers that much more research needs to be done before the government gives its stamp of approval in recognizing "the plant" rather than specific finished products based on demonstrated clinical proof they can be used safely and effectively as medicine.

Data from the National Survey on Drug Use and Health 2019 shows that Colorado (the state with the longest experience with commercial marijuana sales including medical) has much higher rates of marijuana-use and mental health/substance-use disorders compared to nationwide rates. This includes a nearly two-times increase in past-year daily marijuana use for 18–25-year-olds, demonstrating the far-reaching negative impacts that rescheduling marijuana at this time would likely cause.

Comparison of Rates of Mental/Substance Use Disorders Associated with Marijuana Use: National vs. Colorado Data from the National Survey on Drug Use and Health (2019)

Measure/Age Group	National (%)	Colorado (%)	National vs. Colorado P-value
Past Month Marijuana Use (18-25 y)	23.0	37.0	0.0009
Past Year Daily Marijuana Use (18-25y)	7.5	14.8	0.0085
Past Month Marijuana Use (≥ 26y)	10.2	18.8	<0.0001
Substance Use Disorder (SUD) (18+)	7.7	10.9	0.0206
Co-occurring SUD and SMI (18+)	1.4	2.5	0.0430

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Estimates for Colorado are direct single-year estimates for 2019 and will differ from model-based estimates using data from 2018 and 2019.

SAMHSA
Substance Abuse and Mental Health Services Administration

And these negative impacts are exacerbated by the ultra-high potency THC products sold as “medical” marijuana today, products that industry members claim are identical to recreational marijuana products.

In Colorado, many abuses in the medical dispensary markets have been found. Since recreational approval (21-year age gate) adults over 21 with medical marijuana cards began to decrease while 18–20-year-olds with medical marijuana cards increased dramatically (18-year age gate) with 84% reporting severe pain as their qualifying condition. School officials and parents throughout the state said it created a pipeline of high THC products for high schoolers and that something had to be done. Over 50 health and youth serving organizations banded together in support of a major bill to address these abuses (HB 21-1317) in 2021.

This bill was unanimously passed in the Colorado state legislature and resulted in a 56% decrease in marijuana use in patients ages 18-20, a 25% decrease in the number of patients less than 18 years old, and an overall 17% decrease in the total number of medical marijuana patients. The process showed the incredible challenges of recognizing today’s high THC products as a legitimate medicine. It demonstrated the many opportunities for misleading and false claims and abuses in the current markets putting far too many consumers, including children and young people, at undue risk.

Ten Additional Facts About the Realities of Today's THC Markets (both medical & recreational) that show Schedule III will only expand and compound negative consequences nationwide

1. Increase in average potency: Over the past few years, THC, the psychoactive ingredient in marijuana, has increased to 19.6% in bud and to 68.6% in concentrates. Some retail marijuana stores advertise up to 95% THC in concentrate products. Only 7% of products sold in Colorado have a potency lower than 15% THC, a threshold considered high potency by the Colorado Department of Health and Environment (CDPHE). There is little, if any, difference between products sold as a "medicine" versus recreationally.

2. "We are seeing increases in addiction, psychosis, depression, hospitalizations, and suicide," according to the CDPHE's July 2020 Report THC Concentration in Colorado- Marijuana Health Effects and Public Health Concerns.

3. THC is the #1 substance found in teens 15-19 who died by suicide in Colorado in 2021. Almost twice as many deaths as those with alcohol present were reported by coroners.
· Black youth: 66.7% (Males 62.5%)
· Hispanic youth: 49% (Males: 56.3%)
· White youth: 33.3% (Males: 41.7%)

4. Marijuana is not just a plant. There are higher profits in processed products, so market share has shifted to concentrates, vaping, and edibles.

5. Products continue to hide marijuana. Vaporizers, cupcakes, candies, sodas, eyedrops, breath mints, look-alike asthma relief inhalers, and even powders that can be sprinkled on foods and in drinks are being sold. Hidden THC is a marketing tactic targeting children. Placing marijuana and marijuana products on Schedule III will only increase the market for these drugs and will further negatively affect children.

6. Nationally, there has been a 1375% increase in pediatric edible cannabis accidental ingestions over the past five years, with the potential for significant toxicity and hospitalization, and severe adverse health outcomes.

7. Our roads are LESS SAFE. In a 2020 Colorado Department of Transportation report, 69% of marijuana users admitted to driving while high, and 27% reported driving high almost daily. 29.2% of drivers involved in fatal crashes in CO tested positive for THC in 2022. The dangers of drugged driving and the persistent drugged driving enforcement challenges, including the lack of impairment assessment tools for marijuana continue.

8. Even after a decade of commercialized marijuana, regulators can't keep up. Colorado's system of unlimited potency, unrestricted products, and ex-post facto regulations is like "chasing cheetahs with butterfly nets," according to a state health official.

9. Consumers and the public need to be provided with more information. There are still no standard total psychoactive limits on serving/dosage or package amounts across the vast variety and different types of products, leaving consumers and the public uninformed and misinformed.

10. The 2018 Federal Farm Bill unleashed hemp-derived psychoactive THC products in corner stores, gas stations, grocery stores, and head shops across the nation. These products are entirely legal, entirely unregulated and these THC derivatives have the same psychoactive and addictive effects as does delta 9 THC products. Hemp-derived THC products belong in regulated stores where age-restricted sales and additional safeguards exist.

Final Summary

Top health experts predict that a Schedule III designation on the marijuana plant will significantly increase the use of today's new and ultra-potent products, including by those under the age of 21. Rescheduling and declaring medical use for marijuana would substantially normalize the use of the botanical and related products, including regular use, inappropriate recommending and overprescribing while lowering perceptions of harm from these products. This will include many of today's highly deceptive products that appear harmless and are often marketed as health products or medicines when they contain ultra-high amounts of THC, come in kid-friendly forms and flavors and have not been evaluated by the FDA for effectiveness or adverse effects. Placing marijuana and marijuana-derived products on Schedule III guarantees that this will occur as government puts its imprimatur of safety and efficacy on a plethora of products that have never been tested for medical value or safety.

In addition, there is significant concern that rescheduling would wipe out many of the hard fought and heavily negotiated rules and laws around marijuana use which have been put in place in states across the US. Our experience leads us to be extremely concerned that rescheduling will lead to massive uncertainty around the already established state rules and laws leading to a deluge of lawsuits.

We urge you not to reschedule the marijuana plant to Schedule III.

Sincerely,
One Chance to Grow Up

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