Cannabis and Pediatrics

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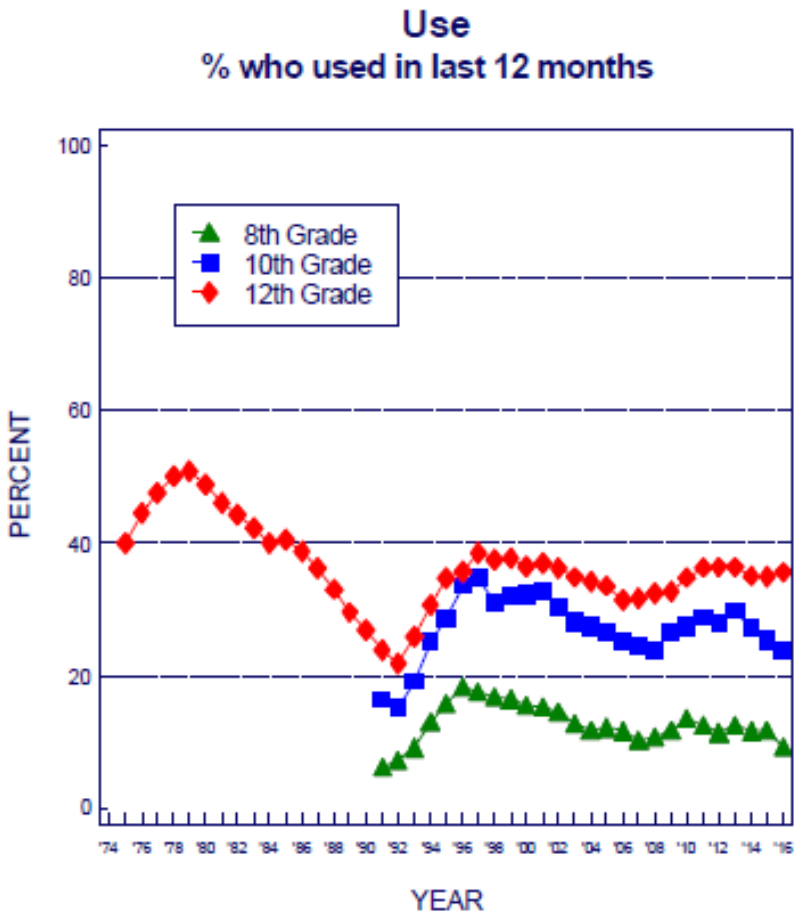
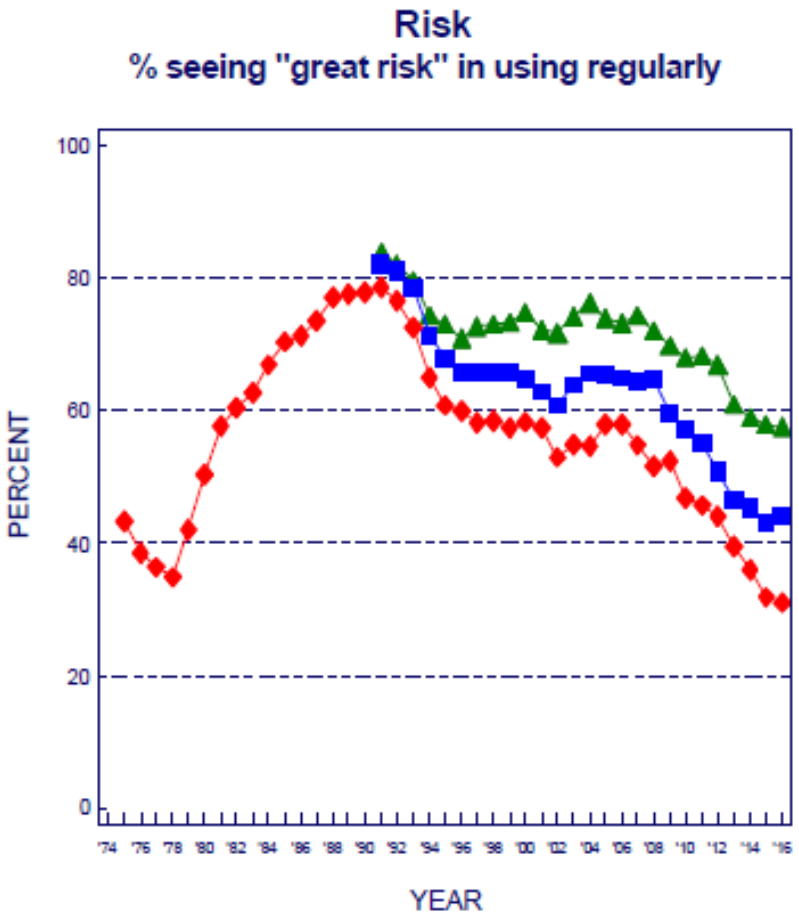
Outline

- Adolescent Trends
- Pediatrics Trends
- Other Impacts

ADOLESCENT TRENDS





Schulenberg, J. E., et al. (2018). Monitoring the Future national survey results on drug use, 1975–2017. Available at http://monitoringthefuture.org/pubs.html#monographs

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Research Letter

ONLINE FIRST

July 8, 2019

Association of Marijuana Laws With Teen Marijuana Use

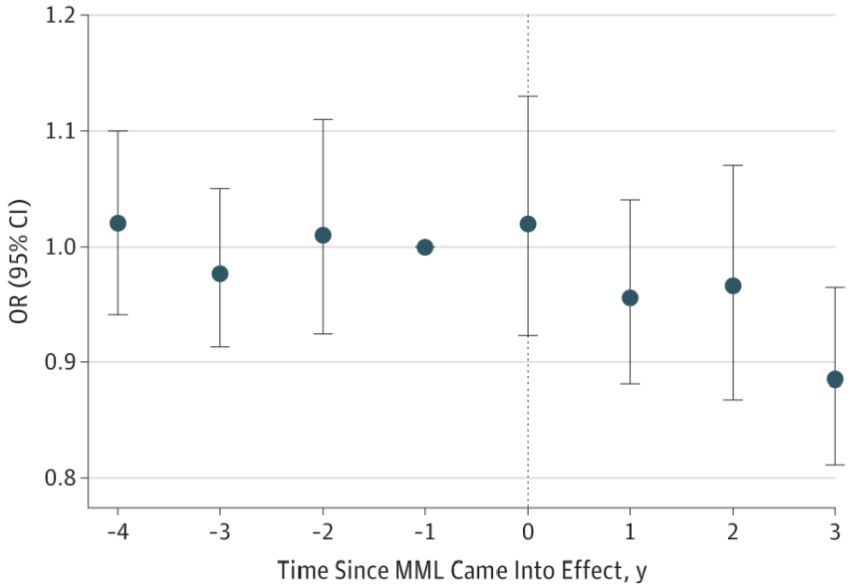
New Estimates From the Youth Risk Behavior Surveys

D. Mark Anderson, PhD[1]; Benjamin Hansen, PhD[2]; Daniel I. Rees, PhD[3]; et al

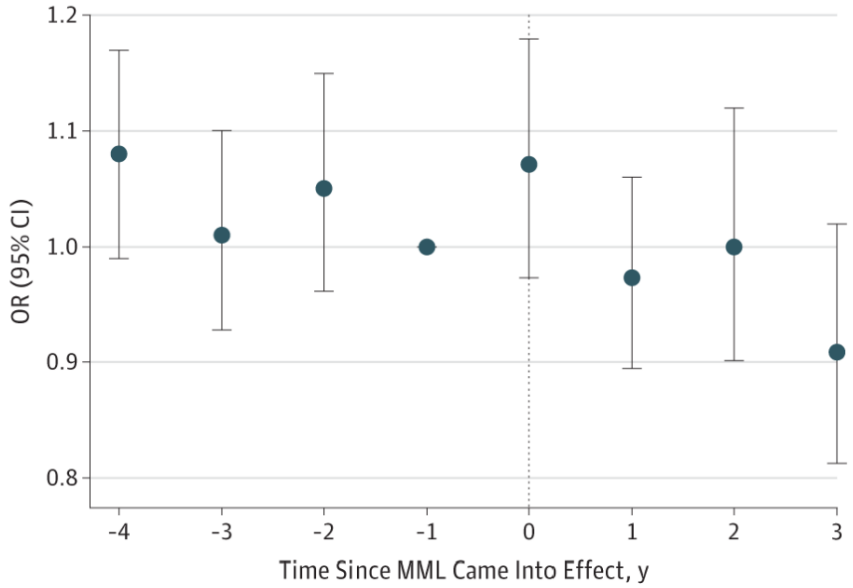
» Author Affiliations | Article Information

JAMA Pediatr. Published online July 8, 2019. doi:10.1001/jamapediatrics.2019.1720

A Pre-MML and post-MML trends in marijuana use



B Pre-MML and post-MML trends in frequent marijuana use



- Youth Risk Behavior Surveys 1993 – 2017
- MMLs no change
- RMLs associated with 8% decrease in odds of marijuana use, and 9% decrease in frequent use

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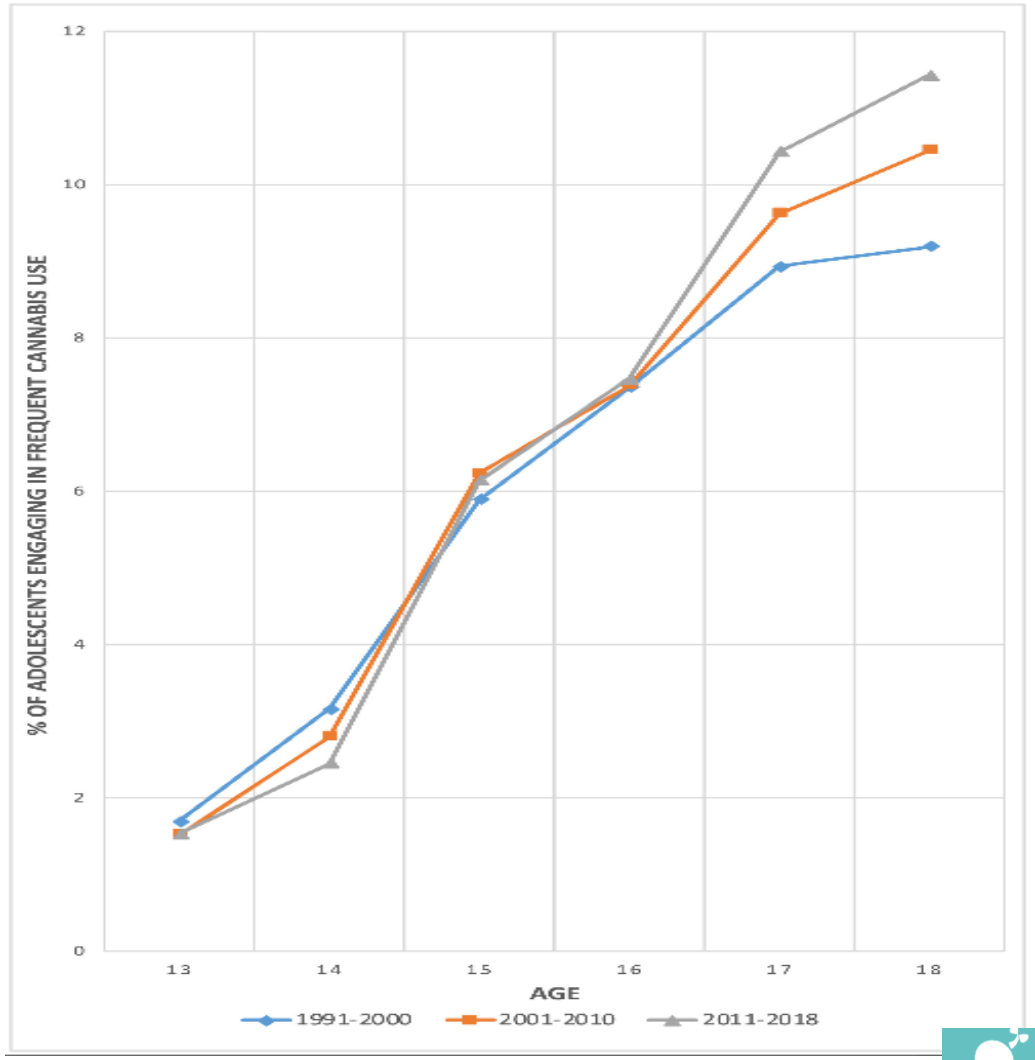
Addiction. 2019 Oct;114(10):1763-1772. doi: 10.1111/add.14665. Epub 2019 Jun 26.

Age, period and cohort effects in frequent cannabis use among US students: 1991-2018.

Hamilton AD[1], Jang JB[2], Patrick ME[3], Schulenberg JE[2,4], Keyes KM[1,5].



- Frequent Cannabis Use increased over study period
- Peak was 11.4% among 18 yo

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Colorado Health Kids Survey

- From 2017 to 2019, there was a significant increase in high school students using 20 to 39 times in the past 30 days (1.7% to 2.8%).

- There was also a significant increase in dabbing to 10.2% and vaporizing 6.8% in 2019. The prevalence of eating and other methods remained the same.

Pediatrics
September 2019, VOLUME 144 / ISSUE 3
Article

Cannabis Concentrate Use in Adolescents

Madeline H. Meier, Meagan Docherty, Scott J. Leischow, Kevin J. Grimm, Dustin Pardini

TABLE 5 Comparison of Lifetime Cannabis Nonusers, Lifetime Cannabis Users Who Had Never Used Concentrates, and Lifetime Concentrate Users on Other Substance Use and Risk and Protective Factors for Substance Use Problems, Adjusted for Sociodemographic Factors

	Group 1: Cannabis Nonusers (*N* = 31 463)		Group 2: Nonconcentrate Cannabis Users (*N* = 4379)		Group 3: Concentrate Users (*N* = 11 300)		Group 2 vs 1		Group 3 vs 1		Group 3 vs 2		
	Mean, %	SE	Mean, %	SE	Mean, %	SE	Effect Size[a]	95% CI	Effect Size[a]	95% CI	Effect Size[a]	95% CI	*N*[b]
Other substance use													
Cigarette use (lifetime)	5.8	0.3	34.0	1.0	47.2	0.8	8.53*	7.82 to 9.32	16.10*	15.03 to 17.26	1.89*	1.74 to 2.04)	44 639
E-cigarette use (lifetime)	20.2	0.5	60.4	0.9	81.7	0.6	7.55*	7.02 to 8.13	24.50*	23.00 to 26.11	3.24*	2.98 to 3.53)	44 751
Alcohol use (lifetime)	29.4	0.4	75.6	0.8	84.6	0.5	9.53*	8.79 to 10.35	17.31*	16.23 to 18.46	1.82*	1.65 to 2.00	44 755
Other drug use (lifetime)	8.8	0.3	26.4	0.8	47.2	0.6	3.76*	3.45 to 4.11	10.54*	9.91 to 11.21	2.80*	2.58 to 3.05	44 702
Age of onset of alcohol (<17)	28.5	0.6	70.8	0.9	80.2	0.6	7.93*	7.34 to 8.57	13.86*	13.04 to 14.72	1.75*	1.60 to 1.91	44 041
Age of onset of cigarette (<17)	5.8	0.3	32.9	1.0	45.6	0.8	8.06*	7.38 to 8.81	14.94*	13.93 to 16.01	1.85*	1.71 to 2.01	44 393
Age of onset of marijuana (<17)	N/A	N/A	82.4	1.1	84.0	1.0	N/A	N/A	N/A	N/A	1.14*	1.02 to 1.26	14 560
Risk and protective factors													
Individual													
Perceived risk of harm from marijuana	2.66	0.01	1.90	0.02	1.70	0.01	−0.68*	−0.71 to −0.65	−0.86*	−0.88 to −0.84	−0.18*	−0.21 to −0.14	42 629
Rebelliousness	1.63	0.01	1.89	0.01	2.03	0.01	0.35*	0.32 to 0.39	0.55*	0.53 to 0.57	0.19*	0.16 to 0.23	42 897
Favorable attitudes: antisocial behavior	1.42	0.00	1.61	0.01	1.75	0.01	0.35*	0.32 to 0.38	0.59*	0.57 to 0.62	0.24*	0.21 to 0.28	42 761
Peer													
Peer use of any substance (past year)	0.48	0.01	1.16	0.01	1.64	0.01	0.69*	0.66 to 0.71	1.17*	1.15 to 1.19	0.48*	0.45 to 0.51	44 457
Peer favorable attitudes: drug use	1.44	0.01	1.95	0.01	2.26	0.01	0.66*	0.63 to 0.69	1.06*	1.04 to 1.08	0.40*	0.37 to 0.44	44 329
Perceived as cool for marijuana use	2.24	0.02	2.84	0.03	3.02	0.02	0.41*	0.38 to 0.44	0.54*	0.52 to 0.56	0.13*	0.09 to 0.16	42 946
Antisocial peers	0.19	0.01	0.33	0.01	0.58	0.01	0.26*	0.23 to 0.29	0.71*	0.69 to 0.74	0.46*	0.42 to 0.49	44 508
Family													
Family history alcohol and/or drug use	58.9	0.4	80.3	0.7	84.6	0.4	3.1*	2.86 to 3.43	4.26*	4.00 to 4.55	1.36*	1.23 to 1.51	41 835
Family conflict	2.24	0.01	2.43	0.01	2.51	0.01	0.25*	0.22 to 0.28	0.35*	0.32 to 0.37	0.10*	0.06 to 0.13	41 987
Poor family management	1.70	0.01	1.94	0.01	2.05	0.01	0.41*	0.37 to 0.44	0.60*	0.57 to 0.62	0.19*	0.15 to 0.22	41 878
Parental favorable attitudes: drug use	1.14	0.00	1.33	0.01	1.46	0.01	0.40*	0.36 to 0.43	0.67*	0.65 to 0.69	0.27*	0.24 to 0.31	42 208
Family attachment	2.88	0.01	2.66	0.01	2.58	0.01	−0.29*	−0.32 to −0.25	−0.39*	−0.41 to −0.36	−0.10*	−0.14 to −0.06	41 335
Prosocial opportunities	2.97	0.01	2.78	0.01	2.68	0.01	−0.26*	−0.29 to −0.23	−0.39*	−0.41 to −0.37	−0.13*	−0.17 to −0.09	41 451
School													
Academic failure	1.96	0.01	2.15	0.01	2.29	0.01	0.27*	0.24 to 0.30	0.47*	0.44 to 0.49	0.20*	0.16 to 0.23	43 836
Low commitment to school	2.62	0.01	2.87	0.01	3.02	0.01	0.38*	0.35 to 0.41	0.60*	0.58 to 0.62	0.22*	0.19 to 0.25	44 703
Community													
Laws and norms favorable to drug use	2.06	0.01	2.30	0.01	2.40	0.01	0.38*	0.35 to 0.41	0.54*	0.52 to 0.56	0.16*	0.13 to 0.20	39 750
Perceived availability of drugs	2.13	0.01	2.68	0.02	2.93	0.01	0.54*	0.51 to 0.57	0.79*	0.77 to 0.81	0.24*	0.21 to 0.28	42 593

Means are estimated marginal means, and percentages are estimated marginal probabilities. Estimates are adjusted for sociodemographic characteristics (linear and quadratic age, grade, sex, race/ethnicity, caregiver education, and free or reduced lunch). N/A, not applicable.

[a] Effect sizes are either mean differences in SD units (for continuous correlates) or odds ratios (for categorical correlates).

[b] Sample sizes for each analysis ranged from 39 750 to 44 755 because of missing data.

* $P < .05$.

JAMA Pediatr. 2019 Feb 1;173(2):185-186. doi: 10.1001/jamapediatrics.2018.3811.

Acute Mental Health Symptoms in Adolescent Marijuana Users.

Levy S[1], Weitzman ER[2].

Table. Demographic Characteristics; Frequency of Cannabis Use; Scores on Depression, Anxiety, and Cannabis Use Disorder Screens; and Associations With Experiencing Marijuana-Related Hallucinations or Paranoia

Cannabis Use/ Mental Health Variable	Total, No. (%) (N = 146)	Hallucinations in Past 12 mo, No. (%)			Paranoia or Anxiety in Past 12 mo, No. (%)		
		Never (n = 106)	Ever (n = 40)	OR (95% CI)[a]	Never (n = 97)	Ever (n = 49)	OR (95% CI)[a]
Cannabis use disorder							
CUD diagnosis	40 (27.4)	21 (52.5)	19 (47.5)	3.76 (1.69-8.34)	19 (47.5)	21 (52.5)	3.15 (1.46-6.78)
No diagnosis	106 (72.6)	85 (80.2)	21 (19.8)	1 [Reference]	78 (73.6)	28 (26.4)	1 [Reference]
Frequency of past-year marijuana use							
Monthly or more	70 (47.9)	42 (60.0)	28 (40.0)	3.81 (1.71-8.50)	37 (52.9)	33 (47.1)	3.30 (1.58-6.89)
Once or twice	76 (52.1)	64 (84.2)	12 (15.8)	1 [Reference]	60 (78.9)	16 (21.1)	1 [Reference]
Anxiety screen							
Positive, score ≥3 on GAD	26 (17.8)	16 (61.5)	10 (38.5)	1.84 (0.74-4.57)	13 (50.0)	13 (50.0)	2.32 (0.96-5.58)
Negative, score <3 on GAD	120 (82.2)	90 (75.0)	30 (25.0)	1 [Reference]	84 (70.0)	36 (30.0)	1 [Reference]
Depression screen							
Positive, score ≥3 on PHQ	35 (24.0)	23 (65.7)	12 (34.3)	1.51 (0.66-3.45)	15 (42.9)	20 (57.1)	3.75 (1.69-8.36)
Negative, score <3 on PHQ	111 (76.0)	83 (74.8)	28 (25.2)	1 [Reference]	82 (73.9)	29 (26.1)	1 [Reference]

Abbreviations: CUD, cannabis use disorder, determined by the modified World Mental Health Composite International Diagnostic Interview[2]; GAD, Generalized Anxiety Scale; OR, odds ratio; PHQ, Patient Health Questionnaire 2.

[a] Odds ratio (95% CI) logistic regression adjusts for age (continuous), sex, and race/ethnicity.

- 40 (27.4%) reported hallucinations
- 49 (33.6%) reported paranoia or anxiety
- 63 (42.9%) reported having at least 1 symptom.
- Increased in users using monthly or more (60% vs 40%)

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Mental Health - Psychosis

- Individuals reporting smoking more potent cannabis, 2.91 (CI 1.52-3.60) greater odds of developing first episode of psychosis compared to those who never used
- Lifetime use of high potency (>10% THC) was associated with a psychotic disorder compared with no lifetime use of cannabis (OR 1.6 CI 1.2-2.2)
- Daily use of high potency (OR 4.8, CI 2.5-6.3) even higher risk

DI Forti 2015
Morrison 2011, 2009
Curran 2018

Mental Health - Psychosis

- Cannabis use > 5 times by 15/16 years of age, associated with psychotic disorder by age 30 (OR 3.02, CI 1.14-7.98)

- Males who used cannabis in adolescents more likely to develop schizophrenia in later years

Mustonen 2018
Zammit 2002

Trends in Young Pediatric Exposures

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Table 1 (b) Prevalence of past-month daily cannabis use among adults with children <18 years in the household by cannabis legalization status and sociodemographic characteristics, NSDUH 2017.

	Cannabis legalization status		
	No MML (n = 7500)[a]	*MML (n = 10,800)*[a]	*RML (n = 3900)*[a]
Overall	200 (2.35%)	500 (3.22%)	200 (4.21%)
Age			
18–25	100 (4.81%)	200 (6.69%)	100 (8.26%)
26–34	<100 (3.21%)	100 (4.79%)	<100 (6.10%)
35–49	<100 (1.55%)	100 (2.27%)	<100 (3.60%)
≥50	<100 (1.02%)	<100 (0.99%)	<100 (0.39%)
Gender			
Male	100 (3.07%)	300 (4.40%)	100 (5.47%)
Female	<100 (1.77%)	200 (2.25%)	105 (3.19%)
Marital status			
Married	<100 (1.15%)	100 (1.80%)	<100 (2.93%)
Widowed/divorced/separated	<100 (3.35%)	<100 (1.99%)	<100 (2.24%)
Never married	100 (4.97%)	300 (6.86%)	100 (8.32%)
Income			
<$20,000	<100 (3.63%)	100 (5.43%)	<100 (7.20%)
$20,000–$74,000	<100 (2.80%)	200 (4.11%)	<100 (4.82%)
≥$75,000	<100 (1.81%)	200 (2.29%)	100 (3.36%)
Race/Ethnicity			
Non-Hispanic White	100 (2.26%)	300 (3.38%)	100 (5.13%)
Non-Hispanic Black	<100 (3.41%)	<100 (4.36%)	<100 (7.35%)
Hispanic	<100 (1.63%)	<100 (2.39%)	<100 (3.35%)
Non-Hispanic Other	<100 (2.61%)	<100 (1.90%)	<100 (2.62%)
Education			
Less than high school	<100 (2.97%)	<100 (4.74%)	<100 (4.87%)
High school or equivalent	<100 (3.28%)	200 (4.29%)	<100 (5.89%)
Some college	<100 (2.84%)	200 (3.98%)	<100 (5.22%)
College graduate or above	<100 (0.72%)	<100 (1.01%)	<100 (2.02%)

MML = medical marijuana laws; NSDUH = National Survey on Drug Use and Health; RML = recreational marijuana laws. [a]Unweighted sample sizes must be rounded to the nearest 100 to use NSDUH restricted-use data in the Research Data Center setting.

- NSDUH
- Past-month cannabis use (11.9%, 9.3%, and 6.1%)
- Daily cannabis use (4.2%, 3.2%, and 2.3%)
- More common in states with recreational marijuana laws (RML), followed by states with medical marijuana laws (MML) and without legal cannabis use.

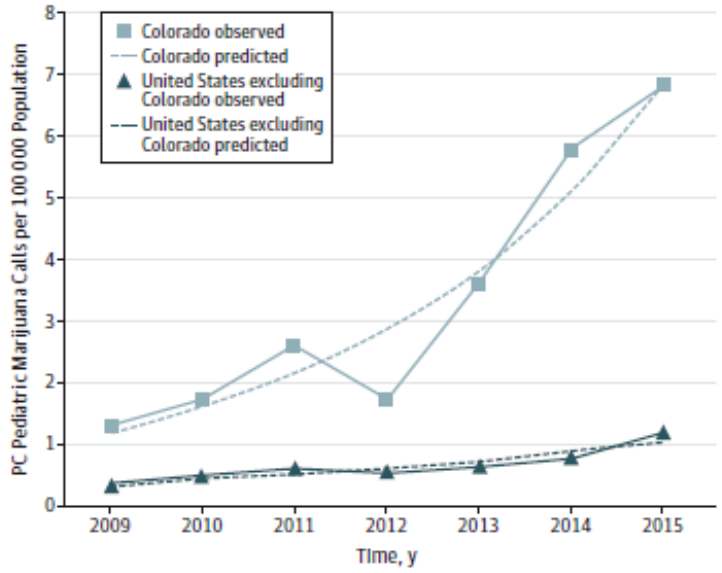
Goodwin et al, 2021

Original Investigation

Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015

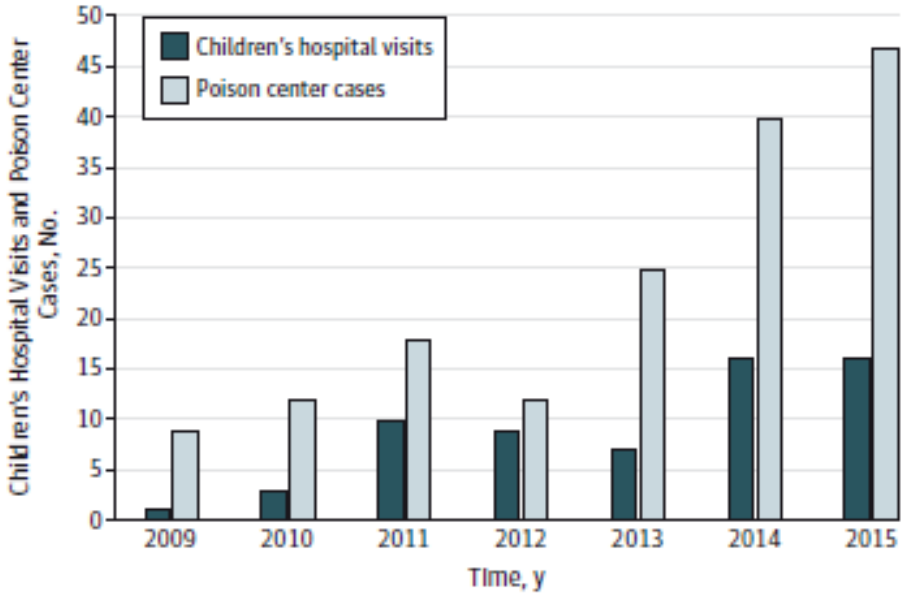
George Sam Wang, MD; Marie-Claire Le Lait, MS; Sara J. Deakyne, MPH; Alvin C. Bronstein, MD; Lalit Bajaj, MD, MPH; Genie Roosevelt, MD, MPH

Figure 2. Colorado Pediatric Marijuana Exposures vs US Pediatric Exposures



Comparison of unintentional marijuana exposure rates between Colorado and the remainder of the United States excluding Colorado per 100 000 population in children 9 years and younger between 2009 and 2015. The Colorado rate = $100\,000 \times e^{-9.5896+0.2902\times time}$ and the United States rate = $100\,000 \times e^{-11.4543+0.1732\times time}$, where time is −6 in 2009, −5 in 2010, −4 in 2011, −3 in 2012, −2 in 2013, −1 in 2014, and −0 in 2015. The rate difference was significant ($P = .04$). PC indicates poison center.

Figure 1. State Pediatric Marijuana Exposures



Annual children's hospital visits and regional poison center cases for unintentional marijuana exposures in children 9 years or younger in Colorado between 2009 and 2015. Children's hospital visits include emergency department visits, urgent care visits, and inpatient hospital admissions.

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PEDIATRICS/ORIGINAL RESEARCH

Association of Unintentional Pediatric Exposures With Decriminalization of Marijuana in the United States

George S. Wang, MD; Genie Roosevelt, MD, MPH; Marie-Claire Le Lait, MS; Erin M. Martinez, MS; Becki Bucher-Bartelson, PhD; Alvin C. Bronstein, MD; Kennon Heard, MD

Wang et al, 2014

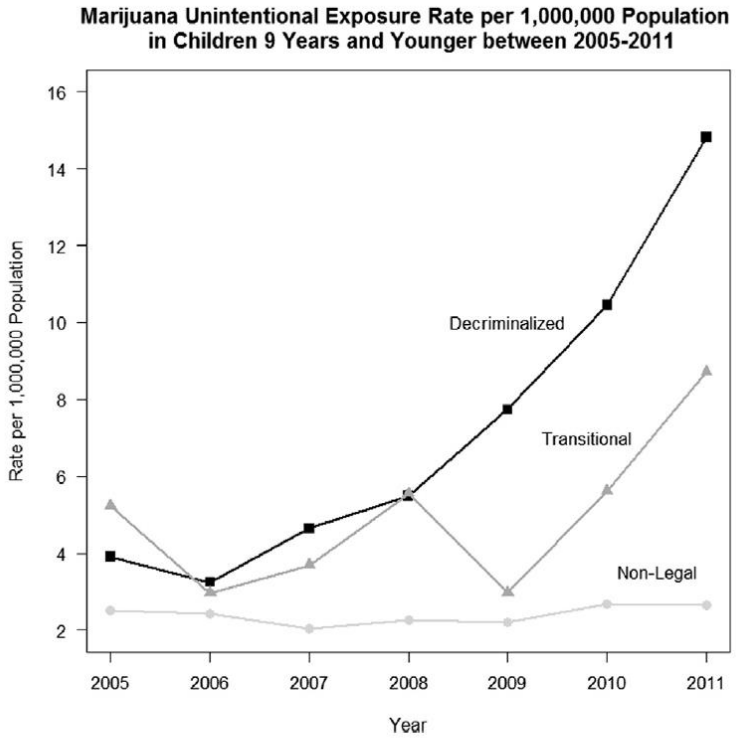

Figure 2. Comparison of unintentional marijuana exposure rates between nonlegal, transitional, and decriminalized states.

- More patients evaluated in health care facility (OR 1.9; 1.5,1.6)
- More patients with major/mod effects (OR 2.1; 1.4, 3.1)
- Admission to critical care units (OR 3.4; 1.8, 6.5)

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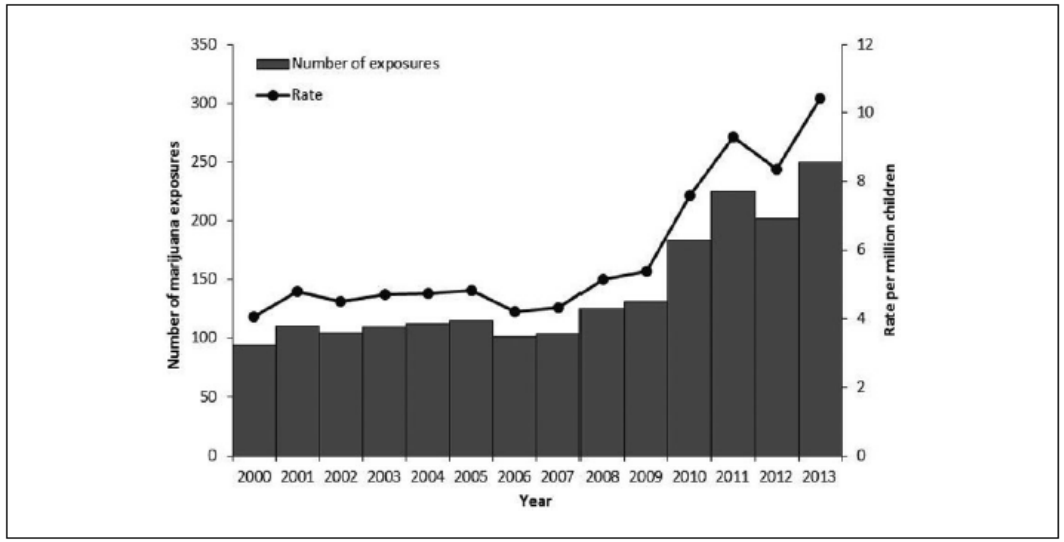

Figure 1. Annual number and rate of marijuana exposures among children younger than 6 years (National Poison Data System 2000-2013).

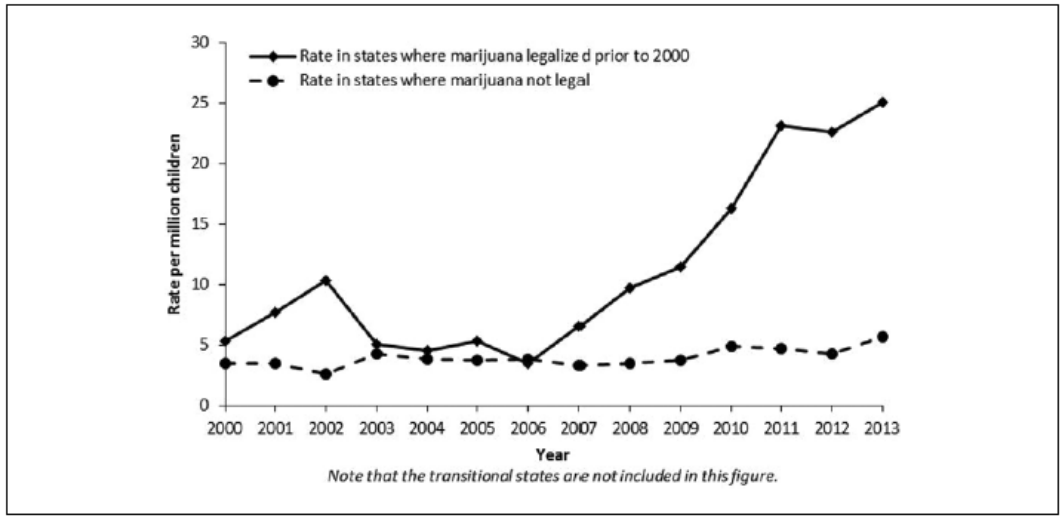

Figure 2. Annual rate of marijuana exposures among children younger than 6 years by marijuana legalization status of state (National Poison Data System 2000-2013).

- 2000 through 2008, no significant change in the annual number or rate of ingestions of marijuana in children < 6 years
- Following 2009, mean annual increase of 27% per year
  - 742 ingestions per year or 2.98 ingestions per 100,000 population
- > 70% of all cases occurred in states with legalized marijuana
- 54.6% received some form of hospital-based care
  - 7.5% required critical care

Onders, et al 2016

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Graham et al 2020

Illicit Drug Exposures in Young Pediatric Patients Reported to the National Poison Data System, 2006-2016

Jessica Graham, MD[1], Jan Leonard, MSPH[1], Shireen Banerji, PharmD[1,2], and George Sam Wang, MD[1,2]

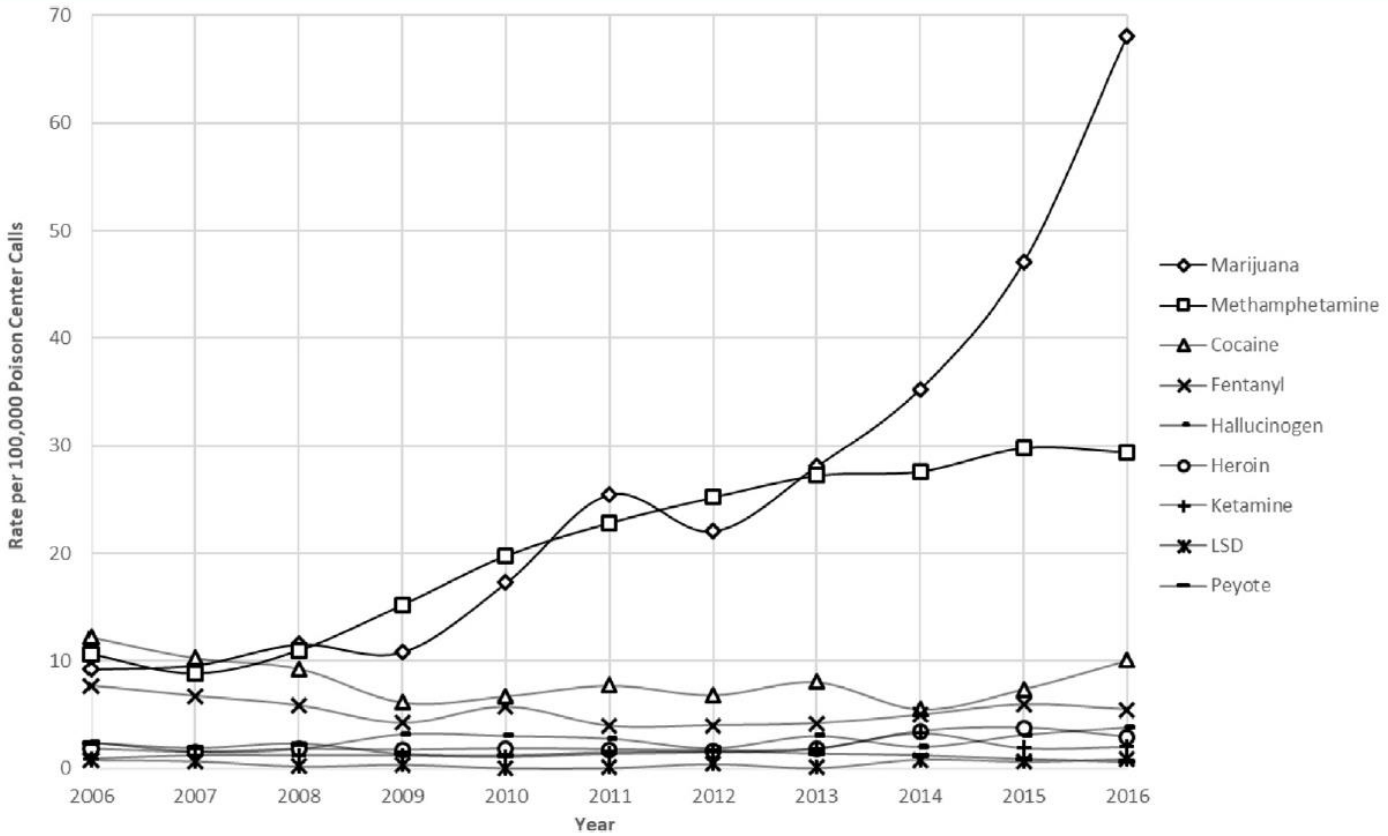

Figure 2. Illicit drug exposures rate per 100 000 poison center calls in young pediatric patients (<10 years of age) between 2006 and 2016. *LSD*, lysergic acid diethylamide.

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CLINICAL TOXICOLOGY
2021, VOL. 59, NO. 4, 326–333
https://doi.org/10.1080/15563650.2020.1806295

Taylor & Francis
Taylor & Francis Group

POISON CENTRE RESEARCH

Pediatric cannabis poisonings in France: more and more frequent and severe

Céline Chartier[a], Françoise Penouil[b], Ingrid Blanc-Brisset[b], Charlotte Pion[c], Alexis Descatha[a,d] and Marie Deguigne[a]

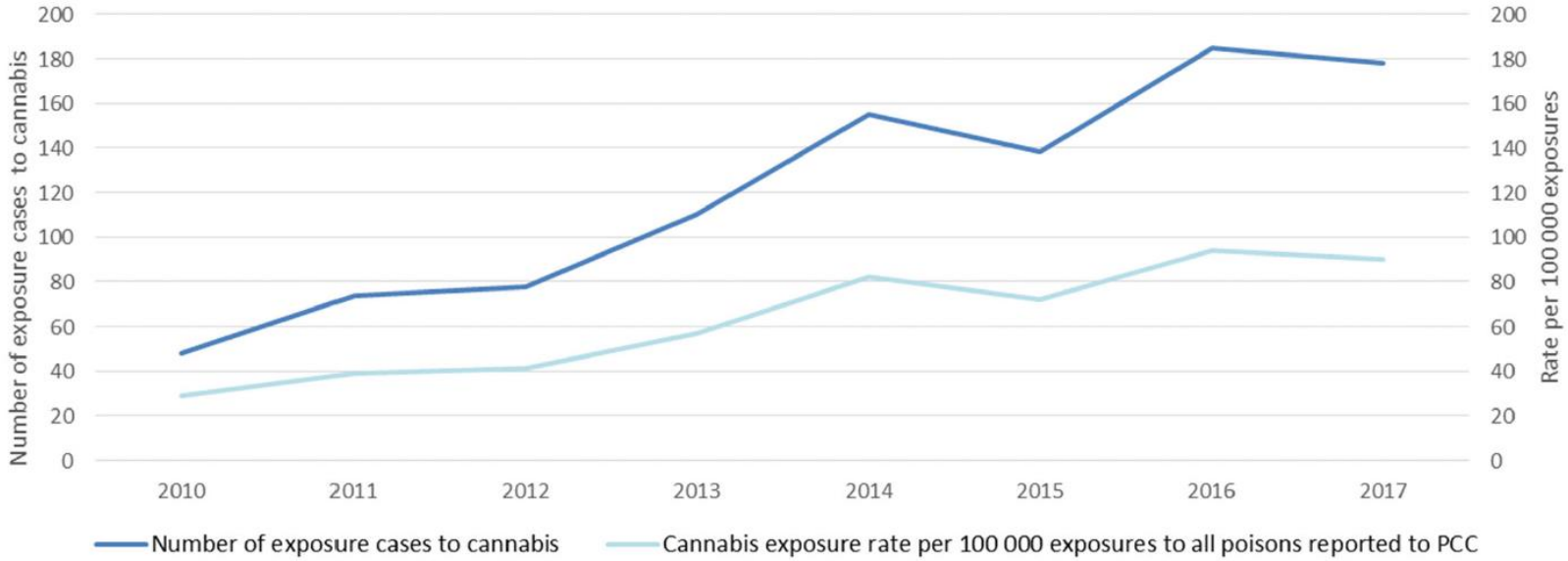

Figure 1. Annual progression of the number of exposure cases.

Chartier et al 2021

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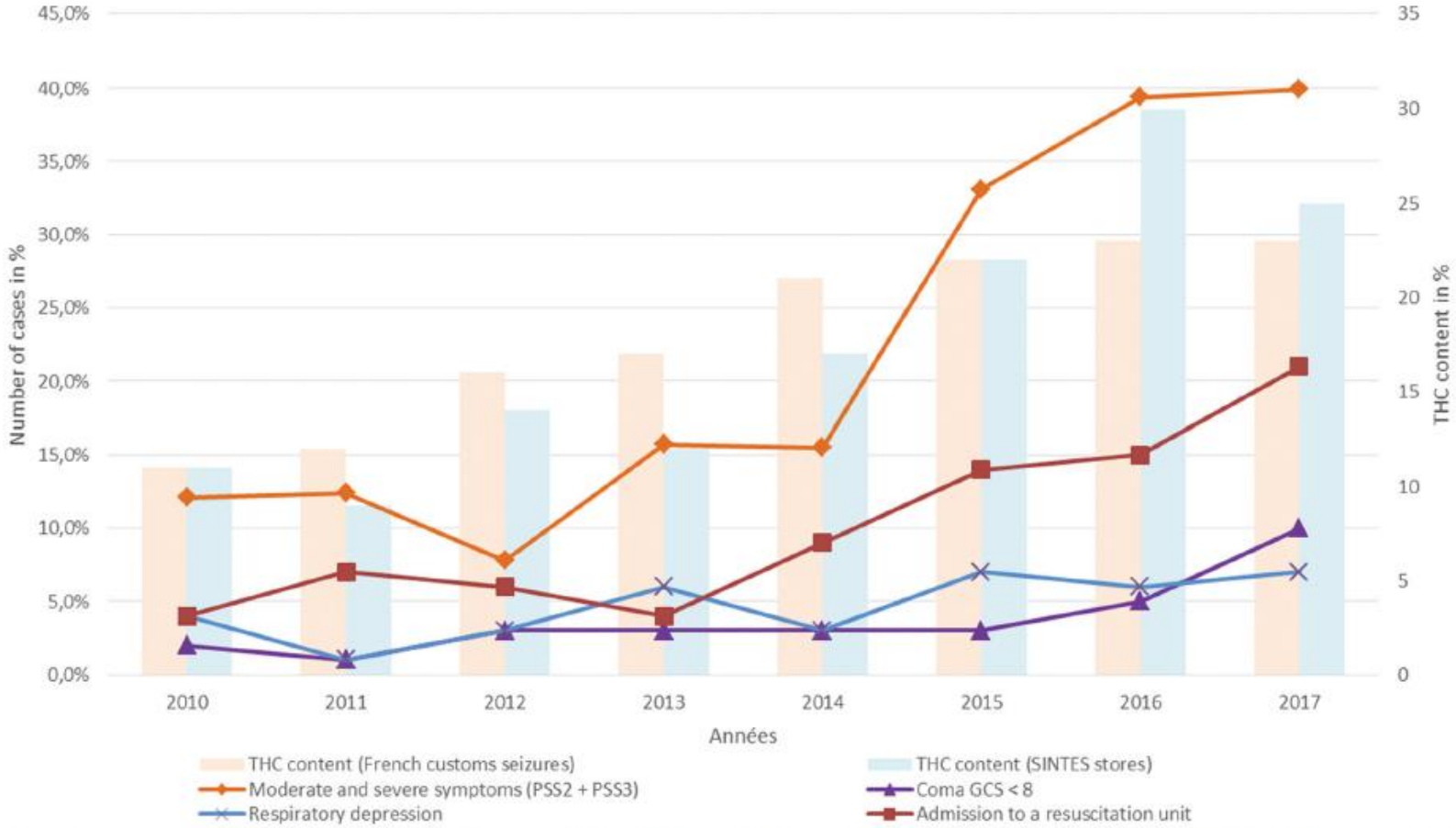

Figure 2. Progression of severe clinical characteristics/treatment of the children and of the THC content of cannabis resin (results were taken from two different sources in France).

Chartier et al 2021

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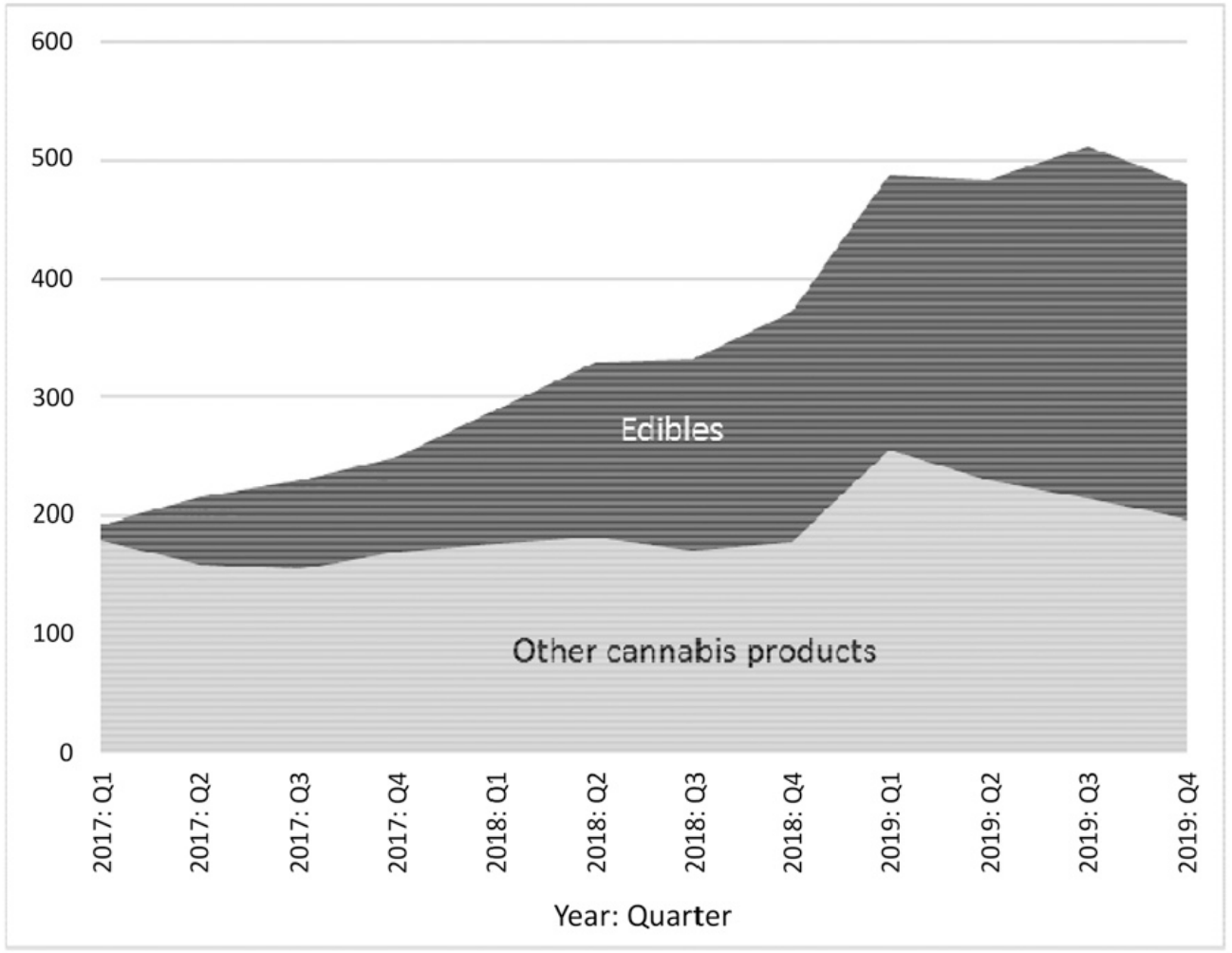

FIGURE 1

Whitehill, et al 2021

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Health Specialty Units

Pregnancy

- NSDUH
  - Past month cannabis use increased from 3.4% to 7.0% from 2002 to 2017
  - Frequency of use increased
    - Most evidence in first trimester - 5.7% to 12.1%
- PRAMS
  - Women in states who legalized recreational cannabis significantly more likely to use cannabis during preconception, prenatal and postpartum timer period
  - Most common reasons for use: anxiety (81.5%), nausea/vomiting (77.8%) and pain (55.15%)

Volkow 2019, Ko 2020, Skelton 2020.

Breastfeeding

- Maternal THC does transfer into breastmilk
  - “small amounts”
  - At least 6 days after last use
  - Small cohort persist up to 6 weeks

- ? How does this impact mental health and physical health of the infant
- ? Compare with not breastfeeding

Second-hand Smoke

- Can be detected in urine, but in small concentrations
- Children with positive results for COOH-THC were more likely to have parents who
  - use marijuana daily
  - smoke marijuana versus other forms of use
  - use in the home
- Increased rate of VRI, but not asthma, OM, ED/UC visits

Children's Hospital Colorado
Here, it's different.™

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University of Colorado
Anschutz Medical Campus

PEHSU
Pediatric Environmental Health Specialty Units

Baker 2018
Bertrand 2018
Johnson 2021
Wilson 2018

Conclusions

- Commonly abuse in adolescents
  - Concerning trends on increased frequency of use and higher potency products
  - Mental health, CUD and secondary impacts
- Increasing pediatric exposures
  - Edibles
- Increase use in pregnant populations
  - For non-recreational purposes
- Other potential risks: Breastfeeding, secondhand smoke

George.wang@childrenscolorado.org

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Health Specialty Units

Cannabis Policy and Regulation: Considerations for Protecting Public Health and Consumer Safety

Gillian Schauer, PhD, MPH
Executive Director
Cannabis Regulators Association (CANNRA)

Presented at:

The Food and Drug Law Institute's Legal and Practical Issues in the Evolving World of Cannabis Regulation

December 2, 2021

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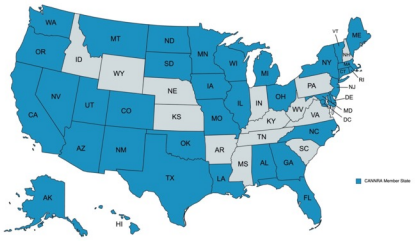
Brief Overview of CANNRA

CANNRA
Cannabis Regulators Association

- A **national non-profit organization of cannabis regulators** from more than 35 states and jurisdictions.
- Not an advocacy group; **takes no formal position for or against cannabis legalization**.
- Mission to **equip policy makers with unbiased information** from the front lines of cannabis legalization. To identify and share best practices that safeguard public health and safety and promote regulatory certainty for industry participants.
- Funded by member agencies.
- No industry or advocacy group membership or funding.
- An affiliate of the Council of State Governments (CSG).

www.cann-ra.org



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Disclosures and Disclaimers

I do not have anything to disclose.

The findings and conclusions in this presentation are my own and do not necessarily represent an official position of CANNRA or of any of the state agencies with whom I work.

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Agenda

- Current Regulatory Landscape
- Policy and Regulatory Considerations for:
  - Promoting Equity
  - Public Health and Safety
  - Hemp-derived products
- Conclusions

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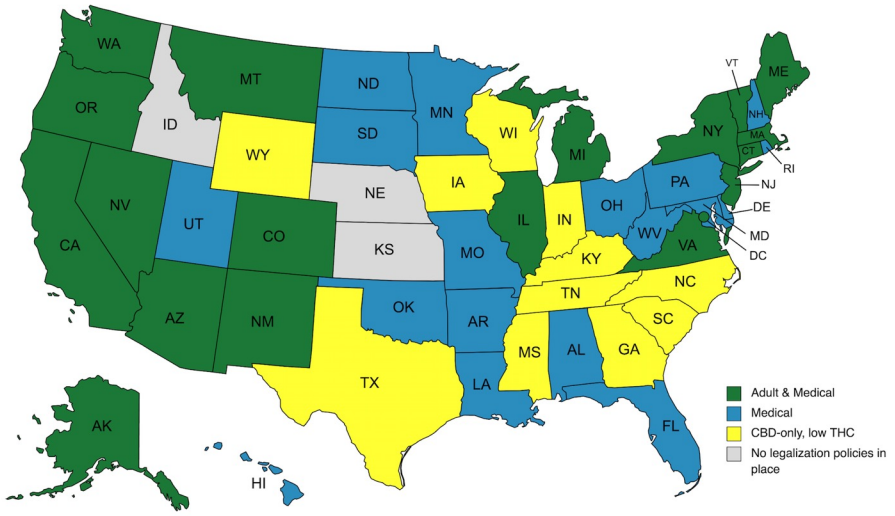
Cannabis policy, by state, October 2021



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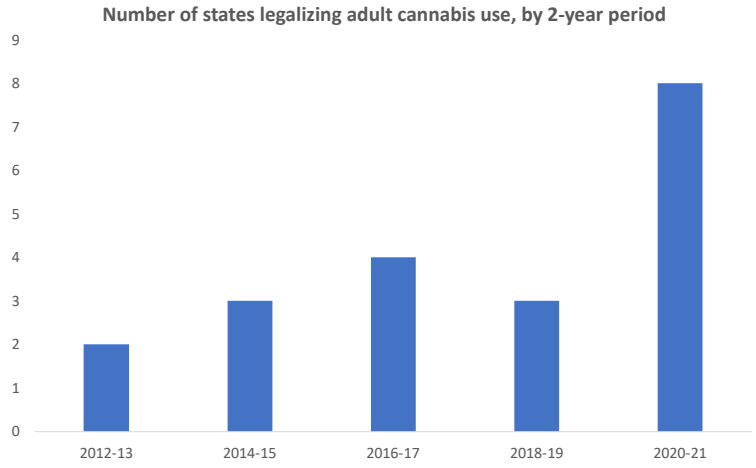
Exponential increases in adult use legalization



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Timeline of Adult Use Cannabis Legalization, by State

State	Year adult use legalization passed	Ballot measure (% support) OR legislative passage	Date retail marketplace opened (opens)
CO	2012	Ballot measure (55%)	January 2014
WA	2012	Ballot measure (56%)	July 2014
OR	2014	Ballot measure (56%)	October 2015 (through medical dispensaries)
AK	2014	Ballot measure (53%)	October 2016
DC	2014	Ballot measure (65%)	No retail marketplace approved
CA	2016	Ballot measure (56%)	January 2018
ME	2016	Ballot measure (50%)	October 2020 (through medical dispensaries)
MA	2016	Ballot measure (54%)	November 2018
NV	2016	Ballot measure (54%)	July 2017 (through medical dispensaries)
VT	2018	Legislative	Expected 2022
MI	2018	Ballot measure (56%)	December 2019
IL	2019	Legislative	January 2020 (through medical dispensaries)
AZ	2020	Ballot measure (60%)	January 2021 (through medical dispensaries)
MT	2020	Ballot measure (57%)	Expected 2022
NJ	2020	Ballot measure (67%)	Expected 2022
SD	2020	Ballot measure (54%)	Legalization overturned by legal challenge
NY	2021	Legislative	Expected 2022 (or later)
VA	2021	Legislative	Expected 2024
NM	2021	Legislative	Expected April, 2022
CT	2021	Legislative	Expected 2022

Source: Schauer, G.L., Cannabis Policy in the United States: Implications for Public Health (in press) *Journal of the National Cancer Institute*

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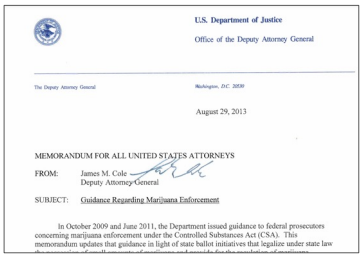
Cannabis Legalization 2.0 (and beyond)

- Broader focus than Cole Memo era
- Increased focus on:
  - Social equity and restorative justice
  - Public health and consumer safety
  - Increased parity in regulations across cannabis (medical, adult use, hemp)



U.S. Department of Justice
Office of the Deputy Attorney General

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law

Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products

THE DENVER POST

Despite legalization, people of color still disproportionately targeted for marijuana, new studies say

Researchers analyzed different sets of police data and found people of color were more likely to be searched and arrested

Forbes

How Hemp And The Farm Bill May Change Life As You Know It

The Washington Post
Democracy Dies in Darkness

Health

As more states legalize marijuana, more children accidentally ingest THC-laced edibles

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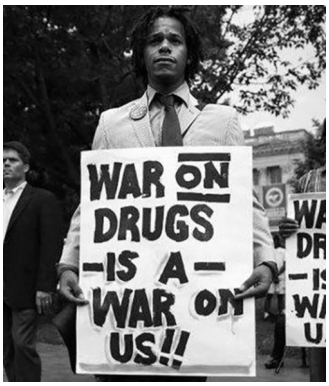
Emphasis on equity and restorative justice



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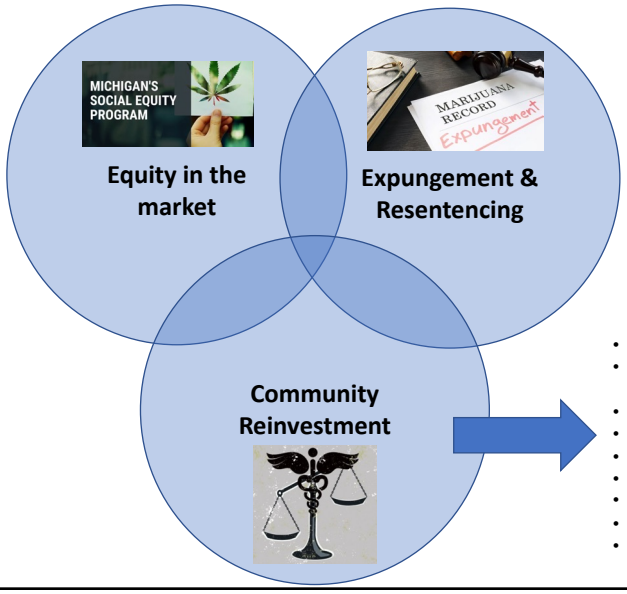
Emphasis on equity and restorative justice



- Job placement
- Mental health and/or substance use disorder treatment
- System navigation services
- Legal services
- Reentry services
- Linkages to medical care
- Housing
- Violence Prevention
- Youth Development

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Emphasis on public health and safety

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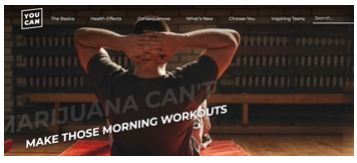
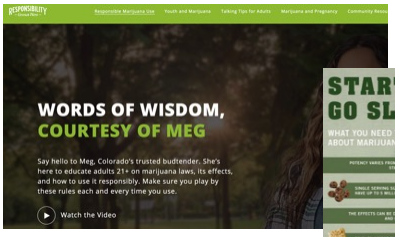
Youth Prevention



Consumer Safety



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Packaging and Labeling

- **Preventing youth appeal/consumption**
  - Plain, uniform, opaque packaging
  - Childproof packaging
- **Protecting/informing consumers:**
  - Labeling for total THC (vs. D9 only)
  - Labeling with processing/manufacturing
  - Universal symbol (on all products)
  - Inclusion of poison center phone number or drug information website
- **Challenges:**
  - Products that still appeal to kids
  - Effectively reaching consumers with essential information

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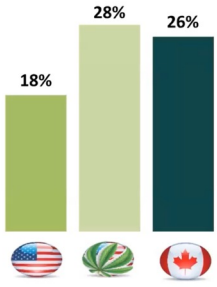
Consumer Awareness & Knowledge

Do you know the amount/number of THC or CBD of the dried herb you used last?

% 'YES'; DRIED HERB USERS (N=9,796)



What are the THC and CBD levels in the DRIED HERB you usually use?

UNIVERSE: DRIED HERB USERS WHO REPORTED KNOWING THC (N=447) AND CBD (N=395)

33% THC

24% CBD

ICPS

Source: The International Cannabis Policy Study (PI: David Hammond, University of Waterloo), 2020 data

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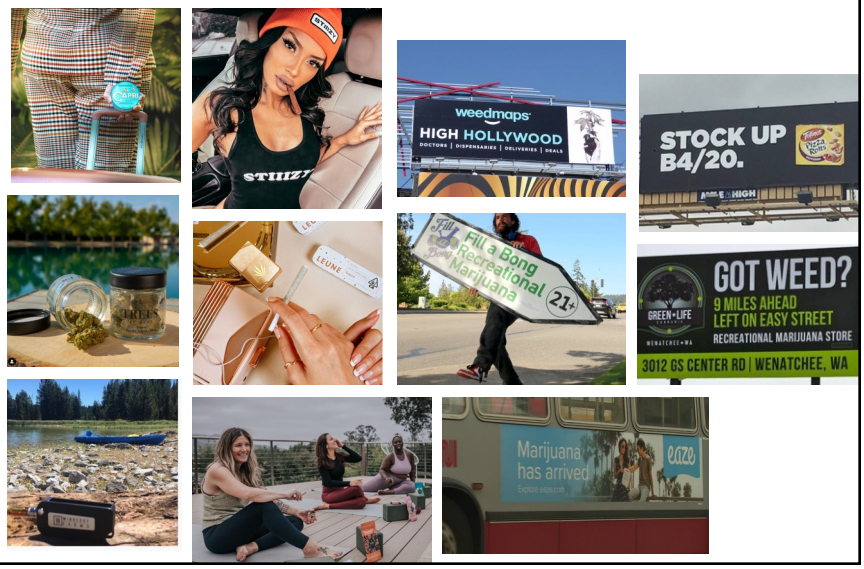
Advertising

Preventing youth exposure:

- Audience restrictions (to prevent youth exposure)
- Limitations (or bans) on advertising in certain outlets
- Restrictions on ad content/purpose
- Warnings on advertisements

Challenges:

- Social media advertising
- Third-party advertising



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Protecting Consumer Safety Post-EVALI

- **More regulatory authority over additives and excipients to prevent future safety issues:**
  - Bans and regulatory authority to ban potentially harmful additives
  - Focus on pharmaceutical grade and/or FDA approved for intended method of use
  - Limits on total additives in vaped products
- **Efforts to detect unsafe constituents, adverse events:**
  - Expanded testing protocols, use of reference and QA labs
  - Use of poison center and Emergency Department data
- **More regulatory authority over vaping devices:**
  - Temperature controls
  - Heating elements made of inert materials
- **Improved approaches to facilitate rapid recall processes**
- **Challenges:**
  - Lacking safety profiles on additives
  - Novel cannabinoids and evolving products

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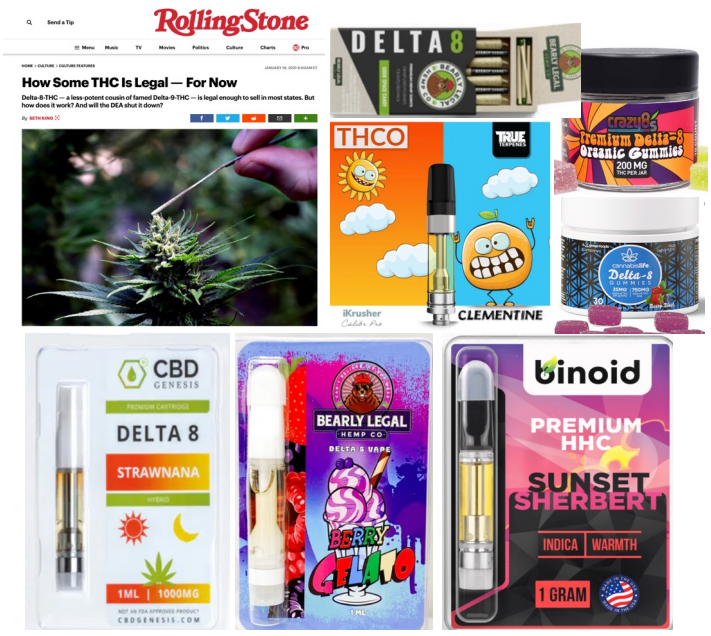
THC isomers and Novel Cannabinoids



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THC isomers and Novel Cannabinoids

Consumer Safety concerns:

- Not subject to the same packaging, labeling requirements
- Not subject to the same testing requirements
  - Some new cannabinoid products have no data from use in humans
  - Potentially dangerous manufacturing
  - Unknown byproducts
- Widely available in retail outlets and online → widely available to youth
- Legal products on the hemp marketplace with with >Delta-9 THC than is allowed in regulated cannabis markets.

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State activities related to novel cannabinoids

→ Attempts to collect data on adverse events to understand potential impacts.

→ Legislative and rule-making work on policies to better protect consumers, markets; to better align cannabis and hemp policies.

Outstanding questions:

- How to regulate impairing products coming from hemp (how and where to draw a line)?
- How to handle molecules that occur naturally in the plant vs. those that do not?
- How to assess and determine safe manufacturing?
- How to create more parity in testing across all cannabis products for consumer safety?
- How to avoid fueling an illicit market?
- How to handle the online marketplace? Interstate commerce?

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Possible Federal Legalization

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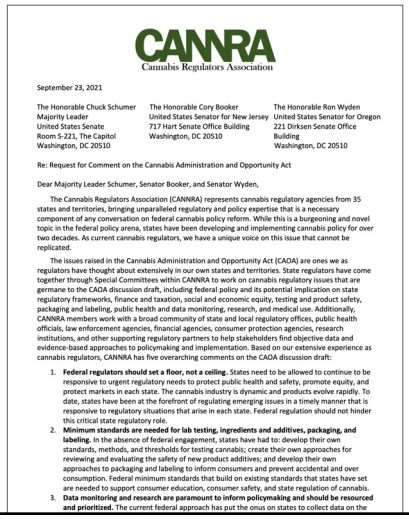
What are some public health and state-based considerations for potential federal legalization?



CANNRA
Cannabis Regulators Association

September 23, 2021

The Honorable Chuck Schumer
Majority Leader
United States Senate
Room S-221, The Capitol
Washington, DC 20510

The Honorable Cory Booker
United States Senator for New Jersey
717 Hart Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
United States Senator for Oregon
221 Dirksen Senate Office Building
Washington, DC 20510

Re: Request for Comment on the Cannabis Administration and Opportunity Act

Dear Majority Leader Schumer, Senator Booker, and Senator Wyden,

The Cannabis Regulators Association (CANNRA) represents cannabis regulatory agencies from 35 states and territories, bringing unparalleled regulatory and policy expertise that is a necessary component of any conversation on federal cannabis policy reform. While this is a burgeoning and novel topic in the federal policy arena, states have been developing and implementing cannabis policy for over two decades. As current cannabis regulators, we have a unique voice on this issue that cannot be replicated.

The issues raised in the Cannabis Administration and Opportunity Act (CAOA) are ones we as regulators have thought about extensively in our own states and territories. State regulators have come together through Special Committees within CANNRA to work on cannabis regulatory issues that are germane to the CAOA discussion draft, including federal policy and its potential implication on state regulatory frameworks, finance and taxation, social and economic equity, testing and product safety, packaging and labeling, public health and data monitoring, research, and medical use. Additionally, CANNRA members work with a broad community of state and local regulatory offices, public health officials, law enforcement agencies, financial agencies, consumer protection agencies, research institutions, and other supporting regulatory partners to help stakeholders find objective data and evidence-based approaches to policymaking and implementation. Based on our extensive experience as cannabis regulators, CANNRA has five overarching comments on the CAOA discussion draft:

1. **Federal regulators should set a floor, not a ceiling.** States need to be allowed to continue to be responsive to urgent regulatory needs to protect public health and safety, promote equity, and protect markets in each state. The cannabis industry is dynamic and products evolve rapidly. To date, states have been at the forefront of regulating emerging issues in a timely manner that is responsive to regulatory situations that arise in each state. Federal regulation should not hinder this critical state regulatory role.
2. **Minimum standards are needed for lab testing, ingredients and additives, packaging, and labeling.** In the absence of federal engagement, states have had to: develop their own standards, methods, and thresholds for testing cannabis; create their own approaches for reviewing and evaluating the safety of new product additives; and develop their own approaches to packaging and labeling to inform consumers and prevent accidental and over consumption. Federal minimum standards that build on existing standards that states have set are needed to support consumer education, consumer safety, and state regulation of cannabis.
3. **Data monitoring and research are paramount to inform policymaking and should be resourced and prioritized.** The current federal approach has put the onus on states to collect data on the

- Federal regulation should set a floor, not a ceiling.
- Protecting consumer safety and promoting equity should be priorities.
- Minimum standards are needed for lab testing, ingredients and additives, packaging, and labeling.
- Data monitoring and research are paramount to inform policymaking and should be resourced and prioritized.
- Revenue generation from cannabis taxes should be reserved to states, with investments in regulation and implementation, research and data monitoring, and initiatives to promote equity.
- More concordance is urgently needed between hemp and cannabis regulation.

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Thank you!

Gillian.Schauer@cann-ra.org

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PUBLIC HEALTH VIEWS ON CANNABIS FDA ISSUES

PROF. JIM O'REILLY
UNIV. CINCINNATI COLLEGE OF MEDICINE

FDLI

WHAT IS FDA'S POWER TO IMPACT HEALTH ASPECTS OF CANNABIS PRODUCTS?

- DEPENDS ON CONGRESS IN 2022 OR LATER
- UNLIKELY CBD CAN MAKE DIRECT BENEFIT CLAIMS
- INTERSECTION OF FTC CLAIMS CONTROL WITH FDA BENEFIT CLAIMS
- NO PREEMPTION OF STATES IF NO CONGL ACTION

GOVERNMENT ROLES IN CANNABIS: THE “BIG EVOLVE”

- 1937 TAX AS BARRIER
- 1970 CONTROLLED SUB. ACT PUT MARIJUANA IN SCHEDULE 1, HIGHEST TARGET
- COST: MASSIVE STREET-LEVEL POLICING
- STRUCTURE: JAIL, PRISON, PROBATION
- WORLD-WIDE USA TREATY PUSH & INTERDICTION
- EXPENSIVE D.E.A. STRUCTURE
- SLOW STATE-LEVEL REFORMS LED TO EVOLUTION

HOW FDA CATEGORIES ARE MIS-FITS WITH CANNABIS

- ***"GENERAL RECOGNITION AS SAFE"*** IS LEGALLY IMPOSSIBLE FOR SCHED. 1 CSA DRUG, YET CONGRESS WILL NOT DETERMINE CANNABIS IS "SAFE" WHEN ADOPTING NEW LEGISLATION
- CLINICAL TRIALS & DRUG APPROVAL STRUCTURE?
- NEW FOOD ADDITIVE ALSO IS BLOCKED
- CANNOT BE G.R.A.S.E., IF SUBSTANCE ALSO N.D.A.
- EPIDIOLEX NDA HAS "FALLOUT IMPACTS"
- WOULD CONGRESS "GET INTO THE WEEDS" ?

ADVERTISING “FOOD” VALUE OF THC-8 HEMP POSES CONFUSING ASPECTS

- CAN MFR CLAIM HEALTH EFFECT OF THE HEMP IN FOOD INGREDIENTS LIKE CANNABIS TWINKIES?
- SYSTEM GOVERNING PROMOTION OF HEALTH BENEFIT FOR FOOD IS NOT A GOOD FIT FOR CANNABIS
- CLAIMS SUPPORT NORMS APPLIED BY FTC & FDA NOT GOOD FIT FOR CBD BENEFIT ASSERTIONS
- HOW DISTINGUISH THC-8 AND NORMAL HEMP ITEM
- CAN STATE A.G.’S DISSENT FROM FED’L GRASE CLAIM TO GAIN VISIBILITY AS “ANTI-DRUG CRUSADER A.G.”
- WHEN STATE AG & FDA DIFFER RE BENEFIT WHO WINS?

WHAT TO WATCH FOR IN CONGRESSIONAL “FIXES”

- HEAVY LOBBYING IS UNDERWAY TO EXPAND
- HOW DOES HIGHER-THC 8 HEMP FIT IN?
- HOW TO DEFINE HEMP W/ ENHANCED PURITY
- WILL CONGRESS EMPOWER FDA TO SET “GMP” OIL EXTRACTION & PURIFICATION NORMS
- CAN FDA SHUT DOWN STATE-LICENSED MFR SITE
- REMEDIES FOR FDA ENFORCEMENT
- WILL BE MODELED ON CANADIAN & STATE NORMS?

CONSEQUENCES IMPACT PUBLIC HEALTH CREDIBILITY OF CANNABIS PROMOTERS

- CONGRESS IS URGED TO PICK WINNERS & LOSERS
- LOBBYISTS URGING CONGRESS TO TILT STANDARDS
- HISTORY SHOWS BAD CHOICES IN STAT'Y TEXT ARE HARD FOR FDA TO RATIONALLY IMPLEMENT IN REGS
- AFTER MASK/ANTI-VAX CONTROVERSIES, WOULD ANOTHER POLITICALLY CONTROVERSIAL CHANGE OF FEDERAL POLICY (RE CANNABINOIDS) UNDERCUT CREDIBILITY OF FEDERAL PUBLIC HEALTH MANAGERS?
- RISK: BLOW-BACK MIGHT HARM FDA CREDIBILITY