

2019 Update on Cannabidiol and Hemp Products

Presented by:

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Drug Testing Advisory Board
June 11 , 2019



SAMHSA
Substance Abuse and Mental Health
1 Services Administration

Presentation Objectives

- Overview Marijuana
- Potency
- Scheduling and Research,
- Policy
- Commercialization of Marijuana

Marijuana Contains Over 400 Chemical Compounds:

- 110 + Cannabinoids
 - Δ 9-THC (psychoactive)
 - CBD (non-psychoactive)
- 200 + Terpenes (odor)
- Flavonoids (color)



Trichome of Marijuana



Cultivated Throughout Recorded History

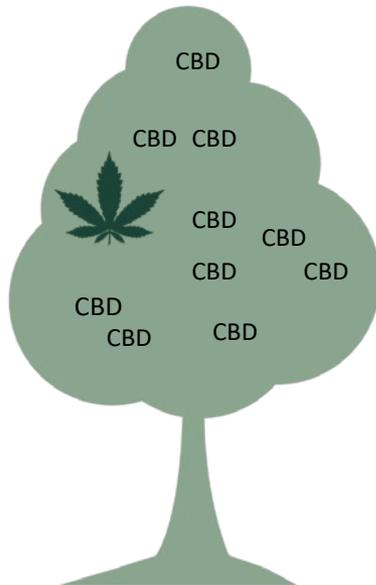
Different Uses:

- **Industrial Fiber** (rope, clothes)
- **Seed Oil** (hemp oil)
- **Food** (ground hemp seed for flour)
- **Recreation** (“high”)
- **Religious Customs** (native cultures in rituals)
- **Medicine** (Marinol[®], and Epidiolex[®] (CBD))

Cannabis Sativa L

Cannabis – Hemp - Marijuana

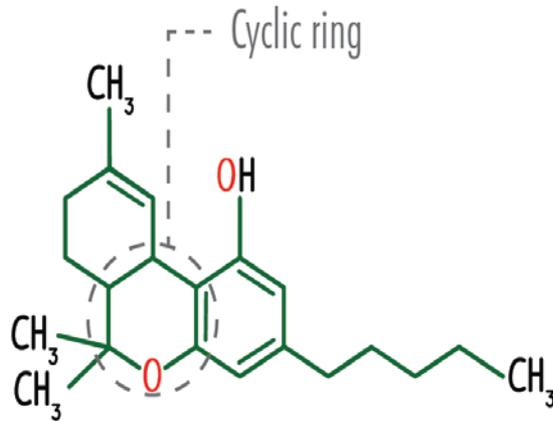
Commercial Hemp



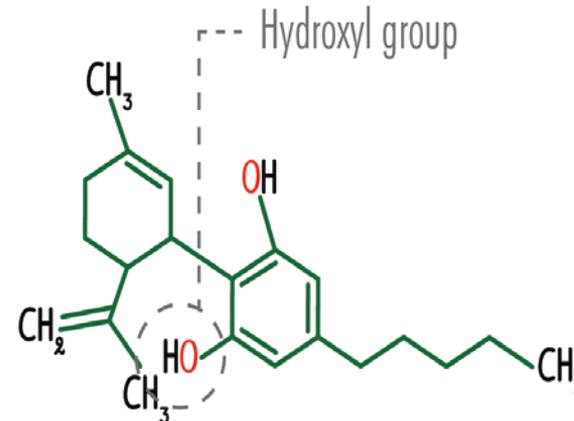
“Medical”/ Recreational
Hemp



Structural Similarity of CBD and Δ 9-THC Chemistry



Tetrahydrocannabinol (THC)



Cannabidiol (CBD)

Δ 9-THC

Molar Mass 314.469

C-21 H-30 O-2

CBD

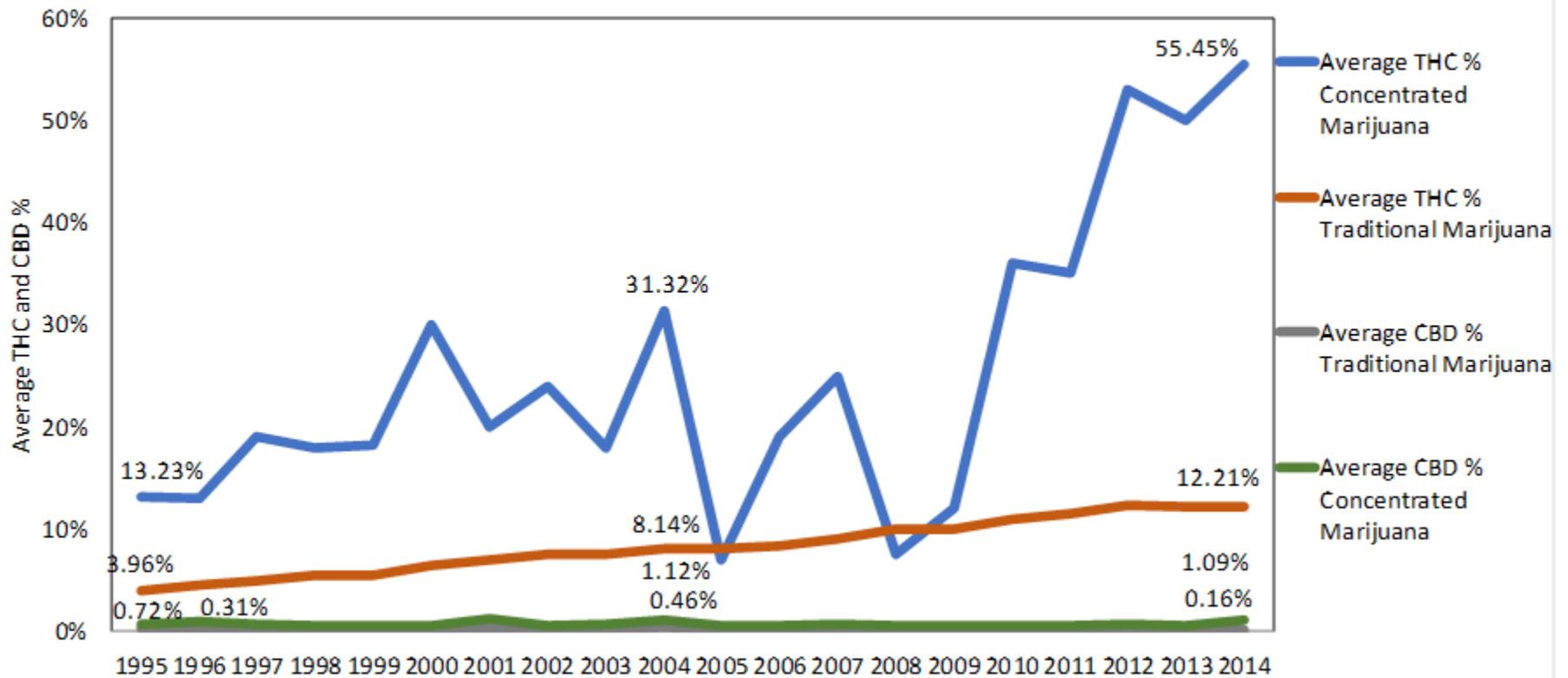
Molar Mass 314.464

C-21 H-30 O-2

Potency: The New Normal

- 1980s Marijuana: 4% THC
- Mexican Marijuana: 6 - 11% THC
- Current 2019 THC: 13 - 20% THC
- Hashish/Hashish Oil: 20 - 40% THC
- New Concentrates: 40 - 80% THC

Average THC and CBD % Marijuana Seizures 1995 – 2014



Marijuana's Acute Effects

Cognition

- Impaired short-term memory
- Difficulty with complex tasks
- Difficulty Learning

Executive Function

- Impaired decision-making
- Increased risky behavior

Mood (especially after high doses or edibles)

- Anxiety – panic attacks
- Psychosis - paranoia

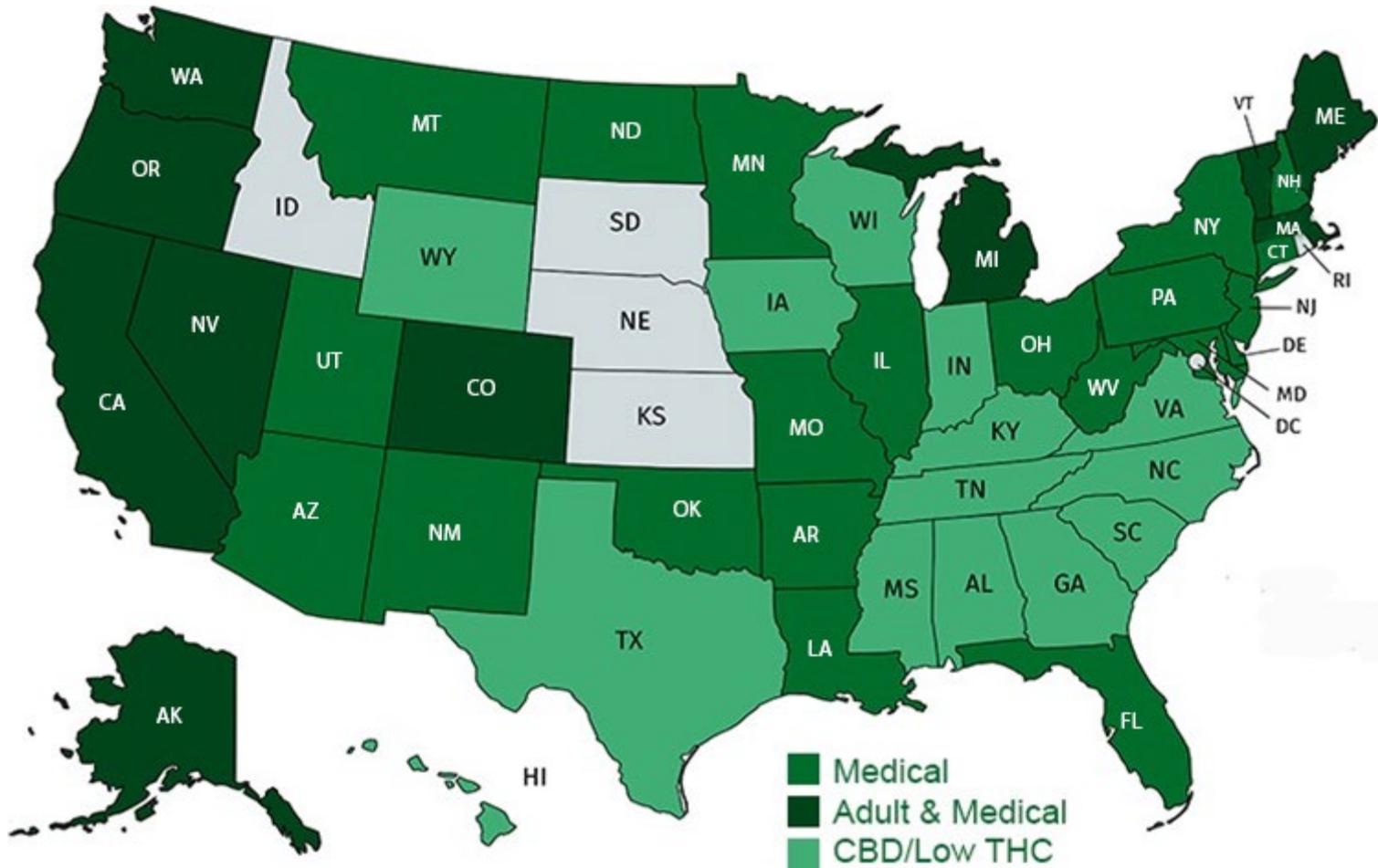
List of Known Marijuana Risk's

- Psychosis
- Agitated Delirium
- Suicides
- Seizures
- Drugged Driving
- Cannabinoid Hyperemesis Syndrome
- Cardiovascular Effects
- Pulmonary Affects
- Contaminant Infections
- Allergic Reactions
- Anti-Coagulant effects due to contaminants

Consuming Marijuana

- Smoking – Marijuana is absorbed through the capillaries in the lungs.
 - **Fast Onset of action short duration**
- Eaten / Drank – The chemicals in marijuana are absorbed into the small intestines.
 - **Slow Onset of action long duration**
- Mixed w/ Other Drugs – Marijuana and alcohol, smoked with cocaine, methamphetamine, PCP, and other drugs sprinkled (Fentanyl) .
 - **Entourage effect increased synergistic effects**

Marijuana Availability in USA 2019



Scheduling

- The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of a drug.
- A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States; a lack of accepted safety for use under medical supervision; and a high potential for abuse. These criteria are set by statute.
- The U.S. Food and Drug Administration (FDA) approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science.
- Recently (8/2016), the FDA and U.S. Drug Enforcement Administration (DEA) were petitioned to evaluate marijuana for potential rescheduling. Based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, it was determined that marijuana would remain a Schedule I controlled substance.

CBD/THC Medical Research

- CBD: Anti-inflammatory, anticonvulsant, antipsychotic, anti-oxidant, neuroprotective, immunomodulatory
- THC: Analgesic, anti-spasmodic, anti-tremor, anti-inflammatory, appetite stimulant, anti-emetic

Farm Bill

115TH CONGRESS
2^D SESSION

H. R. 5485

To amend the Agricultural Marketing Act of 1946 to provide for State and Tribal regulation of hemp production, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 12, 2018

Mr. COMER (for himself and Mr. POLIS) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committees on Energy and Commerce, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

Sec 7606 of the Agricultural Act of 2018 (Farm Bill)

- Permit agricultural research pilot programs to grow industrial hemp.
- The term “industrial hemp” includes the plant *Cannabis sativa* L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis.
- The term “tetrahydrocannabinols” includes all isomers (CBD), acids, salts, and salts of isomers of tetrahydrocannabinols.

Should we be worried about the “Farm Bill” ?

Concerns from a DEA Agent:

- High potency marijuana grown under the guise of “hemp.”
- Easier to sell mislabeled edible products made from hemp that contain THC.
- Impact to drug interdiction efforts and the security of our border by making it difficult to distinguish between marijuana and “hemp.”
- More difficult to detect and prevent citizens and workers who operate planes, trains, trucks, etc. from being under the influence of marijuana.

Commercialization of Marijuana

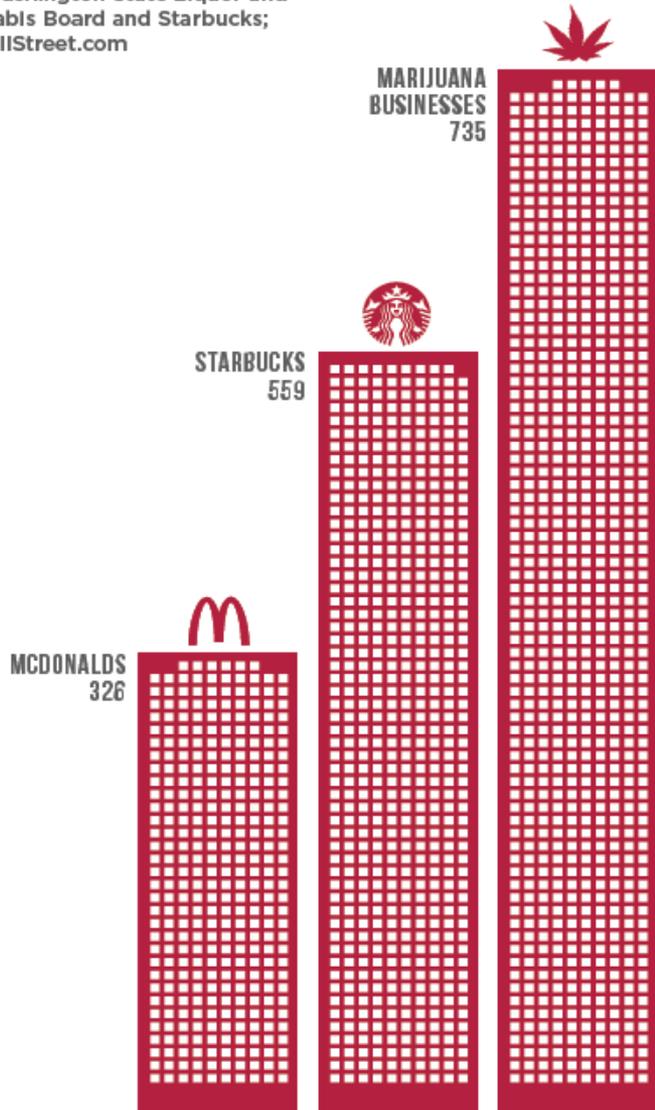
WHEN IS IT OFFICIALLY TIME FOR CONCERN?

WHEN MEDICAL MARIJUANA DISPENSARIES SQUEEZE OUT THE STARBUCKS OUTLETS.



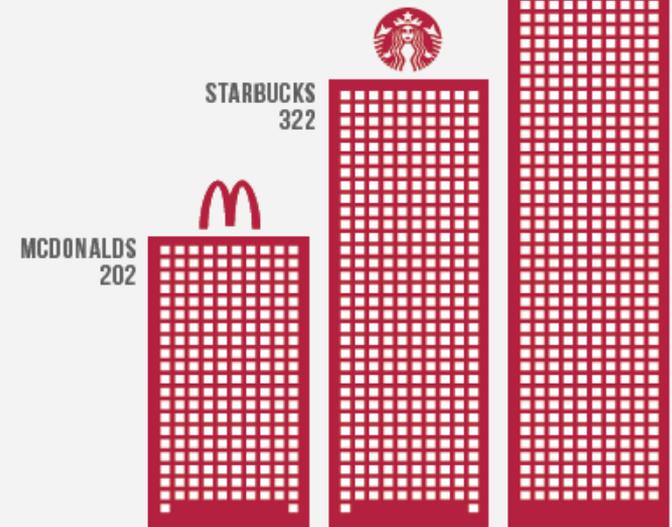
Washington State has more marijuana businesses than Starbucks or McDonalds

Source: NW HIDTA Report, citing the Washington State Liquor and Cannabis Board and Starbucks; 24WallStreet.com

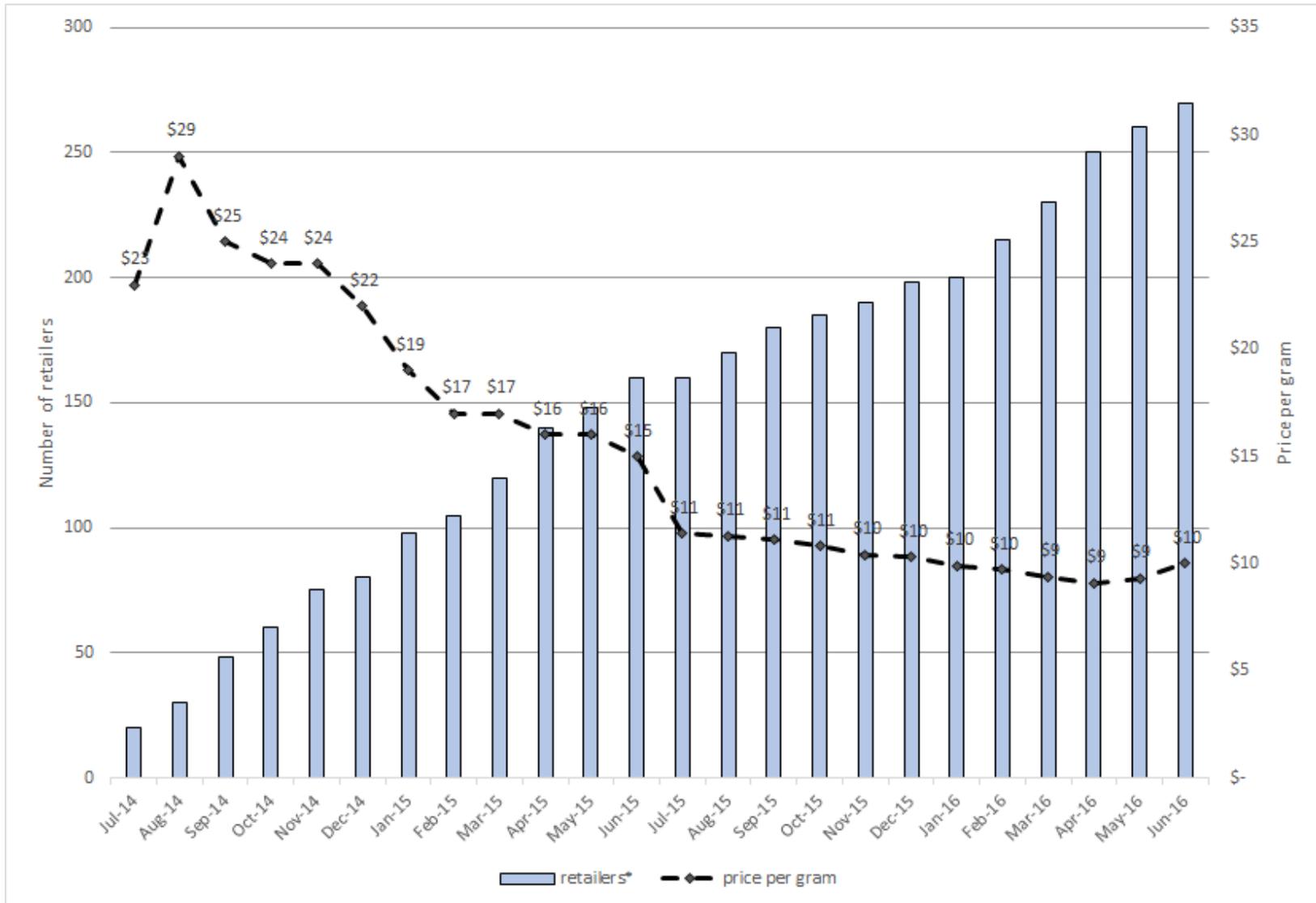


Colorado has more marijuana businesses than McDonalds and Starbucks combined

Source: Rocky Mountain HIDTA report #4 (September 2016)



WA State Price per Gram of Marijuana

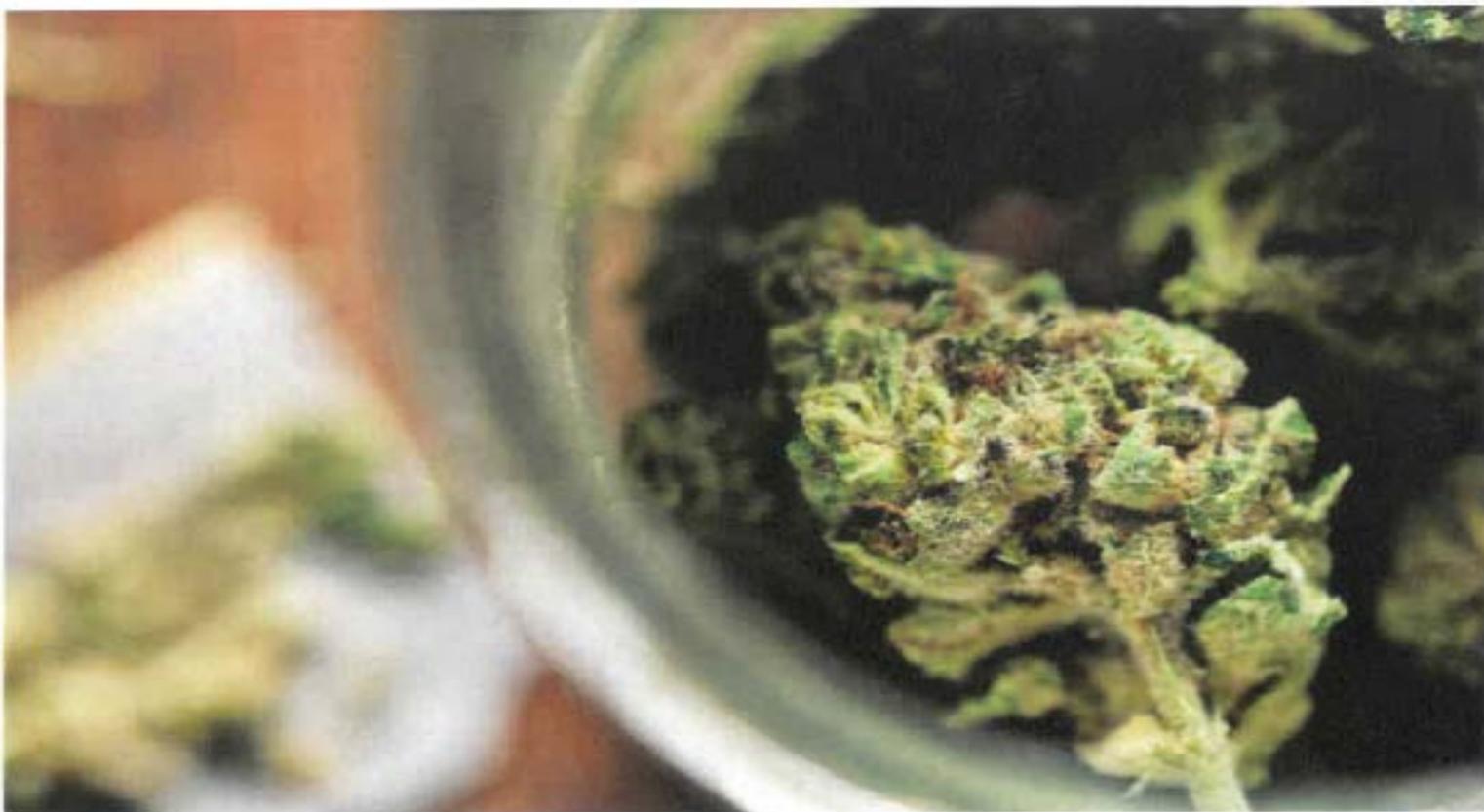


Forecasting and Research Division, WA office of Financial Management, 2017

Today's Headline May 31, 2019

Oregon, awash in marijuana, takes steps to curb production

Andrew Selsky, Associated Press Updated 7:23 am EDT, Friday, May 31, 2019



CBD for Pets



CBD Dosage Chart



SMALL



MEDIUM



LARGE

	DOG WEIGHT	# OF DROPS	DOG WEIGHT	# OF DROPS	DOG WEIGHT	# OF DROPS
250 MG BOTTLE	5-10 LBS	2-4	25-30 LBS	10-12	50-60 LBS	20-24
	10-15 LBS	4-6	30-35 LBS	12-14	60-70 LBS	24-28
	15-20 LBS	6-8	35-40 LBS	14-16	70-80 LBS	28-32
	20-25 LBS	8-10	40-45 LBS	16-18	80-90 LBS	32-36
			45-50 LBS	18-20	90-100 LBS	36-40
	1 DROP = .25 MG CBD				100-110 LBS	40-44
500 MG BOTTLE	5-10 LBS	1-2	25-30 LBS	5-6	50-60 LBS	10-12
	10-15 LBS	2-3	30-35 LBS	6-7	60-70 LBS	12-14
	15-20 LBS	3-4	35-40 LBS	7-8	70-80 LBS	14-16
	20-25 LBS	4-5	40-45 LBS	8-9	80-90 LBS	16-18
			45-50 LBS	9-10	90-100 LBS	18-20
	1 DROP = .50 MG CBD				100-110 LBS	20-22
1000 MG BOTTLE	5-10 LBS	NA	25-30 LBS	2-3	50-60 LBS	5-6
	10-15 LBS	1-2	30-35 LBS	3-4	60-70 LBS	6-7
	15-20 LBS	1-2	35-40 LBS	3-4	70-80 LBS	7-8
	20-25 LBS	2-3	40-45 LBS	4-5	80-90 LBS	8-9
			45-50 LBS	4-5	90-100 LBS	9-10
	1 DROP = 1.0 MG CBD				100-110 LBS	10-11

Comparison Shopping for Pet CBD Oil

PET CBD OIL COMPARISON CHART										
MILLIGRAMS (cost per mg)	holisticpet	Innovet	KING KANINE	HONEST PAWS	petreleaf	dogs naturally	HOLISTICHOUD	4Corners Cannabis	treatibles	
75mg			\$39.99 \$0.53/mg							
90mg										\$34.00 \$0.38/mg
100mg					\$28.99 \$0.29/mg			\$29.99 \$0.30/mg		
125mg		\$25.95 \$0.21/mg		\$39.95 \$0.32/mg						
150mg	\$25.95 \$0.17/mg		\$59.99 \$0.40/mg							
200mg					\$41.99 \$0.21/mg		\$34.99 \$0.17/mg			
225mg										
250mg		\$39.45 \$0.16/mg		\$49.95 \$0.20/mg		\$79.00 \$0.32/mg		\$54.99 \$0.22/mg	\$49.99 \$0.20/mg	\$52.00 \$0.21/mg
300mg	\$39.95 \$0.13/mg		\$89.99 \$0.53/mg		\$65.99 \$0.22/mg					
500mg				\$79.95 \$0.16/mg	\$85.99 \$0.53/mg		\$67.99 \$0.14/mg	\$98.99 \$0.20/mg	\$59.99 \$0.12/mg	
600mg	\$58.95 \$0.10/mg									
750mg		\$85.50 \$0.11/mg								\$120.00 \$0.16/mg
1000mg						\$149.00 \$0.15/mg			\$99.99 \$0.10/mg	
1250mg										
1500mg		\$119.95 \$0.8/mg								\$185.00 \$0.12/mg

* List prices updated 03/28/2019

Industrial Hemp or CBD products ?



CBD pain relief product ?

Revolutionary Pain Relief™ is finally a reality! CBD CLINIC products are the first to combine FDA-approved active ingredients with cannabidiol (CBD), a non-psychoactive and legal hemp extract*. Our proprietary formula begins to immediately interrupt and decrease pain signaling, so you can experience fast and long-lasting relief,

DRUG FACTS

Active ingredients: Menthol 16%, Camphor 11% (Topical Analgesics). **Uses:** Temporarily relieves minor aches and pain of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains. **Warnings:** For external use only. Do not use on wounds or damaged skin. When using this product • avoid contact with eyes or mucous membranes • do not bandage tightly or use with a heating pad. Stop use and ask a doctor if • condition worsens or symptoms persist for more than 7 days • symptoms clear up and occur again within a few days • excessive skin irritation develops. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately. **Directions:** Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 12 years of age: Ask a doctor. **Inactive ingredients:** beeswax (organic), clove oil, cotton seed oil, eucalyptus oil, hemp extract, jojoba seed oil, magnesium oxide, peppermint oil, silver oxide, tea tree oil, zinc oxide.

CONTACT US www.cbdclinic.co or 303-223-0863

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*Cannabidiol Rich Hemp Extract in accordance with Sec. 7606 of Agricultural Act of 2014 (7 U.S.C. 5940)

EXP 07-21-19

Epidiolex® FDA Approved June 27, 2018



Epidiolex[®] (Schedule V)

- GW Pharma cannabinoid product that is a proprietary oral solution of pure [plant-derived cannabidiol](#), or CBD.”
- Treatment for seizures
 - Lennox-Gastaut syndrome
 - Dravet syndrome
- Oral solution; starting dose 2.5 mg/kg twice daily, increase to 5 mg/kg after one week, maximum dose recommended 10 mg/kg
- Patients 2 years of age and older
- Does not produce cannabinoid-like behavioral responses like THC
- Formulated in dehydrated ethanol, sesame seed oil, sucralose, and flavoring
- “Advise patients of the potential for positive cannabis drug screens”
- Average annual cost \$32,000

Policy

OPM Memo Concerning Marijuana Use 2015

- From: Katherine Archuleta, Director, U.S. OPM
- Subject: Federal Laws and Policies Prohibiting Marijuana Use
- Date: May 26,2015
 - “Federal law on marijuana remains unchanged. Marijuana is categorized as a controlled substance under Schedule I of the Controlled substance Act. Thus knowing or **intentional marijuana possession is illegal**, even if an individual has no intent to manufacture, distribute, or dispense marijuana. In addition, Executive Order 12564, Drug-Free Federal Workplace, mandates that (a) Federal employees are required to refrain from use of illegal drugs; (b) the use of illegal drugs by Federal employees, whether on or off duty, is contrary to the efficiency of the service...”

DoD Position on Marijuana in 2018



**PERSONNEL AND
READINESS**

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

FEB 27 2018

MEMORANDUM FOR CHIEF, NATIONAL GUARD BUREAU
ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND
RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE ARMY FOR MANPOWER
AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE NAVY FOR MANPOWER
AND RESERVE AFFAIRS
ASSISTANT SECRETARY OF THE AIR FORCE FOR MANPOWER
AND RESERVE AFFAIRS

SUBJECT: Prohibition on the Use of Marijuana or its Chemical Components by Military
Service Members and Department of Defense Civilian Employees

SAMHSA Memo on Marijuana Oils in 2017



DATE: November 22, 2017

TO: Federal Agency Drug Program Coordinators, Federal Medical Review Officers,
Federal Partners

FROM: Ron Flegel, B.S., MT (ASCP), M.S.
Director, Division of Workplace Programs
Center for Substance Abuse Prevention

SUBJECT: Use of Marijuana Oils or Marijuana Infused Commercial products

Office of the Commissioner
MAJOR LEAGUE BASEBALL



M E M O R A N D U M

TO: All Major League and Minor League Players and Club Employees

FROM: Jon Coyles

DATE: March 14, 2019

RE: Cannabidiol (CBD)

Truth in Labelling: CBD/THC Products

- JHU study (Vandery et al. 2015)
 - Tested for THC and CBD**
 - 75 products purchased- 47 different brands
 - 17% - (13) labelled accurately
 - 23% - (17) under labelled (contained more than advertised)
 - 60% - (45) over labelled (contained less than advertised)
- JHU study (Bonn-Miller et al. 2017)
 - Tested for CBD**
 - 84 products varied from 0.1 to 655 mg/mL
 - 31% - (26) labelled accurately
 - 43% - (36) under labelled (contained more than advertised)
 - 26% - (22) over labelled (contained less than advertised)
 - THC content varied from 0 to 6.4 mg/mL

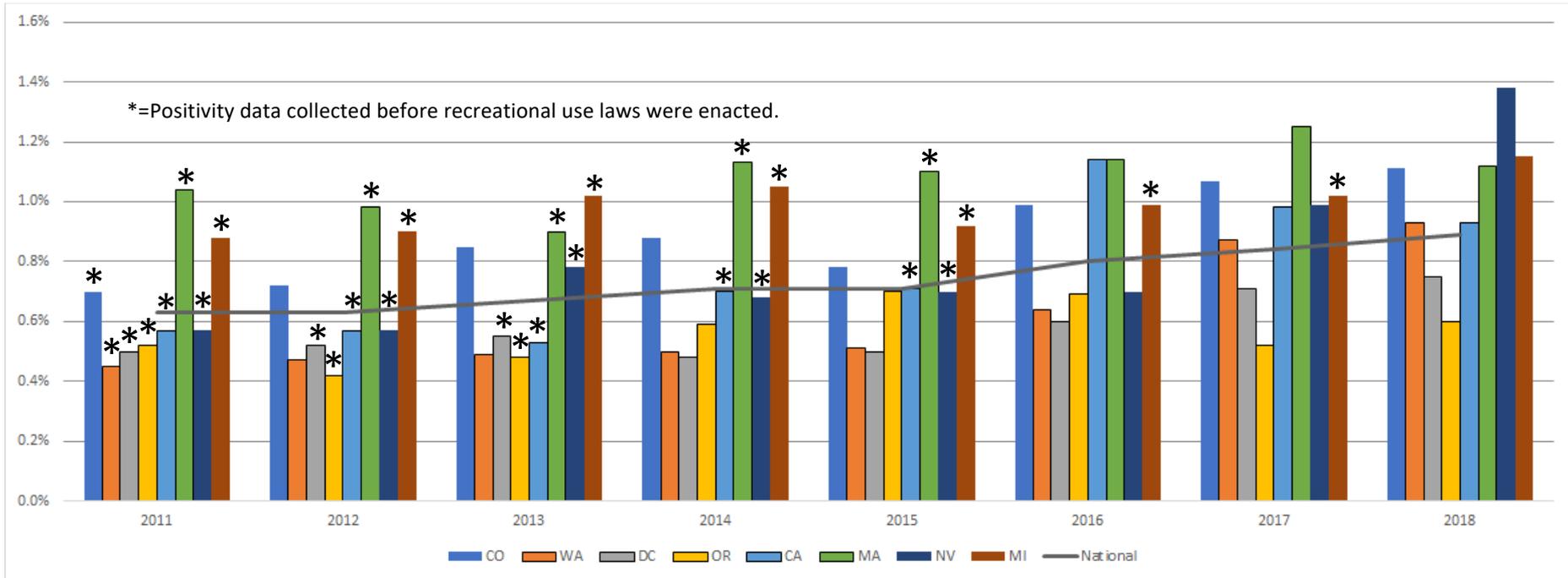
JAMA June 23/30, 2015 Volume 313, Number 24
JAMA November, 2017 Volume 318, Number 17

CBD Scientific Research Questions

- **Can CBD be converted to THC in vitro?**
 - Acid catalyzed conversion of CBD to THC (Gaoni, 1968)
 - CBD converted to THC by derivatization with TFA (Andrews and Paterson, 2012)
 - CBD in SGF converted rapidly to Δ -9-THC and Δ -8-THC in a 1.5:1 ratio (Merrick, et al., 2016) (Watanabe, et al., 2007)
- **Can CBD be converted to THC in vivo?**
 - Rats treated with oral and sc CBD had THC in serum (Hlozek, et al. 2017)
 - Minipigs treated with oral CBD did not have THC in plasma (Wray, et al., 2018)
 - A Conversion of Oral Cannabidiol to Delta9-Tetrahydrocannabinol Seems Not to Occur in Humans (Nahler, et al., 2017)
 - Some literature suggests small amounts of Δ -9-THC and Δ -8-THC are human urinary metabolites of CBD (Ujvary and Hanus, 2016) (Harvey, et al., 1991)

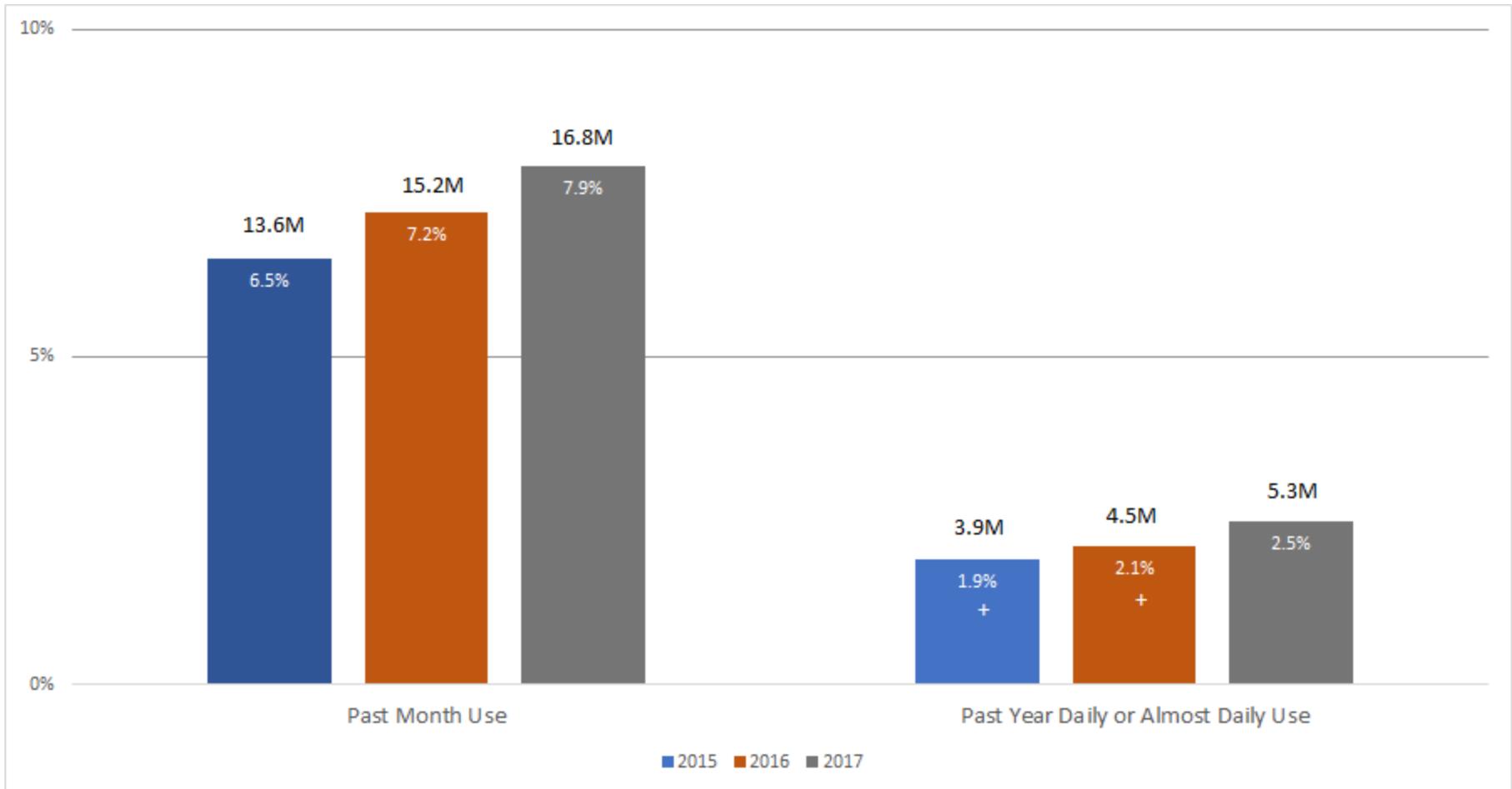
Marijuana Positivity in Recreational Use States

Federal and Federally Mandated Safety-Sensitive Workplace



Quest Diagnostics Drug Testing Index full year 2018

Marijuana Use among Adults, 25+



Questions?

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SAMHSA/CSAP/DWP

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