# Jo McGuire

Chairman and Executive Director

National Drug and Alcohol Screening Association

## Saturday, August 10, 2019

(Room 6)

14:00 - 14:55 WS #108: How Medical Cannabis is Treating the U.S.

15:05 - 16:00 WS #118: How Medical Cannabis is Treating the U.S. (Repeated)

# HOW MEDICAL CANNABIS IS TREATING THE U.S.

**Jo McGuire**
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# **Medical** Cannabis Confusion



Let's get some **clarity** about MC

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# Colorado Medical Cannabis Demographics

Table 2. Top reported conditions by age group

| Age Group | Number of Patients | Percentage on Registry | Top Reported Condition |
|---|---|---|---|
| 0-10 | 167 | 0.20% | Seizures |
| 11-17 | 170 | 0.20% | Severe Pain |
| 18-20 | 3,439 | 4.09% | Severe Pain |
| 21-30 | 18,148 | 21.61% | Severe Pain |
| 31-40 | 18,440 | 21.96% | Severe Pain |
| 41-50 | 13,469 | 16.04% | Severe Pain |
| 51-60 | 12,771 | 15.21% | Severe Pain |
| 61-70 | 13,288 | 15.82% | Severe Pain |
| 71 and Older | 4,092 | 4.87% | Severe Pain |

Table 3. Frequency of conditions

| Reported Condition | Number of Patients Reporting Condition | Percentage of Patients Reporting Condition** |
|---|---|---|
| Cachexia | 1,149 | 1.37% |
| Cancer | 4,416 | 5.26% |
| Glaucoma | 1,132 | 1.35% |
| HIV/AIDS | 0 | 0.00% |
| Muscle Spasms | 30,341 | 36.13% |
| Seizures | 3,015 | 3.59% |
| Severe Nausea | 14,657 | 17.45% |
| Severe Pain | 78,198 | 93.11% |
| Post-Traumatic Stress Disorder (PTSD) | 9,334 | 11.11% |
| Autism Spectrum Disorder | 91 | 0.11% |

**Does not add to 100% as some patients report more than one debilitating or disabling medical condition.

# THC Alone is NOT Medical Cannabis

## THC (tetrahydrocannabinol):

- Psychoactive (the high) with impairing side effects
- Temporarily dulls pain receptors
- Mild to moderate analgesic effect
- Tolerance increases, requiring more
- Becoming more purified → more potent (18-30% in raw plants in CO)
- Disables cannabinoid receptors

You don't "smoke" medicine!

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# Why is Cannabis Federal Schedule 1 in the U.S.?

- ✓ There is a high potential for abuse
- ✓ Lack of any accepted medical use
- ✓ No accepted safety standards for use under medical supervision
- ✓ Unable to regulate dosing standards

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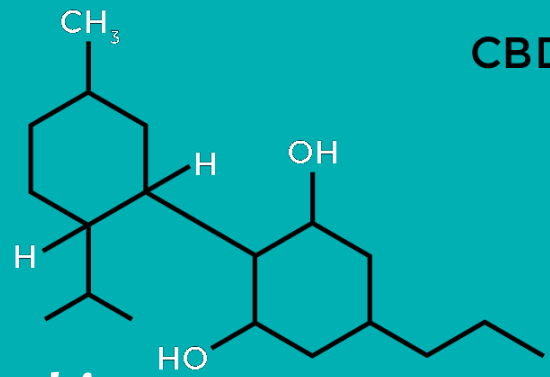
# NO "PRESCRIPTION" FOR MC

# CBD has Potential for Medical Use

## CBD (cannabidiol):

- Suppresses the psychoactive effect of THC
- Cannot exist in raw cannabis in equal amounts to THC over 3%
- Pharmaceutical grade CBD has shown promise in clinical trials as an:
  - Anti-inflammatory
  - Analgesic
  - Anti-convulsant
  - Anti-psychotic
  - Anti-oxidant
  - Neuroprotectant
- ***CBD has been bred out of most modern herbal cannabis***



CBD

Alice P. Mead; Finding the Medicine in Marijuana; Oct 1, 2015; GW Pharmaceuticals

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# CBD Clarity

- Raw CBD (still raw cannabis) is a Schedule 1 drug
- The ratio of THC and CBD used in **pharmaceuticals** is 1:1
- Some OTC products contain CBD from hemp
- The majority of products claiming to contain CBD are fraudulent, containing no CBD
  - Over 600 samples tested in Colorado
  - Most were THC-rich with no CBD
  - Those containing CBD had on average 0.1%

Alice P. Mead; Finding the Medicine in Marijuana; Oct 1, 2015; GW Pharmaceuticals
http://www.nbcnews.com/storyline/legal-pot/legal-weed-surprisingly-strong-dirty-tests-find-n327811

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# Raw Plant is Not Medicine

Standardization and stabilization of the raw plant material is extremely difficult

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# The Modern Medication Approach…

## …is very important (part 1):

- Products required to meet standards of modern medicine
- Standardized by composition and dosage
- Delivered like other pharmaceutical products; not smoked;
- Clinical and preclinical studies ensure physicians have appropriate prescribing information
- Prescription only; patients obtain only through monitored health care sources, i.e., pharmacy

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GW Pharmaceuticals, Mead, 2012; Finding the Medicine in Marijuana

# The Modern Medication Approach…

## …is very important (part 2):

- Reimbursed by health insurance
- Registration/inspection ensures that manufacturing process conducted in accordance with validated quality control tools
  - Manufacturers accountable for defective products
- Promotional activities of manufacturers limited
- Products dispensed under the supervision of licensed health care providers, e.g., physicians, pharmacists

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GW Pharmaceuticals, Mead, 2012; Finding the Medicine in Marijuana

| | "Medical Marijuana" | Cannabis Based Medicine – Sativex® |
|---|---|---|
| **Product Development** | None | World class academic / scientific research programme |
| **Clinical Evaluation** | None | Regulated pre-clinical and clinical evaluation to prove Efficacy, Safety and Quality |
| **Raw Material Production** | Grown in uncontrolled, unregulated conditions resulting in variability<br><br>Herbal cannabis is predominantly grown for high potency of THC only | Consistent materials due to highly controlled growing conditions, growing medium and documentation.<br><br>Sativex® is made from an extract of cannabis plants containing a ratio of 1:1 THC and CBD as well as other active cannabinoids.<br><br>Plants are bred specifically to consistent cannabinoid profile and potency |

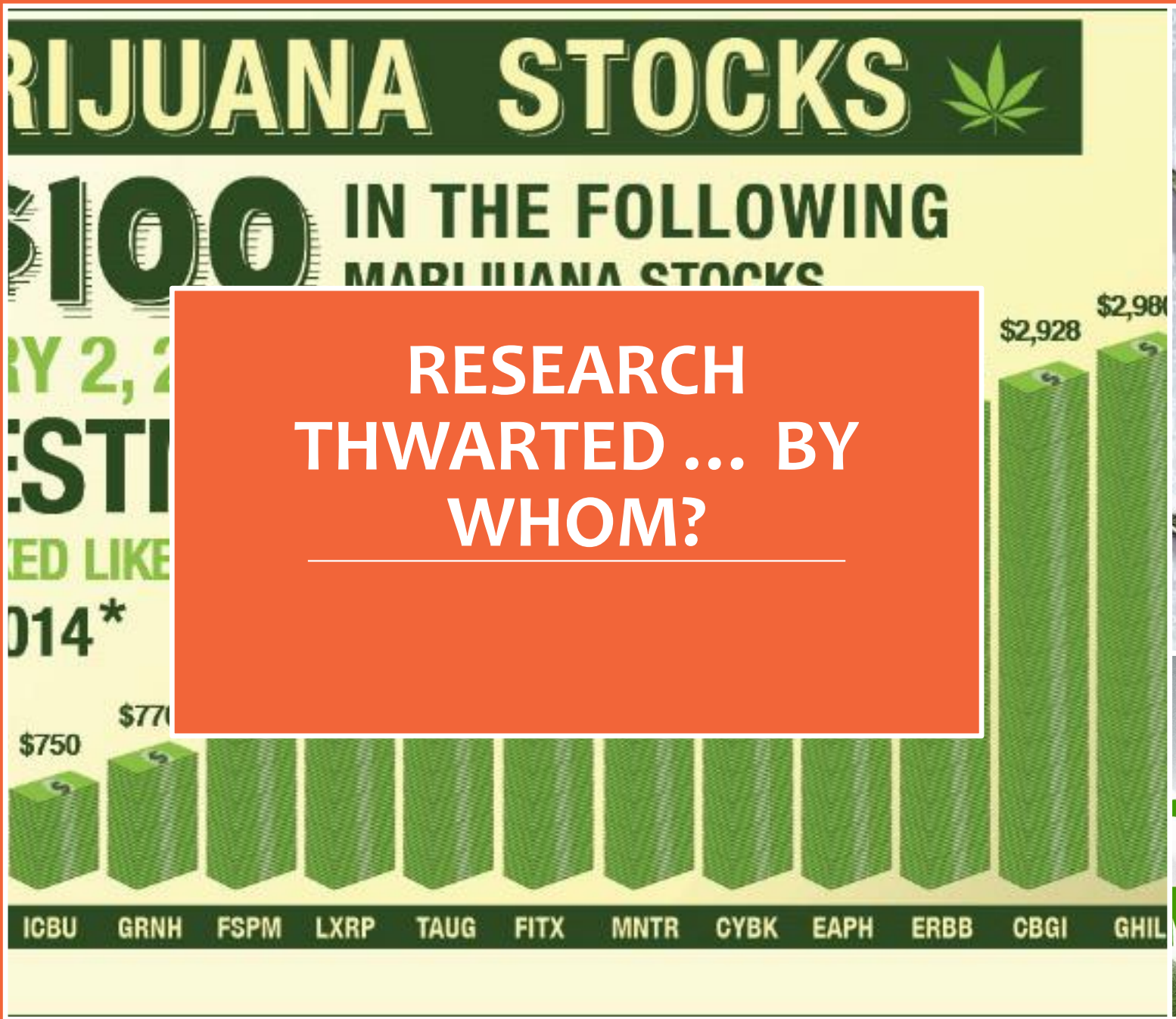
GW Pharmaceuticals, Mead, 2012; Finding the Medicine in Marijuana

| | Medical Marijuana | Cannabis Based Medicine – Sativex® |
|---|---|---|
| **Manufacturing Process** | Process is not registered or regulated in any way | Manufactured to Good Manufacturing Practices (GMP) in regulated facilities to processes that are registered with the competent authorities and inspected regularly |
| | Dried material packaged in basic packaging materials | Results in a quality, consistent and safe product made to the highest pharmaceutical industry standards |

GW Pharmaceuticals, Mead, 2012; Finding the Medicine in Marijuana

| | "Medical Marijuana" | Cannabis Based Medicine – Sativex® |
|---|---|---|
| **Delivery system** | Smoked, inhaled or consumed orally | Novel delivery system, oromucosal spray |
| **Supervision by Patient's Treating Physician** | "Recommending" physician may not be involved in patient's care; treating MD may not be aware of patient's use<br><br>Medical advice given by untrained personnel. | Approved medicine is prescribed by registered physician with access to full product information to make an informed decision<br><br>Patient Leaflet supplied with every pack<br><br>National controls on prescribing and safety monitoring |
| **Security of Supply** | Limited control on provision to patients.<br><br>Easily diverted to non-medical use; no reliable records kept<br><br>None | Secure distribution route from manufacture to patient.<br><br>Packaging designed to protect the product from contamination, adulteration, diversion and counterfeiting |

GW Pharmaceuticals, Mead, 2012; Finding the Medicine in Marijuana




# RESEARCH THWARTED … BY WHOM?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# CBD Clarity

## THC

(Tetrahydrocannabinol)

## CBD

(Cannabidiol)

**Sativex, Epidiolex, Dronabinol**

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# CBD Clarity

## THC + CBD

Artisanal Products

## CBD

Pharmaceuticals

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# Marketed as Medicine




# Pharmaceutical



Photo: GW Pharmaceuticals

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# What About Efficacy?

Unfortunately, there is currently no clear, scientific evidence showing that marijuana improves epilepsy in children. Healthcare providers and families need comprehensive research to assess both the benefits and risks of medical marijuana with more certainty.

## Current CBD studies for the treatment of epilepsy

Children's Hospital Colorado

Phase III placebo controlled studies of cannabidiol (CBD), are being completed currently. When the results from these studies are fully available, we will better understand the potential role of CBD in treatment of epilepsy. In these studies, pharmaceutical grade CBD oil, Epidiolex, is added to current seizure medication treatment regimes.

It's important to note that the CBD oil used in the clinical trials is vastly different than the artisanal cannabis products available in Colorado. In states like Colorado, where medical marijuana and its derivatives are legal, the content of CBD products is not regulated for purity or uniformity. Pharmacy-grade products like Epidiolex have followed Good Manufacturing Processes, meaning that the CBD content is measured by rigorous standards and is carefully monitored for additives or contaminants. Even the equipment used for manufacturing these products meets rigorous standards. None of this is guaranteed to be true for the artisanal products.

www.childrenscolorado.org/conditions-and-advice/marijuana-what-parents-need-to-know/medical-marijuana/medica-marijuana-and-epilepsy/

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# The CBD craze is getting out of hand. The FDA needs to act.

A syringe with a dose of CBD oil is shown in a research laboratory in Fort Collins, Colo., in 2017. (David Zalubowski/AP)

By **Scott Gottlieb**
July 30

*Scott Gottlieb, a resident fellow at the American Enterprise Institute, was the 23rd commissioner of the Food and Drug Administration from May 2017 to April 2019. He consults for and invests in biopharmaceutical companies.*

Cannabidiol — better known as CBD — is everywhere, from small specialty shops to large national retail chains. It can be found in foods, supplements, drugs, oils, creams, pet foods and more, and sellers purport that the compound treats everything from cancer to depression. Analysts say the market could surpass $20 billion by 2024.

But many of the compound's expansive benefits are fanciful, and in fact, the sale of much of the product is illegal under current law. The Food and Drug Administration must act to make sure commercial interests don't strip away any legitimate value that the compound might have.

# What About Efficacy?

## Former Food & Drug Administrator, Scott Gottlieb, Speaks Out

The Washington Post

https://www.washingtonpost.com/opinions/the-cbd-craze-is-getting-out-of-hand-the-fda-needs-to-act/2019/07/30/94c8024c-b211-11e9-8f6c-7828e68cb15f_story.html?fbclid=IwAR1zxbUgp3mYYkJpFwS1I-HFcthmtBTulUu-9z1tKt_oQYE4dD_AgWbJRao

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# "CBD" Products are Everywhere




Photo: Blitzed Vapor CBD Infused Coffee

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# “Gas & Grass” Station



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# Snake Oil?

## What about medical use of other illicit drugs or alcohol?

- There is a movement for decrim of heroin & psilocybin as "medicine"
- How do you make allowance for some illicit drugs and not others?
- We've been down this path historically … why are we repeating history?
- Legislating "medicine" is a bad idea

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# WHAT'S REALLY GOING ON HERE?

# "BIG MARIJUANA" Strategy

*"We are trying to get marijuana reclassified medically. If we do that, we'll be using the issue as a red herring to give marijuana a good name. That's our way of getting to them (New Right) indirectly."*

***NORML Chairman Keith Stroup***
*The Emory Wheel, Emory University*

*"The key to it [legalization] is medical access because once you have hundreds of thousands of people using marijuana medically under medical supervision the whole scam is going to be blown...Once there's medical access and if we continue to do what we have to do-and we will-then we'll get full legalization."*

***Richard 'Dick' Cowen***
***National Director of NORML***
*While at a conference celebrating the anniversary of LSD*

GOAL: Normalise the use of marijuana nationally

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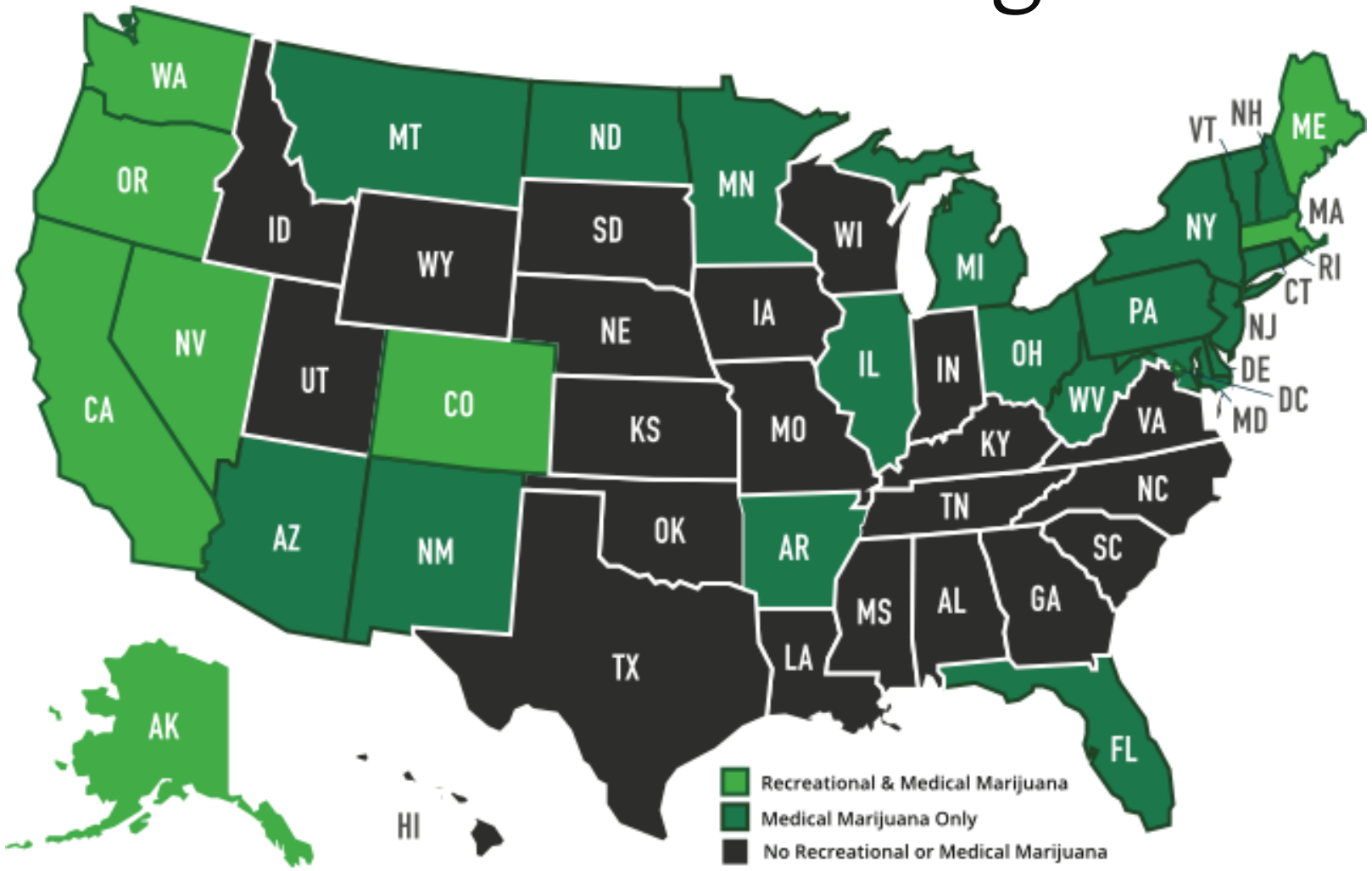
# How Is It Working?




Normalise the use of marijuana nationally

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# “But it’s just a plant…”

## (80 to 90% THC) Concentrates

“Ear Wax”

“Green Crack” Wax

Butane Hash Oil (BHO)

“Budder”

Hash Oil Capsules

“Shatter”

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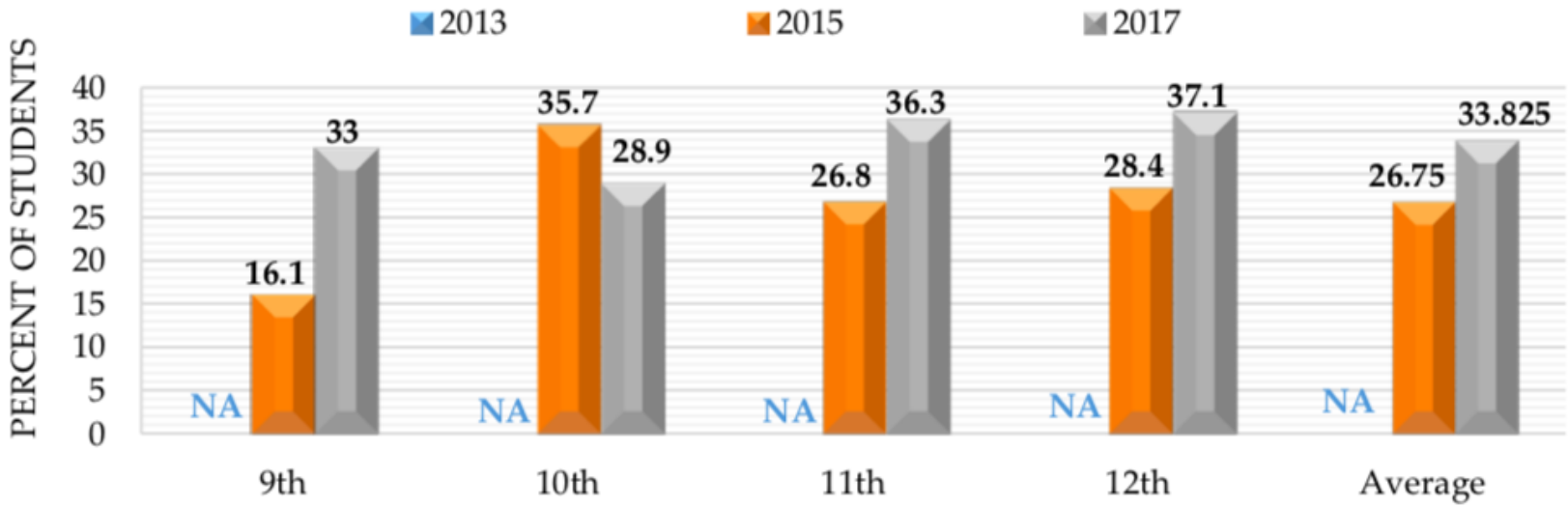
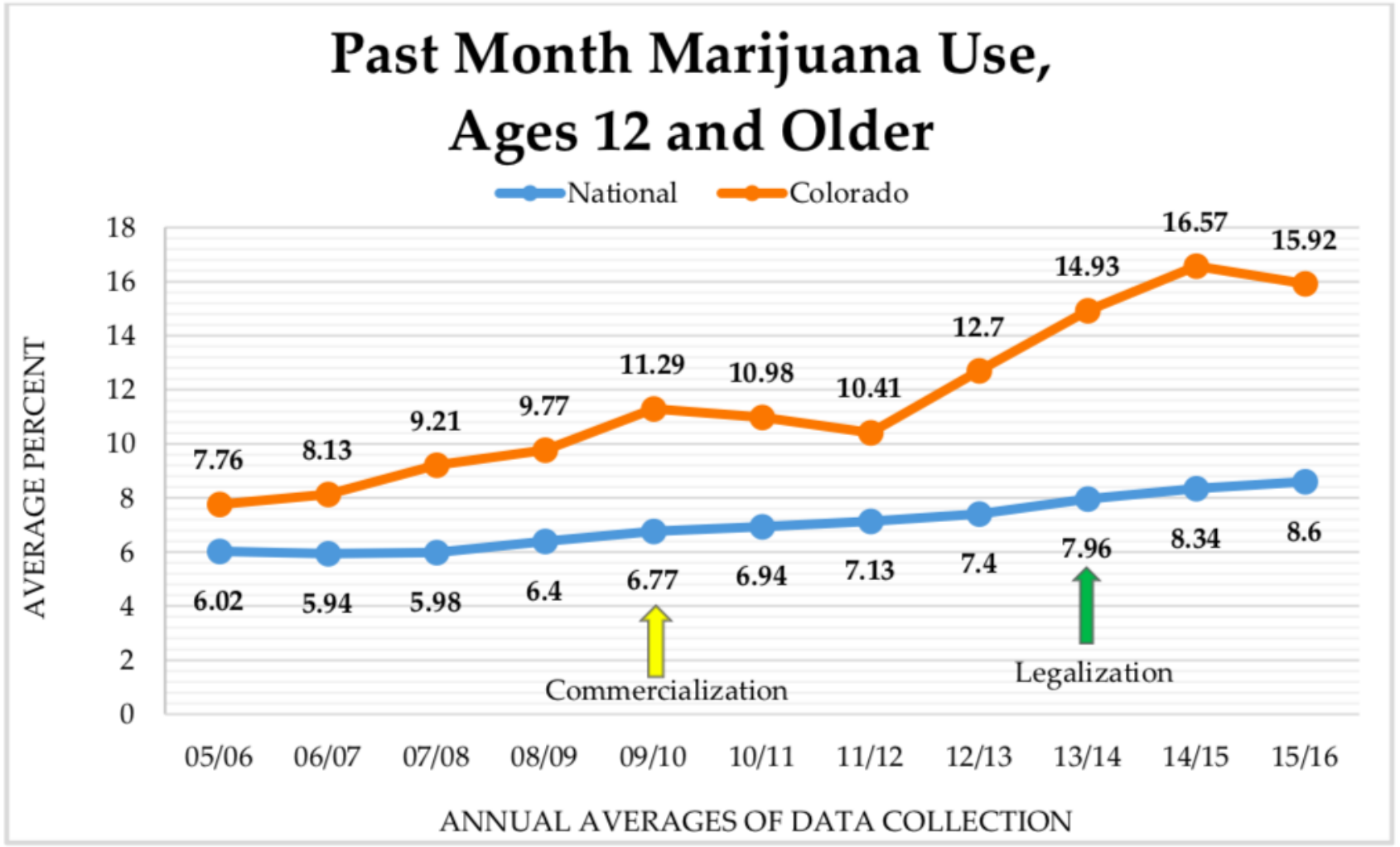
# Among Students Who Used Marijuana within the Past 30 days, the Percentage Who Dabbed* it




*Dabbing is the process of vaporizing concentrated marijuana, usually in the form of wax or resin, by placing it on a heated piece of metal and inhaling the vapors. Concentrated marijuana is known to often contain 70 percent or higher levels of THC, the psychoactive component of marijuana.

**SOURCE:** **Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey**




**SOURCE:** **SAMHSA.gov, National Survey on Drug Use and Health 2015 and 2016**

- Colorado was **85% higher** than the National average in 2015/2016

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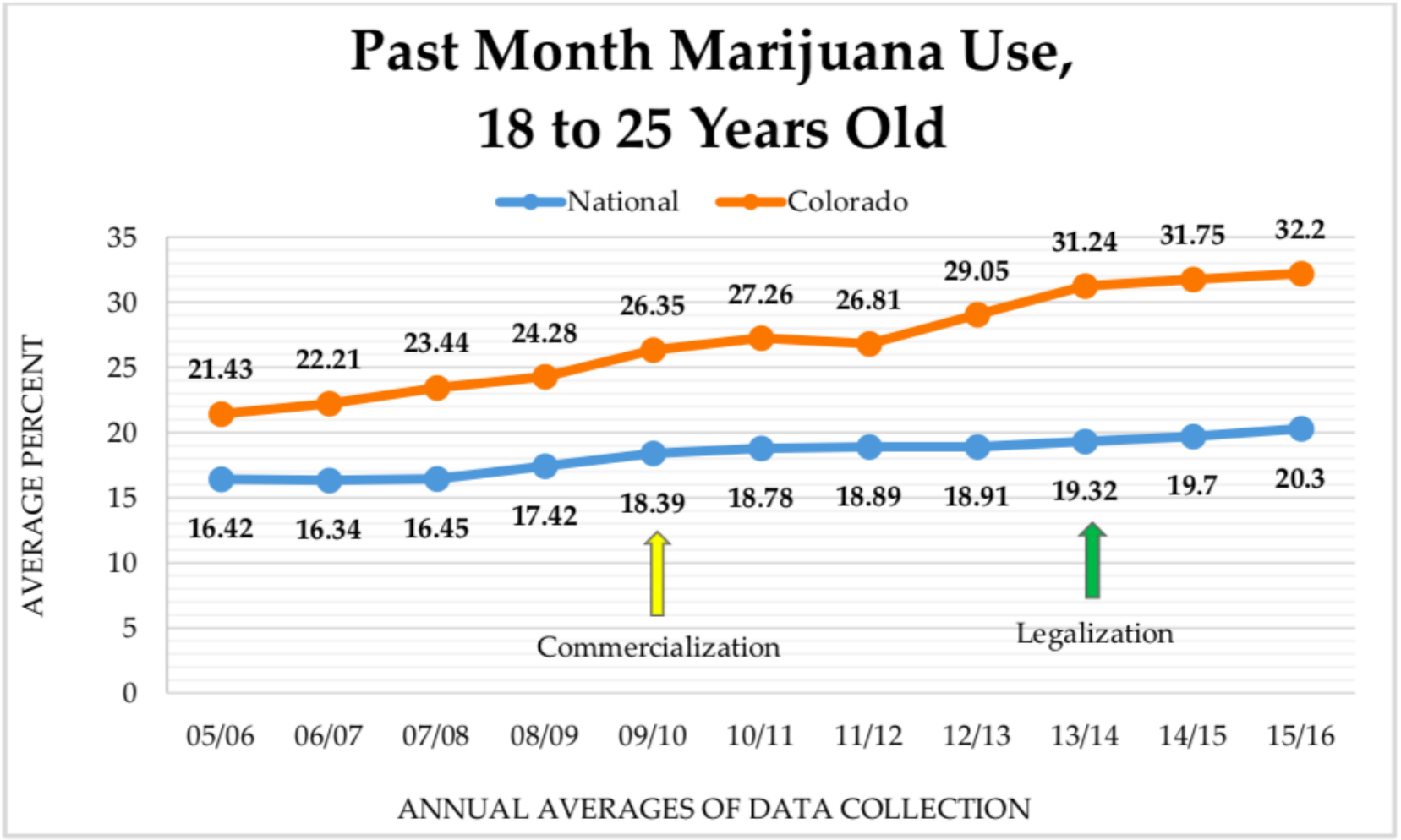
# Past Month Marijuana Use, 18 to 25 Years Old




**SOURCE:** **SAMHSA.gov, National Survey on Drug Use and Health 2015 and 2016**

- Colorado was **59% higher** than the National average in 2015/2016

Terminal

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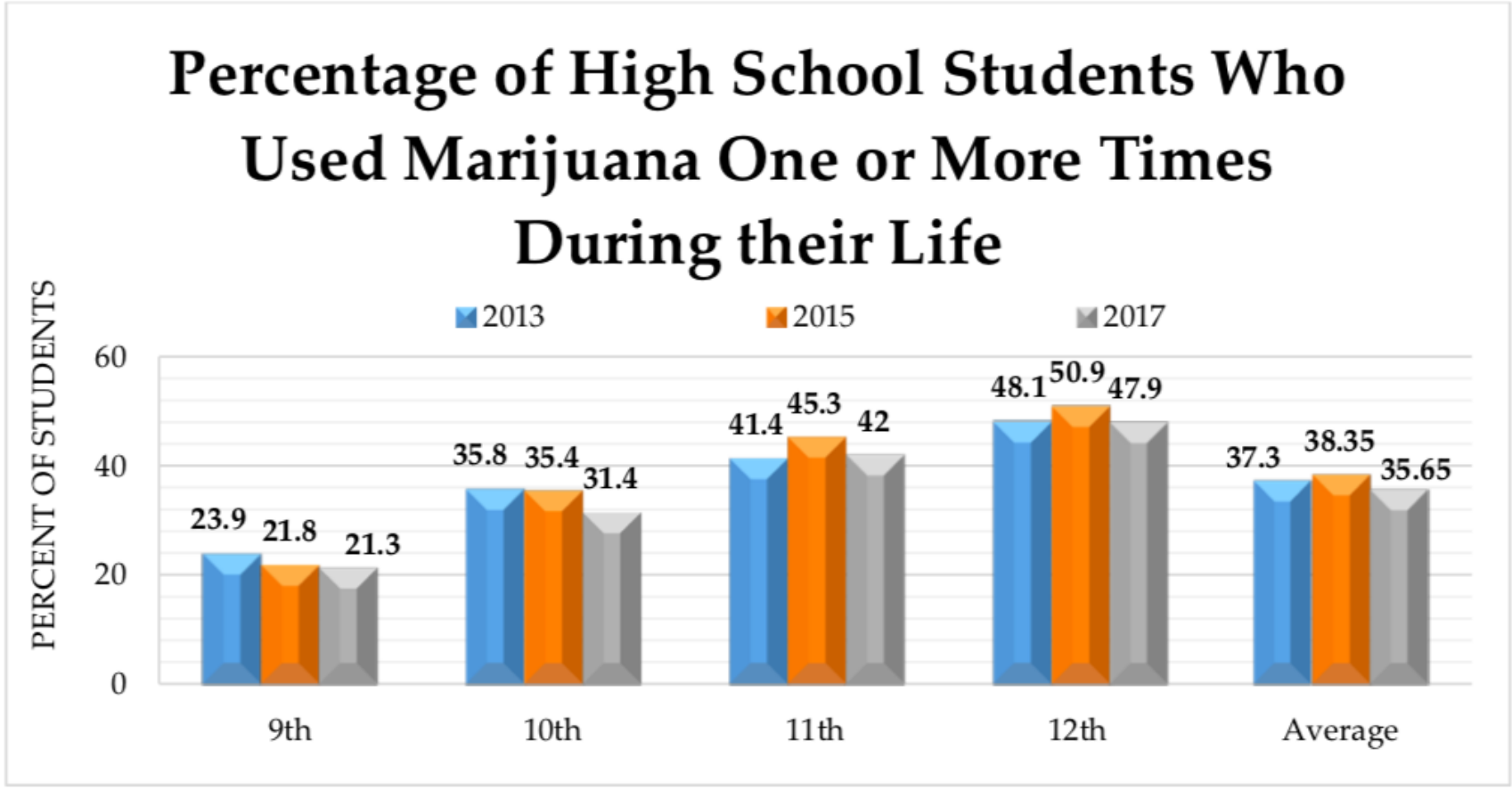
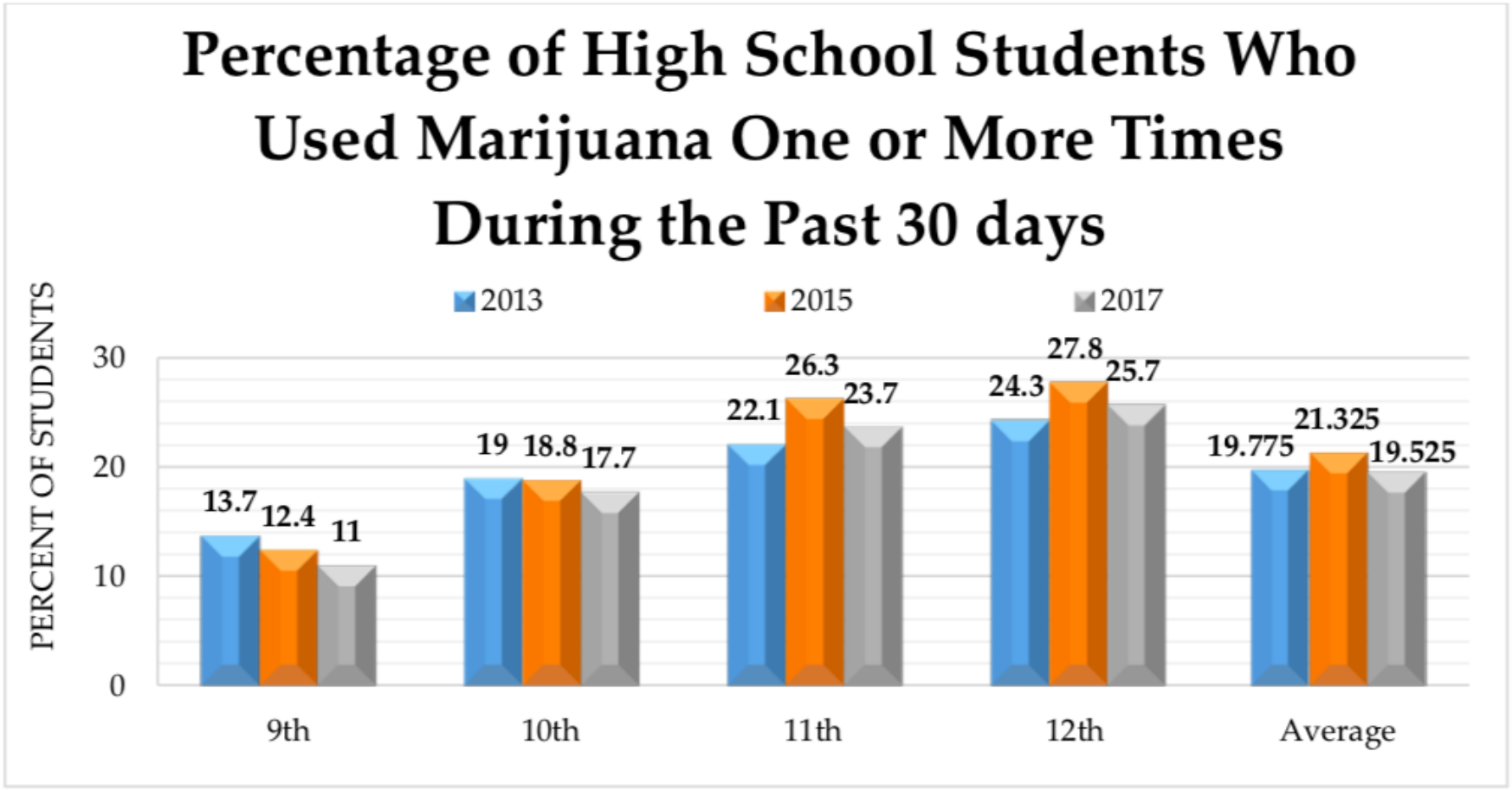
# Healthy Kids Colorado Survey (HKCS) Data



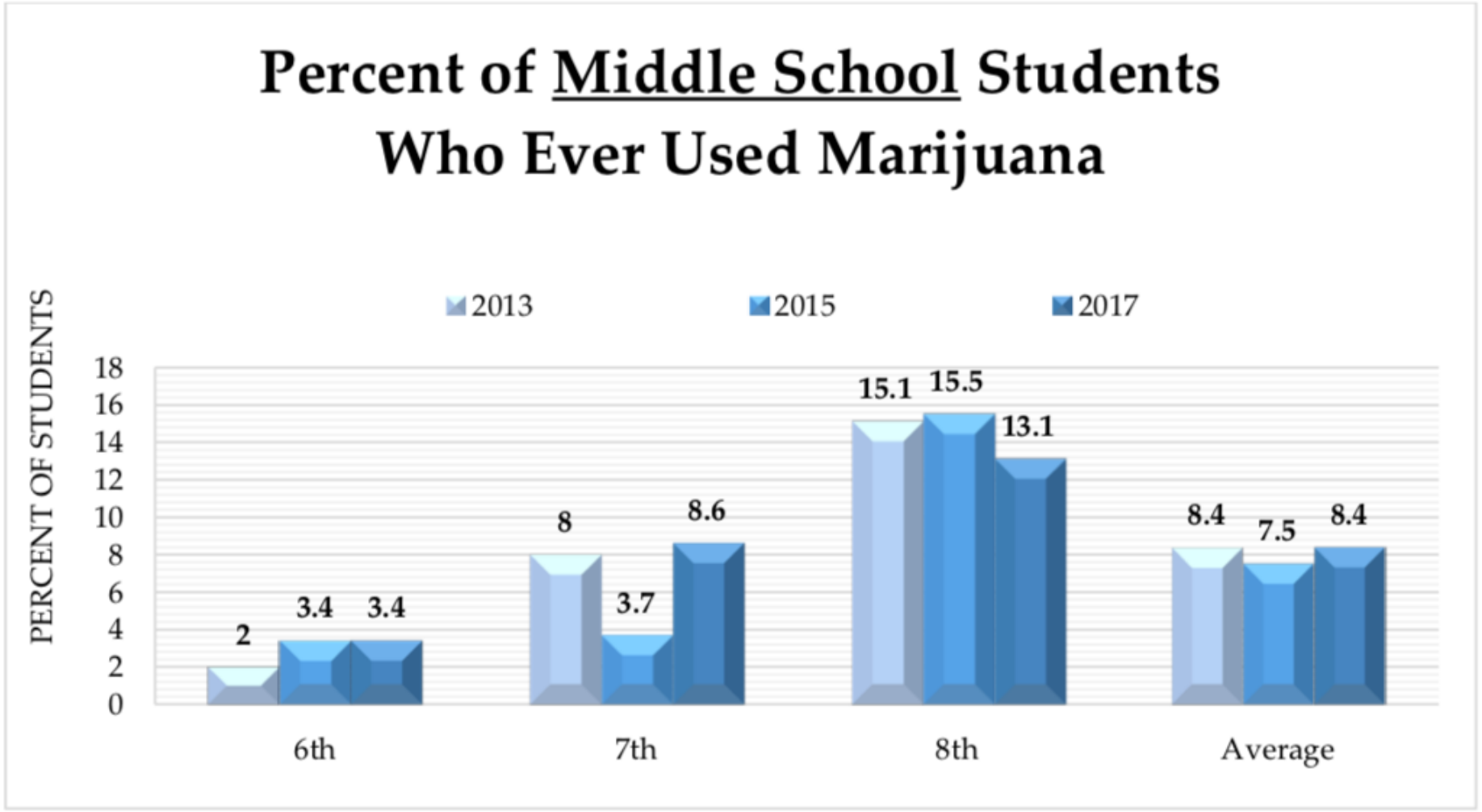

**SOURCE:** Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey

# Percentage of High School Students Who Used Marijuana One or More Times During the Past 30 days




**SOURCE:** Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey

# Percent of Middle School Students Who Ever Used Marijuana




**SOURCE:** Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey

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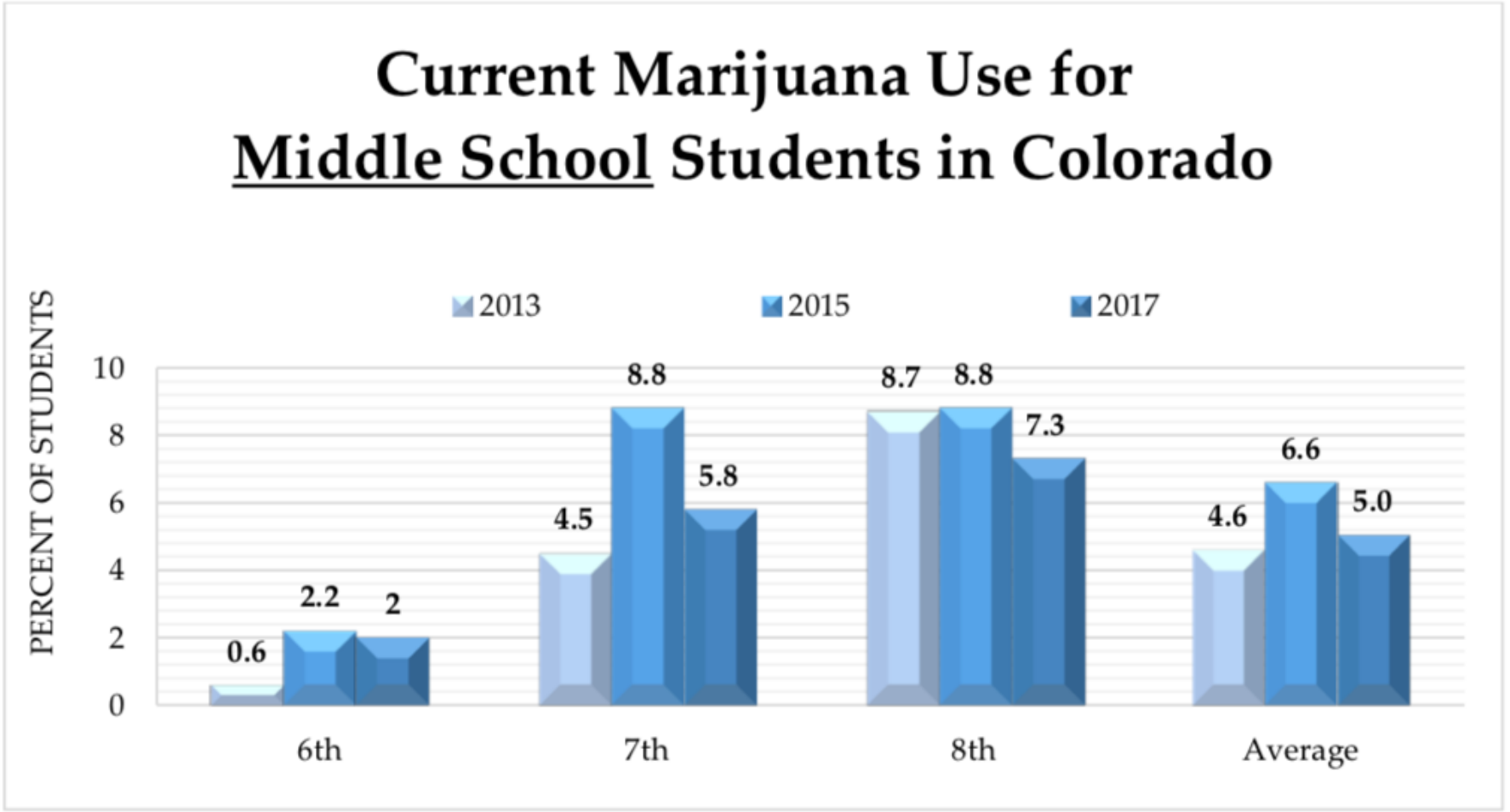
# Current Marijuana Use for Middle School Students in Colorado




**SOURCE:** Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey

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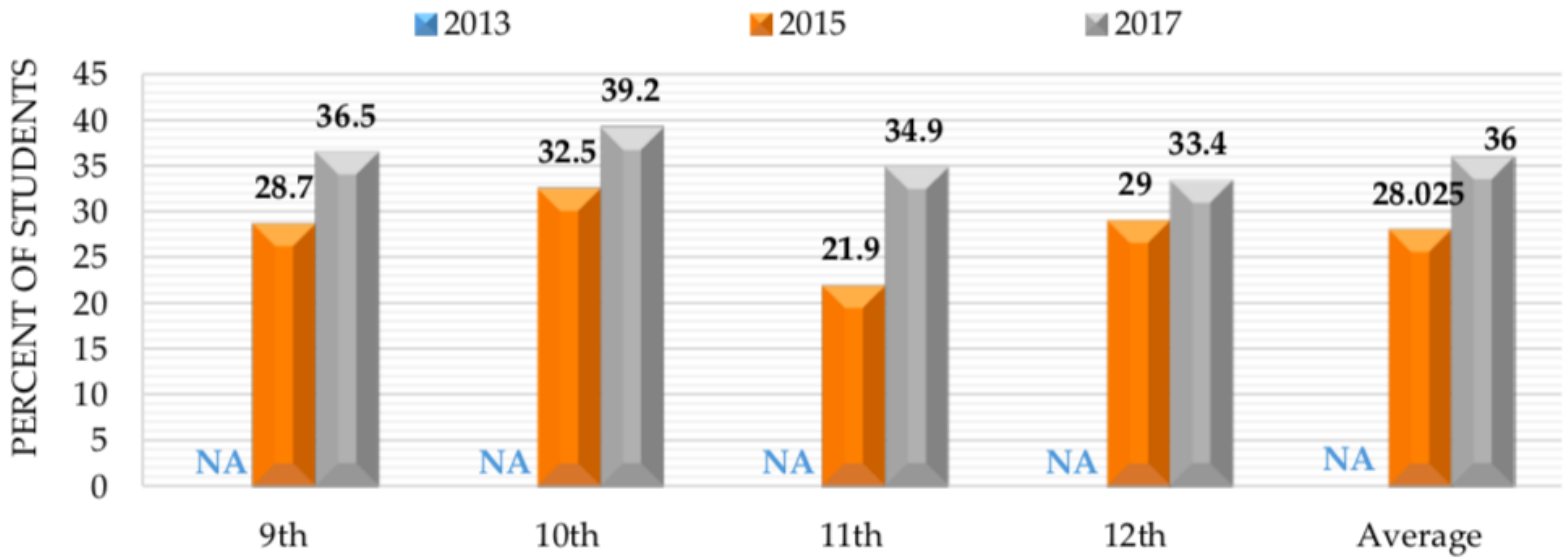
# Among Students who Used Marijuana within the Past 30 Days, the Percentage Who Ate* it




*Eating marijuana most commonly refers to edible products. Edible products contain marijuana concentrates and extracts that have been made for the use of being mixed with food or other products.

**SOURCE:** **Colorado Department of Public Health and Environment, Healthy Kids Colorado Survey**

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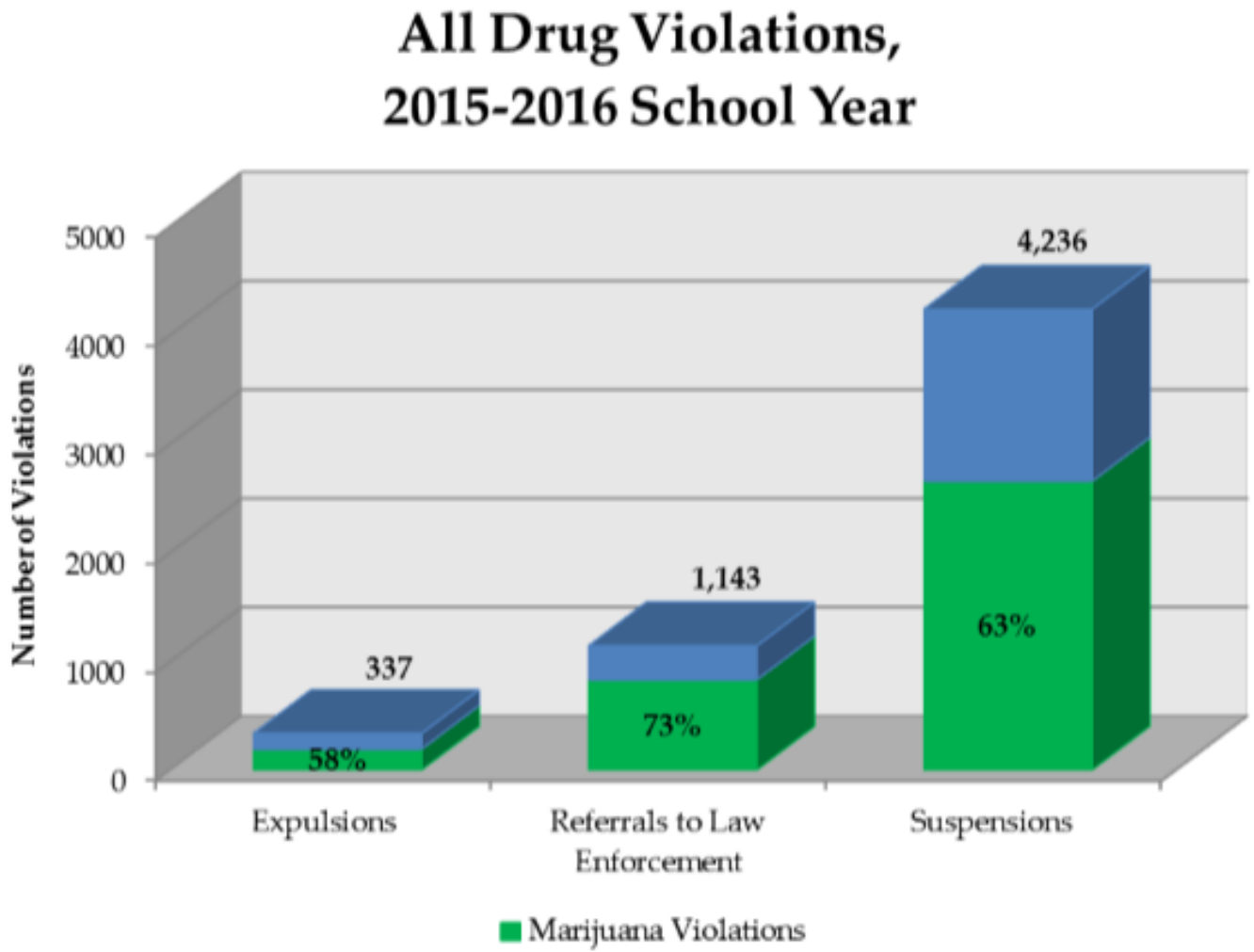
| Colorado Averages Compared to National Averages, Ages 12 and Older (NSDUH 2015/2016) | | |
|---|---|---|
| | Higher | Lower |
| Marijuana Past Month Use | 85% | |
| Perceptions of Risk for Smoking Marijuana | | 63% |
| Age of First Use of Marijuana | 96% | |
| Alcohol Past Month Use | 12% | |
| Cigarette Past Month Use | | 15% |
| Perceptions of Risk for Smoking Cigarettes | 2% | |

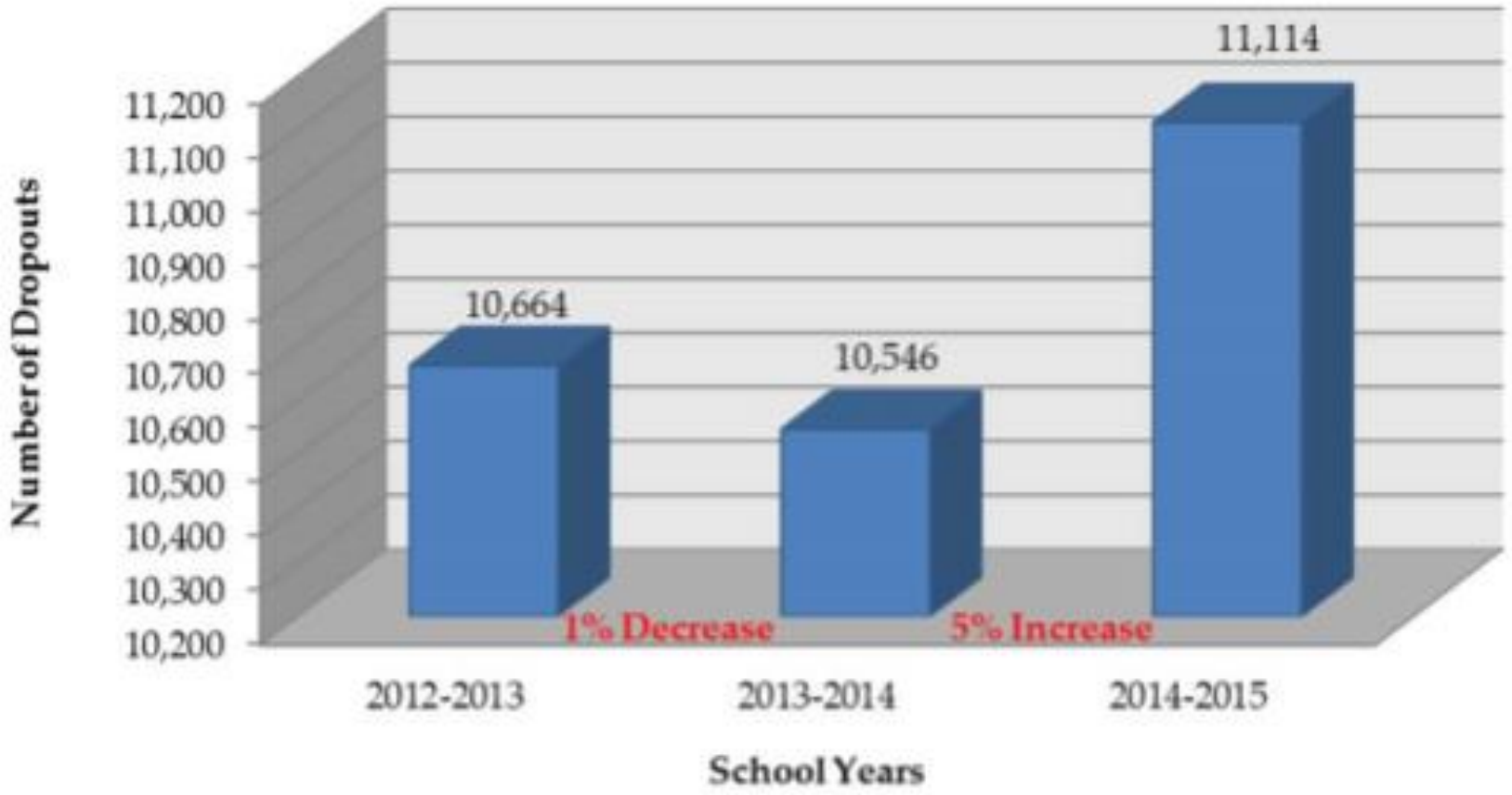
SOURCE: SAMHSA.gov, National Survey on Drug Use and Health 2015 and 2016

Data for the 2016-2017 school year were not available by the time of release for this report.



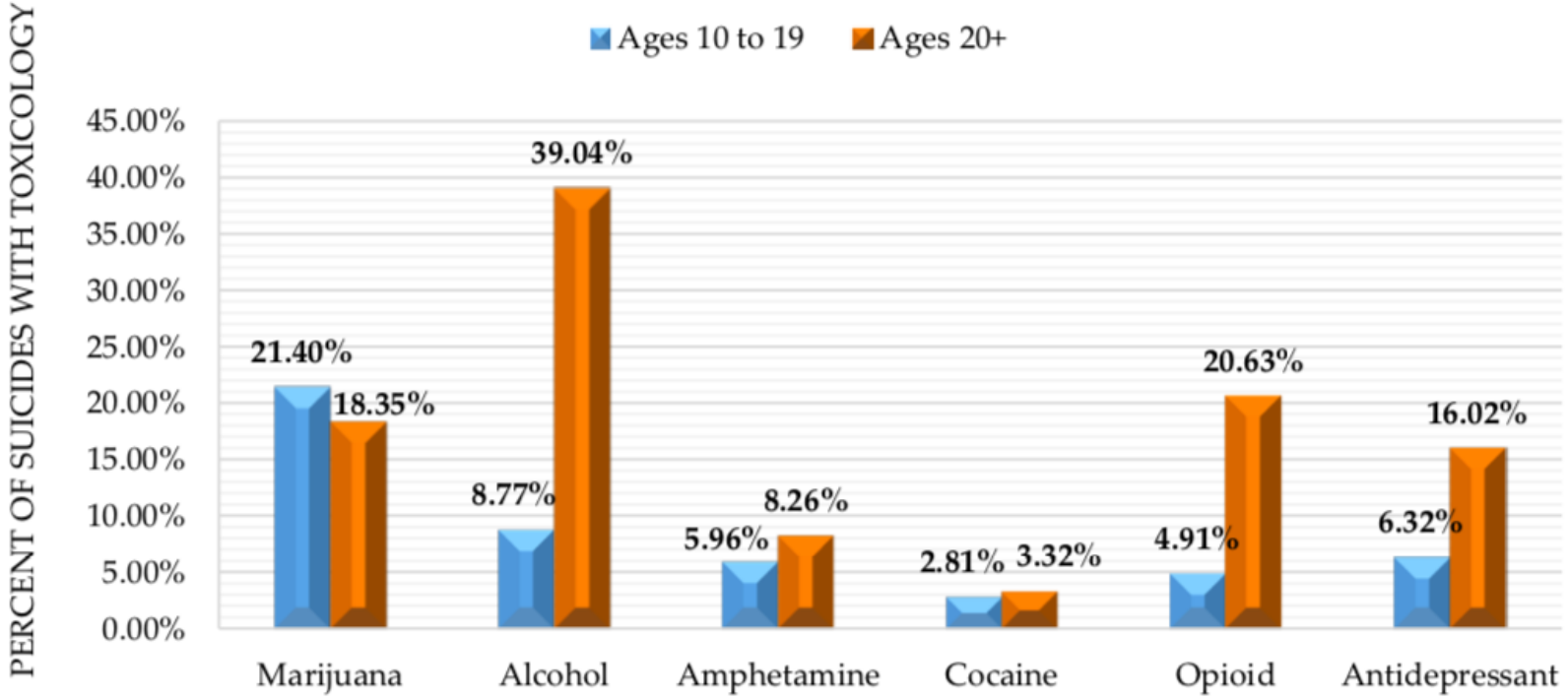

**SOURCE:** **Colorado Department of Education, 10-Year Trend Data: State Suspension and Expulsion Incident Rates and Reasons**

# Colorado School Dropouts




**SOURCE:** Colorado Department of Education

# Average Suicide Toxicology Results by Age Group, 2013-2017*




*The average percent was taken out of all suicides with toxicology results

**SOURCE:** **Colorado Department of Public Health and Environment (CDPHE), Colorado Violent Death Reporting System**

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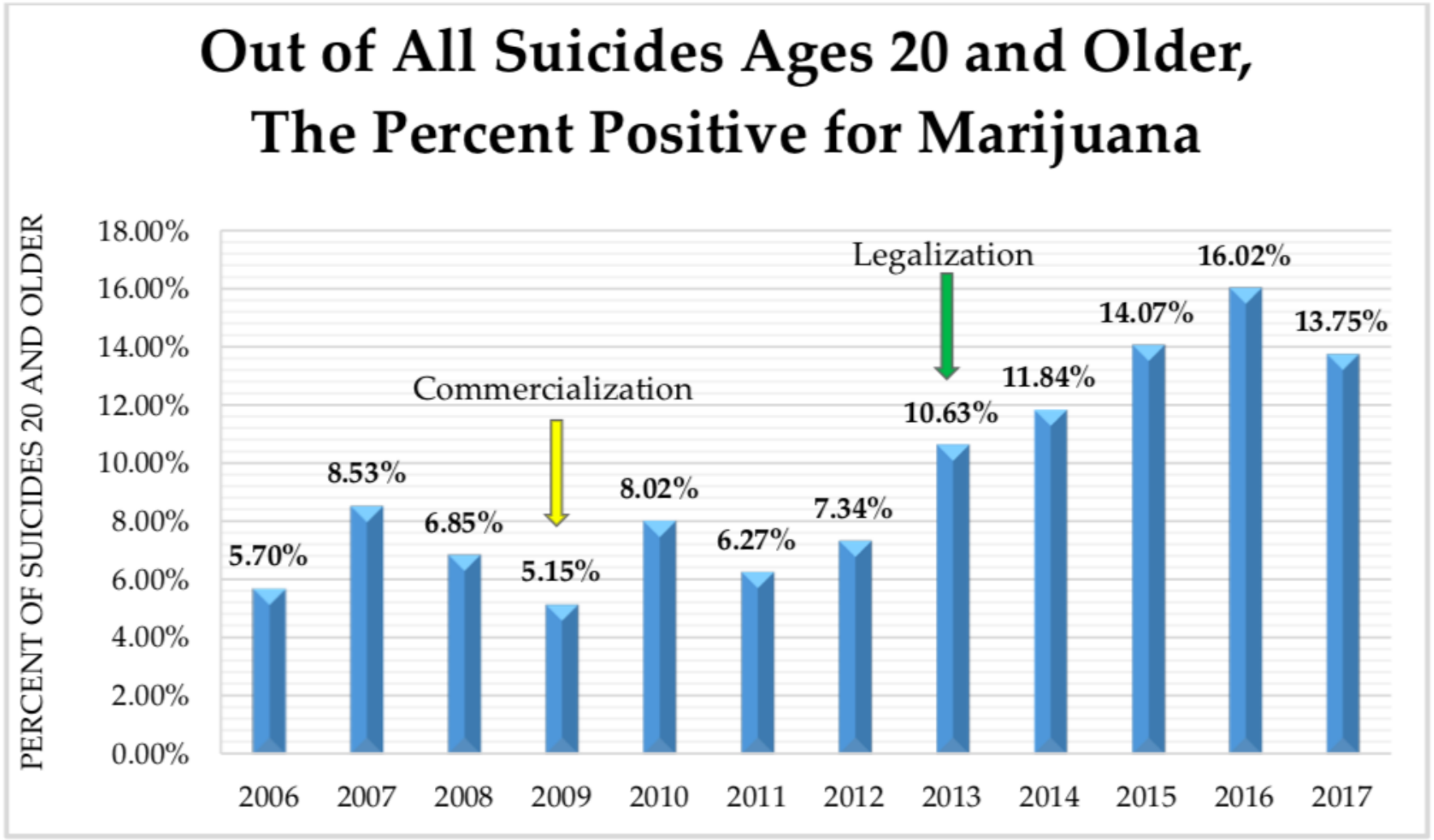
# Out of All Suicides Ages 20 and Older, The Percent Positive for Marijuana




**SOURCE:** **Colorado Department of Public Health and Environment (CDPHE), Colorado Violent Death Reporting System**

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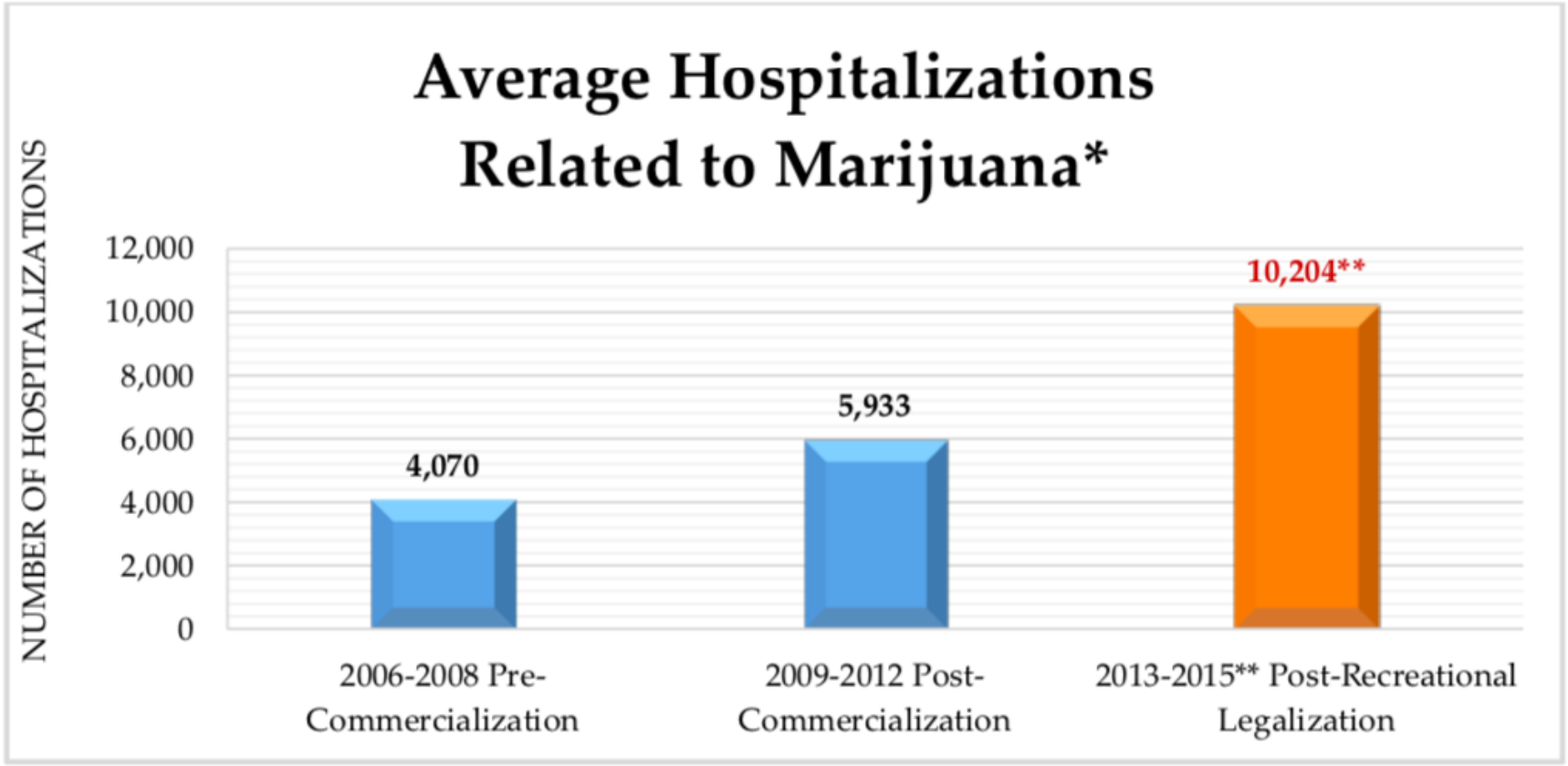
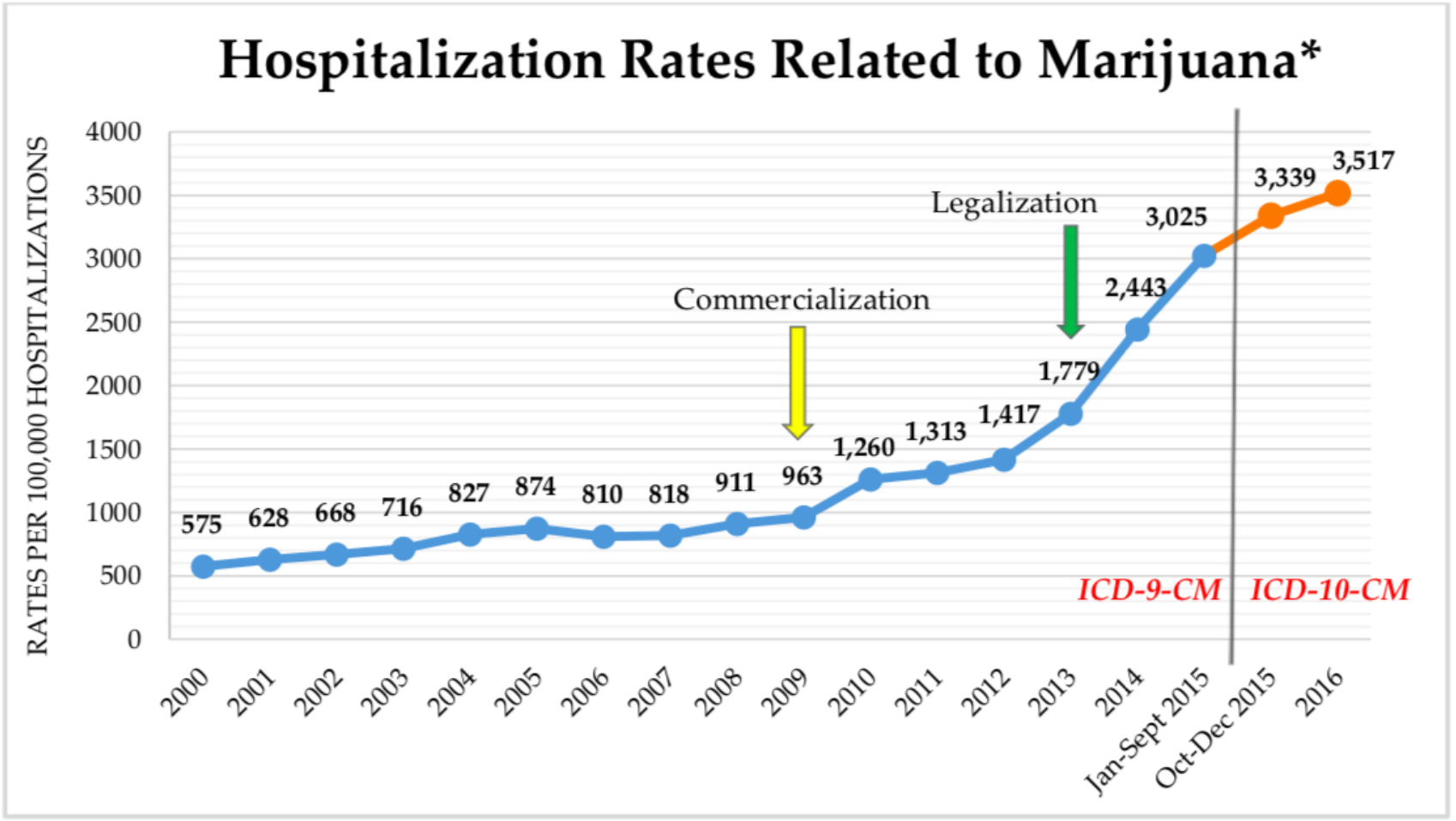



*Hospitalization Visits with Possible Marijuana Exposures, Diagnoses, or Billing Codes

**Only 9 months of comparable 2015 data, see ICD definition on page 36

SOURCE: Colorado Hospital Association, Hospital Discharge Dataset. Statistics prepared by the Health Statistics and Evaluation Branch, Colorado Department of Public Health and Environment

# Hospitalization Rates Related to Marijuana*




*Rates of Hospitalization (HD) Visits with Possible Marijuana Exposures, Diagnoses, or Billing Codes per 100,000 HD visits by Year in Colorado

SOURCE: Marijuana Health Monitoring and Research Program, Colorado Department of Public Health and Environment

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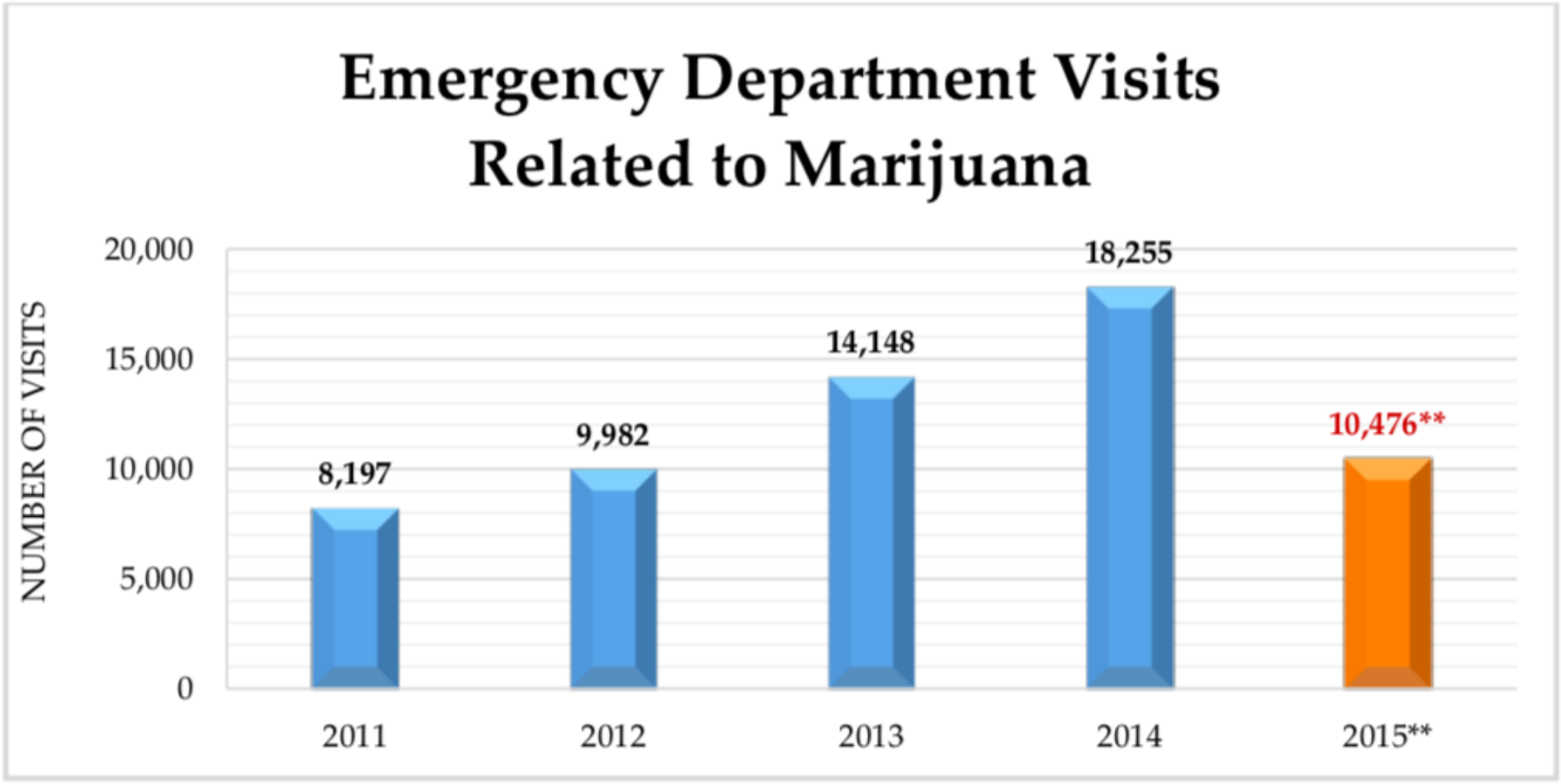
# Emergency Department Visits Related to Marijuana




**Only 9 months of comparable 2015 data, see ICD definition on page 36

SOURCE: Colorado Department of Public Health and Environment, *Monitoring Health Concerns Related to Marijuana in Colorado: 2016*

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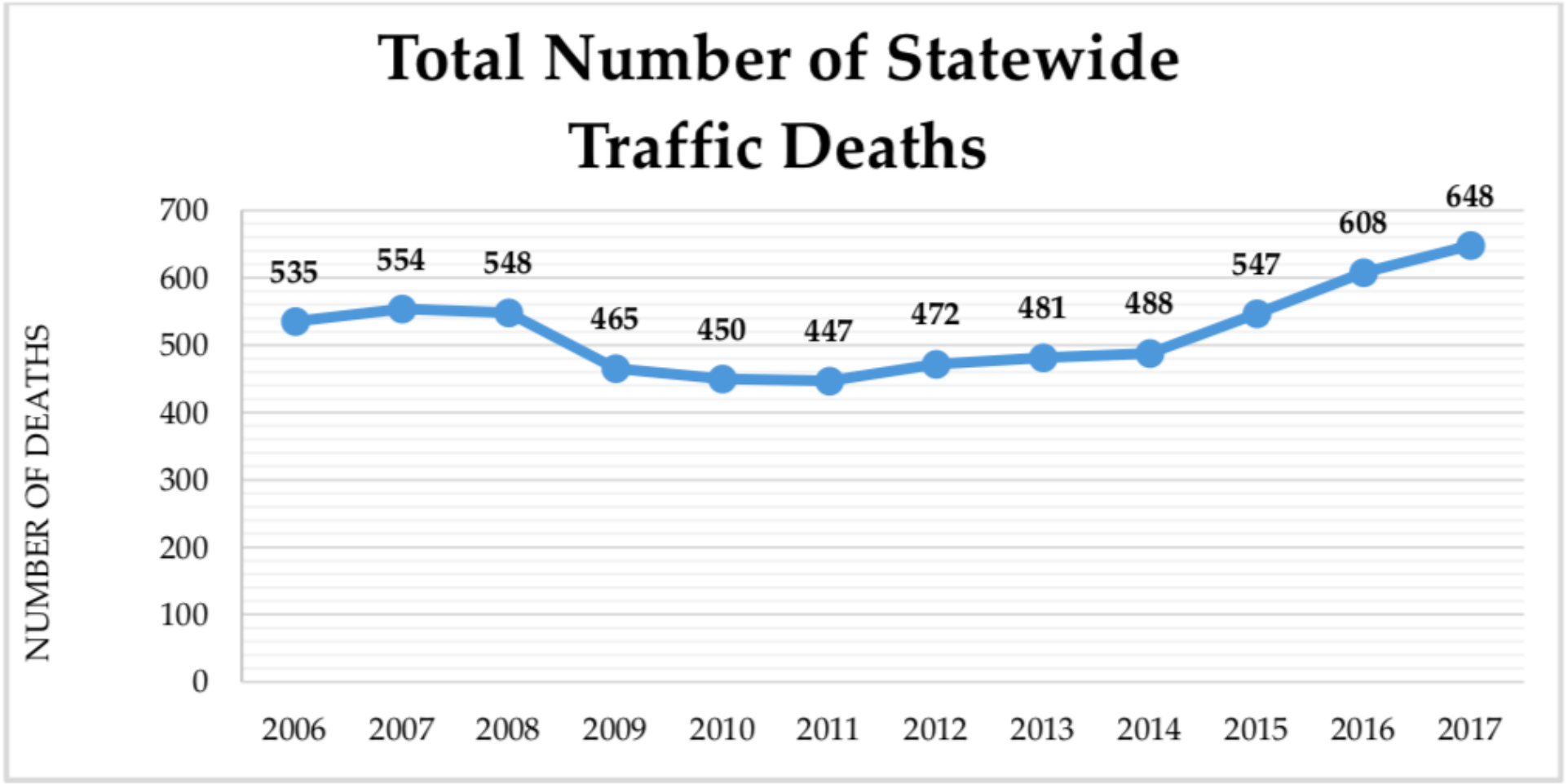
# Total Number of Statewide Traffic Deaths

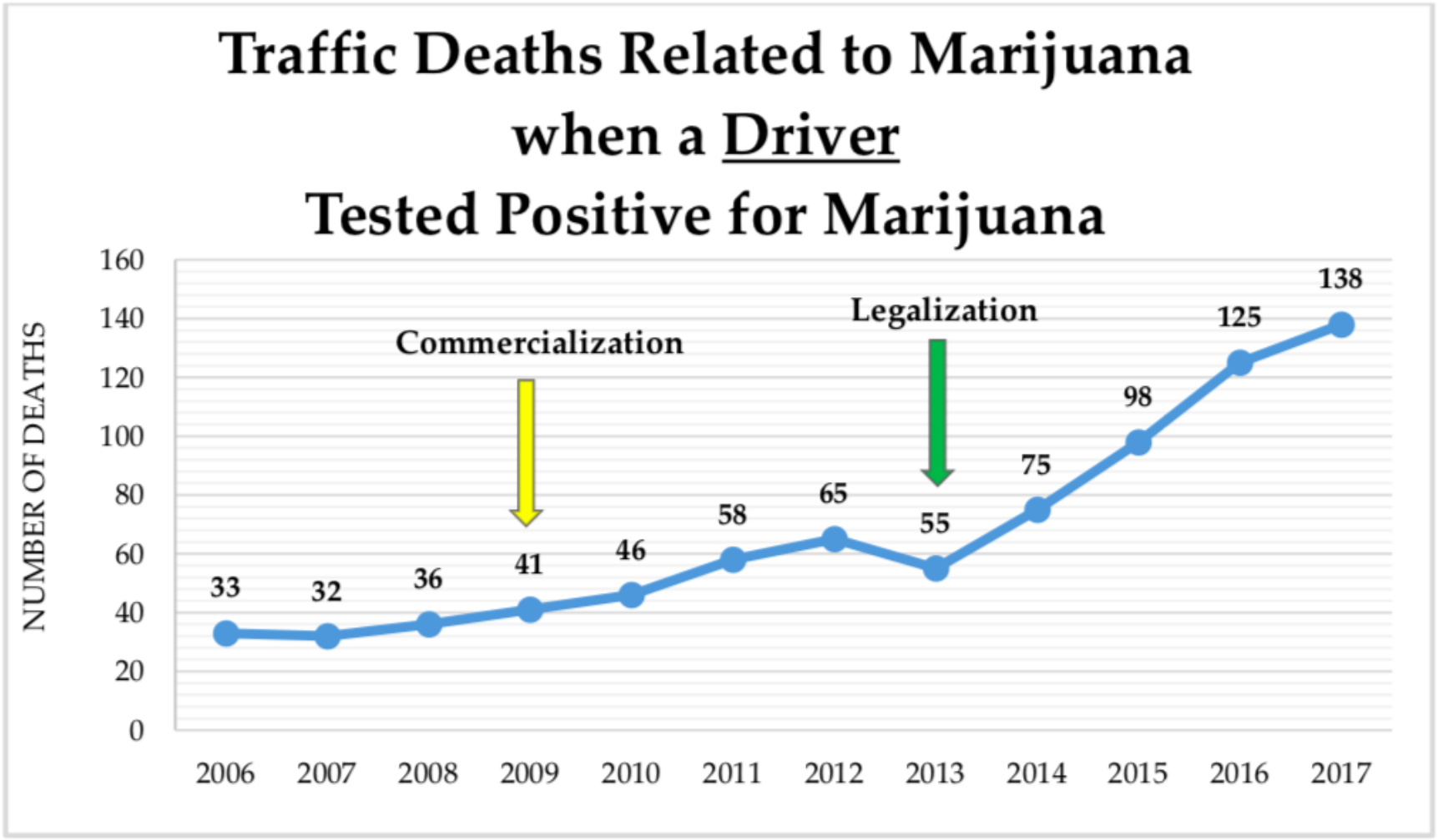



**SOURCE:** National Highway Traffic Safety Administration, Fatality Analysis Reporting System (FARS), 2006-2011 and Colorado Department of Transportation 2012-2017

| Traffic Deaths Related to Marijuana When a DRIVER Tested Positive for Marijuana | | | |
|---|---|---|---|
| **Crash Year** | **Total Statewide Fatalities** | **Fatalities with Drivers Testing Positive for Marijuana** | **Percentage Total Fatalities** |
| **2006** | 535 | 33 | 6.17% |
| **2007** | 554 | 32 | 5.78% |
| **2008** | 548 | 36 | 6.57% |
| **2009** | 465 | 41 | 8.82% |
| **2010** | 450 | 46 | 10.22% |
| **2011** | 447 | 58 | 12.98% |
| **2012** | 472 | 65 | 13.77% |
| **2013** | 481 | 55 | 11.43% |
| **2014** | 488 | 75 | 15.37% |
| **2015** | 547 | 98 | 17.92% |
| **2016** | 608 | 125 | 20.56% |
| **2017** | 648 | 138 | 21.30% |

**SOURCE:** **National Highway Traffic Safety Administration, Fatality Analysis Reporting System (FARS), 2006-2011 and Colorado Department of Transportation 2012-2017**

# Traffic Deaths Related to Marijuana when a Driver Tested Positive for Marijuana




**SOURCE:** National Highway Traffic Safety Administration, Fatality Analysis Reporting System (FARS), 2006-2011 and Colorado Department of Transportation 2012-2017

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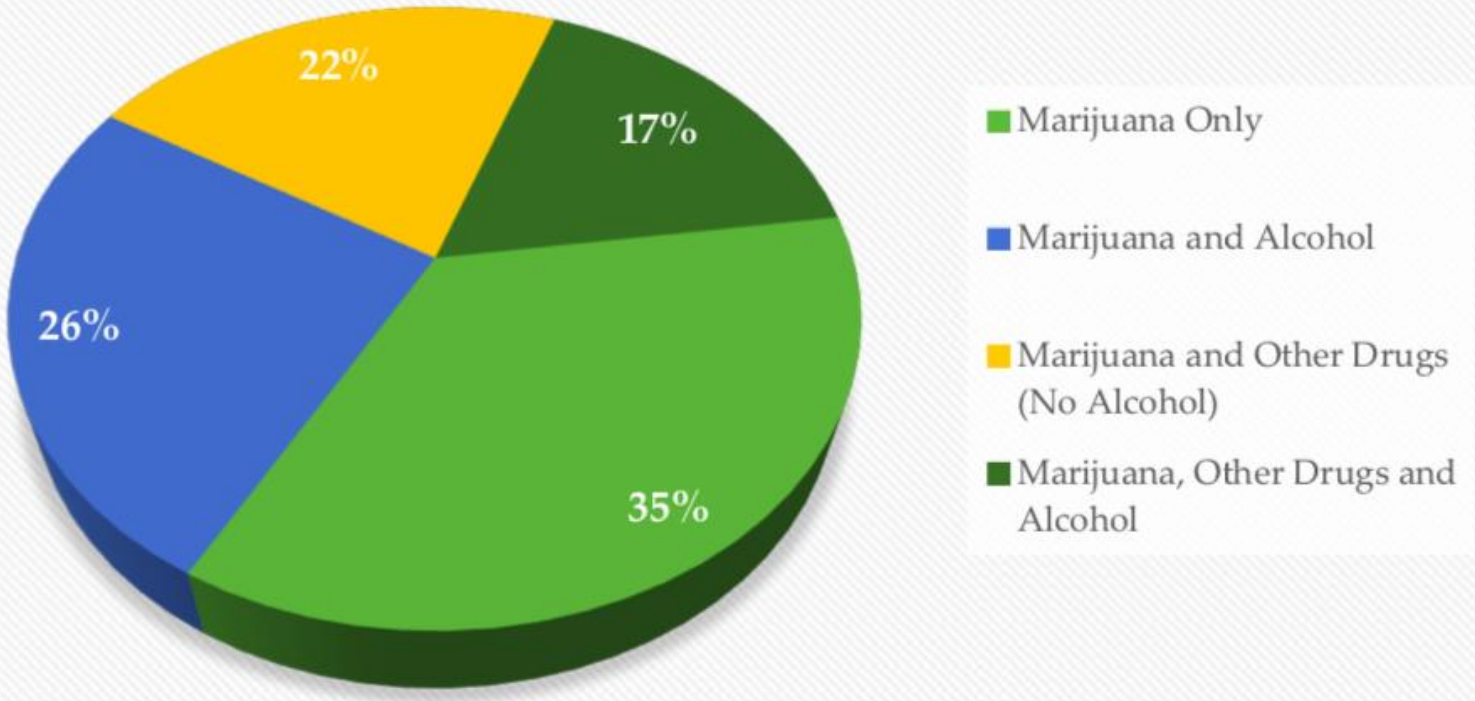
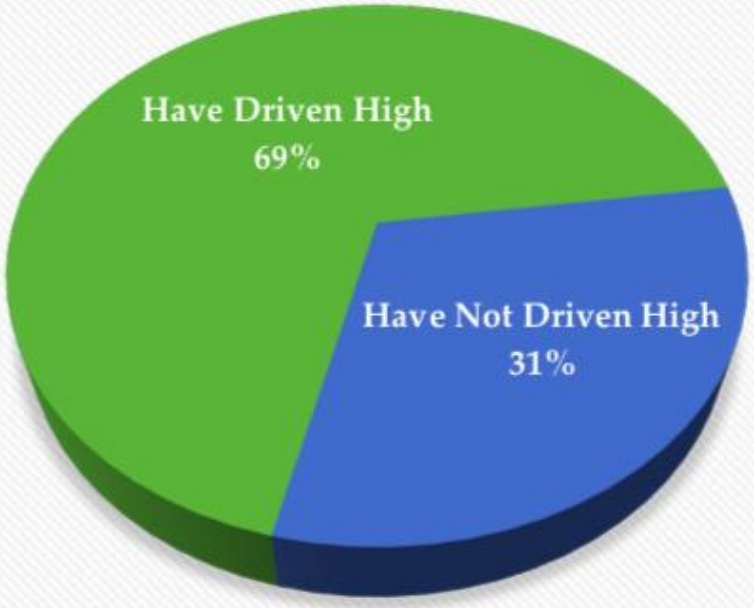
# Drug Combinations for Drivers Positive for Marijuana*, 2017




*Toxicology results for all substances present in individuals who tested positive for marijuana

SOURCE: National Highway Traffic Safety Administration, Fatality Analysis Reporting System (FARS), 2006-2011 and Colorado Department of Transportation 2012-2017

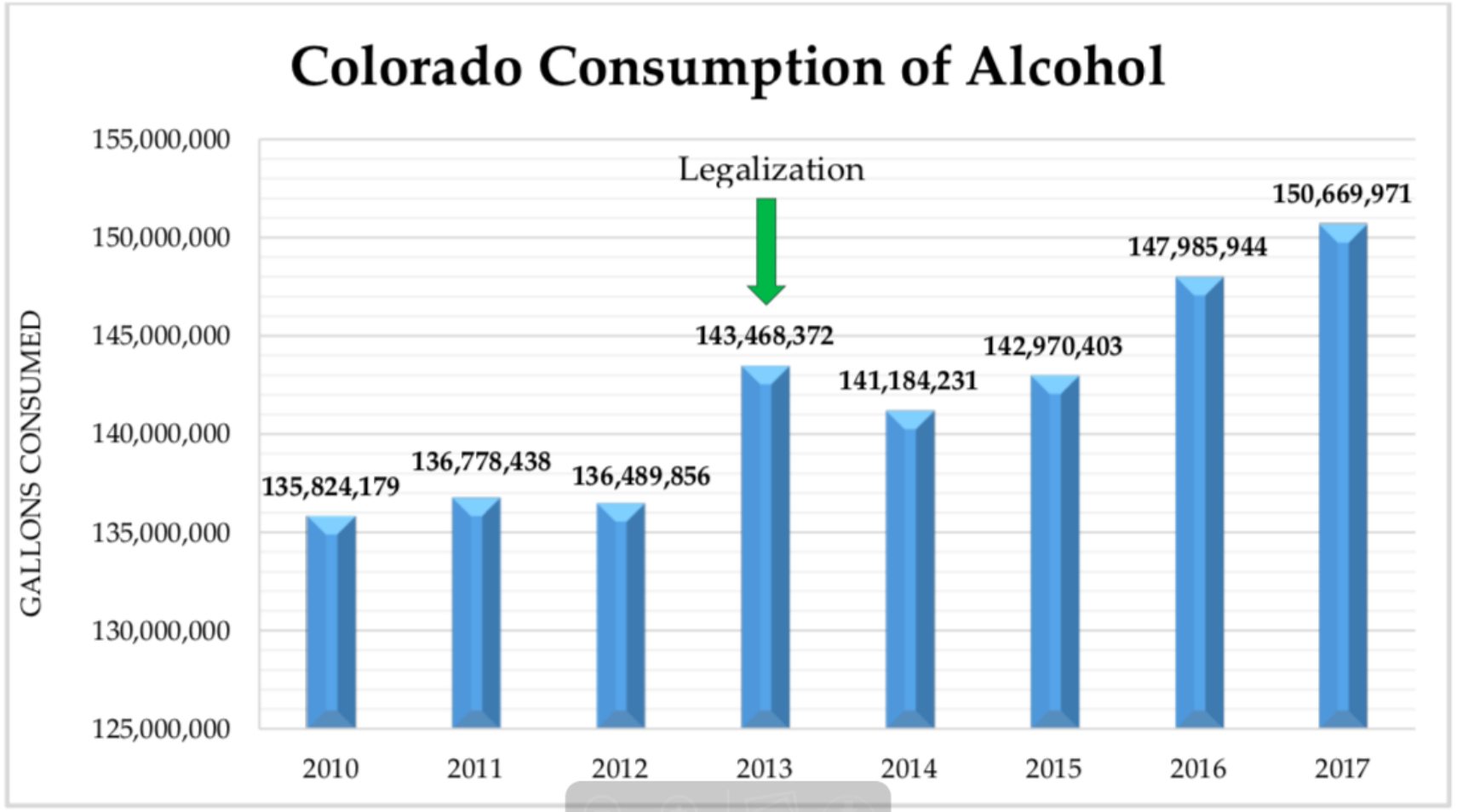
# Percentage of Marijuana Users Who Admit to Driving High within the Last Year




The Colorado Department of Transportation (CDOT) collected survey responses from over 11,000 anonymous marijuana users and non-users.
The above data is part of the preliminary data released by CDOT in April of 2018.

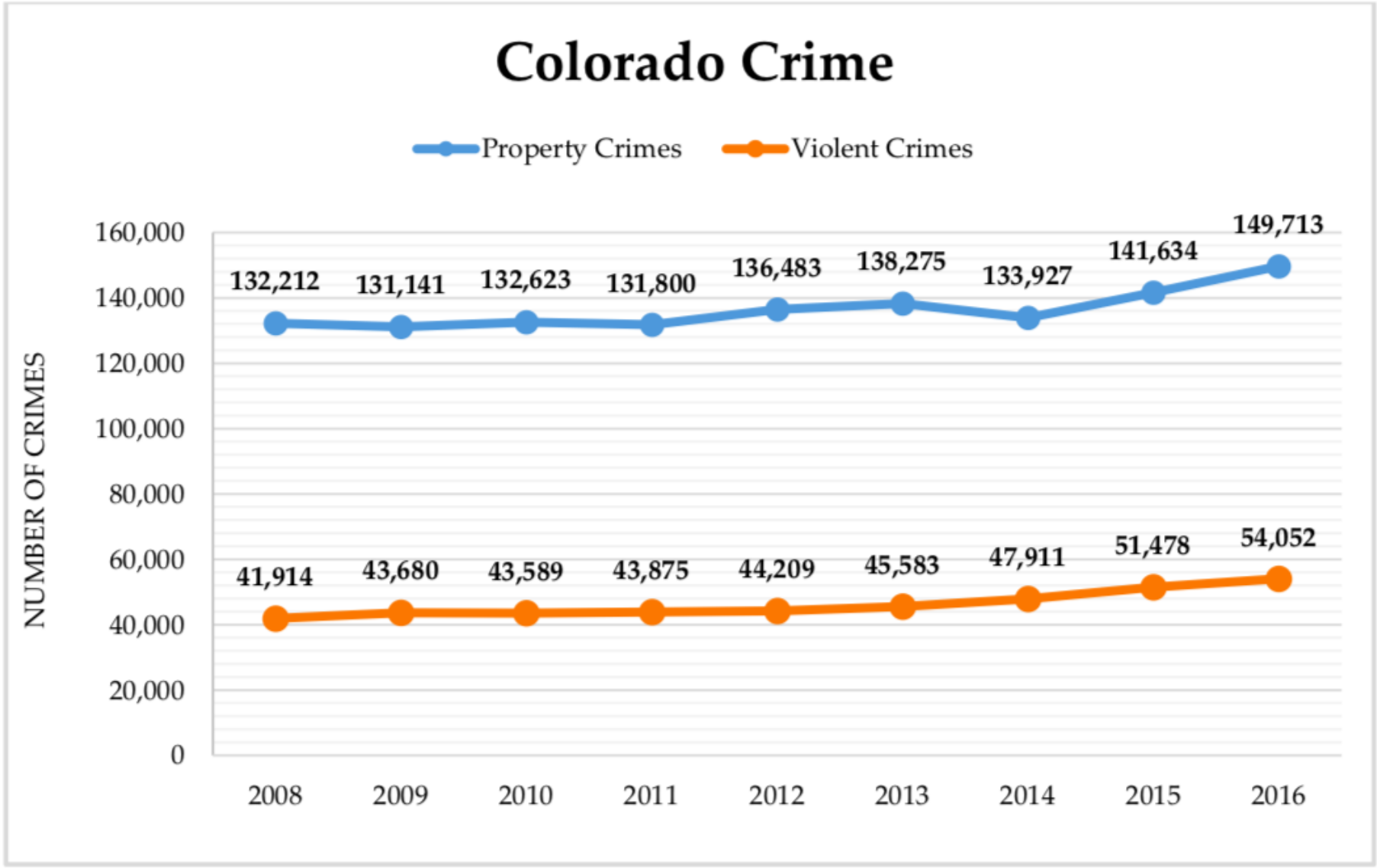
**SOURCE:** **Colorado Department of Transportation, *Cannabis Conversation* Survey**

- **It has been suggested that legalizing marijuana would reduce alcohol consumption. Thus far that theory is not supported by the data.**



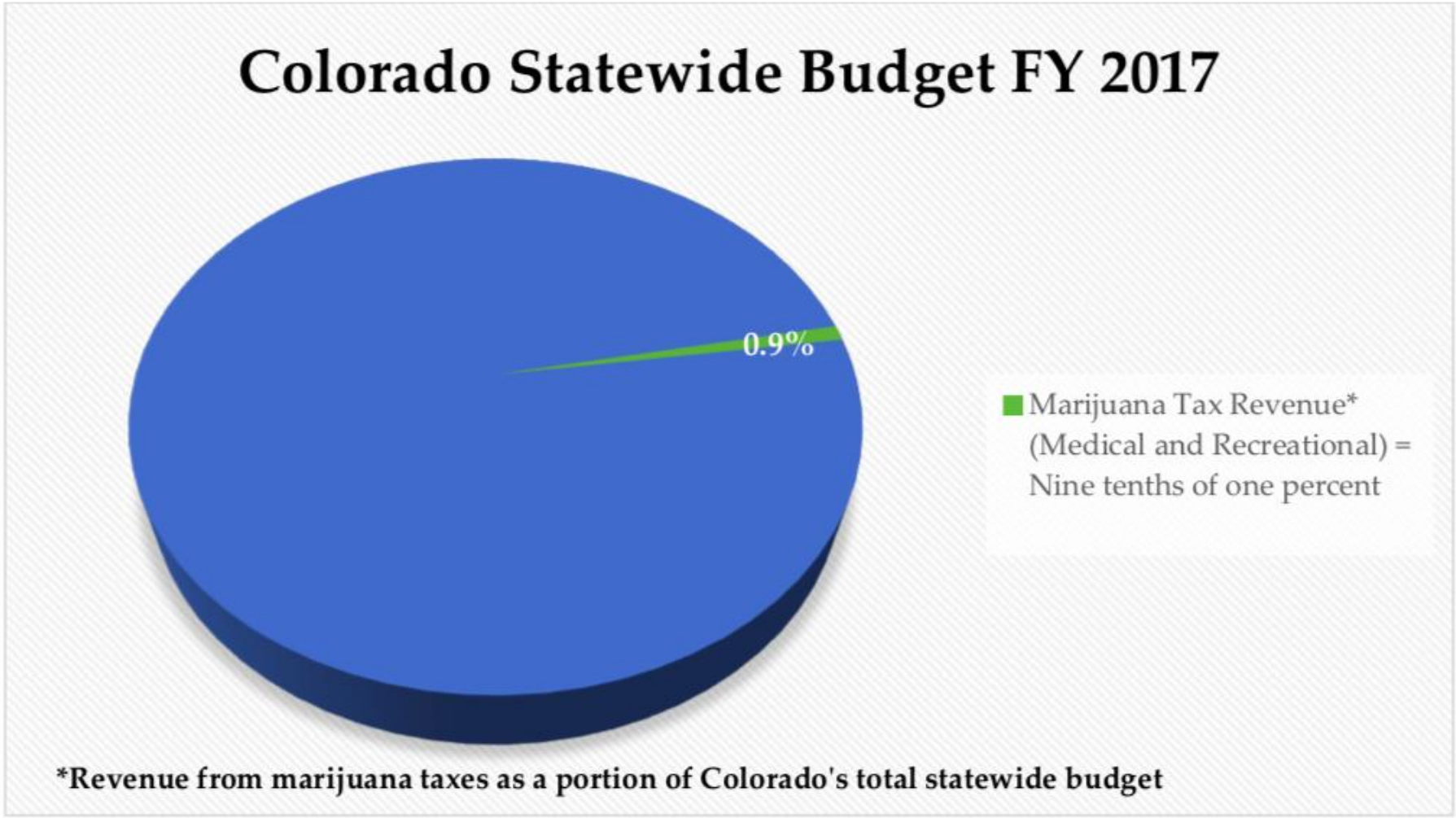

**SOURCE:** **Colorado Department of Revenue, Colorado Liquor Excise Tax**

# Colorado Crime




**SOURCE:** **Colorado Bureau of Investigation, http://crimeinco.cbi.state.co.us/**

# Tax Revenue




**SOURCE:** Governor's Office of State Planning and Budgeting

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# HOW MEDICAL CANNABIS IS TREATING THE U.S.

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