



UF College of Medicine
Department of Psychiatry and Addiction Medicine
Drug Policy Institute



Testimony to Utah Legislature Health and Human Services Interim Committee

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Point 1: Colorado “Experiment” Not Going Well

(a) Adult Use Is Going Up

(b) Youth Access to Marijuana Candies, etc Up

(c) Advertising Rampant

(d) Most localities don’t want to sell marijuana

(e) Tax revenue way below projections; not “funding schools”

Point 2: Legalizing marijuana means “Big Tobacco 2.0”

(a) Private equity firms and “Yale MBAs” now leaders of cannabis movement

(b) Special interests rampant

(c) Tobacco firms now investing in marijuana industry (e.g. with vaporizers)

Point 3: You can have marijuana-based medicines – but there’s a responsible vs irresponsible way to do that.

(a) All CBD is not alike

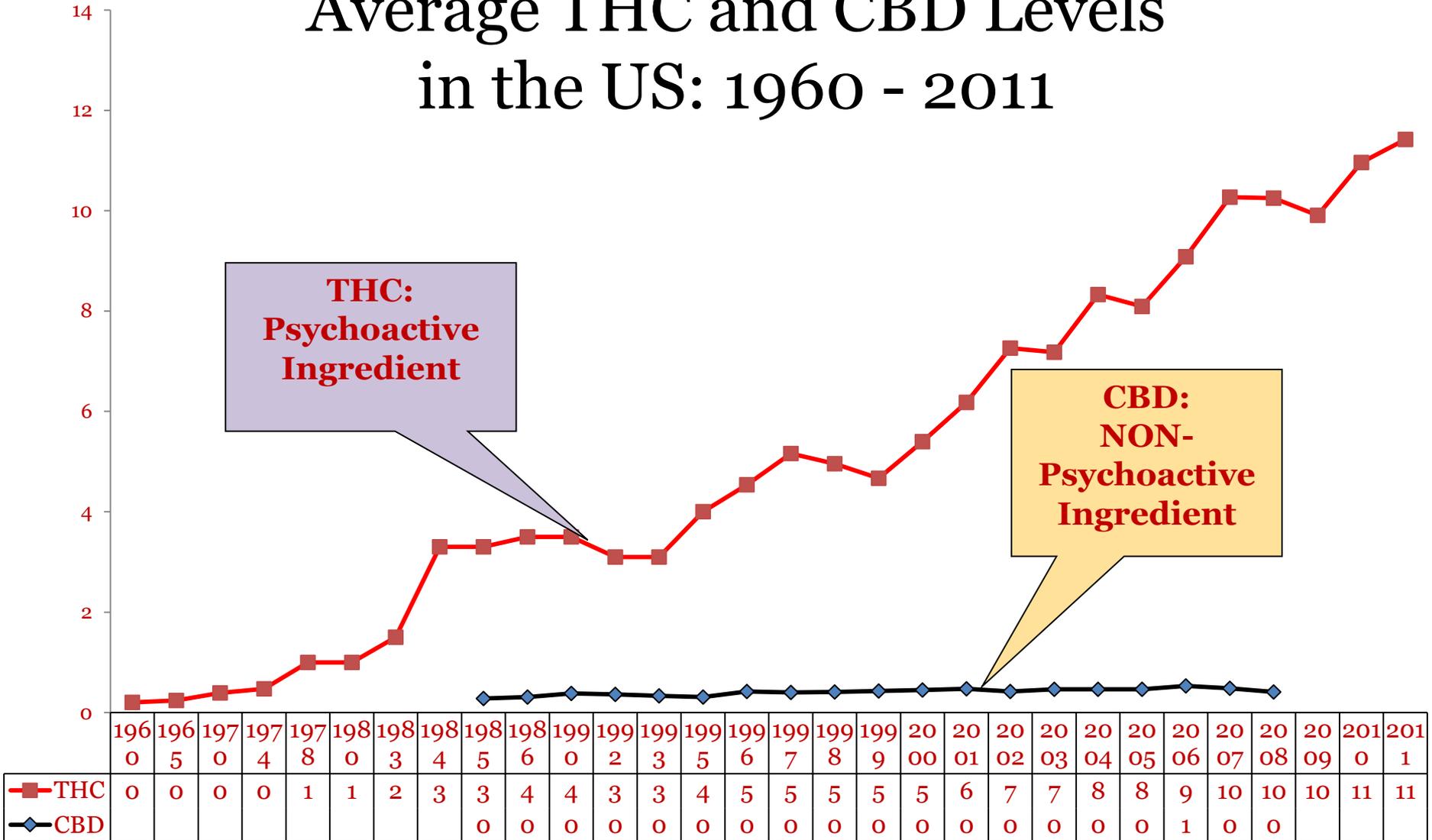
(b) Smoked marijuana isn’t medicine

(c) Research is on the way

Current Status of Federal Law

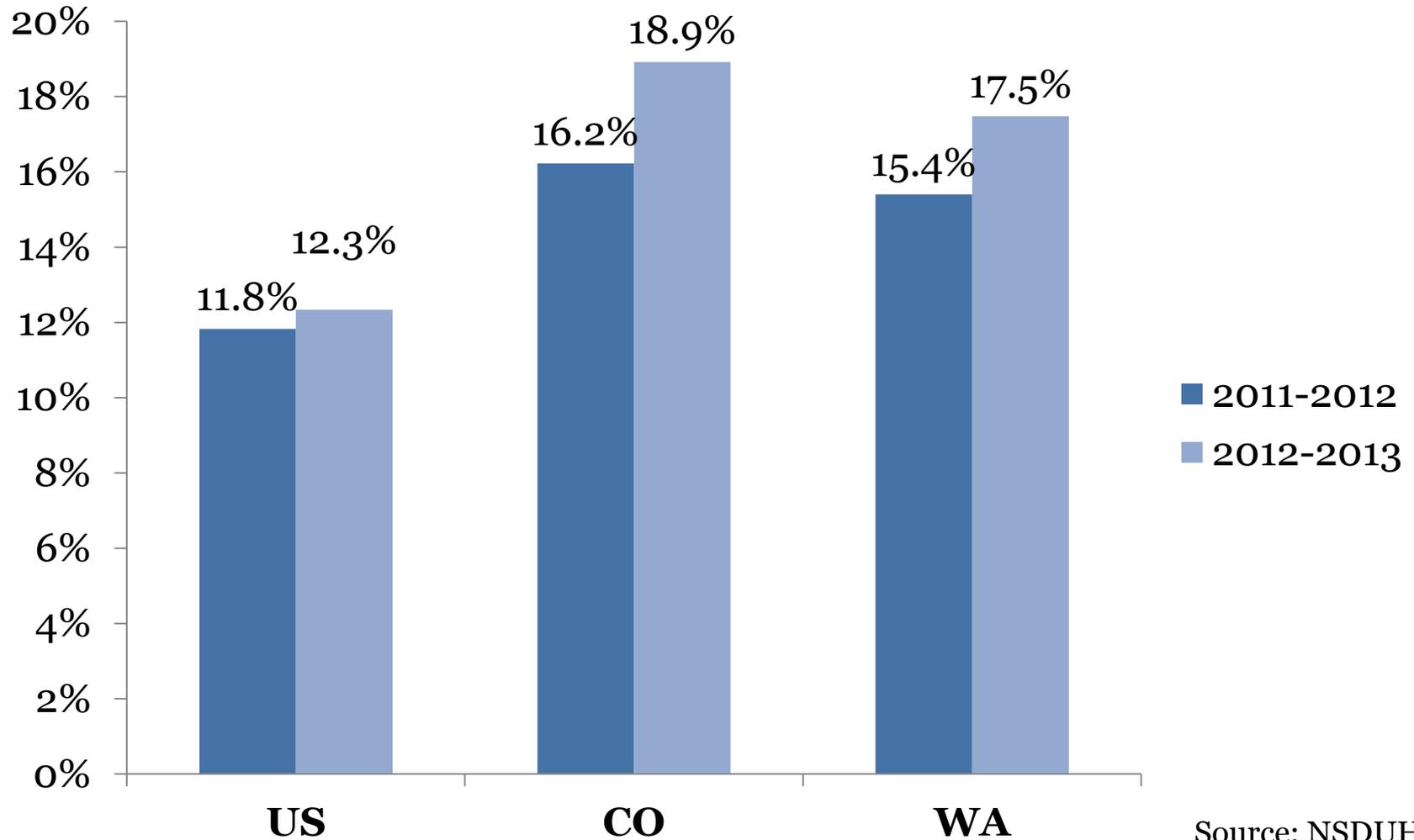
- **Marijuana is a complex plant with hundreds of components (Cannabinoids, terpenes, flavinoids)**
- ***Marijuana is a Schedule I drug, defined as:***
 - high potential for abuse (1 in 10 dependent)
 - no accepted medical use
 - lacks accepted safety for use under medical supervision
 - **Recently confirmed by Federal Court in San Francisco**

Average THC and CBD Levels in the US: 1960 - 2011



***Point 1: Colorado “Experiment”
Not Going Well***

Past-Year Marijuana Use (ages 12+)



Source: NSDUH, 2014

2015 Marijuana Developments

- **Associated Press: [“Two Denver Deaths Linked to Recreational Marijuana Use”](#)**. One includes the under-aged college student who jumped to his death after ingesting a marijuana cookie. There have been many accidents of this nature.
- The number of parents calling the poison-control hotline to report their kids had consumed marijuana has [risen significantly in Colorado](#).
- Marijuana edibles and marijuana vaporizers have been found in middle and high schools. ⁷

Teen Arrests

- Arrests for marijuana use in Denver public schools increased by 6% between 2013 and 2014.
- Kids can easily hide vaporizers and edibles at school; they have no scent or special look.

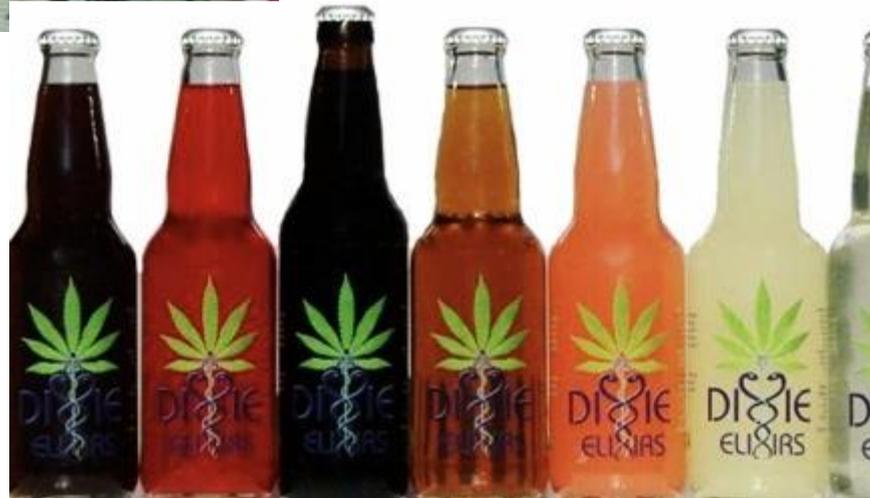
STOP BY & SAY HIGH

\$5 Grams

FREE 1/8
BUY ONE US & GET AN SR FREE

99¢ Joints

\$125 Premium Ounce's Sam-Dam



Looking Outside the State for Qualified Employees



Jim Johnson said his company has encountered so many job candidates who have failed pre-employment drug tests because of their THC use ... it is actively recruiting construction workers from other states.”

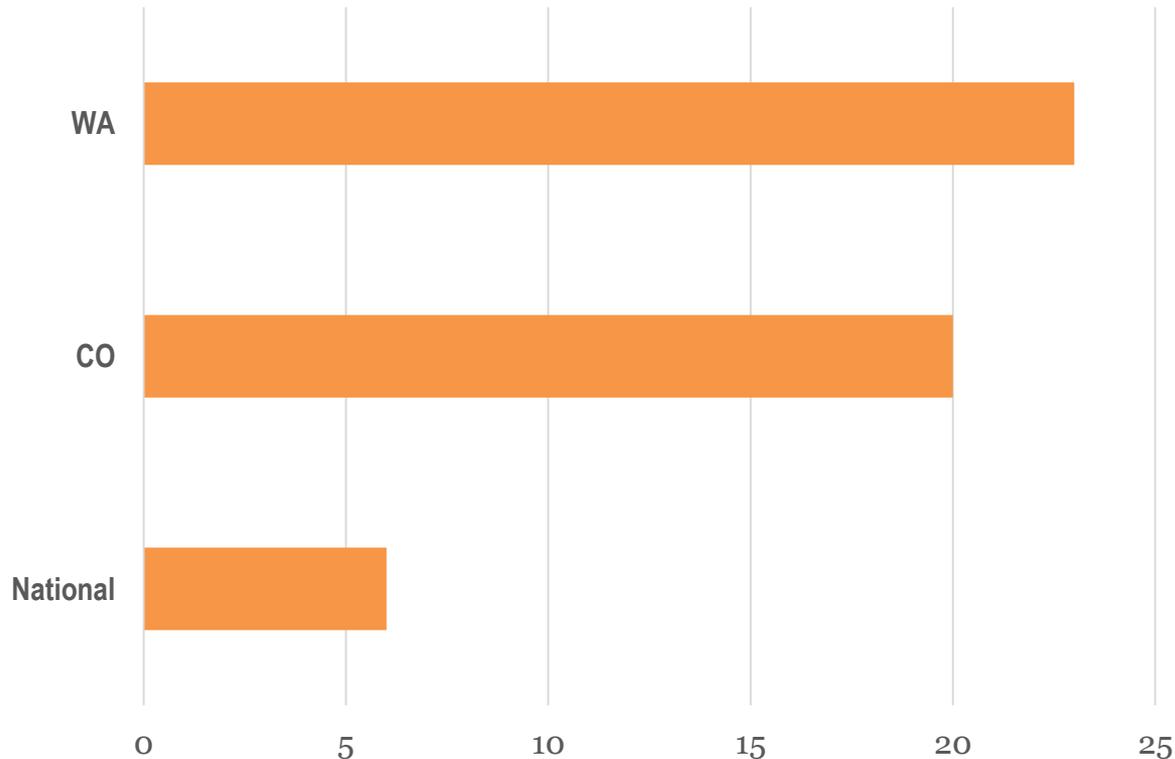
GE Johnson

<http://gazette.com/drug-use-a-problem-for-employers/article/1548427>



Quest Diagnostics Drug Test Index™

**Workplace Pos MJ Tests: Increase
from 2012-2013**



<http://www.questdiagnostics.com/home/physicians/health-trends/drug-testing>



“In February,” Leona Willener said, “more than half the applicants who came to her company looking for work failed the required drug tests because of THC use ... 1 in 3 attempted to cheat the test.”

<http://gazette.com/drug-use-a-problem-for-employers/article/1548427>



Colorado Staffing Agency



Marijuana Edible Displays



98% Pure Marijuana: “Just a Plant” ?



*“Green Crack”
wax*



“Ear Wax”



Butane Hash Oil
(BHO)



Hash Oil Capsules



“Budder”

Copyright SAM and the Slides Authors.
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“Shatter”



FREE DAB!

NO PURCHASE
NECESSARY

BOGO PIPES
12K MASTERCASE 280

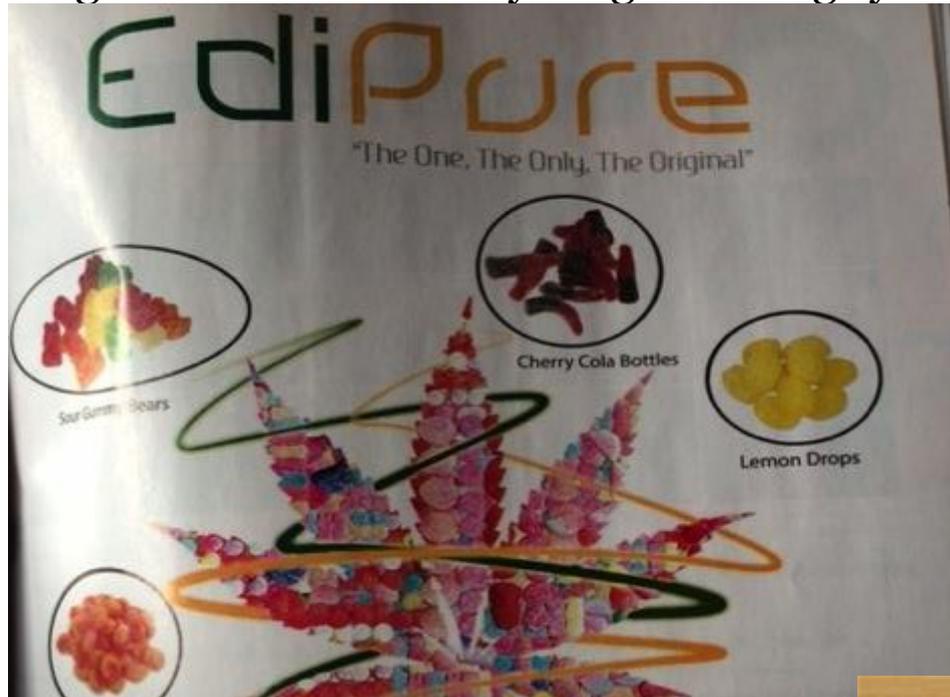
Go Blow's Glass

888 W. COLLEGE BLVD. LAKEWOOD

Matthews

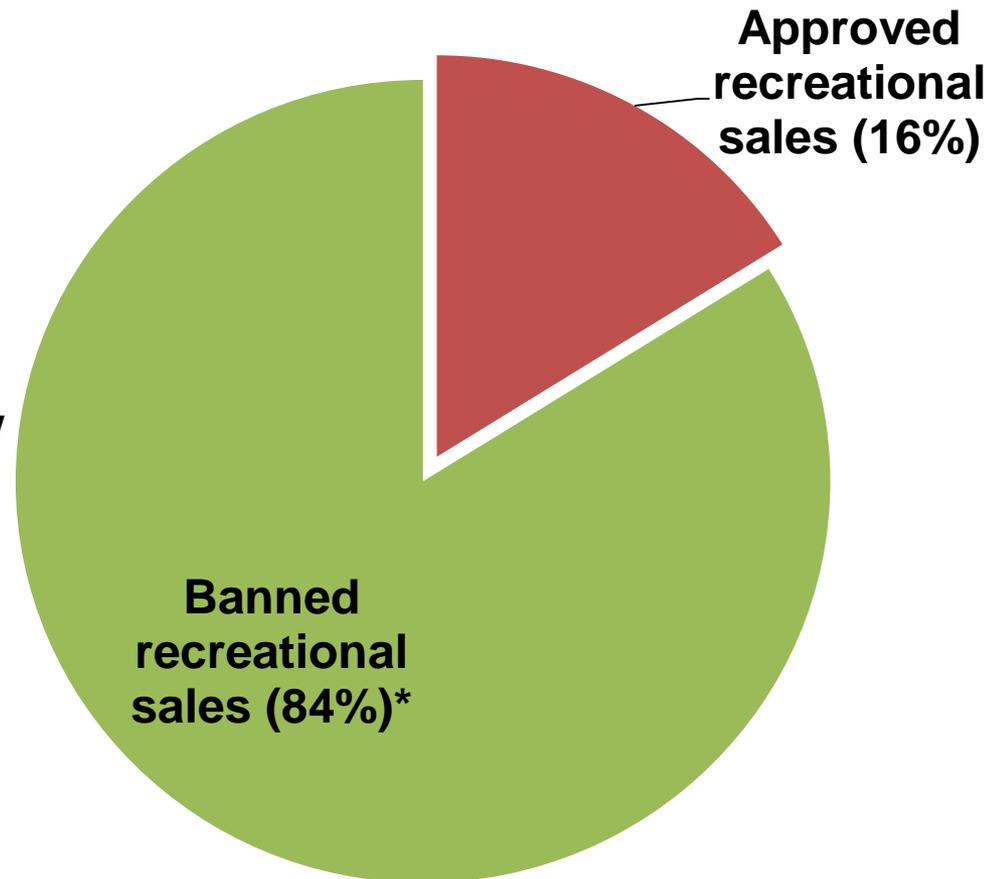


In a report published in the Journal of the American Medical Association last month, Andrew Monte, MD; Richard Zane, MD; and Kennon Heard, MD, pointed to edible marijuana as the culprit behind the most troubling cases arriving at the UCH and Children's Hospital Colorado emergency departments, including severe burns and cycling vomiting syndrome.



Cities Across Colorado are Banning the Recreational Sales of Marijuana

- Of the 31 cities in Colorado that voted in November to allow the recreational sales of marijuana, 26* voted to ban it.



TheUpshot

REVENUE DISAPPOINTMENT

Marijuana Taxes Won't Save State Budgets

APRIL 9, 2015



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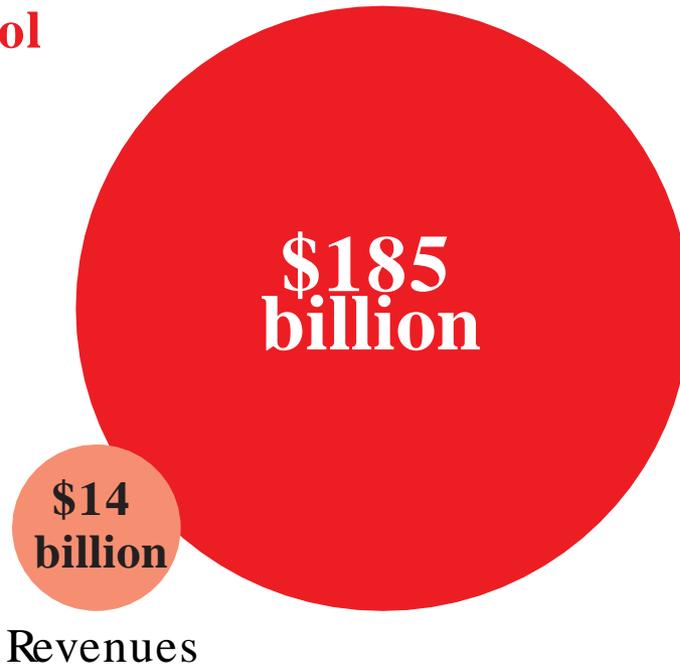
Colorado's marijuana tax collections are not as high as expected.

In February 2014, Gov. John Hickenlooper's office projected Colorado would take in \$118 million in taxes on recreational marijuana in its first full year after legalization. With seven months of revenue data in, his office has cut that projection and believes it will collect just \$69 million through the end of the fiscal year in June, a miss of 42 percent.

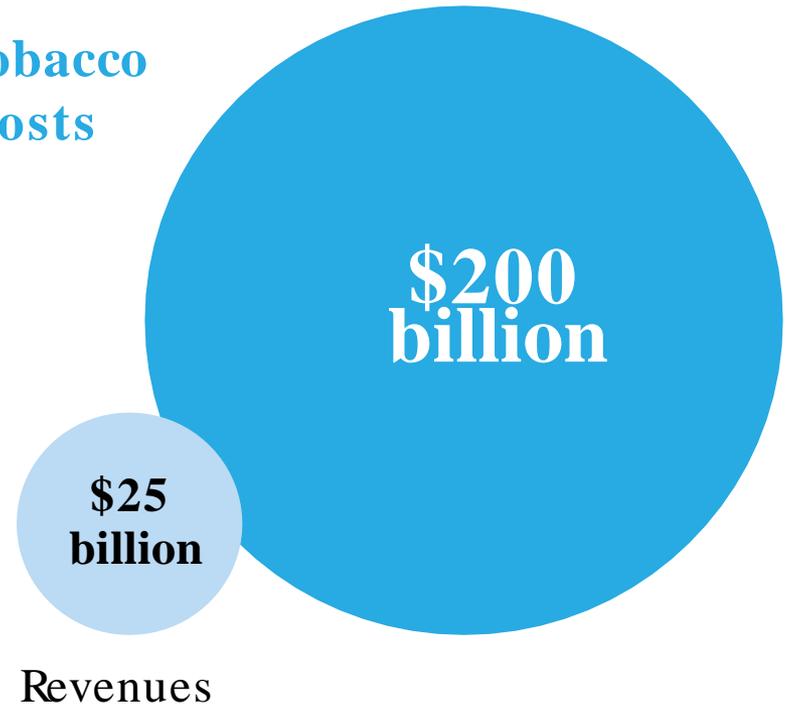
That figure is consequential in two ways. First, it's a wide miss. Second, compared with Colorado's all-funds budget of \$27 billion, neither \$69 million nor \$118 million is a large number.

Alcohol & Tobacco: Money Makers or Dollar Drainers?

**Alcohol
Costs**



**Tobacco
Costs**



State estimates found at <http://www.nytimes.com/2008/08/31/weekinreview/31saul.html?em>; Federal estimates found at https://www.policyarchive.org/bitstream/handle/10207/3314/RS20343_20020110.pdf; Also see <http://www.tobaccofreekids.org/research/factsheets/pdf/0072.pdf>; Campaign for Tobacco Free Kids, see "Smoking-caused costs," on p.2.

Point 2: 'Big Marijuana' or Big Tobacco 2.0

Can we trust companies and
Big Corporations not to target youth and
the vulnerable?



Vaporizing industries: Nicotine and Marijuana

Pax by Ploom

- Japan Tobacco International (JTI) is the third largest international tobacco company behind Philip Morris International.
- In 2011, JTI bought a portion of Ploom a startup based in Silicon Valley that produces a loose-leaf vaporizer that can be used to inhale heated vapor from **marijuana** as well as **tobacco**, called the Pax.



Privateer Holdings:
The first equity company
dedicated to the
marijuana industry.



Early Days of Big Tobacco Messaging

Dr. Batty's



For Your Health
ASTHMA CIGARETTES
SINCE 1901
For the temporary relief of paroxysms of asthma

EFFECTIVELY TREATS:
ASTHMA, HAY FEVER, FOUL BREATH,
HEAD COLDS, CANKER SORES,
BRONCHIAL IRRITATIONS
NOT RECOMMENDED FOR CHILDREN UNDER 6.

According to repeated nationwide surveys,

**More Doctors
Smoke CAMELS
than any other
cigarette!**



Doctors in every branch of medicine were asked, "What cigarette do you smoke?" The brand named most was Camel!

You'll smoke a Camel because you know it's the best. Camel has more taste and spirit, you know, and a better reputation for dependability. Make it a habit and you'll find it's the best. (When you have a cold, you'll find that you can't get any other brand to do the job. It's the only one that really works. It'll be the only one you'll smoke, a cigarette that'll be!

THE DOCTORS' CHOICE IS AMERICA'S CHOICE!





For 30 days, test Camels in your "P-Zone" (P for Peace, P for Taste)

Viceroy
FILTER
the Smoke!




As your Dentist,
I would recommend
VICEROYS



**NOW...Scientific Evidence
on Effects of Smoking!**

A MEDICAL SURVEY is making regular bi-monthly examinations of a group of people from various walks of life. 42 percent of this group have smoked Chesterfield for an average of over ten years.

After ten months, the medical specialists report that the following effects on the nose, throat and lungs of the group that smokes Chesterfield:

**MUCH Milder
CHESTERFIELD
IS BEST FOR YOU**



First and Only Premium Quality Cigarette in Soft Regular and King-Size

‘Big marijuana’

“The use of marijuana ... has important implications for the tobacco industry in terms of an alternative product line. [We] have the land to grow it, the machines to roll it and package it, the distribution to market it. In fact, some firms have registered trademarks, which are taken directly from marijuana street jargon. These trade names are used currently on little-known legal products, but could be switched if and when marijuana is legalized. Estimates indicate that the market in legalized marijuana might be as high as \$10 billion annually.”
From a report commissioned by cigarette manufacturer Brown and Williamson (now merged with R.J. Reynolds) in the 1970s.

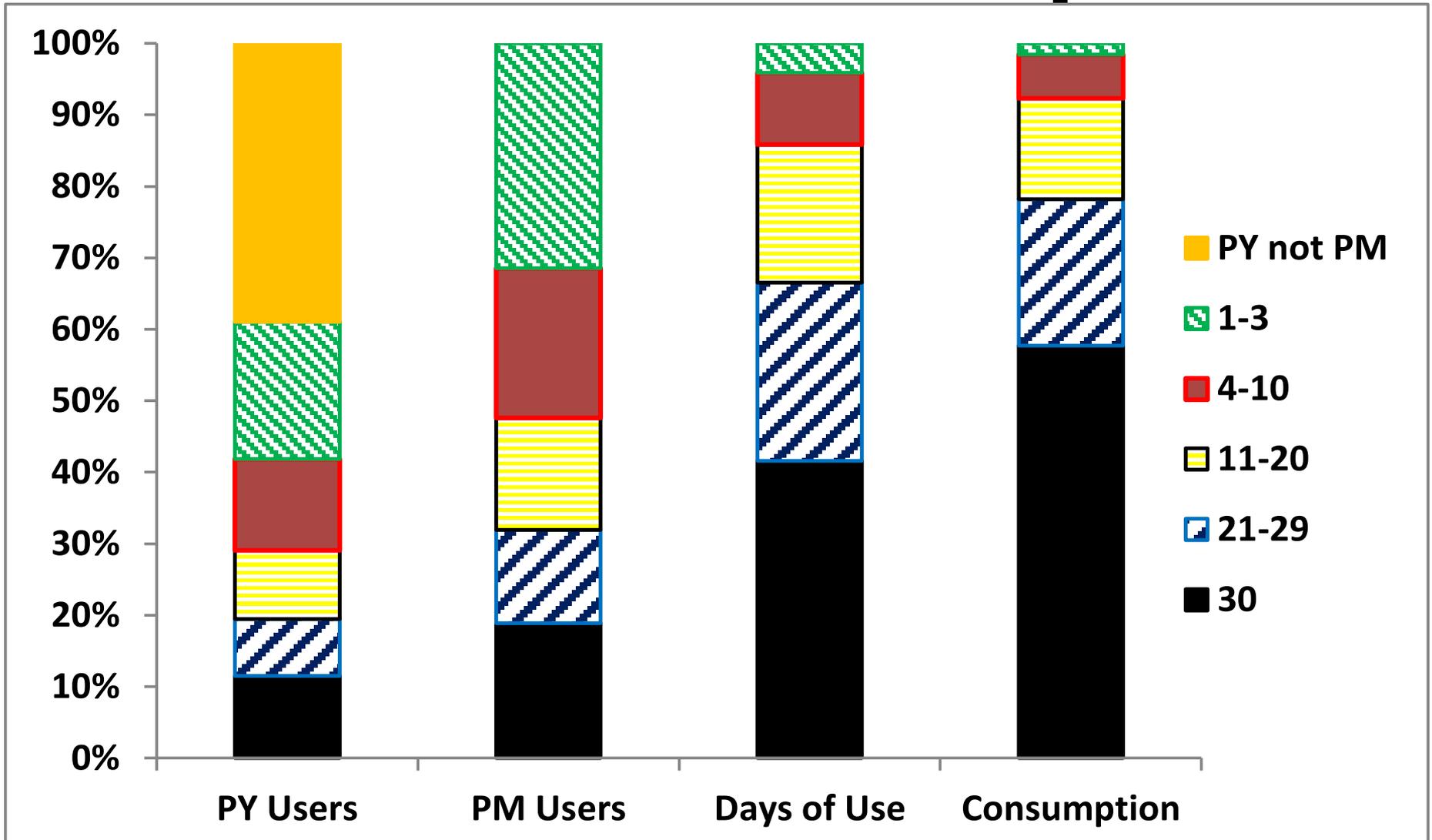
Alcohol and Tobacco: A Model?

- Use levels for alcohol and tobacco are much higher than marijuana
- Industries *promote* addiction and target kids

Schiller JS, Lucas JW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2011. National Center for Health Statistics. Vital Health Stat 10(256). 2012.

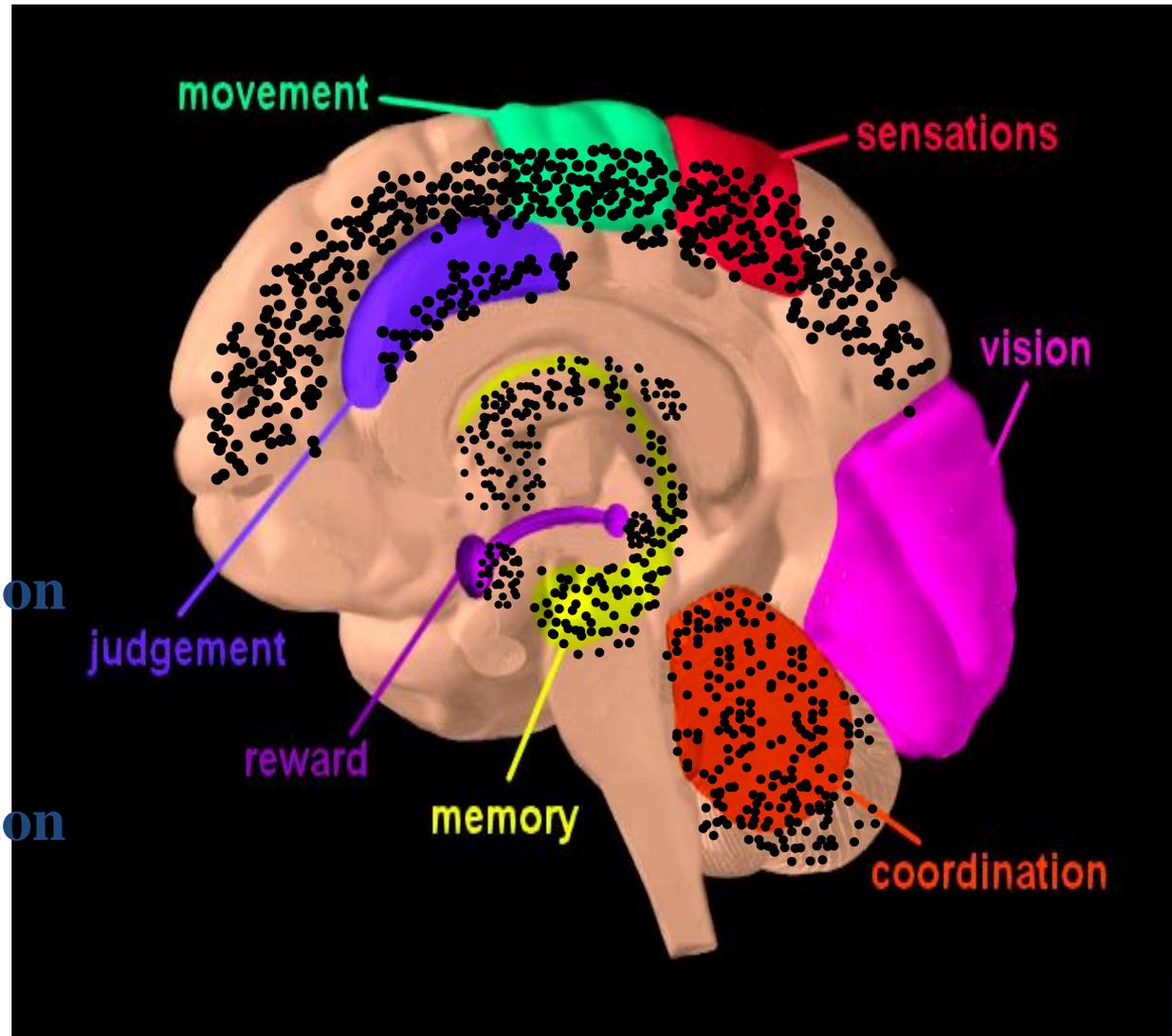
Centers for Disease Control and Prevention. [Vital Signs: Current Cigarette Smoking Among Adults Aged ≥ 18 Years—United States, 2005–2010](#). Morbidity and Mortality Weekly Report 2011;60(33):1207–12

Daily & Near-Daily Users Dominate Consumption



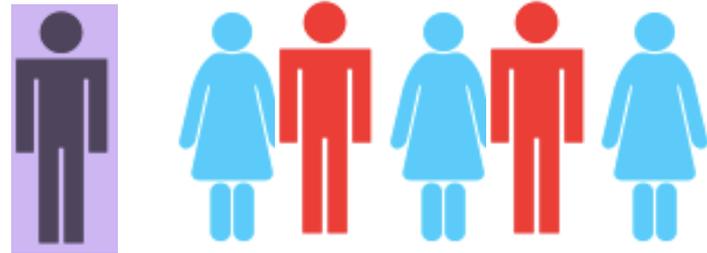
Cannabinoid Receptors Are Located Throughout the Brain and Regulate:

- Brain Development
- Memory & Cognition
- Motivational Systems & Reward
- Appetite
- Immunological Function
- Reproduction
- Movement Coordination
- Pain Regulation & Analgesia



1 in 6 teens become addicted

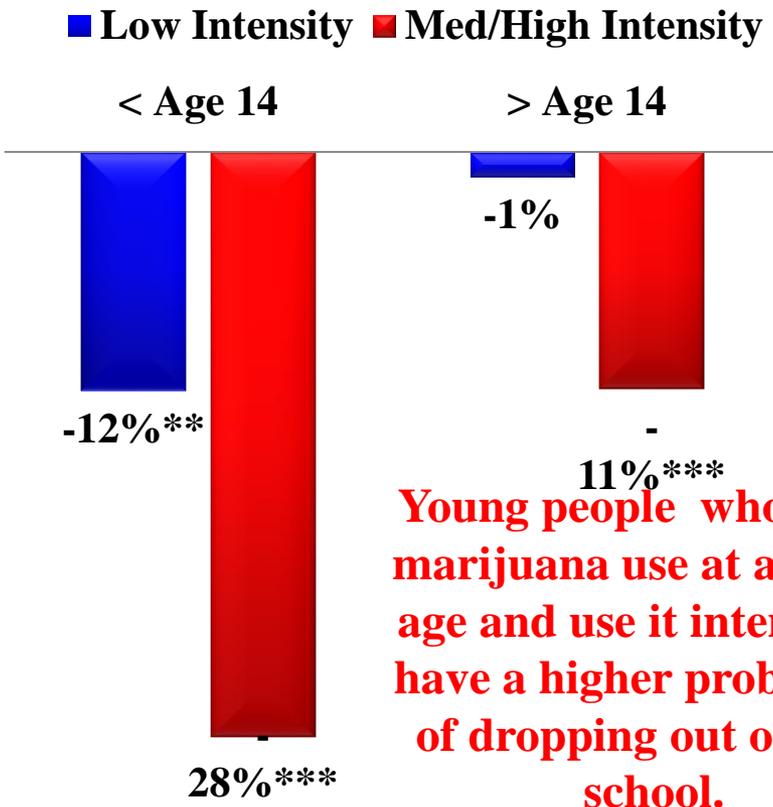
1 in 11 adults and **1 in 6 adolescents** who try marijuana will become addicted to it.



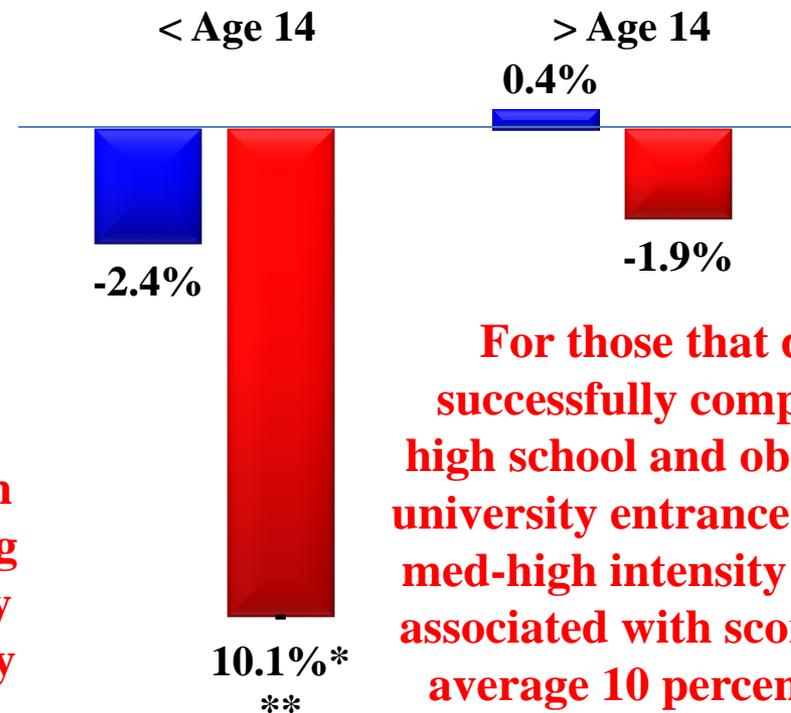
- The adolescent brain is especially susceptible to marijuana use.
- When kids use, they have a greater chance of addiction since their brains are being primed.

Early Marijuana Use and Intensity of Use are Associated with Educational Attainment

High School Completion



University Entrance Score



*** p<0.01, ** p<0.05

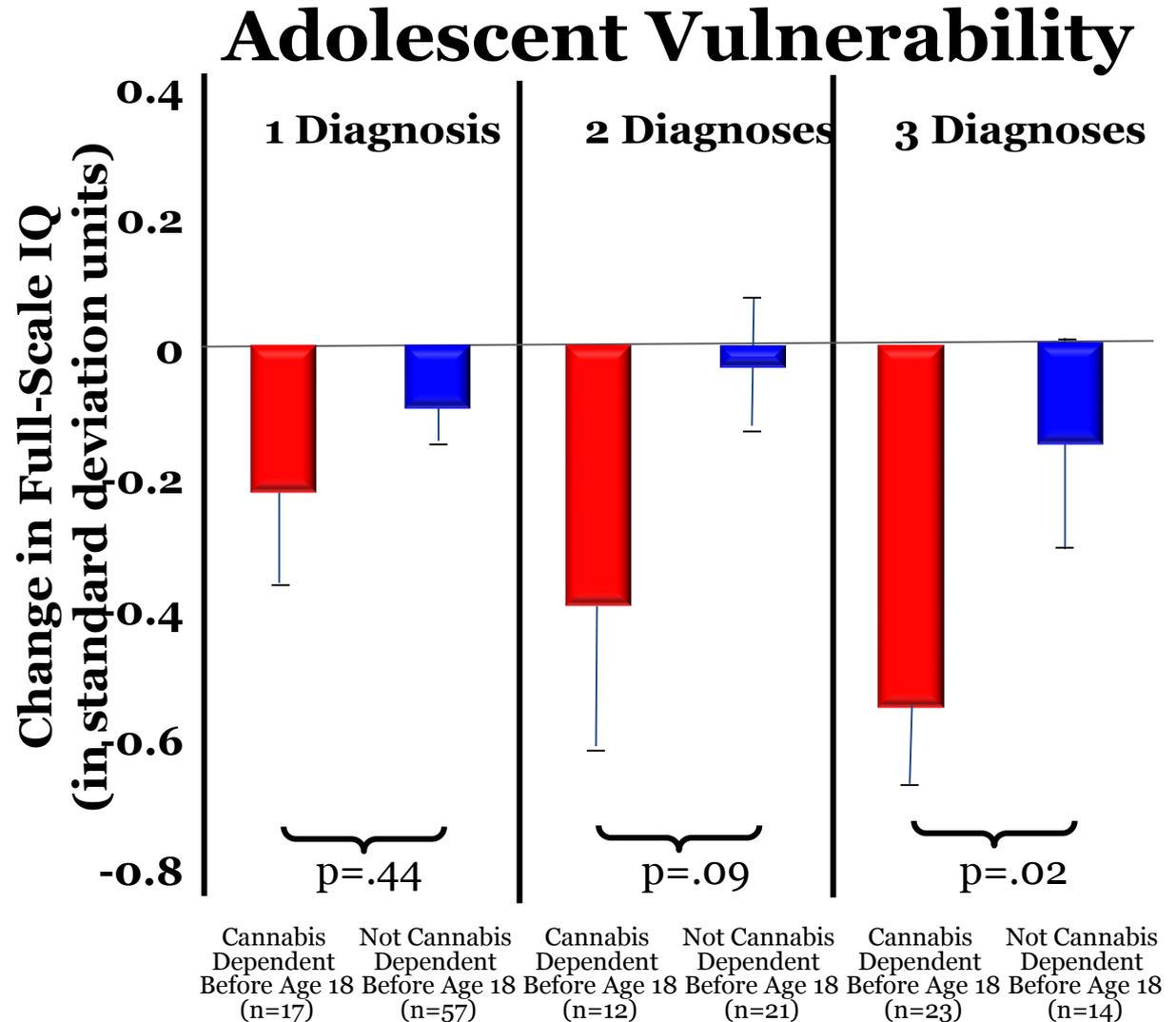
Source: Cobb-Clark et al. <http://ftp.iza.org/dp7790.pdf>

Reductions in IQ

Dunedin
prospective
study of
1037 Ss born
1972/73,

Tested for
IQ at age 13
and 38y.

Tested THC
use ages 18,
21, 26, 32
and 38y

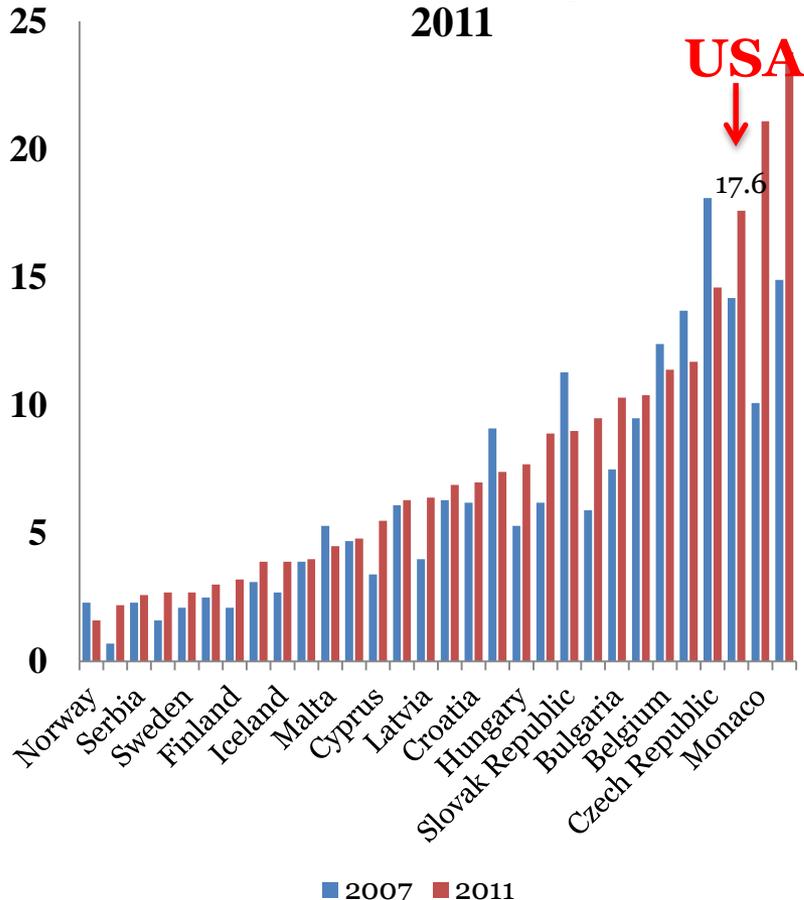


Source: Meier MH et al., PNAS Early Edition 2012.

Can the USA Afford the Risk of Further Increases in Cannabis Use?

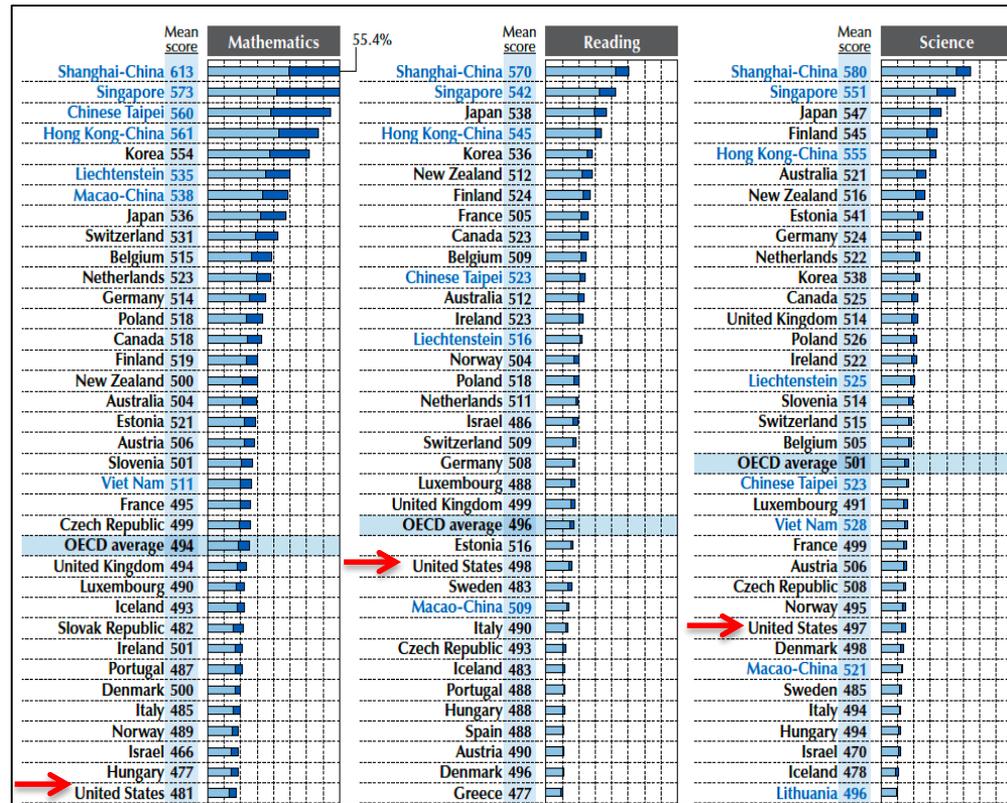
Prevalence of Cannabis Use among High School Students

Past Month Use, Percentages, 2007 and 2011



USA ranks 28th compared with 30 European countries.

International Rankings of Educational Achievement, 2012



Program for International Assessment (PISA)
 USA students ranked 35th in mathematics,
 24th in reading, and 27th in science

**Point 3: All marijuana as
medicine isn't alike**

Current Status of Federal Law

- Marijuana is a Schedule I drug, defined as:
 - high potential for abuse (1 in 10 dependent)
 - no accepted medical use
 - lacks accepted safety for use under medical supervision
 - **Recently confirmed by Federal Court in San Francisco**

Marijuana is a complex plant with hundreds of components (Cannabinoids, terpenes, flavinoids)

How are scheduling decisions made?

- Group files petition with DEA
- DEA requests from the HHS Secretary "a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance."
- The Secretary's findings on scientific and medical issues are binding on the DEA.

FDA Eight-Factor Analysis

- The drug's actual or relative potential for abuse.
- Scientific evidence of its pharmacological effect, if known.
- The state of current scientific knowledge regarding the drug or other substance.
- Its history and current pattern of abuse.
- The scope, duration, and significance of abuse.
- What, if any, risk there is to the public health.
- Its psychological or physiological dependence liability.
- Whether the substance is an immediate precursor of a controlled substance.

FDA Determines Medicine

- The FDA has reviewed the scheduling of marijuana multiple times; most recently in 2006:
 - “No sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.”

Health and Human Services

- FDA has final determination on downscheduling drugs
- Conducts research on the possible therapeutic utility of marijuana-derived medications

What about Sched 1 vs 2?

- For a drug to be prescribed, **it is necessary but not sufficient** for it to be Schedule 2 or lower.
- Some S-2 drugs cannot be prescribed (e.g. raw opium); others can.
- Minor differences between the two; some handling practices are different. Onerous requirements also req. for S-2
- Bottom line: **NEED INDIVIDUAL PRODUCT TO PRESCRIBE. “MARIJUANA” IS NOT A PRODUCT.**

Marijuana-Based Medication Development

- Robust marijuana research program conducted by the US Government
- “The Farm” supplies marijuana in various strains and strengths: University of Mississippi
- 209 active researchers registered with DEA to perform bona fide research with marijuana, marijuana extracts, and THC.
 - Of these 209, a total of 109 are approved to perform bona fide research with marijuana, marijuana extracts, and marijuana derivatives such as cannabidiol and cannabitol.
 - Every researcher who has put forth a valid research proposal has received permission to study marijuana.
 - Studies include evaluation of abuse potential, physical/psychological effects, adverse effects, therapeutic potential, and detection.
 - Fourteen researchers are approved to conduct research with smoked marijuana on human subjects.

Marijuana-based medications

- The raw marijuana plant, which contains nearly 500 different chemical compounds, is not an FDA-approved medicine, though various components and related synthetic compounds can be.
 - For example, *Dronabinol* is one such synthetically produced compound used in the FDA-approved medicine *Marinol*.
 - Another FDA-approved medicine, *Cesamet*, contains the active ingredient *Nabilone*, which has a chemical structure similar to THC, the active ingredient of marijuana.

Marijuana-Based Medications

- NIH is responsible for research into marijuana-derived medications.
- 288 NIH-supported projects on cannabinoids.
 - Characterization of the endocannabinoid system, which is involved in a variety of physiological processes including appetite, pain-sensation, mood, and memory;
 - Development of compounds that affect the cannabinoid system
 - Drug effects, imaging studies, among many others.

Marijuana-Based Medications

- 13 NIH-supported projects that are looking at the potential therapeutic value of cannabis-based compounds.
 - Studies of specific compounds such as dronabinol (synthetic THC) and cannabidiol (CBD), others that are looking at the role of the endocannabinoid system in specific disorders such as depression, models of multiple sclerosis and cancer pain, and studies of novel delivery systems.

CBD as medicine?

- There is some limited anecdotal stories showing CBD effectiveness for epilepsy, especially in children.
- FDA currently has an Investigational New Drug Program with a pure CBD product
- Very different than homegrown CBD w/unknown composition, untested strength and standardization

How to get CBD?

**FDA IND Program
(Investigational New Drug
Program)**

***Today, doctors CAN access
purified CBD***

How to get CBD?

Of course parents shouldn't be locked up or obstructed from getting medicines.

But we should provide a known medication, not unknown ones.

What about internet products with unknown composition?

CBD Products Today

Some companies advertise the following as “high CBD” strains:

Harlequin at 11.6%/6.9% CBD: THC; Canna Tonic at 8.11%/6.9% CBD: THC; Sour Tsunami at 7.24%/4.32% CBD:THC

It is unclear whether their advertised ratios are accurate, i.e., whether the testing results are valid.

Recent internet comments by parents complain that batches of “artisanal” CBD products do not have a consistent or anticipated effect and/or they are horrified that their children become “high”.

Preclinical research suggests that THC can be pro-convulsant in sensitive brains; other research indicates that THC can impair IQ if taken chronically by children and adolescents. Physicians are beginning to report instances of THC toxicity in children taking “high CBD” preparations, e.g., high anxiety, increased seizures, insomnia, and so on.

What about THC for kids?

- No scientific evidence that THC is necessary to synergize the effects of CBD.
 - preclinical research that THC may be pro-convulsant in sensitive brains
 - Physicians are beginning to report instances of THC toxicity in children taking “high CBD” preparations, e.g., high anxiety, increased seizures, insomnia, etc.

Non-FDA formulations

- “High CBD” plant material usually also contains varying levels of THC, sometimes significant amounts.
- Most simple extraction processes cannot reliably extract CBD solely or primarily.
 - Complex and expensive equipment is required to remove THC
 - Research demonstrates that, in many cases, large doses of CBD are needed to achieve a specific therapeutic effect.
 - Accordingly, a child taking a therapeutic dose of CBD (100-1000 milligrams per day) would potentially also be exposed to a large amount of THC.
 - For example, using a 10:1 preparation, a child who ingested 300 mg of CBD per day would also be ingesting 30mg of THC.
 - That is the equivalent of three of the highest dose (10mg) Marinol capsules, which would make most adult patients intoxicated. A 2:1 or 1:1 plant ratio product would contain even higher levels of THC.

American Epilepsy Society

- **The American Epilepsy Society** will present [three new studies](#) on cannabidiol (CBD) and epilepsy at its annual meeting December 2014. Two studies involve a pharmaceutical grade CBD, Epidiolex; one involves CBD from artisanal marijuana, legal for medical and recreational use in Colorado.

Artisanal CBD

- University of Colorado reviewed cases of 58 children with severe epilepsy
 - Parents reported seizure reduction of 50% or more in 1/3 of patients
 - except for two children there was no improvement in their EEGs.
 - **Adverse effects occurred in 47% of patients: 21% experienced increased or new seizures; 10% suffered developmental regression with one patient needing intubation; one patient died.**

Epidiolex CBD

- 23 children with intractable epilepsy
 - dose of 5mg/kg/day, which was gradually increased until tolerance occurred or a maximum dose of 25 mg/kg/day was achieved.
 - After 3 months, 39% of patients had a greater than 50% reduction in seizures; 3 of 9 Dravet Syndrome patients and 1 of 14 patients with other forms of epilepsy were seizure free.

Epidiolex™

- ❑ 98% pure CBD
- ❑ Some effectiveness for seizures
- ❑ Many versions on market which are not purified or standardized



Current Situation

- Many groups are trying to sell or give away CBD in different states without going through any FDA or NIH process. However these products have no such safety assurances.
- We need a long-term solution to expand and accelerate the current research so that every patient who might benefit from CBD can obtain it.

Does medical marijuana lead to increased use?

- Cerda et al: Residents of states with medical marijuana laws have abuse/dependence rates almost twice as high as states with no such laws.
- An additional study in the September 2011 issue of *Annals of Epidemiology* found that, among youths age 12 to 17, marijuana usage rates were higher in states with medical marijuana laws (8.6%) compared with those without such laws (6.9%).

Increased use?

- Vigorous debate, Rees/Anderson: no increase in medical marijuana states (JPAM)
- Pacula (RAND) and Sevigny: Two features – home cultivation and dispensaries – are positively associated with marijuana use and “have important implications for states considering legalization of marijuana.”

Increased use?

- *Lancet* study of 24 states using Monitoring the Future found:
 - **Medical marijuana states had higher 8th, 10th, and 12th grade use than non-MMJ**
 - ***But in MMJ states, use did not increase overall***
 - **In Colorado, however, increase was seen among 10th and 12th graders**

Marijuana policy and adolescents

- Restriction of legalized medical or recreational marijuana within state/district borders and to those ≥ 21 years old does not sufficiently safeguard against widespread adverse effects on youth
 - Youth access legalized marijuana obtained by adults, via diversion (**Salomonsen-Sautel et al., 2012**) and accidental ingestion (**Wang et al., 2013**)
 - Policy changes and marketing efforts have effects across ages and across state lines, with particular impact on youth (**Berg et al., 2015; Richter & Levy, 2014**)

Ways Forward

- ***SAM has recently argued for:***
 - ***Waiving CBD research requirements***
 - ***Starting Compassionate Use Program***
 - ***Expanding Current Programs***

Ways Forward

- *We need federal legislation, or federal modification of current laws:*
 - *Allowing Compassionate Use Program*
 - *Allowing More Research*
- **There is an appetite to do this in Congress; I think this will happen soon.**

In the meantime, could have Utah compassionate legislation with specific sunset provision.



Thank you!

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www.learnaboutsam.org