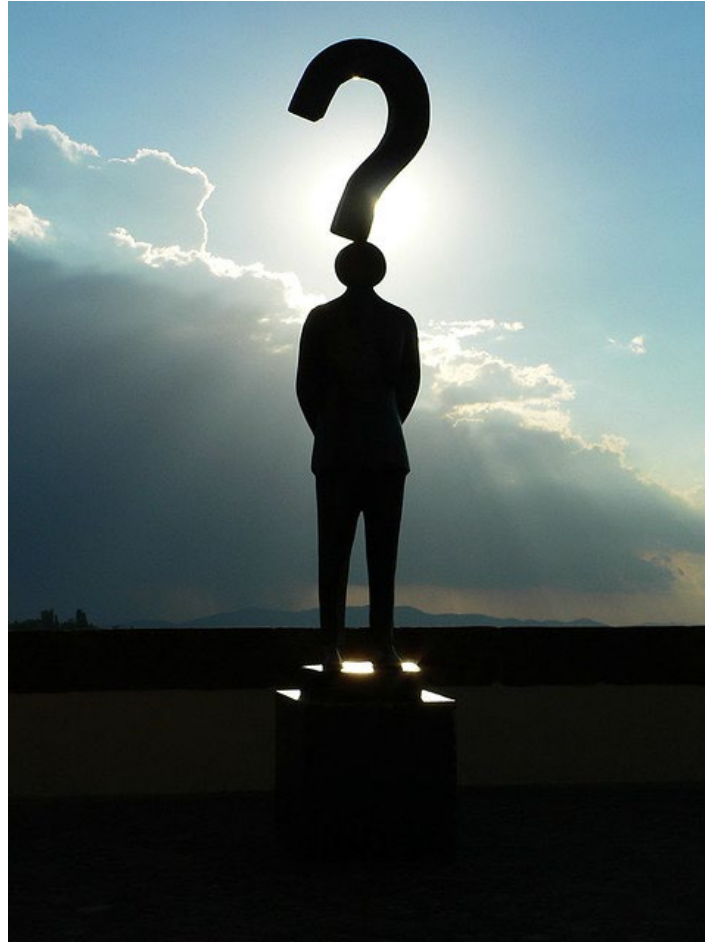


# FDA, Cannabis, Patients and Employers

Classified as a Schedule I drug

- How many legs does a dog have if you call the tail a leg?



- Answer...FOUR. Calling a tail a leg doesn't make it a leg.

# Schedule I Drug

- **Schedule 1 (I) drugs**, substances, or chemicals are defined by the federal government as **drugs** with no currently accepted medical use and a high potential for abuse. **Schedule 1 (I) drugs** are the most dangerous **drugs** of all the **drug schedules** with potentially severe psychological or physical dependence.

# However...

- The psychoactive ingredient in marijuana (**THC**) has been available in the form of dronabinol (Marinol) **since** 1985.
- The FDA approved nabilone (Cesamet) **which is** chemically similar to THC.
- **Cannabidiol (CBD)** is a [phytocannabinoid](#) which is “not psychoactive” and is the active ingredient in **Epidolex**

# May 5, 2019

- **North Carolina great-grandmother, 69, arrested at Disney World over CBD oil in her purse....**
- She was arrested for possession of Hashish, a felony charge, and later released on \$2,000 bail.
- Burkhalter told [Orlando's Fox 35](#) that she was prescribed the CBD oil by her North Carolina doctor.
- "I have really bad arthritis in my legs, in my arms and in my shoulder," she told the local news outlet. "I use (CBD oil) for the pain because it helps."
- Burkhalter said she "didn't know what to think" when getting arrested, adding that, "I've never had one speeding ticket in my life."

# Ohio Medical Cannabis

## 4731-32-02 Certificate to Recommend Medical Marijuana

- OAC specifies requirements to “recommend” cannabis.
- The applicant has completed at least two hours of continuing medical education in a course or courses certified by the Ohio state medical association or the Ohio osteopathic association that assist physicians in both of the following:
  - (a) Diagnosing qualifying medical conditions as defined in section [3796.01](#) of the Revised Code;
  - (b) Treating qualifying medical conditions with medical marijuana, including the characteristics of medical marijuana and possible drug interactions.



# "Qualifying medical condition" (OHIO) means any of the following:

- AIDS
  - Alzheimer's disease
  - cancer
  - Crohn's disease
  - fibromyalgia
  - hepatitis C
  - inflammatory bowel disease
  - pain that is either chronic and severe or intractable
  - positive status for HIV
  - sickle cell anemia
  - spinal cord disease or injury
  - Tourette syndrome
  - ulcerative colitis
  - amyotrophic lateral sclerosis
  - cachexia
  - chronic traumatic encephalopathy
  - epilepsy or another seizure disorder
  - glaucoma
  - Huntington's disease
  - multiple sclerosis
  - Parkinson's disease
  - post-traumatic stress disorder
  - spasticity
  - terminal illness
  - traumatic brain injury
-

- Physicians will need to see their medical marijuana patients in-person **at least once per year**. It is imperative that physicians recommending with their CTR follow the medical board's Standard of Care Rule for the medical marijuana control program.
- Covid pandemic allowed for TELEPHONIC assessments

# Why do we need medical cannabis?

A Report of

*The National Academies of*

SCIENCES • ENGINEERING • MEDICINE

# Evidence

- There is conclusive or substantial evidence cannabis or cannabinoids are effective for:
  - Chronic pain
  - As an antiemetic treatment of chemotherapy-induced nausea and/or vomiting
  - Improving patient reported spasticity secondary to multiple sclerosis

# Evidence

- There is moderate evidence that cannabis cannabinoids are effective for:
  - Improving short-term sleep in patients with sleep disturbance associated with OSA, myalgia, chronic pain, and multiple sclerosis

# Evidence

- There is limited evidence that cannabis or cannabinoids are effective for:
  - Increasing appetite and decreasing weight loss patients with HIV
  - Improving clinically measured spasticity secondary to multiple sclerosis
  - Improving symptoms of Tourette's syndrome
  - Improving social anxiety disorder
  - Improving symptoms of PTSD

# Evidence

- There is limited evidence of statistical association between cannabinoids and:
  - Better outcomes after traumatic brain injury and/or intracranial hemorrhage

# Evidence

- There is limited evidence that cannabis or cannabinoids are ***ineffective*** for:
  - Improving symptoms secondary to dementia
  - Improving intraocular pressure secondary to glaucoma
  - Reducing depressive symptoms in patients with chronic pain and/or multiple sclerosis



# Evidence

- There is no or insufficient evidence to support or refute the conclusion that cannabis or cannabinoids are effective treatment for:
  - Cancer, including glioma
  - Cancer associated anorexia cachexia syndrome and anorexia nervosa
  - Symptoms of irritable bowel syndrome
  - (Epilepsy) **prior to the FDA approval**
  - Spasticity in patients with paralysis due to spinal cord injury
  - Symptoms associated with ALS
  - Chorea and certain neuropsychiatric symptoms associated with Huntington's disease
  - Motor symptoms associated with Parkinson's disease
  - Dystonia
  - Achieving abstinence in patients with SUD
  - Mental health outcomes patients with schizophrenia or schizophreniform psychosis

# Epilepsy...but

**|CONCLUSION 4-6 There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy.**

# Epidiolex – CBD-based and FDA Approved

**EXPERIENCE SIGNIFICANT SEIZURE REDUCTION WITH**

## **The First and Only FDA-Approved Prescription Cannabidiol (CBD)**

**FOR DRAVET AND LGS**

FDA = US Food and Drug Administration.

Dravet = Dravet syndrome.

LGS = Lennox-Gastaut syndrome.

In other words....

Contrary to the rationale for prevailing federal restrictions, considerable published medical opinion holds that **marijuana has value in the treatment or palliation of human disease.**

The lifetime risk of addiction [to marijuana] is estimated to be 9% compared with 32% for tobacco and 15% for alcohol.

# Pharmacologic effects of marijuana

- Physical Findings

- Dilated pupils
- Injected conjunctiva
- ↑ Heart Rate
- ↓ Pupil response to light



- Patient's Report:

- Euphoria or dysphoria
- Altered thoughts
- Disorientation
- "Slowing of time"

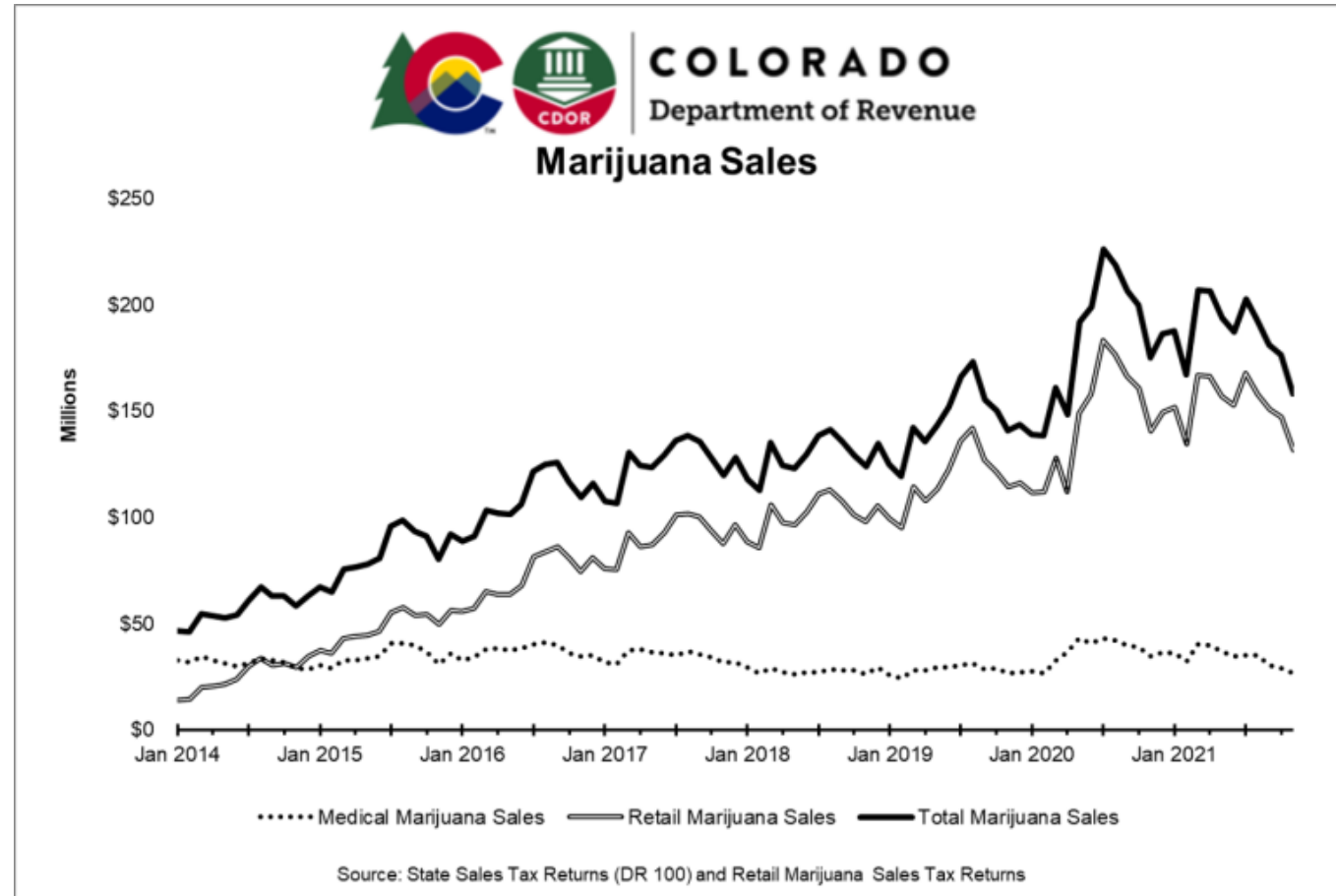
- Other "Findings"

- Increased appetite
- Feeling dizzy or lightheaded
- Dry mouth; cough; N/V

- Impairment Findings

- Impaired motor skills, memory
- Impaired attention, concentration
- Impaired "ability to think."

# Colorado Experience



# Colorado Cannabis Sales....

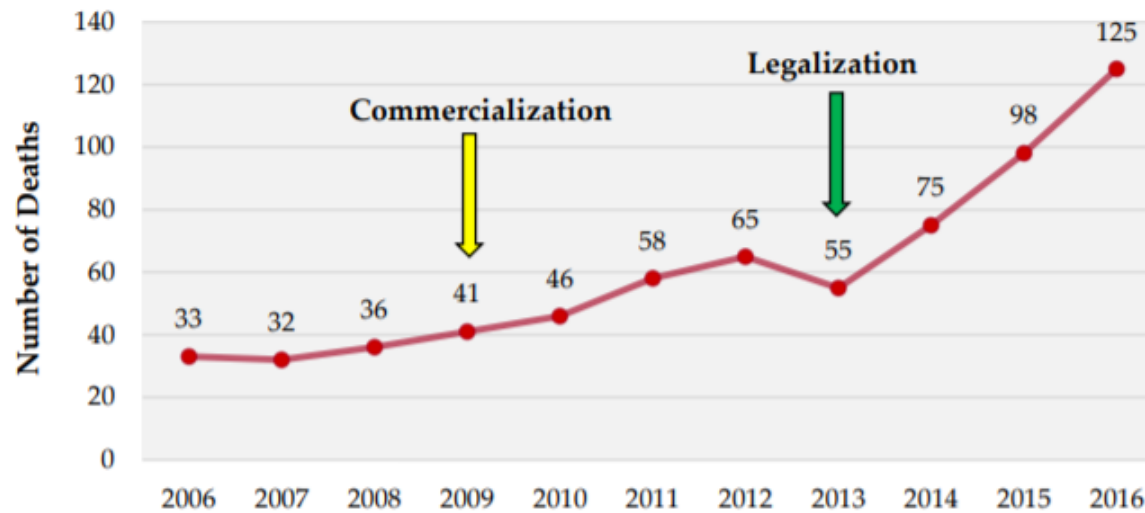
## Marijuana Sales

<b>Calendar Year</b>	<b>Marijuana Sales by Calendar Year</b>	<b>Total Marijuana Sales Since Jan 2014</b>
2014	\$683,523,739	\$683,523,739
2015	\$995,591,255	\$1,679,114,994
2016	\$1,307,203,473	\$2,986,318,467
2017	\$1,507,702,219	\$4,494,020,686
2018	\$1,545,691,080	\$6,039,711,766
2019 (Jan - Feb)	\$244,282,134	\$6,283,993,900

Updated April 2019

# Safe to Drive?

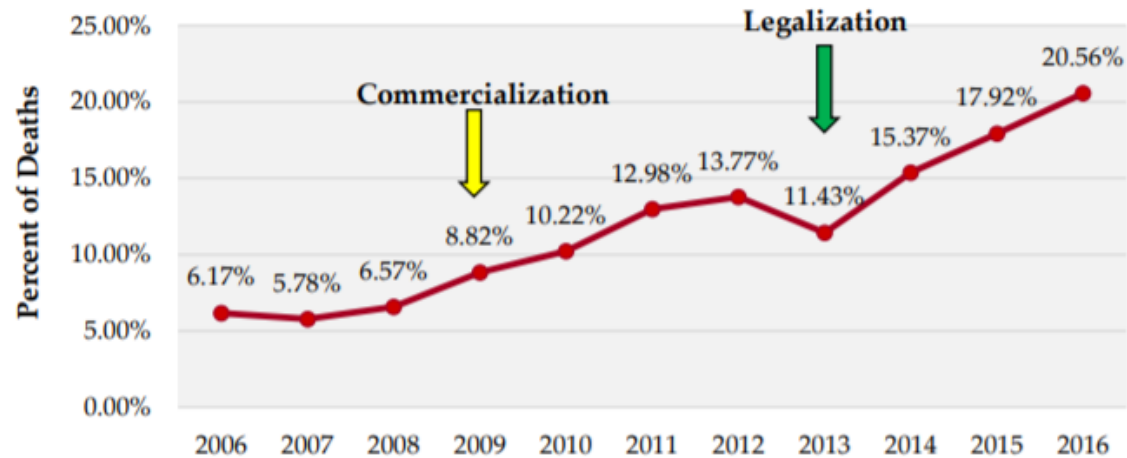
**Traffic Deaths Related to Marijuana when  
a Driver Tested Positive for Marijuana**



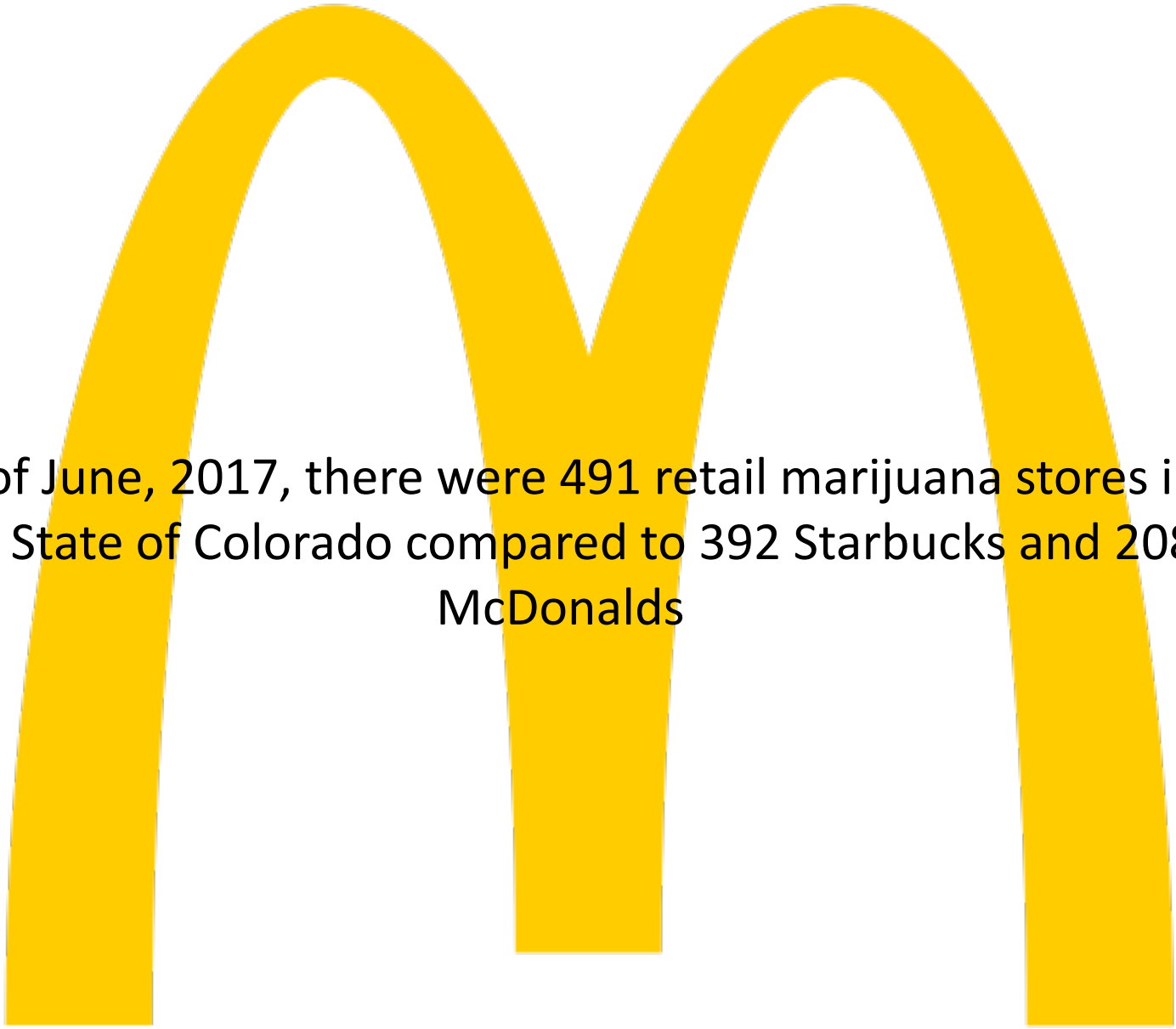
SOURCE: National Highway Traffic Safety Administration, Fatality Analysis Reporting System (FARS), 2006-2011 and Colorado Department of Transportation 2012-2016



## Percent of All Traffic Deaths That Were Marijuana-Related 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 2012-2016



As of June, 2017, there were 491 retail marijuana stores in the State of Colorado compared to 392 Starbucks and 208 McDonalds

# OHIO

- Sales Figures (as of 1/24/2022)
  - 78,632 lbs. of plant material
  - 7,014,697 units of manufactured product
  - \$690.1 million in product sales
  - 5,145,342 total receipts
- 
- Through Nov. 19, the Ohio State Highway Patrol recorded 1,311 traffic crashes involving marijuana, which was already up about 1.2% from all of 2019, according to agency data.
  - The state patrol said there have been 10,807 crashes involving impaired drivers of all kinds through mid-November, or about 83% of last year's total.

# Work, POT, and other “fun substances.”

- The U.S. Substance Abuse and Mental Health Services Administration estimated in 2007 that 8.4% of full-time workers had engaged in some type of illicit drug use within the preceding month.

- “OSHA strongly supports measures that contribute to a drug-free environment and reasonable programs of drug testing within a comprehensive workplace program for certain workplace environments, such as those involving safety-sensitive duties like operating machinery. Such programs, however, need to also take into consideration employee rights to privacy. Although there are no regulations specific to the topic, protection from drug impairment is covered under the general duty clause.”

“In addition to risk of injury, industry must also consider the possibility that increases in absenteeism and presenteeism may occur, as marijuana-containing products become increasingly available to workers. At present there is **inadequate research to draw clear conclusions on the relationship between off-shift marijuana use and workplace safety and productivity.**”

“... occupational physicians [employers] must be alert to the potential for devastating consequences of marijuana-related impairment. This risk was highlighted in 2013 by the allegation that illicit marijuana use was a key contributing factor in a heavy machinery accident that took the lives of six individuals.”

The first recorded cannabis use dates to 2737 BC, by the emperor Shen Neng of China.

Historically, marijuana tea was recommended for the treatment of

- gout
- rheumatism
- malaria and
- poor memory
- seizures
- nausea/vomiting



# Endocannabinoid System - Endogenous

Cannabinoids are critical for normal human physiology, specifically in the control of movement, pain, appetite, memory, immunity, and inflammation.

Despite a growing body of evidence that cannabinoids are medicinally useful, the emergence of a restrictive legal environment stunted both research and application during the twentieth century, ultimately resulting in the withdrawal of support for its use in the care for human disease.

# “Side-Effects”

Negative effect of cannabis on learning and memory, in addition to deficits in attention, concentration, and abstract reasoning.

Research demonstrates that acute cannabis consumption is associated with an increased risk of a motor vehicle crash, and especially for fatal collisions

There has been some testing in the airline industry that correlates with driving impairment. In one **simulator study**, the number of aileron, elevator, and throttle changes, the magnitude of control changes, variation from the center of the runway on landing, and lateral and vertical deviation from an ideal glideslope and center line over the final mile of the landing approach were all impaired at 1, 4, and 24 hours after consumption of marijuana.

Journal of Applied Psychology

1990, Vol 75, No.6, 629-630

*An Evaluation of Preemployment Drug Testing*

Jacques Normand et. al.

- **Abstract**

- Blind longitudinal study of 5,465 job applicants
- Urine tested for illicit drugs
- Employees who had tested positive for illicit drugs had an absenteeism rate 59.3% higher than employees who had tested negative
- Employees who had tested positive also had a 47% higher rate of involuntary turnover than employees who had tested negative
- No significant associations were detected between drug-test results and measures of injury and accident occurrence.

# Impairment at the Workplace

- Observation of impairment
  - Erratic behavior – conflict, overreaction, moodiness
  - Physical features – slurred speech, red eyes, dilated/pinpoint pupils, “odor”
  - Job performance – unsafe activities, tardiness, absenteeism etc
- Response to impairment
  - Clear policy and procedures
    - Process of identifying AND referral (drug and alcohol testing, medical evaluation)
  - Document

# What does this do?

- It points to magnetic North



# Drug Tests and Impairment

- Remember
  - A urine drug test reveals the presence of a drug or metabolite > than the cutoff level
  - The drug test does NOT equal/correlate with impairment
  - The drug or metabolite concentration in the urine does not correlate with use per se
- Blood tests for THC tend to correlate with impairment
  - Blood 1ng/mL risk of crash is 2.18 times greater
  - Blood 5ng/mL risk of crash is 4.72 time greater
- Some states have defined impairment under marijuana when the blood level of THC > 5ng/mL.



# Medical Review Officers (MRO)

- Physicians who are “trained to interpret” urine toxicology tests.
- Serve as a “gate-keeper” for the drug test review process.
- Because marijuana is a scheduled I drug, any test reported with a positive marijuana will be reported as positive (if the donor does not have a valid medical reason for the non-negative test).
- The donor will be advised to inform their employer, or potential employer, if they have a marijuana “card/recommendation.”

# Where are we going?

- “In the midst of the growing [marijuana](#) decriminalization movement, New York City’s city council has [passed a groundbreaking bill](#) that would prevent most employers from requiring job applicants to undergo marijuana drug tests.”

- When it comes to off-duty medical marijuana use, the states are divided. About 20 states **prohibit employers** from discriminating against medical marijuana cardholders or from firing employees for testing positive for marijuana due to off-duty use. Some of these states also require employers to reasonably accommodate an employee who needs medical marijuana to treat a medical condition—for example, by allowing an employee to start work later in the morning because she uses medical marijuana at night to treat glaucoma.
- But other states explicitly **allow employers to fire employees** for off-duty medical marijuana use. And some states don't clearly address the issue—but courts in several of these states have sided with the employer, holding that employers can fire employees for off-duty use of medical marijuana.

- Under Ohio law, **employers are not required to permit or accommodate an employee's use**, possession, or distribution of medical marijuana in or out of the workplace. Employers can refuse to hire, discharge, and discipline an individual because that individual uses medical marijuana.

# OHIO BWC

- “The law specifies that marijuana is covered under “rebuttable presumption.” In general, this means that an employee whose injury was the result of being intoxicated or under the influence of marijuana is not eligible for workers’ compensation. This is the case regardless of whether the marijuana use is recommended by a physician....”

# OHIO

- **FEDERAL CONTRACTOR:** An employer must maintain a drug-free workplace – even free of state-authorized medical marijuana or employs workers in federal safety sensitive positions.
- An employer must also maintain a drug-free workplace if it receives a workers' compensation insurance rebate for a drug-free workplace from the Ohio Bureau of Workers' Compensation and wishes to keep receiving that rebate.

# Other OHIO employers....

- Employers have a choice
  - The OHIO law neither requires nor prohibits accommodations for medical marijuana use.
  - The law provides several, explicit protections for employers who take adverse employment action against employees based on medical marijuana use.

- Employers can:

- Continue with drug testing policies and zero-tolerance, drug-free workplace programs, and employees who are discharged for violation of such policies are ineligible for unemployment compensation benefits



# However...

- Employers who take an adverse employment action based on **medical marijuana** use could be perceived instead as an adverse employment action based on disability or perceived disability, which is prohibited under Ohio law.

# Employer who accommodate

- An employer who tests their employees for drugs could treat positive marijuana tests like other non-negative drug tests
  - Valid prescription
  - Workers with a “recommendation” for medical marijuana
- The employer can even have different drug testing and usage rules for different employment classifications
  - Perhaps continuing drug testing and discipline for marijuana usage among safety-sensitive positions only

- For all employers:
  - Review your current workplace policies
  - Reconsider those policies in light of the new Ohio law and any obligations you might have to maintain a “drug-free” workplace
  - Revise your policies as needed
  - EDUCATE employees about policies