

Oklahoma Medical Marijuana Coalition

Oklahoma Legislative Bicameral Working Group
Aug. 29, 2018



Coalition Members

**American Lung Association –
Oklahoma Chapter**

**Oklahoma Academy of Family
Physicians**

**Oklahoma Academy of
Ophthalmology**

**Oklahoma Academy of
Physician Assistants**

**Oklahoma Behavioral Health
Association**

**Oklahoma Center for Poison
and Drug Information**

**Oklahoma Chapter – American
Academy of Pediatrics**

Oklahoma Hospital Association

Oklahoma Nurses Association

**Oklahoma Osteopathic
Association**

Oklahoma Pain Society

**Oklahoma Pharmacists
Association**

**Oklahoma Psychiatric
Physicians Association**

Oklahoma Psychological

Society

**Oklahoma Society of Addiction
Medicine**

**Oklahoma Society of
Anesthesiologists**

**Oklahoma State Medical
Association**

**Oklahoma Tobacco Research
Center**



Getting It Right From the Beginning



Oklahoma's medical community are not opposed to medical marijuana or cannabis derivatives. We have shown our support in the past by advocating for the legalization of CBD oil in our state and increased research of medical marijuana at the federal level.



Getting It Right From the Beginning



Coalition Goals:

1. Guard Patient Safety By Adopting Standards Used for Other Medicines
2. Ensure Patient Access through a Clear System of Safety and Liability Controls That Address Providers' Concerns
3. Ensure Public Safety by Developing Safeguards, Such as Consistent Product Labeling, Controlled Access and Preventing Secondhand Smoke



Patient Safety and Medical Standards

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Disclaimer: I have no financial relationships with proprietary entities that produce healthcare goods nor marijuana or its derivatives, nor do my immediate family members. The opinions and information in this presentation are on behalf of the coalition and do not necessarily reflect the views and policies of the University of Oklahoma or the hospitals with which I am affiliated.



Patient Safety in Prescribing

Accepted Prescriptive Standards

General Prescriptions (Not Controlled Substances) – 7 Steps

1. Examine patient and define the problem(s)
2. Review medical history and current medications
3. Discuss treatment options
4. Determine the appropriate drug therapy
5. Write a prescription with instructions
6. Discuss dosage, use and possible side effects
7. Follow-up within the first month and periodic re-evaluation at six months to a year



Patient Safety in Prescribing

Accepted Prescriptive Standards

Off-label Use of Medications – 7 Steps

1. Examine patient and define the problem
2. Review medical history and current medications
3. Discuss treatment options
4. Determine the appropriate drug therapy
5. Write a prescription with instructions
6. Discuss dosage, use and possible side effects
7. Follow-up within the first month and periodic re-evaluation at six months to a year.



Patient Safety in Prescribing

Accepted Prescriptive Standards

Controlled Substances (Schedule II Drugs) – 10 Steps**

1. Examine patient and define the problem
2. Review medical history and current medications
3. Discuss treatment options
4. Determine appropriate drug therapy
5. Consult the PMP
6. Write a prescription with instructions
7. Discuss dosage, use and possible side effects
8. Follow-up within the first month
9. Issue 30 day-renewals each month (while needed)
10. Re-evaluation at six months to a year

**** Due to the passage of SB 1446, additional steps including Physician/
Patient agreement and pill limits will be added**



Patient Safety in Prescribing

Oklahoma's Standards Under SQ 788

Medical Marijuana (Schedule 1) – 3 Steps

1. Examine patient and define the problem
2. Review medical history and current medications
3. Write a two-year recommendation

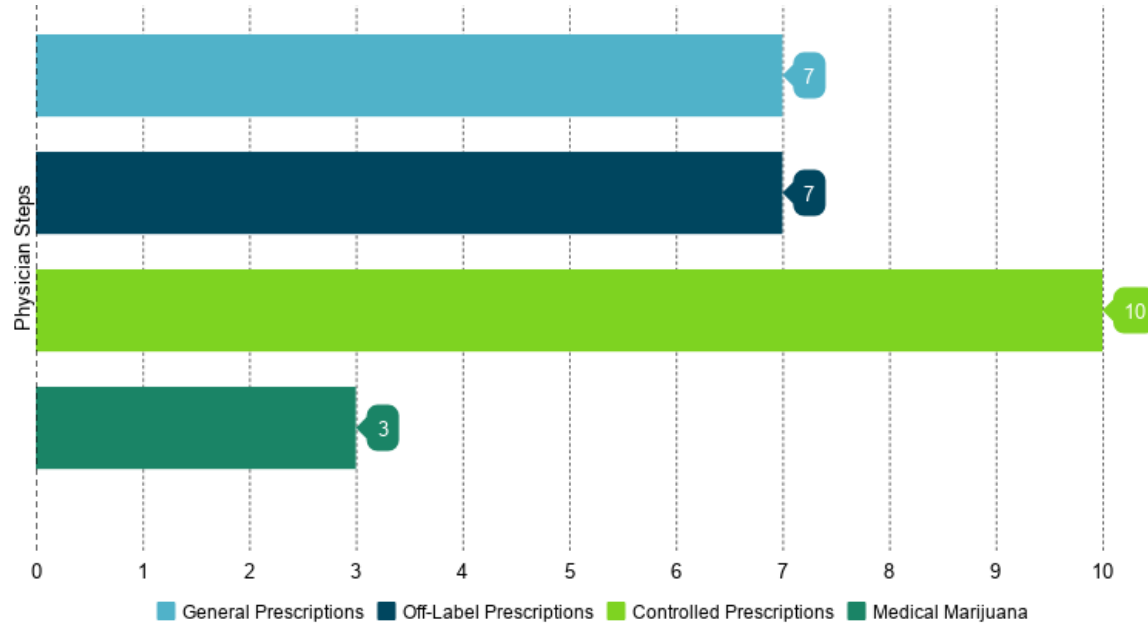
**** No follow-up required**



Oklahoma's medical marijuana recommendation standards must be better defined and include the same standards as controlled dangerous substances (Schedule II) drugs



Patient Safety in Prescribing Prescriptive Standards



Patient Safety and Standard of Care

Standard of care is a medical or psychological treatment guideline that specifies appropriate treatment based on scientific evidence and collaboration between medical and/or psychological professionals involved in the treatment of a given condition.



Oklahoma's providers do not have the ability to use accepted standards of care with medical marijuana as there are no conditions, no control over product strength and dosage, and no required follow-up for two years



Patient Safety and Standard of Care

Defining a “Bona Fide Patient/Doctor” Relationship



The very first line of the Hippocratic Oath is:
“First Do No Harm.” The health and safety
of our patients is our greatest responsibility



Patient Safety and Standard of Care

American Medical Association Code of Ethics (Excerpted)

- A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.



Patient Safety and Standard of Care

American Osteopathic Association Code of Ethics (Excerpted)

- A physician should make a reasonable effort to partner with patients to promote their health and shall practice in accordance with the body of systematized and scientific knowledge related to the healing arts. A physician shall maintain competence in such systematized and scientific knowledge through study and clinical applications.
- A physician shall respect the law. When necessary a physician shall attempt to help formulate the law by all proper means in order to improve patient care and public health.

Source:

<https://osteopathic.org/about/leadership/aoa-governance-documents/code-of-ethics/>

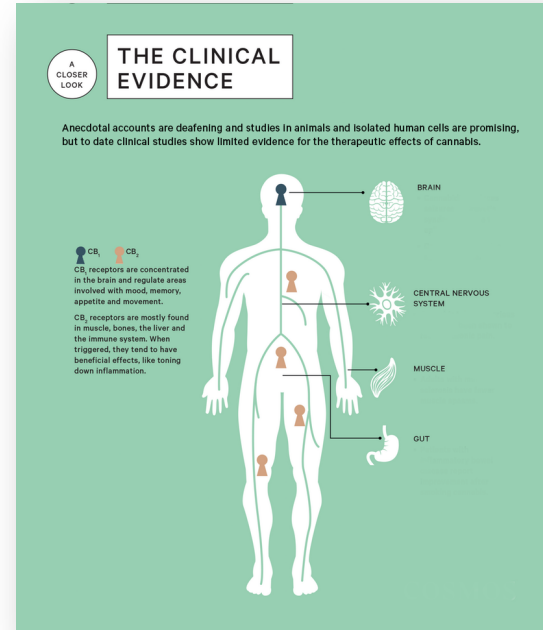


Patient Safety and Standard of Care

Conditions That Are Effectively Treated by Medical Marijuana

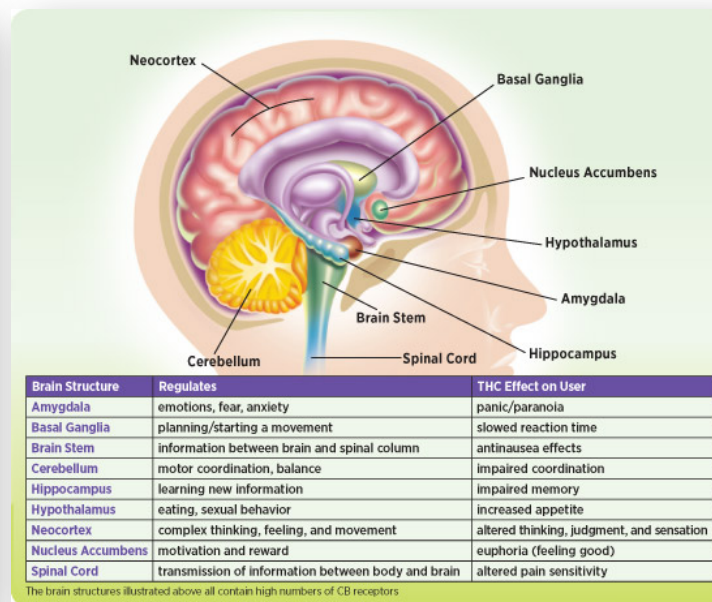
- Epilepsy and Other Seizure Disorders (Unresponsive to Other Forms of Treatment)
- Nausea and Vomiting from Chemotherapy (Unresponsive to Other Forms of Treatment)
- Muscle Spasticity (MS and Parkinson's)
- Relief for Terminal Illness (Expected to Live Less Than 1 Year)
- Wasting Syndrome from HIV/AIDS and Cancer

Conclusive Scientific Evidence for Treatment of Other Ailments is Limited Due to Continued Schedule I Status at the Federal Level



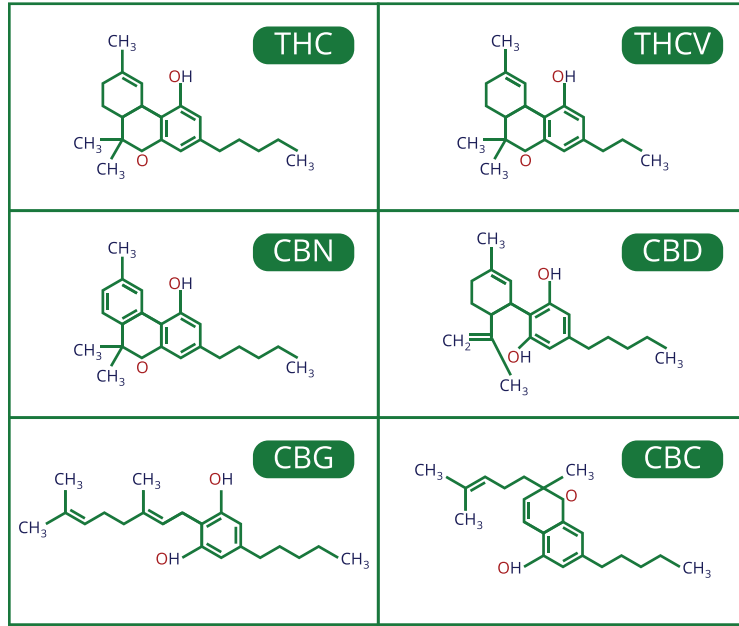
Patient Safety and Standard of Care

How Medical Marijuana Impacts the Brain and Body



Patient Safety and Standard of Care

How Medical Marijuana Impacts the Brain and Body



A cannabis plant is a mixture of +/- 100 cannabinoids and more than 500 chemicals, the strength of which vary greatly across different genetic strains and according to growth conditions.



Patient Safety and Standard of Care

FDA APPROVED CANNABINOID MEDICATIONS		
Substance	Route of Administration	Description
Epidiolex® (FDA Approved)	Oil	Concentrated CBD from Cannabis extract
Nabiximol (Sativex®) (FDA Fast-Tracked)	Oromucosal spray	THC and CBD extract from two Cannabis plant varieties
Dronabinol (Marinol®; Syndros®) (FDA approved)	Oral capsule	Synthetic THC
Nabilone (Cesamet®) (FDA Approved)	Oral capsule	Synthetic cannabinoid—THC analogue



Patient Safety and Standard of Care

Medical Marijuana and FDA Approval

“ FDA’s Role in the Drug Approval Process

The FDA has not approved marijuana as a safe and effective drug for any indication. The agency has, however, approved one specific drug product that contains the purified substance cannabidiol for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. The FDA has also approved two drugs containing a synthetic version of a substance that is present in the marijuana plant and one other drug containing a synthetic substance that acts similarly to compounds from marijuana but is not present in marijuana. The FDA is aware that there is considerable interest in the use of marijuana to attempt to treat a number of medical conditions, including, for example, glaucoma, AIDS wasting syndrome, neuropathic pain, cancer, multiple sclerosis, chemotherapy-induced nausea, and certain seizure disorders.”



Patient Safety and Standard of Care

Example of Clinical Trial Research Phases					
Phase	Primary goal	Dose	Patient monitor	Typical number of participants	Success Rate
Preclinical	Testing of drug in non-human subjects to gather efficacy, toxicity and pharmacokinetic information	Unrestricted	Scientific researcher	Not applicable (in vitro and in vivo only)	
Phase 0	Pharmacokinetics; particularly, oral bioavailability and half-life of the drug	Very small, subtherapeutic	Clinical researcher	10 people	
Phase I	Testing of drug on healthy volunteers for safety; involves testing multiple doses dose-ranging	Often subtherapeutic, but with ascending doses	Clinical researcher	20–100 normal healthy volunteers (or for cancer drugs, cancer patients)	Approximately 70%
Phase II	Testing of drug on patients to assess efficacy and side effects	Therapeutic dose	Clinical researcher	100–300 patients with specific diseases	Approximately 33%
Phase III	Testing of drug on patients to assess efficacy, effectiveness and safety	Therapeutic dose	Clinical researcher and personal physician	300–3,000 patients with specific diseases	25–30%
Phase IV	Postmarketing surveillance – watching drug use in public	Therapeutic dose	Personal physician	Anyone seeking treatment from their physician	N/A



Patient Safety and Standard of Care

Medical Marijuana Studies Offer Few Conclusive Scientific Recommendations

- There are vast differences in study design, characteristics of marijuana or cannabinoid exposure and populations studied
- Studies based on ‘case reports,’ editorials, by ‘anonymous’ authors, commentaries and conference abstracts do not carry the same scientific weight as clinical trials/primary research (must be reproducible)
- At this moment in time, the medical community places highest priority on recently published primary research and reviews since 2011



Patient Safety and Standard of Care

Medical Marijuana Studies Offer Few Conclusive Scientific Recommendations

- Some research on the impact marijuana and compounds found in marijuana is available
- University of Mississippi is the **SINGLE** source of legal marijuana for research
- The marijuana's THC levels are lower than some of the more popular medical marijuana available
- Research approval is very limited (in 2016, only 39 requests for research marijuana were filled)
- Only a few studies have human subjects. Instead, many studies are actually conducted on rats, which results in findings that aren't always consistent with human outcomes.



Patient Safety: Recommendations



1. Oklahoma Must Form the Regulatory Medical Marijuana Board of Patients, Physicians and Health Researchers

- **Develop Best Practices and Clinical Standards**
- **Evaluate Effectiveness of Treatment**
- **Make Patient Safety/Caregiver Recommendations**
- **Review Scientific Research Methods and Outcomes**



Patient Safety: Recommendations



2. Begin Program with Five Specific Qualifying Conditions

- Epilepsy and Other Seizure Disorders
- Nausea and Vomiting from Chemotherapy (Unresponsive to Other Forms of Treatment)
- Muscle Spasticity (MS and Parkinson's)
- Relief for Terminal Illness (Expected to Live Less Than 1 Year)
- Wasting Syndrome from HIV/AIDS and Cancer



Patient Safety: Recommendations



3. Allow Physicians to Withdraw Patient Recommendations in Instances of Misuse, Addiction to Another Substance or Severe Health Risk to the Patient

4. Require Physicians Provide In-Person Exam ONLY Within Their Established Office Locations to Medical Marijuana Patients. Physicians May Not Have Ownership in a Dispensary or Conduct Exams Within a Dispensary



Patient Safety: Recommendations



5. Patient Must Keep Follow-Up Exams to Gauge Interactions and Effectiveness as a Requirement for Renewals
6. Establish a Physician Registry and Require Annual Continuing Medical Education and Updates



Patient Safety: Recommendations



7. Allow Medical Boards the authority to provide guidance on medical marijuana regulatory and safety issues



Patient Safety: Smokeables

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Patient Safety: Smokeable Products

Why Should We Be Concerned About Marijuana

Smoke?

Smoke is smoke. Both tobacco and marijuana smoke cause similar harm to blood vessel function.

The chemicals in marijuana smoke are similar to those in tobacco smoke, including cancer causing agents, such as acetaldehyde, ammonia, arsenic, benzene, cadmium, chromium, formaldehyde, hydrogen cyanide, isoprene, lead, mercury, nickel and quinolone.

The tar found in marijuana smoke is at least three to four times greater than in tobacco smoke.



Patient Safety: Smokeable Products



Marijuana deposits
four times more tar in
the lungs than tobacco



Patient Safety: Smokeable Products

Smoking Is Not the Only Way to Deliver Quick Relief

- It's true that many drugs, including nicotine and cannabinoids, are absorbed into the blood stream very rapidly through the lungs
- In fact, some medications, especially respiratory medications, are given by various types of inhalers
- There are several safer delivery systems for cannabinoids, including ingesting, topical preparations and aerosols



No FDA-approved medications are delivered by smoke



Patient Safety: Smokeable Products

Hazards Of Secondhand Marijuana Smoke

- Secondhand tobacco smoke is known to endanger the heart, blood vessels and lungs. Secondhand marijuana smoke carries these same risks
- THC in secondhand marijuana smoke can also be absorbed by others. In fact, it has been found in bystanders' blood, urine and sputum (mixture of saliva and mucus). In addition, mind-altering effects, such as euphoria or paranoia, have also been measured in bystanders
- Secondhand smoke from marijuana contains matter that can be breathed deeply into the lungs, which can cause lung irritation, asthma attacks and makes respiratory infections more likely. Exposure can also exacerbate existing health problems, especially for people with respiratory conditions like asthma, bronchitis or COPD



Patient Safety: Smokeable Products

Hazards Of Secondhand Marijuana Smoke



According to a study done by the American Academy of Pediatrics, 1 in 6 infants and toddlers admitted to a Colorado hospital with coughing, wheezing and other symptoms of bronchiolitis tested positive for marijuana exposure.



Patient Safety: Smokeable Products

Other Public Health Reasons to Control Secondhand Marijuana Smoke

- Oklahoma's healthcare community has worked for decades to promote smoke-free workplaces and public places. Smoke-free policies eliminate exposure to secondhand smoke, support smokers who are trying to cut back or quit smoking, and reduce initiation and addiction among youth
- Marijuana smoking in public spaces will harm public health and send inconsistent messages, especially to young people.



Patient Safety: Smokeable Products

U.S. 100% Smokefree Laws in Non-Hospitality Workplaces AND Restaurants AND Bars American Nonsmokers' Rights Foundation

As of July 1, 2018

Note: American Indian and Alaska Native sovereign tribal laws are not reflected on this map.

W: 100% Smoke-free Non-Hospitality
Workplaces
R: 100% Smoke-free Restaurants
B: 100% Smoke-free Bars

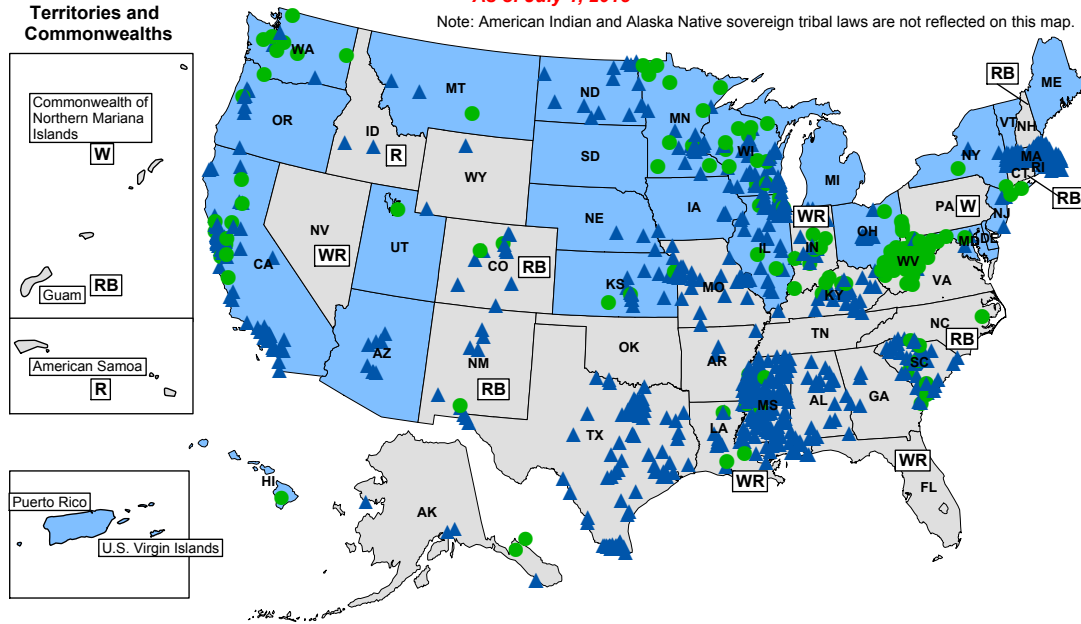
Locality Type with a 100% Smoke-free
WRB Law

▲ City
● County

State and Commonwealth/Territory Law
Type

100% Smokefree Non-Hospitality
Workplace, Restaurant, and Bar
Law

Law doesn't cover 100% Smokefree
Non-Hosp. Workplaces &
Restaurants & Bars



Patient Safety: Recommendations



1. There Is No Medicinal Role In Smoking. If This Is Medical Marijuana, Oklahoma Should Keep Delivery Methods of the Drug Consistent With That of Other Treatments

2. We Must Close Loopholes in Oklahoma's Clean Air Laws, Specifically Titles 21 And 63, to Ensure Smokefree Policies Are Extended to Combustible /Vaped Tobacco and Medical Marijuana



Patient Safety: Recommendations



3. Protect Minors from the Harms of Secondhand Smoke by Outlawing Smoking in Places Not Covered by the Public Places Law, Such as Cars



Patient Safety: Dispensing Practices

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Executive Director, Oklahoma Pharmacists Association

Shonda Lassiter, Pharm.D.

Disclaimer: OPhA is a 501 (c) (6) non profit association that advocates for the profession of pharmacy. Our mission is to unite and promote the profession of pharmacy through advocacy, communication and education. We facilitate in the development of innovative pharmacy practices that demonstrate improved health outcomes for patients.



Patient Safety: Dispensing Practices

Why Pharmacists Should be in Dispensaries

- First and foremost, pharmacists spend 6-8 years in pharmacy school learning about medicinal chemistry, pathophysiology and pharmacotherapy. They have expertise, training and knowledge to know how drugs are absorbed, distributed in the body, metabolized and excreted
- A pharmacist is the best professional to counsel and advise a patient to maximize desired effects and minimize adverse effects of drugs
- A pharmacist's role in understanding, interpreting and evaluating medications ensure positive patient outcomes



Patient Safety: Dispensing Practices

Why Pharmacists Should be in Dispensaries

- Along with marijuana, there can be a great deal of misinformation dispensed in areas where pharmacists are not required.
- For example, a [Denver Health](#) study reports that most dispensaries recommend marijuana to pregnant women with morning sickness, contrary to medical advice - May 9, 2018
- A researcher posing as a pregnant woman called 400 Colorado dispensaries asking about products for morning sickness. Denver Health researcher Dr. Torri Metz says 70 percent recommended marijuana, even though prior research shows pot use in pregnancy may have adverse effects on the fetus.

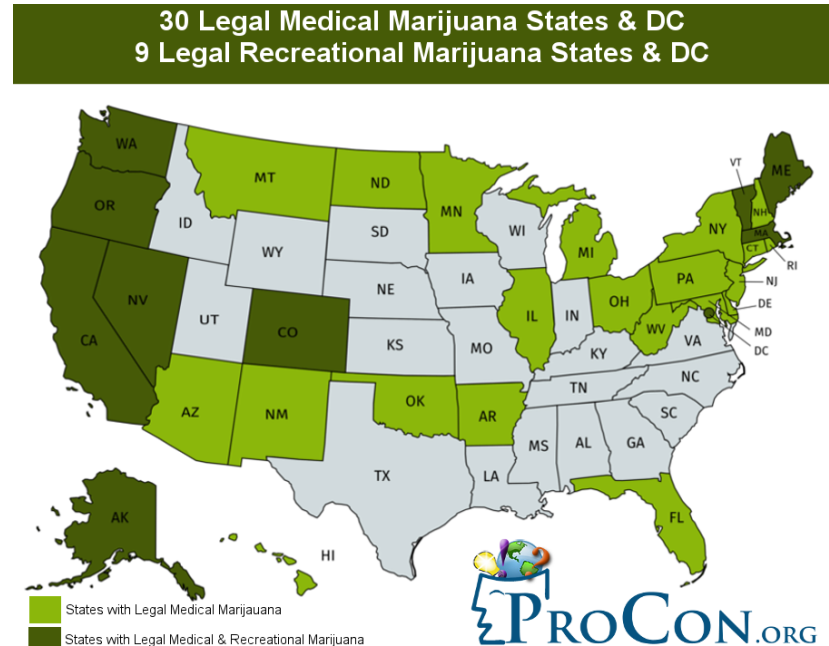
Source: "Recommendations From Cannabis Dispensaries About First-Trimester Cannabis Use" by Betsy Dickson, MD, Chanel Mansfield, MPH, Maryam Guiahi, MD, MSc, Amanda A. Allshouse, MS, Laura M. Borgelt, PharmD, Jeanelle Sheeder, PhD, Robert M. Silver, MD and Torri D. Metz, MD, MS



Patient Safety: Dispensing Practices

Pharmacists' Roles in Other States with Marijuana

- Arkansas requires each marijuana dispensary to appoint a pharmacist consultant
- Connecticut permits only pharmacists to apply for and obtain a marijuana dispensary license Connecticut has also scheduled marijuana as a C-II and requires prescriptions be reported to the PMP



Patient Safety: Dispensing Practices

Pharmacists' Roles in Other States with Marijuana

- Minnesota permits only pharmacists to give final approval for the distribution of medical marijuana to a patient
- New York requires a pharmacist to be on the premises and supervise the activities within a marijuana dispensing facility whenever the facility is open or in operation
- Pennsylvania requires that a physician or pharmacist be on site at all times during hours when a registered dispensary is open



Dispensary pharmacists provide patients with important information about drug interactions and side effects.



Patient Safety: Dispensing Practices

Pharmacists' Position on Medical Marijuana and Their Role



- **Members of the Oklahoma Pharmacists Association (OPhA) were surveyed in the fall of 2017 about the topic of medical marijuana**
- **56.8% of respondents reported they would vote “Yes” to legalize medical marijuana in Oklahoma, only if for medical purposes**
- **72.5% wanted pharmacists to be involved in dispensing for medical purposes**
- **Pharmacists believe that all drugs that are for medical purposes should be under the same regulatory scheme and laws should be uniform. As such respondents objected to SQ788 because it was under the Dept of Health and not the Board of Pharmacy**



Patient Safety: Dispensing Practices

Pharmacists' Role in Medical Marijuana Dispensaries

- Pharmacists are trained in establishing and maintaining confidentiality, privacy and security
- Pharmacists are educated on proper labeling of prescriptions
- Pharmacists are educated on drug interactions. Cannabis is just like any other medication, with drug interactions, side effects, and dosing considerations
- As with any other controlled substance, pharmacists are trained to conduct nightly and monthly audits within state and federal guidelines, respond to discrepancies, and enact policies that ensure there is no diversion of inventory
- Pharmacists are prepared to lead state inspectors through unannounced inspections
- Pharmacists are trained to maintain records regarding delivery and inventory manifests, maintain pedigrees of product



Patient Safety: Dispensing Practices

Pharmacists' Role in Medical Marijuana Dispensaries

- Pharmacists are trained to develop and maintain programs to monitor actual and potential adverse drug events. This would include tracking, review and outcome of adverse drug events
- Pharmacists are trained in how to maintain drugs under conditions that would ensure their safety, identity, strength, quality and purity
- They are trained to develop and maintain drug recall procedures that can be readily activated which assures that drugs involved, inside and outside the dispensary, are returned for proper disposition
- Pharmacists are trained on handling products that are outdated, damaged, deteriorated, misbranded or tainted



Patient Safety: Dispensing Practices

Clearing the Misconceptions About Pharmacists and DEA Licenses

- While the DEA provides a license to individual and mid-level practitioners who prescribe controlled substances, such as M.D., D.O., D.D.S., etc., pharmacists are not required to obtain one.
- Certain businesses must hold a DEA permit such as a pharmacy, hospital, clinic, teaching institution, manufacturer, importer, distributor, researcher, canine handler, analytical labs and narcotic treatment centers
- No pharmacy is able to dispense a Schedule I drug



Pharmacists are not required to hold a DEA permit.



Patient Safety: Dispensing Practices

Need for PMP Access in Dispensaries

- The purpose of the PMP is to have information related to controlled substances available to health care providers to monitor possible side effects and to prevent abuse by monitoring the number of scheduled drugs a patient uses
- It is possible, and recommended, that controlled substances such as medical marijuana be added to the PMP
- Due to patient privacy laws (HIPAA), full access is limited to only certain health care roles, including pharmacists. If no pharmacist or pharmacy technician is involved, OK PMP has the ability to create a limited access role that allows a user to enter data but not review patient records
- However, a pharmacist and a pharmacist's delegate have detailed access the PMP and can review a patient's history.



Patient Safety: Dispensing Practices

An Investment in Healthier Patients

- Pay is dependent on the pharmacist's role, i.e. audits, diversion control, state inspections, maintaining records, drug utilization review, dispensing standards and control, etc.
- According to the US Dept of Labor in May 2017 the annual means wage for a pharmacist in Oklahoma was \$114,190 or \$54.90 an hour
- Retail typically pays more for a pharmacist than consulting pharmacy



Patient Safety: Recommendations



- 1. Recommendations Should Include Physicians Order and Be Transmitted Electronically**

- 2. Require Pharmacist Oversight in Dispensaries**



Patient Safety: Recommendations



- 3. Require Entry of Medical Marijuana Purchases in the PMP to Prevent Controlled Substance Abuse and Interactions**



Patient Safety: Mental Health and Addiction

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Disclaimer: I am solely and exclusively presenting in the capacity as an individual and not representing or attempting to speak on behalf of OSU or the OSU CHS.



Patient Safety: Mental Health and Addiction

Areas of significant health and safety concerns:

1. Potency – High levels of THC
2. Intensity of Use - Daily/near daily use
3. Neonatal exposure
4. Marijuana use and opioids



Patient Safety: Mental Health and Addiction

CONCENTRATE

Indica

BHO Shatter Sunset		+\$20
Honu	68.6% THC 0.7% CBD	1g
BHO Wine Berry		+\$24
Ce Gardens	72.8% THC	1g
CO2 Oil Grape Kush		+\$15
Wildfire	37.3% THC 31.1% CBD	1g
Crumble Sour Grapes		+\$21
WA Grower	72.0% THC 0.4% CBD	1g
Dabber RSO Training Day		+\$30
Liberty Reach	65.8% THC	1a

Potency

- Average THC levels for *commercially sold* marijuana is 20.6% for flower and 68.7% for extracts
- Newer extraction techniques produce extremely high-potency products of 75% THC or more.
- CBD content is falling at the expense of increased THC content



Patient Safety: Mental Health and Addiction

Why does potency matter?

Use of high THC potency marijuana is associated with:

- Increased admission to first time drug treatment
- Increased severity of marijuana dependence and addiction
- Increased risk and earlier onset of psychosis; a 5-fold increase with daily use of high THC, low CBD marijuana
- Higher THC levels may explain the rise in emergency room visits involving marijuana use



Patient Safety: Mental Health and Addiction

Intensity of Use is Increasing

- Daily marijuana use is at the highest level since the early 1980s for college age youth
- Daily or near daily use of marijuana for all ages is up by about 50% from 2002, when only 12% consumed the drug daily or near-daily
- More than 2 in 5 marijuana users are daily or near-daily users – Between 1992 and 2014, the number of daily or near-daily marijuana users grew by 770%
- Marijuana users are nearly three times as likely as drinkers to consume daily



Patient Safety: Mental Health and Addiction

Why does intensity of use matter?

- Higher rates of addiction – 1 in 6 among adolescent users and 25-50% of daily users
- Risk of schizophrenia and psychosis
- Dependence, use of illicit drugs, suicide attempts, depression, and less high school completion/degree attainment among youth
- Highly related to cigarette use – daily marijuana use occurs predominately among cigarette smokers
- Cognitive Decline - Persistent marijuana use linked to significant decrease in IQ (average of 6-8 fewer points) between childhood and midlife
- Injury - There is substantial evidence of an association between marijuana use and increased the risk of being involved in a motor vehicle crash. In states where marijuana use is legal, there is increased risk of overdose injuries. Among marijuana, cocaine and heroin, only marijuana, is associated with significant increases in the number of emergency department visits - a 62% increase when used in combination with other drugs and a 100% increase when used alone



Patient Safety: Mental Health and Addiction

Neonatal Exposure

- Marijuana use during pregnancy is increasing significantly; highest rates of use in the first trimester.
- Nearly 70% of Colorado dispensaries recommended marijuana use to treat nausea in the first trimester (medical dispensaries recommended most frequently at 83%)



Patient Safety: Mental Health and Addiction

Why Does Use During Pregnancy Matter?

- Marijuana crosses the placenta and accumulates in fetal tissues, especially the brain.
- Infants exposed to marijuana in utero have lower birth weight and are more likely to be admitted to the neonatal intensive care unit.
- Documented neurodevelopmental deficits in children, adolescents, and young adults who were prenatally exposed to marijuana.



Patient Safety: Mental Health and Addiction

Marijuana Use and Opioids

- Marijuana use increases non-medical use of opioids
- Marijuana use not necessarily related to decrease in opioid overdose
- Marijuana not useful for chronic pain



Patient Safety: Mental Health and Addiction Recommendations



1. THC Levels Should be Limited to 12% or less
2. No THC Consumption or Sales to Patients Under 25
3. Patients should be assessed for addiction and mental health risk



Patient Safety: Mental Health and Addiction Recommendations



4. Physicians should be required to consult the PMP prior to issuing a recommendation

5. Physician recommendation should include prescriptive orders to include product, route of administration, dose, duration of use and instructions



Patient Safety: Poisoning and Exposures

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Managing Director,
Oklahoma Center for Poison and Drug Information

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Patient Safety: Poisoning and Exposures

Poison control at your fingertips.

Text POISON to 797979
to add poison control as a
contact in your mobile phone.



BE PREPARED ANYTIME & ANYWHERE WITH #POISONHELP



Patient Safety: Poisoning and Exposures

Pediatric Exposures in Oklahoma

- In 2017, the majority of pediatric exposures reported to the Oklahoma Poison Center were among the 13-17 year old age group
- Children ≤ 5 years old accounted for about 15% of pediatric exposures
- Overall, numbers were fairly low (54 reported cases). Reporting exposures to the poison center is not mandatory



Patient Safety: Poisoning and Exposures

Pediatric Exposures

- In Colorado, after legalization of marijuana Emergency Department visits for pediatric exposures doubled after legalization of recreational marijuana
- Nearly 50% of these visits involved children who ate infused edibles
- Calls to the Rocky Mountain Poison and Drug Information Center increased 5-fold from 2009 to 2015

Source: Wang GS, Le Lait M, Deakyne SJ, Bronstein AC, Bajaj L, Roosevelt G. Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015.

JAMA Pediatr. 2016;170(9):e160971



Patient Safety: Poisoning and Exposures

Pediatric Exposures

- Primary effect is drowsiness
- More significant effects including coma (14%) and elevated blood pressure can occur
- 15% of children were hospitalized in an Intensive Care Unit
- As THC concentration increased, likelihood of coma increased

Source: Claudet I, Mouvier S, Labadie M, et al. Unintentional Cannabis Intoxication in Toddlers. Pediatrics. 2017; 140(3):e2017001



Patient Safety: Poisoning and Exposures

Marijuana Transaction Limitations Too Lax Under SQ788

- According to 310:681-5-12, the patient can purchase in a single transaction “...seventy-two (72) ounces of medical marijuana products...”
- No limit on the maximum concentration of THC in the medical marijuana product is specified, however
- A race to produce the most potent products is distinctly possible



Patient Safety: Poisoning and Exposures

Comprehensive Product Testing

- Food Safety Standards Board has recommended to OSDH Board that all edible products be tested for pesticides, solvents, metals and bacterial/fungal contaminants
- Board has not yet voted to adopt recommendations, and no such recommendations exist for plant product
- Studies performed in California, on samples obtained from dispensaries, found a wide array of bacterial and fungal contamination of the product
- Risk of infection is likely to be higher in children, seniors, and the immunocompromised



Sources: Journal of Infection, Volume 76, Issue 5, May 2018, Pages 500-501, Clinical Microbiology and Infection, Volume 23, Issue 4, April 2017, Pages 269-270



Patient Safety: Poisoning and Exposures



POT AND PESTICIDES

Marijuana growers use pesticides to protect against two things: insects and fungus. The EPA regulates pesticide use for agricultural crops, but because marijuana is only legal in certain states and not federally, there are no uniform guidelines for pesticide use in the cannabis industry, and no testing has been done to determine what chemical amounts would be safe to inhale or ingest as concentrates.



Green: Marijuana is legal for recreational and medical use in Alaska, Colorado, Oregon, Washington, and Washington, D.C.
Red: Marijuana is legal for medical use in 23 states.



There are no uniform federal guidelines for testing marijuana products for contaminants or potency. Regulations about testing vary from state to state.



No pesticides have been registered or tested for use on marijuana, and no guidelines have been established. Pesticide use on other crops is federally regulated.



Flowers: Some pesticides used on cannabis are safe when consumed, but not when inhaled.



Concentrates: Extracting concentrates, used to produce edibles, topical products, and inhalants, causes pesticide residues to accumulate at levels 10x higher than on flowers.



Consumers can rinse pesticide residue off conventional produce, but marijuana is sold already dried or cured. Pesticide residues as high as 69.5% were found in pot smoke.

Produced by Food & Environment Reporting Network and SwitchYard Media

THE HIGHLY TOXIC SIX

All six of these chemical compounds are found on the Pesticide Action Network's list of most dangerous pesticides and all are commonly used on marijuana.



Myclobutanil
Fungicide
Developmental and reproductive toxin, suspected endocrine disrupter
Not allowed in WA or CO, but found on tested samples in CO and OR



Pyrethrin
Insecticide
Carcinogen
Approved in WA and CO



Fenoxycarb
Insecticide
Carcinogen, developmental and reproductive toxin, cholinesterase inhibitor
Not allowed in WA; existing stock approved in CO



Thiophanate-methyl
Fungicide
Carcinogen, developmental and reproductive toxin
Not allowed in WA or CO, but found on tested samples in CO



Avermectin
Insecticide
Developmental and reproductive toxin, suspected endocrine disrupter
Not allowed in WA or CO, but found on tested samples in CO

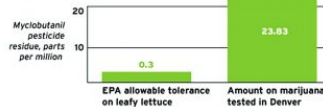


Bifenthrin
Insecticide
Developmental and reproductive toxin, suspected endocrine disrupter, possible carcinogen
Not allowed in WA or CO, but found on tested samples in CO, OR



MYCLOBUTANIL

Myclobutanil is the active chemical compound in the pesticide Eagle 20EW. Myclobutanil is not approved for cannabis in Colorado or Washington, but is still widely used. The EPA standards limit pesticide residue to trace amounts for agricultural products.



Patient Safety: Recommendations



1. Make child-resistant packaging mandatory
2. Use of a universal symbol to indicate the product is derived from marijuana



Patient Safety: Recommendations



3. Specify maximum concentration (or dose per retail unit) for various formulations, including edibles
4. Opaque packaging to limit visibility of product.
5. Poison Center number on all retail packaging



Patient Safety: Recommendations



5. Make all forms of medical marijuana subject to similar testing in order to minimize risk of toxicity.

6. Require batch numbers on all medical marijuana products, and mandate the ability to initiate recall procedures to the patient level should contaminants be identified.



Public Health and Youth Protection

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Director, Master of Public Health Program

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Disclaimer: I am solely and exclusively presenting in the capacity as an individual and not representing or attempting to speak on behalf of OSU or the OSU CHS.

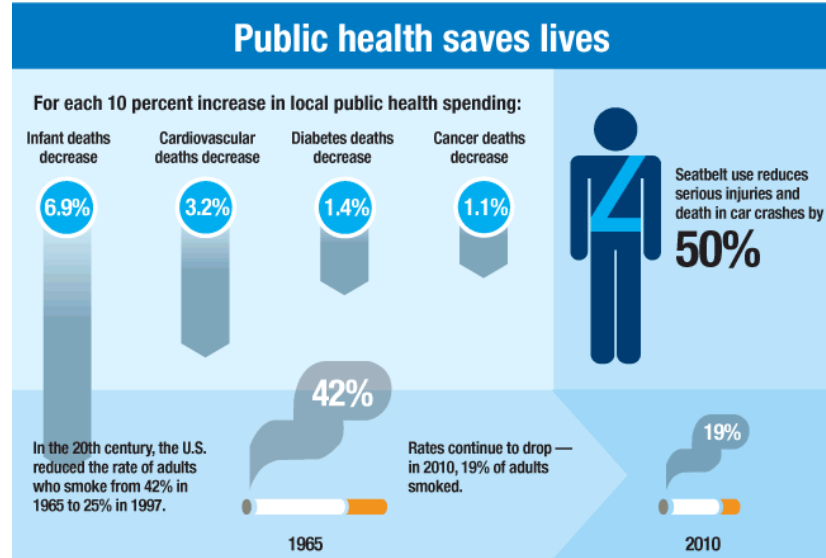


Public Health and Youth Protection

What is Public Health?

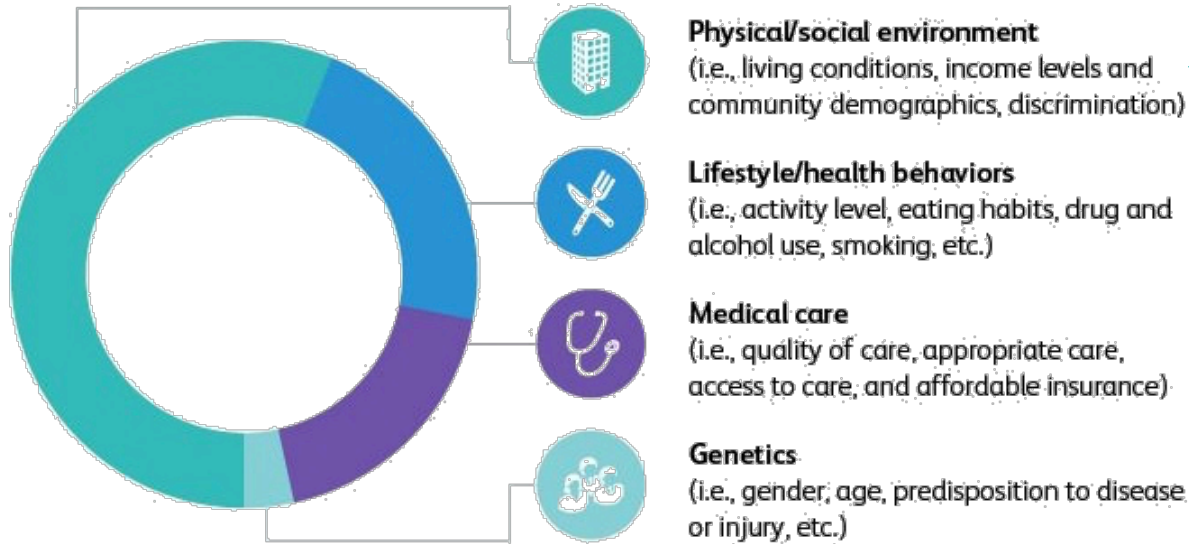


Public health saves money, improves our quality of life, helps children thrive and reduces human suffering.



Public Health and Youth Protection

What Drives Public Health?



Social factors, more than genetics and health care, determine the health of Oklahomans.

¹<http://www.cdc.gov/socialdeterminants/FAQ.html>



Public Health and Youth Protection

What Drives Public Health?

Patient Health:

- Focuses on **individual patients** - How can we achieve optimal health **for my patients?**
- Diagnoses, **treats** and cares for individual patients
- Protects patients with clinical interventions such as treatment planning, education and evidence-based treatments



Public Health:

- Focus on **populations** - How can we achieve optimal health **for Oklahoma?**
- **Prevents** disease and promotes wellbeing for whole community
- Protects the public with health education, study of data, evidence-based programs and policy design



Public Health and Youth Protection

Drivers of Youth Substance Use

Substance use is affected by:

1. **Availability** – Physical and economic access
2. **Perception of harm** – Marketing & social norms

Perceptions of harm are decreasing across all age groups.

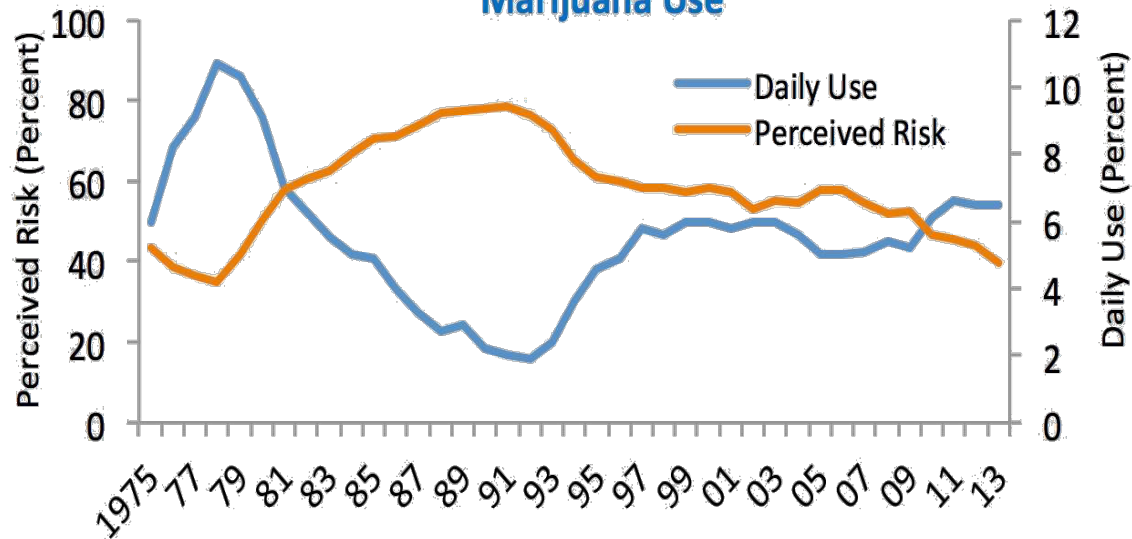


Two currently legal drugs (tobacco and alcohol) are the most costly to society - because they are widely used – not because they are the most dangerous.



Public Health and Youth Protection

Percentage of U.S. 12 Grade Students Reporting Daily Marijuana Use vs. Perceived Risk of Regular Marijuana Use



Source: The Monitoring the Future study, the University of Michigan



Public Health and Youth Protection

Marijuana Use Patterns

- What's happening with youth use?
- We should ask, "Why isn't youth use sharply declining?"
- Use is high in legalized states
- Certain groups of youth are really impacted:
 - Pregnant teens
 - Daily/near daily users
 - Youth smokers



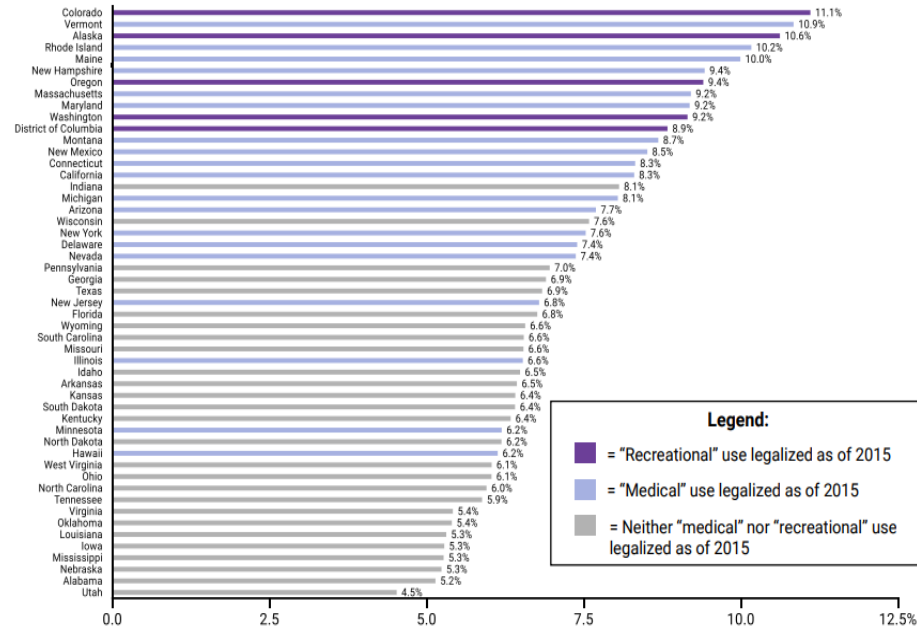
Nearly 52% of youth tobacco smokers are also current marijuana users, compared to just 5% of non-smokers.



Public Health and Youth Protection

Marijuana Use Patterns

Last-month use, ages 12-17 (as of 2015)



Public Health and Youth Protection

The Dangers of Marijuana-Based Advertising



Public Health and Youth Protection

The Dangers of Marijuana-Based Advertising



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The Dangers of Marijuana-Based Advertising



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The Dangers of Marijuana-Based Advertising



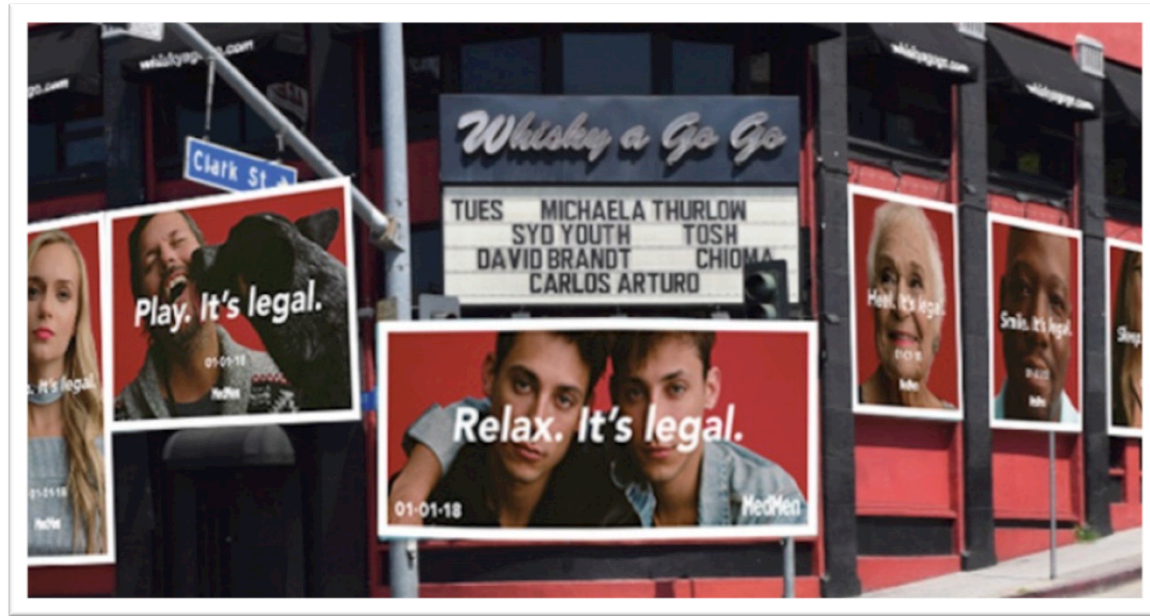
Public Health and Youth Protection

The Dangers of Marijuana-Based Advertising



Public Health and Youth Protection

The Dangers of Marijuana-Based Advertising



Public Health and Youth Protection

Economic Access

W WEDNESDAY	BOGO	BUY ONE, GET ONE 50% OFF
Th THURSDAY	\$50	500 MG TERPENES
F FRIDAY	25% OFF	<small>COLORADO CANNABIS COMPANY</small> CBD PRODUCTS
Su SUNDAY	\$89	SELECT OZ



- The role of price cannot be overstated.
- A number of studies by economists and public health researchers have found that when the price of marijuana decreases, the prevalence of marijuana use increases.
- Marijuana is no ordinary commodity.



Public Health and Youth Protection

Where Will Young People Get Their Information About Marijuana?

- Nearly 60% of Oklahoma youth report **not having even one conversation with a parent** about the dangers of drug use in the last year.
- Oklahoma students are not required to receive drug prevention in schools.
- Exposure to marijuana marketing is prevalent among adolescents.
- Exposure to marketing is significantly associated with adolescents' intention to use marijuana and their actual marijuana use 1 year later.



Public Health and Youth Protection

Where Will Young People Get Their Information About Marijuana?



“Research suggests that roughly 80 percent of marijuana expenditures in the United States are made by 20 percent of the users. These are the heavy users who report using marijuana on a daily or near-daily basis. If a profit-maximizing firm wants to make serious money in the marijuana market, they will have to focus on creating and maintaining a large stock of heavy users. There are also concerns that a for-profit industry and its lobbyists will fight against regulation and taxation.”

- Beau Kilmer on Profit Motive as an issue of concern for states



Public Health and Youth Protection

Physical Access



Public Health and Youth Protection

Table 2 Patient, product safety and dispensary laws by state effective 1 February 2017.

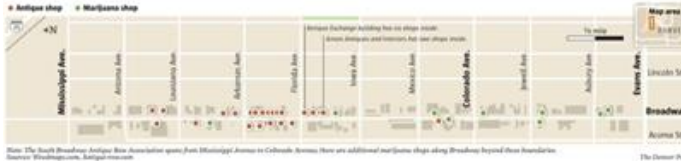
State	Patient							Product safety					Dispensary				
	Requires qualifying diagnosis	Requires patient registration	Requires risk-benefit disclosure	Permits registration revocation	Permits patient cultivation	Protects patient privacy	Protects against discrimination	Requires safety testing for all MM	Requires site safety features	Regulates product packaging	Regulates product labeling	MM waste protocols	Limits dispensary density	Restricts dispensary locations	Permits local zoning	Regulates product supply source(s)	Limits dispensary stock amount
AK ^a	X	X		X	X	X							Not applicable				
AR	X	X		X		X	X		X			X	X	X	X	X	X
AZ	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	
CA	X	X		X	X	X		X	X	X	X		X	X	X	X	
CO	X	X		X	X	X		X	X	X	X	X		X	X	X	X
CT	X	X	X			X	X		X	X	X	X	X	X	X	X	
DC		X		X		X		X	X	X	X	X	X	X		X	
DE	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X
FL ^a	X					X							Not applicable				
HI	X	X	X	X	X	X		X	X	X	X	X	X			X	X
IL	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	
MA	X	X		X	X	X		X	X	X	X	X	X	X	X	X	X
MD	X	X		X	X	X		X	X	X	X	X	X	X	X	X	
ME	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X
MI	X	X		X	X	X	X	X	X	X	X	X			X	X	
MN	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	
MT ^a	X	X	X	X	X	X							Not applicable				
NH	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X
NJ	X	X		X		X			X	X	X	X	X	X	X	X	X
NM	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
NV	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	
NY	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	
OH	X	X	X			X	X			X	X			X	X	X	
OR	X	X		X	X	X		X	X	X	X			X	X	X	
PA	X	X		X		X	X	X	X	X	X	X	X	X	X	X	
RI	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X
VT	X	X		X	X	X			X		X	X	X	X	X	X	X
WA	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X

^aAK, FL and MT have no medical cannabis laws in effect.



Public Health and Youth Protection

Physical Access: Outlet Number and Density



There are reported to be more medical dispensaries in Denver than Starbucks and McDonalds combined

- Applying lessons learned from alcohol
- Alcohol and marijuana outlet density both associated with violent crime.
- An additional one dispensary per square mile in a zip code was associated with a 6.8% increase in the number of marijuana hospitalizations
- Outlets are often disproportionately sited
- Outlet density plays a role in advertising exposure



Public Health and Youth Protection

Physical Access: Co-Location of Sales



Public Health and Youth Protection

Physical Access: Co-Location of Sales



Public Health and Youth Protection

Product Types and Packaging



Public Health and Youth Protection

Product Types and Packaging



Public Health and Youth Protection: Recommendations



1. Develop a public information campaign to clarify the law; highlight risks; and promote quit/treatment programs – consistent and credible messages should be developed by public health professionals not affiliated with commercial marijuana

2. Regulate advertising of commercial marijuana to prohibit false or misleading statements; prohibit advertisements that target or induce young people under 21; prohibit advertising in public transit or property; prohibit outdoor advertising; and limit retail signage and outdoor displays



Public Health and Youth Protection: Recommendations



3. Marijuana and marijuana products should not be in forms that attract or target children
4. Discounted, free, or other product promotions or inducements should not be allowed
5. If high potency and intoxicating products are allowed, differential tax/pricing structures should be used to set higher prices on more harmful products



Public Health and Youth Protection: Recommendations



6. Dispensaries should be limited in number; not be located near places where children frequent; and restricted for density. A system of public notification should be required
7. Dispensaries should not sell products other than medical marijuana and should not be co-located with other businesses. Marijuana sales or sampling should not be allowed off-premise (i.e. community events)
8. Marijuana should be secured behind the counter, no self-service machines or displays, and only licensed adult patients or caregivers should be allowed to enter dispensaries

