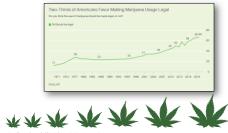
# Cannabis: Are you on drugs? Andrew C.S. Efaw, Esq. Kevin D. Homiak, Esq. Wheeler Trigg O'Donnell LLP efaw@wtotrial.com homiak@wtotrial.com Conflict of Interest Disclosure Andrew Efaw and Kevin Homiak do not have any real or apparent conflicts of interests or vested interests that may have a direct bearing on the subject matter of the continuing education activity. **Learning Objectives** This presentation will enable participants to: • Understand the existing landscape of marijuana legalization and regulation. • Identify potential legal and regulatory barriers and risks associated for hospital and providers. · Consider how hospitals can respond to the increasing acceptance of marijuana in crafting hospital policies.

### **PUBLIC OPINION:**

### 66% Favor Legalization

### October 2019



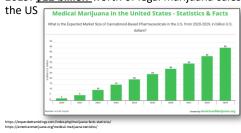
### **PUBLIC OPINION**

			_
ipport for Making Marijuana Legal, by Age and Generation			Total
	Favor	Oppose	Rep/Lean Rep
	%	%	
e e			Dony/Lean Dom
-29 years	81	18	
-49 years	71	29	Men
-64 years	62	36	Women
- years	49	49	
neration			
lennials (born 1980-2000)	80	20	White
neration.X (born 1965-1979)	63	36	Black
by boomers (born 1946-1964) ditionalists (born in 1946 or earlier)	61 40	38 56	Hispanic
kitionalists (born in 1945 or earlier)	40	56	
mbined data from three 2015-2010 polis; Generation Z not shown due to small sample size			Posteraduale
LUP			
			College degree
			Some sollege
			HS or less

https://news.gailup.com/poli/267658/support-legal-marijus na-steady-past-year.aspx

### Legal marijuana sales

### 2019: **\$12** billion worth of legal marijuana sales in



### Medical Use on the Ballot

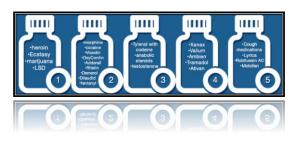
### **Initiatives Underway**

- New Jersey
- New Mexico
- New York
- Vermont
- Arizona
- Florida



ttps://www.oberk.com/marijus nalaws bystatel n2020

FEDERAL LAW: The Controlled Substances Act



https://www.dea.gov/druginfo/ds.shtml

### The Controlled Substances

Act: Schedule 1

"[D]rugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence."



<u>Schedule I</u>: Heroin, LSD, <u>marijuana</u>, MDMA/ecstasy, methaqualone (Quaalude), and peyote

os://www.dea.gov/druginfo/ds.shtml

## The Controlled Substances Act: Schedule II

"[D]rugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous."



<u>Schedule II</u>: Hydrocodone (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

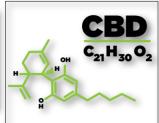
https://www.dea.gov/druginfo/ds.shtml

Science: CBD is NOT THC

#### Psychoactive



Non-psychoactive



### Medical Marijuana: Good Medicine?

"[F]or most qualifying conditions, approval [of medical marijuana] has relied on low-quality scientific evidence, anecdotal reports, individual testimonials, legislative initiatives, and public opinion. Imagine if other drugs were approved through a similar approach. . . . For most of the conditions that qualify for medical marijuana use, the evidence fails to meet FDA standards."

∼Drs. Deepak D'Souza & Mohini Ranganathan

http://jama.jamanetwork.com/article.aspx?articleid=2338230

### Medical Marijuana: Good Medicine?



"The use of marijuana as a medicine is remarkably uncontroversial at the bedside of a cancer patient or a child suffering from convulsions who might be helped."

Steven Patierno, PhD

Professor of Pharmacology and Cancer Biolog
Professor in Community and Family Medicine
Member of the Duke Cancer Institute

http://www.wsj.com/articles/steven-patierno-new-york-does-medical-marijuana-right-1404775955

Testing Potential Medical Uses for MMJ or CBD

- 1. Slow or stop cancer cell growth
- ${\color{red} \textbf{2}}. \quad \text{Prevent conditions that lead to Alzheimer's disease}$
- 3. Relieve arthritis
- 4. Control epileptic seizures
- 5. Relieve pain from multiple sclerosis
- ${\bf 6.}\quad Reduce\, symptoms\, from\, Crohn's\, disease$
- 7. Reduce seizures associated with Dravet's syndrome
- 8. Lessen side effects of Hep-C treatment and improve effectiveness
- 9. Reduce nausea from chemotherapy and stimulate appetite
- 10. Reduce size of brain area damaged by stroke
- 11. Treat inflammatory bowel disease
- 12. Protect brain from concussions (in mice)

Example: Mayo Clinic

Key	y to grades	В		ic pain  and has been studied for the treatment of pain. It has been used in people whose
AB	Strong scientific evidence for this use  Good scientific evidence for this use	С	Ear	pilepsy arly studies suggest that marijuana taken with ntiseizure drugs may lower seizure risk in people
C	Unclear scientific evidence for this use	work)	С	Appetite stimulant  Current studies show that cannabis-based therapy may lack benefit on weight loss and anorexia related to cancer. Early studies
F	Strong scientific evidence against this use (it likely dwork)	oes not	В	Multiple sclerosis  Marijuana has been studied for the relief of multiple sclerosis symptoms, such as nerve pain, muscle spasms, and urinary disorders. The active

http://www.mayoclinic.org/drugs-supplements/marijuana/evidence/hrb-2005970

# Is Medical Marijuana an Effective Drug?

In States that allowed Medical Marijuana to be prescribed, the average doctor prescribed:

- 264 fewer doses of antidepressants
- 541 fewer doses of anti-nausea
- 562 fewer doses of anti-anxiety medication
- · 1862 fewer doses of pain killers



### St. Francis Study

Goal: develop medical marijuana as safer alternative to opioids. Authorized for use by patients under 18

Initial phase involved 60 patients with rib injuries over 8 months

#### Trial ongoing

The first of its kind research study to gauge the effectiveness of Medical Marijuana as a painkiller for traumatic injuries. St. Francis Hospital in Connecticut



## Medical Marijuana and Pediatric Patients

- Strong support for use with autism, epilepsy, and pediatric oncology patients
- At this time, no large, high-quality studies have examined marijuana for the treatment of autism or other developments or behavioral conditions.

## Medical Marijuana and Pediatric Patients

- Journal of Developmental and Behavioral Pediatrics found the known harms of longterm marijuana use outweigh any benefits:
  - Decades of research
  - Decrease in IQ points
  - Increased odds of psychosis
  - Triple the risk of adult anxiety disorder

## Pediatric Patients: Is the research relevant?



THC is likely to cause harm

- THC changes the brain structure and function of developing mice
- MRI studies have revealed significant, widespread neurological changes in long term marijuana studies where THC present

### Animal Use





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# **KEY ISSUE** If marijuana has legitimate medical uses, we can just test it and find out right? **Current Research** Critiquing Medical Use The Washington Post 5 reasons marijuana is not medicine 1. The drug's chemistry must be known and reproducible. 2. There must be adequate safety studies. 3. There must be adequate and well-controlled studies providing efficacy. 4. The drug must be accepted by well-qualified experts. 5. Scientific evidence must be widely available.



"So you had that Catch-22, where marijuana is a Schedule I drug because there's no evidence, and there's no evidence because marijuana is a Schedule I drug."

~Dan Riffle, Director of Federal Policies at the Marijuana Policy Project

Tabp (Towar Sorbina comunities) accessful multi-2014 402/07/more than a varie-vect leastly (ring multiplane would have a degrificant integral on-drugpolicy with larged 1916 55 day, (Hores in reviewed controlly) schedule do-multiplane a water-69753 24



The Schedule I Classification creates significant roadblocks for research:

- Researcher Dr. Sue Sisley is leading the first placebo-controlled trial that uses raw marijuana for PTSD.
- Government approval for the study took over <u>4 years</u>.



http://www.mytimes.com/2014/08/10/us/politics/medical-marijuuna-research-hits-the-wall-of-federal-law.html
https://www.washingtonpost.com/news/wonk/wpr/2015/10/20/the-federal-government-is-saliting-medical-research-major-think-tank-declares/



(unlaw) - Salayar (tradian) - Carrbana (tradian) -

http://www.mayoclinic.org/drugs-supplements/marijuana/related-terms/hrb-2005970



### IS MY MARIJUANA THE SAME AS YOURS?

- The National Institute on Drug Abuse ("NIDA") is the only federally authorized grower. Authorized growing at U. of Miss. for decades.
- In one authorized study, NIDA failed to achieve the phenotype and potency requested.



http://www.mytimes.com/2034/08/20/uu/politici/medical-marijuana-essaarch-hits-the-wall-of-federal-law.html
https://www.wadhingtonpoz.com/national/health-acience/marijuana-essaarch-hampessd-by-accesse-from-government-and-politics-





The IDENTITY CRISIS Problem



### **Political Climate**





### Office of the Attorney General Washington, D. C. 20530 July 24, 2017

ale of marijuana is a crime. The Department remains committed to enforcing the Controlled ubstances Act in a manner that efficiently applies our resources to address the most significan treats to public health and safety. I look forward to working with you on these issues. As you

- "Highway patrol yearly interdection seizures of Colorado marijuana increased 37 percent from 281 to 394 (2015-2015), since recreational marijuana was legitized; from Calessier, in 2015, see were 30 different saiso scientific to receive marijuana from Calessier, in 2015, see were 30 different saiso scientific to receive marijuana from Calessier, in 2015 (2015).
   Seizures of Colorado marijuani "saiso and increased 427 percent after Colorado maristed "recreational marijuani" saiso.

### A Political Solution:

H.R. 3884 / S. 2227

Amends the Controlled Substances Act to provide that the Act's regulatory controls and administrative, civil, and criminal penalties do not apply to with respect to marijuana.  $Removes\ marijuana\ and\ tetrahydrocannabinols\ from\ schedule\ I.$ Prohibits the denial of any federal public benefits, like housing, on the basis of cannabis use and states that use or possession of marijuana would have no adverse impact under immigration laws. Taxes cannabis products at 5% to establish trust funds for job training, re-entry services, legal aid, and small businesses in the marijuana industry

### Reclassification to Schedule II?

January 25, 2019 - Rep. Morgan Griffith (R-VA) introduced a bill to reclassify marijuana as a Schedule II substance

116TH CONGRESS 1st Session	H. R. 171	
To provide for the legitimate use of medicinal marihuana in accordance with the laws of the various States.		

# Increase Access for Veterans? February 12, 2019 - Multiple pieces of legislation introduced to create an exception to the CSA for veterans. H. R. 1151 H. R. 601 **Does Medical Insurance Cover** Marijuana? Coverage under medical insurance is a significant step towards acceptance Courts in several states have exempted workers compensation insurers from covering the costs of medical marijuana Recent ruling in New Mexico requires workplace insurers cover marijuanabased treatments if they are recommended by a physician. Similar rulings have been issued out of courts in Connecticut, Massachusetts and Michigan. VA hospitals won't recognize medical marijuana as a form of medication. \* - Will not endorse of form of treatment - Patients cannot have on them when seeking treatment at VA facilities. - However, cannot deny patients access to care just because they are part of a medical marijuana program. \* http://www.illinoishomepage.net/news/local-news/va-hospitals-wont-recognize-medical-marijuana/497713355 Hospital Philosophies: Opting in or Out?

### Hospital Philosophies: Opting in

This substance has been shown to help patients, especially pediatric patients. Our mission is to serve our patients and their families, so we cannot bluntly state that this will not be allowed within our walls.



- Create committee to meet, gain feedback from the state's health systems, and draft policy
- Committee needs physicians, nurses, pharmacists, and representatives from other agencies (professional boards, drug diversion, etc.).

# Hospital Philosophies: Opting in Example

Mayo Clinic hospitals permit use of medical cannabis among patients registered by the state's approved cannabis patient centers.

If patient is hospitalized, admitting physician decides whether continuation of the theory is appropriate for the stay. If so, physician writes an order. In many hospitals, only capsules and oral liquids allowed. Medication CANNOT be stored or dispensed in the pharmacy. Patient cannot self administer.

\* https://acphospitalist.org/archives/2017/01/marijuana-policies-hospital.htm

# Some States and Hospitals Permit Marijuana in the Facility

- No civil, criminal or disciplinary action for nurse who administers medical marijuana to qualified patients in hospital.
  - No criminal or civil liability for administrators or staff if they permit qualified patients access to non-inhaled preparations of medical marijuana in hospitals.
  - Patients can use vaporized marijuana in separate enclosed rooms of hospitals and residential care facilities
  - Permits medical cannabis use by patients registered with the state who come in with product in original container dispensed by state-approved dispensaries

An Act Containing the Pallitative Use of Marijuana, H.B. 5450 An Act To Increase Parlent Safety in Maine's Medical Merijuana Program, 22 Main Rev. Stat. § 2422, et seç. N.Y. Comp. Codes R. & Regs. Tit. 10, § 1004-18(a)(14)

### Creation of Education Service

#### **Education Service**

If you allow use or marijuana in the hospital, create an education service or team.

- Involve social workers and pharmacist
- Assess drug interactions
- · Provide education to patient/family
  - Provide education to pa
     State law compliance
  - How to store the medication
  - Clear explanation of hospital policy



 This education service is not meant to be confrontational. It provides family with information necessary to take responsibility by use of honest communication about risks and policies.

## Handling & Administering a Schedule I Substance

Risks of handling and administering a Schedule I substance in a pharmacy or hospital without an approved protocol:

- A Federal offense
- Puts the pharmacy's DEA license at risk
- Puts the hospital's federal Medicare reimbursement at risk
- Refer to the Approved Protocol

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### Hospital Philosophies: Opting Out

- As long as CMS does not allow it and the FDA does not allow it to be prescribed, our facility will continue to prohibit its use.
- Acknowledges risk of hospital losing licensure or CMS certification.
- Physician concern about drug interactions.
- Allows for reconsideration when Marijuana is taken off Schedule I.



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### Not Opting In or Opting Out: Compromise Policies

- In California and Maine, use of medical marijuana by hospitalized patients is allowed and the state statute gives state-level protection for clinicians who administer it.
- Physicians are more comfortable administrating MMJ, but the federal prohibition is still a significant issue.



### Don't Ask, Don't Tell

- March approved use of MMJ at its facilities on a "don't ask, don't tell" platform
- Family member can bring MMJ and self administer. Staff does not acknowledge



Allow Family to Administer

Allowable patient use policy provides criteria and procedures for therapeutic use of medical marijuana products while patients are inpatients:

- Release of liability executed by family
- Providers must acknowledge use. This is NOT an endorsement.
- $-\,$  Must appear in the Medication Administration Record in EHR
- Hospital employees will not provide or give product
- Attending physician can determine if use is not allowed
- No inhaled preparations allowed.

### **Development of Policy**

Your hospital received letter signed by multiple patients wanting access to medical marijuana in the hospital. Board meeting follows and you are asked to draft MMJ strategy for a board meeting in 2 months.

- Convene a committee across specialties
- First question: will our hospital permit prescription of medical marijuana by providers and/or use it within the hospital?
- Second question: if patients or families are selfadministering, what will hospital do? Call social services if patient is a child? What is the priority for advocates?

### Pediatric Patients: Reporting Aspects?



Most states require hospital staff report when any child is in need of services because the parent or guardian fails to take actions to provide adequate medical care.

- Is giving a child a schedule I substance abuse or neglect?
- Does age of child matter?

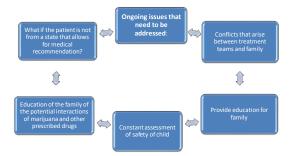
### **Pediatric Patients: Reporting Aspects**

- Consider full psychological assessment in younger patients (13 and under)
- If it is determined that deliberate actions on the part of the parent or lack of supervision led to the child's medical presentation, a report should be considered.
- A report should be considered if the explanation for the use of medical marijuana is unknown, not provided, or not supported.



1	6

### **Pediatric Patient Monitoring**



### **Consent Form**

- Written Form to Include:
  - Addiction and other risks
  - $-\ Confirmation of\ qualifying\ condition$
  - Direction of type of cannabis
  - Note that marijuana is given in reliance of patient's statement of condition, diagnosis, and need for relief
  - Signed by patient

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### Pharmacist Role in Medical Marijuana



- Have a greater liability risk related to marijuana prescriptions and use
- Medical marijuana is outside the pharmacist scope of practice

### Must Pharmacists Assist Dispensaries?

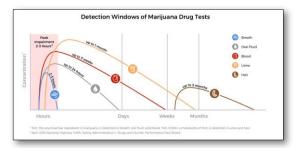
- Four states require a pharmacist to be on-site at dispensaries
  - Connecticut, Minnesota, Arkansas, New York, and Pennsylvania
- Other states are considering the same rule
  - Arkansas
  - · Ohio
- How will these state statutes reconcile with Federal law prohibiting pharmacists from handling or dispensing Schedule I substances?

E2

### Staff/Physician Use

- What if your employee or medical staff member uses marijuana legally (medically or otherwise)? Can you take action?
  - If you are a federal contractor, you cannot allow marijuana, regardless of what state law says.
  - Any other employer can take the conservative approach that substance against federal law and terminate employment.
  - Do you want to eliminate a whole group of educated and talented people because the use legal marijuana on the weekend?

### Staff/Physician Use



 $\label{lem:https://houndlabs.com/2018/09/06/how-long-can-marijuana-be-detected-in-drugtests/$ 

### Driving while stoned? Marijuana breathalyzers expected to hit the street in 2020





### Staff/Physician Use

An institution that relies on federal funding may be at risk with their funding if it does not test people for Schedule I drugs as part of hiring and retention.

- What does your drug policy say?
- When do you test? Who do you test?
- Error in OR?



### Staff/Physician Use

#### BEST PRACTICES FOR HR

- Don't tolerate marijuana use on the job, just as you wouldn't tolerate alcohol use.
- Train managers to spot signs of impairment.
- Think carefully about the type of test your company uses and stay on top of developments in the technology of testing.
- Talk to a lawyer about relevant state laws before setting policies and testing rules
- For companies operating in different states, know that testing policies may need to vary by location.
- Educate employees about the company marijuana-use policy and the repercussions for failed tests, including readom post-positions or reasonable purpleion tests.

https://www.shrm.org/hr-today/news/hr-magazine/fall2019/pages/marijuana-and-the-workplace-its

# Talking Points

- Should hospitals allow patients to have MMJ on site?
- Should hospitals permit a patient's loved-one to provide MMJ?
- Should hospitals allow their physicians to "recommend" MMJ?
- Without more empirical data on the efficacy of MMJ, does it violate the standard of care to <u>recommend</u> MMJ to patients?
- On the other hand, with the state of current research and wide ranging reports of medical benefit, does it violate the standard of care to <u>NOT recommend</u> MMJ to patients?

Questions?

