EMERGING RISK IN MEDICAL MARIJUANA

Anthony E. Abeln, Esq.
Noel B. Dumas, Esq.
Legalized Medical Marijuana
28 States/Districts Have Legalized Medicinal Use of Marijuana In One Form Or Another

- Alabama
- Alaska
- Arizona
- California
- Colorado
- Connecticut
- District of Columbia
- Delaware
- Florida
- Hawaii
- Illinois
- Iowa
- Maine
- Maryland
- Massachusetts
- Michigan
- Minnesota
- Mississippi
- Montana
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- Oregon
- Rhode Island
- Utah
- Vermont
- Washington
In Most States, Structure Of Marijuana System Is Created By Statute/Regulation.

Although States Differ To Some Degree, There Are Two Main Structures:

- Cultivation
  - Who And How Marijuana Is Grown And Processed

- Distribution
  - Who And How Marijuana Is Sold To Patients
Structure/Framework

Distribution System

- All States Are Different And There Are Varying Degrees Of The Extent Of The Regulations.
  - Some States Have Chosen to Be Heavily Regulated And Specific In Their Requirements.
    - Connecticut’s Marijuana Regulation Is 76 Pages Long.
    - New Jersey’s Marijuana Regulation Is 14 Pages Long.
  - But The General Structure And Approach Is The Same.
General Structure And Approach To Distribution.

- Starts With A Certifying Physician
  - Typically A Medical Doctor Or Osteopath Who Is Licensed In Their State.
  - Some States Require Specific Registration Of That Physician As A “Certifying Physician.”
Structure/Framework

- There Must Exist A “Bona Fide Physician-Patient Relationship.”
  - Attempt To Prohibit “Marijuana Mill” Medical Practices:
    - Clinical Visit Required
    - Clinical Visit Must Be In The Usual Course Of His/Her Practice
    - Complete and Document A Full Assessment Including Taking History And Documenting Current Medical Condition
    - Explain The Risks And Benefits Of Marijuana Use
    - Continues To Have A Role In The Ongoing Care/Treatment Of Patient
Certifying Physician Must Make A Determination That The Patient Has A “Debilitating Medical Condition.”

- Usually Defined Within Statute/Regulation:
  - Cancer
  - Glaucoma
  - HIV +
  - AIDS
  - Hepatitis C
  - ALS
  - Crohn’s Disease
  - Parkinsons
  - MS
  - Chronic Pain
  - Muscle Spasticity
  - Seizure Disorder
  - And “Other Debilitating Conditions As Determined By Certifying Physician.”
After A Qualifying Physician Determines Patient Has A Debilitation Medical Condition:

- Patient Must Then Register With The State And Apply For “Qualified Patient” Status.
  - The State Then Issues A Registration Card Which Is Valid For Varying Periods Of Time, Usually No More Than A Year.
- Once Registration Completed, Patient Can Then Obtain Marijuana From A Registered Marijuana Dispensary (“RMD”).
The Structure/Framework Of A Dispensary:

- State Legislatures Had Two Options With Respect To Regulating The Dispensaries:
  - Option #1: Heavily Regulated (i.e.- Methadone Maintenance)
  - Option #2: Industry Self-Regulation
Example Of Heavily Regulated:

- Methadone Maintenance Treatment:
  - Many States Have Strict Mandates As To The Structure Of These Clinics In Both The Required Staff Positions And Their Specific Responsibilities:
    - Each Center Requires A Medical Director Responsible For Specifically Mandated Tasks And Specific Number Of Hours They Must Be Present To: Oversee Nursing Staff, Promulgate Policies And Procedures, Review Test Results, Staff Training, Chart Reviews, Etc…
Example Of Heavily Regulated:

- Methadone Maintenance Treatment:
  - Many States Have Strict Mandates As To The Substance Of The Actual Services Provided:
    - Mandated Counseling Hours
    - Mandated Drug Testing
    - Mandated Policies/Practices Of Patients Who Fail Drug Testing Or Patients Who Continue To Use Illicit Substances
In Terms Of Exposure For Heavily Regulated Jurisdictions:

- Creates Very Well Defined And Precise Standards Of Conduct/Care.
- In Some Jurisdictions, Evidence Of Violation Of Regulation/Statute *per se* Negligence.
    - Plaintiff’s Love Highly Regulated Industries Because The Standard Of Care Is Defined For Them And Can Likely Find Conduct In Any Case Which Does Not Follow The Statute/Regulation Precisely.
    - Juries: Regulations Make The Concept Of Standard Of Care Easier.
Structure/Framework

In Terms Of Marijuana, Most States Have Chosen To Regulate Heavily Certain Aspects And Not Heavily Regulate Other Aspects:

- **Heavily Regulated**
  - Becoming A Licensed Dispensary
  - Becoming A Registered Certifying Physician
  - Becoming A Qualified Patient

- **Less Regulated**
  - The Actual Process Of Dispensing Marijuana
  - The Roles And Responsibilities Of The Dispensaries
Structure/Framework

Statutory/Regulatory Requirements Of Dispensaries

- Most States Do Not Require Any Specific Assessment Of The Patient.
  - No Illicit Drug Testing
  - No Assessment As To Impairment And Driving
  - No Assessment As To Impairment As Evidence Of Drug Abuse
  - No Assessment As To Whether The Patient Is Having Adverse Side Effects
  - No Assessment As To Whether The Dose Is Appropriate
    - In Fact, Some States Specifically Prohibit The Dispensaries From Giving Advice Or Making Recommendations As To What Marijuana Products They Sell.
Structure/Framework

Statutory/Regulatory Requirements Of Dispensaries

- Most States Have Kept The Responsibilities Of The Dispensaries Vague:
  - **Example**: Connecticut- One Of The Most Regulated States.
    - “A Dispensary Shall Exercise Professional Judgment To Determine Whether To Dispense Marijuana To A Qualifying Patient . . . If The Dispensary Suspects That Dispensing Marijuana To The Qualifying Patient May Have Negative Health Or Safety Consequences For The Qualifying Patient Or The Public.”
Structure/Framework

Statutory/Regulatory Requirements Of Dispensaries

- Most States Have Kept The Responsibilities Of The Dispensaries Vague:
  - **Example:** Massachusetts.

  - “A RMD [Registered Marijuana Dispensary] **May** Refuse To Dispense To A Registered Qualifying Patient ... If In The Opinion Of The Dispensary Agent, The Patient Or Public Would Be Placed At Risk.” (Emphasis Added)
Structure/Framework

Risk/Liability Implications:

- The Statutory/Regulatory Scheme Has Direct Impact On Liability Exposure to Dispensaries and Certifying Physicians:
  - Generally Speaking, The Statutory and Regulatory Schemes That Have Been Created Will Likely Shift Liability and Exposure To The Certifying Physicians.
    - More Like Pharmacies, Which Do Not Have Authority To Change Or Alter Prescriptions Made By Physicians. (See infra).
Structure/Framework

Risk/Liability Implications:

- Shifting Liability and Exposure To The Certifying Physicians.
  - No Regulatory Responsibility To Assess Patients For Impairment
  - No Regulatory Responsibility To Perform Drug Testing For Other Illicit Substances (i.e.- Those Which May Have Synergistic Effects)
  - No Regulatory Responsibility To Assess Adverse Side Effects/Dosage Effects/Medication Contra-Indications.
  - Extreme Example: Massachusetts.
    - Regulation Requires All Dispensaries To Be Non-Profit. Cap Implications.
Structure/Framework

- **Risk/Liability Implications:**
  - Whether The Certifying Physician Realizes It Or Not, These Assessments Of Patients Fall On Them.
      - Example: Polysubstance Abuser Who Becomes A Qualified Patient And Synergistic Effect With Marijuana Impairs Ability To Drive Safely Resulting In Car Accident.
Structure/Framework

- Regulatory/Statutory Framework Of The Medicinal Marijuana System Is Fluid And Evolving.
  - Most States, While They Have Legalized Marijuana, Have Simply Laid Down Some Ground Rules And Ordered (Typically The Health And Human Services Department) To Come Up With Regulations As To How It Will Work.
  - Even After Regulations Are Passed, They Are Likely To Evolve With The Emergence Of (Arguably) Unforeseen Issues.
Legal Bases for Liability – Some Potentially Unforeseen Scenarios

1) Is a Dispensary a Pharmacy?

Although a pharmacy clearly has the duty to fill prescriptions correctly…..we have not addressed the issue whether a pharmacy has a duty to warn its customers of the risks and side effects of the drugs it dispenses. A number of jurisdictions have addressed the issue, and the overwhelming majority hold that, in general, a pharmacy has no duty to warn its customers of side effects. We similarly hold that, generally, a pharmacy has no duty to warn its customers of the side effects of prescription drugs.

Cites Pennsylvania law approvingly:

- *Coyle v. Richardson-Merrell, Inc.*, 526 Pa. 208, 584 A.2d 1383 (1991) --notes that “there is good reason to treat pharmacies differently from other retailers of commercial products: pharmacists do not choose which products to make available to consumers and patients do not choose which products to buy..... The pharmacist does not have discretion to alter or refuse to fill a prescription because the risks and benefits of that prescription for that particular patient have already been weighed by the physician.”
Does the Massachusetts regulatory scheme, which allows a discretionary refusal of dispensing marijuana, take dispensaries out of Cottam?

Where does the duty to warn lie?

Does that take the physician off the hook?
Unforeseeable third parties?

- 3rd party liability – narrow rule in Massachusetts:
  - Coombes v. Florio, 450 Mass. 182, 877 N.E.2d 567 (2007) found that a physician “owes a limited duty to third parties, foreseeably at risk from a patient's decision to operate a motor vehicle, to warn the patient of the known side effects of medications the physician has prescribed that might impair the patient's ability as a motorist.”
Broader rule in states like Indiana?
Although physician had no relationship with the other motorist, a third-party victim of driver's conduct, it was reasonably foreseeable that driver, with her medical conditions and under medications prescribed by physician, was at risk of losing consciousness while driving and posed a danger to third persons. Manley v. Sherer, 960 N.E.2d 815 (Ind. Ct. App. 2011).
2014 Vasquez decision in Massachusetts expands third party liability?

- Vasquez, et al. v. Community Health Care, Inc.,
- Patient receives methadone from clinic methadone with no advisory of any kind regarding the effects of the new dosage — which had been increased two days earlier — on his ability to safely operate a motor vehicle. He also allegedly had other illicit drugs in his system that morning.
- Half hour after receiving his dose, he drives and drifts into the another lane.
- Two third parties killed.
- Estates sue, alleging that the clinic was negligent in its care and treatment of patient, which proximately causing their injuries and deaths.
- Clinic moves for summary judgment, on grounds that, among other things, its duty of reasonable care did not extend to non-patient third parties.
- “Here, as in Coombes, liability would be based on the act of prescribing a drug with known side effects that could foreseeably endanger the public .... and ‘requires nothing from a doctor that is not already required.’”
Synergistic Effects of Drug Interactions

- In cases with methadone dispensaries, regular fact pattern involves a car crash, with an allegation that the clinic staff failed to properly monitor a patient’s pattern of multidrug intake.

- With a patient who shows positives in benzodiazepines or marijuana, claim is that the clinic should have ceased providing or more strongly warned of synergistic effects of the drugs.
Typical expert affidavit:

“Combining methadone with benzodiazepines and marijuana can cause serious and potentially dangerous side effects.... These side effects include, but are not limited to, poor concentration, drowsiness and sedation. The combination of methadone with benzodiazepines and marijuana can greatly impair the mental and/or physical abilities required for the safe performance of potentially hazardous tasks, such as driving a car.... A reasonably foreseeable consequence of an individual operating a motor vehicle while combining methadone with benzodiazepines and marijuana is that a vehicle accident may occur and other persons may be injured. A medical director of a methadone clinic should have knowledge of this.”

Taylor v. Smith, 892 So. 2d 887, 892 (Ala. 2004)
Risks to Physician-Prescribers?

- Where there has been limited research on potential interactions (based on federal preclusions), how does the physician make a determination as to potential synergistic effects?
- Does the physician have to evaluate all potential interactions before prescribing? How?
- Is it like any other drug?
- Is it in the PDR?
Learned Intermediary doctrine?

- What happens?
- Manufacturers of drugs duty to warn extends to physicians as the “learned intermediary.”
- What happens when no information is forwarded about risks?
- Who is the learned intermediary in medical marijuana cases?
Violation of federal regulatory authority relative to drugs in conflict with federal law?

Controlled Substances Act (CSA)
- Even if not enforced?
- Negligence per se/Evidence of Negligence?
Much is made of claim that Federal authorities will not enforce CSA as to marijuana.
prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
• Preventing the distribution of marijuana to minors;
• Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
• Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
• Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity:

• Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;

• Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
• Preventing marijuana possession or use on federal property.
Take Away Points

- Although MM Has Been Legalized In Many States, The Process Of How This Will Occur Is Still A Work In Progress.

- However, It Appears That Most States Have Chosen A “Pharmacy” Approach To Dispensaries.

- What This Means Is That Liability Exposure Is Likely To Fall On The Certifying Physicians.

- The Greatest Exposure Will Likely Be Automobile Accidents.