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  Clinical Pharmacy Specialist, Denver Health
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Learning Objectives
- Describe the FDA Quality Compounding Act
- Contrast FDA versus State Board authority over compounded medications
- State requirements of pharmacies that wish to participate in drug take-back programs.

Statement of Disclosure
None of the presenters have relevant financial relationships with commercial interests pertaining to the content presented in this program.

History of Pharmacy Practice and Compounded Products
- 1940-50’s
  - Need to perform pharmaceutical compounding became less important
  - Pharma provided the needed dosage forms and strengths for the then available drugs
  - Role of USP switched from standards for compounded drug products to that of setting industry standards for manufactured drug products
History of Pharmacy Practice and Compounded Products

1960 – 70’s
- IV admixture services were carried out by nursing services
  - Pharmacy simply procured the drugs, stocked the units, and kept patient records for billing purposes
- IV manipulations were low risk because consisted primarily of using commercially available dosage forms
  - Few patients experienced problems

History of Pharmacy Practice and Compounded Products

1980 – 90’s
- Increased number of compounded prescriptions
  - Manufacturers starting to decrease the number of available drugs and dosage forms
  - Providers began to prescribe therapeutic agents or alternative dosage forms that were not commercially available
  - Increased demand for compounded drug products (sterile and non-sterile) from home healthcare, TPN, hospice, pain management, etc.

History of Pharmacy Practice and Compounded Products

National Coordinating Committee on Large Volume Parenterals (NCLVLP)
- 1970 - 80’s - was convened to take the first steps toward correcting this deviation from appropriate compounding standards
  - Developed recommended standards of practice for the preparation, labeling, and quality assurance of hospital pharmacy admixture services
  - ASHP found that these standards were not widely implemented in hospital pharmacies

USP
  - Later becomes official chapter <1206> in 1995
  - Provided specific practice standards and operating guidelines for CSPs
  - Not widely known or followed

ASHP Efforts
History of Pharmacy Practice and Compounded Products

- Congress enacts the US Food and Drug Administration Modernization Act (FDAMA) of 1997
  - Section 503A was entitled “Pharmacy Compounding”
  - The law was designed to protect patients from the unnecessary use of extemporaneously compounded drugs by pharmacists and gave FDA the power to delineate certain drugs that were difficult to compound
  - 2001, SCOTUS declares Section 503A unconstitutional, creating a void of federal regulation of for the pharmacy profession and the FDA

USP <797>

- Includes specific guidelines for:
  - Facility design
  - Environmental and engineering controls
  - Environmental testing
  - Personnel training/testing
  - Standard operating procedures
  - Quality assurance
  - Adverse event reporting
  - Storage and dating

USP Chapter <797>

- Provides MINIMUM practice and quality standards for compounded sterile preparations of drugs and nutrients
- Applies to pre-administration manipulations of compounded sterile preparations including compounding, transportation, and storage.
- Applies to all compounding personnel without distinction as to site or profession – all patients deserve to be protected from errors and contamination

USP <797> Clean Room

- Notes that direct contact is the principal source of contamination in CSPs
- Alternative technologies can be used if proven equivalent or superior to conventional manual work practices are acceptable
- <797> applies to CSPs given via application, implantation, inhalation, injection, insertion, instillation, and irrigation
Immediate-Use Category
(Not in CO rules)
- Exempt from all requirements in <797>
- Only simple aseptic measuring and transfer are needed
- NMT 3 sterile non-hazardous drugs
- NMT 2 entries in one container
- No delays/interruptions
- No contact contamination of ingredients or critical sites

Some Examples:
- At a patient’s bedside
- In an ambulance
- In an ER
- In a war zone
- In a code situation

NOT A LOOPHOLE

USP <797> Risk Levels
- Medium Risk CSP
  - Same as low risk, but:
    - More than 3 products
    - Complex preparation

USP <797> Risk Levels
- High Risk CSP
  - Compounding using manufactured products than are non-sterile
  - Final product requires terminal sterilization
  - Using conditions outside ISO5

Beyond Use Dates (BUD)

Table 1, USP <797> BUD Limitations for CSPs Compounded in a Cleanroom

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>BUD for Controlled Room Temp Storage</th>
<th>BUD for Cold Storage</th>
<th>BUD for Frozen Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>36 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
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</tbody>
</table>
Garbing requirements

<table>
<thead>
<tr>
<th>Garb requirement</th>
<th>Immediate-use</th>
<th>Low Risk (12 hr)</th>
<th>Med Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Makeup/jewelry restrictions</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hand washing</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Hair/facial cover</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Shoe covers</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Low-shed gown</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Sterile Gloves</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Masks</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Personnel Cleansing and Garbing

- Remove outer garments and jewelry (including piercings above the neck)
- Garb order from dirtiest to cleanest
- Don shoe covers, hair covers, beard covers (any facial hair) and face masks (any order is acceptable)
- Perform hand/arm hygiene
- Don disposable gowns

Personnel Cleansing and Garbing

- Inside the clean area, cleanse hands and arms with alcohol-based surgical hand scrub with persistent activity
- Don sterile powder-free gloves compatible with sterile 70% IPA
- Repeatedly apply sterile 70% IPA to contact areas of gloves whenever non-sterile surfaces are touched (e.g., vials, counter tops, carts)

Disaster Strikes in Oct 2012

- New England Compounding Center (NECC)
- Fungal meningitis contaminated methylprednisolone acetate suspension
- 17,600 doses were shipped to 76 facilities in 23 states (not in CO)
- Approximately 14,000 + patients were exposed
- Total number of cases = 720 (48-64 deaths)
- 400+ lawsuits pending
- >4,000 drugs were voluntarily recalled

Investigations

- Oversight and Investigations Subcommittee of the House Energy and Commerce Committee
  - Found that in the 8 months since NECC outbreak, 48 compounding companies were found to be producing and selling drugs contaminated or created in unsafe conditions
  - IN AT LEAST 3 CASES, visible contamination was spotted

Under optimum conditions, many bacteria can double in number each 20 minutes. One bacterium can result in up to 16,000,000* bacteria in just eight hours.¹

8 hours = 24 periods of 20 minutes
2 bacteria² = 16,777,216 bacteria (1.6 X 10⁷)

Bacteria are so small that a single drop of water might contain up to 30 billion (30 with nine zeros!) bacteria.

100,000 bacteria/ml is probably enough to kill you!
Drug Quality and Security Act (H.R. 3204)
- 9/25/13, Voice Vote in US House approved bill
  - In Congress, the vast majority of actions decided by a voice vote are ones for which a strong or even overwhelming majority favors one side, or even unanimous consent
  - “Bad actors concerned more with profit than public health will not be able to operate with impunity again”
- Signed into law by President Obama on 11/27/13

Comments from Senator Harry Reid (D-NV)
“By avoiding the safety inspections required of large-scale drug manufacturers, companies like [New England Compounding Center] can boost profits while risking lives. The legislation on the floor will end that dangerous practice and ensure that patients have access to high-quality custom medications.”
-November 13, 2013

Drug Quality and Security Act
- Creates a new section 503B in the FDCA
  - Under section 503B, a compounder can become an “outsourcing facility.”
  - An outsourcing facility can qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use, but not the exemption from current good manufacturing practice (CGMP) requirements

Drug Quality and Security Act
- Replaces a patchwork of state laws governing distribution of drugs by compounding and traditional pharmacies
- Lets larger drug compounders that produce pharmaceuticals by the batch, rather than one prescription at a time, voluntarily register as outsourcing facility subject to FDA oversight
  - Enable the FDA to ID providers and products, get reports on ADRs and make risk-based inspections

Drug Quality and Security Act
- Criticism of the legislation
  - Voluntary registration for compounding companies is not strong enough to ensure the public safety
  - Drug manufacturers that currently make FDA-approved drugs would, under this bill, have the ability to make and sell drugs to meet shortages and “clinical needs” without seeking premarket approval (e.g., NDA or ANDA)
Non Sterile Compounding

- You have a prescription for “magic mouthwash” and have the following ingredients on hand:
  - Viscous lidocaine (exp. 8/15)
  - Diphenhydramine elixir (exp. 10/17)
  - Maalox® (exp. 3/18)
- You plan to compound 120 mLs. What expiration date will you put on the product?

Non Sterile Compounding

- You become the new manager at a local retail pharmacy. Which of the following is true?
  - You must maintain a written policy and procedure manual encompassing all aspects of non-sterile compounding
  - You must review and update the policy and procedure manual every two years
  - As the new pharmacy manager, you must review, sign, and update the manual within 90 days

Non Sterile Compounding

- Which of the following is true regarding compounding records?
  - A compounding record is the same as a formulation record
  - Compounding records must be kept on site for a total of three years
  - The compounding record must contain names of ingredients of used in the product, quantities, lot numbers and expiration dates
Pharmaceutical Contamination of the Water Supply

Who can be a “collector”?
- Manufacturers
- Distributors
- Reverse distributors
- Narcotic treatment programs
- Hospitals/clinics with an onsite pharmacy
- Retail pharmacies

Take-back programs
- Must be conducted by law enforcement
- Collectors are not authorized to conduct take-back events
- Community agencies, or DEA registrant must partner with law enforcement to hold a take-back event
Mail Back Programs

- Authorized collector must have a means to perform onsite destruction
- Pre-addressed to authorized collector
- Postage prepaid
- Nondescript, tamper-evident, tear resistant
- Unique ID number per package
- Clear instructions to the end user on how to use

Collection Receptacles

- Removal of inner liner:
  - By or under the supervision of at least two authorized employees
  - Must be immediately destroyed (or stored in a manner consistent with storage of other CIIs until destruction can occur)
  - Or delivered to reverse distributor

Collection Receptacles

- Registered collector location
  - Existing security in place
  - Not at community centers or libraries
- Defined receptacle requirements
  - Permanent outer container
  - Removable inner lining
  - Opening of outer container small enough to prevent removal of contents
  - Opening must be able to be locked
- May not use a collection receptacle to dispose of unused controlled substance inventory

Collection Receptacles

- Inner liner must:
  - Be waterproof
  - Be tamper-evident
  - Be tear resistant
  - Carry a unique ID number
- Outer container:
  - Must be able to be securely fastened to a permanent structure
  - Located in immediate proximity where controlled substances are stored

Objectives

- Summarize recent State Board of Pharmacy disciplinary cases.
- Review recent court decisions that affect Colorado pharmacists.
Discipline Cases

- Grounds for Discipline
- Types of Discipline
- Discipline Statistics
- Discipline Cases

Grounds for Discipline

- Dependent on, or habitual / excessive use of liquor / habit forming drug or controlled substance
- Let unlicensed person practice pharmacy
- Pharmacy discipline in another state (or failure to notify SBOP within 30 days)
- Misleading / false/deceptive advertising
- Practicing pharmacy while inactive

2014 SBOP Disciplines

- Investigated by State Board: 350 cases
- Resolved: 325 cases
- Pending (open as of 4/10/15): 25 cases
- Disciplinary action taken by SBOP: 111 cases
  (Cease and Desist Orders and Application denials are not considered discipline)

Grounds for Discipline

- Failure to notify SBOP of, OR Fail to act within the limitations created by:
  - physical or mental illness, or
  - condition that affects ability to treat patients with reasonable skill and safety, or
  - may endanger patient’s health or safety
- Fail to comply with confidential agreement to limit practice
- Suspension or revocation of DEA registration
Types of Disciplinary Actions

- Refusal to renew, suspension, revocation
- Letter of admonition
  (pharmacists and pharmacies)
- [Confidential letter of concern]
- Conditions on license: exams, training, supervision, scope of practice restrictions
- Pharmacies may be fined $500 to $5000 per violation

SBOP Disciplinary Actions - Pharmacists (61)
1/1/14 to 3/31/15

Grounds for (and # of) disciplines
- Dispensing error (26)
- Alcohol / Drug diversion / PHAO (28)
- Out-of-state Rx /
  No MD-patient relationship (4)
- Expired license (1)
- Record keeping (1)
- Denial of reinstatement (1)

Who gets disciplined?

- Prescription Drug Outlets 85
- Pharmacists 61
- Interns 2
- Unlicensed Practice 8
- Wholesalers/Other Outlets 6
- TOTAL DISCIPLINES 162

Looking up SBOP discipline on the web
Disciplinary actions taken against licensees and registrants are public information. You may obtain copies of the disciplinary documents by going to: http://www.dora.state.co.us/doramages/ and entering the appropriate criteria.

SBOP Disciplinary Case # 1
Pharmacist dispensed ketoconazole 2% shampoo on an order for ketoconazole 2% cream

DISCIPLINE?
A. License revocation
B. Letter of admonition
C. Confidential letter of concern
D. $1000 fine

SBOP Disciplinary Case # 2
Pharmacist dispensed 20 tablets of methadone 5mg on an order for 720 methadone 10mg tabs

DISCIPLINE?
A. License suspension for 6 months
B. Confidential letter of concern
C. $1000 fine
D. Letter of admonition
SBOP Disciplinary Case # 3
Intern apparently discussed the NAPLEX exam with a lecturer in an electronic mail message

DISCIPLINE?
A. Intern license probation until pass an ethics class
B. Letter of admonition
C. Halt processing of pharmacist application during probation
D. Retake and pass NAPLEX exam

SBOP Disciplinary Case # 4
Over 18 months, pharmacist dispensed 15 CS Rxs to a CO patient from a FL MD who had lost his CS license. (no valid pre-existing doctor-patient relationship)

DISCIPLINE?
A. Letter of admonition
B. One year probation
C. Disclose discipline to all pharmacy managers / supervisors
D. Retake and pass MPJE exam

SBOP Disciplinary Case # 5
Pharmacy manager practicing on expired license in pharmacy w/ numerous record violations: Rx orders & receipts not in 3 files; no CS inventory; Rx orders not in numerical order; incomplete DEA 222; Tech posting and Initial & final interpretations not current.

DISCIPLINE?
A. Take and pass ethics exam
B. Three year probation
C. Disclose discipline to all pharmacy managers / supervisors
D. Retake and pass MPJE exam

Other SBOP Disciplinary Cases of Note
- July, 2014. PIC practiced for 2 months after license expired (because SBOP did not notify him of need to renew). LOA.
- Sept 2014. SBOP Inspector denied routine inspection at correctional facility because he had not been preapproved a week in advance for entry. LOA.
- Jan 2015. When pharmacist applied for unemployment after being fired, she provided a list of patients (by name) for whom she had transferred prescriptions to show that she was an adequate pharmacist. LOA due to HIPAA violation.
- Sept 2014. Pharmacy had repeat deficiencies upon inspection. 2 year probation and $2200 fine.

Court Cases
- Criminal cases
- Malpractice / negligence
- Dispensing errors
- Duty to warn / Duty not to fill

Criminal / Regulatory Case #1: Jeffrey Clawson
- Jan 17, 2013: Brighton, CO pharmacist charged with collaborating with a group of 15 individuals to fraudulently acquire, divert and distribute large amounts of oxycodone in the Denver metro area and Oklahoma
- Jan 18, 2013: Summary Suspension by SBOP
- April 2013: License voluntarily surrendered
- Jan 2014: Sentenced to 15 years in jail

Colorado Attorney General website, 1/31/2014
13

Criminal Case # 2:
New England Compounding Center
- January 2015: US Attorney's office seized $18M from the owners of NECC
- 12/14: Two NECC pharmacist charged with murder in the deaths caused by the non-sterile injections
- NECC fake patient names on bogus Rxs included: Baby Jesus, L.L. Bean, Hugh Jass, Filet O'Fish, Freddie Mac, Fannie Mae, Coco Puff, Mary Lamb, Bud Weiser, Richard Coors, Raymond Rollingrock and Samuel Adams

Criminal Case # 4:
Mark Graziano
- From 2002 to 2011, Iowa pharmacist, Mark Graziano, diverted 740,888 hydrocodone pills to sell to drug addicts.
- When Graziano cut off one addict's pill supply and reported the addict's drug use to his probation officer, the addict tipped off the Iowa SBOP about Graziano's drug-diversion scheme.
- Graziano pled guilty to drug diversion and tax evasion and was sentenced to 2 years in federal prison and ordered to make restitution for the $577,000 in taxes he evaded.
- His pharmacist license was revoked by the Iowa SBOP.

Criminal Case # 3:
- Missouri pharmacist compounded commercially available pentobarbital for execution of a condemned prisoner by lethal injection.
- A federal judge ruled that the pharmacist who compounded the pentobarbital did so illegally because it is commercially available as Nembutal.
- Judge also ruled that even though drug was compounded illegally, a Rx for lethal injection is a "legitimate medical purpose" and the prisoner was executed.

Civil Penalty – PDMP
People v. Jade Norton, D.O., Denver District Court, Case No. 215CV30373
- Feb 2015: SBOP sues Dr. Norton for violating PDMP statute, alleging that Norton queried PDMP (at least 9 times) for CS information on his ex-wife and disclosed this RX history to his ex-wife’s probation officer (to aid Norton in a custody dispute).
- SBOP seeking injunction against Norton to prevent further PDMP violations, & $90,000 civil penalty.
- NOTE: Pharmacist is liable for PDMP designees

Criminal Cases
Pharmacists and Lethal Injection
- At its March 2015 Annual Meeting, APhA voted to discourage its members from participating in executions by compounding lethal injections because it is “fundamentally contrary to the role of pharmacists as providers of health care.”
- "In Glossip v. Gross, the US Supreme Court heard oral arguments (on 4/29/15) concerning whether Oklahoma’s use of Versed / midazolam to render a prisoner unconscious for lethal injection execution violates the Eighth Amendment’s ban on cruel and unusual punishment.

Malpractice Insurance
- × Most employers provide professional liability insurance for their pharmacists.
- × Employees generally are covered if acting within the course and scope of their employment.
- × The max amount of coverage varies by employer.
- × Individual malpractice policies for pharmacists: Pharmacists Mutual & Health Providers Service Organization (HPSO) - ~ $200/year premium
Malpractice (Negligence)
- Malpractice: professional misconduct or negligence
- Elements: Duty of care; Breach; Injury; Causation
- Duty of care: what a reasonable and prudent pharmacist would do under similar circumstances
  - high degree of care / great care / no mistakes
- If a pharmacist incorrectly fills a Rx (wrong drug, strength or directions), breach of duty is assumed
- For Colorado case law see: DeCordova, 878 P.2d 73 (CO App.1994)

Negligence / Malpractice – Example
Source: ABA Journal, 4/14/15
- Perez, a San Francisco window washer, fell eleven stories from a scaffold, struck and crumpled the roof of MA's Toyota, and suffered a broken pelvis and arm and severe brain trauma.
- MA sues Perez and his employer for negligence in the operation of the window washing equipment, for personal injury, lost wages and damages to his car.
DUTY OF CARE? / BREACH OF DUTY?
INJURY? / CAUSATION?

Pharmacist Malpractice: Illegible Rx
Source: HPSO Legal Case Study (Jan 2015)
- Patient with stage IV lung cancer is prescribed Tarceva
- Pharmacist cannot read the Rx and, rather than verifying the drug name with the physician, incorrectly dispenses Tambocor (cardiac arrhythmia medication)
- Pt takes for 29 days; has multiple falls, dizziness and shortness of breath; is hospitalized for several weeks
- The dispensing error allegedly advanced the patient's disease and hastened her death
- The case was settled for a "low six figure" payment

Malpractice – Why Pharmacists Get Sued
Source: Pharmacist Mutual Claims Study 1996-2013
- Wrong drug: 50%
- Wrong strength: 26%
- Wrong directions: 9%
- Drug Review: 8%
  - Allergies, over & under dose, excessive refills, interactions
- Counseling: 2%
- Non-bodily injury: 2%
  - Confidentiality, defamation, false arrest
- Other: 3%
  - Salary cap, generic, illegal, compounding

Source: Pharmacist Mutual Claims Study 1996-2013
- Drugs most involved in wrong drug, strength or direction claims:
  - Warfarin 7.1%
  - Levothyroxine 5.7%
  - Anti-diabetics 4.5%
  - 2.6% to 3.6%: Amoxicillin / Augmentin, amitriptyline, metoprolol, lisinopril, insulin, prednisone, hydrocodone, oxycodone

Source: 2013 Pharmacist Liability: A Ten Year Analysis (HPSO/CNA)
- 162 closed claims that resulted in an indemnity payment (2002 to 2011)
- Average indemnity payment: $87,000
- 81% of pharmacists worked in a chain or independent pharmacy
- Wrong dose or drug = 75% of closed claims
- Most common patient injuries: Overdose (13.6%) and unexpected death (11.7%)
How could I have made such an error?  
Source: 2013 Pharmacist Liability: A Ten Year Analysis (HPSO/CNA)
- Absence of high-quality patient safety systems
- Over reliance on electronic systems
- Confirmational bias; inattentional blindness
- Continuous changes in computer systems
- Drug shortages and supply delays
- Frequent interruptions (telephone calls, etc.)

How could I have made such an error?  (con’t)  
Source: 2013 Pharmacist Liability: A Ten Year Analysis (HPSO/CNA)
- Inadequate workspace
- Interruptions for vaccine administration
- Lack of adequate rest or break time
- Overwhelming work volume and pace
- Physical health problems & stress related issues
- Poor pharmacy design: high noise levels & excessive visual stimulation

Malpractice – Duty to Warn  
- Over 2 year period, pharmacy dispensed Xanax, Hydrocodone and Oxycodone to patient for “stress syndrome”, 30 times before prior Rx ran out.
- Patient died of drug intoxication & widow sued.
- Florida Court of Appeals refused to dismiss the law suit.

Malpractice – Duty to Warn  
- Dexamethasone RX, confirmed by MD’s office, filled for 24mg the 1st day, 20mg the 2nd day, 16mg 3rd day.
- Package insert: maximum daily dose = 9mg
- Patient experienced extreme energy, sleeplessness and increases heart rate and nausea
- Court ruled pharmacist has a duty to warn a patient or notify the MD of (1) an excessive dosage, or (2) obvious inadequacies on the face of RX

Malpractice – Duty to Warn  
- The Court in the Oleckna case ruling stated:
  “We refuse to interpret a pharmacist’s duty ...as being satisfied by ‘robotic compliance’ with the instructions of the prescribing physician...[T]he prescriptions at issue here are alleged to be unreasonable on their face because they were written in a quantity, frequency, dosage, or combination that a reasonable pharmacist would either have checked with the prescribing physician or warned the patient.”
- At times, pharmacist may have a duty NOT to fill.
SBOP Rules - Drug Regimen Review
New Rx (initial interpretation) / Refills (final evaluation)
» Known allergies
» Rational therapy and contraindications
» Reasonable dose, duration of use, and route of administration (consider: age, gender, other patient factors)
» Reasonable directions for use
» ADE’s, interactions, contraindications
» Therapeutic duplication
» Proper utilization & optimum outcomes
» Abuse / misuse

Keeping Your License in Good Standing: 2015 Colorado Pharmacy Law Update
Tisha Smith, PharmD, BCACP, CACP
Ambulatory Clinical Pharmacist Specialist
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Objectives
- Discuss why hydrocodone combination products were rescheduled and how it has affected pharmacy practice
- Outline the regulatory changes from the State Board in the past year
- Review the upcoming changes for the Pregnancy and Lactation Labeling

WHY PHARMACISTS GET SUED
85%
WRONG DRUG
WRONG STRENGTH
WRONG DIRECTIONS
Duty to warn / Duty NOT to Fill

QUESTIONS

Rescheduling of Hydrocodone Combination Products
Rescheduling of Hydrocodone Combination Products

- DEA enforces the Controlled Substance Act (CSA)
- DEA implements regulations which are designed to prevent, detect and eliminate diversion
  - Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety

Federal Control Substance Act

SCHEDULE II DRUGS

- high potential for abuse
- accepted U.S. medical use
- severe physical or psychological dependence potential

Rescheduling of Hydrocodone Combination Products

- Background
  - Rescheduling was initiated by a petition from a physician in 1999
  - In 2004, DEA submitted a request to HHS for an evaluation of Hydrocodone Combination Products (HCPs) and a scheduling recommendation
  - In January 2013, FDA advisory committee voted 19-10 to recommend rescheduling HCPs from CIII to CII.
  - In December 2013, HHS recommended the rescheduling to the DEA

Rescheduling of Hydrocodone Combination Products

- DEA received 573 comments on the proposed rule to reschedule HCPs
  - 52% supported (or supported with qualifications)
  - 41% opposed rescheduling
  - 7% did not take a definitive position

Rescheduling of Hydrocodone Combination Products

- Who has the authority to add a drug to a schedule or transfer between such schedules?
  - Attorney General
    - Delegated authority to the Administrator of DEA

Which one of the following statements is false?

- Hydrocodone has a similar mechanism of action as oxycodone and morphine
- Hydrocodone is metabolized to hydromorphone
- Adding combination products (ie: APAP, ASA) will decrease the abuse potential of Hydrocodone
- Hydrocodone alone is a schedule II
Rescheduling of Hydrocodone Combination Products

Eight Factor Analysis
- Actual and potential for abuse
- Pharmacology
- Other current scientific knowledge
- History and current pattern of abuse
- Scope, duration and significance of abuse
- Public health risk
- Psychiatric or physiological dependence liability
- If an immediate precursor of a controlled substance

Impact on Pharmacy
- Patient Access to Medicine
- Impacts on Unique Populations
- Impacts on LTFC
- Abuse Prevention
- Diversion Prevention
- Economic Impact
- Requirements applicable to Prescriptions
- Responsibilities of Pharmacists

Rescheduling of Hydrocodone Combination Products

Since 1999, the amount of prescription painkillers prescribed and sold in the U.S. has nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report.
- Hydrocodone is the most frequently prescribed opioid in the United States with nearly 137 million prescriptions for HCPs dispensed in 2013.
- HCPs were the most widely prescribed drug to Medicare beneficiaries in 2013.

Rescheduling of Hydrocodone Combination Products

Concluded that:
- HCPs have a high potential for abuse
- HCPs have an accepted medical use in treatment in the United States
- Abuse of HCPs may lead to severe psychological or physical dependence

Update of State Board Rules

2.00.00 Orders

2.01.10 Information to appear on each order
- The following must appear on each written or oral order except as provided for chart orders for hospitalized patients (hospital chart orders)
  - Date the order was compounded and dispensed
  - Assigned serial number (hospital chart orders are exempt from this requirement)
  - Quantity dispensed if differs from the quantity ordered (LTCP chart orders are exempt from this requirement)
  - Patient address, prescriber address & DEA registration for controlled substances
3.00.00 Dispensing

3.00.25 First Dose Dispensing
- May dispense up to a 72 hr supply of a non-controlled substance to an LTCF resident pursuant to a duplicate copy of an LTCF chart order provided by another Prescription Drug Outlet (PDO) to provide immediate patient care on a one time per order basis, if the following conditions are met:
  - Receiving PDO appropriately documents on the prescription order
  - Receiving PDO maintains the order as a prescription order and complies with all requirements for prescription orders
  - Originating PDO records on the LTCF chart order the name and address of the receiving PDO and the date the order was provided to the receiving PDO

3.00.91 Prescriptions dispensed by PDO for delivery to consumers in other outlet settings.
- When a drug has been dispensed pursuant to a prescription order at a PDO but has not been delivered to the ultimate consumer at another outlet, the drug may be returned to stock only at the originating PDO for subsequent re-dispensing provided that:
  - PDO complies with Board Rules
  - Storage conditions do not in any way compromise the integrity or stability of the drug
  - No controlled substance prescriptions may be returned to stock
  - No compounded or flavored prescriptions may be returned to stock

5.00.00 Outlets

5.00.15 Registration for Non-Resident PDO
- An applicant for a new non-resident PDO registration shall submit the following:
  - Current application with required fee
  - Verification of the current pharmacy license or registration issued by the applicant’s resident Board of Pharmacy
  - Copy of the most recent report detailing an inspection of the non-resident PDO
  - Affidavit attesting that the non-resident PDO shall not ship compounded or other prescription drugs into the state of Colorado without a prescription order for a specific patient

6.00.00 Pharmaceutical Care, Drug Therapy Management and Practice by Protocols

6.00.30 Pharmacist Qualifications
- Any pharmacist engaged in drug therapy management shall meet the following qualifications:
  - Proof of completion of a pharmacy residency
  - Proof of completion of 1 yr of practice experience in pharmacotherapy and 40 hrs of supervised clinical practice and training
  - Completion of a certificate program and 40 hrs of supervised clinical practice and training
  - Completion of at least 40 hrs of ACPE-approved CE regarding clinical practice and 40 hrs of supervised clinical practice and training

6.00.30 Pharmacist Qualifications Continued
- Any pharmacist engaged in drug therapy management shall meet the following qualifications:
  - Current Board specialty certification for the Board of Pharmaceutical Specialties, current certification from the National Institute for Standards in Pharmacist Credentialing
  - In an inpatient or group model closed HMO setting, all the following criteria shall be met:
    - 40 hrs supervised clinical practice and training
    - Protocols must be approved by the health systems medical committee or P&T committee
    - Documented competency of each area of practice

6.00.30 Pharmacist Qualifications Continued
- Any pharmacist engaged in drug therapy management shall meet the following qualifications:
  - Licensed Colorado pharmacist practicing drug therapy management prior to Aug 1, 2005.
  - Provided clinical training, experience and oversight practicing in the disease states
  - Physician with whom they are currently practicing must attest that they are practicing to the standard of care
10.00.00 Emergency Kits

- 10.00.10 PDO or hospital other outlet may provide emergency kits to any of the following facilities:
  - LTCF
  - Hospices
  - Acute Treatment Units
  - Home Health Agencies

11.00.00 Records and Recordkeeping

- 11.07.10 Records of distribution of controlled substances and prescription drugs within hospitals and facilities owned and operated by HMO
  - Records of distribution of controlled substances and prescription drugs shall comply with
    - In a hospital or a facility owned and operated by HMO which operates a registered PDO, a controlled substance or prescription drug may be distributed for floor stock to appropriate areas within the hospital or facility
    - A record of any such distribution shall be made and retained by the PDO for a period of time not less than 2 yrs

10.00.00 Emergency Kits

- 10.00.20 Categories and Limits
  - LTCF, Acute Treatment Units and Inpatient Hospices
    - Number of drugs allowed in the kit is limited to 60
    - Of the 60, 12 may be controlled substances
    - May contain no more than 30 doses of any separate drug dosage form/strength for each drug
  - Container size of each drug shall be limited to unit dose or unit of issue packaging

14.00.00 Other Outlets

- 14.00.05 Eligibility for registration
  - The facilities that may register as other outlets provided all requirements at met:
    - Hospitals not registered as PDO, Federal Qualified Health Centers, Family Planning Clinics, Jails, Colleges/Universities and schools, County or district public health agencies, community/rural health clinics, ambulatory surgical centers, Medical clinics, Hospices
    - Acute Treatment Units, registered, certified or licensed as such by the Colorado Department of Public Health and Environment
    - Telepharmacies

14.00.00 Other Outlets

- 14.00.80 Consultant Pharmacist
  - Consultant pharmacists shall inspect and document the inspection in writing in the following other outlets at the following frequencies:
    - Community clinics, federally qualified health centers, rural health clinics, colleges, Acute Treatment Units, Telepharmacies and universities shall be inspected and visited as follows:
      - Monthly < 2500 dispensing units
      - Every other week, >2500 but < 7501
      - Each week >7501 but less than 12501
      - Twice a week if >12501 but less than 25001
14.00.00 Other Outlets

- 14.00.80 Consultant Pharmacists
  - Shall be responsible for assuring that the other outlet complies with all applicable provisions of Board Rules when compounding non-sterile and sterile products

16.00.00 Limited License

- 16.00.00 Limited License
  - 16.00.00 Limited License
    - 16.00.10 General Criteria
      - The following facilities ("Outlets") to purchase, possess, store and administer drugs in a manner appropriate to outlet as authorized by law
        - For the purpose of capture, sedation or immobilization of animals prior to euthanasia of injured, sick, homeless or unwanted pets and animals
        - The employees, agents or contractors of Colorado Division of wildlife locations are authorized by the agency to capture or immobilize wildlife for animal control, management or research purposes, those locations are considered 'animal control agencies'
        - All drugs purchased, possessed, stored and administered by the outlet shall be obtained from an individual or entity registered by the Board

16.00.00 Limited License

- 16.00.00 Limited License
  - 16.00.30 Security
    - Outlets shall maintain limited access to controlled substances and other drugs
    - All drugs shall be stored in locked cabinets, a safe bolted to the floor or an equivalent secure location
    - Drugs shall be stored at the address registered with the DEA or when being transported for use in the field, drug shall be secured and in the immediate possession of the employees, agents or contractors of the outlet who are authorized by the agency to capture or immobilize wildlife

16.00.00 Limited License

- 16.00.00 Limited License
  - 16.01.01 Acceptable drugs
    - Acepromazine
    - Ketamine
    - Xyalzine
    - Tiletamine & Zolazepam
    - Sodium pentobarbital
    - Butorphanol
    - Azaperone
    - Medetomidine
    - Midazolam
    - Haloperidol
    - Nalbuphine
    - Tolazoline
    - Naltrexone
    - Doxapram
    - Yohimbine
diphendrydramine

18.00.00 Pharmacy Peer Health Assistance Diversion Program

- 18.00.00 Pharmacy Peer Health Assistance Diversion Program
  - 18.00.10 Definitions
    - "Program" means the treatment program and all associated services provided by the PHAO to the program participant
    - "Program Contract" means a contract between the PHAO and a program participant to detail a treatment/recovery plan or other kind of support services plan as determined necessary by the PHAO and to provide other program services as outlined in the contract
20.00.00 Central Prescription Processing

20.00.11 Added Definitions:
- Central Prescription processing contract
- Written contract
- Contract pharmacy
- Party to same central prescription processing contract
- Network pharmacy
- Pharmacies under common ownership
- Shared pharmacy services
- Requests another common ownership or contract pharmacy to conduct initial interpretation

20.00.00 Central Prescription Processing

20.00.60 Operational Standards
- Pharmacy may outsource dispensing provided the pharmacies:
  - Have the same ownership or a central prescription processing contract
  - Share a common electronic file or appropriate technology/interface
  - Registered with the Board as either resident or non-resident prescription drug outlets
- Non-Resident exception

20.00.00 Central Prescription Processing

20.00.90 Responsibilities of Originating Pharmacy
- When transmitting a controlled substance order to a contracted or common ownership pharmacy, shall write central fill on the original order and record the following:
  - Name and address of the pharmacy to whom the order is transmitted
  - DEA registration of the pharmacy, if controlled substance
  - Name of pharmacist transmitting order
  - Date of transmission
  - Subsequent dispensing transaction in the shared pharmacy services process are exempt from the requirements of writing 'central fill' on the original order

Pregnancy & Lactation Labeling

6/30/15: New format replaces pregnancy categories
- Newly approved drug and biological product applications must use new format immediately
- Prior approved drugs will be phased in gradually
- Reorganizes information for health care professionals with prescribing decisions & prescription counseling
- New content & formatting requirements will provide a more consistent way to include relevant information
- New labeling - based on available information regarding potential benefits / risks for mother, fetus and breastfeeding child

Pregnancy- use of drug in pregnant women
- Dosing and potential risks
- Includes information for a pregnancy exposure registry

Lactation- use of drug while breastfeeding
- The amount of drug in breast milk
- Potential effects on the breastfed child

Females and Males of Reproduction Potential- drug use & pregnancy testing, contraception and infertility
Pregnancy & Lactation Labeling
- “Pregnancy” and “Lactation” subsections
  - Risk summary
  - Clinical considerations
  - Data
- Provide more detailed information regarding human and animal data on use of drug & specific adverse reactions of concern for pregnant or breastfeeding women

Objectives
- Discuss recent changes to the Prescription Drug Monitoring Program in Colorado and the observed outcomes of these changes
- Compare and contrast medical marijuana regulation in Colorado with that in other states

Prescription Drug Monitoring Program
Recent Changes and Status Update

Keeping Your License in Good Standing: 2015 Colorado Pharmacy Law Update
Jeannine Dickerhofe, RPh, MS
Senior Manager, Pharmacy Professional Affairs
Kaiser Permanente

Rule 23.00.00 – Electronic Prescription Monitoring Program (PDMP)
Purpose of changes were multiple:
- Increase frequency of reporting controlled substance dispensing data to the PDMP from once every 2 weeks to once daily
- More updated controlled substance prescription dispensing information for prescribers and pharmacists to help reduce prescription drug abuse in Colorado
- Any errors identified need to be corrected and resubmitted within 30 calendar days
PDMP - Continued
23.00.65 Unsolicited Reporting
- Board developed criteria for indicators of misuse, abuse and diversion of controlled substances.
- Based on the criteria, unsolicited reports are generated and provided to responsible prescribing practitioners and dispensing pharmacies.
- Purpose is education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse and diversion.

PDMP – Mandatory Registration
- Mandatory PDMP registration for pharmacists and DEA registered prescribers.
- Latest statistics (March, 2015) is 92% overall registration for all prescribers.
- January, 2015, there were 7569 RPhs in CO, with 7291 active accounts – 96%.
- Letters were sent to licensees who still need to comply – not sure what DORA will do for those that have not registered.

PDMP – Federally owned and operated pharmacies
- November 4, 2014, pharmacies owned and operated by the US Dept of Veterans Affairs in Denver, Grand Junction, Pueblo and Colorado Springs began submitting controlled substance dispensing data into the PDMP.
- Work will continue with other federal agencies, such as the Indian Health Service, to submit data.

PDMP – Creation of Task Force
- Creation of a PDMP Task Force to examine issues, opportunities and weaknesses of the program and make recommendations to make the PDMP a more effective tool to reduce drug abuse in Colorado.
- July 24, 2014 – Executive Director Barbara Kelley sent formal letter to Colorado Consortium to Reduce Prescription Drug Abuse inviting that group to serve as this task force.
- First report from the Consortium will be submitted by July 1, 2015.

PDMP – Continued
PDMP Access
- Up to 3 trained individuals designated by the practitioner or pharmacist may access the PDMP on their behalf through sub-accounts.
- 203 delegate accounts to date, but can’t separate out the pharmacist delegate accounts.
- Pharmacists licensed in other states can access the PDMP.
PDMP – Activity Data
- Daily reporting to the PDMP by in-state and nonresident pharmacies, effective October 15, 2014
- Enhancements to PDMP interface:
  - fewer clicks
  - easier downward flow to query patient info
  - decrease in time involved to obtain information
  - can reset password and user name without help desk
  - morphine equivalent dosing/opioid CSs prescribed

PDMP - Enhancements
- BOP and the Consortium continue to explore new options to improve both the interface and the outcomes achieved from the current PDMP
- More enhancements are on the horizon, but are not funded at this time
- Fees that run the program (license renewals of prescribers) can’t be used for the enhancements
- Even if grants or other monies are received, the enhancement schedule from the vendor is pushing into the end of 2016

PDMP – Statistical Data
Utilization of the PDMP has increased
- Between July 2014 and December 2014, utilization increased from 41% to 56% (more than a one-third increase during this short period of time since HB 14-1283 was enacted)
- In April, 2015 the utilization was at 85% (up 3% even from the month before)
- Mandatory registration for PDMP in other states has shown drastic increase in use for prescribers and dispensers

Medical Marijuana – Legislative History
- California was first state to approve marijuana for therapeutic use in 1996 by Proposition 215
- Medical marijuana programs have been created or authorized in at least 23 states, DC and Guam
- Generally, programs are developed to offer an alternative therapy for treating pain patients with certain chronic disease states, like cancer, HIV/AIDS, glaucoma and MS
- Laws typically require a physician to certify patient’s need for medical marijuana

Recently, approved efforts in an additional 13 states allow use of “low THC, high cannabidiol (CBD)” products for medical reasons in limited situations or as a legal defense
- These programs are not listed as “comprehensive” medical marijuana programs
Medical Marijuana – Legislative History
Criteria to determine if program is "comprehensive"

- Protection from criminal penalties for using marijuana for a medical purpose
- Access to marijuana through home cultivation, dispensaries or some other system that is likely to be implemented
- Must allow a variety of strains; and
- Must allow either smoking or vaporization of some kind of marijuana products, plant material or extract

Medical Marijuana

- How drug is produced, distributed and provided to patient varies from state to state
- Two states now require dispensing by a pharmacist – Connecticut and Minnesota
- Although laws allow pharmacists to dispense marijuana, DEA and other agencies express continued concerns about potential adverse health effects of marijuana.
- DEA has authority to change way particular substance is regulated, but marijuana is still listed as Schedule I

Medical Uses of Marijuana

- Institute of Medicine (IOM) issued report examining potential therapeutic uses of marijuana in response to CA Proposition 215
- "Scientific data indicate potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea & vomiting, and appetite stimulation; smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances. Psychological effects of cannabinoids, such as anxiety reduction, sedation, and euphoria can influence their potential therapeutic value.…..psychological effects can complicate the interpretation of other aspects of the drug’s effect."

Department of Justice (DOJ)

- 2013, as Washington and Colorado implemented recreational use of marijuana, DOJ announced update to their enforcement policy
- Marijuana remains illegal federally, but DOJ expects states to create "strong, state-based enforcement efforts"
- DOJ defers "the right to challenge their legalization laws at this time"
- DOJ reserves right to challenge states at any time it believes action is needed
- With federal government content to defer to states, medical marijuana programs continue to be considered in legislatures across nation

Medical Uses of Marijuana

- Further studies have found marijuana to be effective in relieving some of the symptoms of HIV/AIDS, cancer, glaucoma and multiple sclerosis
- Marijuana is not considered a cure for anything, but rather a palliative treatment for symptoms associated with certain conditions or the adverse effects of medical treatments
- Cannabinoids do not necessarily have to replace opiates – they can complement each other

Department of Justice (DOJ)

- States with medical marijuana laws generally have some form of patient registry
- Patient registry may provide some protection against arrest for possession up to a certain amount of marijuana for personal medicinal use
- 2014, at least 36 states considered bills for new medical marijuana laws
Regulation of Medical Marijuana

- Most common policy questions include how to regulate the recommendation, dispensing, and registration of approved patients
- Some states and locations without dispensary regulation experience a boom in new businesses, in hopes of being approved before presumably stricter regulations – Colorado experienced this issue

Is Medical Marijuana Safe?

- No risk of death by overdose from cannabis – alone or even in massive overdoses
- Like any medication, it brings risks for adverse effects and interactions with certain drugs and conditions
- Some examples of interacting drugs – barbiturates, CNS depressants, tricyclic antidepressants, anticholinergics, lithium
- Can have adverse effects for patients with psychiatric disturbances, cardiac or respiratory disease, vertigo, cancer, pregnant or obese patients and those on immunosuppression

Colorado

- Marijuana can be recommended by MD & used for certain conditions – CA, glaucoma, HIV/AIDS, severe pain or nausea, seizures, MS
- In Colorado, 94% of patients use MMJ for pain
- CDPHE can review petitions to add debilitating conditions, but has denied many – asthma, anxiety & bi-polar disease, atherosclerosis, Crohn’s disease, DM, diabetic retinopathy, Hep C, HTN, MRSA, opioid dependence, PTSD, RA, severe anxiety and clinical depression, Tourette’s syndrome

Colorado

- Bona Fide physician-patient relationship (med history, physical exam, offers follow-up care)
- Valid, unrestricted CO MD license and DEA registration
- MD cannot be paid by dispensary, have ownership interest in dispensary or examine a patient in a dispensary
- Patient <21 y/o must get 2 MD’s approval

Colorado MMJ Dispensaries

- Legalized medical marijuana in 2000 (Colorado Amendment 20)
- Medical Marijuana Registry Card ($15/yr) – from CDPHE
- With Card, patient can possess, acquire, grow, use, transport marijuana/paraphernalia
- Pt can possess 2 oz useable form (seeds, leaves, buds) and up to 6 plants (<3 mature)
- Pharmacies CANNOT dispense marijuana
- Licensed by both state & local government
- 70% of all MMJ must be grown in-house
- Owners & employees must be residents & cannot have drug-related felonies
- Cannot be consumed at the dispensary
- Cannot be used in public or in a manner to cause negligence
- Must be 1000 feet from schools, child-care centers or other dispensaries (Denver)
Connecticut
- First state to require medical marijuana be dispensed by an on-site licensed pharmacist
- 2 years passed before first dispensaries and 4 manufacturers were in business
- Criticism from health care providers – existing research is lacking, as well as federal guidelines, so difficult to determine appropriate prescribing and dosing

Minnesota
- Authorizes pharmacists to work with patients to determine appropriate dose – language is not as detailed as Connecticut’s law
- Pharmacists work directly for Minnesota’s cannabis manufacturers, with each manufacturer required to hire at least one
- Dept of Health is compiling educational information regarding cannabis-based therapy to provide guidance for pharmacists

Connecticut
Questions raised:
- What training and guidelines would best support pharmacists practicing in a medical marijuana dispensary?
- How should pharmacists and other health care providers determine appropriate dosing?

New York
- Authorized with the Compassionate Care Act
- Like Minnesota, limits dosage delivery forms to those authorized by Dept of Health, with smoked cannabis notably prohibited.
- Practitioners must complete a training course and register with the Dept of Health
- Only 5 registered organizations may manufacture and dispense marijuana and each may only operate up to 4 dispensing facilities – maximum of 20 dispensing facilities throughout state
- Patients limited to 30 day supply and required to keep marijuana in original packaging

Minnesota
- SF 2470 – creation of medical cannabis patient registry under Dept of Health
- 2 medical cannabis manufacturers were approved
- 8 distribution facilities will be located across state by July 2016
- Only allows use of cannabis in liquid, pill or vaporized delivery methods that do not require use of dried leaves
- Participating health care providers must provide ongoing reports about patients’ health status to Dept of Health

Maryland
- HB 1101 passed in 2013 authorized academic medical centers to distribute medical marijuana to sick patients
- None of the 5 qualifying teaching hospitals participated
- Two bills were passed to amend 2013 legislation and allow for creation of dispensaries and cultivators to provide drug directly to patients in model similar to other states
Illinois

- Doctors can issue recommendation certifications to patients suffering from 1 of 35 chronic conditions
- Registry identification card will be used to track how much drug has been purchased
- Patients are limited to max of 2.5 oz in 14 day period
- When program fully implemented, can purchase drug from up to 60 dispensing centers across Illinois
- Plants grown in up to 22 cultivation centers (1 for each police district) under Illinois Dept of Agriculture
- Patients prohibited from growing or cultivating their own supplies

What Can Pharmacists Do?

- Because marijuana comes in so many forms and strains, health care providers are advised to use a patient-determined, self-titrated dosing model
- Unanswered questions remain about how best to determine most effective dose and how to involve health care providers
- Until questions are answered, pharmacists should try to foster an environment in which patients feel safe and comfortable disclosing medical marijuana

Debate Over Pharmacist Role

APhA 2015 Annual Meeting – Final Session of House of Delegates saw lively debate over pharmacists’ role in the care of patients using cannabis

Adoption of several APhA policy statements:

- Opposing pharmacist involvement in "furnishing cannabis and its various components for recreational use"

New Pharmacy Organization

National Association of Cannabis Pharmacy (NACP) was launched on April 8, 2014

- Purpose is to support pharmacists who dispense, administer and compound cannabis-based products to treat specialty diseases including MS, HIV, oncology and rheumatoid arthritis
- Aims to provide means to track outcomes of patients taking medical marijuana and the metrics to convert those outcomes into real-world data
- Want to determine safety and efficacy of products that are available or coming into the market
Recreational Marijuana

- Washington and Colorado have already legalized recreational marijuana
- Voters in Oregon, Alaska and District of Columbia weighed in on proposals to allow for legal, recreational use of marijuana in 2014
- All 3 measures passed
- Premise is to regulate marijuana like alcohol

Going Forward

- Can’t make marijuana regulation bullet proof – if the feds want to shut it down, they can
- There’s a reason that CO was largely exempt from MMJ crackdowns, though
  - Better regulatory regime than anywhere else
  - Proved we could keep negative externalities under control
- It is recognized that Colorado is a state that has made the most progress on implementing its law legalizing marijuana for recreational use

Questions????