

SECOND HOUR

LAW REVIEW

A Review of Actual Cases

Case Scenarios

Regulations Across America

Surveys

Unique Products of Abuse

ACTUAL CASES

Brought to you by the letters NMBOP

MISINFORMED PHARMACIST

- Pharmacist Clinician
- Pharmacist stated employer said not to renew clinician license
 - Pharmacist claimed he was acting as an agent of the doctor
- Clinician license lapsed
- Continued prescriptive authority until 2010
 - Approximately 800 prescriptions in two years
 - \$28,000 was paid for by third party payors

MISINFORMED PHARMACIST

BOARD ORDER - JANUARY 2011

- ⦿ Plead no contest
- ⦿ \$5,000 fine
- ⦿ 6 months suspension of pharmacist license
- ⦿ 5 years probation
- ⦿ Surrendered Clinician license with no chance of renewal

MISTAKEN PHARMACIST

FIRST OFFENSE

- Seasoned Pharmacist 20+ years
- Patient was a nine year old boy
- Prescription written for Metadate 40mg
- Prescription filled for Metadose 40mg
- Medication error caught by PCP - mother called about sons extreme fatigue
 - No permanent impairment

MISTAKEN PHARMACIST

BOARD ORDER - OCT 2009

- Pharmacist admits that the events happened as noted in the case report
- \$500 (fine) + \$300 (investigative costs)
- Board approved error prevention CE
- 6 months probation

MISTAKEN PHARMACIST

SECOND OFFENSE

- Same Seasoned Pharmacist 20+ years
- Patient was an elderly lady
- Rx written for Vitamin D 400 IU BID
- Rx filled for 50,000 IU BID
 - 125 times the amount prescribed
- Patient filed a complaint, stating harm

MISTAKEN PHARMACIST

BOARD ORDER - JANUARY 2011

- ⦿ Pharmacist admits to filling Rx and erred when completing the "Final Check"
- ⦿ \$1000 (fine) + \$960 (hearing) + \$760 (transcription) + \$200 (investigative costs)
- ⦿ 30 day suspension of Pharmacist license
- ⦿ 2 years probation
- ⦿ Board approved "Patient Safety" CE

MISTAKEN PHARMACIST MEDICATION ERROR REPORTING - NABP

- 27 states require hospital & medical facilities (including pharmacies) to report med errors
 - NMBOP 16.19.25 - PIC must file a significant adverse drug event report within 15 days of discovery
 - Harm - means temporary or permanent impairment requiring intervention
- NMBOP uses the significant adverse drug event reports in our news letter to educate pharmacists about potential errors

MISGUIDED TECHNICIAN

FIRST OFFENSE

- ⦿ Technician owned pharmacy
- ⦿ No PIC, technician assumed role
- ⦿ When Tech played pharmacist there were several incorrectly filled prescriptions

MISGUIDED TECHNICIAN

1ST BOARD ORDER - JULY 2008

- ⦿ 1 year probation
- ⦿ \$1,000 fine
- ⦿ Violation of probation may result in suspension of technician license

MISGUIDED TECHNICIAN

SECOND OFFENSE

- PTCB expired in 1996
 - Falsified PTCB status to renew New Mexico technician license
- Because of falsifying PTCB, technically had an expired state technician license

MISGUIDED TECHNICIAN

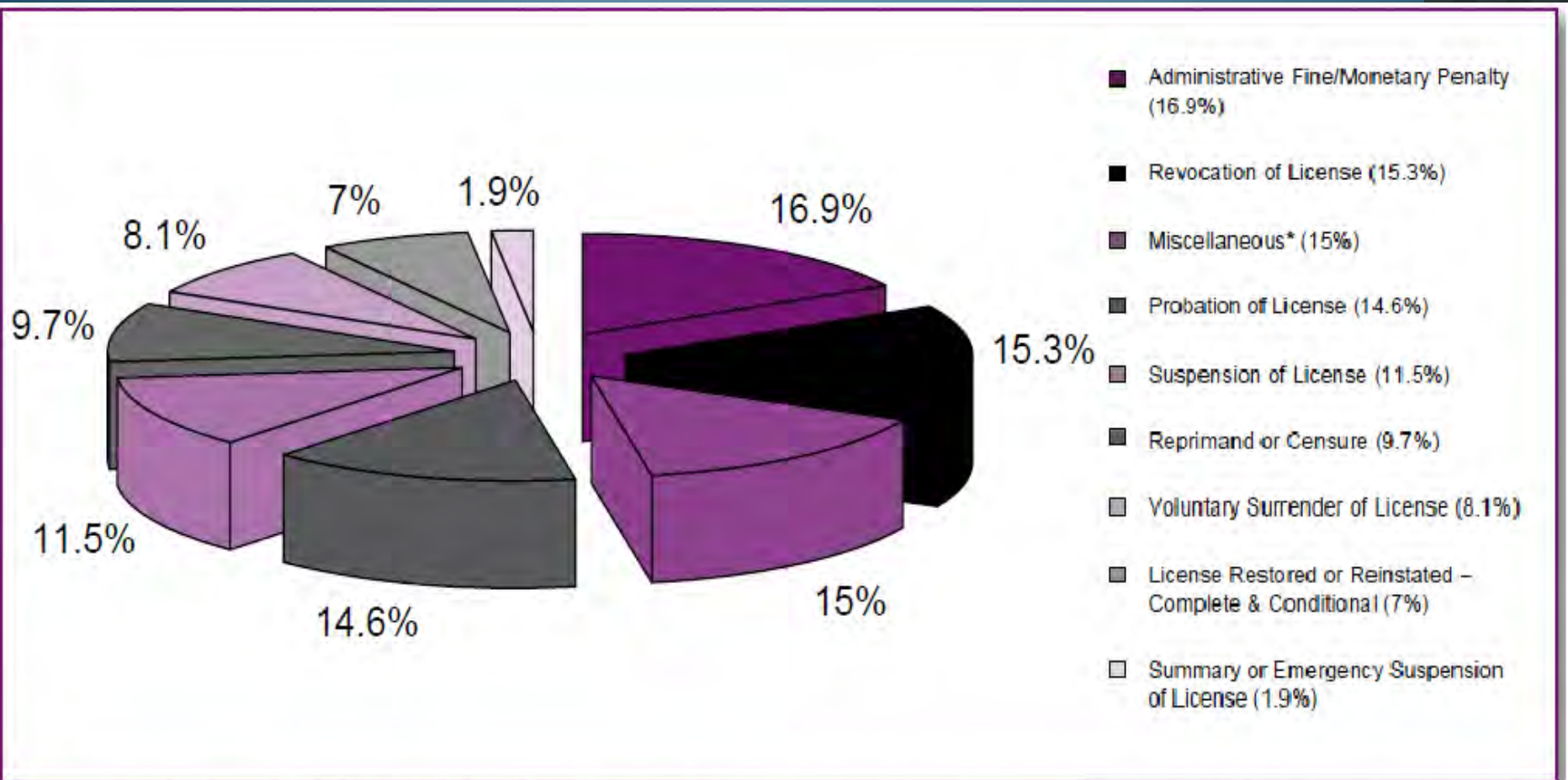
2ND BOARD ORDER - JANUARY 2011

- Plead guilty
- Immediate surrender of technician license
 - Can not reapply for 3 years
- \$5,000 fine + \$250 investigative fee
- Probation of the pharmacy for 3 years
 - Cannot have access to restricted area
 - Monthly reports (signed by PIC) stating what pharmacist worked and when
 - Notify Board within 24 hours of change in PIC

2010 NATIONAL TREND IN DISCIPLINARY ACTION - NABP

- Mandated by the United States Department of Health that disciplinary actions be reported
- A total 5,537 disciplinary actions were reported
 - 3,354 were against pharmacists
 - 2,183 were against pharmacy technicians
- Top three categorizes
 - Administrative Fine/Monetary Penalty
 - Revocation of License
 - Miscellaneous
- Probation of license fell from the top three compared to 2009

DISCIPLINARY ACTIONS REPORTED IN 2010

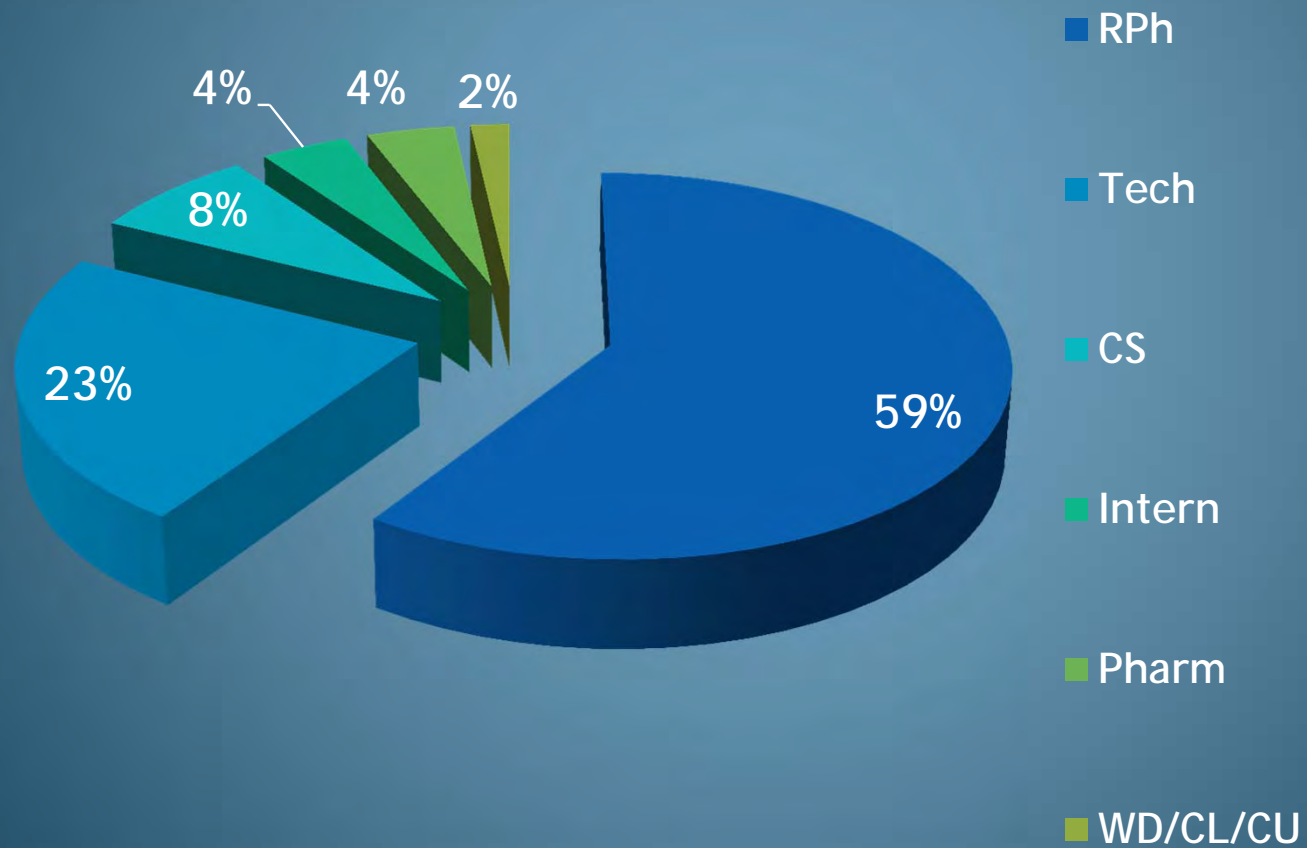


The Miscellaneous category includes denial of initial license, denial of license renewal, extension of previous action, license restoration or reinstatement denied, limitation or restriction on license, other licensure action - not classified, and reduction of previous action.

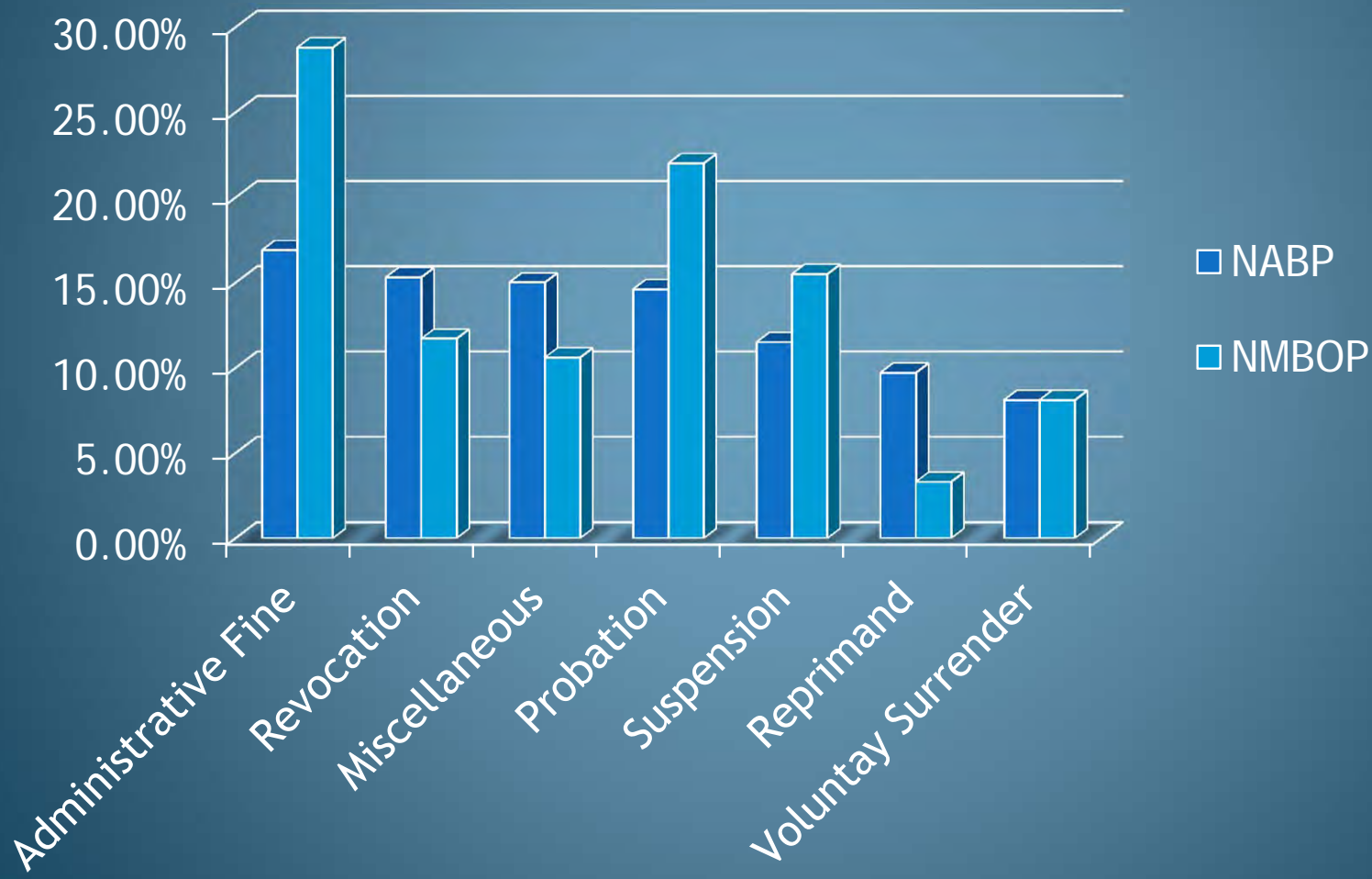
NMBOP DISCIPLINARY TRENDS

- ◎ NMBOP reports disciplinary actions is the Healthcare Integrity and Protection Data Bank
- ◎ From 1999 to 2010 NMBOP had 222 disciplinary action against licensees
 - 132 were against pharmacists
 - 51 were against pharmacy technicians
- ◎ Top three disciplinary actions
 - Administrative Fine/Monetary Penalty
 - Probation
 - Suspension

NMBOP 12 YEAR AVERAGE: 1999-2010 DISCIPLINARY ACTIONS



DISCIPLINARY ACTIONS NMBOP VS NABP



NABP - CPE MONITOR SERVICE



CPE Monitor is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits. It will also offer state boards of pharmacy the

opportunity to electronically authenticate the CPE units completed by their licensees, rather than requiring pharmacists and technicians to submit their proof of completion statements upon request or for random audits.

This initiative will streamline processes for pharmacy practitioners to ensure they are maintaining professional competency requirements. CPE Monitor is expected to save pharmacists, pharmacy technicians, state boards of pharmacy, and CPE providers time and money.

Get an Early Start!

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile ID now to ensure their e-Profile is properly setup. In the latter part of 2011, the e-Profile ID will be required to receive credit for anyCPE activities taken from ACPE-accredited providers.

[Set up your NABP e-Profile to obtain your ID](#)

IMPACTING U.S.

National Cases

RETAIL CHAIN FINED FOR FAILING TO ENFORCE PSE SALES LIMITS

- ◉ Due to its failure to ensure compliance with pseudoephedrine (PSE) product sales limits an agreement with federal prosecutors results in \$75 million in civil penalty and forfeiting the \$2.6 million earned from the unlawful PSE sales
- ◉ From September 2007 to November 2008, the electronic PSE logging system used in its stores did not prevent multiple PSE purchases by an individual on the same day
 - Limit is 3.6 grams per day & 9 grams/month

OHIO PHARMACIST INDICTED FOR ILLEGAL DISPENSING

- An Ohio pharmacist is accused of illegally distributing prescription painkillers and anti-anxiety medications and was indicted on 227 counts
 - Pharmacy owner pleaded guilty in January 2011 to illegal distribution of oxycodone and committing financial and tax crimes. He is awaiting sentencing.
 - Most counts are subject to a 20 year prison sentence each - Possible life in prison
- The charges allege the pharmacist conspired with the doctor & illegally distribute oxycodone, hydrocodone, alprazolam and diazepam
 - The jury convicted the 64-year-old doctor of 12 counts of unlawful distribution of a controlled substance, including four counts that the illegal distribution resulted in death.
 - The doctor directed his customers to a pharmacy in Columbus which filled more than 5,500 prescriptions for high doses of oxycodone and other drugs
 - The pharmacist did not question the excessive dosages

WISCONSIN PHARMACIST ACCUSED OF DISTRIBUTING COUNTERFEIT MEDS

- A pharmacist was arrested and accused by federal prosecutors of conspiring to deliver counterfeit controlled substances
- Informant claims to have ordered millions of anti-anxiety pills and appetite suppressants that were shipped from India, partially damaged and unlabeled
 - The informant, does not hold a license to purchase prescription drugs and was operating an illegal Internet drug outlet
- A second informant claims to have ordered oxycodone, hydrocodone, and a product marketed as generic Viagra which were shipped from India, China, and Wisconsin

MASSACHUSETTS PHARMACIST GUILTY OF FRAUD

- ◉ Pharmacist plead guilty to defrauding Medicaid and Medicare
- ◉ Obtained Rx from individuals suffering chronic diseases
- ◉ Billed Medicare to receive reimbursement
- ◉ Never dispensed the medications
- ◉ Instead paid the patient a small % of reimbursement
- ◉ Medicaid paid at least \$292,000
- ◉ Medicare paid at least \$60,000

INTERSTATE R_x FRAUD SCHEME

- Oregon FBI informed Phoenix FBI, AZ residents travel to various states filling counterfeit Rx
 - Stolen DEA numbers & counterfeit drivers licenses
- 2 suspects were stopped in OK with over 3,000 Oxy 30mg & \$17,700 cash, 49 counterfeit Driver Licenses, marijuana, laptops and scanners
- Counterfeit Rx's were computer generated on security paper for large amount of Oxy
- Ring has traveled from Phoenix to Oregon, Oklahoma, Colorado, Iowa, Washington and Virginia
 - 6 suspects DOB ranging from 1980-1988
- Mode of transportation - rent car from Phoenix

CASE SCENARIOS

Fact or Fiction

ROUTINE CUSTOMER

- 60+ female
- 5 chronic medications in profile
 - All filled for a 30 day supply on January 17th
- On February 1st she states:
 - "Fill whatever is due"
 - "I also need my pain medication"
- Presents a new prescription for coumadin

PRESCRIPTION

**Southwest Medical
Associates, Inc.**

Albuquerque, NM 87109
(505) 823-1010

Name Dr. [unclear] Date 1/11/11
Address 727-9 LA NE

**Coumadin 2mg
TAD
#40**

Form # 1026

Southwest Medical Associates, Inc. M.D.
Refill 0 1 2 3 4 5 PRN

- ❖ Disease States
- ❖ DUR - Drug Disease
Contraindication
- ❖ TAD "Take As
Directed" & insurance
- ❖ Refills -14 days
later

WHAT MORE INFORMATION
WOULD YOU LIKE TO KNOW?

ESTABLISHED CUSTOMER

- ◉ 40+ female
- ◉ Filled twice before
- ◉ Presents with new prescription
- ◉ She mentions she would like to fill it for a three month supply
- ◉ Profile lists Hypertension and Pain

PRESCRIPTION

4207A MONTGOMERY BOULEVARD N.E.
ALBUQUERQUE, NM 87109-6706
(505) 898-2468 TEL. (505) 898-1518 FAX

DEA # _____ LIC. # _____ NPI # _____

NAME _____ AGE _____
ADDRESS 3rd NW DATE 12/23/10

TAMPER-RESISTANT FEATURES INCLUDE: SAFETY-BLUE
ERASE-RESISTANT BACKGROUND, "ILLEGAL" PANTOGRAPH
QUANTITY CHECK-OFF BOXES AND REFILL INDICATOR

Rx

Prozac 20mg
Sig: 1 tab PO QD
DISP: #30

<input type="checkbox"/>	1-24
<input type="checkbox"/>	25-49
<input type="checkbox"/>	50-74
<input type="checkbox"/>	75-100
<input type="checkbox"/>	101-150
<input type="checkbox"/>	151 and over

_____ Units

Refill NR 1 2 4 5

(Signature)

To ensure brand name dispensing, prescriber must write 'No Substitution'
or 'NO SUB' on the prescription.

91FP0007385

- ❖ Disease States
- ❖ DUR - Drug Disease
Contraindication
- ❖ 90 Supply

WHAT MORE INFORMATION
WOULD YOU LIKE TO KNOW?



NEW CUSTOMER

- ◉ 20+ young looking male
- ◉ No signs of physical distress -
Moaning and/or trouble breathing
- ◉ No visible physical impairments -
No cast and/or Crutches/Limping
- ◉ Presents a prescription for Oxycodone 30mg
- ◉ He asks "Can you fill this for me?"

PRESCRIPTION

MP AN ARTIFICIAL WATERMARK IS ON THE BACK - HOLD AT AN ANGLE TO VIEW THIS MARK MP

PRESBYTERIAN

Dennis Angellis, M.D.
Stephanie A. Horoschak, M.D.
Michael D. Miller MSN, RN, PMHNP-BC
Craig Ottenstein, M.D.
8800 Montgomery Blvd. NE
Albuquerque, NM 87111

Amy Robinson, M.D.
Jimmy Romero, M.D.
Syed N. Shah, M.D.
Kothandapany Shalini, M.D.5
Clinic: (505) 462-6400

Name _____ Date 10/22/16

Address 9101 N.W. Phone _____

Rx Oxycodone 30mg
Sig: \bar{ii} po q4h prn # 360
THREE HUNDRED SIXTY

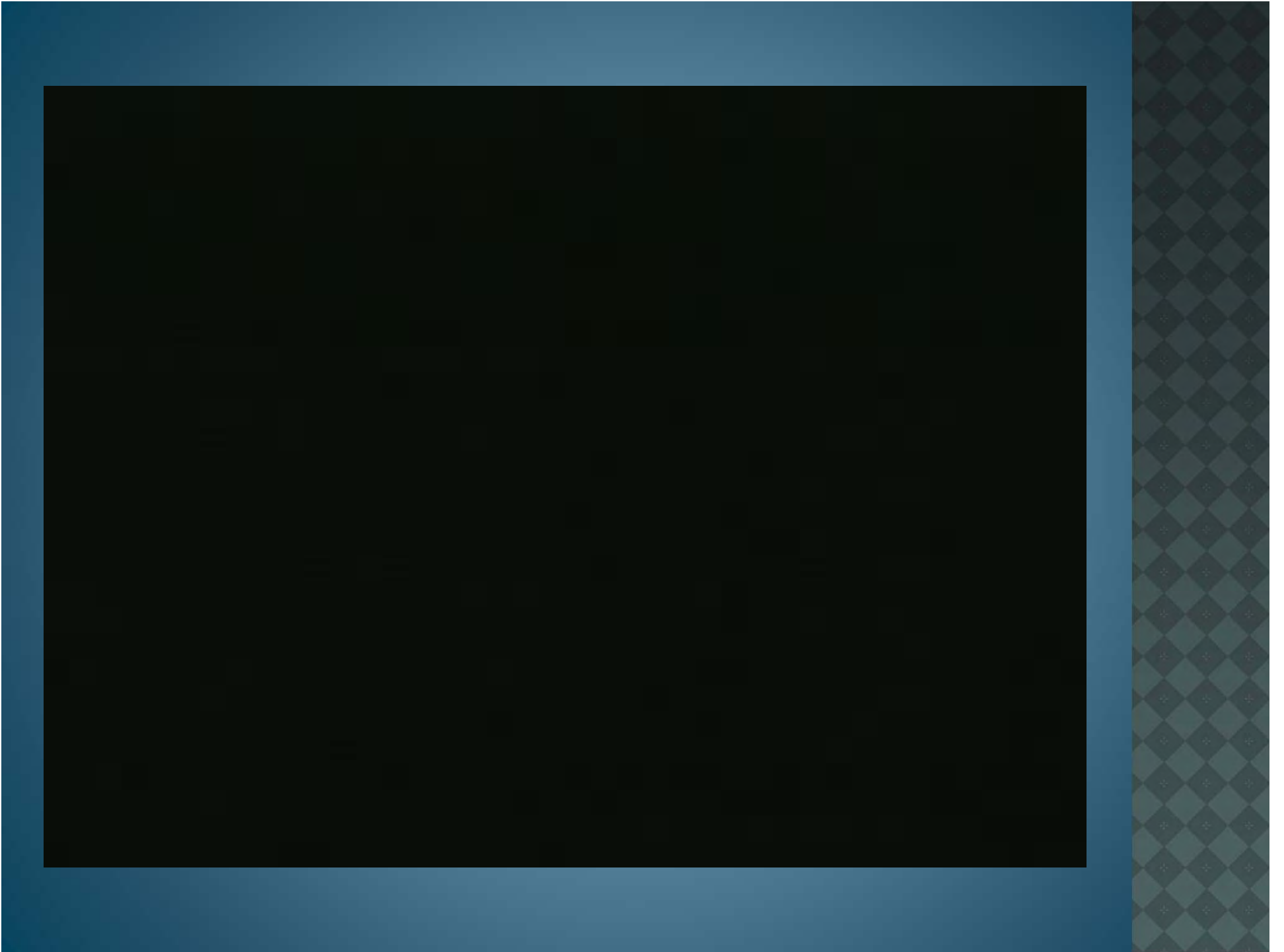
By [Signature]

56-5100-020 (12/09) Non Refill Refill 0 Times

RX'S ON BACK ARE PRINTED IN DISAPPEARING INK. RUB BRISKLY TO ACTIVATE - CHEMICALLY SENSITIVE PAPER

- ❖ Cash
- ❖ Broken Leg
- ❖ AIDS
- ❖ Disease States
- ❖ Drivers License
- ❖ 2 weeks later -
New Rx for #450...DO
YOU FILL IT?

WHAT MORE INFORMATION
WOULD YOU LIKE TO KNOW?



LET FREEDOM RING

Land of the Lost Or
Home of the Brave

IDAHO

FINGERPRINTING REQUIRED

- ◎ Applicants seeking original licensure, registration, and reinstatement through the Idaho BOP are now required to submit fingerprints for Idaho and FBI criminal background checks
 - This includes all pharmacists, technicians, student pharmacists, and all controlled substance registrants, including prescribers
 - This requirement does not pertain to renewals

KANSAS

TECH VERIFYING ANOTHER TECH'S WORK

- A pharmacy technician in a medical care facility may check the work of another pharmacy technician. Limited to filled floor stock, a crash cart tray, a unit-dose cart, or an automated dispensing machine if the checking pharmacy technician meets each of the following criteria:
 - Current pharmacy technician license
 - One year of experience working as a tech plus at least 6 months in the medical care facility, or one year as a tech in the medical care facility at which the checking will be performed.
 - Completed a written training program and passed examination designed by the PIC

TENNESSEE

DISPENSING AFTER DEATH OF A PRESCRIBER

- When pharmacist knows that a practitioner has died, a prescription issued by the practitioner may continue to be dispensed based on the pharmacist's professional judgment and in accordance with the following requirements:
 - If a RX is new and not dispensed, it may be filled up to 90 days after date of death
 - Refills may be filled up to 90 days for CS and 180 for non-scheduled drugs
 - Federal law supersedes state reg. Thus regulation only applies to non-scheduled drugs

OHIO

LIMITS NUMBER OF PRESCRIPTION TRANSFERS

- ◎ Implemented a rule stipulating that prescriptions may only be transferred one time, in the interest of patient safety and to address prescription drug abuse
 - “Copies of prescriptions for dangerous drugs, including both non-controlled substances and controlled substances, shall only be transferred one time”
 - “Pharmacies electronically sharing a real time, online database may transfer a prescription up to the maximum number of refills permitted by law and the prescriber's authorization”

WASHINGTON

TAMPER RESISTANT RX PAPER

- ◎ Beginning July 1st 2010, Rx's must be written on tamper resistant Rx paper approved by the board
 - "Void," "Illegal," or "Copy"
 - Solid color or patterned background
- ◎ Paper must include board approved seal
- ◎ Includes hard copies and electronic generated Rx's
- ◎ Does not affect Rx's given to the pharmacy by telephone, by electronic transmission, by fax, or for in-patient care



WASHINGTON

PAIN MANAGEMENT PRESCRIBING RULES

- Legislature passed a House Bill
- Requires new rules for chronic non-cancer pain
- Does not apply to end of life or acute pain
- Encompassing medical, osteopath, podiatry, dental and nursing professions
 - The 5 professions formed a workgroup to develop a model rule to consider
- Bill repeals existing pain management rules
- Did not include the practice of pharmacy or Pharmacy Board
 - Recommended to workgroup to include communication with RPh in the Rx process

CALIFORNIA

LIMITS TOBACCO PRODUCTS

- San Francisco City ordinance “no person shall sell tobacco products in a pharmacy”
- Premise - patrons generally patronize pharmacies for health care products and services, the sale of tobacco products at these premises sends mixed messages
- Prevents drug stores from selling tobacco but not grocery stores or warehouse stores
 - Total revenue is the majority of the business for pharmacies and drug store
- A particular drug store appealed to a higher court
 - Court overturned lower court - requiring an economic impact study

OREGON

CLARIFIES DRUG UTILIZATION REVIEW

- ◎ Stresses that DURs are a requirement prior to dispensing any prescription or refill
- ◎ Pharmacists who fail to review or rely on computer programming for pertinent information with DURs, are subject to an investigation
- ◎ Computers should be used to their optimal potential, but the computer is but one tool for the pharmacist who performs the DUR

DUR DEFINITION

OREGON

“ . . . evaluating prescription drug orders in light of the information currently provided to the pharmacist by the patient or the patient’s agent and in light of the information contained in the patient’s record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber when appropriate.”

NEW MEXICO

“ ...evaluating or reviewing the patient record in order to determine the appropriateness of the drug therapy for a patient and which includes: clinical abuse/misuse, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage, incorrect duration of drug treatment, drug-allergy interactions and appropriate medication indication and the verification of data entries including the correct interpretation and input of written prescriptions and the drug regimen review.”

SURVEY SAYS...

Expiration? What Expiration?

PHARMACIST SMARMACIST

- Pharmacist communication shown to increase medication adherence and reduce errors
- Barriers to adherence:
 - Lack of awareness among clinicians on basic adherence management principles
 - Poor communications between pts & clinicians
 - Operational aspects of pharmacy & medical practice
- Patient barriers:
 - Side effects
 - Managing multiple Rx's
 - Misunderstanding their disease
 - Forgetfulness
 - A reduced sense of urgency due to asymptomatic conditions

BEFORE CONSULTATION

- 3 out of 4 patients do not take their medication as prescribed
 - 49% have forgotten to take a medication
 - 31% have not filled a prescription
 - 29% have stopped taking medication before it runs out
 - 24% take less medication than prescribed
- \$47 billion in drug-related hospitalizations
- Seniors & children are more prone than others
- Chronically ill pts adherence drops after the first 6 months

AFTER CONSULTATION

○ After consultation:

- Elderly pts using ≥ 3 meds, adherence inc 12%
- Consultation before and after discharge inc 43%
- Counseling combined with dose simplification inc 46%

○ Patient Literature

- 95% of RPh receiving product-specific, patient counseling literature from manufacturers helps in providing effective patient counseling
- Low literacy skills prevents many pts from proper medication adherence because they are not able to understand labels or instructions



"I didn't experience any of the side effects listed in the enclosed literature. Should I be concerned?"

WHAT'S IN YOUR MEDICATION CABINET

- ◎ Study Finds Nearly 40 Percent of American Households Have Expired OTC Medications
 - cough, sore throat and flu among the most common to be found expired when needed
- ◎ Most consumers said they were surprised to find expired drugs in their home
- ◎ The study did not address prescription medication. Would a consumer feel different if it was an expired prescription medication?

THE RESULTS PLEASE

- ◎ 55% would likely use an expired medication, within the first few months after expiration
- ◎ 60% dispose of medications in the household garbage
- ◎ 63 % of consumers would like to be more prepared in case of their own illness or the illness of a family member
- ◎ Half stating they are typically not aware a medication is expired until it is needed
- ◎ More than a third said in the previous six months, they have given their children medication that had expired

PATIENTS SEEK PHARMACISTS ADVICE ABOUT OTC'S - APhA

- ◎ Pharmacists counsel 29 patients/week about OTC medications
- ◎ Many patients deem OTC medications safe because they can be purchased without a prescription
- ◎ Survey consisted of 18 introductory OTC questions and 76 product categories
 - Cough & Cold, pain relievers, Vitamins, GI
- ◎ Pharmacists were asked to write in approximately how many times per week they recommended each product.

THE RESULTS PLEASE

- ◎ When selecting OTC medications
 - 82% of pharmacy customers base their decision on a pharmacist's recommendation
 - 90% of patients seek help identifying the most appropriate product
 - 80% seek counsel regarding using an OTC product with their prescription medications
 - 79% of patients suffering from an acute or chronic condition
 - 65% of patients worried about taking OTC products with a specific disease/condition

**WHERE THERE IS A WILL,
THERE IS A WAY**

Bath Salts?

Salvia?

BATH SALTS - NOT JUST FOR YOUR FEET

- ⊙ Ingredients in “bath salts” include mephedrone & methylenedioxypropylamphetamine (MDPV)
- ⊙ Snort, inject or smoke the powder
- ⊙ Effects from the powder is as powerful as abusing methamphetamine
 - Paranoia, hallucinations, a dangerously rapid heart rate, and suicidal thoughts
 - "It causes intense cravings for it. They'll binge on it three or four days before they show up in an ER. Even though it's a horrible trip, they want to do it again and again," says law enforcement officials

CALGON

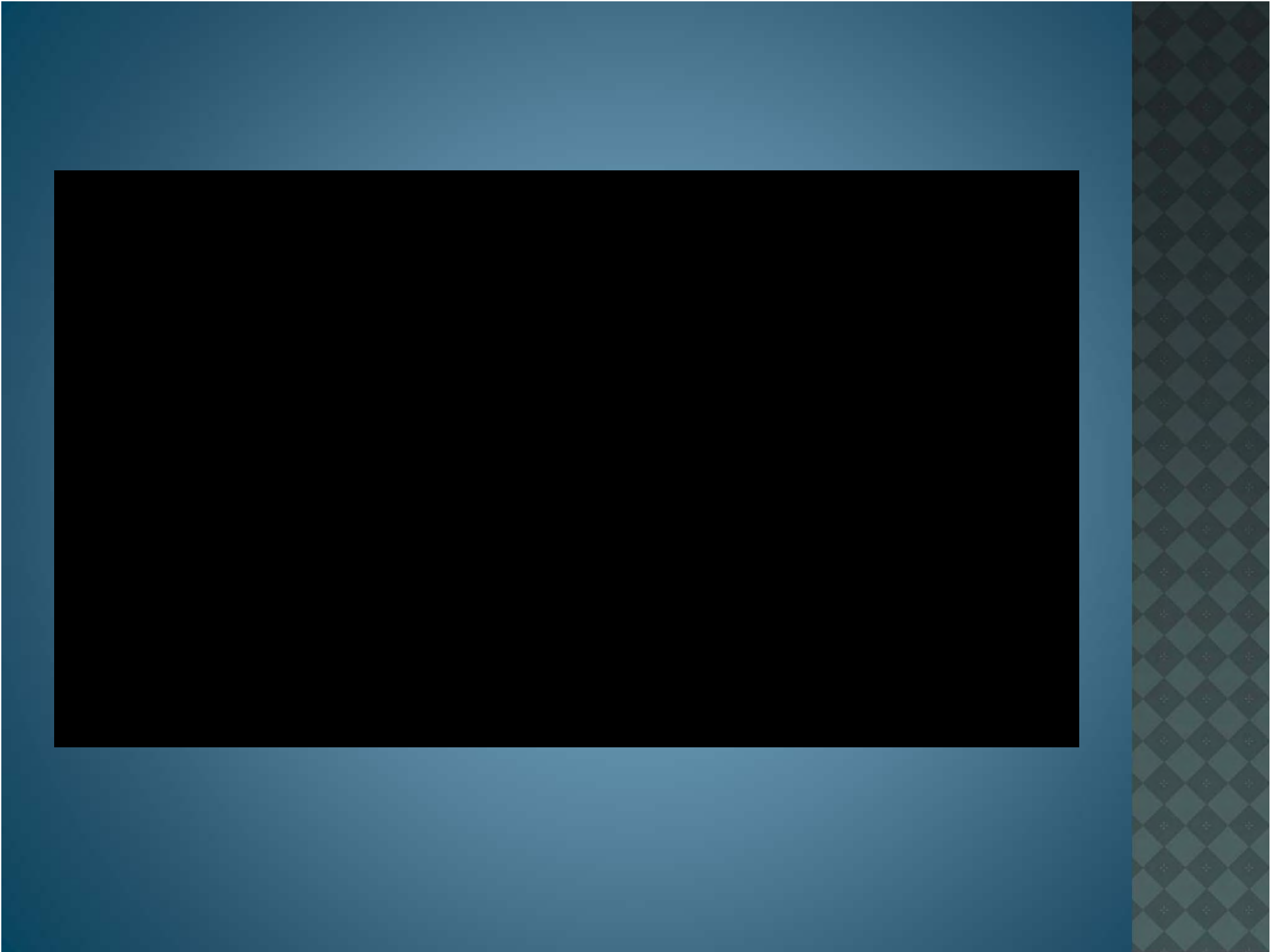
“TAKE ME AWAY”



- ◎ A small packet of the chemicals typically costs as little as \$20
- ◎ Innocuous names: Ivory Wave, Bliss, White Lightning, Hurricane Charlie, Red Dove and Vanilla Sky
- ◎ 2011 Legislation - Senate Bill 134 passed
 - Amended the Controlled Substance Act to include 6 different types of bath salts.
 - Schedule I Controlled Substance
 - Emergency - It is necessary for the public peace, health and safety that this act take effect immediately.

BATH SALTS - AN INTERNATIONAL PROBLEM

- ◎ American Association of Poison Control Centers
 - Took 235 calls related to the use of bath salts in 2010, but there were 214 calls, or about 8 per day, in January 2011
- ◎ At least 25 states have received calls
 - Mississippi, Kentucky, Louisiana, Nevada, and California are among the 25 states that have reported increasing problems with bath salt abuse
 - Louisiana issuing an emergency ban on sales
 - Louisiana leads with the greatest number of cases at 165, or 48 percent of the U.S. total, followed by Florida with at least 38 calls to its poison center
- ◎ The bath salts have already been banned in Britain, Ireland, and other countries



SALVIA

- ◉ *Salvia divinorum* is 1 of almost 1000 species of salvia in the sage family
- ◉ *Divinorum* is the only one with hallucinogenic properties
- ◉ Adolescent and young adult like the ease of access, legality, and lack of detectability
- ◉ Internet companies sell *Salvia divinorum* as a legal hallucinogen



SALVIA DIVINORUM

- ◎ States have passed legislation controlling it: Missouri, Delaware, Louisiana, Maine, Oklahoma, and Tennessee
 - It is controlled in Denmark, Australia, Sweden, and Italy
- ◎ Currently in the US *Salvia divinorum* is not a federal controlled substance
 - The DEA has placed it on the list of “drugs of concern”
- ◎ April 2011 - New Mexico Board of Pharmacy noticed it for a hearing



THE END



"Oh great. Now the FDA is regulating safety coated caplets of eyes of newt."