

PRESCRIPTION DRUG ABUSE & PHARMACY BOARD UPDATE

AN OVERVIEW



**LARRY L. PINSON,
PHARM. D.**

**EXECUTIVE SECRETARY
NEVADA STATE BOARD OF
PHARMACY**

CONFLICT OF INTEREST DISCLOSURE

- I or my spouse have no actual or potential conflict of interest in relation to this program.



LEARNING OBJECTIVES

- Provide an overview of the scope of prescription drug abuse in our state and in our country
- Provide an update on Board of Pharmacy Activities

TEST QUESTIONS

Even though the U.S. comprises approximately 6% of the world's population, what % of the world's supply of opiates do we consume?

- a) 20%
- b) 40%
- c) 60%
- d) 80%
- e) 99%

- The majority of addicts in the U.S. ultimately:
 - a) disappear
 - b) get sober
 - c) die
 - d) continue to use

- A schedule II prescription in Nevada must be tendered to a pharmacy:
 - a) Within 14 days of the date the Rx was written.
 - b) Within 6 months of the date the Rx was written.
 - c) Within 14 days of the “do not fill until” date written on the Rx or the date the Rx was written.
 - d) Within 1 year of the date the Rx was written.

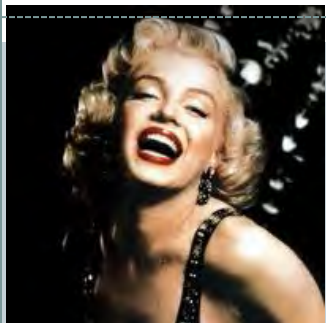
THE DOCTOR SHOPPER . . .



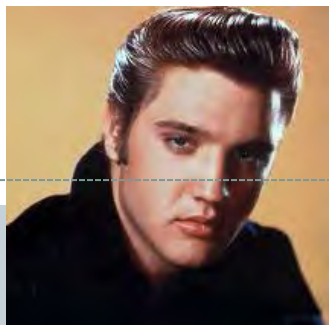
THEIR DRUGS

- Carisoprodol
- Alprazolam
- Hydrocodone
- Oxycodone

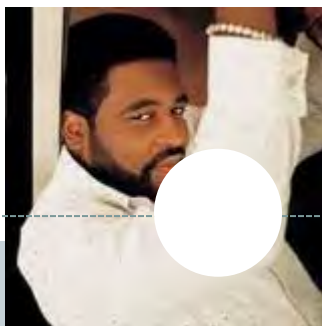




Marilyn Monroe
August 5, 1962



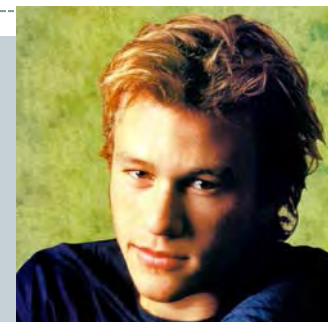
Elvis Presley
August 16, 1977



Gerald Levert
November 10, 2006



**Anna Nicole
Smith**
February 8, 2007

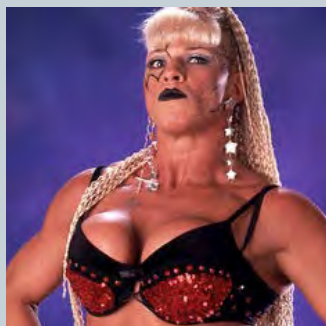


Heath Ledger
January 22, 2008

DEATHS



Michael Jackson
June 25, 2009



Luna Vachon
August 27, 2010



Michael Baze



Whitney Houston
February 11, 2012



Thomas Kinkadee
April 6, 2012



Rush Limbaugh



Steven Tyler



Eminem

ABUSERS



Jack T. Camp, Jr.

October 10, 2010

November 18, 2010

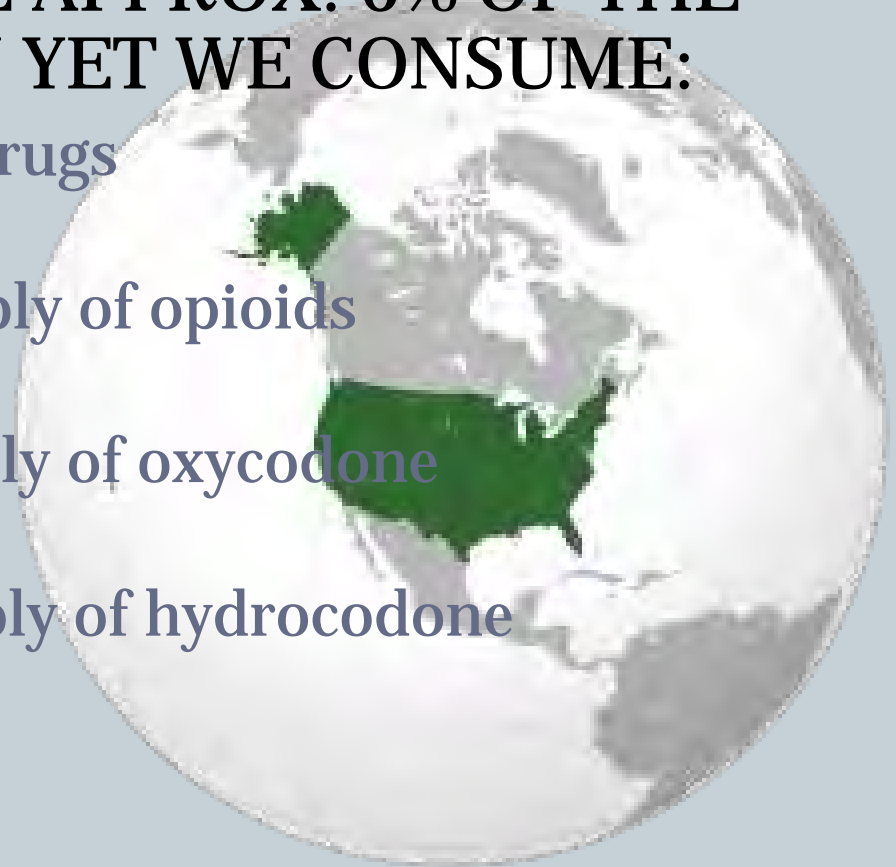
March 10, 2011



Brett Farve

NATIONAL NUMBERS

- **AMERICANS COMPRISE APPROX. 6% OF THE WORLD'S POPULATION YET WE CONSUME:**
 - 60% of all manufactured drugs
 - 80% of the WORLD'S supply of opioids
 - 75% of the WORLD'S supply of oxycodone
 - 99% of the WORLD'S supply of hydrocodone
 - Greeting card . . .



1200mg Morphine Each

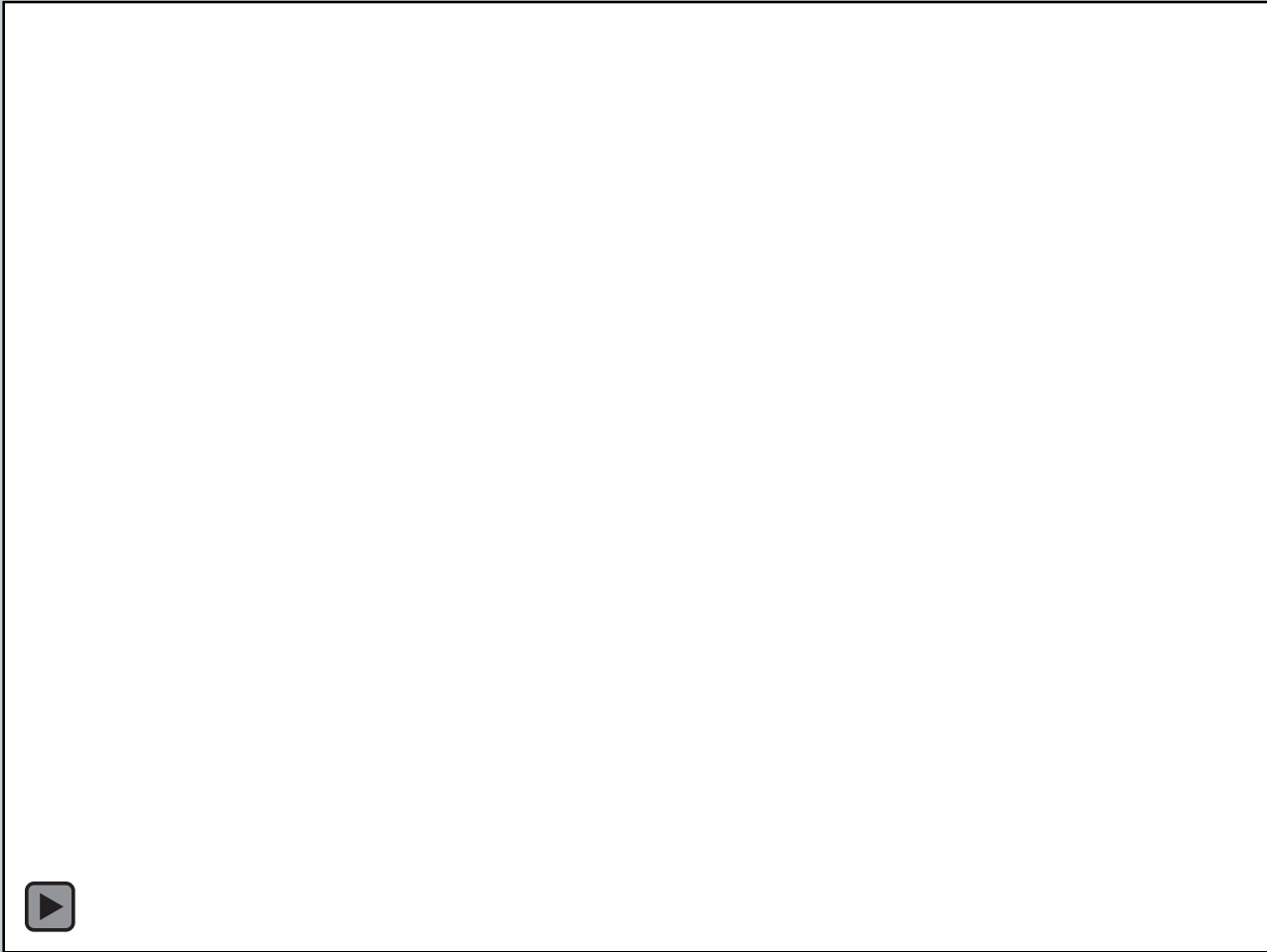
- Drug distribution through pharmaceutical supply chain equivalent to:
 - 1997: 96mg morphine/person
 - 2007: 700mg morphine/person
 - 2011: 1200mg morphine/person
 - Enough prescription pain medication prescribed in 2010 to medicate every American adult q4h for a month!*
- *source: CDC, Overdose Deaths, US 2010



- Every day 2700 youths (age 12-17) abuse an opioid for the first time
- Vital signs: BP, HR, Resp, Temp
 - and the newest: **PAIN**
- Drug companies now “sell sickness” through direct to consumer advertising: **BAD IDEA**



DIRECT TO CONSUMER ADVERTISING



JUST WHAT THE DOCTOR ^X ORDERED.



A PORTION OF THE PROCEEDS FROM THE SALES OF THIS COLLECTION
WILL BE DONATED TO THE MEDICINE ABUSE PROJECT.

SHOP 
BRIAN
LICHTENBERG

Where Prescription Painkiller Overdose Deaths Are The Highest

- Most severe in Southwest and Appalachia
- In 2008, the top three states were New Mexico, West Virginia and Nevada;
 - New Mexico: 27 deaths per 100,000
 - West Virginia: 25.8 deaths per 100,000
 - Nevada: 19.6 deaths per 100,000
- New Mexico and West Virginia rates were nearly 5X that of the lowest rated state, Nebraska.

NEVADA NUMBERS

- In amount of drug consumed per 100 thousand people, Nevada ranks in the nation:
 - #2 for hydrocodone (Vicodin® & Lortab®)
 - #2 for oxycodone (Percodan® & Percocet®)
 - #4 for methadone
 - #7 for codeine
 - #17 for meperidine (Demerol®)



- In 2008, Nevada pharmacies filled 26 million prescriptions for alprazolam (Xanax[®])
- We have a population of only 3-4 million people . . .
- 5% of the total number of practitioners prescribe 88% of the controlled substances.



UNR STUDY 2009-2011

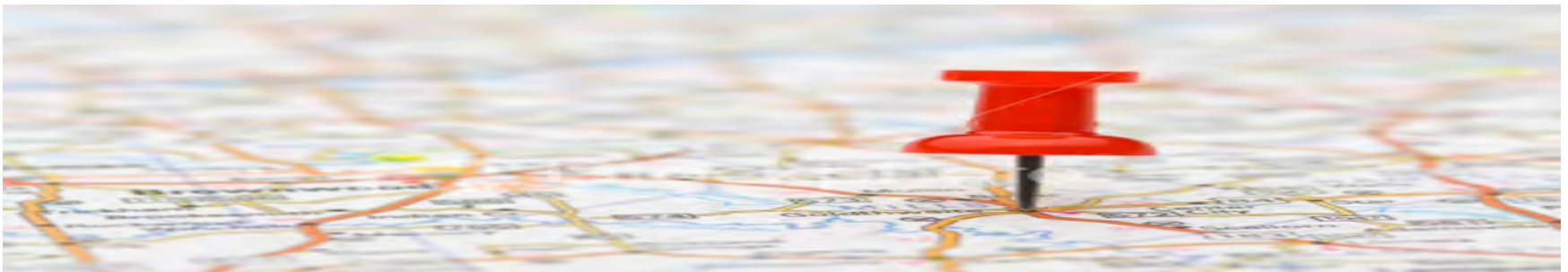
- 509,251,028 doses for 3-4 million residents
 - 187 million doses of hydrocodone
 - 93 million doses of oxycodone
 - 62 million doses for alprazolam
 - 25 million doses of Ambien[®]
 - ✦ (Soma[®] was not counted)



- 84% of these Rx's were written by an MD or DO.
- 15% were written by an APN or PA
- 52% were filled in Las Vegas
 - 18% filled in Reno
 - 12% filled in Henderson



- ZIP Code?
 - Over half from 89169 and 89102 (LV)
 - ✦ W. of I-15 between Charleston & Tropicana
 - ✦ Winchester area; N of airport & between Eastern and Maryland Parkway
 - Most of Reno's from 89511
 - ✦ Southeast & southwest



WHO IS ABUSING?

- Many more men than women (women static) & many more whites & Native Americans than other races.
- Middle-aged adults have the highest prescription opiate overdose rates
- People in rural counties are twice as likely to overdose than people in the cities.

WHAT HAPPENS TO THE ADDICT?

- 40 YR STUDY (1956-1992)
 - 48% - dead (180 people/day die in the U.S.)
 - 22% - sober
 - 15% - disappeared
 - 7% - still using daily
 - 6% - maintenance program
 - 2% - occasional use



HISTORICAL TURNING POINTS

(how our drug culture developed)

- 1860's – Civil War (widespread use of MS & invention of the hypodermic needle)
- 1870's – “Patent Meds”-birth of PHARMA (cocaine put in everything; employers touted ↑ production; 1st advertising; cocaine in Sears Catalog; no studies)
- 1890's – liberal use of narcotics in women; Bayer markets heroine as safe and calls addiction a “weakness”

HISTORICAL TURNING POINTS CONT.

- 1906 – FDA created
- 1914 – Harrison Act (criminalized addiction leading to drug trafficking)
- 1930's – Bill W. and his 12-step program
- 1938 – FDA: must prove worth of a drug (alcohol & tobacco slipped through)
- 1950's – Dexedrine and the housewife
- 1960's – Age of Aquarius, Timothy Leary, the hallucinogens & vitamins

HISTORICAL TURNING POINTS CONT.

- 1970's – Nixon's "War on Drugs" creating the DEA & the Controlled Substances Act forming drug schedules
 - Tried to deal with the drug culture created in the 60's.
- 1974 – First legal methadone maintenance programs
 - 2 million addicts by then and only treated 280K
- 1980's – Reagan's "Just Say No" & first 3rd party payment for drug addiction.
 - ↑ cocaine use→escalated violence

HISTORICAL TURNING POINTS CONT.

- 1990's – Purdue-Fredrick's introduction and aggressive marketing of long acting oral opiates.
 - Explosion of opiate abuse & addiction
 - 2007 guilty plea for felony misbranding and marketing long acting opiates as a “non-addictive” tx of pain resulting in \$634.5 million fine.
 - Opiate Rx's have escalated 350% since 1991 with only a 19% increase in population.
 - 1990's - ↑ meth use and emergence of drug wars (\$1000 drug in Mexico worth \$10,000 in US)



BIG BUSINESS



- Hydrocodone \$5 - \$20/tab (cost=30 cents)
- Vicodin® \$5 - \$25 (cost=\$1)
- Percocet® \$10 - \$15 (cost=\$3.50)
- Oxycodone \$12 - \$40 (cost=\$3.20)
- Oxycontin® \$50 - \$80 (cost=\$3)
- Prometh w Codeine up to \$600/pint
- \$25 to \$35 BILLION BUSINESS!!

TYPICAL HABIT

- **OXYCONTIN®**
 - #10, 80mg tablets per day
 - \$1/mg on street
 - = \$800/day!!
- Both “Dr. shopping” and heroin are less expensive
- Pharmacy robberies on the increase
 - Development of decoy bottles of oxycodone that contain tracking devices
 - Walgreen’s shooting



THREE MAJOR PLAYERS



- The Patient

- ✦ Who wants or needs the drug

- The Pharmacist

- ✦ Who generally must dispense the drug

- The Practitioner

- ✦ Who must prescribe the drug

- **We must understand:**
 - The patient cannot get the drug unless it is prescribed &
 - The pharmacist cannot give the drug unless it is prescribed
- **A pharmacist can only refuse to fill a prescription under two circumstances in Nevada; if in his professional judgment:**
 - The prescription is fraudulent
 - The drug may harm the patient

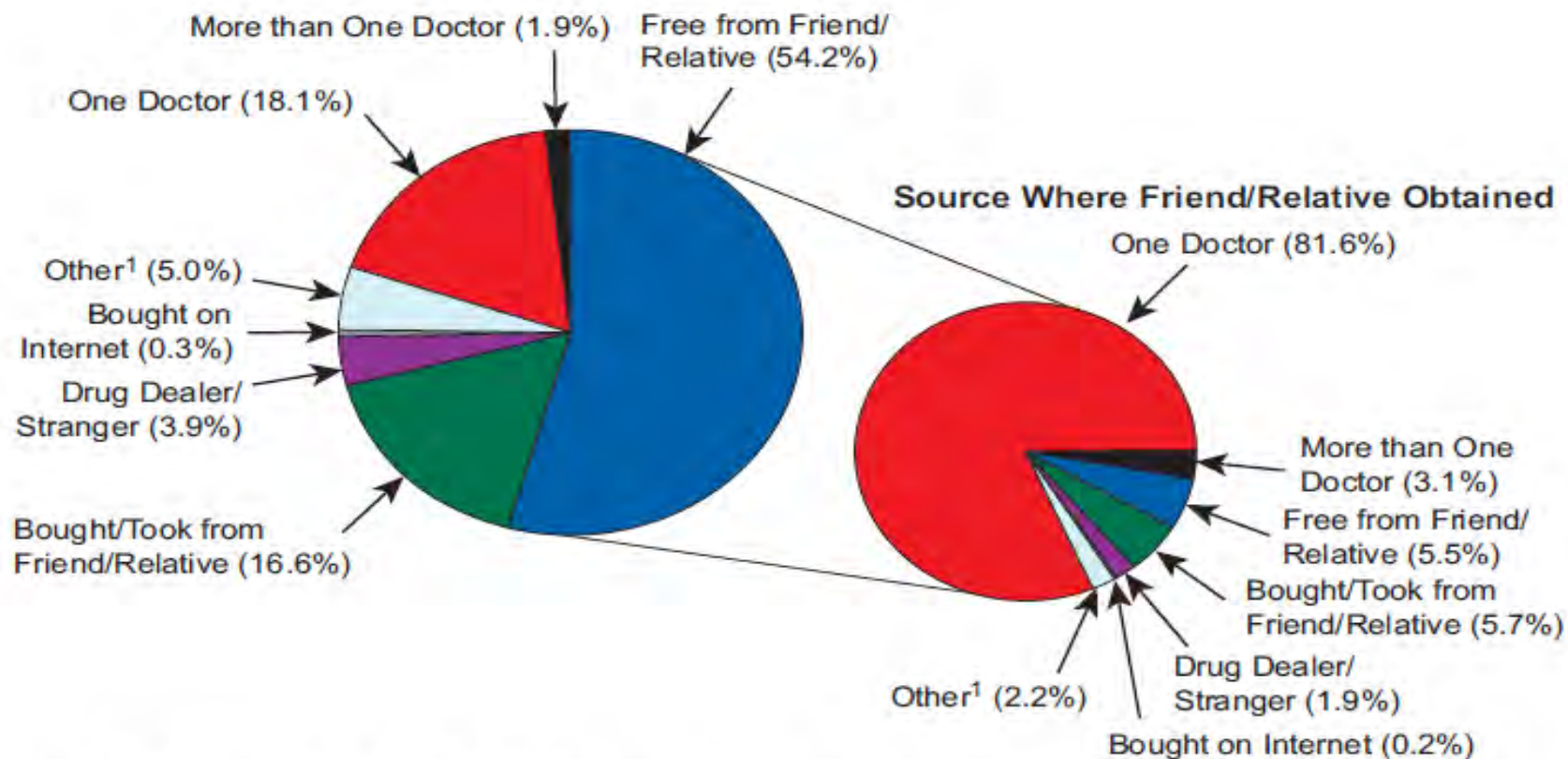


WHERE DO THE DRUGS COME FROM??

- **PRESCRIPTION** drug abuse insinuates that they are prescribed
 - 40% of what is prescribed goes unused by the patient (ending up in medicine cabinets)
 - “Pill Mills” are moving west

Figure 2.14 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2010-2011

Source Where User Obtained



Note: The percentages do not add to 100 percent due to rounding.

¹ The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

- **INTERNET**

- **Craig's list**

- ✦ 11/19/2011: “Need to fill tank of oxy 30mg fuel – bone dry stuck on side of road - \$200 (Las Vegas). As you can see from my ad, I’m actually looking for some 30’s to refuel me . . . I’m new to the area with my fiance.”
- ✦ 12/02/2011: “Zannie Bars - \$3 (Trop & Jones). 2mg zannie bars for sale; white bars; script is now higher; hard to find since docs have got busted; I will be raising prices soon . . .”



New OxyContin® OP



<p>08-27-2010, 01:11 AM</p> <p>mz.mary420 Member</p>  <p>Join Date: May 2010 Location: down south Posts: 6</p>	<p>#17</p> <p>well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞</p> <p>* if anyone has tried to smoke this new formulated shit, please post! thanks</p>
<p>08-27-2010, 06:09 AM</p> <p>mephist00 Member</p>  <p>Join Date: Apr 2008 Location: NY Age: 25 Posts: 628</p>	<p>#18</p> <p>ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..</p> <p>so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok</p> <p>Quote:</p> <p>Originally Posted by stalk <i>I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.</i></p>



Diversion In Pharmacies

- **Pharmacy Technicians (and some pharmacists).**
 - ✦ **Prosecuting 2-3 cases per meeting.**
 - ✦ **May be increasing**
 - **2012 – 9**
 - **2013 – 7**
 - **2014 – 14 (year not over).**
- **Stores increasing security (smock checks; smart shelves; cameras; phony oxycodone bottles).**

Diversion In Pharmacies

- **2014 Cases Involving Diversion of 50-200 Pills More Common.**
 - ✦ **BOP v. Scott – Convicted of Diverting **24,000** doses hydrocodone/APAP**
 - ✦ **BOP v. Bahena – Convicted of Diverting **28,000** doses hydrocodone/APAP**
 - ✦ **BOP v. Oganessian - Convicted of Diverting **55,000** tablets of hydrocodone/APAP**

Checks and Balances of the CSA and the Regulatory Scheme

- **Pharmacists** – “The Last Line of Defense”

“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”
(21 CFR § 1306.04(a))



- **WALGREEN'S SETTLEMENT**

- **June 11. 2013**

- **Largest DEA settlement in history (\$80 million)**
- **6 Florida stores and a distribution center barred from distributing controlled substances for 2 years.**
- **Part of the settlement:**
 - ✦ **Walgreen's will “no longer monetarily or otherwise compensate its pharmacists based on the volume of prescriptions filled.”**



CURRENT ENVIRONMENT

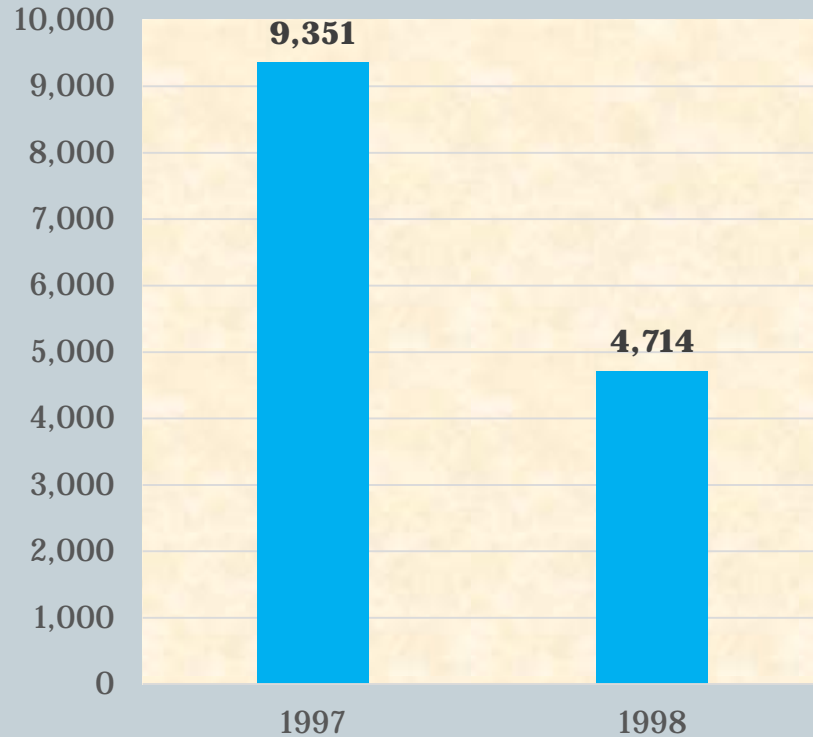
- DEA pressure on both supply and dispensing
- DEA closing of pharmacies (White Cross; Lam's; CVS in FL; Walgreen's - \$80 million)
- Industry reaction:
 - CVS "Black List"
 - Purdue's "Region Zero"
 - ICD-9 codes; MRI's; X-rays; etc.
- End Result:
 - Difficult for legitimate patients to get drug
 - Shift from prescription opiate to heroin?
 - ✦ 566K oxy & 239K heroin in 2010
 - ✦ 358K oxy & 335K heroin in 2012 (Nat'l Survey on Drug Use)

CS PRESCRIPTION ABUSE PREVENTION TASK FORCE

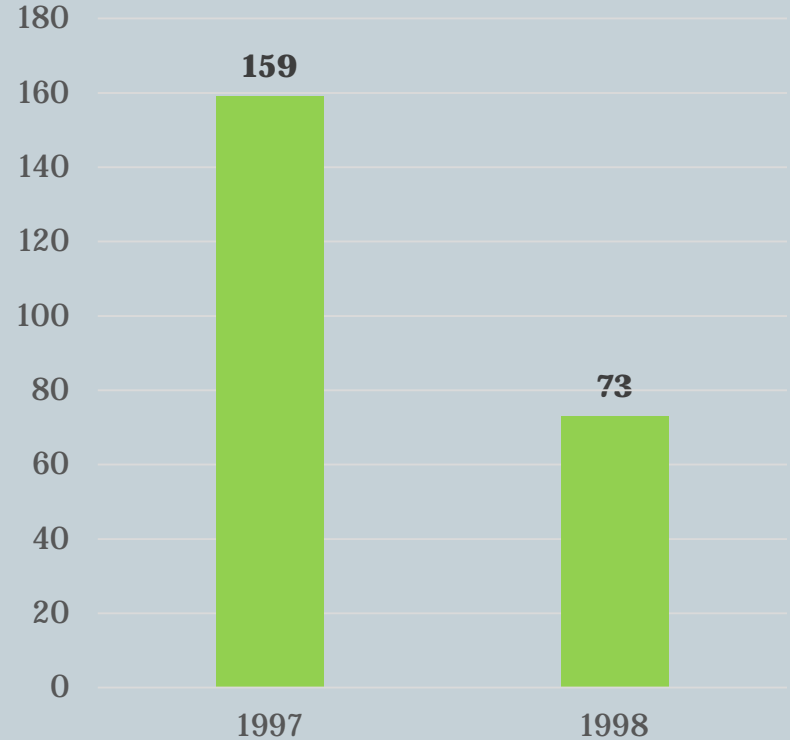
- Hereafter referred to as “The Task Force” or “PMP”
 - What is it?
 - ✦ A database with thresholds and a goal of identifying potential “doctor shoppers” (A FELONY) and referring them for treatment.
 - ✦ Nevada was one of the first states to systematically share prescription information among practitioners and has been doing so since 1997
 - ✦ Working toward data sharing between states (27 states to date)

Initial Impact of Unsolicited Reports

Average Doses



Average Prescriptions



Unsolicited Reports Sent January 2013

	Pre Report (8/1/12 – 1/31/13)	Post Report (8/1/13 – 1/31/14)	% Decline
Prescriptions	23	9	61
Doses	1,424	597	58
Prescribers	8	3	62
Dispensers	8	3	62

- The information above relates to 40 patients.
- Forty-nine unsolicited reports were sent in January 2013.
- Nine patients had no prescriptions filled during the post report period.

- **Standard of Practice (2007)**

- **New legislation?**

- ✦ Require registration to get a CS license?
- ✦ Require a practitioner to run himself ?
- ✦ Require a practitioner to access the system?



HOW TO ACCESS

- WEBSITE: <http://bop.nv.gov/links/PMP/>
- TELEPHONE: 775-687-5694
- Register for access via website



IN SUMMARY

- Prescription drug abuse is a cultural problem within our society with no simple remedy
 - We must all work together at every level:
 - ✦ Federal govt. through education & tracking
 - ✦ State & local govt. through education; support of state PMP; enforcement & strengthening of current laws; access to treatment programs; action by licensing boards
 - ✦ Health Care Insurers through increased coverage for alternative pain tx and Rx claim review programs
 - ✦ Prescribers and Dispensers through education
 - ✦ AND FINALLY the public through education and media campaigns

REGULATORY UPDATE



Recent Regulatory Changes

Tramadol Reclassified to Schedule IV

- As of August 18, 2014 all regulatory requirements applicable to Schedule IV controlled substances apply to tramadol.
- Tramadol on the market since 1995 (Ultram).
- Abuse of tramadol increased significantly in last several years as a substitute for other opioids.

Recent Regulatory Changes

Hydrocodone Combination Products

- As of October 6, 2014 all hydrocodone combination products (HCP's) have been reclassified to Schedule II.
- HCP prescriptions, including refills, issued prior to October 6, 2014 can be treated and filled as Schedule III until April 8, 2015.

Recent Regulatory Changes

- Authorized refills prior to October 6, 2014 may be dispensed up to five times or 6 months from date of original issue.
- No additional refills may be authorized, nor can refills be dispensed beyond the 6 month original issue date or after April 8, 2015.

Regulatory Update

Electronic CII Prescriptions

- NAC 639.7102 has been amended (in December 2012) to allow for the electronic transmission of CII prescriptions.
- Must be from prescriber's secure computer to pharmacy's computer system (not a fax machine).
- Computer program must be approved by Board and listed on Board website.

Regulatory Update

Photo I.D.

Amendments to NAC 639.748

- **Require a Government Issued Photo I.D. for Person Picking Up a Prescription.**
- **Exemption for Existing Customers will Continue.**
- **Exemption for Persons Known to the Pharmacy Staff will Continue.**
- **Exemption for Insurance Payment goes away.**

Recent Regulatory Changes

NPllex

- National Precursor Log Exchange
- Electronic real time tracking of pseudoephedrine (PSE) purchases.
- Mandatory at all Nevada retail pharmacies as of September 3, 2014 (blocked over 8000 sales 1st 3 mo)
- Refer to NRS 639.430 through 639.450 and the BOP letter sent on June 16, 2014 for details.

Regulatory Update

14-Day Rule

- NRS 453.431 and NAC 453.450.
- Statute states “A pharmacist shall not fill a prescription for a controlled substance classified in schedule II unless it has been tendered on or before the 14th day after the date of issue”.

Regulatory Update

14-Day Rule

- What if the CII was written on one date but has a “do not fill until” for another date?
- Nevada Board of Pharmacy’s interpretation is that a CII prescription with a “do no fill until” date must be tendered on or before the 14th day after the do not fill until date.
- Patient is allowed to retain the hard copy prescription until that time.

Recent Regulatory Changes

Drug Disposal

- On October 9, 2014 DEA implemented the Safe and Responsible Drug Disposal Act of 2010.
- Allows for drugs dispensed to an ultimate user to be returned to authorized collectors for disposal, which may be a pharmacy or hospital pharmacy.
- Authorized collectors must first obtain a modified registration from DEA.

Recent Regulatory Changes

- Authorized collectors may operate a collection receptacle at their registered location.
- Authorized collectors may not use approve collection receptacles to dispose of unwanted controlled substances from stock.
- Collectors with an onsite means of destruction may operate a mail-back program.
- Pharmacies (retail or hospital/clinic based) may operate collection receptacles at LTC's.

Regulatory Update

In-Service Training

- November 1, 2014 Inspectors will be checking in-service training for all technicians for the previous licensing period.
- Each technician must have a training file at the pharmacy.
- File should contain single sheet of paper with name, license number and details of type of CE obtained.

Regulatory Update

- Details include date of CE, course provider, name of course, and a sign-off by the pharmacist and technician that the training record is true and accurate.
- Documentation must show 12 hours of in-service training including one hour of Nevada Law per licensing period.
- Nevada Law certificate must be in file.

SYNTHETICS & OTHERS

- **Synthetic cannabinoids**
 - K2; Spice; HU & JWH cmpds
 - 10-100X more potent than THC
- **Substituted cathinones**
 - “Bath salts” (MDVP); “Ivory Wave”; “Cloud 9”
 - 2-3 day trips
- **Over 250 different cmpds in the US**



NECC

The image features a large, light blue rectangular area that occupies most of the frame. At the top center of this area is a white semi-circular cutout. Above this cutout, the letters "NECC" are printed in a bold, purple, serif font. A thin, dark horizontal line runs across the top of the light blue area, just below the "NECC" text. The entire composition is set against a white background.





LEGISLATIVE CONSIDERATIONS

- Opiate Rescue Drugs
- Mandatory use of PMP
 - Self query
 - Which patients?
- Mandatory CE on opiate use
- Pharmaceutical Assisted Suicide

SMILE

- It takes 17 muscles to smile
- It takes 41 muscles to frown
- It takes zero muscles to sit there and look dumb,
so . . .



Questions

- Always Welcome to Contact the Board of Pharmacy With Questions:
 - Phone – (775) 850-1440
 - Email:
 - ✦ Licensing Questions – pharmacy@pharmacy.nv.gov
 - ✦ Law Questions – pedwards@pharmacy.nv.gov
 - ✦ Other General Questions – lpinson@pharmacy.nv.gov

POST TEST QUESTION

Even though the U.S. comprises approximately 6% of the world's population, what % of the world's supply of opiates do we consume?

- a) 20%
- b) 40%
- c) 60%
- d) 80%**
- e) 99%

POST TEST QUESTION

- The majority of addicts in the U.S. ultimately:
 - a) disappear
 - b) get sober
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POST TEST QUESTION

- A schedule II prescription in Nevada must be tendered to a pharmacy:
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