

Prescription Drug Prescribing: Can we make it safer?

SAMHSA-HRSA Center for Integrated Health Solutions

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Disclosure

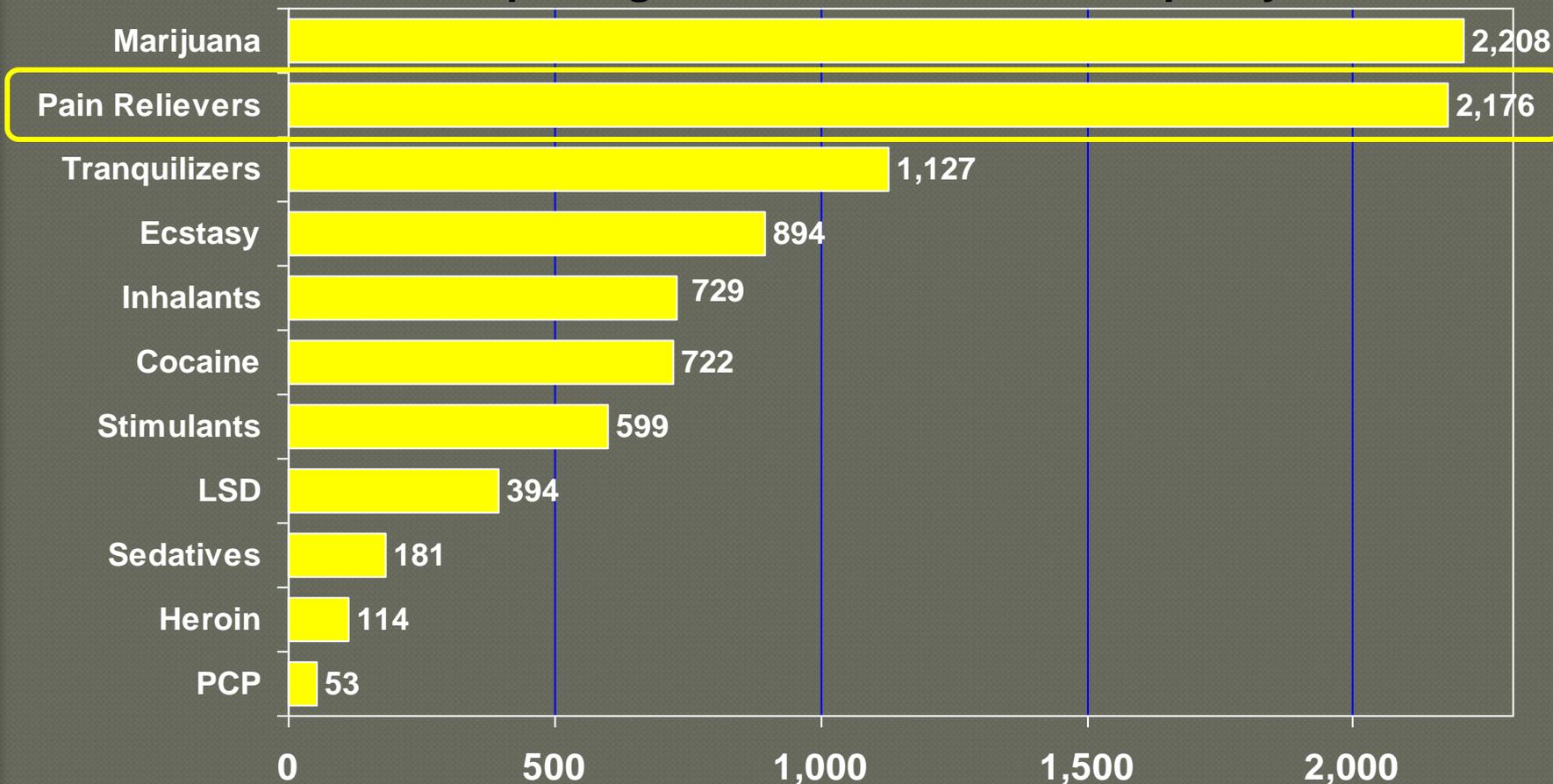
- Anthony Dekker, DO has presented numerous programs on Chronic Pain Management and Addiction Medicine. The opinions of Dr Dekker are not necessarily the opinions of the DoD, the Indian Health Service or the USPHS. Dr Dekker has no conflicts to report.

Opioids in the US

- Chronic Non-Malignant Pain Evaluation and Care evaluations
- Increasing complications from misuse and diversion
- Provider and Pharmacy concerns
- Patient and Community expectations
- DEA investigations
- Patient perceptions of lack of care

Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or older: 2008

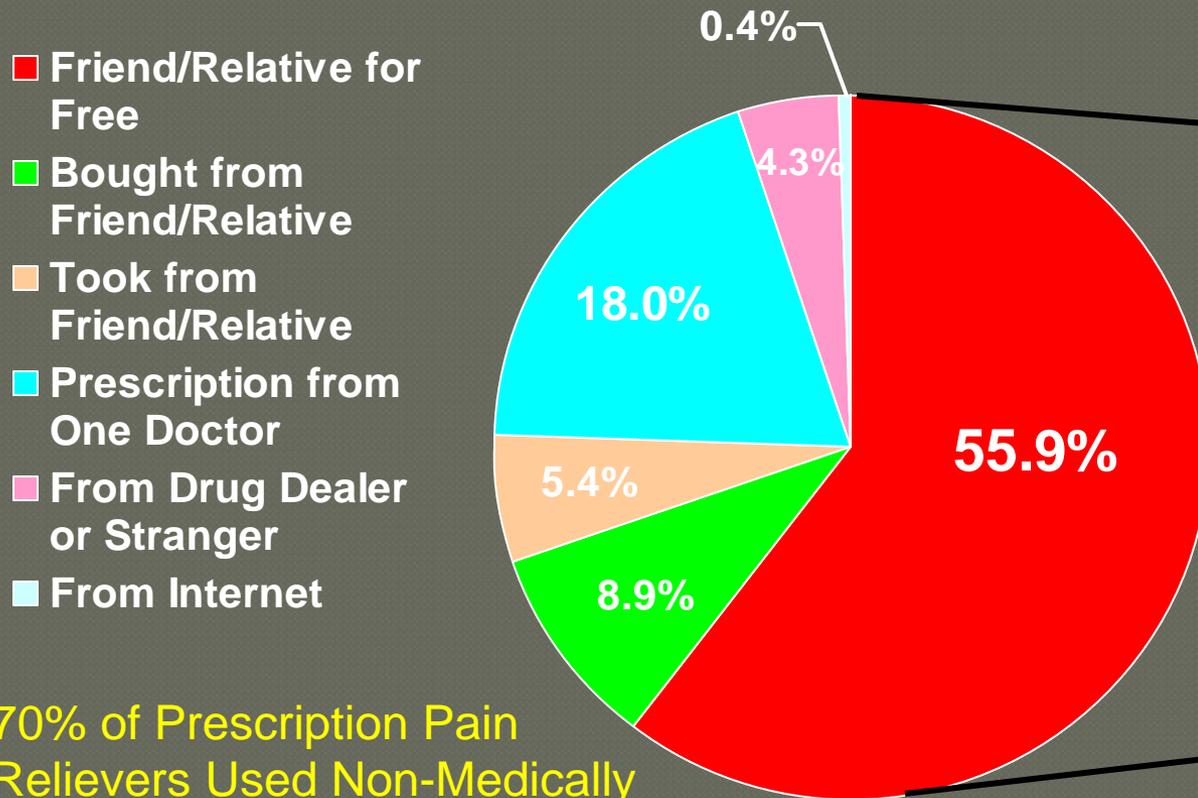
Number of Individuals reporting first use of substance in past year



2012 Fort Belvoir Community Hospital Addiction

Medicine

Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2008



81.7% of pain relievers obtained from friend/relative for free were obtained from one doctor. **1.6%** were obtained from a drug dealer.

70% of Prescription Pain Relievers Used Non-Medically Come from Friends or Relatives

Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.

Source: NSDUH 2008

Chronic Non-Malignant Pain (CNMP)

- Osteoarthritis
- Low back pain
- Myofascial pain
- Fibromyalgia
- Headaches (e.g., migraine, tension-type, cluster)
- “Central pain” (e.g., spinal cord injury, stroke, MS)
- Chronic abdominal pain (e.g., chronic pancreatitis, chronic PUD, IBS)
- CRPS, Types I and II
- Phantom limb pain
- Peripheral neuropathy
- Neuralgia (e.g., post-herpetic, trigeminal)

Treatment Goals

- In malignant pain we treat to goal
- In chronic non malignant pain we treat to function

Treatment goals in managing CNMP

- Improve patient functioning
- Identify, eliminate/reduce pain reinforcers
- Increase physical activity
- Decrease or eliminate illegal or complicating drug use

The goal is NOT pain eradication!

CNMP:

The clinical challenge

- ⊙ **Be aware of the “Heart Sink” patient.**
- ⊙ **Be aware of the borderline patient**
- ⊙ **Remain within your area of expertise.**
- ⊙ **Stay grounded in your role.**
 - **FIRST....Do no harm**
 - **THEN.....**
 - **Cure sometimes**
 - **Comfort always**

Non-pharmacologic treatments for CNMP

- ✓ Physical therapy – conditioning, thermal therapies
- ✓ Pain Psychology – relaxation / counseling / expectations orientation
- ✓ Traditional Indian Medicine
- ✓ Massage therapy
- ✓ Osteopathic and Chiropractic Manipulative Therapies
- ✓ Spinal manipulation
- ✓ Acupuncture, with and without stimulation
- ✓ TENS units
- ✓ Nerve ablations and blocks
- ✓ Pain management group
- ✓ Yoga and meditation

Non-opioid medications for CNMP

- Acetaminophen
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Tricyclics
- Anti-depressants/anxiolytics
- Anti-convulsants
- Muscle relaxants
- Topical preparations—e.g. anesthetics, aromatics
- Others (e.g., tramadol)

Indications for opioid therapy

1. Is there a *clear diagnosis*?
2. Is there *documentation* of an adequate work-up?
3. Is there *impairment of function*?
4. Has non-opioid multimodal therapy *failed*?
5. Have *contraindications* been ruled out?

Begin opioid therapy:

Document

Monitor

Avoid poly-pharmacy

Contraindications to opioid therapy

- ⦿ Allergy to opioid medications ~ *relative*
- ⦿ Current addiction to opioids ~ *?absolute*
- ⦿ Past addiction to opioids ~ *?absolute*
- ⦿ Current /past addiction, opioids never involved ~ *relative; absolute if cocaine*
- ⦿ Severe COPD or OSA~ *relative*
- ⦿ *Concurrent Sedative hypnotics~relative*

Pain Patient on Chronic Opioids

+

St Agnes Provider

Are chronic opioids appropriate?

YES!

Re-document:

Diagnosis
Work-up
Treatment goal
Functional status
Pain P&P ↓

Monitor Progress:

Medication counts
Function
Refill flow chart
Occasional urine toxicology
Adjust medications
Watch for scams

UNSURE

Physical Dependence vs Addiction:

Chemical dependence screening
Toxicology tests
Medication counts
Monitor for scams
Reassess for appropriateness

YES!

Discontinue opioids
Instruct patient on withdrawal symptoms
OBOT Buprenorphine
Tell patient to go to ER if symptoms emerge

NO

Educate patient on need to discontinue opioids

Emergency?

ie: overdoses
selling meds
altering Rx

NO!

Stop or quick taper (document in chart)

↓ OR
10-week structured taper

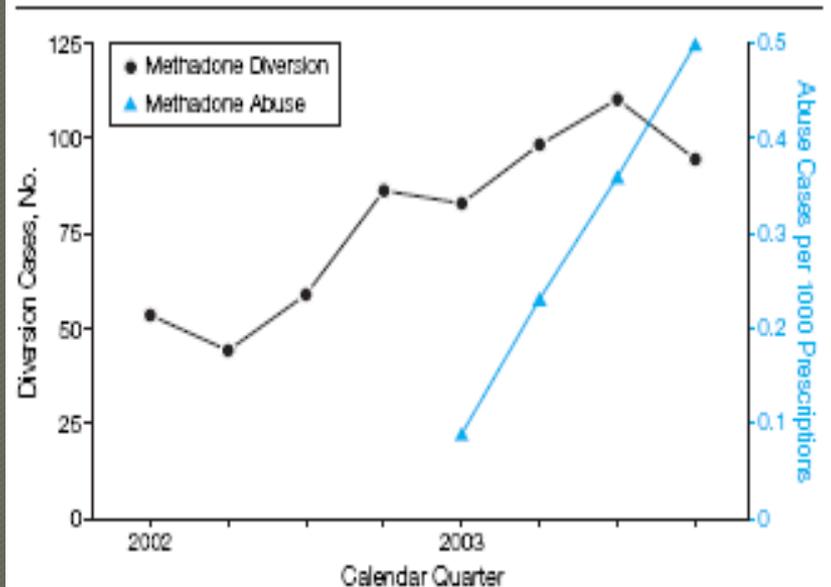
↓ OR
Discontinue opioids at end of structured taper

FDA Methadone Warning

FDA ALERT [11/2006]: Death, Narcotic Overdose, and Serious Cardiac Arrhythmias

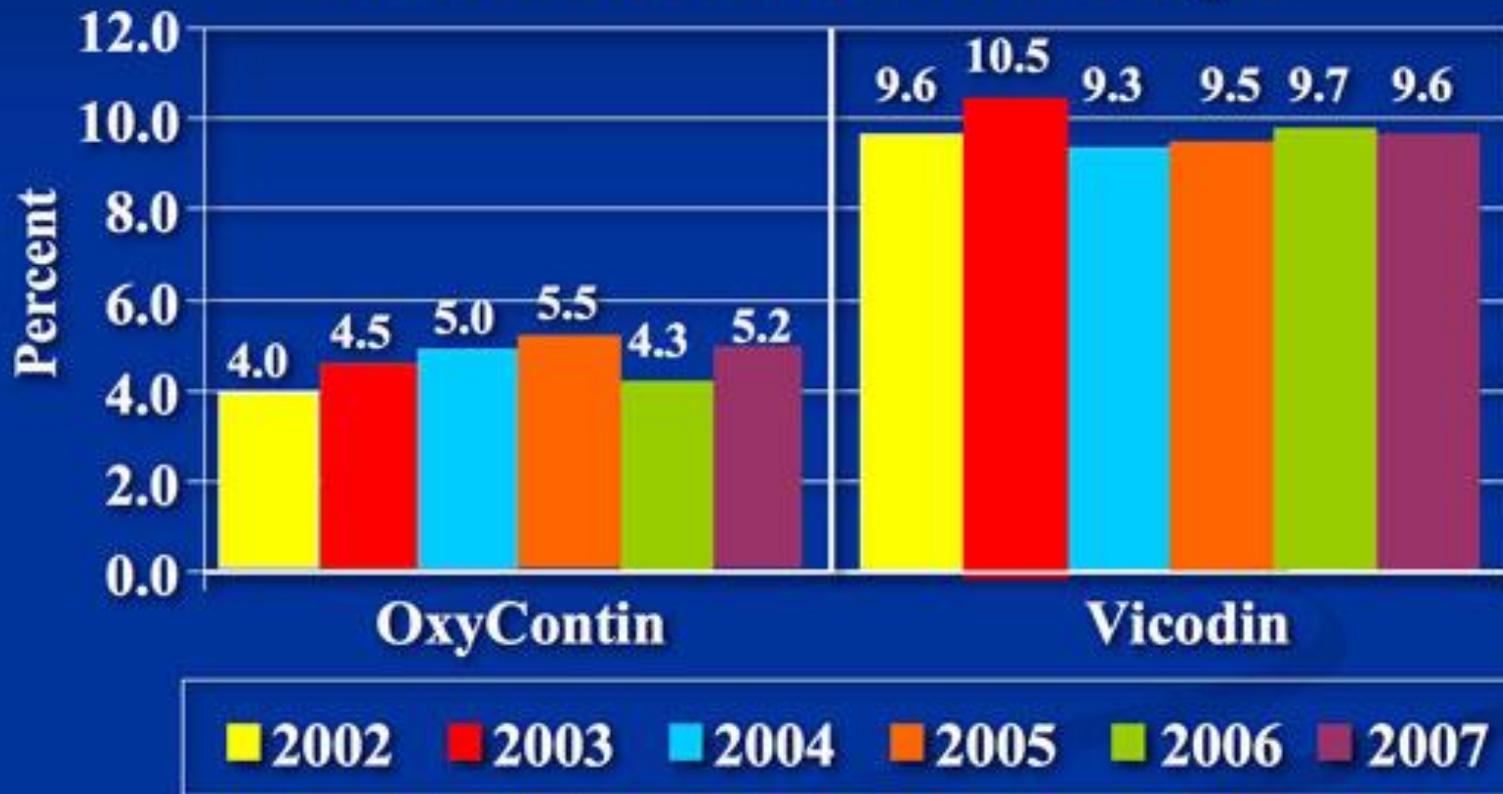
FDA has reviewed reports of death and life-threatening side effects such as slowed or stopped breathing, and dangerous changes in heart beat in patients receiving methadone. These serious side effects may occur because methadone may build up in the body to a toxic level if it is taken too often, if the amount taken is too high, or if it is taken with certain other medicines or supplements. Methadone has specific toxic effects on the heart (QT prolongation and Torsades de Pointes). Physicians prescribing methadone should be familiar with methadone's toxicities and unique pharmacologic properties. **Methadone's elimination half-life (8-59 hours) is longer than its duration of analgesic action (4-8 hours).** Methadone doses for pain should be carefully selected and slowly titrated to analgesic effect even in patients who are opioid-tolerant. Physicians should closely monitor patients when converting them from other opioids and changing the methadone dose, and thoroughly instruct patients how to take methadone. Healthcare professionals should tell patients to take no more methadone than has been prescribed without first talking to their physician.

Figure. Methadone Abuse Cases per 1000 Prescriptions and Diversion Cases, 2002-2003



Issues of Concern

Percent of 12th Graders Reporting Nonmedical Use of OxyContin and Vicodin in the Past Year Remained High



No year-to-year differences are statistically significant.

Upper Graph Fig 2a

- Type 1 (*Home with "EtOH/Street"*) has increased by **3196%**
 - **Steep and accelerating rate ($p < 0.001$)**
- Type 2 (*Home without EtOH/Street*) and Type 3 (*Non-Home with EtOH/Street*) increased 564% and 555%, respectively
- Type 4 (*Non-Home without "EtOH/Street"*) only increased 5%

Lower Graph Fig 2b

- Type 1 has three components:
 - Fatal Medication Errors
 - Occurring at home
 - In conjunction with EtOH/Street drugs
- The 3 components graphed separately show slight increase
- Component combined (Type 1) shows steep increase by **3196%**

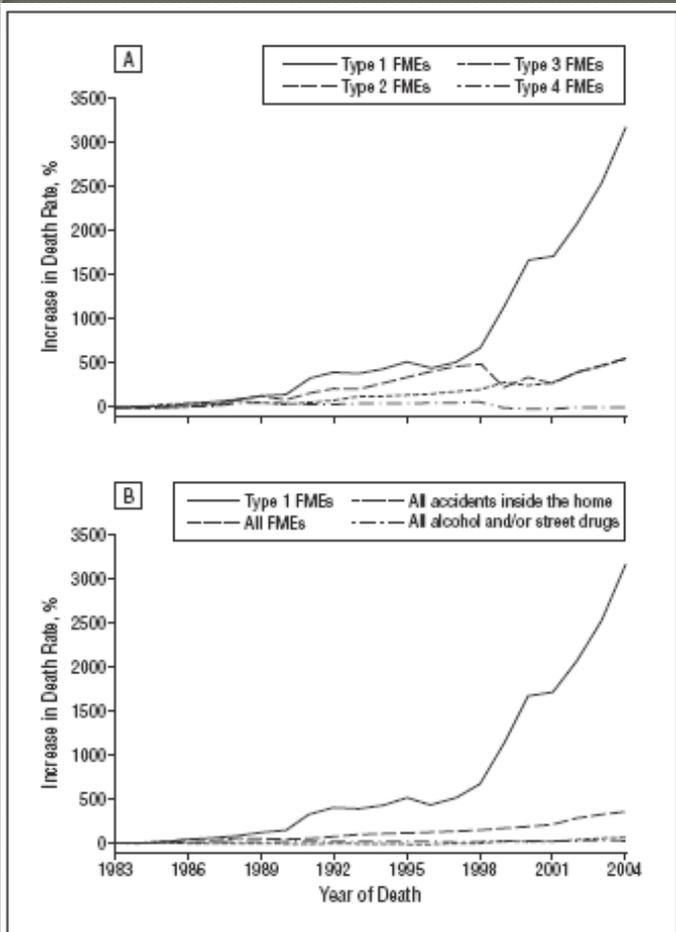


Figure 2. Trends in the US fatal medication error (FME) death rate by type of circumstance in which the FME occurs (A) and for various comparison groups (B) (January 1, 1983–December 31, 2004).

Schedules of Substances

Schedule I



No Accepted Medical Use
High Potential for Abuse/Dependency
Example: LSD, Heroin, SynCans, BS

Schedule II



Accepted Medical Use
High Potential for Abuse/Dependency
Example: Morphine, Oxycodone

Schedule III



Accepted Medical Use
Less Potential for Abuse/Dependency
Example: Hydrocodone compounds

Schedule IV



Accepted Medical Use
Low Potential for Abuse/Dependency
Example: Benzodiazepines

Schedule V

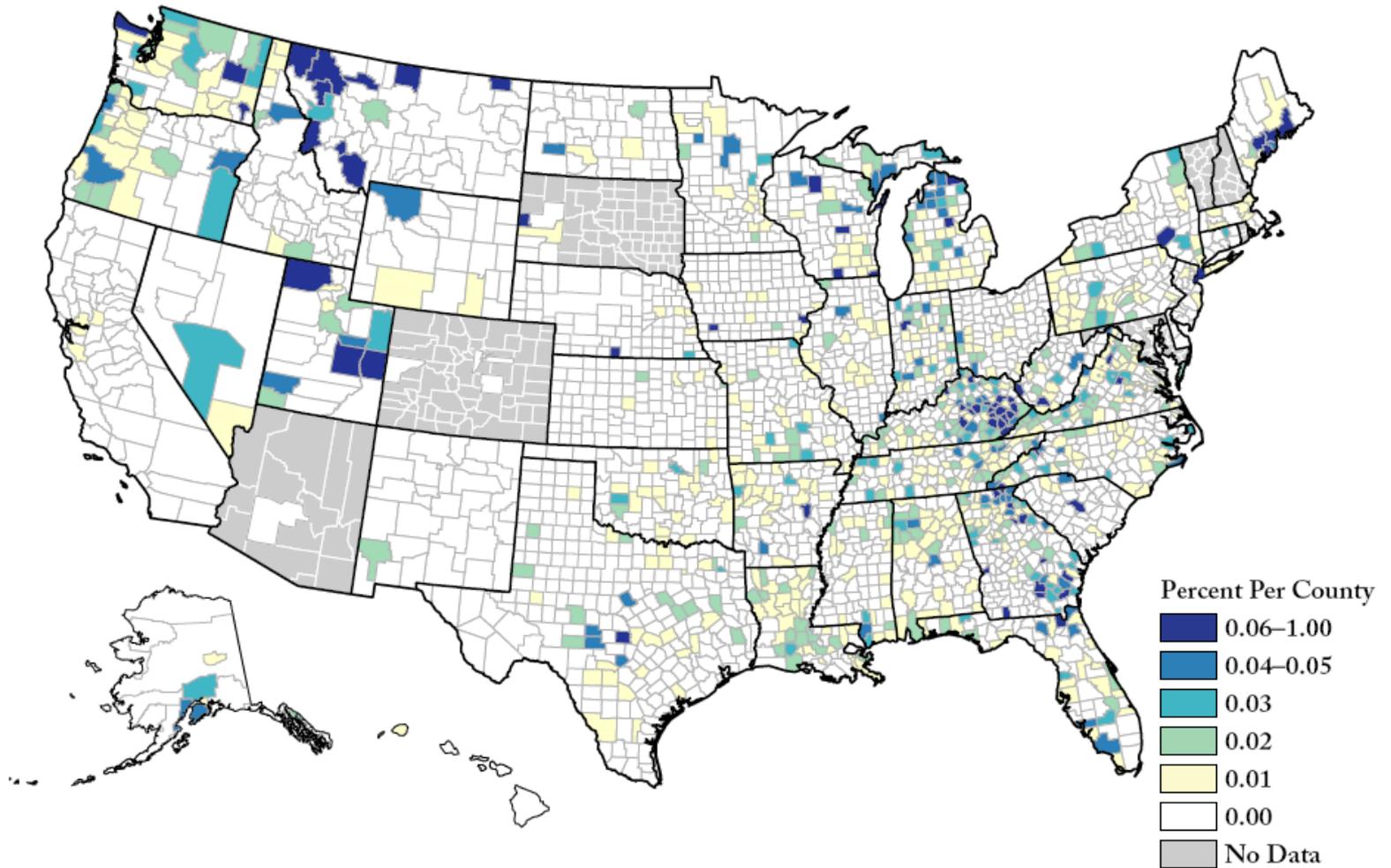


Accepted Medical Use
Low Potential for Abuse/Dependency
Example: Codeine cough syrup

Prescription Requirements

- DEA does not define nor regulate medical practice standards.
- There are no federal limits on the quantity of controlled substances that may be prescribed.
- Corresponding responsibility for proper prescribing & dispensing rests with the pharmacist who fills the prescription.

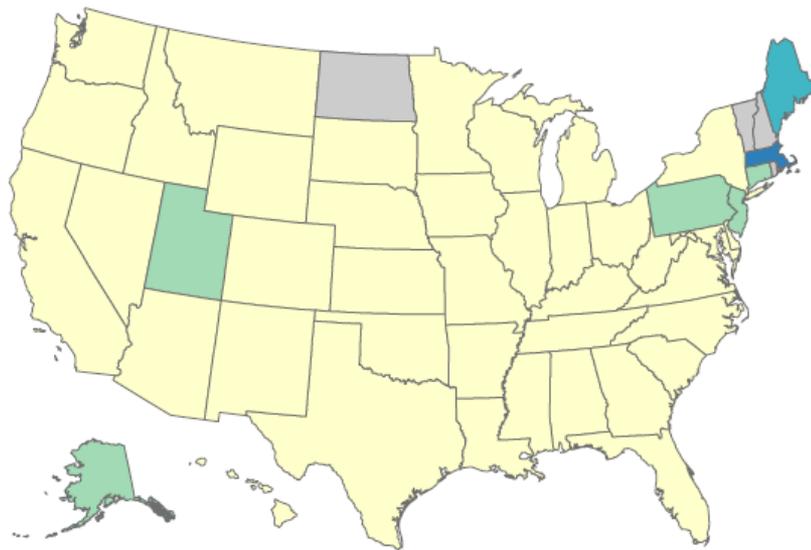
Percent of analyzed drug items identified as methadone, by county, 2008.



Note: NFLIS data for NYPD Crime Laboratory are not specific to individual counties within New York City.

NFLIS Buprenorphine Data

Figure 11. Percent of analyzed drug items identified as buprenorphine, by state, 2005.



Percent Per State

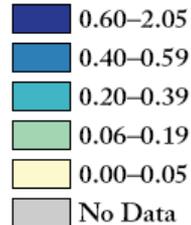
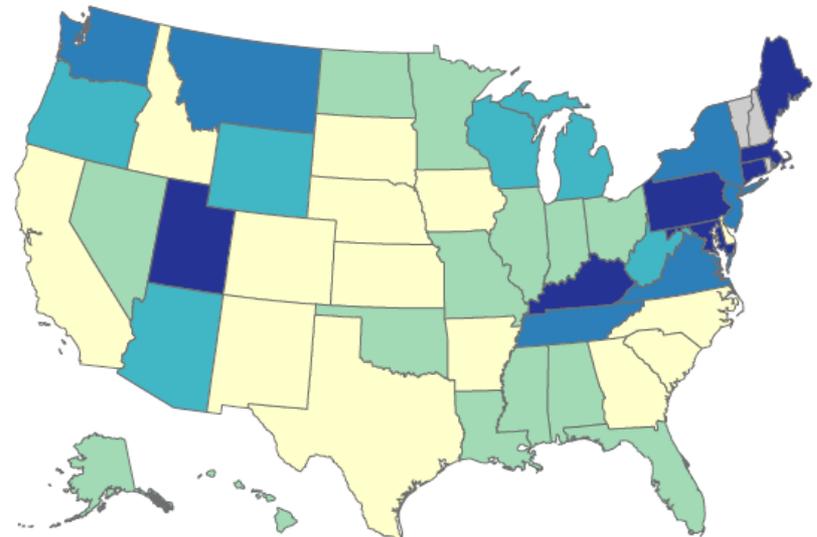
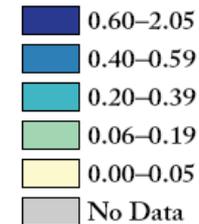


Figure 12. Percent of analyzed drug items identified as buprenorphine, by state, 2008.



Percent Per State

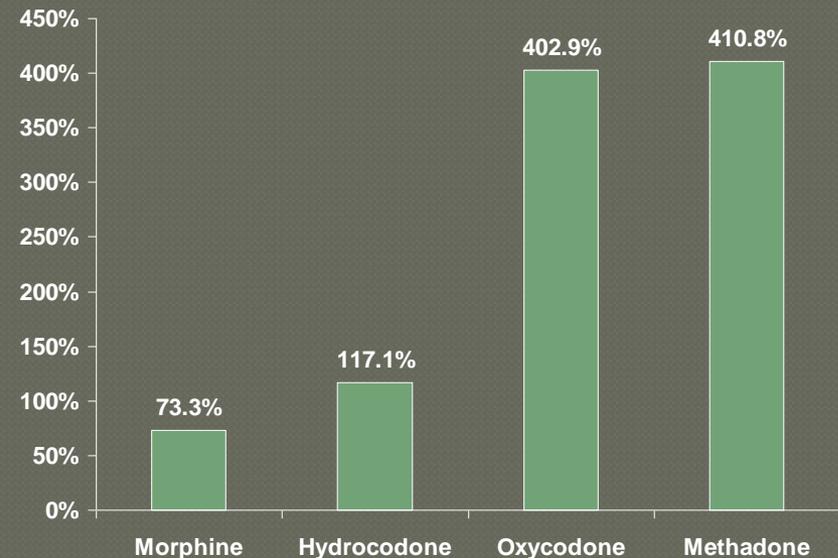


NASPER

National All Schedules Prescription Electronic Reporting Act

- Signed into law by President Bush August 2005
- Point of care reference to all controlled substances prescribed to a given patient
- State PMP is to monitor patients and providers
- Treatment tool vs. Law enforcement tool?

Sale of Opioids 1997-2002



Source: 2002 National Survey on Drug Use and Health (NSDUH).

Results from the 2002 National Survey on Drug Use and Health: National Findings. Department of Health and Human Services

Medical issues in opioid prescribing

○ Potential benefits

- Analgesia
- Function
- Quality of life
- Lower costs

○ Potential risks

- Toxicity
- Functional impairment
- Physical dependence
- Addiction
- Hyperalgesia
- Overdose

Review of opioid efficacy (cont.)

- **In long-term studies:**
 - Usually observational – non randomized / poorly controlled
 - Treatment durations ≤ 6 years.
 - Patients usually attain satisfactory analgesia with moderate non-escalating doses (≤ 195 mg morphine/d), often accompanied by an improvement in function, with minimal risk of addiction.
- The question of whether benefits can be maintained over years rather than months remains unanswered.
 - Ballantyne JC: Southern Med J 2006; 99(11):1245-1255

Conclusions as to opioid efficacy

- Opioids are an essential treatment for some patients with CNMP.
 - They are rarely sufficient
 - They almost never provide total lasting relief
 - They ultimately fail for many
 - They pose some hazards to patients and society
- It is not possible to accurately predict who will be helped – but those with contraindications are at high risk

Conclusions as to opioid efficacy

- A trial (3-6 mo \pm) generally is safe
(IF contraindications are ruled out)
- People who expect to take opioids and lie around the house while they get well, won't.
 - Push functional restoration, exercises
 - Lifestyle changes and weight loss
 - Make increased drugs contingent on increased activity

Desirable patient characteristics:

- No substance abuse disorder
- Reliable
- History of good medical compliance
- Willing to do their part to recover
- Recognizes that opioids are only a partial solution
- Good support (no substance abusers in the home)

If prescribing opioids:

- Establish treatment goals, such as:
 - Functional improvement
 - Work
 - Play
 - Socialization
 - Affective normalization
 - Pain *reduction* (versus pain *relief*)

Formulate a treatment plan:

- Goals
 - Pain
 - Function
 - What should the person do anatomically?
 - Quality of life
 - Affect?
- Opioids or not
- Other treatment components

Practical suggestions:

- Have realistic expectations
- Treat the entire patient, holistic care
- Select appropriate patients
 - Screen for contraindications!
 - If pain does not result primarily from activity in the nociceptive system, it will not be eliminated by
 - Opioids / Spinal fusion / Epidural steroid injections / Antidepressants / NSAIDs

Monitor for outcomes

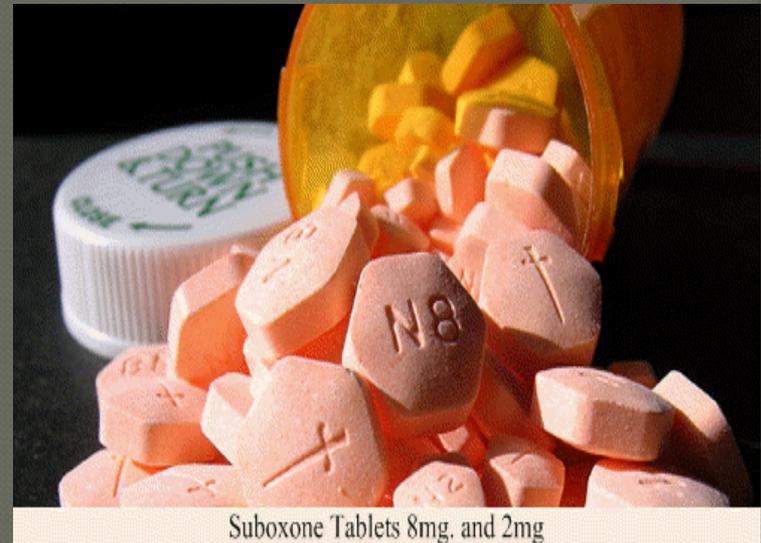
- Analgesia – pain level – 0 -10
- Affect – Beck Depression Inventory, Zung, Ham-D
- Activity level – Pain Disability Index, Oswestry
- Adverse effects – cognition, alertness
- Aberrant behaviors – multisourcing, lost drugs

If not effective,

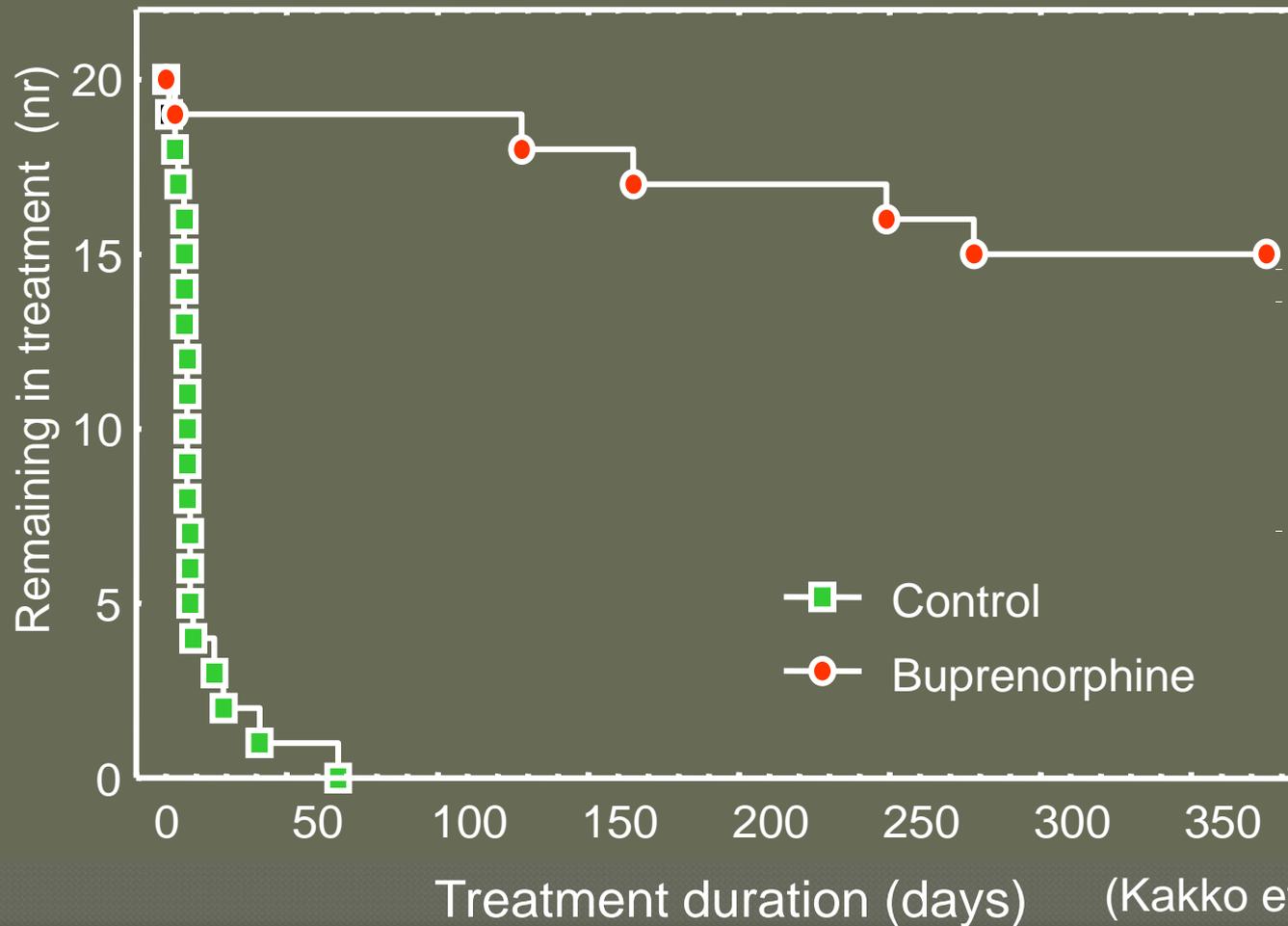


Drug Abuse Treatment Act (DATA) 2000 Schedule III substances Sublingual Buprenorphine

- **ADDICTION:**
 - **Obtain DEA waiver; MD/DO**
 - **30 patients only for addiction**
 - 2007: 30/100 pt limit
 - **Once or BID daily dosing**
- **Other issues:**
 - **Expensive \$3.15 per tab (FSS)
\$8 Retail**
 - **DEA waiver required**
 - **Must be in a program**
 - **Subutex to be stopped ****

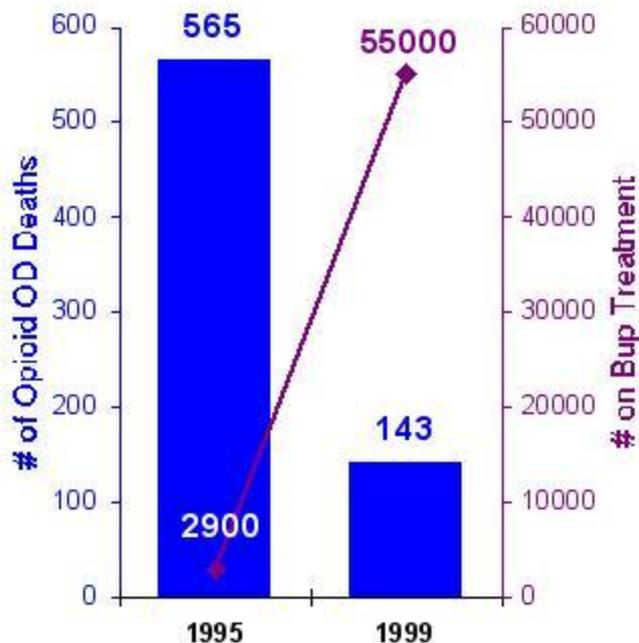


Buprenorphine Maintenance/Withdrawal: Retention



(Kakko et al., 2003)

Opioid Overdose Deaths Decline 79% After Introduction of Buprenorphine in France



Ling et al. J Subst Abuse Treat 2002;23:87-92.
Auriacombe et al. JAMA 2001;285:45.

- French primary care MDs permitted to prescribe without special education or licensing since 1995
- Extensive certification requirements and practice limits continue in force in the U.S.

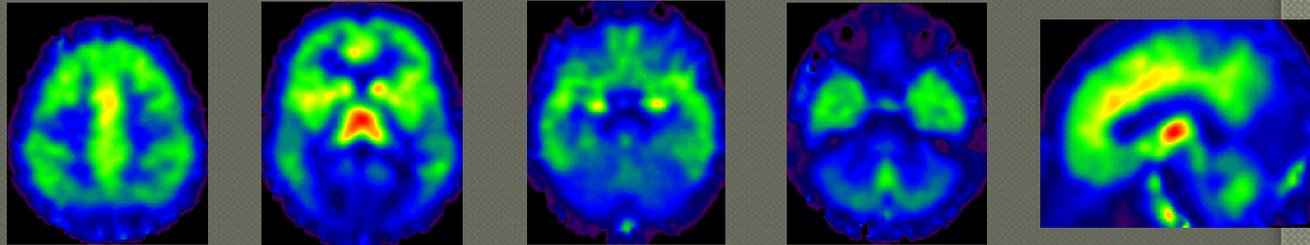


Effects of Buprenorphine Dose on μ -Opioid Receptor Availability in a Representative Subject

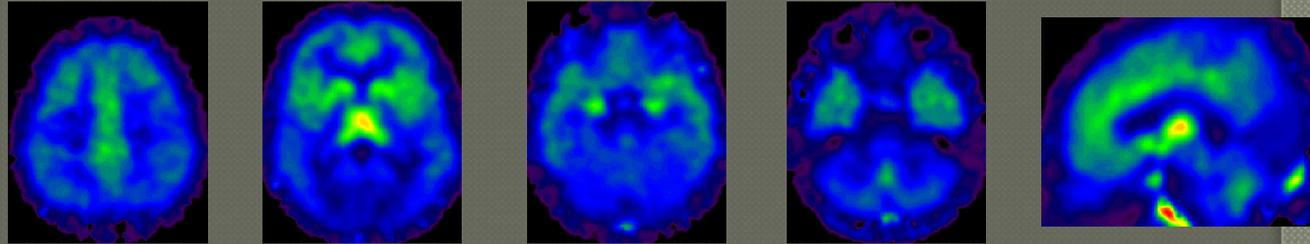
MRI



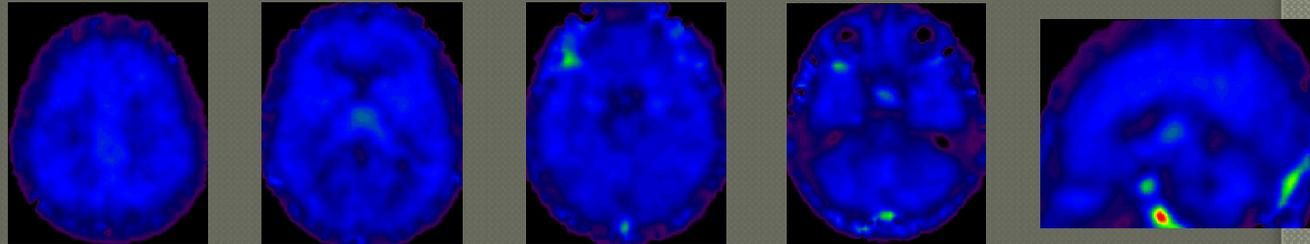
Bup 00 mg



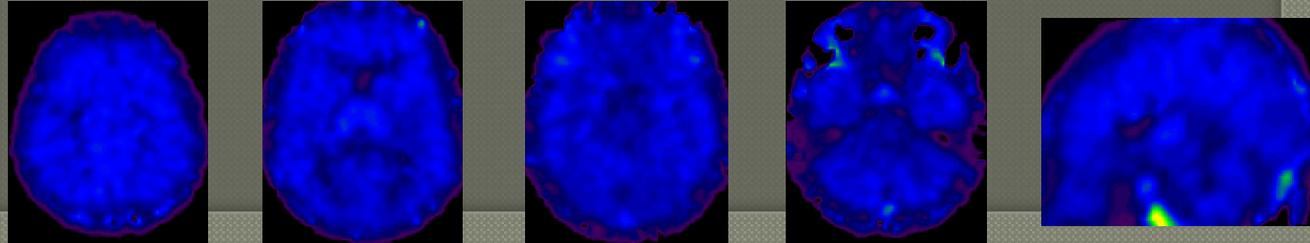
Bup 02 mg



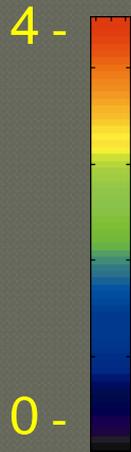
Bup 16 mg



Bup 32 mg



Binding Potential (Bmax/Kd)



Chronic Pain Treatment

- **Controlled Substance Work Group, Sole Provider**
- **Chronic Pain Treatment Work Group**
 - Review and update the Chronic Pain Treatment Policy and Procedure
 - Support the Chronic Pain Treatment Team
 - Establish and Support the Chronic Pain Review Team
 - Educate the patient, family, community and providers in the areas of Chronic Pain Evaluation and Treatment