PUBLIC HEALTH GRAND ROUNDS

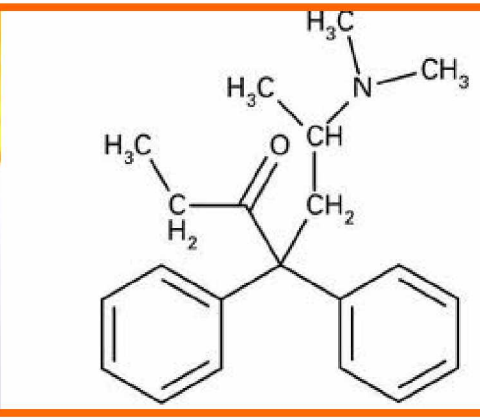
Office of the Director

February 17, 2011

PRESCRIPTION DRUG OVERDOSES: AN AMERICAN EPIDEMIC

- **Grant Baldwin, PhD, MPH**
  Centers for Disease Control and Prevention
  Why Are Drug Overdoses a Public Health Problem?
- **Len Paulozzi, MD, MPH**
  Centers for Disease Control and Prevention
  Rationale for Prevention Strategies
- **Gary Franklin, MD, MPH**
  Washington State Agency Medical Directors Group
  Washington State Opioid Guidelines and Regulations
- **R. Gil Kerlikowske**
  Office of National Drug Control Policy
  Prescription Drug Abuse: Federal Policy Perspective

WHY ARE DRUG OVERDOSES A PUBLIC HEALTH PROBLEM?



Grant Baldwin, PhD, MPH

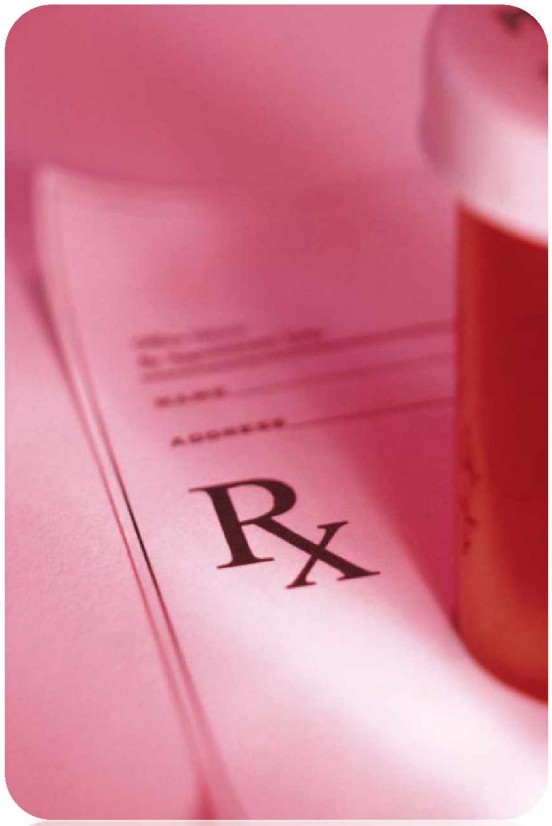
Director, Division of Unintentional Injury Prevention

National Center for Injury Prevention and Control

Centers for Disease Control and Prevention

Prescription Drug Overdose Definition

- Type of poisoning
- Prescription drugs used **in amounts** or **in ways** NOT recommended
- No harm intended by user
- Limited number of ingestions by young children or innocent mistakes by patients

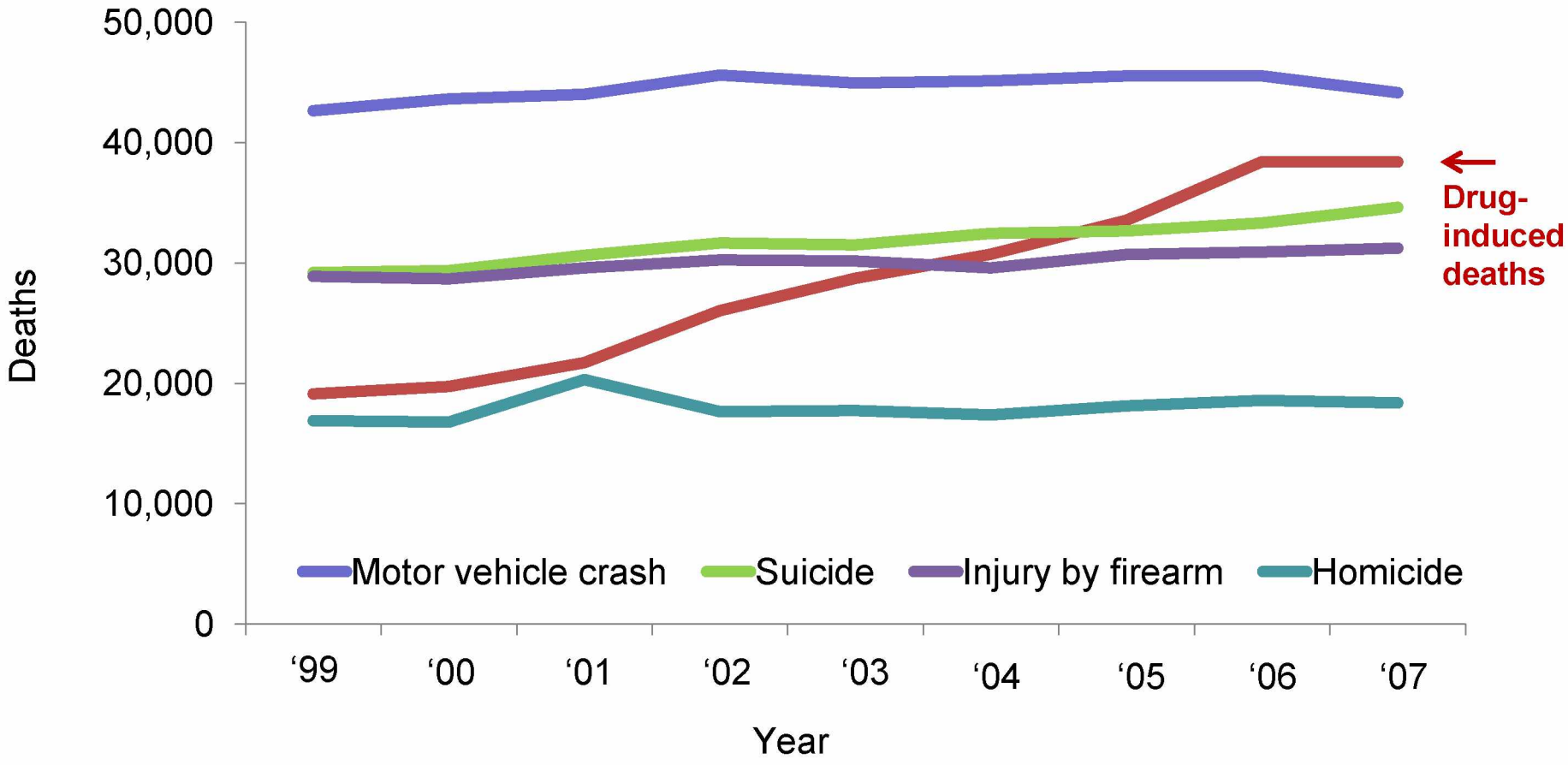


Prescription Drugs Overdose
Type of Drugs and Reasons for Use

- **Types of drugs**
  - Drugs that depress breathing
    - Opioid analgesics
    - Sedative/hypnotics
  - Usually multiple drugs involved
  - Frequently combined with illicit drugs

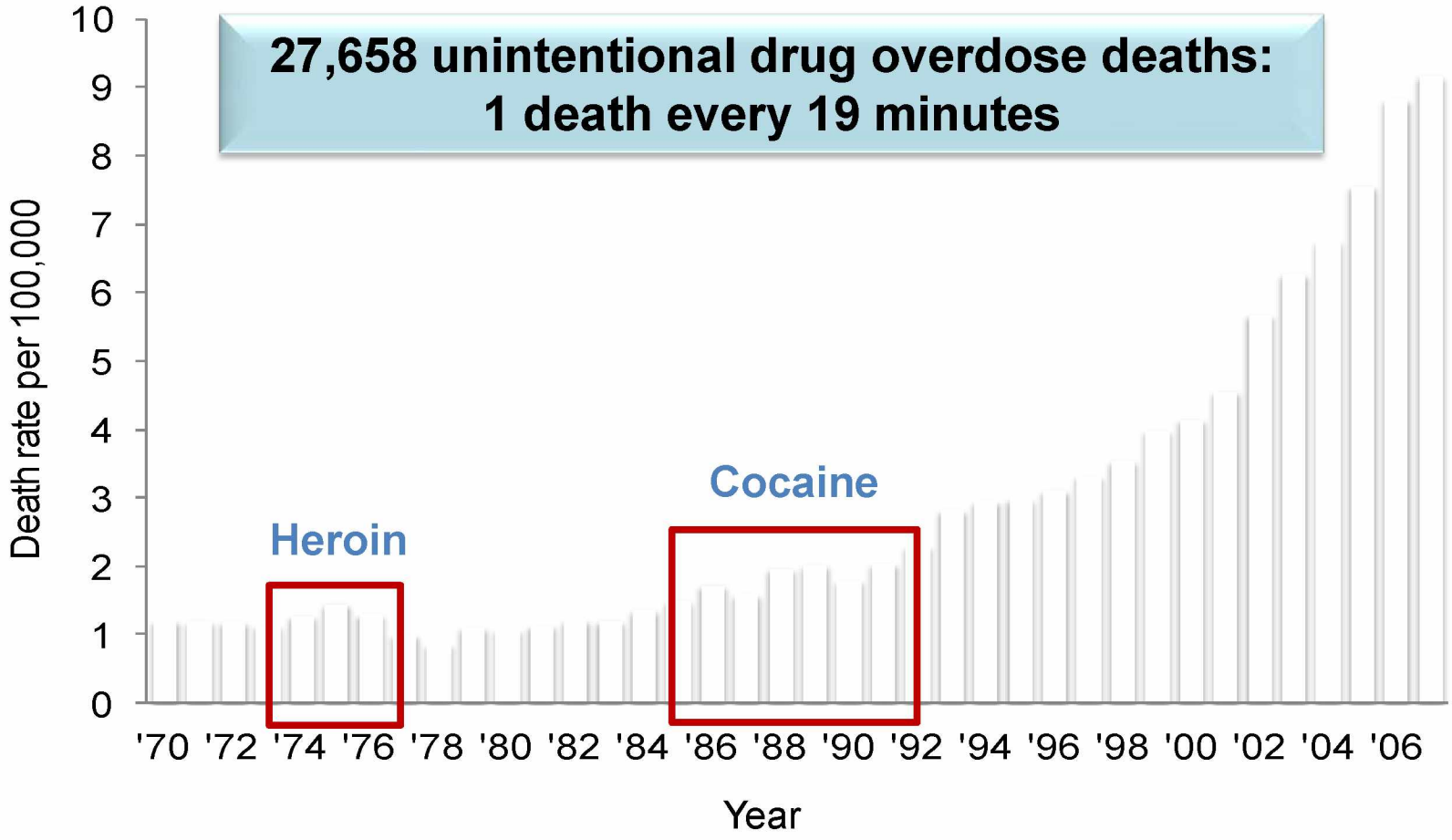
- **Reason for use**
  - Original use of drug might have been their intended purpose: relief of pain or anxiety
  - Development of tolerance
  - Escalated use for “high”

Drug-induced and Other Types of Injury Deaths United States, 1999–2007



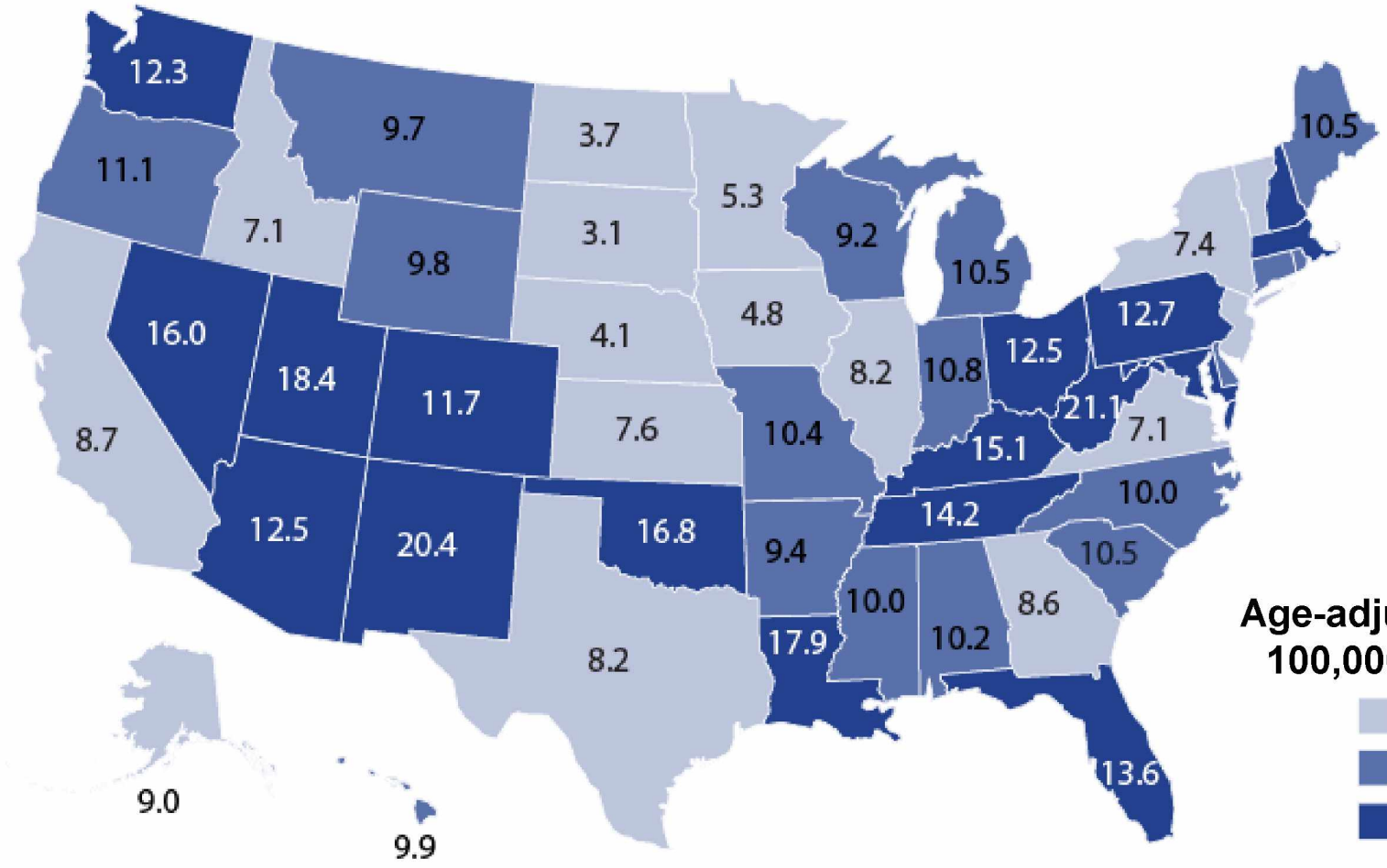
Xu JQ, et al. Deaths: Final Data for 2007, National Vital Statistics Reports, 2010;58 (19)
http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf

Unintentional Drug Overdose Deaths
United States, 1970–2007



National Vital Statistics System. http://wonder.cdc.gov

Unintentional and Undetermined Intent Drug Overdose Death Rates by State, 2007



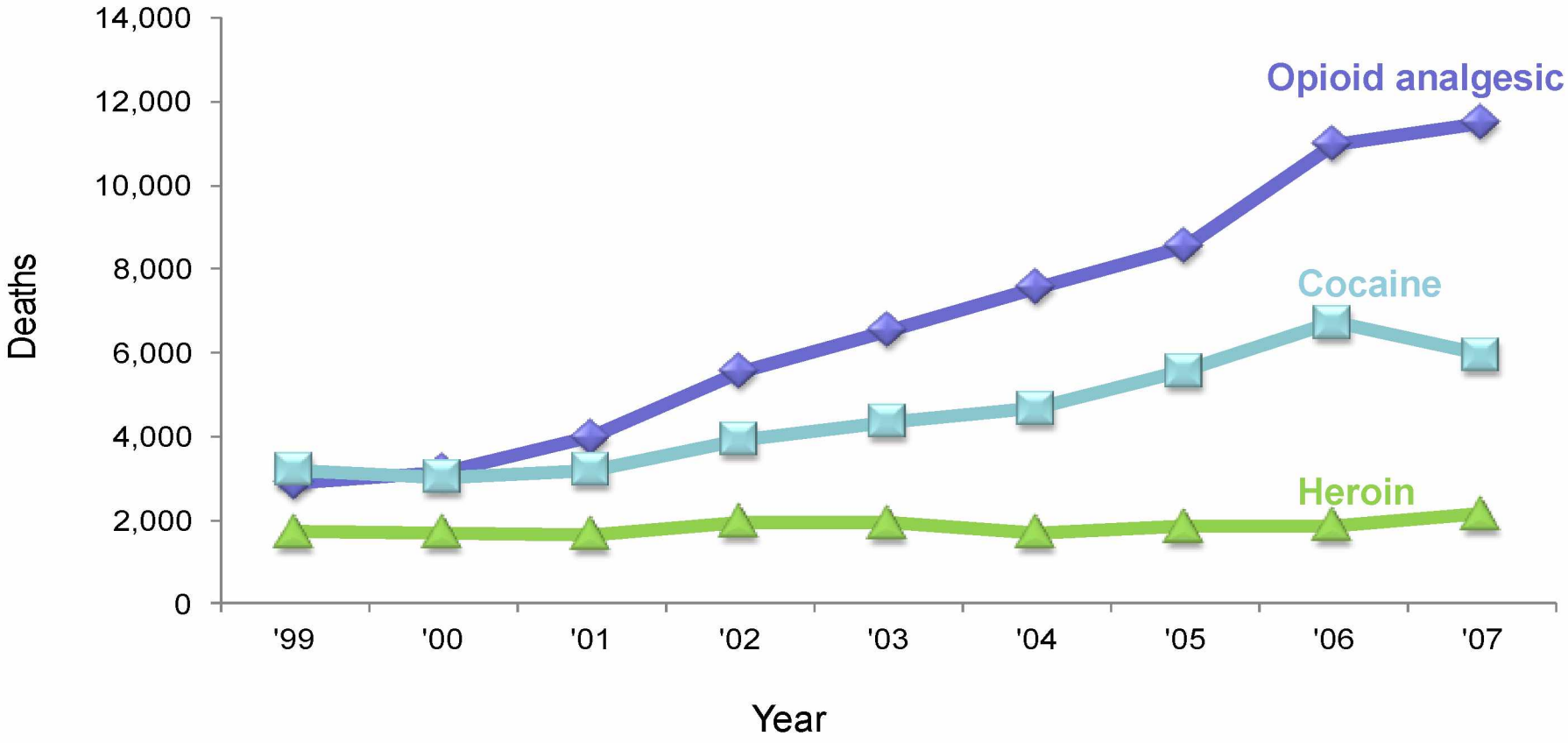
MD	12.5
MA	12.5
NH	11.7
RI	11.1
CT	11.1
DE	9.8
DC	8.8
VT	7.9
NJ	7.5

Age-adjusted rate per 100,000 population

- 3.1-9.0
- 9.1-11.4
- 11.5-21.1

National Vital Statistics System. http://wonder.cdc.gov

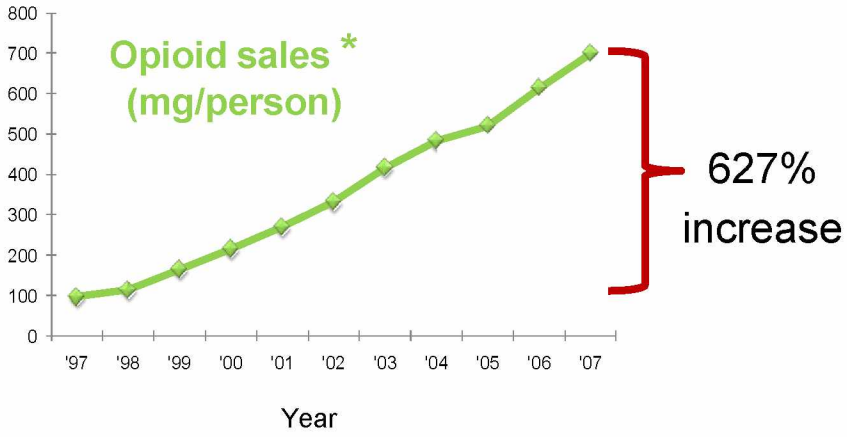
Unintentional Overdose Deaths Involving Opioid Analgesics, Cocaine, and Heroin United States, 1999–2007

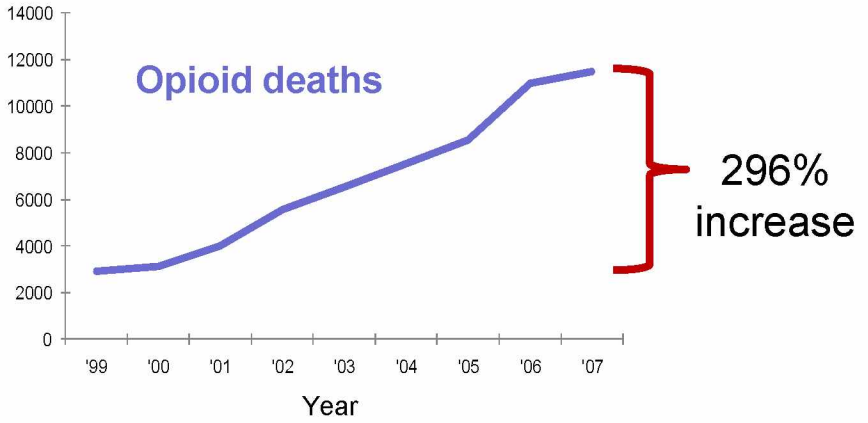


National Vital Statistics System. http://wonder.cdc.gov, multiple cause dataset

Unintentional Overdose Deaths Involving Opioid Analgesics Parallel Opioid Sales United States, 1997–2007

- **Distribution by drug companies**
  - 96 mg/person in 1997
  - 698 mg/person in 2007
    - Enough for every American to take 5 mg Vicodin every 4 hrs for 3 weeks
- **Overdose deaths**
  - 2,901 in 1999
  - 11,499 in 2007

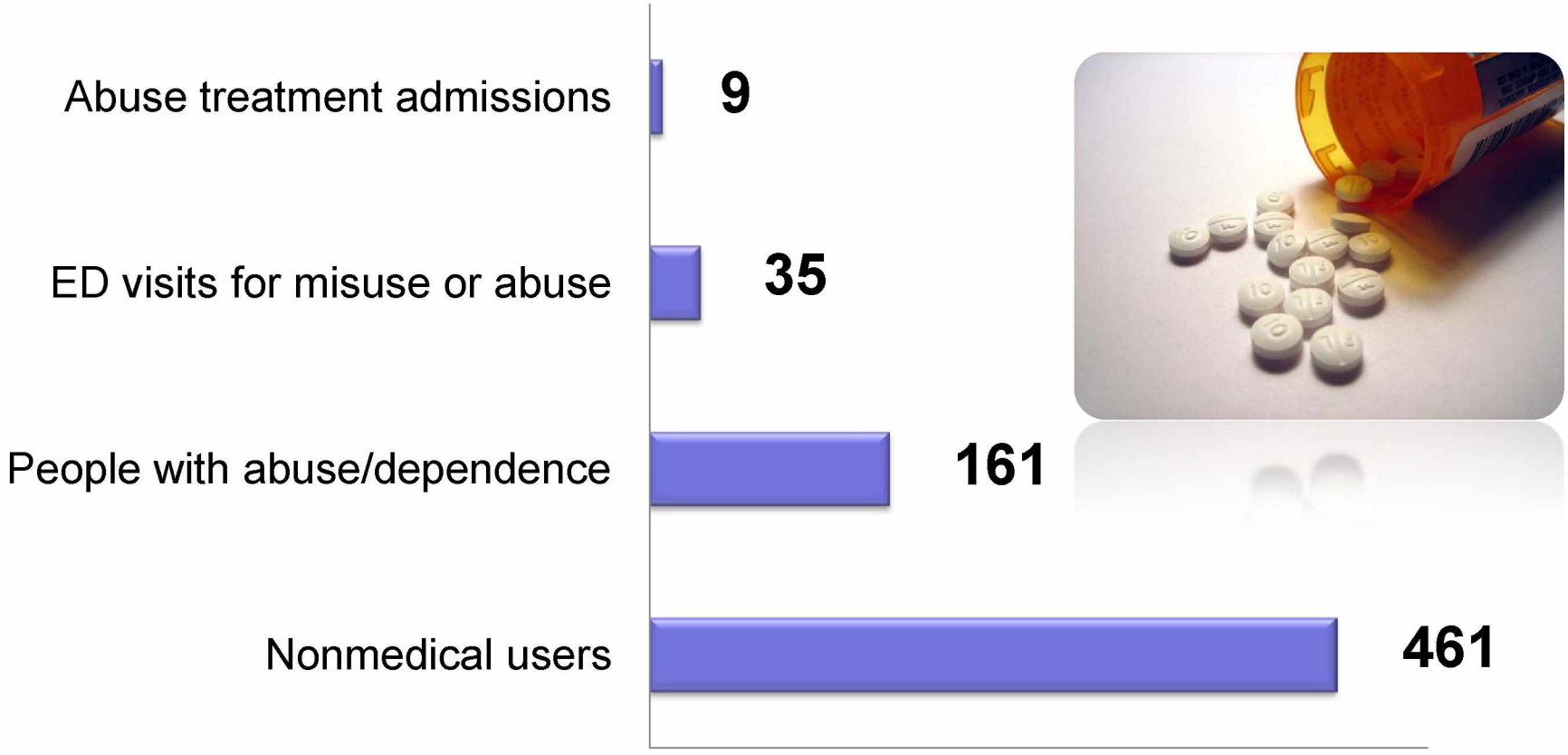




National Vital Statistics System, multiple cause of death data set and Drug Enforcement Administration ARCOS System
* 2007 opioid sales figure is preliminary

Public Health Impact of Opioid Analgesic Use

For every 1 overdose death there are

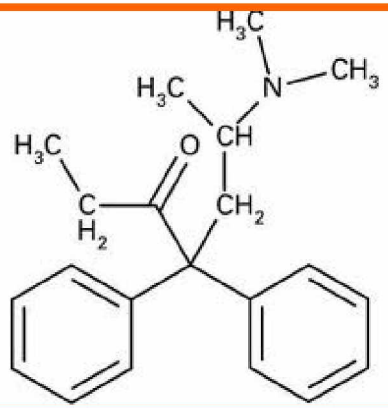


Treatment admissions are for primary use of opioids from Treatment Exposure Data set
Emergency department (ED) visits are from DAWN, Drug Abuse Warning Network, https://dawninfo.samhsa.gov/default.asp
Abuse/dependence and nonmedical use in the past month are from the National Survey on Drug Use and Health

Far-reaching Public Health Impact of Widespread Opioid Analgesic Use

- **Mental impairment leads to other types of unintentional injuries**
  - Falls and fractures among elderly
  - Motor vehicle crashes involving "drugged driving"
- **Substance abuse leads to intentional injuries**
  - Drug-related self harm and drug-crime-related interpersonal violence
- **Intravenous use of drugs leads to infections**
  - HIV transmission related to injection of dissolved tablets
  - Hepatitis C: "Graduating" from oral OxyContin to injected heroin
- **Reproductive health effects**
  - Congenital defects associated with opioid exposure *in utero*
  - Newborn withdrawal syndrome
  - Infertility from chronic heavy use

RATIONALE FOR PREVENTION STRATEGIES



Len Paulozzi, MD, MPH

Medical Epidemiologist, Division of Unintentional Injury Prevention

National Center for Injury Prevention and Control

Centers for Disease Control and Prevention

High-risk Grou
Opioid Abuse and Ov

- Men for overdose deaths
- Ages 20–64 for deaths and emergency department visits
- Whites
- Medicaid populations
- Rural populations
- Mentally ill, especially people with depression

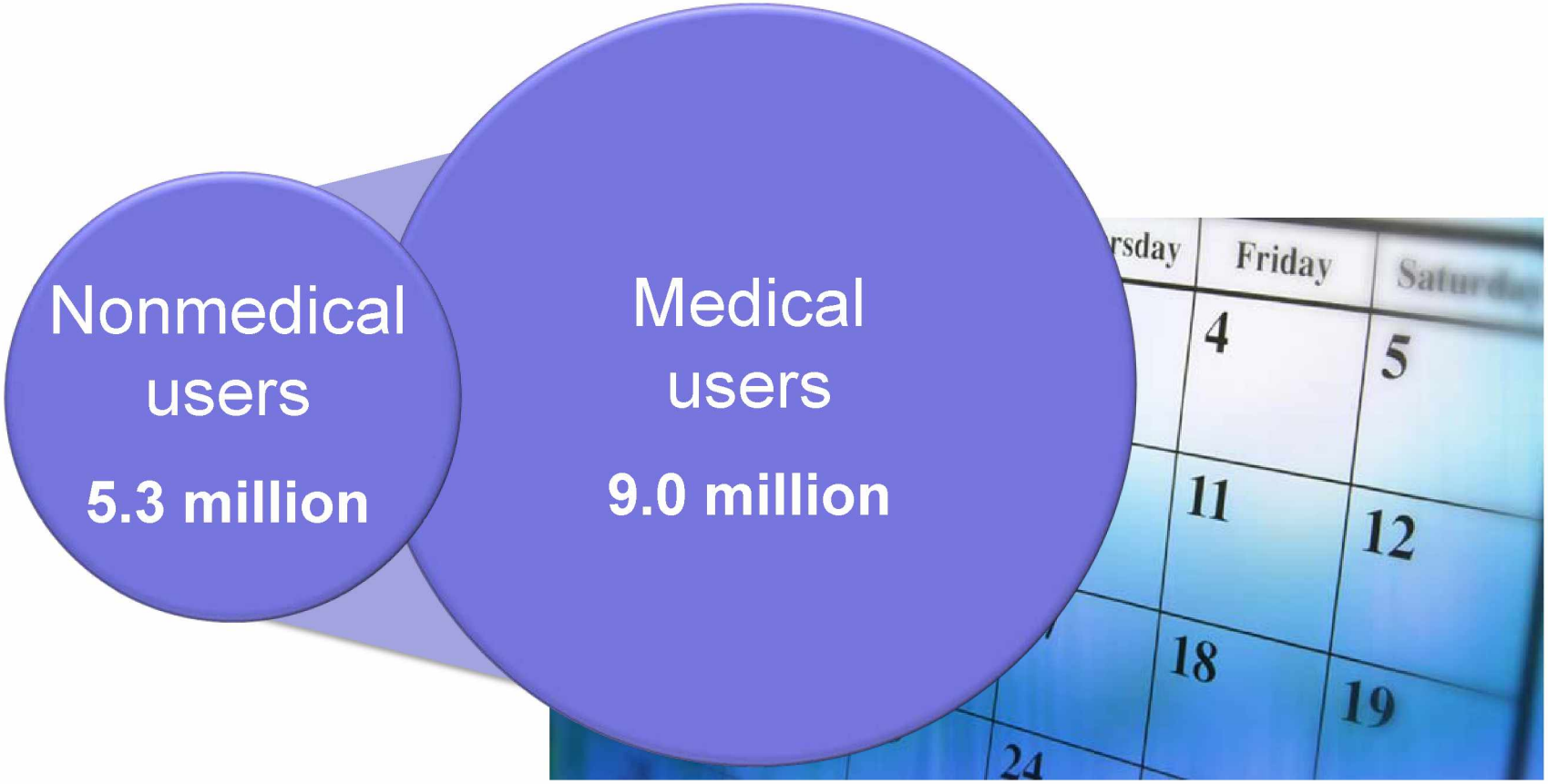
National Vital Statistics System, Drug Abuse Warning Network. https://dawnin
Hall AJ, et al. JAMA 2008;300:2613-20

ups for
erdose Deaths

nfo.samhsa.gov/default.asp

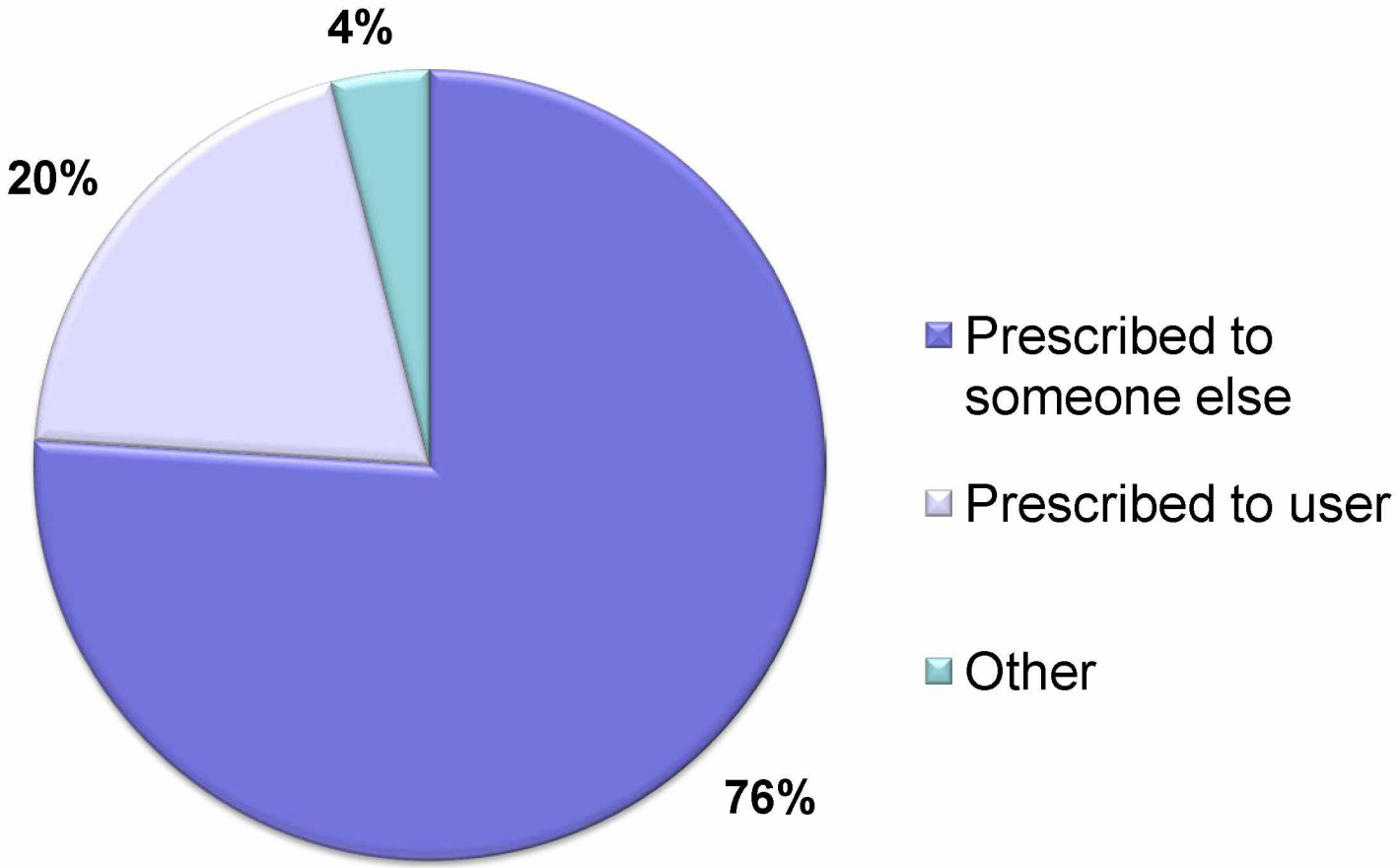
DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Opioid Analgesics: Users in the Past Month



National Survey on Drug Use and Health, 2009. http://www.oas.samhsa.gov

Opioid Analgesics: Sources for Nonmedical Users United States, 2009



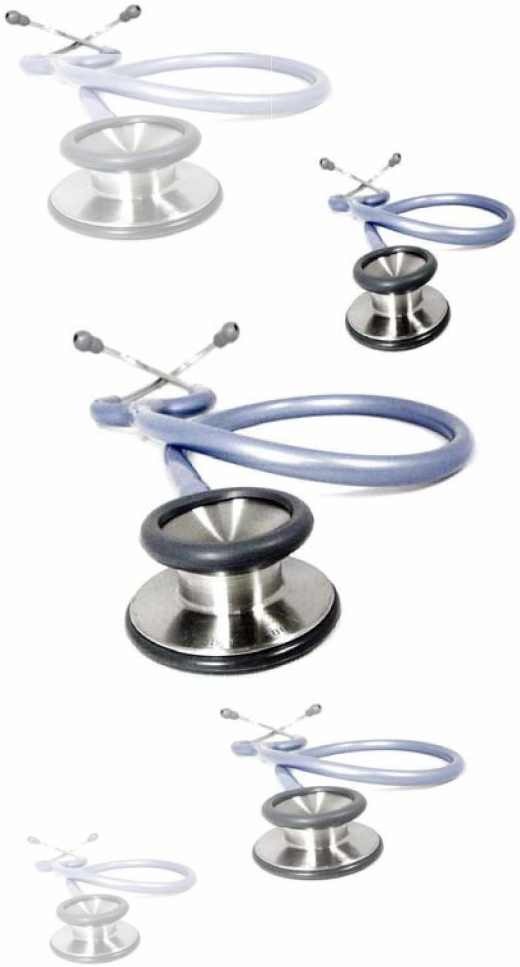
National Survey on Drug Use and Health. Summary of national findings, 2008-2009
http://www.oas.samhsa.gov

Nonmedical Users Among People Dying of Opioid Overdoses

Study population of prescription opioid-related deaths	% without opioid prescription
West Virginia, 2006	66
Utah, 2008–2009	37
Ohio, 2006–2008	25

West Virginia: Hall AJ, et all. JAMA 2008;300:2613-20
Ohio: Ohio Department of Health. www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx
Utah: Lanier W. 2010. CDC Epidemic Intelligence Service Conference

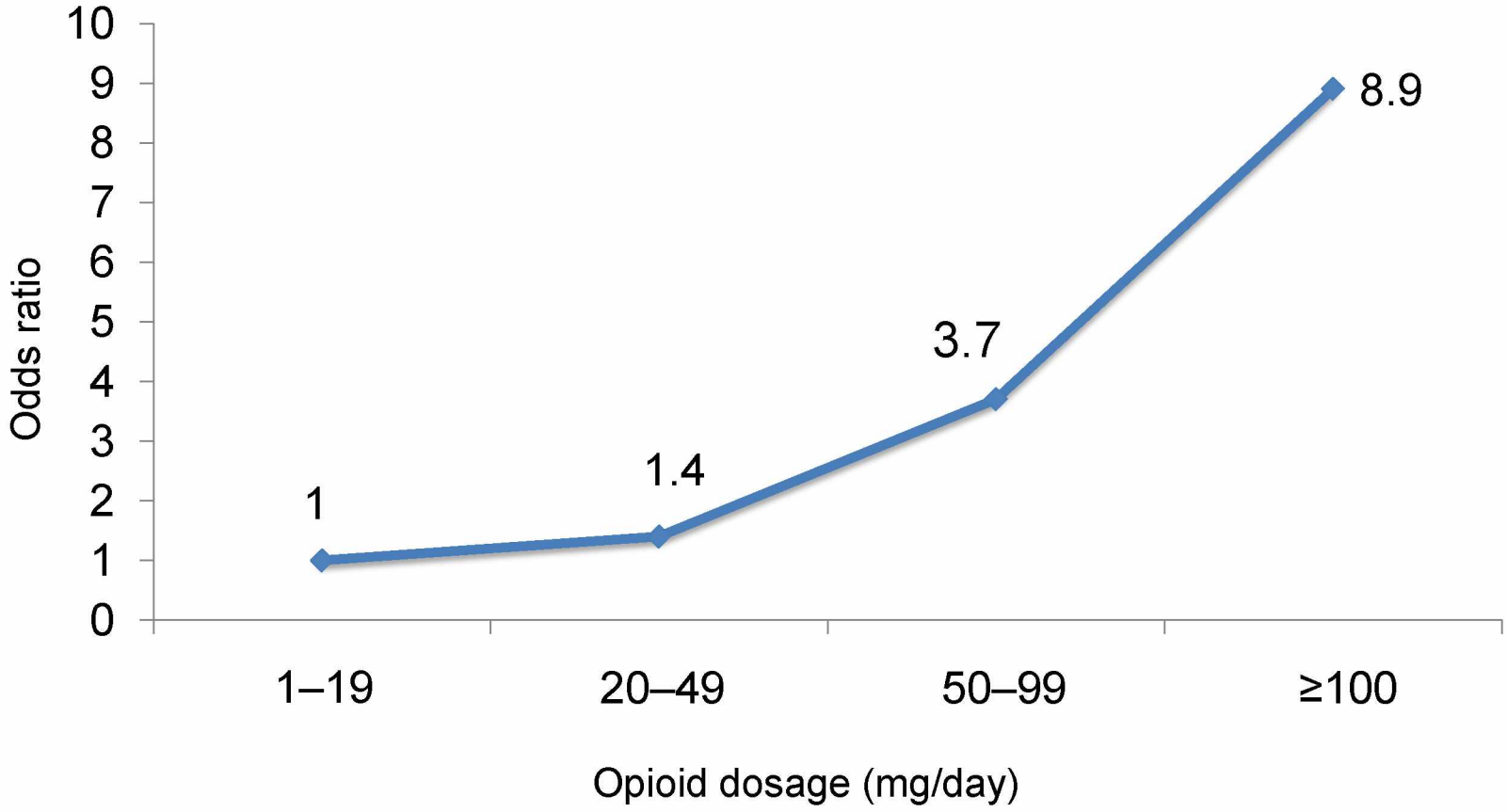
History of Seeing Multiple Prescribers among People Dying of Opioid Overdoses



Definition	% deaths
≥5 prescribers per year West Virginia, 2006	21
Average of 5 prescribers per year over 3 years Ohio, 2006–2008	16

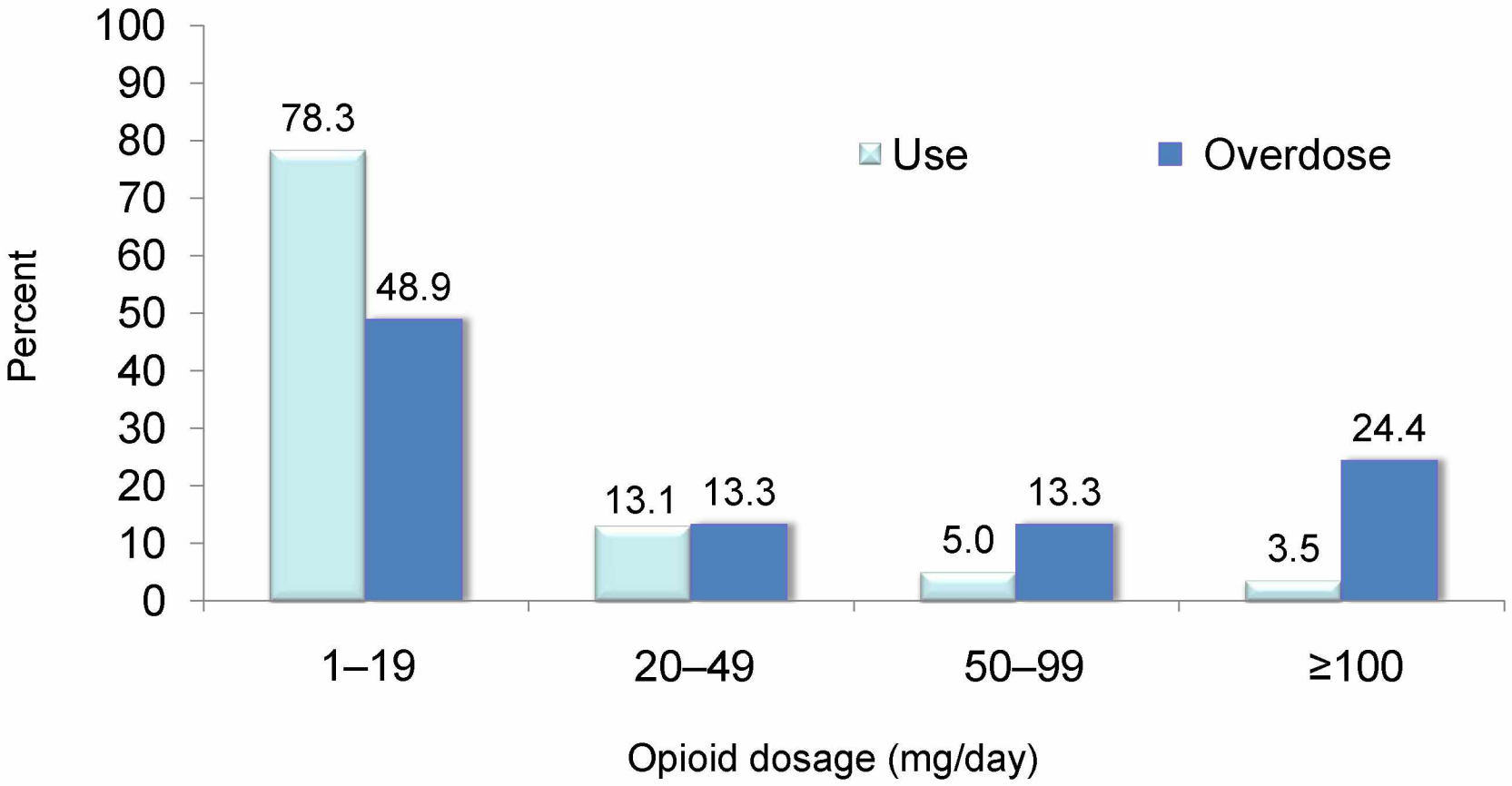
West Virginia: Hall AJ, et all. JAMA 2008;300:2613-20
Ohio: Ohio Department of Health. www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx

Risk of Overdose by Prescribed Opioid Dosage among Medical Users of Opioids



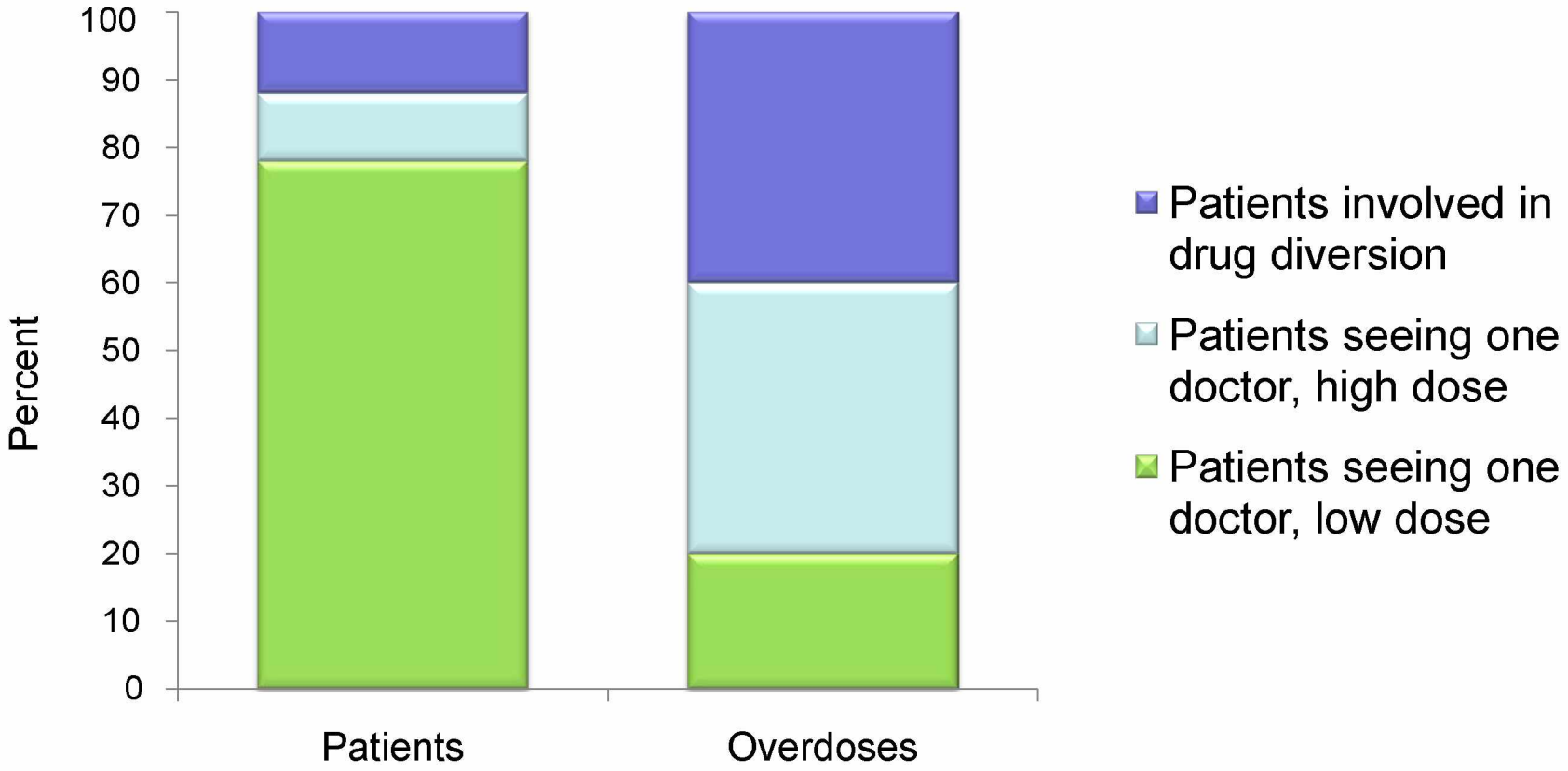
Dunn KM, et al. Ann Int Med 2010;152:85-92

Distributions of Opioid Usage and Overdoses by Prescribed Opioid Dosage



Dunn KM, et al. Ann Int Med 2010;152:85-92

Distribution of Patients and Overdoses by Risk Group



High Impact Strategies

- **Improve usage and effectiveness of prescription drug monitoring programs**
- **Use insurance mechanisms to**
  - Prevent doctor shopping
  - Reduce inappropriate use of opioids
- **Improve state legislation**

Strategies Targeting High-risk Groups: Monitoring and Insurance

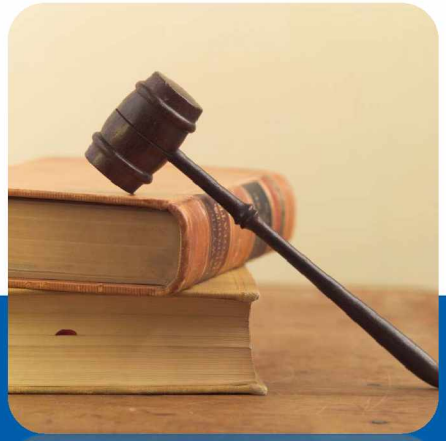
- **Improve effectiveness of prescription drug monitoring programs**
  - Track the rate of use of multiple providers and high dosage,
- **Restrict selected patients to one provider and one pharmacy (by Medicaid and others insurers)**
- **Insurers can restrict payment for inappropriate use, e.g., use of long-acting opioids for short-term pain**

STRATEGIES

Strategies Targeting High-risk Groups: Improving Legislation and Enforcement

- **Improve legislation and enforcement of existing laws including**
  - Doctor shopping: Laws exist in 33 states
  - Reduce “pill mills” and other fraud through
    - Licensure and inspection laws: 3 states
    - Requirements for physical exams before prescribing: 32 states
    - Stopping drug distribution to “pill mills”
  - Dispensing practice: ID requirement at dispensing: 11 states

STRATEGIES



Strategies Targeting High-risk Groups: Improving Physician Practice

- **Develop physician guidelines**
  - Especially in emergency departments
  - With accountability
- **Improve physician competence for safe prescribing of methadone**
- **Use single copy, serialized, tamper-resistant paper prescription forms or E-prescribing**

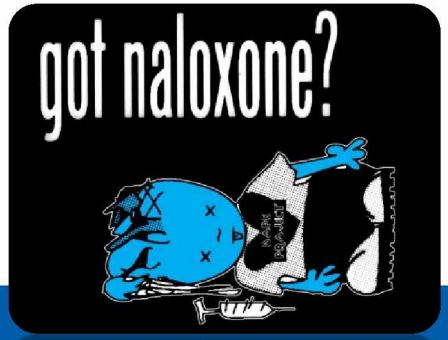
STRATEGIES

http://www.dpt.samhsa.gov/pdf/Methadone_Report_10%2018%2007_Brief%20w%20attch.pdf

Strategies Targeting High-risk Groups: Secondary and Tertiary Prevention

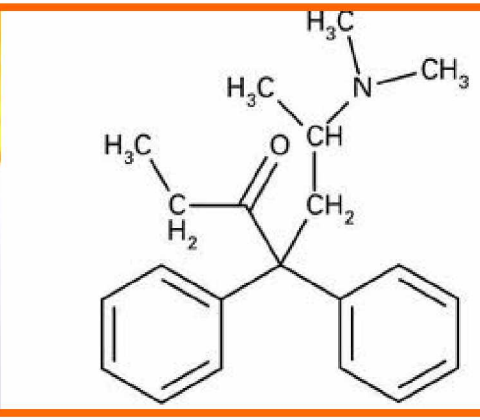
- **Expand use of overdose harm reduction programs**
  - Including more widespread distribution of the opioid antidote, naloxone
- **Expand use of buprenorphine for treatment of opioid dependence**

STRATEGIES



WASHINGTON STATE OPIOID GUIDELINES AND REGULATIONS





Gary Franklin, MD, MPH

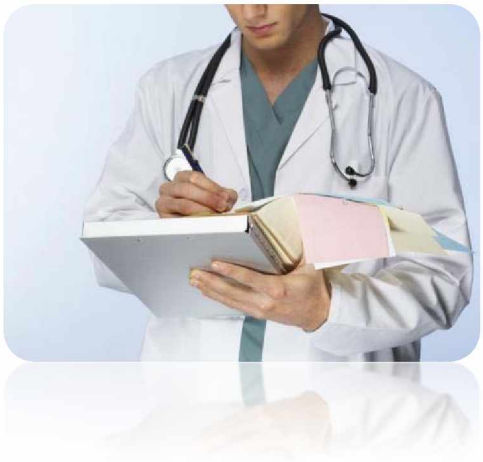
Medical Director, WA Dept of Labor and Industries
Chair, Washington State Agency Medical Directors Group
Research Professor, Occupational and Environmental Health, Neurology, and Health Services, University of Washington

"To write prescriptions is easy, but to come to an understanding with people is hard."

– Franz Kafka, *A Country Doctor*

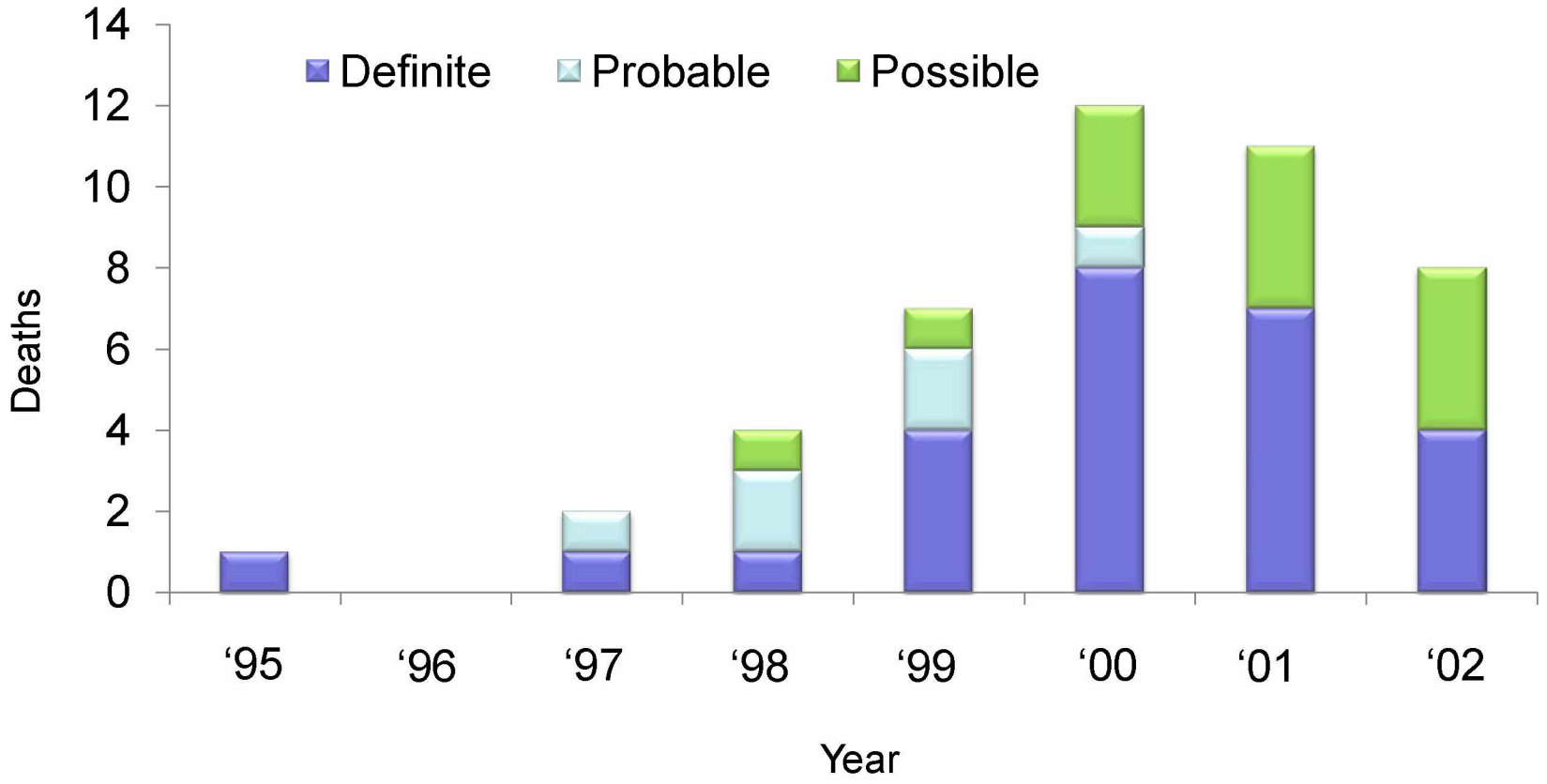
Change in National Norms for Use of Opioids for Chronic, Non-cancer Pain

- **By the late 1990s, at least 20 states passed new laws, regulations, or policies moving from near prohibition of opioids to use without dosing guidance**
  - WA law: "No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed." (WAC 246-919-830, 12/1999)
- **Laws were based on weak science and good experience with cancer pain**



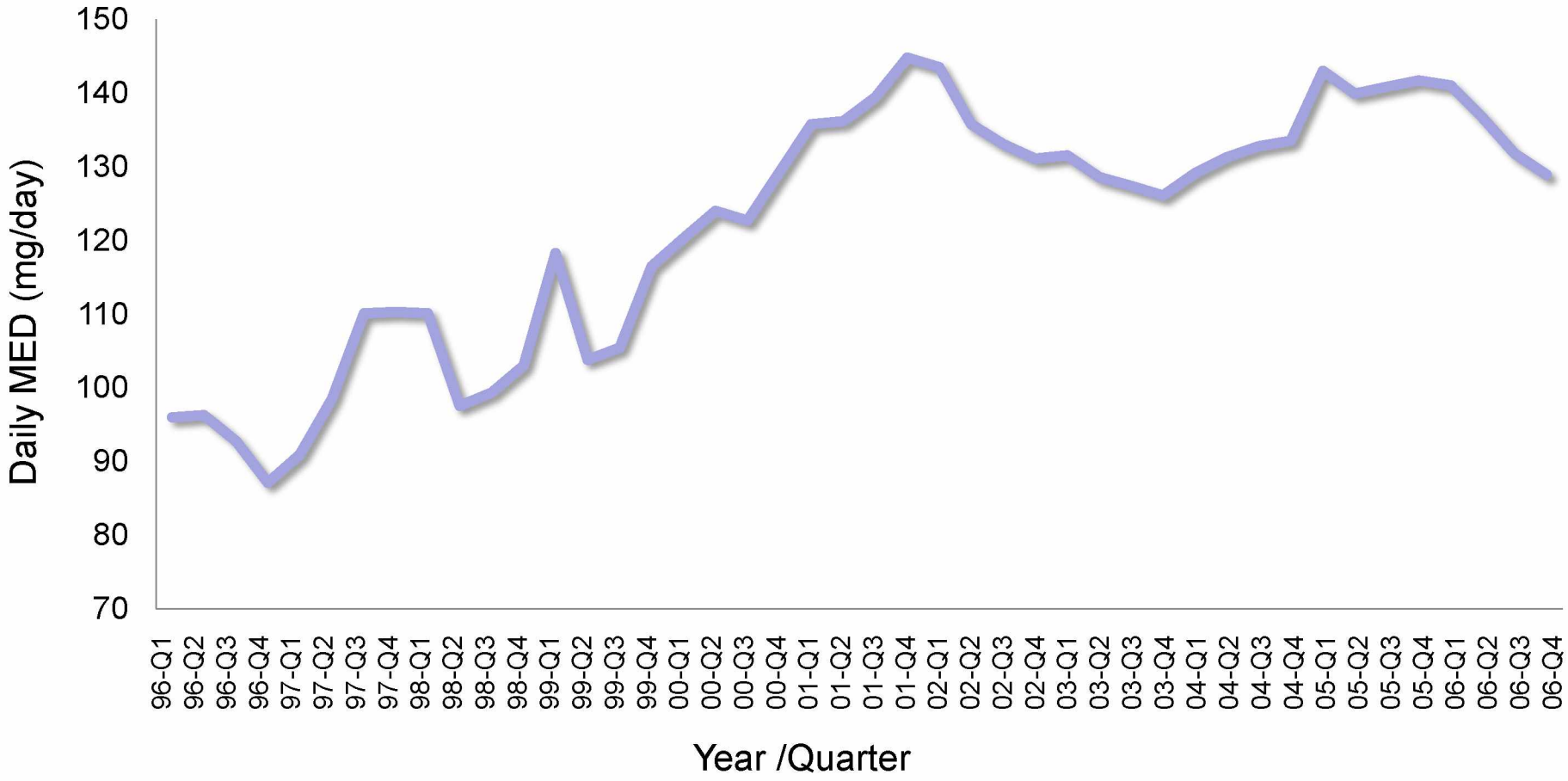
WAC, Washington Administrative Code

Opioid-related Deaths, Washington State Workers' Compensation, 1995–2002



Franklin GM, et al. Am J Ind Med 2005;48:91-9

Average Daily Dosage of Long-acting Opioids Washington State Workers' Compensation, 1996–2006



MED, Morphine equivalent dose

Limitations of Long-term (>3 Months) Opioid Therapy

- Overall, the evidence for long-term analgesic efficacy is weak
- Putative mechanisms for failed opioid analgesia may be related to rampant tolerance
- The premise that tolerance can always be overcome by dose escalation is now questioned
- 100% of patients on opioids chronically develop dependence

Ballantyne J. Pain Physician 2007;10:479-91

Chronic Opioid Use among Workers with Back Injuries, Washington State, 2002–2005

- **Prospective study of 1,843 injured workers with back pain**
- **37.6% received an opioid early, most on first visit**
- **6.0% received opioids for 1 year**
  - Daily dose increased significantly from 1st – 4th quarters after injury
- **Clinically significant improvement was limited to a fraction of patients**
  - 26% patients improved in pain and 16% improved in function

Franklin GM, et al. Clin J Pain 2009;25:743-51

Strategies in Washington State to Address Opioid Overdosing

- Provide Opioid Dosing Guidance for primary care providers
- Strengthen the legislation
- Improve physician access to pain management specialists
- Offer community-based treatment of chronic pain

Washington Agency Medical Directors' Opioid Dosing Guidelines

- Developed with clinical pain experts in 2006
- Implemented April 1, 2007
- First guideline to emphasize dosing guidance
- Educational pilot, not new standard or rule
- National Guideline Clearinghouse
  - http://www.guideline.gov/content.aspx?id=23792&search=wa+opioids

Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain:

An educational aid to improve care and safety with opioid therapy

2010 Update

AMDG agency medical directors' group

www.agencymeddirectors.wa.gov

Washington Agency Medical Directors' Opioid Dosing Guidelines

- **Part I – If patient has not had clear improvement in pain AND function at 120 mg MED (morphine equivalent dose) "take a deep breath"**
  - If needed, get one-time pain management consultation (certified in pain, neurology, or psychiatry)
- **Part II – Guidance for patients already on very high doses >120 mg MED**

The main emphasis was on preventing future cohorts of high-dose patients

Guidance for Primary Care Providers on Safe and Effective Use of Opioids for Chronic Non-cancer Pain

- **Establish an opioid treatment agreement**
- **Screen for**
  - Prior or current substance abuse
  - Depression
- **Use random urine drug screening judiciously**
  - Shows patient is taking prescribed drugs
  - Identifies non-prescribed drugs
- **Do not use concomitant sedative-hypnotics**
- **Track pain and function to recognize tolerance**
- **Seek help if dose reaches 120 mg MED, and pain and function have not substantially improved**

http://www.agencymeddirectors.wa.gov/opioiddosing.asp
MED, Morphine equivalent dose

Washington State Primary Care Survey 2009: Physician Concerns

Please check the statement that most accurately reflects your experience when prescribing opioids for chronic, non-cancer pain	
NO concerns about development of psychological dependence, addiction, or diversion	2%
OCCASIONAL concerns about development of psychological dependence, addiction, or diversion	45%
FREQUENT concerns about development of psychological dependence, addiction, or diversion	54%

Interim Evaluation of the Opioid Dosing Guidelines. http://www.agencymeddirectors.wa.gov

Washington State Primary Care Survey 2009: Adherence to State Guidelines

Guidance	Never or almost never	Sometimes	Often	Always or almost always
Use treatment agreement	10%	22%	20%	49%
Screen for substance abuse	<1%	3%	15%	81%
Screen for mental illness	<1%	12%	30%	58%
Use random urine screen	30%	32%	18%	20%
Use patient education	34%	38%	19%	9%
Track pain	40%	31%	15%	15%
Track physical function	69%	20%	7%	5%

Interim Evaluation of the Opioid Dosing Guidelines. http://www.agencymeddirectors.wa.gov

Open-source Tools Added to June 2010 Update of Opioid Dosing Guidelines

- Opioid Risk Tool: Screen for past and current substance abuse
- CAGE-AID screen for alcohol or drug abuse
- Patient Health Questionnaire-9 screen for depression
- 2-question tool for tracking pain and function
- Advice on urine drug testing

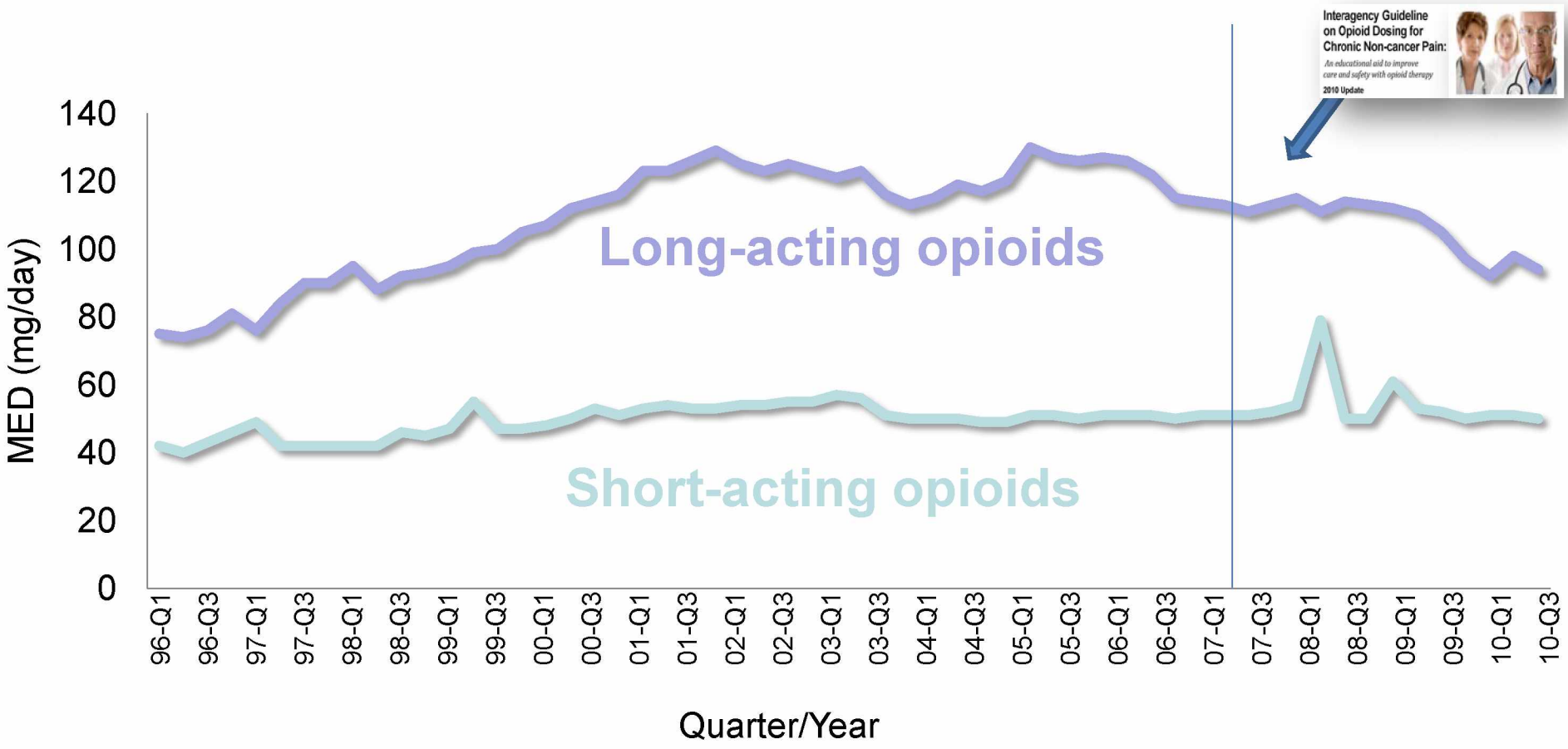
OPIOID DOSE CALCULATOR

Opioid (oral or transdermal)	Mg per day	Morphine equivalents
codeine		0
fentanyl transdermal (in mcg/hr)		0
hydrocodone	20	20
hydromorphone		0
methadone		
up to 20mg per day		
21 to 40mg per day		
41 to 60mg per day	50	500
>60mg per day		0
morphine		0
oxycodone		0
oxymorphone		0
TOTAL daily morphine equivalent dose (MED) =		**520**

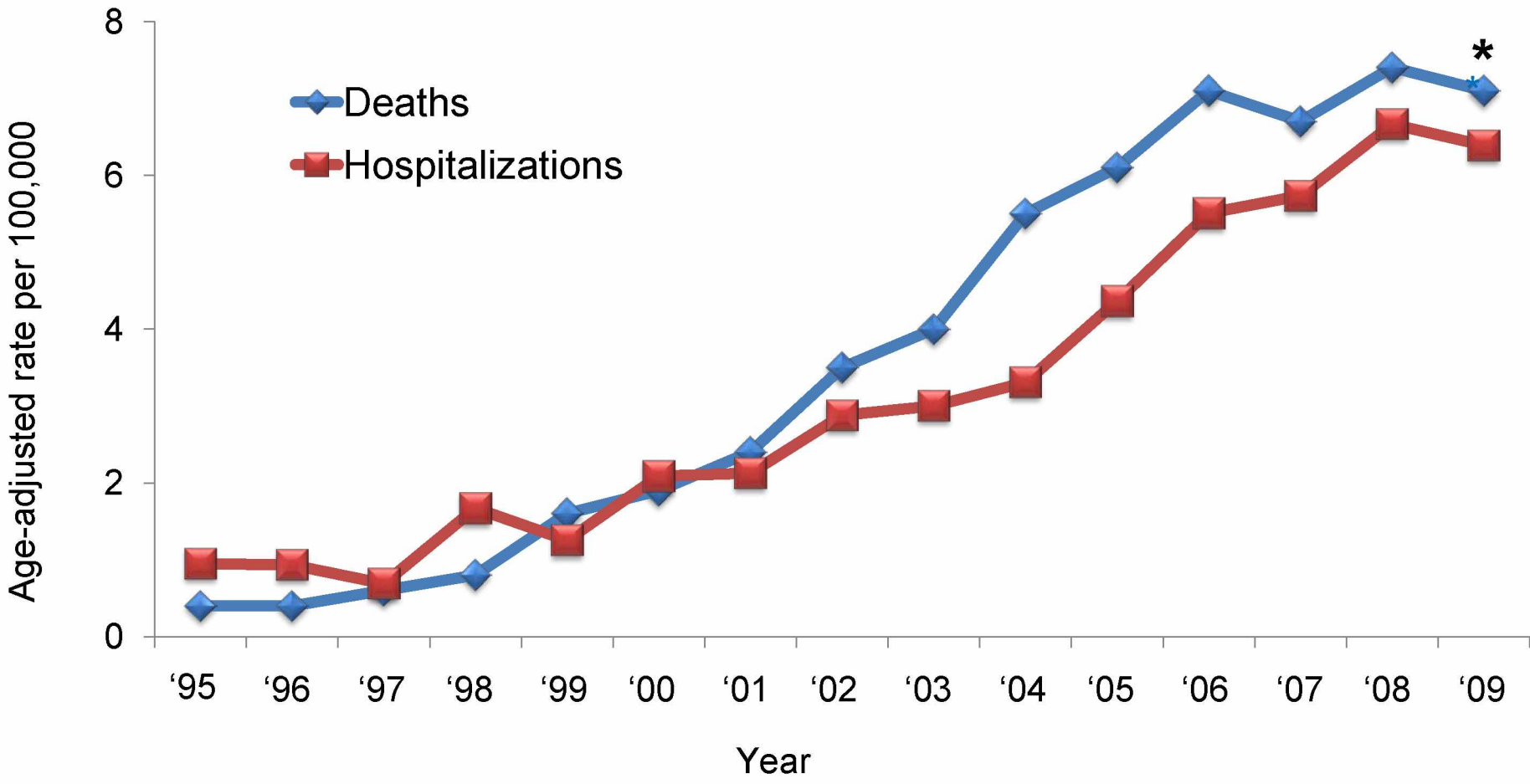
http://www.agencymeddirectors.wa.gov/opioiddosing.asp#DC

CAGE, “cut down” “annoyed” “guilty” “eye-opener”

Average Daily Dosage for Opioids, Washington Workers' Compensation, 1996–2010



Unintentional Prescription Opioid Overdose Death and Hospitalization Rates Washington State, 1995–2009



*Tramadol-only deaths included in 2009, but not in prior years.
Washington State Department of Health, Death Certificates and Comprehensive Abstract Reporting System (CHARS)

Washington State Legislation on Opioid Treatment in 2010

- Repeals current regulation; new expected by June 2011
- Provides specific dosing guidance and guidance on consultations, assessments, and tracking
- Signed into law by Governor Gregoire on March 25, 2010

Washington State Opioid Treatment Regulations (DRAFT)

- **Emphasize tracking patients for improved pain AND function**
- **Emphasize widely agreed-upon best practices**
  - Screening for substance abuse and other comorbidities
  - Prudent use of urine drug screens
  - Opioid treatment agreement
  - Single pharmacy and single prescriber
- **Encourage use of Prescription Monitoring Program and Emergency Department Information Exchange, when available**

Improving Physician Access to Pain Specialists in Washington State

- **Issue**
  - Moderate capacity problem: not enough pain specialists
  - Interventional anesthesiologists generally will not see these patients to assist with opioid issues
- **Solution**
  - Advanced training for primary care to increase proficiency
  - Have successfully "beta tested" telemedicine consults and webinar trainings with pain specialists and primary care physicians
  - Telephonic or video consultation with experts
  - Public payers working on payment codes to incentivize these activities

Components Being Developed for Community-based Treatment of Chronic Pain

- Cognitive behavioral therapy
- Graded exercise
- Activity coaching
- Interdisciplinary care
- Care coordination

Lessons Learned from Washington State

- Opioid overdose is a public health crisis
- High doses and rampant tolerance are key factors
- A more comprehensive approach to effectively treating chronic pain must be developed
- Statewide change through collaboration is needed
- Prescriber education requires appropriate tools and dosing guidance
- Prescriber education alone is not adequate
- New state regulations are needed to ensure best practices and to prevent worst practices

PRESCRIPTION DRUG ABUSE: FEDERAL POLICY PERSPECTIVE

R. Gil Kerlikowske

Director

Office of National Drug Control Policy

Executive Office of the President

www.whitehousedrugpolicy.gov

Overview

- Authority and role of the White House Office of National Drug Control Policy (ONDCP)
- Federal policy perspective
- Federal, state, local, and tribal coordination

ONDCP's Authority

- Established by the Anti-Drug Abuse Act of 1988
- Principal purpose: Establish policies, priorities, and objectives for the nation's drug control program
- Goals: Reduce illicit drug use, manufacturing, and trafficking, drug-related crime and violence, and drug-related health consequences

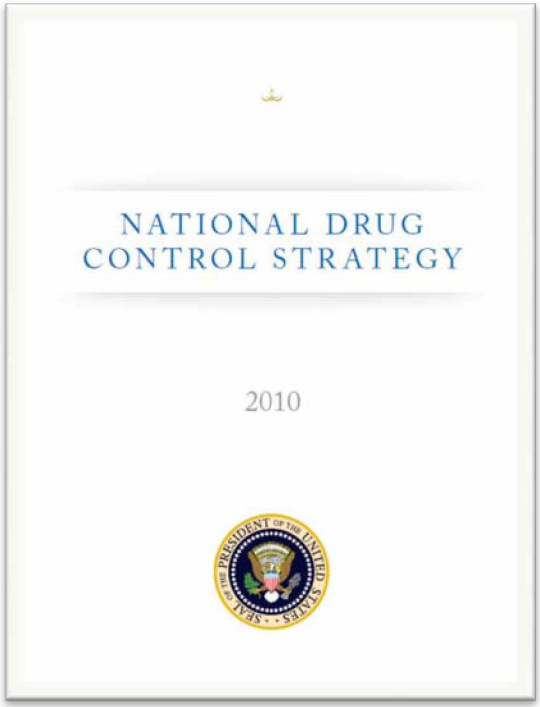
ONDCP's Role

- Responsible for developing the *National Drug Control Strategy*
- Advise the President regarding Federal Drug Control Agencies' activities
- Coordinate/oversee international and domestic anti-drug efforts of executive branch agencies
- Establish a program, budget, and guidelines for cooperation among federal, state, and local entities

www.whitehousedrugpolicy.gov

2010 National Drug Control Strategy

- Science-based, public health approach to drug policy
- Coordinated federal effort on 106 action items



www.whitehousedrugpolicy.gov/strategy

2010 National Drug Control Strategy Signature Initiatives

- **Three signature initiatives**
  - Prescription drug abuse
  - Prevention
  - Drugged driving

www.whitehousedrugpolicy.gov

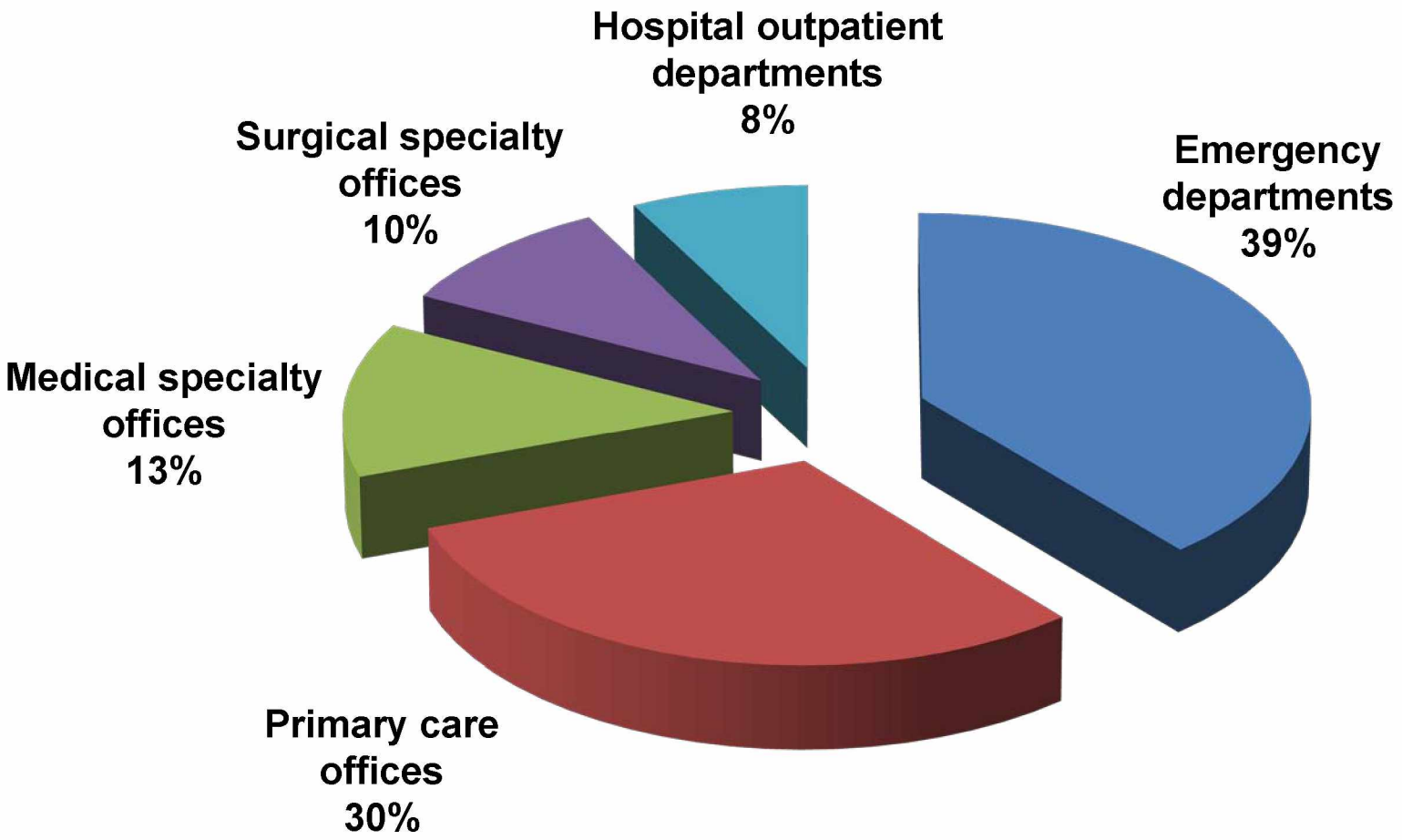
Federal Policy Perspective

- **Policy must balance the desire to minimize abuse with the need to ensure legitimate access**
- **Multifaceted approach and collaboration among federal, state, local, and tribal groups is key**
- **Four focus areas**
  1. Education
  2. Prescription drug monitoring programs
  3. Proper medication disposal
  4. Enforcement

1. Education

- **Education for parents and patients**
  - Increase awareness
  - Safe medication use, storage, and disposal
- **Education for health care providers**
  - Appropriate prescribing
  - Adverse events and drug interactions
  - Identifying those at risk for abuse
  - Counseling on proper storage and disposal
  - Screening, intervention, and referral for those misusing or abusing prescription drugs

Distribution of Narcotic Analgesics to Patients by Health Care Setting



Raofi S, Schappert SM. Medication therapy in ambulatory medical care: United States, 2003–04 National Center for Health Statistics. Vital Health Stat 13(163). 2006. http://www.cdc.gov/nchs/data/series/sr_13/sr13_163.pdf

2. Prescription Drug Monitoring Programs (PDMPs)

- **Tool to identify**
  - Inappropriate prescribing, dispensing, and drug-seeking behavior
  - Drug interactions and therapeutic duplication
- **Goals**
  - All states have operational PDMPs
  - Mechanisms in place for communication between states
  - High utilization among health care providers
    - Regular part of office visit like checking insurance coverage
- **Positive data are starting to surface***
  - More data on effectiveness and outcomes is needed

*Baehren DF, et al. Ann Emerg Med. 2010 Jul;56(1):19-23.e1-3. Epub 2010 January 4
http://chfs.ky.gov/NR/rdonlyres/24493B2E-B1A1-4399-89AD
1625953BAD43/0/KASPEREvaluationFinalReport10152010.pdf. Accessed January 2011
http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_whole.pdf

3. Proper Medication Disposal

- **National Take Back Day**
  - September 2010: 121 tons of drugs were taken back at >4,000 sites across the country
  - April 30, 2011: Next Take Back Day

- **Secure and Responsible Drug Disposal Act 2010**
  - Object: Allow ultimate users to give back controlled substances to an authorized entity
- **Drug Enforcement Administration rule-making underway**

3. Proper Medication Disposal

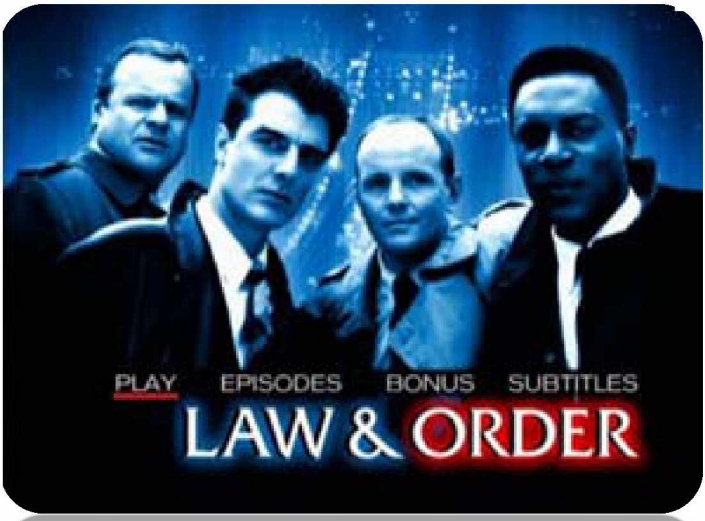
- **Goals**
  - To be easily accessible and an environmentally friendly method of drug disposal
  - To be cost-effective and not a burden on consumers
  - To reduce the amount of prescription drugs available for diversion and abuse

4. Enforce

- **Assist states in addressing "shopping**
  - Provide technical assistance to states on model regulations/laws for pain clinics
  - Encourage high-intensity drug trafficking areas to work on prescription drug abuse issues
  - Support prescription drug abuse-related training programs for law enforcement

ment

pill mills" and doctor



Federal, State, Local, and Tribal Coordination

PARENTS.
THE ANTI-DRUG.

Drug Free Communities
SUPPORT PROGRAM

above the influence

Drug Free Communities Program (DFC)

- **Support community coalitions in their efforts to reduce local substance use**
  - Reduce substance use among youth in the community
  - Increase collaboration in the community regarding substance use
- **1,600 grantees since 1997**
- **$85.6 million awarded to 746 DFCs in 2009**
- **Planning process based on SAMHSA's Strategic Prevention Framework**
  - Assessment, capacity, planning, implementation, and evaluation
- **56% of current grantees target prescription drug abuse in their communities**

http://www.ondcp.gov/dfc
http://www.jointogether.org/resources/samhsas-strategic-prevention.html
SAMSHA, Substance Abuse and Mental Health Services Administration

Drug Free Communities

http://www.ondcp.gov/dfc

National Youth Anti-Drug Media Campaign

www.abovetheinfluence.com

National Youth Anti-Drug Media Campaign

- **Combined national and local approach**
  - Engaging Local Communities: Aimed at getting teens to share insights about positive and negative influences in their communities and their approach to "staying above it"
- **Balances broad prevention messaging at the national level with targeted efforts at the local community level**
- **"Self-reported exposure to the ONDCP campaign predicted reduced marijuana use"**

Slater MD, et al. Assessing Media Campaigns Linking Marijuana Non-Use with Autonomy and Aspirations: "Be Under Your Own Influence" and ONDCP's "Above the Influence". Prev Sci. 2011. DOI 10.1007/s11121-010-0194-1.

Conclusions

- Prescription drug abuse and its consequences are the fastest growing drug problem in America
- Comprehensive four pillar approach addresses each aspect of the prescription drug abuse epidemic
- Parents, peers, youth influencers, health care professionals, and policy-makers all have a role to play
- Success will come from coordination and collaboration at the federal, state, local, and tribal level