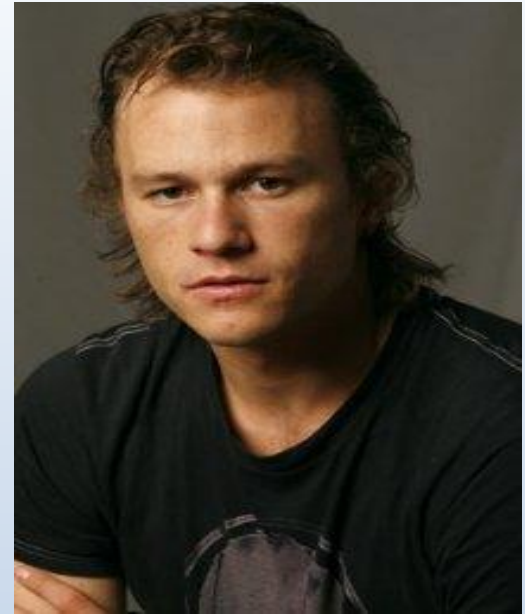
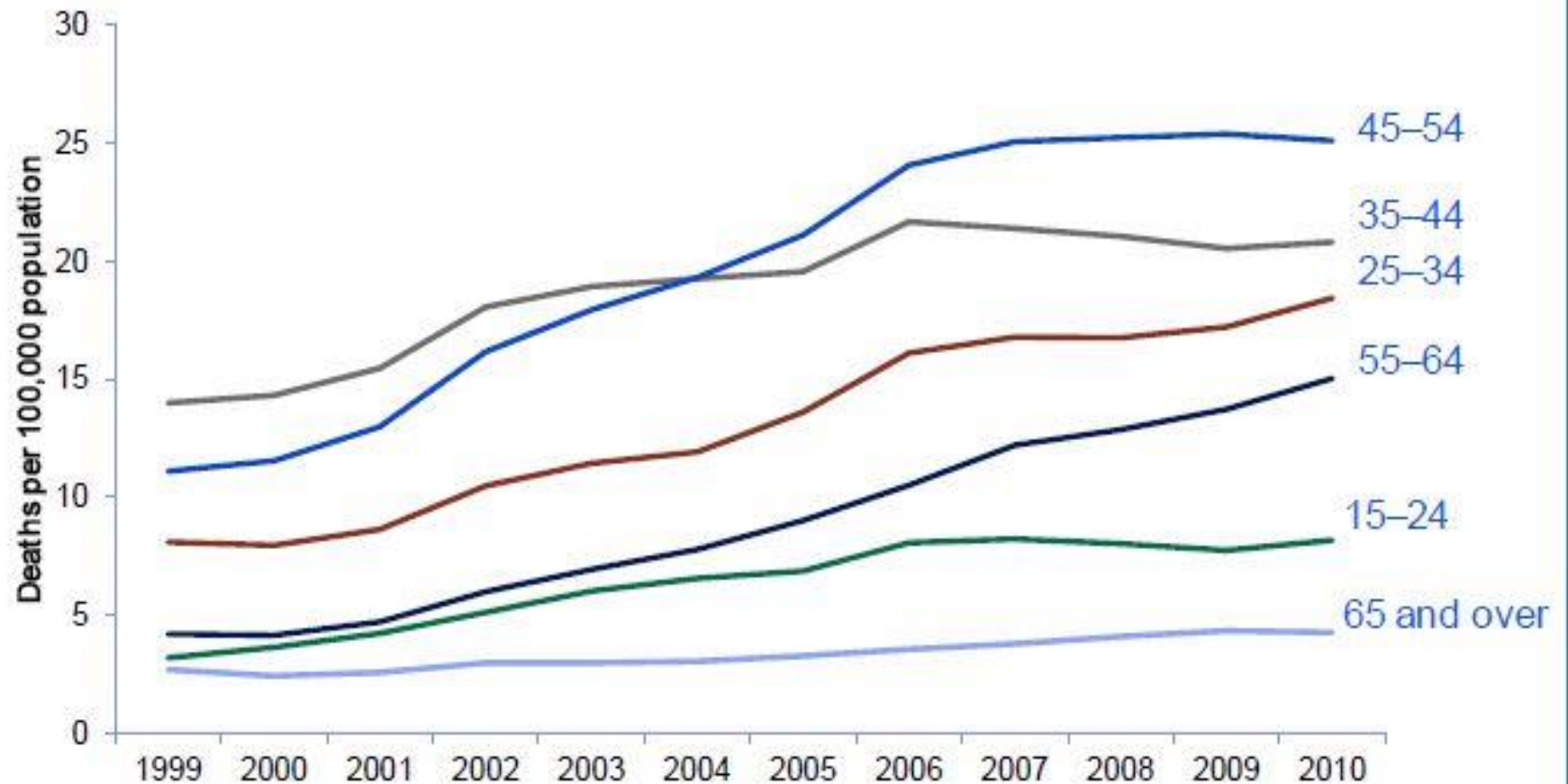


The Opioid Epidemic

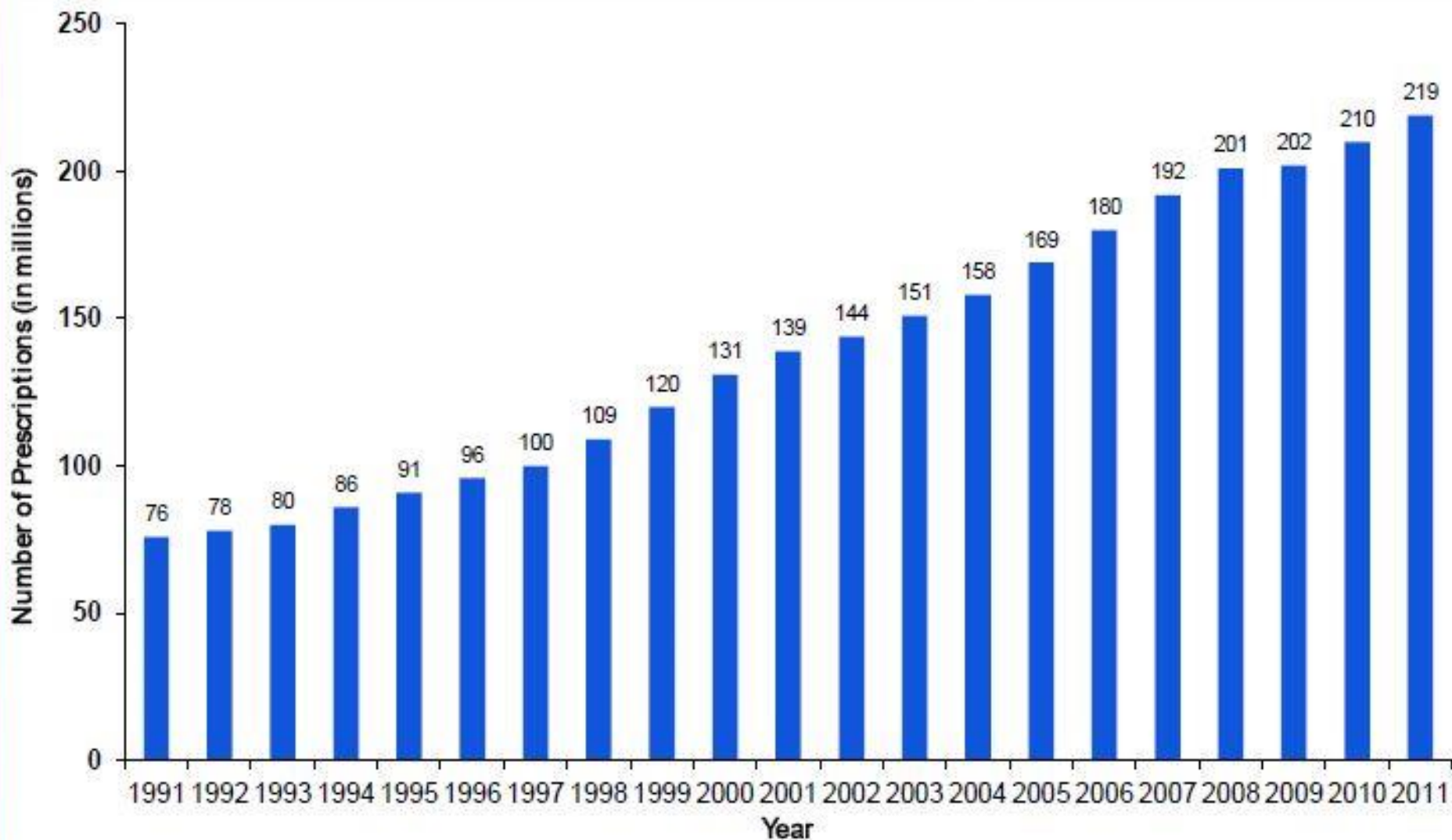
- Physicians
- Pharmacists
- Health Care Institutions



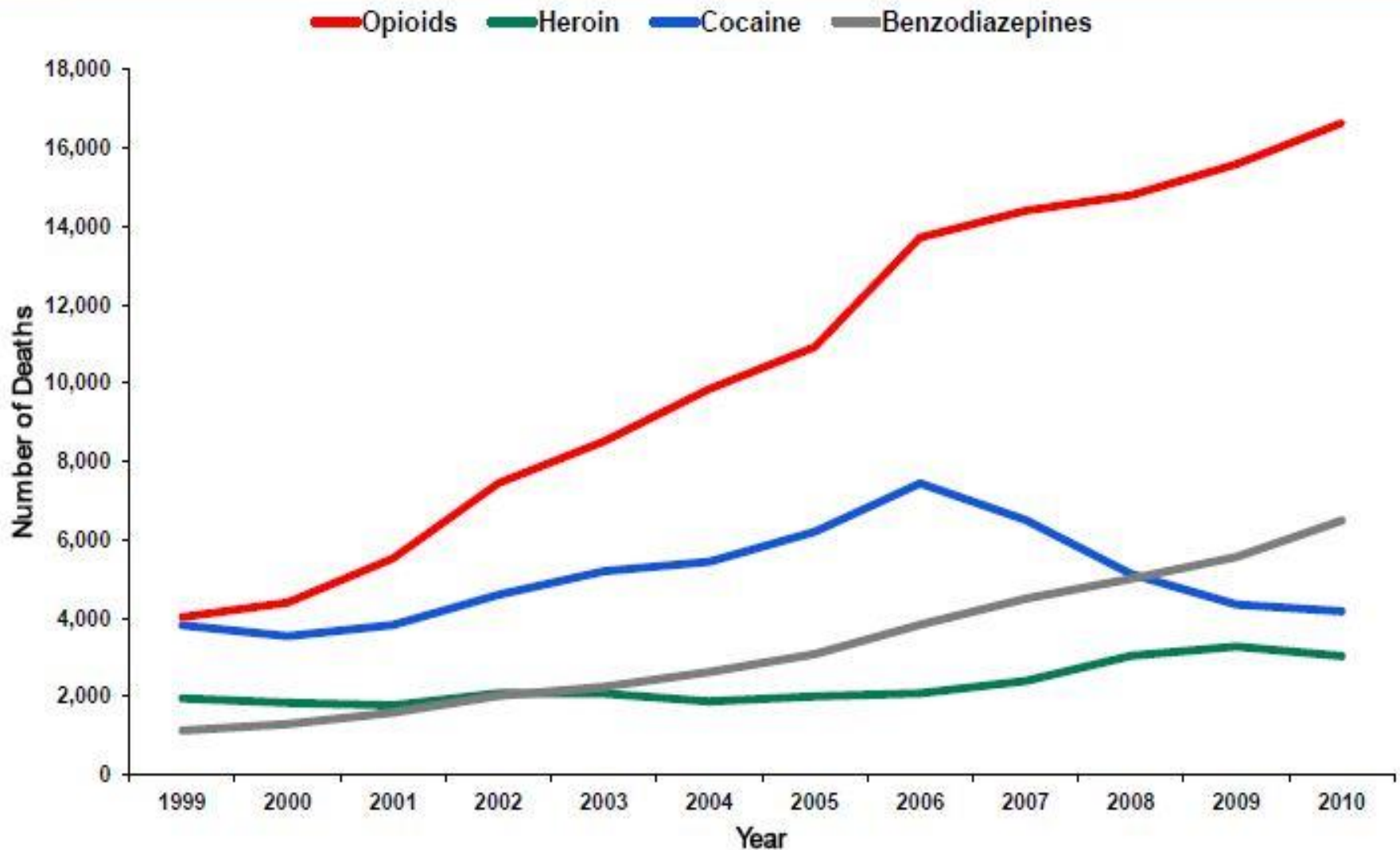
Drug Overdose Death Rates by Age— United States, 1999–2010



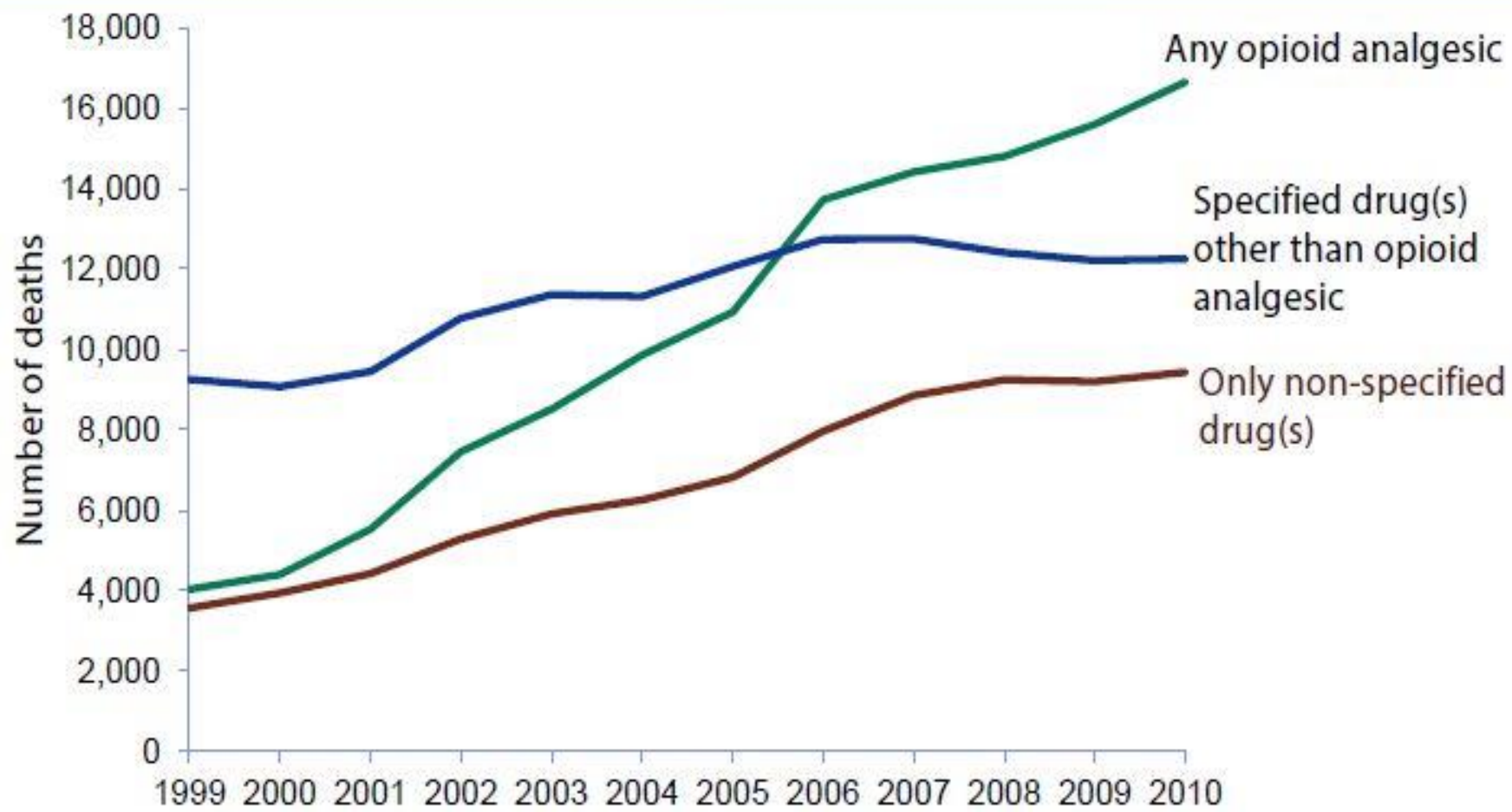
Opioid Prescriptions Dispensed by Retail Pharmacies—United States, 1991–2011



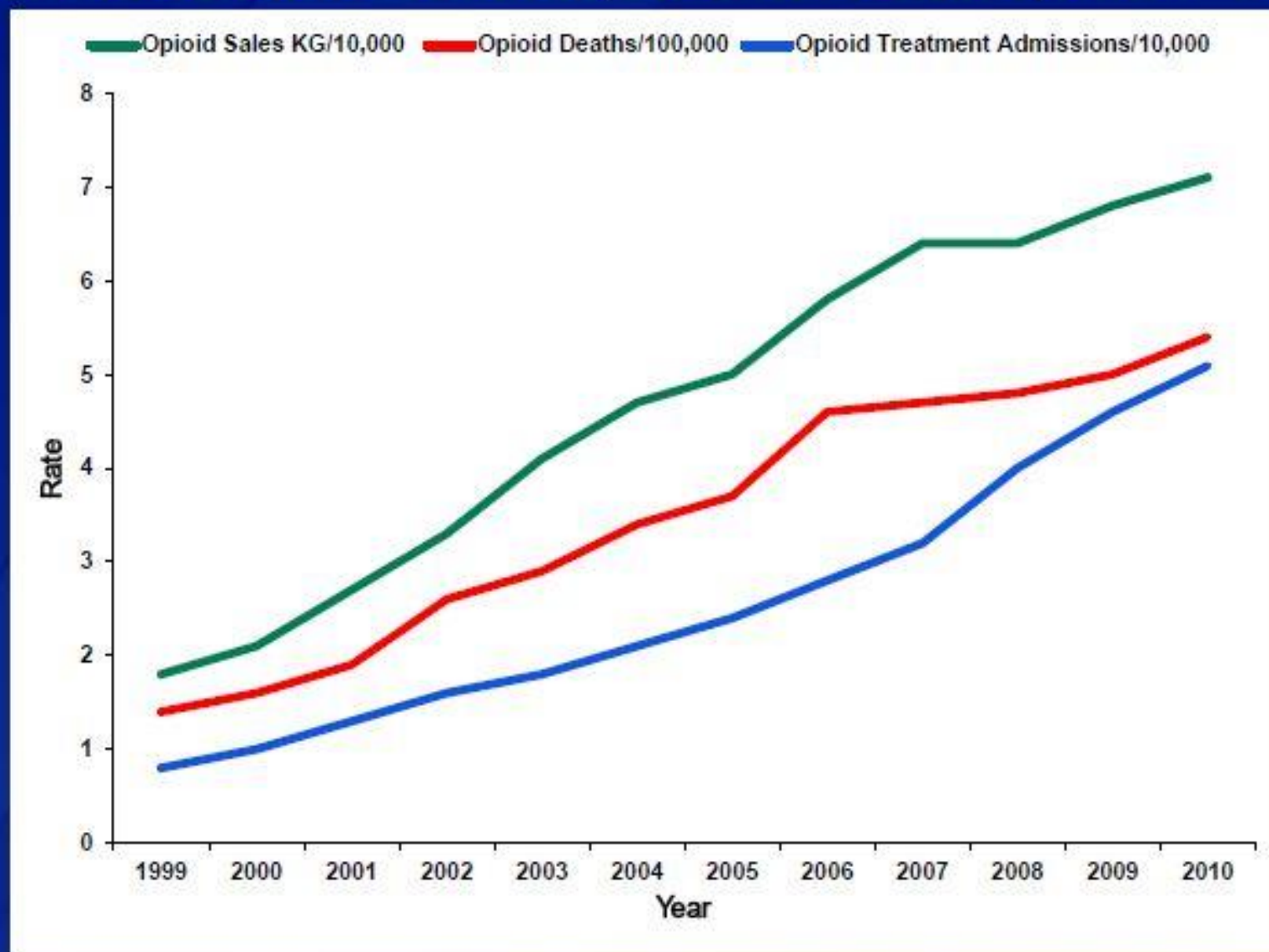
Drug Overdose Deaths by Major Drug Type, United States, 1999–2010



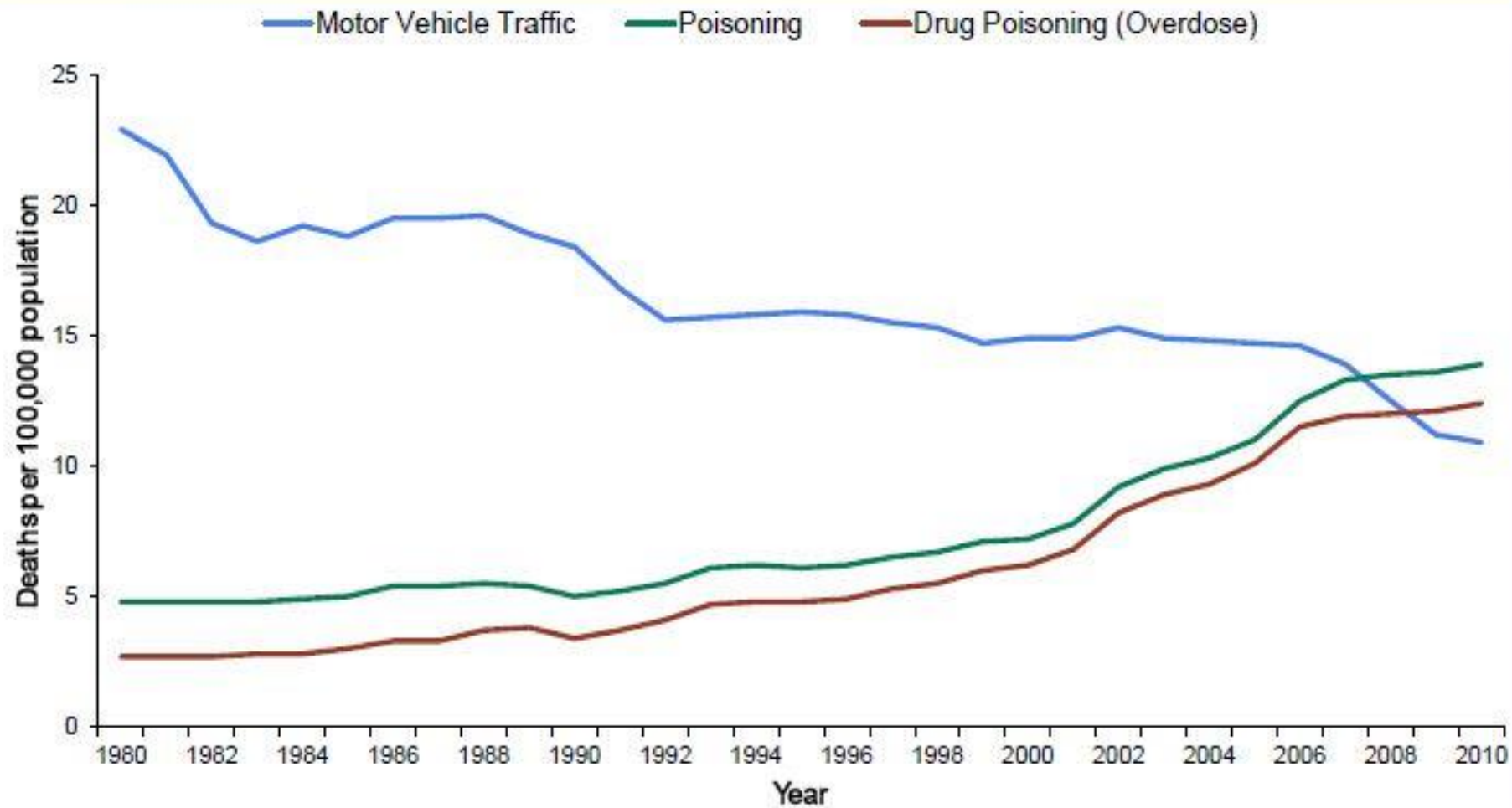
Number of Drug Overdose Deaths Involving Opioid Pain Relievers and Other Drugs United States, 1999–2010



Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, United States, 1999–2010



Motor Vehicle Traffic, Poisoning, and Drug Poisoning (Overdose) Death Rates United States, 1980–2010



A Baby's Life Shouldn't Begin With Detox

Born Drug-Free
FLORIDA

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Florida's Prescription Drug Diversion and Abuse Roadmap 2012–2015



CDC in Context of National Response



EPIDEMIC:
RESPONDING TO AMERICA'S
PRESCRIPTION
DRUG ABUSE CRISIS

2011



- ❑ **Blueprint for federal government**
- ❑ **Focus areas**
 - I. Education
 - II. Monitoring
 - III. Disposal
 - IV. Enforcement
- ❑ **CDC role : fits within our mission and complements other federal agencies**

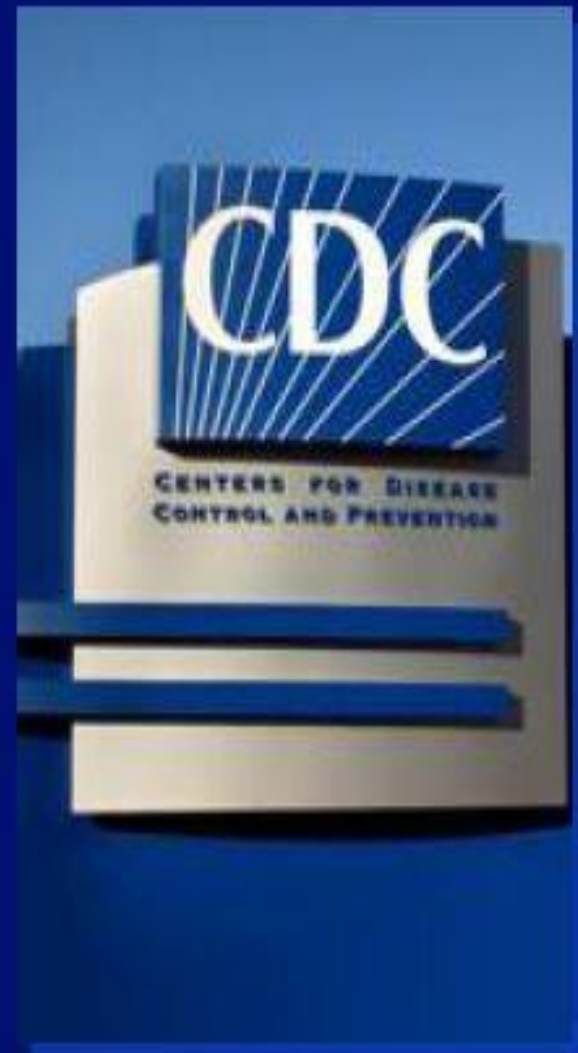
Prescriber Education

- In April 2011, FDA announced the elements of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of extended-release and long-acting (ER/LA) opioid analgesics outweigh the risks.
- As part of the REMS, all ER/LA opioid analgesic companies must provide:

- Education for prescribers of these medications, which will be provided through accredited continuing education (CE) activities supported by independent educational grants from ER/LA opioid analgesic companies.
- Information that prescribers can use when counseling patients about the risks and benefits of ER/LA opioid analgesic use.

Intervention Recommendations

- ❑ Prescription drug monitoring programs
- ❑ Patient review and restriction programs
- ❑ Laws/regulations/policies
- ❑ Insurers and pharmacy benefit managers mechanisms
- ❑ Clinical guidelines



Patient Review and Restriction Programs (aka "Lock-In" Programs)

- ❑ Applies to patients with inappropriate use of controlled substances
- ❑ 1 prescriber and 1 pharmacy for controlled substances
- ❑ Improve coordination of care and ensure appropriate access for patients at high risk for overdose
- ❑ Evaluations show cost savings as well as reductions in ED visits and numbers of providers and pharmacies



Insurer/Pharmacy Benefit Manager (PBM) Mechanisms

- ❑ Reimbursement incentives/disincentives
- ❑ Formulary development
- ❑ Quantity limits
- ❑ Step therapies/prior authorization
- ❑ Real-time claims analysis
- ❑ Retrospective claims review programs

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UnitedHealthcare[®]

 Health Net[®]

 Health Net[®]

Clinical Guidelines

- ❑ Improve prescribing and treatment
- ❑ Basis for standard of accepted medical practice for purposes of licensure board actions
- ❑ Several consensus guidelines available
- ❑ Common themes among guidelines

THE AMERICAN MEDICAL ASSOCIATION, 535 N. Dearborn Street, Chicago, IL 60610-5000
 www.ama-assn.org

Opioid Treatment Guidelines

Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain

Roger Chou,¹ Gilbert I. Fanciulli,² Remy G. Rice,³ Jeremy A. Adler,⁴ Lavin C. Malachuk,⁵ Pamela Casson,⁶ Marilee J. Crookson,⁷ David A. Fortman,⁸ Kirby M. Foley,⁹ Jeffrey Rubin,¹⁰ Aaron M. Gilson,¹¹ Alexander Kufner,¹² Alexander Mazonko,¹³ Patrick O. McCarthy,¹⁴ Steven D. Pevnik,¹⁵ David W. Pickford,¹⁶ Joseph K. Portier,¹⁷ Ben A. Roth,¹⁸ Richard G. Roberts,¹⁹ Kevin H. Todd,²⁰ and Christa M. Sedbrook,²¹ for the American Pain Society-American Academy of Physical Medicine and Rehabilitation

¹Oregon Health Division, Portland, Oregon; ²Department of Medical Information and Clinical Epidemiology, Oregon Health and Science University, Portland, Oregon; ³Pain Management Center, Department of Neurology, Massachusetts General Hospital, Boston, Massachusetts; ⁴Pain Research Center, Department of Anesthesiology, University of Utah, Salt Lake City, Utah; ⁵Health Pain Medicine, University of Colorado, Denver, Colorado; ⁶Division of Pain Medicine, Department of Anesthesiology and Critical Care, Massachusetts General Hospital, Boston; ⁷General Clinical Centers, Seattle, Washington; ⁸Pain Management Clinic, Kaiser Permanente Portland, Portland, Oregon; ⁹Division of Anesthesiology, Neurological Surgery and Pain Management, University of Miami, Miami, Florida; ¹⁰Pain and Palliative Care Service, Department of Neurology, Massachusetts General Hospital, Boston, Massachusetts; ¹¹Division of Pain Management, Department of Anesthesiology, University of Colorado, Denver, Colorado; ¹²Department of Anesthesiology and Pain Medicine, University of Michigan, Ann Arbor, Michigan; ¹³Department of Anesthesiology, University of California, San Francisco, California; ¹⁴Department of Anesthesiology, University of California, San Francisco, California; ¹⁵Department of Anesthesiology, University of California, San Francisco, California; ¹⁶Department of Anesthesiology, University of California, San Francisco, California; ¹⁷Department of Anesthesiology, University of California, San Francisco, California; ¹⁸Department of Anesthesiology, University of California, San Francisco, California; ¹⁹Department of Anesthesiology, University of California, San Francisco, California; ²⁰Department of Anesthesiology, University of California, San Francisco, California; ²¹Department of Anesthesiology, University of California, San Francisco, California.

Abstract: Use of chronic opioid therapy for chronic noncancer pain has increased substantially. The American Pain Society and the American Academy of Physical Medicine and Rehabilitation have developed clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain and recommend a multi-disciplinary approach to the evaluation, prescribing, and treatment of chronic noncancer pain. Although opioids are limited, the expert panel concluded that chronic opioid therapy can be an effective therapy for

AMDG
 AMERICAN MEDICAL GROUP

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

An evidence-based tool to improve outcomes of safety with opioid therapy

What is New in this Revised Guideline

- New data including scientific evidence to support the 130mg MME dosing threshold
- Tools for calculating dosages of opioids during treatment and when tapering
- Updated screening tools for assessing risk factors above threshold and addiction
- Updated lexicon scale for tracking function and pain
- New drug testing guidance and algorithm
- Information on access to monitoring and consultation (including telemedicine options)
- New patient education materials and resources
- Guidance on coordinating with emergency departments to reduce opioid abuse
- New clinical tool and resources to help streamline clinical care

You can find the guideline and related tools at the Washington State Agency Medical Director's site at www.wa.gov/pt/meddir

City Health Information

December 2011 The New York City Department of Health and Mental Hygiene

PREVENTING MISUSE OF PRESCRIPTION OPIOID DRUGS

- Physicians should identify one physician as a major role in reducing risks associated with opioid analgesics, particularly fatal drug overdose.
- For acute pain:
 - If opioids are warranted, prescribe only short-acting agents.
 - A 3-day supply is usually sufficient.
- For chronic noncancer pain:
 - Avoid prescribing opioids unless other approaches to analgesia have been demonstrated to be ineffective.
 - Avoid whenever possible prescribing opioids in patients taking benzodiazepines because of the risk of fatal respiratory depression.

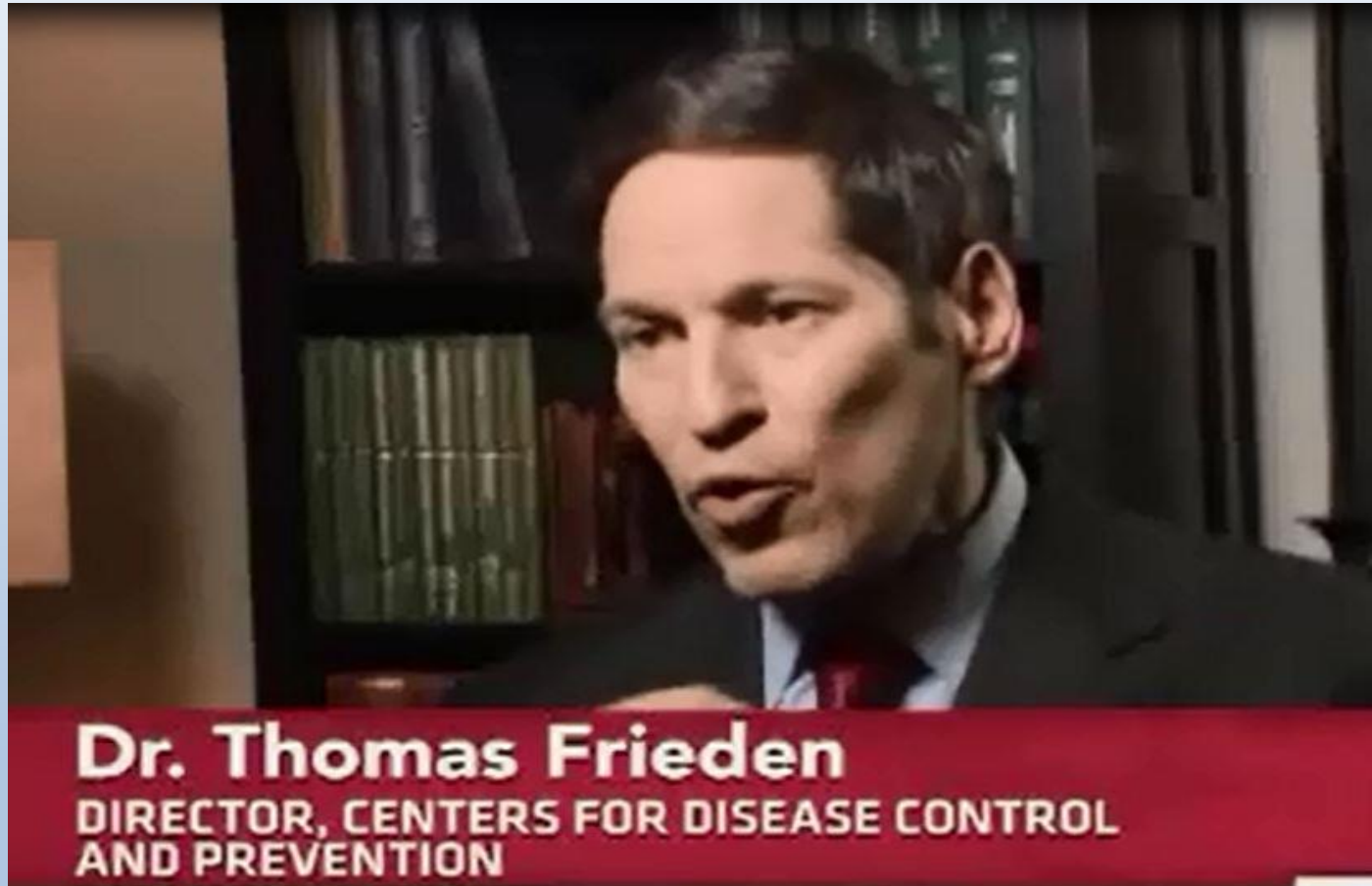
The use of prescription opioids to manage pain has increased in the past 20 years in the United States. Although opioids are indicated and effective for the management of certain types of acute pain and cancer pain, their role in treating chronic noncancer pain is not well established.

Concerns exist with the growing opioid prescribing, especially related health problems have increased. Between 2004 and 2008, the number of emergency department visits for opioid analgesic misuse and abuse in New York City (NYC) more than doubled, rising from approximately 1,000 to more than 3,000 visits.¹ In 2009, 1 in every 4 opioid analgesic prescriptions prescribed in NYC included a patient education card about the risks of opioid drug prescribing, available through the "Be Well NYC" initiative of the Department of Health and Mental Hygiene. The card includes information on recognizing and preventing opioid misuse, including the "Be Well NYC" initiative of the Department of Health and Mental Hygiene. The card includes information on recognizing and preventing opioid misuse, including the "Be Well NYC" initiative of the Department of Health and Mental Hygiene.

Emergency Department Visits for Opioid Misuse and Abuse

The use of prescription opioids to manage pain has increased in the past 20 years in the United States. Although opioids are indicated and effective for the management of certain types of acute pain and cancer pain, their role in treating chronic noncancer pain is not well established.

But Wait...What a Generation of Doctors Learned Was Wrong.



PBS special, 5/2/13

Cautious, Evidence-Based Opioid Prescribing



Despite low-quality evidence supporting practice change,¹⁻⁶ use of chronic opioid therapy (COT) for chronic non-cancer pain increased dramatically over the past two decades.³⁴⁻³⁶ Concurrently, opioid analgesic overdose deaths, addiction, misuse and diversion have increased markedly.^{20,37}

COT may provide modest, variable short-term pain relief for some patients with chronic pain. Long-term benefits of COT for chronic pain have not been established. Potential medical and behavioral harms of opioids are an important concern, particularly at higher dosage levels and in higher risk or medically complex patients. While COT at lower doses may be a useful

Overview of Pharmacist Liabilities

- Pharmacy Robberies
- Criminal Liability
- Civil Liability
- CMS Issues
- Board Investigations

Pharmacy Robberies

- Chain Pharmacies reported 517 armed robberies January '12-January '13
- Retail Pharmacies reported 214 armed robberies January '12-January '13

Pharmacy Armed Robberies

Rankings by State

January 1 thru December 31, 2012 (720)

Rank	State	Total	Rank	State	Total	Rank	State	Total	Rank	State	Total	Rank	State	Total
1	IN	110	12	CO	19	23	MN	10	34	NV	4	45	WY	1
2	AZ	61	13	SC	18	24	AL	10	35	GA	4	46	DE	1
3	OH	43	14	NC	18	25	NH	6	36	MS	3	47	SD	0
4	PA	40	15	OK	17	26	LA	6	37	NE	3	48	ID	0
5	ME	35	16	KY	16	27	MO	6	38	IA	3	49	HI	0
6	CA	34	17	VA	16	28	NM	6	39	KS	2	50	AK	0
7	TN	28	18	FL	16	29	WA	6	40	VT	2			
8	TX	25	19	WI	15	30	AR	6	41	WV	2			
9	MD	25	20	NJ	13	31	OR	5	42	UT	2			
10	MA	23	21	IL	13	32	RI	5	43	PR	2			
11	NY	22	22	MI	12	33	CT	4	44	MT	2			

How Robberies Impact Pharmacies

- Psychological impact
- Loss of employees
- Loss of business
- Time and expense
 - DEA, police and insurance investigation and reporting

“Hardening the Target” – Making the store less attractive

- Employees trained on suspicious persons and behaviors and what to do if a robbery occurs
- Front counter easily visible from the outside
- Video surveillance prominent
- High pharmacy counter
- Bullet resistant glass
- Time delay safe

Response to a Robbery

R

- **React**

E

- **Eyewitness**

A

- **Activate alarm (maybe)**

C

- **Call Police**

T

- **Take charge of the scene**

Mama Bear



Oklahoma pharmacist once called hero, now convicted murderer in attempted robbery

By Tim Talley

Associated Press

POSTED: 05/26/2011 12:01:00 AM CDT | UPDATED: 3 YEARS AGO

OKLAHOMA CITY - A jury Thursday convicted an Oklahoma City pharmacist of first-degree murder, saying he went too far when he pumped six bullets into a teenager who tried to rob the drug store where he worked, and suggested he spend the rest of his life in prison.

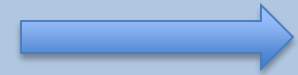
Jerome Ersland, 59, had been hailed as a hero for protecting two co-workers during the May 19, 2009, robbery attempt at the Reliable Discount Pharmacy in a crime-ridden neighborhood in south Oklahoma City.



Why pharmacist liability is so high

- Pharmacists are consistently viewed as the “last line of defense” in making sure a prescription is right – that it is the correct drug, that dosage is correct and that the person should be receiving the prescription

How that applies to prescription narcotics



The Corresponding Responsibility Doctrine

- The United States Controlled Substances Act (CSA) is the statutory basis for federal oversight of controlled substance regulation in the United States.
- The CSA provides the pharmacist an affirmative obligation to only fill prescriptions that are **“issued in the usual course of professional treatment,”** and prescriptions that do not meet this requirement are considered improper.

- The pharmacist **must exercise sound professional judgment** regarding the validity of a prescription prior to dispensing. The pharmacist should not assume that every controlled substance prescription is improper, but rather **take affirmative steps to ensure the prescription's validity**

- (A)n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) **and the person knowingly filling** such a purported prescription, as well as the person issuing it, shall be subject to the **penalties** provided for violations of the provisions of law relating to controlled substances.

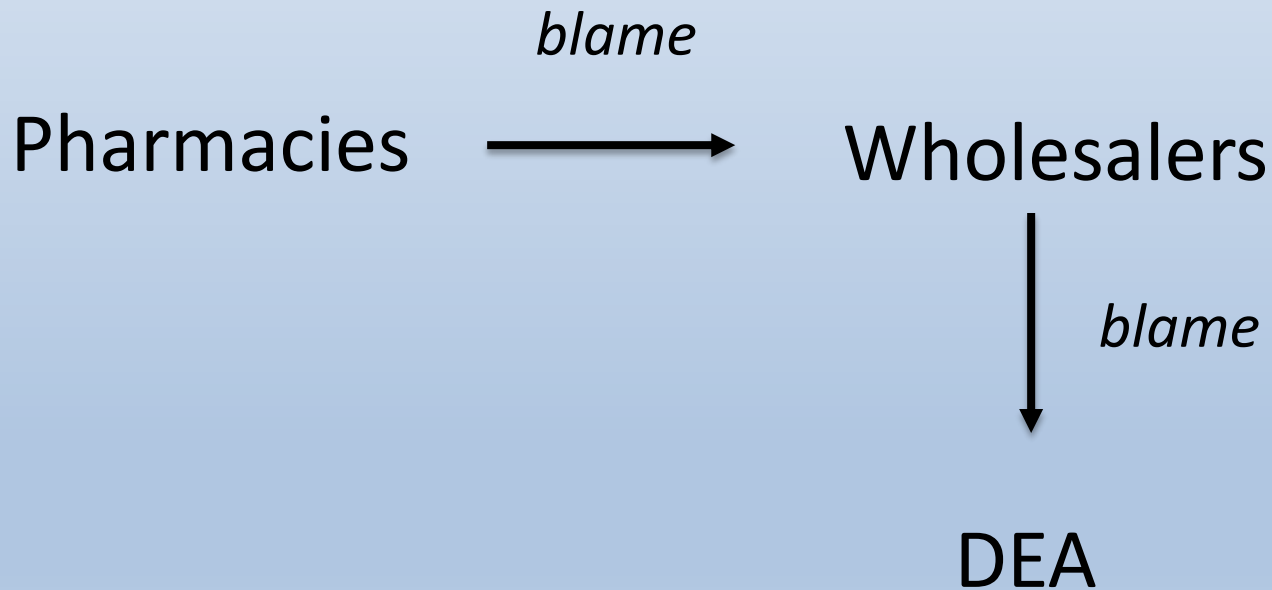
21 C.F.R. § 1306.04(a)

Other Problems



Tipline investigation: The Secret Rx War

Inadequate Supply of Pain Meds to Meet the Medical Needs of the Community



One Response

National Target Drug Good Faith Dispensing Checklist

Patient Name: _____ Rx #: _____ Date: _____

Please select drug & provide strength (tablets/capsules only):

Oxycodone _____ Hydromorphone _____ Methadone _____ Other (optional - district specific) _____

Check boxes that apply to determine if the prescription can be filled. Attach checklist to hard copy of Rx.

	Yes	No	Mandatory Checklist Requirements; Must be Yes to fill prescription.	RPh/Tech. Initials
1	<input type="checkbox"/>	<input type="checkbox"/>	Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up.	
2	<input type="checkbox"/>	<input type="checkbox"/>	No GFD refusal for this particular prescription in patient comments on IC+ profile.	
3	<input type="checkbox"/>	<input type="checkbox"/>	If available in your state, PDMP has been reviewed, printed and attached to hard copy.	
			Additional Checklist Requirements; every "no" is a red flag. Use your professional judgment to assess the prescription.	
4	<input type="checkbox"/>	<input type="checkbox"/>	Patient has received this prescription from Walgreens before.	
5	<input type="checkbox"/>	<input type="checkbox"/>	This prescription is from the same prescriber for the same medication as the previous fill.	
6	<input type="checkbox"/>	<input type="checkbox"/>	Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained.	
7	<input type="checkbox"/>	<input type="checkbox"/>	Prescription is being filled on time.	
8	<input type="checkbox"/>	<input type="checkbox"/>	3rd Party Insurance is billed (cash or a cash discount card is a red flag).	
9	<input type="checkbox"/>	<input type="checkbox"/>	Quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card.	
10	<input type="checkbox"/>	<input type="checkbox"/>	Patient has been on this same medication strength and dose for less than 6 months.	

If in your professional judgement a call to the prescriber is warranted, review step 11.

If no call is required, complete this form with your signature.

11.	<input type="checkbox"/>	<input type="checkbox"/>	<p>Call to Prescriber</p> <p>To begin the conversation with the prescriber, verify/confirm any number of the following points (document in notes section).</p> <ul style="list-style-type: none"> *Prescription is written within prescriber's scope of practice *Diagnosis *Therapeutic regimen is within standard of care *Expected length of treatment *Date of last physical and pain assessment *Use of alternative/lesser prescription medications for pain control *Coordination with other clinicians involved in patient care <p>For Hospice and Oncology patients only:</p> <p>If unable to reach the prescriber, RPh may fill the Rx without verification by the prescriber provided the elements of Good Faith Dispensing are met.</p>	
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attest that I have used the Good Faith Dispensing Checklist validation procedures and my professional judgement to review this prescription and I have:

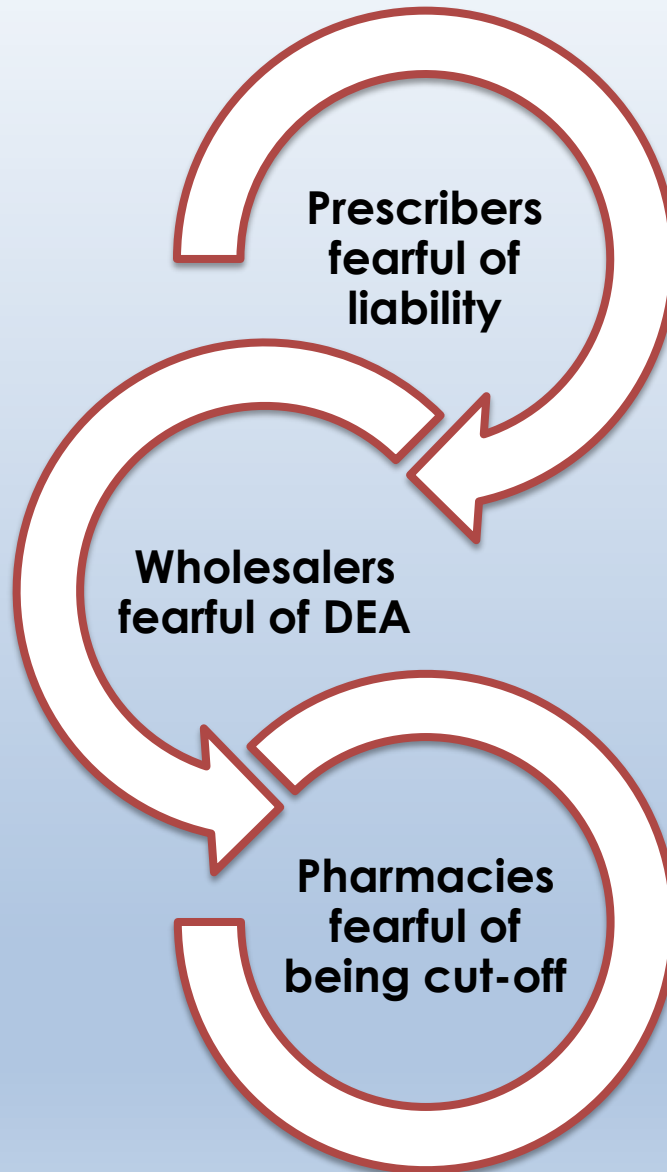
- Dispensed: Product review Pharmacist signature _____
- Refused: Pharmacist signature _____
- (RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)

Possible “red flags” that could lead to the prescription being denied include:

- A pain medication not previously filled at Walgreens
- A new doctor writing a prescription for the same pain medication
- A doctor writing a prescription who is not in a “reasonable geographic location” near the pharmacy.

- A patient paying for a prescription in cash
- A patient seeking an early refill of a prescription
- A patient seeking an “excessive” number of pills
- A patient taking the same pain medication for more than 6 months

Viscous cycle



Staff and Employee Vetting



Traveling medical technician who was charged in July with causing an outbreak of Hep C in New Hampshire.

New US House bill would require drug testing for pharma employees

By Zachary Brennan, 26-Feb-2014

Pharma industry employees and wholesalers with access to narcotic APIs would be subject to background checks and drug testing under new proposals being considered in the US.

<http://www.in-pharmatechnologist.com/Regulatory-Safety/New-US-House-bill-would-require-drug-testing-for-pharma-employees>

**Andrew Kolodny, M.D.** Become a fanChief Medical Officer of Phoenix House and President of
Physicians For Responsible Opioid Prescribing

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8

Zohydro: The FDA-Approved Prescription for Addiction

Posted: 02/26/2014 12:05 am EST | Updated: 02/26/2014 12:59 am EST



In a few weeks, a powerful new opioid painkiller called Zohydro is expected to hit the market. Zohydro's easily crushed capsules will contain up to 50 milligrams of pure hydrocodone; that's 10 times more hydrocodone than a regular Vicodin. One capsule will pack enough hydrocodone to kill a child. An adult lacking a tolerance to opioids could overdose from taking just two capsules.

Many folks on the front line of our nation's opioid-addiction epidemic were shocked that the FDA approved Zohydro despite the strong objection of an FDA advisory committee, which voted 11-to-2 against it. This may be the first time in history that the FDA will allow a drug to be released despite a landslide vote to keep it off the market.

Concerned about FDA approval of Zohydro? You are in good company. This morning a letter signed by more than 40 organizations was sent to FDA Commissioner Hamburg, urging her to keep Zohydro off the market. The organizations include some of the most prominent addiction-treatment agencies in the country, including Hazelden, Caron, and Phoenix House. Other co-signers include CASAColumbia, the American Society of Addiction Medicine, Blue Cross Blue Shield, the consumer advocacy group Public Citizen, and dozens of community-based addiction-prevention organizations.

Understandably, concerns about Zohydro have focused on the fact that, like the original version of OxyContin, it can be easily crushed -- a feature that makes it especially lethal. But there are other good reasons to be concerned about Zohydro. It isn't just bad for so-called "abusers" who crush the capsules; Zohydro's risks will also outweigh benefits when swallowed whole by the chronic-pain patients Zohydro's maker is targeting.

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