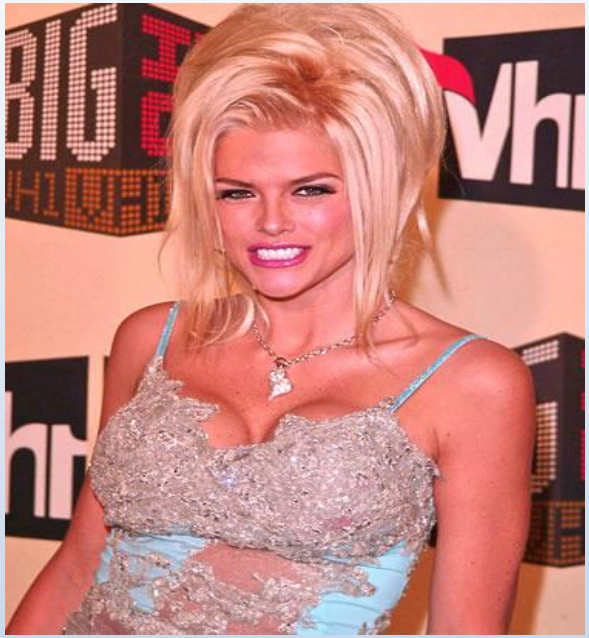
The Opioid Epidemic

- Physicians
- Pharmacists
- Health Care Institutions


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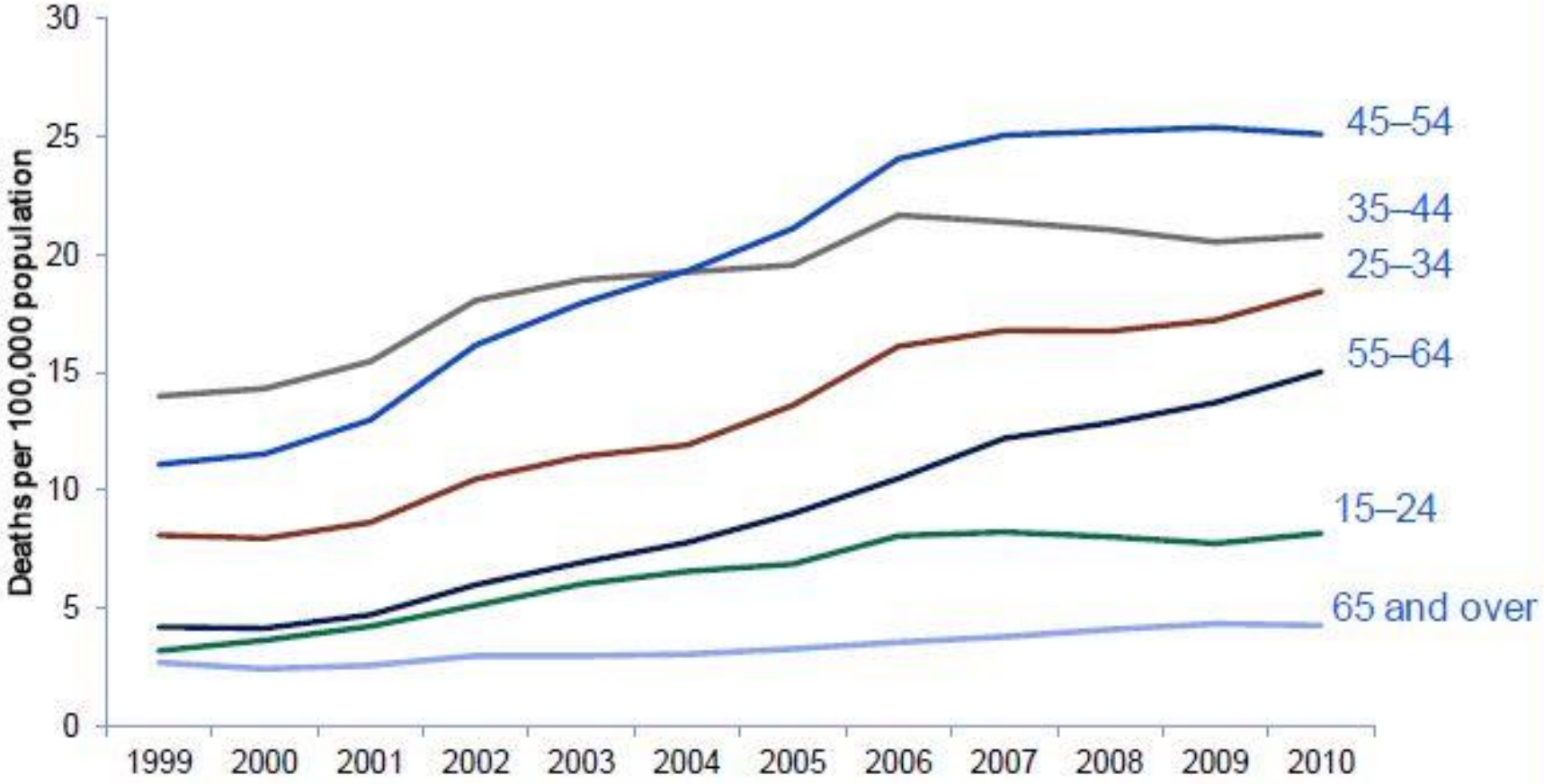
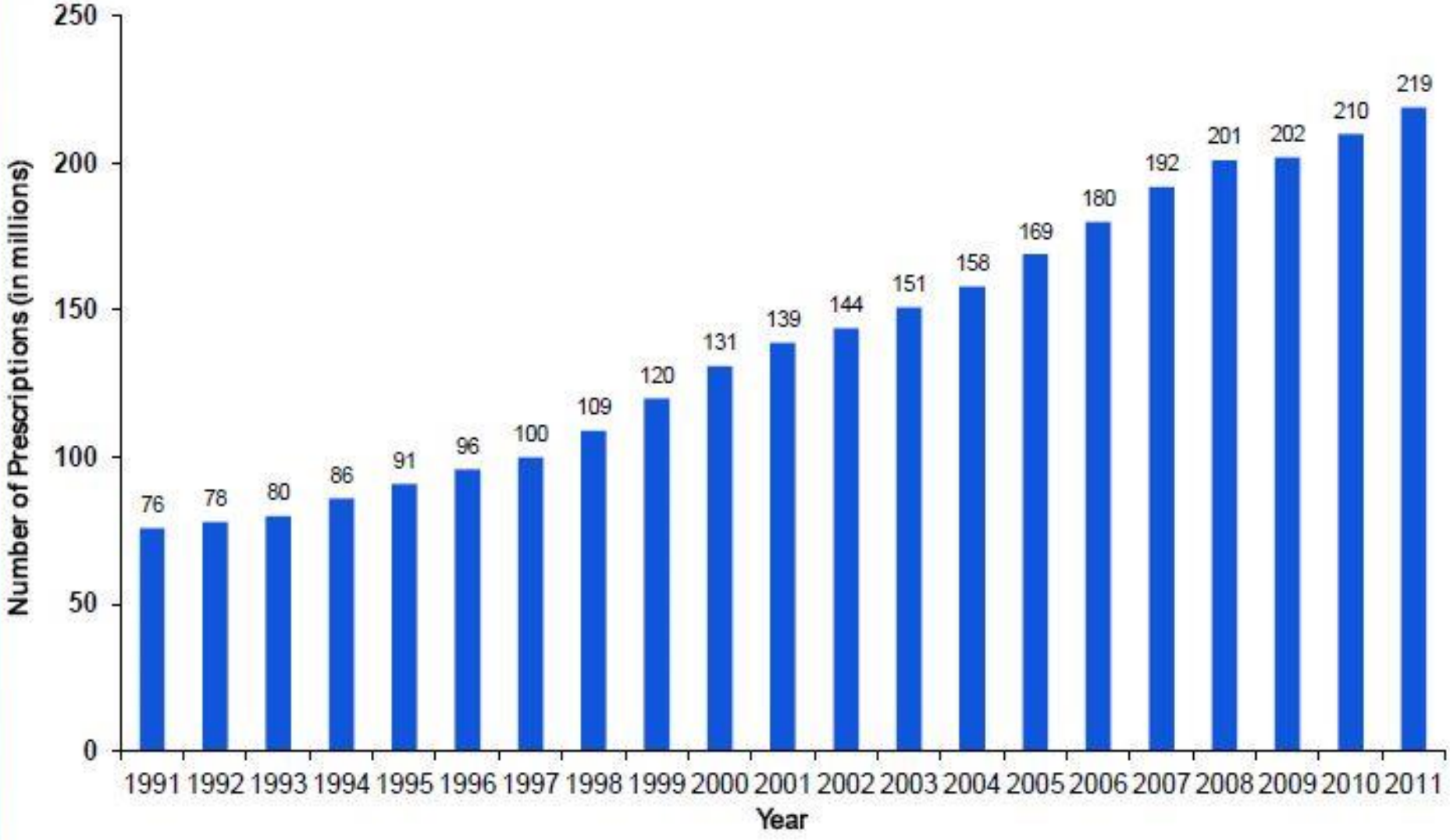
Drug Overdose Death Rates by Age—United States, 1999–2010



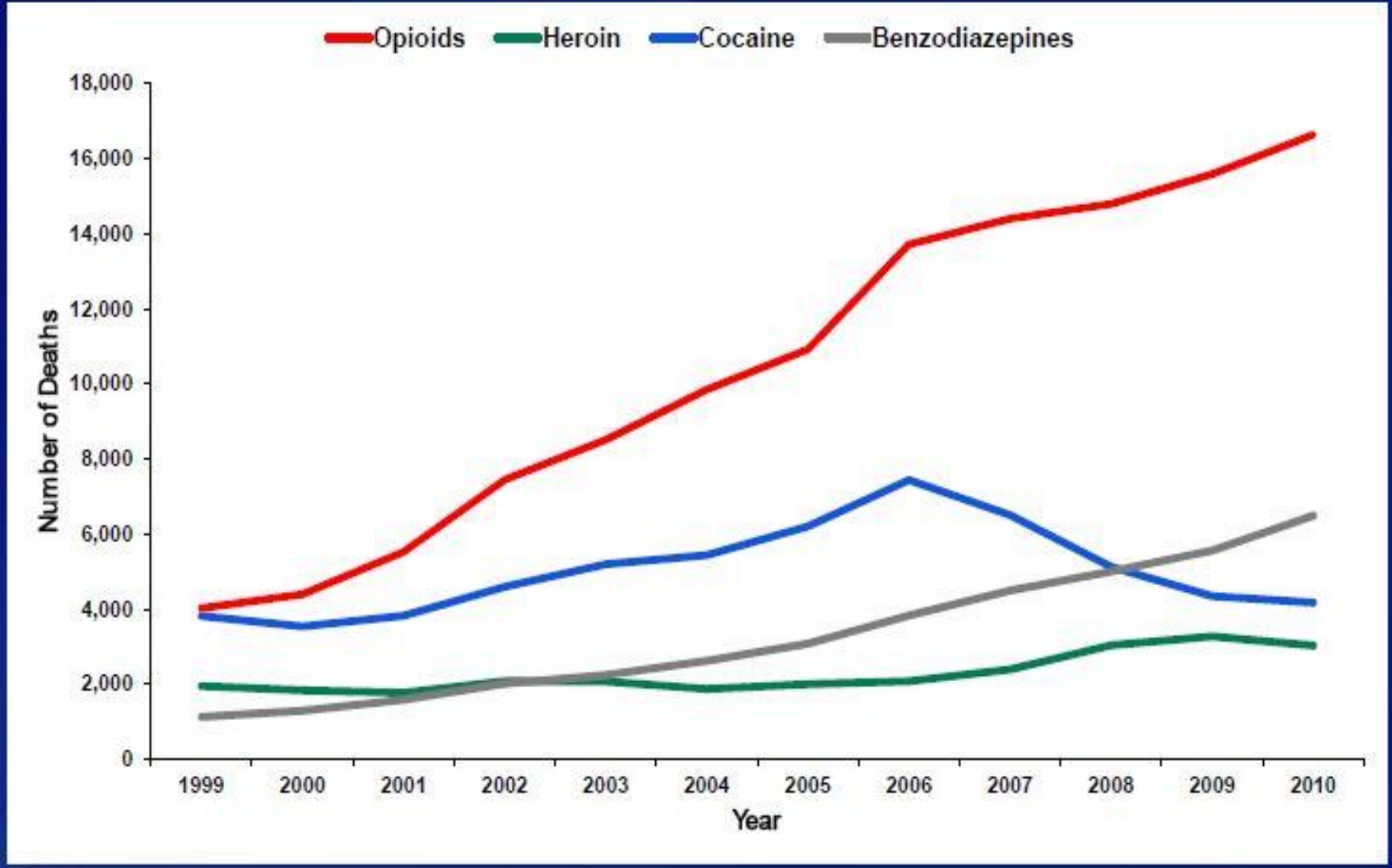
CDC, NCHS, National Vital Statistics System.

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



IMS Vector One. From "Prescription Drug Abuse: It's Not what the doctor ordered." Nora Volkow National Prescription Drug Abuse Summit, April 2012. Available at http://www.slideshare.net/OPUNITE/nora-volkow-final-edits.

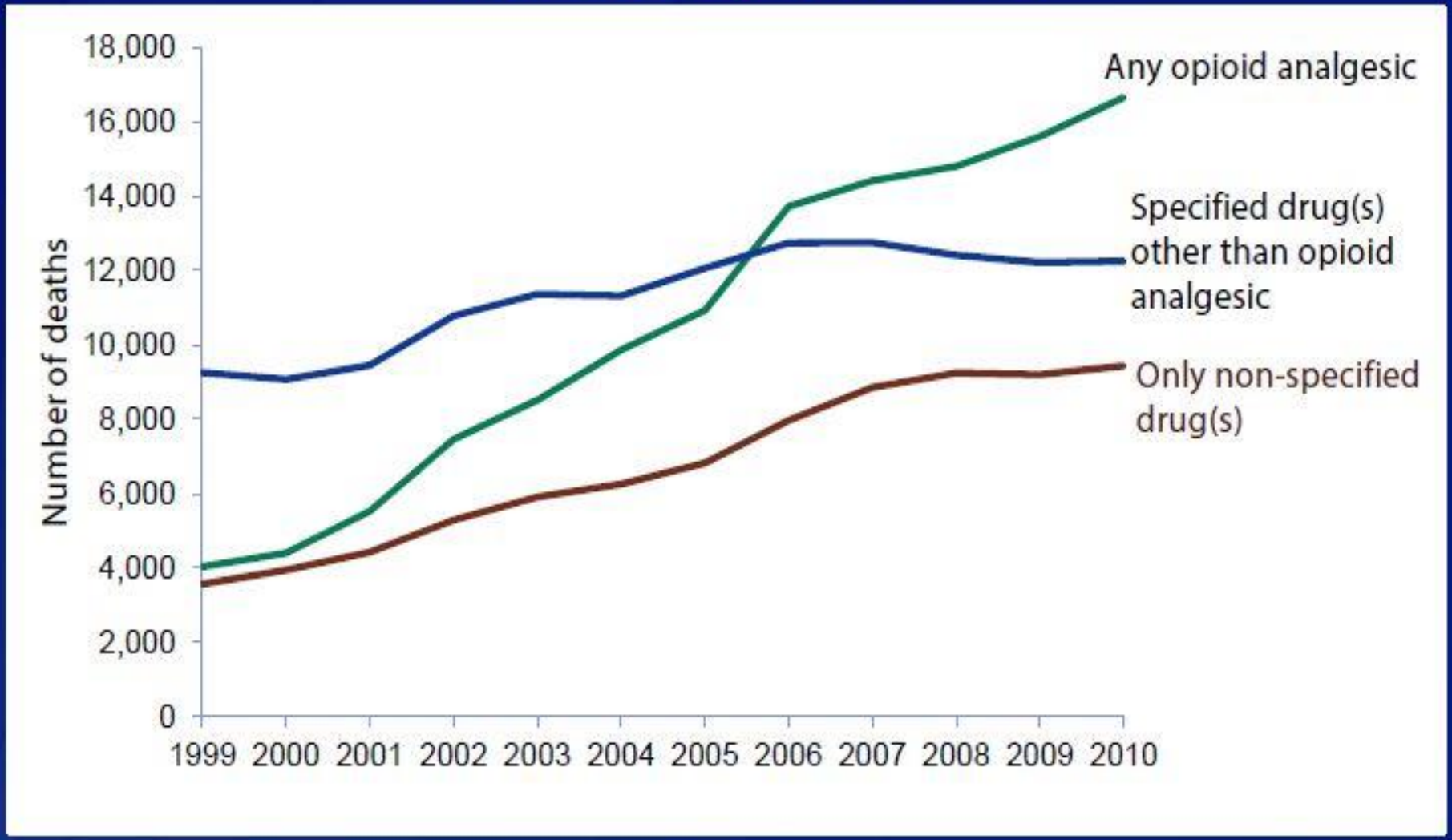
Drug Overdose Deaths by Major Drug Type, United States, 1999–2010



CDC, National Center for Health Statistics, National Vital Statistics System, CDC Wonder. Updated with 2010 mortality data.

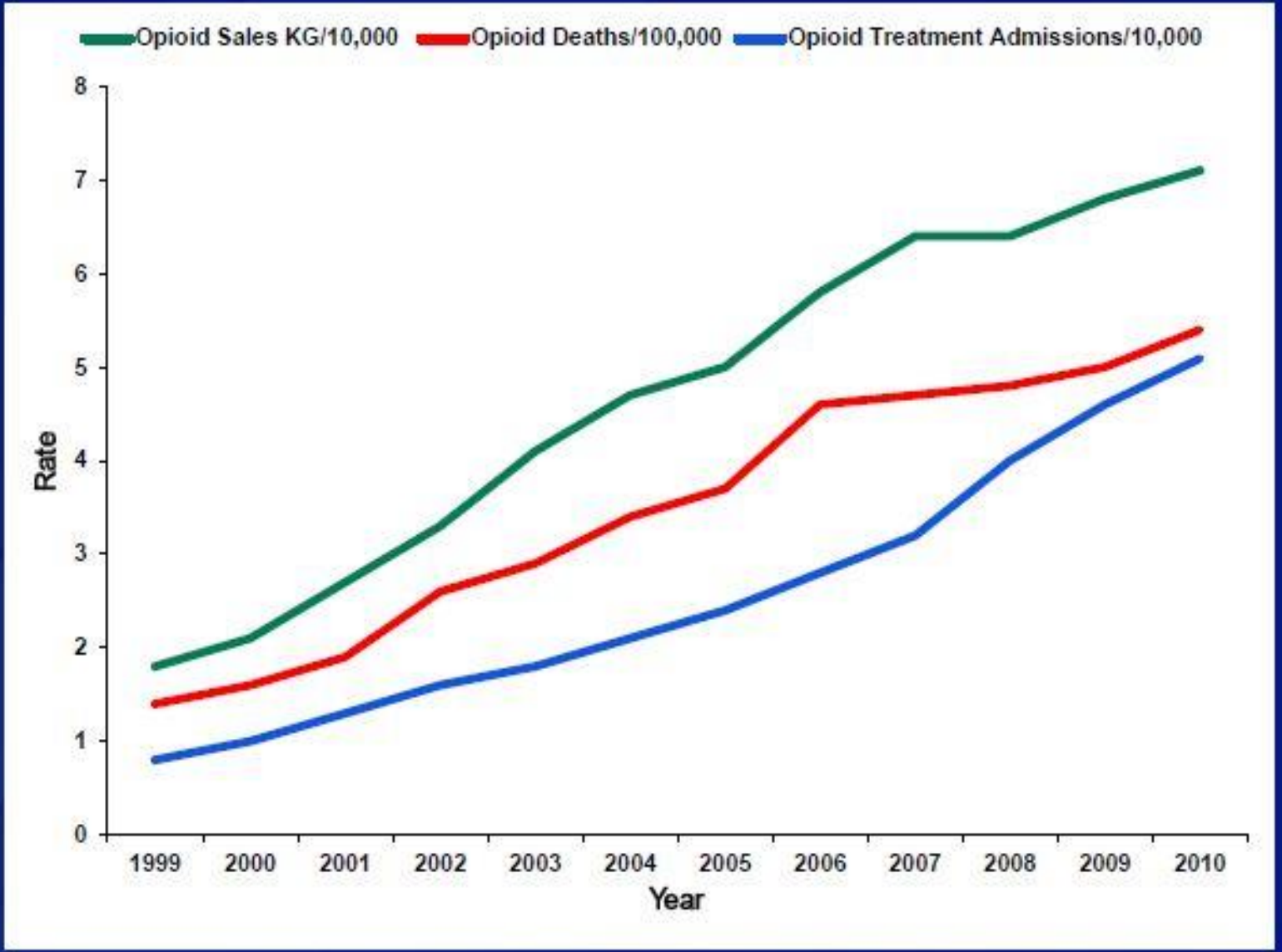
Number of Drug Overdose Deaths Involving Opioid Pain Relievers and Other Drugs

United States, 1999–2010



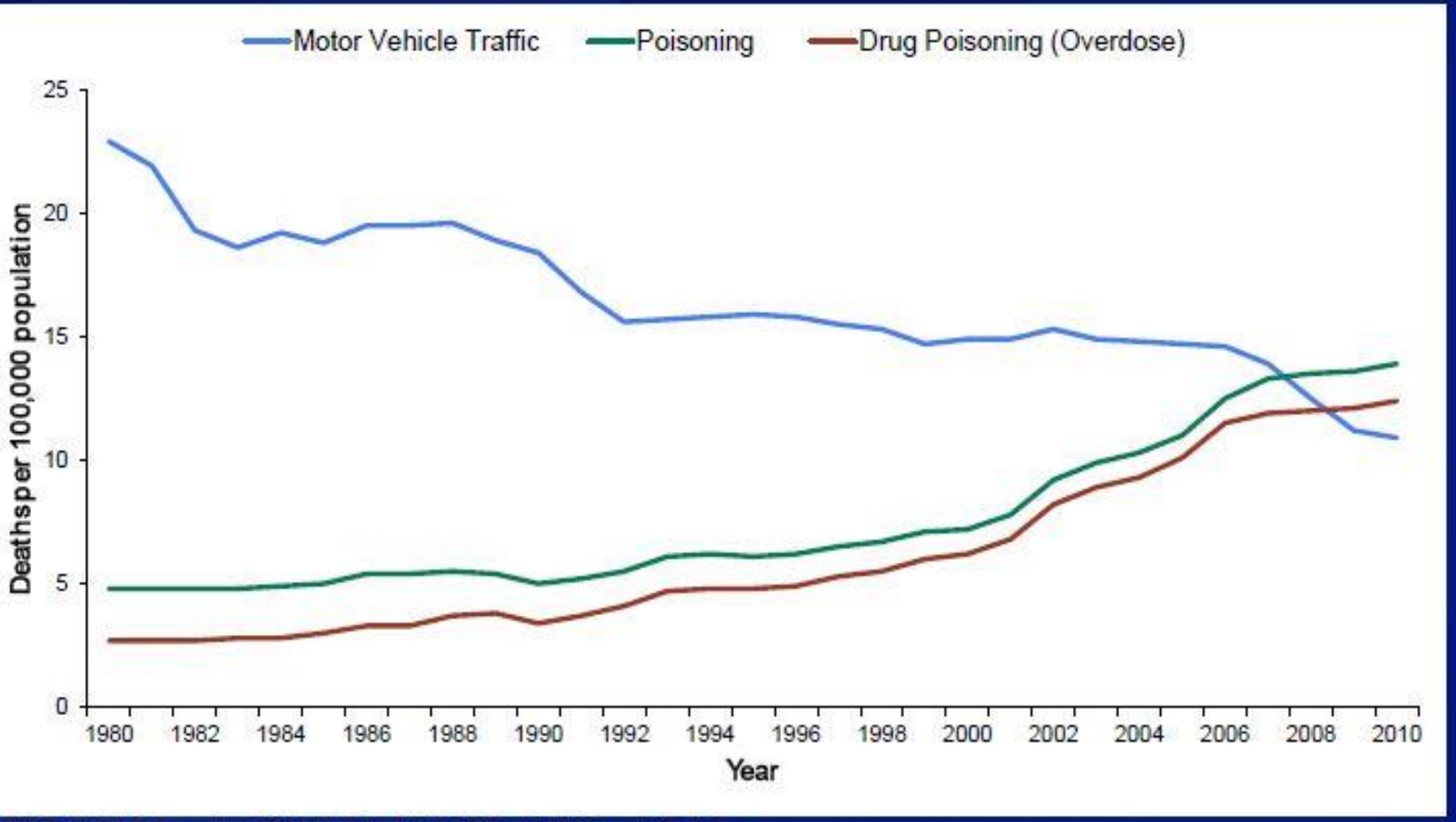
CDC, National Center for Health Statistics, National Vital Statistics System.

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



CDC. *MMWR* 2011 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm60e1101a1.htm?s_cid=mm60e1101a1_w Updated with 2009 mortality and 2010 treatment admission data.

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



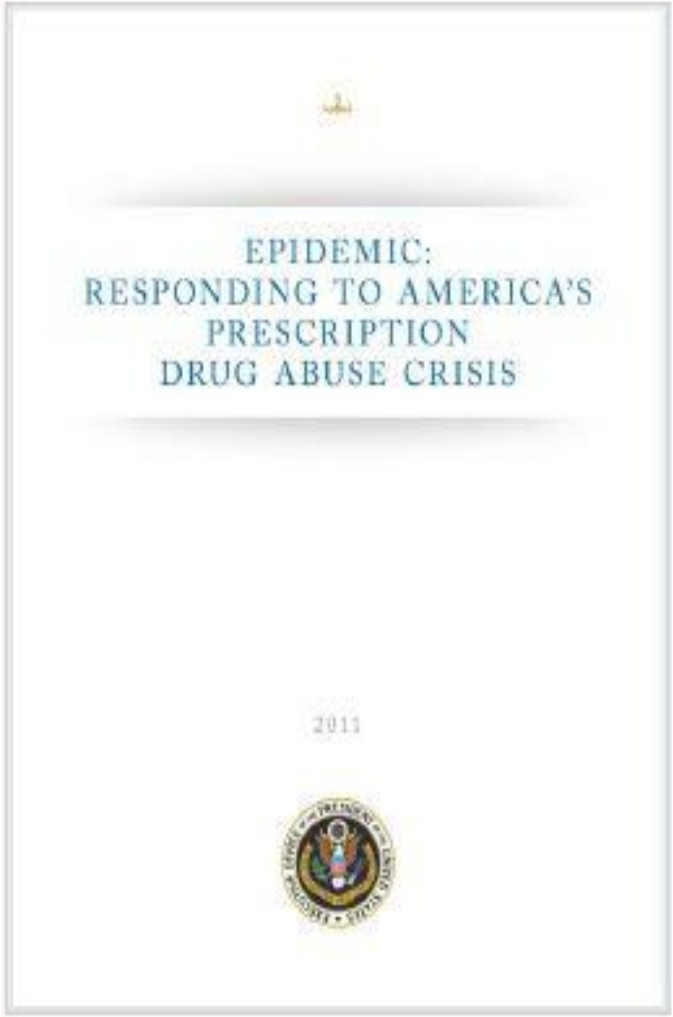
NCHS Data Brief, December, 2011. Updated with 2009 and 2010 mortality data.

A Baby's Life Shouldn't Begin With Detox

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

http://myfloridalegal.com/webfiles.nsf/WF/KGRG-T8L5K/$file/PrescriptionDrugDiversionAndAbuseRoadmap.pdf

CDC in Context of National Response



- 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.

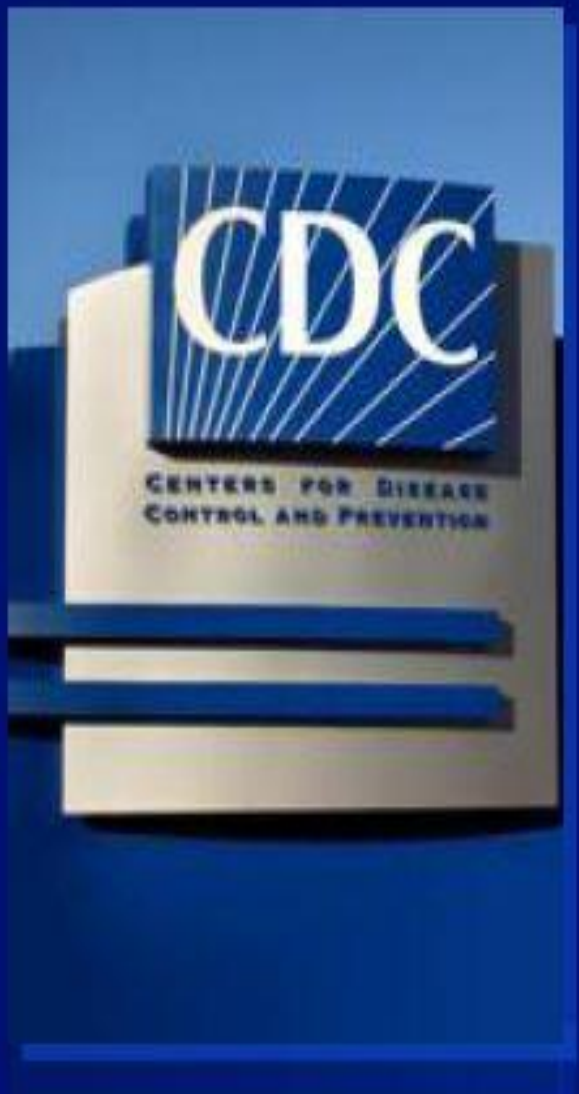
- As part of the REMS, all ER/LA opioid analgesic companies must provide:

- 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)

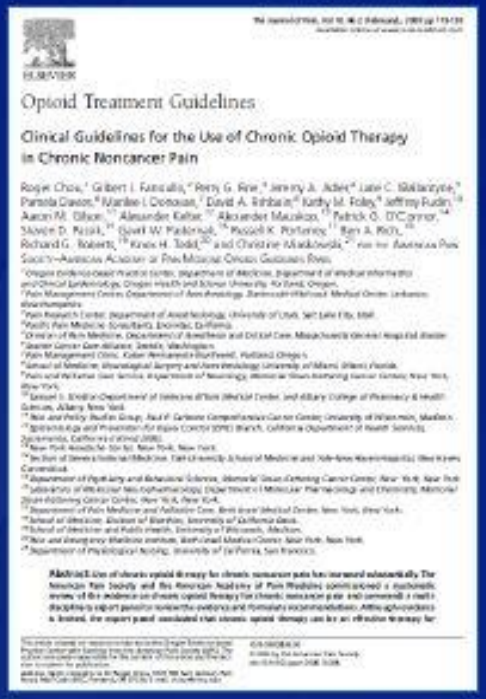
- Applies to patients with inappropriate use of controlled substances
- 1 prescriber and 1 pharmacy for controlled substances
- Improve coordination of care and ensure appropriate access for patients at high risk for overdose
- Evaluations show cost savings as well as reductions in ED visits and numbers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

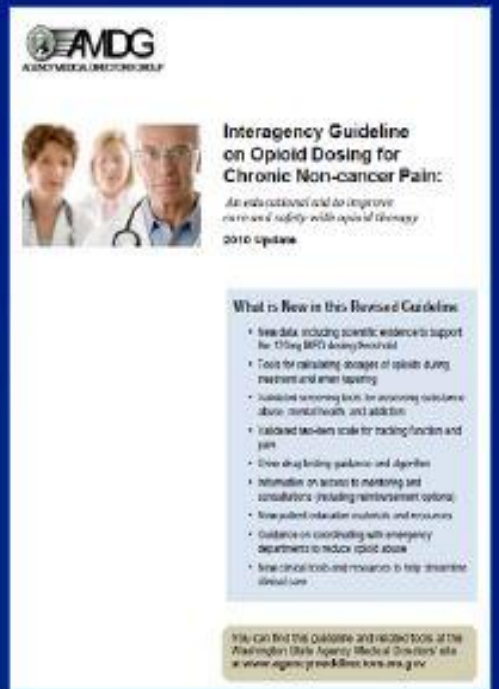
Clinical Guidelines

- 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



Opioid Treatment Guidelines

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



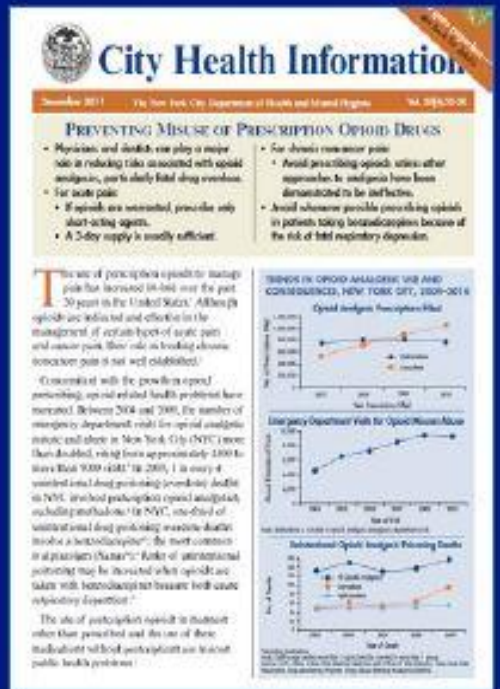
AMDG

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

An evidence-informed tool to improve outcomes and safety with opioid therapy

2010 Update

What is New in this Revised Guideline



City Health Information

Preventing Misuse of Prescription Opioid Drugs

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			

Source: DEA Drug Theft & Loss Database as of January 9, 2013

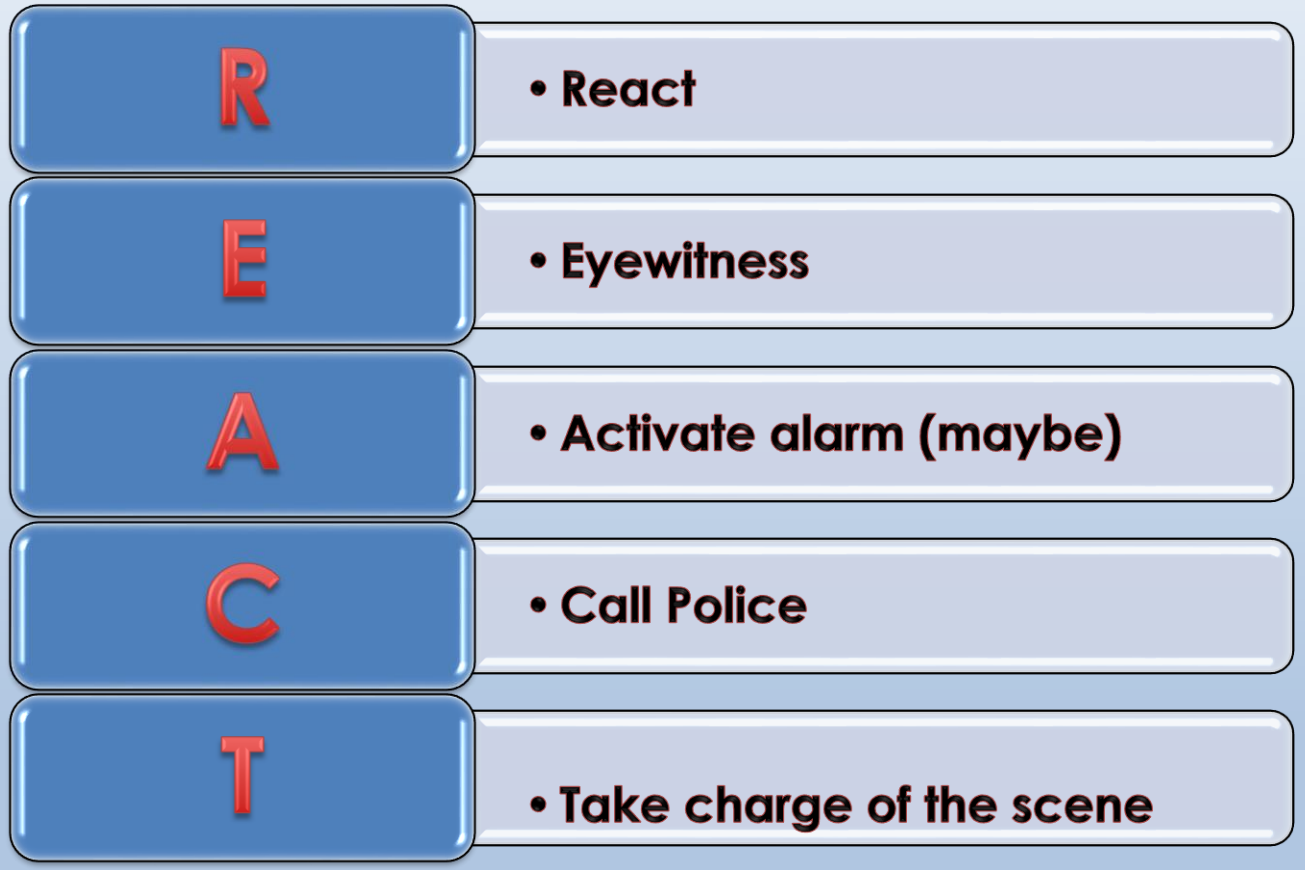
How Robberies Impact Pharmacies

- 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



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**

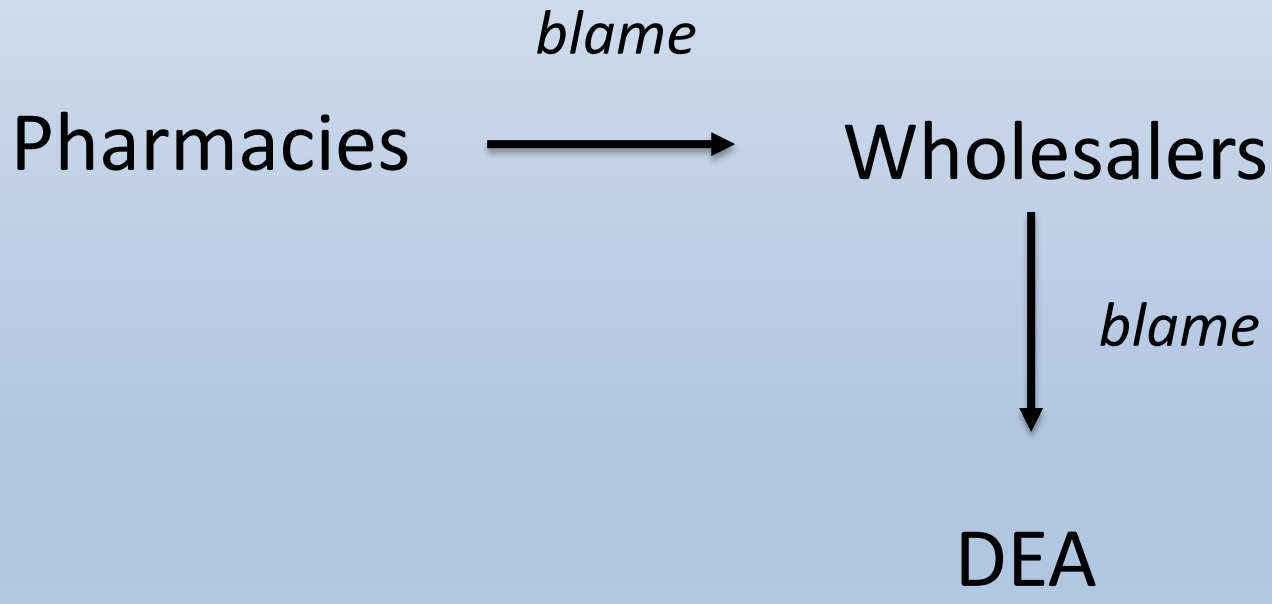
- (A)n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) **and the person knowingly filling** such a purported prescription, 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	☐	☐	Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up.	
2	☐	☐	No GFD refusal for this particular prescription in patient comments on IC+ profile.	
3	☐	☐	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	☐	☐	Patient has received this prescription from Walgreens before.	
5	☐	☐	This prescription is from the same prescriber for the same medication as the previous fill.	
6	☐	☐	Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained.	
7	☐	☐	Prescription is being filled on time.	
8	☐	☐	3rd Party Insurance is billed (cash or a cash discount card is a red flag).	
9	☐	☐	Quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card.	
10	☐	☐	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	☐	☐	**Call to Prescriber** To begin the conversation with the prescriber, verify/confirm any number of the following points (*document in notes section*). *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 **For Hospice and Oncology patients only:** 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.

I 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 _____

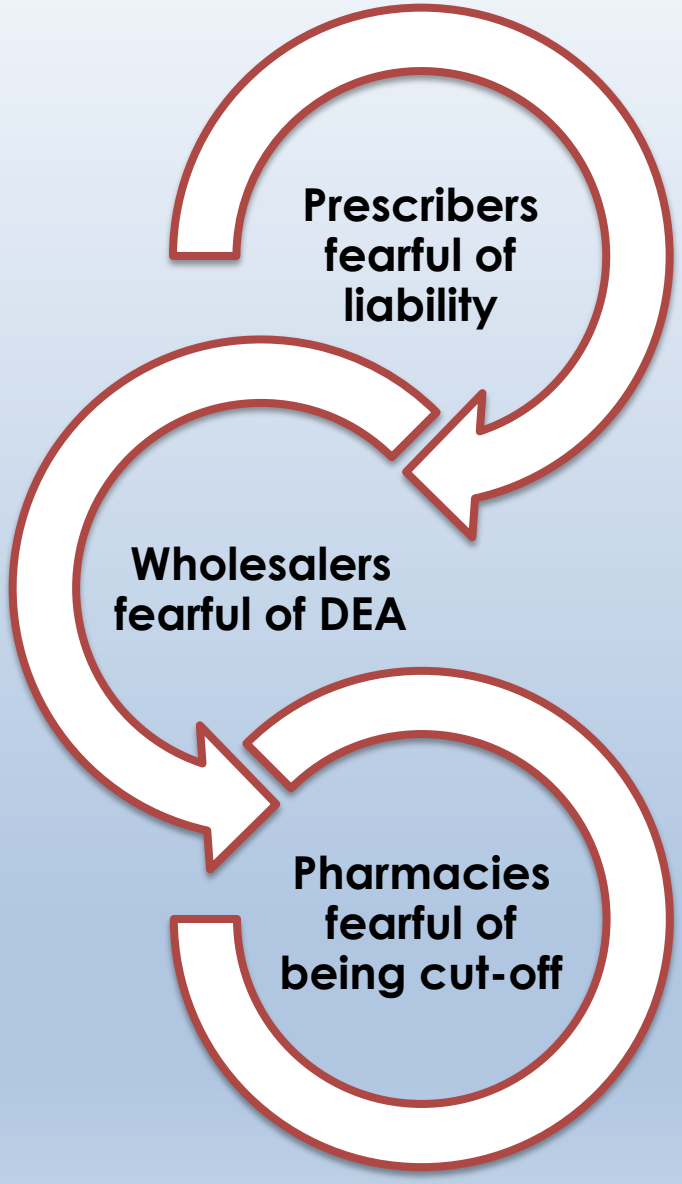
(RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)

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

February 27, 2014
HUFF POST SCIENCE

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

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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