

Legal Aspects of Overdose Prevention

22st National Conference on
Pharmaceutical and Chemical Diversion

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Network for Public Health Law

Overview

- Opioid overdose is at epidemic levels
- Opioid overdose death is largely preventable
 - Much of increase related to inappropriate prescribing
 - Evidence-based treatment is available
 - Overdose typically reversible w/ naloxone
- Law, regulation, policy and administrative inertia contribute to overdose in many ways
- Important for all parties to work together

Overdose Prevention Continuum

Reducing improper prescribing

- Use of PMPs with best practices
- Non-opioid therapy
- Prescriber and dispenser education
- Modification of insurance incentives (e.g. methadone as pain treatment)
- Care coordination
- Enforcement efforts

Addressing addiction

- Provider education
- Increased access to evidence-based treatment
- Acknowledgement of addiction as medical condition
- Pharmacy lock-in where appropriate
- Jail diversion programs

Improving access to overdose care

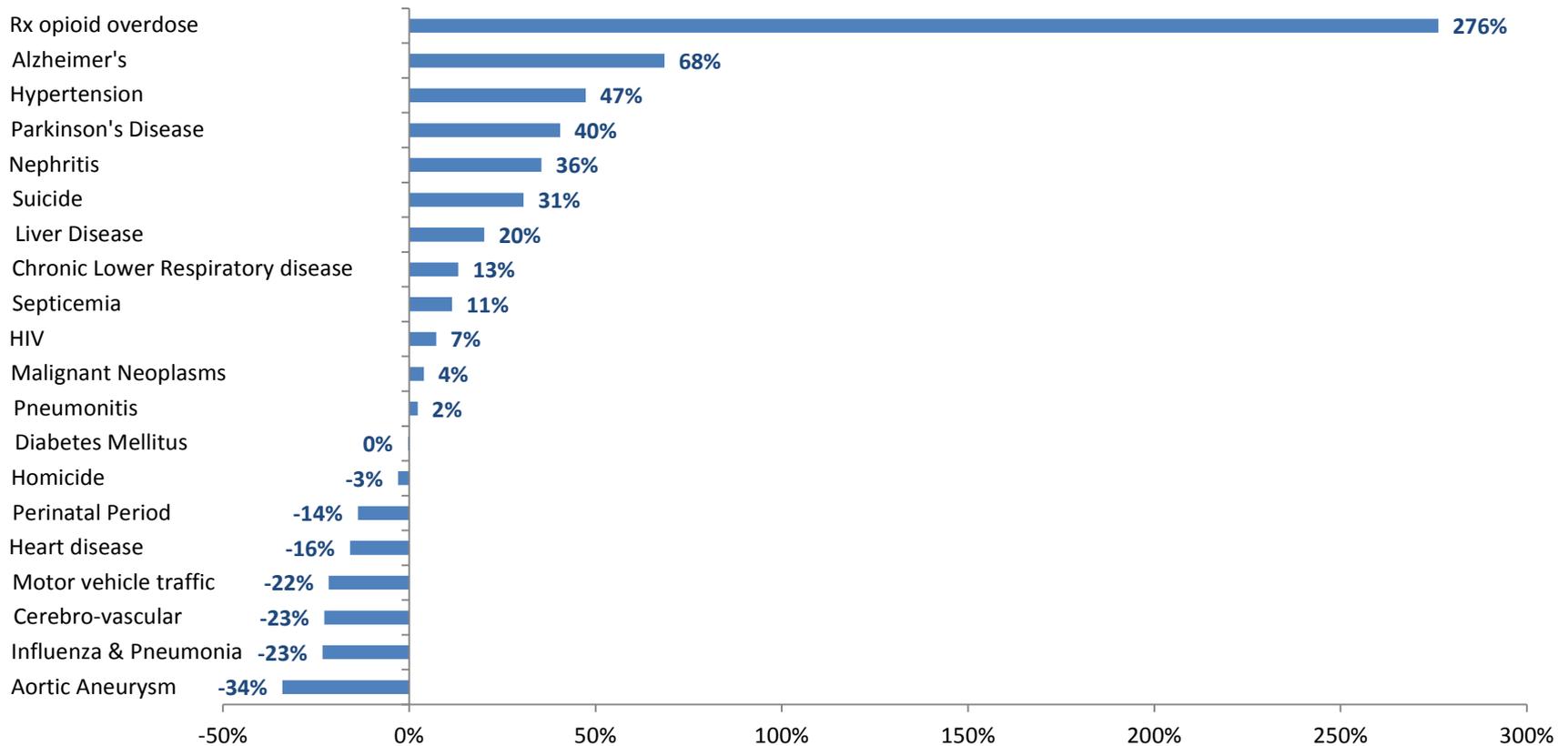
- Increased naloxone access and overdose response training for:
 - community members
 - first responders
- Good Samaritan 911 legislation
- Law enforcement education

Opioid overdose deaths key points

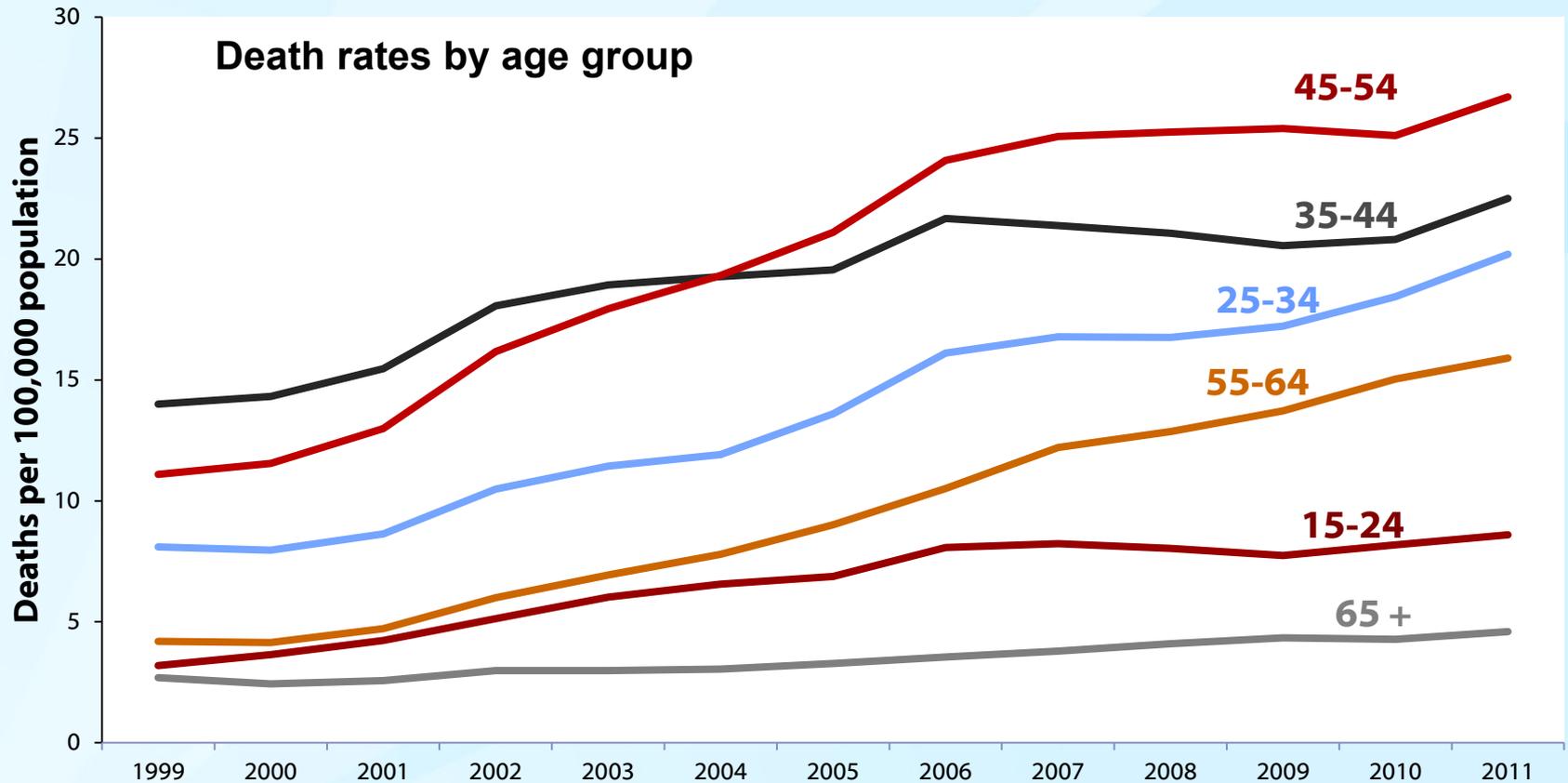
- Increasing at a faster rate than deaths from any major cause
- Increasing dramatically along with increased prescribing of opioid pain relievers
- Patients receiving opioids at high doses and from multiple prescribers at highest risk

Opioid pain reliever-related overdose deaths increasing at a faster rate than deaths from any major cause

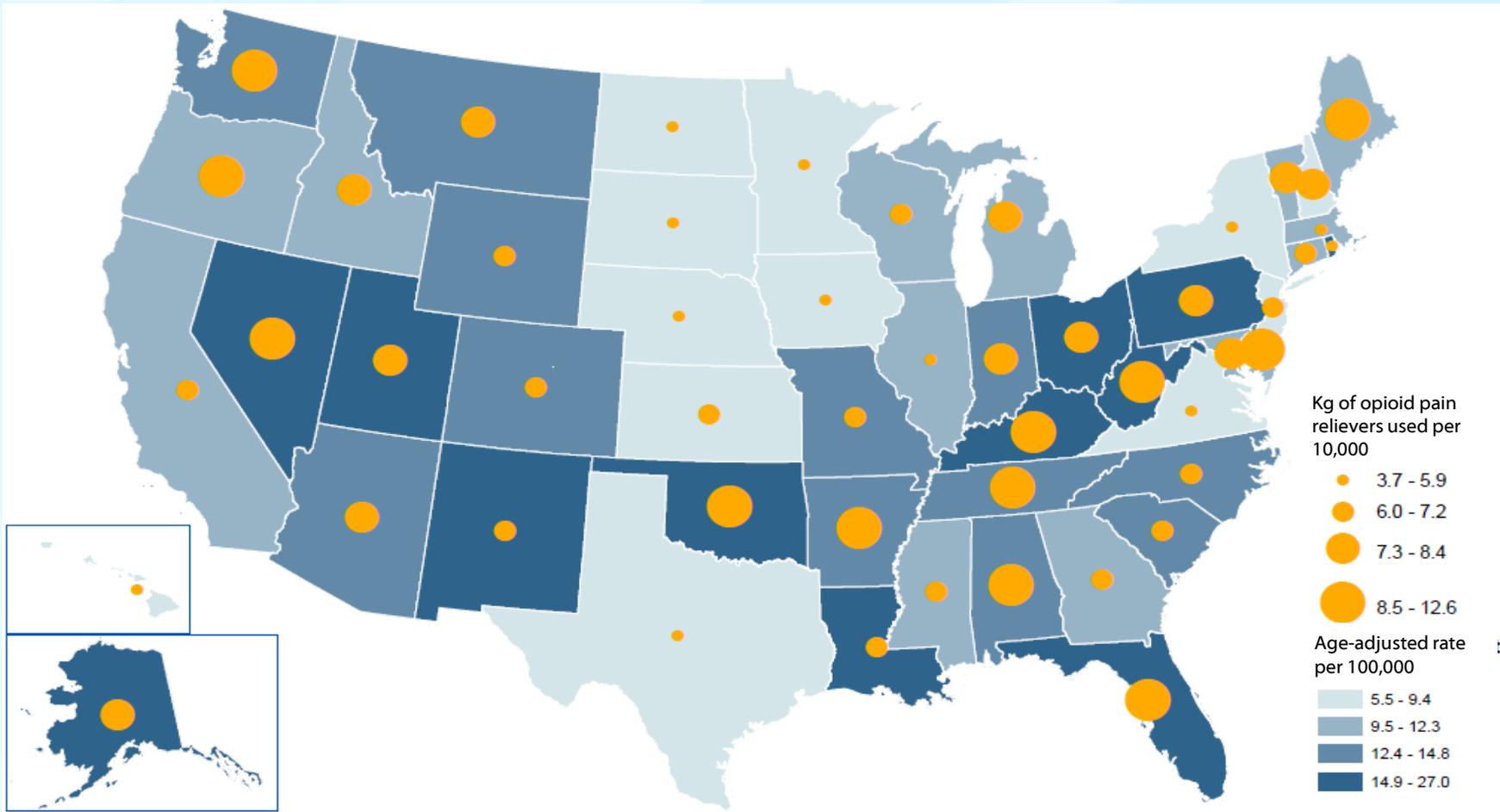
% change in number of deaths, United States, 2000-2010



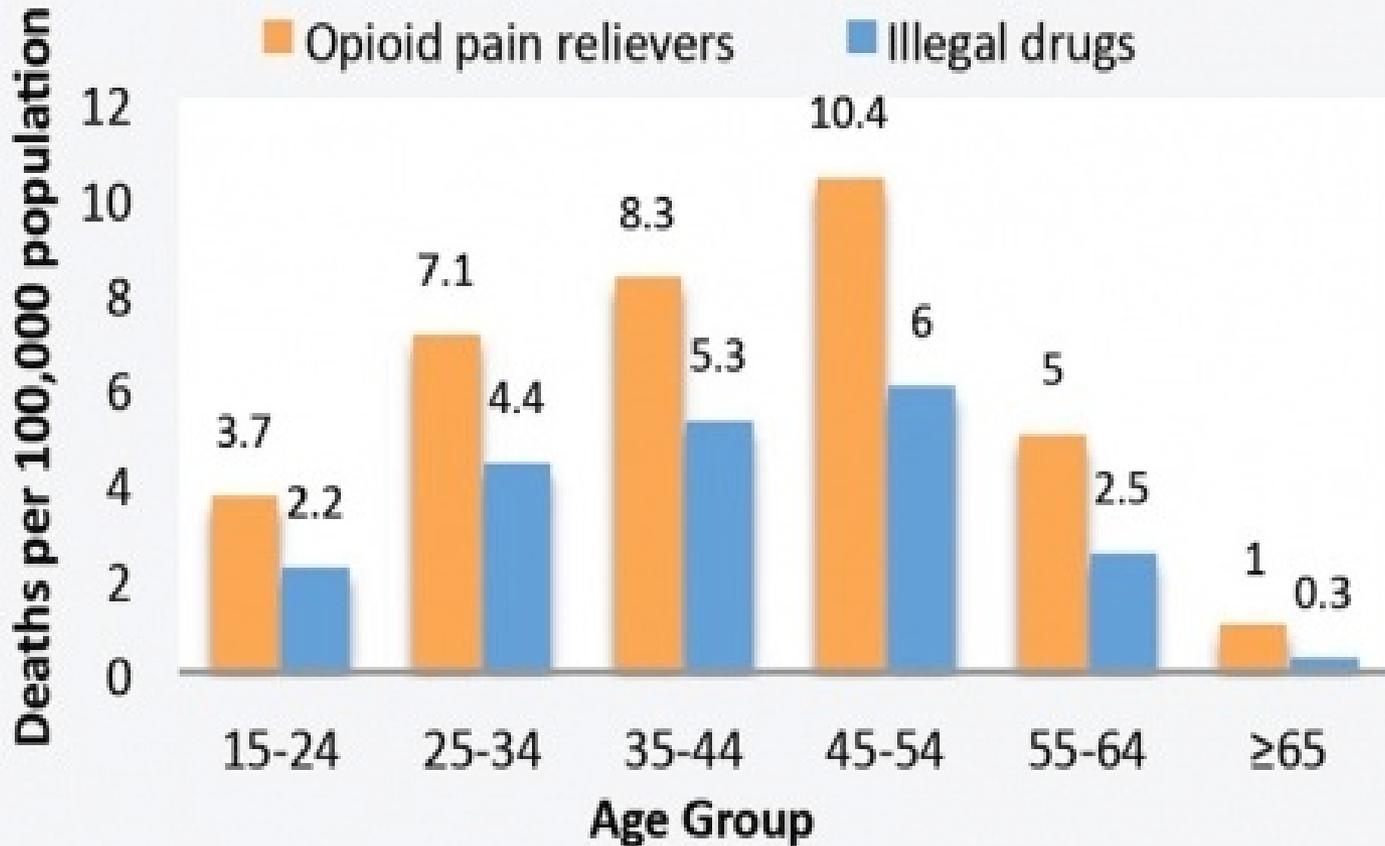
Middle-aged adults are at greatest risk for drug overdose in the United States



Drug overdose death rate 2008 and opioid pain reliever sales rate 2010

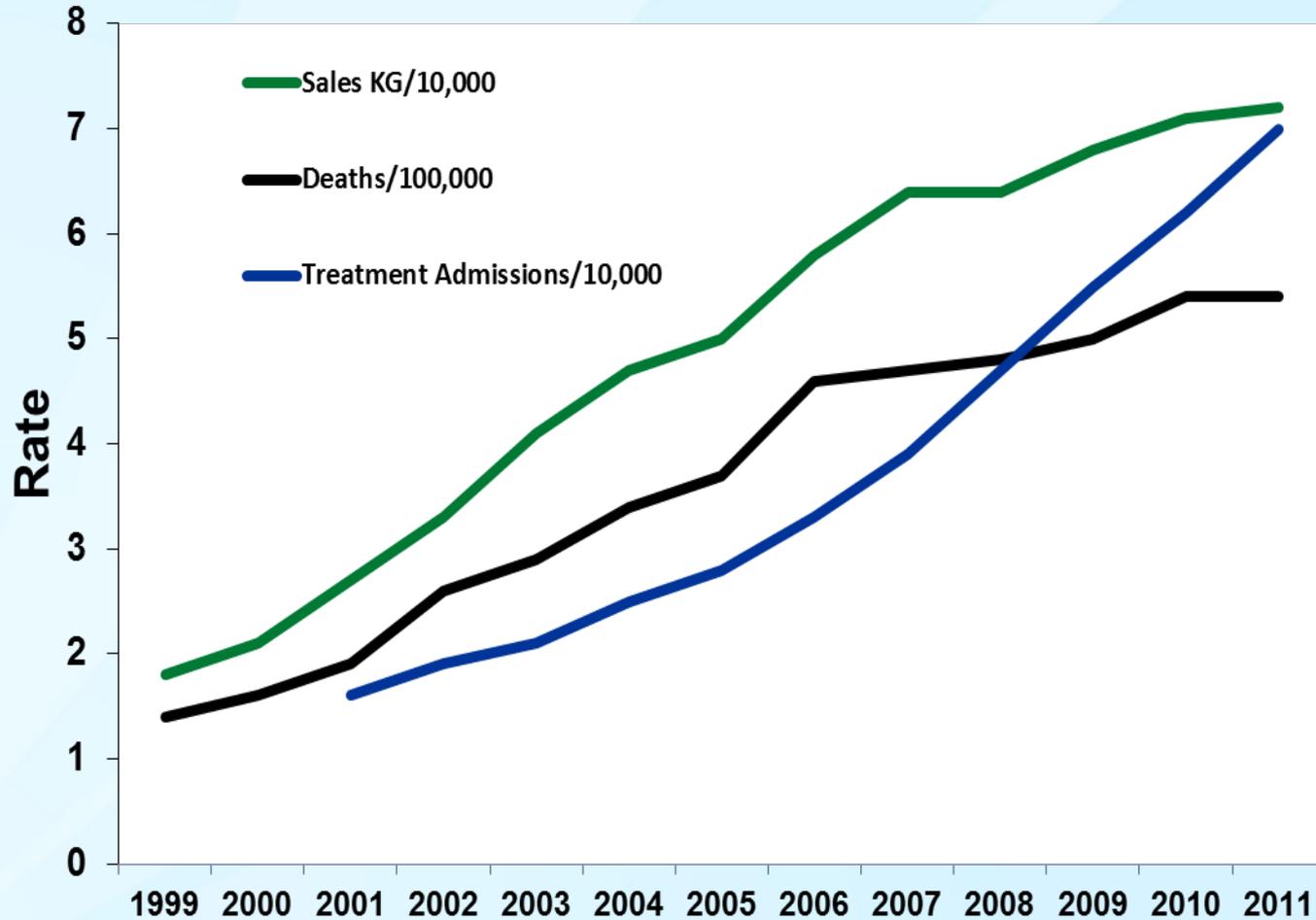


Deaths from Opioid Pain Relievers vs. All Illegal Drugs



Source: CDC, Morbidity and Mortality Weekly Report, 60(43): 1489, 2011.

Opioid-related overdose death rates and treatment admissions increased over time along with opioid sales

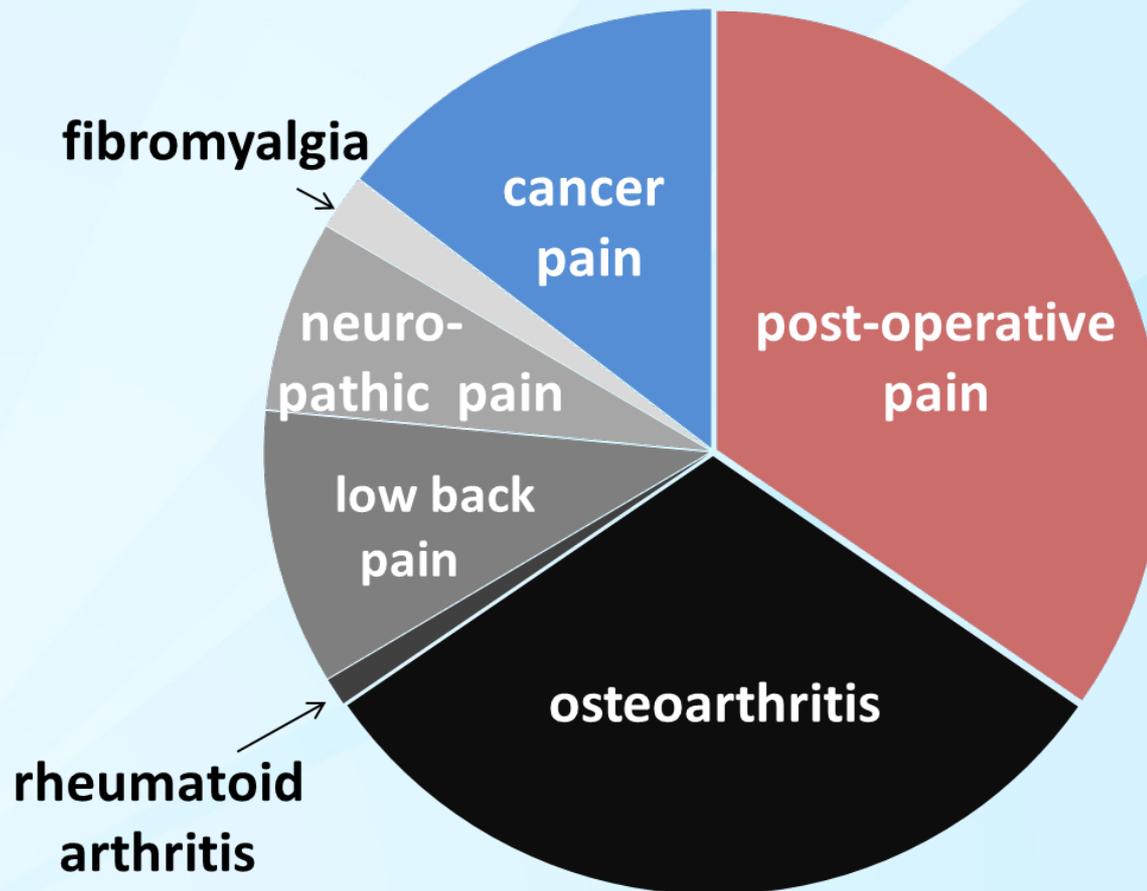


United States, 1999-2011. National Vital Statistics System, DEA's Automation of Reports and Consolidated Orders System, SAMHSA's TEDS. Treatment admission rates are per 10,000 people ages 12+.

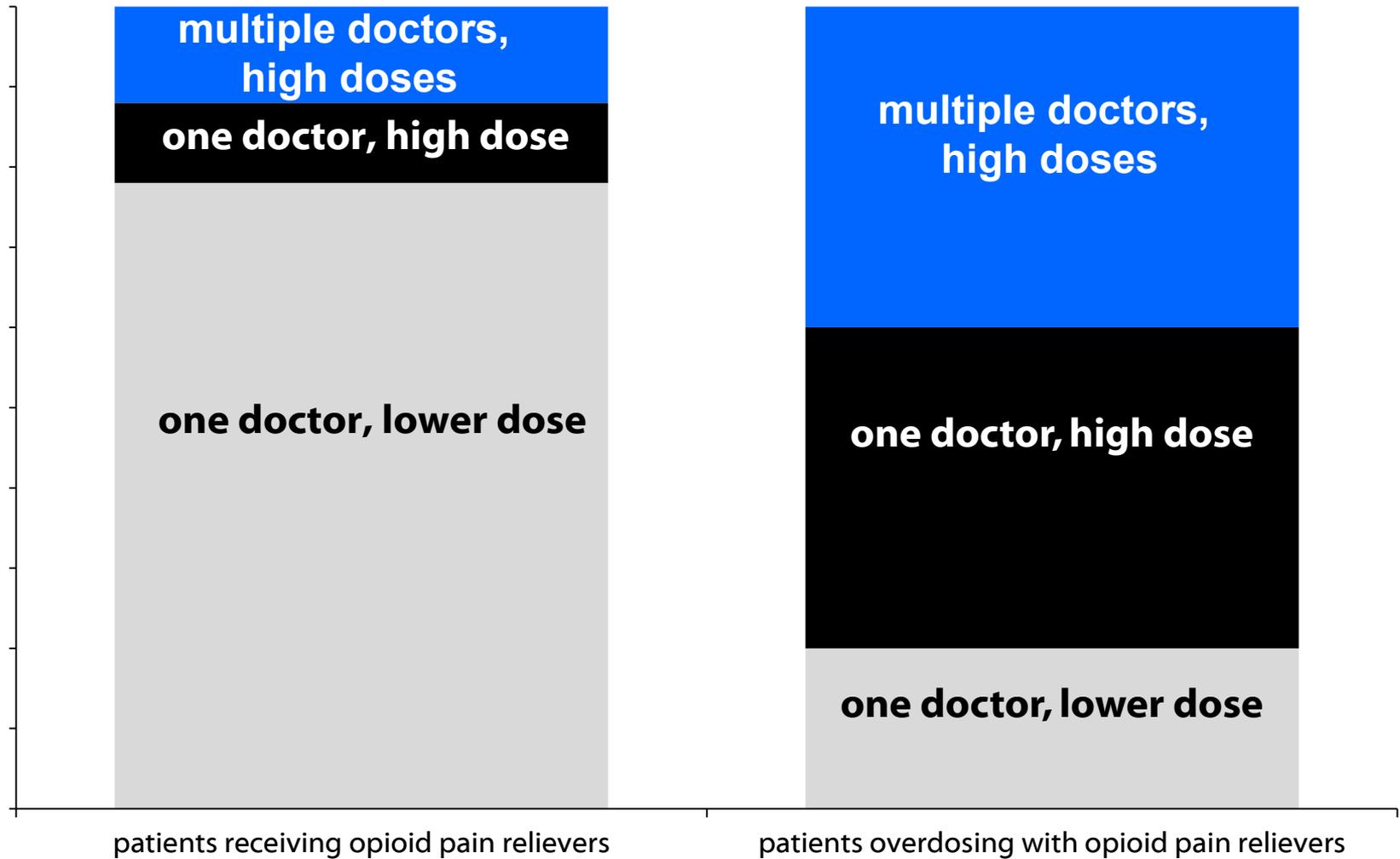
Half of US opioids market is treatment for chronic, non-cancer pain

U.S. opioids market revenues for 7 leading indications, 2010

Source: GBI Research. Opioids Market to 2017. June 2011

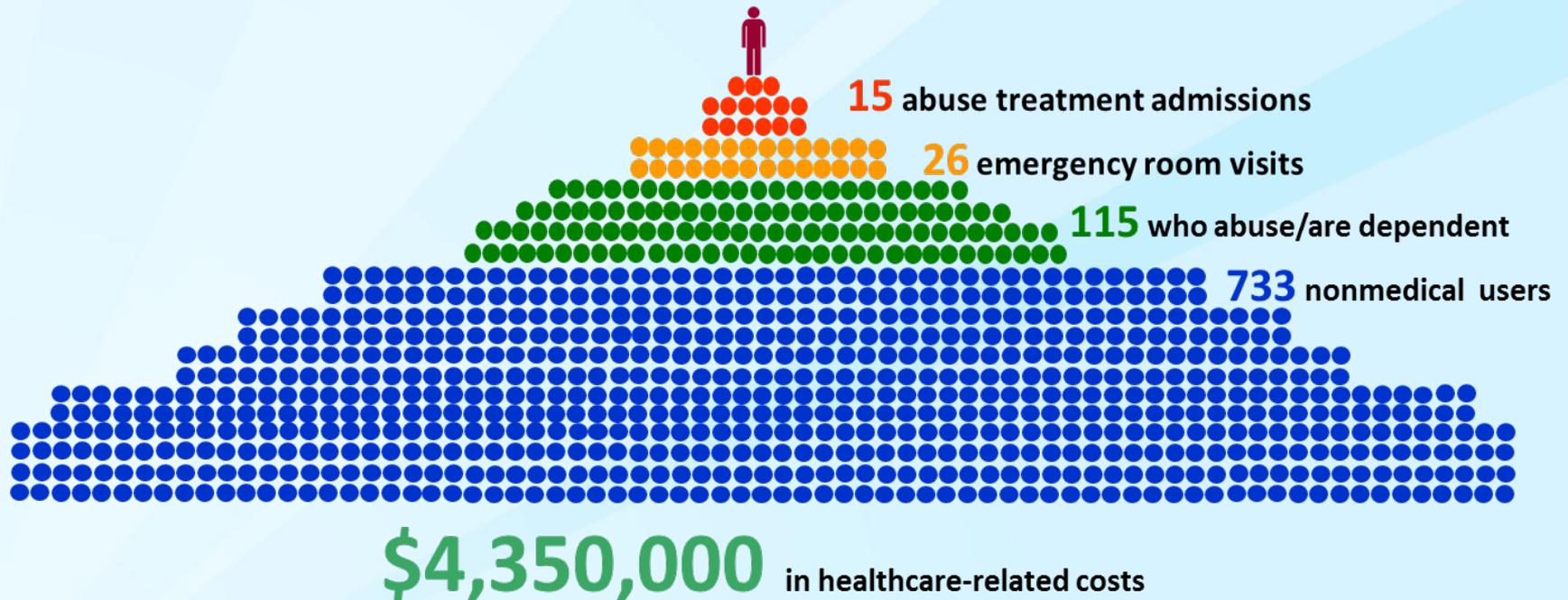


Patients receiving high doses of opioid pain relievers account for disproportionate share of overdoses



Deaths are the tip of the iceberg

For every **1** opioid overdose death in 2010 there were...

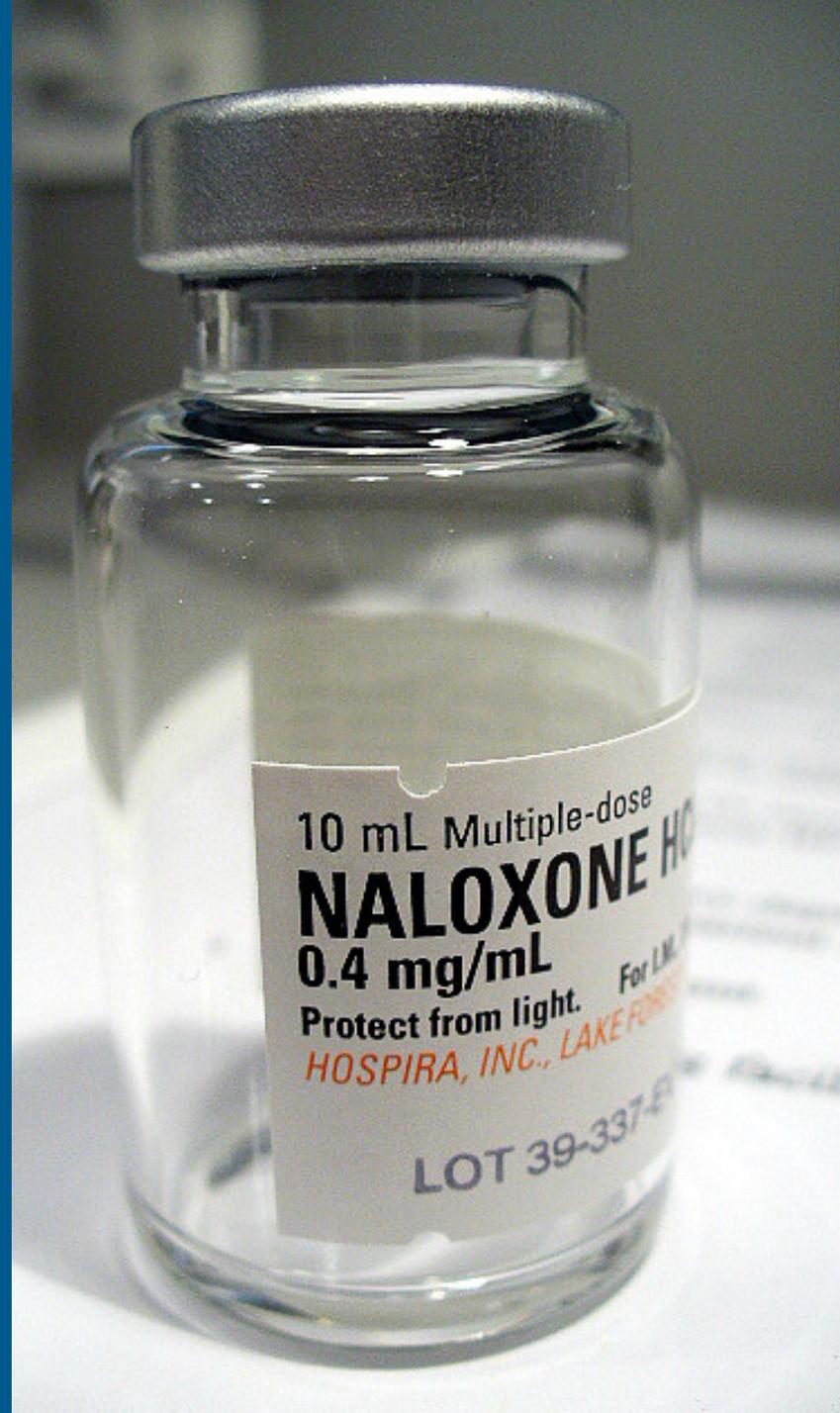


SAMHSA NSDUH, DAWN, TEDS data sets

Coalition Against Insurance Fraud. Prescription for Peril. <http://www.insurancefraud.org/downloads/drugDiversion.pdf> 2007.

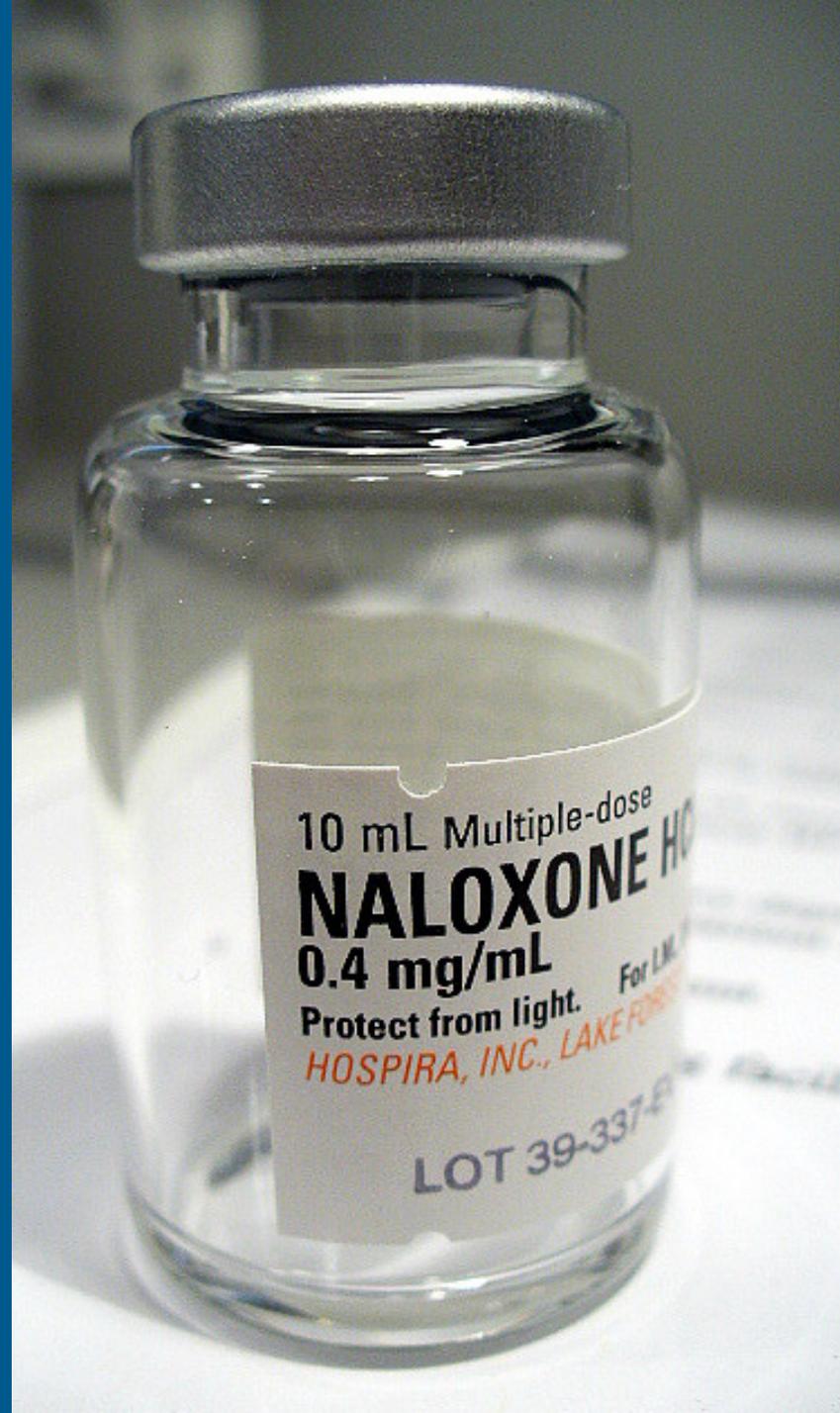
Naloxone overview

- Reverses clinical and toxic effects of opioid overdose
- Extremely good risk profile
- No effect if opioids not present
- May cause withdrawal



Naloxone overview

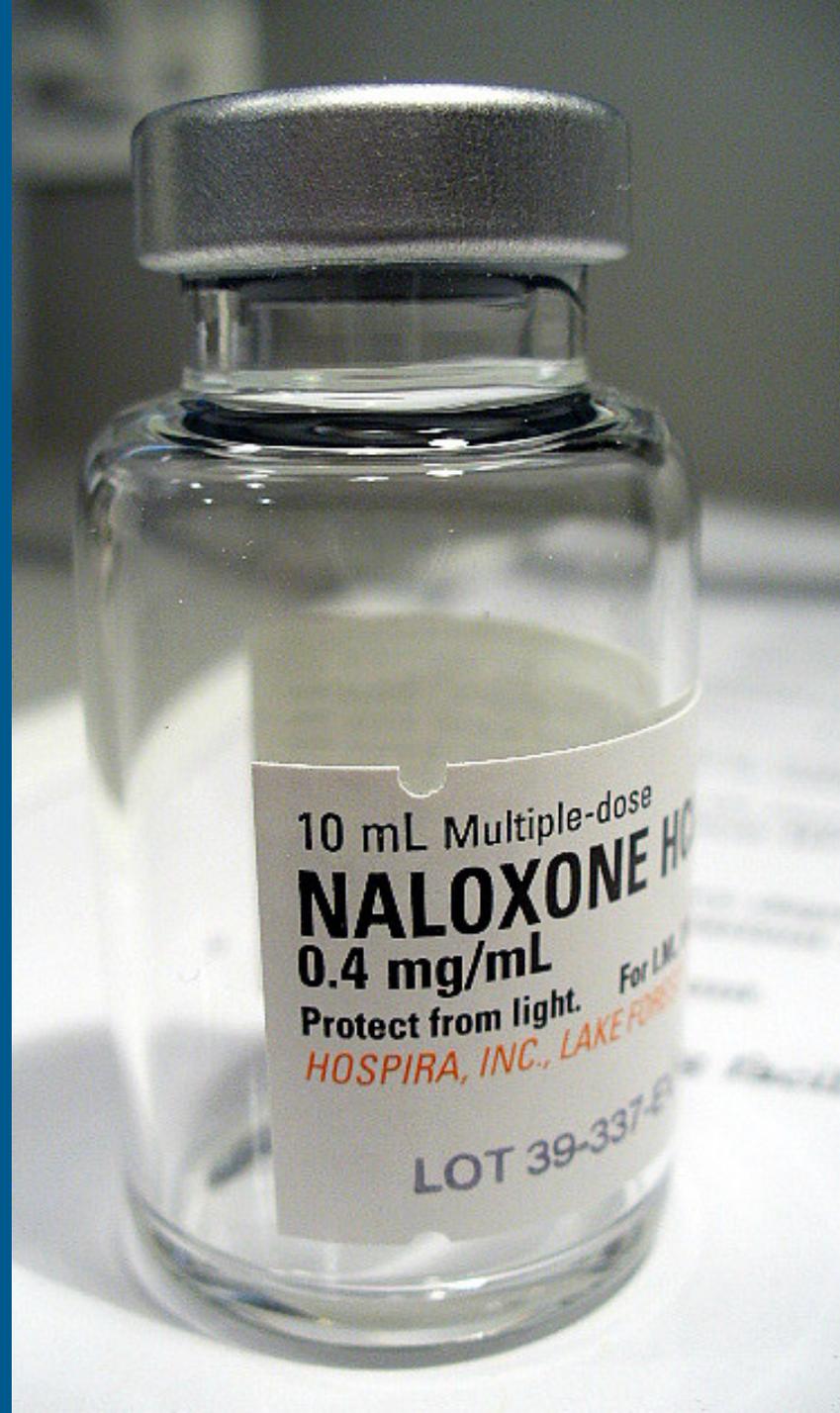
- Pure opioid antagonist
- Not psychoactive
- Not scheduled
- No abuse potential



Naloxone overview

Naloxone takes effect in 2 to 5 minutes

Naloxone wears off in 30 to 90 minutes



Why increase naloxone access

- Most opioid users do not use alone
- Bystanders can recognize and respond to overdoses
- Fear of calling 911
- Lack of first responder access
- Extensive evidence of feasibility & effectiveness
- Prescriber liability concerns

Barriers to Naloxone Access

All of these legal/regulatory barriers are unintended consequences of attempts to address other problems

Unfortunately, they have the side effect of preventing access to naloxone, possibly costing lives

Luckily, they can be easily modified to remove that side effect while maintaining original intent of laws/regulations

Naloxone Access/Good Samaritan Best Practices: The Big 4

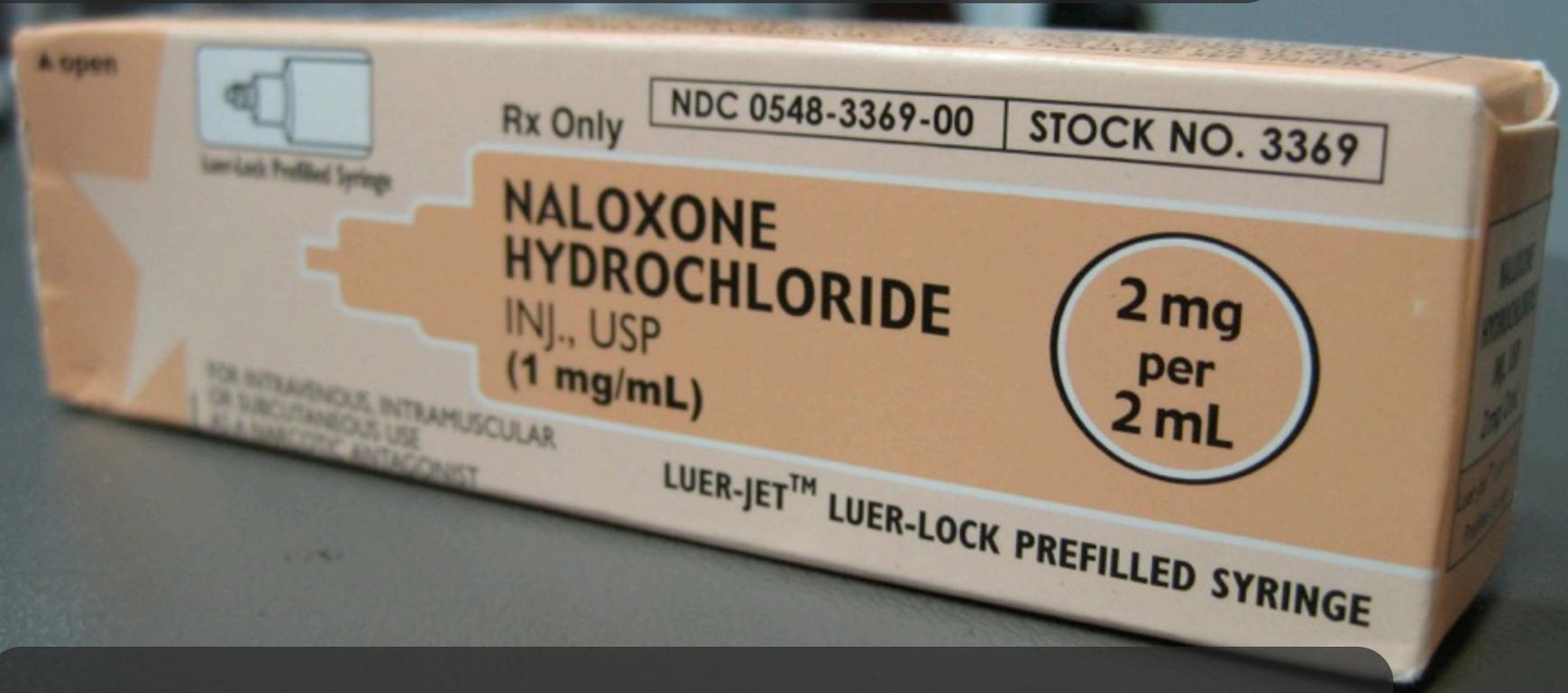


Best Practice #1



**Limit liability for naloxone prescribers
& administrators** acting in good faith

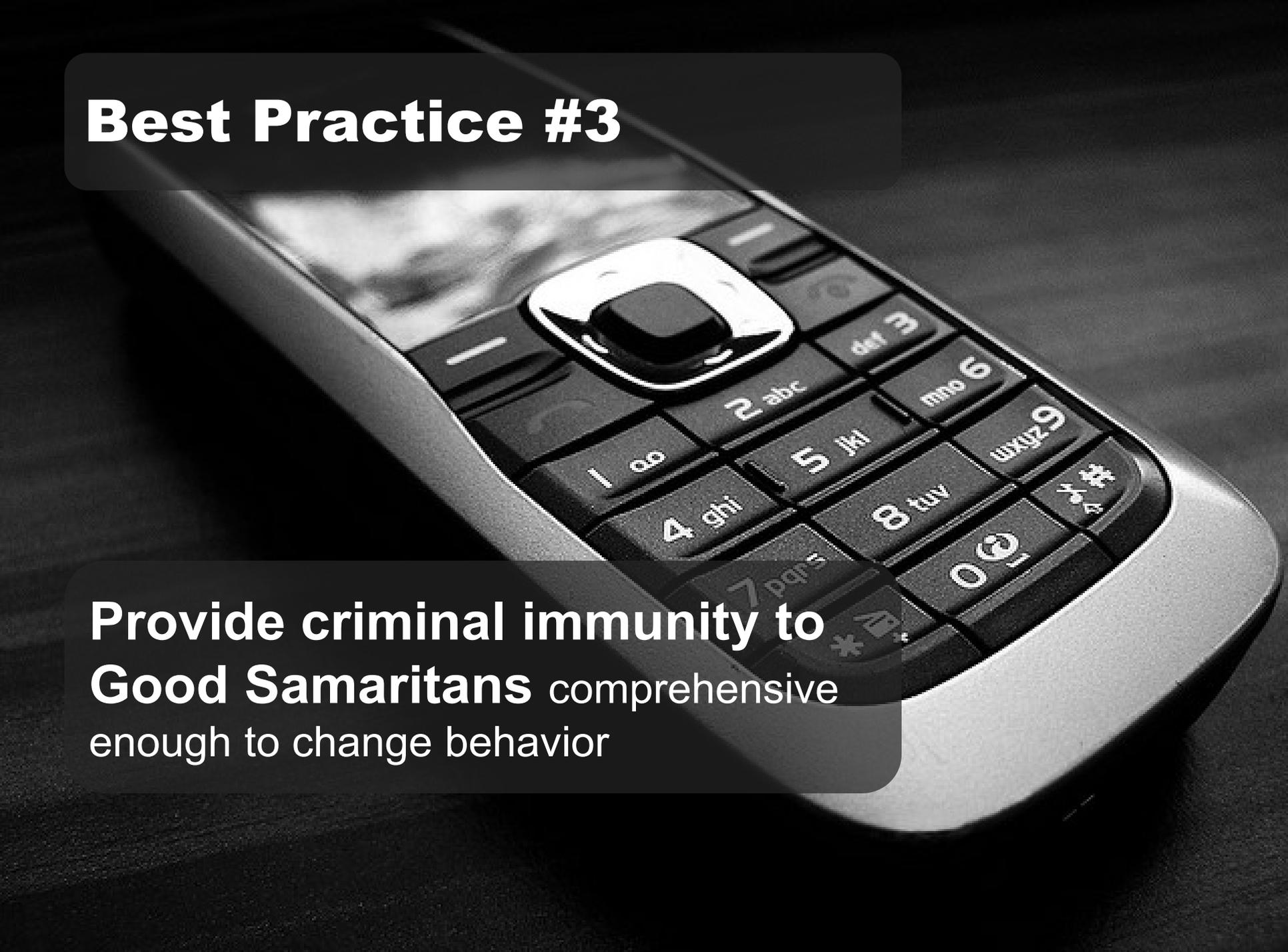
Best Practice #2



Non-patient specific prescription

Best Practice #3

Provide criminal immunity to Good Samaritans comprehensive enough to change behavior



Best Practice #4



AMBULANCE
FIRE DEPARTMENT
AGENCY MEDICAL
SERVICE

Modify scope of practice
so that properly trained first responders
can administer naloxone

Support for Increased Naloxone Access

American Medical Association

American Pharmaceutical Association

American Public Health Association

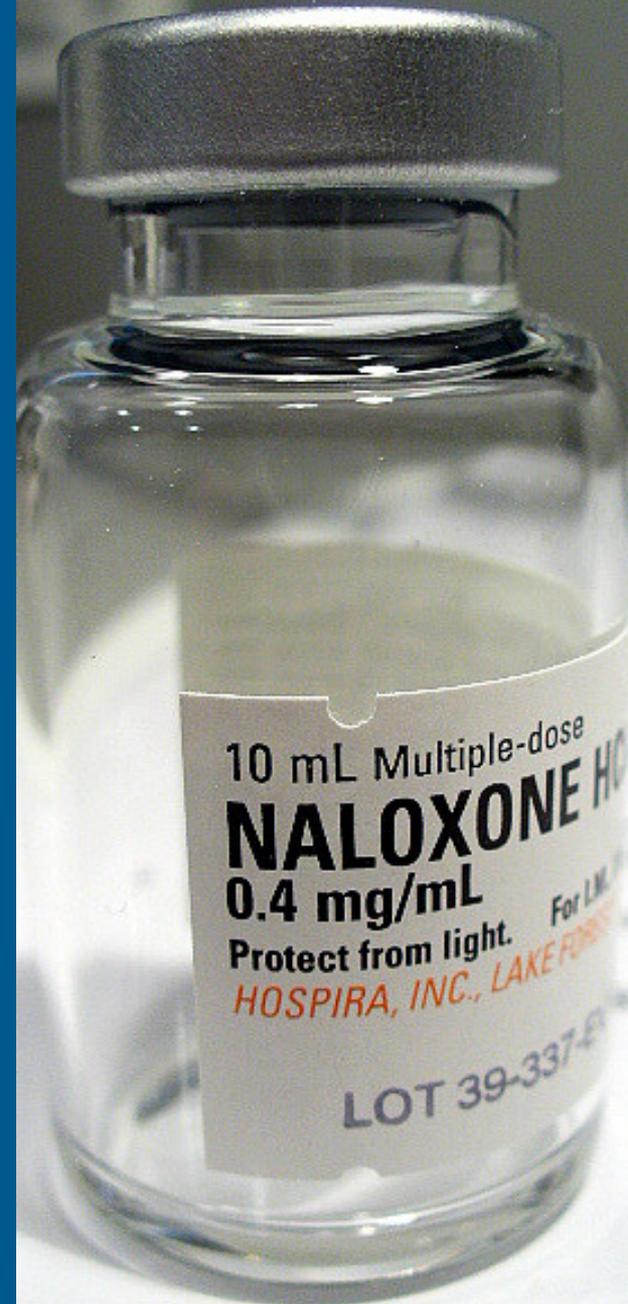
American Society of Addiction Medicine

Attorney General of the United States

National Association of Drug Diversion
Investigators

Office of National Drug Control Policy

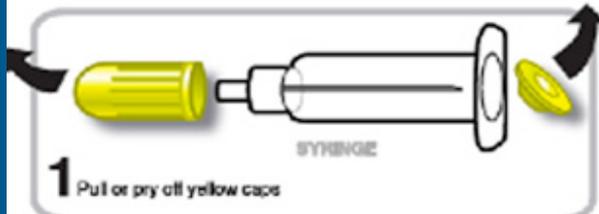
U.S. Conference of Mayors



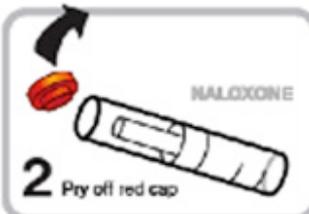


HOW TO GIVE NASAL SPRAY NARCAN

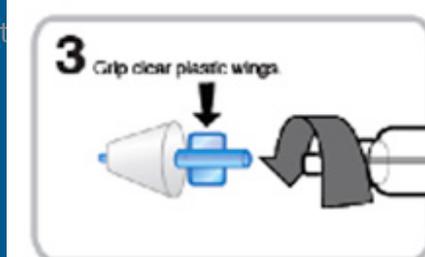
1 Pull or pry off yellow caps



2 Pry off red cap



3 Grip clear plastic wings



4 Score capsule of naloxone into barrel of syringe



5 Insert white cone into nostril; give a short, vigorous push on end of capsule to spray naloxone into nose. One half of the capsule into each nostril



6 If no reaction in 2-5 minutes, give the second dose.

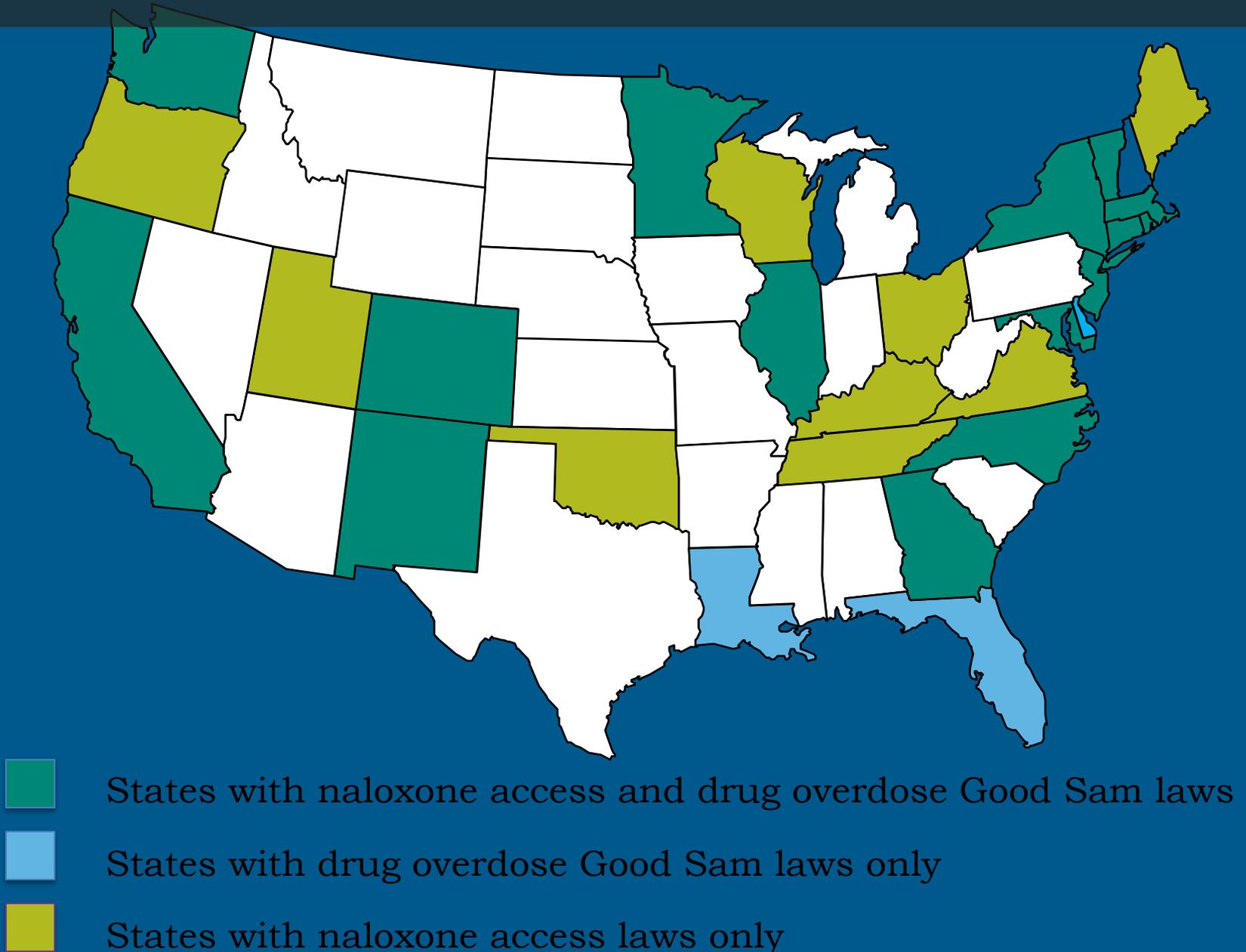
Push to spray.

HARM REDUCTION COALITION
 30 WEST 20TH ST, NEW YORK, NY 10011-3207

IM device

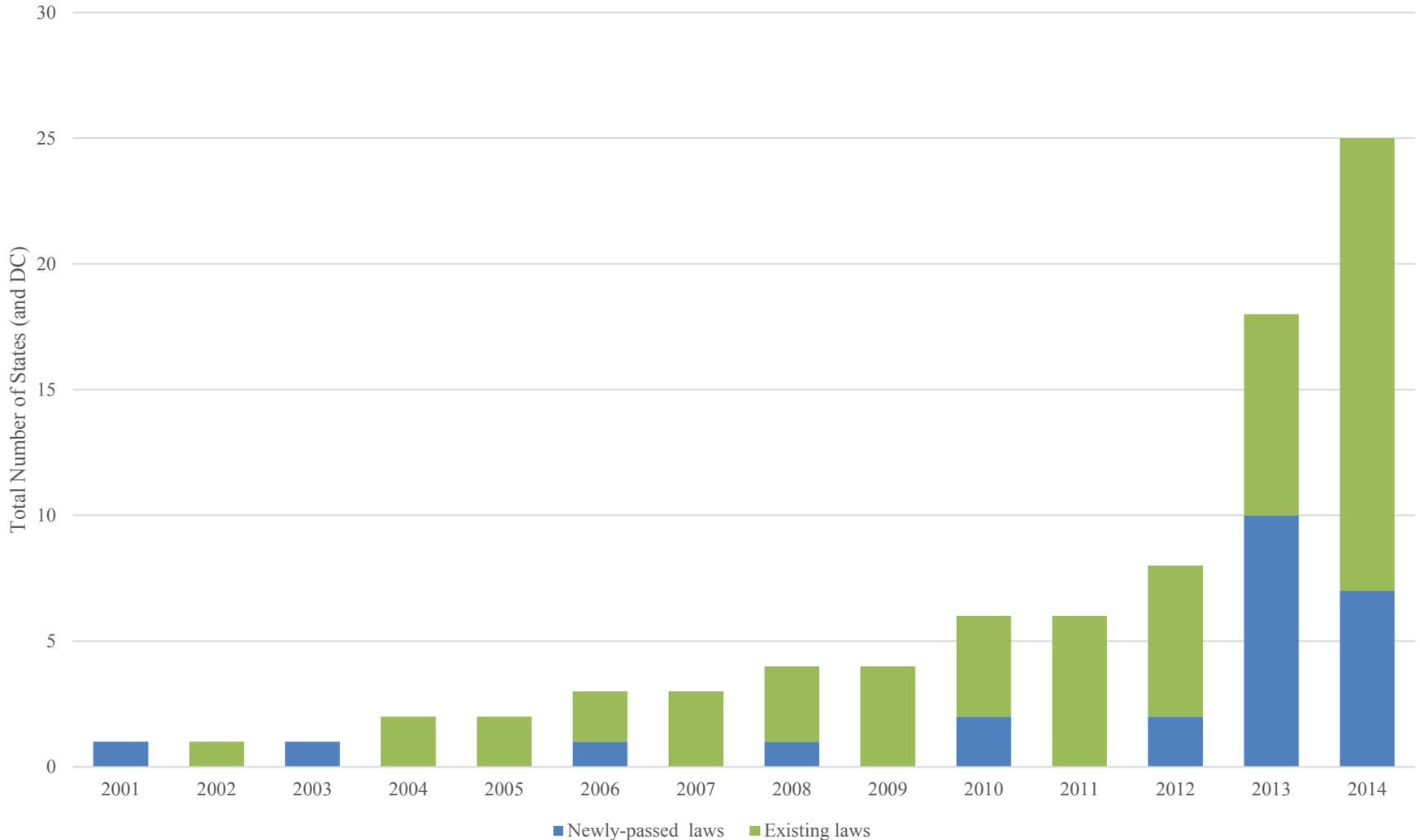


States with Naloxone Access & Good Samaritan Laws

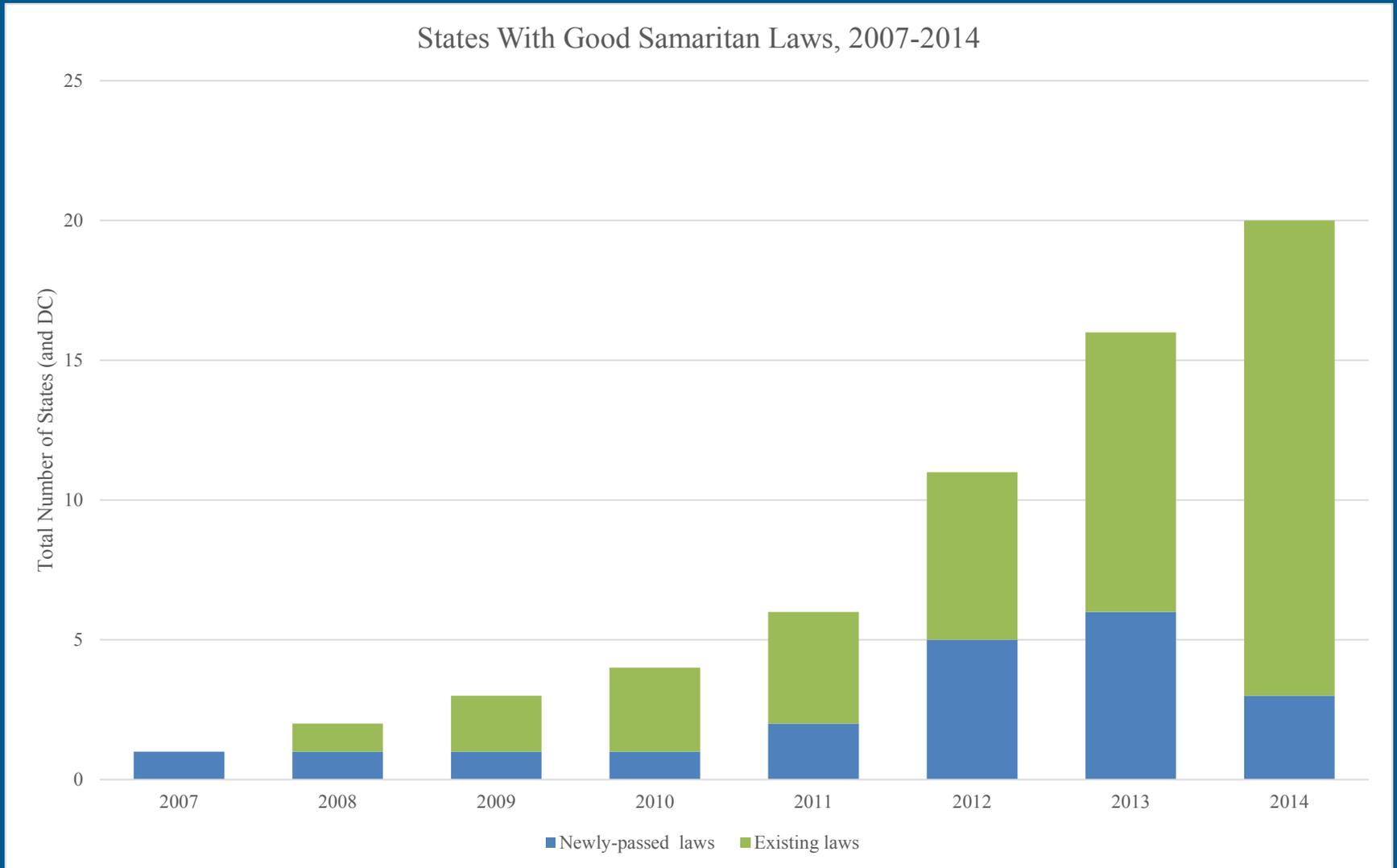


States with Naloxone Access Laws, 2001 - 2014

States With Naloxone Access Laws, 2001-2014



States with Good Samaritan laws, 2007 - 2014





Naloxone “should be in the patrol cars of every law enforcement professional across the nation.”

– Acting Director Botticelli, ONDCP

“I am confident that expanding the availability of naloxone has the potential to save the lives, families and futures of countless people across the nation.”

– Attorney General Holder

LEO naloxone administration

- Law enforcement often first on scene of overdose, particularly in rural areas
- Officers can be quickly trained in proper use
- Many officers report positive impressions – good PR
- May improve community relations
- Relatively inexpensive, readily available from EMS and public health agencies
- Protects officers, k-9s as well as public

Law enforcement naloxone

- Over 250 departments across the country now carry naloxone
- New York state recently allocated \$5 million in seizure funds to purchase naloxone and provide training
- 11 states have added naloxone administration to LEO scope of practice
- Additional 11 states carry under general naloxone access laws

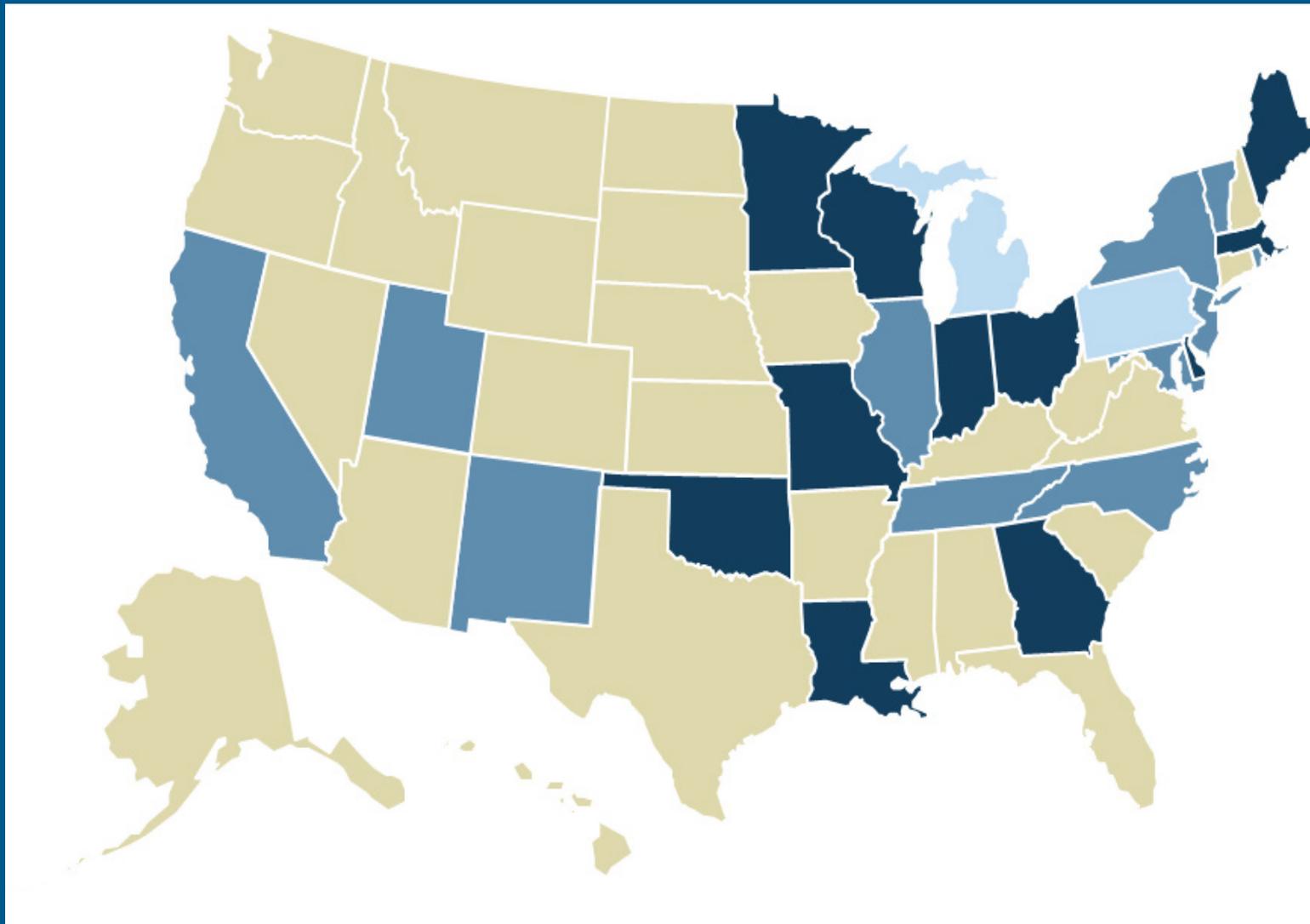
Liability Risk

- Like physicians, LEOs tend to overestimate their civil liability risk
- Liability is generally no different than that of any other law enforcement activity – very low
 - General liability risk is low
 - LEOs are typically immune from suit for acts or omissions taken in good faith and in the scope of their employment
 - Most states further indemnify officers
 - Agencies covered by sovereign immunity and state Tort Claims Acts
 - 16 states provide immunity for naloxone administration

Common questions

- **Cost**
 - Cost of nasal device is around \$20, less than a shift's worth of gas
 - Can use forfeiture funds, may be able to get bulk purchasing through EMS or public health
- **Precipitated withdrawal**
 - Risk greatly reduced with nasal or IM administration vs. IV/IVP
 - Reports of violent behavior from LE-administered naloxone are rare
- **Not my job**
 - Saving lives is good for you, good for the victim and good for the department
 - Serving and protecting increasingly means things like CPR, AED, etc

States with Law Enforcement Naloxone Administration



Parting Thoughts

- Overdose risk has many drivers
- No magic bullets
 - Changing practice requires engagement with and action from public health and elected officials, the medical and treatment communities, law enforcement, clergy, community groups, etc.
- Must address overdose throughout the continuum
- As with all policy interventions, results should be independently and rigorously evaluated

Contact information

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Questions?

