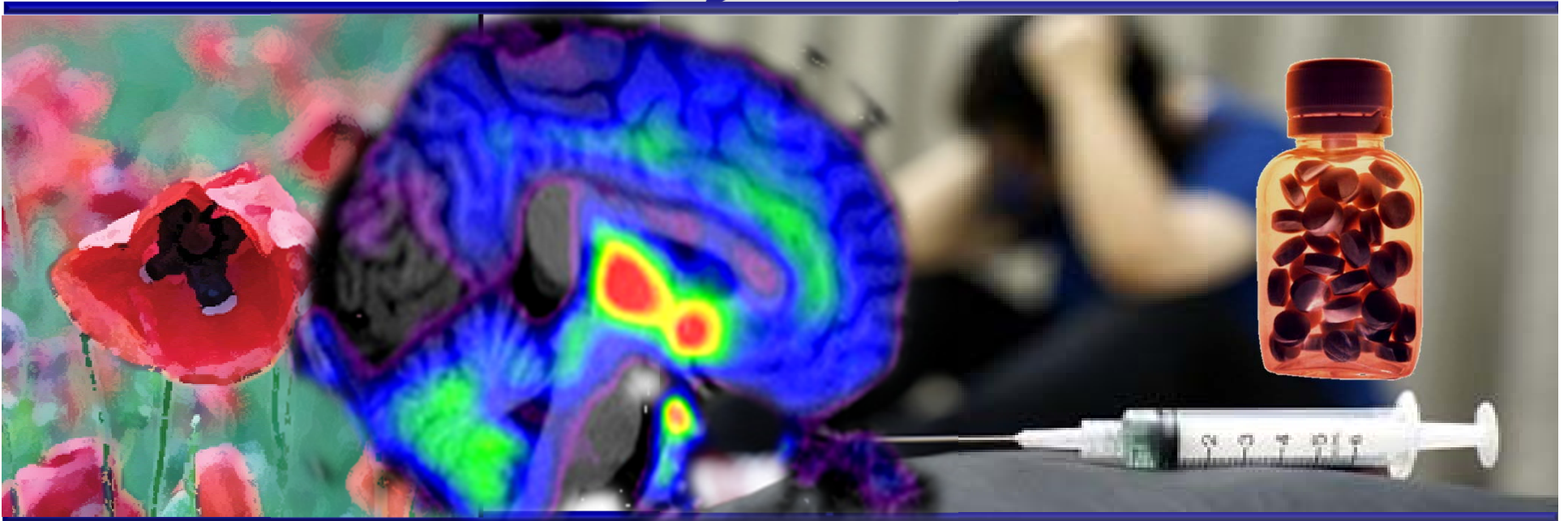


Changing Federal Health Care Policies

A view from NIDA



Carlos Blanco, M.D., Ph.D.

Director

Division of Epidemiology, Services and Prevention
National Institute on Drug Abuse



Four Major Themes Where *Science and Practice Are Needed* to Inform Policy

- **MARIJUANA:** Population impact shifting legal landscape

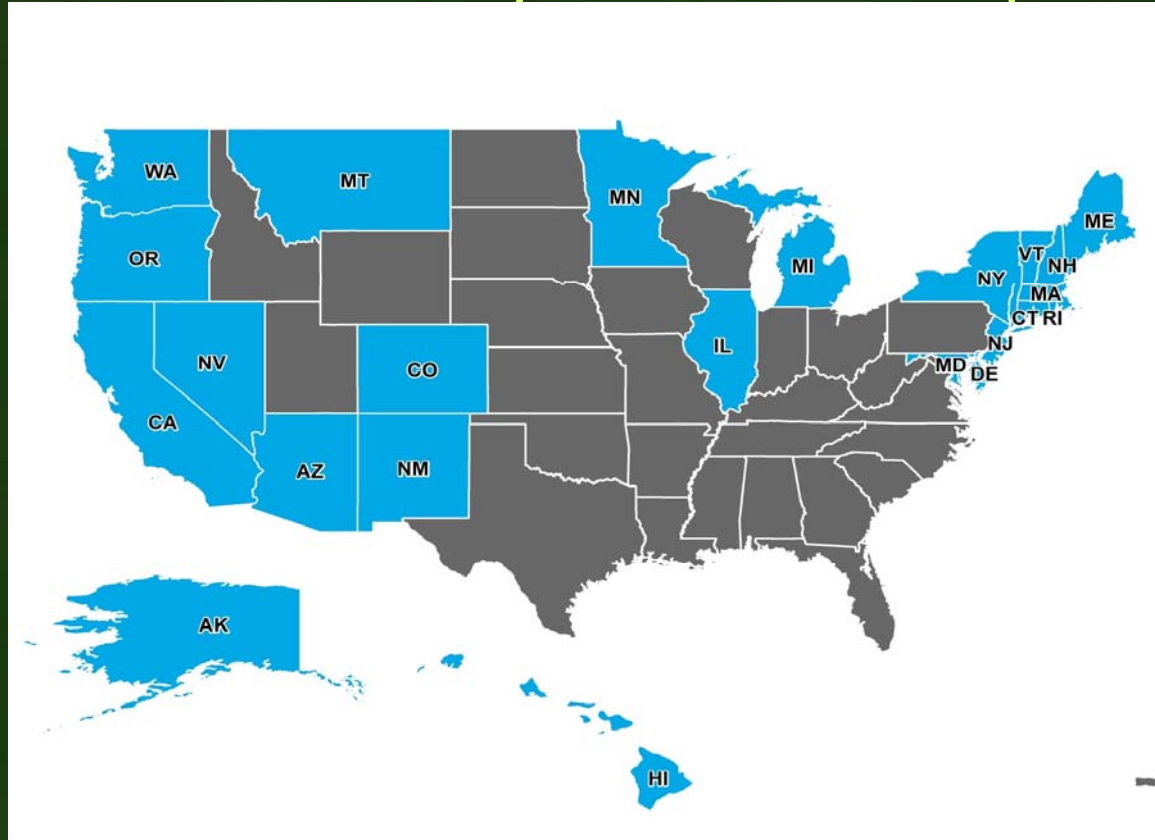


- **E-CIGARETTES:** Promise and Perils

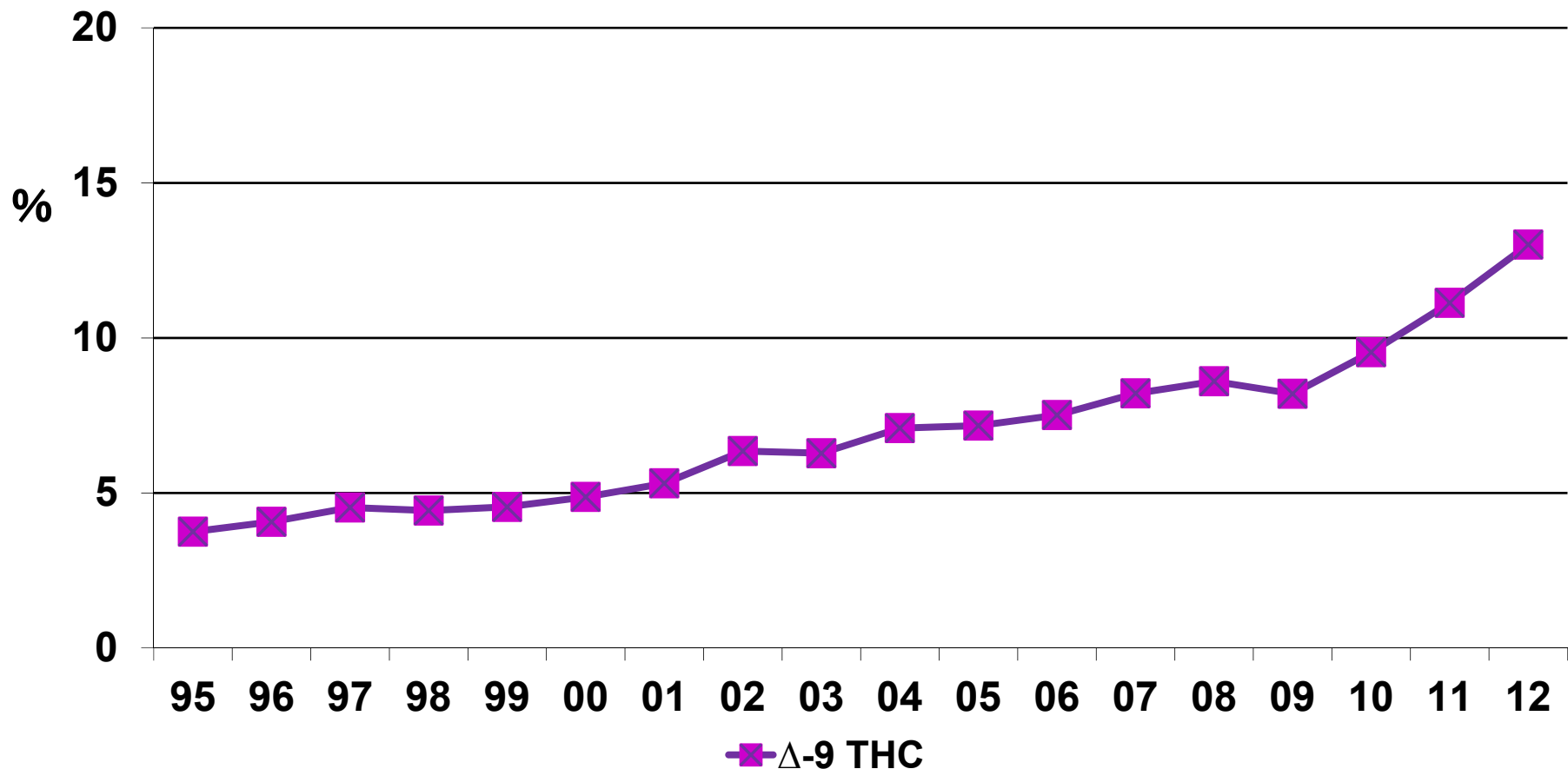


- **OPIOIDS:** Pain and Addiction
- **LEARNING HEALTHCARE SYSTEMS:** From Research to Practice and Back

Medical Marijuana States: 23 plus DC
Recreational Marijuana States: 4 plus DC



Marijuana Potency (% Δ -9 THC) Tripled in Past 20 Years



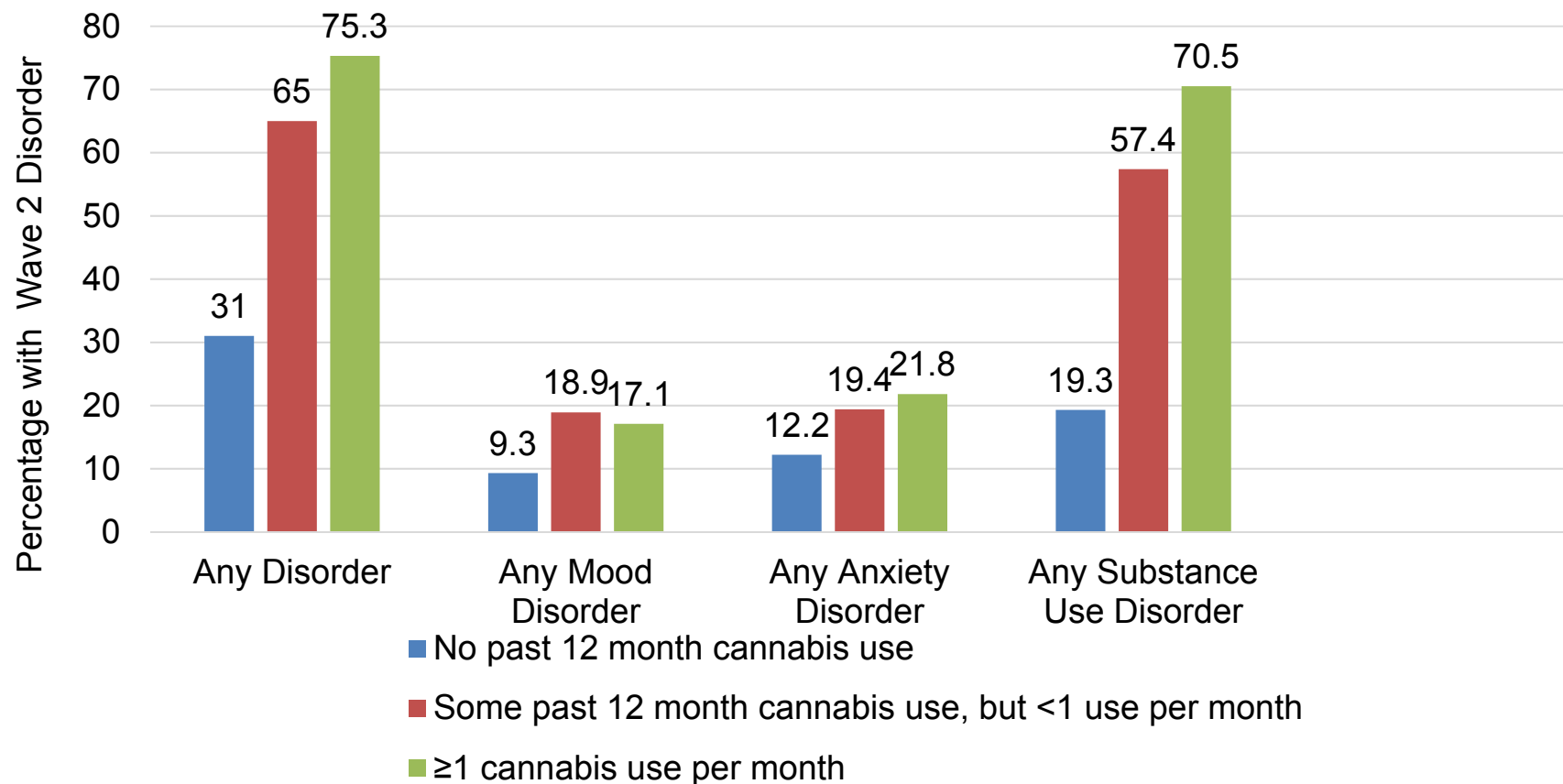
SOURCE: University of Mississippi Marijuana Project (potency data)

Science = Solutions

Four Major Adverse Outcomes

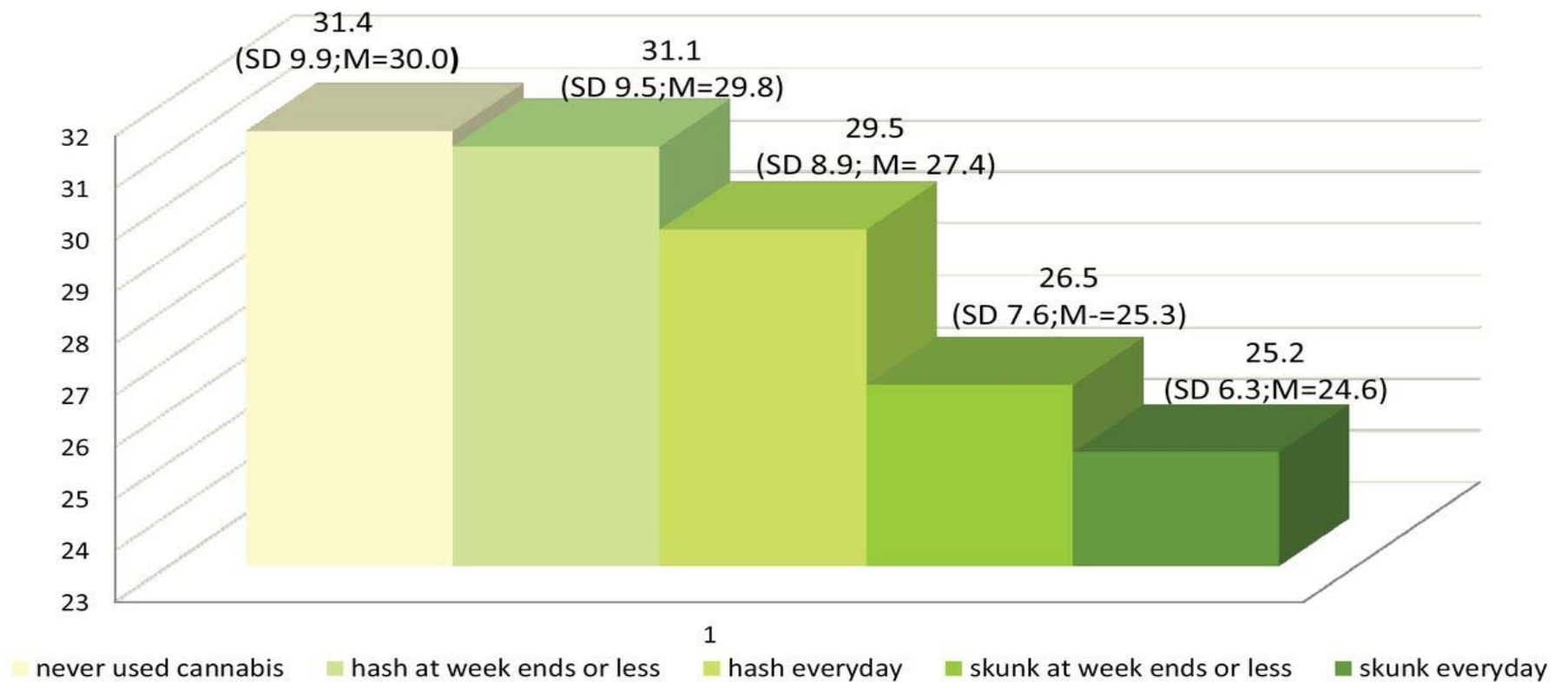
- *Substance Use Disorders*
- *Psychosis*
- *Cognition*
- *Brain Development*

Prevalence of Wave 2 psychiatric disorders by level of Wave 1 cannabis use in the NESARC (Blanco et al., JAMA Psychiatry, 2016).



High Potency Marijuana and Earlier Onset of Psychosis

Mean age (yrs) of onset of psychosis by degree of exposure to cannabis



Di Forti M et al. Schizophr Bull 2013;schbul.sbt181



Adolescent Brain Cognitive Development

Teen Brains. Today's Science. Brighter Future.

A longitudinal study of about 10,000 children from ages 9-10 through early adulthood to assess factors that influence individual brain development trajectories and functional outcomes

Source: www.abcdstudy.org

Conflicting Information Regarding Prevalence

- *Effect of legalization on youth use*
 - States with medical marijuana have higher prevalence
 - No differential increase over time in the short term
- *Trends in use in the general population*
- *Trends in cannabis use disorders*
 - NESARC-III findings
 - NSDUH findings

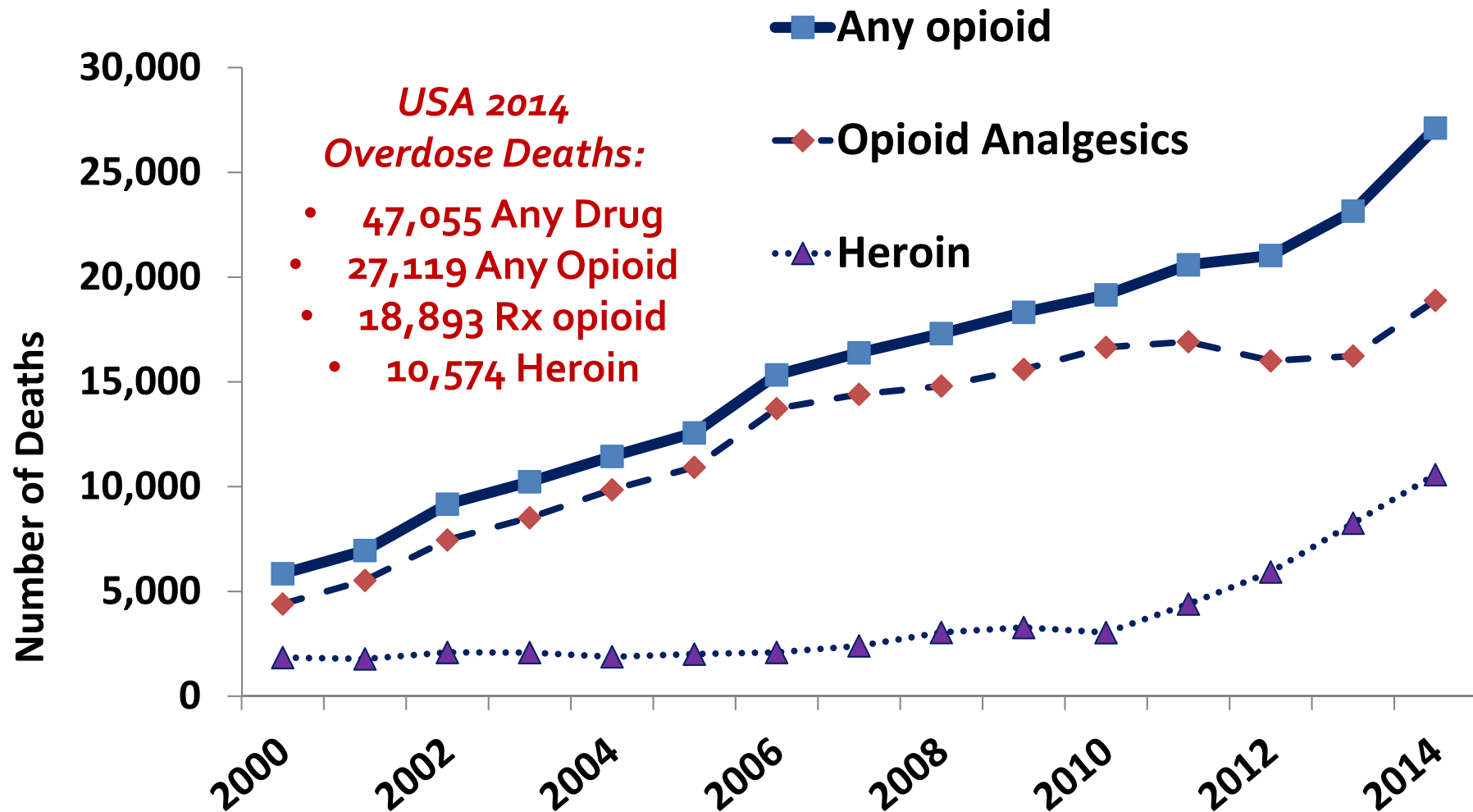
What Do We **Need To Know?**

- *How does shifting policy environment and variations in policy impact health outcomes? Deconstructing policy*
- *What are the differential effects of policy changes on vulnerable groups?*
- *What are the prevention needs of youth who may have greater access and exposure to marijuana use?*
- *Testing for screening, treating and preventing cannabis use and CUD in medical settings?*

What Do We **Need To Know**?

- *How does increasing potency of marijuana impact behavior, health outcomes, and treatment needs?*
- *Impact of delivery systems: edibles, vaping*
- *Interactions between marijuana/alcohol/tobacco*
 - *Complementarity vs substitution*
 - *Impact on driving*
 - *Other Outcomes*

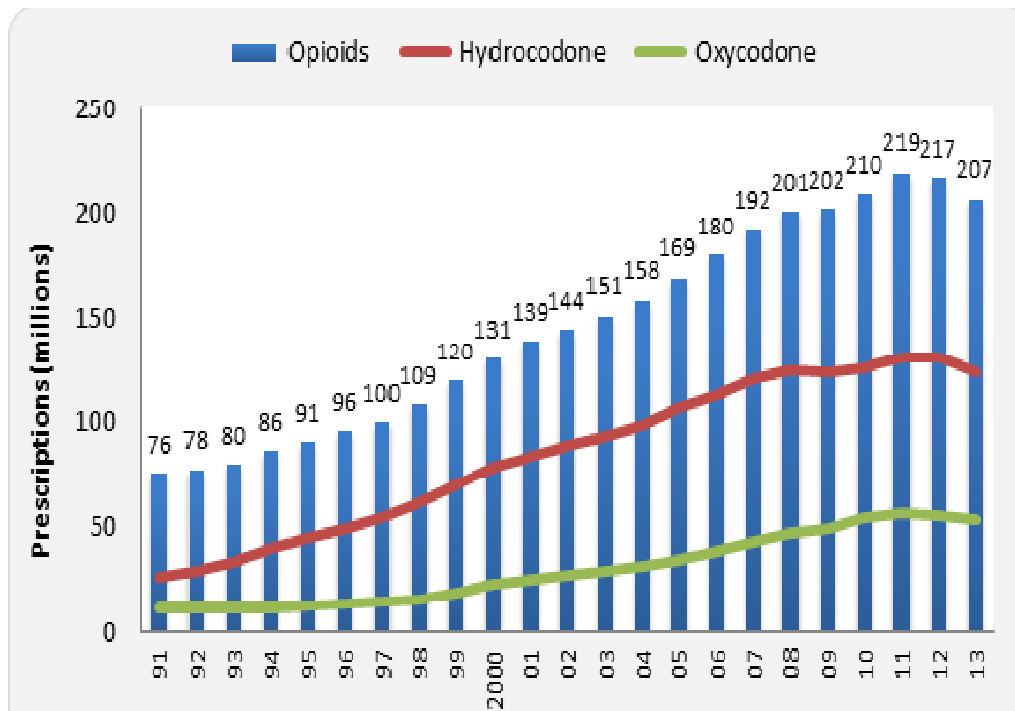
Marked *Increases in Prescription Opioid and Heroin Overdose Deaths* in the USA 2000 to 2014



Source: CDC, NVSS 2000-2014

High Levels of Opioid Prescriptions have Facilitated Diversion & Contributed to Overdose Deaths

Near Tripling of Opioid Prescriptions from U.S. Retail Pharmacies, 1991-2013



IMS Health, Vector One®: National, 1991-2011
IMS Health, National Prescription Audit, 2012-2013

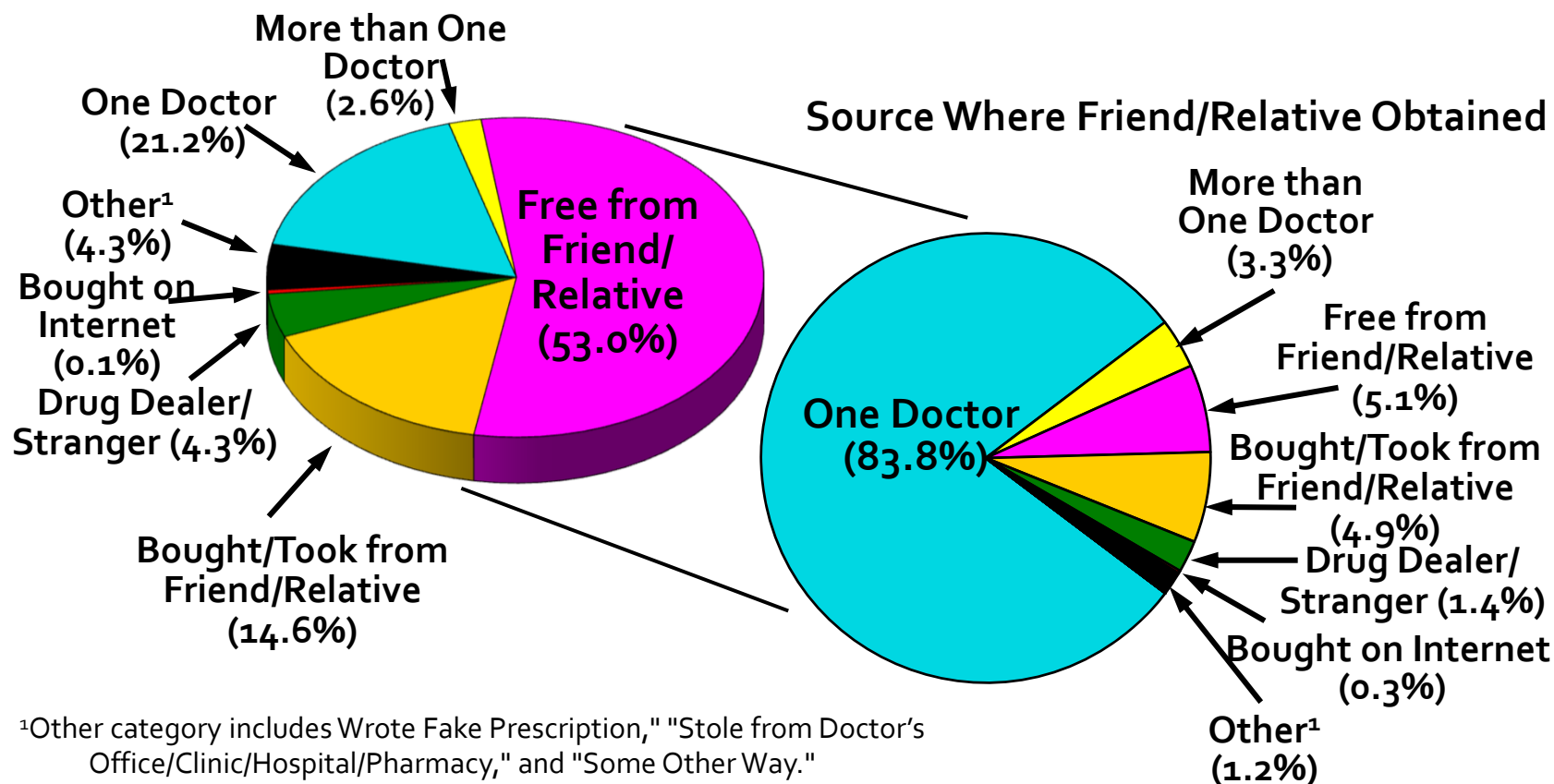
Total Rx Opioid Tablets Dispensed in Retail Pharmacies in the USA:

- **2013 15,972,304,698**
- **2014 15,606,882,755**

Source: Jones CM, et al. *JAMA Internal Medicine* 2016; doi: 10.1001/jamainternmed.2015.7799

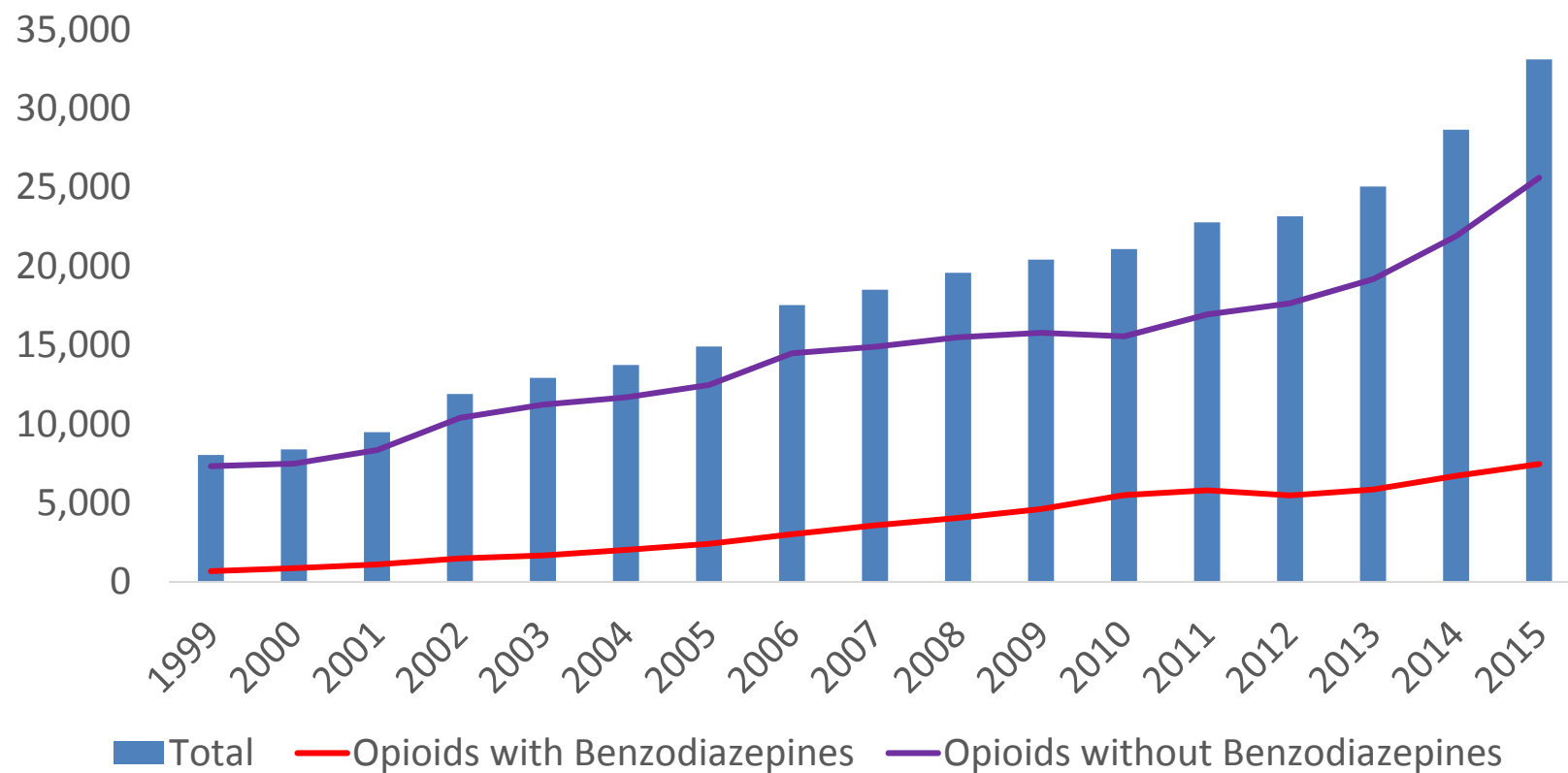
People Abusing Analgesics *DIRECTLY & INDIRECTLY Obtain Them by Prescription*: Most Recent Pill Source

Source Where Respondent Age 12+ Obtained Analgesics:



Source: SAMHSA, 2012 and 2013 National Survey on Drug Use and Health

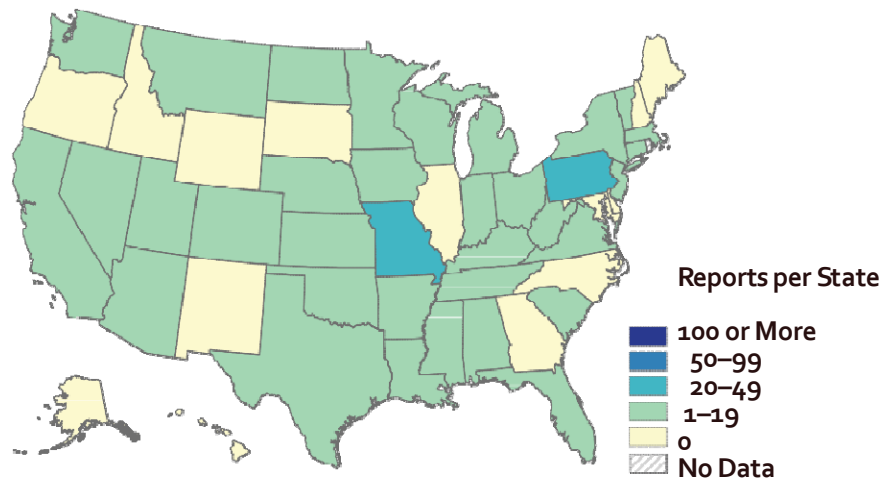
Benzodiazepine involvement in opioid overdose



Source: National Center for Health Statistics, CDC Wonder

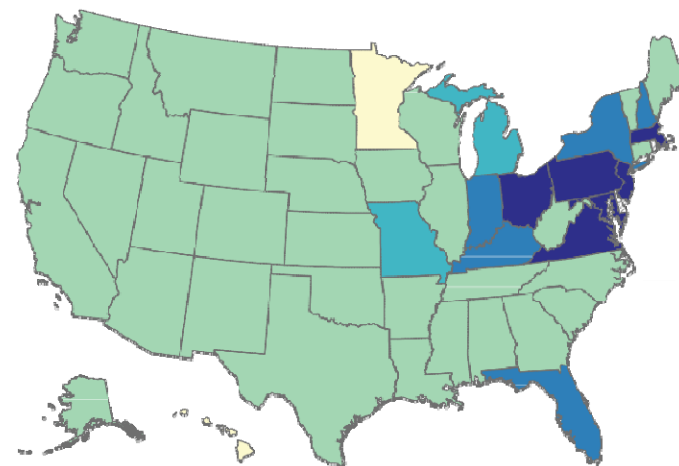
Increases in Fentanyl Reports in Northeast, Midwest and South

Jan.— June 2009



35 States reported analyzing fentanyl during the first half of 2009. No States had more than 49 fentanyl reports. Two States had between 20 and 49 reports.

Jan.— June 2014



In the first half of 2014, 46 States reported fentanyl, including 6 with 100 or more reports and 5 States between 50 and 99. Highest numbers mainly in Midwest and Northeast.

Four Opioid Priority Areas

- Opioid prescribing practices to prevent addiction and overdose
- The expanded use of naloxone, to treat overdoses
- Expanded use of medication assisted treatment (MAT) for opioid use disorders
- Improve treatment of pain



➤ One Solution....



***Opioid Prescribing
Guidelines***

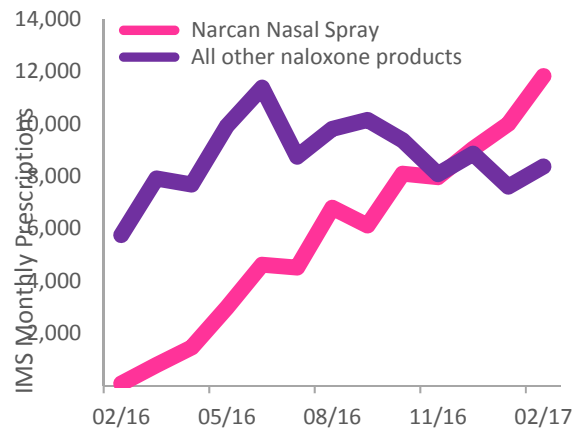
- Intended for primary care providers
- Applies to patients >18 years old in chronic pain outside of end-of-life care
- Builds on joint CDC, NIDA, ONC, SAMHSA summary on “Common Elements in Guidelines for Prescribing Opioids for Chronic Pain” and the NIH Pathways to Prevention for Opioids in Treating Chronic Pain
- PUBLISHED MARCH 15, 2016



User Friendly Naloxone

NARCAN® Nasal
Spray device
\$37.50 per 4mg

Approved by FDA
November 2015



- Naloxone Px increased 3.5X in past year
- NARCAN® Nasal Spray is the most prescribed naloxone
- 900,000 NARCAN® Nasal Spray doses distributed since launch in 2/16

Overdose Treatment: Saving Lives for Future Recovery

- New stronger, longer acting formulations to address more potent opioids (e.g. fentanyl)
- Stimulation devices to prevent respiratory depression
- Overdose detection and alert technologies
- Post-overdose interventions to ensure engagement in treatment

Medications Are *Effective* and *Save Lives*

Medication Assisted Treatment (MAT)

DECREASES:

- Opioid use
- Opioid-related overdose deaths
- Criminal activity
- Infectious disease transmission

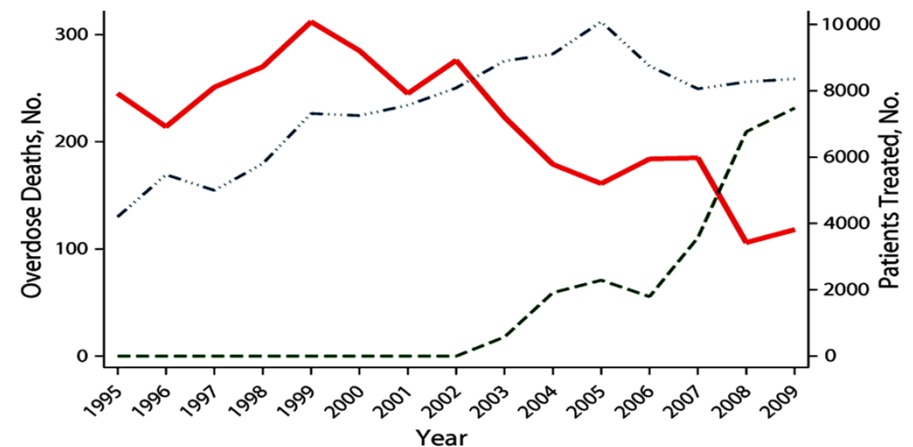
And INCREASES

- Social functioning
- Retention in treatment

But MAT is *highly underutilized*

Opioid Agonist Treatments Decreased Heroin OD Deaths

*Baltimore, Maryland,
1995-2009*



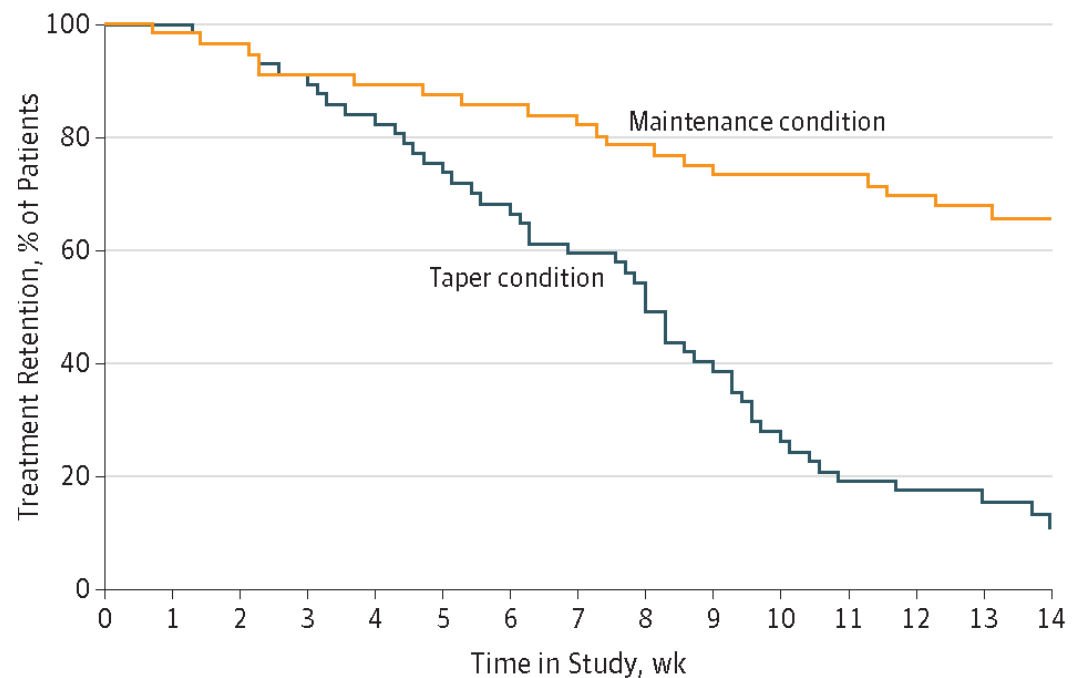
Schwartz RP et al., Am J Public Health 2013.

Science = Solutions

Sustained Recovery Requires *Sustained Care*

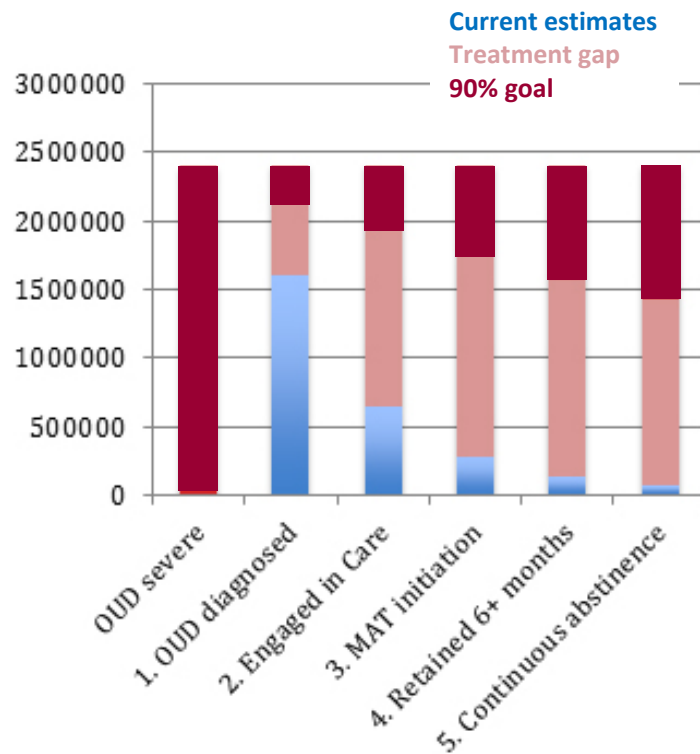
- Opioid addiction is a chronic brain disorder that requires sustained medical treatment
- 21st Century Cures Act provides \$1 Billion for treatment over 2 years
- Funding for this new treatment capacity must be maintained to prevent harm to patients

Reduced Treatment Retention When Tapered Off Buprenorphine



Fiellin DA et al. *JAMA Internal Med.* 2014;174(12):1947-1954.

OUD Cascade of Care in USA

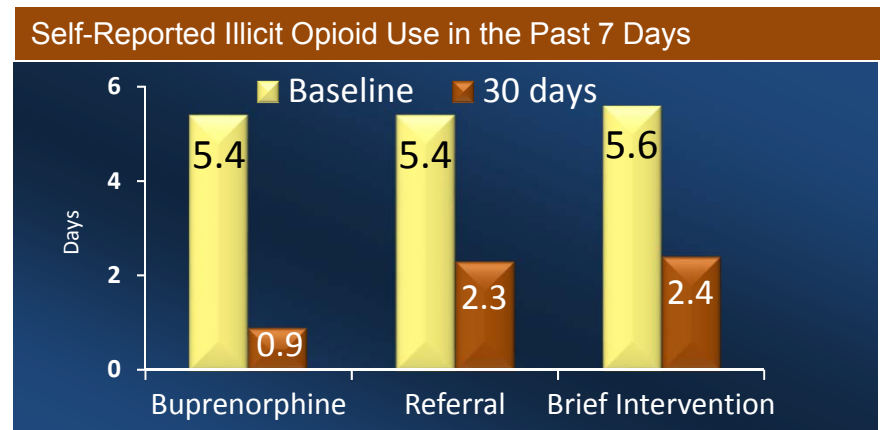


Williams AR, Nunes E, Olfson M. Health Affairs Blog, 2017

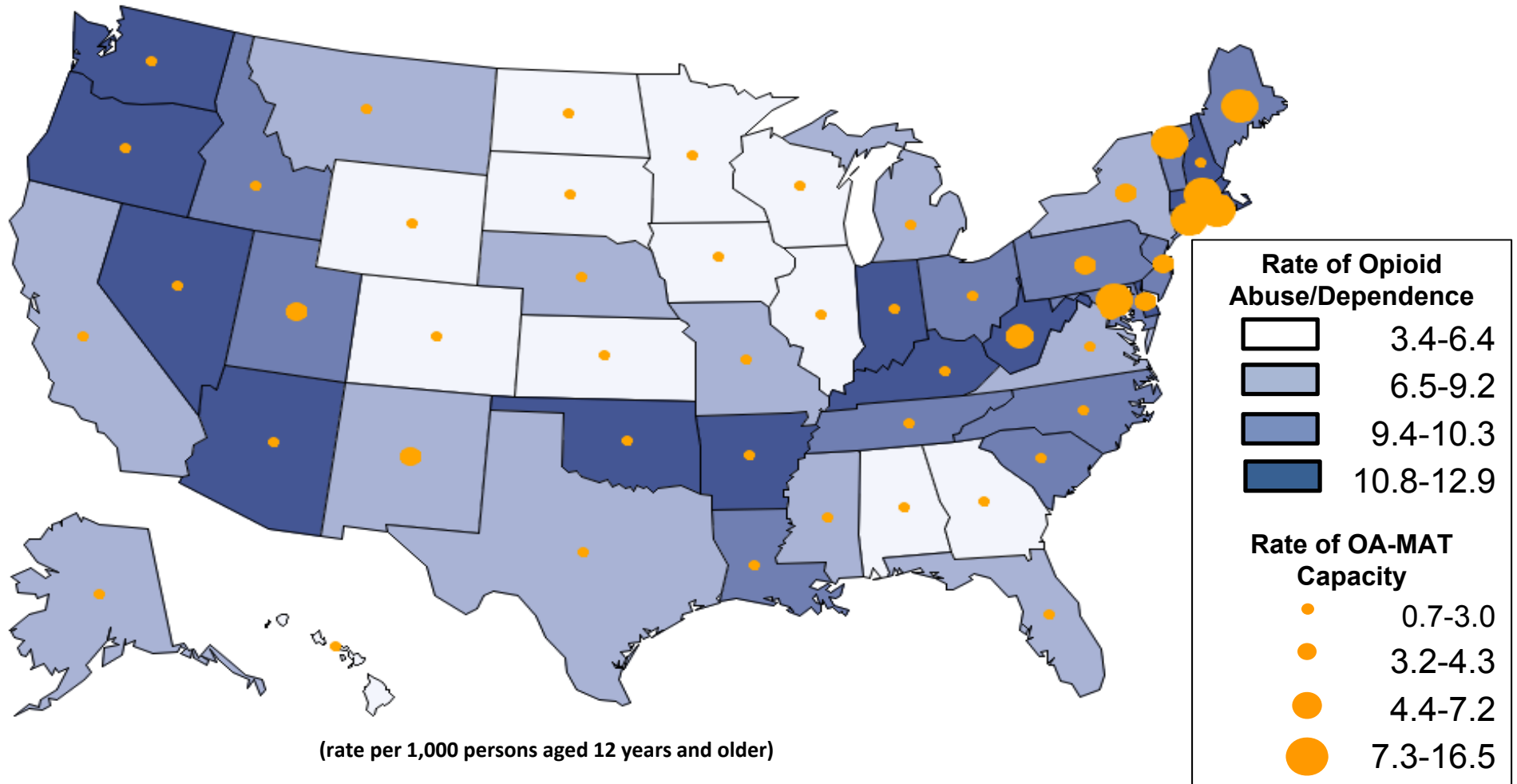
Engage the Healthcare System in OUD Treatment

Emergency Department-Initiated Buprenorphine

- Reduced self-reported, illicit opioid use
- Increased engagement in addiction treatment
- Decreased use of inpatient addiction treatment services



Additional Challenge: *Lack of medication-assisted treatment capacity*



Source: Jones CM, et al. Am J Public Health . 2015; 105(8):e55-63.

What Do We **Need To Know**?

- **PREVENTION:**

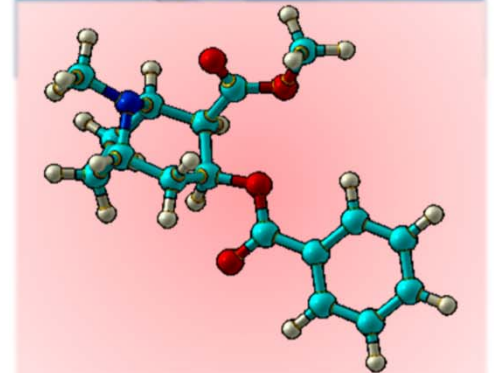
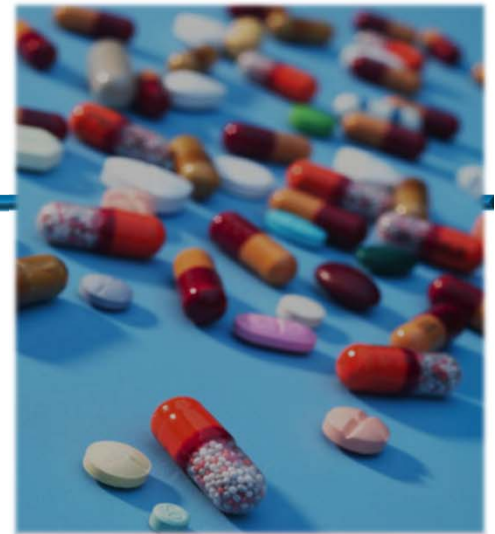
- Less Abusable Analgesics
 - Alternative Therapeutics

- **IMPLEMENTATION SCIENCE:**

- Expansion of naloxone use
 - Large scale implementation of MAT

- **NEW MEDICATIONS:**

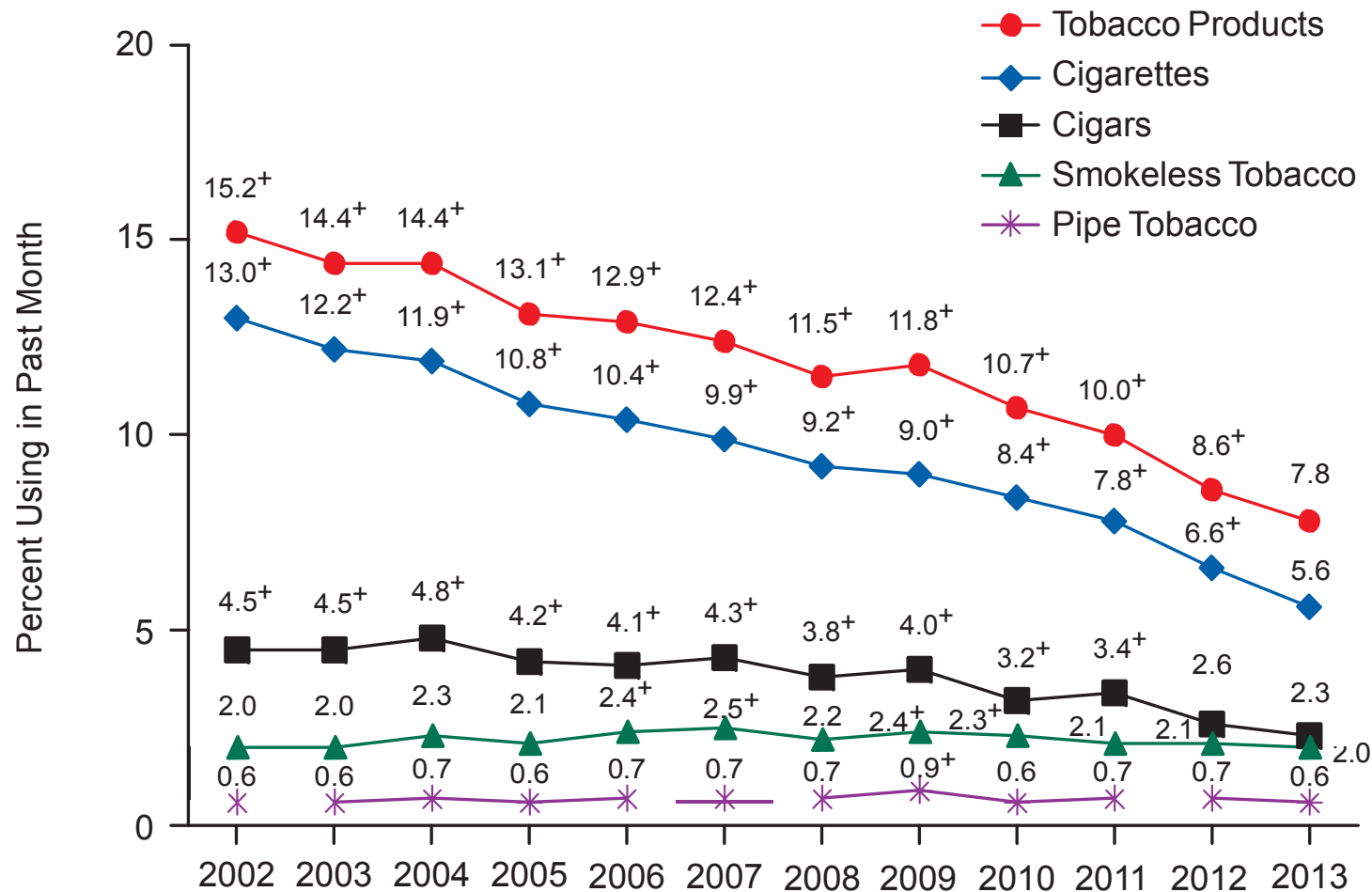
- Nasal naloxone
 - Implantable buprenorphine



Quick Glance at Tobacco Use among Adults

- While in recent decades there has been a decreased in tobacco use, e-cigarette) have emerged
- One in five American adults (21.3%) use a tobacco product in 2013 (NATS; Agaku et al., 2014), or roughly 50 million people.
- Current tobacco use varies by age (SAMHSA, 2014)
 - ~ 37% among young adults (18-25)
 - ~ 26% among adults (26+)
 - ~ 8% among youth (12-17)

National Survey on Drug Use and Health (NSDUH): Trends in Past 30-Day Tobacco Use among 12-17 Year Olds

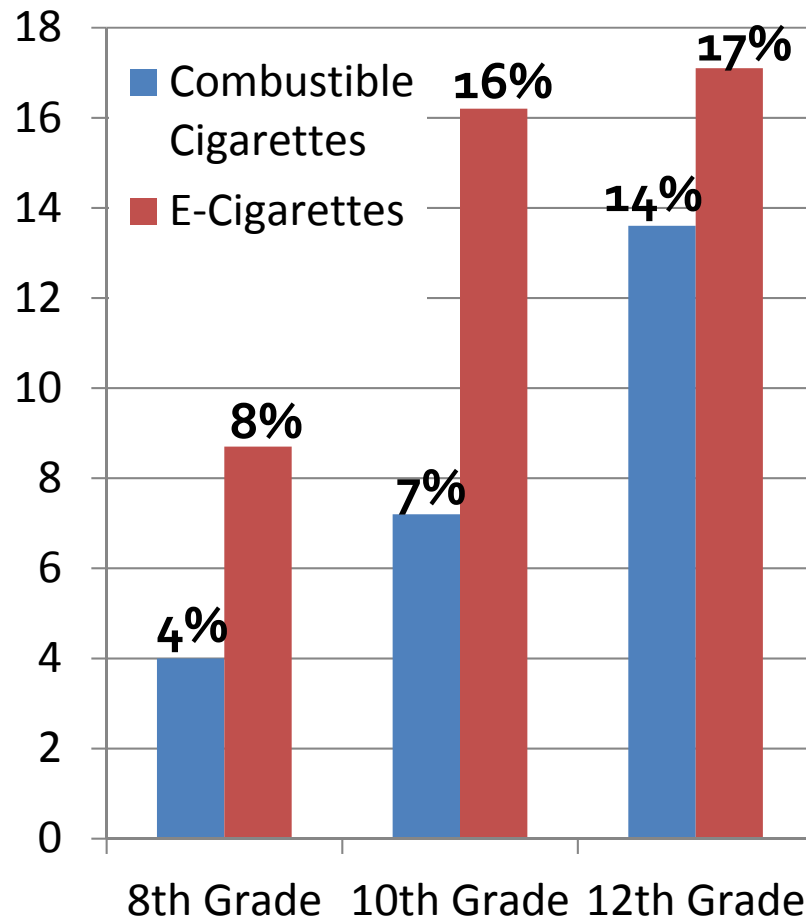


⁺ Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.

Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: summary of national findings, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

More U.S. Youth Use *E-Cigs* Than Combustible Cigs

2014 Past Month E-Cig vs. Combustibles in USA Students



*Monitoring the Future Study 2014,
University of Michigan*

In a prospective study of 14 year old students, *E-Cigarette use predicting onset* of:

- Any combustible 2.75 AOR
- Combustible cigs 1.73 AOR

Leventhal, et al. *JAMA* 2015;314(7):700-707.

2012-2013 U.S. study of 12-17 year olds (n=13,561), *first tobacco product was flavored* among users:

- Cigarettes 50%
- Smokeless 69%
- E-Cigarettes 81%

Ambrose, et al. *JAMA*, 26 October 2015

Emerging Research Issues on E-cigarettes

- Potential benefits and harm at the individual and public health level
- E-cigarette use as cigarette-smoking cessation
- E-cigarette as a gateway to combustible cigarette use (especially among youth)
- E-cigarette use leading to re-normalization of cigarette smoking (especially among youth)
- Exposure of nicotine to the developing brain and how changes in e-cigarette devices may impact this exposure
- Concurrent use of e-cigarettes with marijuana and/or other substances

Population Assessment of Tobacco and Health (PATH) Study

PATH Study Overview

- A nationally representative longitudinal study of tobacco use, its determinants, and its impacts
- Funded by the FDA Center for Tobacco Products
- Administered by the NIH National Institute on Drug Abuse
- Developed by FDA and NIH with assistance from:

Westat and the Westat Scientific Partners

Project Director

David Maklan, Westat

Principal Investigator

Andrew Hyland, Roswell Park Cancer Institute

Roswell Park Cancer Institute
Medical University of South Carolina
University of California San Diego
Rutgers University

Geisel School of Medicine at Dartmouth
Truth Initiative
University of Waterloo
University of Minnesota

Longitudinal Study Design

Tobacco product use and changes **over time**

Tobacco product use **initiation, cessation, and relapse**

Poly-tobacco **use and switching** between tobacco products

Emergence of **addiction and dependence**

Health conditions potentially related to tobacco use

Exposures from tobacco product use and related biomarkers

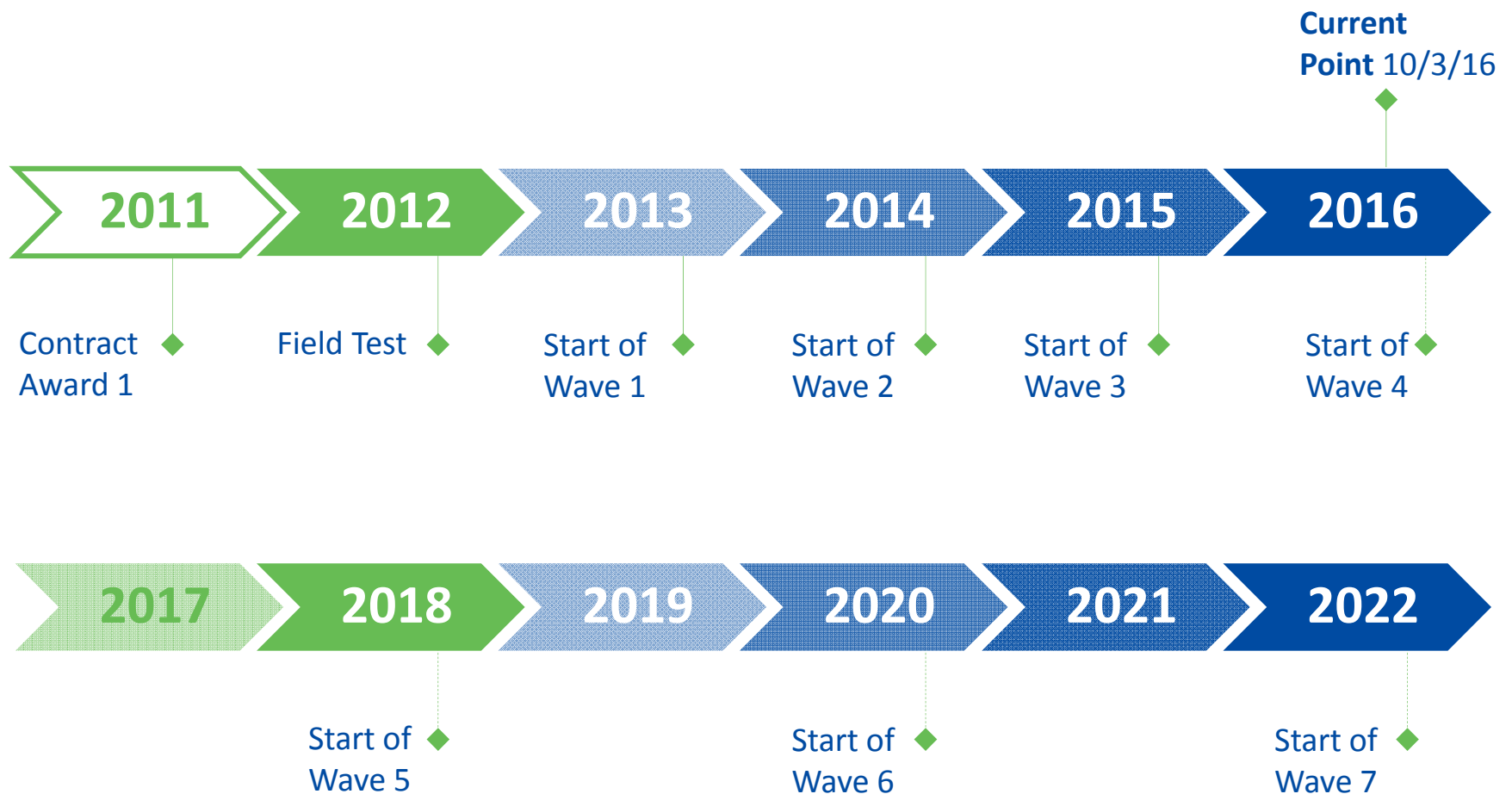
Changes in awareness, knowledge, attitudes, and beliefs about tobacco products

The **evolving** tobacco product market, regulatory activities, and tobacco product use

Measures of tobacco use, health, regulatory domains, and mediators/moderators

Tracking of changes wave-to-wave, overall and by subgroup

PATH Study Timeline



Wave 1 Design Features

Longitudinal cohort design

Nationally representative sample of U.S. civilian, non-institutionalized population ages 12 years and older

Sample size: N=45,971

(N=32,320 adults 18+ years;
N=13,651 youth 12-17 years)

Baseline data collection: September 2013
– December 2014

Sample includes **never, current, and former tobacco users**

Four-stage, stratified

probability sample design

Up to two adults (oversampled for tobacco users, African Americans, and young adults ages 18-24) and **up to two youths** (at random) per household

The weighted response rate for the Household Screener was **54.0%**.

Among screened households, the overall weighted response rate was 74.0% for the Adult Interview and 78.4% for the Youth Interview.

Developing a Learning Healthcare System

- From Science to Practice and Back
- Examples:
 - JJ-TRIALS: Correctional System and NIDA
 - HIV, HCV and SUD in rural communities: CDC, ARC, SAMHSA, NIDA and local governments
 - 21st Centuries Act: States/SAMHSA/NIDA Collaboration
- The Future: Can we create an ongoing State/NIDA partnership?

www.drugabuse.gov

Science = Solutions

The Prescription Opioid Epidemic & Heroin

Research Report Series

National Institute on Drug Abuse

Principles of Drug Abuse
Treatment for Criminal
Justice Populations | A Research-Based Guide

National Institutes of Health
U.S. Department of Health
and Human Services

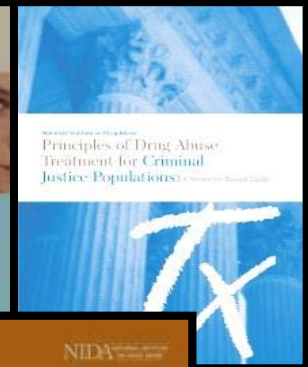
National Institute on Drug Abuse
SEEKING DRUG ABUSE TREATMENT:
KNOW WHAT TO ASK



U.S. Department of Health and Human Services
National Institutes of Health



the National Institute on Drug Abuse
MEDIA GUIDE
how to find what you need
to know about drug abuse
and addiction



Research Report Series

Prescription Drugs: Abuse and Addiction

What is prescription
drug abuse?

Prescription drug abuse is the use of a medication without a prescription, in a way other than as prescribed, or for the experience or feelings created. According to recent national surveys, prescription medications, such as those used to treat pain, anxiety, depression, and anxiety, are being abused in a way never only to experience strong effects drug users. The consequences of this abuse have been steadily increasing, reflected in increased treatment admissions, emergency room visits, and overdose deaths.

NIDAMED