Office of National Drug Control Policy

• Component of the Executive Office of the President
• Coordinates drug-control activities and related funding across the Federal Government
• Produces the annual *National Drug Control Strategy*
National Drug Control Strategy

• The President’s science-based plan to reform drug policy:
  1) Prevent drug use before it ever begins through education
  2) Expand access to treatment for addicted Americans
  3) Reform our criminal justice system
  4) Support Americans in recovery

• Signature initiatives:
  – Prescription Drug Abuse
  – Prevention
  – Drugged Driving

Drug Poisoning and Other Injury Death Rates 1999-2011

**NOTE:** Suicide and homicide include deaths by drug poisoning or firearms.

### United States Drug Poisoning Deaths Involving Opioid Analgesics, Cocaine and Heroin

#### Number of Deaths

<table>
<thead>
<tr>
<th>Year</th>
<th>Opioid Analgesics</th>
<th>Cocaine</th>
<th>Heroin *</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>4,030</td>
<td>3,822</td>
<td>1,963</td>
</tr>
<tr>
<td>2000</td>
<td>4,400</td>
<td>3,544</td>
<td>1,843</td>
</tr>
<tr>
<td>2001</td>
<td>5,528</td>
<td>3,833</td>
<td>1,784</td>
</tr>
<tr>
<td>2002</td>
<td>7,456</td>
<td>4,599</td>
<td>2,092</td>
</tr>
<tr>
<td>2003</td>
<td>8,517</td>
<td>5,199</td>
<td>2,084</td>
</tr>
<tr>
<td>2004</td>
<td>9,857</td>
<td>5,443</td>
<td>1,879</td>
</tr>
<tr>
<td>2005</td>
<td>10,928</td>
<td>6,208</td>
<td>2,010</td>
</tr>
<tr>
<td>2006</td>
<td>13,723</td>
<td>7,448</td>
<td>2,089</td>
</tr>
<tr>
<td>2007</td>
<td>14,408</td>
<td>6,512</td>
<td>2,402</td>
</tr>
<tr>
<td>2008</td>
<td>14,800</td>
<td>5,129</td>
<td>3,041</td>
</tr>
<tr>
<td>2009</td>
<td>15,597</td>
<td>4,350</td>
<td>3,278</td>
</tr>
<tr>
<td>2010</td>
<td>16,651</td>
<td>4,183</td>
<td>3,036</td>
</tr>
<tr>
<td>2011</td>
<td>16,917</td>
<td>4,681</td>
<td></td>
</tr>
</tbody>
</table>

Note: Not all drug poisoning deaths specify the drug(s) involved, and a death may involve more than one specific substance. The rise in 2005-2006 in opioid deaths is related to non-pharmaceutical fentanyl (see [link](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm)). *Heroin includes opium.

Prescription Misuse in the United States
(All Drugs Combined)

- 6.8 million Americans reported current non-medical use of prescription drugs in 2013.¹
- Approximately 1 in 5 people using drugs for the first time in 2013 began by using a prescription drug non-medically.²
- Of the 41,340 drug overdose deaths in 2011 in America, 22,810 involved prescription drugs.
  - 16,917 involved opioid painkillers (vs. 4,681 involving cocaine and 4,397 involving heroin)³
- $55.7 billion in costs for prescription drug abuse in 2007, including $25 billion in direct health care costs and $5.1 billion in criminal justice costs.⁴
- Studies have found that individuals abusing opioids generate, on average, annual direct health care costs 8.7 times higher than non-abusers.⁵

¹, ². Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. U.S. Department of Health and Human Services. [September 2014].
³. National Center for Health Statistics/CDC. Unpublished special tabulations of 2011 Multiple Cause of Death data (June 10, 2014).
Heroin Use or Non-Medical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older: 2002-2013

**Numbers of Users (Thousands) Aged 12+**

Source: SAMHSA, 2013 National Survey on Drug Use and Health (September 2014).
Estimated Number of Lifetime Heroin Users among Persons Aged 12 or Older: 1990 to 2013

Source: SAMHSA, 2013 National Survey on Drug Use and Health (September 2014) for 2002 to 2013; data prior to 2002 are from the National Household Survey on Drug Abuse.
High Toxicity of Opioids

Number of Florida Drug-Involved Deaths

Source: Drugs Identified in Deceased Persons by Florida Medical Examiners, 2006-2013 mid-year reports
New Users in the Past Year of Specific Illicit Drugs among Persons Aged 12 or Older, 2013

Past Year Initiates of Specific Illicit Drugs

- Marijuana: 2,427
- Tranquilizers: 1,539
- Ecstasy: 1,180
- Cocaine: 751
- Stimulants: 603
- Inhalants: 601
- LSD: 583
- Heroin: 482
- Sedatives: 163
- PCP: 128

First Specific Drug Associated with Initiation of Illicit Drug Use

- Marijuana (70.3%)
- Pain Relievers (12.6%)
- Stimulants (9.7%)
- Halucinogens (2.9%)
- Sedatives (0.5%)
- Inhalants (0.3%)
- Tranquilizers (5.2%)
- Opioids (0.2%)
- Cocaine (0.1%)

Note: The specific drug refers to the drug that was used for the first time in the past year, regardless of whether it was the first drug ever used.

Source: SAMHSA, 2013 National Survey on Drug Use and Health (September 2014).
Trajectories? Majority from Family & Friends to Customer

Source: 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-46, HHS Publication No. (SMA) 13-4795, Sept 2014. (Figure 2.16 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2011-2012)
Source of Prescription Pain Relievers

How different misusers of pain relievers get their drugs

<table>
<thead>
<tr>
<th>Methods and sources for obtaining pain relievers</th>
<th>Recent Initiates</th>
<th>Occasional Users</th>
<th>Frequent or Chronic Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bought from friend/relative, dealer, or internet</td>
<td>9%</td>
<td>13%</td>
<td>28%</td>
</tr>
<tr>
<td>Prescribed from 1 or more doctors</td>
<td>17%</td>
<td>17%</td>
<td>25%</td>
</tr>
<tr>
<td>Obtained from friend/relative for free or w/o asking</td>
<td>68%</td>
<td>65%</td>
<td>41%</td>
</tr>
</tbody>
</table>

Source: Unpublished data from SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2009-2010
Non-medical Prescription Opioid Users Who Try Heroin

• Prescription opioid use is a risk factor for heroin use. Approximately 4 out of 5 of heroin users ages 12-49 used prescription opioids before heroin initiation.¹

• Among non-medical prescription opioid users, heroin use is relatively rare; across a five year period following initiation, only 3.6% of people who used prescription opioids non-medically tried heroin.²

• Injection-drug users report tolerance motivates them to try heroin.³

• New research shows heroin effects, price, availability and ease of use motivate heroin users who formerly used prescription opioids.⁴

2. Ibid
Heroin Indicators Show Increased Availability

• Close correlation between independent indicators
  – Street heron seizures (NFLIS)
  – Workplace drug testing positives (Quest DTI)

• Heroin seizures

Sources:
1) National Forensic Laboratory Information System (NFLIS)
2) Quest Diagnostics Drug Testing Index
3) National Seizure System
Prescription Drug Abuse Prevention Plan

• Coordinated effort across the Federal Government

• Four focus areas:
  1) Education
  2) Tracking and Monitoring
  3) Proper Disposal of Medication
  4) Enforcement

Education

Needs

- Expanded health care provider knowledge on prescribing, identification of patients at risk for abuse, use of PDMPs in clinical practice, and addressing substance use disorders
- Screening, intervention, and referral to treatment for those misusing or abusing prescription drugs
- Ensure community leaders, parents, and young people understand the dangers of prescription drug misuse

Main Actions

- Legislation requiring mandatory education for all clinicians who prescribe controlled substances
- Increased substance abuse education in health profession schools, residency programs, and continuing education
- Expedited research on the development of abuse-deterrent formulations
Goals

- PDMP in every state and interoperability among states
- Use of the system by prescribers to identify patients potentially at risk for or engaged in prescription drug misuse or at risk for medication interaction

Main Actions

- Secured language for Department of Veterans Affairs to share prescription drug data with state PDMPs
- Now 24 states can share data across state lines
- Pilot projects with ONC and SAMHSA in Illinois, Indiana, Kansas, Michigan, Nebraska, North Dakota, Ohio, Oklahoma, Tennessee, and Washington State
Drug Disposal

- New rules released by Drug Enforcement Administration (DEA) on Sept. 8, 2014 (effective October 9, 2014)
- MANUFACTURERS, DISTRIBUTORS
  - Certain DEA registrants may be authorized collectors.
  - On-site destruction or mail-back
- LAW ENFORCEMENT: authorized to hold take-backs
- PATIENTS
  - Follow label guidelines
  - Household disposal
  - Long-term Care Facilities (on behalf of patients)
Enforcement

Goals

- Increase law enforcement and prosecutor training around prescription drug diversion and abuse
- Assist states in addressing “pill mills” and doctor shopping

Main Actions

- Provide technical assistance to states on model regulations/laws for pain clinics
- Encourage High Intensity Drug Trafficking Areas (HIDTAs) to focus on prescription drug diversion cases
- Support prescription drug abuse-related training for law enforcement agencies and criminal justice leaders
Perceived Need for and Effort Made to Receive Specialty Treatment Among Persons Aged 12 or Older Needing But Not Receiving Treatment: 2013

7,608,000 Needing Treatment for Illicit Drug Problem

Source: SAMHSA, 2013 National Survey on Drug Use and Health (September 2014).
Expanding Treatment

• Ensure availability of medication-assisted treatment (MAT) for treatment of addiction (i.e., buprenorphine/naltrexone [Suboxone], methadone, Vivitrol).

• Employers: Ensure that health plans offer adequate coverage for screening and treatment for substance use disorders, including medication-assisted treatment (MAT).

• State Health Leadership: Inventory treatment availability and work within Affordable Care Act/state-run health marketplaces to ensure proper resourcing.
A small percentage (approximately 10%) of Americans with substance use disorders received treatment at a specialty facility. Long-term maintenance treatment with an FDA-approved medication for treating opioid use disorders or relapse-prevention combined with behavioral therapies – has been shown to be more effective than treatment without medication. MAT can be cost-effective, prevent criminal recidivism and blood-borne infection from injection, and save lives by preventing overdose. In 2013, only 8% (1,167) of treatment facilities were certified by the federal oversight agency to provide Opioid Treatment Programs (with methadone and/or buprenorphine).

1 SAMHSA National Survey of Substance Abuse Treatment Services (N-SSATS): 2012 -- Data on Substance Abuse Treatment Facilities (December 2013)
2 SAMHSA National Survey of Substance Abuse Treatment Services (N-SSATS): 2012 -- Data on Substance Abuse Treatment Facilities (December 2013)
**Naloxone**

- The Administration supports the use of naloxone by public health and law enforcement professionals to prevent drug-related deaths because of how effective the drug can be.
  - It is legal to prescribe naloxone to patients at risk for overdose to be administered by family members or others who are available.

- ONDCP understands some have concerns that widespread availability of naloxone does not further the objective of reducing opioid misuse directly.
  - However, ONDCP supports this along with overdose education because some victims are in circumstances which make obtaining or succeeding at treatment difficult, and overdose education with naloxone may save a life and enable eventual participation in treatment.
Naloxone Autoinjector

- FDA recently approved a new auto-injector that provides verbal instructions out loud to the rescuer during the rescue (similar to the technology used for defibrillators).\(^1\)

- Approval was specifically for rescue without requirement for training;

- The medication is prescribed to the patient but can be used by caregiver or as law permits by first responder;

- Comes with a “trainer” to practice “sham rescues”;

- This may mitigate concerns about administration
  - by non-medical personnel;
  - Using traditional needle & syringe; or
  - Off-label use of nasal inhaler kits.

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1. Drug Label source: [http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205787Orig1s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205787Orig1s000lbl.pdf)
State Naloxone And Good Samaritan Legislation

**STATUS OF RELATED LEGISLATION**

As of 15 July 2014

- Controlled Substance/Paraphernalia Possession Protections [22 states & DC]
- Lay Administration Criminal Liability Protections [23 states & DC]
- Lay Administration Civil Liability Protections [20 states & DC]
- Prescriber Criminal Liability Protections [14 states]
- Prescriber Civil Liability Protections [13 states]
- Allows Third Party Prescriptions [24 states]

* Only if examiner has received training.
† Only applies to lay responders.
‡ In Idaho and Indiana, evidence of providing assistance to someone experiencing an overdose can be presented as a mitigating factor at sentencing to a conviction for possession of a controlled substance and/or paraphernalia. Utah allows evidence of providing assistance to someone experiencing an overdose to be used as an affirmative defense to an allegation of possession of a controlled substance and/or paraphernalia.

Source: Office of National Drug Control Policy (ONDCP) searches of state legislative information from the following online databases pulled the information on the chart, and were current as of July 10, 2014:
- http://www.countydruglaws.com/
- http://drugseizures.org/

Created by ONDCP: August 25, 2014
Recent FDA Actions on Opioids

• **Safety Labeling Changes:** In September 2013, FDA announced labeling changes for extended-release/long-acting (ER/LA) opioids. Changes include:
  
  o New language stating ER/LA opioids are only for management of severe pain requiring long-term opioid treatment and for which alternative treatment options are inadequate
  
  o New boxed warning that chronic maternal use during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS)
  
  o Changes to several sections of drug labeling, including Dosage and Administration; Warnings and Precautions; Drug Interactions; Use in Specific Populations; Patient Counseling Information, and the Medication Guide

• **Abuse-Deterrent Labeling:** In April 2013, FDA announced approval of updated labeling for reformulated OxyContin that describes the medication’s abuse-deterrent properties. This is the first time FDA has approved such a claim.

• **Evzio:** In April 2014, FDA announced approval of Evzio (naloxone hydrochloride injection), which rapidly delivers a single dose of the drug naloxone via a hand-held auto-injector.
Hepatitis C Risk Reduction: Substance Use Disorder Treatment as Prevention

- No vaccine for Hepatitis C.
- After remaining relatively flat from 2006-2010, in 2011 the CDC reported a 44.7% increase in new Hepatitis C infections.¹
- Predominantly in white adolescents and young adults with histories of injection drug use and prior use of prescription opioids, mostly in non-urban areas.²
- Risk counseling is not enough to change behavior.²
- Drug treatment attendance is associated with injection cessation and decreases risk.²
- Access to sterile drug prep equipment/syringes and in communities most in need is scarce.²

Recent Actions on Opioid Safety

• FDA required:
  – A risk evaluation and mitigation strategy (REMS) for extended/release long-acting (ER/LA) opioids
  – Post-marketing studies to look at addiction and overdose rates.
  – Box warning for Neonatal Abstinence Syndrome.
  – New language restricting use of ER/LA opioids to those with pain severe enough to require around-the-clock analgesia and for which alternatives are insufficient.

• FDA recommended and DEA rescheduled all hydrocodone products to Controlled Substances Act Schedule II

Current Opportunities

• Adopt/expand use of Screening, Brief Intervention, and Referral to Treatment (SBIRT) billing codes to reimburse for screening/early intervention/identification of people with active substance use disorders.

• Expand screening efforts to identify patients at risk for overdose or other escalations (including transition to heroin) including checking the PDMP, use of drugs and alcohol in combination

• Consider using abuse-deterrent formulations on formularies, in prescribing to students and use methods to ensure adherence and minimize diversion like urine drug screening, opioid contracts

• Expand access to overdose awareness education and naloxone, particularly among high-risk patient populations.

• Promote expanded use of medications for addiction treatment (i.e., buprenorphine/naloxone [Suboxone], methadone, Vivitrol).
For More Information:

WhiteHouse.gov/ONDCP