

Prescribing Solutions for America's Prescription Drug Crisis

**Presentation to the 2013 Mental Health Symposium:
Focus on Addiction**

Utah Valley University

February 22, 2013



John T. Carnevale, Ph.D.
President,
Carnevale Associates, LLC

John@carnevaleassociates.com
www.carnevaleassociates.com

Defining Nonmedical Use of Prescription Drugs

**INDIVIDUALS
WITHOUT A PRESCRIPTION**

**INDIVIDUALS
WITH A PRESCRIPTION**

Use the medication
consistent with the doctor's orders

Use the medication
inconsistent with doctor's orders

Use the medication only for the
experience or feeling it caused

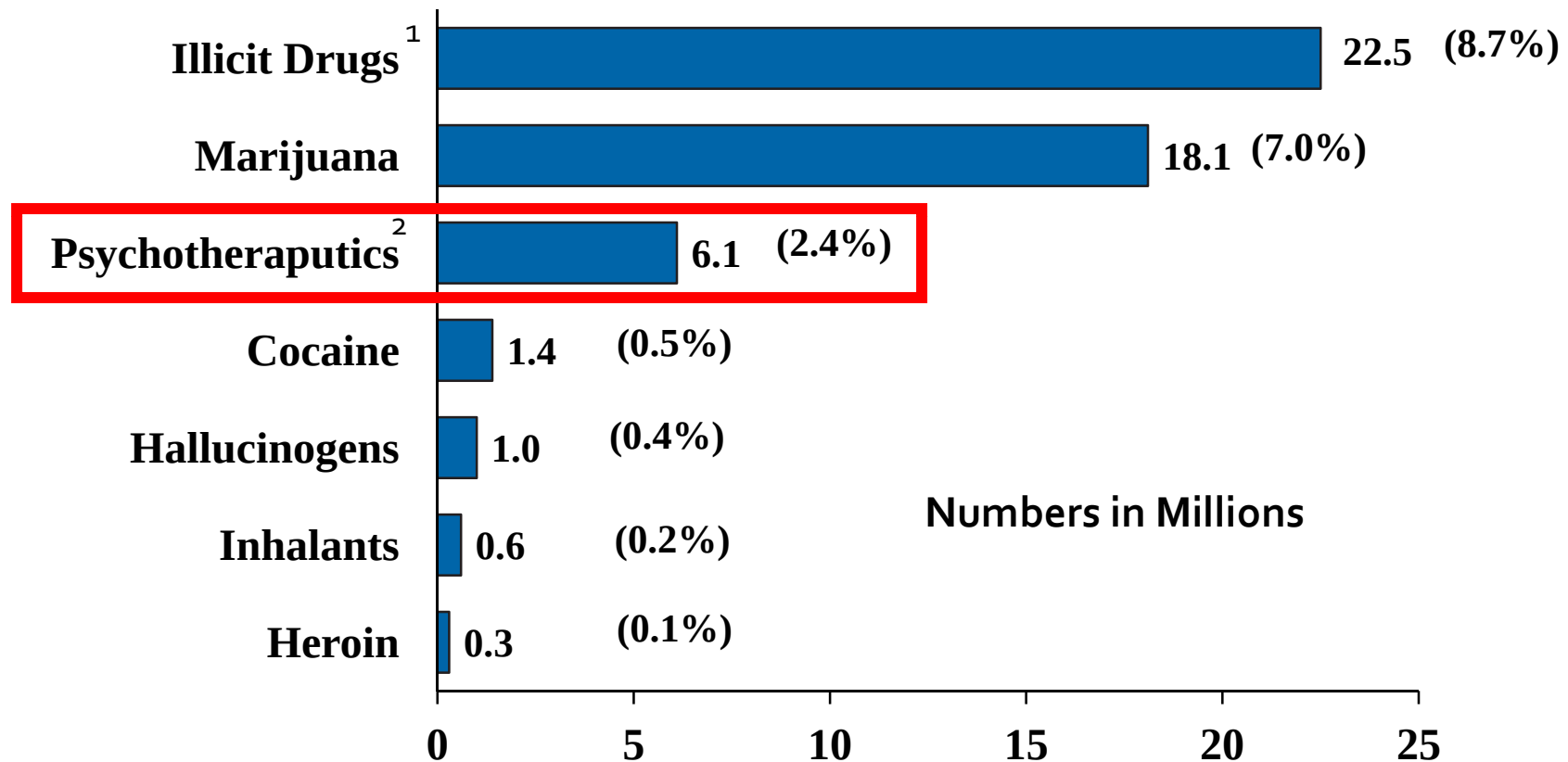


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Prescription Drug Abuse is a Major Problem

(Past Month Use)

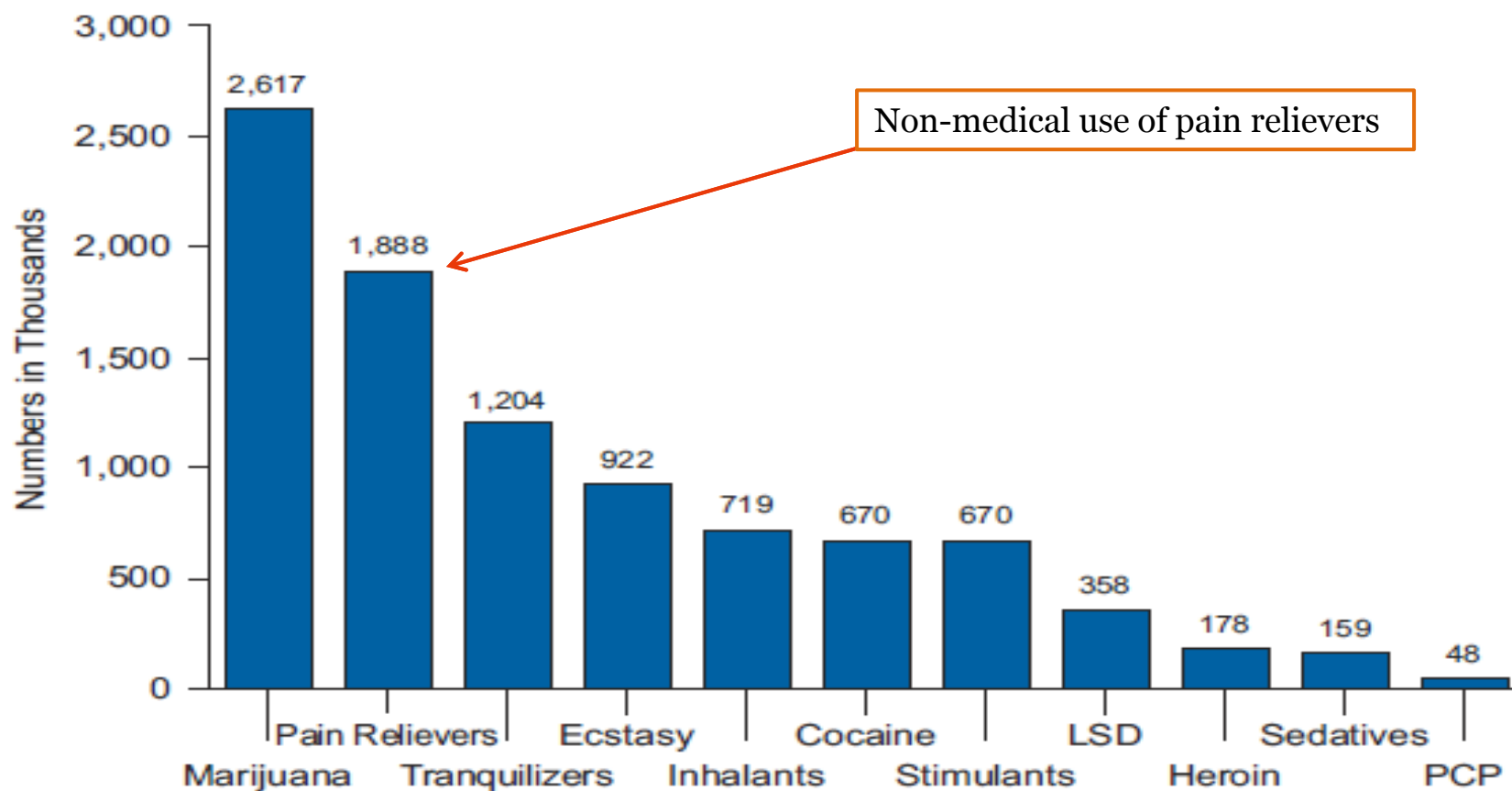


Source: SAMHSA, 2011 National Survey on Drug Use and Health

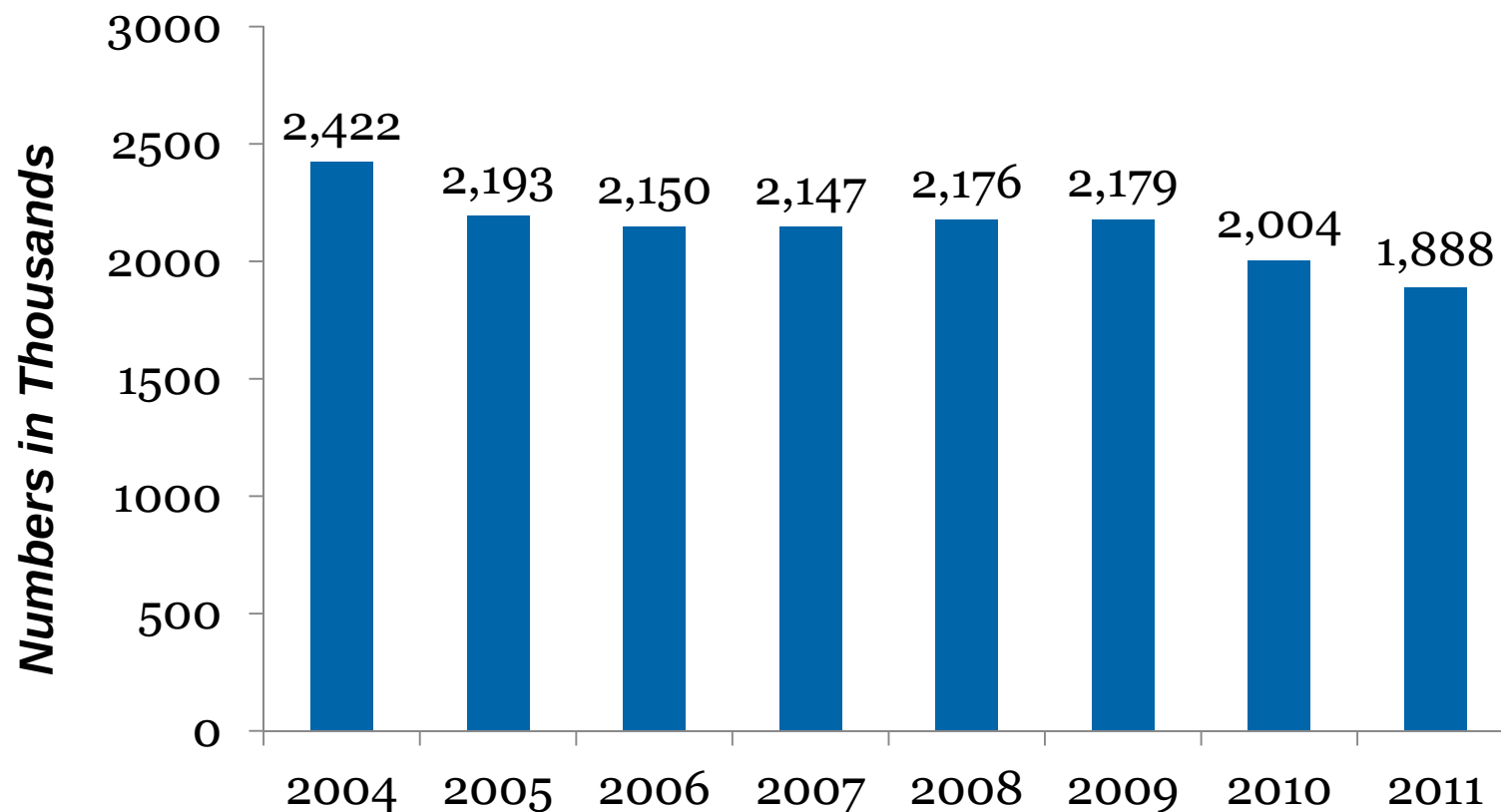
¹ Illicit Drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type drugs used non-medically.

² Psychotherapeutics include the nonmedical use of any prescription-type pain relievers, tranquilizers, stimulants, or sedatives. Over-the-counter substances are not included.

Past Year Initiates of Specific Drugs, 2011

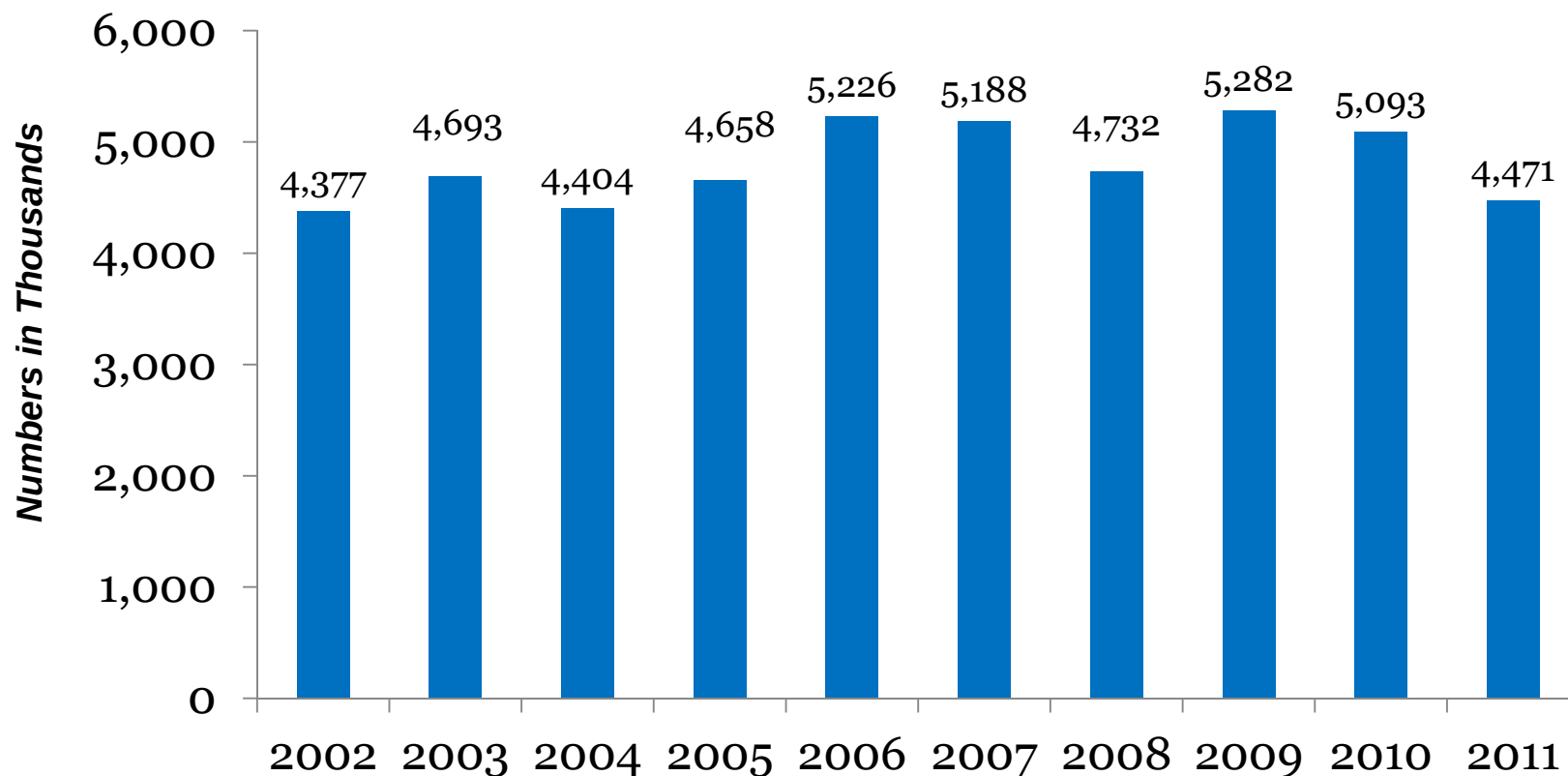


Trend in Past Year Initiates of Pain Relievers among Persons Aged 12 or Older: 2004-2011



Nonmedical Use of Pain Relievers among Persons Aged 12 or Older: 2002-2011

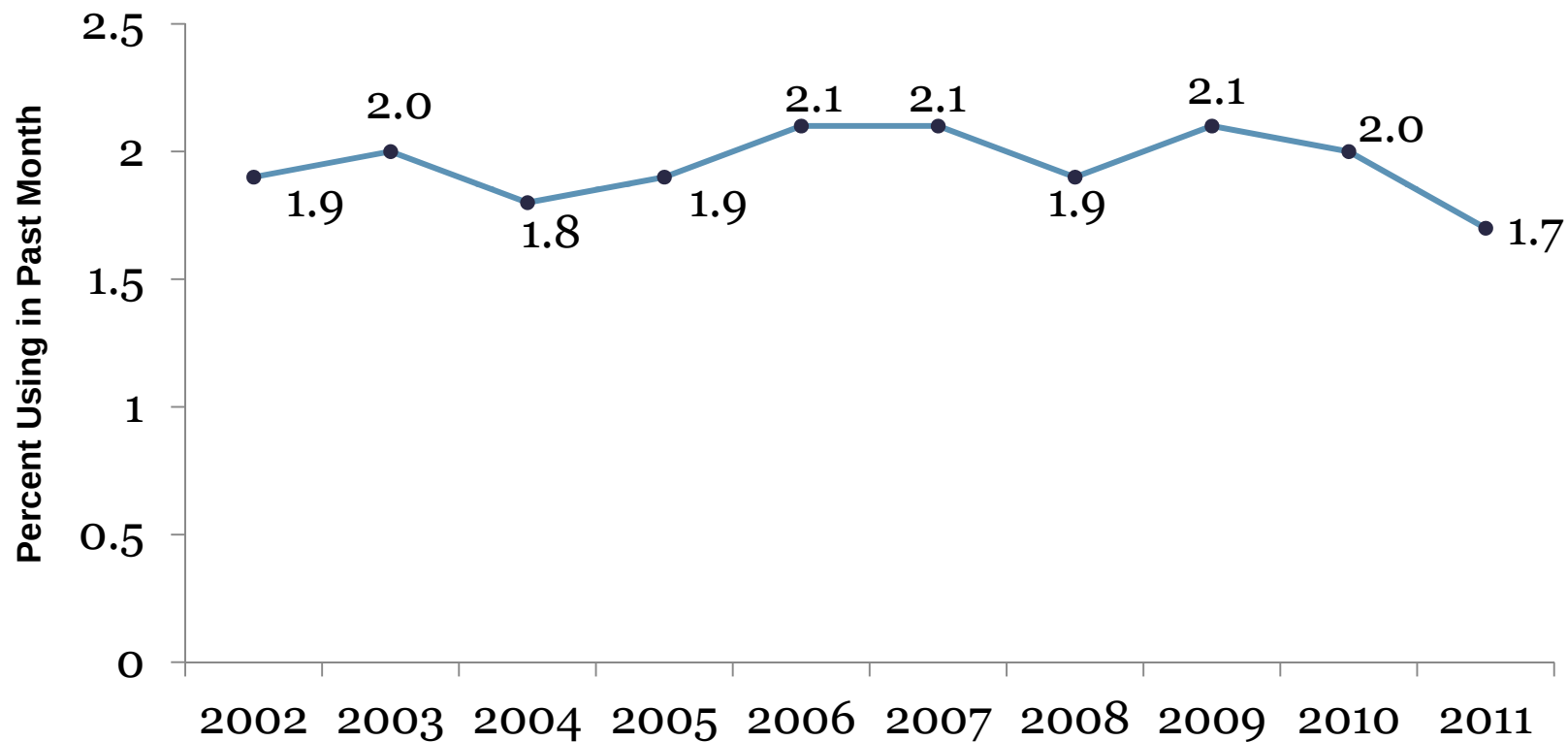
(Past Month Use; Number in Thousands)



Source: SAMHSA, 2002-2011 NSDUHs.

Nonmedical Use of Pain Relievers among Persons Aged 12 or Older: 2002-2011

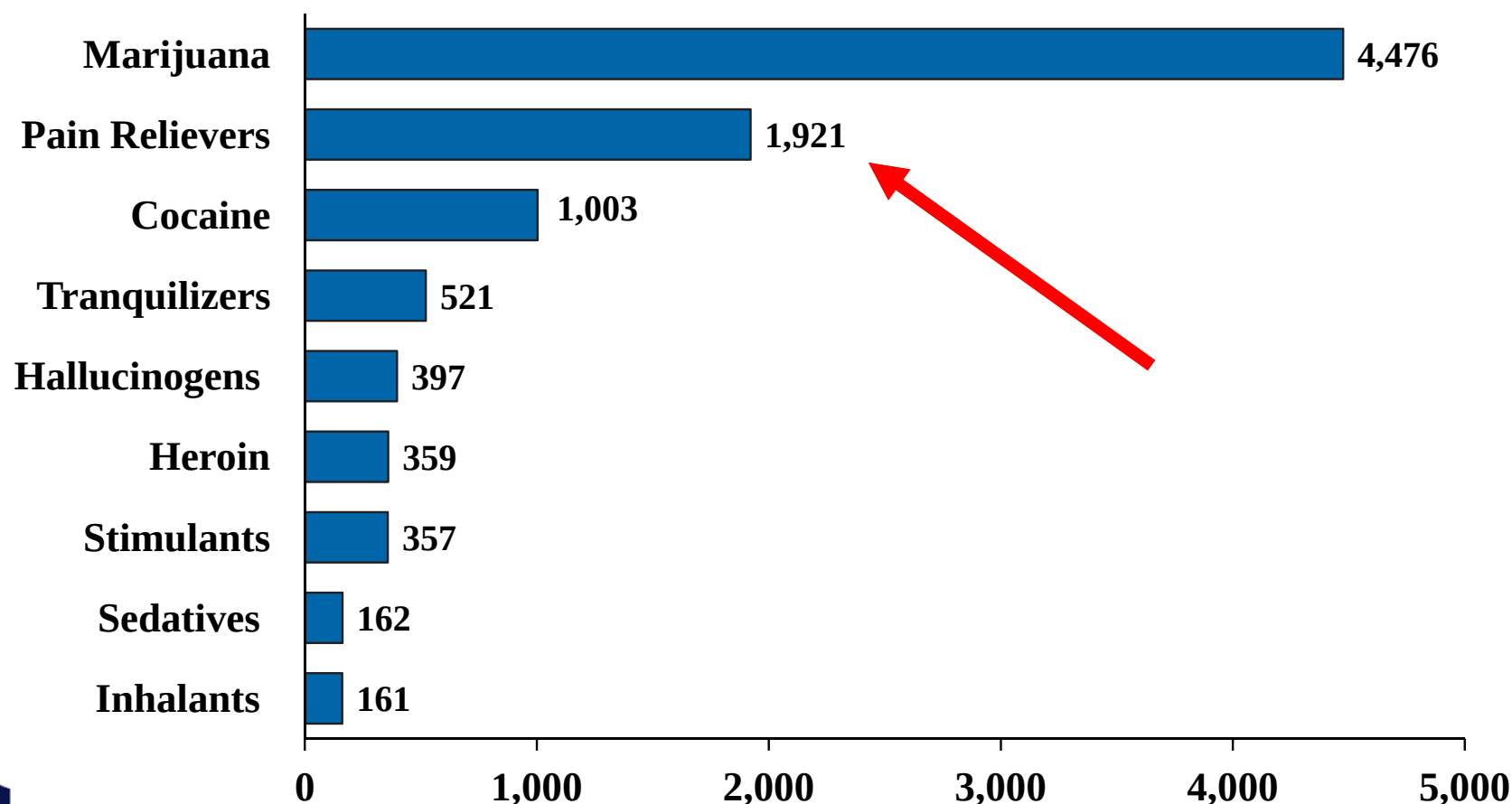
(Past Month Use; Trend is show in Percents)



Source: SAMHSA, 2002-2011 NSDUHs.

Dependence on or Abuse of Specific Illicit Drugs in the Past Year among Persons Aged 12 or Older: 2010

(Numbers in Thousands)



Emergency Room Visits Increasing

- In 2010 alone, more than 1.3 million emergency department visits involved the non-medical use of prescription drugs
- This level is more than double the estimate from six years earlier and outnumbers visits involving all other illicit drugs combined

Linkage to Heroin Use

- There are also indications that for some, prescription opiate abuse can lead to use of heroin, an illicit opiate.
- Heroin use appears to be increasing, particularly among younger people outside of metropolitan areas.
- NSDUH data indicate the number of persons who were past year heroin users in 2011 (620,000) was significantly higher than the number in 2007 (373,000).

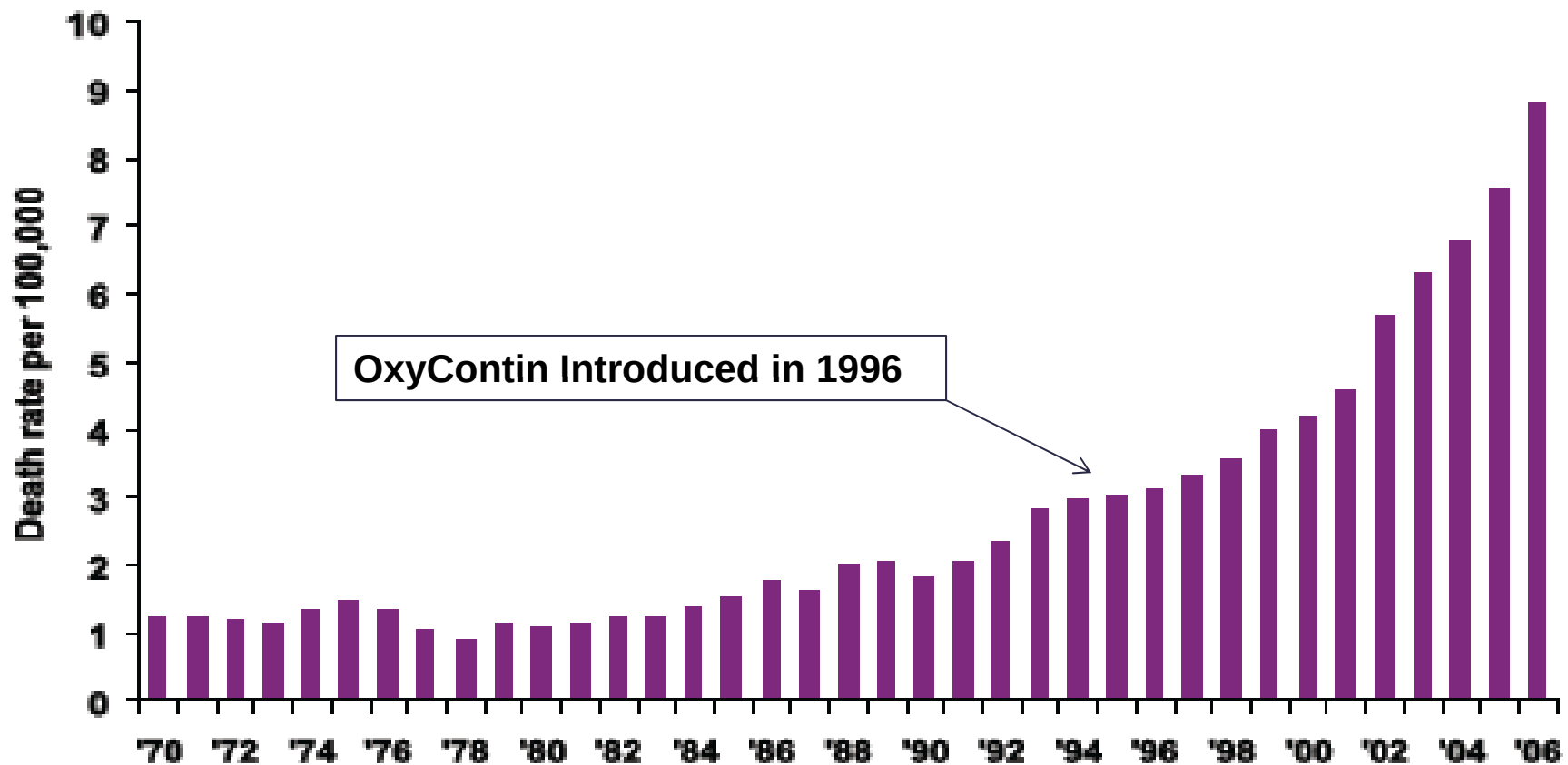
Treatment admissions for prescription drugs are increasing

- The overall rate of substance abuse treatment admissions among those aged 12 and older in the U.S. has remained nearly constant over the 1999 to 2009 period but...
 - there has been a dramatic rise (430 percent) in the rate of treatment admissions for the abuse of prescription pain relievers during this period; and
 - the rate of treatment admissions primarily linked to pain relievers rose from 10 per 100,000 in the population in 1999 to 53 per 100,000 population in 2009.

Dramatic Rise In Deaths

- In 2010, more than 38,300 Americans died from drug overdose deaths
- Prescription drugs – particularly opioid pain relievers – were involved in a significant proportion of those deaths
- Opioid pain relievers were involved in over 16,600 of these deaths, approximately four times the number of deaths just a decade earlier in 2000

DEATHS: Marked Increase in Unintentional Drug Overdoses



CDC Declared Prescription Drug Abuse an Epidemic

- The consequences associated with prescription drug abuse are so significant that the Centers for Disease Control and Prevention (CDC) characterized prescription drug abuse as a public health epidemic, a label that further underscores the need for urgent policy, program, and community-led responses

What is driving these increases?

- According to National Institute on Drug Abuse, the number of opioid-specific prescriptions increased 175 percent (from 75.5 million to 209 million) from 2000 to 2009.
- There are misperceptions about the safety of prescription drugs among the general public—after all, they are prescribed by a doctor!

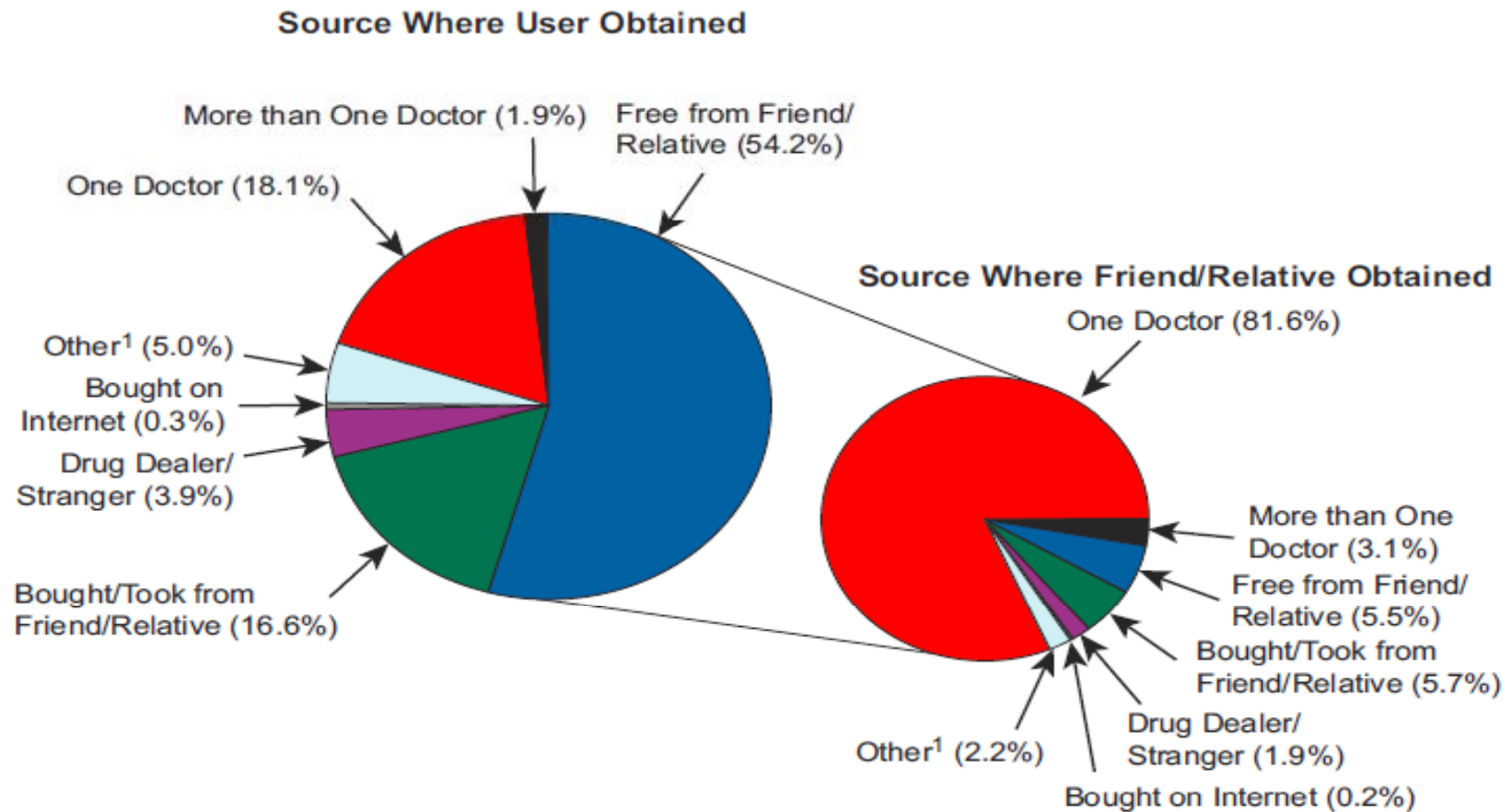
Where do people obtain prescription drugs for non- medical use?



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People Abusing Pain relievers Mostly Do Not Obtain Them Directly by Prescription: *Most Recent Source for Ages 12+*



So, How Significant is Doctor Shopping?

- Policy officials tend to target “doctor shoppers” as the drivers of the current prescription drug epidemic. Evidence suggests they are low hanging fruit, but are a small share of the population of prescription drug abusers:
 - Law enforcement efforts to shut down pill mills and doctor shopping rings can have substantial public health benefits by reducing the supply of prescription drugs for street trafficking (Brandeis, The Center for Excellence, 2012 Study). [Note: the effect was not quantified.]
 - One study found that questionable prescriptions averaged about 1.6 percent for pain relievers (Simeone and Holland, 2006).
 - Another study found that 0.30 percent of 25,161,024 subjects exposed to opioids exhibited doctor shopping behavior (Cepeda et. al, 2012)

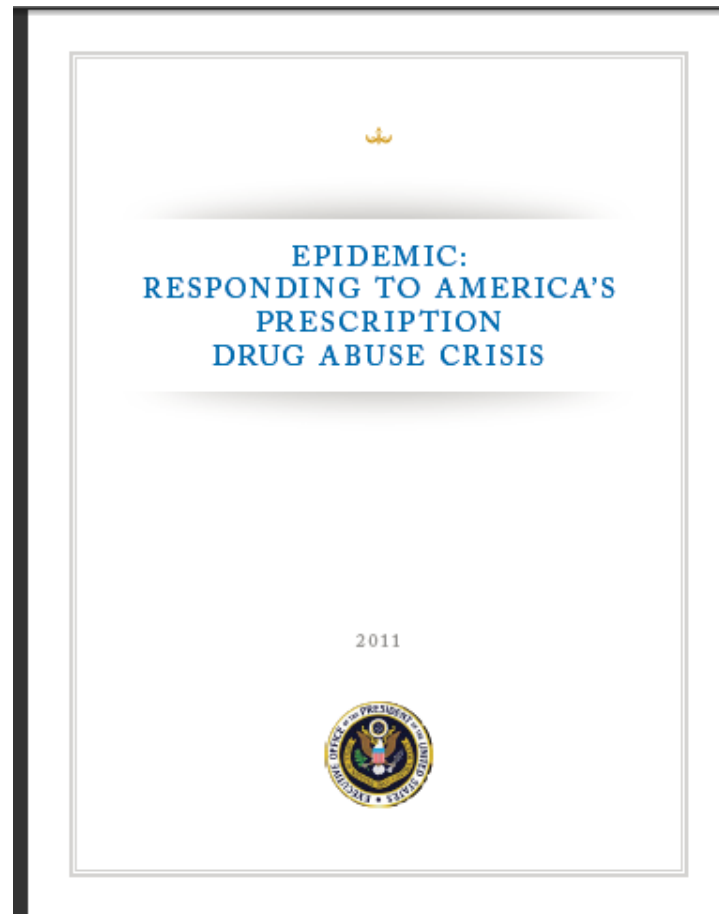
So what is currently being
done about the prescription
drug epidemic?



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U.S. National Drug Control Policy: 2011 Prescription Drug Abuse Plan



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The Four Pillars of the Strategy

- ONDCP claims that its prescription drug strategy strikes a balance between the need to prevent diversion and abuse of pharmaceuticals and the need to ensure legitimate access to prescription drugs.
- It focuses on four major pillars that include education for prescribers and the public; prescription monitoring; safe drug disposal; and effective enforcement.

More about the Four Pillars of ONDCP's Prescription Drug Strategy

Epidemic: Responding to America's Prescription Drug Abuse Crisis

- **Education.** A crucial first step in tackling the problem of prescription drug abuse is to educate parents, youth, and patients about the dangers of abusing prescription drugs while requiring prescribers to receive training in the safe and appropriate use of these drugs.
- **Monitoring.** Implement prescription drug monitoring programs (PDMPs) in every state, and enhance PDMPs to make sure they can share data across states and are used by healthcare providers.
- **Proper Medication Disposal.** Develop convenient and environmentally responsible prescription drug disposal programs to help reduce prescription drug diversion.
- **Enforcement.** Provide law enforcement with the tools necessary to eliminate improper prescribing practices and reduce “pill mills” and “doctor shopping.”

The ONDCP Prescription Drug Strategy: Analysis of Each Pillar

Pillar 1: Education

Education's Main Target

- Educate Physicians about -Opioid Painkiller Prescribing and Train Physicians in other Pain Management Modalities
 - Family practitioners, internists, dentists, and pain specialists, are charged with the important task of managing their patients' pain, often by prescribing opioid pain relievers, when in fact other treatments may be advisable and more appropriate
 - The ONDCP is promoting mandatory education for prescribers
- Several states, including Iowa, Massachusetts, and Utah have passed mandatory prescriber education legislation. These laws require important education for health care providers on the abuse potential of prescription medications and the best ways to deliver quality care while ensuring patient and public safety.

SAMHSA's Partnership for Success II Program

- Targets two priorities: 1) underage drinking among persons aged 12 to 20; and 2) prescription drug misuse among persons aged 12-25.
- With regard to prescription drug abuse, 12-25 year olds represent 39% of the total 6.1 million abusers in 2011; the remaining 61% are older than 25 years of age.

FDA's Opioid Risk Evaluation and Mitigation Strategy (REMS)

- This is FDA's Blueprint for provider education.
- Announced by the Food and Drug Administration for long-acting and extended release opioids in April 2011.
- Five elements:
 - Medication Guide
 - Communication Plan
 - Elements to Assure Safe Use
 - Implementation System
 - Timetable for Submission of Assessments
- Training is currently voluntary; may become mandatory for DEA licensing or renewal.

The ONDCP Prescription Drug Strategy: Analysis of Each Pillar

Pillar 2: Prescription Drug Monitoring



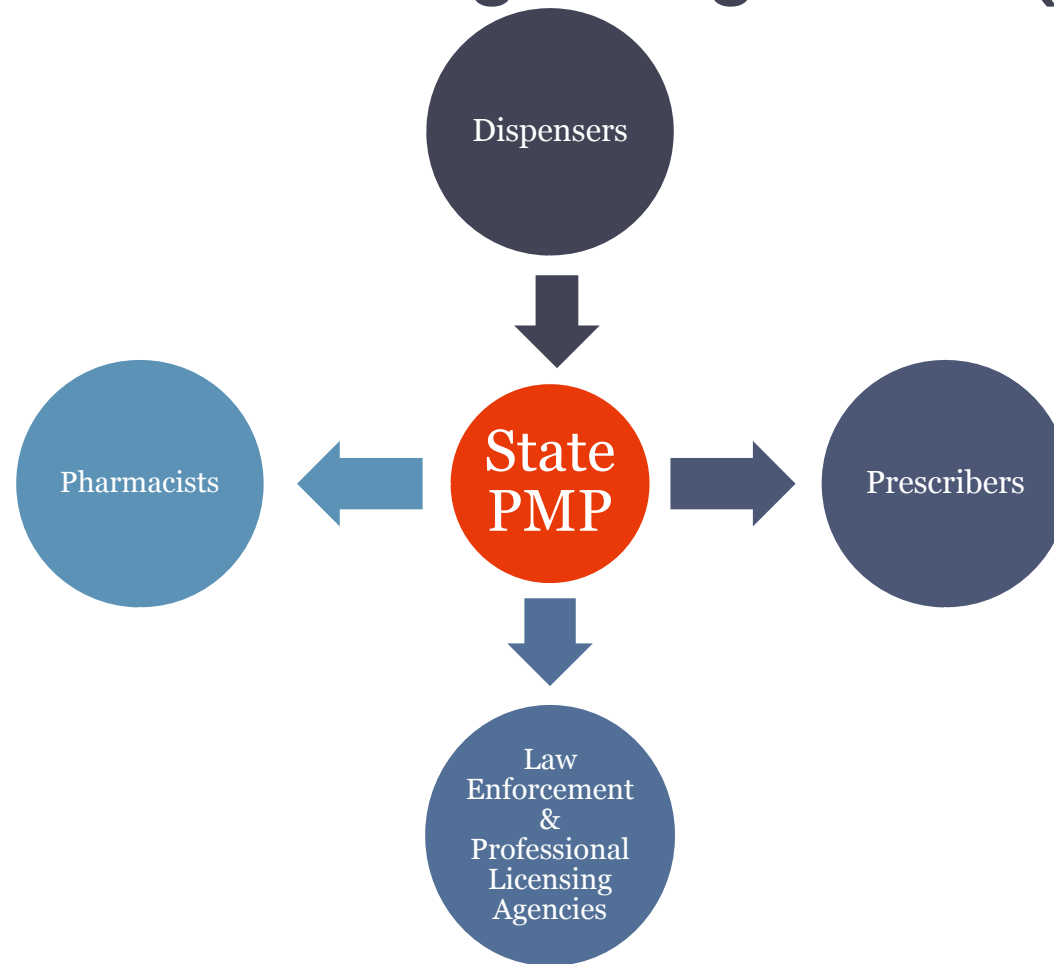
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What are PMPs?

- Prescription Drug Monitoring Programs (PDMPs) are state-administered databases that monitor the prescribing and dispensing of controlled substances.
- Information contained in the PDMP can be used by prescribers and pharmacists to detect drug-drug interactions and identify patients who may be doctor shopping (seeing multiple doctors to fraudulently obtain prescriptions), need substance abuse treatment, or are at risk for overdose.
- In accordance with state laws, PDMP information may also be used by state regulatory and law enforcement officials to pursue cases involving prescribers or pharmacists operating outside the bounds of proper practice, “pill mills,” and other pathways of diversion. In 2006, only 20 states had PDMPs.
- Today, 49 states have laws authorizing PDMPs, and 40 states have operational programs. Missouri and Washington, DC have yet to authorize PDMPs.

A State-based Tool: Prescription Drug Monitoring Programs (PMPs)



Evidence of PMP Effectiveness

- Two studies have demonstrated the effectiveness of PMPs and best practices:
 - Simeone and Holland (2006): first study to find that PDMPs reduce the per capita supply of prescription pain relievers and stimulants and in so doing reduce the probability of abuse for these drugs. It was the first study to show that states which are proactive in their approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach to regulation.
 - Brandeis Center of Excellence: (2012): Study focused on history of PMPs, best practices, and evidence of PMP Effectiveness. Found that states with PMPs were less likely to experience diversion; states with “proactive” PMPs had less availability of pain relievers compared to states that were not proactive.

The ONDCP Prescription Drug Strategy: Analysis of Each Pillar

Pillar 3: Proper Medication Disposal

What are “Takeback” Programs?

- There are a variety of pharmaceutical disposal or takeback programs in place to recover unused (scheduled) medications from consumers.
- In general, the programs have followed one of two models: periodic “collection events” at which consumers can drop off drugs at specially arranged sites, or continuously running programs where consumers can drop off medicines at pharmacies or household hazardous waste (HHW) collection facilities.
- None of the programs offers residents incentives to participate, such as financial rewards for participation or prohibitions on disposal of drugs by conventional means.

What About Take-Back Programs?

The 2011 Carnevale Associates, LLC study:

- Analyze prescription drug takeback programs to learn about their characteristics, associated costs, and how such efforts are funded; and
- Identify (opportunistic sampling) takeback programs within and outside the U.S. and collect data wherever possible about each program.

What We Found

- The 2011 Carnevale Associates, LLC Study found:
 - There is no evidence that take-back programs are effective in limiting access to prescription drugs by those who are at the heart of the epidemic.
 - Additional research is needed to determine whether take-back programs achieve environmental or substance abuse outcomes.
 - The limited data strongly indicate that ongoing bin-based (ongoing drop-off) programs appear to be the most cost efficient; event-based programs and mailbacks are least efficient.

DEA Proposed Rule re: Takebacks

- Under the old rules, only law enforcement could take back controlled substances-- effectively limiting the game to drop boxes at police stations or takeback days/mailback programs that worked explicitly with law enforcement. Pharmacy based bins (though popular) were not lawfully able to take controlled drugs. They were big for environmental/safety reasons but played no role in SA prevention.
- Under the new rules, those restrictions are relaxed. Now manufacturers, distributors, reverse distributors and retail pharmacies may also establish bins and/or mailback programs to accept controlled meds.

CALLC Comment on the Rule

First Point:

- Though Carnevale Associates, LLC (CALLC) applauds the enhanced access to takeback programs outlined in DEA's proposed rules, the rules appear to prevent takebacks from conducting detailed inventories of the drugs they collect. CALLC clearly recognizes DEA's mandate to secure the safe disposal of controlled substances and prevent diversion; however, we are concerned that the rules create new obstacles to research and may, in turn, hamper future substance abuse policy decisions.

CALLC Comment on the Rule

Second Point:

- Takeback programs serve numerous purposes, including but not limited to environmental protection and public safety (e.g. accidental child poisoning). However, takebacks are also promoted as a form of substance abuse prevention. Despite that assertion, there is no concrete evidence that takeback programs impact prescription drug abuse. Takebacks obviously reduce the supply of prescription drugs but no research has explored whether such programs actually affect abuse.

CALLC Comment on the Rule

Third Point:

- While safe and secure drug disposal is important for society, we believe that substance abuse policymakers require additional research on the effectiveness and cost-effectiveness of takebacks before cementing them as key pieces of any substance abuse prevention plan. To determine the effectiveness and cost-effectiveness of takeback programs, researchers must be able to assess programs' collections. At the most basic level, such data collection can tell policymakers (a) whether controlled substances are being collected, (b) which substances are collected, and (c) in what volume they are collected. Coupled with other data, researchers can then begin to inform an assessment of takebacks' impact on substance abuse. Only when armed with that information can policymakers make informed decisions about substance abuse prevention. While some alternative research methods may remain if these rules are finalized, we encourage DEA to consider the research & policymaking implications of the proposed rule.

The ONDCP Prescription Drug Strategy: Analysis of Each Pillar

Pillar 4: Enforcement

ONDCP's Enforcement Plan

- Assist States to Address Doctor Shopping and Pill Mills
- Drive Illegal Internet Pharmacies Out of Business
- Crack Down on Rogue Pain Clinics that Do Not Follow Appropriate Prescription Practices

But Wait a Minute.....

- Assist States to Address Doctor Shopping and Pill Mills?
 - But the Household Survey (NSDUH) says that 1.9% of people who abuse pain relievers used more than one doctor; and 3.1% got them from a friend who went to more than one doctor.
 - The math is tricky, but 1.9% times is 84,949 people...divided by the 50 state and DC is an average of 1,666 people per state. Is it worth it?
 - We don't know the sample size of friends who doctor shop, but 3.1% of them did obtain them from more than one doctor. Question: how many of them are abusers versus distributors using doctor shopping to earn income?

But Wait a Minute.....

- Drive Illegal Internet Pharmacies Out of Business?
 - But the Household Survey (NSDUH) says that 0.3% of people who abuse pain relievers obtained them on the internet.
 - Hmmm, 0.3% times 4,471,000 is 13,413 people...divided by 50 states and DC is an average of 263 potential people per state. Question: Will targeting “illegal” internet pharmacies make a dent is the level of abuse?

But Wait a Minute.....

- Crack Down on Rogue Pain Clinics that Do Not Follow Appropriate Prescription Practices?
 - What is a rogue pain clinic?
 - ONDCP does not offer any estimate.
 - Florida seems to be the only state that has data suggesting this may be a problem—but there is no data describing how closing these clinics affects prescription drug abuse.

The ONDCP Prescription Drug Strategy: Other Noteworthy Action



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Abuse-Deterrent Formulation of OxyContin

- In August 2010, an abuse-deterrent formulation of OxyContin was introduced that was difficult to crush for purposes of injection or inhalation.
- A New England Journal of Medicine (July 2012) study that the new formulation reduced abuse from 35.6 percent of respondents before the release of the formulation to 12.8 percent 21 months later.
- While 24 percent found a way to still abuse the new formulation, 66 percent switched to another opioid, with “heroin” being the most likely drug of choice.

My Summary Opinion with Regard to ONDCP's Four Pillars

- PMPs—seem to be the best tool with regard to understanding and tracking prescribing behavior; prevention/treatment community would be well advised to work with PMPs to obtain local area information about hotspots to determine where to target resources.
- Provider/parent, youth/young adult education programs seem very promising with regard to modifying prescribing behavior and teaching those who obtain prescriptions about the risk/harms of prescription drugs.
- Enforcement can utilize PMPs to target pill mills and doctor shopping; low hanging fruit but its significance is quite questionable.
- Take-back programs show little evidence of effectiveness with respect to affecting prescription drug abuse.

Questions and Discussion

John T. Carnevale, Ph.D.
President, Carnevale Associates, LLC
John@carnevaleassociates.com
www.carnevaleassociates.com