

**Questions for the Record for
Dr. Daniel Sosin, Acting Director of the National Center for Injury Prevention and Control
From
“Examining the Growing Problems of Prescription Drug and Heroin Abuse”
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
April 29, 2014**

**Attachment 1—Additional Questions for the Record
The Honorable Michael C. Burgess**

- 1. I am told that abuse and misuse of medicines is flat or slightly declining. What are the recent statistics over the last few years on non-medical use of prescription drugs? And since the government sites statistics that 70% of those who use medicines non-medically are getting them from family or friends, what is causing the flattening or decline?**

Answer: The rate of past month nonmedical use of prescription drugs among young adults aged 18 to 25 in 2012 was 5.3 percent – similar to rates in 2010 and 2011, but significantly lower than the rate from 2009 (6.4 percent), according to the Substance Abuse and Mental Health Services Administration’s (SAMHSA’s) 2012 National Survey on Drug Use and Health (NSDUH).

Overall, nonmedical use of psychotherapeutic drugs among people age 12 years and up has ranged from 19.9 percent to 20.9 percent during 2002-2012, according to the NSDUH. For prescription pain relievers, the percentage has ranged from 12.6 percent to 14.2 percent during this time period. These percentages did not change significantly from 2010 to 2012. However, relatively flat rates of nonmedical use among *all* nonmedical users masks a sharp increase in opioid abuse by a small number of “heavy users.”

The percentage of people using pain relievers nonmedically 200 or more days a year—the “heavy users”—increased 75 percent from 2002-2003 to 2009-2010.¹ These are the users whose nonmedical use is more likely to be considered “abuse” and who account for a disproportionate share of overdoses. While the overall rate of nonmedical use of opioids has not grown substantially over the last decade, the smaller subset of high-risk “heavy users” has increased sharply. CDC has not yet examined use rates for these “heavy users” for 2011 and 2012, and future research will indicate whether the sharp growth in this group has continued.

¹ Jones CM. Frequency of Prescription Pain Reliever Nonmedical Use: 2002-2003 and 2009-2010. JAMA Intern Med. 2012;172(16):1265-1267.

The Honorable Jan Schakowsky

- 1. What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of pop up clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and pop up clinics, so I am interested in seeing what they are doing to help us combat the crisis.**

Answer: While CDC is not aware of the pharmaceutical industry's efforts to address pop up clinics, CDC is aware of some steps the pharmaceutical industry has taken to address prescription drug abuse. These include reformulating two opioid products in an effort to make them abuse-resistant, funding of the Researched Abuse, Diversion and Addiction-Related Surveillance system, and offering voluntary education programs for health care providers.

- 2. What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?**

Answer: New opioid drugs are being introduced to market, and FDA oversees the process for the approval of new drugs. CDC defers to FDA's regulatory authority regarding new opioid drugs entering the market.

CDC's work to prevent prescription drug overdoses addresses the impacts of both new and existing controlled substances on the public's health. CDC monitors and tracks prescribing data using IMS Health data, which helps to understand prescribing trends for different types of opioid pain relievers. CDC's efforts to improve prescribing practices of these drugs for all patients (*e.g.*, volume of pills prescribed and recommended dosage) and to strengthen prescription drug monitoring programs as a tool to promote safer prescribing also address the prescribing of newer opioid drugs. These surveillance and prevention programs are designed to address the risks posed by all opioid pain relievers, whether they are long-established opioids like methadone or recently approved medications.

- 3. Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?**

Answer: Most of the nonmedical use or overdose death cases involving opioids are related to Schedule II drugs such as oxycodone, morphine, oxymorphone, fentanyl, and methadone. Drug products containing limited amounts of hydrocodone in combination with other active ingredients currently are Schedule III and account for 135 million prescriptions per year, roughly half of all opioid prescriptions. HHS recently recommended to DEA that hydrocodone combination products be moved to Schedule II. On February 27, 2014, DEA published a Notice of Proposed Rulemaking proposing to reschedule hydrocodone combination products to Schedule II.

- 4. According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?**

Answer: The data cited by Dr. Clark indicate that excess opioid pain reliever pills are diverted to nonmedical users who may misuse or abuse the drugs. A recent CDC analysis of these data (gathered from SAMHSA's NSDUH) further demonstrate the role that prescribing plays in nonmedical use. The study found that the opioid source for nonmedical users varies significantly depending on the frequency of nonmedical use. For instance, the highest-use, highest risk nonmedical users (*i.e.*, those who reported nonmedical opioid use more than 200 days a year) reported that the last time they used, they were more likely to obtain their opioids from doctors' prescriptions than any from other source.² Heavy users also account for a disproportionate fraction of all opioid overdoses compared with light users.³

The primary insight CDC gained from the NSDUH data is the key role of prescribing. Whether a nonmedical user obtains an opioid from a friend or family member or directly from a physician, virtually all the drugs originate from a health care provider's prescription. Efforts to promote safe prescribing (*e.g.*, prescriber education programs), effective prescription drug monitoring programs that can give doctors critical information about their patients' histories, patient review and restriction programs that can protect high risk patients, or pain clinic laws to shut down rogue prescribers) are critical to addressing the inappropriate prescribing at the root of the epidemic.

² Jones CM, Paulozzi LJ, Mack KA. Sources of Prescription Opioid Pain Relievers by Frequency of Past-Year Nonmedical Use: United States, 2008-2011. *JAMA Intern Med.* 2014;174(5):802-803.

³ Paulozzi LJ, Zhang K, Jone CM, Mack KA. Risk of Adverse Health Outcomes with Increasing Duration and Regularity of Opioid Therapy. *Journal of the American Board of Family Medicine.* May-June 2014; 27(3) 329-38.

The Honorable Ben Ray Lujan

- 1. As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me what your office is doing to address the challenges of rural districts like New Mexico?**

Answer: The prescription drug overdose epidemic has impacted some rural communities where limited resources and poverty can make prevention difficult. CDC recognizes the needs of these communities and has designed initiatives to ensure that states, including those with many rural communities, can compete for the assistance and support they need to advance prevention.

For example, CDC's new Funding Opportunity Announcement (FOA), Prevention Boost, is an initiative to accelerate PDO prevention in states through direct support to state health departments. The initiative targets funding to states that have both a high burden of prescription drug overdoses and have demonstrated readiness and capacity to achieve impact. Under the FOA's evaluation criteria, applications from states with the highest drug overdose burden will be weighted somewhat more favorably than states with a lower burden to ensure that prevention dollars go towards achieving the maximum impact. Similarly, the initiative in the President's Fiscal Year (FY) 2015 Budget proposes increased funding of \$15.6 million to support additional states with a high prescription drug overdose death burden to ensure those states have the maximum opportunity to receive support to reduce prescription drug overdose deaths through the existing Core Violence and Injury Prevention Program (Core VIPP).

- 2. Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse:**

- **The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public?**

Answer: DEA leads the effort to increase public awareness and promote drug take back events. Safe disposal is one part of a much larger effort to address prescription drug abuse and overdoses.

- **Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs?**

Answer: Access to substance abuse treatment is a crucial part of helping those already dependent on and addicted to opioid pain relievers. It is crucial that providers in both primary and specialty care settings become trained in medication-assisted treatment (MAT), an approach that uses FDA-approved pharmacological treatments such as methadone, Naltrexone (Vivitrol) Buprenorphine Buprenorphine/Naloxone. MAT should be offered in combination with psychosocial treatments, for patients with opioid use disorders. Equally important, use of these medications should be covered as part of a comprehensive approach to treating prescription and illicit substance use disorders.

On April 24, 2014, a commentary on MAT jointly written by the directors of CDC, SAMHSA, the Centers for Medicare & Medicaid Services (CMS), and NIDA, was published in the New England Journal of Medicine.⁴ As noted in that article, the three types of MAT—methadone, buprenorphine, and naltrexone—are underutilized. Of the 2.5 million Americans 12 years of age or older who abused or were dependent on opioids in 2012 (according to the National Survey on Drug Use and Health conducted by SAMHSA), fewer than one million received MAT. The article also cites a recent report from the American Society of Addiction Medicine describing public and private insurance coverage for MATs that highlights several policy-related obstacles, such as limits on MAT dosages, annual or lifetime medication limits, initial authorization and reauthorization requirements, poor counseling coverage, and other barriers.⁵

CDC is working with states to implement comprehensive strategies for overdose prevention that include MAT, as well as enhanced surveillance of prescriptions and clinical practices. Through CDC's existing Core-VIPP-funded states, 16 out of the 20 funded have highlighted prescription drug abuse as a statewide prevention priority. CDC is also establishing statewide norms to provide better tools for the medical community in making prescription decisions. Prevention efforts that focus on changing behaviors that have led to the problem are crucial to reducing prescription drug abuse and overdose, so that the need for treatment will be also be reduced.

- **The need to expand access to naloxone to the public as prescription drug abuse continues to rise?**

Answer: Naloxone is a promising and useful tool to reverse opioid overdose deaths, and it is a piece of a broad approach to reverse this epidemic. CDC's primary focus is to address the underlying causes of the epidemic so last resort necessities like naloxone are not necessary.

- **A lack of funding for implementation of proven strategies?**

Answer: States need support to identify and implement effective strategies for prevention of prescription drug overdoses. Supporting states to expand effective prevention measures—especially those aimed at changing the prescribing behaviors that drive the epidemic—is a central tenet of CDC's strategy to preventing prescription drug overdoses. The President's FY 2015 Budget is designed to meet this important prevention need. Both would provide direct, targeted assistance to states to help implement, expand, and evaluate key prescription drug and overdose prevention interventions.

- **The need for legislation?**

Answer: States have broad authority to regulate the prescribing and dispensing of prescription drugs and do so in a variety of ways. Some states interventions have shown promising results, as highlighted below.

⁴ Volkow ND, Frieden TR, Hyde PS, Cha S. Medication-Assisted Therapies -- Tackling the Opioid-Overdose Epidemic. NEJM. April 23, 2014. Available at URL: <http://www.nejm.org/doi/full/10.1056/NEJMp1402780>.

⁵ ASAM. Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. 2013. Available at URL: <http://www.asam.org/docs/advocacy/Implications-for-Opioid-Addiction-Treatment>.

Prescription Drug Monitoring Programs (PDMPs) are state-run databases that track controlled substance prescribing and dispensing. PDMPs have tremendous potential to inform prescribers about patient histories, identify troubling patterns, and provide key information about the epidemic. However, PDMPs vary considerably between states (*e.g.*, some PDMPs are real-time while others have a long delay). Some states now have statutes mandating that prescribers of controlled substances use the state PDMP. Approximately 14 states mandate prescribers to use the PDMP in certain circumstances. Initial examinations of the impacts of these mandated use laws are promising. For example, in New York state, according to an initial analysis by the PDMP Center of Excellence at Brandeis University, in the first full quarter following the PDMP use mandate:

- The number of prescriptions for all opioids decreased 9.53 percent.
- Patients receiving opioids from multiple sources (*i.e.*, when individuals saw five prescribers/five pharmacies over three months, also called “doctor shopping”) decreased by 74.8 percent.
- The number of prescriptions for buprenorphine—a drug used to treat opioid dependence—increased 14.6 percent.

These initial results suggest that the increased use of the PDMP may prevent high risk behaviors, reduce overprescribing, and help get assistance to people at risk for opioid abuse and overdose.

Some states have also enacted and are enforcing laws to prevent doctor shopping and the operation of rogue pain clinics or “pill mills,” and other laws to reduce opioid painkiller diversion and abuse while safeguarding legitimate access to pain management services. Some states are also enacting “immunity” laws that provide limited immunity for people seeking medical attention during an overdose, laws that increase access to Naloxone (a medication that can reverse opioid overdoses), and laws or policies that increase access to medication-assisted treatment for opioid dependence. Some of these laws have significant promise. For instance, while further evaluation is needed, some initial reports show that after Florida passed a pill mill law, it saw a subsequent drop in oxycodone overdose deaths.

3. Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin—and other illicit drugs—has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its “Prescription Drug Abuse Prevention Plan” with the goal to reduce non-medical use of prescription drugs by 15% in 5 years.

- What is the progress of this initiative? Is there evidence that this plan is having an impact?

Answer: The White House Office of National Drug Control Policy’s (ONDCP’s) Prescription Drug Abuse Prevention plan was instrumental in calling attention to this epidemic and helping to coordinate the efforts of Federal agencies to advance prevention. In the plan, CDC was charged as the lead agency for the following actions: developing clinical guidelines on opioid prescribing with the American College of Emergency Physician (ACEP) and advancing epidemiological studies on patterns of opioid abuse. CDC completed the joint development of ACEP clinical guidelines on opioid prescribing in 2012.⁶ CDC continues to advance epidemiological studies on prescription drug use and abuse. For instance, a new surveillance system is in development—called the Prescription

⁶ <http://www.acep.org/Content.aspx?id=88136>.

Behavior Surveillance System—that uses de-identified data from multiple state PDMPs to create an innovative and timely new way to monitor prescribing trends and patterns. This summer CDC will release Vital Signs, a major scientific release that will examine opioid prescribing rates in all 50 states using IMS Health data. These, and other studies, are in addition to our routine analyses of drug overdose mortality data.

CDC defers to ONDCP about specific progress on other parts of the Prescription Drug Abuse Prevention Plan.

- **Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?**

Answer: The number of persons meeting the criteria for heroin dependence or abuse more than doubled from 2007 to 2012. In 2012, more than two million people reported opioid abuse/dependence compared to about 467,000 people reporting dependence on or abuse of heroin.⁷ While prescription opioid abuse and overdose rates remain far above heroin rates, the heroin increases are concerning.

Studies of people who use heroin show one consistent fact: in most cases, heroin use follows prescription opioid use. More than three out of four people who reported both past-year opioid misuse and heroin use said they used opioids non-medically—that is, without a prescription or for the feeling the drugs cause—prior to heroin initiation. The increased prescribing of opioid pain relievers appears to have increased opioid dependence and addiction and driven demand for heroin.

It is too early to tell how reductions in prescription drug abuse and overdose will impact heroin use and overdose rates. Based on the trends identified above, reducing overprescribing of opioids may reduce the number of people who initiate on heroin. HHS will continue to rigorously monitor both prescription drug and heroin trends and evaluate ways to prevent opioid addiction and abuse.

4. **You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further this is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types of programs in New Mexico?**

Answer: CDC does not have any current plans to expand treatment access in prison and jail facilities as this is outside of the purview of our mission. CDC is working with states to implement comprehensive strategies for overdose prevention that include medication-assisted therapies, as well as enhanced surveillance of prescriptions and clinical practices.

⁷ SAMHSA. Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings. Table 7.3 <http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm>.

- 5. I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to—so that there is a greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?**

Answer: CDC posts Funding Opportunity Announcements on the website www.grants.gov. The website is the best resource for identifying available CDC funding. Additionally, the National Center for Injury Prevention and Control at CDC maintains a listserv which announces funding opportunities to state and national partners and communicates critical budget updates related to injury prevention and control. Individuals and organizations may e-mail CDC's Injury Center at injurycenter@cdc.gov with direct questions or to request to be added to the Injury Center listserv.

- 6. What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?**

Answer: Many studies have identified people at lower income/education levels or enrolled in Medicaid to be at a higher risk for drug abuse and its consequences, such as fatal overdoses. For example, in Washington State, the Medicaid population had a 5.7 times greater risk of dying from an opioid overdose than the non-Medicaid population.⁸ CDC is not aware of any studies identifying strategies linking economic development with substance abuse prevention or treatment.

⁸ Coolen P, Best S, Lima A, Sabel J, Paulozzi L. Overdose deaths involving prescription opioids among Medicaid enrollees— Washington, 2004–2007. MMWR 2009;58(42):1171–1175.

Attachment 2—Member Requests for the Record

The Honorable Michael C. Burgess

- 1. The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?**

Answer: The prescription drug overdose epidemic is a complicated public health problem that requires action from multiple sectors. Unlike previous drug abuse epidemics, the drugs driving the increase in overdose deaths can be traced primarily to prescribing practices, which required a new approach to prevention. Investments to date in prevention, treatment, and law enforcement have been important in getting to where we are today. For instance, in 2005 less than half of states had a prescription drug monitoring program; today, 49 states have one. Advances like these are laying an important foundation for reversing the epidemic.

But, there is more that can be done. In particular, the high rates of opioid prescribing that have marked the steady increase in overdose deaths over the last fifteen years need to be addressed. CDC’s approach to the epidemic focuses on “upstream” prevention—that is, the prescribing and patient behaviors that drive prescription opioid abuse, addiction, and overdose. CDC’s strategy for prescription drug overdose prevention is three-fold: (1) improving the tracking and monitoring of prescribing and overdose trends; (2) supplying health care providers with data, tools, and guidance for evidence-based decision making that improves population health; and (3) strengthening state efforts by scaling up effective public health interventions. Continued progress in these areas, as well as advances in law enforcement (*e.g.*, implementation of pain clinic laws) and substance abuse treatment access for those already addicted to opioids are important steps to continue work to reduce prescription drug overdoses.

Collaboration between and amongst Federal agencies is essential to prescription drug overdose prevention activities. For example, CDC is developing the prescription behavioral surveillance system. This is an early warning surveillance and evaluation tool using data from multiple state PDMPs. With this new tool, states can spot patterns that they could never have seen using only their own PDMPs. This project is an example of interagency collaboration. CDC is partnering with FDA—who is supporting the project to improve prescriber education—and the Bureau of Justice Assistance—who administers the Harold Rogers Prescription Drug Monitoring Program—to bring the agencies’ unique strengths together.

- 2. What is the cost of a single dose of naloxone? Is the cost of naloxone a barrier to making the antidote more readily available?**

Answer: According to a recent (non-CDC) study, programs traditionally pay approximately \$6 per dose, \$15 per kit of injectable naloxone, and \$30 per kit of intranasal naloxone.⁹ Most programs dispense injectable naloxone. CDC has not conducted any studies regarding the cost of naloxone as a barrier to making it more readily available.

⁹ Coffin PO, Sullivan SD. Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal. *Ann Intern Med.* 2013;158:1-9.

The Honorable Steve Scalise

- 1. According to the GAO report, there are 15 federal agencies and 76 abuse prevention or treatment programs. The GAO report identified overlap in 59 of the 76 programs. Please discuss what your agency is doing to address that overlap and the problems addressed in the GAO report.**

Answer: While CDC does not administer any of the 76 programs listed in the 2013 GAO report. CDC believes close coordination with other Federal agencies, including SAMHSA, CMS, FDA, ONDCP, HHS' Office of the National Coordinator for Health Information Technology (ONC), NIDA, and the Department of Justice, is key to CDC's approach to fighting the prescription drug abuse epidemic. One example of this interagency collaboration is the work with SAMHSA to advance PDMP Integration with electronic health records (EHRs). Under this initiative, SAMHSA funded a program to help integrate PDMPs into EHR systems to make PDMPs easy to use in doctors' day-to-day practices. CDC is leading the evaluation of these efforts, leveraging our expertise in program evaluation to make sure that other states and health systems can learn from this initiative's experience.

CDC also participates in the HHS Behavioral Health Coordinating Committee (BHCC) to align CDC's work with the efforts of other Federal agencies within HHS. The coordination at the BHCC level is supported by extensive networks of communication and collaboration from staff level researchers at CDC and other agencies to regular communications between agency leadership on this priority topic. CDC is also engaged with ONDCP in advancing multiple items in the Prescription Drug Abuse Prevention Plan and National Drug Control Strategy.

Finally, CDC works to avoid unnecessary overlap and duplication by leveraging CDC's particular expertise in addressing this epidemic. As the Nation's public health agency, CDC has experience working with state health departments to monitor health trends and advance data-driven, evidence-based prevention and evaluation. This unique niche is reflected in the President's FY 2015 Budget initiative, leveraging the state health departments and state injury prevention programs to address the key driver of the epidemic—inappropriate opioid prescribing. This “upstream” focus on prescribing practices complements the work of other agencies, like SAMHSA's emphasis on substance abuse treatment, NIDA's biomedical research on addiction and treatment, and ONC's work on health information technology systems.