

Testimony Before the
House Energy and Commerce Oversight and Investigation Subcommittee
Hearing on
“Examining the Growing Problems of Prescription Drug and Heroin Abuse”
April 29, 2014

Statement of H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM

Director, Center for Substance Abuse Treatment

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

Good morning Chairman Murphy, Ranking Member DeGette, and distinguished members of the Energy and Commerce Oversight and Investigation Subcommittee. My name is Dr. H. Westley Clark, and I am the Director of the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency of the Department of Health and Human Services (HHS). I am pleased to address SAMHSA's role in preventing non-medical use of prescription opioids, and treating individuals who abuse or misuse prescription opioids and heroin.

SAMHSA's Role

SAMHSA was established in 1992 and is directed by the Congress to effectively target substance abuse and mental health services to the people most in need of them, and to translate research in these areas more effectively and more rapidly into the general health care system. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA strives to create awareness that:

- Behavioral health is essential for health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

SAMHSA serves as a national voice on mental health and mental illness, substance abuse, and behavioral health systems of care. It coordinates behavioral health surveillance to better understand the impact of substance abuse and mental illness on children, adults, and families, as well as the costs associated with treatment. SAMHSA helps to ensure dollars are invested in evidence-based and data-driven programs and initiatives that result in improved health and resilience.

SAMHSA applies strategic, data-driven solutions to field-driven priorities. To this end, SAMHSA helps states, territories, and tribes build and improve basic and proven practices and system capacity by encouraging innovation, supporting more efficient approaches, and incorporating research-based programs and best practices into funded programs so they can produce measureable results. In addition, SAMHSA's longstanding partnerships with other Federal agencies, Tribal governments, systems, national stakeholders, and the public have uniquely positioned SAMHSA to collaborate and coordinate across multiple program areas, collect best practices and develop expertise around behavioral health services, and, understand and respond to the full breadth of the behavioral health needs of children, individuals and families across the country.

Substance abuse, substance use disorders, poor emotional health, and mental illnesses take a toll on individuals, families, and communities. These conditions cost lives and productivity, and strain families and resources in the same way as untreated physical illnesses. SAMHSA works to focus the Nation's attention on these preventable and treatable problems.

The challenges of the non-medical use of prescription opioids as well as heroin abuse are complex issues that require epidemiological surveillance, distribution chain integrity,

interventions, prescriber education, access to effective treatment services, and further research. No organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical partners, public health administrators, state governments, and community organizations all are needed to implement educational outreach and intervention strategies targeted to a range of discrete audiences, including physicians, pharmacists, patients, educators, parents, high school and college students, adults at high risk, older adults, and many others. Outreach to physicians as well as pharmacists needs to be complemented by education, screening, intervention, and treatment services for those misusing or abusing opioids.

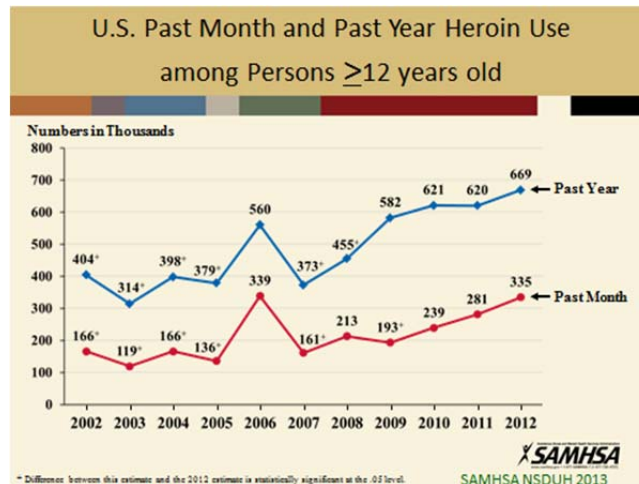
SAMHSA's strategy to reduce the non-medical use of prescription opioids as well as heroin use and to assist individuals who misuse or abuse these drugs is in alignment with the Office of National Drug Control Policy's (ONDCP) four-part strategy: education for prescribers, patients, and the public; prescription monitoring; safe drug disposal; and effective enforcement. SAMHSA works across HHS through the Behavioral Health Coordinating Committee's Prescription Drug Abuse Subcommittee. As a result, SAMHSA has partnerships with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health, the Centers for Medicare & Medicaid Services, the Office of the National Coordinator for Health Information Technology (ONC), the Office of the Assistant Secretary for Health, and the Office of the Assistant Secretary for Planning and Evaluation aimed at preventing and treating the non-medical use of prescription drugs. SAMHSA is also represented on the ONDCP Interagency Workgroup on Prescription Drug Abuse.

What the Current Data Show

According to the 2012 National Survey of Drug Use and Health (NSDUH), which SAMHSA conducts annually, 6.8 million people (aged 12 and older) reported nonmedical use of psychotherapeutics during the past month.¹ That equals 2.6 percent of the U.S. population. In addition, 335,000, or 0.1 percent of the population, reported past month use of heroin. Although the total number reporting heroin use is significantly lower than reported nonmedical use of psychotherapeutics, the numbers have been increasing fairly steadily since 2007 -- both for past month use, as well as past year use. In fact, past month heroin use has more than doubled in six years, going from 161,000 in 2007 to 335,000 in 2012.²

¹Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

² Id.



Preventing Opioid and Heroin Misuse and Abuse

SAMHSA prevention programs address opioid abuse. In fact, preventing and reducing the non-medical use of prescription drugs are specific goals of SAMHSA’s Prevention of Substance Abuse and Mental Illness Strategic Initiative.

The Strategic Prevention Framework - Partnerships for Success (SPF-PFS) grant program, one of SAMHSA’s prevention initiatives, requires grantees to build capacity in communities of high need to address one or both of two national priorities: underage drinking among persons aged 12-20 and prescription drug misuse and abuse among persons aged 12-25. Also, the Fiscal Year (FY) 2014 Request for Application for the SPF-PFS program alerts applicants that they can choose a third area of focus which may include preventing and reducing heroin abuse. In addition, the President’s FY 2015 Budget proposes a new \$10 million initiative to combat the non-medical use of prescription drugs, “The Strategic Prevention Framework Rx,” for the prevention of prescription drug misuse and abuse in high-priority age groups (including young- and middle-aged adults) through education and prevention. This new program is to be implemented in collaboration with the CDC’s prescription drug abuse efforts.

SAMHSA also supports the “Not Worth the Risk, Even If It’s Legal” education campaign, which encourages parents to talk to their teens about preventing prescription drug abuse. Another educational program, “Prevention of Prescription Abuse in the Workplace,” is designed to support workplace-based prevention of misuse and abuse of prescription drugs for employers, employees, and their families.

In addition, SAMHSA recognizes the significant role of the states and jurisdictions in meeting the challenge of substance abuse. Therefore, SAMHSA has indicated to states and jurisdictions that Substance Abuse Prevention and Treatment Block Grant (SABG) primary set-aside funds may be utilized to support overdose prevention education and training.

Finally, SAMHSA's third National Prevention Week (May 18-24) is dedicated to increasing public awareness of substance abuse and mental health issues. The activities scheduled for May 20th are specifically dedicated to the prevention of prescription drug abuse and marijuana use.

Prescriber Education

The high degree of diversion of prescription medications is also of great concern. According to 2011-2012 NSDUH data, 69 percent of those who used pain relievers non-medically in the past year obtained them from a friend or relative.³ About 82 percent of those relatives or friends obtained their medications from one doctor.

A recent study using NSDUH data studied the different sources used by low-risk opioid users versus high-risk users. The lowest-use/lowest-risk group, which made up 63.9 percent of the sample group, obtained opioids from multiple sources. However, the highest-risk/highest-use group of opioid users was more likely to obtain opioids from a physician's prescription or from a drug dealer than were the other two user/risk groups.⁴ Therefore, education must be directed toward physicians and prescribers, as well as communities – and must address the cultural phenomena surrounding medication sharing.

SAMHSA has developed a series of medical education courses designed to help physicians provide appropriate pain management while minimizing the risk of pain medication abuse. Although these courses focus on pain medications, they teach skills that apply to all medications that can be abused. In addition, SAMHSA has partnered with Boston University School of Medicine and the Massachusetts Board of Medicine to develop a series of online courses on prescribing for pain. The courses are available 24/7 to any physician or other health care provider in any state, at no cost. More than 25,000 certificates of completion have been issued since the inception of this program. In a follow-up survey of the 2012 course, more than 76 percent of the respondents said they either have changed the way they practice or are in the process of making such changes as a result of what they learned. SAMHSA also offers live Continuing Medical Education courses in partnership with state health departments, medical societies, medical licensing boards, medical schools, and state Prescription Drug Monitoring Programs (PDMPs). In addition, SAMHSA has developed special courses for the Indian Health Service, community health centers, and U.S. military hospitals. More than nine thousand physicians and other health professionals have completed a live course offered at one of 50 sites in 28 states.

SAMHSA supports training in the use of buprenorphine for the treatment of opioid substance use disorders via the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT). Training is available via live in person, live on-line and recorded modules accessible at

³Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

⁴Jones, C.M., PharmD, MPH; Paulozzi, L.J., MD, MPH; Mack, KA, PhD (3/4/2014), Sources of prescription opioid pain relievers by frequency of past-year nonmedical use: United States, 2008-2011, *JAMA Internal Medicine*. Retrieved from <http://archinte.jamanetwork.com/> by a Health Services Research Library User on 03/21/2014

any time. This same support system provides a variety of training opportunities on more advanced topics related to medication assisted treatment with buprenorphine to physicians and other health professionals. An important feature of PCSS-MAT is the mentorship it provides for individuals entering the field of addiction treatment with buprenorphine.

SAMHSA also funds the Prescribers' Clinical Support System for Opioid Therapies (PCSS-O). PCSS-O is a collaborative project led by American Academy of Addiction Psychiatry with the six other leading medical societies. Program tools focus on the safe use of opioids in treatment of pain, including training on how to recognize non-medical, abuse, and dependence in those with pain. PCSS-O has also introduced an iPhone Application that brings together evidence-based resources that are currently available to clinicians in safe and effective use of these medications.

Prescription Drug Monitoring Programs

In 2011, SAMHSA initiated the Enhancing Access to PDMPs Project to improve access to PDMPs and to reduce prescription drug abuse, misuse and overdose in the United States. The project is funded by SAMHSA and managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. Pilot programs have tested new ways to integrate and provide clinicians access to PDMP data, including connecting through a Health Information Exchange (HIE) and looking at how data can be sent in near real-time from a pharmacy to the PDMP. The program also focuses on creating and disseminating messaging to PDMP stakeholders, especially prescribers and dispensers. The current phase of the project launched in October 2013 and focuses on bringing together PDMP and Health IT stakeholders to establish a standardized approach to retrieving prescription drug data from PDMPs and delivering that data to health IT systems for authorized health care providers to use to inform clinical decision-making.

SAMHSA's Cooperative Agreements for Electronic Health Record (EHR) and Prescription Drug Monitoring Program (PDMP) Data Integration and Interoperability Expansion awarded funds in FY 2013 to seven states to integrate their PDMPs into EHRs and other health information technology systems. The purpose is to increase the use of PDMPs by facilitating the secure and timely transmission of prescription drug information to prescribers, dispensers, and other entities. The major goals of the program are: (1) to improve the quality of prescription drug information available to healthcare providers by integrating PDMP data into existing technologies (e.g. EHRs, HIEs); and (2) support real-time access to prescription drug information by integrating PDMP data into existing clinical workflows. Additionally, for the first cohort grantees, they are required to strengthen state PDMPs by increasing interoperability between states.

Treatment of Individuals with Prescription Opioid and Heroin Addiction

The abuse and misuse of opioids is a complex issue. The challenge cannot be met unless those needing treatment receive it. However, according to the 2012 NSDUH, only 10.8 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received

treatment at a specialty facility.⁵ The challenge cannot be met unless those needing treatment receive it. However, according to the 2012 NSDUH, only 10.8 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received treatment at a specialty facility.⁶

Of all the barriers reported to receipt of treatment, the largest is the lack of recognition that treatment is needed. The 2012 NSDUH data show that 94.6 percent of those identified as needing treatment for dependence or abuse of an illicit drug did not receive that treatment because they did not feel they needed it.⁷ Another 3.7 percent felt they needed treatment but still did not seek it. And, even for those who seek treatment there are significant barriers. Foremost among those barriers are lack of health coverage and inability to pay for treatment— reported by NSDUH at 48.3 percent in 2012.⁸ These data, however, were collected before the Marketplaces established by the Affordable Care Act were opened and before most states that are choosing to expand Medicaid did so. Of those respondents who indicated they had not sought treatment, 17.4 percent were worried that treatment might have a negative effect on their jobs or might cause their neighbors or communities to have a negative opinion of them. Other barriers reported included not knowing where to go for treatment (8.9 percent), not having any or convenient transportation (8.2 percent), and not having the time (7.1 percent).⁹

SAMHSA’s Treatment Episode Data Set tracks substance abuse treatment admissions and discharges at facilities that receive public funding. Of the 1.8 million admissions to treatment (aged 12 and older) reported by TEDS in 2011, 465,000 (or 25 percent) involved opioids as the primary substance of abuse.¹⁰ An additional 117,000 admissions involved opioids as the secondary or tertiary substance of abuse. Three and a half percent of those served by SAMHSA’s substance abuse treatment grant programs report heroin as their primary substance of abuse at intake. Although this figure may appear low, heroin is the fourth most reported drug – after alcohol, marijuana, and cocaine. An estimated 7.7 percent report abuse of a wide range of psychotherapeutics, including benzodiazepines, Oxycontin/oxycodone, Percocet, morphine, barbiturates, etc. This number represents an increase in primary opioid admissions from 2001, when they represented 18 percent. Heroin represented 88 percent of all primary opioid admissions in 2001 but declined to 60 percent in 2011. Admissions for primary heroin abuse were fairly steady over this time period -- representing 16 percent of total admissions (aged 12 and older) in 2001 and 15 percent in 2011. However, an increase in primary heroin admissions has occurred between 2007 and 2011, following a previous decline. Primary admissions for other opioids (including pain relievers and misused methadone) increased from two percent in 2001 to 10 percent in 2011. Those admitted to treatment for injection heroin use reported that they had

⁷Id.

⁸Id.

⁹Id.

¹⁰Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2001-2011. National Admissions to Substance Abuse Treatment Services*. BHSIS Series S-65, HHS Publication No. (SMA) 13-4772. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

been using heroin an average of 9.9 years before first admission. As troubling as this figure is, it is actually down from 2001, when the average of years of use before treatment was twelve.

TEDS data also report that in 2011 a majority of admissions to treatment for heroin and other opioid use reported using an average of two substances. The most reported substances in addition to the primary opioid use were marijuana, alcohol, cocaine, and tranquilizers.¹¹ According to the NSDUH, in 2012, among the 17 million heavy drinkers aged 12 or older, 31 percent were current drug users. Twenty-three percent of past month cigarette smokers (aged 12 and older) reported current use of an illicit drug, and 40.7 percent of adults with past year substance use disorder had a co-occurring mental illness in 2012. However, of those 8.4 million adults with co-occurring substance use and mental health disorders, only 7.9 percent received both mental health care and specialty substance use treatment.¹²

For those addicted to opioids medication-assisted treatment (MAT) is an evidence-based method of treatment.¹³ However, TEDS reports that the inclusion of MAT in the management plan for primary heroin admissions declined from 36 percent in 2001 to 27 percent in 2011. This may be attributed to the availability of buprenorphine in the non-specialty treatment setting, from which TEDS data is not collected.

SAMSHA is responsible for overseeing the regulatory compliance of Opioid Treatment Programs (OTPs). OTPs must maintain certification with SAMHSA in order to operate. SAMHSA cooperates with state level and local agencies, the Drug Enforcement Administration and approved accrediting organizations to accomplish this. OTPs provide medication assisted treatment and counseling services for opioid use disorders using either methadone or buprenorphine. OTPs provide these medications directly to their respective patients. Currently there are 1,311 OTPs in operation.

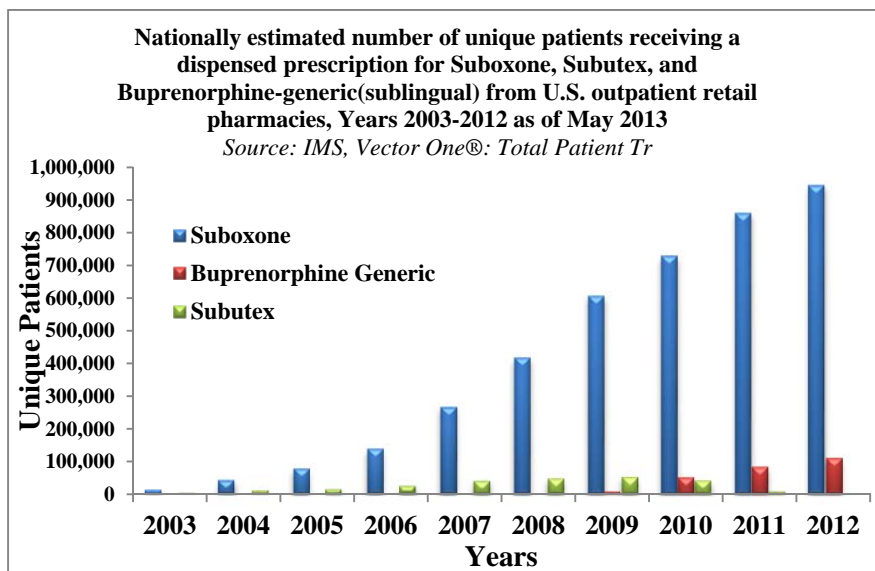
In accordance with Drug Addiction Treatment Act of 2000 (DATA 2000), physicians wishing to treat opioid use disorders with buprenorphine in a practice setting not subject to the regulations which apply to OTPs, such as a private practice or non-OTP treatment program, must request a waiver from SAMHSA. Initially physicians are restricted to treating a maximum of 30 patients at a time. After one year of experience with buprenorphine, physicians may choose to request SAMHSA increase their patient limit to 100. SAMHSA coordinates both of these steps with the DEA. There are currently 26,143 physicians with a waiver to prescribe buprenorphine for opioid dependence. Of these, 7,745 are authorized to treat up to 100 patients. By way of comparison there are currently more than 850,000 physicians registered with the DEA to prescribe controlled

¹¹ Id.

¹² Id.

¹³ Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Methadone: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2; and Catherine Anne Fullerton, M.D., M.P.H.; Meelee Kim, M.A.; Cindy Parks Thomas, Ph.D.; D. Russell Lyman, Ph.D.; Leslie B. Montejano, M.A., C.C.R.P.; Richard H. Dougherty, Ph.D.; Allen S. Daniels, Ed.D.; Sushmita Shoma Ghose, Ph.D.; Miriam E. Delphin-Rittmon, Ph.D. (2/1/2014), Medication-Assisted Treatment With Buprenorphine: Assessing the Evidence, *Psychiatric Services* 2014 Vol 65, No. 2.

substances who are also eligible to seek a waiver allowing them to treat opioid use disorders with buprenorphine in a practice setting not subject to the regulations which apply to OTPs. Nonetheless, the existing complement of waived physicians treated almost 900,000 patients with buprenorphine/naloxone combination medication in 2012.¹⁴



One program that has focused activities on clients with opioid addiction is SAMHSA’s Pregnant and Postpartum Women’s (PPW) initiative. SAMHSA encourages the PPW grantees to accept women with opioid addictions into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering medication-assisted treatment to their clients on-site while the women are closely monitored and provided the medication as clinically appropriate. This allows women to remain in treatment longer, resulting in healthier births.

In SAMHSA’s criminal justice programs – including those in the re-entry program – grantees are allowed to use up to 20 percent of their grant awards for medication-assisted treatment, or MAT. SAMHSA’s Screening, Brief Intervention and Referral to Treatment (SBIRT) program provides screening for illicit drugs, including heroin and other opioids (including prescription opioid medication abuse). To date, more than two million patients have received screening – with approximately 12 percent receiving a brief intervention, brief treatment, or referral to treatment. Realizing the importance of including behavioral health in medical school curricula, SAMHSA funds the SBIRT Medical Residency training programs. Each of the medical residency grant programs includes prescription opioids and/or pain management/treatment modules. To date, 6,141 medical residents and 13,686 nonresidents have been trained. Nonresidents include physician assistants, psychologists, social workers, and other health care professionals.

¹⁴ IMS, Vector One®: Total Patient Tr.

The President's FY 2015 Budget proposes an additional \$20 million for a new program, the "Primary Care and Addiction Services Integration" program, which will enable substance abuse treatment providers to offer a full array of both physical health and substance abuse services to clients.

Opioid Overdose Prevention

SAMHA has also developed tools to help educate first responders about naloxone. When administered quickly and effectively, naloxone rapidly restores breathing to a victim in the throes of an opioid overdose. Because police are often the first on the scene of an overdose, local law enforcement agencies can train and equip their personnel with naloxone as a means of improving response. SAMHSA has communicated to SABG grantees that, at the state's discretion, block grant funds – other than primary prevention set-aside funds – may be used to support first-responder naloxone initiatives.

Also, SAMHSA recently published an Opioid Overdose Toolkit to educate individuals, families, first responders, prescribing providers, persons in recovery from substance abuse, and community members about steps to take to prevent opioid overdose and to treat overdoses (including the use of naloxone). The toolkit is available for download from the SAMHSA website. SAMHSA continues to promote the availability of the toolkit through various social media outlets to reach a wide range of populations.

On April 2, SAMHSA sent a letter to state agencies that administer the SABG to clarify that, at a State's discretion, SABG funds (other than primary prevention set-aside funds) may be utilized to purchase naloxone (Narcan®) and the necessary materials to assemble overdose kits and to cover the costs associated with the dissemination of such kits.

Finally, SAMHSA recently alerted the treatment community and the general public that since the beginning of the year a marked increase in deaths reportedly linked to the use of heroin contaminated with the drug fentanyl has been noted. Fentanyl is a form of opioid and when used in combination with heroin can rapidly cause respiratory depression that can lead to respiratory arrest and even death.

Conclusion

As I stated earlier in my testimony, prescription opioid and heroin abuse is a complex issue. It requires a concerted effort by many. SAMHSA's prevention and treatment strategies to address drug misuse and abuse are both targeted specifically to the drugs themselves and to programs that support prevention, intervention, and treatment of substance abuse disorders, which can have a significant long-term impact on this serious public health problem. Through these and other educational and public service activities, SAMHSA continues to focus on our mission of reducing the impact of substance abuse and mental illness on America's communities.

Thank you for this opportunity. I welcome any questions that you may have.