Substance Abuse and Mental Health Services Administration
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Testimony Before the

House Energy and Commerce Oversight and Investigation Subcommittee

Hearing on "What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?"

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Good morning Chairman Murphy, Ranking Member DeGette, and distinguished members of the Energy and Commerce Oversight and Investigation Subcommittee. My name is Pamela Hyde, and I am the Administrator of 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. 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. Specifically, 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 supports the Secretary of Health and Human Services initiative to address opioid-related overdose, death, and dependence through our programs and initiatives that address three key areas: opioid prescribing practices, increasing use of naloxone, and expanding use of medication-assisted treatment (MAT). [1] In addition, SAMHSA's programs support the Office of National Drug Control Policy's (ONDCP) four-part Prescription Drug Abuse Prevention Plan. SAMHSA works across HHS through the Behavioral Health Coordinating Council'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 (NIH), the Centers for Medicare & Medicaid Services (CMS), 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.

The challenges of the non-medical use of prescription opioids, as well as heroin abuse, are complex issues that require epidemiological surveillance, interventions, and access to further research. In addition, non-medical use of prescription opioids requires distribution chain integrity and prescriber education. No organization or agency can address the problem alone; a coordinated response is required. The Federal Government, medical and other health partners,

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[1] Department of Health and Human Services. HHS Takes Strong Steps to Address Opioid-drug Related Overdose, Death and Dependence. March 26, 2015.
http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf

public health officials, 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 prescribers, as well as pharmacists, on proper prescribing and dispensing of opioid pharmacotherapies needs to be complemented by education, screening, intervention, and treatment services for those who use heroin and/or prescription opioids non-medically.

What the Current Data Show

According to the 2013 National Survey of Drug Use and Health (NSDUH), which SAMHSA conducts annually, 4.8 million individuals (aged 12 and older) reported nonmedical use of opiates, including prescription pain relievers and heroin, during the past month.[2] That equals 2.6 percent of the U.S. civilian non-institutionalized population, of which 289,000 individuals reported past month use of heroin. Although the total number reporting heroin use is significantly lower than reported nonmedical use of prescription opiates, the numbers have been increasing fairly steadily since 2007 – both for past month use, as well as past year heroin use. In fact, past month heroin use more than doubled in five years from 161,000 individuals in 2007 to 335,000 in 2012. However, the number of people reporting past month use decreased to 289,000 in 2013.[3]

Of the individuals admitted to treatment in 2012, 285,451(16.3 percent) people reported heroin as their primary drug of abuse. Another 169,868 (9.7 percent) people reported prescription opioids as their primary drug of abuse. This represents a 9.5 percent and a 2.5 percent increase respectively for the period 2005 to 2012.[4]

Opioid and Heroin Addiction Treatment

The challenge of addressing misuse of opioids cannot be met unless those needing treatment receive it. However, according to the 2013 NSDUH, only 10.9 percent of persons (12 and older) who needed treatment for a drug or alcohol use problem received treatment, which includes hospitals (inpatient only), drug or alcohol rehabilitation facilities (inpatient or outpatient), or mental health centers. It does not include treatment at an emergency room, private doctor's office, self-help group, prison or jail, or hospital as an outpatient.

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[2] Substance Abuse and Mental Health Services Administration, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-48, HHS Publication No. (SMA) 14-4863. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014. NOTE: NSDUH includes information on the use of illicit drugs, alcohol, and tobacco in the civilian, noninstitutionalized population of the United States aged 12 years old or older.

[3] Id.

[4] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2002-2012. National Admissions to Substance Abuse Treatment Services*. BHSIS Series S-71, HHS Publication No. (SMA) 14-4850. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014. Retrieved from http://www.samhsa.gov/data/sites/default/files/2002_2012_TEDS_National/2002_2012_ Treatment_ Episode_ Data_ Set_ National_Tables.htm

Of the barriers to receipt of treatment reported, the largest is the lack of recognition that treatment is needed. The 2013 NSDUH data show that 95.5 percent of those identified as needing treatment for dependence or misuse of an illicit drug did not receive that treatment because they did not feel they needed it.[5] This emphasizes the need for increases in education and prevention programs. Another 2.9 percent felt they needed treatment but still did not seek it. And, even for those who seek treatment there are significant barriers. Barriers reported in the 2013 NSDUH findings include lack of health insurance coverage and inability to pay for treatment (37 percent).[6] Another 8.2 percent of people seeking treatment had health insurance that did not offer coverage or did not cover the full cost for treatment. Other barriers reported included not knowing where to go for treatment (9.0 percent), not having any transportation or the hours were not convenient (8.0 percent), and fear of possible negative effects on their job (6.6 percent).[7]

SAMHSA's programs are designed to help provide treatment and services for people with substance use disorders (SUD), support the families of people with SUDs, foster supportive communities, and prevent costly behavioral health problems. Consistent with those aims, a number of SAMHSA's programs support the Secretary's initiative regarding expanding the use of medication-assisted treatment (MAT). For those addicted to opioids, MAT is an evidence-based method of treatment that has proven to be an important part of effective treatment for opioid use disorder, decreasing craving and withdrawal symptoms, blocking euphoria if relapse occurs, and augmenting the effect of counseling.[8]

In 2015, Congress appropriated to SAMHSA $12 million to expand or enhance MAT and other clinically appropriate services for persons with opioid use disorders. The "Medication-Assisted Treatment for Prescription Drug and Opioid Addiction" (MAT-PDOA) grant program will target those states that have experienced the highest rates of admissions for treatment of opioid use disorders. Under MAT-PDOA states will fund at least two high-risk communities with the greatest need to improve or expand access to MAT services, with a focus on heroin and prescription opioids. Through this program, SAMHSA seeks to: 1) increase the number of individuals receiving MAT services, including screening, and case management; 2) increase the number of individuals receiving integrated care, including organized delivery and/or coordination of medical, behavioral or social and recovery support services; and 3) decrease illicit drug use at 6-months follow-up. MAT is to be provided in combination with comprehensive substance use disorder treatment, including but not limited to: counseling, behavioral therapies and when needed pharmacotherapy for co-occurring alcohol use disorder. The Administration has requested $25.1 million for MAT-PDOA in the Fiscal Year (FY) 2016

[5]Substance Abuse and Mental Health Services Administration, NSDUH, Op cit.
[6] Id.
[7] Id.
[8] 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. & Kraus et al., 2011; NIDA, 2012.

President's Budget (an increase of $13.1 million over FY 2015). The proposed FY 2016 funding would increase the number of states receiving funding from 11 to 22 and would serve an additional 24 high-risk communities.

A number of other SAMHSA programs enhance access to opioid use disorder treatment, including MAT. Through the Pregnant and Postpartum Women's (PPW) initiative, SAMHSA encourages grantees to accept pregnant women with opioid addictions into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering MAT to their clients on-site while the women may be closely monitored and provided the medication as clinically appropriate. This results in women remaining in treatment longer, resulting in healthier births.[9] Additionally, in SAMHSA's criminal justice programs – including the re-entry program – grantees are encouraged to use up to 20 percent of their grant awards for MAT.[10] Finally, SAMHSA's Screening, Brief Intervention and Referral to Treatment (SBIRT) program provides screening for illicit drugs, including heroin and other opioids in primary care settings, hospital emergency rooms and trauma centers, and other community settings. To date, more than two million patients have received screening – with approximately 12 percent receiving a brief intervention, brief treatment, or referral to treatment.[11] To assist health care practitioners in understanding how to use SBIRT SAMHSA created the SBIRT Medical Residency and the Allied Health Professionals Training programs. These programs promote a multi-disciplinary team approach to the integration of behavioral health into medical health care. Each program includes prescription opioids and/or pain management/treatment modules. The curricula address identification of medication misuse and use of illicit substances and appropriate brief intervention and referral steps. To date, 6,629 medical residents and 14,502 nonresidents (e.g., physician assistants and psychologists) have been trained.[12]

The President's FY 2016 Budget proposes an additional $20 million for a new program, the "Primary Care and Addiction Services Integration" program, which would enable substance use treatment providers to offer a full array of both physical health and substance use services to clients, including MAT. These grants would improve coordination and integration of services, improve quality, access, and reliability of healthcare to improve health outcomes and reduce the cost of care by controlling physical healthcare costs.[13]

SAMHSA also has primary responsibility for regulating Opioid Treatment Programs (OTPs). OTPs provide MAT and counseling services for opioid use disorders directly to their respective patients. OTPs must maintain certification with SAMHSA in order to operate. SAMHSA

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[9] Substance Abuse and Mental Health Services Administration (2014) *Preliminary Cross-site Data Analysis*
[10] *Grants to Expand Substance Abuse Treatment Capacity in Adult and Family Drug Courts*, http://www.samhsa.gov/grants/grant-announcements/ti-15-002
[11] SAMHSA (2002-February 2015). The Services Accountability Improvement System. Retrieved on February 13, 2015 from https://www.samhsa-grpa.samhsa.gov
[12] Id.
[13] Not only do people with substance use disorder experience health disparities in morbidity and mortality, Medicare and Medicaid cost data demonstrate that for people with multiple chronic conditions, costs are significantly higher when one of those conditions is a substance use disorder. Currently, a significant component of the overall higher cost of care for those with substance use disorder is untreated chronic disease. Boyd, C., Clark, R., Leff, B., Richards, T., Weiss, C., Wolff, J. (2011, August). *Clarifying Multimorbidity for Medicaid Programs to Improve Targeting and Delivering Clinical Services*. Presented to SAMHSA, Rockville, MD. & Barnett, P.G. (2009). Comparison of costs and utilization among buprenorphine and methadone patients. *Addiction*, 104, 982-992.

cooperates with state agencies, the Drug Enforcement Administration (DEA) and approved accrediting organizations to accomplish this. Currently there are 1,369 OTPs in operation, with an additional 59 pending SAMHSA certification.

Consistent with the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians wishing to treat opioid use disorders with buprenorphine in a practice setting not subject to Opioid Treatment Program regulations, such as a private practice or non-OTP treatment program, must request a waiver from SAMHSA. Initially physicians in these settings are restricted to treating a maximum of 30 patients at a time. After one year of experience with buprenorphine, physicians may choose to request that SAMHSA increase their patient limit to 100. SAMHSA coordinates both of these steps with the DEA. Of the approximately 877,000 physicians registered with the DEA to prescribe controlled substances, there are currently 29,194 physicians with a waiver to prescribe buprenorphine for opioid dependence. Of these, 9,011 (31 percent) are authorized to treat up to 100 patients. These 29,194 waivered physicians treated an estimated 1 million patients with buprenorphine mono- and buprenorphine/naloxone combination medications in 2012, which is a 62 fold increase since 2003.[14]

Recognizing that there is a need to further educate providers regarding the use of injectable extended-release naltrexone in addition to the more heavily regulated opioid agonist therapies, SAMHSA has developed a wide variety of educational and clinical practice guidelines. These include "Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorders: A Brief Guide" released in January 2015. SAMHSA also plans to convene a meeting on the use of opioid antagonist therapies in 2016 to bring together researchers, clinicians, and others specifically to review the literature and clinical experiences with naltrexone.

Preventing Opioid Misuse and Heroin Use

In support of the training and educational priority area of the Secretary's initiative, SAMHSA's prevention programs focus on educating providers and communities regarding opioid misuse and providing them with the tools to better identify and target at-risk populations.

Substance Abuse Prevention and Treatment Block Grant (SABG) state grantees are required to use at least 20 percent of their grant allotment on primary prevention strategies that target individuals in the general population and sub-groups that are at high risk for substance abuse. Many grantees use prevention funding to target the prevention of prescription drug and heroin use, particularly among youth. Over 80 percent (83.3 percent) of state grantees reported that they planned to use 2015 SABG funding to target prescription drug use prevention, making prescription drugs the second most targeted substance among state grantees. Additionally, more than one third of grantees (36.7 percent) reported that they planned to use 2015 SABG funding to target the prevention of heroin use.[15] States will report on their progress throughout the fiscal year, and SAMHSA will continue to monitor their activity.

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[14] *IMS, Vector One®: Total Patient Tr.* as cited in Clark, H.W. (April 29, 2014), Testimony before the House Energy and Commerce Oversight and Investigation Subcommittee Hearing on Prescription Abuse and Heroin Abuse, p. 9

[15] 2015 Substance Abuse Prevention and Treatment Block Grant Plan

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 to20 and prescription drug misuse and abuse among persons aged 12 to 25. The FY 2014 SPF-PFS grantees were able to choose a third area of focus which may include preventing and reducing heroin use. The President's FY 2016 Budget proposes a new $10 million initiative to combat the non-medical use of prescription drugs. "The Strategic Prevention Framework Rx" will provide funds to develop capacity and expertise in the use of data from state prescription drug monitoring programs to identify communities by geography and high-risk populations (e.g., age group), particularly those communities that are in need of primary and secondary prevention. Funding will support up to 20 state planning grants, technical assistance, and evaluation to build capacity to address prescription drug misuse, and overdose prevention efforts, in conjunction with other state and local partners. This initiative uses PDMP data to identify opportunities in communities for prevention programs, connecting patients to treatment resources and is designed to complement CDC's Prescription Drug Overdose: Prevention for States, which focuses on using PDMP data to affect prescribing behaviors of practitioners.

SAMHSA has also funded 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.

SAMHSA also recognizes the importance of recovery and has included Recovery Support as one of our strategic initiatives. Recovery services are the clinically-based structured processes that coordinate and facilitate recovery after acute treatment. In March 2015, SAMHSA issued revised "Federal Guidelines for Opioid Treatment Programs," which include new guidance on recovery. According to the revised guidelines, OTPs should include recovery support services in their clients' treatment plans, either providing recovery support directly or via referral to adequate and accessible community services. With adequate treatment and recovery supports, recovery can and should be the expectation.

Opioid Overdose Prevention

SAMHSA has also developed tools to help educate first responders about naloxone, which support the Secretary's initiative regarding increasing the use of naloxone. When administered in a timely manner 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 may be used to support first-responder naloxone initiatives. For example, SABG primary prevention set-aside funds may be utilized to support overdose prevention education and training. Additionally, SABG funds other than primary prevention set-aside funds may be used to purchase naloxone and the necessary materials to assemble overdose kits as well as to cover the costs associated with the dissemination of such kits. However, SAMHSA encourages public and private insurers to pay for this medication for those at risk or for those living with people at risk.

SAMHSA also published an Opioid Overdose Prevention Toolkit in 2013 (updated in 2014) 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 the most downloaded document on the SAMHSA website, and SAMHSA continues to promote its availability through various social media outlets to reach a wide range of populations.

Additionally, the President's FY 2016 budget includes $12 million for SAMHSA to fund "Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths," which will provide states with funds to purchase and distribute naloxone, equip first responders in high-risk communities, support education on the use of naloxone and other overdose death prevention strategies, and cover expenses incurred in disseminating overdose kits.

Finally, SAMHSA alerted the treatment community and the general public in 2014 about the marked increase in deaths reportedly linked to the use of heroin contaminated with clandestinely produced fentanyl has been noted.[16] Fentanyl is a synthetic opiate analgesic and when used in combination with heroin can rapidly cause respiratory depression that can lead to respiratory arrest and even death. These deaths underline the need for increased access to overdose rescue medications.

Prescriber Education

According to 2012-2013 NSDUH data, 68 percent of those who used pain relievers non-medically in the past year obtained them from a friend or relative.[17] About 84 percent of those relatives or friends each obtained their medications from a single doctor. While many individuals prescribed opioids may have a legitimate need for pain relievers, it is essential for prescribers to reduce inappropriate prescribing and for patients to know how to use and dispose of their medications. Therefore, a core aspect of the Secretary's initiative – to provide guidance around appropriate opioid prescribing practices –focuses on unnecessary or excessive prescribing.

SAMHSA has developed a series of medical education courses designed to help physicians provide appropriate pain management while minimizing the risk of pain medication misuse. SAMHSA is partnering with CDC in its development of the CDC Opioid Prescribing Guidelines for Chronic Pain. Together with CDC, SAMHSA will help disseminate and encourage uptake of the new guidelines. In addition, SAMHSA has partnered with Boston University School of Medicine and the Massachusetts Board of Medicine to develop a series of free, online courses on prescribing for pain. More than 62,000 certificates of completion have been issued since the inception of this program.[18] SAMHSA also offers live Continuing Medical Education courses in partnership with state health departments, medical societies, licensing boards, schools, and state

[16] SAMHSA (February 7, 2014) *SAMHSA issues Advisory to treatment community on the danger of heroin contaminated with fentanyl and what can be done to save lives*, http://www.samhsa.gov/newsroom/press-announcements/201402071000

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

[18] Boston University School of Medicine, www.opoioidprescribing.com

Prescription Drug Monitoring Programs (PDMPs), as well as special courses for the Indian Health Service, community health centers, and U.S. military hospitals. SAMHSA supports training in the use of all FDA-approved medications for the treatment of opioid use disorders via the Physician Clinical Support System for Medication Assisted Treatment. SAMHSA also funds the Prescribers' Clinical Support System for Opioid Therapies, a collaborative project led by American Academy of Addiction Psychiatry with 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, misuse, and dependence in those with pain.

Prescription Drug Monitoring Programs

In 2011, SAMHSA initiated the Enhancing Access to Prescription Drug Monitoring Programs (PDMPs) Project, which uses health information technology to improve access to PDMPs in an effort to reduce prescription drug misuse and overdose. The project was funded by SAMHSA and managed by the Office of the National Coordinator for Health Information Technology in collaboration with SAMHSA, CDC, and ONDCP. SAMHSA also funded the PDMP EHR Integration and Interoperability Cooperative Agreement program in FY 2012 and the Electronic Health Record and PDMP Data Integration Cooperative Agreement in FY 2013. These programs bring funding directly to states to complete integration projects. These cooperative agreements build upon previous efforts by increasing scale and integration implementation throughout the states. Most of the first cohort grantees have been able to integrate their state PDMPs into health information exchanges and EHRs and expand interoperability with other states.

SAMHSA's activities in this area complement CDC's activities to maximize the use of state-based PDMPs as a public health tool to assist in clinical decision-making and in conducting public health surveillance. They also complement ONC's Enhancing Access to PDMPs Using Health IT Project and S&I Framework Initiative, which focuses on exploring and pilot testing technical standards to enable data exchange between PDMPs and Health IT systems. This has not been done previously and may facilitate more widespread use of PDMPs by prescribers and pharmacists who will be able to obtain PDMP data securely and easily from the IT systems they use daily to support prescribing decisions.

Conclusion

Prescription opioid misuse and heroin use are complex issues. They require a concerted and coordinated effort across HHS and the Federal Government. SAMHSA's prevention and treatment strategies to address drug misuse are both targeted specifically to the drugs themselves and to programs that support prevention, intervention, and treatment of substance use 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 while collaborating with our sister agencies and partners within and outside of the Federal Government.

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