Testimony Before the

U.S. Senate Committee on the Judiciary

Hearing on

"Attacking America's Epidemic of Heroin and Prescription Drug Abuse"

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Good morning Chairman Grassley, Ranking Member Leahy, and distinguished members of the Senate Committee on the Judiciary. My name is Kana Enomoto, and I am the Acting 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 be here—along with my colleagues from the Office of National Drug Control Policy (ONDCP), National Institute on Drug Abuse (NIDA), and the Drug Enforcement Administration (DEA)—to discuss the current public health crisis related to opioids. Thank you, Chairman Grassley, for having this hearing.

The problems of prescription opioid misuse, heroin and fentanyl use, and substance use disorders are complex and require epidemiological surveillance, prevention, interventions, policy changes and further research. No organization or agency can address these problems alone; a coordinated response is required. The Federal Government, medical and other health partners, 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, 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.

SAMHSA

SAMHSA's mission is to reduce the impact of substance misuse and mental illness on America's communities. SAMHSA was established in 1992 and directed by the Congress to target substance use prevention and treatment and mental health services to people most in need of them and to enhance the delivery of behavioral health services to all. Substance misuse, 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, yet the majority of those who need treatment do not receive it. SAMHSA strives to close this gap by raising awareness that:

- Behavioral health is essential to health;
- Prevention works;
- Treatment is effective; and
- People recover.

SAMHSA is working with its partners across the Administration to address the current opioid public health crisis. SAMHSA is participating in the cross-departmental and intra-departmental workgroups to ensure coordination of policy and programs. SAMHSA also supported the Department of Justice's National Heroin Task Force, as well as ONDCP's four-part Prescription Drug Abuse Prevention Plan and is an active participant in the Interagency Workgroup on Prescription Drug Abuse.

SAMHSA also 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 (including the Office of the Surgeon General), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) working to prevent and treat the non-medical use of prescription drugs and heroin.

As you may know, in October the Surgeon General announced that he would be developing a report on Substance Use, Addiction and Health. SAMHSA is providing technical assistance with the development of this report and we look forward to its release.

SAMHSA's Role in the Secretary's Evidence-Based Opioid Initiative

SAMHSA is a key player in Secretary Burwell's initiative to address opioid misuse. This initiative focuses on three specific areas targeted for their potential to produce the most impact:

(1) Improving opioid prescribing practices;
(2) Increasing the use of naloxone; and
(3) Expanding use of medication-assisted treatment (MAT) and recovery support services for individuals with an opioid use disorder.

According to the 2014 National Survey on Drug Use and Health (NSDUH), which SAMHSA conducts annually, 4.3 million individuals (aged 12 and older) reported non-medical use of prescription pain relievers during the past month and 435,000 reported using heroin.[1] That equals 1.6 percent of the population non-medically using prescription pain relievers and 0.2 percent of the population using heroin. Although reports of heroin use are significantly lower than reported prescription opioid non-medical use, the numbers have been increasing fairly steadily since 2007. In fact, reported heroin use more than doubled in seven years from 161,000 individuals in 2007 to 435,000 in 2014.

[1] Center for Behavioral Health Statistics and Quality. (2015). *Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health* (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from http://www.samhsa.gov/data/

Of the individuals admitted to treatment in 2013, 18.8 percent of admissions were for heroin. Another 9.2 percent of admissions were for other opioids.[2] What these data do not fully reflect is the pain felt at losing a job, a home, or a cherished family member. Opioid and heroin use destabilizes families, disrupts the health care system, and imposes enormous financial and human costs on American society.

Improving Prescriber Practices

SAMHSA understands the importance of modifying prescribing behavior and providing prescribers with the information and the tools that are needed to appropriately treat patients with chronic pain.

Since 2007, over 72,000 prescribing primary care physicians and other healthcare professionals have received continuing education credits from SAMHSA's courses on prescribing opioids for chronic pain. This technical assistance is provided through SAMHSA's Providers' Clinical Support System for Opioid Therapies, a free national training and mentoring network that provides clinical support to physicians, dentists, and other medical professionals in the appropriate use of opioids for the treatment of chronic pain and screening and treating opioid use disorder.

SAMHSA has also addressed the issue of prescribing practices through various efforts related to increasing Prescription Drug Monitoring Program (PDMP) interoperability among states and intra-operability among the PDMP, electronic health records (EHR), health information exchanges and pharmacies. The Enhancing Access to PMDPs Project was funded by SAMHSA and managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. SAMHSA also funded the PDMP EHR Integration and Interoperability Cooperative Agreement program in Fiscal Year (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.

The Congress recently provided the additional funding SAMHSA requested for opioid misuse prevention that will allow PDMPs to be utilized to target localities where states should focus their prevention efforts. In FY 2016, the Congress appropriated $10 million for a new initiative, the "Strategic Prevention Framework Rx" (SPF Rx), which will allow states to enhance the use of data from PDMPs by identifying communities by geography and high-risk populations (e.g., age group), including those in need of prevention programs, connect patients to treatment resources, and complement CDC's Prescription Drug Overdose: Prevention for States program, which has a component that focuses on using PDMP data to inform the prescribing behaviors of practitioners.

[2] Center for Behavioral Health Statistics and Quality. (2015). *Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health* (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from http://www.samhsa.gov/data/

SAMHSA expects grantees to continue to use the Strategic Prevention Framework (SPF) process at both the State/tribal and community levels to meet the goals of the SPF Partnerships for Success (PFS) Program. There are five steps in this process: (1) assess needs; (2) build capacity; (3) plan; (4) implement; and (5) evaluate. Using the SPF process is critical to ensuring that states/tribes and their communities work together to use data driven decision making processes to develop effective prevention strategies and sustainable prevention infrastructures. The SPF PFS grantees are using SPF PFS funds to target two priorities: (1) underage drinking among persons aged 12-20; and (2) prescription drug misuse among persons aged 12-25. At their discretion, states/tribes may also use their SPF PFS funds to target an additional data driven priority (e.g., heroin, marijuana use). States and tribes developed an approach to funding communities of high need that ensures all funded communities will receive ongoing guidance and support from the state/tribe, including technical assistance and training for the duration of the SPF PFS project. .

A core aspect of the Secretary's initiative is to provide guidance on opioid prescribing practices focusing on inappropriate or excessive prescribing. SAMHSA supports CDC in this effort and once CDC's *Guideline for Prescribing Opioids for Chronic Pain* is finalized, SAMHSA will help disseminate and encourage uptake of the new guidelines.

Opioid Overdose Prevention – Expanding the Use of Naloxone

SAMHSA is also working to carry out a significant portion of the Opioid Initiative's second priority area – preventing opioid overdoses by expanding the use and distribution of naloxone. When administered in a timely manner, 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 their personnel on overdose prevention and equip them with naloxone as a means of improving response.

In 2014, SAMHSA clarified that at the state's discretion its Substance Abuse Prevention and Treatment Block Grant (SABG) 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 materials to assemble overdose kits as well as to cover 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 use disorders (SUD), and community members about steps to take to prevent opioid overdose and respond to 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. SAMHSA also offers a naloxone and overdose prevention course for prescribers and pharmacists.

The Congress provided SAMHSA an additional $12 million in FY 2016 to initiate a Prevention of Prescription Drug/Opioid Overdose-Related Deaths grant program which will provide funds to states for the purchase of naloxone and for training first responders in communities of high need.

Expanding MAT and Recovery Services

MAT is an evidence-based approach which combines behavioral therapy with medications to treat SUDs, including opioid use disorders. Research shows that medications are effective for decreasing opioid craving and withdrawal symptoms, blocking euphoria if relapse occurs, and augmenting the effect of counseling.[3]

SAMHSA has a key role in ensuring access to MAT for opioid use disorders and last year, thanks to Ranking Member Leahy and many other members, $12 million was provided to SAMHSA for new grants to increase capacity and provide accessible, effective, comprehensive, coordinated care, and evidence-based MAT and recovery support services to individuals with opioid use disorders. In FY 2015, the program supported grants in 11 states (including Iowa and Vermont) at $1.0 million for each of three years. In addition, SAMHSA used $1.0 million to support a contract to provide technical assistance to new grantees.

In FY 2016, the Congress appropriated $25 million for MAT-PDOA, an increase of $13 million over FY 2015. The FY 2016 funding will increase the number of states receiving funding from 11 to 22, and will serve an additional 24 high-risk communities. This increased investment in the fight against opioid and heroin use disorders is similar to provisions in the Comprehensive Addiction and Recovery Act of 2015, introduced by Senators Whitehouse and Portman in the Senate, and by Representatives Sensenbrenner and Tim Ryan in the House. We thank these Members of the Congress for their leadership on this issue, and we look forward to working with the sponsors and this Committee going forward.to ensure that HHS has a leading role on the public health activities envisioned in the bill since HHS has the infrastructure and technical expertise necessary to effectively administer these programs and maximize their impact."

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 use disorders into residential treatment settings, and in recent years many of the PPW treatment providers have begun administering MAT onsite to the women admitted to their programs due to an opioid use disorder. As a result, pregnant women recovering from opioid use disorders are remaining in treatment longer, resulting in healthier births.[4] I want to thank Senator Ayotte for her leadership in this area as well.

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[3] 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.

[4] Substance Abuse and Mental Health Services Administration (2014) *Preliminary Cross-site Data Analysis*

SAMHSA has also worked with ONDCP and the Department of Justice (DOJ) to expand access to MAT for justice-involved individuals with opioid use disorders by adding language to our drug court and offender reentry program grant applications ensuring clinically appropriate MAT with FDA-approved medication is not denied or restricted. These grantees are encouraged to use up to 20 percent of their grant awards for MAT.

SAMHSA also funds the Providers' Clinical Support System for Medication Assisted Treatment which provides technical assistance on proper dispensing and prescribing of FDA-approved medications for opioid use disorders. 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 methadone and buprenorphine, SAMHSA has developed a wide variety of 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, like naltrexone, in May to bring together researchers, clinicians, and others specifically to review the literature and clinical experiences with naltrexone.

SAMHSA also has primary responsibility for regulating Opioid Treatment Programs (OTPs). OTPs provide all three FDA-approved opioid use disorder medications (methadone, buprenorphine and naltrexone) and counseling services for opioid use disorders directly to their respective patients. OTPs must maintain certification with SAMHSA in order to operate. SAMHSA cooperates with state agencies, the Drug Enforcement Administration (DEA) and approved accrediting organizations to accomplish this. Currently there are 1,402 OTPs in operation, with an additional 51 pending SAMHSA certification.

Consistent with the Controlled Substances Act, as amended by 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 OTP regulations, such as a private practice or non-OTP treatment program, must submit a notice of intent to SAMHSA. Initially physicians in these settings are restricted to treating a maximum of 30 patients at a time. After one year of experience, physicians desiring to increase their patient limit to 100 may submit a second notification to SAMHSA of the need and intent to treat up to 100 patients. SAMHSA coordinates processing of these notifications with DEA. Of the approximately 1,176,185 physicians registered with DEA to prescribe controlled substances, there are currently 31,552 physicians with a waiver to prescribe buprenorphine for opioid dependence.[5] Of these, 10,176 are authorized to treat up to 100 patients.

SAMHSA is working to find other ways to expand access to MAT. On September 17th, 2015, Secretary Burwell announced that the Department would be drafting a regulation to increase the highest patient limit for physicians that have a waiver to prescribe buprenorphine. As the Secretary noted, in drafting the regulation the Department's goals are to increase access to MAT, ensure the provision of quality care, and at the same time prevent diversion. SAMHSA has led

[5] SAMHSA, Retrieved January 7, 2016, from http://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/physician-program-data

this effort for the Department working in close partnership with ASPE. Because we are currently in the rulemaking phase, we are limited in what we can say about the content of the impending Notice of Proposed Rulemaking (NPRM). We are pleased to say that due to the urgency of the opioid public health crisis, we worked on an expedited timeline and the NPRM is at the Office of Management and Budget (OMB) for interagency review at this time.

Finally, SAMHSA has done significant work to ensure that behavioral health treatment is appropriately financed and implemented to support integrated care across an array of health systems and programs. SAMHSA's report, "Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders," provides clinicians and policy makers a resource guide for developing beneficial medication coverage and financing policies. The report presents innovative coverage and financing approaches that are being used to ensure cost-effective and treatment-effective outcomes. To complement this effort, SAMHSA engaged with its Federal partners (CMS, CDC, NIDA, National Institute on Alcohol Abuse and Alcoholism) to issue a CMS Informational Bulletin on MAT to inform states and other stakeholders about effective practices for identifying and treatingt mental and substance use disorders covered under Medicaid. Additionally, CMS and SAMHSA jointly issued an Informational Bulletin on coverage of behavioral health services for youth with substance use disorders to assist states in designing a benefit that meets the needs of youth with substance use disorders and their families and to help states comply with their obligations under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment requirements. The services described were designed to enable youth to address their substance use disorders, to receive treatment and continuing care, and participate in recovery services and supports.

Criminal Justice Activities

A public health approach to addressing the opioid crisis is vital and the Secretary's initiative takes such an approach. At the same time, public health agencies and organizations understand the importance of working with our colleagues in the criminal justice field. SAMHSA's criminal justice portfolio includes several grant programs that focus on diversion, alternatives to incarceration, drug courts, and re-entry from incarceration for adolescents and adults with substance use disorders, and/or co-occurring substance use and mental disorders.

Drug Courts

SAMHSA's adult drug court programs support a variety of services, including treatment for diverse populations at risk; wraparound/recovery support services designed to improve access and retention; drug testing for illicit substances required for supervision, treatment adherence, and therapeutic intervention; education support; relapse prevention and long-term management; MAT; and HIV testing conducted in accordance with state and local requirements.

SAMHSA's treatment drug court grant programs focus on Tribal Healing to Wellness Courts, Juvenile Treatment Drug Courts, and SAMHSA's collaboration with DOJ's Bureau of Justice Assistance. In FY 2015, SAMHSA supported the continuation of 103 drug court grants, and provided funding to 35 new adult and family drug court grants and 10 new BJA jointly funded

drug court grants. The Congress expanded this provision – new in FY 2015 – from $50 million for Drug Courts to a new total of $60 million in FY 2016.

Offender Reentry Program

In addition to SAMHSA's drug court portfolio, criminal justice funds also support Offender Reentry Program (ORP) grants, which provide screening, assessment, comprehensive treatment, and recovery support services to offenders reentering the community, as well as offenders who are currently on or being released from probation or parole. Funding for ORP may be used for a variety of services, including but not limited to screening, comprehensive individual assessment for substance use and/or co-occurring mental disorders, case management, referrals related to substance abuse treatment for clients, alcohol and drug treatment, wrap-around services, drug testing, and relapse prevention and long-term management support.

In FY 2015, SAMHSA supported 30 three-year ORP grant continuations, and up to 18 new ORP grants, which will have a particular emphasis on opioid overdose prevention.

Conclusion

On behalf of SAMHSA, I appreciate the opportunity to testify today and share with you our prevention, treatment and recovery support strategies. We look forward to partnering with you as well and thank you for your leadership on this issue.

I welcome any questions that you may have.