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Testimony Before the

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Hearing to Examine "America's Insatiable Demand for Drugs: Assessing the Federal Response"

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Good morning Chairman Johnson, Ranking Member Carper, and distinguished members of the Committee. My name is Kana Enomoto, and I am the Principal Deputy 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), to discuss the importance of preventing substance misuse and ensuring appropriate treatment and recovery support services for individuals with substance use disorders in America.

The problems of prescription misuse, illicit drug 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.

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 implement the *National Drug Control Strategy*. SAMHSA is participating in various cross-departmental and intra-departmental workgroups to ensure coordination of policy and programs.

SAMHSA also works across HHS through the Behavioral Health Coordinating Council. 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 (OASH), the Office of the Surgeon General (SG), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) working to prevent substance misuse and treat substance use disorders.

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 *National Drug Control Strategy (Strategy)*

In fiscal year (FY) 2017, a total of $31.1 billion, an increase of more than $500 million over FY 2016 enacted, was requested by the President to support National Drug Control Strategy (Strategy) efforts to reduce drug use. The Administration's 21st century approach to drug policy works to reduce illicit drug use and its consequences in the United States. This evidence-based plan balances public health and public safety efforts to prevent, treat and provide recovery from the disease of addiction. In FY 2017, for the first time, the Administration proposes more funding for demand reduction than supply reduction. SAMHSA plays a key role in the prevention and treatment aspects of the Strategy, many of which also support HHS Secretary Burwell's initiative to address opioid misuse, abuse, and overdose.

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, abuse, and overdose. 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.

Of the 47,055 drug overdose deaths in 2014, heroin was involved in 10,574 drug overdose deaths, while opioid analgesics were involved in 20,808 drug overdose deaths. Among the opioid analgesic category, there were more than 5,544 drug overdose deaths involving synthetic narcotics other than methadone, which includes fentanyl. The number of opioid overdose deaths involving synthetic narcotics more than doubled from two years earlier (2,628 in 2012).[1]

Of the individuals admitted to treatment in 2013, 18.8 percent of admissions were for heroin.

[1] Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2014* on CDC WONDER Online Database, released 2015. Data are from the Multiple Cause of Death Files, 1999-2014, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at http://wonder.cdc.gov/mcd-icd10.html, December 2015.

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.

SAMHSA's Opioid Proposals in the President's FY17 Budget

Addressing the crisis of opioid overdose from prescription pain relievers, heroin, and illicit fentanyl is a major priority for SAMHSA. The President's Budget recognizes the need for immediate action and proposes to address the opioid epidemic with a $1 billion two-year investment in new mandatory funding. This investment of mandatory funds makes a bold commitment to build the addictions workforce and bolster the continuum of services for prevention, treatment, and recovery.

Of the $1 billion in new mandatory funding, SAMHSA proposes $920 million over two years to support cooperative agreements with states to expand access to treatment for opioid use disorders. In each of FYs 2017 and 2018, SAMHSA would provide $460 million in new mandatory funding toward State Targeted Response Cooperative Agreements for states to help individuals seek and successfully complete treatment and sustain recovery from opioid use disorders. Evidence-based strategies that states might consider include training and certifying opioid use disorder treatment providers and supporting delivery of MAT. Program goals include: reducing the cost of care, expanding access, engaging patients, and addressing the negative attitudes associated with accessing opioid use disorder treatment.

Another component of the Administration's two-year initiative includes $30 million in new mandatory funding for SAMHSA to implement Cohort Monitoring and Evaluation of MAT, to evaluate the effectiveness of treatment programs employing medication-assisted treatment under real-world conditions. This program will help identify opportunities to improve treatment for patients with opioid use disorders.

In addition to the new mandatory investments, SAMHSA continues and expands existing strategies to address opioid use disorders. SAMHSA is requesting $50.1 million to double the size of the Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA) program. The funding will support 23 new MAT-PDOA state grants in providing FDA-approved MAT in conjunction with psychosocial interventions to those living with opioid use disorders.

[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/

[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/

To help further expand access to treatment, SAMHSA's Budget Request includes a $10 million pilot project, the Buprenorphine-Prescribing Authority Demonstration, aimed at increasing the types of practitioners able to prescribe buprenorphine, a medication for opioid use disorder treatment, where allowed by state law. This demonstration will test the safety and effectiveness of allowing prescribing buprenorphine by non-physician advance practice providers.

In conjunction with these treatment efforts, SAMHSA is also proposing continued investments to prevent the misuse and overdose deaths related to prescription drugs, heroin, and fentanyl. The FY 2017 Budget maintains investments in the Prevention of Prescription Drug and Opioid Overdose Related Deaths program at $12 million. This program focuses on overdose death prevention strategies such as naloxone distribution and education of first responders on its use along with other prevention strategies. Additionally, SAMHSA requests continued support ($10 million) of the Strategic Prevention Framework-Rx program which enables states to enhance, implement, and evaluate strategies to prevent prescription drug misuse. These continued and expanded efforts build upon SAMHSA's numerous activities geared toward preventing prescription drug and opioid misuse and treating opioid use disorders, including: courses for healthcare professionals on prescribing opioids for pain, prescription drug monitoring program interoperability enhancement, development and implementation of the Opioid Overdose Prevention Toolkit, and clarification on the allowable use of SABG funds to support equipping first responders with naloxone.

SAMHSA's Ongoing Work to Address the Opioids Epidemic

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.

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 includes a component focused on enhancing prescription drug monitoring programs and leveraging them as public health tools.

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 these 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.

Another core aspect of the Secretary's initiative is to provide guidance on opioid prescribing practices focusing on inappropriate or excessive prescribing. Recently, CDC released the *Guideline for Prescribing Opioids for Chronic Pain*, to guide primary care providers in appropriate prescribing of opioids to improve pain management and patient safety. SAMHSA supports CDC in this effort and will help disseminate and encourage uptake of the new guideline.

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 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. In FY2016, Congress appropriated $12 million for a new initiative at SAMHSA, the "Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths" (PDO), which allows states to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among individuals 18 years of age and older by training first responders and other key community sectors on the prevention of prescription drug/opioid overdose-related deaths and implementing secondary prevention strategies, including the purchase and distribution of naloxone to first responders and others in high-need communities.

In FY 2016, 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.

The President's FY 2017 budget requests $1 billion in mandatory funding over two years to expand access to treatment, and requests more than $90 million in additional discretionary funds that will support targeted enforcement activities and help the federal government to continue and expand current efforts across the Departments of Justice (DOJ) and HHS to expand state-level prescription drug overdose prevention strategies, increase the availability of medication-assisted treatment programs, improve access to the overdose-reversal drug naloxone, and support targeted enforcement activities. As stated above, this epidemic requires a comprehensive approach, which includes funding to expand access to treatment and help individuals who seek treatment to successfully complete it and sustain recovery. We look forward to working with Congress to make the much needed investments to tackle this crisis.

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]

SAMHSA's budget request for FY 2017 includes innovation grants through the PPW program, which will test different models for family-centered treatment programs, including outpatient treatment programs. Outpatient services are not currently an allowable use of funds, and would offer substance use disorder treatment for pregnant and postpartum women, without separating them from their minor children and other family members in the home.

SAMHSA has also worked with ONDCP and DOJ to expand access to MAT for justice-involved individuals with opioid use disorders by adding language to our drug court grant applications ensuring clinically beneficial MAT with FDA-approved medications is not denied or restricted. However, a judge retains judicial discretion to mitigate/reduce the risk of misuse or diversion of these medications. These Drug Court program 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.

[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*

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 1,189,000 physicians registered with DEA to prescribe controlled substances, there are currently 32,243 physicians with a waiver to prescribe buprenorphine for opioid dependence.[5] Of these, 10,473 are authorized to treat up to 100 patients.

SAMHSA is working to find other ways to expand access to MAT. On March 30, 2016, we released a Notice of Proposed Rulemaking (NPRM) that would increase the patient limit for certain qualified physicians that have a waiver to prescribe buprenorphine. The NPRM would allow a waivered practitioner to increase their patient base from 100 to 200 if they request approval for the higher patient limit and fulfill several additional requirements. We believe the NPRM will achieve the goals of expanding access to buprenorphine, increasing the quality of treatment for opioid use disorders, and limiting the diversion of buprenorphine. In addition, to ascertain if allowing additional categories of prescribers to obtain DATA 2000 waivers would help address provider shortage while maintaining safety and quality of care, the President's FY 2017 Budget is proposing a pilot study in states where practice laws already provide advanced practice registered nurses and physician's assistants the necessary practice scope and prescribing authority to provide office-based opioid treatment.

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, and the 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 treating 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.

[5] SAMHSA, Retrieved March 21, 2016, from http://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/physician-program-data

Criminal Justice Activities

A public health approach to addressing substance use disorders is vital. At the same time, public health agencies and organizations understand the importance of working with our public safety 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. 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.