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Testimony Before the

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on Prescription Drug Abuse

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Good morning Chairman Pitts, Ranking Member Pallone, and Members of the 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 drugs, and treating individuals who abuse prescription drugs.

SAMHSA's Role

SAMHSA was established in 1992 and is directed by 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.

The challenge of prescription drug misuse and abuse is a complex issue that requires epidemiological surveillance, distribution chain integrity, interventions, prescriber education, access to effective treatment services, and more research by the private and public sectors. Thus, 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 international 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 prescription drugs.

SAMHSA's strategy to reduce prescription drug abuse and assist individuals who misuse or abuse prescription 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 the Department of Health and Human Services through the Behavioral Health Coordinating Committee's (BHCC) 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 prescription drug misuse and abuse. SAMHSA is represented on the ONDCP Interagency Workgroup on Prescription Drugs.

Prevalence of Non-medical Prescription Drug Use

SAMHSA's National Survey on Drug Use and Health (NSDUH) is an integral part of our national surveillance of non-medical use of prescription drugs. According to 2011 NSDUH data, nonmedical prescription drug use ranks as the second most common class of illicit drug use in the United States.[1] The NSDUH found that in 2011, 1.9 million persons aged 12 or older initiated non-medical use of prescription pain relievers in the preceding year. Marijuana was the only illicit drug with more initiates in 2011.[2] The 2011 NSDUH also found that males were more likely than females to report non-medical prescription pain reliever use in the preceding year, and young adults (18 to 25) had the highest rate of reported prior-year non-medical use.[3]

The 2011 NSDUH also revealed that an estimated 54 percent of the prior-year non-medical users of prescription pain relievers obtained the drugs for free from a friend or relative. The next most common source was a single doctor (18 percent), followed by individuals who bought or took drugs from a relative or friend (17 percent). Other less-frequent sources included buying drugs from a drug dealer or other stranger, obtaining them from more than one doctor, and less than one percent reported getting them from the internet.[4]

Recent data indicate that the rate of non-medical use declined slightly between 2010 and 2011[5] and suggest that national, state, and local efforts to reduce prescription drug misuse may be beginning to have an impact. However, with an annual average of 15.7 million people aged 12 or older having misused prescription drugs between 2005 and 2011, there is still much work left to be done.

State Prescription Drug Monitoring Programs

State prescription drug monitoring programs (PDMPs) are an important component of government efforts to prevent and reduce controlled substance diversion and abuse. State PDMPs collect, monitor, and analyze scheduled or controlled prescription drugs, with the goal of preventing prescription drug misuse and abuse and illegal diversion. Forty-six states operate PDMPs; three states (Georgia, New Hampshire, and Maryland) have enacted PDMP-establishing

[1] Center for Behavioral Health Statistics and Quality. (2012). *Results from the 2011 National Survey on Drug Use and Health: Summary of national findings* (HHS Publication No. SMA 12-4713, NSDUH Series H-44). Rockville, MD: Substance Abuse and Mental Health Services Administration. The survey defined "non-medical use" as use without a prescription of the individual's own or use simply for the experience or feeling the drugs caused.
[2] Id.
[3] Id.
[4] Id.
[5] Id.

legislation but do not yet operate PDMPs; and one state (Missouri) and the District of Columbia have not enacted legislation.[6]

The National All-Schedules Prescription Electronic Reporting Act of 2005 (NASPER) created a grant program administered by SAMHSA for states to implement or enhance PDMPs. SAMHSA received NASPER funding from Congress in Fiscal Year (FY) 2009 and FY 2010, and provided 26 grants to 14 states. In FYs 2011 and 2012, Congress did not appropriate funding for NASPER.

In FY 2011, SAMHSA also funded the Enhancing Access To PDMPs Through Health Information Technology Project, which was managed by ONC in collaboration with SAMHSA, CDC, and ONDCP. This project stems from joint efforts of public sector and private industry experts that participated in the White House Roundtable on Health Information Technology and Prescription Drug Abuse in June 2011. In turn, the BHCC Prescription Drug Abuse and Health Information Technology Subcommittees created the "Action Plan for Improving Access to Prescription Drug Monitoring Programs through Health Information Technology."[7] The project's purpose is to use health information technology (health IT) to increase timely access to PDMP data for three types of medical professionals within a variety of care settings:

- Ambulatory clinic healthcare providers (*e.g.*, physicians, nurses, nurse practitioners);
- Emergency Department physicians; and
- Dispensing pharmacists.

The project set out to investigate and develop the standards necessary to utilize existing technologies, the health information exchanges, and the PDMPs to improve, with appropriate privacy protections, the tracking of opioid use by implementing pilot studies and establishing work groups. The first part of the project involving the work groups was completed, and a report was published summarizing the work groups' findings, in August 2012.[8] The second part of the project identified, developed, and implemented six pilots that tested new technology that links state PDMPs and providers' electronic health record (EHR) systems. The results demonstrated the value-add of increased access to state PDMP data at the point of care. For example, , pilot participants reported that the functionality streamlined their clinical workflows, made PDMP data easier to access, and helped better inform clinical decisionmaking.

In FY 2012, SAMHSA and ONC extended the project, scaled up some of the existing pilots (*i.e.*, increased the number of pilot sites or of states supplying PDMP data), and launched new pilots to test new types of data integration. In total, seven pilots were launched or expanded. Additionally, a website, "PDMPConnect" was developed that will serve as a nexus of resources for prescribers, dispensers, health IT developers, and PDMP-related organizations. PDMPConnect will be launched in the near future to provide ongoing information to the prescriber and dispenser communities about the types of data connectivity programs underway, identify and provide the resources needed to create PDMP/health IT connections, and provide

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[6] *Status of Prescription Drug Monitoring Programs (PDMPs)*, PDMP Training & Technical Assistance Center, available at http://pdmpassist.org/pdf/pmpprogramstatus2013.pdf (last revised June 5, 2013).

[7] http://www.healthit.gov/sites/default/files/rules-regulation/063012-final-action-plan-clearance.pdf.

[8] http://www.healthit.gov/sites/default/files/rules-regulation/063012-final-action-plan-clearance.pdf.

video stories, articles, and news flashes to educate and build awareness about the field. Moreover, the technical framework for PDMP integration is being examined to address challenges in interoperability through the Standards and Interoperability Framework.

In FY 2012, SAMHSA established the PDMP Electronic Health Record Integration and Interoperability Expansion program, with $4 million in funding from the Prevention and Public Health Fund. Working collaboratively with the Harold Rogers Prescription Drug Monitoring National Training and Technical Assistance Program at the Department of Justice (DOJ), this program complements existing Federal efforts by improving real-time access to PDMP data through integration into existing technologies, like EHRs, to improve the ability of state PDMPs to reduce the nature, scope, and extent of misuse. The program also strengthens currently-operational state PDMPs by providing resources to make the changes necessary to increase the PDMPs' interoperability. Nine states received funding to allow for system modifications to expand interoperability; EHR and pharmacy system enhancement; adoption of specifications for exchanging PDMP reports; and modification of EHR and pharmacy systems to permit new linkages. CDC will evaluate the program and report on the best practices developed and how they can be utilized by other states working to link PDMPs to other health IT systems.

In FY 2013, SAMHSA, using budget authority, anticipates awarding up to eight grants for EHR and PDMP data integration. Unlike the FY 2012 grants, the FY 2013 program will not focus on state-to-state interoperability. The purpose of this program is to reduce prescription drug misuse and abuse by providing healthcare providers with access to PDMP data to make sound clinical decisions without disturbing their regular clinical workflow.

Finally, SAMHSA staff participates in projects with other agencies to increase PDMP use to identify emerging prescription drug abuse problems.

Additional Efforts in Preventing and Treating Prescription Drug Misuse and Abuse

Education

Current prescribers: SAMHSA supports the education of prescribers through formal continuing medical education courses and other less formal efforts, *e.g.*, webinars hosted by SAMHSA's opioid prescriber clinical support system (PCSS) grantee (the American Academy of Addiction Psychiatry). SAMHSA has prioritized these prescribing courses for states with the highest rates of opioid-related mortality (*e.g.*, New Mexico, West Virginia). The PCSS—Opioids is a national mentoring network offering support (*e.g.*, clinical updates, evidence-based outcomes, and training) to physicians and other medical professionals in the appropriate use of methadone and other opioids for the treatment of chronic pain and opioid addiction. This program also addresses the nation's rise in opioid-associated morbidity and mortality that has been spurred by misuse/abuse, and fatal drug interactions involving methadone and other prescription medications, over-the-counter medications, and illicit drugs.

SAMHSA also supports the Medical Education and Supporting Services for Opioid Treatment Program to educate and prepare opioid treatment programs (OTPs) to achieve accreditation by SAMHSA's approved accreditation organizations. Accreditation has been shown to improve treatment outcomes and access to treatment for patients and provides the opportunity for OTPs to

incorporate best practices in their treatment programs. Other goals include improving OTP administration and management, increasing staff retention, providing more OTP staff training, increasing availability of comprehensive services and emergency services, and improving patient outcomes.

SAMHSA also works with ONDCP to provide outreach and disseminate educational materials to various sectors of our society that encounter this class of drugs.

Educating future prescription drug prescribers: SAMHSA's Screening, Brief Intervention, Referral to Treatment (SBIRT) program is an important tool for early identification of persons who might be at risk for opioid dependency and other substance use disorders. SAMHSA's SBIRT Residency grant program addresses future prescribers and includes screening for prescription drug abuse, and more recently has emphasized the use of state PDMPs.

The SBIRT program was established to engage health professionals in the identification, counseling, referral, and ongoing medical management of persons with substance use disorders. Through SBIRT, states, territories, and tribal organizations are eligible to receive grants to implement screening, brief intervention and referral to treatment services for adults in primary care and community health settings, for substance misuse and substance use disorders. This program is based on research showing that by simply asking questions regarding unhealthy behavior and conducting brief interventions, patients are more likely to avoid the behavior in the future and seek help if they believe they have a problem. In 2011, over 213,000 clients were served by the SBIRT Program. The percentage of clients reporting abstinence at follow-up tripled compared to the percentage reporting abstinence at baseline.

Prevention and Early Intervention

Substance Abuse Prevention and Treatment Block Grant Prevention Set-Aside:
The Substance Abuse Prevention and Treatment Block Grant (SABG) is a formula-based grant provided to states and territories to provide financial support for its prevention and treatment programs and services. Federal statute requires states and territories to direct at least 20 percent of the SABG toward substance abuse prevention services. For many states and territories, this funding represents the vast majority of their substance abuse prevention budget. Under the SABG states are requested to identify the categories of substances, including prescription drugs, they intend to address with the 20 percent set-aside for prevention based on data collected and analyzed from statewide and local needs assessments.

Strategic Prevention Framework/Partnerships for Success: The Strategic Prevention Framework/Partnerships for Success (SPF/PFS) is designed to address two of the nation's top substance abuse prevention priorities, including underage drinking and prescription drug misuse and abuse among persons aged 12 to 25. Under this program, states and jurisdictions are funded to implement a strategic planning process and to use data to identify which of the two priorities will be addressed with this grant's funding. The majority (85 percent) of grant funding must be allocated to communities of high need, which then use the funds to enhance their community-level infrastructures using the strategic planning process; leverage, redistribute, and/or realign funds for prevention activities; implement a comprehensive prevention approach, including a mix of evidence-based programs, policies, and practices that best address selected prevention

priorities; identify technical assistance and training needs and develop responsive activities; and collect and report community-level data. The program is based on the premise that changes at the community level will, over time, lead to measurable changes at the state level. By working together to foster change, states and their SPF/PFS funded communities of high need can more effectively begin to overcome the challenges underlying their substance abuse prevention priorities and achieve the goals of the SPF/PFS.

Drug-Free Communities: The Drug-Free Communities (DFC) program is a collaborative effort directed by ONDCP and administered by SAMHSA. DFC has two goals:

1. Establish and strengthen collaboration among communities, public and private non-profit agencies, and Federal, state, local, and tribal governments to support the efforts of community coalitions working to prevent and reduce substance use among youth.

2. Reduce substance use among youth and, over time, reduce substance abuse among adults by addressing the factors in a community that increase the risk of substance abuse and promoting the factors that minimize the risk of substance abuse.

Grantees funded under DFC target prescription drug misuse and abuse if the data collected and analyzed in their respective communities indicate it is a problem that needs to be addressed.

Prevention of Prescription Drug Abuse in the Workplace Technical Assistance: The Prevention of Prescription Drug Abuse in the Workplace (PAW) program provides technical assistance to SAMHSA grantees, employers, unions, and other communities and collaborates with partner organizations. PAW educational/technical assistance resources include fact sheets, online products, occupational-specific screening and assessment tools, presentations, trainings, and literature reviews. Topics such as developing specific workplace prescription drug abuse policies; integrating prescription abuse messaging into current programs and community outreach activities; and prescription drug abuse evaluation activities and metrics are addressed.

Tribal Prescription Drug Summit: In response to tribal leaders' concerns about an increase in the use and abuse of prescription drugs in American Indian communities, SAMHSA co-sponsored a Tribal Prescription Drug Abuse Summit in June 2012. The summit brought together tribal leaders and representatives of the Health Resources and Services Administration, SAMHSA, area Indian Health Service providers, behavioral health directors, and representatives of the Great Lakes and National American Indian and Alaska Native Addiction Technology Transfer Centers. The goal of the summit was to discuss the tribal perspective on prescription drug abuse and the Federal efforts and programs to address the issue and to create an action plan to move forward. Topics focused on four pillars of the action plan: education, monitoring, disposal, and enforcement. Participants continue to assess the effectiveness of the four pillars of the action plan against prescription drug abuse.

Prescription Drug Abuse Treatment

Treatment of opioid dependence/addiction is a critical element of SAMHSA's strategy and includes psychotherapeutic approaches such as cognitive behavioral therapy, as well as expanding and improving access to the three FDA-approved medical treatments: (1) methadone,

which is regulated by FDA, SAMHSA, and DOJ's Drug Enforcement Administration (DEA); (2) buprenorphine, for which SAMHSA and DEA together process waivers enabling physicians in outpatient settings to prescribe products for opioid dependence; and (3) oral and extended-release injectable naltrexone. SAMHSA also has been working with other Federal agencies to explore "telemedicine" enabling treatment in rural settings. SAMHSA is continuously educating providers and consumers about these medical treatments through educational efforts, the PCSS model referenced above, and interactions with provider communities. SAMHSA works with the FDA to ensure that the safety of these medications is continuously monitored and analyzed. For example, SAMHSA convened expert panels and work groups with the FDA to assess methadone's safety for cardiac health; methadone-overdose-related mortality; the risk of pediatric exposure to buprenorphine; and diversion of these medications for illicit or inappropriate use. SAMHSA convened a similar meeting to develop guidelines for the medicine Vivitrol, an injectable medicine indicated for monthly administration to treat opioid dependence.

SAMHSA provides direct funding for the treatment of substance abuse, including prescription drug abuse. The SABG is the largest program; the President's FY 2014 Budget includes $1.8 billion for this program, of which 80 percent is for treatment (the other 20 percent is directed to prevention).

Regulation and Certification

SAMHSA regulates OTPs that use methadone and buprenorphine products approved by FDA to treat patients with opioid dependence (42 CFR Part 8). SAMHSA carries out this responsibility in coordination with DEA, states, the District of Columbia, and territories by enforcing regulations that established an accreditation-based system.

The Drug Addiction Treatment Act of 2000 (DATA) permits qualified physicians to prescribe certain opioid treatment medications for the treatment of opioid addiction in the outpatient setting. Under DATA, qualifying physicians are ''certified'' to obtain waivers from the requirement under 21 U.S.C. § 823(g) to obtain approval from SAMHSA as OTPs. As of June 1, 2013, there are 23,000 active DATA-certified doctors eligible to prescribe buprenorphine products, and 6,440 active physicians may prescribe for up to 100 patients.

Conclusion

As I stated earlier in my testimony, prescription drug misuse and 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 prescription drugs themselves and to programs that support prevention, intervention, and treatment of addictions, which can have a significant long-term impact on this serious public health problem.

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