Hearing before the Senate Committee on the Judiciary
"Attacking America's Epidemic of Heroin and Prescription Drug Abuse"
January 27, 2016

Question for the Record from Chairman Charles E. Grassley

Q1: As you know, alternative, non-opioid medications are being developed that are not addictive and can be used to treat acute pain. What if anything can the Department of Health and Human Services do to help encourage the development and use of these medications?

Response: SAMHSA's activities include a focus on the prevention and treatment of opioid use disorders. Other agencies are charged with addressing drug development.

The FDA and NIH have large roles to play in drug discovery and development. SAMHSA is providing expert input to CDC as they develop their Guidelines for Prescribing Opioids for Chronic Pain, which will soon be released. In addition, SAMHSA published an Opioid Overdose Prevention Toolkit in 2013 (updated in 2014) to educate prescribing providers, first responders, persons in recovery from substance use disorder, and many other stakeholders 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.

However, SAMHSA does play a crucial role in ensuring that Opioid Treatment Programs (OTPs) have a diversion control plan to prevent misuse of opioids provided during treatment. That plan is reviewed by the accreditation organizations and monitored by SAMHSA. SAMHSA works with the Drug Enforcement Administration and responds to allegations of diversion. SAMHSA emphasized diversion in our 2015 accreditation guidelines and in our ongoing training for OTPs. SAMHSA works with state opioid treatment authorities to share information. SAMHSA also provides guidelines for identifying and treating adults who have substance use disorder or have misused, or are at risk of misusing, prescription medication. Specifically, SAMHSA Treatment Improvement Protocol (TIP) 54: "Managing Chronic Pain in Adults with or in Recovery from Substance Use Disorders" guides clinicians through the process of conducting a thorough assessment; developing a treatment plan that addresses pain, functional impairment, and psychological symptoms; and closely monitoring patients for relapse. It also explains the benefits of working in teams with other health care professionals, including psychologists, pharmacists, addiction counselors, and how to engage caregivers, family members, and patients themselves in managing pain and improving quality of life.

Questions for the Record Submitted by Senator Richard Blumenthal

Q1: As you may know, on Thursday, January 28 in Atlanta, the CDC convened a public meeting of its scientific counselors to review its draft opioid prescribing guidelines. These guidelines were developed by leading experts and rigorously reviewed to reflect best clinical practices. They promise to greatly improve primary care prescribing, reducing both the skyrocketing use of opioids and the plague of overdose deaths nationwide.

The guidelines were initially going to be released this month, but were delayed. We appreciate CDC's strong desire for stakeholder input and concerns about patient access, but we are troubled by reports that this delay occurred after opposition from companies that have a significant financial stake in the sale of opioid painkillers.

A number of my colleagues, including Senators Feinstein and Durbin, and I have urged Secretary Burwell and CDC Director, Dr. Tom Friedman to resist special interest efforts to weaken the guidelines

Mr. Botticelli, in your testimony, you highlight that the interrelationship between prescription opioids and heroin indicates that we must continue to push for mandatory education and training of opioid prescribers.

a. **Mr. Botticelli and Ms. Enomoto, in the absence of [CDC Director] Dr. Frieden, I'd like you to comment if you can on the critical public health importance of the guidelines, and confirm that the Department is committed to issuing the strongest possible set or recommendations as soon as possible.**

Answer: From 1999 to 2014, more than 230,000 people died from overdose related to prescription opioids. More than 20,000 people died from overdoses involving prescription opioids in 2014 alone. Between 1999 and 2010, prescribing and sales of opioids quadrupled, without a change in the amount of pain Americans report.[1] This increase is a key driver of the opioid overdose epidemic.

Patients with chronic pain deserve safe and effective pain management. To this end, CDC is developing guidelines for prescribers of opioid pain analgesics. The guidelines will include recommendations to improve patient safety and care for those with chronic pain and address the ongoing prescription opioid overdose epidemic. The guidelines are intended for primary care providers who are treating adult patients for chronic pain, and not for active cancer treatment, palliative care, or end-of-life care. SAMHSA is committed to assisting CDC in developing these guidelines so that they can ultimately be an effective tool for providers.

[1] **Frenk SM, Porter KS, and Paulozzi LJ. Prescription Opioid Analgesic Use Among Adults: United States, 1999 – 2012., National Center for Health Statistics Data Brief, February 2015.**

Q2: Ms. Enomoto, in your testimony you mentioned the Pregnant and Postpartum Women's (PPW) initiative, a SAMSHA program that encourages grantees to accept pregnant women with opioid use disorders into residential treatment settings. You mentioned that many of these treatment providers have aided pregnant women to recover from opioid use disorder and deliver healthier babies. Federal funding for these types of programs is very important because many times pregnant women are turned away by treatment providers that do not have the resources to provide them with medical care.

This is particularly worrisome in states like Tennessee where pregnant women with substance use disorders can be charged with criminal fetal assault if the child has neonatal abstinence syndrome (NAS). There are 18 states that consider substance use during pregnancy to be child abuse. Fifteen states require medical professionals to report suspected drug abuse during pregnancy.

Yet, Mr. Botticelli, in your testimony you rightly noted that if these opioids were withdrawn during pregnancy, fetal harm could result. Connecticut's response has been to create a targeted drug treatment for pregnant women. The CT Department of Mental Health and Addiction Services sponsors many residential and community programs targeted at helping pregnant women with substance use disorders.

a. **Ms. Enomoto and Mr. Botticelli, what are your recommendations for ensuring pregnant women with opioid use disorders have access to appropriate treatment during their pregnancies without opening themselves up to criminal prosecution should their child be born with NAS?**·

Answer: Thank you for this question. Data demonstrate that treatment is effective, but only when providers and patients know what actions to take. To that end, SAMHSA is developing educational materials targeted to consumers, policy makers, providers, and managers of systems serving pregnant women who use opioids.

Substance use disorder is a medical condition and is treatable. When pregnant women have early access to quality substance use disorder treatment services (which minimizes fetal exposure to illicit substance) and medical support (which prevents withdrawal during pregnancy, which is harmful to the fetus), outcomes for both the mothers and infants are significantly improved. Pregnant women with opioid use disorders often lack access to and motivation for treatment due to stigmatization and fear of losing their children. State criminal penalties for the use of substances during pregnancy may be intended to serve as a deterrent for drug use during pregnancy and to protect the health and well-being of the infant. However, criminalization has not been shown to be effective at deterring drug use during pregnancy or protecting the health and well-being of the infant.

Instead, research shows that medication-assisted treatment or MAT, a combination of medication and behavioral therapies, is most successful for treating pregnant women with opioid use disorders, and offers the safest outcomes for the baby. Research supports the use of MAT, and for the long-term benefit of both infants and mothers, medication-assisted treatment is typically

the clinical recommendation instead of withdrawal or abstinence. SAMHSA is developing a document on MAT for pregnant and post-partum women, with input from an outside panel and a team of experts from across the Federal Government. Although methadone has been the most common treatment for pregnant women with opioid use disorders for some time, this document will provide support for use of buprenorphine as well, thus increasing access to care for many women and helping providers better understand the risks and benefits of these options.

SAMHSA and the Administration for Children, Youth, and Family (ACYF)'s National Center on Substance Abuse and Child Welfare (NCASCW) also are providing in-depth technical assistance to strengthen the capacity of states and local jurisdictions to improve the safety, health, and well-being of substance exposed infants, with an emphasis on opioid dependent women, and the recovery of pregnant and parenting women and their families. Connecticut has been participating in this initiative and has had leadership from Connecticut's Department of Children and Families, Department of Mental Health Addiction Services and Advanced Behavioral Health, among others. Connecticut's team is focusing on, 1) earlier identification and screening of pregnant women with substance use disorders, particularly opioids; 2) consistent identification and reporting of infants with prenatal substance exposure; and, 3) a protocol for assessing the needs of postpartum women and their infants and developing a plan of safe care prior to discharge from the hospital that provides assurances for the safety of the infant while addressing the needs of the infant and his/her mother.

Possible ways for States and others to ensure that pregnant women with opioid use disorders have access to the most clinically effective and appropriate treatment during their pregnancies include:

- **Work with various systems to adopt integrated collaborative approaches**, including unprecedented judicial leadership in collaboration with behavioral health, child welfare, and other systems for intervening and supporting pregnant women with substance use disorders. Early initiation of and retention in treatment, as well as appropriate and timely access to care for the mothers and infants, should be the agreed upon outcome rather than criminal prosecution. Professionals in the child welfare, judicial, medical, and addiction treatment systems generally share significant concerns about pregnant women who misuse opioids and newborns with NAS and other problems related to in-utero drug or alcohol exposure. However, at times, the responses of various systems to the needs of these families diverge, resulting in apparent conflicts among treatment practices, medical recommendations, and the policies and oversight provided by courts and child welfare services. Divergent views and conflicting practices lead to confusion.

- **Expand substance use disorder treatment options for pregnant and postpartum women** that allow children to remain with mothers, while providing coordinated and integrated care for them and their family members. Family can play a critical role in motivating women with drug problems to enter and stay in treatment. However, there is a deficit in comprehensive family-centered treatment options in both residential and non-residential treatment settings for this population.

SAMHSA will soon publish a new document entitled *A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders,* intended to help providers coordinate the treatment needs of this population of women and infants. It is our hope that this guidance will support the efforts of communities to proactively address this issue in a supportive and coordinated way.

Q3: As some of you may know, I serve as Ranking Member of the Senate Veterans' Affairs Committee and have studied research that has shown that peer support programs within the VA helps patients become more active in treatment, which can promote recovery.

I have also introduced legislation that would require VA to expand its integration of peer support programs for mental health services into primary care teams at VA medical centers as many veterans in need of mental health care may enter the VA system through a primary care center

a. Ms. Enomoto, could you comment on how peer support from a fellow veteran might help veterans deal with stigma related to seeking mental health/substance abuse services? And whether giving veterans a chance to use peer support through their primary care teams at VA would be helpful for veterans in need of substance abuse treatment.

Answer: The value of lived experience of both mental and substance use disorders, found in peer support services, has increased access to treatment, retention in treatment, and is effective in supporting longer-term recovery. In a peer-helping-peer service alliance, a peer leader in stable recovery provides support services to peers seeking help in establishing or maintaining their recovery. Both parties are helped by the interaction as each peer's recovery is strengthened. Non-hierarchical, reciprocal, and accessible relationships are especially helpful to veterans in a number of ways, including creating communities of recovery that instill hope and knowledge that recovery from behavioral health conditions is possible and is supported by fellow peers.

Peer recovery supports are portable and can be delivered in a variety of settings, including primary care, emergency rooms, treatment centers, social service systems, work placement, and criminal justice environments. Additionally, peer providers are embedded in the communities in which veterans work and live, including recovery residences, faith organizations, community centers, and collegiate recovery programs to name a few. These qualities of peer support all lead to combating stigma and discriminatory practices not only through mutual learning, but through joint vision and united action to address stigma and barriers as recovery communities take root. Through a peer mentoring relationship, veterans can be assisted in a real-life way by those who understand not only addiction and/or mental illness and recovery from those conditions, but how to manage readjustment to non-military communities, navigate health-care systems, and gain needed resources.

Peer support in primary care teams is essential in engaging a veteran in need of care in a non-threatening, strength-based approach. Through dialogue with someone with shared life experiences, peer support providers play an essential role on a care team. They can serve as care

coordinator for the team, helping to identify a comprehensive array of services and working with his/her mentee to develop their own recovery plan from a person-centered approach.

Questions for the Record from Senator Dianne Feinstein

1. Institutions of Mental Disease

Q: As the hearing testimony made clear, there is a serious gap between those who need treatment for their opioid addiction and those who receive it.

One reason for this may be the Institutions of Mental Disease (IMD) exclusion, which prohibits substance abuse facilities with more than 16 beds from receiving Medicaid reimbursement for patients ages 21 to 64.

While the IMD exclusion was originally implemented to deinstitutionalize psychiatric care, it appears that it has had the unintended consequence of limiting access to in-patient and residential treatment for substance abuse disorders.

a. ***Do you believe the 16-bed limit should be increased or eliminated? Please explain****.*

Access to acute care services, whether in the hospital or in the community, is an essential component of an effective behavioral health treatment continuum of care. As you know, an effective behavioral health service system needs the capacity to provide inpatient acute services to those who need them. In addition to the Medicaid emergency psychiatric demonstration, HHS has employed several strategies to increase access to inpatient psychiatric services. In the Medicaid managed care notice of proposed rulemaking, the Centers for Medicare & Medicaid Services (CMS) proposes that managed care plans may receive a capitation payment from the state for enrollees who have a short term stay of no more than 15 days per month in an IMD so long as the facility is an inpatient hospital facility or a sub-acute facility providing short term crisis residential services. CMS is in the process of reviewing comments received on the Notice of Proposed Rulemaking and anticipates issuing a Final Rule later this year.

Supporting individuals with acute behavioral health needs also can be achieved in service areas other than IMDs. Congressional actions have invested in first episode psychosis, crisis systems development, medication assisted treatment expansion, and suicide prevention efforts. Preventing and mitigating exacerbations of behavioral health conditions before the need for acute services, is critical.

CMS also announced a new Medicaid Section 1115 demonstration opportunity designed to support states' efforts to provide a more effective continuum of care to individuals with

substance use disorder (SUD). This demonstration opportunity identifies a number of important benefit, practice and system reforms that foster improved care and health outcomes for individuals with SUD. One important reform is the ability to provide coverage for short-term inpatient and residential SUD services, including treatment provided in IMDs as part of a comprehensive substance use disorder strategy.

b. Do you believe the criteria used to determine whether a facility is an Institution of Mental Disease should be amended to exclude substance abuse treatment facilities? If not, why not?

We believe it is critical to ensure that individuals with SUD are able to receive the treatment they need. HHS has taken several steps to increase access and quality of care for individuals with SUD, including through the Medicaid managed care notice of proposed rulemaking and the Medicaid Section 1115 demonstration guidance.

Additionally, HHS has taken several steps to expand access to treatment, increase provider awareness, and provide states with guidance on various approaches they can take to expand treatment options for individuals with SUD. On July 11, 2014, SAMHSA, CMS, the Centers for Disease Control and Prevention, the National Institute of Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism released an informational bulletin to provide states information about medication assisted treatment (MAT), examples of state-based initiatives, and resources to ensure the proper delivery of these services. CMS also created the Medicaid Innovation Accelerator Program (IAP) to support state efforts to accelerate Medicaid innovation, including system reforms through new delivery models, data analytics, quality measurement, and rapid-cycle learning and evaluation.

Through the IAP, CMS is supporting states with expert resources, coaching opportunities, and hands-on technical assistance to accelerate policy, program, and payment reforms appropriate for a robust SUD system. We believe this initiative will support participating states to better identify individuals with SUD, expand coverage for evidence-based and promising SUD services and enhance provider capacity to effectively treat individuals with SUD.

On January 28, 2016, CMS released an information bulletin describing best practices for addressing prescription opioid overdoses, misuse, and addiction that describes several Medicaid pharmacy benefit strategies states may employ to mitigate prescription drug abuse and discusses strategies to increase the provision of naloxone to reverse an opioid overdose. Additionally, in September 2015, Secretary Burwell announced that HHS would soon publish a notice of proposed rulemaking that would increase the patient limit for qualified physicians to treat opioid use disorder.

2. Prevention

Q: Increasing access to treatment was a recurring theme throughout the hearing, and I wholeheartedly agree this is a critical element to reducing prescription drug abuse.

But, research also shows that the most cost effective way to deal with drug abuse is to stop use before it starts.

a. Given that substance abuse prevention can save as much as $7 for every dollar invested, will the President's Fiscal Year 2017 budget request include an increase for prevention programs, such as the Drug Free Communities program?

While, as of this hearing date, no information regarding the President's FY 2017 Budget request is available, prevention will remain a priority for the Department. SAMHSA maintains a strong focus on prevention through existing programs that develop the capacity of states, communities, primary care providers, early childhood systems, and school systems to prevent the onset of substance use and promote mental health and wellness.

These prevention programs, including ONDCP's Drug-Free Communities (DFC) Support Program, touch the lives of many people in preventing substance use. In FY2013, DFC's catchment area reached a total population of approximately 73.4 million, or 23.8 percent of the population of the United States. These catchment areas include approximately 2.9 million middle school students between the ages of 12-14 and 4.1 million high school students between the ages of 15-18.

In those areas, DFC has achieved significant positive outcomes across all substances and ages. According to program reports, prevalence of youth substance use has declined significantly in DFC communities. Prevalence of past 30-day use declined significantly between the first and the most recent data reports across all substances (alcohol, tobacco, marijuana) and school levels (middle and high school). Among DFC grantees that reported data from 2013, there was a significant decline in prevalence of past 30-day alcohol use at both the middle school level (-1.4 percentage points) and high school level (-3.2 percentage points) from the most recent prior report.

Other existing programs to reduce substance use in communities include the Strategic Prevention Framework - Partnerships for Success grant program, that targets underage drinking in people aged 12 to 20, prescription drug misuse in people aged 12 to 25, and other data-driven substance abuse prevention priorities; the Sober Truth on Preventing Underage Drinking Act Grants; the Strategic Prevention Framework for Prescription Drugs that targets high-risk communities for prescription drug misuse by using Prescription Drug Monitoring Program data; the Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths that provides support to states to train and provide naloxone to first responders in high-risk communities; the Capacity Building

Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults grants; the Tribal Behavioral Health Grants program, which addresses the high incidence of substance abuse and suicide among AI/AN populations; and the Substance Abuse Prevention and Treatment Block Grant.

SAMHSA will continue to focus on these efforts continue to respond to public health priorities, and will strive to continue making progress toward preventing substance abuse in America's communities.