House Committee on Energy and Commerce

Hearing titled, "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives"

October 25, 2017

Written testimony on behalf of the following witnesses from the Department of Health and Human Services (HHS):

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Good morning Chairman Walden, Ranking Member Pallone, and Members of the Committee. Thank you for the opportunity to discuss the opioid crisis in the United States and the Federal response. From the start of his Administration, President Trump has made addressing the opioid epidemic a top priority, and at the Department of Health and Human Services (HHS) we share the President's commitment to bringing an end to this crisis, which is exacting a toll on individuals, families, and communities across the country. The Department has made the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. According the Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. Over the past decade, the U.S. has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Preliminary data for 2016 indicate at least 64,000 drug overdose deaths, the highest number ever recorded in the U.S. Too many of our citizens are being robbed of their God-given potential in the prime of their life.

The opioid epidemic in the U.S. is fundamentally tied to two primary issues. The first issue was the significant rise in opioid analgesic prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but well-intentioned healthcare providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse, addiction, and overdose, such as prescribing at high doses and for longer durations. The second issue is a lack of health system and healthcare provider capacity to identify and engage individuals, and provide them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment (MAT). It is well-documented that the majority of people with opioid addiction in the U.S. do not receive treatment, and even among those who do, many do not receive evidence-based care. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis. Further, there is a need for more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing drugs to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. While this statement does not represent an exhaustive list of HHS activities underway, SAMHSA, CDC, NIH, and FDA bring unique expertise and capabilities that enable HHS to take a comprehensive, complementary, and flexible approach to the opioid crisis.

Substance Abuse and Mental Health Services Administration (SAMHSA)
As HHS's lead agency for behavioral health, SAMHSA's core mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA supports a portfolio of activities that address all five prongs of HHS's Opioid Strategy.

Improving Access to Prevention, Treatment, and Recovery Support Services
SAMHSA administers the Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). By providing $485 million to states and U.S. territories in fiscal year (FY) 2017, this program allows states to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder. The President's Budget requests $500 million for this program in FY 2018, the full level authorized by Congress.

The Substance Abuse Prevention and Treatment Block Grant (SABG), first authorized in 1992, is a vital source of funding for states that accounts for approximately 32 percent of total state substance abuse agency funding. For many people seeking to recover from opioid addiction, this public funding represents the only support for treatment. In addition, the block grant's flexible structure enables states to use the funds to address pressing challenges within their communities, such as the opioid crisis.

SAMHSA also has several initiatives aimed specifically at advancing the utilization of MAT for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT-PDOA) program expands MAT access by providing grants to states with the highest rates of treatment admissions for opioid addiction. Twenty-two states are currently funded by MAT-PDOA, and in September 2017, SAMHSA awarded $35

million dollars over three years in additional MAT-PDOA grants to six states.

SAMHSA also provides critical funding for MAT for specific high-risk and vulnerable populations, such as those involved with the criminal justice system and pregnant and postpartum women. SAMHSA's criminal justice grantees can use up to 20 percent of their grant awards for the purchase of FDA-approved medications for treatment of opioid and alcohol addiction. Since 2013, SAMHSA has seen a steady increase in the number of drug courts integrating MAT into their programs with 57 percent of active programs currently integrating MAT.

Under SAMHSA's Pregnant and Postpartum Women's (PPW) program, which serves women with opioid or other substance use disorders who are pregnant and/or newly parenting, grantees are encouraged to ensure access to MAT for opioid addiction, which has been shown to improve birth outcomes. Last month SAMHSA awarded $9.8 million over three years for new State Pilot PPW grants authorized by the Comprehensive Addiction and Recovery Act (CARA, P.L. 114-198) and $49 million over five years in new PPW service grants to support the recovery of pregnant and postpartum women struggling with substance abuse, including opioid addiction.

A well-documented challenge to improving access to opioid use disorder treatment is a lack of providers who can provide MAT. SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Provider's Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides mentoring of newly trained physicians by experienced specialists, maintains a library of evidence-based practice materials, and offers at no cost to the trainee the required DATA 2000 waiver training to enable providers to prescribe buprenorphine for opioid addiction treatment.

SAMHSA regulates opioid treatment programs (OTPs), which dispense methadone and may also dispense and prescribe buprenorphine and administer extended-release naltrexone. In coordination with the Drug Enforcement Administration (DEA) and states, territories, and the District of Columbia, SAMHSA reviews new and renewal applications for OTPs through an accreditation process that ensures programs have sound risk management practices in place and are using evidence-based treatments. SAMHSA also oversees physicians, nurse practitioners (NPs), and physician assistants' (PAs) ability to prescribe buprenorphine in office-based outpatient treatment settings. Last year, SAMHSA published a final rule which allows certain qualified physicians who have obtained a waiver to prescribe buprenorphine for up to 100 patients for at least a year, to now acquire a waiver to treat up to 275 patients. The regulation provides that these licensed physicians can become eligible for the patient limit of 275 either by being board certified in Addiction Medicine or Addiction Psychiatry or by practicing in a qualified practice setting.

These physicians are required to complete a SAMHSA reporting form each year to ensure that physicians prescribing at the new, higher level are in compliance with safe and appropriate prescribing practices. As of September 19th, 3,573 physicians have obtained a waiver to treat up to 275 patients. Most recently, SAMHSA began processing waivers to allow NPs and PAs to prescribe buprenorphine in accordance with the requirements of CARA. As of September 19th, 2,756 NPs and 773 PAs have received a waiver.

SAMHSA also promotes recovery through targeted grants, such as last month's award of $4.6 million over three years in Building Communities of Recovery program grants, created by CARA. The purpose of this program is to mobilize resources within and outside of the recovery community to increase the availability and quality of long-term recovery supports for individuals in or seeking recovery from addiction. These grants are intended to support the development, enhancement, expansion, and delivery of recovery support services as well as promotion of and education about recovery. Programs will be principally governed by people in recovery from substance abuse and addiction who reflect the community served.

Targeting Overdose-Reversing Drugs

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing, through funding and technical assistance, the availability and use of naloxone to reverse overdose. SAMHSA's "Opioid Overdose Prevention Toolkit," first released in 2013, is one of SAMHSA's most downloaded resources. The Toolkit provides information on risks for opioid overdose, recognition of overdose, and how to provide emergency care in an overdose situation. The Toolkit is intended for community members, first responders, prescribers, people who have recovered from an opioid overdose and family members, as well as communities and local governments.

SAMHSA provides a number of funding streams that can be used to expand access to naloxone. States are able to use Opioid STR funds to purchase and distribute naloxone, and some states are also using a portion of their SABG funds for opioid overdose prevention activities.

SAMHSA is currently providing $11 million per year in Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths to 12 states. These grants are also being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as how to purchase and distribute naloxone.

In September 2017, SAMHSA awarded funding for grants authorized by CARA, including almost $46 million over five years to grantees in 22 states to provide resources to first responders and treatment providers who work directly with the populations at highest risk for opioid overdose.

Strengthening Public Health Data and Reporting

SAMHSA's National Survey on Drug Use and Health (NSDUH) provides key national and state level data on a variety of substance use and mental health topics, including

opioid misuse. NSDUH is a vital part of the surveillance effort related to opioids, and the data from NSDUH has been used to track historical and emerging trends in opioid misuse, including geographic and demographic variability.

SAMHSA also works collaboratively with other agencies to better understand the epidemic through sharing of data and assessing the implications of that data and develops publications based on NSDUH and other national surveys and data. Examples of recent SAMHSA publications include: Trends in the Use of Methadone, Buprenorphine, and Extended-release Naltrexone at Substance Abuse Treatment Facilities; Trends in Average Days' Supply of Opioid Medications in Medicaid and Commercial Insurance; and Opioid Prescribing Trends for Adolescents and Young Adults with Commercial Insurance and Medicaid.

Supporting Cutting-Edge Research

SAMHSA is building on existing partnerships with the NIH to improve the research to practice pipeline and is committed to promoting evidence-based practices and service delivery models. The newly formed Office of the Chief Medical Officer and the National Mental Health and Substance Use Policy Laboratory, which were authorized through the 21st Century Cures Act to promote evidence-based practices and service delivery models, will be pivotal to these efforts. Additionally, the National Mental Health and Substance Use Policy Laboratory will assist in addressing the opioid crisis through its evaluation of models that would benefit from further development and through expanding, replicating, or scaling evidence-based practices across wider areas as we seek to increase access to and delivery of the best treatment services for opioid use disorders across America.

Centers for Disease Control and Prevention (CDC)

As the Nation's public health and prevention agency, CDC's expertise and leadership is essential in reversing the opioid epidemic. It was CDC that first identified the increase in opioid overdose deaths in 2004, and since then the agency has applied its scientific expertise to track the epidemic and develop evidence-based prevention strategies. Through various programs and initiatives, CDC supports all five parts of the Secretary's Opioid Strategy:

Strengthening Public Health Data and Reporting

Timely, high-quality data help both public health officials and law enforcement understand the extent of the problem and how it is evolving, develop interventions, focus resources where they are needed most, and evaluate the success of prevention and response efforts. Understanding that data is crucial, CDC is helping states build capacity to monitor the scope of the epidemic and better focus their prevention activities through several programs and activities.

CDC's Overdose Prevention in States (OPIS) provides resources and scientific support to 45 states and Washington, D.C. through three programs. The first two programs, Prescription Drug Overdose: Prevention for States (PfS) and Data-Driven Prevention Initiative (DDPI), provide states with the resources, tools and technical expertise to execute and evaluate prevention strategies to improve safe prescribing practices and prevent prescription drug misuse, abuse, and overdose. States use their funding to

advance prevention in four key areas: 1) Enhancing Prescription Drug Monitoring Programs (PDMP) and leveraging them as public health tools; 2) Improving health system and insurer practices for safer opioid prescribing; 3) Evaluating policies that may have an impact on the opioid epidemic (e.g.. naloxone distribution and Good Samaritan laws); and 4) Quickly responding to emerging and critical needs.

CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program, the third program under OPIS, funds 32 states and Washington, D.C. Started in 2016, ESOOS strives to improve the timeliness of reporting both fatal and non-fatal opioid overdoses and associated risk factors in order to inform public health responses within and across states. What is particularly unique and innovative about this program is the use of emergency department and emergency medical services (EMS) data to track and analyze morbidity data. ESOOS uses this data to establish an early warning system to detect sharp increases (e.g. potential outbreaks) or decreases (e.g. successful intervention efforts) in non-fatal overdoses.

CDC has made progress in improving the timeliness of data reporting and is now releasing quarterly and, as of August 2017, monthly provisional counts of overall drug and opioid overdose deaths in the Vital Statistics Rapid Release (VSRR) series. CDC also relies on its existing infrastructure to monitor rates of new cases of HIV and viral hepatitis in many states. CDC is working with Coroners and Medical examiners to improve both comprehensive toxicology efforts that help with the detection of fentanyl analogs and the capacity for mortality surveillance by identifying ways to help strengthen case management systems to report data more easily and quickly. While CDC has made progress, improvements are needed to build infrastructure (medical examiners, coroners, toxicological testing, additional electronic reporting, etc.). A stronger disease detection system will identify potential problems sooner.

CDC is also tracking opioid use among pregnant and reproductive-aged women and its impact on the mother and newborn as a part of the Treating for Two: Safer Medication Use in Pregnancy initiative. Pilot programs are underway to obtain state-level estimates of NAS to better understand hospital readmissions and long-term adverse outcomes among infants identified with NAS.

In addition to providing funding and technical assistance, CDC conducts epidemiological investigations (Epi-Aids) in states, providing on the ground assistance during a public health crisis. Between 2012 and 2015, Massachusetts experienced a surge of opioid-related deaths, from 698 to 1,747, with over 74 percent of these deaths involving fentanyl. The Massachusetts Department of Public Health (MDPH) called on CDC to help investigate the extent to which illicitly-manufactured fentanyl (IMF) contributed to the surge in opioid-related overdose deaths. CDC worked closely with the MDPH, SAMHSA, and DEA to determine whether IMF mixed with or sold as heroin was the primary cause of the surge of deaths and found that 82 percent of fentanyl-related overdose deaths were suspected to have involved IMF.

To stop the surge, CDC recommended that the MDPH train physicians, treatment

providers, and law enforcement on overdose prevention, screen at-risk people for heroin or fentanyl use, and expand access to naloxone. CDC also recommended outreach to those who experienced an opioid overdose, had a history of substance abuse, or were accessing health programs for active users to link them to treatment and educate them on the dangers of fentanyl.

Often, CDC's work in states leads to further, national initiatives. The 2015 response to an HIV and Hepatitis C (HCV) outbreak in Scott County, Indiana, led to a CDC analysis which identified over 220 U.S. communities that could be especially vulnerable to HIV and HCV outbreaks among persons who inject opioid drugs. One of those states, Tennessee, used CDC's assessment to do further analysis of the state's vulnerabilities. As a result, Tennessee is working to direct its HIV and viral hepatitis resources where they are most needed.

In addition to working with states, a partnership across sectors is necessary. CDC has been working on initiatives with law enforcement agencies, like the DEA, to strengthen public health and law enforcement collaboration on the federal level.

In addition, the Heroin Response Strategy (HRS), funded by the Office of National Drug Control Policy (ONDCP) and deployed in eight High Intensity Drug Trafficking Areas (HIDTAs), covering 20 states, links public health and public safety at the state level. CDC works with the HIDTA directors to sharpen strategic directions, ensure proper coordination and training, support the 20 public health analysts embedded in the program, and improve performance measurement. There is currently a shortage of evidence to guide public health-law enforcement integrated community response, thus as part of the HRS, CDC is launching eight pilot projects across the 20-state initiative to build scientific evidence about what works.

Advancing the Practice of Pain Management

Another of CDC's key focus areas is supplying health care providers with the tools and resources necessary to advance the practice of pain management. In March 2016, CDC released the Guideline for Prescribing Opioids for Chronic Pain, which was developed to help primary care doctors provide safer, more effective care for patients with chronic pain outside of active cancer, palliative, and end-of-life care. The Guideline provides 12 voluntary recommendations for prescribing opioids for patients 18 and older, in primary care settings, based on the most current scientific evidence. This helps patients and physicians better understand and assess risks and benefits of opioid therapy and determine the optimal method for each patient to manage their pain.

CDC has created a number of resources for health care providers to make the Guideline easy to understand and access. Earlier this year, CDC launched the first in a series of interactive, online trainings which provide sample scenarios, feedback, and resources for each recommendation. CDC is also capitalizing on technology to help disseminate the Guideline through the development of an Opioid Guideline Application (mobile app) which contains all of the Guideline recommendations, a morphine milligram equivalent (MME) calculator, and an interactive interviewing feature to help providers prescribe

with confidence. Other materials developed for providers, pharmacists, and patients include graphics, fact sheets, posters, and podcasts, all available on CDC's website.

CDC is also committed to educating consumers about the risks of opioids and the importance of discussing safer, more effective pain management options with their healthcare providers. In September 2017, CDC released the Rx Awareness communications campaign to increase awareness about the risks of prescription opioids and deter inappropriate use. The campaign features real-life accounts of individuals living in recovery, and those who have lost someone to an overdose. CDC is running digital, radio, and out-of-home campaign ads for 14 weeks in select states (KY, MA, NM, and OH) with broader release anticipated in 22 additional OPIS funded states.

Improving Access to Prevention, Treatment, and Recovery Support Services
CDC brings scientific expertise and leverages existing relationships with health systems to link patients who need MAT to the appropriate care. As part of the OPIS effort, several states funded under the PfS program are supporting health system approaches to link patients to treatment and recovery services. For example, states are building systems that facilitate better linkages to treatment, emergency room peer patient navigators, and data dashboards to identify hot spots for treatment needs.

Additionally, CDC is conducting an epidemiologic study to assess what type of MAT (methadone maintenance; buprenorphine; naltrexone) or counseling and other non-medication interventions is most effective, and which contextual, provider, and individual factors influence implementation, prevent relapse, and improve patient wellbeing over a two-year period. This study can help identify who may benefit from which type of treatment to ensure individuals receive the treatment best suited to their needs.

Targeting Overdose-Reversing Drugs
CDC is currently working with SAMHSA to evaluate its Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths program with the goals of describing and understanding the scope and impact of naloxone education and distribution efforts in high-need communities and to identify barriers and potential solutions to increase program effectiveness. Additionally, states funded under OPIS are evaluating practices to improve the distribution and use of overdose reversing drugs and Good Samaritan laws (policies that protect the victim and the bystander from drug possession charges). States utilize CDC data to identify communities experiencing a significant increase in opioid overdose deaths, which helps to inform both the targeted distribution of naloxone and the training of community members, EMS, and law enforcement on naloxone administration.

Supporting Cutting-Edge Research
To better understand the epidemic, identify risk and protective factors, and determine effective interventions, CDC also funds innovative research to prevent misuse and abuse. One CDC funded project at the Carolinas Medical Center in Charlotte, North Carolina, is working to assess and compare changes in prescribing behaviors when providers are presented with electronic alerts on potential misuse or abuse of opioids. This research will inform efforts to improve clinical decision-making. In addition, CDC funds

academic research centers to conduct translational research in order to better understand how to get information into the hands of practitioners. For example, the Johns Hopkins Injury Control Research Center (ICRC) is working to reduce injured patients' risk for opioid misuse through mobile health technology while the West Virginia University (WVU) ICRC was instrumental in the development and implementation of a pilot take-home program for naloxone in rural communities. There were at least 25 overdose reversals in the first nine months of the program in 16 counties. As part of a rapid response project using CDC funds, the WVU ICRC distributed 8,250 naloxone kits to first response agencies and take-home naloxone programs throughout the state in the first half of 2017.

National Institutes of Health (NIH)

NIH is the lead HHS agency providing support for cutting-edge research on pain and opioid misuse, addiction, and overdose. Drug addiction is a complex neurological condition, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the crisis and informing future efforts. Pain is an equally complex condition. To this end, NIH supports a range of activities to advance research on pain and addiction.

Supporting Cutting-Edge Research

Because the most effective way to end opioid misuse and addiction is to prevent it from beginning, NIH is supporting innovative research to better understand what makes an individual vulnerable to opioid misuse. For example, the Adolescent Brain Cognitive Development (ABCD) study, the largest long-term study of brain development and child health in the U.S., will help build an evidence base to draw on for a future of precision medicine approaches to prevent opioid addiction.

With the goal of bringing scientific solutions to the opioid crisis, NIH is exploring ways to promote 1) new, innovative medications and technologies to treat opioid addiction and improve overdose prevention and reversal interventions, and 2) safe, effective, non-addictive strategies to manage pain. In April 2017, NIH Director Francis S. Collins, M.D., Ph.D., met with research and development leaders from the world's leading biopharmaceutical companies to discuss new ways for government and industry to work together to address the opioid crisis. NIH continued meetings throughout the summer. As part of these ongoing discussions, NIH participated in a recent meeting with Pharmaceutical CEOs convened by Governor Christie, co-chair of the President's Commission on Combating Drug Addiction and the Opioid Crisis, in Trenton, New Jersey, on September 18th. Some advances NIH is working to promote may occur rapidly, such as improved formulations of existing medications, longer-acting overdose-reversal drugs, and repurposing of treatments approved for other conditions. Others may take longer, such as novel overdose-reversal medications and identifying biomarkers to measure pain in patients. Our goal for these activities is to cut in half the time needed to develop new safe and effective therapeutics to help end the opioid crisis.

NIH will continue to build upon breakthroughs in the treatment of opioid addiction and the reversal of opioid overdose and find ways to advance the development of new products. For example, buprenorphine, one of the three FDA-approved options for MAT treatment, was developed through a partnership between NIH and industry. The intramural program of the National Institute on Drug Abuse (NIDA) conducted the early clinical studies on buprenorphine and then later partnered with industry to develop user-friendly and abuse deterrent formulations. In addition, a NIH public-private partnership helped to develop the only FDA-approved intranasal naloxone product to reverse opioid overdose, an invaluable tool to those on the front lines combating the opioid crisis. In 2013, NIDA funded a biopharmaceutical company for clinical studies to evaluate the pharmacokinetic properties – how much and how rapidly the naloxone is absorbed – of an intranasal formulation. In 2015, the intranasal naloxone was approved by the FDA. With knowledge gained from neuroscience advances, NIH researchers now seek ways to turn the tide in the opioid crisis through a wider range of formulations of existing and new medications, as well as innovative strategies to treat opioid use disorder and prevent and reverse overdose.

NIH is also working toward preventing the most serious health consequences for infants born with NAS. Currently, NIH research aims to determine more precise dosing of buprenorphine in pregnant women, and to reduce the time to develop new treatments. NIH is also launching a new effort on opioid use in pregnancy, to study the effects of medically supervised opioid withdrawal on mother and newborn, and better understand the genetic or epigenetic factors associated with opioid use on neonatal outcomes. NIH will also develop and pilot a common study protocol to generate evidence for best practices in treating newborns with NAS, through a partnership between the NIH Neonatal Research Network and the new IDeA States Pediatric Clinical Trials Network.

NIH researchers are also working to build an understanding of how to effectively integrate prevention and treatment services within healthcare and community systems. For example, NIH is studying strategies to improve the implementation of MAT for people with opioid use disorder in the criminal justice system. This research aims to optimize implementation of evidence-based screening, assessment, and treatment services by juvenile justice agencies and improve coordination with community healthcare providers in a way that promotes long-term recovery from opioid addiction in real-world settings.

Advance the Practice of Pain Management

Our mission to end the opioid crisis will not be successful until we can provide patients with better options for the treatment of pain, which touches 25 million Americans every day. NIH funds a broad range of research on pain, from basic research into the molecular, genetic, and bio-behavioral basis of chronic pain to large-scale clinical studies of potential treatments. NIH funded basic research has identified a myriad of potential targets for future non-addictive therapies. Pathological pain and addiction are classic disorders of brain circuits and the neurotechnologies emanating from the US BRAIN Initiative enable scientists to explore these circuits to advance both diagnostics and therapeutics. Research efforts to understand and alleviate pain depend on better objective

measures of the pain experience for patients. To address this, NIH also supports development of resources to advance the research agenda. One example is the Patient-Reported Outcomes Measurement Information System (PROMIS). PROMIS provides a rigorously tested patient-reported outcome measurement tool to measure pain, fatigue, physical functioning, and emotional well-being.

NIH works with Federal partners across government to carry out cutting-edge research on pain. Through the Interagency Pain Research Coordinating Committee, NIH developed the Federal Pain Research Strategy, a long-term strategic plan to coordinate and advance the federal research agenda on pain. The Strategy's research priorities include prevention of acute and chronic pain, management of acute pain, transition from acute to chronic pain, and understanding the disparities that influence pain and pain management. Ongoing projects that already are advancing the goals laid out in the Strategy include the NIH-DoD-VA Pain Management Collaboratory program, which recently announced $81 million in research funding to implement cost-effective large-scale clinical research in military and veteran healthcare delivery organizations, focusing on non-pharmacologic approaches to pain management and other comorbid conditions.

Beyond research activities, NIH is engaged in efforts to advance the HHS Opioid Strategy pillar of advancing the practice of pain management. NIH worked with HHS and agencies across government to develop the National Pain Strategy, the government's first broad-ranging effort to improve how pain is perceived, assessed, and treated, which highlights the need for evidence based treatments. NIH is actively working with other Departments and Agencies and external stakeholders to implement the Strategy. In addition, NIH is supporting Centers of Excellence for Pain Education that act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to enhance education about pain and pain care.

Food and Drug Administration (FDA)

FDA, the Agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, is focusing on three broad areas to help address the opioid crisis: lowering overall exposure to opioid drugs and, in turn, reducing the number of new cases of addiction; enabling more opportunities for those currently addicted to opioid drugs to seek MAT that can help them recover; and helping expedite the development of progressively more-effective abuse deterrent formulations of opioid drugs, and better still, non-opioid alternatives for the treatment of pain. To advance these goals, FDA, earlier this year, established an Opioid Policy Steering Committee that brings together the Agency's most senior career leaders to explore and develop additional tools and strategies to confront the opioid crisis.

Support Cutting-Edge Research

Abuse Deterrent Formulations (ADF): FDA's emphasis on assessing the full public health effects of opioids is reflected in the Agency's ongoing work to support the development of forms of prescription opioids that deter abuse. The Agency strongly

supports a transition from the current market dominated by conventional opioids to one in which the majority of opioids have meaningful abuse-deterrent properties. In support of this transition and potential future actions against products without these properties, FDA is focusing its efforts on determining how effective the current abuse deterrent products are in the real world. To assist this effort, the Agency recently gathered independent experts for a scientific workshop to discuss both the existing science and what else is needed to properly assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death. Separately, FDA is working to support generic forms of abuse deterrent opioids by issuing final guidance on their development, in recognition of the important role generic drugs play in the United States.

Alternatives to Opioids for Pain: FDA strongly supports the development of new treatment options for patients in pain, especially treatments that do not have the same addictive features of traditional opioids. To advance both non-addictive and non-pharmacologic treatments for pain, FDA commits to using all of the Agency's authorities. This includes programs such as the Fast Track and Breakthrough Therapy Designations that are intended to facilitate development and to expedite review of products that, for example, are intended to treat a serious condition for which there is an unmet medical need. As a part of these efforts, FDA is meeting with innovators who are pursuing non-opioid alternatives for the treatment of pain to provide guidance on their individual products. Agency steps also include a more careful consideration of non-drug alternatives for pain, such as medical devices that can deliver more localized analgesia. FDA is considering how to more closely fit medical device alternatives into a comprehensive approach to the development of treatments for pain.

We know that developing non-opioid and non-addictive pain medicines is challenging for many reasons; therefore, FDA is interested in progressing the entire field of pain drug development. To address the issues related to the trials needed for approval, FDA has participated in a public-private-partnership (PPP) under the Critical Path initiative, the Analgesic Clinical Trial Translation, Innovations, Opportunities, and Networks (ACTTION). The ACTTION PPP is a collaboration among a broad spectrum of national and international groups aimed at advancing the science in this area, including academia, FDA and other government agencies, pharmaceutical and device companies, professional organizations, and patient advocacy groups.

At the same time as we are prioritizing work on non-opioid and non-abusable pain medicines, FDA is also taking new steps to help facilitate the development of medications that can help patients with addiction recover as well as overdose reversal drugs, such as naloxone. FDA is laying the groundwork for naloxone to be available more broadly and is supporting research aimed at encouraging the potential development of over the counter naloxone products.

Advance the Practice of Pain Management

Changes in Prescribing: To reduce the rate of new opioid addiction, we need to decrease overall exposure to opioids. For many people, that first prescription will be for an immediate release (IR) formulation of the drug. Some people will go on to become

addicted and abuse longer-acting formulations that can deliver higher doses, especially when manipulated. Some of these people will eventually move onto street drugs, such as heroin, which are increasingly the low-cost alternative. We know that this route of addiction correlates with exposure. A certain percentage of patients exposed to opioids will go on to develop an addiction to the drugs. One approach to reducing the rate of new addiction, then, is to reduce exposure to prescription opioid drugs. To accomplish this, we need to explore ways to use our regulatory authorities to influence how opioids are prescribed to make sure that only appropriately indicated patients are prescribed opioids, and that the prescriptions are written for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place. We are exploring whether FDA should take additional steps to make sure that general prescribing and the number of opioid doses that an individual patient can be dispensed, is more closely tailored to the medical indication. Among other steps, FDA is soliciting public input on these questions in the form of a public docket that was established the week of September 25.

Expanded Education through Modification of Opioid REMS, and Changes to the Education Blueprint: Since 2012, FDA has required manufacturers of extended-release long-acting opioids to make available educational materials through a Risk Evaluation and Mitigation Strategy (REMS). We know that most of the exposure to opioids is not from extended-release or long-acting formulations, but from IR formulations like hydrocodone and acetaminophen or oxycodone and acetaminophen combinations. In fact, about 90 percent of all opioid prescriptions in the United States are written for IR formulations of these drugs. IR opioid products serve as the gateway for patients and non-patients who may continue to use or misuse these products, which could lead to new addiction. Given this fact, we need to advance policies that rationalize the prescribing and dispensing of IR opioid drugs.

As one step, FDA has determined that a REMS to support education is also necessary for the prescribing of IR opioid products. This regulatory tool is needed to ensure that the benefits of these drugs continue to outweigh the risks of adverse outcomes (addiction, overdose, and death) resulting from inappropriate prescribing, abuse, and misuse, and that providers are properly informed about suitable prescribing and the risks and benefits associated with opioid drugs. FDA has announced its intention to update the existing REMS on extended-release/long-acting opioid analgesics, and for the first time, extend these same regulatory requirements (including prescriber training) to the manufacturers of IR opioid analgesic products. FDA is currently implementing that plan. We have also announced plans to revise the Blueprint used to create education materials to include broader information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). To start this process, the relevant letters, detailing the new requirements, were recently sent to sponsors that manufacture the IR drugs.

In addition to the efforts described above, HHS continues to engage with a broad range of stakeholders – state and local governments, addiction specialists, medical, nursing, dental, and

pharmacy providers, community and faith-based organizations, private-sector partners, community organizations, and law enforcement partners – to share best practices, build collaborations, and identify barriers that could prevent success. We are committed to this fight and will continue to advance a multi-pronged strategy, never forgetting that behind all the statistics are individuals, families, and communities who are being torn apart each day. Our guiding vision must be to improve the lives of all Americans who have been touched by this crisis. That will be the true measure of our success.

Lastly, HHS, through the President's FY 2018 budget, has requested more than $800 million to continue to support the Department's critical opioid investments. We look forward to continuing to work with Congress to identify solutions and to secure the funding needed to turn the tide against the opioid crisis.

Thank you again for inviting SAMHSA, CDC, NIH, and FDA to testify today. We look forward to answering your questions.