Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders"
March 3, 2020

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The Honorable Frank Pallone, Jr. (D-NJ)

1. Data tells us that there are approximately two million Americans with opioid use disorder. What further steps can the Congress or the Department of Health and Human Services (HHS) take to help encourage more medical professionals to screen and treat patients with opioid use disorder?

Response:

HHS recognizes that no two patients or communities are exactly alike; but we know that everything we do must be based on the best possible science and evidence. The HHS 5-Point Strategy to combat the opioid crisis provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Strategy aims to:

1. 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;
2. Target the availability and distribution of overdose-reversing medications 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;
3. 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;
4. 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
5. 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.

HHS continues to prioritize access to better addiction prevention, treatment, and recovery services, and emphasize the critical importance of medication-assisted treatment (MAT) as a component of evidence-based therapy, through several key programs. Below are some examples:

- In April 2019, NIH awarded more than $350 million to research sites in 4 states - Kentucky, Massachusetts, New York, and Ohio - with the ultimate goal of decreasing opioid overdose deaths by 40% in select communities over 3 years. The study will assess the effectiveness of coordinated continuums of care designed to: reduce overdose fatalities and events; decrease the incidence of OUD; increase the number of individuals receiving medication to treat OUD, retained in treatment, and receiving recovery support services; and increase the distribution of naloxone.

- In September 2019, SAMHSA released $932 million in funding to all 50 states through its State Opioid Response (SOR) grant program. The grants aim to address the opioid crisis by increasing access to MAT, reducing unmet treatment need, and reducing opioid overdose-related deaths through the provision of prevention, treatment, and recovery activities for opioid use disorder.

- HRSA's Rural Communities Opioid Response Program (RCORP) is a multi-year initiative that aims to address barriers to access in the hardest hit rural communities related to substance use disorder, focusing on increasing access to a broad range of prevention, treatment, and recovery services. Since FY 2018, HRSA has awarded $157 million dollars through the RCORP Planning, Implementation, Medication-Assisted Treatment Expansion, Centers of Excellence on Substance Use Disorders, and Evaluation.

- CMS' Maternal Opioid Misuse (MOM) Model aims to increase access to effective SUD treatment through a focus on improving the quality of care for pregnant and postpartum Medicaid beneficiaries with OUD and their infants. This innovative payment model will support the delivery of coordinated and integrated physical health care, behavioral health care, and critical wrap-around services and will leverage the use of existing Medicaid flexibility to pay for sustainable care for the model population.

To achieve these objectives, HHS works with federal, state and local partners, the academic community; law enforcement and first responders; non-profit organizations including faith-based organizations; the commercial sector and many other sectors. HHS will continue working towards expanding access to treatment and recovery services for persons with substance use disorder.

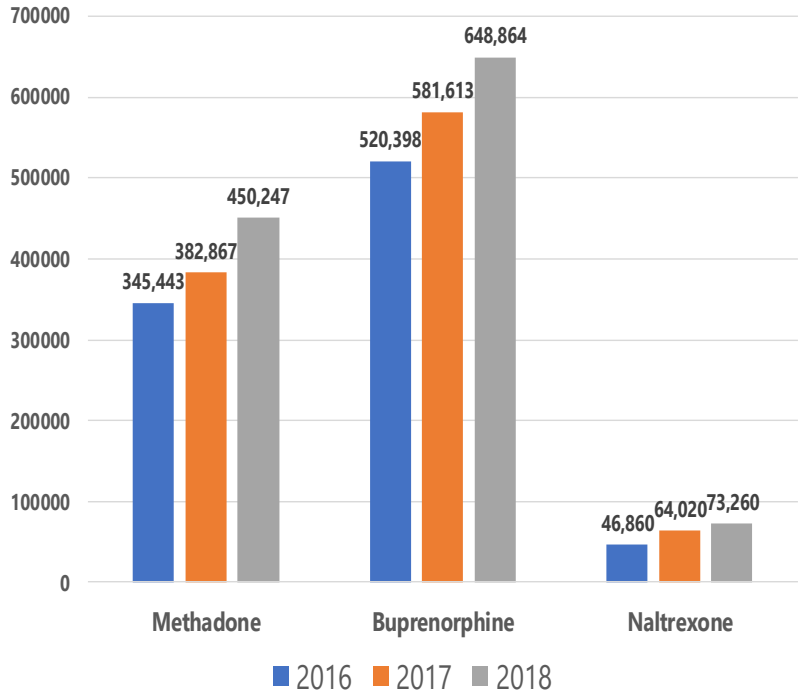
2. One of the key goals of the State Opioid Response Grants established under SAMHSA was to address the opioid crisis by increasing access to medication-assisted treatment, among other things. Recipients of these funds must deliver evidence-based treatment interventions that include Food and Drug Administration (FDA)-approved medications specifically for the treatment of opioid use disorder, psychosocial interventions, and report progress toward increasing availability of medication-assisted treatment for opioid use disorder and reducing opioid-related overdose deaths. What steps are HHS and the Substance Abuse and Mental Health Administration (SAMHSA) taking to ensure that the grantees under this program are meeting these grant requirements? If a state or grantee were not meeting these requirements, what actions could HHS or SAMHSA take in response? What progress have grant recipients under this program made towards increasing availability of medication-assisted treatment and how do you measure progress? Is HHS or SAMHSA experiencing any challenges with implementation of this grant program?

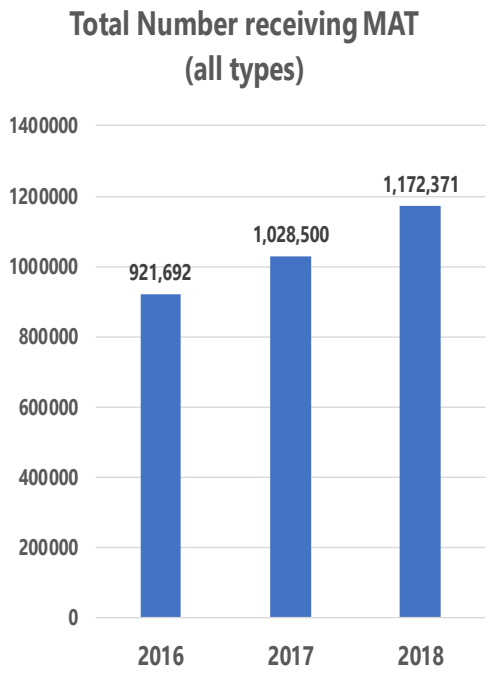
Response:

SAMHSA will gather information about services offered and which of the FDA approved medications are offered at the respective facilities. Grantees are also required to submit Government Performance and Results Act (GPRA) data. If a grantee does not submit the data, the grant project officer makes direct inquiries to determine the cause of noncompliance. Noncompliance with the reporting requirement can result in the withholding of funding. SAMHSA also performs site visits to grantees to audit operations. Additionally, all opioid treatment programs (OTPs) are required to be accredited through an accreditation body. The oversight of the address-based sampling evaluations occur on a rolling basis through reports submitted to SAMHSA and by site visits to the OTPs to ensure compliance. Issues identified must be corrected, and future site visits are scheduled. If the violations are serious accreditation can be denied and consequently certification may be revoked. Accreditation is a condition of licensure for the state where the OTP operates, and also a condition to receive SAMHSA certification. Grantees sometimes submit incomplete data, which limits effective data collection. Overall availability and use of medication-assisted treatment has increased while heroin use has decreased.

The figure below reflects data from the National Survey of Substance Abuse Treatment Services (N-SSATS) client count data to determine the 2016 and 2017 number of people who received medication-assisted treatment. Data received directly from Opioid Treatment Programs were used to determine the number of people who received methadone in 2018. (N-SSATS collects client counts every other year (except for a one time collection in 2016), so N-SSATS client count data was not available for 2018). SAMHSA used the IQVIA database to produce the 2016, 2017, 2018 numbers of people in buprenorphine treatment. (IQVIA is a commercial database which provides pharmaceutical prescription information by capturing weekly prescription dispensing through a platform designed exclusively for healthcare reporting.) A link to information

about this database is https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/prescription-information. SAMHSA used data from the pharmaceutical company, Alkermes, to obtain the numbers of people using naltrexone in 2016, 2017 and 2018. Medication assisted treatment has increased across categories of FDA approved medications year over year. With 1,172,371 individuals receiving medication assisted treatment in 2018 compared to 921,692 in 2016 this represents a 27 percent increase.





3. Can you provide an update on how Tribal Opioid Response grants are currently being utilized in tribal communities? Is HHS or SAMHSA experiencing any challenges with implementation of this grant program?

Response:
Fiscal Year (FY) 2018 and FY 2019 Tribal Opioid Response (TOR) grantees are currently in varying stages of completing their Comprehensive Strategic Plans and implementation of culturally appropriate and evidence-based treatment, prevention, and recovery support activities including medication assisted treatment using one of the three FDA-approved medications for the treatment of opioid use disorder (OUD). Tribal communities tailored the use of TOR funds to address the unmet need for OUD services and to decrease opioid overdose related deaths within their communities.

The following are examples of various activities performed by grantees:

Prevention:
Grantees used a number of culturally relevant evidence-based practices (EBPs) to conduct prevention outreach and education with schools, tribal leaders, and community members such as the Life Skills curriculum, Red Cliff Wellness School Curriculum, and Healthy Way of Living Model in school systems. Grantees engaged in extensive naloxone trainings with first responders, law enforcement, and tribal casino employees to widely disseminate and distribute naloxone kits. Community prevention activities included drug takeback days, health fairs, opioid awareness events, and sobriety walks.

Treatment:
Grantees used funds to provide direct or referral inpatient or outpatient services to close gaps across the treatment continuum. Grantees implemented individual and group counseling, telehealth, case management, and referrals to other needed services. TOR grantees utilized evidence-based models for the delivery of medication-assisted treatment using one of the three FDA-approved medications for the treatment of OUD, along with behavioral therapies including cognitive-behavioral therapy, dialectical behavioral therapy, motivational enhancement, motivational interviewing, contingency management, eye movement desensitization and reprocessing (EMDR), and other EBPs.

Recovery:
Grantees conducted a wide range of activities to support individuals in recovery from OUD such as the use of peer recovery support specialists to assist clients with meeting treatment and recovery goals, recovery housing, group recovery programs, case management, transportation assistance, employment services, aftercare services, relapse prevention, and culturally-appropriate 12-step programs.

In response to the question about any challenges experienced, SAMHSA did experience delays with FY2018 TOR implementation related to grantee vacancies, staff turnover, training, reporting, broader behavioral health workforce shortages in rural areas, tribal government processes and/or changes in tribal leadership. Grantees also cited client barriers such as lack of transportation, stable housing, or child care. In an effort to strengthen the management of the TOR program, SAMHSA moved the TOR program to the Office of Tribal Affairs and Policy (OTAP) within SAMHSA. OTAP serves as SAMHSA's primary point of contact on behavioral health policy and program matters facing American Indians and Alaska Natives. As a result of this change, OTAP put together a new team of government project officers to assist grantees with the administration of their grants and ensure timely responsiveness to questions. This change was made in response to feedback received from tribal leaders in order to streamline management and overcome challenges faced by TOR grantees.

4. How does the risk of using stimulants and opioids differ? What is different about how we measure the prevalence of stimulant use? What treatment options exist for patients

with cocaine use disorder or methamphetamine use disorder? What is your agency doing to improve evidence-based treatment pathways for these patients?

Response:

How does the risk of using stimulants and opioids differ?

Opioids and stimulants, including methamphetamine and cocaine, are both highly addictive categories of drugs and can have serious adverse consequences when misused. Information on the risks associated with these substances is available on the website of the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), including at the links listed below. While opioids and stimulants evoke very different subjective experiences and have nearly opposite effects on central nervous system activity, both categories of drugs have high addiction liability and carry other serious health risks. In brief, in addition to fatal overdose, the risks of opioid misuse include respiratory depression, lung diseases such as tuberculosis and pneumonia, structural and functional changes in the brain, depression, and other mental health conditions. There are specific consequences associated with different routes of administration. For example, injection drug use increases the risks of infectious disease such as HIV and hepatitis, and chronic injection use can lead to scarred and/or collapsed veins, bacterial infections of the blood vessels and heart valves, abscesses and other soft-tissue infections. Snorting opioids may damage mucosal tissue in the nose and perforate the nasal septum.

Cocaine and other stimulant misuse is also associated with a range of adverse—and sometimes fatal—effects, including heart attacks and strokes, elevated body temperature, cognitive problems, mood disturbances and psychosis, including violent behavior, and structural and functional changes in the brain. Severe physical effects, including weight loss, tooth decay, and skin sores, are often observed in people who have used methamphetamines chronically. Like opioids, stimulants, can be consumed through various routes of administration, including injection, smoking, and snorting, with specific risks associated with each (e.g., injection drug use increase risk of infectious disease and smoking crack can damage the lungs).

For more information on the risk associated with these drugs, please see:
Methamphetamine: https://www.drugabuse.gov/publications/research-reports/methamphetamine/overview
Cocaine: https://www.drugabuse.gov/publications/research-reports/cocaine/what-cocaine
Heroin: https://www.drugabuse.gov/publications/research-reports/heroin/overview
Prescription drugs: https://www.drugabuse.gov/publications/misuse-prescription-drugs/overview

What is different about how we measure the prevalence of stimulant use?

Nationally representative estimates of drug use prevalence are derived from the same sources across drug classes. Therefore, the way prevalence estimates are developed does

not vary by drug type. The annual National Survey on Drug Use and Health (NSDUH), which is directed by the Substance Use and Mental Health Services Administration, is one of the major sources of statistical information on the prevalence of drug use in the United States. NSDUH is a household survey that tracks drug use and mental illness measures among civilian, non-institutional populations aged 12 or older. It collects information on past month, past year, and lifetime use of opioids (including heroin and prescription opioids) and stimulants (including methamphetamine, cocaine, and prescription stimulants). The NIDA-supported Monitoring the Future survey collects data annually from 8th, 10th, and 12th graders on past month, past year, and lifetime use of heroin, prescription opioids, cocaine, crack, amphetamine, methamphetamine, and prescription stimulants. In addition to surveys that directly assess individual drug use, HHS supports data collection initiatives to assess drug use at the community-level. For example, earlier this year, HHS announced an agreement with Millennium Health to provide near real-time, de-identified drug testing data that will facilitate enhanced surveillance and analysis of emerging drug use trends, providing a more-timely estimation of these changes prior to the reporting of drug overdose deaths. For more information, see: https://www.hhs.gov/about/news/2020/01/07/millennium-health-donates-data-help-fight-drug-overdose-crisis.html

What treatment options exist for patients with cocaine use disorder or methamphetamine use disorder?

Behavioral therapies, such as contingency management and cognitive behavioral therapy are currently the most effective treatments for stimulant use disorders. Contingency management is a therapeutic technique that involves providing patients with tangible incentives for engaging in treatment and maintaining abstinence. Cognitive behavioral therapy helps patients develop critical skills that support long-term abstinence—including the ability to recognize the situations in which they are most likely to use drugs, avoid these situations, and cope more effectively with a range of problems associated with drug use. The Matrix Model—a 16-week comprehensive behavioral treatment approach that combines behavioral therapy, family education, individual counseling, 12-step support, drug testing, and encouragement for non-drug-related activities—has been shown to be effective in reducing methamphetamine misuse. At present, there are no FDA-approved medications for the treatment of cocaine, methamphetamine, or other stimulant use disorders.

What is your agency doing to improve evidence-based treatment pathways for these patients?

Developing new and improved treatments for stimulant use disorders is a priority for NIDA. The Institute is currently supporting more than 100 studies on methamphetamine alone, approximately half of which are clinical studies. NIDA has a robust portfolio of research aimed at developing new treatments for stimulant use disorders that spans the therapeutics development pipeline, from early preclinical research to clinical trials. For example, NIDA-supported researchers are examining a monoclonal antibody treatment

for methamphetamine use disorder in conjunction with behavioral therapy and conducting a study to evaluate the efficacy of combination of naltrexone and bupropion—two drugs approved by the FDA for other indications—for methamphetamine use disorder. NIDA also continues to support basic research to elucidate the mechanisms by which stimulant use can lead to addiction, work that is critical to identifying new targets for future drug development. Additionally, through its Addiction Technology Transfer Center Network, SAMHSA can provide support to states in implementing evidence-based practices across funded and regulated substance use disorder treatment systems. This can include practices for addressing stimulant use disorders.

5. Please provide an update on HHS efforts to find opioid alternatives to treat pain. What further steps can the Congress or HHS take to help encourage the development of opioid alternatives?

Response:
The NIH Helping End Addition Long-term (HEAL) Initiative seeks to develop scientific solutions to the opioid crisis across the full spectrum of biomedical research. In 2019 NIH directed $945 million in funding towards more than 375 projects through the HEAL Initiative. Research supported through the Initiative is working to discover safer and more effective treatment options for pain and to expedite the development of therapies to treat opioid use disorder and overdose. Projects to develop opioid alternatives cover a range of approaches, including discovery and validation of new targets for pain therapeutics, development of appropriate models and assays to accelerate new therapy development to clinical testing of new treatments for safety and effectiveness. In addition, implementation science efforts seek to integrate evidence-based interventions for pain management in large healthcare systems. As part of its response to the opioid crisis, NIH intends to maximize the availability of HEAL research findings and publications through sharing of data to promote dissemination of new knowledge and accelerate research to accelerate delivery of new pain treatments into the clinic.

NIH is supporting discovery research on new targets for novel medications and devices to treat pain. Studies are underway to identify compounds that target receptors and ion channels integral to non-opioid pain pathways in the nervous system. Many of these studies focus on treatment of neuropathic pain such as diabetic nerve pain, and orofacial pain such as headache. In addition, NIH supports studies on anti-inflammatory compounds to treat chronic pain conditions such as osteoarthritis. The NIH Blueprint Neurotherapeutics Program for drug discovery is funding studies for advanced stage development of analgesics such as non-addictive kappa opioid receptor antagonists for treatment of migraine and a safe, non-opioid to reduce diabetic nerve pain. NIH supported basic science research that led to the understanding of the role of calcitonin gene-related peptide therapy for migraine and nerve growth factor therapy for

inflammatory pain. Drugs that target these molecules' function are now approved by the FDA to treat migraine and osteoarthritis pain, respectively.

Through the HEAL Initiative, NIH also is partnering with academia and industry to bring in promising new drugs and devices that can be tested in the Early Phase Pain Investigation Clinical research network for safety and efficacy of novel drugs and devices. This network also supports discovery research on different pain conditions. Through HEAL, NIH established the Pain Management Effectiveness Research Network which supports phase III effectiveness trials on a variety of pharmacological and nonpharmacological therapies for different pain conditions, including post-surgical pain, chronic musculoskeletal pain, knee osteoarthritis, and cancer pain.

Through the HEAL Initiative's Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing program, NIH supports pragmatic clinical trials on how best to imbed effective non-pharmacological treatments for pain into large health care settings. Current implementation trials focus on treatments for low back pain, fibromyalgia and post-operative pain.

NIH is most appreciative of the support provided to establish the infrastructure and research resources of the HEAL Initiative and looks forward to providing updates on the progress of the funded studies. This initiative will allow NIH to enhance study findings through future research. As this evidence base for safe and effective treatment evolves, it will be essential that the knowledge of best practices translate into improved care.

6. The SUPPORT Act required HHS to establish an interagency substance use disorder coordinating committee. The SUPPORT Act also required the interagency committee to meet biannually to identify areas for improved coordinating and to provide recommendations for improving substance use disorder programs and activities. Who has been appointed to this committee? What activities does the interagency coordinating committee intend to undertake moving forward? Does the committee plan to provide Congress with suggested recommendations on further actions needed to help respond to or mitigate the ongoing opioid crisis?

Response:
Interdepartmental Substance Use Disorders Coordinating Committee Roster is chaired by the Assistant Secretary for Mental Health and Substance Use, Elinore F. McCance-Katz, M.D., Ph.D. The designated federal officer is Tracy Goss. The current roster of members include Chad Audi, Ph.D., Caleb Banta-Green Ph.D., M.P.H, M.S.W.
Honorable Nancy L. Butts, J.D., Meredith Canada, M.S.W, M.P.A, L.C.S.W, Kathleen M. Carroll, Ph.D., Jamie Chrisman Low, M.Ed., N.C.C, Susan Dawson, Ed.D, PMHNP-BC, Nicholas D. Estabrook, Judy Goforth Parker, Ph.D., A.P.R.N., F.A.C.H.E., Sara A. Goldsby, M.S.W, M.P.H, Erik P. Hess, M.D., MS.c, Keith Humphreys, Ph.D., Steven M. Jenkusky, M.D., M.A., F.A.P.A**,** Sheryl Ryan, M.D., F.A.A.P Amanda S. (Patient &

Advocate)**,** Cynthia Seivwright, M.A., L.C.M.H.C, CQIA
Daniel Sledge, BA, LP, Richard Spoth, Ph.D.**,** Luis R.Torres, PhD.
EX-OFFICIO MEMBERS include The Honorable Alex M. Azar II**,** Leola Brooks**,** Aimee Viana, Julia Hearthway, John Gibbs, Amanda Liskamm**,** Wilson Compton, M.D., M.P.E.**,** Debra Houry, M.D., M.P.H, Ronald Kline, M.D.**,** Jennifer Burden, Ph.D
Patricia A. Powell, Ph.D., Jacqueline Ponti-Lazaruk, and Celia Winchell, M.D.

The committee meets to discuss the current state of SUD prevalence, treatment and challenges. Updates are given regarding new products, initiatives, and guidance. This information is shared among members to distribute to stakeholders.

The Honorable Greg Walden (R-OR)

1. Dr. Giroir, the SUPPORT Act required HHS to study the type of care being provided by physicians who prescribe buprenorphine to more than 100 patients. Based on the findings of its report, HHS was asked to offer its recommendation as to where the patient limits should be set (should they be lower, higher, or stay the same). This report is due by the end of October.

    A. Do you expect HHS to meet this deadline?

    Response:
    Yes, SAMHSA and HHS expect to meet this deadline.

        a. If not, when can we expect it? n/a

The Honorable Markwayne Mullin (R-OK)

1. Dr. Giroir - I introduced a bipartisan bill with Representative Blumenauer that takes steps to align statute 42 CFR Part 2 with HIPAA. We introduced this bill because of our concern that Part 2 makes it "difficult or impossible" to share addiction medical records in coordinated care settings. These patients tend to have multiple chronic conditions which make care coordination even more important to ensure patient safety. Our bill makes it easier for doctors to share addiction records for treatment, payment, and health care operations.

    A. After 20 years of this addiction crisis, why do providers continue to struggle with this issue?

        a. Is it the lack of seeing the full medical record?

        Response:
        The opioid epidemic in the United States can be attributed to a variety of factors. For example, there was a significant rise in opioid analgesic

prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but also 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 long durations. One additional factor is a lack of health system and healthcare provider capacity to identify and engage individuals with opioid use disorders, and to provide them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment. Additionally, while significant progress has been made in better integrating specialty SUD care with other care, the legacy of separate systems and regulatory regimes continues to present challenges around communication and coordination of care. In some cases, the lack of information sharing is critical to care coordination and may be a factor in providing SUD-related care to a patient. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis.

i. Or fear of prescribing medication assisted treatments because some of them don't mix well with certain medications?

Response:
MAT is a valuable intervention that has been proven to be an effective treatment for OUD and several programs within HHS are aimed at improving access to MAT. In regards to drug interactions, prescribing information about drug interactions is readily available, and many MAT providers will make educated shared decisions with their patients.

2. If our Committee is going to pass a bill to remove training for doctors who prescribe medication assisted treatments, shouldn't doctors be able to see if the MAT they are prescribing their patient could cause harm based on their other medications?

Response:
Provided they have access to a prescription drug monitoring program (PDMP), providers should generally be able to determine whether a patient is taking a medication that could have problematic interactions with the medication they are considering for a patient with OUD. One caveat is that methadone administered through and opioid treatment program (OTP) may not be reported to the PDMP. While Opioid Treatment Programs (OTPS), which administer, but do not prescribe methadone, can now report methadone administration to PDMPs, they are not required to do so as such reporting discloses not only that the patient is taking methadone, but that they are receiving services at an OTP. Therefore, a PDMP query may not reveal the receipt of methadone for the treatment of OUD. With the passage of the SUPPORT Act and continued support from the Administration and Congress, HHS continues to invest in strengthening the capacity of states to monitor the opioid overdose epidemic and target their prevention activities. For

example, sections 7161 and 7162 authorized activities aimed at preventing overdoses and authorized CDC's support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs), collect public health data, and also encourages data sharing between states, respectively. In FY 2019, CDC awarded $301 million through Overdose Data to Action (OD2A) cooperative agreements to scale up prevention and response activities in states, cities, territories, and tribes, including enhancements to PDMPs as a form of public health surveillance and as a clinical decision-making tool. OD2A recipients are undertaking PDMP activities to ensure universal use among providers within a state, including more timely data contained within a PDMP, sending proactive (or unsolicited) reports to providers to inform prescribing, ensuring that PDMPs are easy to use and access by providers, and ensuring inter- and intrastate interoperability. These activities are improving safe and effective opioid prescribing, informing clinical practice, and protecting patients at risk.

3. If our Committee also passed a bill to create 1,000 extra GME slots for addiction medicine, would those doctors have all the tools necessary to help patients safely if part 2 stays as is?

Response:
HHS is committed to expanding and adapting our efforts to best address the dynamic drug overdose epidemic. As a tenet of our 5-Point Strategy, HHS is committed to ensuring access to prevention, treatment, and recovery services are available to all with a substance use disorder. Through several initiatives across HHS like HRSA's workforce investments, SAMHSA's Provider Clinical Support System, and CDC's PDMP activities, the Department continues to support the addiction medicine workforce as they play an integral role in addressing the evolving crisis.