

RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
R. GIL KERLIKOWSKE
DIRECTOR
OFFICE OF NATIONAL DRUG CONTROL POLICY

FOLLOWING JUNE 14, 2013, HEARING ENTITLED,
“EXAMINING THE FEDERAL GOVERNMENT’S RESPONSE TO THE PRESCRIPTION
DRUG ABUSE CRISIS”
SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Joseph R. Pitts

1. In 2012, the FDA, in partnership with other regulatory and law enforcement agencies, undertook Operation Pangea V and took action against more than 4,100 internet pharmacies. Operation Pangea V resulted in the shutdown of more than 18,000 illegal pharmacy websites and seized approximately \$10.5 million worth of pharmaceuticals worldwide. This operation illustrates the magnitude of the internet pharmacy problem. Online Pharmacies have proven to be very problematic and dangerous as they often do not require any prescription. How is ONDCP combating online pharmacies?

ANSWER: While research shows that less than one percent of individuals abusing or misusing prescription drugs obtain them from Internet sales, the Federal Government has taken steps to reduce the role of illegal Internet pharmacies in diversion of opioid pharmaceuticals¹. The Ryan Haight Online Pharmacy Consumer Protection Act requires Internet pharmacies dispensing controlled substances to obtain a special Drug Enforcement Administration (DEA) registration and report monthly to DEA, to disclose detailed information on their home page, and to not provide such pharmaceuticals to individuals who have not had at least one face-to-face evaluation by a prescribing medical practitioner, subject to limited exceptions for telemedicine practice. It is designed to allow DEA to better monitor unlawful Internet pharmacy operations, and reduces the number of Internet pharmacies distributing controlled substances illegally. Pharmacies that are lawfully registered with DEA and whose dispensing of controlled substances via the Internet consists of filling or refilling prescriptions for Schedule III-V controlled substances (as specified in 21 U.S.C. § 802(55) and (56)) are exempt from the Ryan Haight Act definition of “online pharmacy.” Those online pharmacies and websites that continue to unlawfully sell opioid pharmaceuticals and other controlled substances are typically located outside the United States, and to date, DEA has not registered any online pharmacies pursuant to the Ryan Haight Act.

¹ Substance Abuse and Mental Health Services Administration. *Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2012]. Available: <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#2.16>

Within the Office of National Drug Control Policy (ONDCP), the High Intensity Drug Trafficking Areas (HIDTA) program provides designated areas around the country with funds to establish multi-agency task forces to address drug enforcement issues within their respective areas. Of the 28 HIDTAs, 19 (including 4 of the 5 regions comprising the Southwest Border HIDTA) have identified Internet pharmacies as a growing threat to their area.

Most investigations conducted by HIDTA task forces focus on poly-drug organizations and not specifically on Internet sales of illegal drugs. Given the role the Internet has played in the illegal distribution of pharmaceuticals, however, some HIDTAs have specifically targeted them.

For example, the Nevada HIDTA funds a task force called Pharm-Net that specifically targets pharmaceuticals purchased over the Internet. This unique task force has been in place since 2006. The Pharm-Net task force focuses on sources of supply, including on-line pharmacies, and drug trafficking organizations that divert pharmaceutical controlled substances. Many of the targeted organizations involve medical professionals such as doctors, pharmacists or other health care workers with access to controlled substances or prescriptions to obtain controlled substances.

ONDCP will continue to work with DEA, the Food and Drug Administration (FDA), and other agencies to address online operations illegally diverting these medications and will continue to partner with international, state, and local law enforcement agencies to further suppress illegal online sources of prescription drug diversion.

2. How does the ONDCP allocate its funds to address prescription drug abuse?

ANSWER: ONDCP partners with several agencies to coordinate funding for the action items listed in the 2011 *Prescription Drug Abuse Prevention Plan (Plan)* under the National Drug Control Budget. For example:

- The Administration has requested \$7 million in FY 2014 for the Prescription Drug Monitoring Program of the Department of Justice's Office of Justice Programs to enhance the capacity of regulatory agencies and health care providers to collect and analyze controlled substance prescription data;
- The DEA's Diversion Control Program (DCP), with a request of \$360.9 million in FY 2014, aids in preventing the diversion of pharmaceutical controlled substances;
- The National Institute on Drug Abuse (NIDA) supports research to better understand the patterns and motivations underlying prescription drug abuse, the development and testing of prevention programs, pain medications with reduced abuse potential, and treatments for prescription drug abuse and opioid overdose. NIDA released findings in 2013 in the following areas: Problem Behaviors Can Signal Risk in Prescribing Opioids to Teens; Preclinical trials of an Oxycodone Vaccine successful; Thoughts of Suicide May Persist Among Nonmedical Prescription Opiate Users; and Few Teens With Prescription Opioid Use Disorders Receive Treatment; and
- The Substance Abuse and Mental Health Services Administration (SAMHSA) is reviewing applications for up to approximately \$2.8 million in Cooperative Agreements

for Electronic Health Record and Prescription Drug Monitoring Program Data Integration grants. SAMHSA is also awarding up to \$750,000 to help enable opioid treatment programs to develop electronic health record systems.

In FY 2012, ONDCP spent \$1 million from HIDTA's discretionary funding to support investigations to disrupt and dismantle drug trafficking organizations suspected of violating Federal, state, or local statutes pertaining to the diversion of licit pharmaceutical controlled substances. The investigations also targeted rogue pain clinics, physicians who prescribe scheduled drugs without a valid medical reason, and pharmacies that illegally dispense or divert controlled drugs.

With a request of \$85.6 million in FY 2014, ONDCP also funds nearly 700 Drug Free Communities (DFC) Support Program coalitions across the country. Many of these community coalitions have prevention initiatives geared toward reducing prescription drug abuse and misuse. Coalitions supported by the DFC program, which is administered by SAMHSA, work with youth, parents, schools, law enforcement, business professionals, media, local, state and tribal government, and other community members to identify and address local youth substance use problems and create sustainable community-level change. Through the use of environmental prevention strategies, DFC coalitions use comprehensive approaches to address prescription drug abuse such as raising awareness for prescribers, parents, and youth; organizing prescription drug take-back events; and developing systems for safe disposal of prescription drugs. DFC grantees have identified prescription drug abuse as a priority for their coalitions.

3. How does the CDC, FDA and ONDCP work together during the development of a promising treatment which could help address the national priority of abating the drug abuse crisis? While obviously approval of any new medication is under the purview of the FDA, I'd like to know more about the extent to which each of your agencies provide your expertise to one another when a therapy with this potential is under review.

ANSWER: As acknowledged, there are very strict rules governing the review and approval of medications, including restrictions on the role Federal agencies outside the FDA can play in these processes. However, as part of the overall effort to curb prescription drug diversion and abuse, the Administration has established clear objectives to promote the development of promising treatments.

One aspect of the Administration's *Plan* relates to the development of abuse deterrent formulations of opioids. The Plan has two specific action items to advance this work. The first item, led by the Department of Health and Human Services (HHS), calls for expediting research through grants, partnerships with academic institutions, and priority New Drug Application review by the FDA to develop treatments for pain with no abuse potential as well as the development of abuse-deterrent formulations of opioid medications and other drugs with abuse potential. NIDA is funding grants for the development of such medications.

The second action item, also led by HHS, calls for providing guidance to the pharmaceutical industry on developing abuse-deterrent drug formulations and on post-market assessment of their

performance. In January 2013, FDA issued draft guidance on the development of abuse-deterrent opioid drug products, as required by the Food and Drug Administration Safety and Innovation Act. Recent actions by FDA concerning abuse-deterrent formulations of well-known prescription opioid drugs demonstrate that FDA is using the available scientific information to make its determinations concerning the marketing by drug manufacturers of purported abuse-deterrent formulations.

NIDA has prioritized the development of medications to treat substance use disorders. To accelerate the progress of medications development, NIDA has increased collaboration with pharmaceutical industry and biotech companies, is evaluating compounds with relevant mechanisms that have been “de-risked”, awarding larger grants for shorter duration to obtain quicker results, and having the flexibility to prioritize projects as needed. NIDA is also funding a promising approach to treat substance use disorders that uses anti-drug enzymes or antibodies to neutralize the substance while it is still in the bloodstream, keeping it from entering the brain. NIDA scientists also review the eight factor evaluation of abuse liability required under the Controlled Substances Act (CSA) for scheduling of medications, once the evaluations are performed by the FDA.

The Centers for Disease Control and Prevention (CDC) regularly works with FDA on efforts to improve understanding of abuse and overdose risks, public health implications of abuse, and how safer products or those with abuse-deterrent properties might impact the public health burden. CDC is also engaged with FDA to improve surveillance capacity to better evaluate the impact or potential impact of products under development.

One other aspect of sharing between FDA, CDC and ONDCP that has been valuable has been exchange of information about prescription drug use and misuse. Both FDA and CDC scientists are working hard to track this epidemic and share this information where possible and needed with ONDCP and other parts of the Federal Government. While new medications continue to be developed, broader adoption of existing medicines to manage substance use disorders is necessary. In one important step, working with interagency partners, the Department of Defense is currently working on rulemaking to allow for TRICARE coverage of treatment of substance use disorders through medication-assisted treatment, such as methadone or buprenorphine.

ONDCP will continue to work with NIDA, FDA, CDC, and other Federal interagency partners to help ensure innovative treatments are developed and tested safely and efficiently, and that existing treatment modalities are widely available to those that need them. There is significant potential in medication-assisted treatment, and we must ensure that these options are widely available, particularly in underserved communities in rural and other areas with limited treatment infrastructure. ONDCP continues to urge the medical research and substance abuse treatment fields to develop new therapies and more fully incorporate existing, evidence-based treatment modalities into health care.

Full implementation of the Affordable Care Act includes treatment for substance use disorders as one of the ten Essential Health Benefits, as well as application of the Mental Health Parity and Addiction Equity Act of 2008 to these benefits, so that substance use disorders are treated the same as other chronic health disorders. ONDCP continues to work with its Federal partners to

ensure that clinically effective and cost effective substance use disorder services are integrated into the U.S. healthcare system.

4. How do you measure the success of the *Prescription Drug Abuse Prevention Plan*?

ANSWER: The Administration has established a number of specific goals to help gauge success of the *Plan* and ongoing efforts to reduce and prevent abuse of prescription drugs. The overarching five-year goal, as outlined in the *National Drug Control Strategy*, is a 15 percent reduction in non-medical use of prescription-type psychotherapeutic drugs in the past year among people 12 years of age and older.

ONDCP has established a multi-pronged approach to assess progress on these goals. From a strategic level, the Performance Reporting System (PRS) is a monitoring system that assesses interagency progress toward achieving the Goals and Objectives of the *Strategy*. The *Strategy* addresses the importance of both prevention and early intervention. Three PRS measures address non-medical use of prescription drugs: (1) percent of respondents in the past year using prescription-type drugs non-medically, age 12 – 17; (2) percent of respondents in the past year using prescription-type drugs non-medically, age 18 – 25; and (3) and percent of respondents in the past year using prescription-type drugs non-medically, age 26+. From an operational perspective, the ONDCP Delivery Unit tracks progress on action items that support achieving the Goals of the *Strategy*, including supplemental strategies such as the *Prescription Drug Abuse Action Plan*.

Historic strides have been made in preventing doctor shopping by working with states to expand the use of prescription drug monitoring programs (PDMPs). In 2006, only 20 states had PDMPs. Today, 49 states have laws authorizing these databases, and 47 states have operational programs. Each day, these programs are helping to rein in the diversion of prescription drugs for non-medical use by enhancing the ability of prescribers, pharmacists, and state authorities to prevent abuse.

ONDCP has worked extensively with medical professionals to provide training on how to properly prescribe painkillers. In conjunction with NIDA, ONDCP has made available two free online training tools for healthcare professionals who prescribe these powerful drugs. Already, nearly 60,000 clinicians have completed these training courses in less than a year. Moreover, FDA now requires manufacturers of extended-release and long-acting painkillers to make available free or low-cost continuing education to prescribers under the Risk Evaluation and Mitigation Strategy for extended-release and long-acting (ER/LA) opioid analgesic drugs (ER/LA Opioid Analgesic REMS). The FDA expects companies to train at least 60 percent of the approximately 320,000 prescribers of these drugs within the next four years.

Through support of DEA's National Prescription Drug Take-Back Day initiatives, communities have reasonable ways to dispose of unneeded or expired medications languishing in home medicine cabinets. These events have already collected and safely disposed of almost three million pounds of medications, draining a key source of drugs that are often diverted for abuse.

Progress has been made under all four pillars, and there are signs in recent years that this national effort is working. One example is non-medical prescription drug use among young adults. The rate of non-medical use of prescription drugs among young adults (18 to 25 years old) in 2012 was 5.3 percent. While this rate is similar to rates seen in 2010 and 2012, it is lower than the rate in the years 2003 through 2007 and 2009 (which ranged from 5.9 to 6.5 percent).² While not definitive, these new data underscore the need for ongoing focus on reducing and preventing prescription drug abuse.

5. Why has ONDCP prioritized reauthorizing NASPER?

ANSWER: When the Administration released the *Plan* in 2011, the number of states that had PDMPs was significantly less than today, and those PDMPs were only beginning to commence operation, let alone work with each other. At that time, there were two Federal programs: the Harold Rogers Prescription Drug Monitoring Program (HRPDMP) grants, administered by the Bureau of Justice Assistance (BJA) in the Department of Justice; and the National All Schedules Prescription Electronic Reporting (NASPER) program, administered by the Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS. As originally conceived, HRPDMP grants could be used to plan a state PDMP, but to be eligible for a NASPER grant a state needed to have PDMP legislation in place. During the initial years of NASPER's authorization, there was still a need to support widespread establishment and implementation of PDMPs, as well as ensuring that states would make their PDMPs more interoperable and use them as a public health tool, not primarily a law enforcement tool.

Given that 49 states now have legislation authorizing PDMPs and 47 states have operational programs, the focus in supporting PDMPs has shifted from getting PDMPs started to improving the utility of existing PDMPs and enhancing their interoperability, both with other state PDMPs and with other health information technology systems.

We are committed to working with SAMHSA and BJA to ensure a streamlined Federal approach to provide support for state PDMPs. We continue to support both BJA's efforts to fund and enhance PDMPs through the HRPDMP and SAMHSA's efforts through its PDMP and EHR Integration grants.

6. Are you investigating a strategy involving drug packaging?

ANSWER: In April 2013, FDA announced approval of updated labeling for reformulated OxyContin® (oxycodone hydrochloride) stating that the product has physiochemical properties that are expected to make abuse via injection difficult and are expected to reduce abuse via the intranasal route (snorting). This is the first time that FDA has approved labeling that

² Substance Abuse and Mental Health Services Administration. *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*. U.S. Department of Health and Human Services. [September 2013]. Available:

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#ch2.3>

characterizes a product's abuse-deterrent properties. Including information about a product's abuse-deterrent properties in labeling is important to inform health care providers, patients, and the public about the product's predicted or actual abuse potential. FDA continues to encourage pharmaceutical manufacturers to seek approval of proposed product labeling that highlights product safety and other properties and appropriately characterizes the abuse-deterrent properties of a product. The FDA's guidance around such labeling notes that labeling language regarding abuse deterrence should describe the drug's specific abuse-deterrent properties, as well as the specific routes of abuse that the drug has been developed to deter.

7. In the document *Epidemic: Responding to America's Prescription Drug Abuse Crisis*, one of the primary action items is educating prescribers. You note that you would like to amend Federal law to require the training. In conjunction with this legislative approach has your agency talked to medical, nursing, and pharmaceutical schools about including this in the curriculum?

ANSWER: Yes, the Administration is working with a number of health care practitioner organizations and associations, as well as medical colleges and faculty to promote the widespread adoption of this safe prescribing and substance abuse content by medical educators. For example, ONDCP is working with the American Dental Association to ensure that safe prescribing education is properly tailored to dental students and professionals. Additionally, ONDCP leadership has met with a host of medical and pharmacy school deans and faculty, including a keynote address and a private meeting at the 2012 American Association of Colleges of Pharmacy Annual Meeting in Orlando, FL, and staff-level engagements with the Association of American Medical Colleges, encouraging these associations and their members to strengthen and expand curricula around safe prescribing, abuse-potential of medications, and recognizing the signs and intervening with patients with substance use disorders. These messages are reinforced in work with state Medical and Pharmacy Boards, as well as their national counterparts. All of these efforts inform education, not only in medical, nursing, dental, and pharmacy schools, but also continuing education over the course of health care professional careers.

In 2011, ONDCP convened a meeting with leaders in pharmacy education to encourage pharmacy schools to expand educational offerings. The Administration has also taken a number of steps to promote expanded continuing medical education for prescribers, so that current prescribers receive further training in prescribing controlled substances, particularly opioid pain relievers. The Administration is committed to making convenient, free or low-cost tools and training available to a broad spectrum of prescribers and dispensers of these controlled substances.

ONDCP worked with NIDA to develop two free online continuing education training tools for healthcare professionals who prescribe opioid analgesics. Since these tools became available in October 2012, nearly 60,000 clinicians (primarily physicians and nurses) have completed coursework eligible for continuing medical education credit—as well as training on the abuse potential of these medications and management of patients to whom they are prescribed.

SAMHSA is providing training on prescription drug abuse for physicians and other health professionals both online and in-person in 20 states with particularly high rates of opioid dispensing. In addition, the FDA has developed a Risk Evaluation and Mitigation Strategy for ER/LA opioid analgesics. Approved in July 2012, the ER/LA Opioid Analgesic REMS requires all manufacturers of ER/LA opioids to make available training for prescribers of these medications.³ The training must include information that prescribers can use when counseling patients about the risks and benefits of opioid use. The FDA expects the training to be provided free or at low-cost by continuing education providers and at least 60 percent of the approximately 320,000 active prescribers of ER/LA opioids to be trained within four years from when training is available.⁴ A number of these education programs are already available or will be available to health care providers in the near future.

8. It is clear that the prescription drug abuse crisis is extremely complicated and constantly changing. Has the ONDCP altered the prescription drug abuse plan to accommodate for the evolving epidemic? If so, how has the plan changed?

a. What caused the changes in strategy?

b. What have been the strongest and most effective parts of the strategy?

ANSWER: ONDCP regularly engages with partners at the Federal, state, and local levels to adapt and respond to emerging issues related to prescription drug diversion and abuse. ONDCP also works with interagency partners to examine the latest research and data to better inform ongoing work to reduce prescription drug abuse and its consequences. The Administration is focused on addressing some of the most pronounced consequences of this epidemic, including overdose deaths and emerging issues like heroin use as well as neonatal abstinence syndrome and maternal addiction.

With recent rises in overdose deaths across the country,⁵ ONDCP has increased its focus on comprehensive overdose prevention, recognizing that overdoses can be prevented, antidotes are available, and treatment is imperative. ONDCP is working with Federal partners and state and local authorities to expand access to naloxone, an emergency opioid overdose reversal medication, for first responders who encounter overdose victims. The agency is also closely examining Good Samaritan laws, which provide limited protections for individuals who call 911 in overdose situations, to remove perceived barriers to calling for help. These steps are critical as part of a larger effort to inform the public, law enforcement, and health care professionals about the nature of prescription drug abuse, addiction, and overdose prevention.

³ Food and Drug Administration. Extended Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS). U.S. Department of Health and Human Services. [August 2012]. Available: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>

⁴ Food and Drug Administration. Extended Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS). U.S. Department of Health and Human Services. [August 2012]. Available: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>

⁵ CDC/Wonder; data extracted on January 28, 2013.

Another area of expanded focus is the nexus between prescription drug abuse and heroin use. The number of primary admissions for heroin treatment services among 18 to 24 year olds increased from 37,000 in 2000 to 60,000 in 2011.⁶ Epidemiologists in all regions of the United States report increases in heroin use among young adults and those outside of urban areas.⁷ Research also indicates that injection-drug users report prescription opioid use predates their heroin use, and increased tolerance to prescription opioids and lower costs motivate them to try heroin.⁸ ONDCP and researchers with the CDC are closely monitoring these trends to determine whether there is a relationship between prescription drug initiation and transition to heroin use, particularly among young people. The Administration is also ensuring that comprehensive overdose prevention properly considers the role of heroin in overdose, and is underscoring the importance of getting individuals abusing prescription drug into treatment before their tolerance leads to injection drug use.

The Administration is also taking steps to understand and address the clinical and policy issues related to maternal addiction, including neo-natal abstinence syndrome (NAS), the withdrawal symptoms exhibited by some infants born to mothers exposed to illicit drugs and certain medications during pregnancy. Many hospitals with little experience caring for drug exposed newborns prior to the prescription drug abuse epidemic are now witnessing increases in births requiring additional hospital resources. Between 2000 and 2009, the rate of hospitals billing for NAS increased from 1.2 to 3.4 per 1,000 hospital births per year.⁹ This translates to roughly one infant per hour born with signs of drug withdrawal. In August 2012, ONDCP hosted a national leadership meeting that focused on NAS and evidence-based treatment and prevention options for maternal addiction. The conclusions reached at this meeting are reflected in a renewed emphasis on maternal addiction and neonatal abstinence syndrome in the *National Drug Control Strategy*.

The Administration's efforts around PDMPs and health information technology (IT) have also progressed. In support of the *Plan*, ONDCP convened a Roundtable on Health IT and Prescription Drug Abuse shortly after the *Plan's* release. Over 30 attendees from the public and private sectors discussed integrating these innovative technologies with PDMPs so that prescribers and pharmacists can more easily and effectively access and use the PDMP data. They agreed on nine pilot studies, and HHS contracted with the MITRE Corporation to facilitate the development of some of these pilots.¹⁰

⁶ Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Treatment Episode Data Set (TEDS). Data extracted as of October 15, 2012.

⁷ Proceedings of June 2012, NIDA CEWG (Unpublished Data from NIDA).

⁸ Lankenau SE, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. *Int J Drug Policy*. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.

⁹ Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009" *JAMA*. 2012 May 9;307(18):1934-40. Available: <http://www.ncbi.nlm.nih.gov/pubmed/22546608>

¹⁰ Prescription Drug Abuse and Health Information Technology Workgroup, Behavioral Health Coordinating Committee, U.S. Department of Health and Human Services. "Action Plan For Improving Access to Prescription Drug Monitoring Programs Through Health Information Technology." June 30, 2011.

The pilots, which were completed in 2012 and early 2013, yielded encouraging results.¹¹ For example, one of Indiana’s health information organizations, the Indiana Network for Patient Care, leveraged its hospital network to offer information from the State PDMP along with a “narcotic score” alert (using a formula to determine high risk based on the number of prescriptions) to emergency room doctors as part of their normal view of a patient’s record. In Kansas, a secure e-mail protocol called “DIRECT” was used to send a PDMP report securely from the PDMP to a provider’s electronic health record (EHR) when a certain threshold was met, such as when the patient sought to fill five prescriptions from five providers during one calendar quarter. Finally, in Michigan, a vendor of an electronic prescribing (e-prescribing) module worked with that State’s PDMP to pull information from the PDMP when a provider electronically prescribed a medication using the module. This allowed providers to receive alerts concerning previous prescriptions of controlled substances before submitting a new prescription.

The mechanisms developed for these pilots and others conducted during the two year process remain in place in their respective states. While preliminary evidence and prescriber reaction were positive, wider implementation and more research will be needed to prove the effectiveness of these methods in increasing prescriber use of PDMP data, leading to appropriate interventions when drug-seeking behavior is discovered. To further encourage the development of innovative health IT integration with PDMPs, SAMHSA awarded nine two-year grants in FY 2011 and is in the process of awarding up to \$2.8 million in grants to states this year.¹² As part of these health IT integration efforts, SAMHSA and Office of the National Coordinator for Health IT (ONC) are working with states to explore data standards that would allow PDMPs and health IT systems to be more interoperable. This work is aimed at allowing EHRs to use PDMP data more effectively for clinical purposes.

These and other efforts build upon the foundational 2011 *Plan*, and ONDCP and Federal interagency partners continue to respond to emerging issues, and identify new opportunities to prevent the diversion and abuse of prescription medications.

9. In your testimony, you note that 49 states have laws authorizing PDMPs. Why do Missouri and the District of Columbia not have legislation authorizing PDMPs?

- a. Which states have the best PDMP programs?**
- b. What makes PDMPs effective?**
- c. Are all PDMPs built upon a similar model?**
- d. Are there any outstanding PDMPs that have proven to be more successful than others?**
- e. Would you please explain the importance of state PDMPs being interoperable with other states; PDMPs?**

ANSWER:

¹¹ MITRE. Connecting Prescribers and Dispensers to PDMPs through Health IT: Six Pilot Studies and Their Impact. 2012. http://www.healthit.gov/sites/default/files/pdmp_pilot_studies_summary_0.pdf

¹² Substance Abuse and Mental Health Services Administration. Cooperative Agreements for Electronic Health Record (EHR) and Prescription Drug Monitoring Program (PDMP) Data Integration. RFA No. TI-13-013. 2013 <http://www.samhsa.gov/grants/2013/ti-13-013.pdf>.

Missouri and District of Columbia

ONDCP has engaged in discussions with leaders in both the Missouri and the District of Columbia governments about potential legislation to authorize PDMPs in their jurisdictions. Missouri's legislature considered multiple bill proposals during the past legislative session to authorize a PDMP. Two such bills were considered in the Missouri Senate Committee on Veterans' Affairs and Health on March 7, 2013.^{13,14} The two bills both included provisions to address concerns expressed by members of the legislature about maintaining the privacy of individuals who are filling prescriptions for controlled substances. The 2013 Missouri legislative session ended on May 17. My office will continue discussions with State leadership in Missouri about the importance of PDMPs in preventing prescription drug abuse and will support their efforts to pass legislation in the 2014 legislative session.

With advice and encouragement from ONDCP, the Washington D.C. Department of Health and the Mayor's office have worked with the Washington D.C. City Council to develop a proposal that would authorize a District-wide PDMP. As a result of their efforts, City Council Chairman Mendelson introduced legislation in February 2013 that would authorize a PDMP.¹⁵ The Council's Committee on Health held a public hearing on July 12 and heard extensive witness testimony in support of the legislation.¹⁶ We are hopeful that the District of Columbia will soon authorize the creation of a PDMP.

PDMP Models

All state PDMPs are built upon a general model. They collect information reported electronically by dispensers of controlled medications to a database managed by the state. PDMPs give certain persons or agencies access to the information, often through a web portal, in order to deter the over-dispensing of prescription drugs.

However, there are some important variations within this common state PDMP structure. States have different requirements about how frequently dispensers must report to the state PDMP, ranging from real-time reporting to monthly reporting.^{17,18} Importantly, state PDMPs also vary in terms of which agency they assign to house and manage the database. Some states house their PDMP in one of their law enforcement divisions, such as their Bureau of Narcotics¹⁹ or their

¹³ Missouri Senate, Missouri Senate Bill 233, Bill Status.

http://www.senate.mo.gov/13info/BTS_Web/Bill.aspx?SessionType=R&BillID=17590490

¹⁴ Missouri Senate Bill 146, LR Number 0976S.01I.

http://www.senate.mo.gov/13info/BTS_Web/Bill.aspx?SessionType=R&BillID=17254382

¹⁵ Council of the District of Columbia, Legislative Information Management System, Legislation, Legislation No. B20-0127. <http://dcclims1.dccouncil.us/lims/legislation.aspx?LegNo=B20-0127>.

¹⁶ Council of the District of Columbia. Council Hearing Archive. Committee on Health, Public Hearing, Yvette M. Alexander, Chairperson, July 12, 2013. <http://dccouncil.us/granicus/archive/>.

¹⁷ Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obnidd/Prescription_Monitoring_Program/

¹⁸ Alaska Prescription Drug Monitoring Program. Dispenser Information. <http://www.alaskapdmp.com/dispenser/>

¹⁹ Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obnidd/Prescription_Monitoring_Program/

Attorney General's office.²⁰ Other states house their database in the Department of Public Health,²¹ the State Board of Pharmacy,²² or State medical licensing boards.²³

States also vary in how they obtain funds for running their PDMP. Some states rely solely on Federal grant monies and private donations, expressly prohibiting the use of State funds.²⁴ In addition to Federal grants, states fund their PDMPs with general funds, licensure fees, and civil and administrative recoveries. BJA recently released a technical assistance document on funding options for state PDMPs developed by the Prescription Drug Monitoring Program Training and Technical Assistance Center.²⁵ This document provides helpful tips to states on ways that other states have supported their PDMPs with funding.

Effective PDMPs and State Examples

New research shows that relative to states without PDMPs, states with PDMPs mitigate the prevalence of prescription opioid abuse and misuse in both the general population and among those in opioid treatment programs.²⁶ Although some states' PDMPs have existed for several years, many are early in the establishment and implementation process. As a result, there is a paucity of available research on effectiveness and outcomes of implementing specific PDMP features. In September 2012, the Prescription Monitoring Program Center of Excellence at Brandeis University, a BJA-funded program, published a paper of PDMP best practices.²⁷ This paper examined observations about PDMPs from peer-reviewed journals and developed 35 potential best practices for PDMPs. However, the authors noted that there are major gaps, such as a lack of randomized control trials, systematic reviews, or meta-analyses that need addressing in future research.²⁸ Based on Brandeis's analysis and the underlying research on PDMPs, the following list represents what the ONDCP believes are promising practices, which, if enacted, would improve the utility of PDMPs as public health tools. The ensuing discussion includes examples of state PDMPs that illustrate these practices:

1. Access to and regular consultation of PDMPs by prescribers and other healthcare professionals;

²⁰ State of California Dept. of Justice, Office of the Attorney General. CURES/PDMP. <http://oag.ca.gov/cures-pdmp>

²¹ Rhode Island Department of Health. Prescription Drug Monitoring Program.

<http://www.health.ri.gov/programs/prescriptionmonitoring/>

²² Health Information Designs. Colorado Prescription Monitoring Program. <http://www.hidinc.com/copdmp>

²³ State of Indiana Professional Licensing Agency. Indiana Scheduled Prescription Electronic Collection and Tracking Program (INSPECT). <http://www.in.gov/pla/inspect/index.htm>

²⁴ Revised Statutes of the State of New Hampshire (Title XXX, Ch. 318-B) § 318-B:32: "II. All costs incurred by the board for the implementation and operation of the program shall be supported through grants, gifts, or user contributions. The board may charge a fee to individuals who request their own prescription information. The amount charged for an individual's request for his or her prescription information shall not exceed the actual cost of providing that information. III. There shall be no state general funds appropriated for the implementation or operation of the program."

²⁵ PDMP Training and Technical Assistance Center. Funding Options for Prescription Drug Monitoring Programs. 2013 http://www.pdmpassist.org/pdf/PDMP_Funding_Options_TAG.pdf

²⁶ Reifler LM, Droz D, Bailey JE, Schnoll SH, Fant R, Dart RC, Bucher Bartelson B. Do prescription monitoring programs impact state trends in opioid abuse/misuse? *Pain Medicine* 2012; 13: 434-442.

²⁷ Clark T, Eadie J, Kreiner P, Strickler G. Prescription Drug Monitoring Program Center of Excellence. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. September 20, 2012, http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.

²⁸ *Ibid* at 64

2. Real- or near-real-time collection and reporting of prescription drug data;
3. Unsolicited reporting of prescription drug use information to prescribers and pharmacists;
4. Access by researchers and medical examiners to individual-level PDMP data for surveillance/research;
5. Interstate data sharing/harmonization and interoperability of data across states.

Access to and consultation of PDMPs by prescribers and other healthcare professionals:

Not all states currently allow or encourage prescribers and/or dispensers to access the data. In Pennsylvania, for example, State law does not allow prescribers to access the PDMP; it is solely used as law enforcement tool.²⁹ States that do allow access approach giving access differently. In some states, registration and access are completely optional.³⁰ In other states, such as Kentucky, access is mandatory before prescribing or dispensing controlled substances.³¹ Regardless of whether or not states require checking the PDMP, states will not experience the full benefit of these databases unless prescribers and pharmacists use the data as an opportunity to intervene and help individuals get treatment for addiction. As mentioned previously, states that are working to improve prescriber access to their PDMPs through electronic health records have had some success in making access to the information a part of the prescriber's existing workflow. These technological developments will continue to be important both in states where access is required to prescribe certain controlled substances and in states where access to the data remains optional.

Some states only give PDMP access to providers who have controlled substance prescription privileges. PDMP legislation in Maryland, Indiana, North Dakota, Utah, and Colorado authorizes PDMP access to providers other than prescribers.^{32,33,34,35,36} Providers who do not

²⁹ Title 28 PA Consolidated Statute, Chapter 25, Subchapter A, Section 25.131 available at <http://www.pacode.com/secure/data/028/chapter25/chap25toc.html#25.131>. See also <http://www.attorneygeneral.gov/drugs.aspx?id=5946>

³⁰ Criminal Offenses (720 ILCS 570), Illinois Controlled Substances Act.

<http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=1941&ChapterID=53>

³¹ Kentucky (Title 18, Chapter 218A) § 218A.202: “(2) A practitioner or a pharmacist authorized to prescribe or dispense controlled substances to humans shall register with the cabinet to use the system provided for in this section and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure and shall not have to pay a fee or tax specifically dedicated to the operation of the system . . . (1) Prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a practitioner shall: . . . (b) Query the electronic monitoring system established in Section 4 of this Act for all available data on the patient;”

³² Maryland (Title 21, Subtitle 2A) § 21-2A-06: “(b) The Program shall disclose prescription monitoring data, in accordance with regulations adopted by the Secretary, to: . . . (5) A rehabilitation program under a health occupations board, on issuance of an administrative subpoena Maryland Senate Bill Page 13 line 30 linked to May 24, 2012. <http://mlis.state.md.us/2011rs/bills/sb/sb0883t.pdf>

³³ Indiana (Title 35, Article 48, Chapter 7) § 35-48-7-11.1: “(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons: . . . (8) A substance abuse assistance program for a licensed health care provider who: (A) has prescriptive authority under IC 25; and (B) is participating in the assistance program

³⁴ North Dakota (Title 19, Chapter 19-03.5) § 19-03.5.03: “3. Unless disclosure is prohibited by law, the board may provide data in the central repository to: . . . j. A licensed addiction counselor for the purpose of providing services for a licensed treatment program in this state

³⁵ Utah CONTROLLED SUBSTANCE DATABASE ACT 58-37f-301. 2. Access to database.(i) a mental health therapist, if: (i) the information relates to a patient who is: (A) enrolled in a licensed substance abuse treatment program; and (B) receiving treatment from, or under the direction of, the mental health therapist as part of the

prescribe controlled substances, such as counselors, may use PDMP data to identify patients who are continuing to access controlled substances while they are pursuing treatment, and intervene appropriately.

Real- or near-real-time collection and reporting of prescription drug data:

As health providers, dispensers, and others begin to use PDMPs and are given better access to them, it is important for states to ensure that they have access to as accurate a list of the prescriptions dispensed as possible. Any lag time between the prescription being dispensed, and being recorded in the PDMP presents an opportunity for pill mills and doctor shoppers to evade detection. State law mandates that dispensers report prescribing data to the PDMP anywhere from instantaneously to monthly.^{37,38} Oklahoma was the first state to require “real time” reporting, or within 5 minutes of delivery of the substance, starting in January 2012.³⁹ While it is too early to measure the effectiveness of real time reporting, prescribers have voiced concern with relying on PDMP data when there is substantial lag time. As a result, real-time reporting may provide another incentive for prescribers and dispensers to check and use the PDMP data.

Unsolicited reporting of patients’ prescription drug use information to prescribers and pharmacists:

States report data from their PDMPs to those authorized to see it in two different ways: “solicited” and “unsolicited.” Solicited reports are those that the PDMP returns upon an authorized request. For example, a prescriber might log on to the PDMP through a web portal and type in identifying information about a patient to retrieve the list of controlled substances dispensed to that patient. Unsolicited reports are sent from the PDMP, either manually or in an automated fashion, to specific persons authorized by State law when a pre-determined threshold of excessive dispensing is met. While it is very important for PDMPs to offer solicited reports, unsolicited reports provide a way to inform prescribers, dispensers, licensing board employees, and other users about excessive prescribing and dispensing even if they do not check the PDMP regularly. States such as Nevada have created an automated mechanism to trigger the creation of an unsolicited report to a prescriber when a patient exceeds a pre-established threshold for the number of providers and pharmacies visited within a given time period.⁴⁰ A study of Wyoming’s

patient's participation in the licensed substance abuse treatment program described in Subsection (2)(i)(i)(A);(ii) the information is sought for the purpose of determining whether the patient is using a controlled substance while the patient is enrolled in the licensed substance abuse treatment program described in Subsection (2)(i)(i)(A); and (iii) the licensed substance abuse treatment program described in Subsection (2)(i)(i)(A) is associated with a practitioner who: (A) is a physician, a physician assistant, an advance practice registered nurse, or a pharmacist; and (B) is available to consult with the mental health therapist regarding the information obtained by the mental health therapist, under Subsection (2)(i), from the database http://www.dopl.utah.gov/programs/csdb/58-37f_2012-01-01.pdf

³⁶ Colorado (Title 12, Article 22, Part 7) § 12-22-705: “(3) The program is available for query only to the following persons or groups of persons: . . . (c) Practitioners engaged in a legitimate program to monitor a patient’s controlled substance abuse

³⁷ Alaska Prescription Drug Monitoring Program. Dispenser Information. <http://www.alaskapdmp.com/dispenser/>Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obnnd/Prescription_Monitoring_Program/

³⁸ Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Prescription Monitoring Program. http://www.ok.gov/obnnd/Prescription_Monitoring_Program/

³⁹ Ibid.

⁴⁰ Prescription Monitoring Program Center of Excellence at Brandeis, Notes from the Field 2.5 Nevada’s Proactive PMP: The Impact of Unsolicited Reports http://www.pmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf

PDMP showed that unsolicited reports can increase the frequency with which practitioners request solicited reports from the PDMP, suggesting that unsolicited reporting raises awareness about the database and its usefulness to providers.⁴¹

Access by researchers and medical examiners to individual-level PDMP data for surveillance/research:

PDMP data, particularly when combined with data from other sources, can provide researchers and state officials with valuable information about the scope and location of prescription drug abuse. For example, epidemiologists in Utah matched individual patient death records and poison control center data to individual PDMP records to identify a range of issues, including the source of the medication involved with overdose deaths.⁴² Researchers in New Mexico similarly used PDMP data to show that some types of controlled prescription drugs presented a higher risk of overdose than others and that certain doses or combinations of controlled medications were also particularly risky.⁴³ Access to individual-level PDMP data, consistent with applicable privacy safeguards, permits a fuller understanding of the extent of the prescription drug abuse problem.

State Interoperability

While prescription drug monitoring programs have shown positive effects within states, doctor shoppers and pill mills can evade detection by doing business across state lines. A recent study showed that “shoppers” of opioids travelled a median of over 83 miles to obtain their prescriptions in 2008. Almost 20% of these individuals travelled across state lines.⁴⁴ The study concluded that effective data sharing between state PDMPs may improve program effectiveness in reducing opioid shopping behavior.

BJA, the Office of the National Coordinator for Health Information Technology (ONC) at HHS, and private entities, such as the National Association of Boards of Pharmacy (NABP) and the Alliance of States with Prescription Monitoring Programs, have worked on architecture and standards to allow the interoperability needed for interstate data sharing. There are currently 15 states that are sharing information through the PMP InterConnect hub, established by the NABP using the standards developed with the support of BJA and the Alliance of States with Prescription Monitoring Programs.⁴⁵ In addition to the data being shareable across state lines, it is essential that practitioners be allowed by state law to access the prescription information from states in which they are not licensed. Some state PDMP laws currently do not allow the sharing PDMP data to prescribers in other states.

⁴¹ PMP Center of Excellence, “Trends in Wyoming PMP prescription history reporting: evidence for a decrease in doctor shopping?” 2010. http://www.pmpexcellence.org/sites/all/pdfs/NFF_wyoming_rev_11_16_10.pdf.

⁴² Sims SA, Snow LA, Porucznik CA. Surveillance of methadone-related adverse drug events using multiple public health data sources. *J Biomed Inform.* 2007 Aug;40(4):382-9

⁴³ Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of being prescribed controlled substances and risk of drug overdose death. *Pain Med.* 2012 Jan;13(1):87-95

⁴⁴ Cepeda MS, Fife D, Yuan Y, Mastrogiovanni G, Distance Traveled and Frequency of Interstate Opioid Dispensing in Opioid Shoppers and Nonshoppers. *J Pain.* 2013 Jun 19. pii: S1526-5900(13)00992-9. “Shoppers” was defined in the study as individuals who fill more than three opioid prescriptions from multiple doctors in at least three different pharmacies with at least one day of overlap.

⁴⁵ National Association of Boards of Pharmacy. NABP PMP Interconnect Map. June 28, 2013. http://www.nabp.net/system/redactor_assets/documents/569/Set_41_WI_and_NE_6-28-13.pdf.

Conclusion

Improving PDMP quality, harmonization, and interoperability and, in some cases, establishing PDMPs authorized by newly-passed state laws will ensure they provide maximal utility as surveillance and public health clinical decision support tools, augmenting their initial use as enforcement tools.

The Honorable Bill Cassidy and H. Morgan Griffith

An L.A. Times investigation recently uncovered that a small number of doctors were responsible for most of the prescription drug overdose deaths between 2006 and 2011 in Los Angeles, Orange, Ventura and San Diego counties of California. The investigation consisted of examining publicly available cause-of-death, toxicology reports and other information in county coroners' files, including lists of prescription medications found at death scenes. If an L.A. Times reporter can uncover provider-specific data on inappropriate prescribing of prescription drugs from publically available data, why can't the federal or state governments do so as effectively with even more robust data monitoring tools?

ANSWER: The recent *Los Angeles Times* investigative report did much to bring the Nation's attention to the problem of prescription drug overdose. Unfortunately, many of the data sources used by the *Times*' reporters are not consistently collected or uniformly available to the public across jurisdictions. For reporting on overdose deaths, the Federal Government relies upon cause of death data compiled by the Centers for Disease Control and Prevention (CDC) from death certificates prepared by local coroners and medical examiners. These death certificates do not routinely provide the level of detail, such as specific drugs that may have been involved in a death, which was reported in the *Times*. This is especially true with respect to scene of death investigations and provider-specific data on inappropriate prescribing, and these sorts of data have been proven to be of great value in determining the extent of this problem. In 2009, the CDC and local public health and safety officials investigated overdose deaths in West Virginia and found results similar to those reported by the *Times*.⁴⁶ However, such special investigations are labor intensive, costly, and dependent upon close collaboration with local authorities and access to the data.

The Administration is committed to working with partners at the state and local level to identify and address all pathways of diversion, including "pill mills" and improper prescribing. Innovative enforcement strategies, particularly those involving collaboration across Federal, state, and local agencies, are helping many communities shut down these illegal operations.

In accordance with state laws, prescription drug monitoring program (PDMP) information may also be used by state regulatory and law enforcement officials to pursue cases involving prescribers or pharmacists operating outside the bounds of proper practice, "pill mills," and other sources of diversion. But these important programs can function more effectively. We are working with our Federal partners and states to make these systems more user-friendly so that agencies tasked with detecting fraud, such as medical boards and licensing agencies can access or receive PDMP information more quickly and easily. Additionally, the Drug Enforcement Administration makes its registrant database available to any state, without a fee, for use in their PDMP or other state agency charged with investigating health care fraud or controlled substance diversion.

⁴⁶ Paulozzi LJ, Logan JE, Hall AJ, McKinstry E, Kaplan JA, Crosby AE. A comparison of drug overdose deaths involving methadone and other opioid analgesics in West Virginia. *Addiction* 2009;104(9):1541-8.

Also, increased reporting and access to PDMP information from entities outside of law enforcement and prescribers can be useful. Some states have allowed medical examiners to access individual level PDMP data. This access allows them to make comparisons to other information, such as death records, which can help in determining a cause of death and detecting “pill mill” operations.

In addition, the National Institute of Justice awarded three new grants in FY 2012 to promote research on illegal prescription drug market interventions: Identifying High Risk Prescribers Using PDMP Data: A Tool for Law Enforcement; Non-Medical Use of Prescription Drugs: Policy Change, Law Enforcement Activity, and Diversion Tactics; and Optimizing Prescription Drug Monitoring Programs to Support Law Enforcement Activities. These grants are enabling Federal, state, and local law enforcement agencies to better use data and share best practices to shut down sources of diversion.

Further, CDC is analyzing various data sources to identify appropriate metrics for outlier prescribers. CDC is also working with Brandeis PDMP COE to validate these metrics using various state and national data sources.

The Honorable Gus Bilirakis

1. Recently, there was a drug summit in Pasco County, FL where public health officials were talking about the growing problem of babies born addicted to prescription drugs. The Pasco-Pinellas area ranks first in the state for babies born addicted. What tools, programs and grants are available for my community to combat this problem?

ANSWER: The Federal Government supports state and local efforts to help prevent and treat the growing problem of babies born exposed to prescription drugs. The Attachment lists grant programs awarded to state and local groups in Florida in FY 2012 that could be used in part to help reduce drug use. Highlighted below are a few specific Federal programs that target prescription drug abuse and treatment of prescription drug dependence both in the mothers and their newborns:

Department of Health and Human Services

- **Administration for Children and Families - Promoting Safe and Stable Families Program:** Provides competitive grants for regional partnerships to provide services and activities to work with children and families impacted by a parent's or caretaker's substance abuse.
- **Center for Medicare and Medicaid Services - Medical Assistance Program - Grants to States for Medicaid:** Shares the cost for Medicaid services which may include the treatment of prescription drug dependence both in the mothers and their newborns.
- **Health Resources and Services Administration - Healthy Start Initiative** - provides for universal risk screening of pregnant women and newborn infants to identify those at risk of poor birth, health and developmental outcomes. Healthy Start includes targeted support services that address identified risks including prevention and treatment of prescription drug dependence both in the mothers and their newborns.
- **National Institutes of Health - Drug Abuse and Addiction Research Programs:** Provides research into the prescription drug abuse and prevention and treatment of prescription drug dependence both in the mothers and their newborns.
- **Substance Abuse and Mental Health Services Administration (SAMHSA) - Block Grants for Prevention and Treatment of Substance Abuse:** Provides states with flexible funding which can be allocated to localities for the prevention and treatment of prescription drug dependence both in the mothers and their newborns.
- **SAMHSA - Projects of Regional and National Significance - Cooperative Agreement for the Physician Clinical Support System for the Treatment of Substance Use Disorders with Buprenorphine:** The SAMHSA-funded Physician Clinical Support System (PCSS) is designed to assist practicing physicians, in accordance with the Drug Addiction Treatment Act of 2000, in incorporating into their practices the treatment of prescription opioid and heroin dependent patients using buprenorphine.

- **SAMHSA - Projects of Regional and National Significance - Cooperative Agreement for the Physician Clinical Support System for Medication Assisted Treatment.** The SAMHSA-funded Physician Clinical Support System (PCSS-MAT) is designed to assist physicians **interested in** incorporating into their practice the treatment of prescription opioid **addicted** patients using Food and Drug Administration approved medications (buprenorphine, methadone and naltrexone **(oral and extended release)**).
- **SAMHSA - Projects of Regional and National Significance - Screening, Brief Intervention and Referral to Treatment:** Supports a health system-level approach to screening and brief intervention within primary care, general medical and community settings—including physician offices, hospitals, educational institutions, and mental health centers including screening for prescription drug dependence both in the mothers and their newborns.
- **SAMHSA - Projects of Regional and National Significance - Pregnant & Postpartum Women Residential Treatment for Pregnant and Postpartum Women and Residential Treatment for Women and their Children:** Provides cost effective, comprehensive, coordinated systems of care to improve outcomes for the entire family that can be sustained over time. To accomplish this comprehensive service system, it is necessary to partner with multiple systems of care. These partnerships include agencies/organizations such as local public housing authorities (for permanent housing for families), child welfare, health, mental health, family court, criminal justice, employment, education programs, and child-serving agencies.

More information on each of these efforts is available on the agency web sites.

2. What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?

ANSWER: It is clear that we are not doing enough to prepare our health care providers to adequately address pain management, substance abuse, and use safe prescribing practices. As many healthcare providers would agree, managing a patient’s pain is a crucial and often very difficult task. However, research indicates that students in medical school receive on average only 11 hours of training on pain education, and most schools do not offer specific training on opioids, substance abuse and addiction, or clinical decision making.⁴⁷ A 2011 Government Accountability Office report on education efforts related to prescription pain reliever abuse found that “most prescribers receive little training on the importance of appropriate prescribing and dispensing of prescription pain relievers, on how to recognize substance abuse in their patients, or on treating pain.”⁴⁸

⁴⁷ Mezei, L., et al. Pain Education in North American Medical Schools. *The Journal of Pain*. 12(12):1199-1208. 2011.

⁴⁸ U.S. Government Accountability Office. *Prescription Pain Reliever Abuse*. [December 2011]. Available: <http://www.gao.gov/assets/590/587301.pdf>

For these reasons, the Administration continues to support mandatory education on proper prescribing and addiction potential for prescribers and dispensers of these controlled substances, including for prescribers working for the Federal Government. Several states, including Iowa,⁴⁹ Massachusetts,⁵⁰ and Utah,⁵¹ have passed mandatory prescriber education legislation, and we strongly encourage other states to explore this as an option.

⁴⁹ Iowa Board of Medicine. “New rules require physicians to complete training on chronic pain, end-of-life care.” State of Iowa. [August 2011]. Available: http://medicalboard.iowa.gov/Board%20News/2011/New%20rules%20physicians%20to%20complete%20training%20chronic%20pain_08182011.pdf

⁵⁰ Executive Office of Health and Human Services. “PMP and Mandatory Educational Requirements for Prescribers.” Commonwealth of Massachusetts. [October 2011]. Available: <http://www.mass.gov/eohhs/provider/licensing/occupational/dentist/pmp-and-mandatory-educational-requirements-for-pre.html>

⁵¹ Utah Division of Occupational and Professional Licensing. *Utah Controlled Substances Act, 58-37-6.5*. State of Utah. [May 2012]. Available: <http://www.dopl.utah.gov/laws/58-37.pdf#page=24>