AMA
AMERICAN MEDICAL ASSOCIATION

ama-assn.org
t (312) 464-5000

January 7, 2014

The Honorable Joseph Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone:

On behalf of the physician and student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the additional questions submitted by Representatives Ed Whitfield and Kathy Castor as part of the Committee on Energy and Commerce Subcommittee on Health's hearing entitled, "Examining Public Health Legislation to Help Local Communities." For ease of reference, I have included the questions transmitted in your letter along with the responses below. The AMA applauds your leadership in working to ensure passage of H.R. 3528, the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2013" (NASPER 2013). In short, passage of NASPER 2013 and full appropriations are urgently needed to ensure that physicians across the country have patient specific information at the point-of-care as part of their workflow to combat prescription drug abuse while ensuring patients with the legitimate need of pain management continue to have access to medically necessary care. With the telecommunication and related technological advances we are experiencing—which can be implemented when funded adequately—prescription drug monitoring programs will be able to offer individualized information to support clinical decision-making as well as population based data to establish a public health set of solutions and education programs for prescribers, state policy-makers, and the impacted communities.

Questions Posed By the Honorable Ed Whitfield

1. According to a recent report by the Department of Health and Human Services, drug overdose rates have increased five-fold since 1980, and in 2009 drug overdose deaths outnumbered those of motor vehicle crashes for the first time in U.S. history. Would you elaborate on the reasons why we have seen such an alarming increase in overdose deaths? Apart from the tragic deaths that occur as a result of drug overdose, what other impacts does this problem have on our health care system?

   Drug overdose deaths include illicit drugs and a wide variety of prescription drugs, many of which are not controlled substances. In 2010, 57 percent of overdose deaths involved pharmaceuticals. Of these, approximately 75 percent were unintentional, 17 percent were suicides, and the rest were undetermined. Opioids (75 percent), benzodiazepines (29 percent), antidepressants (18 percent), and antiepileptic and antiparkinsonism drugs (8 percent) were the pharmaceuticals, alone or in combination, most commonly involved in prescription drug-related overdose deaths.

   The increase in prescription drug overdose death corresponds to the rise in overall prescribing rates and diversion and abuse of prescription drugs, particularly certain opioids, coupled with a lack of treatment options for those suffering from addiction, and correspondingly low awareness and use of

overdose prevention options, such as naloxone in community-based settings. It also reflects that until relatively recently, most physicians and county and state health regulators and policy-makers have not had access to robust epidemiological data to identify doctor-shoppers, prescriber-specific information, and trends in local and regional areas. The availability of this information to prescribers, dispensers, and public health policy-makers would support individualized prescribing, as well as targeted educational and regulatory policies based on specific needs of local and state jurisdictions. While there is a national public health crisis, local and regional jurisdictions face different causes, challenges and patterns of abuse, diversion, overdose and death. NASPER 2013 will provide support for prescription drug monitoring programs that are proven to provide data that can be used by prescribers and public policy-makers and regulators to implement targeted policies rapidly as this epidemic of addiction evolves.

This overdose trend is exacerbated by the limited access to existing options to treat prescription drug addiction, limited patient resources or insurance coverage for such treatment, and equally low awareness of where to go for help among many who suffer from addiction. The availability of in-patient programs to treat prescription drug addiction is far exceeded by the number of individuals requiring such treatment. Unfortunately, despite efforts to increase the number of physicians who offer out-patient treatment, the number participating in such programs remains far too low to meet the existing and growing need of individuals requiring such medical care. Low awareness among physicians may be one factor for the current participation rates, but other factors that have been raised include the regulatory requirements and interactions with a law enforcement agency—the Drug Enforcement Administration (DEA) —which conducts onsite unannounced audits without regard to the operations of a medical practice which can be highly disruptive to scheduled patients—including those in practices where the majority of the patients are not receiving medical care for addiction.

The costs of prescription drug overdose to the health care system are significant as treatment for overdose typically will occur in hospital emergency departments—the frontlines of many public health crises. Unfortunately, there remain far too few treatment programs and out-patient providers available to reverse the current trend of addiction. Considerable effort and resources must be invested to rapidly and safely increase the availability of addiction treatment programs. The number of unintentional overdoses has increased in a parallel fashion with the estimated number of emergency department visits and the number of patients seeking substance abuse treatment of opioid dependence and addiction. In addition to the direct health care costs shouldered by hospitals in the emergency department, including uncompensated care for patients who need to be stabilized but do not have health insurance or financial resources, the indirect costs, while more difficult to quantify, are no less significant or important. These are costs borne by other patients who have delayed treatment and access to medical services in emergency departments or hospital in-patient care.

2. Reports have shown that there is a correlation between opioid-related morbidity and mortality and the prescribing and dispensing of opioid analgesics. Would you discuss the factors surrounding the rise in opioid prescribing we have seen in recent history? What are some of the issues physicians face when approached by patients who are seeking treatment for pain? How do we balance the need to ensure access to pain treatment for those who legitimately need it with stemming the epidemic of abuse we are faced with?

There are a host of factors that have led to the rise in opioid prescribing. The last 15 years have seen a greater emphasis on managing pain as 2001-2010 was declared the "Decade of Pain Control and Research," the Joint Commission on Accreditation of Healthcare Organizations' (Joint Commission) standards were implemented mandating an aggressive evaluation and treatment of patient-reported pain, and patient satisfaction surveys on pain have assumed an increasing role in prescriber and hospital evaluation. Other major factors include the rise of criminal syndicates running pill-mills, as well as the systematic lack of access to mental health services, which is significant factor for the most at-risk population abusing prescription drugs.

In 2001, the Joint Commission made pain management a condition of accreditation. Those facilities that fail to follow the requirements risk their accreditation. Even with this emphasis, there is evidence that there remains systemic under-treatment of pain. As a result, in 2010 as part of the Affordable Care Act (ACA), the U.S. Department of Health and Human Services (HHS) was required to commission a report from the Institute of Medicine (IOM) to examine pain as a public health problem. In 2011 the IOM issued the report with a recommended action plan that emphasized a population-level prevention and management strategy. The IOM called for improved data to ensure that the groups of people currently underdiagnosed and undertreated were provided appropriate medical care and encouraged federal and state agencies and private organizations to accelerate the collection of data on pain incidence, prevalence, and treatments. It is estimated that nearly one-third of people will experience chronic pain at some point in their lives. As the Baby Boom portion of the population ages, the need to appropriately address pain management needs will only grow. Prescription drug monitoring programs that emphasize a public health approach dovetail with efforts to identify those inappropriately seeking prescription drugs for non-medical uses, while ensuring those who have legitimate need of pain treatment receive medically necessary care. The pressure to appropriately treat pain has increased since underprescribing pain medications is considered as inappropriate as overprescribing. For example, there are media reports that the Oregon and California medical boards have disciplined physicians for undertreating pain, and New Mexico revised its medical practice act to specify that under-treatment may be grounds for unprofessional conduct.

A second major factor involves criminal actors. With the advent of higher potency and long-acting opioid analgesic products, a number of high-volume "pill mills" have emerged in various states, contributing to the doubling in opioid analgesic use, which has occurred over the last decade. The DEA has documented the ability of these criminal syndicates to move from one state to another once the federal government and local jurisdiction implement effective enforcement strategies to shut-down these criminal enterprises that enlist unscrupulous prescribers and/or dispensers in illegal conduct. Continued coordinated efforts among the DEA and local jurisdictions to combat pill mills will remain essential as such individuals are not interested in educational opportunities or information on doctor shoppers at the point-of-care to inform clinical decision-making.

Finally, another significant factor involves the lack of access to mental health services. People with mental health disorders are at increased risk for heavy therapeutic use, non-medical use, and overdose of opioids. The Center for Disease Control and Prevention (CDC) analysis highlights the frequent involvement of other drugs typically prescribed for mental health conditions in overdose deaths. According to HHS, in 2012, nearly 91 million adults lived in areas where shortages of mental health professionals made it hard to obtain treatment. HHS told Congress this year that 55 percent of U.S.

counties have no practicing mental health professionals. And even in well-served areas, demand is so high that it can be difficult for new patients to be accepted by a provider.

Developing a public health-based approach to harmful drug use requires having treatment services available for those with substance use disorders, including addiction. Between 2004 and 2012, the number with opioid analgesic dependence or abuse increased from 1.4 million to 2.1 million and the number of persons with heroin dependence or abuse in 2012 (467,000) was approximately twice the number in 2002 (214,000). In 2012, only about 11 percent of those persons aged 12 or older needing treatment for an illicit drug problem received treatment in a specialized facility. Among those who reported that they believed they needed treatment for their illicit drug or alcohol use problem, the primary reason for not receiving treatment was a lack of insurance coverage and inability to pay the cost.

Reductions in the supply of prescription drugs, however, may be a key factor in the unintended yet tragic, consequence of increases in illicit drug use—most commonly, heroin. Heroin is a less expensive yet more potent opiate. According to the National Survey on Drug Use and Health, "[t]he number of persons who were past year heroin users in 2011 (620,000) was higher than the number in 2007 (373,000)." The AMA urges Congress, as it considers strategies to curb inappropriate use of prescription drugs, to support efforts to address the need for the prevention of illicit drug use and the treatment of those who are addicted. Just addressing the supply will not by itself solve the problem of demand and could drive an unintended increase in overdose and death.

3. & 4. Combined Answer. According to the Department of Health and Human Services HHS, one of the most promising clinical tools to address prescription drug abuse are state PDMPs. These programs are designed to monitor prescribing and dispensing of controlled substances and can provide a prescriber or pharmacist with critical information regarding a patient's prescription history. Why have PDMPs been successful in curbing abuse of prescription drugs? Would you describe for the Committee how these PDMPs function and what role providers play within the system? What are the biggest challenges faced by stakeholders, such as states, providers, and pharmacies when it comes to PDMPs?

4. According to the Department of Health and Human Services, as of July 2013, 47 states had operations PDMPs. However, they are significantly underutilized by providers. A number of factors contribute to this underutilization, including cumbersome nature of accessing current systems and privacy concerns. Would you elaborate on some of the factors that may lead to underutilization of PDMPs? What steps can be taken to increase prescriber usage of PDMPs? States such as Kentucky and New York have actually passed laws requiring prescriber registration and utilization of PDMPs. What is your take on this approach?

In 2005, NASPER was signed into law. Although millions were authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMPs. In theory, PDMPs were to provide reliable and actionable information. In reality, however, it has been only in the past couple of years that most states have finally passed state legislation establishing PDMPs, and the majority of PDMPs are not real-time, interoperable, or available at the point of care as part of a physician's workflow. Only five states provide data within 24 hours, according to the National Alliance for Model State Drug Laws (NAMSDL); one state provides data within three days,

32 states take up to a week to provide data, and nine states take between two weeks and one month. With respect to interstate interoperability, NMSDL reports that 43 states can legally share data across state lines, but only 20 can legally share data with other PDMPs. Continued support for interstate interoperability will help move this issue forward.

PDMPs need to be adequately funded, maintained and modernized to ensure their long-term ability to help combat prescription drug abuse, misuse and diversion. The Congressional Research Service estimates that PDMP costs may vary widely, with start-up costs ranging from $450,000 to over $1.5 million and annual operating costs ranging from $125,000 to nearly $1 million. There is a pressing need right now for Congress to appropriate funding for NASPER, but state and private funding will be needed to maintain and undertake much needed upgrades and modernization of PDMPs. The AMA continues to strongly advocate for federal and state funding to ensure PDMPs have the support they need.

In the instances when PDMPs have been adequately maintained and funded, are available at the point-of-care with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned. This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances.

Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs. There is an immediate need to upgrade existing PDMPs and to ensure that prescribers have appropriate latitude to assess when consultation is needed. For example, while it makes sense for a pain medicine specialist to regularly consult a modernized PDMP that provides comprehensive, accurate data for his or her patients to review patient compliance and the potential for doctor shopping, it may not be necessary for an orthopedic surgeon to consult a PDMP prior to prescribing pain medicine to control post-surgical pain in a pediatric patient. Similarly, it makes sense for a physician who is contemplating initiating treatment with opioids, but believes the patient may be a risk for aberrant behavior or a physician who is treating patients with chronic pain with opioid analgesics, to consult the PDMP, if the PDMP data are reliable and accurate.

The key to determining which physicians should regularly check a PDMP prior to prescribing a controlled substance is to carefully consider the type of practice and the patient population of the physician. For example, the vast differences between providing care in an oncology practice, interventional radiology practice, or emergency department raise different issues whose "solutions for prescription drug abuse and diversion" cannot be understood or achieved through a one-size-fits-all mandate to check the PDMP.

5. One method that has been suggested to increase use of PDMPs is to leverage health information technologies such as electronic health records and clinical decision support tools that would streamline access to PDMP system. What are the benefits and risks of this type of integration? Do you think this is a mechanism that would be embraced by the provider community?

Currently, physicians and other health care providers are working to implement requirements related to electronic health records (EHR) and many are also incorporating decision support tools. While, ideally, vendors would offer options to integrate such information, the technical challenges remain significant for many aspects of EHR adoption and implementation. The first priority for PDMP adoption would be to ensure that such programs are modernized and have a public health focus. The AMA strongly supports efforts by the National Association of Boards of Pharmacy (NABP) to promote the "PMP InterConnect" program, an interstate data sharing hub that is operated by NABP at no cost to the states. NABP reports that by the first quarter of 2014, 25 states will be using the system and sharing data across state lines. Despite this success and positive impact on the public health, PDMPs are still being asked to comply with the Bureau of Justice Assistance (BJA) technological standards that reportedly are onerous and do not enhance the program. We understand that congressional leaders have urged BJA to approach this issue with greater flexibility, but it has not been forthcoming. NASPER grants do not include such requirements which should accelerate the uptake of the InterConnect program and enhance the quality of the data physicians and other prescribers and dispensers receive. Furthermore, the public health focus of NASPER is essential since over 95 percent of PDMP usage comes from healthcare providers.

6. A key component of our battle against prescription drug abuse is education—particularly as it relates to pain management and substance abuse. Would you describe the current system of education for physicians as it relates to these aspects of health care? What are the biggest problems with the current system of provider education and what can be done to improve it?

This response is specific for physicians and physicians-in-training pursuing an MD degree, and does not address the current state of education for doctors of osteopathy and dentists, or nurse practitioners and physicians assistants who may have independent prescribing privileges for controlled substances depending on their location.

Medical education curricula across the continuum address pain management and substance abuse. The organization that accredits undergraduate medical education, the Liaison Committee on Medical Education (LCME) contains a standard (ED-10) that includes pain management and substance abuse as subjects that should be present in required courses and clerkships in medical schools. In a survey of medical schools for the academic year 2012-2013, all 135 schools that responded included pain management and substance abuse within a course required for graduation. An opportunity exists to provide grants to fund innovative approaches and increased integration of pain topics into medical school curricula.

Pain management and substance abuse are also included in graduate medical education curricula. Several specialties address management of pain and/or substance abuse as important foci of the health care delivered by certified specialists, including Addiction Psychiatry and Medical Toxicology and Pain Medicine (a subspecialty of Anesthesiology, Neurology, Physical Medicine and Rehabilitation, and Psychiatry). In addition, the primary care specialties of Internal Medicine and Family Medicine require their trainees to demonstrate proficiency in the use of pharmacotherapy. More recently, attention has been devoted to developing targeted training to assist residents in managing issues at the interface of substance abuse and chronic pain.

In 2007 the National Institute on Drug Abuse (NIDA) partnered with eight medical schools around the country and the AMA's Innovative Strategies for Transforming Education of Physicians medical education research collaborative. These Centers of Excellence for Physician Information developed innovative drug abuse and addiction curriculum resources with the goal of helping to fill the gaps in current medical students/resident physician curricula. These curriculum resources are available on the NIDA Web site as a service to academic medical centers seeking scientifically—accurate instructional information on substance abuse.

At least 25 state medical societies sponsor courses on various aspects related to pain management and responsible opioid prescribing. Based on grant support from the Substance Abuse and Mental Health Services Administration and as part of the Prescriber Clinical Support System for Opioid Therapies (www.pcss-o.org), the AMA offers an updated comprehensive course on pain management that reflects contemporary concerns about the role of opioid analgesics in the management of chronic pain. Course materials are freely available. As part of our collaborative efforts in the PCSS-O, the AMA also is offering a series of free webinars on various aspects related to the intersection of pain, substance use disorders, and responsible opioid prescribing.

At least 10 states require that physicians complete continuing medical education (CME) in pain management and/or responsible controlled substance prescribing in order to renew their medical license. The AMA supports positive incentives to encourage prescribers to take CME in pain management and /or responsible controlled substance prescribing. National mandatory CME raises a number of concerns as a one-size—fits—all approach does not account for differential training that physicians receive including specialty, the state patterns of abuse and diversion, and the physician patient mix served. All of these are relevant factors in assessing whether CME in pain management and/or responsible controlled substance prescribing is appropriate for a physician. There are two areas where congressional funding to support research would support targeted, high-value evidence to drive policymaking. Funding research to evaluate the efficacy of existing state mandatory CME requirements, some of which have been in place for a number of years, would be highly beneficial. In addition, comparative effectiveness research to assess the impact on outcomes of modernized PDMPs that provide individualized patient-specific information at the point of care as compared to other broader strategies such as mandatory CME, would also improve the ability of lawmakers to craft solutions to meet the particular patterns of abuse and diversion in a particular state.

The opportunity remains to provide physician tools at the point of care that can be relied upon when making individualized, patient-centered determinations that we know will work if properly modernized. This is particularly true when addressing pain management or addiction. While PDMPs are not considered part of prescriber education, the information generated by a modernized PDMP can support both individualized clinical decision-making as well as targeted education efforts. The reauthorization of NASPER is an important opportunity to support informed physician clinical decision-making in order to ensure patients in need of patient management receive medically necessary care and those who require treatment for addiction are also correctly identified.

7. Many experts believe that prescribing guidelines related to opioids have the potential to reduce the instance of abuse. They are intended to help providers identify patients who are appropriate candidates for opioids and provide information on treating and monitoring them. It is my understanding many states have issued guidance but that research pointing to their effectiveness is

limited. Do you believe a defined set of prescribing guidelines has the potential to reduce abuse? What is the best way to go about formulating these guidelines and how do we maximize utilization of these guidelines?

Practice (or prescribing) guidelines are generally most applicable and effective when the disease or condition in question has readily identifiable, evidence-based diagnostic and treatment criteria. The question as stated does not acknowledge that the issues of appropriate pain management and reducing abuse/diversion of controlled substances cannot (or should not) be separated with respect to their overall impacts on public health. Pain in responsive human beings is a conscious experience involving interpretation of (painful) sensory input that is influenced by emotion, cognition, memory, interpersonal and social context and other factors. Because there is no objective indicator for pain (and pain cannot be proved or disproved) the best clinical approach in most circumstances is to assume that the patient is reporting a true experience, unless there is evidence to the contrary. Accepting a patient's complaint as valid does not require clinical identification of a physical cause, or demand the initiation of a specific treatment. In patients suffering from neuropathic or central pain syndromes, pain generating mechanisms develop and become persistent after the original injury has healed. Accordingly, the evaluation and assessment of persistent pain, in particular, has multiple dimensions.

Similarly, the ability of clinicians to identify individuals who are intent on diverting controlled substances, or who may eventually develop behaviors consistent with a substance use disorder is a (very) imprecise science. While we would agree that patients being considered for long term opioid therapy should be screened for a concurrent substance use disorder and for factors that may increase the risk of drugs with abuse liability, existing tools have limited utility. The occurrence of aberrant drug-related behaviors varies, exists along a continuum, and can be difficult to interpret. In general, the use of a universal precautions approach coupled with a comprehensive patient evaluation and risk assessment is recommended, along with a patient-centered treatment plan that incorporates a structured periodic review and compliance monitoring to inform the overall management strategy.

A balanced view in the development of policies, laws, and regulations should extend to the clinical setting. Pain is highly prevalent and destructive. Opioids and other controlled drugs are essential medications and have many legitimate medical uses. Prescription drug abuse, addiction, diversion and unintentional overdose are serious risks that must be considered whenever these drugs are potentially appropriate. An overt focus only on the abuse potential of a drug may lead to practice patterns that avoid their use even in the face of a generally accepted indication and situations where they are never used for a more controversial indication (e.g., chronic non-cancer pain) even when a subset of patients obtains clear benefit. Conversely, clinicians who are not sufficiently cognizant of the public health problem of prescription drug abuse may not apply appropriate risk assessment and management strategies. Pain is highly individualized, varies in its dimensions across practice settings, and presents unique challenges depending on the medical specialty. Accordingly, a "one-size—fits—all" approach to clinical guidance is insufficient and will not promote a balanced approach to addressing this problem. A common philosophical approach and tool kit that can be applied in an individualized manner is needed.

Question Posed The Honorable Kathy Castor

Dr. Stack, you mentioned in your testimony the benefits of PDMPs with up-to-date information for physicians to access. If Congress reauthorizes NASPER and fully funds it, what will this mean for combating prescription drug abuse?

> Reauthorization of NASPER and full appropriations is urgently needed to ensure that physicians across the country have patient-specific information at the point-of-care as part of their workflow to combat prescription drug abuse while ensuring patients with the legitimate need of pain management continue to have access to medically necessary care. In light of the telecommunication and technological advances we are experiencing—PDMPs will be able to offer individualized information to support clinical decision-making as well as population based data to establish a public health set of solutions and education programs for prescribers, state policy-makers, and the impacted communities. The AMA continues to strongly advocate for federal and state support to ensure PDMPs have the support they need. In the those instances when PDMPs have been adequately maintained and funded, are available at the point-of-care with up-to-date information, and integrated into physician workflow, the efficacy of PDMPs is remarkable. As a pilot, Ohio placed PDMPs in emergency departments and found that 41 percent of prescribers given PDMP data altered their prescribing for patients receiving multiple simultaneous narcotic prescriptions. Of these providers, 63 percent prescribed no narcotics or fewer narcotics than originally planned. This indicates that PDMP data can help inform sound clinical decision-making to ensure prescriptions are medically-necessary, reducing illicit use of controlled substances. Modernized PDMPs can provide physicians with a basic tool to make treatment determinations based on patient-specific needs.

Thank you again for the opportunity to provide the AMA's views on the importance of funding to support PDMPs. The AMA urges Congress to act swiftly to re-authorize NASPER and provide full appropriations.

Sincerely,

Steven J. Stack, MD
Chair, Board of Trustees

cc: James L. Madara, MD