RESPONSES TO
QUESTIONS SUBMITTED FOR THE RECORD TO
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FOLLOWING MAY 1, 2015, HEARING ENTITLED,
"WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT
THE OPIOID ABUSE EPIDEMIC?"
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

The Honorable Marsha Blackburn

1. ONDCP's plan recognized that "as a Nation, we must take urgent action to ensure the appropriate balance between the benefits prescription medications offer in improving lives and the risks they pose. No one agency, system, or profession is solely responsible for this undertaking. We must address this issue as partners in public health and public safety."

   With all this in minds, does ONDCP support the goals of the "Assuring Patient Access and Effective Drug Enforcement Act," H.R. 471, which would require all affected stakeholders to work together to develop solutions in a collaborative manner to combat prescription drug abuse while also making sure that legitimate patients can still access their critical pain medications?

ANSWER:

It is important that any measure to address the prescription opioid epidemic addresses the public health consequences of the epidemic while ensuring that the tools available to law enforcement to address the public safety aspects of illicit drug use are not compromised. We do note that the House-passed version of H.R. 471 removes the Office of National Drug Control Policy (ONDCP) as a partner in the report to Congress on the effects of law enforcement activities on patient access to medications. We believe that ONDCP would have important contributions in the collaborative development of materials that address this subject, as you have suggested in your statements in regard to this bill.[1]

Nonmedical prescription pain medicine use is more common than use of any category of illicit drug in the United States except for marijuana. In 2013, over 4.5 million Americans ages 12 and older reported using prescription pain relievers non-medically within the past month.[2] In 2011 alone, 1.2 million emergency department (ED) visits involved the non-medical use of

[1] Blackburn Leads Effort to Combat Prescription Drug Abuse, Press Release, April 21, 2015. Available: http://blackburn.house.gov/news/documentsingle.aspx?DocumentID=397716

[2] Substance Abuse and Mental Health Services Administration. *Results from the 2013 National Survey on Drug Use and Health: Detailed Tables*. Department of Health and Human Services. [November 2014]. Available: http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabsPDFWHTML2013/Web/HTML/NSDUH-DetTabsSect7peTabs1to45-2013.htm#tab7.3b

pharmaceuticals.[3] Of these 1.2 million ED visits, opioid pain relievers accounted for the single largest drug class, accounting for approximately 488,000 visits. This is nearly triple (2.8 times) the number of ED visits involving opioid pain relievers just 7 years earlier in 2004 (173,000). Opioid pain relievers were involved in over 16,200 of the nearly 44,000 drug overdose deaths in 2013.[4] And these figures do not include deaths involving heroin, an illicit opioid that we are observing in increasing numbers.

Increased access to prescription painkillers in the past 15 years has corresponded with these substance use and medical consequences. The opioid drug abuse epidemic has grown proportionally with the tremendous increase in the prescribing of these medications since the mid-1990s. Therefore, two of the four pillars of the Administration's *Prescription Drug Abuse Prevention Plan (Plan)*[5] – education and monitoring – focus on ways that prescribers more safely can provide opioid medications to their patients who legitimately need them to address their medical needs while avoiding prescribing these drugs for patients who may be using them non-medically or may not benefit from their use.

Managing patients' pain is a crucial area of clinical practice, but research indicates that health care practitioners receive little training on pain management, safe opioid prescribing, or recognizing and treating substance use disorders.[6,7] Thus, one of the pillars of the *Plan* focuses on the need for prescribers to become better educated about appropriate prescribing practices. One of the action items in the Plan is requiring mandatory prescriber education connected to controlled substances licensure. The low response rates by prescribers to voluntary programs underscores the need for a mandatory education requirement on safer prescribing and substance use disorders, as has been adopted in at least eight states. We are gratified that some Members of Congress have proposed measures to enact mandatory prescriber education. We also note that efforts to train and educate health professionals on safe opioid prescribing, including the development of prescribing guidelines for chronic pain by the Centers for Disease Control and Prevention, is one of the three priority areas of the initiative announced by the Department of Health and Human Services (HHS) in March 2015 aimed at reducing opioid dependence and overdose.[8]

The Plan's second pillar, monitoring, also addresses a way to transform prescriber practices to avoid the over-prescription or inappropriate prescribing of opioid drugs. Prescription Drug Monitoring Program (PDMP) data can help prescribers and pharmacists identify patients who may be at risk for substance use disorders, overdose, or other significant health consequences of

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[3] Substance Abuse and Mental Health Services Administration. *Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits*. U.S. Department of Health and Human Services. [May 2013]. Available: http://www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm#5.2

[4] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death, 1999-2013 on CDC WONDER Online Database, released 2015. Extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on January 30, 2015.

[5] Office of National Drug Control Policy. *Epidemic: Responding to America's Prescription Drug Abuse Crisis* [2011] Available: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf

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

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

[8] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. [March 2015]. Available: http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/ib_OpioidInitiative.pdf.

misusing prescription opioids. They also identify patients who may benefit from substance use disorder assessment and, if indicated, treatment. State regulatory and law enforcement agencies may also use this information to identify and prevent risky prescribing and possible diversion of controlled substances. Aggregate data from PDMPs can also be used to track the impact of policy changes on prescribing rates.

The third pillar of the *Plan*, proper medication disposal, addresses ways in which patients may become proactive in addressing this epidemic by providing means to dispose of unused, unneeded, or expired medications in a manner that will help prevent diversion and abuse and will help to reduce the introduction of drugs into the environment.

Action in these three areas will be helpful to address the opioid drug abuse epidemic, but we must be mindful of the continued need for the fourth pillar of the *Plan* – appropriate law enforcement – so that, like with all drug policy matters, we can approach this problem by addressing a public health concern while ensuring public safety. Our law enforcement partners have begun to adopt this balanced public health/public safety approach where practicable. For example, the law enforcement community has been receptive to equipping first responders with naloxone, an emergency opioid overdose reversal medication. Laws that provide criminal and/or civil liability protections to lay persons or first responders who administer naloxone enhance more widespread use, when needed, of naloxone. These actions to break the cycle of drug use, crime, and incarceration are transforming law enforcement as a partner in providing public health services, helping those with substance use disorders get the treatment that they need. Increasing access to naloxone is another priority area of the HHS opioid initiative.

As you correctly point out, we must take an approach to addressing the opioid drug abuse epidemic that balances the need to address the health concerns of both those who with legitimate need for pain medications and those with untreated substance use disorders with the need to support our law enforcement partners in their efforts to protect public safety.

The Honorable Michael Burgess

1. While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?

ANSWER:

In a Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs),[1] the Office of the National Coordinator for Health Information Technology (ONC) at the Department of Health and Human Services proposed as a requirement for certification that electronic health records (EHRs) be capable of "streamlining access to PDMP [prescription drug monitoring program] data." There was general support by the public for the proposed certification criteria; however, the Meaningful Use Workgroup of the Health IT Policy Committee (a Federal Advisory Committee), which was tasked with further exploring the inclusion of the PDMP criterion, ultimately decided that the technical standards to share information between an EHR system and a PDMP were not mature enough at the time to be required for certification.

In an effort to solve this interoperability challenge, ONC and HHS's Substance Abuse and Mental Health Services Administration are leading work through the Standards and Interoperability (S&I) Framework's PDMP/Health IT Integration initiative to examine the technical standards necessary to enable seamless data exchange between PDMPs and health IT systems (e.g., electronic health records, health information exchanges, and pharmacy systems).[2] PDMPs and health IT systems use different standards to communicate. This work harmonizes and maps the data elements of those standards to enable the information contained within the PDMP to be delivered directly to the hands of healthcare providers via their health IT systems, consequently solving the issue of having to log in to multiple systems and interrupting the clinical workflow to get the valuable PDMP data.

The S&I Framework, a collaborative community of participants from the public and private sectors focused on facilitating the functional exchange of health information, is pilot testing three standards (National Council for Prescription Drug Programs (NCPDP) 10.6; American Society for Automation in Pharmacy (ASAP) Web Services; and HL7 V2 messaging) that the S&I community agreed on. Currently, there are 5 active pilot teams testing the NCPDP 10.6 standard, with the anticipated deadline being late summer 2015. The ultimate timeline for the initiative is still being determined. Upon completion of NCPDP pilot testing, work will begin to pilot test the other standards, and a more precise timeline to achieve PDMP/Health IT integration will become clearer, as well as the necessary steps to facilitate this integration.

[1] http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf (Jan 2013)
[2] See http://wiki.siframework.org/PDMP+%26+Health+IT+Integration+Homepage

The Honorable David McKinley

1. What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?

ANSWER:

Science demonstrates that the recent rise in opioid use disorders and the dramatic medical and social consequences we are seeing, including overdose, heroin use, injection drug use, and babies born exposed to opioids, all have roots in prescription opioid prescribing. It is essential for prescribing practices to change. While it is important to pursue all the action items in the Administration's *Prescription Drug Abuse Prevention Plan*, the single most important thing we can do is institute a mandatory requirement for the existing prescriber workforce to undergo training on safe opioid prescribing and substance use disorders. ONDCP is working with the Federal partners to determine the best approach to instituting mandatory prescriber education.