

October 31, 2017

The Honorable Chris Christie
Chair, President's Commission on Combating Drug Addiction and the Opioid Crisis
c/o The Office of National Drug Control Policy (ONDCP)
The White House
Washington, DC 20502

Re: President's Declaration of the Opioid Epidemic as a National Public Health Emergency

Dear Governor Christie:

On behalf of McKesson, I am pleased to submit comments on the President's Declaration of the Opioid Epidemic as a "national public health emergency." Our comments include recommendations which we have previously shared with the Commission, as well as new recommendations, which we believe will help to ensure that we can be, as the President stated, "the generation that ends the opioid epidemic."

About McKesson

For 184 years, McKesson has led the industry in the delivery of medicines and healthcare products. McKesson is the nation's largest distributor of pharmaceuticals as well as the leading supplier of biotechnology and specialty pharmaceutical products and services for providers and patients.

The Opioid Abuse Epidemic

Our country's opioid abuse epidemic is affecting communities across America at increasingly alarming rates. The opioid epidemic is a complicated, multi-faceted public health crisis that cannot be solved by any one stakeholder. We believe that it needs to be addressed through a comprehensive approach that includes the doctors, patients, pharmacists, insurance companies, government payers (such as Medicaid and Medicare), distributors, manufacturers, law enforcement, and regulators.

McKesson's White Paper on Combating the Opioid Epidemic

As the epidemic worsened in recent years, we wanted to help the healthcare system at large look at holistic ways to combat the problem. That's why two years ago, we created an internal task force of experts, including clinicians and public policy experts. Earlier this year, the group released its policy paper, "Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions," which includes six major areas of policy recommendations that we believe will help curb the opioid epidemic. The implementation of these policy and business solutions could significantly slow the abuse and diversion of opioids, to the benefit of patients and their families.

The policy paper details McKesson's recommendations to improve prescribing and dispensing practices towards our country's shared goal: to combat and ultimately end the opioid abuse and misuse epidemic. Our recommendations include the following:

- Require all payers and providers to use opioid management programs
- Require e-prescribing for all controlled substances nationally

- Harness the Food and Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) Program
- Fully leverage data analytics to identify patients most at risk and integrate a National Patient Safety Network into the pharmacy dispensing process (including cash prescriptions) and prescriber e-prescribing process
- Improve information sharing among Prescription Drug Monitoring Programs (PDMPs)
- Permit partial refills to reduce risks associated with an excess of unused pills

The policy paper also highlights McKesson's efforts to promote a secure supply chain and educate and equip our customers, prescribers and pharmacists. The policy paper is available at: www.mckesson.com/opioidpaper.

Additionally, we support the following:

- Requiring the Drug Enforcement Administration (DEA) to work closely with industry, and medical and pain communities, to revisit the annual quota on the production of opioids. The DEA should continue to evaluate the appropriate production limits (and/or revisit the DEA's quota for individual manufacturers)
- Enacting a national policy to limit the number of opioids prescribed, such as PhRMA's recent proposal to limit pills to a seven-day supply for acute pain treatment

We believe these changes can be acted upon quickly. Some may require federal or state legislation or regulatory action.

McKesson Comments on the President's Declaration of the Opioid Epidemic a National Emergency

McKesson supports the President's declaration of the opioid epidemic as a national public health emergency. We welcome this step which will help to tackle the opioid crisis in new ways and with a deepened sense of urgency. We support the President's call for the development and more widespread use of non-addictive painkillers, broader education and prevention efforts, and efforts to study and promote best practices for pain management. We urge the Administration and Congress to continue to explore both the adequacy of funding levels, and the most innovative public and private sector-generated public policy ideas that are critical to fighting this crisis.

In particular, we urge the Administration to consider the following recommendations, which we strongly believe are necessary to fulfilling the President's goal of ending the opioid epidemic as quickly as possible:

- Prioritize a National Patient Safety Network for Safe Dispensing and Prescribing of Opioids
- Leverage the Expertise and Experience of Pharmacists to Address the Opioid Epidemic

Prioritize a National Patient Safety Network for Safe Dispensing and Prescribing of Opioids

McKesson applauds the Commission for its continued focus on enhancement of prevention efforts and its recognition of the important role that technology and data can play in ending the epidemic. We support improvements in both formal and continuing medical education to address inappropriate overprescribing and to better inform clinical practice in pain management.

Education alone, however, is insufficient to fully address the opioid crisis. To make the most informed dispensing decisions, pharmacists need access to robust, real-time information that can draw upon and analyze data across all 50 states. This tool, a National Patient Safety Network ("Network"), as envisioned by the National Council for Prescription Drug Programs (NCPDP), a standards development organization providing healthcare solutions, would identify "red flags" and alert dispensers whenever patient safety

issues are identified. For example, in instances where there may be non-medical use of opioids, the Network would notify the pharmacist who could *voluntarily* check the prescription drug monitoring program (PDMP) before dispensing. According to an IMS Health study of the scope of the opioid misuse issue from a patient perspective, seven percent of patients were considered high risk to the point that a clinical decision should have been made by a doctor or a pharmacist not to prescribe or dispense a controlled substance.¹

The Network would complement PDMPs in two significant ways by: (1) providing alerts to dispensing pharmacists that are based on real-time, comprehensive prescription history data for all patients, regardless of location or setting of care, and (2) promoting more effective use of PDMP information since pharmacists would know when to consult the PDMP rather than having to check it for all patients. This tool is necessary because under the current system, pharmacists must leave their workstations to check a PDMP, and have no basis for knowing whether such a check is likely to yield clinically relevant information.² Unsurprisingly, research indicates that pharmacists do not always consult PDMPs. For example, a survey of pharmacists in Maine found that, in 2014, only 56 percent were using the state's PDMP.³ Delivering alerts through the very same system that pharmacists use as part of their dispensing process would save significant time and, most importantly, would increase the likelihood that pharmacists consult their PDMPs.

The Network could also benefit physicians, who according to two surveys (2014 and 2015), cited the time-consuming nature of retrieving data from PDMPs as a barrier to their use.^{4,5} The 2014 survey found that while doctors prescribed opioids for an average of 35 patients a month, they retrieved data from a PDMP for an average of only eight patients a month.⁶ The NCPDP solution proposes that all electronic prescriptions, as well as all pharmacy dispensing activity, be evaluated against the Network.

We urge the President to direct the FDA to utilize its existing REMS authority, to the fullest extent possible under the law, to support the development of a National Patient Safety Network. We believe this will help to bolster PDMP utilization in every state, promote data sharing and coordination, and ultimately save lives.

Leverage the Expertise and Experience of Pharmacists to Address the Opioid Epidemic

McKesson is pleased that last week, FDA Commissioner Dr. Scott Gottlieb called for the expanded use of medication-assisted treatment (MAT) for opioid addiction, as a means to reduce overdoses and deaths. Pharmacists can provide this MAT which combines the use of medication with counseling and behavioral therapies to treat substance use disorders. Pharmacists can also administer Naloxone, a drug that reverses an opioid overdose without a prescription, where allowed by state law using a statewide protocol.

Our country's opioid epidemic is the public health crisis of our time. Therefore, we must make it a priority to harness the full breadth of all of our clinical capabilities. Pharmacists can help address our nation's opioid epidemic by leveraging their relationship with patients. Pharmacists are uniquely positioned to have a comprehensive view of a patient's health status. They see the prescriptions and diagnoses of multiple physicians. This vantage point allows pharmacists to detect potential problems of drug interactions with opioids, potential misuse and/or signs of potential abuse. Additionally, pharmacists provide counseling and education to patients, and are viewed as a trusted resource for information.

Given our country's impending physician shortage crisis and the availability of highly skilled, medically-trained pharmacists that are ready and able to help now, we encourage the Administration to consider policies that make it easier for pharmacists to provide MAT and other clinical services to individuals suffering from opioid addiction.

Conclusion

On behalf of our CEO, John Hammergren, and the 70,000 men and women of McKesson, I can assure you that McKesson stands ready to work with the Administration, the Commission, Congress, the states, and all

stakeholders to implement new solutions to tackle the opioid epidemic. We are committed to engaging with all who share our dedication to acting with urgency to address this epidemic and working together to end this national crisis. We would welcome the opportunity to further share our perspectives and experiences with the Commission. Should you have any questions, please contact Matt Shiraki, Director of Public Policy, at Matt.Shiraki@McKesson.com.

Sincerely,



Pete Slone

References

¹ "IMS Health Study on Controlled Substance Misuse Underscores Importance of Clinical Intervention at Point of Prescribing," NCPDP Foundation Study, Source: CS Ratings, QuintilesIMS, time period reflects 12 months ending February 2016. Available at: <http://ncpdpfoundation.org/news-events.aspx>

² "NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances." Paper. National Council for Prescription Drug Programs. November, 2016. Available at: [http://www.ncdp.org/NCPDP/media/pdf/wp/NCPDP_PDMP_WhitePaper_201611-\(2\).pdf](http://www.ncdp.org/NCPDP/media/pdf/wp/NCPDP_PDMP_WhitePaper_201611-(2).pdf)

³ Piper, Brian J., Clare E. Desrosiers, John W. Lipovsky, Matthew A. Rodney, Robert P. Baker, Kenneth L. Mccall, Stephanie D. Nichols, and Sarah L. Martin. "Use and Misuse of Opioids in Maine: Results From Pharmacists, the Prescription Monitoring, and the Diversion Alert Programs." *Journal of Studies on Alcohol and Drugs* 77, no. 4 (2016): 556-65

⁴ Lainie Rutkow, Lydia Turner, Eleanor Lucas, Catherine Hwang and G. Caleb Alexander. Most Primary Care Physicians Are Aware Of Prescription Drug Monitoring Programs, But Many Find The Data Difficult To Access. *Health Affairs* 34, no.3 (2015):484-492

⁵ Gillian J. Leichtling, Jessica M. Irvine, Christi Hildebran, Deborah J. Cohen, Sara E. Hallvik, Richard A. Deyo, Clinicians' Use of Prescription Drug Monitoring Programs in Clinical Practice and Decision-Making: Table 1, *Pain Medicine*, 2016, pnw251

⁶ Ibid.