June 15, 2016

Dear Conferees:

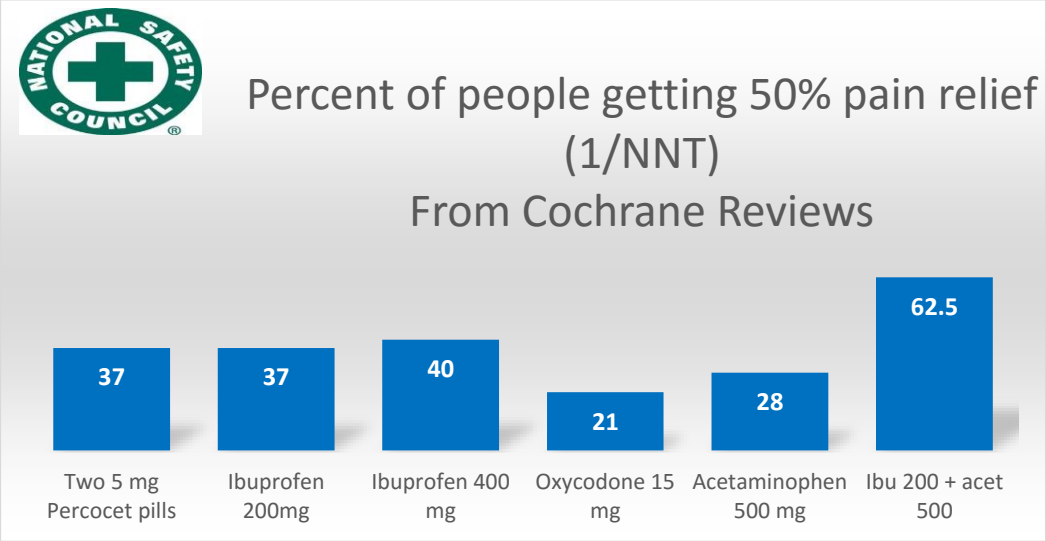
The United States is in the midst of a severe epidemic of opioid addiction and overdose deaths. Drug overdose deaths, once rare, have increased sharply over the past 20 years and recently surpassed car crashes as the leading cause of unintentional death. From 2000 to 2014, nearly 235,000 American lives were lost to opioid-related overdoses (190,000 from prescription opioids and another 55,000 from heroin, including many deaths involving both drug groups). Of the 25,760 deaths relating to pharmaceutical overdose in 2014, 18,893 involved opioid analgesics. Heroin overdoses took another 10,556 lives. Four out of five heroin users started on prescription opioids.

As a diverse group of national, state and local organizations dedicated to fighting opioid abuse, we would like to highlight actions we know will save lives as you prepare to consider Congressional action to respond to this epidemic.

The Epidemic

Opioids have long been used to treat both chronic (long-term) pain and acute, subacute, and/or post-operative pain, and prescription rates over the past 15 years have crept higher and higher.

However, opioids have never been proven to be effective for the treatment of long-term pain,[1] and, in reality, over-the-counter medications can be even more effective in the treatment of most pain. The American College of Occupational and Environmental Medicine (ACOEM) medical treatment guidelines support this conclusion – quality evidence currently fails to demonstrate superiority of opioids to other medications and treatments for treatment of pain.[2,3,4] In fact, when updating its guidelines in 2014, ACOEM used an extensive systematic review that met Institute of Medicine (IOM) and Cochrane Collaboration criteria. This systematic review identified 263 studies for the treatment of pain with opioids (of which 157 met inclusion criteria); yet we were unable to identify quality evidence of effectiveness of opioids for the treatment of chronic non-cancer paint (CNCP). Despite this lack of evidence of their efficacy, opioids are among the most widely prescribed medications in the United States.



[1] Chou R, Turner JA, Devine EB, et al. The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop. *Ann Intern Med*. 2015;162(4):276. doi:10.7326/M14-2559.

This epidemic has a wide-ranging impact that reaches family members and friends of anyone with a substance use disorder and touches colleagues at their workplaces. Opioids affect workers on the job, as they cause impairment even when taken as prescribed and compound the effects of workplace injuries, accounting for 25% of workers' compensation drug costs. Workers using prescribed opioids may be unfit to perform their safety-sensitive tasks such as operating an aircraft, driving a truck, or operating heavy equipment, especially if the medication adversely affects their ability to perform their duties safely. Opioids pose an increased risk for motor vehicle crashes, as well as in other safety-sensitive and cognitively demanding jobs. Additionally, when used after a workplace injury, opioids double the risk of disability one year later.[2,3,4]

It is clear that those who are prescribed opioids are not aware of the risks associated with these medications. A National Safety Council (NSC) survey found that 45% of Americans who use prescription opioids do not realize they are doing so. Sixty-seven percent of opioid users believe their medications are addictive, but 9 in 10 are not concerned about becoming addicted themselves.

Furthermore, a March 2016 NSC survey of board-certified family and internal medicine physicians found that 99%prescribe these highly addictive medications for longer than the three-day period recommended in the recent Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain. Twenty-three percent prescribe at least a one-month supply. While 99%of doctors surveyed said they have seen a pill-seeking patient or evidence of opioid misuse, only 38 percent usually refer those patients to treatment. The survey also found that 74% of doctors incorrectly believe opioids are the most effective way to treat pain.

Comprehensive Solution

Prescription drug misuse and overdose is a complex problem which requires a comprehensive, multifaceted solution. As you consider legislation to address this solution, we believe this comprehensive approach must include:

- Increased education on effective pain treatment and the risks of opioid use for providers and the public, including mandatory prescriber education and prescribing guidelines
- Use of opioid consent and treatment agreements for patients being treated with opioids for subacute and chronic pain and referral to substance use disorder treatment for patients when indicated
- Effective prescription drug monitoring programs (PDMPs), including interoperability between states, integration into clinical workflow and medical records and timely collection of data
- Expanded access to naloxone, including allowing for third-party prescribing and standing orders
- Reduced barriers to treatment of opioid use disorder by increasing availability and affordability, including medication assisted treatment (MAT)
- Adequate funding of prescription drug overdose efforts at the federal and state levels

Each of these concrete components is critical to effectively fighting this growing epidemic.

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[2] Lipton, B., Colon, D., & Robertson, J. Workers compensation prescription drug study: 2013 update. 2013.
[3] Cherrier, M. M., Amory, J. K., Ersek, M., Risler, L., & Shen, D. D. Comparative cognitive and subjective side effects of immediate-release oxycodone in healthy middle-aged and older adults. The Journal of Pain : Official Journal of the American Pain Society. 2009.
[4] Franklin, G. M., Stover, B. D., Turner, J. a, Fulton-Kehoe, D., & Wickizer, T. M. Early opioid prescription and subsequent disability among workers with back injuries: the disability risk identification study cohort. Spine. 2008.

Education & Prescribing Guidelines

The CDC has shown that the increase in opioid prescribing has resulted in increased admissions for treatment of opioid use disorder and overdose deaths, without a corresponding decrease in reported pain. Additionally, a large number of medical schools offer less than five hours in instruction on pain management, with one study finding only 3.8 percent of 104 surveyed U.S. medical schools had a required pain course.[5]

It is already the standard of care for doctors to either have ongoing continuing education or document proficiency in order to prescribe certain dangerous medications, perform certain procedures or operate in certain states.

- Hospital Privileges—Physicians and mid-level providers must document training and proficiency in certain areas of knowledge and procedures before the granting of hospital admitting privileges.
- Accutane—Physicians must have expertise in the treatment of acne and in the use of isotretinoin to prescribe Accutane®.[6]
- Buprenorphine—Physicians must take eight hours of training to become certified to prescribe buprenorphine. Following certification, physicians are subject to periodic review of their records and practices by the DEA.
- Kentucky—Doctors are required to take 4.5 hours of activity related to KASPER (Kentucky All Schedule Prescription Electronic Reporting), pain management or addiction disorders. They must also read *Responsible Opioid Prescribing: a Clinician's Guide* and complete on online exam.
- New Mexico—Prescribers who are registered with the DEA must complete a five hour CME about pain and addiction.

Requiring prescribers applying for new or renewed controlled substances licenses to complete continuing education about effective chronic and acute pain treatment, responsible prescribing that includes the use of state PDMPs, and addiction identification is a common sense way to target those doctors who are prescribing opioids. This additional information ensures that providers can make well-informed decisions on medical treatment based on best practices and the latest research, carefully weighing the benefits and risks of opioids and their alternatives.

The recently released CDC Guideline is another critical tool in protecting people from the adverse effects of these medications. Evidence suggests that these prescribing guidelines can reduce opioid-related harms, but only if thoroughly implemented. For example, opioid overdose deaths declined in Washington State following the introduction of guidelines that called for more cautious prescribing. The Washington Department of Health reported a 29% decrease in prescription opioid-related fatalities since implementation of its Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain in November 2014.

The CDC Guideline by definition is not a requirement and it will not dictate medical decisions. However, for those physicians who seek data on how to effectively treat chronic pain, this guideline provides that information and is a valuable tool. It is incumbent upon Congress to provide adequate funding for CDC to build the tools and resources necessary to reach providers and educate them on the scientific basis for and importance of the Guideline.

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[5] Mezei, L & Murinson, Beth B. Pain Education in North American Medical Schools. The Journal of Pain : Official Journal of the American Pain Society. 2011.

[6] http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm094308.htm

In addition, resources and efforts should be committed to educating the public. This educational outreach ensures that patients are in the best position to make informed decisions on their course of treatment in consultation with their medical provider. Patients should be fully informed of the risks and benefits of opioids and the availability of alternative treatments. Furthermore, research published in 2013 found that patients who were more informed and confident about managing their health decisions had lower healthcare costs than those who were not, even when adjusting for other patient differences such as demographics and severity of illness.[7] Congress should encourage the CDC and other public health agencies to partner with nonprofits and other stakeholders to disseminate more information and make that information widely available to the general public.

Also, incorporating opioid consent and treatment agreements in to the practice of pain treatment can lead to a conversation to help improve patient understanding and improve education about these medications.

Prescription Drug Monitoring Programs (PDMPs)

PDMPs play an important role in any effective approach to the prescription opioid epidemic. PDMPs collect prescription information that, in turn, can be shared with medical providers and pharmacists to inform clinical decision-making. In the case of opioids, PDMPs allow physicians to ensure they are not prescribing dangerous drug combinations or an excessive dose of opioids for a patient. Proper utilization of PDMPs also prevent doctor shopping or situations involving patients going to multiple providers for prescriptions.

PDMPs also allow for the use of drug management programs, which are also known as patient review and restriction (PRR) or “lock-in” programs. These programs can prevent opioid and prescription drug misuse by assigning at-risk patients to pre-designated pharmacies and prescribers to fill prescriptions.

We support federal funding to help states fully implement and streamline PDMPs, including interoperability between states, integration into clinical workflow and medical records and timely collection of data.

Naloxone

Naloxone is an opioid antagonist that can save lives, reversing an opioid overdose with no negative side effects. Available by prescription, naloxone is not a controlled substance and has no abuse potential. It is also extremely safe. We strongly support the availability of naloxone throughout the United States and believes this can be accomplished in a few different ways.

As naloxone is not available over the counter, Congress can encourage states to implement standing orders for naloxone so that anyone in that state can receive naloxone without a prescription. Further, Medicare, Medicaid and private sector insurers should include naloxone as a covered drug in their drug formularies with lowest possible co-pay. This allows people who are taking opioids to obtain naloxone at the same time they receive their opioid prescription. Finally, public education on the importance of naloxone is necessary to promote the availability and effectiveness of naloxone and to ensure loved ones are ready to respond in the event of an opioid overdose.

Medication Assisted Treatment (MAT)

Finally, access to treatment is key to help those suffering from the disease of addiction. MAT and ongoing recovery support services can help people enter into and maintain recovery, therefore reducing the risk of relapse. Without MAT, patients experience a very high rate of relapse. However, access to MAT remains limited due to a low number of practicing addiction treatment specialists and limits on the number of patients they can treat with buprenorphine. Allowing physicians to treat more than 100 patients will

[7] "Health Policy Brief: Patient Engagement," *Health Affairs*, February 14, 2013.

increase access to life-saving treatment. Also, allowing more approved providers, like nurse practitioners and physician assistants, to prescribe buprenorphine will enable more individuals to receive treatment.

Additionally, both government funded programs and private insurance companies should allow for complete treatment of this chronic illness. While naloxone can save lives, only effective and accessible treatment can help patients recover from addiction.

Conclusion

Thank you for considering these comments. Too many Americans are losing their lives every day to prescription drug and heroin overdoses. Together, these provisions reflect an effective, comprehensive approach to a complex problem. We look forward to supporting your efforts to fight the growing opioid overdose epidemic and save lives.

Sincerely,

American Association of Occupational Health Nurses
American College of Occupational and Environmental Medicine
American Society of Addiction Medicine
Campbell Institute
Illinois Alcohol and Drug Dependence Association
International Certification & Reciprocity Consortium
National Council for Behavioral Health
National Safety Council
Safe States Alliance
Shatterproof
Washington Association of Alcoholism & Addiction Programs