

For a Healthier America: Strategies to Combat Prescription Drug Abuse

Given the growing toll related to the abuse of prescription opioids and heroin, we must collectively redouble our efforts to prevent the misuse, abuse and diversion of prescription medicines. We need a balanced approach that ensures appropriate access and use of prescription medicines by patients for legitimate medical needs under the direction and care of a licensed health care professional, but that also reduces the potential for misuse, abuse and diversion. While 94 percent of the prescription medicines most susceptible to abuse are generic,¹ the Pharmaceutical Research and Manufacturers of America (PhRMA) and its members are committed to supporting the appropriate use of prescription medicines and working with others to collectively address this complex public health challenge.

PhRMA strongly supports the following legislative reforms to combat prescription drug abuse.

Improve the Use and Effectiveness of Prescription Drug Monitoring Programs

Consistent use of prescription drug monitoring programs (PDMPs) is one of the most promising tools in preventing and detecting potential doctor shoppers while allowing for legitimate medical use of needed medicines. These state-run databases collect, analyze and share dispensing information on controlled substances, providing critical information to providers to inform their prescribing.

We support public policies to:

- Mandate PDMP registration, use and training
- Strengthen PDMP structure and usability
- Support appropriate oversight

PhRMA strongly supports efforts to improve the use and effectiveness of PDMPs, including, but not limited to, expanding interoperability and standardization of key program elements to promote uniformity of data elements, improving accessibility and use and promoting real time data entry and access. Regular assessments of these tools are also needed to ensure they are

¹ Among the most abused prescription medicines (opioids, CNS drugs, and stimulants) an estimated 93.7% of prescriptions at the retail level were for generic medicines in calendar year 2015. PhRMA analysis of IMS National Prescription Audit, April 29, 2016.

meeting stated policy goals and not negatively impacting access to needed medicines among those with a legitimate medical need.

Improve Education and Training Related to Prescription Drug Abuse, Pain Management and Treatment Options

As physicians and other prescribers are often on the frontlines of the fight against prescription drug abuse, they need ongoing training to ensure they meet the legitimate medical needs of patients while reducing the potential for abuse. Expanded educational efforts are also needed to ensure that the public, patients, caregivers and others understand the dangers of prescription drug abuse and their role in reducing the potential for abuse. Public policies should:

- *Expand public awareness and education efforts* focused on the dangers of prescription abuse and not sharing medications with others, the importance of patient adherence to the regimen prescribed, the need to securely store medications to prevent access by anyone other than the patient or caregiver and appropriate methods to dispose of any unused medicines, as well as how to assist an overdose victim.
- *Mandate continuing prescriber education and training* for use by health care providers to support appropriate prescribing of controlled substances, effective pain management, guidance specific to prescribing of opioids and non-opioid analgesics and the use of PDMPs.
- *Support the development of evidence-based clinical guidelines by health care providers* to inform the selection of the appropriate treatment options for the management of pain, including medication selection, dosage, duration, follow up and discontinuation, as well as guidance to patients on their first opioid prescription for acute pain to ensure patients receive only the appropriate quantity and dosage for the expected duration of pain severe enough to require opioids.
- *Require enhanced prescriber training* on how to identify patients at risk for prescription drug abuse, appropriate steps to take to referring patients to needed treatment and available treatment options, including overdose reversal agents and medications to treat addiction (e.g., buprenorphine, methadone and naltrexone).

Increase Coverage and Access to Range of Treatment Options

Prescription drug abuse is a complex problem with no single solution. Similarly, there is no one form of treatment that is most effective. We support a comprehensive approach to treating those with opioid use disorders and addiction to other controlled substances, with the first step being the need to assure sufficient treatment capacity. Public policies should:

- *Increase coverage and access to the full range of treatment and recovery services needed, which vary from a range of in-patient and out-patient treatment options, medication-assisted treatment (e.g., buprenorphine, methadone, and naltrexone), and other treatment options.*
- *Expand access to overdose reversal agents (e.g., naloxone), including expanding training of first responders on how to prevent overdose, the appropriate use of these agents, and the need to seek immediate care for those experiencing an overdose.*
- *Assess whether, and under what circumstances, civil immunity could or should be granted to a person for aiding on a voluntary basis in an emergency those at peril or who are otherwise incapacitated in a potential overdose situation by administering an opioid reversal agent and ensuring prompt access to additional medical treatment.*

Encourage the Development and Use of Abuse Deterrent Formulations (ADF), Non-Opioid Pain Medications and Medications to Treat Addiction and Prevent Overdose

ADF medications make certain types of abuse, such as crushing a tablet to snort the contents or dissolving a capsule in order to inject its contents, more difficult or less rewarding. ADF products are an important treatment option that can help prevent widespread abuse by impeding delivery of the active ingredient. Similarly, non-opioid pain medications are an important treatment option for patients, as are medications to treat addiction and overdose. Recognizing the public health benefits of these treatment options, policies need to foster their development and use. We support:

- *Using FDA’s existing authority to expedite the review and encourage the development of non-opioid pain medications, ADF products, products to treat opioid addiction and products that can prevent opioid drug overdose and death.*
- *Applying FDA’s existing authority to remove from the market non-ADF versions of the same drug, following the approval of an ADF formulation of the brand drug.*
- *Finalizing FDA guidance to inform the development of generic ADF products, given more than 94% of opioids are generic.*
- *Assessing the adequacy of coverage and access policies related to ADF products given the demonstrated potential of these products to reduce the potential for abuse, as well as for non-opioid pain medications, medications to treat addiction and medications to prevent overdose.*

Strengthen Efforts to Combat Prescription Drug Diversion and Abuse

The impact of drug diversion goes beyond just the cost of the prescription drugs that have been diverted for illicit purposes. Prescription drug diversion not only results in increased costs to the health care system through doctor shopping and other forms of fraud, but it also results in an increased burden on first responders and law enforcement who face the human toll of

addiction and overdose and its devastating consequences on patients and their families. We support policies to:

- *Expand law enforcement efforts to prosecute and shut down key sources of diversion, including rogue online pharmacies, which have been identified as a key source for diverted controlled substances. A recent National Association of Boards of Pharmacy review of online pharmacy websites found that more than 90 percent appeared to be operating in conflict with pharmacy laws and practice standards, highlighting the need to maintain a focus on addressing these illegal sites.*
- *Clarify regulations to better distinguish between legitimate pain management clinic practices and illegitimate practices or “pill mills,” which pose as legitimate pain management clinics but provide controlled substances inappropriately, often on a cash-only basis and without requiring a prescription solely for financial gain. Clarifying the regulations related to legitimate pain management clinics would facilitate law enforcement’s ability to shut down and prosecute those operating “pill mills.”*

PhRMA and its members are committed to continuing to work with stakeholders in both the private and public sectors to address this complex and challenging public health issue.