For a Healthier America: Reducing Prescription Drug Misuse and Abuse

The misuse and abuse of prescription medicines is a growing public health problem. In addition to the tragic toll on families and communities, prescription drug abuse results in increased costs to the health care and the criminal justice systems.\(^1\) 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 address the diversion, misuse, and abuse of prescription medicines. When used appropriately and under the direction and care of a licensed health care professional, prescription medicines can improve and save lives. However, prescription medicines can cause negative health consequences if they are used inappropriately and not as intended.

While more than 90 percent of the prescription medicines most susceptible to abuse are generic,\(^2\) PhRMA and its members are committed to supporting the appropriate use of prescription medicines and working with others to address the diversion, misuse, and abuse of prescription medicines. As policies are considered to address this public health issue, a careful balance needs to be struck to ensure that efforts aimed at minimizing the potential for diversion, misuse, and abuse of prescription medicines do not restrict access for patients with legitimate medical needs. To meaningfully address this issue, we put forth the following policy recommendations intended to inform policy proposals at the state and federal levels.

- **Improving the Use and Effectiveness of Prescription Drug Monitoring Programs (PDMPs):** Given the demonstrated effectiveness of these state-run electronic databases in helping identify potential doctor shopping (the process by which individuals visit numerous doctors in an attempt to obtain multiple prescriptions for particular drugs) and inappropriate prescribing, we support efforts to improve the oversight and effectiveness of PDMPs, expanded interoperability, and increased standardization to facilitate the timeliness and reliability of data contained in PDMPs.

- **Expanding Efforts to Identify and Shut Down “Pill Mills”:** Strengthening the regulation of the legitimate practice of pain clinics will help reduce the activities of “pill mills” (e.g., facilities that inappropriately provide access to controlled substances) while protecting the activities of

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\(^2\) Among the most abused prescription medicines (opioids, CNS drugs, and stimulants) an estimated 93.6% of prescriptions at the retail level were for generic medicines in calendar year 2013. PhRMA analysis of IMS National Prescription Audit, June 16, 2014.
legitimate healthcare providers. Unlike the legitimate practice of pain management, “pill mills” are driven solely by financial interests with no regard for medical necessity.

- **Strengthening Efforts to Combat Prescription Drug Diversion, Abuse, and Fraud:** Given that most pharmaceuticals abused in the United States are diverted by doctor shopping, forged prescriptions, theft and, increasingly, via the Internet, we support expanded efforts to address these sources.

- **Expanding and Improving Public and Professional Awareness, Education, and Training Related to Prescription Drug Abuse:** To reduce and guard against prescription drug abuse, a more comprehensive approach to public education and awareness and provider training is needed to increase awareness of the dangers of prescription drug abuse, ensure appropriate use of medicines, and promote appropriate prescribing practices, including training on use of PDMPs, and screening, brief intervention and referral for treatment of patients suspected of misusing and abusing prescription medicines.

- **Encouraging the Use and Development of Abuse Deterrent Formulations (ADF) to enhance patient safety:** ADF medicines have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredient. When an innovator has developed and FDA has approved such a formulation, in order to enhance patient safety, FDA should not approve a generic formulation of the medicine that does not incorporate comparable abuse deterrence. The science of abuse deterrence is challenging and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. Public policies should encourage the scientific and clinical research needed to advance the development and assessment of abuse-deterrent technologies.

Additional background on each of these areas is provided below.

**Improving the Use and Effectiveness of Prescription Drug Monitoring Programs (PDMPs)**

State PDMPs serve to collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing health care providers. The specific purpose of these programs is to support states’ efforts in deterring diversion, inappropriate prescribing, and misuse and abuse of controlled substances.

Given the demonstrated effectiveness of these state-run electronic databases in helping identify potential doctor shopping and inappropriate prescribing and use, we support:

- **Improving the oversight and effectiveness of PDMPs**, including developing standards related to the access and use of PDMP data to ensure legitimate use while protecting patient privacy; conducting assessments of ease of PDMP use by users to identify potential improvements; and evaluating PDMPs regularly to ensure they are achieving their stated policy goals and not negatively impacting legitimate patient access to medicines.
• **Promoting interoperability among PDMPs** given that the misuse and abuse of prescription medicines does not observe state boundaries. To facilitate ease of use and to eventually enable nationwide query and reporting capability across states, policies are needed to promote broader adoption of e-prescribing and the use of electronic health records and integration with PDMPs across states.

• **Increasing standardization to facilitate the timeliness and reliability of data contained in PDMPs.** While states PDMPs are increasingly available to health providers and dispensers with greater ease and efficiency, further enhancements are needed to promote broader adoption of this important tool.

**Expanding Efforts to Identify and Shut Down “Pill Mills” Through Increased Regulation of Pain Clinics**

We support the development of a model pain clinic law and accompanying regulations that include clear distinctions between “pill mills” and legitimate pain clinics to facilitate law enforcement’s ability to shut down “pill mills.” (i.e., facilities that inappropriately provide access to controlled substances) while protecting the activities of legitimate healthcare providers. The National Alliance for Model State Drug Laws (NAMSDL) and others have determined that a “pill mill” is not indicative of a particular medical facility or location but rather a set of behaviors that are driven by financial, not medical interests, and have no regard for therapeutic benefit or medical necessity.

Central to any legislation or model state law is:

• **The need to clearly define and distinguish “pill mills” from legitimate pain clinics,** with key indicators of each included in the table below to inform the development of legislative definitions.

• **Inclusion of references to relevant state statutes and regulations that legitimate pain clinics must comply with** including but not limited to any specific training requirements for persons practicing in pain clinics, clinic inspection requirements, and state statutes or regulations related to the data and records that pain clinics are required to maintain.
### Indicators of “Pill Mills” vs. Legitimate Pain Clinics

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<th>Indicators of “Pill Mills”</th>
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<tr>
<td>• No maintenance of previous medical records;</td>
<td>• The clinic maintains appropriate registration, certification or licensure with DEA and appropriate state regulatory bodies.</td>
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<td>• Physical exams are not required or inadequate exams are performed;</td>
<td>• The clinic ensures appropriate ownership qualifications, i.e., holding certain licenses and/or board certifications.</td>
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<td>• Failure to screen for substance abuse disorders;</td>
<td>• The clinic employs a Medical Director or Clinical Manager as a designee to bear certain responsibilities relative to clinic operation and compliance.</td>
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<td>• The care provided is not individualized, e.g., there is no variance in scheduled visits, no referrals to other specialists, or the combination of medications prescribed do not vary considerably;</td>
<td>• The clinic adheres to state requirements concerning prescription drug monitoring programs.</td>
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<tr>
<td>• The primary mode of therapy provided is prescribing of controlled substances;</td>
<td>• The clinic maintains certain records and/or collects certain data as required by law.</td>
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<td>• High volume of care;</td>
<td>• The clinic is held responsible for administrative and/or clinical penalties and fees for violations relating to pain clinic provisions.</td>
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<td>• No appointments taken and walk-ins are the norm;</td>
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<td>• Only cash payment accepted;</td>
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<td>• “Patients” travel very long distances without any legitimate reason.</td>
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### Strengthening Efforts to Combat Prescription Drug Diversion, Abuse, and Fraud

According to the DEA, most pharmaceuticals abused in the United States are diverted by doctor shopping, forged prescriptions, theft and, the Internet. To combat these sources of diversion, fraud, and abuse, we support:

• **Expanding efforts within public programs aimed at detecting potential doctor shopping** and referring potential fraud to appropriate authorities for further investigation.

• **Assessing the adequacy of existing efforts aimed at ensuring the accuracy and currency of CMS assigned provider and beneficiary identifiers** as well as DEA registrant identification and increasing penalties for illegal use of such identifiers.

• **Expanding DEA’s efforts to target rogue online pharmacies for prosecution**, including supporting enforcement of online pharmacies compliance with state licensure requirements, specifically “the requirements of state law concerning the licensure of pharmacies in each state from which it, and
in each state to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such state.\(^3\)

- **Strengthening PDMPs and expanding efforts to shut down “pill mills” to address doctor shopping.**

**Expanding and Improving Public and Professional Awareness, Education, and Training Related to Prescription Drug Abuse**

To reduce and guard against prescription drug abuse, a more comprehensive approach to public education and awareness and provider training is needed. We support:

- **Expanding awareness and education on prescription drug misuse and abuse** through increased engagement among all stakeholders, including but not limited to health care providers, educators, parents and other care givers, and other members of the community regarding the importance of appropriate use of prescription medicines (including not sharing medicines with others), secure storage of prescription medicines, and safe disposal of unused or expired medicines.

- **Increasing public awareness of existing programs and resources at the local, state, and federal levels** to assist with prevention, screening, brief intervention and referral for treatment of patients suspected of prescription drug misuse and abuse. Similarly, a key federal priority should be to assess whether current treatment capacity is adequate to treat those struggling with addiction to prescription medicines and to identify and disseminate effective treatment approaches.

- **Improving and expanding provider education efforts** focused on (1) appropriate prescribing practices, particularly with regard to pain management not only to prevent prescription drug misuse and abuse but also to ensure better patient outcomes; (2) education on the use of PDMPs; and (3) training on screening, brief intervention and referral for treatment of patients suspected of misusing and abusing prescription medicines. Given the substantial costs related to doctor shopping to public programs, PDMP education and use should be mandatory for Medicare and Medicaid providers where PDMPs are fully operational.

- **Encouraging providers, state medical societies, and specialty groups, including non-physician prescribers such as dentists, to engage in consensus-driven process to review and assess the adequacy of current clinical guidelines** as well as existing training and educational opportunities and potential enhancements aimed at (1) assuring continued legitimate access to medicines for those with a clinical need, (2) identifying potential fraud, diversion, misuse, and abuse, and (3) appropriately educating patients regarding appropriate use.

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**Encouraging the Use of and Development of Abuse Deterrent Formulations Would Enhance Patient Safety.**

For the past several years, innovative biopharmaceutical companies have developed abuse-deterrent formulations for some medicines that are susceptible to widespread abuse (e.g., opioids); these formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredient (“abuse-deterrent formulations”). When an innovator has developed, and FDA has approved, such a formulation, FDA should not approve a generic formulation of the medicine that does not incorporate comparable abuse deterrence. Permitting the approval of generic products that lack comparable abuse deterrence not only undermines the incentive for industry to invest in important new abuse-deterrent technologies, but more importantly, fails to mitigate a public and societal health risk.

In addition, when an abuse deterrent formulation of a drug has been approved, PhRMA encourages FDA to exercise its authority to remove from the market non-abuse deterrent generic formulations of the same drug.

The science of abuse deterrence is challenging and both the formulation technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. Public policies should encourage the scientific and clinical research needed to advance the development and assessment of abuse-deterrent technologies.

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Prescription medicines save and improve lives every day but when misused or abused, devastating consequences can result. At the same time, any policies in this area should not unintentionally create barriers to patient access to needed medicines. Appropriate use of medicines is an important issue to all of our member companies. We look forward to working with other stakeholders on this important issue.