



Pharmaceutical Companies Must Apply Science and Technology To Prevent Prescription Drug Abuse

In 2009, 2.6 million adults aged 12 and older used prescription drugs nonmedically for the first time in the past year, which averages out to 7,000 initiates per day.ⁱ

The prevalent and growing abuse of prescription drugs is a concern that pharmaceutical companies have a societal responsibility to help address. One way the manufacturers of pharmaceutical products can do this is to develop formulations that introduce limits to abuse.

Definitions

Misuse is the use of a medication for a medical purpose other than as directed or indicated, whether willfulⁱⁱ or unintentional, and whether harm results or not. Alternately, abuse is the intentional self-administration of a medication for a nonmedical purpose such as 'getting high.'ⁱⁱⁱ

Abuse-deterrent formulations (ADFs)

People tamper with extended-release opioid pain relievers by crushing or chewing them to release a large dose at once. ADFs provide much needed medication to patients in a form that is more difficult to abuse.ⁱⁱ

Abuse-deterrent formulations may help:

- Reduce unintentional misuse
- Lessen medications' attractiveness to potential abusers
- Make health care providers more comfortable prescribing certain medications

The goal is:

- To provide therapeutic benefit when taken in the appropriate dosage
- To lessen euphoria abusers experience when they attempt to abuse medications

ADF technologies and their effects:^{ii,iii,iv,v,vi}

Technology	Intended ADF Effect
Hard shells and viscous gels	Make chewing, crushing, and dissolving more difficult
Sequestered irritants	Create unpleasant effects when the product is altered for purposes of abuse
Inactive prodrugs	Require metabolization in GI tract to produce the active ingredient
Antagonists	When crushed or chewed, an antagonist is released to reduce euphoria

These formulations are just one part of the effort to manage prescription drug abuse risk.ⁱⁱ No formulation will be completely abuse-proof, but this approach lessens the opportunity for abuse.

CLAAD offers the following additional recommendations to pharmaceutical companies to help address prescription drug abuse:

- Cooperate with other pharmaceutical companies to minimize the risks of innovative drugs and their generic equivalents under a single risk evaluation and mitigation strategy (REMS).
- Collaborate with other pharmaceutical manufacturers to provide a degree of conformity within the Medication Guides and communication plans of various medications of the same class.
- Develop new non-opioid pain relievers for moderate to severe pain.
- Work with the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) to begin employing and evaluating on-dose technology that is embedded into individual doses of a medication for tracking purposes to determine whether it helps to prevent and intervene in prescription drug diversion.
- Provide financial support for state prescription monitoring programs through trustworthy, independent not-for-profit organizations such as the Alliance of States with Prescription Monitoring Programs and the National Alliance for Model State Drug Laws.

For more information on strategies to deter prescription drug abuse, see CLAAD's *2010 National Prescription Drug Abuse Prevention Strategy*, available online at www.claad.org.

ⁱ Substance Abuse and Mental Health Services Administration. (2010). *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings* (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings). Rockville, MD.

ⁱⁱ Katz NP, et al. Challenges in the development of prescription opioid abuse-deterrent formulations. *Clin J Pain*. 2007;23:648-60. Office of Applied Studies, NSDUH Series: H-32, DHHS Publication No. SMA 07-4293. Rockville, MD. 2007.

ⁱⁱⁱ Katz NP, et al. Foundations of opioid risk management. *Clin J Pain*. 2007;23:103-18.

^{iv} Gershell L, Goater JJ. Making gains in pain. *Nat Rev Drug Discov*. 2006;5:889-90.

^v Webster LR, et al. Oxytrex minimizes physical dependence while providing effective analgesia: a randomized controlled trial in low back pain. *J Pain*. 2006;7:937-46.

^{vi} Lavine G. Abuse deterrence focus of upcoming opioid formulations. *Am J Health-Syst Pharm*. 2008;65:381,5.