

Foster the Development and Use of Abuse Deterrent Formulations ADFs, Alternatives to Opioids Analgesics, Medicines to Treat Addiction, and Medicines to Treat Opioid Overdose

The challenge of prescription drug abuse is multifaceted and requires a multi-pronged approach that ensures that patients with legitimate medical needs receive the treatments they need, offers a range of options for prescribers and patients to appropriately treat acute and chronic pain, and fosters the development of medications to treat addiction and address opioid overdose.

Specifically, we support policies to foster the development and use of:

- Abuse deterrent formulations (ADFs), which make certain types of abuse, such as crushing a tablet in order to snort the contents or dissolving a capsule in order to inject its contents, more difficult or less rewarding.
- Non-opioid analgesics, which can serve as an adjunct to opioid medications (allowing in some cases more limited use of opioids) and/or as an alternative treatment option for some patients.
- Medications to treat addiction, which can help patients stay drug and alcohol free as part of a comprehensive treatment plan (e.g., buprenorphine, methadone and naltrexon).
- Medications to reverse opioid and heroin overdoses in cases of emergency (e.g., naloxone products).

To help reduce prescription drug abuse and addiction, we:

- *Urge the FDA to use its existing expedited review authorities* to encourage the development of non-opioid pain medications, products that treat opioid abuse, products that can prevent opioid drug overdose and death.
- *Support assessments of the adequacy of coverage and access policies* related to ADF products, non-opioid analgesics, medications to treat addiction, and medications to prevent opioid overdose, given the importance of these products to addressing this public health challenge. With regard to ADF products, payers often provide preferred formulary placement for generic formulations that lack abuse deterrent characteristics, despite the usefulness of abuse-deterrent formulations in preventing abuse and reducing health care costs associated with abuse. Coverage and payment policies should consider the public health benefits of use of these products.

The following are further reforms needed to foster the development of ADF products, which are an important treatment option as they can help prevent widespread abuse by impeding delivery of the active ingredient when manipulated (e.g., crushed, dissolved, etc.).

Fostering the Development and Use of ADFs

Innovative biopharmaceutical companies have made substantial R&D investments to develop ADFs for some medicines that are susceptible to abuse (e.g., opioids). These formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredient or by making abuse of the drug more difficult or less rewarding. 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. We encourage the FDA to exercise its authority to protect the public health by:

- *Incentivizing the development of ADFs, which is in the best interest of patients.*
 - 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.
- *Swiftly finalizing guidance to inform the development of generic ADFs, given that 94% of the most frequently abused opioids are generic.*
- *Improving product labeling to better distinguish non-ADF formulations from ADF formulations and to clearly reference the potential public health benefits of ADF products.*

Equally important as fostering the development and use of these products is the need for continuing training and education of prescribers to ensure appropriate prescribing of controlled substances, including ADF products, effective pain management, and guidance to inform opioid selection, dosage, duration, follow up, and discontinuation.