Association for Accessible Medicines
Opioid Policy Statement
February 2018

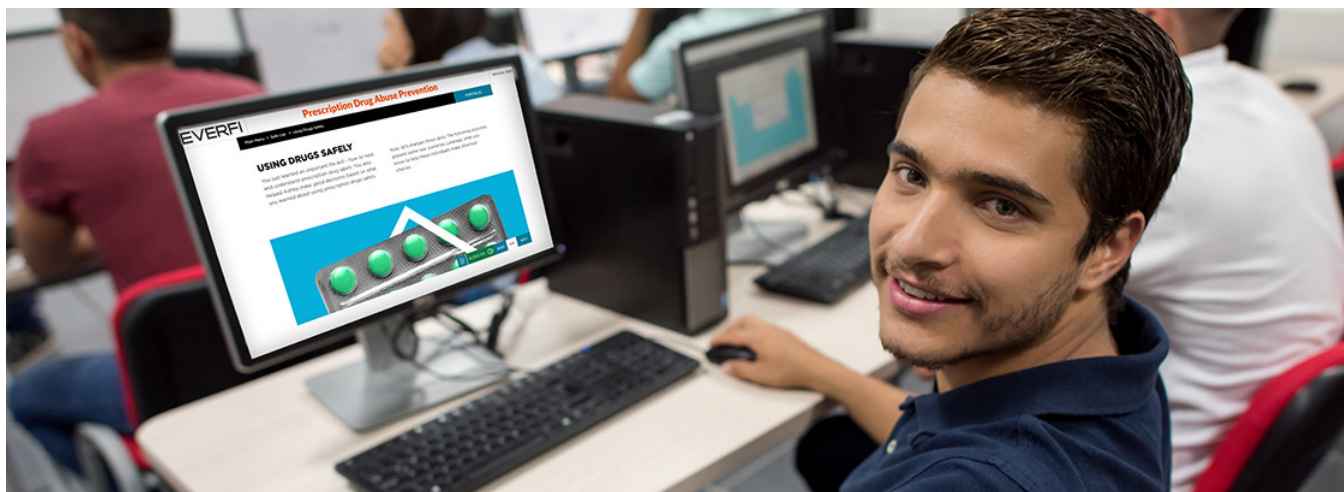### Patient safety is a top priority for the generic drug industry.

AAM is strongly committed to ensuring patient access to medicines while supporting efforts to reduce misuse of prescription medication. It is a public health and patient safety imperative that patients take medicines as prescribed and adhere to the instructions of their doctor, pharmacist or healthcare provider.

Prescription adherence, safe storage and proper disposal help prevent medication abuse and ensure that patients get the full value of safe, effective and more affordable generic drugs. Therefore, AAM and its members support a range of collaborative strategies and new public policies to reduce drug abuse while ensuring access to medicines for patients who need them.

What is AAM doing to curb prescription drug abuse?

AAM and its members support education for prescribers and providers, and partner with leading national organizations dedicated to promoting public health and preventing abuse.

- AAM supports the Community Anti-Drug Coalitions of America (CADCA), the national membership organization representing over 5,000 coalitions and affiliates working to make America's communities safe, healthy and drug-free.

- AAM is a member of the National Council on Patient Education and Information (NCPIE) and supports its many prescription drug abuse prevention programs including:

  - **Taking Action to Prevent and Address Prescription Drug Abuse: A Resource Kit for College Campuses** designed to help inform and mobilize college campuses to raise awareness about and address the misuse and abuse of prescription drugs, and **Prescription Drug Abuse Prevention**: **Resources for Community Action™ guide**.

- Last year, AAM approached Washington, D.C.-based education-technology company **EVERFI**—the leading provider of alcohol abuse and sexual assault prevention training for our nation's colleges and universities—and asked the organization to develop a module to help students understand the safe use, storage and disposal of prescription drugs. With our financial support, EVERFI developed and made available a prescription drug abuse prevention curriculum, free of charge, to any college in America. More than 36,000 students have already taken the course and we are encouraged by the very positive results. AAM is working to increase utilization nationally for the higher ed program and to complement it with earlier intervention. AAM and EVERFI have brought together supply chain partners, including chain drug stores and brand manufacturers, to finance the rollout of a K-12 program to some of the hardest-hit communities in our country.

AAM and EVERFI bring prescription drug prevention curriculum to students

What public policies does AAM support to combat prescription drug abuse?

- AAM supports efforts to reduce prescription drug abuse and diversion through expanded use of Prescription Drug Monitoring Programs (PDMP) across the country. The association also supports improving the effectiveness of PDMPs by increasing interoperability and standardization. Consistent with these principles, AAM supports the "Prescription Drug Monitoring Act of 2017" introduced by Senators Klobuchar and Portman. The bill would require States that receive Federal funding for PDMPs to require prescribers to check their state PDMP prior to treatment and to require dispensers to report information into the PDMP. The legislation also would expand efforts to facilitate the sharing of PDMP information among providers across state lines.

- AAM supports initiatives to assist physicians and other prescribers in the proper prescribing of prescription drugs, particularly opioids. This includes the five recommendations of the American Medical Association's Task Force to Reduce Opioid Abuse:

  1. Register and use your state prescription drug monitoring program to check your patient's prescription history.
  2. Educate yourself on managing pain and promoting safe, responsible opioid prescribing.
  3. Support overdose prevention measures, such as increased access to naloxone.
  4. Reduce the stigma of substance use disorder and enhance access to treatment.
  5. Ensure patients in pain aren't stigmatized and can receive comprehensive treatment.

- As part of such efforts, AAM supports requiring mandatory, ongoing training for providers on best practices in pain management such as the CDC guidelines for treatment of chronic pain, "doctor shopping" and use of PDMPs, and other issues related to the safe use of opioids.

- AAM supports reducing the potential for diversion and fraudulent prescribing by requiring the use of electronic prescribing for controlled substances. This practice holds the potential to reduce opportunities for diversion and meaningfully contribute to combatting prescription drug misuse. The "Every Prescription Conveyed Securely Act" would require greater use of electronic prescribing for controlled services in Medicare Part D.

- AAM supports consideration of a 7-day limit on prescriptions of opioids for acute pain. Such limits should include appropriate exceptions to balance the need for patients to obtain needed care, including when the prescriber, in their medical judgement, determines that a lengthier prescription is necessary.

- AAM supports the continued implementation of the CARA Act, which allows Medicare Part D plan sponsors to use several utilization management tools that have proven effective in the commercial sector at reducing abuse of opioids. In particular, AAM supports the use of "lock-in" programs, which restrict beneficiaries suspected of inappropriate opioid use to one prescriber, one pharmacy, or both. This solution allows the beneficiary to continue to access opioids as therapeutically

appropriate, but requires those prescriptions to be coordinated through a single prescriber or pharmacy. The program as described requires patients and prescribers to be notified before a patient is enrolled, and allows the patient time to appeal the decision and select providers that are most convenient to the patient. Appropriate management of those taking opioids for extended periods of time is one way to combat abuse.

- AAM supports proper disposal of unused or unwanted prescription drugs through U.S. Drug Enforcement Agency Take Back days. However, AAM is concerned by proposals to institute mandates on manufacturers to fund such programs. Such mandates would only increase costs and limit access to patients who are most in need. Some states are considering proposals that would not only require drug manufacturers to fund drug takeback programs, but that would place the financial burden on low cost generics rather than higher priced brand drugs.

- AAM supports ensuring patient access to needed addiction treatment services.

How do generic manufacturers prevent misuse of their products?

In addition to the measures characterized above, generic drug manufacturers continue to develop medicines, such as opioids for pain management, with abuse deterrent formulations (ADF). Abuse-deterrent technology makes it harder to misuse medicines by crushing tablets for snorting or further dissolving products with intent to inject the contents. As the Food and Drug Administration (FDA) notes, this does not mean the product is impossible to abuse or that these properties necessarily prevent addiction, overdose or death.

> It is important to note that future FDA-approved generic products with ADF will be just as abuse deterrent as their brand counterparts. Additionally, AAM will continue to work with FDA on draft guidance on generic ADF products.

AAM:

- Encourages FDA to work with drug makers so that they are better able to bring innovation to the development of ADF prescription opioids. Requiring a specific type of ADF technology – rather than making the determination based on scientific results – will stifle and hamper these much-needed creative solutions.

- Believes that FDA's determination of whether a generic prescription opioid receives ADF labeling should not be based on whether the generic has an identical ADF technology.