



**Your Generics and Biosimilars Industry**

**Testimony of**

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**Combating the Opioid Crisis: Prevention and Public Health Solutions**

**U.S. House of Representatives  
Committee on Energy and Commerce  
Subcommittee on Health**

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### Introduction

Chairman Burgess, Ranking Member Green, Chairman Walden, Ranking Member Pallone and members of the Subcommittee, thank you for the opportunity to testify today on solutions to our national opioid crisis and the safe use and disposal of prescription medicines. I am Jeff Francer, Senior Vice President and General Counsel at the Association for Accessible Medicines (AAM).

AAM's core mission is to improve the lives of patients by advancing timely access to affordable FDA-approved generic and biosimilar medications. We are the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Generic and biosimilar medicines serve as the backbone of prescription drug savings and now represent greater than 89% of all prescriptions dispensed in the U.S., but only 26% of total expenditures on prescription drugs, saving patients, payers, and taxpayers nearly \$5 billion every week.<sup>1</sup>

AAM commends the Subcommittee for its continued efforts to address the public health crisis of opioid prescription drug abuse. We are also encouraged by the continued focus of the Administration, including FDA Commissioner Gottlieb, on addressing this challenge. According to the National Institute on Drug Abuse, more than 90 Americans die each day after overdosing on opioids.<sup>2</sup> The Centers for Disease Control and Prevention estimates that the total 'economic burden' of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.<sup>3</sup>

Ensuring patient safety is of the utmost importance for generic drug and biosimilars manufacturers. 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 other healthcare provider. Enhanced prescriber training, prescription adherence, safe storage and proper disposal all can help prevent medication abuse and ensure that patients get the full benefit of safe, effective and more affordable generic medicines.

It is critical that we combat the misuse of prescription medication while maintaining legitimate, uninterrupted access to medicines to patients in need. Generic drug

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<sup>1</sup> AAM 2017 Generic Drug Access & Savings in the U.S., <http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>

<sup>2</sup> National Institute on Drug Abuse.

<sup>3</sup> Schuchat A, Houry D, Guy GP. New Data on Opioid Use and Prescribing in the United States. JAMA. 2017;318(5):425–426.

manufacturers play a key role in producing affordable FDA-approved therapies for the treatment of patients. Importantly, under the Hatch-Waxman amendments that govern the approval of generic medicines, our manufacturers create bioequivalent versions of brand name drugs using the same labeling, and if necessary, the same or an equally protective Risk Evaluation and Mitigation Strategy. Typically, generic drug manufacturers do not promote drugs to physicians or directly to patients, as the brand name manufacturers do. Moreover, once our companies sell generic drugs to a wholesaler, the company does not control the further sale of the medicine to retail pharmacies. Currently, three large purchasing consortiums made up of wholesale distributors and retail pharmacies control 90% of the generic medicines sold in the United States.

### AAM Policy Principles

AAM believes that a comprehensive approach to the opioid crisis should help ensure responsible drug promotional activities and prescribing. Recent data reflect the importance of thoughtful and comprehensive public policy in addressing this public health issue. For instance, the total number of prescriptions for Hydrocodone have declined by more than 40% since 2012.<sup>4</sup> During this period, the CDC acted to improve opioid prescribing practices through the CDC Guideline for Prescribing Opioids for Chronic Pain.<sup>5</sup> Yet, at the same time, overdose deaths from heroin and synthetic opioids increased significantly.

Thus, AAM and its members support a range of collaborative strategies and public policies to reduce drug abuse while ensuring appropriate access to medicines for patients who need them, and we recently released a white paper detailing our proposed solutions. This effort will require a multi-faceted and coordinated approach that seeks to:

- Reduce inappropriate prescribing;
- Ensure the safe use of medicines consistent with FDA-approved labeling; and
- Maintain the availability of treatment for individuals struggling with addiction.

As such, AAM supports expanding and improving the use and effectiveness of Prescription Drug Monitoring Programs (PDMP) by increasing interoperability and standardization across the country. Consistent with these principles, AAM supports the “Prescription Drug Monitoring Act of 2017” introduced by Senators Amy Klobuchar (D-MN) and Rob Portman (R-OH) and Representatives Evan Jenkins (R-WV) and Tim

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<sup>4</sup> IQVIA, National Prescription Audit, September 2017.

<sup>5</sup> Available at [www.cdc.gov](http://www.cdc.gov)

Ryan (D-OH). 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 also 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:<sup>6</sup>

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.

In addition, 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", introduced by Senators Michael Bennet (D-CO) and Dean Heller (R-NV) and Representatives Katherine Clark (D-MA) and Markwayne Mullin (R-IN), 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 could 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.

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<sup>6</sup> American Medical Association, Reversing the Opioid Epidemic, available at <https://www.ama-assn.org/delivering-care/reversing-opioid-epidemic>.

AAM also supports the continued implementation of the Comprehensive Addiction and Recovery Act. Among other provisions, the legislation allows Medicare Part D plan sponsors to use several utilization management tools that appear to be effective in the commercial sector at reducing abuse of opioids. 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 national U.S. Drug Enforcement Agency Take Back days. We note that just this week Secretary Azar emphasized the importance of the DEA Takeback Program and continuing to improve its results. However, AAM is concerned by the continued growth of state and local proposals to institute mandates on manufacturers to fund such programs. AAM looks forward to working to address this issue in a coordinated way that ensures patient access to affordable generic medicines where medically appropriate.

### **AAM’s Ongoing Efforts to Address Prescription Drug Abuse**

AAM and its members support enhanced education for prescribers and providers, and we have partnered with leading national organizations dedicated to promoting public health and preventing abuse. 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 importance of safe use, storage and disposal of prescription drugs.

Young adults between the ages of 18-25 year old abuse opioids at a higher rate than the rest of the population. According to the 2015 College Prescription Drug Study (CPDS), 10.2% of undergraduates reported using pain medications for non-medical reasons. Opioid-related deaths among Americans age 24 and under almost doubled from 2005 to 2015, when 3,165 were reported, according to the Kaiser Family Foundation, based on data from the Centers for Disease Control and Prevention.

With AAM's financial support, EVERFI has developed and made available a prescription drug abuse prevention curriculum, free of charge, to any college in America in order to help this at-risk demographic make healthy decisions. More than 36,000 students – at schools that include some of the largest land grant colleges in the nation, to the Ivy League to our military academies - have already taken the course since its launch last fall and that number is growing with each successive semester.

The course is producing volumes of data to better understand the challenge of prescription drug misuse in the college community, and to measure the impact of the program. Already, 75 percent of students reported that because of the course they are more confident in their ability to intervene if a friend is misusing prescription drugs, while 73 percent said they now know where to find resources for drug abuse at their institution.

AAM is working to increase student participation in the higher education program nationally and to complement the higher education curriculum with earlier intervention. AAM and EVERFI have brought together national business leaders and pharmaceutical supply chain partners, including chain drug stores, to fund the rollout of a K-12 prescription drug misuse program to some of the hardest-hit communities in our country.

In addition, 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 also a member of the National Council on Patient Information and Education (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.

### **Abuse-Deterrent Formulations of Generic Opioids**

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. However, as the FDA has noted,

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 medicines with ADF will be just as abuse deterrent as their brand name counterparts. As FDA continues its efforts, AAM encourages FDA to continue to work with drug makers so that they are better able to bring innovation to the development of ADF prescription opioids. 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 – rather the determination should be based on scientific results. Requiring a specific type of technology could stifle and hamper these much-needed features in generic medicines.

### **Views on Proposed Legislation**

AAM commends the Subcommittee for its continued efforts to enhance our public health response to the opioid crisis. We are presently reviewing the proposed bills, and will follow up with detailed comments. In the interim, we suggest several principles for the Subcommittee to consider in evaluating proposed legislation:

- Legislation should not prevent legitimate and uninterrupted patient access to care.
- Legislation should not limit FDA's discretion to ensure the safety of medicines, and should maintain equal scientific and regulatory standards for brand and generic medicines alike; and
- Legislation should not hinder the ability of manufacturers to collaborate with supply chain partners and federal and local agencies to prevent and treat addiction.

### **Conclusion**

AAM looks forward to continuing to work with the Subcommittee to help address our national opioid crisis and help ensure the proper prescription and use of FDA-approved medicines. I would be happy to answer any questions.