Your Generics & Biosimilars Industry

October 23, 2017

The Honorable Donald White
Senate Banking and Insurance Committee
286 Main Capitol
Harrisburg, PA 17120-3041

Re: AAM Opposition to SB 637

Dear Chairman White,

On behalf of the Association for Accessible Medicines (AAM) I am writing to respectfully oppose SB 637 as introduced and as proposed to be amended by the Committee on October 24, 2017. SB 637 provides no benefit to patients and instead could disrupt the generic marketplace that saved Pennsylvania $11.6 billion, $1.9 billion savings in Medicaid alone, in 2016.[1]

AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities, and manufacture more than 61 billion doses in the United States every year. AAM's core mission is to improve the lives of patients by advancing timely access to affordable generic and biosimilar medications.

Generics represent greater than 89% of all prescriptions dispensed in the U.S., but only 26% of expenditures on prescription drugs, saving patients and payers nearly $5 billion every week.[2] Last year the U.S. Department of Health and Human Services released a comprehensive analysis unequivocally stating, "generic drug prices are not an important part of the drug cost problem facing the nation."

SB 637's Increased Administrative Burdens Could Harm Generic Competition

Proposed transparency amendments to SB 637 treat all drugs identically, even though generic drug markets are fundamentally different than brands. This oversight could have unintended consequences for generic manufacturers and the fragile generic marketplace. The market dynamics of brand and generic drugs are very different. Unlike the brand market, where a single manufacturer sets and controls their prices, the generic

[1] AAM Generic Drugs Save Pennsylvania (2017). https://d2bpmykqia4k9e.cloudfront.net/downloads/Pennsylvania-Savings.pdf.
[2] AAM Generic Drug Access & Savings Report in the US (2017). http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.

industry follows a multi-competitor model with drug prices decreasing as more competitors enter the marketplace.[3] In fact, since 2008, generic drug prices have declined by more than 60 percent, while brand prices have continued to increase.[4]

SB 637's reporting provisions require manufacturers to report annually certain information for each prescription medication "delivered for treatment in [Pennsylvania]." This is problematic for several reasons. First, generic manufacturers primarily sell their products to three national wholesalers that in turn sell these products to pharmacies all over the country. Thus, a manufacturer may not know whether its products were delivered for treatment in Pennsylvania.

Second, SB 637's reporting provisions threaten generic manufacturers' ability to keep costs down, which ultimately threatens the number of generic manufacturers in the market. Unlike brand manufacturers, who focus on a smaller number of high-margin products at any given time, generic manufacturers manage a much larger portfolio of products. Many of the largest generic manufacturers maintain portfolios of hundreds, even over a thousand, assorted products for which the legislation would require a detailed annual report as well as a third-party audit before filing. These onerous administrative reporting and auditing provisions for generic products create significant costs for manufacturers, undermining the competitive environment that has been proven to lower generic costs.

Third, SB 637 requires manufacturers to report annual list price history and cost increases for each product. Not only would reporting list price changes by month be burdensome for generic manufacturers, but it also serves little utility in a price transparency discussion that focuses on manufacturer costs. Generic drugs are subject to a variety of market factors that cause frequent cost fluctuations. Much of this variation can be traced to characteristics inherent in the generic market that are not present in the brand market. Since generic manufacturers compete on price, it is normal business practice for a generic product's cost to increase and decrease many times during the natural course of business. These increases are not an indication of an upward trend for a product. In a four-year sample that AAM examined, 53% of products saw a 50% increase in their Wholesale Acquisition Cost (WAC), one measure of a drug's list price, during a 12-month period, while generics as a whole decreased in cost. These products often see fluctuations as purchasing habits change or competitors enter and exit the market.

Finally, SB 637's reliance on price increases expressed as percentages only tells one side of the story. A three-cent increase on a one-cent generic pill, while often temporary and related to market dynamics beyond a manufacturer's control, looks like a much larger increase as a percentage – 300% – than a monopoly brand product that increases in price from $10,000 to $15,000 – a 50% increase, but with a more significant impact on state spending.

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[3] AAM Supply Chain Brief, October 2017. https://www.accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf.

[4] Department of Health and Human Resources. Understanding Recent Trends in Generic Drug Prices. ASPE Issue Brief, January 27, 2016. https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices.

SB 637 Will Not Benefit Patients

While the intent of SB 637 is laudable, patients will not benefit by SB 637's transparency provisions since comparing pharmaceutical pricing to costs will not always yield accurate results. For example, amoxicillin/ potassium clavulanate, commonly referred to by its branded name Augmentin and used for the treatment of infections, is sold by generic manufacturers for pennies per pill. However, by the time a patient picks it up at the pharmacy counter, it may have a cash price as high as $60 for 20 pills, or $20 for a fill for patients with commercial insurance.[5] This is a direct result of supply chain forces on pharmaceutical retail pricing, for which the generic manufacturer has no control. Even if a generic manufacturer reported the information related to producing such an inexpensive pill, patients would not see any benefit since these prices are not set by the manufacturer.

Legislation that fails to distinguish between the brand and generic marketplaces could have the unintended consequence of harming generic savings and decreasing patient access and increasing costs. As such, AAM respectfully urges this committee to oppose SB 637 as proposed to be amended by the Committee.

Respectfully,

Carrie Hartgen
Vice President, State Government Affairs

[5] Data on manufacturer sales from CMS Average Manufacturer Price (AMP) data. Typical pharmacy prices from GoodRx.com.