Association for Accessible Medicines

Your Generics & Biosimilars Industry

May 14, 2021

Representative Rachel Prusak
Chairwoman, House Committee on Health Care
900 Court St. NE, H-489
Salem, Oregon 97301

Dear Representative Prusak,

The Association for Accessible Medicines ("AAM") is the leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

AAM Opposes Alleged "Pay-For-Delay" Settlements.

Unfortunately, as it is currently drafted, SB 764 will unduly restrict pro-competitive, pro-patient settlements that allow lower-cost generic and biosimilar drugs to come to market sooner than waiting for brand drug company patents to expire. The limits that SB 764 will put on these settlements will force Oregonians to continue to pay higher prices for monopolized drugs instead of encouraging generic manufacturers to aggressively attack brand patents. Patent settlements significantly accelerate access to more affordable medicines by an average of 81 months and in some cases by more than a decade.

This pro-patient result is frequently not achievable when generic manufacturers are sued by brand companies for patent infringement and settlements are not reached. Studies have shown brand companies win patent suits nearly 70% of the time, and settlement is the only way to provide timely market entry for lower-priced generic and biosimilar drugs. In fact, when a generic company loses in court it is precluded from entering the market until that patent expires—even if other companies settle and are allowed into the market sooner—thus reducing the competition that drives generic prices down. Yet again, Oregon patients will unnecessarily suffer higher medication costs when this occurs.

In 2013, in its *Actavis* decision, the United States Supreme Court held that unjustified and large reverse payments are subject to antitrust scrutiny. Since this decision, the Federal Trade Commission (FTC) has reviewed all Hatch-Waxman and BPCIA settlements and brings enforcement actions when warranted. By 2017, the type of alleged "pay-for-delay" settlements opposed by the proponents of SB 764 and AAM had been significantly reduced without threatening the pro-patient settlements that allow generic drugs onto the market sooner. Oregon should not attempt to legislatively correct a problem that has been solved with a new law and its unintended consequences of reduced access to lower-cost drugs.

Finally, **SB 764 will benefit brand pharmaceutical companies** that are working to build larger and larger patent thickets around their best selling and most profitable drugs. For example, AbbVie has obtained over 100 patents on Humira, a drug that makes its owner more money per year than the entire National Football League. Due to aggressive patent challenges by biosimilar manufacturers, lower-cost Humira

will be available to patients 11 full years prior to those patents expiring. Legislation like SB 764 puts those savings for Oregonians in jeopardy and would allow the AbbVie's of the World to continue to raise prices without competition. While PhRMA has opposed SB 764, it is largely based on its desire to avoid additional lawsuits, not because of the impact the law will have by limiting generic competition.

AAM supports ending alleged "pay-for-delay" settlements as defined by the United States Supreme Court. These unjustified, large reverse payments are not good for the industry nor patients who rely on lower drug prices. AAM is happy to support legislation that appropriately penalizes these settlements but must oppose SB 764 due to its overbroad and likely unconstitutional impact on patient access to lower-cost drugs.

Should you have any questions, please feel free to contact me at brett.michelin@accessiblemeds.org.

Sincerely,

Brett Michelin
Senior Director, State Government Affairs
Association for Accessible Medicines

Cc: House Committee on Health Care