

Your Generics & Biosimilars Industry

May 3, 2021

Dear HHS Conferees:

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

There are a number of provisions impacting prescription drugs in the House and Senate HHS bills. AAM is opposed to two provisions in the House version of the HHS bill due to the impact on Minnesota patients' access to more affordable generic and biosimilar prescription drugs:

Generic Drug Price Gouging Prohibited (House Article 5, Sections 1-6) Rather than focusing on drugs that drive high patient and taxpayer spending, this targets low-cost generic drugs. In addition, it has unprecedented requirements for manufacturers and is likely unconstitutional. For these reasons, AAM is opposed to this provision.

In 2019 alone, the use of generic and biosimilar drugs saved Minnesota \$4.5 billion and the United States \$313 billion. In fact, generics account for 90% of all U.S. prescriptions but only 20% of costs. However, the bill does not impact the highest-priced drugs, but would instead disturb the national market for generic medicines that provide tremendous savings to patients and taxpayers. This bill specifically targets generic drugs, even though the Kaiser Family Foundation Health System Tracker has found these medications only account for 3% of U.S. healthcare spending. This bill ignores the fact that brand-name drug prices are responsible for high prescription drug spending.

In addition, the bill would prevent a manufacturer from exiting the market. This is an unprecedented requirement for manufacturers selling products in the state, particularly for those drugs that consistently provide the most savings for your constituents.

Finally, the bill is very similar to legislation passed in Maryland in 2017. Because a state may not regulate commercial transactions that occur wholly outside of its borders the Maryland law was deemed unconstitutional by a federal court. Specifically, this legislation was found to violate the Commerce Clause of the U.S. Constitution by the Fourth Circuit Court of Appeals, and the U.S. Supreme Court denied review of that decision. Like Maryland, most transactions related to generic drug prices occur outside of Minnesota.

Alternative Biologic Products (House Article 5, Sections 9, 11, 12, 21) AAM appreciates the goals of the bill author, Rep. Schultz and proponents, of driving cost savings through greater access to biosimilar drugs. Unfortunately, the language in the House bill will not create the competition needed to create savings from biosimilars. The language limits health plans from having a preference for any product over another (reference/biosimilar/interchangeable) regardless of price. This not only discourages, but actively prevents health plans from taking steps to encourage their beneficiaries to use lower cost medicines. As a result, patients won't receive the benefit of accessing lower cost medicines and are denied the full value of their coverage.







Your Generics & Biosimilars Industry

Moreover, requiring plans to cover higher-cost brands on the same level as lower-cost biosimilars does not encourage providers to use lower cost biosimilars even if they have a lower net cost than the reference biologic. AAM shares the goal of increasing utilization of lower-cost medications, we do not believe this language will create the needed competition to result in that outcome.

For the past few weeks, AAM was pleased to work with Senator Nelson, Mayo Clinic, Essentia Health and other hospital providers to pursue mutually agreeable language. This collaboration resulted in agreement on compromise language that we encourage the conference committee to adopt as a replacement to the current language in the House bill, should you move forward with a biosimilar provision. We believe passage of this compromise language will reduce drug costs for Minnesotans by encouraging the use of biosimilars. We look forward to the potential for increased use of biosimilars and the benefits it will provide Minnesota consumers.

Please feel free to contact me at brett.michelin@accessiblemeds.org with any questions.

Sincerely,

Brett Michelin

Senior Director, State Government Affairs Association for Accessible Medicines

Bet Melylin



