Your Generics & Biosimilars Industry

January 23, 2023

Representative Zack Stephenson
Chair, House Commerce Finance and Policy
100 Rev. Martin Luther King Jr. Blvd.
St. Paul, MN 55103

Regarding: HF 17
AAM Position: Oppose

Dear Representative Stephenson,

On behalf of generic and biosimilar manufacturers, the Association for Accessible Medicines (AAM) writes to convey its opposition to House File 17. AAM is the leading trade association for the developers and manufacturers of generic and biosimilar medicines. Its core mission is to improve the lives of patients by advancing timely access to high quality, affordable, and FDA-approved generic and biosimilar medicines. AAM is concerned with both policies proposed in the legislation: the provisions narrowly targeting generic medicines for "excessive price increases" and the creation of a drug affordability board. While intended to lower costs for patients, portions of HF 17 would have the opposite effect and jeopardize patient access to low-cost medicines.

"Excessive Price Increases" Provisions Misguidedly Target Generic Medicines
Sections 1 through 6 prohibit "excessive price increases" of generic or off-patent medicines. State proposals seeking to regulate the price of generic medicines have been found to be unconstitutional. For example, the state of Maryland passed a substantially similar proposal (HB 631) in 2017. The Fourth Circuit Court of Appeals held that HB 631 violated the dormant Commerce Clause of the U.S. Constitution because states may not regulate commercial transactions that occur wholly outside its borders. Most financial transactions related to generic drugs occur across multiple state lines. The U. S. Supreme Court has held for almost a century that no state may "project its legislation into [another state] by regulating the price to be paid in that state, even when the goods sold in that out-of-state transaction are destined for resale in the state."

Further, HF 17 fails to focus on the prescription drugs responsible for increasing health care costs and instead penalizes generic manufacturers who introduce cost-lowering competition against high-cost brand-name drugs. By conditioning review of a drug on the percentage change in the price, the proposal is more likely to focus on lower-cost medicines even though these do not increase overall spending. In fact, the small number of generics that take a price increase do not result in increased costs – often because other competing manufacturers of the same generic do not increase prices. This generally results in a significant loss of market share for the manufacturer that increased its price but not an increase in costs for patients or other payers.

Generic and biosimilar medicines saved Minnesotans $5.3 billion in 2021 and were 91% of all prescriptions filled but only 18% of drug spending. Low-cost generics allow patients to more easily afford their prescriptions and remain adherent to treatment. The result is lower out-of-pocket costs for patients and better outcomes for the health care system. Continued patient access to low-cost, life-saving generic medicines is at risk due to these provisions and, thus, AAM must oppose HF 17.

Prescription Drug Affordability Boards Must Focus on High-Cost Brand-Name Drugs

Sections 7 through 17 would establish the Prescription Drug Affordability Act. While AAM has been able to take a neutral position on similar legislation passed in certain states, concerns remain about how particular policies would impact patient access to generic and biosimilar medicines. For example, Section 12 of HF 17 contains provisions regarding the identification of drugs for the board to review. The intent of the legislation is for the board to review price increases that cause affordability problems for patients and it differentiates what will trigger a review between brand-name drugs or biologics and biosimilars. Brand-name drugs and biologics will be reviewed based on a price increase or high list price at market introduction. But even though the intent of the bill is to scrutinize drugs that are creating new affordability problems, the bill would subject biosimilars to review even when they cost less than the brand.

The marketplace for biosimilars and interchangeable biologics is still developing, and biosimilar prices are rapidly declining. In fact, the average sales price of biosimilars today is less than half what the brand price was when the biosimilar launched. And this competition in turn is forcing brands to reduce their prices 25% on average. Accordingly, the biosimilar price at launch does not create new affordability problems. Instead, biosimilars are a solution to affordability and have resulted in more than 150 million days of new patient treatment because of their lower prices.

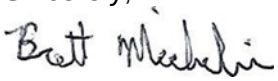
However, due to the nature of health plan formulary contracting, many biosimilar manufacturers will likely compete for formulary placement based not on front-end discounts but on back-end rebates. Regardless of the initial price of the biosimilar, patients will ultimately save. However, under the provisions of HF 17, biosimilar medicines could be subject to review and potentially upper payment limits, while the more expensive brand-name biologic would not.

For instance, a recent IQVIA report highlights this dynamic through the lens of a new insulin biosimilar. In response to market dynamics, the manufacturer launched two versions of the biosimilar – a branded version that was discounted by 5 percent but with back-end rebates and an unbranded version with a list price discount of roughly 65 percent. IQVIA concluded, “For some payers, products with higher list prices such as Lantus and interchangeable Semglee, may be more financially favorable, due in part to contracted rebates, even when compared to an option that is less than half the list price (WAC) such as insulin glargine.”

Biosimilars did not launch in the U.S. until 2015 and really began to impact the market by 2019. Use of biosimilars delivered over $7 billion in savings in 2021, and those savings will only grow. However, it is a young and developing market, we are still learning how it will operate. AAM stands ready to work with you as it’s important to avoid provisions that block future savings from biosimilar competition.

We would welcome the opportunity to discuss our views on House File 17 with you further. If you have any questions, please feel free to contact me at brett.michelin@accessiblemeds.org.

Sincerely,



Brett Michelin
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Association for Accessible Medicines