Your Generics & Biosimilars Industry

March 16, 2023

Senator Matt Klein
Chair, Senate Commerce and Consumer Protection
95 University Avenue
Minnesota Senate Building, 2105
St. Paul, MN 55155

Regarding: SF 328
AAM Position: Oppose

Dear Senator Klein,

On behalf of generic and biosimilar manufacturers, the Association for Accessible Medicines (AAM) writes to convey its opposition to Senate File 328. 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. Generic and biosimilar drug manufacturers saved Minnesota $5.3 billion in 2021 and lower-cost biosimilar drugs have increased patient access to care by more than 150 million days of therapy. The mandated reporting requirements with state posting of misleading information, lack of clarity in the drafting of this bill, and prohibition on changes to generic drug price are unnecessary and potentially could harm patient access to low-cost medicines. For these reasons, AAM must oppose SF 328.

SF 328 would require all drug manufacturers that produce a drug with a wholesale acquisition cost (WAC) of $100 or more for a 30-day supply or for a single course of treatment to report information to the state regardless of the amount of savings these medications may provide. This report will be in addition to the Minnesota Prescription Drug Price Transparency Act and would result in conflicting information on the state's website. Moreover, none of the information obtained from SF 328 will result in lower prescription drug costs for Minnesota patients.

The state is required to publish information obtained from the manufacturer, including the WAC price and the Average Wholesale Price (AWP). Neither the WAC nor the AWP reflect the patient costs at a pharmacy counter and public posting of this information may cause confusion leading patients to forgo medically necessary prescriptions. Manufacturers typically sell medications at a significantly reduced price from the listed WAC and AWP. Health plans and pharmacy benefit managers (PBMs) largely determine what a patient's share of cost —if any— will be at the pharmacy counter. This means there can be a significant difference between a generic medicine's WAC price and the cost to the patient. Thus, this information will not aid a patient's health care decisions and could result in a prescription not being filled.

If a generic drug with a WAC of $100 or more is placed on a formulary by any health plan, a manufacturer of that drug can only increase the price of a drug with 90-day advance notice for that calendar year. The bill is not clear if this provision will apply to only the manufacturer that has a WAC of $100 or to all manufacturers of that drug—many of whom may be significantly below the $100 threshold. This provision may be interpreted to place pricing restrictions on all generic manufacturers, not just the manufacturer which was required to reported. Is it the intent of this bill to impact the business decisions of one manufacturer to the actions of another?

Generic manufacturers typically sell medications to wholesalers, and these transactions generally occur outside of Minnesota. Federal courts have clearly held that one state cannot regulate commerce that occurs outside of its borders and SF 328 raises significant legal concerns.

For these reasons, AAM opposes SF 328. If you have any questions or concerns regarding this opposition, please feel free to contact me at brett.michelin@accessiblemeds.org.

Sincerely,

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