March 4, 2024

Representative Tina Liebling
Chairwoman, House Health Finance and Policy
477 State Office Building
100 Rev. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Regarding: HF 4098
AAM Position: Oppose

Dear Representative Liebling,

On behalf of generic and biosimilar manufacturers, the Association for Accessible Medicines (AAM) writes to convey its opposition to House File 4098. 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 and its patients $5.7 billion alone in 2022.

House File 4098 amends the Opiate Product Registration Fee program. The changes in reporting requirements will not provide useful information for the Board of Pharmacy to manage this program. Further, the bill will increase potential liability to drug manufacturers who are not engaged in the production of opioids—which is not the intent of this law. For these reasons, AAM must oppose HF 4098.

The Opiate Product Registration Fee program currently requires a manufacturer that is engaged in the production of an opiate to report to the board every sale, delivery, or other distribution of an opiate into the state. The purpose of the required reporting is to assist the board in assessing fees against those manufacturers that meet specified production levels. However, the changes contained in HF 4098 would require ALL drug manufacturers, whether they are engaged in opiate production or not, to report to the board. This could result in hundreds of reports being submitted to the board from manufacturers NOT engaged in the sale, delivery, or other distribution of opiates. This creates additional work for the board that provides no useful data.

The current law also allows the board to assess a $500 per day penalty against an opiate manufacturer or wholesaler that does not submit a required report to the Opiate Product Registration program. HF 4098 will expand that penalty to every drug manufacturer that does not even produce opiates. The opiate program is designed to assess fees on large opiate manufacturers that sell, deliver, or distribute into the state. It was not intended to impact every manufacturer that is not even engaged in the production of these products.

For these reasons, the Association for Accessible Medicines must oppose HF 4098. If you have any questions regarding this opposition, please feel free to contact me at brett.michelin@accessiblemeds.org.

Sincerely,

Brett Michelin

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