

A HARD PILL TO SWALLOW

Brand drug companies are trying to limit your access to cost-saving generic drugs and biosimilars

HOW MUCH DOES IT COST US ALL?

Over  **\$5,000,000,000** each year

Misuse of FDA patient safety programs such as Risk Evaluation and Mitigation Strategies (REMS) cost patients, payors, government programs and the entire health care system billions annually.



Separate studies project that biosimilars, alternatives to costly brand biologic medicines, could save up to

\$250,000,000,000

in the next **10 YEARS**

WE CAN BE SAFE AND FAIR

Patient safety is a top priority of the AAM and its Biosimilars Council. Our members strongly support current FDA-mandated REMS to ensure that the benefits of a drug outweigh its safety risks.

However, we must curtail brand drug companies exploiting regulatory loopholes to block patient access and delay market entry of generics and biosimilars. Patients deserve safety and competitive choices in the marketplace.

Brand drug companies are working hard to **S L O W D O W N** access to new generic drugs and biosimilars



Certain brand drug companies have been denying manufacturers of generic drugs or biosimilars access to the product samples they need to conduct bioequivalence studies necessary to gain FDA approval and pursue market entry.

Generic drug savings in the U.S.

Generics are 89% of prescriptions dispensed but only 27% of total drug costs

Medicare savings-

 **\$67.6 B**

 **\$1,737**
per enrollee

Medicaid savings-

 **\$32.7 B**

 **\$450**
per enrollee