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Patients Lose When Brand Drug Manufacturers Game the Generic Drug Approval Process

More Americans are growing anxious about the rising cost of health care and their access to affordable medicines. They're looking for answers from our leaders in Washington. And while there may not be one single answer, we must acknowledge the problems we are facing and the players in the industry that are contributing to them.

More and more, brand pharmaceutical companies are exploiting a broken system by stifling competition and denying Americans access to affordable generic prescription drugs to the tune of \$5.4 billion a year in lost savings, with a government price tag of \$1.8 billion.

The Food and Drug Administration (FDA) considers generic drug alternatives to brand name drugs through an Abbreviated New Drug Application (ANDA). Safety protocols known as Risk Evaluation Mitigation Strategies (REMS) accompany certain brand drugs and are designed to ensure the distribution of these drugs follows certain FDA safety procedures. These systems are well intentioned and designed to have patients' best interest at heart, yet gaping loopholes in the process are having the opposite effect.

Here's how it works: when a generic or biosimilar drug maker is interested in bringing a competitive medicine to the marketplace, the generic drug company must first acquire the most basic component of the process: purchasing samples from the branded drug company. The catch is, as the FDA has reported, generic companies are often simply unable to acquire the samples essential to testing and meeting requirements necessary to developing an application for a generic drug. More troubling, some brand manufacturers are now using similar mechanisms, of their own making, to block generic and biosimilar drug developers from obtaining necessary samples without any FDA mandate.

The reason for this is simple: some branded drug companies are using every means possible to thwart lower cost alternatives from entering the market. This is a major problem, especially considering that nearly 9 of every 10 of the 12 million prescriptions taken each day is a generic. And despite their near universal usage, generics accounts for a mere 28 percent of the amount spent on prescriptions.

The bottom line is that generic drugs are saving the American health care system \$5 billion per week, yet the current system is limiting patient access to these savings. That's a lot of money being left on the table.

Congress has the ability to fix this problem and foster more competition in the prescription drug market by passing two initiatives that are currently circulating on Capitol Hill. The FAST Act which has been proposed in the House and the CREATES Act in the Senate are viable reforms that could prevent the current anti-competitive business practices that are increasing costs in the American health care system and impeding patient access to more affordable generic drugs. Any fix considered by Congress must ensure that generic and biosimilar drug makers aren't inappropriately stymied by brand drug makers from bringing more safe, effective, lower-cost alternative medicines to market—either by brands misusing FDA safety programs or placing artificial restrictions on access to their products.

Now, more than ever, Americans are looking to Washington for answers to problems in our health care system. It's time to start showing them some results. The Generic Pharmaceutical Association is now proposing 5 concrete policy prescriptions, including this one - curbing the abuses of REMS and REMS-like programs - that policymakers can enact today to spur competition and bring treatments within reach for more Americans.