

July 12, 2016

The Honorable Chuck Grassley
The Honorable Patrick J. Leahy
Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, D.C., 20510

Dear Chairman Grassley, Ranking Member Leahy and members of the Senate Judiciary Committee:

As national organizations representing a wide range of U.S. consumers, we write today in support of S. 3056, **the CREATES Act**. This legislation takes necessary steps to address the affordability and accessibility of prescription drugs. According to the Centers for Disease Control and Prevention's [National Center for Health Statistics](#), prescription drugs account for nearly 10 percent of the \$3 trillion of U.S. health care expenditures each year. According to a [study by Truveris](#), prescription drug prices increased by [10 percent during 2015](#), compared to 2 percent for other [consumer goods and services](#). A 2016 [analysis by Reuters](#) found prices increases for the top ten prescription drugs to have increased between 50 percent to 5,000 percent over the last 5 years. IMS Health data indicates that sales for the top 10 drugs went up 44 percent to \$54 billion in 2014, from 2011, despite the fact that prescriptions for these medications dropped 22 percent.

Part of the solution to stabilize and ultimately lower medication costs is to increase competition in the marketplace. Thanks to the success of the 1984 landmark Hatch-Waxman Act, generic drugs are making many treatments more accessible by lowering costs for consumers. In fact, from 2005 to 2014, generic drugs saved consumers and our government some \$1.68 trillion, and savings have steadily increased each year. Not only are brand name medications priced on average 300% higher than generics, but these prices are increasing at a faster rate due to a lack of competition. In 2015 alone, the price of brand drugs [increased 50% faster than the average increase in drug prices](#).

One of the principle reasons for the high and rising costs, as members of this committee understand, is that brand drug manufacturers can obstruct competitive entry, even for drugs with expired patents. This is because brand manufacturers have been able to impede the ability of rivals to buy samples of their drugs for testing. Because the FDA's [REMS program](#) allows brand manufacturers to restrict channel distribution, brand manufacturers can sometimes prevent generic manufacturers from buying samples of the originator drug. Without these critical samples, generic drugs cannot be tested for effectiveness, which prevents the FDA from obtaining the necessary information it needs for approval.

With this loophole, brand manufacturers with expired patents can block competition and keep prices higher, which means that patients, hospitals, insurers and government plans will pay significantly more. [One study estimated](#) the annual cost of this delay to the health care system to be \$5.4 billion, including \$1.8 billion in additional payments by the government, and nearly \$1

billion more in patient out-of-pocket costs. Money aside, higher drug prices also discourage patient access to medication, which can cost lives.

Similar delays are happening with a new class of drugs known as *biosimilars*. This next generation of drugs are often used to treat some of the most serious, life-threatening diseases. Biosimilar substitutes have existed in Europe and many other countries for well over a decade, but the same barriers generics are facing are now being used to stall these lifesaving drugs from being introduced to the U.S. market.

The CREATES Act gives generic pharmaceutical manufacturers, for the first time, legal recourse to obtain product samples and access to shared safety protocols. The passage of this legislation would be a monumental win for consumers and assure that biosimilar drugs can be tested for safety and effectiveness.

Removing competitive barriers by ending these anticompetitive practices are essential to bringing lower cost drugs to market and benefitting patients. That's why we believe the CREATES Act is pro-consumer and we urge your consideration of this bill. The bill works to close the regulatory loophole and encourages market competition, as well as end other barriers to competition being exploited by brand pharmaceutical companies – and all while saving lives and money. In short, market competition will mean lower drug prices and greater access for patients.

We thank this committee for its leadership to end these abusive practices that ultimately deny patients the ability to afford lifesaving medicines.

Respectfully,

Steve Pociask
President
American Consumer Institute

Ken McEldowney
Executive Director
Consumer Action

Carmen Balber
Executive Director
Consumer Watchdog

Peter Maybarduk
Access to Medicines Director
Public Citizen

Stephen Ellis
Vice President
Taxpayers for Common Sense