June 14, 2017

Chairman Chuck Grassley
Senate Judiciary Committee
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

Ranking Member Dianne Feinstein
Senate Judiciary Committee
United States Senate
331 Hart Senate Office Building
Washington, DC 20510

Dear Chairman and Ranking Member:

As national organizations representing a wide range of U.S. consumers, we write today in support of S. 974, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017. What the CREATES Act represents is a market-based way that contributes to giving consumers access to lower cost prescription drugs without stifling innovation. This legislation takes necessary steps to address the affordability and accessibility of prescription drugs.

According to IMS Health, Americans spent some $424 billion last year on prescription drugs, accounting for nearly 20 percent of all health care expenditures. A new Segal report projects drug prices to continue increasing, climbing another 12 percent in 2017. The increasing financial strain facing patients and essential government health care programs is staggering.

Part of the solution to stabilize and ultimately lower medication costs is to increase competition for off-patent drugs. Thanks to the success of the 1984 landmark Hatch-Waxman Act, generic drugs are making many treatments more accessible by driving down costs for consumers. In fact, in the last decade, generic drugs saved consumers and our government some $1.68 trillion, and this savings has grown steadily each year. Not only are brand name medications priced on average 300% higher than generics, 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. Because the FDA's REMS program allows brand manufacturers to restrict channel distribution, these companies can sometimes prevent generic and biosimilar 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 without any tangible benefit. 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. The government savings alone would top $3 billion over a 10-year period, according to estimates from the Congressional Budget Office. Money aside, higher drug prices also discourage patient access to medication, which can cost lives.

Removing impediments to competitive entry is essential to bringing lower cost drugs to market and benefitting patients. That's why we believe the CREATES Act is pro-consumer, and we strongly support the legislation. We thank the committees for their leadership in curbing these abusive practices that ultimately deny patients access to lifesaving medicines.

Respectfully,

James L. Martin
Founder/Chairman
60 Plus Association

Steve Pociask
President/Chairman
American Consumer Institute

Andrew F. Quinlan
President
Center for Freedom and Prosperity

Jonathan Bydlak
President
Coalition to Reduce Spending

Wayne T. Brough
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Alden F. Abbott*
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Institute for Liberty

Jeff Stier
Senior Fellow/Director, Risk Analysis Division
National Center for Public Policy Research

Lew Uhler
President and Founder
National Tax Limitation Committee

Hector V. Barreto
Chairman
The Latino Coalition

cc: Senate Judiciary Committee Members

*Mr. Abbott's title and affiliation with the Heritage Foundation are for identification purposes only. The views expressed are those of Mr. Abbott and do not necessarily represent the views of the Heritage Foundation.