

April 27, 2017

Re: Pass the *Creating and Restoring Equal Access to Equivalent Samples Act of 2017*

Dear Leader McConnell, Minority Leader Schumer, Speaker Ryan, Minority Leader Pelosi, Chairman Grassley, Ranking Member Feinstein, Chairman Goodlatte, Ranking Member Conyers and members of the Senate and House Judiciary Committees:

The undersigned organizations representing healthcare providers, clinical researchers, public health experts, and consumer and taxpayer advocates are committed to advancing public health and promoting access to affordable medicines. We are writing to express our support for and urge you to pass the *Creating and Restoring Equal Access to Equivalent Samples Act of 2017* (CREATES Act), a bipartisan, bicameral reform to bring down drug prices.

Generic competition has been proven to be an effective method to bring down prescription drug prices and is an integral component of limiting costs in our healthcare system. Lawmakers strived to strike a balance between innovation and access through the *Drug Price Competition and Patent Term Restoration Act*, commonly known as the Hatch-Waxman Act, but too often brand-name prescription drug companies abuse regulatory and other systems to prevent generic competition and preserve monopolies. Those tactics allow them to charge exorbitant prices, leading to increased healthcare costs, higher premiums and out-of-pocket expenses for consumers and, at times, putting medicines out of reach of the people who need them to lead healthy and productive lives.

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which included new requirements to provide additional safeguards for use of certain high-risk prescription drugs through Risk Evaluation and Mitigation Strategy (REMS) programs. While REMS programs can help ensure safety with certain drugs, brand name companies at times abuse REMS programs to prevent potential competitors from attaining FDA approval for generic and biosimilar products that, once approved, would compete with the originator's drug.

These abuses from brand-name drug companies take three forms^{1,2}: 1) invoking the existence of a REMS program as a rationale for denying a generic company access to a sample they require to pursue an abbreviated new drug application (ANDA), 2) attaining method patents on a REMS program itself to prevent generic firms from making use of the same REMS program as required under the FDAAA, and 3) refusing to negotiate a shared REMS with a generic firm to prevent launch of a competing generic product that is otherwise ready for FDA approval.

While the CREATES Act could be strengthened to address anticompetitive patenting of REMS, the measures of the bill provide strong remedies to the other two forms of REMS abuse. By curbing REMS abuses, the CREATES Act is estimated to save taxpayers more than three billion dollars over the next decade. In the context of annual national prescription drug spending projected to reach \$610-640 billion

¹ Sarpatwari A, Avorn J, Kesselheim AS. Using a drug-safety tool to prevent competition. *N Engl J Med*. 2014;370(16):1476-1478. Accessed at: <http://www.nejm.org/doi/pdf/10.1056/NEJMp1400488>.

² Testimony of Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, before the U.S. House of Representatives' Committee on Oversight and Government Reform's Subcommittee on Health Care, Benefits, and Administrative Rules. March 22, 2017. Accessed at: <https://oversight.house.gov/wp-content/uploads/2017/03/Leicher-Testimony-House-OGR-Hearing-3.22.17.pdf>.

in 2018³, this is only a modest step, yet it is an important bipartisan remedy to one form of anticompetitive and monopolistic abuse that the drug industry uses to price gouge consumers. Please pass the CREATES Act without delay.

Sincerely,

ACT UP/ NY

AFL-CIO

American College of Physicians (ACP)

Center for Medicare Advocacy

Doctors for America

Families USA

Health Global Access Project (Health GAP)

Knowledge Ecology International (KEI)

National Physicians Alliance (NPA)

National Center for Health Research (NCHR)

National Committee to Preserve Social Security & Medicare (NCPSSM)

Public Citizen

Social Security Works (SSW)

Taxpayers for Common Sense

Treatment Action Group (TAG)

Universities Allied for Essential Medicines (UAEM)

³ IMS Institute for Healthcare Informatics. Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020. April 2016. Accessed at: <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf>