



October 26, 2016

President Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Obama:

As organizations that represent millions of Americans, including consumers, retirees, and patients, and that provide medical care globally, we are concerned about recent reports that your Administration is working behind the scenes to craft Trans-Pacific Partnership (TPP) implementing legislation and possibly enter into side letters that would mean even more lengthy monopoly protections for biologics than the already onerous provisions in the TPP agreement. It is our understanding that this could bind the United States to a 12-year market exclusivity period for biologics and block the U.S. and other countries from reducing the amount of time expensive biologic drugs are protected from competition from less expensive biosimilar drugs.

Throughout the TPP negotiations, our organizations called for provisions that improve both innovation and access to affordable medicines. Though we each have our own critiques of the TPP, we share a view that no TPP commitment should be taken to worsen the plight of Americans already struggling to afford the high and growing prices of prescription drugs, as are millions of people around the world. We salute your Administration for using your budget proposals to suggest ways to improve the affordability of prescription drugs, including reducing the current 12-year market exclusivity period for biologic drugs. We also strongly support your work to continue implementing the new biosimilar approval pathway to increase price competition.

Biologics are fast becoming the future of pharmaceuticals. These drugs are used to treat many diseases – such as multiple sclerosis, rheumatoid arthritis, cancer and others – that often affect older populations. However, the cost of these drugs can put these treatments out of reach for those who need them most, even those with comprehensive health

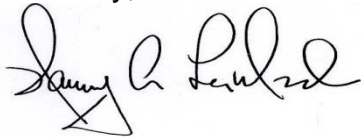
insurance. The daily costs associated with biologics are approximately 22 times higher than the daily costs associated with small-molecule drugs. With annual costs that can reach as high as \$600,000 per individual, the high price of biologic drugs not only has adverse effects on consumers, but also on taxpayer-funded programs like Medicare and Medicaid.

Reportedly, under your Administration's discussions with key legislators the United States' current 12-year market exclusivity period would be included in TPP implementing legislation. This would go beyond the TPP provisions that already require at least eight years of exclusivity, or at least five years of exclusivity plus additional protections. Binding the U.S. and any other TPP party to an international obligation that requires a 12 year exclusivity period would not only undermine your proposal but future proposals to provide no more than seven years of market exclusivity to enable lower cost biosimilars to come to market sooner.

A change that binds the U.S. government to a 12-year market exclusivity period for brand-name biologics would prevent U.S. policymakers from taking action to reduce the costs associated with biologic drugs. In fact, Senators Sherrod Brown (D-OH) and John McCain (R-AZ) and several House Democrats have introduced the Price Relief, Innovation, and Competition for Essential Drugs Act (PRICED Act), which would reduce the biologic market exclusivity period from 12 to seven years, as you have proposed in your budget. Providing for 12-years of market exclusivity as part of U.S. implementation of the TPP would mean accepting unnecessarily long drug monopolies at the expense of people's health and financial solvency. According to the Federal Trade Commission, no exclusivity time is needed to promote innovation given patent protections and other market pricing incentives.

We strongly urge you not to include language in the TPP implementing legislation committing the United States to 12-years of exclusivity or enter into side letters to extend the biologics exclusivity period for any TPP signatory country. We ask you to stand by your previous support for reducing U.S. market exclusivity to seven years for high cost biologic medicines.

Sincerely,



Nancy A. LeMond
Executive Vice President and Chief Advocacy & Engagement Officer
AARP



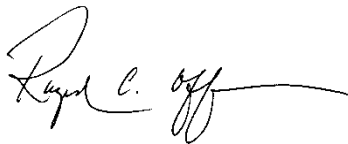
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CC: Ambassador Michael Froman, United States Trade Representative