



October 22, 2013

Ambassador Michael Froman  
United States Trade Representative  
600 17th Street NW  
Washington, DC 20508

*Submitted electronically via correspondence@ustr.eop.gov*

Dear Ambassador Froman:

As the nation's largest nonprofit, nonpartisan organization representing the interests of Americans age 50 and older and their families, we are writing to comment on the ongoing negotiations surrounding the Trans-Pacific Partnership (TPP) and the issue of market exclusivity for biologic drugs. It is our understanding that market exclusivity is one of the outstanding issues negotiators are working to resolve with the goal of completing the trade agreement before the end of the year. **AARP strongly believes the final trade agreement should not bind the U.S. to a 12-year market exclusivity period for brand-name biologic drugs.**

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 for 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 \$400,000, the high price of biologic drugs not only has adverse effects on consumers, but also on other health care payers, including public programs like Medicare and Medicaid.

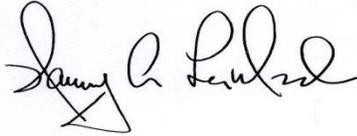
The Patient Protection and Affordable Care Act (ACA) recognized there was a need for less expensive follow-on biologics, or biosimilars, both to help ensure access to biologic drugs and to reduce the economic burden they impose. However, the ACA created a 12-year market exclusivity period for brand-name biologics even though the Federal Trade Commission concluded that no additional exclusivity beyond the term of the patent was necessary to maintain innovation and competition in the industry. Numerous generic drug manufacturers have said the 12 years of market exclusivity provided by the ACA makes developing biosimilars prohibitively risky from a business perspective.

The Administration itself has proposed reducing the exclusivity period for brand-name biologics in its most recent FY 2014 budget and previous budgets. AARP strongly supports this proposal and believes increasing the availability of biosimilars will be a critical element of any comprehensive effort to contain health care costs. In fact, AARP has endorsed

reducing the market exclusivity period for brand-name biologics from twelve years to seven that would result in a \$3.8 billion savings (OMB, 2012) and biosimilars with prices that are 40 percent lower than their brand-name counterparts (CBO, 2011). However, should the U.S. agree to the TPP with a provision requiring a 12-year market exclusivity period for brand-name biologics, U.S. policymakers would be prevented from taking action to reduce the costs associated with biologic drugs for U.S. consumers. AARP also believes the U.S. should seek to deter so-called “evergreening” practices under the TPP, and manufacturers should have to demonstrate a clear, significant clinical advantage over the reference product in order to receive an additional period of exclusivity.

Thank you for considering our comments. If you have any questions, please do not hesitate to contact me or KJ Hertz on our Government Affairs staff at (202) 434-3732 or [khertz@aarp.org](mailto:khertz@aarp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Nancy A. Leamond". The signature is fluid and cursive, with a large initial "N" and "L".

Nancy A. Leamond  
Executive Vice President  
State and National Group

cc: Barbara Weisel, Assistant U.S. Trade Representative for Southeast Asia and the Pacific, Office of the U.S. Trade Representative