June 27, 2018

The Honorable Robert Lighthizer
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Lighthizer:

I write to you to express AARP’s strong desire that the renegotiated text of the North American Free Trade Agreement (NAFTA) not include harmful provisions that would reduce competition in the prescription drug market and increase prescription drug costs for American consumers. More specifically, AARP strongly opposes efforts to add harmful provisions to the renegotiated text of NAFTA that would extend or enhance monopoly protections for already-expensive biologic drugs.

AARP, with its nearly 38 million members in all 50 States, the District of Columbia, and the U.S. territories, is a nonpartisan, nonprofit, nationwide organization that helps strengthen communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

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

AARP strongly believes that the United States’ current 12-year market exclusivity period for brand name biologics is too long. Thus, we are greatly concerned by reports that a 12-year market exclusivity period could be included in renegotiated text of NAFTA. AARP supports lowering the exclusivity period for biologics from 12 to 7 years. Using an international obligation to bind the U.S. to its problematic 12-year market exclusivity period will limit policymakers’ ability to increase competition and reduce the costs associated with biologic drugs in the future.
AARP is also concerned by proposals that would expand prescription drug patent linkage, or make market approval of a generic drug conditional on the absence of a patent. Specifically, we are concerned about efforts to expand patent linkage to all drugs with a patent, unlike U.S. law which limits linkage to three types of patents covering small molecule drugs: drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. Extending patent linkage to biologics – which would also require a change in U.S. law – would be extremely detrimental to the development of the US biosimilar market.

AARP is encouraged by the Administration’s focus on lowering drug prices, including accelerating efforts to implement the biosimilar approval pathway. The high price of brand name biologic drugs not only has adverse effects on consumers, but also on taxpayer-funded programs like Medicare and Medicaid. Consequently, it is critical that we take steps to enhance and improve the U.S. biosimilar market. The inclusion of market exclusivity or linkage provisions in the renegotiated NAFTA text would take us in the opposite direction. We ask you to reject the inclusion of those policies in a renegotiated NAFTA and stand by your previous support for enhancing competition and making prescription drugs more affordable and accessible for all Americans.

Sincerely,

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