

November 5, 2018

The Honorable Robert E. Lighthizer
U.S. Trade Representative
600 17th Street, NW
Washington, D.C. 20508

Dear Ambassador Lighthizer:

We are writing jointly to express our serious concern that the recently renegotiated version of the North American Free Trade Agreement (NAFTA) – now proposed to be called the U.S.-Mexico-Canada Free Trade Agreement (USMCA) – will exacerbate the problem of high prescription drug prices in the United States. This trade agreement, if left in its current form, will keep drug prices high in the United States, to the detriment of our nation’s patients, job creators, workers, and taxpayers. Furthermore, several provisions within the agreement are inconsistent with U.S. law and, if left unchanged, could lead to inappropriate modifications to U.S. law or cause the United States to be in violation of the agreement on day one of its enactment. We call on you, together with the other Administration and Congressional leaders copied on this letter, to help improve the agreement before it is finalized to assure American patients and taxpayers that neither the market for affordable generic and biosimilar medicines, nor U.S. sovereignty over drug price regulation, is put at risk as a result of the USMCA.

I. The Proposed USMCA Will Slow Biosimilar Development and Harm Generic Drug Competition in the U.S.

Encouraging biosimilar development and enhancing generic and biosimilar competition is critical to lowering drug prices. Yet the USMCA would establish new monopolies for already costly brand-name medicines. Raising barriers to affordable medicines through trade agreements delays patient access to competitive generic and biosimilar medicines that have lower prices than their brand-name counterparts. We are deeply concerned that the 10-year brand-name biologic exclusivity provision proposed in the USMCA, as well as the other barriers it adds to generic and biosimilar competition, will slow the development of biosimilars and limit patient access to more affordable medicines. Even if Congress later decides that these pharmaceutical monopoly periods are not needed to incentivize the development of new medicines, as currently written, this trade agreement will prevent Congress from taking corrective action and lowering drug prices.

II. Improving USMCA to Enhance Access to Affordable Medicines

Contrary to the intent of Congress, the USMCA provisions on pharmaceuticals do not adequately balance the joint priorities of innovation with access to medicine.¹

While the proposed USMCA text includes numerous monopoly protections and deterrents to competition — extended biologics exclusivity, broad exclusivities for drugs, patent term extensions and patent term adjustments, to name a few — the agreement lacks critical features of U.S. law that encourage generic and biosimilar competition. The imbalance in the proposed USMCA should be addressed through changes to the proposed agreement such as including: a more robust regulatory review provision (“Bolar”); an appropriate incentive to encourage market entry by generic and biosimilar applicants; requirements for transparency around patents and exclusivities; and, a “best mode” requirement. Only with the addition of such provisions can we be assured that, consistent with the Administration’s goal of lowering drug prices, price competition from affordable generic and biosimilar medicines will be available to American patients, taxpayers, and healthcare payers. In addition, USTR

¹ Bipartisan Congressional Trade Priorities and Accountability Act of 2015, Pub. L. No. 114-26, Sec. 102(b)(5)(C) (creating a principle trade objective “to ensure that trade agreements foster innovation and promote access to medicines.”)

and Congress should ensure that the USMCA is consistent with the terms used in U.S. law, particularly the Drug Price Competition and Patent Term Restoration Act (known as the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act, as well as the balance provided in U.S. law. The USMCA should not extend brand-name drug patents or exclusivities beyond U.S. law in any way, including through definitions of terms in the agreement, such as biologics, nor should it interfere with future Congressional actions to promote generic and biosimilar competition, reform U.S. patent law, or otherwise promote affordable life-saving medicines.

In conclusion, we look forward to working with you and Congress to foster a free, fair, and balanced trade agreement with Mexico and Canada that ensures an adequate balance between access to affordable medicines and support for pharmaceutical innovation.

Sincerely,

AARP

Academy of Managed Care Pharmacy (AMCP)

AFL-CIO

Alliance for Retired Americans

America's Health Insurance Plans (AHIP)

American College of Physicians

American Consumer Institute

American Federation of State, County and Municipal Employees (AFSCME)

American Federation of Teachers

Association for Accessible Medicines

Blue Cross Blue Shield Association

Center for Freedom and Prosperity

Coalition to Reduce Spending

Consumer Action

FreedomWorks

Frontiers of Freedom

Global Healthy Living Foundation

Healthcare Supply Chain Association (HSCA)

Innovation Defense Foundation

Jubilee USA Network

Kaiser Permanente

Knowledge Ecology International

National Coalition on Health Care

NETWORK Lobby for Catholic Social Justice

Ohio Public Employees Retirement System

Patients for Affordable Drugs

Public Sector HealthCare Roundtable

R Street Institute

SEIU

Cc: The Honorable Mitch McConnell, Majority Leader, United States Senate
The Honorable Charles Schumer, Democratic Leader, United States Senate
The Honorable Paul Ryan, Speaker, United States House of Representatives
The Honorable Nancy Pelosi, Democratic Leader, United States House of Representatives
The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services
The Honorable Scott Gottlieb, M.D., Commissioner of Food and Drugs
The Honorable Seema Verma, Administrator, Centers for Medicare and Medicaid
The Honorable C.J. Mahoney, Deputy U.S. Trade Representative