## Congress of the United States

July 11, 2019

Mashington, D.C. 20515

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

Dear Ambassador Lighthizer:

We write to express our strong opposition to provisions that limit access to medicines in the revised NAFTA agreement, also known as United States-Mexico-Canada Agreement (USMCA). Without changes to the underlying trade agreement, patients will pay the high price of prescription drugs for longer and experience no relief from the financial burden often imposed on them and their families by unaffordable medication. We, thus, encourage you to amend the USMCA to increase competition and enhance patient access to more affordable prescription drugs, reflecting the balance achieved in the bipartisan May 10, 2007 agreement.

The USMCA would keep drug prices out of reach for patients by increasing and locking in 10 years of marketing exclusivity for brand biologics, expanding the scope of brand biologics eligible for protection, and making it easier for brand-name drug companies to extend their monopolies through additional patents, patent extensions, and other forms of patent "evergreening." As recently noted by the Food and Drug Administration (FDA), brand biologics now represent 40 percent of all spending on prescription drugs and, from 2010 to 2015, comprised 70 percent of the growth in drug spending. Brand biologics are "forecasted to be the fastest growing segment of drug spending in the coming years." Unfortunately, due to the aforementioned provisions, the USMCA would only exacerbate this trend. Unless the USMCA text is amended, it would limit Congress' ability to adjust the biologics exclusivity period, instead locking the US into policies that keep cancer and other drug prices high while exporting this model to Mexico, which has no additional exclusivity period for biologics, and to Canada, which has an eight-year period.

In order to reduce the cost of prescription drugs for America's patients, patient access to more affordable biosimilars must be enhanced and not delayed by additional monopoly protections for brand biologics. A recent Politico/Harvard poll found lowering prescription drug prices as one of the top overall priorities for the new Congress, with 89 percent of Republicans and 94 percent of Democrats saying it is "extremely important." In contrast, however, polling from Morning Consult found 75 percent of the public is concerned that the USMCA will negatively impact drug prices and 81 percent believe our trade policies should increase — not decrease — access to affordable medicines.

We, therefore, request revisions to the access to medicines provisions in the USMCA to make them consistent with the bipartisan May 10<sup>th</sup> standard. Improving patient access to more affordable medicines, in particular biosimilars, is essential to lowering prescription drug prices and a critical

<sup>&</sup>lt;sup>1</sup> FDA Commissioner Scott Gottlieb, M.D., Remarks on the Release of the FDA's Biosimilars Action Plan, July 28, 2018, available online.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Politico/Harvard, "Americans' Health and Education Priorities for the New Congress in 2019," January 2019, available online.

<sup>&</sup>lt;sup>4</sup> Morning Consult, "Americans believe the new U.S.-Mexico-Canada trade agreement (USMCA) will keep drug prices high," October 26-28, 2018, available online.

component of the Administration's *Blueprint to Lower Drug Prices*. Otherwise, the USMCA only doubles down on the unsustainable trend of skyrocketing prescription drug costs by extending the monopoly protections awarded to brand-name drug companies.

We look forward to your reply and would be glad to work with you to improve the access to medicines provisions in the USMCA to benefit America's patients.

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