COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

May 3, 2019

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

Dear Ambassador Lighthizer:

As our Committee prepares to consider the renegotiated trade agreement with Canada and Mexico ("the new Agreement"), we write to express our concern about how the new Agreement will affect Congress's ability to adequately address the rising cost of health care in the United States.

In 2007, as part of the May 10 Agreement, House Democrats secured changes to the intellectual property provisions in four trade agreements that had been signed but were still awaiting Congressional consideration. We had been expressing serious concerns for several years regarding these provisions in our trade agreements. The concern was that the scales had been tipped too heavily against access for people in need of life-saving medications in developing countries. The rules were favoring manufacturers' demand for further incentives to innovate.

By the early 2000s, Acquired Immunodeficiency Syndrome (AIDS) had become a global pandemic. However, promising therapies remained out of reach for the majority of those affected because of their cost. At that time, because the drugs were available only from the companies that controlled the patents, one year of antiretroviral treatment cost around $10,000 per patient. That was equivalent to roughly two or three times the per capita income in Peru. Once generic alternatives became available, the average cost of treatment dropped dramatically and the number of people living with Human Immunodeficiency Virus (HIV) receiving treatment increased substantially, especially in developing countries.

With these facts in mind, House Democrats considered that it was necessary at that time to strike a new balance between access to medicine and innovation. As a result, four elements in the then-pending trade agreements were changed as part of May 10: data protection for marketing approval, patent term extension, linking marketing approval to patent status, and a side letter on public health affirming language from the Doha Declaration.

In 2007, our concern was that people in developing countries were being denied access to health care. Today, we are also concerned that Americans are being priced out of access.

In November, Democrats regained the majority in the House of Representatives on promises to ensure Americans will have better, more affordable access to health care, including prescription drugs. We are serving in the 116th Congress under that very clear mandate. As we review the new Agreement, we will be considering its terms through the lens of this mandate.

U.S. law seeks to balance innovation and access to medicines. Founded by rights granted in the Constitution, the United States provides robust intellectual property protections and enforcement that fosters the world's most innovative therapeutic development. We believe it is critical that the United States remains the leader in health care innovation. However, we also believe that Americans are entitled to timely access to affordable health care and medicines. Our laws and regulations provide incentives and safeguards that encourage and allow generic competitors to enter the market when appropriate, lowering costs over time. As the health care industry evolves, Congress develops and sometimes revisits key legislation that sets out these rules, addressing the balance between innovation and access.

The new Agreement seeks to export standards like the ones set in current U.S. laws and policies. Similar to May 10, our attention is drawn to provisions such as the number of years of market exclusivity provided for and the definition of biological pharmaceuticals, usage of secondary patents, linkage of a valid patent to marketing approval of a drug, and the Bolar exemption. We note that the new Agreement does not export some of the safeguards and incentives the U.S. system provides for generic companies to be the first to enter into our market.

Our concern is not that the new Agreement will change U.S. law. But at the same time, we do not want to be limited in addressing the current health care landscape, which is not working for many Americans. In addition, the standards set in the new Agreement will significantly change the intellectual property regimes in Canada and Mexico. This will almost certainly lead to higher costs for health care for their citizens and for Americans who have opportunities to procure their medicines in those jurisdictions. As our constituents continue to face rising health care costs, our concern is that the new Agreement will hamper or otherwise prevent our efforts to address the pressing needs of Americans.

We look forward to working closely with you to resolve the issues we have raised in this letter. Americans deserve a health care system that they can afford.

Sincerely,

Richard E. Neal

The Honorable Richard E. Neal
Chairman

Earl Blumenauer

The Honorable Earl Blumenauer
Chairman, Subcommittee on Trade

The Honorable John Lewis

The Honorable Mike Thompson

The Honorable John B. Larson

The Honorable Ron Kind

The Honorable Danny K. Davis

The Honorable Linda T. Sánchez

The Honorable Brian Higgins

The Honorable Terri A. Sewell

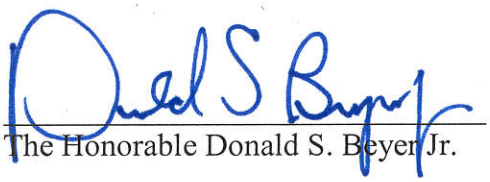
The Honorable Suzan K. DelBene

The Honorable Judy Chu

The Honorable Gwen Moore

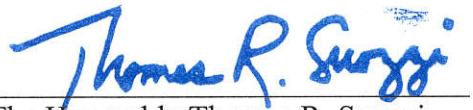
The Honorable Daniel T. Kildee

The Honorable Brendan F. Boyle

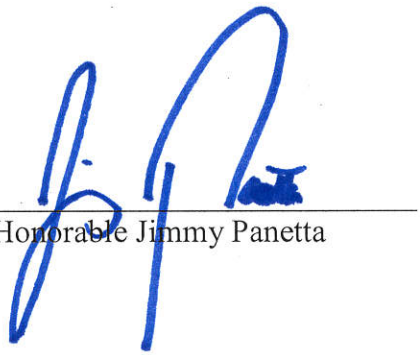


The Honorable Donald S. Beyer Jr.

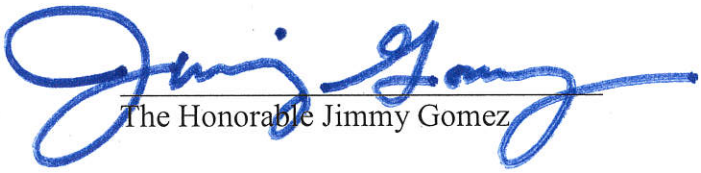
The Honorable Dwight Evans



The Honorable Thomas R. Suozzi



The Honorable Jimmy Panetta



The Honorable Jimmy Gomez

The Honorable Steven Horsford