# USMCA and Medical Innovation

**PREPARED FOR THE PASS USMCA COALITION**

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## Introduction

I want to take this opportunity to dispel some myths concerning the implementation of the U.S.-Mexico-Canada Agreement ("USMCA") and specifically the intellectual property protections for pharmaceuticals contained therein. The current discussions regarding the pharmaceutical provisions in the USMCA are not new: during my tenure as Secretary of Health and Human Services, these issues were under active debate, including in the context of the free trade agreements ("FTAs") negotiated and concluded during that period. Then, as now, it is a fact that FTAs do not change U.S. law, nor should Congress use them as a vehicle to change U.S. laws. Congress always has the ability to change the laws about pharmaceuticals if it determines that such changes are in the best interests of the American people.

The current debate about data protections for pharmaceutical products in the context of USMCA as limiting Congress's legislative power is therefore completely unnecessary; rather, it is just a stalling tactic for a hugely important trade bill. Additionally, the concern that this provision will somehow raise drug prices for U.S. patients is misplaced. Lastly, protections for intellectual property in the pharmaceutical field are absolutely essential to create and maintain the conditions for continued innovations, and to sustain a key job-creator for the American economy. Instead of focusing on this one provision, Congress should debate the merits of the overall agreement. In doing so, I believe Members will make the right choice, and pass the bill.

## Myth 1: The USMCA Will Change U.S. Domestic Law

The power to change U.S. laws rests with Congress, and passing the USMCA does not and cannot change that fact. The implementation of the USMCA also does not require any change to U.S. laws relating to pharmaceuticals; instead, it merely brings Canada and Mexico closer to the standards under current U.S. law. This is the case with FTAs generally, and would be the case even if the Trump Administration had not made additional assurances in this regard.

Specifically, U.S. law is and always has been the redline of negotiating positions for the United States in FTAs, and the U.S. government negotiators work hard to protect those lines, even when other countries attempt to push them beyond the laws Congress already has put in place. This is because U.S. negotiators are – to use a sports metaphor – running the Congressional football down the field. They are limited by the mandate they have been given by Congress in the conduct of their negotiations.

Furthermore, Congress always takes steps to provide additional protections to ensure that FTAs do not change U.S. laws: In fact, implementing legislation for FTAs always have contained express reservation language that preserves U.S. federal and state sovereignty to legislate as the federal or state legislature wishes in the future. For example, the legislation

implementing the Korea-U.S. Free Trade Agreement ("KORUS"), the most recently-implemented U.S. FTA from 2012, states:

> SEC. 102. RELATIONSHIP OF THE AGREEMENT TO UNITED STATES AND STATE LAW. (a) RELATIONSHIP OF AGREEMENT TO UNITED STATES LAW.—(1) UNITED STATES LAW TO PREVAIL IN CONFLICT.—No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect. (2) CONSTRUCTION.—Nothing in this Act shall be construed— (A) to amend or modify any law of the United States, or (B) to limit any authority conferred under any law of the United States, unless specifically provided for in this Act.

Unless Congress envisions a radical departure from previous FTA implementing legislation, this kind of language will be included in the USMCA implementing legislation as well.

The Trump Administration has made repeated assurances that this provision of the USMCA will not impact existing U.S. laws on the same topic. Ambassador Lighthizer reiterated these points during his June 19, 2019 hearing before the House Ways and Means Committee, noting that Congress – not the USMCA – changes the laws of the United States. He stated the same in his responses to Questions for the Record from the Senate Finance Committee. While he did not need to make these assurances, because of the realities noted above, I am glad he did so, to emphasize that all of the policymakers involved in the trade and drug pricing discussions must and will stay within their proper lanes. Ambassador Lighthizer is many things: an experienced trade lawyer and a skilled negotiator, for instance. But, one thing he is not an expert on is U.S. drug pricing policies. Therefore, even if he could change U.S. laws through FTA negotiations, I, for one, would not want him to do so on such a complex domestic law and policy topic. His focus is rightly on global competitiveness and raising international standards, which includes protecting U.S. intellectual property rights.

## Myth 2: The USMCA Will Raise Drug Prices

Current U.S. law mandates a twelve-year data protection period for biologics. The USMCA provision reflecting this issue, contained in Article 20.49 of the Agreement, calls for the parties to the Agreement to maintain such protection for at least ten years. The USMCA provision, therefore, is two years lower than the U.S. legal threshold, and as such the USMCA will not and cannot affect drug prices in the Unites States.

Further, I would note that this provision is in the USMCA agreement because Congress itself directed USTR to include it. Congress mandated this intent in the IP objective of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, which provides trade promotion authority ("TPA") under which USTR negotiated the USMCA:


> The principal negotiating objectives of the United States regarding trade-related intellectual property are…ensuring that the provisions of any trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law.

Members from both sides of the aisle urged USTR to include strong intellectual property protections for pharmaceutical products in the Agreement, and Ambassador Lighthizer wholeheartedly embraced this task, describing the importance of limiting the ability of Canada and Mexico to free-ride off of U.S. innovations on pharmaceuticals in testimony he gave while the negotiations were underway. And USTR negotiators followed this directive by getting as close as possible to the standard under current U.S. law in the relevant USMCA provision.

Moreover, it is empirically the case that past FTAs in which drug pricing also was a crucial issue, including those negotiated during my tenure as Secretary, have not resulted in changes in drug prices in the United States. A recent study from ndp analytics found that "pharmaceutical expenditures as a share of healthcare expenditures in the U.S. remained unchanged from 2012.

There are a number of other appropriate ways that both the Administration and Congress can address drug pricing. In fact, these conversations are happening right now, led by Secretary Azar and supported by the White House. Both Houses of Congress have been very active in this area as well. These are the proper avenues for debating drug pricing given the complexities and the various stakeholders involved. I have no doubt that these discussions will continue even after the USMCA is passed.

## Myth 3: This Provision Is Bad Policy

The kind of innovation required to develop breakthrough pharmaceutical technologies is the result of a careful balance of incentives, including strong intellectual property rights such as patent protection and the data exclusivity provisions for biologics that are enshrined in U.S. law. The numbers help to illustrate this: it currently takes ten to fifteen years to develop a new medicine. Only a small percentage of these projects ever reach patients, but each project still represents huge investments for the companies that undertake the necessary research and development ("R&D"). On average, it costs $2.6 billion to develop a new medicine; in 2017 alone total investment in R&D for new treatments and cures was estimated at $71.4 billion. These costs are not recouped without at least a significant data protection period. Lawmakers recognized this issue even as it sought to address concerns of increasing access to medicines. They ultimately settled on a twelve-year data exclusivity period in 2010, based on extensive analysis, which was widely supported by Congressional Democrats and Republicans and signed into law by then- President Obama. These regulatory data protection policies in the US, and in the USMCA, also do not prohibit a generic medicine company from doing its own research, development, and application for review and approval in the US, Mexico or Canada.

Protecting U.S. intellectual property is no doubt a priority for this Administration, as demonstrated by the strong actions that the President has directed USTR to take in that area. This should be the case regardless of what the product is, from movies to computer technology to innovative drugs and cures. In fact, it is especially important when the product involves drug innovation and the cure of diseases. This is an industry where the U.S. is a global leader. It is an industry that, in addition to being dedicated to improving and saving lives, creates thousands of jobs in the United States and in which private-sector investments dwarf those of governments. Pharmaceutical intellectual property rights are worthy of our protection, consistent with current U.S. law. This is precisely what the USMCA provision is trying to do, i.e., bringing the standards of protecting innovation in Canada and Mexico up to the same level as in the United States.

## Conclusion

The current debate about biologics in the USMCA is a sideshow that attempts to distract from the main event. Congress should stop its foot-dragging and vote on the USMCA for what it is: a trade bill that encourages other countries to meet existing U.S. standards. As a wholly separate matter, we can continue to discuss drug pricing and intellectual property issues here in the United States in the proper forum and with the right people. Nothing in the USMCA prevents us from continuing to do that.

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