



New U.S.-Mexico-Canada Trade Agreement Upholds Congressional Prerogatives

PREPARED FOR THE PASS USMCA COALITION

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Introduction and Executive Summary

U.S. trade agreements have sought in part to lift other countries' standards – in areas like labor rights, environmental regulations and intellectual property protections – and move them closer to our own. In doing so, such agreements have never sought to circumvent or undermine the ability of Congress to establish new policies or to change domestic law.

These two points are relevant to the current debate regarding Congressional approval of the [U.S.-Mexico-Canada Agreement](#) (USMCA), the trade deal that could replace the North American Free Trade Agreement, known as NAFTA.

NAFTA was an important agreement for its time. It helped grow the economies of the United States as well as Canada and Mexico, while strengthening regional integration and competitiveness to unprecedented levels. But the world has changed since that agreement was negotiated in the early 1990s, and USMCA includes important updates.

As Congress moves closer to a decision on approval this fall, discussions are under way between the administration, led by U.S. Trade Representative Robert Lighthizer, and the trade working group, established by House Speaker Nancy Pelosi, to resolve outstanding questions and to seek to secure bipartisan support.

One issue that has arisen concerns an aspect of the agreement's intellectual property chapter – [Article 20.49](#), which establishes data exclusivity standards for advanced “biologic” medicines – and whether that could limit Congress' ability to set policy and modify domestic law in any way.

It would not, for two reasons:

First, [Trade Promotion Authority](#) (TPA) – which was most recently renewed by Congress and signed into law by President Obama in 2015 – requires the U.S. Trade Representative to negotiate trade agreements that reflect America's high standards across the board, including with respect to intellectual property protections. If lawmakers have concerns with existing U.S. laws, they can work to change those laws at any time, regardless of whether there is a trade agreement in place with Canada, Mexico or any other trading partner.

Second, the language of existing trade agreements – and their implementing statutes – preserves Congress' ability to legislate at any point. The same would be true of USMCA. Simply put, USMCA obligations would not constrain Congress' authority or ability to revise U.S. law or policy.

Congress Mandated that the Executive Branch Use FTA Negotiations to Raise Global Standards Closer to U.S. Levels

In trade negotiations, U.S. government officials work to persuade partners that America's standards should be emulated by other countries. As Secretary of State John Kerry and Secretary of Defense Ash Carter [wrote](#) in 2015, “[b]y leading on trade, the U.S. can help start a global race



to the top on standards and develop a global economy...[that] encourages other nations to adopt our high standards.”

When I served as Acting and Deputy U.S. Trade Representative during the Obama Administration, we worked hard to raise global standards closer to our own, including in the area of intellectual property protection, especially given the role that innovation and creativity play in growing the U.S. economy and supporting jobs with higher wages.

The executive branch did not invent this principle; it is a goal shared equally by Congress. As TPA makes clear, “[t]he 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.”

USMCA achieves this objective in several ways, including through [Article 20.49](#), which requires all three countries to provide “at least ten years” of data exclusivity for new biologics. Biologics are an advanced class of medicines made from living organisms that can [help treat](#) a variety of illnesses and diseases for which there may not be other treatments. The provision in USMCA would raise the standard in Canada from eight years and address Mexico’s absence of any standard, bringing both closer to the U.S. standard. Twelve years has been the standard in the United States since President Obama signed the [Patient Protection and Affordable Care Act](#) (PPACA) into law, which included that provision as part of the “Biologics Price Competition and Innovation Act of 2009.” The phrase “at least” in USMCA ensures that America’s twelve-year standard is not changed by the agreement.

Even if Congress were to suggest a lower threshold in USMCA than ten years, it would not change America’s existing twelve-year standard. Rather, it would only enable Canada and Mexico to reduce the protections they would otherwise be obligated to afford U.S. intellectual property, thereby undermining one of our comparative advantages. It would also run counter to the negotiating mandate Congress gave USTR.

FTAs Can be Modified if U.S. Laws Change

Questions have been raised regarding whether a trade agreement might restrict Congress’ ability to lower the nation’s data exclusivity standard for biologics to below ten years at a future date. USMCA would not constrain the United States in this manner, and in fact the agreement specifies that it can be modified. If Congress were to enact legislation lowering the domestic data exclusivity period to less than ten years, then the parties could amend the agreement under [Article 34.3](#). Neither Canada nor Mexico would appear likely to resist such an amendment.

The principle that Congress may modify U.S. laws on any subject in the future is clear and reaffirmed by the very authority that enabled the executive branch to negotiate USMCA. [Section 108\(b\)](#) of TPA states that “[n]o provision of any trade agreement entered into under [TPA] shall prevent the United States ... from amending or modifying any law of the United States.”

It is unambiguous that Congress maintains the ability to change U.S. law, unaffected by any USMCA provision.



FTAs Are Negotiated Based on Current U.S. Law

The overriding principle is that trade agreements reflect current U.S. laws and standards at the time they were negotiated. It would be highly impractical – as well as inconsistent with Congress’ prerogatives and its TPA directives – for trade negotiators to be asked to try to speculate about what U.S. laws might change in the future, and in which direction.

As noted, neither USMCA’s pharmaceutical provisions nor other parts of the agreement could restrict Congress’ ability to legislate. If it did, then any aspect of U.S. law that is considered an obligation in USMCA or other trade agreements – whether with respect to intellectual property, labor, environmental or other protections – would need to be analyzed against the possibility that U.S. law might one day change. It would be difficult, if not impossible, for Congress or the executive branch to adopt such a speculative approach in any negotiation.

FTAs are Not an Appropriate Vehicle to Make Changes to U.S. Law

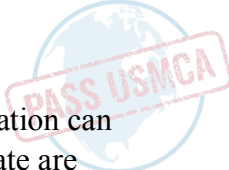
Since [Article 20.49](#) is based on the standards that Congress enacted in domestic law, concerns about whether ten or twelve years is the appropriate standard should be directed at debate over U.S. law. There was robust public debate at the time when the twelve-year standard for biologics was enacted, reflecting compromises reached by Members of Congress based on a variety of stakeholder perspectives and competing considerations. For example, there was research and analysis demonstrating the need to balance – on the one hand – incentivizing innovation and recouping research and development costs with – on the other hand – increasing access to medicines and boosting production of generic drugs. The measure that resulted had bipartisan support and, as noted above, was signed into law by President Obama as part of the PPACA.

Seeking to withhold approval of a trade agreement that has significant benefits for all three economies would not be an effective or appropriate way to suggest changes to U.S. law.

In a similar vein, efforts to lower the intellectual property standards in USMCA also would not change U.S. law. They would only authorize Canada and Mexico to maintain lower standards. This would work to the disadvantage of U.S. workers and companies that depend on strong protections. It could also work to the detriment of U.S. consumers, for improving protections in Canada and Mexico could potentially lower the cost of drugs in the U.S. market as the burden of developing them could be spread more across the three countries.

USMCA Warrants Bipartisan Support

USMCA does not affect U.S. drug prices because it does not change rules that affect how the U.S. pharmaceutical market operates. But excessive drug prices rightly concern Congress, and this is

A circular logo with a globe in the background and the text "PASS USMCA" in a red, stamp-like font across the top.

a critical issue to address. This may even be an area where Congress and the administration can find common ground this fall. But while the policy goals underpinning the current debate are laudable, it is also important to differentiate between steps that could reduce costs, and those – like supporting USMCA – that would not affect costs.

Some observers acknowledge that USMCA will not impact U.S. drug prices but worry that patients in Canada or Mexico could end up paying more. According to [data analyzed by the Council on Foreign Relations](#), even when trade agreements with the United States demand strong intellectual property protections on pharmaceuticals, there has not been a “discernible shift” in pharmaceutical spending on drugs.

With USMCA, USTR has negotiated a trade deal that is consistent with Congress’ directives and prerogatives, and it deserves bipartisan support. The intellectual property chapter of USMCA does not require any changes to U.S. law, including with respect to data protection. And nothing in USMCA would constrain Congress’ authority to change U.S. law in the future.

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