



**IMPROVEMENTS TO THE USMCA  
Secured by Democrats in the “December 10th Agreement”**

*Wins for the People in the New North American Free Trade Agreement*

In April of 2019, the U.S. International Trade Commission (USITC) issued a [report](#) on the likely impact of the United States-Mexico-Canada Agreement (USMCA) on the U.S. economy. Based on two key assumptions, the USITC estimated that the USMCA would have a positive effect on the U.S. economy. First, the USITC assumed that the agreement would be fully enforced; and second, it assumed that some of the agreement’s provisions would reduce uncertainty and spur economic activity.

House Democrats, including the USMCA Working Group led by Speaker of the House Nancy Pelosi and Ways and Means Committee Chairman Richard E. Neal, have made the theoretical assumptions of enforcement and increased certainty a reality for American workers and families. On December 10, 2019, House Democrats announced changes negotiated with the Trump Administration that were approved by the United States, Canada, and Mexico on the same day. Those changes strengthen the agreement’s rules and enforcement mechanisms—including in the areas of labor, environment, and in the overall agreement—and revise the pharmaceutical provisions to promote competition and drive down the high cost of prescription drugs.

The package of outcomes in the four key areas of (1) Labor; (2) Environment; (3) Access to Medicines; and (4) Enforcement, are detailed below.

**1. Labor**

The renegotiation of the North American Free Trade Agreement (NAFTA) is premised on the recognition that the NAFTA failed to raise wages and working conditions in Mexico, hurting American workers, especially in our industrial manufacturing sector. Because the labor provisions in the NAFTA were ineffective in raising standards for workers across the NAFTA region, House Democrats sought to make sure they are meaningful this time. The goals in this negotiation were to secure improvements to the provisions in the USMCA including:

- High-standard rules for worker protection that are strong and clear enough to be enforceable;
- Mechanisms and resources to monitor whether internationally recognized core labor rights are being afforded to workers; and
- Mechanisms, resources, and commitment to hold partners and actors accountable to commitments and rules in the agreement.

The new terms that House Democrats negotiated in the revised USMCA accomplish the following:

- A. Strengthening Rules:** The labor rules in U.S. trade agreements have proven difficult, if not impossible, to enforce. Five key changes will be made to strengthen the rules with a view to improving their enforceability:
  - 1. Create a presumption that violations occur in “a manner affecting trade or investment between the Parties.”** As the Guatemala panel decision under the Central America Free Trade Agreement (CAFTA) demonstrated, this language establishes a hurdle to labor enforcement. In response, the USCMA will include a provision that presumes violations affect trade and requires that the other Party demonstrate otherwise.
  - 2. Strengthen language in the Forced Labor provision to make it effectively enforceable.** The USMCA will remove the phrase “through measures it considers appropriate” and footnote ten regarding potential inconsistencies with other international obligations.
  - 3. Remove “sustained or recurring course of action or inaction” from the provision on violence.** Acts of violence and intimidation should not need to be repeated in order to be actionable as a denial of freedom of association or the right to collective bargaining.
  - 4. Strengthen steel rules of origin in the automotive sector to support U.S. manufacturing.** After a transition period, this provision will ensure that steel used in the automotive sector will only receive preferential treatment under the USMCA if it is melted and poured in the region.
  - 5. Create a new enforcement mechanism to address unfair trade in trucking services.** Building on the exception negotiated in the Services chapter of the USMCA, the implementing bill will establish a new process at the USITC that will protect U.S. truckers and companies from surges in trucking services from Mexico.
  
- B. Establishing a Robust Monitoring Program:** The United States has failed to effectively monitor the labor provisions in trade agreements. The USMCA implementing bill will establish an interagency committee with devoted funding that will be responsible for actively monitoring Mexico’s compliance with the labor chapter, including the following activities:
  - 1. Establish an Independent Review Body.** The implementing bill will establish an independent review body that will make determinations regarding whether Mexico is satisfactorily implementing its labor reform and general labor laws based on objective benchmarks. Negative determinations will lead to dispute settlement.

2. **Devote Robust Resources.** The committee will receive funding for staff from USTR and the U.S. Department of Labor (DOL) devoted to monitoring and enforcement, including multiple labor attachés based in Mexico.
  3. **Engage with Key Stakeholders.** The committee will be required to consult regularly with key stakeholders, including the Labor Advisory Committee. The committee will also coordinate with other key stakeholders, including International Labor Organization (ILO), Inter-American Development Bank (IDB), Mexico, and Canada.
  4. **Link Monitoring with Enforcement.** The committee’s monitoring work will be directly related to enforcement actions taken by USTR, including establishing priority sectors and facilities. The committee will also review petitions submitted by outside stakeholders.
- C. Creating Labor-Specific Enforcement Tools:** State-to-state dispute settlement by itself has not provided sufficient leverage to ensure that U.S. trading partners live up to their labor commitments. In recognition of this concern, the USMCA will establish an enforcement mechanism that:
1. Takes immediate effect upon entry into force of the agreement;
  2. Provides for facility-based enforcement of labor standards in the agreement within 150 days;
  3. Covers all manufactured goods and services traded between the United States and Mexico;
  4. Requires verification of compliance by independent labor experts; and
  5. Leads to the imposition of penalties on goods and services—which can be applied during the course of the verification—that are not produced in compliance with the agreement’s labor standards. In the case of repeat offenders, the agreement provides that the United States can block entry of those goods.
- D. Supporting Mexico’s Reforms:** While Mexico is responsible for implementing its labor reform, the United States can play a supportive role. The USMCA implementing bill will devote significant resources to support capacity building efforts in Mexico, including training and educating Mexican workers.
- E. Committing Robust Resources for Implementing and Enforcing the Agreement’s Labor Provision:** The obligations in trade agreements are only valuable if they are actively monitored and enforced, which has been particularly true for labor obligations. The implementing bill will provide increased funding to monitor and enforce the USMCA, as well as provide significant capacity building resources to support Mexico’s labor reform, including \$240 million over four years, including:

1. \$30 million for USTR to monitor and enforce the labor obligations in the USMCA;
2. \$30 million for DOL to monitor and enforce the USMCA, including funding five Labor Attache positions in Mexico; and
3. \$180 in capacity building for grants issued by DOL to support the implementation of Mexico's labor reform, including worker-training programs. This funding will go a long way toward ensuring that the potential of Mexico's labor reform will actually be realized.

## 2. Environment

Democrats' experience with NAFTA also has shown that a failure to comply with and enforce environmental standards in Mexico has had negative economic consequences and undermined American competitiveness. It has resulted in environmental externalities, infrastructural degradation, and health hazards that do not recognize borders. In the 25 years since NAFTA was passed, some environmental concerns have evolved into existential threats. The environmental protections in this agreement should address that reality. Because the provisions in NAFTA were ineffective in raising environmental standards across the NAFTA region, we must make sure they are meaningful this time. House Democrats' goals in this negotiation were to secure improvements to the provisions in the USMCA including:

- High-standard rules that are strong and clear enough to be enforceable;
- Mechanisms and resources to monitor whether environmental protections are being applied; and
- Mechanisms, resources, and commitment to hold partners and actors accountable to commitments in the agreement.

The new terms that House Democrats negotiated in the revised USMCA accomplish the following:

**A. Strengthening the Rules:** The environmental rules in U.S. trade agreements have never been fully enforced. Key changes will be made to the USCMA to strengthen the rules with a view to improving their enforceability:

1. **Create a presumption that violations occur in "a manner affecting trade or investment between the Parties."** As the Guatemala panel decision under the CAFTA demonstrated, this language establishes a hurdle to enforcement. In response, the USCMA will include a provision that presumes violations affect trade and requires that the other Party demonstrate otherwise.

## **2. Require Parties to live up to their obligations under Multilateral Environment Agreements (MEAs)**

a. The Parties must adopt, maintain, and implement laws, regulations and all other measures necessary to fulfill the Parties existing obligations under each of the following MEAs:

- Convention on International Trade in Endangered Species
- Montreal Protocol on Ozone Depleting Substances
- Convention on Marine Pollution
- Inter-American Tropical Tuna Convention
- Ramsar Convention on the Wetlands
- International Convention for the Regulation of Whaling
- Convention on Conservation of Antarctic Marine Living Resources

The MEAs listed include current and future mutually-agreed protocols, amendments, annexes or adjustments to the listed MEAs to which the Parties have agreed.

b. The Parties can agree in writing to modify the listed MEAs to include any other environmental or conservation agreement.

c. In the event of any inconsistency between the FTA and the obligations set out in any listed MEA, the FTA does not preclude a Party from taking a particular measure to comply with its obligations under the MEA, provided that the primary purpose of the measure is not to impose a disguised restriction on trade.

## **3. Protect the Ozone**

a. Each Party must take measures to control the production and consumption of, and trade in, all substances controlled by the Montreal Protocol, including all existing and future amendments to the Montreal Protocol to which the Parties are party.

b. The Parties shall cooperate to address matters of mutual interest related to all substance, not solely substances considered “ozone-depleting.”

## **B. Establishing a robust implementation, monitoring and enforcement program**

**1. Timing.** The implementing bill will establish an interagency committee to implement, monitor and enforce the environment obligations under the FTA.

- 2. Membership.** Membership of the committee will include USTR, the U.S. Department of State, U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), USDA U.S. Forest Service (USFS), the U.S. Department of the Interior (DOI), the U.S. Department of Homeland Security (DHS) Customs and Border Protection (CBP), the U.S. Department of Justice (DOJ), the U.S. Agency for International Development (USAID), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Commerce (DOC) National Oceanic and Atmospheric Administration (NOAA).
- 3. Assessment.** The committee will develop an assessment of Mexico and Canada's relevant environmental laws and regulations necessary to implement their respective Environment Chapter obligations and identify key priority areas for continued assessment and monitoring, technical assistance and capacity building, and enhanced cooperation, within 90 days of establishment of the committee and before entry into force of the agreement. The assessment must be updated after five years of the agreement being in force.
- 4. Monitoring.** In addition to routine monitoring of Canada's and Mexico's implementation of the obligations, the committee will review and respond to all factual records of Commission for Environmental Cooperation (CEC) submissions and public comments seeking verification of customs shipments of potentially illegally taken wild fauna and flora.
- 5. Coordination.** The committee allows for better coordination and implementation of existing authorities under U.S. law to enforce environmental laws, including, the Marine Mammal Protection Act; the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act; the Pelly Amendment; the Agreement on Port State Measures to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing; the Endangered Species Act; the Lacey Act; the Migratory Bird Act; the Eliminate, Neutralize and Disrupt Wildlife Trafficking Act; and the Wild Bird Conservation Act.
- 6. Enforcement.** The committee can request at any time that additional enforcement action be taken under the agreement or other existing U.S. authorities under federal law.
- 7. Reporting.** USTR will report to Congress on steps the Parties have taken to implement and enforce the commitments in the Environment Chapter of the Agreement.

### **C. Enhancing Enforcement**

- 1. Verification Process.** The United States and Mexico have entered into a customs verification agreement that will allow for either Party to request that a shipment be verified. The mechanism will target shipments related to illegally taken wild fauna or flora. The mechanism will set forth precise process for conducting verification and additional steps that must be taken pursuant to the outcomes of a request.

**D. Environmental Infrastructure:** A capital increase for the North American Development Bank will be authorized and additional resources will be provided to the Bank to finance environmental infrastructure projects related to water pollution, water and wastewater treatment, water conservation, municipal solid waste, stormwater drainage, air quality, and renewable energy.

**E. Committing Robust Resources for Implementing and Enforcing the Agreement's Environment Provisions:** Resources cover \$80 million over four years, including –

1. \$20 million for USTR to lead the interagency committee in monitoring and enforcing the environment obligations in the USMCA, including funding three environment-focused attaches assigned to Mexico;
2. \$40 million to the Trade Enforcement Trust Fund to be used for environment-focused enforcement efforts;
3. \$4 million for the EPA to assist in their work on the Commission for Environmental Cooperation, a U.S.-Mexico-Canada cooperation body set up under the USMCA;
4. \$8 million for NOAA to combat illegal, unreported, and unregulated fishing and enhance the implementation of the Seafood Import Monitoring Program; and
5. \$8 million for U.S. Department of Agriculture - APHIS and U.S. Fish and Wildlife Services to implement the Lacey Act.

**F. Committing Robust Resources to Address Pollution:**

1. Securing \$300 million over four years for EPA grants under the Border Water Infrastructure Program to address pollution on the U.S.- Mexico border, particularly the Tijuana River Valley;
2. Securing \$8 million over four years for NOAA to address marine debris in our shared North America waters; and
3. Securing \$215 million for NADBank over five years for environment infrastructure projects.

### 3. Access to Affordable Medicines

The Democrats' House majority is founded on a promise to our constituents to improve access to affordable health care and prescription drugs. To this end, the goals in this negotiation were to: preserve Congress's power to pass laws that bring down high prescription drug costs; ensure fair terms of competition between branded and generic drugs so that patients have better access to affordable medicines; and recognize key access to medicine principles from the [May 10, 2007](#) Agreement between House Democrats and the Executive Branch. The terms of the revised USMCA are as follows:

- A. Preserving Congressional Power to Bring Down High Prescription Drug Costs:** The revised USMCA deletes provisions that would have locked-in U.S. laws that favor branded pharmaceuticals over generics to the detriment of patients' access to affordable medicines. These provisions address three topics: biologic drugs; secondary patents for new uses of known products; and an exclusivity period for new clinical information. In each of these areas, House Democrats have pending legislation that would cut back on these monopoly-like protections for branded pharmaceutical companies. Democratic revisions deleting USMCA provisions in these areas preserve Congressional power to continue to legislate to bring down high prescription drug costs.
- 1. Biologics.** The Democratic revision to the USMCA removes the biologics provision, and all references to it, from the intellectual property chapter. This provision required that the United States, Canada, and Mexico provide at least 10 years of market exclusivity for biologics. During this 10-year period, which is separate and apart from the 20-year patent term, a biologic would be protected from the competition from generics or "biosimilars" that brings down prices. The removal of this provision preserves the policy space needed to drive down the high price of biologics. It also ensures we do not export overly long exclusivity periods to Mexico and Canada.
  - 2. Secondary Patents.** The Democratic revision removes the requirement that the United States, Canada, and Mexico confirm the availability of patents for new uses of known products. In a practice known as "patent evergreening," branded pharmaceutical companies file hundreds of these secondary patents on minor variations of drugs, with the goal of keeping generic products off the market. Congressional Democrats have introduced legislation to stop patent evergreening and promote competition. The Democratic fix ensures that we don't lock-in patent evergreening here or require its export to Mexico and Canada.
  - 3. New Clinical Information.** The Democratic revision to the USMCA removes the requirement that the United States, Canada, and Mexico provide at least three years of additional exclusivity for new clinical information submitted to support new uses of previously-approved pharmaceutical products. Like the extended exclusivities associated with biologics and secondary patents, this is another mechanism used by branded pharmaceutical companies to delay generic competition and price reductions. It is also another area in which

Congressional Democrats are working hard to improve U.S. law and not export harmful policies.

**B. Ensure Fair Terms of Competition Between Branded and Generic Drugs to Promote Access to Medicine:** The U.S. Congress passed The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as “Hatch-Waxman,” to balance incentives for the initial innovation of a pharmaceutical with opportunities for follow-on competition from less expensive generic drugs. The following revisions focus on ensuring that the USMCA reflects the balance in U.S. law to promote access to medicines.

- 1. Regulatory Review.** The revision adds new language to the regulatory review provision to ensure that it is consistent with U.S. law and fosters competition. A strong regulatory review provision enables generic and biosimilar manufacturers to use a patented invention during the patent term to develop information needed to obtain regulatory approval the moment the patent expires. The revision clarifies the circumstance in which such use is permissible to reduce the risk that generic manufacturers would be sued for legitimate activity.
- 2. Data Exclusivity.** Two revisions limit USMCA provisions on data protection. Under U.S. law, branded pharmaceutical companies may obtain a form of data protection known as new chemical entity (NCE) exclusivity for a period of five years. Consistent with U.S. law, the first revision enables a generic company to seek approval in less than five years when the branded company receives notice of the generic’s claim and does not bring legal action within 45 days. The second revision ensures that NCE exclusivity is limited to those products with the same active moiety or molecule as the branded product, consistent with U.S. law.

**C. Reflect Key Principles from the May 10 Agreement**

- 1. Patent Linkage.** Consistent with the May 10 Agreement, revisions to the provision on patent linkage promote improved access to chemically-synthesized drugs (the U.S. does not apply linkage to biologics). First, the revision removes the concept of “hard linkage” from the trade agreement template. Under hard linkage, a regulatory agency can deny marketing approval for the generic when the patent holder does not consent. Under an annex to the agreement, Mexico may continue its current system, which involves coordination between the regulatory authority and the patent office, only if it ensures that persons directly affected by the proceeding are provided notice and a reasonable opportunity to be heard, prior to a final administrative action.

Also, to improve transparency and incentives for generic competition, the Parties may provide effective rewards to generics for the successful assertion of a patent’s non-infringement. The Parties may further provide public information on the patents and exclusivity periods related to approved

pharmaceutical products to facilitate patent challenges and the prompt market entry of generics.

2. **Patent Term Adjustment.** Revisions to the provision on patent term adjustment align the provision more closely with the May 10 Agreement and U.S. law by providing non-exhaustive examples of limitations on patent term adjustment for regulatory delays.

#### 4. **Enforcement and Enforceability**

Without enforceability and enforcement, any agreement is just words on a page. A new and improved, more modern trade agreement with Canada and Mexico only deserves consideration by the House of Representatives if it incorporates enforcement mechanisms that will provide everyone with confidence that the rules are meaningful. Given the lacking enforcement record in the NAFTA, the goals in this negotiation were to secure improvements to the provisions in the new NAFTA that:

- Fix the procedures in the NAFTA’s state-to-state dispute settlement mechanism that have allowed parties to block the formation of an arbitral panel and frustrate formal enforcement for all obligations, across the agreement.
- Establish enhanced enforcement mechanisms to secure compliance with the labor rules in the new agreement.
- Establish enhanced enforcement mechanisms to secure compliance with the environmental rules in the new agreement.

The fixes that House Democrats negotiated in the USMCA accomplish the following:

##### **A. Prevents Panel Blocking and Improves the Automaticity and Efficiency of the State-to-State Dispute Settlement Mechanism**

**Prevents Panel Blocking:** The amendments remove the requirement for the Free Trade Commission (“Commission”) to convene before a panel is established and allows the complaining party to appoint the panelists if the defending party refused to participate in or does not show up to the choosing by lot procedure. First, the USMCA, like NAFTA, may allow a defending party to block the formation of a panel because under both agreements, the Commission is required to meet before a panel is formed. A disputing party may prevent the Commission from meeting, which would then prevent the panel from forming. Second, the USMCA, like NAFTA, may allow a defending party in a dispute to prevent the appointment of a panelist. This is because, under both agreements, where disputing parties cannot agree on a panel chair, the party “chosen by lot” is to select the chair. If that party is the defending party and declines to make such a selection, the process is stalled and no panel is formed to hear the dispute. The amendments by the House Democrats fix these procedural loopholes and help ensure that USMCA is fully enforceable.

- B. Creates Enhanced Enforcement for Labor Provisions (see Section I.C above)**
- C. Creates Enhanced Enforcement for Environment Provisions (see Section II. C above)**
- D. Requires the Development of Rules of Evidence for Use in all Enforcement Mechanisms**

The revised USMCA will require the development of rules of evidence for use in all enforcement mechanisms. The rules of evidence would allow disputing parties to submit anonymous testimony, redacted evidence, testimony in person, via declaration, affidavit, report, teleconference, or videoconference. In addition, the Panel would be permitted to accept evidentiary stipulations in advance of the hearing, request the production of documents, and take an adverse inference for non-responses.

The evidentiary challenges encountered with litigating the Guatemala Labor Dispute under CAFTA have made it clear that rules of evidence are necessary in order to ensure that labor provisions are enforceable. The revised USMCA would be the first U.S. trade agreement to require the development of rules of evidence for use in dispute settlement proceedings—an important step in ensuring that trade agreements are fully enforceable.