



FROM THE OFFICE OF  
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## THE NEW NAFTA

After months of negotiations with the U.S. Trade Representative (USTR), House Democrats have made considerable improvements to the new North American Free Trade Agreement (NAFTA) in several areas.

### PREScription DRUGS

- **Preservation of Congress's Power to Legislate:** House Democrats removed provisions that contribute to high prescription drug prices to preserve Congress's ability to change U.S. law to improve access to affordable medicines.
  - Removed provision requiring the parties to provide at least 10 years of exclusivity for biologics, some of the most expensive drugs on the market.
  - Removed provision requiring the parties to confirm that patents would be available for new uses of known products. This provision would have locked in the practice of "patent evergreening," in which pharmaceutical companies obtain hundreds of patents related to a product to block generic competition and price reductions.
  - Removed provision requiring three additional years of exclusivity for clinical information submitted in connection with new uses of previously approved pharmaceutical products. This is another way that pharmaceutical companies delay competition and access to affordable medicines.

- **Ensuring Fair Competition:** House Democrats' revisions focus on maintaining the balance between competition and incentives for innovation.
  - Revised regulatory review provision to clarify the circumstances in which generic and biosimilar companies may use a patented invention so that they can obtain marketing approval on day one of patent expiration.
  - Revised data protection provision to incorporate limitations in U.S. law that foster generic competition.
- **Reflecting May 10th Principles:** House Democrats pushed for key principles to improve access to medicines that were included in previous U.S. trade agreements with Peru, Panama and Colombia.
  - Revised patent linkage provision to remove the “hard linkage” of regulatory approval and patent status. Under an annex to the agreement, Mexico must ensure that all interested parties receive notice and an opportunity to be heard. The revision also includes language that permits incentives for generic competition and improves transparency.
  - Revised patent term adjustment provision to provide non-exhaustive examples of limitations on the adjustment of patent terms for regulatory delays.

## **ENFORCEMENT**

- **Stronger Rules:** House Democrats closed enforcement loopholes and streamlined the dispute settlement system to ensure that our trading partners live up to their commitments.
  - Removed language allowing a responding party to block the formation of a dispute settlement panel.
  - For the first time in a trade agreement, created rules of evidence to help the United States successfully litigate labor, environmental and other fact-intensive disputes.

## WORKERS

- **Stronger Rules:** The labor rules in U.S. trade agreements have proven difficult, if not impossible, to enforce. House Democrats made key changes to strengthen the rules.
  - Removed language making it difficult to prove that our trading partners are failing to live up to commitments to protect workers from violence.
  - Created a presumption that a labor violation affects trade and investment and will require the other government to prove otherwise.
  - Removed language in the Forced Labor provision that had made it effectively unenforceable.
- **Robust Monitoring:** House Democrats demanded new mechanisms and resources to ensure that United States effectively monitors Mexico's compliance with the agreement's labor obligations.
  - Created an interagency committee that will monitor Mexico's labor reform implementation and compliance with labor obligations.
  - Created ongoing reporting requirements to Congress.
  - Established key benchmarks for Mexico's labor reform implementation process. Failure to comply with these benchmarks will lead to enforcement action under the agreement.
  - Established Labor Attachés that will be based in Mexico and will provide on-the-ground information about Mexico's labor practices.
- **Rapid-Response Enhanced Labor Enforcement:** State-to-state dispute settlement has not ensured that U.S. trading partners live up to their labor commitments. Responding to this concern, House Democrats established a new and enhanced labor-specific enforcement mechanism that takes immediate effect upon entry into the agreement.

- Provides for facility-based enforcement of labor obligations in the agreement within a rapid timeframe.
- Covers all manufactured goods and all services traded between the United States and Mexico.
- Requires verification of compliance by independent labor experts.
- Levies penalties on goods and services that are not produced in compliance with the freedom of association and collective bargaining obligations.

## **ENVIRONMENT**

- **Stronger Rules:** House Democrats insisted on the inclusion of strong, high-standard rules that are clear and enforceable.
  - Created a presumption that an environmental violation affects trade and investment and will require the other government to prove otherwise.
  - Added commitment that all parties will adopt, implement and maintain seven multilateral environment agreements (MEAs), and include additional language that allows all parties to agree to add to the list of covered MEAs.
  - Restored a provision in the old NAFTA that prioritizes MEA commitments when implementing MEA and trade agreement obligations.
  - Removed language in order to allow the Montreal Protocol to be covered in this agreement.
- **Robust Monitoring:** House Democrats urged the creation of new mechanisms and the allocation of additional resources to monitor the enforce of environmental protections.
  - Created an interagency committee that will:

- Conduct an assessment of the current environment landscape in Canada and Mexico;
  - Monitor the implementation of the environment obligations and recommend enforcement actions in connection to the new NAFTA; and
  - Provide a platform for better coordination, utilization and funding of U.S. efforts to strengthen environment practices amongst NAFTA Parties.
- Established environment-focused attachés in Mexico City that will regularly monitor Mexico's environment laws, regulations and practices.
- **New Accountability:** To hold partners and actors accountable to the agreement, House Democrats insisted on creating and enhancing relevant mechanisms, resources and commitments.
  - Created a new customs verification mechanism to ensure that only legally harvested and taken flora and fauna are traded through Mexico.
  - Instituted a new authorization of the North American Development Bank and funding for U.S. Environmental Protection Agency grants under the Border Water Infrastructure Program to address pollution on the U.S.- Mexico border.
  - Required additional funds to the Trade Enforcement Trust Fund to be used for environment-focused enforcement efforts.