



Big Pharma Rigged the Revised NAFTA to KEEP DRUG PRICES HIGH

The revised North American Free Trade Agreement (NAFTA) signed by Donald Trump in 2018 would lock in high U.S. medicine prices, while drug prices are already too high. NAFTA 2.0 guarantees pharmaceutical corporations special monopoly protections so they can block competition from generics and charge more in all three NAFTA nations. The deal would tie Congress' hands, thwarting the changes needed to lower drug prices. And that is exactly why the pharmaceutical firms celebrate the deal: "*The IP standards in the USMCA far exceed those in any other international trade agreement,*" [crowded PhRMA](#), while [BIO declared](#), "*The USMCA sets important new standards for U.S. trade policy.*"

The Big Pharma Giveaways in NAFTA 2.0 Must Be Removed

No "free trade" agreement should lock in protectionist monopolies that contribute to high drug prices. Nor should any trade deal undermine this or future Congresses' ability to ensure Americans have access to affordable medicine. But that is precisely what the revised NAFTA does.

In 2018, Democrats won a majority in the House of Representatives on a unified pledge to lower drug prices. NAFTA 2.0 can only become law if Congress approves it. That means the new Democratic House majority has the leverage to get the Pharma giveaways eliminated.

Pharma is trying to convince Congress that somehow cutting the drug firm monopolies in the deal would doom it. The opposite is true: All four of the last U.S. free trade agreements that ultimately were enacted by Congress had to be altered after they were signed in order to win a majority. These agreements with Peru, Korea, Colombia and Panama would not have passed unless they were modified to roll back extreme pharma provisions and strengthen labor and environmental terms.

Today's situation is similar. In 2006, George W. Bush completed four trade deals he thought would be considered by a GOP House and Senate. But the Democrats won the House in the midterm. In 2007, Speaker Nancy Pelosi refused to hold a vote on the pacts unless and until Bush made improvements. The Pharma goodies in Trump's NAFTA deal may have appealed to a GOP Congress. But now the Democrats control the House and the NAFTA 2.0 text must be altered to remove the Pharma giveaways.

Specific NAFTA 2.0 Terms That Threaten Affordable Medicines

Guaranteeing 10 Years of Special Monopoly Protections for Biologic Drugs

Biologic drugs are medical products (including vaccines and many new cancer and heart disease treatments) derived from living organisms. These cutting-edge drugs now frequently exceed \$100,000 per person per year. According to the FDA, brand-name biologics and specialty drugs represented 2 percent of all U.S. prescriptions, but almost 40 percent of total drug spending.

The NAFTA 2.0 text requires each country to provide drug makers at least 10-years of "marketing exclusivity" for new biologic medicines. (Article 20.49.1) That means regulatory authorities cannot authorize the sale of medical products that rely on a competitor's safety and efficacy data, even if a drug doesn't have patent protection. This monopoly for brand-name drugs would keep cheaper "biosimilars" (i.e., generic biologics) off the market. Some cancer-patient activists call this a "Death Sentence Clause," as it would cut off access to drugs that are necessary to extend the lives of people suffering from cancer. Pharma attempts to justify longer patents by claiming that biologics cost more to develop, but recent [research](#) found no evidence to substantiate that claim.

Members of Congress have created [legislation](#) to cut the current U.S. biologic marketing exclusivity period from 12 to five years. This would save patients and taxpayers billions. But this pro-health, cost-cutting reform would violate NAFTA 2.0, and thus expose the United States to tariff sanctions. The deal sets a floor – a guaranteed marketing monopoly for drug firms – but not a ceiling on monopoly duration. So, NAFTA 2.0 would not reduce the U.S. biologics exclusivity term to ten year. Rather, it would undermine Congress’ ability to reduce the exclusivity period and make biologic drugs more affordable.

Moreover, NAFTA 2.0 would export our high-drug-price policies to Mexico, which now has no special exclusivity period for biologic drugs, and to Canada, which now has an eight-year period. Other nations rejected drug firms’ demands in Trans-Pacific Partnership (TPP) talks. TPP required five-years of marketing exclusivity for biologics along with other measures that could extend exclusivity depending on circumstances. After the United States left the TPP, this controversial provision was shelved altogether. A Boston University [study](#) found that even without requiring signatory countries to provide special marketing exclusivity monopolies for brand-name biologics producers, the U.S.-Chile Free Trade Agreement’s imposition of longer patents and other protections raised prices for these medicines.

Expanding What Drugs Get the Special Biologics Protections

Makers of affordable biosimilars as well as other analysts are concerned that the definition of “biologic” would expand the list of drugs that qualify for the special monopoly protections. That means longer monopolies for more drugs – raising prices. According to the Association for Accessible Medicines (AAM), this definition of biologics (Article 20.49 (2)) would allow brand-name drug firms that make products containing “chemically synthesized polypeptides” to newly request additional exclusivity applicable to biologics. This would mean seven new years of special monopolies that block competition and keep prices higher for patients and the healthcare system.

AAM has listed seven examples of drugs that could get longer monopolies under this definition: diabetes treatments Victoza, Saxenda, Glucagon and Ozempic; osteoporosis treatment Forteo; heart failure treatment Natrecor; and short bowel syndrome treatment Gattex.

Extending Monopoly Terms Through Evergreening and Patent Extensions

NAFTA 2.0 requires nations to have overly permissive standards to extend patent monopolies through minor changes with little innovation and potentially no added therapeutic benefit. An example of such “patent evergreening” is to switch to an extended-release capsule just before a patent expires without changing anything else. The resulting secondary patent delays generic competition and limits access to cheaper generic drugs. Specifically, Article 20.36(2) requires secondary patents on new uses of a known product, new methods of using a known product, or new processes of using a known product.

NAFTA 2.0 also requires nations to provide patent term extensions and grant longer periods of monopoly protection for perceived administrative delays. (Article 20.44) That means pharmaceutical firms can get longer monopolies if they feel a regulatory authority took longer than it should have to review their product. NAFTA 2.0 includes patent term extensions for perceived delays in the patent examination and regulatory review periods. Patent term extensions preclude early market entry of generics, impeding access to affordable medicines. These measures do not go beyond existing U.S. law, but rather their inclusion in NAFTA 2.0 would tie Congress’ hands and prevent future reforms.

NAFTA 2.0 is not the transformational replacement of the corporate-rigged trade-pact model that many Americans have demanded. But if we fight to get the Big Pharma giveaways out, swift and certain enforcement of improved labor and environmental standards in, and achieve other key improvements — then a final package *could* stop some of NAFTA’s continuing, serious damage across North America. Cutting the extreme monopoly protections for pharmaceutical firms from the revised NAFTA is not only eminently doable. It is in the interest of people in all three NAFTA countries. It also is the only way a revised NAFTA can obtain the broad support it needs to pass.