



Renegotiating NAFTA: Threats to Affordable Medicines

Prescription drug corporations raise the prices of needed medicines every year, compromising patients' health and finances. The brand-name pharmaceutical business model relies on maximizing profits by selling at very high prices to the few, rather than affordable prices to the many. Unless there is competition from generic medicines, there is little reason for these firms to bring prices down. In many nations, including the United States, high medicine prices result in rationing of treatment: patients who need the medicines simply do not have access to them.

The 1993 North American Free Trade Agreement (NAFTA) was the first “trade” agreement that included new monopoly powers for Big Pharma companies. NAFTA was negotiated behind closed doors under the influence of hundreds of corporate advisors while the public and Congress were shut out. As a result, excessive patent and other intellectual property protections that block competition and keep prices high were inserted. Each NAFTA country is required to ensure that its domestic policies comply with those rules. Given that “free trade” is supposed to be about increased competition, and most people had no idea that a “free trade” deal would impose new monopoly rights for drug companies, NAFTA and many agreements modeled on it that followed provided a way for the industry to expand its power and keep prices high.

As a candidate, President Trump promised he would make NAFTA “a lot better.” Renegotiations started in August 2017, but once again, talks are occurring behind closed doors. The secrecy means it is impossible to know for sure what is being negotiated in our name. The administration appears to have adopted some long-demanded progressive changes to eliminate NAFTA’s job outsourcing incentives. **But when it comes to the NAFTA rules that affect medicine prices, Trump’s team is continuing to push the wish list of Big Pharma corporations.**

Big pharmaceutical companies have outlined their NAFTA demands in official submissions to the U.S. government. They want added to NAFTA a whole raft of extreme new powers and privileges to raise prices that the U.S. government had forced into the Trans-Pacific Partnership (TPP). Those TPP rules received widespread criticism — from the Vatican to consumer groups to The Economist magazine — for undermining consumers’ access to affordable medicines. And they were fiercely resisted by negotiators from other TPP countries. The fight *for* access to medicines and *against* Pharma greed ultimately dragged out the TPP negotiation for years. After the TPP could not obtain majority support in Congress, the other TPP countries suspended some of the most extreme U.S.-demanded provisions. But the NAFTA renegotiations could revive these dangerous terms that would lock in high prices here and raise prices in Mexico and Canada.

If Big Pharma corporations and the Trump administration succeed in inserting these new rules into NAFTA, we would get locked into the bad policies that have made high U.S. medicine prices an outrage and export these life-threatening rules to other countries.

If included in a renegotiated NAFTA, these revived TPP proposals would require every signatory country to ensure its domestic laws guarantee drug companies' expanded monopoly powers. Expanding these rules beyond what is now in NAFTA would lock in bad U.S. policies and require Canada and Mexico to adopt them, leading consumers and government health programs to pay higher prices on more drugs for longer — or leave people without needed treatment. These proposals include:

- “Evergreening” patents, meaning making monopoly rights last longer with lax patentability standards that help keep older medicines under monopoly control and thus let corporations charge higher prices;
- Strengthened corporate control over clinical test data with “data exclusivity” requirements that mean governments must wait to register generic versions of medicines;
- Imposing “marketing exclusivity” rules that lock in domestically and export 12-year monopolies on cutting-edge biologic medicines, such as many new cancer treatments;
- Extending monopoly patent terms beyond 20 years by requiring governments to make “adjustments;”
- Heightening border controls, which could be used even to limit people from importing less expensive medicine for personal use; and
- New rights for pharmaceutical corporations to have a role in government healthcare programs' drug coverage and reimbursement decisions, potentially thwarting cost-saving reforms, such as best practices for Medicare Part D bulk-purchasing negotiation powers.

If these terms were added to NAFTA during renegotiation, they would establish and lock in rules that limit competition and contribute to preventable suffering of North America's approximately 500 million people. Given that all of the NAFTA countries already have adopted the original NAFTA and World Trade Organization rules that heavily favored the pharmaceutical corporations, NAFTA renegotiation could result in even greater power to raise prices for pharmaceutical executives who are ripping off patients everywhere.

These NAFTA rules would not be alterable without consensus by all signatories. Any renegotiated NAFTA would set the parameters to which the current and future Congresses, U.S. state legislatures and NAFTA governments would be constrained with respect to policies for reducing medicine prices and protecting public health and the nations' fiscal health. Just one critical example: NAFTA's limits on future policy space could restrict high-profile reform efforts, first and foremost, for Medicare Part D price negotiations.

Big Pharma-desired NAFTA Rules That Would Limit Competition and Promote High Medicine

Costs

Exclusivity for Biologic Medicines:

- The most controversial medicine-related provision may concern biotech drugs, or biologics, which are medical products derived from living organisms. Biologics include many new cancer treatments, with prices frequently exceeding \$100,000 per person. Most health systems cannot pay such prices without compromising other health care priorities.
- Reportedly, the U.S. NAFTA negotiators have demanded 12-year automatic monopolies (“exclusivity”) for biologics. That means NAFTA would not allow national regulatory authorities to authorize the sale of products that rely on a competitor's safety and efficacy data, *even in the absence of patents*. Some cancer patient activists have called this provision a “Death Sentence Clause,” as it would cut off access to drugs that are necessary to extend the lives of people suffering from cancer.



- During the TPP negotiations, other countries pushed back hard against Big Pharma’s demands on biologics. The battle over biologics and access to cancer treatment was responsible for dragging out talks for years. The pharmaceutical industry and U.S. Trade Representative failed to convince the other TPP nations to accept the 12-year monopoly, but the TPP did include a five-year period. After the United States pulled out of the TPP, the other countries shelved this controversial provision.
- If a revised NAFTA included such a “death sentence clause” or any period of extended monopolies for biologic medicines, the United States would be locked into its current bad system that keeps cancer medicine prices sky-high. And this damaging regime would be exported to Mexico, which now does not provide any additional exclusivity period for biologic medicines, and to Canada, which now has an eight-year period. Such changes to Mexican and Canadian law would reduce access to lifesaving drugs.

Evergreening and Lax Patentability Standards:

- Big Pharma’s wish list includes weak patentability and patent examination standards to undermine the stronger rules in Mexico and Canada. Pharma’s changes would make it even easier to patent minor modifications to older, otherwise off-patent medicines, such as patenting dosages and formulations. This contributes to extended monopoly control over important drugs, contributing little to innovation but greatly to price.

Patent Term Extensions:

- Under NAFTA, each country must provide a 20-year patent term. The pharmaceutical industry wants NAFTA renegotiations to require countries to extend that period if a patent office or drug regulatory agency requires more time to review a patent application or drug than Big Pharma thinks is reasonable. Patent extensions (called “adjustments” in the negotiations) mean generic drugs are kept off the market for longer, so prices of brand-name drugs can remain high.

New Rights for Pharmaceutical Firms to Meddle in Government Health Programs’ Policies on Drug Pricing and Reimbursement

- **The pharmaceutical industry is seeking to add harmful TPP provisions to NAFTA that could limit government health programs’ abilities to negotiate for or otherwise achieve lower medicine prices.** These terms, found in a cynically-dubbed “Transparency Annex” in the TPP, would be directly aimed at gutting Canada’s drug pricing system. But the terms could also constrain important price-cutting reforms in the United States. If the TPP is any guide, the demanded terms could include:

Drug companies having a role in government policy deliberations on what medicines and medical devices will be covered in government healthcare programs, and their prices;

Decisions not taking into consideration if there are effective, more affordable alternatives; and

Drug firms having special, broader rights to challenge government decisions that the firms oppose.

- **Such terms in NAFTA would reduce the flexibility and policy space that Congress would have to protect public health.** These terms could limit the tools our government has to increase generic drug competition and get the best price for our seniors and for safety net providers.



- **Such an Annex could constrain reforms for Medicare Part D drug price negotiation.** Ninety-two percent of Americans favor allowing Medicare to negotiate directly with drug corporations to lower prices for Part D beneficiaries. Creating a national formulary of medicines the program would cover would be a key aspect of this reform and would provide Medicare with substantial leverage to obtain discounts. Public Citizen estimates that savings could reach \$16 billion annually. If terms like those in the TPP Transparency Annex were included in NAFTA, they could constrain the factors Medicare may consider when deciding what drugs to cover or what rights drug firms would have to influence Medicare’s decisions. This could limit the effectiveness of one of the most significant and popular proposed reforms to reduce U.S. drug prices.
- **Could companies use a new NAFTA Annex to compel Medicare to cover expensive products without a corresponding benefit to public health?** Currently, Medicare reimbursement is limited to products that are “reasonable and necessary” for treatment. But Big Pharma wants decisions that “recognize the value” of pharmaceutical products or medical devices through the “operation of competitive markets” or their “objectively demonstrated therapeutic significance,” regardless of whether there are effective, affordable alternatives. Including such language in NAFTA could expose our domestic health care policies to attack by drug and device manufacturers.

Rolling Back Congressional Democrats’ Reforms for Developing Country Access to Affordable Medicines

- If the above rules are included in a NAFTA renegotiation, it would roll back the reforms made in the so-called “May 10, 2007 Agreement” that congressional Democrats won with respect to U.S. trade agreement rules on medicines. The May 10 Agreement began to reduce the negative consequences of U.S. free trade pacts for access to medicines in developing countries, such as Mexico. It did not eliminate these harms or create health benefits per se, but it established some modest limits for how much harm U.S. trade policy would facilitate. Many people’s lives are at stake. A renegotiated NAFTA should, at minimum, respect this modest progress in U.S. trade policy. Thus far we have no signs it will do so.