Patient Access to Affordable Medicines:

How a Renegotiated NAFTA Could Keep Drug Prices High for Patients

Key Background and Resources

U.S.-Mexico Agreement on 10 Years Keeps Brand Drug Prices High for Longer

The recent agreement between the U.S. and Mexico on a renegotiated NAFTA includes "10 years of data protection for biologic drugs" and an "expanded scope of products eligible for protection."

- Providing additional years of exclusivity (i.e., monopoly) serves only to keep brand drug prices high and keeps more affordable medicines out of reach for patients for longer.

Spending on brand biologic drugs is driving pharmaceutical spending growth in the U.S. and continues unabated.

- Biologics "grew by 12.6% in 2017, averaging 11.2% for the last five years" (IQVIA 2018). Net spending totaled close to $120 billion last year.
- According to the FDA, biologics now comprise almost 40 percent of total prescription drug spending, and represented 70 percent of the growth in drug spending between 2010-15.

The key to lowering drug prices for patients is by increasing competition through more access to safe, affordable generics and biosimilars in the U.S. and around the world.

- Increasing competition is a central component of HHS's Blueprint to Lower Drug Prices. And for good reason!
- Experience shows prescription drug costs decline by more than 60% after 12 months of generics entering the market (IQVIA 2016).

A Renegotiated NAFTA Should Lower – Not Increase – Drug Prices for Patients

USTR can and should pursue trade policies to lower prescription drug costs for patients. AAM provided several recommendations as part of its comments on the Blueprint:

- Competition abroad could be enhanced with new incentives for generic entry;
- Full transparency of all patents and exclusivities could be required;
- Strong regulatory review ("Bolar") provisions ensure expedited launch of generics and biosimilars; and,
- Disclosure of the best mode for carrying out an invention could be mandatory.

Balanced trade agreements can help ensure a robust global generic and biosimilars market.

- With the high cost of prescription drugs continuing to be a top health care priority for the American patients, there are steps a renegotiated NAFTA could take to lower prescription drug prices.
- However, a renegotiated NAFTA that only increases brand drug exclusivity to 10 years for Mexico and Canada would run counter to efforts to lower prescription drug costs.

Higher Drug Prices Abroad ≠ Lower Drug Prices in the U.S.

Extending exclusivity periods and imposing new barriers to competition through U.S. trade agreements does not lower the high cost of brand-name prescription drugs in the U.S.

- Health policy experts, incl. former HHS Sec. Tommy Thompson, note how these policies only delay competition and will not lower brand-name prescription drug prices for Americans.
- Over 100 organizations sent a letter in January noting, "it is vital that the NAFTA party governments reject any provisions that would expand or strengthen pharmaceutical monopolies and enforcement at the expense of access to affordable medicines."
- In June, AARP wrote to USTR, "AARP strongly opposes efforts to add harmful provisions to the renegotiated text of NAFTA that would extend or enhance monopoly protections for already-expensive biologic drugs."
- The Leadership Council of Aging Organizations commented, "It is absolutely wrong to grant new monopoly protections sought by pharmaceutical CEOs for biologic medicines, like insulin. We would also oppose revising NAFTA to force countries to allow

'evergreen' patents … or to issue new patent terms for new uses of old drugs. All such schemes are used to block the entry of generic drugs into the market and raise prices for working families."

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Imposes Additional Barrier to Emerging Biosimilars Market in U.S.

Blocking the ability of U.S. manufacturers to enter the prescription drug markets of other countries will further impede R&D on biosimilars here at home and put in jeopardy up to $54 billion in projected cost savings.

- Patients could have saved "more than $4.5 billion in 2017" if Americans had the opportunity to purchase successfully marketed, FDA-approved biosimilar prescription drugs according to the FDA. Only three biosimilars were available in 2017 even though the FDA approved 11 through 2018.

FDA Commissioner Scott Gottlieb, M.D. recently commented "biosimilars are not being developed or submitted for approval because of marketplace dynamics that are viewed as unfavorable to biosimilars."

Biosimilars offer safe, effective, more accessible treatment alternatives for patients needing biological therapies. Recent analysis shows 1.2 million U.S. patients could gain access to these new treatments by 2025 as the result of biosimilar availability.

- Avalere also found biosimilar access "could be significantly applicable to women, older adults, and low-income individuals."

Growing Export Markets for Generics and Biosimilars is in U.S. National Interest

U.S. generic drug sales reached an estimated $70 billion in 2017 – representing a quarter of the global market.

- Growth in generics "is driving, and will continue to drive, most of the projected growth in emerging markets over the coming decade."

However, an unlevel playing field in U.S. trade agreements, limits the ability of U.S.-based generic and biosimilar manufacturers to export medicines and meet global demand for safe and more-affordable prescription drugs.

RESOURCES

North American Generic Drugmakers Call for Rejection of New Exclusivity Period for Biologics

August 28, 2018 — https://bit.ly/2Quuyt0

"The announced trade understanding between the U.S. and Mexico to extend brand name biologic data protection to ten years will harm patients who seek more affordable medicines. This provision would harm the growing biosimilar industry, which aims to provide price competition to some of the most expensive prescription drugs and allow patients to benefit from affordable medicines. The U.S., Mexico and Canada should reject these provisions, which would benefit brand name drug companies to the detriment of public health and the affordability of medical care."

Trade Agreements Should Promote Patient Access to More Affordable Generics and Biosimilars

August 2018 — https://bit.ly/2N9jT9f

"Rather than increasing brand-name drug exclusivity, the U.S. should instead enhance patient access to generics and biosimilars. AAM – joined by its counterparts in Mexico and Canada – provided recommendations to the U.S. Trade Representative in September 2017 and submitted comments to the Department of Health and Human Services in response to the Trump Administration's Blueprint to Lower Drug Prices.

"That view, however, has not been the one advanced by the U.S. at the negotiating table … A revised NAFTA must not extend monopoly protections for brand-name drugs, keeping prices for patients higher for longer, and delaying competition from more affordable generics and biosimilars."

AAM and Sister Associations in Canada and Mexico: Governments Should Not Raise Drug Prices in Renegotiated NAFTA

September 29, 2017 — https://bit.ly/2Nb8cix

"Davis, McKeon and Martinez note that including a new provision in NAFTA to mandate biologic drug exclusivity – above and beyond the protections already provided by voluminous patents – will harm the growing biosimilar industry, which aims to provide price competition to the most expensive biological drugs and allow patients to benefit from affordable biological medicines. Davis stated, 'As President Trump and FDA Commissioner Gottlieb search for ways to lower prescription drug costs by enhancing generic drug competition and streamlining the biosimilar approval process, increasing branded biologic exclusivity in NAFTA would damage the growing U.S. biosimilar industry and harm North American patients who seek safe, effective, and affordable alternatives to costly biologic drugs."