



# the campaign for **SUSTAINABLE Rx PRICING**

June 18, 2019

Dear Member of Congress:

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based coalition of leaders – physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists and businesses — promoting bipartisan, market-based solutions to lower drug prices in America. We appreciate the bipartisan attention and activity that lawmakers in Congress have placed on tackling the crisis of rising prescription drug prices with greater competition and boosted transparency.

At a time when one in four Americans cannot afford their medications, policymakers in Washington must keep that momentum going, while also ensuring progress is not undermined by misguided policies.

That is why we are so concerned with certain provisions contained in the U.S.-Mexico-Canada Agreement (USMCA) that could undermine congressional efforts to lower drug prices.

CSRxP believes that trade agreements are important tools to drive economic growth and support the development of the U.S. health care sector. Successful agreements include provisions that alleviate market access barriers, spur competition, incentivize innovation, provide added benefits for patients and drive down costs. We believe an updated North American trade agreement can accomplish all of those goals — including lowering prescription drug prices for American patients.

Unfortunately, USMCA falls short on this issue of critical importance for the American people. Of specific concern to CSRxP are the following:

- 1) **Biologic Exclusivity**: In recent years, Congress has weighed lowering the period of exclusivity on biologics to seven years, which would be impossible under USMCA in its current form. Establishing a 10-year floor for biologic exclusivity will hamper the flexibility lawmakers need to address the rising cost of biologics, an increasingly prescribed, highly expensive class of medicines.
- 2) **Definition of a Biologic**: U.S. law currently excludes chemically synthesized polypeptides (CSPs) from the definition of a biologic. This growing class of medicines treats patients with a wide variety of chronic conditions, including cancer, diabetes, heart failure and osteoporosis. By including CSPs in the definition of a biologic, the exclusivity period will be expanded by as much as seven years, which would impede competition and incentivize price hikes — forcing patients and taxpayers to pay more over a longer period of time.
- 3) **Scope of Drug Exclusivities**: Under U.S. law, a generic manufacturer can submit an application to sell a drug in the U.S. four years after the original patented medicine (new chemical entity) received marketing authorization. The patent holder then has 45 days to file a patent infringement lawsuit. If that lawsuit is not filed, a generic drug may be approved by the FDA and not have to wait until the five-year exclusivity expires. The USMCA's ambiguous language appears to make it impossible to enter the market before the five-year exclusivity period expires, even if the original patent holder does not challenge the generic manufacturer's



right to sell the product. This will unnecessarily extend monopolies on certain drugs and delay competition that can drive down prices for patients.

Congress has a tremendous opportunity to ensure the USMCA aligns with the goals set out in the Bipartisan Trade Priorities Act of 2015, which included a commitment to patient access to more-affordable generic and biosimilar medicines both in the United States and abroad.

We strongly encourage Members of Congress to work in a bipartisan manner to see the USMCA amended to protect American patients by addressing these concerns.

We thank the many Members of Congress, from both sides of the aisle, who have led on the crisis of rising prescription drug prices in America and urge them to prioritize this issue in USMCA discussions.

Sincerely,

Lauren Aronson  
Executive Director  
The Campaign for Sustainable Rx Pricing