January 22, 2019

Dear Member of Congress,

The undersigned organizations representing healthcare providers, patients, public health experts, workers, people of faith, and consumers are committed to advancing public health and promoting access to affordable medicines. Access to affordable healthcare and medicines is one of few demands that now unites the American public.

We write to you today with concern that provisions currently included in the proposed NAFTA 2.0 (referred to by the Trump administration as the United States-Mexico-Canada Agreement) would entrench and expand prescription drug monopoly protections, thwart competition and thus undermine efforts to expand access to affordable medicines.

Today, high prescription drug prices force people across the United States to choose whether to take the medicines they need, or, instead, to ration or simply go without needed treatments in order to be able pay for other necessities like food and shelter. Nearly one-in-four Americans report that they or another family member have not filled a recent prescription because of cost. Not being able to afford needed medicines is causing preventable suffering and death. These day-to-day impacts of high medicine prices are driving the national demand for reform. High drug prices that force patients to ration or go without needed medicines also result in increased health care costs both for consumers and government programs.

NAFTA 2.0 includes terms that would lock in place existing U.S. policies that have led to high medicine prices, undermining the authority of this and future Congresses to implement important reforms to expand generic and biosimilar competition, lower medicine prices and expand access. This is the case because NAFTA 2.0 includes expansive terms relating to patent and other non-trade policy matters to which the U.S. Congress will be obliged to conform our domestic policies. Once implemented, changes to the NAFTA 2.0 terms would require consensus among all of the signatory countries. And, if Congress enacted policies that conflict with NAFTA 2.0 terms, the United States would become subject to trade sanctions – tariffs on U.S. exports – unless and until Congress' actions were reversed.

The current text of NAFTA 2.0 mandates a minimum 10-year marketing exclusivity period for new biologic medicines, which includes many of the critical new treatments for cancer and heart disease and even vaccines. Absent competition, corporations routinely price these products at more than one hundred thousand dollars per patient per year. Members of the U.S. House of Representatives and the U.S. Senate have introduced legislation<sup>iv,v</sup> that would spur biosimilar competition in the United States by decreasing biologic marketing exclusivity to seven years. Reducing the U.S. biologics exclusivity period from the current 12-year term to seven years would save patients and taxpayers billions of dollars. Congressional enactment of this pro-health, cost-cutting reform, which would more fairly balance consumer and industry interests, would violate the terms of NAFTA 2.0 as currently drafted and thus could subject the United States to tariff sanctions.

Further, NAFTA 2.0 would lock the United States into:

- policies that extend patent terms for perceived delays in patent examinations and FDA reviews,
- marketing exclusivities that prevent competition even after a medicine's patent term expires, and
- requirements to provide secondary patents that facilitate patent "evergreening," which extends
  monopoly protections well beyond 20-year patent terms without any increased therapeutic benefits
  for patients.

Additionally, NAFTA 2.0 includes rules regarding procedures for pharmaceutical reimbursement decisions that prescription drug manufacturers may argue entitle them to on-going influence over Medicare decision-making processes with respect to which products are covered and how much to reimburse for those products.<sup>1</sup>

Expansive patent and marketing exclusivity rules are some of the major factors that have resulted in U.S. consumers and the U.S. government routinely paying more for prescription drugs than people and governments in other countries throughout the world. Locking the United States into the policies that have led to high medicine prices here will not remedy our problem, nor will trying to impose these U.S. policies on Mexico and Canada through NAFTA 2.0. The negative impact on access to medicines through the expansion of monopoly powers and limits on competition would be felt for years to come, and would not be limited to the 490 million people living in the U.S., Mexico and Canada. It would be a dangerous blueprint for future agreements.

The use of NAFTA 2.0 to export our high-medicine-price policies to Mexico and Canada reflects an incorrect belief that lower medicine prices elsewhere are the cause of high prices here. This claim contradicts the evidence. In reality, prescription drug corporations charge high prices in the United States to maximize profits because our current policies provide these firms protections that allow them to do so<sup>vii</sup>, not because of their research & development costs or because of the prices of their products in other countries. In fact, pharmaceutical firms' revenue that is attributable only to higher prices for prescription drugs when sold in the United States than when sold abroad – i.e. the U.S. pricing premium – is greater than those companies' *global* R&D expenditures.

Instead of exporting high medicines prices to other countries and locking in current U.S. policies by imposing expansive monopoly protections through NAFTA 2.0, we urge legislators to pursue domestic medicine-pricing reforms that would curb monopoly abuses, promote competition, stop price spikes and leverage government negotiating power.

We urge you to demand that the administration eliminate the provisions in the NAFTA 2.0 text that undermine affordable access to medicines in the United States and abroad. It is imperative that NAFTA 2.0 and any other future U.S. trade deals do not thwart domestic reforms to lower prescription drug prices and make medicines affordable and accessible.

CIP	$\sim \sim \sim \sim$	ely,
. TII		HIV.

<sup>1</sup> See Article 29.7: Procedural Fairness

AFL-CIO

Aging Life Care Association

Alliance for Retired Americans

**American Family Voices** 

American Federation of State, County and Municipal Employees

American Federation of Teachers

American Medical Student Association

American Muslim Health Professionals

Association of Flight Attendants-CWA

**Business Initiative for Health Policy** 

Center for Medicare Advocacy

Center for Policy Analysis on Trade and Health (CPATH)

Center for Popular Democracy Action

Chronic Illness Advocacy & Awareness Group

Clinicians for Progressive Care

Coalition to Protect Patient Choice

Coalition to Reduce Spending

Columban Center for Advocacy and Outreach

**Communications Workers of America** 

Community Catalyst `

**Consumer Action** 

**Consumer Reports** 

**CREDO Action** 

**Doctors for America** 

**End AIDS Now** 

Families USA

Foundation for Integrative AIDS Research

Franciscan Action Network

**Global Justice Institute** 

Health Care for America Now

Health GAP

Interfaith Center on Corporate Responsibility (ICCR)

International Association of Machinists and Aerospace Workers

International Brotherhood of Boilermakers

International Brotherhood of Electrical Workers

Justice in Aging

**Knowledge Ecology International** 

Labor Campaign for Single Payer

Latinos for a Secure Retirement

Maryknoll Office of Global Concerns

Médecins Sans Frontières/Doctors Without Borders USA

Medicare Rights Center

Metropolitan Community Churches

National Advocacy Center of the Sisters of the Good Shepherd

National Center for Health Research

National Coalition on Health Care

National Committee to Preserve Social Security and Medicare

**National Education Association** 

National Health Law Program

National Physicians Alliance

National Women's Health Network

**NETWORK Lobby for Catholic Social Justice** 

Oxfam America

Partners in Health

**People Demanding Action** 

People of Faith for Access to Medicines

People's Action

Presbyterian Church (USA)

**Prescription Justice** 

**Public Citizen** 

R Street Institute

Raising Women's Voices for the Health Care We Need

Service Employees International Union

**Social Security Works** 

T1International

The United Methodist Church, General Board of Church and Society

**Treatment Action Group** 

Union for Affordable Cancer Treatment

**UNITE HERE** 

United Church of Christ, Justice and Witness Ministries

Universities Allied for Essential Medicines (UAEM)

cc: Robert Lighthizer, United States Trade Representative

<sup>&</sup>lt;sup>1</sup> Kesselheim, Aaron S., Avorn, Jerry, Sarpatwari, Ameet. (2016, August 23). The High Cost of Prescription Drugs in the United States. Retrieved November 4, 2018, from <a href="http://jamanetwork.com/journals/jama/article-abstract/2545691">http://jamanetwork.com/journals/jama/article-abstract/2545691</a>

ii Donald Chaires, George Denault, Jane Doe, John Doe, Brittany Gilleland, Gerald Girard, Sara Hasselbach, Lindsey Kinhan, Joseph McLaughlin, Mattew Teachman, and Karyn Wofford v. Sanofi U.S., Novo Nordisk Inc., and Eli Lilly and Company (Class Action Complaint, United States District Court, District of Massachusetts January 30, 2017). Retrieved November 6, 2018 from https://static01.nyt.com/science/01-30-

<sup>17</sup> Insulin Class Action Complaint Hagens Berman.PDF

iii IMS Institute for Healthcare Informatics, Avoidable costs in US healthcare (2013). Available at www.webcitation.org/6fatM9xnn

<sup>&</sup>lt;sup>iv</sup> Affordable Medications Act. (S. 3411, 115th Congress). <a href="https://www.congress.gov/bill/115th-congress/senate-bill/3411/text">https://www.congress.gov/bill/115th-congress/senate-bill/3411/text</a>

<sup>&</sup>lt;sup>v</sup> *Improving Access to Affordable Prescription Drugs Act.* (H.R. 1776, 115th Congress). https://www.congress.gov/bill/115th-congress/house-bill/1776/text

vi Public Citizen. (2017, June). Exporting Monopoly Rules Does Not Lower U.S. Prescription Drug Prices. Retrieved October 31, 2018 from: <a href="https://www.citizen.org/system/files/case">https://www.citizen.org/system/files/case</a> documents/trump-drug-pricing-eo-trade-and-monopolies-memo.pdf

vii ASPE. Prescription Drugs: Innovation, Spending, & Patient Access. U.S. Department of Health & Human Services. (Dec. 7, 2016). <a href="https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf">https://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf</a>

viii Nancy Yu, Zachary Helms, & Peter Bach. R&D Costs for Pharmaceutical Companies Do Not Explain Elevated U.S. Drug Prices. Health Affairs Blog. (Mar. 7, 2017) <a href="http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/">http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/</a>