The Trans-Pacific Partnership (TPP) threatens access to affordable cancer treatments and other biologics

Patients fighting cancer, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease and other serious illnesses rely increasingly on biotech medicines called "biologics" to live. In fact, most novel cancer-fighting drugs are biologics. These new generation treatments are derived from living organisms and include vaccines, gene therapies, cellular therapies, and allergy shots, among other products. However, they are prohibitively expensive. In 2012, 11 of the 12 cancer drugs approved by the FDA cost more than $100,000.

Biosimilars, generic versions of biologics, are expected to cut costs and provide consumers with more affordable options. But the U.S. is currently negotiating a Trans-Pacific Partnership Agreement (TPP) with 11 other Asia-Pacific countries that would block access to the more affordable therapies by preventing biosimilars manufacturers from entering the market.

Data and market exclusivity

Market exclusivity provides a brand-name company with an absolute monopoly for a determined period after its product receives marketing approval. During this period, a drug regulatory authority cannot approve a competing product for market entry.

Typically, a drug regulatory authority relies on the clinical trial data submitted by a brand-name company to approve generic medicines. Under **data exclusivity**, the regulatory authority cannot rely on the brand-name company's clinical test data to determine safety and efficacy. The biosimilar applicant must duplicate the time-consuming and expensive clinical trials even though the outcome is already known or wait until the end of the data exclusivity period to apply for market approval.

Exclusivity for biologics would put lives at risk and threaten the financial stability of government health programs

In the **U.S.**, the use of biologics therapy can cost up to $400,000 annually even for patients with comprehensive coverage. These high costs are in part due to exclusivity protections in U.S. law that block market entry for more affordable biosimilars. To cut costs, the White House has proposed reducing the U.S. exclusivity from 12 to 7 years, however the TPP could lock-in a longer period and preclude cost-saving amendments to U.S. law.

In **Peru**, breast cancer is a leading cause of death for women. The most effective treatments against the disease are far beyond consumers' reach. For instance, trastuzumab (Herceptin) costs around $47,500, approximately eight times Peru's Gross National Income (GNI) per capita of $5,880. With limited access to the medicines they need, many women are unable to adhere to treatment guidelines and/or may abandon treatment altogether.

In **Vietnam**, up to 4% of the population suffers from hepatitis C, an inflammation of the liver. A full course of biologics treatment (48 weeks) can cost up to $10,000, more than seven times the GNI per capita ($1,400). The latest treatment is even more expensive, costing $1,000 per pill. Since the national health insurance plan is unable to provide comprehensive coverage, many must forego treatment and risk liver cancer.

In **Chile**, more than 100,000 individuals suffer from rheumatoid arthritis, 10% of whom are not responding to traditional therapy and need biologics. In 2012, Chileans affected by the disease went to the streets to urge the government to provide treatment coverage for the high-cost drugs.

Blocking access to biosimilars could result in a global health crisis

By 2030, the global cancer burden is expected to increase by 75% with 22 million new cases annually if current trends continue. Although the rate of cancer prevalence is higher in wealthier countries, 80% of global deaths occur in low and middle-income countries, where oftentimes less than 1% of public and private healthcare expenditures are dedicated to cancer. Legally blocking biosimilar competition in the Asia-Pacific region could disincentivize biosimilar manufacture and limit the global competition necessary to drive prices down for all.

U.S. exclusivity for biologics produces billions in extra healthcare costs for Americans

- The U.S. is the only country in the world to provide a special, extra-long period of market exclusivity for biologics. As a result, more affordable biosimilars are blocked from market entry for twelve years, costing Americans billions of dollars in extra healthcare costs annually.
- The White House has repeatedly proposed to reduce this period to seven years to control costs. According to the White House budget for FY 13 and FY 14, such changes would save $3 billion over 10 years for federal programs including Medicare and Medicaid (and tens of billions in savings when counting consumer expenditures).
- Yet behind closed doors, the Obama Administration proposes trade policies in the TPP that would make it close to impossible for Congress to change the law in the future to contain healthcare expenditures.

Special exclusivity measures for biologics are unnecessary for promoting innovation

- According to a Federal Trade Commission (FTC) report, long data exclusivity periods are unnecessary to promote innovation as brand-name firms already have large incentives under the patent system to conduct research and development (R&D). Patents are 20-year exclusive rights under which innovators recoup their costs and earn substantial profits. Exclusive rights to registration data can confer an additional marketing monopoly and impede access to lower-cost biosimilars even where there is no patent or after patent expiration.

Data exclusivity measures are unethical

- When a biologic treatment is under data exclusivity, biosimilars manufacturers are unable to rely on a brand-name company's clinical test data to demonstrate safety and efficacy. This means that if a biosimilars manufacturer wishes to enter the market before the end of exclusivity, it must duplicate clinical trials on human subjects and animals even though the outcome is already known—a violation of medical ethics.

Across the world, people fighting against cancer, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease and other serious illnesses need access to new specialty treatments—biologics—that have promising potential to extend lives. But the cost of these therapies is astronomical. Due to a robust lobbying campaign, Congress has implemented special 12-years exclusivity in U.S. law. This blocks market entry for more affordable versions of biologics. The pharmaceutical industry is seeking to lock in similar monopoly measures for the Asia-Pacific region potentially costing consumers billions in extra healthcare costs annually. But national health programs in developing countries already struggle to provide coverage for these high-cost drugs and the White House has proposed reducing this period to save costs. Thus, imposing exclusivity for biologics in the TPP is at odds with domestic and global efforts to alleviate cost burdens for medical treatment and could result in preventable death and suffering for many, perhaps millions, of consumers in the Asia-Pacific.