

On August 12, 2016, the Obama Administration put Congress on notice that it will send lawmakers a bill to implement the Trans Pacific Partnership (TPP) trade agreement. The vote on TPP is likely to come after the elections. The TPP agreement contains various provisions that could affect drug prices for all Americans, including seniors. These provisions would jeopardize the government's ability to negotiate lower prices for drugs in public programs including Medicare and Medicaid and block patent reform.

### **TPP Locks in Patent Protections for Drugs & May Block Future Reform**

The United States grants more lengthy patents and other forms of regulatory protections to pharmaceutical corporations than other countries. The U.S. Trade Representative, at the urging of pharmaceutical companies, pressured other countries to provide the same protections, and set them in stone, as part of the TPP agreement. In doing so, U.S. negotiators are jeopardizing our country's ability to implement patent reform in the future and will lock in high prescription drug prices for consumers.

**Exclusivity for biologics:** The TPP locks in a lengthy exclusivity period for biologics – drugs used to treat various types of cancer and other chronic conditions like rheumatoid arthritis and multiple sclerosis. The agreement protects pharmaceutical corporation monopolies at the expense of patient access to life-saving medicines

**Evergreening:** The TPP requires countries to grant “evergreen” patents or patent extensions for small changes in the formula, dosage or administration of a drug, regardless of whether these minor alterations improve the efficacy of the drug. This also keeps generic versions from being developed and extends corporate monopolies.

### **Corporate Rights in TPP Could Supersede U.S. Laws and Courts**

It is troubling that the TPP agreement includes investor-state dispute settlements (ISDS), a mechanism by which global corporations can sue countries over trade violations.

Under ISDS, an international tribunal which does not have to comply with U.S. laws or take the impact of a trade dispute on American citizens into consideration, is empowered to make binding decisions. ISDS gives corporations a new way to seek compensation, often at the expense of the public good. Using this mechanism, pharmaceutical companies can skirt U.S. laws and make even greater profits.

ISDS claims are growing in numbers. In 2012 alone, 58 cases were filed. Eli Lilly was the first drug company to file an ISDS claim. The company is challenging a court decision in Canada that rejected the company's attempt to extend patents for Strattera and Zyprexa. Eli Lilly is seeking \$500 million in compensation from Canada.

## **TPP Could Limit Cost Control Measures in Public Programs**

The federal government, as the administrator of Medicare, works to lower the cost of prescription drugs for patients and the government, through rebates, discounts and drug formularies. However, the TPP agreement includes language that puts the interests of drug and medical device companies above those of beneficiaries and taxpayers by providing an opportunity for drug and device manufacturers to seek higher reimbursements rates.

Specifically, it requires countries to make available a review process for health care reimbursements decision and to follow TPP procedural rules and principles – but the process is not required to be open to the public or to consider alternate views. The vague language in this section provides no assurance that government agencies are protected from a legal challenge. Thus, under this transparency provision, global corporations could contest reimbursement policies through ISDS.

Under this procedure, Medicare could be subject to a challenge by a foreign pharmaceutical company or a foreign subsidiary of a U.S. company. In contrast, citizens concerned about ensuring that Medicare gets the best value for its dollar are not guaranteed any formal role in such a challenge.

Also, this agreement could tie the hands of future Congresses to enact legislation to negotiate drug prices under Medicare or enact a Medicare drug rebate program, which would save taxpayers \$121 billion over 10 years.