United States Senate

WASHINGTON, DC 20510

The Honorable Ron Kirk
United States Trade Representative
The White House

September 10, 2012

Dear Ambassador Kirk:

We are encouraged that the U.S. is continuing to work toward the development of the Trans Pacific Partnership Free Trade Agreement (TPP). High quality FTAs, like those recently ratified with Korea, Colombia, and Panama, level economic playing fields and make it easier for U.S. companies to do business and compete abroad. We are hopeful that the TPP negotiations produce an agreement of this caliber.

As you work toward this, one issue that must be appropriately addressed is intellectual property (IP) protection. Within this context, it is especially critical that protections be extended to the biopharmaceutical industry, which is a driver of American innovation that provides jobs and exports for the U.S. and Oklahoma while creating new lifesaving medicines for patients around the world.

Currently, America's biopharmaceutical research companies have 901 biotechnology medicines and vaccines in development, many of which are biologics targeting more than 100 debilitating and life-threatening diseases, including 352 for cancer and related conditions, 188 for infectious diseases, 69 for autoimmune diseases, and 59 for cardiovascular diseases.

In 2010, there were approximately 1,000 clinical trials underway in Oklahoma. On average, it costs \$1.2 billion and takes over a decade to develop a new medicine, and this includes those that are made up of complex, large-molecules characteristic of biologics. With recent advances in medical technology, we are just beginning to see the vast potential that biologics have to treat and cure diseases.

Protection of IP globally will allow U.S. firms to compete on a level playing field and ensure the U.S. biopharmaceutical industry continues to lead the world in the innovation and discovery of the therapies of the future. U.S. law is very clear and provides for a 12-year term of regulatory data protection for biologics, and we believe this should serve as the baseline for the administration's objectives for this aspect of the negotiation. Is this consistent with the administration's position on biologic data protections?

In Oklahoma alone, the bioscience industry supports more than 18,500 jobs. Securing strong IP protections across all disciplines in the TPP will help Oklahoma maintain and continue to grow a healthy bioscience industry. This is a critical component of any high caliber FTA, and we hope you address the issue with adequate respect of the actions Congress has taken to speak on this particular issue.

Sincerely,

United States Senator

Tom Coburn, M.D. United States Senator