The TPP Trade Agreement and Biopharmaceutical Protections

The Trans-Pacific Partnership (TPP) negotiations represent an opportunity to underscore our commitment to continued biomedical innovation through the inclusion of strong biopharmaceutical IP and transparency provisions. The Administration and other TPP parties are pressing to conclude the agreement by the end of 2013. It is critical that the final agreement **builds on the strong IP and transparency protections in the Korea-U.S. Free Trade Agreement (KORUS), as well as reflects U.S. law for the protection of biologics**. Doing so will ensure that our nation remains the leading innovator of biopharmaceutical products for the world's patients, while also increasing U.S. exports and expanding valuable employment opportunities for U.S. workers.

The U.S. innovative biopharmaceutical industry supported 3.4 million U.S. jobs in 2011[1] and exported over $50 billion in biopharmaceuticals in 2012, making the sector the third largest U.S. exporter among R&D-intensive industries.[2] In order to build on both our medical and economic advancements, U.S. negotiators must seek and secure the following:

Biopharmaceutical IP Protections

- The TPP agreement must build on the strong IP protections in KORUS (data protection for small molecules, effective patent enforcement and patent term adjustment) and reflect U.S. law for biologics, which provides 12 years of regulatory data protection.
- There is strong bipartisan support in the U.S. Congress for the inclusion of 12 years of regulatory data protection for biologics in the TPP agreement. Further, in order to continue its stated adherence to expired Trade Promotion Authority procedures, the Administration must use the TPP negotiations to bring the IP protections in partner countries up to the same level as in U.S. law. In the case of biologics, this means USTR must table and seek to secure 12 years of regulatory data protection.

Transparency Protections

- A strong pharmaceuticals chapter, founded on the provisions contained in Chapter 5 of KORUS, is essential to promoting the development of and patient access to high quality patented and generic pharmaceutical products.
- Policy and regulatory procedures and decisions regarding how medicines are approved, regulated and reimbursed should be governed by transparent and verifiable rules guided by science-based decision making.
- There should also be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right of appeal to an independent, objective court or administrative body. This is a matter affecting innovative and generic industries alike, and one which must be addressed in the TPP negotiations.

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[1] Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry*, July 2013. Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America.

[2] U.S. International Trade Commission, Trade DataWeb, accessed July 12, 2013, at http://dataweb.usitc.gov/ (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).