COMMITTEE ON FINANCIAL SERVICES
SUBCOMMITTEES:
CAPITAL MARKETS AND
GOVERNMENT SPONSORED ENTERPRISES
OVERSIGHT AND INVESTIGATIONS

WASHINGTON OFFICE:
119 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5541

DISTRICT OFFICES:
211 STATE STREET, 2ND FLOOR
BRIDGEPORT, CT 06604

888 WASHINGTON BLVD., 10TH FLOOR
STAMFORD, CT 06901

TOLL FREE: (866) 453-0028

James A. Himes
Congress of the United States
4th District, Connecticut

July 28, 2015

The Honorable Michael Froman
United States Trade Representative
Office of the United States Trade Representative
600 17th Street Northwest
Washington, DC 20508

Dear Ambassador Froman,

Thank you for your efforts to negotiate a strong, modern Trans-Pacific Partnership (TPP) agreement, and for maintaining an ongoing dialogue with my colleagues and me. Together, I hope we can advance our nation's economy, uphold our strong values, and craft a truly progressive trade agreement.

On July 24, ten of my colleagues and I sent a letter to you on the intellectual property (IP) provisions in the proposed TPP relating to pharmaceutical and biopharmaceutical medications. We highlighted the effective balance that we have both in U.S. law and in the May 10th agreement governing recent trade deals that simultaneously and vigorously promote innovation and maintain access to lifesaving medications.

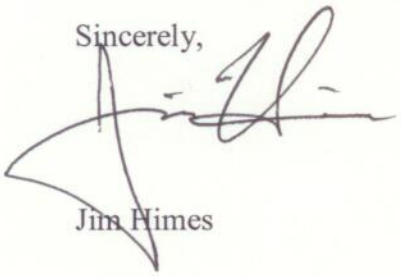
Many of the provisions put forth in the proposed TPP do indeed reflect this proper balance, but I am concerned that language advanced in the negotiations by the United States on patent linkage for both traditional medications and biologics differs significantly and possibly dangerously from U.S. law.

First, as I understand it, linkage for traditional medications would be mandatory for all TPP nations, but key accompanying provisions that provide a pathway for generic medicines in The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman) and the Medicare Modernization Act (MMA) have not been included. Without these safeguards we effectively use to balance innovation and access, generics could face undue obstacles to market entry in the region.

Second, in the proposed text, linkage would be mandatory for all "pharmaceutical products," including biologics. The Biologics Price Competition and Innovation Act (BPCIA), in establishing U.S. patent law in this space, created a different pathway for biologic treatments than the Hatch-Waxman linkage system. Extending linkage to biologics poses several significant issues, including the potential to delay biosimilars from entering the market and to force a change in U.S. law on a complex topic that was rigorously debated and established in the BPCIA.

I understand that issues surrounding access to medicines in the TPP are still under negotiation. During the upcoming ministerial round in Hawaii, I urge the U.S. negotiating team to advocate for specific language in the underlying text that ensures access to affordable and often lifesaving medicines for developing countries without removing critical IP protections promoting innovation. Replicating the spirit of the balance in pharmaceutical and biopharmaceutical IP law we have in the U.S. to protect vulnerable populations is essential to forming a robust and progressive 21st century trade agreement.

Sincerely,



Jim Himes