Congress of the United States
Washington, DC 20515

July 23, 2015

Ambassador Michael Froman
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Froman:

We appreciate the hard work that you and your team have invested in advancing America's interests in trade negotiations and your efforts to create the most progressive Trade Promotion Authority (TPA) in history. The content and passage of TPA reflects that hard work.

Now that TPA is law, we write to emphasize what was said at our last meeting with the President: our support for TPA does not translate into automatic support for the Trans Pacific Partnership (TPP). At the conclusion of the negotiations, we will consider whether our constituents and country are better off with, or without, an agreement. Congress drafted TPA to provide the American people with an unprecedented opportunity to review the terms of the agreement. This long-overdue level of transparency requires that any final TPP agreement is able to withstand their careful scrutiny.

We are concerned that the TPP would fail this scrutiny if it does not meet or exceed the standards set under the May 10th Agreement, reached by House Democrats and the Bush White House in 2007, with respect to timely access to affordable medicines in developing countries.

Indeed, the recently passed TPA required USTR to both "ensure that trade agreements foster innovation and promote access to medicines." In the United States, we have developed a system over time that has created the proper balance between these twin goals. We have strong intellectual property (IP) protections that support the world's most innovative pharmaceutical and biopharmaceutical industry. We also have incentives and safeguards that effectively encourage and allow generic competitors to enter the market when appropriate to lower costs over time. These rules are laid out in specialized provisions in the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman), the Medicare Modernization Act (MMA), and the Biologics Price Competition and Innovation Act (BPCIA) – which was included in the Affordable Care Act. An approach leading to similar outcomes should be secured in a final TPP

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agreement. A TPP that inhibits a balanced approach could unreasonably delay the timely and affordable access to medicines in certain TPP countries.

In an agreement spanning countries with diverse economies, we do not expect a one-size-fits-all approach to secure these outcomes. It is our hope that our negotiators pursue a balanced approach that reflects the varying degrees of economic development, legal traditions, and practices that exist within TPP countries. We believe this can be achieved by including an approach that's equal to or stronger than the May 10th Agreement.

Central to the May 10th Agreement is the requirement that countries adopt procedures and remedies for the expeditious adjudication of disputes concerning both the infringement and validity of pharmaceutical patents. A truly progressive agreement will have strong protections for marketing exclusivity for test data, but in a way that also incentivizes manufacturers to seek marketing approval for new drugs in a developing country shortly after they receive such approval in the United States. It would also have alternatives to mandatory extensions for regulatory approval delays in developing countries, consistent with the balanced approach we hope our negotiators will pursue.

Additionally, we think it critical a final TPP agreement include language ensuring IP obligations do not prevent member countries from taking measures to protect public health and, in particular, to promote access to medicines for all.

The TPP will also likely include IP provisions for biologic medicines. Although some consider biologics to be a novel issue that is going to be addressed for the first time in TPP, these medicines did exist at the time of the May 10th Agreement. Though the BPCIA, which created a path for generic approval of biologics, had not yet been passed, the May 10th Agreement embodies the principle that our trade agreements should incentivize innovation while ensuring access to medicines in developing countries. We urge our negotiators to consider this balance when determining how biologics will be addressed and to seek a regional standard that promotes both innovation and access to medicines in all partner countries.

A high standards agreement would ensure strong patent protections that promote both original and improvement inventions. Such a system promotes competition and leads to innovation. Our previous agreements have protected this important objective by embracing the framework of Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS). We would hope that a final TPP agreement reflects, but does not exceed, the balanced approach for securing patents on both original and improvement inventions as outlined in TRIPS.

For the first time in a trade agreement, countries will have varying transition periods for implementing TPP's IP obligations. The metric guiding each country's implementation should not be arbitrary and should account for their respective levels of development, capacity, and existing practices.

As we continue our review of the TPP and highlight additional concerns, we urge you to give careful consideration to this request to clarify the intellectual property provisions as they relate to access to medicines. As members who support trade done right, we strongly believe that TPP must not inhibit access to lifesaving medicines. We look forward to continuing our work with you to ensure the Transpacific Partnership is as strong as possible and is worthy of widespread support, including ours.

Sincerely,

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Member of Congress

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