

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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December 6, 2013

The Honorable Michael Froman
United States Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Froman:

I understand that Senator Hatch sent you a letter earlier this week asking that you consider excluding countries from the Trans-Pacific Partnership (TPP) that are not willing to accede to twelve years of data protection for biologic medicines. While I have worked closely with Senator Hatch on important health issues, including the generic drug law that we co-authored in 1984, I strongly disagree that the United States should be proposing twelve years of exclusivity.

The United States only recently established its biosimilars pathway when it enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. No. 111-148) and the consequences of PPACA's mandated twelve years of biologics exclusivity are not yet known. Proposing twelve years of exclusivity in the context of TPP negotiations would conflict with stated Administration policy, as reflected in President Obama's FY 2014 budget proposal, recommending that the exclusivity period for biologics be reduced to seven years. Were the TPP ultimately to contain a twelve year biologics exclusivity provision, it would impede the ability of Congress to achieve the President's proposed seven year change because doing so would run afoul of U.S. trade obligations.

As we have discussed before, it is also critical that USTR ensure that developing countries are not left behind in this agreement. The United States must ensure that the TPP does not result in generic medicines becoming available in TPP developing countries later than in the United States. In addition, the patent flexibilities available to developing nations in the Doha Declaration on Public Health should not be denied or weakened in the agreement.

I look forward to continuing to work with you on TPP to ensure that the final accord is a 21st century agreement that protects and promotes public health for all agreement partners.

Sincerely,



HENRY A. WAXMAN
Member of Congress