

# Congress of the United States

Washington, DC 20515

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August 4, 2011

The President  
The White House  
Washington, DC

Dear President Obama:

As the United States prepares to propose text on intellectual property rights concerning pharmaceuticals in the negotiations of the Trans-Pacific Partnership (TPP), we strongly recommend that the United States refrain from negotiating any provisions related to exclusivity for biosimilar medicines.

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) last year. Therefore, the consequences of PPACA's mandated 12 years of biologics exclusivity are not yet known. Additionally, the Food and Drug Administration has not yet promulgated any regulations to implement the biosimilars provisions of the new law, nor has the Agency approved any biosimilars in the United States.

Proposing 12 years of exclusivity in the context of TPP negotiations would also conflict with stated Administration policy, as reflected in the FY 2012 budget proposal, recommending that the exclusivity period for biologics be reduced to 7 years. According to the Administration's budget, a term of 7 years of exclusivity, instead of 12 years would achieve an estimated \$2.34 billion in savings over the next decade.<sup>1</sup>

Were the TPP ultimately to contain a 12 year biologics exclusivity provision, it would impede the ability of Congress to achieve the Administration's proposed 7 year change without running afoul of U.S. trade obligations. We see no reason for the United States to agree to such a provision, much less to propose it.

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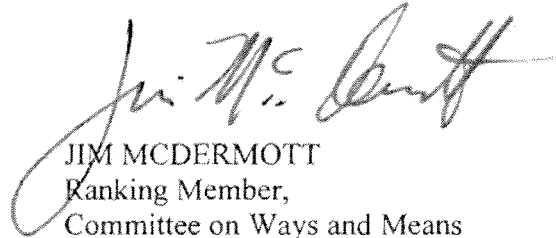
<sup>1</sup> see Office of Management and Budget, *Fiscal Year 2012 Terminations, Reductions, and Savings* (February 2011) at 119. "Under the Administration proposal, beginning in 2012, innovator brand biologic manufacturers would have 7 years of exclusivity and would be prohibited from receiving additional exclusivity by "evergreening" their products. According to the Federal Trade Commission, 12-year exclusivity is unnecessary to promote innovation by brand biologic drug manufacturers and can potentially harm consumers by directing scarce research and development funding toward developing low-risk clinical data for drug products with proven mechanisms of action rather than toward new products to address unmet medical needs. The Administration policy strikes a balance between promoting affordable access to medication while at the same time encouraging innovation to develop needed therapies."

We thank you for your hard work to provide consumers in the U.S. access to more affordable medicines, particularly biologics. We look forward to working closely with you as TPP negotiations advance.

Sincerely,



HENRY A. WAXMAN  
Ranking Member,  
Committee on Energy and Commerce



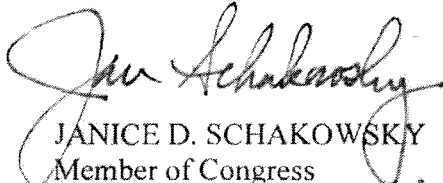
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Subcommittee on Trade



FORTNEY PETE STARK  
Ranking Member,  
Committee on Ways and Means  
Subcommittee on Health



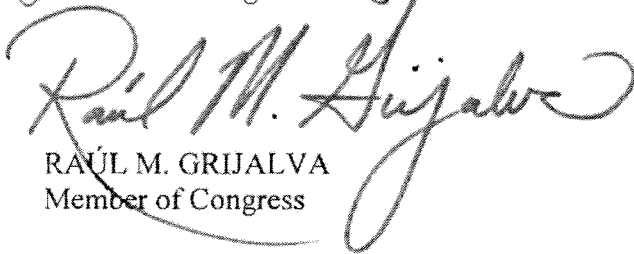
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Subcommittee on Labor, Health and  
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Member of Congress



PETER WELCH  
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