



Hon. Sander Levin
Ranking Member, Committee on Ways & Means
1236 Longworth House Office Building
Washington, D.C. 20515

December 8, 2015

Dear Ranking Member Levin:

The Generic Pharmaceutical Association (GPhA) and its Biosimilars Council appreciate the opportunity to provide input into the session you are hosting today focusing on access to medicines in the series “Trading Views: Real Debates on Key Issues in TPP.” As is the case with many stakeholders, GPhA continues to review and evaluate the final text of the Trans-Pacific Partnership (TPP) that Congress will consider, and remains hopeful that the agreement achieves the goal of promoting access to safe, effective and affordable medicines for roughly 800 million patients all over the world. A TPP that encourages competition from more affordable medicines can help lower health spending worldwide. Furthermore, trade provisions that facilitate both the development of innovative, life-saving medicines and the availability of affordable generic medicines are a win for patients. We applaud all the negotiating countries and their representatives for working diligently over the last several months in an effort to strike this balance.

Competition in the biologics marketplace through the creation of a pathway that ensures access to safe, effective and affordable biosimilars will reduce health costs for patients, governments and the entire healthcare system. GPhA shares the health cost concerns of the current administration and strongly agrees in principle with proposed exclusivity reductions — extending monopolies on biologic medicines is not a sustainable enterprise.

That is why GPhA consistently urged all parties to adhere to the letter and spirit of the New Trade Policy’s (the May 10th agreement) provisions regarding exclusivity for biologic medicines. Embracing the precedent set by the May 10th agreement allows the United States to remain globally competitive while establishing balanced intellectual property provisions among trading partners. While we are concerned that the TPP’s inclusion of extensive mandatory exclusivity periods for both small molecules and biologic medicines does not align to the May 10th agreement, we also recognize the TPP has come a long way from the original proposals which sought to impose mandatory patent linkage for all products, including biologics, and the imposition of 12 years of exclusivity for biologics medicines in the U.S. and signatory countries. Both of these points, if implemented, would have been detrimental to making lower cost versions of medicine available to patients around the world.

It is also critical that this agreement avoids locking the United States in a policy position that limits Congress from modifying U.S. pharmaceutical law in the future. There is no question that the final intellectual property (IP) chapter (Chapter 18) relating to pharmaceuticals showed marked and significant improvements from the original proposals. GPhA was pleased that

certain provisions which would have exceeded U.S. law, such as requiring patent linkage for biologic drugs, were corrected. However, under U.S. law, our industry is also protected from indefinite evergreening of patents by carefully crafted laws and a robust judicial system. Our industry is encouraged to challenge weak or invalid pharmaceutical patents, and to seek early market entry in order to ensure that patients have access to safe, effective and affordable generics at the earliest possible date. We remain concerned that these balancing measures are not included in TPP, and in fact certain provisions remained which threaten the ability of countries to limit the evergreening of patents.

GPhA and its members look forward to continuing to work with Congress on the technical details of the final TPP agreement to ensure that it promotes patient health, economic growth and health savings.

Sincerely,

A handwritten signature in black ink, appearing to read "Chester Davis, Jr.", written in a cursive style.

Chester "Chip" Davis, Jr., J.D.
President & Chief Executive Officer