

**Testimony of
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**Before the
House Committee on Ways and Means Democrats**

**“Trading Views: Real Debates on Key Issues in TPP”
Hearing on Access to Medicines**

December 8, 2015
210 Cannon House Office Building
Washington, DC

Thank you Ranking Member Levin for the invitation to appear before the House Ways and Means Committee Democrats today on the subject of the Trans-Pacific Partnership and medicines. The TPP represents a tremendously important trade agreement that will set the terms of trade, competition, and innovation across many advanced industries going forward. While many parts of the agreement will positively impact bio innovation and the societal benefits it can bring around the world, other provisions fall short and will inhibit the development of the next generation of breakthrough medicines.

The TPP contains numerous provisions that will directly impact the future of global biopharmaceutical innovation. Many of these are constructive. For example, the TPP includes measures that improve transparency in the listing and reimbursement programs run by national health care authorities. It requires TPP parties to provide adjustments for unreasonable curtailments of effective patent terms. And the TPP commits countries such as Malaysia, Mexico, Vietnam, and Peru, which lacked data protection periods for biologic drugs, to introduce them.

However, while such measures represent laudable progress, the TPP agreement falls short in several aspects with regard to creating the conditions in which biological innovation can flourish to the maximum extent possible within the TPP region. Most significantly, the TPP fails to secure 12 years of data exclusivity protection for the clinical trial data that validates the safety and efficacy of novel biologic drugs. On a bipartisan basis, Congress articulated as a key TPP negotiating objective securing 12 years of data exclusivity protection, the standard which prevails in U.S. law. Biologic drugs—drugs derived from and produced within living organisms—represent the future of biomedical innovation. But biologics are enormously risky, time-consuming, and expensive to develop—a process that on average takes 12 to 14 years and over \$2.6 billion—meaning that biologics makers have a limited amount of time in which to recoup their investment before the drug’s IP rights expire. That’s why Congress established 12 years of data protection: to strike an appropriate balance between promoting competition and providing adequate incentives to support continued innovation of new treatments and cures.

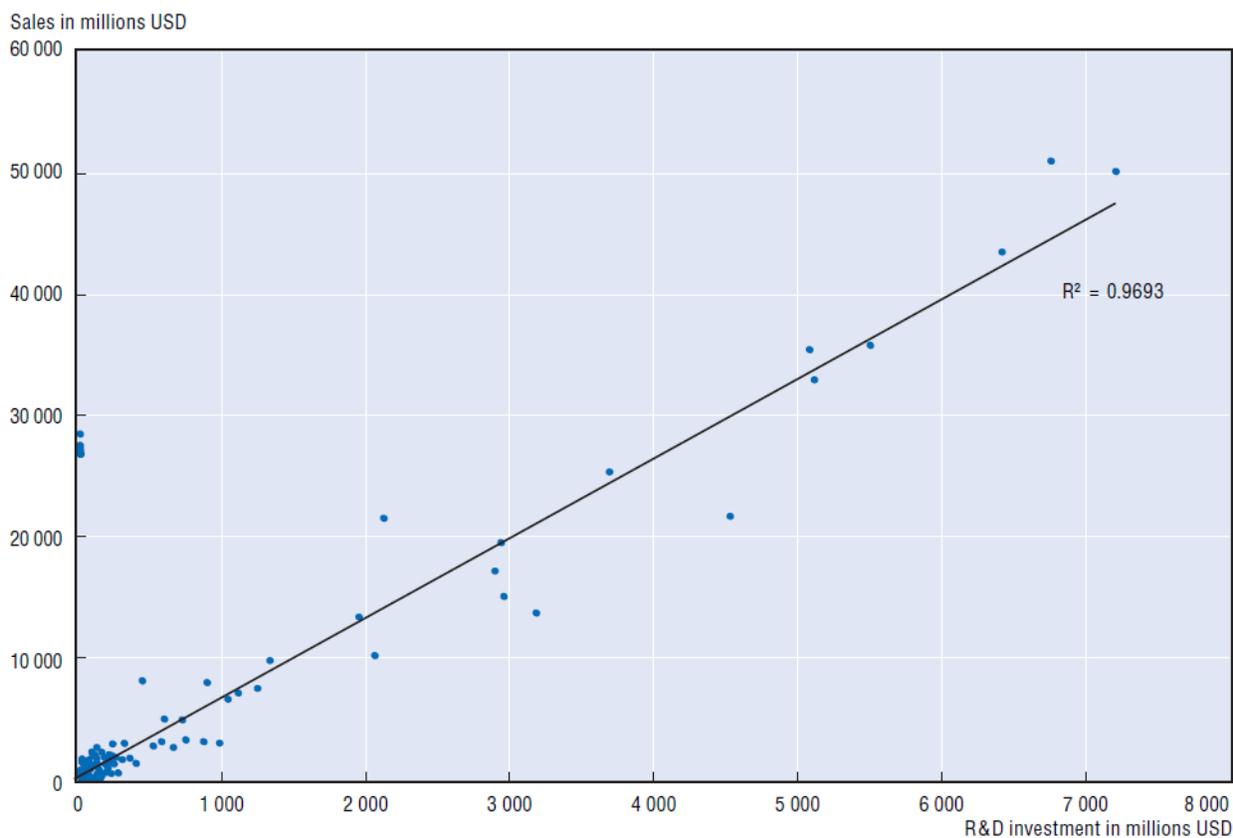
And while access to medicines is certainly important, it presumes in the first place the existence of medicines. And that requires a system that permits the profits earned from one generation of biomedical innovation to sow the seeds for investment in the next. As the OECD explains, and this graphic (Figure 1) vividly shows, “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.” In other words, more revenues means more R&D, more medical discovery, more innovative biologics drugs, and ultimately more generic competitors. For proof that this dynamic works, consider that generics already comprise 85 percent of the U.S. market for prescription drugs, and generics account for several commonly prescribed breast cancer drugs today.

With global markets already accounting for more than half of U.S. life sciences firms’ revenues, companies need to be able to recoup their investments abroad as well as in the United States, and that’s why it’s critical the TPP includes robust data protection terms. Yet the TPP parties that have rejected additional data protections for biologics—reportedly because doing so could increase spending in their health care systems—are both free-riding off U.S. investments in medical discovery and development and not doing their share to incur the real expense it takes to develop innovative biologic drugs.

Finally, in considering access to medicines, policymakers must not only consider access for citizens in developing vs. developed countries, but also the interests of present vs. future generations. We must be deeply concerned with continuing to invest to find solutions to diseases and conditions which remain unsolved by medical science. Doing so requires preserving sufficient incentives to invest in biomedical research. Otherwise, we'll be left with the stock of drugs we have today, and our children will end up taking the same drugs we're taking.

One of the hallmarks of the progressive movement has been investing for the future. And ensuring that the TPP gets the conditions right for sustained biomedical innovation is essential for developing the next-generation of breakthrough medicines. Thank you, and I look forward to your questions.

Figure 1: R&D expenditures and sales in the pharmaceutical industry, 2006



Note: The data were prepared on the basis of annual reports and consolidated accounts received up to and including 31 July 2006. Annual reports with a year-end older than 30 months from the cut-off date or a publication date older than 24 months from cut-off date are excluded.

Source: DIUS (2007).

Source: Organization for Economic Cooperation and Development, Pharmaceutical Pricing Policies in a Global Market (OECD, 2008), 190, <http://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm>.