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TESTIMONY OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

BEFORE THE

HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

"The U.S.-E.U. Free Trade Agreement: Tipping Over the Regulatory Barriers"

July 24, 2013

TESTIMONY SUMMARY OF JOHN J. CASTELLANI, PRESIDENT AND CEO OF
THE PHARMACEUTICAL RESEARCH AND MANUFACTUERS OF AMERICA (PhRMA)
BEFORE THE HOUSE ENERGY & COMMERCE SUBCOMMITTEE
ON COMMERCE, MANUFACTURING & TRADE
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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients live longer, healthier, and more productive lives.

PhRMA and its member companies strongly support the negotiation of a comprehensive and ambitious trade liberalizing agreement between the U.S. and the EU, and welcome the expansion of the world's most dynamic trading relationship. The proposed agreement will provide an important opportunity for the two sides to demonstrate international economic leadership, and to establish minimum benchmark standards that the U.S. and the EU should seek in all future trade agreements with third parties.

The U.S. innovative biopharmaceutical industry provides significant benefits to our economy. PhRMA's member companies invested almost $50 billion in R&D for new medicines in 2012. The industry supported 3.4 million jobs across the United States in 2011 and generated over $50 billion in exports in 2012. Yet our industry faces substantial expense and risk in the course of bringing innovative medicines to market, with only 2 out of every ten approved medicines recouping their development costs.

PhRMA believes it is critical that the Transatlantic Trade and Investment Partnership (TTIP) agreement include robust provisions that further collaboration and create new opportunities for the innovative biopharmaceutical industry to thrive, contributing to growth in the U.S. and EU and benefiting patients around the world. To be meaningful and comprehensive, the U.S.-EU negotiations should address market access provisions, intellectual property protections, and regulatory compatibility initiatives.

Short-sighted cost containment measures have severely impacted our members' businesses in Europe. A U.S.-EU agreement should recognize the value biopharmaceuticals can provide in reducing other more costly medical interventions and in improving the lives of patients. Agreed-to principles should include respect for the right of health care providers to prescribe appropriate medicines based on clinical need. Other market access provisions should ensure transparent, timely, and predictable pricing and reimbursement processes that provide applicants with meaningful due process.

Strong intellectual property protections are critical to the biopharmaceutical industry. A U.S.-EU agreement should be a standard-setting agreement that places a high value on IP as the lifeblood of innovation and highlights countries like India, with weak and deteriorating IP regimes, as outliers in the global market. To that end, an agreement should, among other things, ensure 12 years of regulatory data protection for biologics, clarify patentability standards, implement patent term adjustments necessary to incentivize further investment in biopharmaceutical R&D, and secure effective patent enforcement systems that allow for early patent dispute resolution.

Finally, addressing unnecessary and duplicative regulatory requirements can help enhance efficiency of drug development, optimize deployment of limited agency resources, and expedite patient access to new, innovative, and life-saving medicines. Regulatory compatibility initiatives that can achieve these goals include reducing redundant testing, seeking mutual recognition of Good Manufacturing and Clinical Practices inspections, and establishing a procedure for the development of scientific and other regulatory guidelines for specific therapeutic areas.

Chairman Lee Terry, my name is John J. Castellani, President & CEO at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am very pleased to appear before the subcommittee to reflect the innovative biopharmaceutical's perspective on the proposed Transatlantic Trade and Investment Partnership.

Up to 80% of the medicines currently in development around the world are being researched and tested in the United States and the European Union. This figure is a testament to the fact that the United States and the European Union, as a general matter, provide the strongest global support for biopharmaceutical research and development. The continued, strength, however, of the innovative biopharmaceutical industry in both regions is far from guaranteed. On the contrary, the time and investment required to research and develop new drugs continues to increase and the global ecosystem to support innovation grows more hostile. As a result, PhRMA and its member companies strongly support the promise of a high-standard trade liberalizing agreement between the United States and the European Union (EU) that eliminates unnecessary non-tariff barriers between these regions and establishes a model for the United States and the EU to seek in all future bilateral, plurilateral, and multilateral trade agreements.

PhRMA represents America's leading biopharmaceutical companies. Our member companies pioneer new ways to save lives, cure disease, and promote longer, healthier, and more productive lives. In 2012, PhRMA's members alone invested almost $50 billion in advanced research and development of new medicines to treat human diseases and conditions. Further, in 2011 the U.S. biopharmaceutical sector employed more than 810,000 workers, supported a total of 3.4 million

jobs across the country, and contributed $789 billion in economic output when direct, indirect, and induced effects are considered.

PhRMA welcomes the expansion of the world's most dynamic trading relationship that already contributes to the economies and job creation on both sides of the Atlantic.
Negotiations between the U.S. and the EU to enhance the trade relationship between these regions should be comprehensive and ambitious, addressing not only regulatory compatibility initiatives, but also intellectual property protections, market access provisions, and customs and public procurement measures. PhRMA believes that further reduction of non-tariff barriers in both markets will spur future and critical innovation.

That said, there are a number of issues of considerable concern to the industry in the current European environment:

- Short-sighted cost containment measures – ostensibly proposed in response to the financial crisis, but too often implemented without predictable, transparent and consultative processes – have significantly impacted our member's businesses in Europe, with negative spill over as a result of parallel trade and international reference pricing. These measures raise serious concerns regarding the commitment in a number of EU Member States to adequately reward innovation.
- Another issue of concern to the industry is the EMA's current and proposed data disclosure policies. The biopharmaceutical industry is firmly committed to enhancing the public health through responsible reporting and publication of clinical research and safety information. However, disclosure of companies' non-public data submitted in clinical

and pre-clinical dossiers and patient-level data sets risks damaging public health and patient welfare. PhRMA and its members urge the U.S. government to engage with the EU in every available venue to ensure responsible data sharing that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research by adequately shielding confidential commercial information from inappropriate disclosure. The EMA's current and proposed data disclosure policies jeopardize these principles.

As a more general matter, PhRMA recommends that the biopharmaceutical market access commitments included in the Korean-U.S. Free Trade Agreement (KORUS) and the EU-Korea Free Trade Agreement form the basis for the market access commitments included in any U.S.-EU trade liberalizing agreement. Key principles, however, that should be built into an EU-U.S. pharmaceuticals chapter include:

- Recognizing the value biopharmaceuticals can play in reducing other more costly medical expenditures and improving the lives of patients (consistent with Article 5.1(b) of KORUS); and
- Respecting the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need.

Further, both the United States and the EU recognize that IP protections are the lifeblood of innovation. As a result, both, as a general matter, provide strong IP protections within the rubric of their respective systems and any agreement between the United States and the EU should not

dilute these protections. Particular areas, however, where PhRMA would encourage enhancements and greater alignment between the respective IP systems include:

- Strong regulatory data protection provisions. This should include 12 years of regulatory data protection for biologics as provided by U.S. law;
- Affirmation or harmonization of certain patent standards;
- Seeking patent term adjustments for patent office delays in the EU; and
- Ensuring that the EU Member States adopt effective patent enforcement system or systems that allow for early resolution of pharmaceutical patent disputes before an infringing product is launched on the market.

With several countries, such as India, pursuing industrial policies that invalidate IP protections, it is imperative that the U.S. and EU seek similar commitments to strong IP from their trading partners as part of their free trade agreements with other countries.

In addition, PhRMA has proposed a number of regulatory compatibility initiatives, per a joint submission with its European sister association last fall. These proposals seek:

- Greater coordination to reduce the regulatory burden for both sponsors and agencies;
- To increase collaboration under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
- To establish a procedure for developing scientific and other regulatory guidelines for specific therapeutic areas; and

- To ensure that national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary, harmonized international standards.

By addressing these key issues and promoting even greater regulatory cooperation between the U.S. Food and Drug Administration and the European Medicines Agency, PhRMA believes that the U.S. Government and the European Commission will help spur further biopharmaceutical innovation, which will lead to healthier patients and more dynamic economies.

In summary, the proposed agreement provides an important opportunity for the two sides to demonstrate international economic leadership and a steadfast commitment to free trade, as well as to establish minimum benchmark standards that the United States and the European Union should seek in all future bilateral, plurilateral, and multilateral trade agreements.

We thank you for the opportunity to provide these comments and look forward to being an active stakeholder throughout the negotiations.