



**U.S. Biopharmaceutical Innovation and U.S. Trade Policy:
The Importance of Trade Agreements in Keeping Foreign Markets Open**

Submission for the Record

February 18, 2011

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this written submission for the record in conjunction with the hearings held on January 25 and February 9, 2011, to examine the U.S. trade policy agenda and its relationship to U.S. economic growth and job creation. In this statement, we focus on the contributions of the research-based biopharmaceutical industry to the U.S. economy and to U.S. exports, as well as the importance of enhancing the global competitiveness of our industry through negotiating and enforcing strong trade agreements containing high-standard, market-opening commitments and intellectual property rights (IPR) protections. A good example of such an agreement is the Korea-United States FTA (KORUS FTA), which we believe will serve to strengthen the U.S. economy, jobs, and exports. We also discuss the importance of initiatives like the proposed Trans-Pacific Partnership (TPP) in creating more consistent, market-based policies in the treatment of biopharmaceutical products by other governments, especially given the proliferation of restrictive, discriminatory practices in some markets that threaten the ability of our industry to compete globally.

PhRMA represents the country's leading innovative biopharmaceutical companies. Our members are devoted to developing medicines that allow patients around the world to live longer, healthier and more productive lives. In 2009 alone, the research-based biopharmaceutical industry contributed approximately \$65.3 billion to R&D for new medicines to help find cures to diseases affecting all regions and populations of the globe.¹ In order to continue to foster economic growth in the United States and the much-needed medical breakthroughs that will save lives, we must continue to pursue public policies that promote innovation, and that require the protection of intellectual property rights and the removal of critical barriers to market access. Free trade agreements offer a compelling approach to addressing many of the concerns affecting our industry in exporting to and competing effectively in foreign markets.

The Biopharmaceutical Industry's Contributions to the U.S. Economy and U.S. Exports

The U.S. biopharmaceutical industry is a major U.S. employer, supporting over 3.1 million jobs nationwide, including direct employment of over 655,000 Americans.² In 2008, every direct job

¹ 2010 PhRMA Pharmaceutical Industry Profile.

² L. R. Burns, *The Biopharmaceutical Sector Impact on the U.S. Economy: Analysis at the National, State and Local Levels* (Washington, D.C.: Archstone Consulting LLC, 2010).

in the biopharmaceutical sector supported 3.7 jobs in other sectors.³ The industry consists of companies ranging from large, multinational enterprises to medium and small companies. It also includes a network of suppliers, distributors and others who contribute to ensuring patients receive the medicines they need.

PhRMA member companies are important drivers of high-quality, innovative job creation in the United States, investing more per employee in research and development than other manufacturing sectors. Our industry is also a significant contributor to U.S. economic growth. The biopharmaceutical sector's direct contribution to U.S. gross domestic product (GDP) in 2008, \$114.6 billion, was approximately three and one-half times the average per sector for the rest of the U.S. economy.⁴ Moreover, the per job contribution to GDP by the biopharmaceutical sector is more than double the average in the rest of the economy.⁵

On average, U.S. biopharmaceutical employees earned annual wages of \$96,563 (excluding benefits) and paid an average of \$24,033 in federal taxes, and an average of \$3,653 in state taxes, or approximately three times the average amount paid by U.S. workers in the rest of the economy.⁶

These figures are driven in large part by exports. In 2009, the biopharmaceutical industry exported \$46 billion, or approximately 5 percent of total U.S. goods exports, making the United States the world's third largest pharmaceutical exporter. This made the biopharmaceutical sector the second largest U.S. export sector (after aerospace products and parts).⁷ Our industry has shown steady and strong export performance in the recent past, with 2009 marking an increase from \$36.7 billion in 2007 and \$41.7 billion in 2008.⁸

As strong as our recent performance has been, it could be even stronger. Barriers to exportation still remain, as do limits on the ability to market and distribute innovative biopharmaceutical products in particular countries. We are encouraged by the important steps the pending KORUS FTA makes towards eliminating those barriers and creating new export opportunities that will lead to high-skilled, high-value job creation in the United States. Moreover, we believe that the KORUS FTA should serve as the model to build off of in future trade agreements, including the TPP. Such trade agreements benefit not only the biopharmaceutical sector, but also key U.S. trading partners and the global economy.

³ Id.

⁴ Id.

⁵ Id.

⁶ Id.

⁷ U.S. International Trade Commission, Trade DataWeb, accessed February 1, 2011, at <http://dataweb.usitc.gov/> (query run of U.S. domestic exports classified by 4-digit NAIC code).

⁸ Id.

The KORUS FTA Represents a “Gold Standard” for Opening Foreign Markets to U.S. Biopharmaceutical Innovative Products and Protecting the Intellectual Property Embedded in Those Products

PhRMA views the KORUS FTA as the model for other FTAs, including the TPP that the United States may pursue. The agreement’s provisions represent the most thorough articulation in any U.S. FTA of commitments to open markets, institute ethical business practices, promote transparency, and strengthen the protection of intellectual property rights. The comprehensive commitments in the KORUS FTA represent an excellent model to build on for future FTA negotiations, including the TPP.

As the world’s 14th largest economy, Korea represents an important export market for U.S. biopharmaceutical companies, despite the reality that the operating environment in Korea has for many years presented our industry with numerous challenges. Given that Korea has a single-payer system, the most important hurdle that must be overcome in gaining access to the national healthcare system is being granted a meaningful right to participate in the Korean market. The KORUS FTA accomplishes this important objective by establishing a level playing field so that U.S. research-based biopharmaceutical companies can compete on equal terms with Korea’s domestic firms. Without appropriate market access for innovative pharmaceutical manufacturers, Korean patients may not be able to benefit from the most innovative therapies and treatments. Korea’s national health insurance system is in the position of unilaterally determining which new medicines are available to Korean patients and at what prices they may be sold. Innovative biopharmaceutical products, which are mainly imported into Korea by U.S. and other multinational companies, only gained access to Korea’s national healthcare system in August 1999. Since then, biopharmaceutical companies in the United States and other countries have struggled to overcome various impediments to operating successfully in the market, including, but not limited to:

- A government pricing and reimbursement (P&R) system that is non-transparent and heavily focused on price-cutting and cost-containment, and not sufficiently concerned with rewarding innovation;
- Decisions that are not science-based and do not reflect international norms and best practices; and,
- Use of unethical business practices by local industry that led to efforts by the Korean Government to impose new (and still emerging) disciplines on the ability of biopharmaceutical companies, both foreign and domestic, to provide physicians with the latest information on innovative medicines.

Faithful implementation by Korea of the provisions negotiated in the KORUS FTA will make many meaningful strides toward addressing these issues and ensuring that U.S. biopharmaceutical companies have fair and non-discriminatory access to this important market. Moreover, the Pharmaceuticals and Medical Devices chapter of the KORUS FTA provides a strong precedent for future U.S. free trade agreements. Overall the chapter sets a high standard for market-opening that our industry would support replicating and building on in future U.S. FTA negotiations.

Key provisions in the KORUS FTA that help to address the issues listed above are as follows:

A set of agreed general principles that underscore the importance of:

- Adequate access to biopharmaceutical products in order to provide high quality healthcare and reduce overall healthcare expenditures;
- Economic incentives and competitive markets to provide conditions that encourage the development of biopharmaceutical products;
- Government support for research and development, intellectual property protections, and other incentives for innovation; and
- Promoting innovation and access to pharmaceuticals through transparent and accountable procedures.

Lack of transparency in Korea's reimbursement and product listing decisions is a difficult, long-standing issue for U.S. biopharmaceutical companies. Therefore, PhRMA has been especially pleased with the forward-leaning, extensive transparency provisions in the Pharmaceuticals and Medical Devices chapter of the KORUS FTA, which:

- Ensure that, in general, laws, regulations and procedures are published for review and comment before they are adopted, and that all stakeholders have a meaningful opportunity to provide comments;
- Make available a process whereby the applicant for listing of a pharmaceutical product for reimbursement may obtain independent review of the original listing determination and the level of reimbursement;
- Ensure that applicants receive meaningful and detailed written information regarding the bases for recommendations or determinations related to listing or reimbursement decisions; and
- Create a Medicines and Medical Devices Committee, co-chaired by health and trade officials, to monitor and support implementation of and promote discussion of issues related to the Pharmaceuticals and Medical Devices chapter.

The KORUS FTA contains other important provisions that ensure strong protection of intellectual property rights, the lifeblood of the biopharmaceutical industry. These provisions include, in particular:

- Agreement by Korea to establish effective patent enforcement mechanisms to help prevent patent-infringing products from gaining access to the market;
- Provision of at least a five-year period of data protection (*i.e.*, a period during which persons other than the originator of proprietary data are prohibited from using that data to meet safety and efficacy standards in the marketing approval process); and

- The possibility that the term of a patent can be adjusted to compensate for unreasonable delays that occur in the patent registration and marketing approval processes.

Korea's willingness to take concrete steps to increase the protection and enforcement of intellectual property rights will be highly beneficial to Korean, U.S., and other foreign firms, and to Korea's own goal of enhancing its life sciences sector.

With the expected entry into force of the EU-Korea Free Trade Agreement on July 1, 2011, the urgency of implementing the KORUS FTA becomes evident, particularly if U.S. exporters are to have access to Korea's market comparable to that enjoyed by their counterparts within the European Union. PhRMA applauds the action by the House Ways and Means Committee to hold its hearing on January 25 to begin the important process of moving the KORUS FTA forward expeditiously over the months ahead.

For the U.S. biopharmaceutical industry, the KORUS FTA, particularly its transparency and intellectual property rights provisions, represents a 21st century standard that should stand as a model for other U.S. free trade agreements, including the TPP that is currently being negotiated. As demonstrated in this submission, entry into force of the KORUS agreement will enable the innovative biopharmaceutical industry to put its export "muscle" to work, growing the U.S. economy and contributing to the creation of high-paying and high-skilled U.S. jobs in the process. Our industry looks forward to the day when the KORUS Agreement is in force, and our access to Korea's market becomes more stable and predictable as a result of its path-breaking, market-opening provisions.

The Role of Trans-Pacific Partnership Negotiations in Shaping the Global Competitiveness of the U.S. Innovative Biopharmaceutical Industry

PhRMA favors the TPP negotiations as a comprehensive policy mechanism for addressing commercially meaningful intellectual property rights and removing market access barriers that hamper our industry's global competitiveness, particularly with the four countries with which the United States does not have existing free trade agreements (Brunei Darussalam, Malaysia, New Zealand and Vietnam). This is especially important given the likelihood that the TPP will serve as a "docking station" for other countries in the Pacific region (including possibly China, Japan, and Canada, to name a few) to join on to in the future.

A strong TPP template that builds on the elements of the KORUS FTA and establishes a new model for future U.S. free trade agreements will best enhance the ability of the U.S. biopharmaceutical innovative industry to expand U.S. exports and create high-skilled, high-value science and engineering jobs.

Key elements the TPP should contain to achieve these goals include:

- **Provide clear, market-based support for innovation.** The TPP agreement should include specific commitments to promote regulatory transparency, accountability and objectivity, particularly in government drug approval and drug reimbursement processes. Regulatory barriers can too often result in delaying or restricting patient access to the latest innovative medicines. Restrictions on biopharmaceutical reimbursement proposed as fiscal policy

measures often are disproportionate to the share of pharmaceuticals relative to overall healthcare expenditures. The KORUS FTA addresses this issue. For example, it contains a commitment to promote the development of high-quality patented and off-patent biopharmaceutical products as part of improving public health as well as the obligation to appropriately recognize the value of patented products when setting government reimbursement levels.

- **Engage on foreign government price control and cost containment policies.** Government price controls and cost containment policies include a wide range of practices, including for example, direct and indirect price controls, profit controls, *ad hoc* government price cuts, international and therapeutic reference pricing, mandatory rebates, physician budget constraints, marketing approvals, limits on promotion of medicines, and many others. Such policies can delay or reduce the availability of new medicines and limit market entry prospects for U.S. biopharmaceutical companies. The TPP provides the opportunity to engage other governments on the broad range of policies used to control prices and contain costs in the biopharmaceutical sector.
- **Maintain high-standard protection for intellectual property rights, coupled with rigorous enforcement.** High-standard protection for and enforcement of intellectual property rights provide the framework for U.S. companies to retain high-quality knowledge-based jobs in the United States, and for U.S. innovative companies to continue to invest in technological advances. This is no less true for U.S. biopharmaceutical firms, which depend on strong IP protection to provide market-based incentives for innovation, creativity and advanced global drug discovery, the benefits of which improve patient care around the world. Strong IP enforcement and protection help to maintain the levels of R&D investment required for development of new medicines.
- **Promote greater transparency in government policy and regulatory decision-making.** Decisions on how drugs are approved, regulated, procured and made available to patients should be made transparently and be guided by scientific principles. Manufacturers and other stakeholders should have meaningful opportunities for input to health authorities and other regulatory agencies regarding these decisions, and a right of appeal on specific decisions to an independent, objective court or administrative body. These issues affect innovative and generic manufacturers alike and deserve attention in the TPP negotiations.⁹
- **Ensure the TPP empowers patients.** Patients, physicians and other healthcare providers are key stakeholders in government regulatory and policy decision-making processes. The TPP should require that all stakeholders have access to the information necessary to allow them to make informed decisions.
- **The TPP should require governments' healthcare programs to respect the specialized expertise and therapeutic judgment of all healthcare providers, including physicians and nurse practitioners.** Healthcare professionals should have the freedom to prescribe medications that best address patients' needs.

⁹ See, for example, PhRMA-GPhA Joint Transparency Principles.

The TPP and U.S. Trade Policy in General Should Address Other Governments’ Trade Policies that Limit the Ability of U.S. Biopharmaceutical Companies to Compete

The long-term importance of the TPP for the U.S. biopharmaceutical industry is that it will limit the ability of future parties to the agreement to implement policies that discriminate in favor of domestic producers while restricting the ability of U.S. biopharmaceutical companies and other multinational firms to compete. Such violations of national treatment often appear to be prohibited by existing international trade agreements. Despite these existing agreements, however, governments have succeeded in imposing discriminatory rules and practices adversely affecting the market access of innovative biopharmaceutical producers. Often these rules exploit gaps in the trade agreement disciplines on national treatment. Examples include:

- **Requirements to establish local manufacturing or transfer intellectual property.** Indonesia, though not currently a participant in the TPP negotiations, could join the TPP at a later date, or may decide to participate in a future Free Trade Area of the Asia Pacific (FTAAP) as a member of the Asia Pacific Economic Cooperation (APEC) forum. Indonesia has issued a government decree that sets unreasonable conditions for market entry. Only companies meeting Indonesian licensing requirements will be allowed to obtain marketing approval for their biopharmaceutical products. In order to obtain such regulatory approval, companies must either establish a factory in Indonesia or transfer sensitive intellectual property to a local Indonesian company. Licensing requirements generally are used in the biopharmaceutical sector to ensure that producers meet globally recognized good manufacturing and good distribution practices. Indonesia’s decree, however, uses licensing requirements as a means of severely limiting access to its market for our sector.
- ***De facto* bans on imports.** Some governments impose additional requirements on biopharmaceutical producers that, in effect, prevent market entry. An example would be failure by a government to recognize the internationally accepted certification of good manufacturing practices (GMP) from another country unless a mutual recognition agreement (MRA) with that country is in place. Such a measure amounts to a *de facto* ban on imports in the guise of sound health policy.

Conclusion

The U.S. biopharmaceutical industry is both a leading export industry and a strong contributor to U.S. economic expansion through the creation of high-skilled, high-value, knowledge-based jobs. As such, our industry relies heavily on comprehensive, high-standard trade agreements to open foreign markets and help create new export opportunities for U.S. biopharmaceutical innovative medicines. Our industry supports trade agreements that provide strong and comprehensive protection for intellectual property rights, make government pricing and reimbursement policies more transparent and accountable and remove discriminatory trade barriers that limit or prevent entry for U.S. research-based medicines.

PhRMA looks forward to the speedy ratification of the KORUS FTA. Its “gold standard” provisions recognize the value of innovation, increase transparency and create a Medicines and Medical Devices Committee for addressing future developments in our sector, and establish a

model for the TPP and future U.S. free trade agreements. Accordingly, we greatly appreciate the Committee's efforts to push for approval of the KORUS FTA in as early a timeframe as possible.

Finally, the TPP negotiations represent an opportunity to raise the level of trade commitments by key U.S. trading partners on the protection of intellectual property rights and related undertakings affecting market entry and competitive opportunities for the U.S. biopharmaceutical industry. We believe the TPP's ambition should be to provide a template for future trade liberalization, not only in the Asia Pacific region, but also for future U.S. free trade agreements with potential trade partners in any part of the world. The U.S. biopharmaceutical industry is global in scope, and we have the potential to increase our R&D investment and level of U.S. employment every time foreign markets become more open. Using U.S. trade agreements, and U.S. trade policy broadly, to address and dismantle trade barriers our industry faces in overseas markets is a winning strategy that adds to the innovative capacity and global competitiveness of the United States, while also expanding valuable employment opportunities for knowledge-based workers. PhRMA looks forward to working with the Committee and its Members in support of the objectives outlined in this Statement.