Prepared Statement

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On

"The Transatlantic Trade and Investment Partnership: Achieving the Potential"

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Chairman Baucus, Ranking Member Hatch, and members of the Committee, I very much appreciate the opportunity to address the Committee on the Transatlantic Trade and Investment Partnership (TTIP) – a negotiation of great importance to Eli Lilly and Company, the innovative biopharmaceutical industry, and the business community.

Eli Lilly and Company is a global biopharmaceutical company headquartered in Indianapolis, Indiana. Our company was founded in 1876. In addition to our global presence, we are truly an integrated transatlantic company. We have approximately 38,000 employees worldwide, including 9,000 in Europe. More than 7,700 of our global employees, or 20%, are engaged in research and development. In 2012 we invested over $5.2 billion in R&D, representing 23% of our revenue. Over the last decade our R&D investment in Europe has doubled to over $600 million. One third of our clinical trials take place in Europe, which represents a total investment of nearly $170 million. We have research and development facilities located in eight countries including the UK and Spain. We have manufacturing plants located in 13 countries including France, Ireland, Italy, Spain and the UK. Our products are marketed in 125 countries. Our European facilities alone export to more than 100 countries. In the U.S. we employ more than 16,500 people. Our European investments also support U.S. jobs, and demonstrate the importance of transatlantic trade to our business.

Lilly and the biopharmaceutical industry believe that TTIP represents a unique opportunity to promote the highest standards of intellectual property protection, market access and regulation in particular for the IP driven sectors in which the EU and U.S. enjoy a global advantage. We also believe that the two governments should use TTIP to work together to maintain and grow that advantage.

As such, Lilly has been focused on the possibility of a transatlantic trade agreement for some time. We serve as Co-Chairs of the Business Coalition on Transatlantic Trade (BCTT), and I personally am the incoming U.S. Co-Chair of the Trans-Atlantic Business Dialogue. Lilly is an active member of the Transatlantic Business Council (TABC), the US Chamber of Commerce, the National Association of Manufacturers (NAM), The Business Roundtable (BRT), The Pharmaceutical Researchers and Manufacturers of America (PhRMA), and the Biotechnology Industry Association (BIO), among others. Through our membership in these organizations, Lilly has advocated for and promoted the TTIP on both sides of the Atlantic and is a vocal supporter of a comprehensive and ambitious agreement.

During my remarks, I will address the broad list of issues that have been put forward by the business community and will provide you with some specific real-world examples of how the completion of an ambitious TTIP agreement could benefit companies like Lilly, our employees, and the patients that rely on our medicines -- both present and future.

I would like to note that in light of both the ongoing Trans-Pacific Partnership (TPP) negotiations and Transatlantic Trade and Investment Partnership (TTIP) agreement talks, the consideration of legislation to renew Trade Promotion Authority (TPA) could provide an important opportunity to strengthen and grow the U.S. economy by identifying policies to advance trade liberalization. Principally, we believe that our nation's trade policy should seek to maximize U.S. companies' access to overseas markets, secure strong IP rights, and to minimize the use of tariff and non-tariff barriers as well as broad open-

ended exceptions to obligations. It should be the policy of the United States to ensure that our trading partners do not condition market access on forced localization policies, including the transmission of intellectual property rights or the building of business infrastructure in their markets. Equally important, TPA legislation should safeguard against policies such as government price controls and cost containment measures that operate as non-tariff barriers and can dramatically impact U.S. companies' ability to enter and compete in new and existing markets. These objectives should be supported and advanced by all U.S. government agencies with expertise in the areas of international trade, as well as the regulation of pharmaceuticals. I would like to acknowledge Chairman Baucus and Ranking Member Hatch for their leadership on this issue and underline that the business community stands ready to work with you and your staff on a high-standard TPA Bill.

One of the ways that Lilly is working to achieve the potential we see in TTIP is through serving as a Co-Chair on the Business Council for Transatlantic Trade's (BCTT) Steering Committee with other significant players in the in the transatlantic economy. The BCTT also includes many of the major multi-sectoral industry organizations. These sector-specific industry associations have been joined by dozens of other companies in coalition working groups tasked with defining the priorities of the business community in these negotiations.

The members of the BCTT support an ambitious, comprehensive, and high-standard trade and investment agreement between the United States and the European Union. We understand that while there is considerable enthusiasm on both sides of the ocean for TTIP, the sheer scale of the negotiations could lead to one side or the other trying to damper expectations. In contrast, the BCTT and other business organizations believe strongly that this agreement must meet several key expectations. By "ambitious," BCTT members urge negotiators to find creative ways to address emerging opportunities in the 21st century economy, such as trade in digital goods and services, as well as longstanding challenges in such areas as sanitary and phyto-sanitary (SPS) barriers, technical barriers to trade (TBT), trade facilitation, and regulatory barriers to trade and investment. By "comprehensive," we believe the agreement must cover trade in industrial goods, food and agricultural goods, services, investment, procurement, protection of intellectual property rights (IPR), and regulatory issues. BCTT members believe that there should be no exclusion of specific sectors or commodities. By "high-standard," we entreat that TTIP set the highest possible standards for third countries to work towards in the areas of investment, intellectual property rights, competition policy, treatment of state-supported enterprises, and elimination of localization requirements, among others.

Broadly-speaking, the business community has been united it its enthusiasm for an ambitious agreement. This negotiation will no doubt be complicated and challenging, but we know that the U.S. negotiators will be up to this task and we stand ready to work with them to provide solutions that overcome hurdles identified during the negotiations. While the agenda and stated timelines for TTIP are indeed ambitious, I believe I speak for many in our sector who would prefer that negotiators take the time needed, within reason, to achieve a comprehensive agreement rather than rush to meet an imposed deadline. On substance, the BCTT believes that the agreement should:

- Eliminate virtually all consumer, industrial, and agricultural tariffs upon entry into force, and for those that remain, specify phase-out periods that reflect scheduled tariff elimination under other U.S. and EU trade agreements.
- In the case of services, liberalize all modes of delivery and apply them to all sectors, including financial services.
- Facilitate the flow of goods in the supply chain by adopting common customs electronic data filing systems, minimizing inefficiencies in our security regimes and modernizing our customs and other government agencies' border clearance processes.
- Include disciplines on technical barriers to trade (TBTs) to ensure the least trade restrictive approaches to the regulation of goods.
- Support a common agreement on what constitutes an international standard.
- Include a binding chapter on SPS measures that reinforces the importance of science- and risk-based regulations and decision-making.
- Establish a framework for regulatory cooperation across all sectors, including financial services, to enable our regulators to become more efficient, transparent, and effective in fulfilling their mandate to protect consumers, investors, workers, and the environment. U.S. and EU regulators should determine where their regimes reach functionally equivalent outcomes that would allow a product or service sold in one market be made available in the other.
- Provide new tools and a governing process to guide cooperation on a horizontal and sector-specific basis. Regulatory cooperation is not about less or more regulation. We seek better processes that enable regulators to fulfill their statutory obligations in a manner that is not market-distorting.
- Create a binding framework with clear, consistent, and predictable rules on cloud computing and other ICT services, cross-border information flows, and prohibitions on requirements for local servers or infrastructure. Such a framework must allow for flexibility on the method used to achieve high levels of privacy protection and continue cooperative work on security matters. These provisions will not only bolster transatlantic digital trade, but will also serve as a global benchmark.
- Include a full investment promotion and protection chapter, reflecting at least the high standard of protections in the 2012 U.S. model Bilateral Investment Treaty (BIT). This includes a robust investor-state dispute settlement (ISDS) mechanism, which is essential to show the world our willingness to commit to the same set of rules that we urge trading partners to uphold.
- Commit both sides to further improve existing laws, regulatory measures, and standards regarding intellectual property rights (IPR) protection. Joint efforts to raise the standard of IP protection can also serve as the basis for promoting economic growth associated with robust IP protection and enforcement in third countries.
- Establish that all levels of government and public entities in the EU and the U.S. will commit to consider on a fully non-discriminatory basis bids to provide goods and services from firms based in the United States or the EU.
- Demonstrate unified transatlantic leadership in highlighting acceptable transparency and due process obligations with regard to competition enforcement proceedings, and in ensuring that

state-owned enterprises comply with their multilateral and bilateral trade and investment obligations.

In particular, IPR is a critical issue that should be included in the negotiations. As a company, an industry, and a business community, we believe it is essential that this agreement maintains and promotes effective and standard-setting levels of intellectual property protection.

Intellectual property rights are a critical driver of the American and European economies. As has been noted in numerous joint statements by the European Union and the United States, both partners recognize the importance of promoting effective and robust protection of intellectual property. The strong protections and enforcement provisions that both the EU and the U.S. currently provide in their domestic markets is evidence of this commitment and is an important foundation that should be recognized in the TTIP.

TTIP negotiators are fully aware that time and resources deployed trying to fully harmonize their IP systems are not well-spent. Instead, as the High-Level Working Group (HLWG) report notes, the Parties are willing to address and cooperate extensively on several issues of common concern that "would not only be relevant to bilateral commerce, but would also contribute to the progressive strengthening of the multilateral trading system."

An IP climate that establishes effective protection and enforcement mechanisms provides innovative companies -- of all sizes, and across sectors -- the incentives to commercialize and bring their products to market. This, in turn, facilitates the creation of jobs, continued innovation, public safety, and access to new technologies. In the United States alone, a U.S. Department of Commerce study found that IP industries support at least 40 million jobs, contribute more than $5 trillion or 34.8% to the GDP, and $775 billion in exports. Similarly, a September 2013 study Commissioned by the European Patent Office (EPO) and the Office for Harmonization in the Internal Market (OHIM) found that IP-intensive industries create 77 million jobs and generate 40% of the total economic activity throughout the EU - roughly 4.7 trillion Euros annually.

TTIP must protect and foster an IP climate central to strong economic growth. Conversely, the TTIP agreement must also address impediments to effective IP protection in the EU and globally. Effective protection and enforcement of intellectual property rights create an environment in which innovators receive the incentives to invest in the research, development, and commercialization of leading-edge technologies. Moreover, in such an environment, innovators are more likely to share their innovations and transfer technology voluntarily to others, knowing that the terms on which they do this will be respected and effectively enforced if necessary.

The TTIP is an important opportunity for the United States and the EU to improve upon specific issues affecting the innovation environment in both markets and to collaborate on improving global standards for IP. In the bilateral context, TTIP negotiators should ensure that this agreement does not undermine the rights of trademark holders or prevent the use of common names in international commerce.

Additionally, the TTIP is an opportunity to address practices in Europe that weaken intellectual property protection. This includes the inadequate protection of confidential commercial information submitted to marketing approval authorities from inappropriate disclosure. More specifically, the current and proposed policies of the European Medicines Agency (EMA) regarding disclosure of such data do not adequately protect patient privacy and do not protect confidential commercial information consistent with the EU's existing trade obligations. These policies must be addressed in order to implement responsible data sharing that effectively safeguards the privacy of patients, preserves the integrity of the regulatory system, and preserves incentives for investments in biomedical research.

The agreement should enhance global protection of trade secrets. This is one IP issue where the United States and EU share a mutual interest in developing a common positive agenda. Although some of a company's most valuable assets can be embodied in trade secrets, this type of IP often is subject to the weakest legal protections as compared to other types of IP. The entire economic value of a trade secret stems from the competitive advantage conferred by the confidential nature of the information. Once disclosed, trade secrets cannot be recovered because this form of IP does not give its owner an exclusive right (in contrast to a patent, for example).

Trade secret misappropriation is on the rise due to greater global competitiveness and a significant increase in the use of digital devices that process data on a nearly constant basis, which in turn increases the targets for cyber attacks. Moreover, some governments are requesting excessive amounts of confidential information as a condition of product approval, which raises a different kind of disclosure risk.

The TTIP should be used to develop a comprehensive, model trade secret protection system that can be promoted globally. This system should effectively (i) address trade secret theft, (ii) increase government to government cooperation to minimize cross-border incidences of trade secret theft, (iii) minimize increasing government requests for excessive and unnecessary confidential information (trade secrets) as a condition of product approval (market access), and (iv) address inadequate government procedures to protect the confidential information they receive.

Both the U.S. and EU governments are currently reviewing their respective trade secret laws to determine how they could be improved. A TTIP commitment to identify and adhere to the basic elements of a model trade secret law, and promote it globally, is especially important because the relevant obligations in Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights require only minimum levels of protection for trade secrets. Separate from model legislation effectively addressing trade secret theft, a comprehensive trade secret protection system also should require governments to justify requests for disclosure of trade secrets as a condition of product approval or market access.

I would now like to take the opportunity to address some specific areas of interest in the agreement for Lilly and the biopharmaceutical sector. My goal is to give you some context for what this agreement could mean for us as a global business and some context on what issues are most important to our industry.

As a company and as an industry, like many others, we are increasingly making products for the whole world, not just one single market. More and more, we are finding it difficult to include Europe as part of the business case to take a medicine forward, either due to market uncertainty, IP enforcement issues, or not receiving a fair price. In some cases, we terminate a new medicine's development because of this – presumably a medicine that could benefit Europe, the U.S., and probably many others. Because of the lack of alignment on a global standard for regulation, access or IP the result is that fewer treatments or cures reach the market. We believe that this represents a real tax on public health.

Because of this, we believe TTIP should set ambitious standards for pharmaceuticals in the fields of regulatory harmonization, intellectual property protection and enforcement, and market access. This is critical to ensure rapid access for patients to new medicines, the support of an industry that directly provides over 1.2 million highly skilled jobs in the transatlantic economy, and an appropriate benchmark for future trade agreements with other countries. For example, the innovative biopharmaceutical industry directly employed nearly 810,000 people and indirectly supported 3.4 million jobs across the United States in 2011. The industry generated nearly $51 billion in exports alone in 2012, and PhRMA member companies invested almost $50 billion in R&D for new medicines last year. At the same time, our industry faces substantial costs and risks in the course of bringing innovative medicines to market. Of five thousand to ten thousand potential compounds considered, only 250 compounds may show sufficient potential to undergo pre-clinical testing. Only five of those compounds, however, will enter clinical trials, and only one will ultimately be approved. Even then, only two out of every ten approved medicines will recoup R&D costs. Overall, it is estimated that developing a new medicine takes 10-15 years on average, and costs approximately $1.3 billion.

The TTIP agreement has the potential to facilitate further collaboration and create new markets and opportunities for the innovative biopharmaceutical industry to thrive. With the help of an ambitious, comprehensive, and high-standard agreement, our industry will create and market a generation of new medicines that will contribute to economic growth and prosperity in the U.S. and EU and will benefit patients around the world.

For Lilly, this agreement represents a significant opportunity to address regulatory duplication, increase stability and reward for innovation through the IP system, and address long-standing concerns about market access and transparency.

With regard to the biopharmaceutical industry, our industry believes it is critical that the TTIP agreement includes robust provisions, which:

Promote regulatory compatibility.

- Address regulatory differences and duplicative requirements that can impede efficiency in global drug development;
- Reduce redundant testing and optimize deployment of limited regulatory agency resources while preserving patient protections and encouraging expedited patient access; and

- Coordinate marketing application data disclosure policies to protect patients and preserve incentives for biomedical research.

Strengthen intellectual property protections.

- Ensure strong intellectual property protections, including 12 years of regulatory data protection for biologics;
- Clarify patentability standards and implement patent term adjustments necessary to incentivize further investment in biopharmaceutical R&D; and
- Adopt effective patent enforcement systems that allow for early patent dispute resolution.

Enhance market access.

- The further reduction of non-tariff barriers in both markets will spur tomorrow's innovations for the benefit of patients around the world. To this end, the Korean-U.S. Free Trade Agreement (KORUS) should be the foundation of the TTIP.

Ensure alignment between the U.S. and the EU as they engage with third parties, such as India, China, and Canada, thereby promoting high biopharmaceutical policy standards and access to innovative medicines throughout the world.

Regulatory Compatibility

The United States' innovative biopharmaceutical industry strongly supports efforts to address regulatory differences and duplicative requirements that can impede efficiency in global drug development, review, and evaluation. Addressing these important issues can help to enhance efficiency of drug development, reduce redundant testing, and optimize deployment of limited regulatory agency resources. At the same time, regulatory coordination can lead to expedited patient access to new, innovative, life-saving medicines.

Significant partnership already exists between the FDA and EMA, both bilaterally and internationally, through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH). The regulatory compatibility proposals outlined here build on those efforts. Indeed, a U.S.-EU agreement will be a unique opportunity to develop even greater streamlined processes and procedures, and to set high biopharmaceutical policy standards ensuring access to innovative medicines throughout the world. To this end, specific regulatory compatibility proposals that our industry would like to see pursued as part of the TTIP include:

- Coordination to reduce the regulatory burden for sponsors and agencies.
    - Recognize each other's Good Manufacturing Practices and Good Clinical Practices inspections.
    - Grant sponsors the right to receive parallel scientific advice upon request for all medicines.
    - If successful, formally adopt the current pilot program between the U.S. and EU agencies to conduct parallel assessment of Quality by Design applications.

- Addressing current and proposed data disclosure policies.
    - Disclosure of companies' non-public data submitted in clinical and pre-clinical dossiers and patient-level data sets (at the time of patient registration, drug approval, and discontinuation of research programs) risks damaging public health and patient welfare.
    - Engage with the EU to ensure responsible data sharing that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research.
    - Include provisions that adequately shield confidential commercial information from inappropriate disclosure.

- Increased collaboration under the auspices of the ICH.
    - U.S. and EU agencies should work together to achieve greater regulatory compatibility in the scope, content, and timing of submission of pediatric investigation plans (EU) and pediatric plans (U.S.), so that companies are required to prepare only a single plan for submission in both territories.
    - Seek greater collaboration on pharmacovigilance issues including post-market testing, risk management requirements and format, and deadlines for adverse event reporting through a specific "cluster" on this topic.
    - Revise existing guidance to reduce the requirements for duplicative local bridging requirements.
    - Develop a harmonized structural framework and methodology for benefit-risk assessments (agencies would retain authority to make different risk-benefit judgments under their individual approval schemes).
    - Develop a harmonized approach to post-approval variation submissions for manufacturing changes.

- Implementation of a collaborative process for developing therapeutic area guidelines.
    - The U.S. and EU should establish a procedure for developing scientific and other regulatory guidelines for specific therapeutic areas.

- Addressing falsified medicines/product verification issues. The EU and U.S. should work together to ensure that their national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary, harmonized international standards.

Intellectual Property Rights

The innovative biopharmaceutical industry, which supports millions of jobs in the U.S., relies on strong intellectual property rights protection and enforcement to recoup the substantial costs of developing lifesaving medicines. Recognizing that IP is the lifeblood of innovation, the EU, like the U.S., generally affords strong IP protections to innovative biopharmaceuticals within the rubric of its system, and any agreement between the U.S. and the EU must not dilute these protections. These protections and the underlying principles on which they are founded should be included by the U.S. and the EU in all future

trade agreements with other countries. Specific IP issues around which PhRMA and its member companies **strongly encourage the U.S. and Europe to secure greater convergence as part of the TTIP include:**

- Seeking similar IP protections to those afforded under U.S. law.
    - Negotiate strong regulatory data protection provisions. As per U.S. law, the U.S. should seek 12 years of regulatory data protection for biologics.

- Clarification of patentability standards.
    - Provide that the scope of patent eligible subject matter includes medical process inventions (such as methods of therapy) and plant or non-human animal inventions.
    - Impose no limits on improvement inventions beyond the normal standards applied to determine patentability.
    - Clarify the criteria that must be met to demonstrate novelty.
    - Stipulate that determinations of whether an invention is not obvious should be made on a case-by-case basis.
    - Elucidate that broad disclosures of compounds do not anticipate all specific molecules within their scope absent specific teachings or directions to one of ordinary skill in the art.
    - Provide greater clarity regarding what constitutes adequate disclosure of the invention and the nature of what additional information can later be presented to support the patent application.
    - Ensuring that the patent system provides an appropriate grace period.

- Restoration of lost patent life.
    - Delays at the patent office and the time taken during the marketing approval process reduce the effective patent life over which an innovative manufacturer can seek to recoup the significant investments required to bring a successful medicine to market.
    - The patent term should be adjusted and/or restored to compensate for both regulatory approval process and patent office delays (the EU currently addresses only the former).

- Ensuring effective patent enforcement.
    - Strict enforcement of IP protections is particularly important to the biopharmaceutical industry given the significant cost and time required to develop a new medicine – on average, over $1.2 billion over 10-15 years – and the relatively short remaining period over which a manufacturer can recoup this investment.
    - It is essential to adopt effective patent enforcement systems that allow for early resolution of patent disputes before a patent-infringing product is launched on the market. Allowing an infringing product to enter the market during a dispute harms the innovative manufacturer – very often irreparably.

The U.S. and EU should not impose trademark limitations other than those necessary to protect public health.

Market Access

Biopharmaceuticals face unique market access challenges. In most markets, access for biopharmaceuticals is dependent not only on manufacturers meeting strict regulatory approval standards, but also obtaining reasonable government pricing and positive reimbursement determinations. Both the U.S. and the EU have included specific pharmaceutical (and medical device) chapters in recent FTAs addressing these challenges. Those provisions were designed to ensure that the regulatory approval and reimbursement procedures for medicines are governed by transparent and verifiable rules founded on science-based decision making. These FTA chapters have also recognized that there should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies both in the development and specific implementation of all relevant laws, regulations, and procedures. Furthermore, applicants affected by a negative determination should be provided the right of appeal to an independent objective court or administrative body.

Building on the common provisions contained in the pharmaceutical and medical device chapters of the U.S. and EU FTAs with Korea, we strongly encourage the Parties to:

- Adopt meaningful general principles.
    - Recognize the value biopharmaceuticals can provide in reducing other more costly medical interventions and in improving the lives of patients;
    - Respect the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need;
    - Recognize the value of ethical interactions between biopharmaceutical representatives and health care professionals; and
    - Agree that any reimbursement controls/determinations should only apply to products dispensed and reimbursed in that country.

- Promote access to innovation.
    - Clarify that if a government entity of a Party establishes prices for patented biopharmaceuticals based on prices of the same product in other countries, it should only reference countries that are similar in terms of their socio-economic level, populations, disease burdens, and health care systems, and should never be set by reference to prices for the same product in countries in economic crisis; and
    - Provide that during the patent term of a biopharmaceutical product, the government price for that product should be based on the value of that product and should never be set by reference to prices for generic products.

- Ensure transparent government regulation.
    - Clarify that the pharmaceuticals chapter applies to laws, regulations, and procedures concerning all aspects of securing market access for biopharmaceuticals, including, but not limited to, health-technology assessments, demand-side measures, and “clawback” mechanisms;

    - Ensure that applications to the EU Member States are processed within a reasonable, specified period, i.e., per the timelines mandated in the EU Transparency Directive; and
    - Add similar language to that contained in Article 3.4(h) of the EU-Korea FTA requiring each Party to ensure that stakeholders with legitimate commercial interests have access to full information about each Party's pricing and reimbursement systems and processes (excluding confidential business information).

- Authorize dissemination of information to patients and health care professionals.
    - Permit manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites as long as the information is truthful and not misleading, includes a balance of risks and benefits, and is limited to indications for which the relevant regulatory authority has granted market approval for that medicine.

- Eliminate barriers to market access/patient access.
    - Respect the payment terms established by U.S. law and the EU's Late Payments Directive, respectively; and
    - Ensure that any "clawback" or rebate tax levied by a Party in response to an economic crisis should not disproportionately burden patented biopharmaceutical manufacturers (i.e., should be borne by the entire supply chain), and should be subject to a transparent, annual review process with an opportunity to comment. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

In conclusion, Lilly is one company among many within our industry and in the broad business community that believes TTIP is a once-in-a-lifetime opportunity to address longstanding trade issues, create new markets, and simplify transatlantic business. We look forward to working with the Committee and Congress to ensure that this agreement meets the expectations of the business community, creates jobs, and enhances the competitiveness of our two economies. Thank you for the opportunity to testify today. I welcome any questions that you may have.