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May 10, 2013

Mr. Douglas Bell
Chair, Trade Policy Staff Committee
Executive Office of the President
600 17th Street, N.W.
Washington, D.C. 20508

Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (Apr. 1, 2013)

The Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies welcome the opportunity to provide comments on the proposed Transatlantic Trade and Investment Partnership and indicate their interest in testifying at the hearing scheduled for May 29-30. A summary of the testimony to be given at the hearing is attached. As a general matter, PhRMA and its members strongly support the negotiation of a high-standard trade liberalizing agreement between the United States and the European Union (EU). PhRMA welcomes the expansion of the world's most dynamic trading relationship that already contributes to strong economic dynamism and job creation on both sides of the Atlantic. The proposed agreement would provide 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.

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.[1] Further, in 2009 the U.S. biopharmaceutical sector employed more than 650,000 workers, supported a total of 4 million jobs across the country, and contributed more than $917 billion in economic output when direct, indirect, and induced effects are considered.[2]

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, tariffs[3] and public procurement measures. The United States and the EU already provide the greatest global support for pharmaceutical research and development and PhRMA believes that

[1] PhRMA Annual Member Survey (Washington, DC: PhRMA 2013).
[2] Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation*, July 2011. Battelle Memorial Institute. Prepared for the Pharmaceutical Research and Manufacturers of America. (Battelle Report)
[3] Specifically, the U.S. and EU should agree to immediately eliminate tariffs on all chemicals and materials used to manufacture medicines, regardless of whether they are yet identified in the Annex to the WTO Pharmaceutical Agreement. Further, both the United States and the EU should require trading partners in all future free trade agreements who are not yet a signatory to the WTO Pharmaceutical Agreement to sign on to that agreement.

further reduction of non-tariff barriers in both markets will spur future and critical innovation. In addition to enhancing the partnership between the EU and the U.S., efforts should be made to ensure alignment in engagement with other countries. Such engagements can only be enhanced by developing a common understanding and (where relevant) a joint approach between the U.S. and the EU on key issues, to allow for high pharmaceutical policy standards and access to innovative medicines throughout the world.

With specific regard to the biopharmaceutical industry, PhRMA recommends that the pharmaceutical 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. Further, although both the United States and the EU offer strong IP protections within their respective systems, certain aspects of their IP regimes could be harmonized as detailed below. Similarly, PhRMA summarizes below the regulatory compatibility initiatives that it identified in its joint submission with its European sister association last fall.[4] By addressing these key issues and promoting greater regulatory cooperation between the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), PhRMA believes that the U.S. Government and the European Commission will help spur further pharmaceutical innovation, which will lead to healthier patients and more dynamic economies.

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. Companies publish their research, collaborate with academic researchers, and disclose clinical trial information at the time of patient registration, drug approval, and for medicines whose research programs have been discontinued. 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

[4] PhRMA and EFPIA's Response to the Request for Public Comments on Promoting U.S. EC Regulatory Compatibility, (Oct. 31, 2012), available at http://www.regulations.gov/#!documentDetail;D=USTR-2012-0028-0021 (last visited May 10, 2013).

adequately shielding confidential commercial information from inappropriate disclosure. The EMA's current and proposed data disclosure policies jeopardize these principles.

I. The Biopharmaceutical Industry is Important to the U.S. Economy

U.S. innovation and ingenuity represent our comparative advantage in the global trading arena, and will continue to be essential to America's future prosperity and growth. Capitalizing on this advantage will be critical to sustaining and growing U.S. jobs in the biosciences, particularly in the biopharmaceutical sector, and their contributions to the nation's GDP. Few industries provide more high-quality, high-paying, and high-productivity jobs in the United States than the biopharmaceutical sector. Total jobs supported by industry across the U.S. in 2009 totaled 4.0 million jobs,[5] including more than 650,000 direct jobs.[6] Direct employment in the biopharmaceutical sector grew almost twice as fast as employment in the rest of the economy between 1998 to 2008. Further, for every $1 in output generated by the biopharmaceutical sector, another $1.4 in output is generated in other sectors of the economy, reflecting the high multiplier effect of the sector. Nevertheless, our industry faces tremendous loss of revenue that has been widely attributed to fallout of the Global financial crisis, including the deep austerity measures in Europe, threatening jobs, slowdowns in research and development, loss of exports, increased pressure to outsource, and more.[7]

At the same time, PhRMA member companies make substantial investments in research and development, further fueling the U.S. economy and advancing public health through the discovery and development of new cures and treatment options for patients. In 2012, PhRMA members alone invested $48.5 billion in research and development for new medicines, most of this investment made in the United States.[8] Furthermore, looking at manufacturing jobs specifically, the average biopharmaceutical company spends approximately $105,000 on R&D per direct employee, more than ten times the average R&D spend per employee in manufacturing industries overall.[9] Moreover, according to the most recent data from the National Science Foundation, the U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business R&D, representing nearly 20 percent of all domestic R&D funded by U.S. businesses.[10] With more medicines in development in the United States than in the rest of the world combined, the United States accounts for approximately 3,240 products in development in 2011, in large

[5] Battelle Report.
[6] Id.
[7] Sources including PricewaterhouseCoopers, *Exploring the Relationship between Revenues and Employment in the Biopharmaceutical Industry*, PwC Research Report, June 2009, Table 1; and Ryan, B., Deutsche Bank, "4Q'10 Review & Model Book," Feb.14, 2011; Peterson, T, J.P. Morgan, "Pharma R&D Post-Mortem," Feb. 16, 2011.
[8] PhRMA Annual Member Survey (Washington, DC: PhRMA, 2013).
[9] Pham, N., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs Wages, and Exports*, NDP Consulting (April 2010), *available at* http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last visited May 10, 2013).
[10] Science and Engineering Indicators 2012, National Science Foundation, Division of Science Resource Statistics. 2012.

part due to robust IP protections and other strong incentives that foster the environment needed to support continued research and development investment.[11]

A 2012 study by the U.S. Department of Commerce found that IP-intensive areas of manufacturing produce relatively much larger benefits to the U.S. economy, and that pharmaceuticals and biopharmaceuticals are generating the greatest such benefits.[12] In fact, a study on "The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports" found that R&D spending for the pharmaceutical industry had the fastest growth among IP-intensive sectors analyzed, increasing an average of 20.7 percent a year between 2000 and 2007.[13] Moreover, our industry is a strong and growing source of exports. Growing nearly 50% over six years, it is estimated that the value of biopharmaceutical exports was $260 billion between 2006 and 2011. In 2011 alone, the biopharmaceutical industry exported approximately $48 billion,[14] making the biopharmaceutical sector the fourth largest in exports among R&D intensive industries.[15]

II. Building on Common Ground to Ensure Transparency and Due Process in Approving, Pricing and Reimbursing Pharmaceuticals

Pharmaceuticals face unique market access challenges. In particular, in most markets, market access for pharmaceuticals is dependent not only on manufacturers meeting strict regulatory approval standards, but also in obtaining positive government pricing and reimbursement determinations. Recognizing these challenges, both the EU and the United States have included specific pharmaceuticals (and medical devices) chapters in their recent FTAs to ensure that the regulatory procedures and decisions regarding the approval and reimbursement of medicines are governed by transparent and verifiable rules guided by science-based decision making. These 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 these common provisions contained in KORUS and the EU-Korea FTA, PhRMA strongly encourages the following enhancements:

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[11] Adis R&D Insight Database, Wolters Kluwer Health (accessed 10 February 2012).
[12] Intellectual Property and the U.S. Economy: Industries in Focus. United States Department of Commerce. March, 2012.
[13] Pham, N., *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs Wages, and Exports*, NDP Consulting (April 2010), *available at* http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last visited May 10, 2013).
[14] U.S. International Trade Commission, Trade DataWeb, accessed January 20, 2013, at http://dataweb.usitc.gov/ (query run of U.S. domestic exports classified by 4-digit NAIC code 3254).
[15] Industry export data from PhRMA analysis of data from United States International Trade Administration.

A. General Provisions/Principles

Add the following general principles indicating that the United States and the European Union (the Parties):

- Recognize the value pharmaceuticals can play in reducing other more costly medical expenditures and improving the lives of patients (consistent with Article 5.1(b) of KORUS);

- 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 pharmaceutical representatives and health care professionals; and

- Agree that any reimbursement controls/determinations should apply only to products dispensed and reimbursed in that country (consistent with Recommendation 6 of the G10 Medicines Report[16] and Recommendation 9.2 of the High Level Pharmaceutical Forum Final Report[17]).

In addition, consistent with Article 1(f) of the EU-Korea FTA, identify specific international organizations/workstreams to foster further cooperation among the Parties to improve patient access to safe and effective medicines.

B. Access to Innovation

Both the European Union and the United States agree that innovative medicines should be priced and reimbursed at levels that appropriately recognize their value to patients and society. To promote development of innovative medicines and thereby ensure patient access to those medicines, the Parties should:

- Recognize that prices of medicines should be based on a variety of criteria that reflect such considerations as benefits to patients, patterns of disease burden, national socio-economic indicators, etc. International reference pricing as a mechanism to set prices for pharmaceutical products suffers from serious flaws both from a policy and methodology perspective. It prevents companies from having a more differentiated approach to pricing, which would take all these factors into account, and creates a negative price spiral, especially where the calculation of the price is based on lowest price.

- Clarify that if a government entity in the U.S. or EU establishes prices for innovative pharmaceuticals based on prices of the same product in other countries, it should only be

[16] G10 medicines Report (May 7, 2002), available at http://ec.europa.eu/health/files/phabiocom/docs/g10-medicines_en.pdf (last visited May 10, 2013)

[17] High Level Pharmaceutical Forum 2005-2008, Conclusions and Recommendations (October 2, 2008), available at http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmaforum_final_conclusions_brochure_en.pdf (last visited May 10, 2013).

used as a reference mechanism to facilitate negotiations with a manufacturer, rather than a rigid or even singular determinant of a product's price. It should rely on publicly available prices and respect the confidentiality of prices negotiated with other countries. It should only reference countries that are similar in terms of their socio-economic level, populations, disease burdens and health care systems. Government prices for innovative pharmaceuticals should never be set by reference to prices for the same product in countries in economic and political crisis (for example, countries receiving aid from the International Monetary Fund); and

- To appropriately recognize innovation, the government price for an innovative product should never be set by reference to prices for generic products. (We propose adding a provision in the Government Procurement chapter similarly prohibiting tenders in which an innovative pharmaceutical is priced based on generic product(s) included in the tender.)

Further, to the extent that there are similar but slightly different access provisions in KORUS and the EU-Korea FTA, we propose as follows:

- Consistent with Article 2(b)(ii) of the EU-Korea FTA, provide that after a decision on the reimbursement amount is made, a manufacturer should be permitted to apply for an increased amount of reimbursement based on evidence of the safety, efficacy, quality and benefits of that pharmaceutical.

- Add a similar provision to that contained in Article 2(b)(v) of the EU-Korea FTA, to provide manufacturers with meaningful opportunities to comment before any potential "emergency" government price cuts are implemented and the ability to seek independent review of such potential price cuts.

- Emphasize (consistent with Article 5.2(c) of KORUS), that a manufacturer should be permitted to apply for reimbursement for additional medical indications based solely on evidence of safety and efficacy.

C. Transparency

A transparent, timely and predictable pricing and reimbursement process that provides applicants with meaningful due process is essential to ensure patient access to innovative medicines. The existing transparency commitments in KORUS and the EU-Korea FTA,[18] should be enhanced, as follows:

- Add language clarifying that all of these provisions apply to laws, regulations and procedures concerning all aspects of the pricing and reimbursement process, including, but not limited to, health technology assessments or other medical assessments of the

[18] The transparency commitments in the EU-Korea FTA are rooted in Directive 89/105/EC on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.

clinical effectiveness of a pharmaceutical, demand-side measures and "clawback" mechanisms.

- Consistent with Article 3.2(c) of the EU-Korea FTA, clarify that the obligation to address substantive comments in writing and explain any substantive revisions made to proposed regulations should be completed before the proposed regulations are adopted.

- With regard to the obligation to ensure that all applications are processed within a reasonable, specified period (Article 5.3.5(a) of KORUS), specifically note that the applicable timeline for EU Member States should be the timelines stipulated in the EU Transparency Directive.

- Consistent with Article 3.4(a) of the EU-Korea FTA, include language providing that if an application is inadequate or insufficient, the relevant authority must notify the applicant of what additional information is required to resume the application review process in a timely manner.

- The language contained in Article 3.4(d) of the EU-Korea FTA, which emphasizes the information that must be provided if the relevant authority makes a negative reimbursement determination, is preferable to the similar language in Article 5.3.5(d) of KORUS.

- Include the language from Article 3.4(e) of the EU-Korea FTA requiring that the final reimbursement notice should advise the applicant of their rights and the relevant timelines for seeking an independent review of the reimbursement decision.

- 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. To the extent such systems and processes include the use of positive and/or negative lists, updated positive lists should be published annually and negative lists, if any, every six months. However, the Parties should not be able to disclose confidential information contained in agreements signed between private sector actors (e.g., pharmaceutical companies) and government entities that were entered into with the explicit understanding that the details included in those agreements would be kept confidential.

- Add language clarifying that in the framework of pricing and reimbursement decisions, countries shall not duplicate the assessment conducted by regulatory agencies for market approval purposes.

D. Dissemination of Information to Patients and Health Care Professionals

In order to make informed decisions, health care professionals and patients need to have access to information concerning their health care options. This includes understanding the benefits and risks associated with a medicine deemed to be medically appropriate by a patient's physician or health care provider. Consistent, therefore, with Article 5.4 of KORUS, PhRMA and its member

companies request that the proposed agreement between the United States and the European Union include language permitting manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites, based, of course, on such information being truthful, not misleading and balanced and limited to indications for which the relevant regulatory authority has granted market approval for that medicine.

E. Regulatory Cooperation

More specific regulatory cooperation proposals are noted below. One general provision, however, that could be added to those included under Article 5.6 of KORUS would be that the Parties agree not to impose new regulatory requirements unless the relevant agency has the technical capacity and human resources to implement those requirements within "reasonable, specified" time limits (consistent with Article 5.3.5(a) of KORUS).

F. Medicines and Medical Devices Committee

Both KORUS and the EU-Korea FTA created a medicines and medical device committee or working group to provide a venue for the Parties to discuss implementation issues and to ensure ongoing coordination. PhRMA and its member companies strongly support the formation of a similar committee or working group as part of the proposed agreement between the EU and the United States, and would refer to the language contained in Article 5.7 of KORUS as the preferable model.

G. Other Barriers to Market Access/Patient Access

PhRMA and its members recognize the significant fiscal challenges faced by all governments and stand ready to be a partner in finding solutions. However, cost containment measures that disproportionately burden the innovative pharmaceutical sector or that are developed and implemented without a predictable, transparent, and consultative process, discourage the long-term R&D investment required for innovative medicines, thereby impeding patient access to desperately needed new medicines. With this in mind, PhRMA urges the United States to seek the following additional terms as part of the pharmaceutical provisions of the proposed agreement:

- Parties agree to respect the payment terms established by U.S. law/the EU's Late Payments Directive, respectively.

- Any "clawback" or rebate tax levied by a Party in response to an economic crisis should not disproportionately burden innovative pharmaceutical manufacturers (i.e., any tax should be borne by the entire supply chain), and should be subject to a transparent, annual review process that affords those subject to the tax the opportunity to comment on whether it remains necessary to continue the tax. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

III. Reinforcing Strong Intellectual Property Protections and Enforcement

The innovative biopharmaceutical industry relies on strong intellectual property (IP) protections and enforcement to recoup the substantial costs of developing life-saving medicines and support millions of jobs in the United States and the EU. Recognizing that IP protections are the lifeblood of innovation, the United States and the EU, 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. (Further, the EU and the U.S. should seek similar commitments to strong IP from their trading partners as part of their free trade agreements with other countries.) Particular areas, however, where PhRMA would encourage enhancements and greater alignment between the respective IP systems are as follows:

A. Regulatory Measures

As part of the proposed negotiations, the U.S. Government should seek similar IP protections to those afforded under U.S. law. In particular:

- The U.S. Government should negotiate strong regulatory data protection provisions. Accordingly, consistent with U.S. law, the U.S. should seek at least 12 years of regulatory data protection for biologics.

- As discussed in more detail below under our regulatory compatibility proposals, the U.S. Government should fully engage with the EU to address its current and proposed marketing application data disclosure policies. Responsible data sharing protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research.

Further, consistent with existing law in the U.S. and EU, both should also include provisions in future free trade agreements with other countries indicating that if a Party's regulatory authority asks a manufacturer to conduct pediatric studies, that Party should provide appropriate IP incentives.

B. Patent Standards

The proposed EU-U.S. trade liberalization agreement offers an opportunity to affirm a number of high-level Intellectual Property (IP) principles and for the countries involved to seek broader harmonization of their IP systems. PhRMA proposes that the following patent standards that are relevant to the pharmaceutical sector should be addressed as follows:

- Clearly 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 inventions, including improvement and selection inventions, beyond the normal standards applied to determine patentability.

- Clarify novelty in the following ways:

    - A claimed invention shall be found novel if each and every element or step of the claimed invention was not explicitly or inherently disclosed in the prior art;

    - To inherently anticipate a claimed invention, the subject matter disclosed in the prior art must necessarily possess the undisclosed features, properties or attributes of the claimed invention; and

    - An invention comprised of forms, structures or complexes of a molecule that are distinct from forms, structures or complexes known in the prior art shall be considered novel if the invention as claimed is not identically described either explicitly or inherently in the prior art.

- 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. For example, biological data for a representative number of molecules, which demonstrates to the person of ordinary skill that the claimed invention works should be considered to be an adequate disclosure. The applicant should be able to provide data to the patent office after the filing date to support patentability of an invention.

- Ensure that the patent system provides a grace period that strikes a fair balance in ensuring that an inventor does not lose rights to a patent after a first disclosure to the public, but also provides for sufficient legal certainty for third parties by ensuring that information that has been publicly disclosed but not made the subject of a timely filed patent is freely available. Whereas the United States provides a one-year grace period, the EU provides no grace period.

C. <u>Restoring Lost Patent Life</u>

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. To encourage efficient review processes and ensure that the manufacturer does not bear the costs caused by those delays, the patent term should be adjusted and/or restored to compensate for these delays. Currently the EU only addresses the time taken during the regulatory approval process, not patent office delays.

D. Pharmaceutical Patent Enforcement Standards

High-level IP standards are meaningless without strict enforcement of those standards. This is particularly true in the case of pharmaceuticals, 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 potentially recoup this investment. If a patent-infringing product is allowed to enter a market while a patent-infringement dispute is ongoing, the innovative manufacturer, even if successful in that dispute, is rarely restored to the position that they would have been in but for the launch of the patent-infringing product. It is essential, therefore, that the EU Member States adopt effective patent enforcement systems (or a unified system) that allow for early resolution of patent disputes before an infringing product is launched on the market. The Orange Book (U.S.) mechanism is one model for early resolution of patent disputes.

E. Trademarks

As a matter of principle and to establish a benchmark for future free trade agreements with other countries, the United States and the EU should agree not to impose limitations, other than those necessary to protect public health, on the use of trademarks. In addition, the proposed agreement provides the United States and the EU with an opportunity to discuss reforming internal processes at both the FDA and EMA so that regulatory consideration of trademarks can occur with more predictability and earlier in the approval process.

IV. An Opportunity to Increase Regulatory Compatibility in the Pharmaceutical Sector

The 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 and optimize deployment of limited regulatory agency resources, and at the same time, lead to expedited patient access to new, innovative and life-saving medicines. With this in mind, PhRMA, in conjunction with its European sister association (the European Federation of Pharmaceutical Industries and Associations (EFPIA)) submitted joint comments last fall identifying specific regulatory compatibility initiatives to pursue as part of a potential free trade agreement between the United States and the EU.[19] Those initiatives are summarized below.

One issue, however, that requires immediate attention, concerns recent guidance and policies announced by the EMA that non-clinical and clinical data including study reports submitted by an applicant to obtain marketing approval may be publicly released if requested by a third party.[20] Further, the EMA has expressed its intention to develop a system for disclosing such

[19] PhRMA and EFPIA's Response to the Request for Public Comments on Promoting U.S. EC Regulatory Compatibility, (Oct. 31, 2012), available at http://www.regulations.gov/#!documentDetail;D=USTR-2012-0028-0021 (last visited May 10, 2013).

[20] HMA/EMA Guidance Document on the identification of commercially confidential information (March 2012), available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf (last visited May 10, 2013).

information, including patient-level data, on its own initiative.[21] The EMA's novel current and proposed policies regarding the disclosure of companies' confidential commercial information in marketing applications are inconsistent with the treatment of such information by the U.S. FDA. It is also contrary to years of precedent in Europe of protection of confidential commercial information.

The biopharmaceutical industry is firmly committed to enhancing the public health through responsible reporting and publication of clinical research and safety information. Companies publish their research, collaborate with academic researchers, and disclose clinical trial information at the time of patient registration, drug approval, and for medicines whose research programs have been discontinued. The industry is committed to engaging in a multi-stakeholder dialog to advance responsible data sharing arrangements.

The EMA's current practices, in addition to its proposed policies to proactively disclose companies' non-public data submitted in clinical and pre-clinical dossiers and patient-level data sets, risk damaging public health and patient welfare. Government disclosure of companies' unprocessed, non-contextualized raw data and technical analysis provides little benefit to practicing healthcare professionals and their patients. On the contrary, disclosure of such clinical trial data, including confidential commercial information, threatens patient privacy by facilitating patient re-identification from anonymized patient-level data sets; encourages second guessing of the EMA's expert regulatory decisions, thereby undermining patient trust in the safety and effectiveness of approved medicines; and harms incentives to invest in biomedical research. The primary beneficiaries of such non-public information are competitors who wish to free-ride off of the investments of the innovators.

Further, failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In order to benefit public health in the long run, data disclosure policies must preserve patient privacy, respect the integrity of regulatory systems, and maintain incentives to invest in innovative medical research, consistent with 21 C.F.R. §§ 312.130; 312.45(c); 314.430; 601.51(c) and Article 39(3) of TRIPS. For these reasons, PhRMA and its members urge the U.S. Government to engage with the EU in every available venue to resolve this issue.

With regard to PhRMA's other regulatory compatibility proposals, the biopharmaceutical industry would like to emphasize the significant ongoing partnership and coordination between the FDA and EMA, both bilaterally and internationally through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Most of the regulatory compatibility proposals identified below are founded on these existing efforts. The innovative biopharmaceutical industry believes that an enhanced EU-U.S. relationship could be a unique opportunity to seek even greater compatibility and to create

[21] Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006, OJ 2012 C302/7 (June 10, 2012), available at http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf (last visited May 10, 2013).

streamlined processes and procedures between the EU and the U.S. To this end, our specific regulatory compatibility proposals are as follows:

A. Greater Coordination to Reduce Regulatory Burden for Sponsors and Agencies

PhRMA and EFPIA have sought to identify proposals that eliminate unnecessary inefficiencies and redundancies in the regulatory approval process, all the while preserving patient protections. These proposals reduce the regulatory burden for sponsors and agencies, and would allow new cures to move more rapidly from test-tubes to trial testing to therapeutic use:

- Provide mutual recognition of 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.

B. Increase Collaboration under the Auspices of the ICH

PhRMA and EFPIA have identified a number of work streams where we could seek increased collaboration on ongoing efforts 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 plans, 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 and 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.

C. 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.

D. Falsified Medicines/Product Verification

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.

The biopharmaceutical industry looks forward to further engaging with the FDA, EMA and the EU Member States' authorities to explore these and any other regulatory compatibility proposals that respect the agencies' rights to ensure the public health, safety and welfare of the patients in their regions, while reducing both the regulators' and the industry's administrative burdens.

V. Conclusion

In summary, PhRMA and its members 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 partnership offers 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 U.S. and EU should seek in all future trade agreements with other countries.

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

Sincerely,

/s/

Jay Taylor