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SUBMITTED ELECTRONICALLY

Mr. Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

PUBLIC DOCUMENT
USTR-2018-0035

Re: Request for Comments on Negotiating Objectives for a U.S.-European Union Trade Agreement, 83 Fed. Reg. 57,526 (November 15, 2018)

Dear Mr. Gresser:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the notice of public hearing and request for comments and indicate our interest in testifying at the hearing scheduled for December 14. 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 agreement between the United States and the European Union (EU). PhRMA welcomes the expansion of the world's largest 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 EU should seek vis-à-vis each other and in all future trade agreements.

PhRMA member companies are devoted to inventing, manufacturing, and distributing valuable medicines that enable people to live longer, healthier, and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports nearly 4.7 million jobs across the economy, including more than 800,000 direct jobs, and contributes nearly $1.3 trillion in economic output on an annual basis when direct, indirect, and induced effects are considered.[1] Our sector also continues to be one of the most research-intensive in America, annually investing an estimated $90 billion in researching and developing new medicines.[2] Innovators in this critical sector depend on strong regulatory systems, robust intellectual property (IP) protections

[1] TEConomy Partners; for PhRMA. The Economic Impact of the U.S. Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; July 2017.

[2] Research!America, U.S. Investments in Medical and Health Research and Development, 2013-2016, Arlington, VA, Fall 2017, available at https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf (last visited Dec. 9, 2018).

and enforcement, and fair and transparent access to overseas markets through the operation of competitive markets or by adopting or maintaining procedures that appropriately recognize the value of innovative medicines. With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients and contribute powerfully to the American economy.

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 IP protections, market access provisions, and customs, tariffs[3] and public procurement measures. The United States and the EU are home to some of the most innovative biopharmaceutical companies in the world, such that the 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 compatible pharmaceutical regulatory and policy standards and access to innovative medicines throughout the world.

With specific regard to the biopharmaceutical industry, PhRMA recommends that the negotiations address several issues concerning market access, IP protection and enforcement, and regulatory compatibility. Regarding market access, PhRMA recommends that the pharmaceutical market access commitments included in the U.S.-Korea 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 agreement. Other U.S. and EU trade agreements, including the recently signed United States-Mexico-Canada Agreement (USMCA) and the EU-Singapore Free Trade Agreement, also contain provisions addressing market access for pharmaceuticals. Regarding IP protection and enforcement, although both the United States and the EU offer strong IP protections within their respective systems, there have been some troubling proposals in Europe over the last couple of years that appear to draw into question Europe's commitment to innovation (detailed further below). Regarding regulatory initiatives, the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is the cornerstone of regulatory cooperation. Both the U.S. and EU have a high degree of implementation, and both should continue to seek global implementation of ICH guidelines. PhRMA summarizes below some additional regulatory initiatives that could be pursued as part of the proposed trade agreement. 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.

Specific issues of considerable concern to the industry in the current European environment include:

[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.

- **Government Price Setting** – In many EU Member States, governments are the primary payer of health care and medicines and in effect dictate prices. This commanding position often results in EU Member States failing to appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide, and in some cases outright delay or deny patient access to new innovative treatments. Governments in the EU Member States are increasingly employing a range of regulatory measures, including international reference pricing, therapeutic reference pricing, mandatory price cuts and clawback taxes, and flawed health technology assessments. These measures are often layered to exert maximum pressure on prices.

  With these concerns in mind, PhRMA welcomes the Administration's continued focus on the problem of advanced economies undervaluing U.S. innovative medicines.[4] As more countries impose price controls, the burden for financing medical advances has been increasingly borne by U.S. patients and biopharmaceutical innovators, while patients abroad have suffered decreased access to improved therapies over the long term.[5] It remains critical for the U.S. Government to engage on these issues with its trading partners, and to require immediate and meaningful steps to resolve existing barriers and to ensure patients have faster access to new treatments and cures.

- **EU Incentives Review** – The EU is contemplating potentially sweeping changes that could weaken IP protections for biopharmaceuticals and create an unlevel playing field for transatlantic medicines trade and investment. PhRMA and its member companies are concerned that this review will result in the weakening of existing incentive mechanisms for innovation. Of particular concern are the legislative proposals issued on May 28, 2018, to amend the EU's patent term restoration mechanism (Regulation EC 469/2009 concerning Supplementary Protection Certificates (SPCs)) with the objective of introducing an SPC manufacturing waiver. The waiver would allow companies to manufacture generic and biosimilar products in Europe during the effective SPC period for export purposes to third (non-EU) countries. The proposal reduces IP rights and we are concerned that this sends a signal to the world that Europe is weakening its commitment to IP incentives and innovation.

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[4] Office of the U.S. Trade Representative, *2018 Special 301 Report*, April 2018, available at https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf (last visited Dec. 9, 2018); Office of the U.S. Trade Representative, *USTR Engagement on Pharmaceutical and Medical Device Issues*, April 2018, available at https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/april/ustr-engagement-pharmaceutical-and (last visited Dec. 9, 2018); The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf, (last visited Dec. 9, 2018); U.S. Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018, available at https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (last visited Dec. 9, 2018).

[5] U.S. Department of Commerce, International Trade Administration, Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation, December 2004, available at https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Dec. 9, 2018); The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (last visited Dec. 9, 2018).

I. 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 FTAs (see, e.g., KORUS and the EU-Korea FTA) to ensure that all regulatory procedures and decisions regarding the approval and reimbursement of medicines (including health technology assessments or other medical assessments of the clinical effectiveness of a pharmaceutical, demand-size measures and "clawback" mechanisms) 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. Applications should be processed within a reasonable, specific period, consistent with the timelines stipulated in the EU Transparency Directive.[6] If an application is deemed inadequate, the applicant should be advised what additional information is required to resume the application review process in a timely manner. Furthermore, if an application is denied, the applicant should be provided the right of appeal to an independent objective court or administrative body.

As in KORUS, the pharmaceuticals chapter affords an opportunity to recognize the value pharmaceuticals can play in reducing other costlier medical expenditures and improving the lives of patients. As such, 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 value criteria that reflect such considerations as benefits to patients and health care systems, patterns of disease burden, and national socio-economic indicators. Accordingly, international reference pricing as a mechanism to set prices for pharmaceutical products suffers from serious flaws both from a policy and methodology perspective. Similarly, narrow approaches to health technology assessment, such as rigid cost-effectiveness methodologies, should not be the principle framework for assessing value.

- Appropriately recognize innovation by ensuring that the government price for a patented product is never set by reference to prices for off-patent or 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.)

[6] Further, the Parties should agree not to impose new requirements (such as health technology assessments) unless the relevant agency has the technical capacity and human resources to implement those requirements within "reasonable, specified" time limits.

Finally, 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.

II. Reinforcing Strong Intellectual Property Protections and Enforcement

The innovative biopharmaceutical industry – and the millions of jobs that it supports the United States and the EU – relies on strong IP protections and enforcement to protect innovators from unfair competition from other manufacturers who have not incurred the same complex, costly and risky process to develop a new medicine. Recognizing that IP protections are the lifeblood of innovation, the United States and the EU should capitalize on this proposed Agreement to reaffirm their existing commitments to IP incentives for innovators and secure the highest international standards. 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. With this goal in mind, particular areas where PhRMA would encourage enhancements and clarity related to the respective IP systems are as follows:

- **Regulatory Data Protection** – As part of the proposed negotiations, and consistent with the negotiating objectives set forth in the Bipartisan Congressional Trade Priorities Act of 2015 (TPA), the U.S. Government should seek IP protections that meet the highest international standards, including at least 12 years of regulatory data protection for biologics.

- **Patent Standards** – In view of the importance of IP for biopharmaceutical innovation, the proposed EU-U.S. trade agreement offers an opportunity to affirm a number of high-level IP principles. These are critical not only in the EU and U.S., but also at a global level, and include principles relating to the three substantive patentability criteria (i.e., novelty, inventive step and capable of industrial application (or utility)); the scope of patentable subject matter (which should include medical process inventions, such as methods of therapy, and plant or non-human animal inventions); the need for case-by-case determinations of whether an invention is not obvious; patentability must not be negated by the manner in which the invention was made; 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; and avoid over-restrictive and artificial criteria for added matter.

- **Grace Period** – 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.

- **Restoring 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. 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. Furthermore, consistent with their very purpose, SPCs (as employed in the EU) or similar mechanisms to restore lost patent life should provide the same protections, scope, and rights as those enjoyed during the regular patent term.

- **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 over many years required to develop a new medicine 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.

- **Third country cooperation** – the United States and EU should agree to build on existing cooperation to advocate for high IP standards globally and to work together to ensure that IP standards are properly adhered to in third countries.

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

The innovative biopharmaceutical industry strongly supports efforts to address incompatible or duplicative regulatory requirements that can impede efficiency in global drug development, review and evaluation. Addressing these important issues can help to enhance 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. In this regard, the biopharmaceutical industry would like to emphasize the significant ongoing partnership and coordination between the FDA and EMA, both bilaterally and internationally through the ICH. 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 streamlined processes and procedures between the EU and the U.S. Building on the regulatory provisions included in the recently concluded USMCA, specific regulatory compatibility proposals that we would propose the U.S. and EU Governments pursue through the proposed trade negotiations are as follows:

- **Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP)** – It is critical that the U.S. and EU Governments continue to implement the MRA concluded in 2017, covering the full scope of products included in the agreement, and the inclusion of vaccines. To the fullest extent, inspectors should seek to avoid duplication of both pre- and post-approval inspections. Once that is achieved, the Parties should consider expanding the scope of the MRA to also cover investigational medicinal products and advanced therapy medicinal products.

- **MRA on Good Clinical Practice (GCP)** – Clinical research is global. Duplication of inspections absorbs both industry and regulatory authority resources that could be used in other ways to oversee/reduce risk in more effective ways. An MRA for GCP inspections between the U.S. and EU would increase regulatory authority capacity to inspect clinical investigator sites and sponsors by avoiding inefficient duplication of work and eliminate redundant time spent by clinical investigators hosting inspections from EU and U.S. regulatory authorities.

- **Alignment in the Area of Medicines for Pediatrics** – Better alignment of pediatric scientific approaches between the EU and U.S. would reduce duplication and streamline medicines development for children, reducing the time and costs of conducting trials for industry while avoiding redundant clinical trials in children, and ensuring that children have faster access to new medicines.

- **Innovation** – Science and technology is rapidly presenting new opportunities in the development and use of medicines, and aligned regulatory approaches are important to avoid duplicative or inconsistent regulatory requirements that may inhibit patient access to new medicines. Therefore, it is important to prioritize upstream discussions between the EU and U.S. on evolving science and technology (e.g., for new sources of evidence) to support the development of medicines and their assessment.

Finally, the U.S. Government should continue to engage with the EU on its current and proposed marketing application data disclosure policies. Responsible data sharing processes must protect patient privacy, maintain the integrity of the regulatory review process, and preserve incentives for biomedical research.

IV. Conclusion

In summary, PhRMA and its members strongly support the negotiation of a comprehensive and ambitious trade 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