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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-2018-0036

Re: Request for Comments on Negotiating Objectives for a U.S.-UK Trade Agreement, 83 Fed. Reg. 57,790 (November 16, 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 January 29. 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 United Kingdom (UK). PhRMA welcomes the expansion of this significant 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 UK 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 and enforcement, and fair and transparent access to overseas markets through the operation of competitive markets or the adoption or maintenance of procedures that appropriately recognize

[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 Jan. 15, 2019).

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, contribute meaningfully to the American economy, and reinforce our unparalleled contributions to global innovation.

In 2017, the biopharmaceutical industry exported more than $55.8 billion in biopharmaceuticals, making the sector one of the top U.S. exporters among IP-intensive industries. The UK is a critical destination for U.S. biopharmaceutical exports, representing the seventh largest export market for biopharmaceuticals in 2017, with exports to the UK valued at over $3.6 billion.[3] At the same time, the United States imported over $5.5 billion of biopharmaceuticals from the UK in 2017,[4] indicative of the significant need to negotiate a free and fair trade agreement that eliminates non-tariff barriers and fosters greater exports to this important market.

Negotiations between the U.S. and the UK to enhance the trade relationship between these partners should be as comprehensive and ambitious as possible, recognizing that the current scope of the trade agreement remains uncertain pending the ongoing Brexit negotiations. The United States and the UK 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 UK and the U.S., efforts should be made to ensure alignment in engagement with other countries, including through the development of common understandings and, where appropriate and relevant, joint approaches between the U.S. and the UK on key issues. Such alignment ultimately would 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 (1) market access, (2) IP protection and enforcement, and (3) regulatory compatibility. The recently concluded U.S.-Mexico-Canada Agreement (USMCA) provides a very strong base from which to negotiate a trade agreement with the UK. Addressing the UK's trade impediments (discussed further below and in PhRMA's most recent comments on the National Trade Estimate Report) – including through the establishment of rules to ensure that the UK appropriately values and protects innovation – would facilitate greater access for U.S. biopharmaceutical exports in this market.

I. Building on Common Ground to Ensure Transparency, Due Process, and Appropriate Recognition of Value in Pricing and Reimbursing Pharmaceuticals

Pharmaceuticals face unique market access challenges. In particular, in most markets, market access for pharmaceuticals is dependent on manufacturers not only meeting strict regulatory approval standards, but also obtaining positive government pricing and reimbursement determinations. Due to long-standing market access barriers such as rigid health technology assessments (HTA), government price controls, insufficient health care budgets, and increasingly punitive and proactive national procurement initiatives and local barriers to

[3] See PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration (ITA), http://tse.export.gov/tse/tsehome.aspx (accessed Dec. 27, 2018).

[4] Id.

uptake, the ability of UK patients to access the latest, innovative medicines can be difficult. Recognizing these types of challenges in other countries, the United States has included specific pharmaceuticals (and medical devices) chapters in its recent FTAs (see, e.g., USMCA and the United States-South Korea Free Trade Agreement (KORUS)) to ensure that regulatory procedures and decisions regarding the pricing 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 also have 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 the specific implementation of all relevant laws, regulations, and procedures. Applications should be processed within a reasonable, specific period. If an application is deemed inadequate, then the applicant should be advised concerning what additional information is required to resume the application review process in a timely manner. Furthermore, if an application is denied, then the applicant should be provided the right of appeal to an independent and objective court or administrative body.

The pharmaceuticals chapters also have afforded a compelling opportunity to recognize the value that 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. Unfortunately, UK patients experience materially longer delays in accessing new medicines than patients elsewhere because of rigid national HTA processes, sub-national duplicative assessment or commissioning processes, and prescribing policies and incentives aimed at containing costs to meet unreasonable budgets.[5] For every 100 patients in comparable countries who get access to a new medicine in its first year of launch, only 18 patients in the UK receive the same.[6] Moreover, during the first 5 years after the launch of a new medicine, UK patients are significantly less likely to have access than patients living in other countries.[7]

Another key cause for the UK's low and slow patient access to new medicines is the high rate of rejections or imposition of restrictions by NICE, which operates using a standard cost-effectiveness threshold of between £20,000 and £30,000 per QALY. This threshold has not been revised – even in line with inflation – since NICE's inception in 1999. This results in ever-increasing requirements for protracted commercial negotiations. Innovative medicines exceeding a cost per QALY threshold of £30,000 (or £50,000 for end-of-life interventions) are generally viewed as not cost-effective, leaving clinically superior products that carry high development costs and/or small populations from which to recoup expenses without access. In addition, as companies develop new medicines, often in areas where there are many older off-patent medicines that are much lower in cost, demonstration of "cost-effectiveness" becomes exceedingly difficult by design.

[5] IQVIA. (2017). P&R Concise Guide: United Kingdom.

[6] OHE analysis of 61 medicines launched in the UK since 2007 compared to 16 countries (2014).

[7] Office for Life Sciences, "Life sciences competitiveness indicators," Apr. 2017.

Using QALYs to rigidly measure cost-effectiveness in this way fails to recognize the full value of innovative medicines and has turned the UK's HTA into a blunt cost containment tool. In this context, between March 2000 and December 2017, just 57% of all technology appraisals were recommended by NICE in-line with marketing authorization; while 23% were recommended in a restricted subset of patients, 1% under the Cancer Drug Fund (CDF), and 4% in research only – and 15% were rejected altogether. Recommendations for cancer medicines were even more restrictive with just 37% of cancer appraisals recommended in-line with marketing authorization; while 32% were recommended in a restricted subset of patients, 4% under the CDF, 3% in research only – and 27% rejected altogether.[8]

To promote development of innovative medicines and thereby ensure patient access to those medicines, the Parties must recognize that prices of medicines should be based on a variety of value criteria that reflect considerations such as the tangible benefits to patients and health care systems, patterns of disease burden, and national socio-economic indicators. Narrow approaches to HTA, such as rigid cost-effectiveness methodologies, should not be the principle framework for assessing value.

Finally, the proposed trade agreement should create 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 such a committee or working group as part of the proposed agreement.

II. Reinforcing Strong Intellectual Property Protections and Enforcement

Biopharmaceutical innovators – and the millions of jobs they support in the United States and the UK – rely on strong IP protection and enforcement to research and develop valuable new treatments and cures for patients. To drive discovery and to maintain the global competitiveness of their innovative economies, the United States and the UK should capitalize on this proposed agreement to reaffirm their existing IP commitments and to secure the highest international standards. Further, the UK and U.S. should seek similar commitments to strong IP from their trading partners as part of their free trade agreements with other countries. U.S. trade negotiators should prioritize results in the following areas:

- **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 (RDP) for biologics. Furthermore, contrary to recent proposals in the context of Brexit scenario planning for a no-deal outcome, any RDP provided in the UK should be measured from the date of first marketing approval in the UK, not in the European Union (EU) or elsewhere.[9]

[8] National Institute for Health and Care Excellence (NICE), available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data (last visited Jan. 15, 2019).

[9] See Department of Health and Social Care, How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal (updated Jan. 3, 2019), available at https://www.gov.uk/government/publications/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal/how-medicines-medical-devices-and-clinical-trials-would-be-regulated-if-theres-no-brexit-deal (last visited Jan. 15, 2019).

- **Patent Standards** – In view of the importance of IP for biopharmaceutical innovation, the proposed U.S.-UK trade agreement offers an opportunity to affirm a number of high-level IP principles. These are critical not only in the UK 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 be presented at a later date to support the patent application; and avoid over-restrictive and/or artificial criteria for added matter. Finally, courts must not extend their jurisdiction to adjudicate patentability or patent-worthiness of pending patent applications or subject matters that have not been claimed in an issued patent.

- **Grace Period** – Within the rubric of the European Patent Convention, seek the provision of a one-year grace period in the UK 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.

- **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 new medicine to patients. To encourage efficient review processes and to return some of the patent life lost to those delays, the patent term should be adjusted/restored to compensate for these delays. Such adjustment/restoration – whether accomplished through Supplementary Protection Certificates (as currently employed in the UK) or similar mechanisms – must 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 it would have been in but for the launch of the patent-infringing product. It is essential, therefore, that the UK maintain an effective patent enforcement system that allows for early resolution of patent disputes before an infringing product is launched on the market.

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,

manufacturing, review, and evaluation. Addressing these important issues can help to enhance drug development, optimize deployment of limited regulatory agency resources, and lead to expedited patient access to new, innovative, and life-saving medicines. In this regard, the biopharmaceutical industry would like to emphasize the significant historical partnership and coordination between the U.S. Food and Drug Administration and the UK Medicines and Healthcare Products Regulatory Agency internationally through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), with the participation of the UK previously facilitated through its membership in the EU. The development and implementation of ICH's technical and regulatory guidelines remain the cornerstone of international regulatory cooperation. Both the U.S. and UK currently have a high degree of implementation, and both should continue to seek global implementation of ICH guidelines.

Building on the regulatory provisions included in the recently concluded USMCA, the U.S.-UK Trade Agreement should include a Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) (similar to that concluded between the U.S. and the EU in 2017).

Similarly, an MRA for Good Clinical Practice inspections between the U.S. and UK 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 UK and U.S. regulatory authorities. Better alignment of pediatric scientific approaches between the UK 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. Finally, science and technology are 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 UK and U.S. on evolving science and technology (e.g., for new sources of evidence) to support the development of medicines and their assessment.

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 UK that is aligned with and leads emerging global standards. The proposed partnership offers an important opportunity for the two countries 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 UK should seek in all future trade agreements with other countries.

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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