aam
Association for Accessible Medicines

Your Generics and Biosimilars Industry

December 9, 2018

Mr. Edward Gresser
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, NW
Washington, DC 20230

RE: Negotiating Objectives for the U.S.-European Union Trade Agreement: Request to Testify and Written Comments (Docket Number USTR-2018-0035)

Dear Mr. Gresser:

In response to the above-referenced notice, the Association for Affordable Medicine (AAM) hereby submits its request to testify as well as written comments in preparation for the negotiation of a U.S.-European Union (EU) Trade Agreement. AAM represents manufacturers and distributors of generic pharmaceuticals and biosimilar medicines. Generic medicines comprise 90% of prescriptions dispensed in the United States, yet at only 23% of total prescription drug spending. In 2016, AAM members manufactured over 61 billion doses of prescription medicines in the United States at 149 facilities in 16 states. Our members manufacture generic and biosimilar medicines in the U.S. for domestic use and for export markets, including the EU.

AAM requests the opportunity to provide testimony at the December 14, 2018, hearing. The witness will be:

- Jeffrey K. Francer
  Senior Vice President & General Counsel
  Association for Accessible Medicines
  601 New Jersey Ave. NW, Suite 850
  Washington, DC 20001

  Tel: 202-249-7128

AAM's testimony will address the issues covered in the remainder of this submission.

I. Intellectual Property Rights and Access to Affordable Medicines

AAM and its members are driven by the belief that access to safe, effective and affordable generic and biosimilar medicines can improve patients' lives and provide savings to healthcare systems. In the last decade the availability of low cost generic medicines has saved U.S. patients, taxpayers, and insurers $1.67 trillion. AAM appreciates the opportunity to share its thoughts on objectives for the U.S.-EU Trade Agreement negotiations to ensure that the final agreement maintains the appropriate balance between intellectual property rights (IPR) protection and access to affordable medicines reflected conceptually in U.S. law and required by the Bipartisan Congressional Trade Priorities and Accountability Act (TPA) of 2015.

AAM supports provisions in U.S. trade agreements which, as required by the negotiating objectives in the TPA, maintain a balance "to ensure that trade agreements foster innovation and promote access to medicines" and the cost-savings that generic and biosimilar pharmaceuticals provide. Any trade agreement reached with the EU must maintain this careful balance.

We note at the outset that the U.S. and EU already have strong protection of intellectual property and strong engines for innovation under existing protections. Thus, it is unclear whether there needs to be a pharmaceutical IPR chapter. Europe still has lower levels of generic drug utilization compared to the U.S., and it therefore represents a significant market opportunity for the generic/biosimilar industry to grow. Accordingly, if the U.S.-EU free trade agreement does contain an IPR chapter, it should reflect a true balance between innovation and access to affordable medicines.

Without appropriate balance which facilitates and incentivizes the development, approval, and timely marketing of generic and biosimilar medicines, AAM opposes the inclusion of IPR provisions such as longer pharmaceutical data exclusivity periods or mandates to extend pharmaceutical patent terms based on delays in granting the patent or obtaining marketing approval. AAM does not believe that the current U.S.-Mexico-Canada Agreement (USMCA) pharmaceutical provisions establish the appropriate balance between protecting innovation and encouraging access to medicines and, thus, does not serve as an appropriate model for the U.S.-EU Trade Agreement.

If there is an IPR chapter in a U.S.-EU free trade agreement, AAM recommends that it address the following specific issues in order to facilitate the timely development of, and patient access to, generic and biosimilar products in the U.S. and the EU:

- **Access to foreign markets is critical for the development of biologics.** Like small-molecule generic medicines, biosimilars are projected to provide significant cost savings to patients in the U.S. and our healthcare system. One estimate suggests that biosimilars could save the U.S. healthcare system $250 billion over 10 years.[1] The global biologics sector is still young and is rapidly evolving. Delaying patient access to biosimilars in the EU harms patients, because U.S. biosimilar exporters would be blocked from potential markets, hampering their ability to invest in the development of biosimilars for the U.S. market – thus striking a new blow to the nascent and fragile biosimilars industry in this country. Moreover, including additional biologic exclusivity in trade agreements would mean that the Trump Administration would be hand-cuffed by an international agreement from lowering biologic exclusivity to fewer years if it were determined that such a change would be necessary to create a vibrant biosimilar market competition in the U.S. – a severe infringement on U.S. sovereignty and policy options.

  Allowing each FTA partner to adopt the exclusivity period that best suits its industry will ensure that the market can adjust as needed to maintain the balance between fostering innovation and bringing cost-saving biosimilar alternatives to patients. Being able to sell new biologics in markets beyond the United States allows the fixed costs of developing these products over a much broader patient base.

- **Enhance generic competition by requiring an incentive to promote generic competition.** Currently, the U.S. is one of the only countries in the world that has an intellectual property framework that includes a reward to promote generic competition. This framework has served as an incentive to challenge the validity or applicability of non-innovative pharmaceutical patents, thus helping to expedite entry of generic drugs to the market for the benefit of patients, insurers, and U.S. taxpayers. This mechanism, which is often referred to as "paragraph IV 180-days exclusivity," has been, since its implementation, a driver of early generic access and has contributed greatly to the number of

[1] Miller S. The $250 Billion Potential of Biosimilars. Express Scripts website. April 23, 2013. Available at: http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars .

patent challenges. Establishing a formal system to reward generic competition, *e.g.*, 180-day exclusivity, would enhance the market for U.S.-made generic medicines in the EU.

- **Provide a clear regulatory review ("Bolar") provision.** Consistent with U.S. law, a clear, specific regulatory review clause allows generics and biosimilars manufacturers to use a patented invention during the period of patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval from health regulatory authorities. The regulatory review clause is an important provision, which facilitates the production and introduction of generics and biosimilars manufacturers into the market on the date of patent expiry. While the USMCA provides for an undefined "regulatory review" exception, the current language does not provide necessary certainty and clarity. A stronger regulatory review clause is needed to allow generic and biosimilar manufacturers to use a patented invention during the period of patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval from health regulatory authorities. The regulatory review clause is a crucial provision that facilitates the introduction of generics and biosimilars into the market on the date of patent expiry. The U.S.-EU Trade Agreement should provide for a Bolar provision that is just as clear and robust as that granted in U.S. law to ensure the timely launch of generics and biosimilars upon patent or exclusivity expiry.[2]

- **Best Mode.** Under U.S. law, a patent specification must "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."[3] As the U.S. Patent and Trademark Office has noted, "The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves."[4] According to the TRIPs Agreement, patent authorities may require the applicant to indicate the best mode for carrying-out the invention

[2] 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.")
[3] 35 U.S.C. § 112(a).
[4] U.S. Patent and Trademark Office, Manual of Patent Examining Procedure, Ch. 2100 § 2165 "The Best Mode Requirement," *available at* https://www.uspto.gov/web/offices/pac/mpep/s2165.html .

known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. Therefore, under the best mode requirement if there are several ways in which the invention may be put into practice, the applicant can be required to disclose that which is most practicable. Consistent with U.S. law, the U.S.-EU Trade Agreement patent provisions should make disclosure of the best mode mandatory.

- **Ensure the scope of any biologics protection is not broader than that provided for in U.S. law.** USMCA could be interpreted to mandate that countries provide at least 10 years of biologic exclusivity for certain pharmaceutical products that Congress has chosen to exclude from the scope of biologic exclusivity under U.S. law. Specifically, in defining a biologic subject to exclusivity, section 351(i)(1) of the Public Health Service Act expressly excludes a protein that is a "chemically synthesized polypeptide." Article 20.F.14.2 of the proposed USMCA contains no such exception. Accordingly, a protein that is a chemically synthesized polypeptide would appear to be entitled to biologic exclusivity under the agreement, even though those products are not biologics in the U.S. and therefore not entitled to biologic exclusivity under our statute. In USMCA, the definition of a biologic limits the scope to products produced "using biotechnology processes." However, the remainder of the definition is written with a high degree of specificity, and largely tracks the U.S. statutory definition – but drops the explicit exception. If the U.S.-EU Trade Agreement includes an exclusivity period for biologics, the scope of this provision should be clarified in some fashion to fully capture all aspects of the definition used in U.S. law, including the exception.

II. Technical and Regulatory Barriers to Trade in Pharmaceuticals

The pharmaceutical sector is global in nature, and U.S. companies are currently unable to leverage fully their global supply chains when seeking to bring new, more affordable generic or biosimilar medicines to patients. The regulatory environment for generic medicines has not kept pace with the market-driven globalization of pharmaceutical supply chains. The U.S.-EU Trade Agreement presents an opportunity to address technical and other regulatory barriers that restrict market access for U.S. exports of generic and biosimilar products. Specifically, an agreement with the EU should incorporate provisions to address:

- **Regulatory Harmonization and Recognition.** The inclusion of provisions that will facilitate a single development program for generic and biosimilar medicines and decrease the burden of redundant inspections by regulators will expedite development and trade in prescription medicines generally. In particular, regulatory harmonization should include the following:

    - Creation of single development programs for generic, complex generic, and biosimilar medicines. The Directorate-General for Health and Food Safety (DG SANTE), the European Medicines Agency (EMA), and the U.S. Food and Drug Administration (FDA) all support global development for pharmaceuticals, have signed a confidentiality commitment, and have longstanding cooperation in many pharmaceutical areas, including the November 2017 mutual recognition agreement of inspections of manufacturing sites for human medicines in their respective territories. Therefore, the U.S.-EU trade agreement presents a critical opportunity to further cooperate on a true single EU/U.S. development framework for biosimilar medicines.

    - Development of a biosimilars framework that would allow bridging studies to be waived in specific circumstances based on core scientific and regulatory principles established for current products. This will avoid unnecessary, and therefore unethical, clinical bridging studies. It will also eliminate the multiplication of the same bridging studies by different sponsors, support true global development, reduce development and approval timelines and thereby improve patient access and affordability for health systems overall and increase competition.

- **Regulatory Approval for Generic Drugs.** Regulators should ensure timely review of generic medicines with a special emphasis on expediting the approval of "first generics" – instances where there is not generic competition with the branded drug.

AAM appreciates the opportunity to provide input on the upcoming U.S.-EU Trade Agreement negotiations. We look forward to working with you on these and other matters on the Administration's trade policy agenda.

Sincerely,

/s/

Jeffrey K. Francer
Senior Vice President & General Counsel