

June 12, 2017

**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  
DOC-2017-0006

**Re: Request for Comments on Negotiating Objectives Regarding Modernization of The North American Free Trade Agreement with Canada and Mexico, 82 Fed. Reg. 23,699 (May 23, 2017)**

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 on negotiating objectives regarding modernization of the North American Free Trade Agreement (NAFTA) with Canada and Mexico, 82 Fed. Reg. 23,699 (May 23, 2017).

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. Innovators in this critical sector depend on strong regulatory systems, robust intellectual property protections and enforcement, and on fair and transparent access to overseas markets. With the right policies and incentives in place at home and abroad, they can continue to bring valuable new medicines to patients and contribute powerfully to the American economy.

NAFTA has provided a framework for encouraging biopharmaceutical trade throughout North America. NAFTA helped to secure Canada and Mexico as top destinations for U.S. biopharmaceutical exports in large part due to its effect on the elimination of tariffs and duties. In 2016, the biopharmaceutical industry exported more than \$52 billion in biopharmaceuticals, including \$3.9 billion to Canada and \$1.4 billion to Mexico, making the sector one of the top U.S. exporters among intellectual property-intensive industries.<sup>i</sup> Together, our NAFTA partners account for more than 10% of total U.S. biopharmaceutical exports.<sup>ii</sup>

Still, the U.S. is currently experiencing a \$717 million trade deficit in pharmaceutical products with Canada and a shrinking \$1.2 billion surplus in pharmaceutical products with Mexico.<sup>iii</sup> As highlighted previously by a Department of Commerce study on U.S. manufacturing, one important means of promoting U.S. growth and jobs in the manufacturing sector is to open markets for U.S. products.<sup>iv</sup> Given its highly competitive nature, the U.S. biopharmaceutical industry offers a very promising means to address trade imbalances through expanded U.S. exports.

U.S. biopharmaceutical manufacturers rely on predictable and transparent intellectual property (IP) policies that support innovation ecosystems to produce valuable new medicines for patients. These

policies are fundamental to innovation, providing necessary incentives for the discovery of new treatments and cures, and also fundamental to sustaining continued economic growth and job creation in America. While NAFTA provided a strong baseline for protection of IP, which helped shape the World Trade Organization Agreement (WTO) on Trade-Related Aspects of Intellectual Property Rights (TRIPS), there are several areas where gaps remain. Addressing Canada and Mexico's trade impediments (further detailed in the attached paper), including the lack of or inadequate enforcement of existing NAFTA obligations, as well as ensuring that both partners properly value and protect innovation, optimize customs operations and rules, and abide by procurement obligations, would allow U.S. biopharmaceutical exports to expand and thereby help to balance existing trade flows.

We stand ready to engage with the Administration as it defines a path forward in NAFTA renegotiations. Consistent with the Bipartisan Congressional Trade Priorities Act of 2015, the review of our trading relationship with our North American partners provides an opportunity to examine the implementation of existing obligations and to ensure that provisions reflect standards that are found in U.S. law. Should the U.S. Government pursue robust negotiating objectives related to NAFTA, advancing policies that promote and reward medical innovation should be a priority.

Sincerely,

/s/

Jay T. Taylor

## I. Implement and Enforce Existing NAFTA and International Obligations

As a first step, reviewing our trading relationship with Mexico and Canada provides a critical platform for the United States to seek to resolve a number of outstanding issues that stem from the failure to implement or enforce existing commitments under NAFTA and other existing international obligations. This is a potentially productive basis to effectively address such practices to spur U.S. innovation and regain a level-playing field for U.S. companies. At a minimum, the U.S. Government should:

- **Enforce patentability standards:** Contrary to NAFTA and longstanding international obligations and norms, the Canadian judiciary has created a new and heightened standard for determining patent “utility.” This standard, referred to as the “promise doctrine,” has resulted in 28 court decisions invalidating 25 biopharmaceutical patents for lack of utility since 2005. This doctrine has also been applied in a discriminatory manner: since 2005, not a single non-biopharmaceutical patent has been revoked for lack of utility. No other country has a patent utility test like Canada’s – none of the patents revoked by Canada have been found to lack utility in any other country.

NAFTA trading partners are required to determine patentability according to the standards set forth in NAFTA, which provide that, if any invention is new, non-obvious, and useful (“utility”), that invention is entitled to be patented. Specifically, it is well-accepted that inventions possess utility if they can be made or used in any kind of industry, including biopharmaceuticals.

Unfortunately, a recent NAFTA Tribunal did not address whether the “promise doctrine” is consistent with NAFTA rules (issuing its decision based on a threshold investment dispute issue). Canada remains the only country in the world that interprets patent utility in this manner, breaking the letter and spirit of its NAFTA and other international commitments on IP rights. This doctrine continues to undermine patent protection and removes a critical incentive that drives and sustains biopharmaceutical innovation.

- **Enforce and implement provisions protecting confidential business information – including regulatory data protection:** The protection of confidential business information and regulatory data protection (RDP) remain uncertain with both NAFTA trading partners. Mexico has taken initial steps to implement RDP provisions in 2012 by issuing guidelines to key federal agencies. However, the guidelines can be rescinded at any time because they have not been reflected in any national regulations or legislation. They also do not explicitly recognize biologic medicines as “new chemical entities” – a term used in NAFTA and well-accepted to include small molecule and biologic medicines.

NAFTA and TRIPS also require confidential business information (CBI), including biopharmaceutical clinical trial and other data, to be protected against disclosure except where “necessary to protect the public.” However, Canada has lowered this objective threshold by permitting the Ministry of Health to disclose CBI related to biopharmaceutical products if the Minister “believes” that the information “may” protect the public. There is no necessity requirement for disclosure to occur, only that it be related to protecting or promoting health. NAFTA and other international obligations do not refer to disclosure for the promotion of health, but rather disclosure needed to protect health of the public.

## II. Promote Adequate and Effective Protection of American Medical Innovation

As the Administration considers objectives for negotiations, ensuring that NAFTA continues to encourage and value innovation will significantly contribute to greater opportunities for trade and investment and improve U.S. biopharmaceutical competitiveness. This may include augmenting objectives and principles of previously negotiated outcomes by securing commitments that reflect a standard of protection similar to that found in U.S. law. Such commitments should appropriately recognize and reward the value of innovative medicines, provide due process, reflect international best practices and norms, and uphold 21<sup>st</sup> century-level IP standards. These commitments are critical features of U.S. law that are reflected in a number of U.S. trade agreements entered into since NAFTA. Should the U.S. Government pursue robust negotiating objectives related to NAFTA, the U.S. Government should secure commitments that:

- ***Create early and effective resolution mechanisms for patent disputes:*** Mechanisms such as patent linkage and effective preliminary injunctive relief, which provide for the early resolution of patent disputes before potentially infringing follow-on products enter a market, are essential for effective enforcement. The premature launch of a product that is later found to infringe a patent may disrupt patient treatment, require governments to adjust and re-adjust national formularies and reimbursement policies, and cause commercial damages that are impossible to repair later. For example, in Mexico the process for seeking and enforcing a preliminary injunction is especially onerous for the patent holders as preliminary injunctions may be lifted by filing a counter-bond only and seeking damages for a patent infringement requires both civil and administrative decisions. Furthermore, although it had appeared within the context of the Comprehensive Economic Trade Agreement (CETA) with the EU that Canada would provide innovators with a right of appeal equivalent to that provided to generic companies, the proposed regulations to implement this commitment are contrary to this objective.
- ***Refine regulatory data protection rules:*** Regulatory data protection (RDP) complements patents on innovative medicines and provides critical incentives for investment in new treatments and cures. As in the U.S., NAFTA should be updated to provide five years of RDP for combination products containing at least one new active ingredient and three years of RDP for new clinical information submitted to secure marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration. Moreover, RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Because they are often made through the use of living organisms, biologics are so complex that it is possible for follow-on manufacturers to produce a version, “biosimilar,” of the original biologic that may not be covered within the scope of the innovator’s patent. For this reason and others, U.S. law provides twelve years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.
- ***Enhance patent term restoration mechanisms for delays caused by regulatory processes:*** Patent term restoration provisions in trade agreements and national laws are critical to address unreasonable patent examination delays and some portion of the time incurred in getting a new medicine on the market. Such provisions support initiatives to increase the efficiency of patent prosecution, reduce patent backlogs, and expedite marketing approval and reimbursement reviews. Moreover, any implementation of patent term restoration that does not confer full patent rights,

e.g., that would provide an exception for “manufacturing for export” or other infringing activities, would not be consistent with the fundamental purpose of restoring a portion of the patent term lost during the marketing approval or reimbursement review processes and should not be permitted.

- ***Refine patentability standards:*** National laws, regulations or judicial decisions that prohibit patents on certain types of biopharmaceutical inventions or impose additional or heightened patentability criteria restrict patient access to valuable new medicines and undermine investment in future treatments and cures. These restrictions prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can improve health outcomes and reduce costs by making it easier for patients to take medicines and by improving patient adherence to prescribed therapies.
- ***Clarify limited exceptions to patent rights:*** Patents drive and enable research and development that delivers new treatments and cures. Limited exceptions to patent rights, including compulsory licenses, should be considered in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made on public health grounds through fair and transparent processes that involve participation by all stakeholders and consider all the facts and options.
- ***Adopt clear rules related to the research exemption and corresponding border measures:*** Mexico allows generic manufacturers to import active pharmaceutical ingredients and other raw materials contained in a patented pharmaceutical to conduct research during the last three years of the patent term in order to generate information necessary to support an abbreviated application for marketing approval. It does not, however, provide appropriate safeguards to ensure that the quantities of patented raw pharmaceutical ingredients imported under these provisions are strictly limited to research activities and thus do not conflict with a patent owners’ legitimate interests. As part of the NAFTA renegotiations, provisions should be included to ensure that Mexico implements such safeguards.
- ***Ensure that pricing and reimbursement decisions appropriately recognize and reward the value of medicines:*** Policies imposed by trading partners that artificially lower the prices of medicines can hamper investment in research and development and delay or reduce the availability of new medicines for patients. In order to address these concerns, government pricing policies should appropriately recognize the value of innovative pharmaceuticals, for example, by making determinations through competitive market-based mechanisms. As such, the NAFTA renegotiations provide an opportunity, per the U.S. Trade Promotion Authority granted by the Bipartisan Congressional Trade Priorities Act of 2015, “to ensure that government regulatory reimbursement regimes [in Mexico and Canada] are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for United States products.” In Canada, for example, the Patented Medicines Pricing Review Board (PMPRB) is seeking to update its pricing guidelines and the Ministry of Health has recently announced its intent to update pricing regulations. Changes to the PMPRB mandate could affect how Canadian pharmaceutical prices are established and benchmarked against pricing in other markets, which could potentially impact patient access to medicines.

- ***Ensure that procedures and rules that apply to pharmaceutical pricing and reimbursement decisions are predictable and transparent:*** The intensive investment in the development of innovative medicines requires a predictable and transparent public policy environment that fosters medical advancements and a favorable business environment. This includes creating efficient and transparent processes for bringing new medicines to market, such as publishing rules related to pricing and reimbursement in advance of adoption, making decisions in a timely fashion, and allowing stakeholders meaningful opportunity to participate in the development of rules and regulations in the pharmaceutical sector.
- ***Ensure transparency and application of international standards in the drug approval process:*** A strong regulatory framework not only ensures patients have fast access to safe, high-quality, and effective medicines, but also encourages scientific research and innovative drug development. Technical regulations, standards, and conformity assessment procedures, including marketing authorization and notification procedures, should seek to adopt harmonized regulatory best practices and international, science-based regulatory standards. Linking regulatory approval with pricing decisions, for example, is inconsistent with international, science-based regulatory standards and risks distorting regulatory science decisions with budgetary considerations.

---

<sup>i</sup> PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration (ITA), <http://tse.export.gov/tse/tsehome.aspx>.

<sup>ii</sup> U.S. International Trade Commission, Dataweb. U.S. Domestic Exports for NAICS Code 3254 (Pharmaceuticals).

<sup>iii</sup> U.S. International Trade Commission, Dataweb. U.S. Trade Balance with Mexico and Canada for NAICS Code 3254 (Pharmaceuticals).

<sup>iv</sup> U.S. Department of Commerce, Manufacturing in America: A Comprehensive Strategy to Address the Challenges to U.S. Manufacturers, January 2004, at 10, [https://www.nist.gov/sites/default/files/documents/2017/05/09/DOC\\_MFG\\_Report\\_Complete-2.pdf](https://www.nist.gov/sites/default/files/documents/2017/05/09/DOC_MFG_Report_Complete-2.pdf).