Your Generics and Biosimilars Industry

April 17, 2020

The Honorable Lisa R. Barton
Secretary
International Trade Commission
500 E Street SW
Washington, DC 20436

Re: *COVID-19 Related Goods: U.S. Imports and Tariffs* (Inv. No. 332-576)

Dear Ms. Barton:

The Association for Accessible Medicines (AAM) is pleased to provide comments on the International Trade Commission's investigation into imported goods related to the fight against COVID-19 announced in your April 13, 2020, press release announcing the investigation. AAM represents the manufacturers and distributors of finished generic pharmaceuticals, biosimilars, and bulk pharmaceutical chemicals and suppliers of other goods and services to the generic drug industry. AAM and its members are driven by the belief that access to safe, effective and affordable generic and biosimilar medicines can improve people's lives and provide significant savings to the U.S. healthcare system. AAM members provide more than 36,000 jobs at nearly 150 facilities, and manufacture more than 61 billion doses of prescription medicines in the United States every year.

Finished pharmaceuticals and API are critical to the fight against COVID-19, whether as testing components, vaccines, or treatments. More than 80 clinical trials are underway in the United States testing both new and existing drugs for their effectiveness against COIVD-19. For the reasons explained below, finished pharmaceuticals and active pharmaceutical ingredients (API) were removed from the Annex of products subject to additional Section 301 duties. Imposing an additional tariff on these products would have caused economic harm to U.S. interests, specifically U.S. interest in lowering the cost of prescription drugs. For similar reasons, the Administration should avoid other measures that would disrupt existing pharmaceutical supply chains at a time when they are being stressed to deliver critical drugs to sick patients in the United States.

A. Finished Pharmaceutical Products and API Should Remain Free From Tariffs

AAM and its member companies successfully argued against imposing an additional 25 percent duty on pharmaceutical products and API. Imposing tariffs would cause disproportionate economic harm to U.S. interests, including the interests of consumers, by dramatically increasing the cost of prescription drugs. AAM has been aligned with President Trump's objective of lowering prescription drug prices. A vibrant generic and biosimilar industry in the United States is key to that objective. The use of generic drugs in the United States resulted in $292.6 billion dollars in savings in 2018 and

nearly $2 trillion in the ten-year period (2009-2018).[1] Generic drugs are also a critical tool to tackle the U.S. deficit. Together, generic usage by Medicare and Medicaid saved taxpayers more than $137 billion last year.[2] The potential savings are also significant in the developing biosimilars industry, which has been projected to create as much as $54 billion in additional savings over the next decade.[3] Adding a tariff on pharmaceuticals is a significant departure from the United States' approach to pharmaceutical tariffs for the past 20 years. Since 1995, the United States and 21 of its trading partners have eliminated import duties on pharmaceuticals and API under the WTO Pharmaceutical Agreement.[4] Imposing tariffs on pharmaceuticals such as API would undermine efforts to increase U.S. pharmaceutical manufacturing in the United States the cost of manufacturing generics and biosimilars in the U.S. and, thus, raising prescription drug prices for patients.

B. The Administration Should Avoid Other Measures That Interrupt Existing Pharmaceutical Supply Chains

The fight against COVID-19 has drawn attention to the global nature of today's supply chains, including for pharmaceuticals. AAM members support the diversification of the pharmaceutical supply chain — and incentives to increase manufacturing in the United States — over the long term. But in the near term, the Administration must avoid actions that could disrupt global supply chains and hinder our response to the COVID-19 emergency.

Generic and biosimilar medicines play an integral role in America's health and well-being. In addition, generic manufacturers are directly involved in the treatment and care of patients with COVID-19. Generic medicines help treat the symptoms of the illness (for example, acetaminophen to reduce fever and cough suppressants such as dextromethorphan) and AAM's members are partnering with health organizations and governments around the world to evaluate the use of currently available generic medicines for the treatment of patients with COVID-19.

In order to meet the health care needs of America's patients, 60 percent of all generic finished dosage form (FDF) facilities and 87 percent of all generic active pharmaceutical ingredients (API) facilities are currently located outside of the United States. Shifting the manufacturing and production of generic medicines and API to the United States to diversify the supply chain is a desirable long-term goal, but it is simply not feasible in the short-term and would negatively impact patient access to low-cost generics. Current regulations and costs – setting aside the additional economic limitations posed by COVID-19 – require 5-10 years and up to $1 billion to establish a new FDA-approved facility in the

[1] AAM, "Generic Drug Savings and Access in the United States," 2019, p. 10.
[2] AAM, "Generic Drug Savings and Access in the United States," 2018, p. 4.
[3] AAM, "Generic Drug Savings and Access in the United States," 2019, p. 16.
[4] Nilanjan Banik & Philip Stevens, *Pharmaceutical Tariffs, Trade Flows and Emerging Economies*, Geneva Network (2015), https://geneva-network.com/article/medicine-tariffs-make-sense/.

United States. Even shifting production from one facility to another requires FDA approval, a minimum of 18 months and an investment of several million dollars.

Actions such as proposals to apply "Buy America" provisions to the manufacturing and production of generic medicines and API or imposing tariffs on pharmaceutical imports into the United States would disrupt already-stressed pharmaceutical supply chains and could ultimately limit patient access to essential medicines, increase the risk of shortages, and increase the cost of prescription drugs. Diversifying supply chains, including through an increased manufacturing presence in the United States, is a critical goal for the generic and biosimilar industry. However, any immediate requirement for increased U.S. manufacturing of API or finished pharmaceuticals would be impossible to meet and thus could have a detrimental impact on the supply of medicines for America's patients. This is especially important now when the supply chain for many manufacturers is stressed due to the COVID-19 crisis.

C. Conclusion

AAM's members provide essential medicines that improve the clinical therapy of our patients in the United States against some of the most pressing health conditions, including COVID-19. Global competition in the pharmaceutical sector has successfully helped to drive down drug costs and prevent shortages in the U.S., particularly for generic medicines. To avoid increasing the cost of critical drugs or creating even greater stress on already fragile supply chains, the ITC's 332 report on COVID-19 should recognize the importance of finished pharmaceuticals and API in the fight against COVID-19 and recommend against the use of tariffs or other regulations requiring the manufacture of generic or biosimilar medications in the United States.

Sincerely,

/s/

Jonathan Kimball
Vice President, Trade and International Affairs