



May 11, 2018

[Submitted electronically via regulations.gov]
Office of the United States Trade Representative
600 17th St. NW
Washington, DC 20006

RE: Notice of Determination, Request for Comments, and Notice of Public Hearing
[Docket No. USTR–2018–0005]

ASHP thanks the United States Trade Representative (USTR) for the opportunity to comment on the proposed tariffs for certain Chinese imports. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

As the USTR determines which products should be subject to tariffs, we urge caution in applying these penalties to the active pharmaceutical ingredients (API) used in the manufacture of finished pharmaceuticals for American consumers. We are concerned that tariffs may disrupt supply of API, which could, in turn, upend pharmaceutical manufacturing and create new medication shortages or exacerbate existing shortages.

Hospitals, health systems, and other healthcare facilities face intermittent shortages of critical medications, often due to manufacturing delays but sometimes attributable to natural disasters or supply-and-demand problems.¹ Both the U.S. Food & Drug Administration (FDA) and ASHP maintain drug shortages lists that track drug availability and provide detail, when available, about the reasons for shortages.² In the past year, providers have encountered shortages of such basic products as saline, sterile water, and small-volume parenterals, which are the foundation of intravenous (IV) bags. Currently, hospitals and other providers are facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. IV opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, are also used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. Having diminished

¹ ASHP, Drug Shortage Statistics, available at <https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>

² ASHP shortage list, which is maintained in partnership with the University of Utah, is available at <https://www.ashp.org/drug-shortages/current-shortages>. FDA's shortage list is available at <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. Generally, ASHP's list is more comprehensive, including regional shortages and product that is currently being produced but is not available through the supply chain, while FDA's list includes only those products that are not being produced. Additional information regarding differences between the lists is available at <https://www.ashp.org/Drug-Shortages/Current-Shortages/FDA-and-ASHP-Shortage-Parameters>.

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supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for healthcare staff.

While supply of API is not the cause of the shortages mentioned above, application of tariffs to API could result in significant unintended consequences, including manufacturing disruption or delay. Any resulting shortages could have serious ramifications for patient care in the United States. Thus, we strongly urge the USTR to consult with the FDA about the possibility of shortages before imposing any tariffs on API.

We thank the USTR for the opportunity to comment on the proposed tariffs, and we stand ready to assist your office in any way possible. Please contact me via email at jschulte@ashp.org or by phone at (301)-664-8698 if you have any questions or wish to discuss our comments further.

Sincerely,

A handwritten signature in black ink that reads "Jillanne Schulte Wall". The signature is written in a cursive, slightly slanted style.

Jillanne Schulte Wall, J.D.
Director, Federal Regulatory Affairs