



COLLEGE of AMERICAN PATHOLOGISTS

October 15, 2025

The Honorable Howard Lutnick
Secretary
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Re: Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices (XRIN 0694-XC134)

Dear Secretary Lutnick,

The College of American Pathologists (CAP) appreciates the opportunity to comment on the *Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices*. The CAP is deeply concerned about the impact of tariffs on laboratory products, including diagnostic medical supplies, equipment, and devices. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, we serve patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of using diagnostic products to deliver high quality diagnostic services to patients and other physicians. Pathologists consistently rely on access to supplies like test kits, plastic pipette tips, specimen acquisition swabs and transport media, much of which is impacted by the medical supply chain, to diagnosis cancer, infectious diseases and other emergent pathogens. These products are necessary for pathologists to deliver the timely, accurate, and necessary testing Americans need for diagnosis and care planning.

Given the extreme importance of these products to pathologists, the patients they serve, and the health of our great nation, the CAP urges the administration to exempt medical device products from the imposed tariffs, particularly those products necessary for the development and provision of critical diagnostic services. Further, the CAP urges the Administration to pursue an exemption from these products, in its negotiations, from any retaliatory tariffs other countries might impose.

Since the tariffs were announced, our members have reported that laboratories are experiencing increased prices of laboratory equipment and medical supplies due to the tariffs. Manufacturing companies are itemizing "tariff surcharges" on invoices. Laboratories, hospitals, and health systems have no way to cover these additional costs because reimbursements have not increased. These additional costs, on top of federal and private payer reimbursement cuts, could delay and/or limit necessary testing, accelerate consolidation, decrease innovation in laboratory medicine, and compound the difficulties pathologists currently face in managing declining and shifting resources as



they continue to care for the communities they serve. Ultimately, increased financial pressure on providers, hospitals, and health systems, particularly those located in rural and medically underserved areas, will threaten patient access and care.

Department of Commerce Request for Information Comments

We offer the following examples in response to the Department of Commerce's request for comments and information regarding:

(ii) the extent to which domestic production of PPE, medical consumables, and medical equipment, including devices, can meet domestic demand;

- Laboratories are experiencing increases in the prices of personal protective equipment and disposable plastics – which are very important in the lab because what we do in testing involves a lot of pipette tips and cartridges.
- Companies that manufacture plastic parts may begin looking at domestic manufacturing. But one thing that's somewhat unique about laboratory inventory is that precision is incredibly important. Pipettes and tubes have very, very tight tolerances in terms of size and volume. Though products are disposable, they are not made from cheap plastic. They are expensive and the process of manufacturing is expensive. Increased domestic production and new US manufacturing facilities are not feasible in the short term.
- We are also seeing price increases for polymerase chain reaction (PCR) test materials. Pathologists use PCR methods to test for infectious diseases, to look for genetic changes in tumors, to diagnose genetic diseases, or to identify viruses, bacteria, fungi, and parasites. PCR tests are very sensitive and assist with detecting low viral loads and infections in vulnerable individuals.
- The tariffs are also affecting blood collection bags/sets. Blood centers have been absorbing the cost of the tariffs, but they have announced implementation of tariff surcharge recovery fees on all red blood cell units. One center is charging \$3 per red blood cell unit.

“(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for PPE, medical consumables, and medical equipment, including devices.”

- We have begun to see an increase in the cost of reagents, as some are manufactured overseas. A reagent is a substance used to carry out a laboratory test. Reagents may be used in a chemical reaction to detect, measure, or make other substances. We're hearing that there's a particular increase in reagents dealing with molecular analysis, which looks at genomic analysis, DNA and RNA. Those are very specialized reagents, and many of those are manufactured overseas.
- The US imported over \$60 billion of in-vitro diagnostic (IVD) testing materials in 2024. According to data from the US Bureau of Labor Statistics that was analyzed by the *National Journal*, most of the IVD imports (total of \$20 billion) came from Ireland, followed by \$9.8 billion from Singapore, \$6.9 billion from Germany, around \$5.5 billion each from Netherlands



COLLEGE of AMERICAN PATHOLOGISTS

and Japan, \$3 billion from Belgium, a little over \$2 billion from United Kingdom and Italy, and \$1 billion from Austria.

The CAP understands the Administration's desire to incentivize domestic manufacturing, but until that happens in sufficient quantities to allow pathologists to continue to provide top-quality care for their patients, the CAP urges the Administration to exempt medical device products from any tariffs. We look forward to working with the Administration, Congress, and other agencies to help promote and advance policies that achieve the best care possible for our nation's most valuable assets, its people. Please contact Michael Hurlbut at mhurlbu@cap.org if you have any questions or would like to discuss our request.

Sincerely,
College of American Pathologists