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May 7, 2025

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Re: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket No. 250414-0065, XRIN 0694-XC120]

Dear Deputy Assistant Secretary Longnecker and Director Astle,

Thank you for the opportunity to comment on the issue of pharmaceutical tariffs and their impact on patients in the United States.

We respectfully request that you do not impose tariffs on pharmaceutical products and that, at a minimum, imports from friendly nations (e.g., EU countries, United Kingdom, Switzerland, Canada, Mexico, India, et al), and other non-hostile countries, be exempted from pharmaceutical tariffs.

A tariff on pharmaceutical products is the wrong battle, on the wrong battlefield, against the wrong enemy—and it will be American patients who are the victims.

Before we elaborate on our position, it is important to understand that our perspective is based on our mission: ICAN, International Cancer Advocacy Network, is dedicated to helping Stage IV cancer patients—the most serious stage of cancer. As a 501(c)(3) tax-exempt charitable organization (EIN 86-0818253), we have assisted the complex cases of more than 19,000 Stage IV patients in all 50 states and 82 countries since our founding in 1996 (<https://askican.org>).

Our goal is to extend life with the highest achievable quality of life. ICAN’s small staff and nearly 100 volunteers provide numerous services—at no cost to patients and families—and connect patients to second opinions and appropriate clinical trials. ICAN helps patients understand the importance of molecular profiling, their anatomic pathology report, and their molecular diagnosis (germline and somatic). We connect patients to opportunities for compassionate use. We provide oncology nursing services to help patients navigate side effects as handling side effects is often the key to staying on a drug and letting it work. Everything we do ultimately revolves around access to finding the best drugs at the right time.

In addition, ICAN now leads four rare cancer groups:

- **Biomarker Collaborative** (<https://biomarkercollaborative.org>) is a consortium of biomarker groups and general cancer organizations emphasizing comprehensive biomarker testing and clinical trials.
- **Exon 20 Group** (<https://exon20group.org>) is an international coalition and multi-stakeholder organization dedicated to better managing and then curing cancers caused by two gene mutations each found in more than 25 cancers: EGFR exon 20 and HER2 exon 20 insertions.
- **MET Crusaders** (<https://metcrusaders.org>) focus on MET gene alterations: METex14 skipping mutation/amplification/overexpression.
- **PD-L1 Amplifieds** (<https://pdl1amplifieds.org>), focus on “PD-L1 Amplification” a diagnosis found only by next-generation sequencing (NGS)/comprehensive biomarker testing. If found, PD-L1-amplified patients may be candidates for immune checkpoint blockade therapy.

All of these Stage IV patients are dependent upon access to drugs now and in the future. The goal is to keep one step ahead of the cancer. Some are cured. Many have their lives extended for a precious five or even ten or more years—and die of something else (often old age).

We believe that tariffs on pharmaceutical products would hurt these patients—and all patients who are fighting lethal and chronic diseases.

This is our reasoning:

Tariffs on pharmaceutical imports will almost certainly have a negative effect on two key areas of concern to all patients:

- 1) Negative effects on access to the best medicines available now.
- 2) Negative effects on the development of the best medicines available in the future through the drug discovery pipeline.

1) **Access to the Best Medicines Now:** Fighting a lethal or chronic disease is not the same as making a consumer purchase. When consumers choose among competing commercial products—some of which might be produced in the United States versus those made in other countries such as automobiles—they can factor in price, quality, and other considerations, including the most fundamental decision of all: whether to buy or not. Patients fighting lethal and chronic diseases usually do not have the luxury of choosing among good alternatives—let alone choosing not to “purchase.” They must be on a regimen, and that regimen is what has been determined through the clinical trials process, and through experience, to be the best regimen that gives them the greatest chance of a cure, a longer life, fewer side effects, and so forth.

If pharmaceutical tariffs lead to patients either not being able to afford the treatment, or health care systems taking the drug out of their formulary, or access reduced or denied for any other reason due to the tariffs, then patients will suffer.

Ask yourself about such a treatment decision if it was your loved one, a friend, or you: You would want access to the best drug available.

There should be no doubt that costs of the top cancer drugs will rise if tariffs are imposed: First, through a tariff on imported drugs. Foreign companies, such as Astellas, Astra Zeneca, Daiichi Sanyko, Novartis, Roche, Takeda, Taiho, among others, are all responsible for critical drugs that save, extend, and improve American lives. For many patients, there are no equivalent substitutes and make no mistake about it: it is patients who will pay the ultimate price. Second, costs of drugs manufactured by American companies in America for American consumers will also rise because of the tariff on pharmaceutical components used in their manufacture.

One great irony of the proposed tariffs is that much of this increased cost will be paid by the federal government. Medicaid, Medicare, the VA, and federal employee health programs will all be picking up the tab for the increased cost of pharmaceuticals for the patients in their programs. Although cancer (and other lethal and chronic diseases) can affect anyone at any age, it is disproportionately found in older people—thus Medicare and the VA will be paying for most seniors. Many of the non-seniors will have their healthcare covered by Medicaid, federal health programs, or the VA.

Tariffs will hurt our domestic manufacturers. Our pharmaceutical manufacturing sector is flourishing. If tariffs are designed to help American manufacturing, then the biopharma sector is one area that does not need the help. It is expanding, and it is a net exporter. Indeed, tariffs would almost certainly hurt American pharmaceutical competitiveness around the world since the cost of manufacturing would be raised by the tariffs on the pharmaceutical imports that are incorporated into American manufacturing and then exported.

2) **Access to the Best Medicines in the Future:** The drug discovery pipeline is a long one. It is not like creating next year’s consumer products. Decisions to develop a drug are made many years before that drug is ever approved by the Food and Drug Administration after the long clinical trials process.

If costs go up in one area, without a corresponding revenue increase, then that leads to a reduction elsewhere—it is simple common sense economics. Unfortunately, the two areas that will most likely be hurt by pharmaceutical tariffs are research and development by established companies, and investment in newer companies. Anything that adds costs to manufacturing—and yes, reduces potential profitability—will reduce investment in R & D and in start-ups.

For these basic reasons, we hope you will reject pharmaceutical tariffs and let America's pharmaceutical companies, researchers, and physicians focus solely on what is best for the patients they serve as they battle cancer and other lethal and chronic diseases.

Thank you for your consideration.

Respectfully submitted,

Marcia K. Horn

Marcia K. Horn, JD

President and CEO

ICAN, International Cancer Advocacy Network