May 7, 2025

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

Mr. Eric Longnecker
Deputy Assistant Secretary for
Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

RE: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients XRIN 0694-XC120

Dear Secretary Lutnick and Deputy Asst. Secretary Longnecker:

The Kedrion Biopharma group of companies, including its U.S. subsidiaries Kedrion Biopharma, Inc. and KEDPlasma, LLC. (together, "Kedrion") appreciates the opportunity to provide these comments on the Section 232 investigation into the imports of pharmaceuticals and pharmaceutical ingredients. We respectfully submit that any steps taken to address national security concerns relating to the import of pharmaceuticals and pharmaceutical ingredients should not extend to plasma-derived therapies due to the unique features of such products, the long and highly regulated collection and production processes for such life-saving medicines, and the delicate balance that exists to produce and supply these medicines in a manner that is predictable and cost-effective.

Executive Summary

Kedrion urges the Administration to clearly distinguish plasma-derived therapies (PDTs) from other categories of pharmaceutical products in the context of this Section 232 investigation. The inclusion of these therapies in any trade-restrictive measures—such as tariffs or import limitations—would not enhance national security. On the contrary, it would directly endanger the lives of American patients who depend on uninterrupted access to these life-saving medicines.

Kedrion is not just a stakeholder—we are a critical link in the health security chain of the United States. Our U.S. footprint includes 70 plasma collection centers and a major production site in Melville, New York. We employ over 2,000 U.S.-based professionals at these facilities, at our U.S. headquarters in Fort Lee, New Jersey, and throughout the country in finance, medical, commercial, legal, and other roles. **Unlike traditional pharmaceutical companies who may depend on APIs sourced abroad, we produce medicines for American patients exclusively from human plasma that has been collected in the United States**. Without the plasma we collect, American patients

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would not have access to the life-changing and life-saving therapies that they depend on.

Like all producers of PDTs, we depend on a highly specialized, tightly regulated, and geographically integrated global production network.

Despite considerable investments over the past 10 years to expand plasma collections and production capabilities and capacity to meet demand, there are still periodic shortages of PDTs due to fluctuations in plasma collections and the inherently complex process to extract proteins from plasma without damaging them and to provide these proteins in a practical formulation, and the risk of these occasional shortages is expected to continue for certain PDTs. The global network for producing PDTs seeks to minimize these risks and maintain consistent supplies and efficiency. Trade restrictions would not bring production back onshore; they would reduce available therapies, drive up costs, and jeopardize patient outcomes.

The production of PDTs is more complex, time-intensive, highly regulated than for chemical entities, and the production process cannot be replicated or moved quickly. Constructing and licensing a new facility can take upwards 7 and 10 years and over $1 billion in investment, in capital. The ability to respond to rising demand hinges on incentivizing expansion—especially in the collection and processing of plasma and the inspection of new facilities. A more targeted approach—one rooted in tax policy and investment stimulus—would better serve both national security and public health.

In many cases, plasma-derived therapies are the only medicine to treat debilitating and life-threatening rare conditions. There are no generic substitutes and often no alternative treatments. For these patients, every delay, every disruption in supply, threatens their well-being. Additionally, PDTs serve as key treatments in life-saving emergency room situations across the country, including albumin to treat burns and PDTs to treat rabies.

The U.S. would be more adequately served by focusing on incentivizing the growth of U.S. PDT production and plasma collection rather than implementing measures that could restrict therapies.

Who Is Kedrion?

Kedrion Biopharma is a global player in the biopharmaceutical sector dedicated to collecting and fractionating plasma to produce and distribute plasma-derived therapies for rare, ultra-rare, and debilitating conditions like Coagulation and Neurological Disorders, Immunodeficiencies, and Rh sensitization. With a portfolio of 38 products, Kedrion is the world's fifth largest player in the plasma-derived space. At Kedrion, science meets humanity, ensuring that innovation and care go hand in hand. Partnering with the medical-scientific community, institutions, patient advocacy groups, and research bodies, Kedrion is committed to fostering innovation and improving patients' access to care.

Kedrion maintains its global headquarters in Italy and has its main subsidiaries in the United States and England. Kedrion owns and operates 70 plasma collection facilities

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in the United States and 7 production facilities across North America and Europe, including facilities in Laval, Quebec, Canada; Elstree, United Kingdom, Bolognana, Italy; and Melville, New York. These production facilities have existed for many years, stretching back over 70 years in the case of our facility in the UK. Our U.S. headquarters is in Fort Lee, New Jersey and houses employees across all functions to serve American patients and operations.

We see the U.S. as key for our future CAPEX investments and as a market for our therapies, and we are committed to providing life-saving therapies for American patients for years to come.

Understanding Plasma-Derived Therapies: Unique and Irreplaceable

PDTs are produced from human plasma and used to treat orphan and ultra-rare conditions such as primary immunodeficiencies, hereditary bleeding disorders, Rh sensitization, and congenital plasminogen deficiency. As plasma cannot be synthesized, individual therapies depend on significant donations: 130 donations are needed to treat one patient with primary immunodeficiency for one year and over 1200 donations are required to treat a patient with hemophilia for a year.

PDTs are recognized as different from pharmaceuticals produced from chemicals in a number of respects including the following.

No Generics

PDTs are human body biologics with no therapeutic substitutes. Disrupting the supply of any PDT directly impacts patients who rely on that medicine.

American Plasma, American Patients

PDTs for American patients are exclusively produced from plasma collected in the United States. Plasma collection is highly regulated, resource-intensive, and time-consuming. Plasma collection is a critical activity for Kedrion in the US. The company operates state-of-the-art plasma collection centers, ensuring the highest standards of health and safety. Plasma is collected through a process called plasmapheresis, where blood drawn from the donor is separated into plasma and returned to the donor. Kedrion collected more than 3 million liters of U.S. plasma in 2024, up from 2.1 million liters in 2020.

Production Process is Distinct

Unlike chemical pharmaceuticals, which are typically produced in 30 to 45 days, PDTs take 7 to 12 months to produce due to plasma testing, fractionation, viral inactivation, purification, and fill-finish processes. The collection process alone requires specialized equipment, quality assurance procedures, and holding times. The production process for PDTs is similarly unique, complex, expensive and time-consuming, requiring special attention to maintain the integrity of the essential qualities of the source plasma. These factors are magnified in the case of new facilities and changes to existing facilities, and these complexities have contributed to the fragile supply situation that exists.

Facilities must meet FDA, EMA, and Health Canada standards, creating a high barrier to entry and limiting short-term supply expansion. Any potential

substitution would require extensive analysis and testing, resulting in significant expenditure of resources and energy to verify their replaceability.

These distinctions are part of why, during President Trump's first term, his administration exempted immune globulin from the Most Favored Nation Model in 2018.

Kedrion's Contribution to U.S. Health Security

Kedrion has a substantial U.S. footprint. We have more than 70 FDA-licensed plasma centers across 23 states and have more than 2,000 employees. Kedrion has invested $143 million in our major production hub in Melville, NY, since 2011, and has an additional $32 million investments planned for routine maintenance and reliability improvements in the near future.

Our facility in Melville is currently Kedrion's second-largest production facility, and the site of production of one of its immunoglobulin products, as well as RhoGam, which has, since 1968, protected generations of Rh-positive babies from Rh sensitization and resulting hemolytic disease of the fetus and newborn, a condition before the advent of RhoGam, affected nearly 10 percent of all pregnancies and contributed significantly to fetal deaths in the U.S.

We agree with the Administration's view of the U.S. as a key home for pharmaceutical investment and development. In addition to our continued investment in expanding production and capacity in Melville, Kedrion is planning further expansion and investments of at least $125 million in the facility in the next five years. Kedrion is also planning to expand our plasma center footprint, as well as making investments in commercials, finance, legal, regulatory, medical, and research and development in the U.S.

A Delicate Balance--Global Supply Chain Built for Quality, Not Cost Cutting

We understand and appreciate that the U.S. government is concerned by potential export restrictions focused on pharmaceuticals or APIs from countries that may have an adversarial or contentious relationship with the U.S. However, Kedrion's integrated industrial footprint was designed in response to U.S. regulatory requirements and is confined to western countries where national security risks are reduced.

Kedrion has not offshored production to places like China, India or Ireland. Kedrion is using its historical footprint while doing everything it can to invest in the U.S. while aligning with regulatory, quality and technical requirements.

Thus, Kedrion's PDT production spans multiple facilities due to specialized expertise.

With a geographic footprint concentrated in Europe, the UK, Canada and the United States, we submit that any national security concerns are reduced and outweighed by the health risks of interrupting supplies of PDTs Kedrion is not processing plasma in countries like Russia or China. Kedrion is processing plasma in traditionally allied countries in facilities that have been in pe for many years and were established based on FDA regulations that limit processing of non-US plasma at US facilities. This

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approach allows Kedrion (and other producers of PDTs) to use a single facility to produce medicines from plasma that was collected in the United States and to produce medicines from plasma that is collected outside the United States.

Patient Impacts: Rising Prices and the Stories Behind the Statistics
Kedrion has developed and commercializes two medicines in the US that are the only treatments available to directly treat pediatric and adult patients with two very rare and ultra orphan bleeding disorders.

> **Ryplazim**
> A six-year-old boy born with plasminogen deficiency faced corneal lesions, airway obstruction, and repeated hospitalizations. With Ryplazim, his condition stabilized dramatically. Any delay in treatment puts his sight and life at risk.
>
> **Coagadex**
> A teenager with hereditary Factor X deficiency—fewer than 500 U.S. cases—experienced life-threatening bleeding episodes. Coagadex allowed her to attend school, play sports, and avoid transfusions.

Applying tariffs to these products will have detrimental impacts on those same patients. These potential tariffs could disrupt treatment of rare diseases; risk forcing therapy redirection to untariffed markets; and shrinking domestic inventory by 15 to 25 percent according to industry estimates.

For years, including with President Trump's recent Executive Order, the U.S. has made drug price reduction a key policy priority and these potential tariffs – and the subsequent increase in therapy costs – run counter to those efforts. Any tariffs threaten to destabilize supply of critical orphan drugs that will have real-life consequences for some of the most vulnerable populations.

These are not hypothetical risks. For patients described above with ultra-rare diseases, Kedrion's US FDA approved **PDTs are the only specific and targeted treatments available**.

Policy Recommendations: Carve-Outs and Incentives
We appreciate the U.S. government's commitment to protecting national security and ensuring a healthy and robust domestic pharmaceutical industry. However, we believe that there are a number of policy and regulatory changes that are more likely to produce the stated results than simply levying tariffs.

Supporting U.S. plasma collection through regulatory clarity and donor compensation protection. The demand for plasma-derived therapies has grown consistently and outpaces supply. The U.S. should create a regulatory environment that allows donors continue to be compensated for their time spent donating; encourages investment in U.S. plasma collection capacity; and maintains incentives to encourage capital investments to improve and grow collection facilities. The best vehicle to protect the uninterrupted supply of plasma-derived therapies is to support—and grow—the current plasma collection environment in the United States.

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Incentivizing domestic investment: tax credits, accelerated approval timelines for U.S.-based facilities. The economics of building new facilities, which can take between 7 and 10 years and over $1 billion in investment, mean that companies need to justify significant volume capacity expansions that could similarly be at risk due to trade barriers. Tax policy changes are more likely than tariffs to generate the desired outcome of increasing domestic manufacturing.

Preserving U.S. content protections. As recognized with the tariffs announced on April 2, the value of content sourced in the U.S. should not be subject to tariffs. In the case of Kedrion's therapies this would primarily include U.S.-sourced plasma. We strongly believe that if the Administration decides to levy tariffs on pharmaceuticals, it should ensure that U.S. content is exempt from tariffs, as it has in response to similar Sec. 232 investigations.

Conclusion – Medical Necessity and protecting access to life saving PDTs Must Prevail

Tariffs on plasma-derived therapies would not bolster national security; they will instead jeopardize the health of Americans by reducing access to therapies that are biologically unique, medically irreplaceable, and lifesaving.

The plasma supply chain already strikes a delicate balance and production processes are already stretched thin. Any trade restrictions could create delays, shrink inventories, and potentially encourage manufacturers to redirect supplies away from the U.S. market.

American patients who depend on therapies like Ryplazim, Coagadex and Immunoglobulins like Gammaplex do not have the luxury of time. They cannot wait for new facilities to come online or for production to be reshored. They need their treatments now. A disruption to the global supply chain for these products is not an abstract concern – it is a direct threat.

The Administration has an opportunity to draw a clear distinction: between strategic vulnerability and medical necessity.

We respectfully urge you to recognize that plasma-derived therapies are different, exempt PDTs from any tariffs or other trade restrictions, and to adopt policies that incentivize – not punish – investments in this critical industry.

Respectfully,

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