CSL

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May 7, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce

RE: BIS Docket No. 250414-0065 Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Mr. Astle:

CSL appreciates the opportunity to provide comments in response to the Bureau of Industry and Security (BIS) request for public comments on the Section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients.

CSL exists to provide our therapies to patients and to protect the public health in countries around the world. Moreover, as a biotechnology company with a strong and longstanding presence in the U.S., we share the Administration's goals both of ensuring a vibrant pharmaceutical industry ecosystem and safeguarding the country's national security.

At the same time, we do not believe life-saving therapies should be subject to tariffs. Broadly imposing tariffs on the pharmaceutical sector would disrupt and limit U.S. patients' access to therapies, increase costs for patients and the healthcare system, raise manufacturing costs, and limit company resources that are available for biomedical innovation, capital investments, and jobs in the U.S. In this way, tariffs on CSL and the broader biopharmaceutical sector will be counterproductive and fundamentally undermine the goals of reinforcing domestic manufacturing and national security. It is therefore essential that policies that impact the biopharmaceutical sector are crafted with careful consideration for the nuances of this ecosystem.

In these comments, we focus on certain areas that are within our core expertise that we believe present special circumstances warranting exemption from any tariffs – namely, plasma-derived therapies.

We also ask that any tariffs on pharmaceuticals should:

- Provide for a case-by-case exemption in cases where warranted based on important factors such as the severity of disease in question, the availability of treatment options, and/or the impact that tariffs could have on price competition and costs under federal healthcare programs;
- Recognize foreign trade zones and permit all types of drawbacks for pharmaceuticals and inputs that are imported for later export;
- Exempt capital equipment used by the biotechnology industry in the production of medicines;

- Be phased in to allow supply chain adjustments over the required five years; and
- Be targeted at countries of national security concern rather than long-standing allies.

We elaborate on these comments below.

I. Overview of CSL: Serving Patients and the Public Health for Over 100 Years.

CSL is a global biotechnology company based in Australia with a strong and longstanding U.S. presence and a portfolio of lifesaving medicines. Since our start in 1916, we have been driven by our promise to save lives using the latest biomedical technologies.

CSL focuses on three core businesses: **CSL Behring**, which has its Head Office in King of Prussia, Pennsylvania, and is the global leader in producing source plasma and plasma-derived therapies as well as other medicines for the treatment of rare and serious diseases; **CSL Seqirus**, which specializes in seasonal and pandemic vaccines to combat influenza and other pathogens; and **CSL Vifor**, which focuses on iron deficiency and kidney disease.

Our products treat Americans with a broad range of life-threatening and debilitating conditions and have been instrumental in ensuring the United States is prepared for potential pandemics. Today, CSL operates in over 100 countries and employs more than 32,000 people worldwide.

CSL's history of innovation, dedication to public health, and global reach makes it an invaluable partner for the U.S. government. Our proven track record in developing life-saving therapies and vaccines, coupled with our substantial presence in the United States, positions CSL as a critical resource in addressing current and future healthcare challenges.

II. CSL Contributes Significantly to U.S. Economic Security

We believe that economic security contributes to national security, and CSL provides economic security to communities all across the United States. CSL is proud to employ more than 19,000 people in 44 states across the U.S., representing all three of our Business Units and comprising more than 60 percent of our global workforce. Our U.S. operations include 330 plasma collection centers; a plasma testing lab in Knoxville, Tennessee; two plasma logistics centers, one in Indiana and one in Texas; a plasma therapy manufacturing facility in Kankakee, Illinois; a vaccine manufacturing plant in Holly Springs, North Carolina; an R&D center in Waltham, Massachusetts, as well clinical trial operations across the country; and significant workforce presence at our corporate offices in King of Prussia, Pennsylvania; Summit, New Jersey; and Boca Raton, Florida; and a field-based workforce located across the country.

Indeed, the U.S. has by far the largest footprint for CSL of all the countries in which we operate. Over the past seven years alone -- and partially due to growth driven by President Trump's Tax Cuts and Jobs Act (TCJA) -- we

have invested more than $3.1 billion in capital expenditures and created 6,540 new jobs across our U.S. manufacturing, plasma collection, and corporate operations.

The 19,000 jobs CSL provides in the U.S. offer opportunities for a wide swath of the workforce, from individuals without a college degree, whom we provide with the training needed to perform roles such as technicians working in our plasma processing area; to phlebotomy roles which employ individuals with medical backgrounds, such as nurses and EMTs. In addition, our CSL Plasma organization has executive staff at tiered location-based levels, many of whom have worked their way up from in-center roles. Our plasma centers serve as an entry point into the healthcare sector for thousands of team members every year. In addition, CSL provides valuable manufacturing jobs at our locations throughout the United States.

Finally, looking to the future we are planning to expand our US presence through significant new capital investments over the next five years, including as much as $2 billion to expand our U.S. onshore production capacity at a site yet to be selected. These strategic future capital investments will continue to support economic growth and economic security in the U.S., generating high-quality jobs, strengthening U.S. manufacturing capabilities, and catalyzing innovation across industries through research and supply-chain partnerships.

III. Tariffs should not be applied to plasma-derived therapies, where they could cause unintended disruption in the biotech ecosystem and undermine national security and patient care

The plasma-derived therapy sector, like the broader biotechnology industry, delivers important, life-saving medicines. The process needed to produce these therapies, however, is dramatically different from the broader industry, with profound consequences for policies like tariffs.

The plasma sector harnesses the human body to treat serious and rare conditions. Plasma is part of the blood and contains proteins that support critical bodily functions, such as clotting blood or fighting infection. Serious and life-threatening diseases can arise when individual plasma proteins that are linked to specific bodily functions do not work properly or are missing entirely.

Examples of these conditions follow:

- **Hereditary Angioedema** is caused by a missing protein which helps regulate inflammation. Patients can experience severe swelling which can be fatal if their airway becomes obstructed. This condition affects 6,000-10,000 patients in the U.S.
- **Hemophilia A** is a hereditary bleeding disorder caused by the lack of clotting favor VIII. Individuals with this condition suffer from bleeding into joints and other complications. There are approximately 33,000 people with Hemophilia A in the U.S.
- **Hemophilia B** is a blood clotting disorder caused by a mutation of the Factor IX gene. It is more rare than Hemophilia A, affecting approximately 7,000 people in U.S.
- **Von Willebrand Disease** is the most common bleeding disorder, with common symptoms including excessive menstrual bleeding and nosebleeds. There are several kinds of VWD, and symptoms severity can vary. VWB affects approximately 3.2M people in U.S.

- **Primary Immunodeficiency Disease (PID)** is a genetic condition that prevents an individual's immune system from functioning properly. There are more than 550 different forms of PID. This condition causes a high potential for infection and an inability for affected individuals to fight off infections with typical antibiotics. There are approximately 500,000 PID patients in U.S.
- **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** is a rare autoimmune disorder that affects the nervous system of children and adults. Nerves in the arms and legs of patients may become weakened and lead to paralysis. There are approximately 30,000 CIDP patients in U.S.
- **Alpha-1 Antitrypsin Deficiency (AATD)** is one of the most common serious hereditary disorders and can lead to life-threatening liver disease in children and adults, and lung disease in adults. This disorder affects 100,000 patients in U.S.

Each of these conditions can be treated with therapies made from human plasma, and for many patients, these plasma therapies are the only treatment option. Plasma therapies also are used to treat other conditions such as maternal blood incompatibility with fetuses and newborns; shock, trauma, and severe burns; and reversing the effects of anticoagulants in an emergency surgical setting.

Producing plasma therapies requires a uniquely complex and costly process. The plasma sector does not simply procure active pharmaceutical ingredients and manufacture them into finished products. Instead, the industry must collect the therapeutically active plasma proteins from healthy human donors and concentrate these proteins into drug products that treat a given disease or condition.

All of the plasma therapies that CSL delivers to patients in the U.S. are made from plasma that is collected in the U.S., and this activity comprises the majority of the value in creating the finished therapies. This constitutes a strong foundation for national security.

It can take hundreds to thousands of plasma donations to treat a single patient for one year. For example, it takes 900 plasma donations, from many donors, to treat one individual living with AATD for one year. With approximately 10,000 patients who need treatment for AATD living in the U.S., addressing the needs of these patients for one year requires nine million plasma donations. This involves the operation of an extensive fleet of plasma collection centers to produce the source plasma used to make therapies, as well as a multi-phase production process to turn the plasma into finished products.

As a result, the plasma sector faces a much higher cost-of-goods of almost 60 percent compared to 14 percent for small-molecule pharmaceuticals. Just standing up a single plasma collection center costs $2-3 million, not accounting for operating and infrastructure maintenance costs; and it typically takes 3+ years for a center to mature to optimal productivity.

The plasma industry also frequently manages volatility. The plasma sector is still recovering from a dramatic rise in plasma collection costs that resulted from the COVID-19 pandemic. The costs to collect a liter of plasma rose 63 percent between 2020 and 2022, and even now they remain 37 percent above pre-pandemic levels. This shock has

been difficult to absorb in an industry with high operating costs, long production lead times, and tight margins. Moreover, given the complex supply chain for plasma-derived medicines (from donor to patient), historic supply shortages created challenges for the many patients who depend upon these important medicines. Such situations have become less frequent over the past decade due to investments by CSL and other plasma companies.

For these reasons, the potential impact of tariffs on the relatively fragile plasma sector, and even the uncertainty created by their specter, would present a significant threat to the economics of a delicately balanced operating model, and would jeopardize U.S. patient access to these important therapies. It also would undermine our capital investment plans and could adversely impact our operating footprint and employment as well as the contributions we make to the local communities in which we operate. Accordingly, we suggest that plasma-derived therapies should be exempt from any proposed pharmaceutical tariffs.

IV. Tariffs on Pharmaceuticals Should Be Further Targeted To Recognize the Potential Impact on Patient Care and the Complexity and Global Nature of Biopharmaceutical Markets and Supply Chains

In addition to avoiding the therapy areas discussed above, any tariffs on pharmaceuticals should be further targeted to ensure the Administration's goals of a vibrant U.S. sector and strong national security can be achieved without compromising patient care or undermining important market dynamics in the United States.

Case-by-case exclusions. The government should ensure that exemptions from pharmaceutical sector tariffs are available where supported by compelling public policy rationale. This should consider factors such as the severity of disease involved as well as the availability of different treatment options (recognizing that patients are different and the best medicine for one patient may not be the best option for another). The government also should consider exemptions in cases where tariffs would undermine pricing competition and/or increase costs under federal healthcare programs.

Recognizing foreign trade zones and permitting duty drawbacks. Following well-established principles under the U.S. trade laws, any tariffs on pharmaceuticals should recognize free trade zones and permit all types of drawbacks, under which tariffs on imported goods could be offset with tariff refund claims against exports. Products imported for manufacturing and subsequent re-export should not be subject to tariffs, as this would only undermine US manufacturing competitiveness. Duty drawback programs should be permitted for these re-exported products, ensuring that tariffs do not hinder U.S. manufacturing processes or lead to job losses. By adopting this approach, the U.S. can safeguard national security while fostering a thriving manufacturing sector.

Exempting tariffs on capital equipment. CSL has significant manufacturing and R&D operations in the U.S. which, like others in the biotechnology sector, require significant and capital-intensive investments. To facilitate the expansion of domestic manufacturing capacity and R&D, the U.S. should exempt the import of capital equipment from tariffs. This would build resilient domestic manufacturing and innovation capacities.

Phasing in tariffs to reflect time needed to transition. The biopharmaceutical sector requires significant time to build ramp up manufacturing operations. For our operations at CSL, it can be especially lengthy and complex due to the nature of plasma manufacturing and can take as long as five years for readiness completion. This is driven by the need to meet rigorous regulatory standards with inspections and approvals that can add further delays.

Tariffs would place a competitive disadvantage for U.S. biotechnology R&D leadership and will slow the industry's ability to invest in manufacturing and innovation in the U.S. rather than accelerating that investment.

Targeting countries of national concern. CSL's global supply chain is crucial to our ability to deliver high-quality products to patients in the U.S. and worldwide. It enables flexibility in planning, changing demands, market conditions and rapid response to pandemic outbreaks. Our global network outside of the U.S. is positioned in friendly countries including Switzerland, Germany, Australia, and the UK, and provides resilience in supply, mitigating risks, and ensuring continuity.

CSL understands the Administration's concern that certain countries may "weaponize" control over pharmaceutical supplies. Therefore, CSL encourages the U.S. government to focus its investigation on these specific non-allied countries, rather than on all imports of pharmaceuticals, active pharmaceutical ingredients, and other derivative articles from the many trading countries that have been reliable partners in the past. This approach would encourage diversity in technologies, experiences, and knowledge sharing with allied countries, ultimately enhancing the US's own innovation and manufacturing capabilities. Strong geostrategic and economic relationships with allies like Australia, Switzerland, EU, and the UK help mitigate supply disruptions by ensuring there is redundancy built into the supply chain, bolstering national security and public health resilience.

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In conclusion, CSL appreciates the opportunity to contribute to the public consultation in the Section 232 investigation process. We would like to reaffirm our strong commitment to supporting national security in the United States, and to ensuring a vibrant biopharmaceutical sector.

We welcome the opportunity to work with the Administration to help formulate policies that will achieve these ends while continuing to allow us to continue to innovate, expand our domestic capacity, and deliver the critical medicines we develop to patients in the U.S. who depend on them.

Please contact Mary-Lacey Reuther, Head of U.S. Policy, Advocacy and Government Affairs, CSL Behring, for any questions or follow-up regarding this submission. Mary-Lacey can be reached via email at mary-lacey.reuther@cslbehring.com, and by phone 202-841-4686.

Sincerely,

/s/ Michael Deem

Michael Deem
SVP and Head of Operations, CSL