May 5, 2025

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

Submitted electronically via https://www.regulations.gov

Re: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket Number BIS-2025-0022]

Dear Secretary Lutnick,

Premier Inc. appreciates the opportunity to submit comments in response to the *Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket Number BIS-2025-0022]* which was published in the *Federal Register* on April 16, 2025.

For healthcare supply chains, disruptive events such as natural disasters, geopolitical tensions and public health emergencies create a domino effect, impacting an organization's operations and the delivery of products and services our patients depend on. Healthcare supply chains continue to face an unprecedented number of complex and compounding challenges rarely seen throughout history. Economic challenges, disruptive events and more have served as a setback to the U.S. realizing its goal of true supply chain resiliency and independence from countries such as China. For example:

- September 2024's Hurricane Helene damaged critical IV fluids manufacturing infrastructure in North Carolina, which led to shortages for more than 86 percent of U.S. healthcare providers nationwide;
- In the summer of 2022, shortages of made-in-China contrast media, critical for diagnostic imaging, compromised care for up to 10 percent of U.S. patients in key clinical categories; and
- A December 2022 FDA inspection of a sterile injectable manufacturer in India found poor quality outcomes and resulted in widespread shortages of generic oncology medications.

While these are a few significant and recent examples of critical healthcare product shortages, the reality is that issues have persisted for decades. And unlike consumer goods or other items subject to tariffs where Americans can forego purchasing them for the period necessary for market forces to adjust and meet demand, healthcare supplies have a direct correlation to the safety and national security of Americans as any disruption to their availability jeopardizes the health of our nation. Americans cannot forego access to lifesaving medications.

While Premier recognizes the value that the thoughtful and targeted use of tariffs can provide to supply chain resiliency in the long-term, material increases in tariffs on healthcare supplies coupled with rapid implementation timelines can result in unintended consequences that increase costs and shortages in the short-term. ***Therefore, Premier recommends that any unified trade policy on pharmaceuticals ensure that overarching supply chain resiliency goals are met while minimizing the downstream impact to patient care.*** Specifically, Premier urges the Department of Commerce to:

- Develop a targeted approach to tariff implementation on pharmaceuticals that considers medications deemed essential by the Food and Drug administration (FDA) and Department of Defense (DOD) separately from all other medications due to their direct impact on national security;

- Provide a slow and steady glidepath approach to tariff implementation on pharmaceuticals to help ensure that both manufacturers and healthcare providers have sufficient time to respond and adapt to new tariffs while continuing to deliver essential healthcare services effectively;
- Clarify the specific pharmaceutical categories that are or are not subject to tariffs including clear definitions for the components of drugs subject to tariffs and the intersection of drugs and their associated delivery mechanisms;
- Study the impacts of tariffs on the pharmaceutical supply chain to ensure that tariffs are meeting the end goal of spurring domestic ingenuity and identify any unintended consequences, such as increases in costs or shortages, necessitating swift remediation to prevent patient harm; and
- Augment supply chain resiliency efforts through additional mechanisms such as tax incentives supporting domestic manufacturing and the creation of trusted trade partnerships for near-shoring.

Premier submitted related comments to USTR on March 17, 2025, outlining similar tariff concerns and recommendations.

I. BACKGROUND ON PREMIER INC. AND OUR LEADERSHIP IN PHARMACEUTICAL SUPPLY CHAIN RESILIENCY

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,350 U.S. hospitals and approximately 325,000 continuum of care providers to transform healthcare. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories, a strategy that has increased domestic manufacturing and identified new sources of critical supplies. Premier's ultimate goal is to ensure healthcare providers always have access to the supplies they need to treat the patients they serve.

A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

Premier has been a long-standing leader and advocate for supply chain resiliency for more than twenty years and is committed to diversifying the healthcare supply chain from both a policy perspective via legislative and regulatory action as well as pursuing actionable, market-based solutions. For example, Premier's Integrated Pharmacy Program leverages essential clinical data to deliver improved quality, safety and resiliency of pharmaceuticals.

A key component to Premier's success in creating pharmaceutical supply chain resiliency is the stringent contracting and vetting process manufacturers that wish to work with Premier must undergo. This includes sharing information regarding the location of their finished dose manufacturing and active pharmaceutical ingredient (API) sources. In addition, all manufacturers participating in Premier programs are vetted to enable more geographically diverse production capability, adequate buffer inventory, and surge capabilities to meet sudden spikes in demand. Finally, manufacturers are asked to share their redundancy and contingency plans to ensure an ongoing supply of products and mitigate risk. Premier maintains this level of information for almost 6,000 unique National Drug Codes (NDCs) and leverages the information to assign a supply chain resiliency risk score to each product. That score is then utilized by Premier and its hospital-led advisory committees to make contracting decisions that are in the best interest of patient care and supply chain resiliency. As a result of this process which rewards transparency and quality, Premier has been able to create a diverse pharmacy portfolio that mitigates overreliance on a single country or geographical region to the extent possible.

Since 2019, Premier's voluntary ProvideGx Program identifies safe, high-quality supply sources for essential drugs that are or may be at risk of being added to the national drug shortage list. Guided by health systems with more than 1,600 hospitals across the nation, ProvideGx creates long-term committed buying contracts that provide participating manufacturers with the incentive needed to diversify their supply chains and produce high-quality products. Premier's market-based programs, including ProvideGx, currently provide hospitals access to more than 150 drugs that are or have been recently designated as shortage drugs.

Premier has continued to bring resiliency to the market by incenting the domestic manufacture of essential generic medications through investments in VGYAAN (Skillman, NJ) and Exela Pharma Sciences (Lenoir, NC), which combined are working to bring new, domestic sources of 20 different essential generic medications to market, with more anticipated.

Premier's ongoing commitment to addressing pharmaceutical supply chain resiliency also includes diligent advocacy efforts over the years including serving as the lead proponent of the Mitigating Emergency Drug Shortages (MEDS) Act, which was incorporated and signed into law as part of the CARES Act in March 2020.

Premier will continue to innovate and collaborate across diverse stakeholders to address pharmaceutical supply chain resiliency and increase domestic manufacturing.

II. THE INTERSECTION OF THE PHARMACEUTICAL SUPPLY CHAIN AND NATIONAL SECURITY

Despite the foregoing efforts by Premier to diversify the pharmaceutical supply chain, there are many essential medicines that continue to be overly reliant on a single supplier, country, or region for manufacturing, leading to potential shortages and disruptions to patient care. It is important to note the following:

- All medications are not created equal from a national security perspective. While all medications provide a level of clinical benefit to patients, few are considered to be essential such that an inability to access such medications would result in catastrophic outcomes for Americans and threaten our national security. From this perspective, Premier's analysis regarding the intersection of the pharmaceutical supply chain and national security focuses on the medications identified in:
    - The Food and Drug Administration List of Essential Medicines, Medical Countermeasures, and Critical Inputs as required by Executive Order 13944; and
    - The Department of Defense List of Essential Medicines, Medical Countermeasures, and Critical Inputs as required by Executive Order 13944.

  Most medications deemed essential by the FDA and DOD are generic medications that are often prone to drug shortages due to many reasons, including manufacturing and quality problems, delays and discontinuations. Therefore, the pharmaceutical supply chain for essential medicines is vulnerable and unlikely to be able to absorb any additional preventable shocks.

- The manufacturing of pharmaceuticals is a highly regulated and complex process that takes significant financial investment and time. On average a new U.S.-based manufacturing facility takes five years to come online and retooling of an existing domestic manufacturing facility takes at least 18 months. Therefore, the repatriation of the pharmaceutical supply chain cannot occur overnight, and any tariff policies must account for the length of time necessary to ramp up domestic production of these essential medications.

- In addition to the medication itself, it is important to note that the availability of a medication is also dependent on the availability of the delivery mechanism associated with that medication – such as needles, syringes, glass vials, rubber stoppers, metal crimps, IV fluid bags, etc. Therefore, any disruption to the availability of these medical devices and supplies can also impact the availability of medications.

Based on Premier's extensive data regarding the country of origin for drugs and their corresponding APIs, Premier offers the following case studies to highlight challenges with medications deemed critical for national security and their current manufacturing footprint.[1] Premier urges the Department of Commerce to further study the current manufacturing landscape of all essential medicines when weighing the establishment of targeted and thoughtful tariff policies.

- **Case Study #1 – Essential Medicines with Sufficient Domestic Manufacturing Footprints for Both API and Finished Dose: Sodium Bicarbonate**

  Sodium bicarbonate injection is most commonly used for urgent treatment of cardiac emergencies, such as cardiac arrest, heart attacks, strokes and other life-threatening emergencies. The medication is also used to treat excessive acid or potassium in the blood stream, metabolic acidosis, hyperkalemia, dehydration and certain drug overdoses.

  Sodium bicarbonate has been on and off the FDA drug shortage list since 2017 when supply constraints were so dire that the FDA permitted the import of Australian product which was priced 300 percent higher than U.S.-approved products. To help create a consistent and reliable supply for this essential medication, Premier invested in and worked with U.S.-based manufacturer Exela Pharma Sciences to bring a new domestic source of sodium bicarbonate – both the API and finished dose - to market. Premier's investment helped enable the total domestic manufacturing of sodium bicarbonate to now account for over 97 percent of U.S. patient utilization.

  However, it is important to note that while sodium bicarbonate is predominantly manufactured in the U.S., the product remains at risk of shortage. This is a key example to demonstrate that domestic manufacturing alone does not equate to product availability and more investments from public and private partners are necessary to create quality, resilient and sustainable domestic manufacturing sources for essential medicines in quantities that can meet our nation's needs.

- **Case Study #2 – Essential Medicines with Sufficient Domestic Manufacturing Footprint for Finished Dose and API but Not for Key Starting Materials: Fentanyl Citrate**

  Fentanyl citrate is an essential medication used for its analgesic and anesthetic properties, particularly in connection with surgery. Fentanyl has been on and off the FDA drug shortage list since 2012.

  While there are several domestic manufacturers of the finished dose and API, the key starting materials necessary for the manufacture of fentanyl API are derived overseas. Specifically, poppy seeds are primarily grown in Afghanistan and Australia which are then transported primarily to China for processing. This creates an upstream overreliance on, and production bottleneck by, foreign countries. In this scenario, addressing the national security risk associated with fentanyl will require investments to move key starting material processing to the U.S. as well as agricultural investments to grow poppy seeds in the U.S.

- **Case Study #3a – Essential Medicines with Insufficient Domestic Manufacturing Footprint for Finished Dose and API: Cephalosporin Antibiotics**

  Cephalosporin antibiotics refers to a class of medications that are used to treat a wide variety of bacterial infections, including pneumonia, skin infections, urinary tract infections and ear infections. Cephalosporin antibiotics have been on and off the FDA drug shortage list since 2015.

[1] The information provided is based on data that Premier has access to and may not be exhaustive of all available supply options. This information is provided for illustrative purposes only.

Cephalosporin antibiotics have no known domestic manufacturers of the finished dose. In addition, there are two predominant API manufacturers for these products located in Italy and China. Although Italy is traditionally considered a U.S. ally, it imposed export embargoes on key medical supplies during the COVID-19 pandemic, affecting the availability of essential products in the U.S. This further demonstrates that overreliance on foreign countries for our essential medicines extends beyond China.

- **Case Study #3b – Essential Medicines with Insufficient Domestic Manufacturing Footprint for Finished Dose and API: Heparin**

  Heparin is an anticoagulant that prevents the formation of blood clots that can ultimately lead to venous and arterial thromboembolic events if not properly treated. It is also used to treat pediatric patients with leukemia. The drug has been on and off the FDA drug shortage list since 2017.

  Heparin has historically experienced supply volatility due to difficulties associated with obtaining the raw materials necessary to make it, which are derived from pig intestines. Currently, the two major porcine cell lines for heparin are located in China and Spain and there is little U.S.-based source of raw materials available. In addition, over 75 percent of finished dose heparin is manufactured outside of the U.S.

  In 2020, Premier partnered with Fresenius Kabi to help diversify sourcing of heparin API out of China. More recently, Premier has partnered with Sagent Pharmaceuticals to further diversify sourcing of heparin out of China. In addition, there is a domestic manufacturer of heparin; however, their current manufacturing capacity is unable to meet U.S. patient demand absent additional private and public sector investments.

  Heparin serves as an example where investments must be made to move more finished dose and API manufacturing to the U.S. as well as agricultural investments to create a domestic source of the necessary raw materials from porcine intestines.

These examples show some of the challenges manufacturers and providers experience in the pharmaceutical supply chain and the need to look at medications individually to understand the specific implications for national security. The U.S. needs a balanced policy to ensure a resilient, globally diverse supply chain.

III. TRADE POLICY AND THE APPLICATION OF TARIFFS ON PHARMACEUTICALS MUST BE BALANCED WITH PATIENT SAFETY

Tariffs on healthcare products can provide an opportunity to reinforce the domestic supply chain, bolster medical product availability and protect patient care. But they cannot be implemented in a vacuum and must be used in a balanced approach with actionable outcomes that can be directly correlated to a measurable improvement in the resiliency of the U.S. healthcare supply chain. ***Policymakers must ensure that tariffs on pharmaceuticals do not result in unintended consequences that lead to patient harm.***

Accordingly, Premier urges the Department of Commerce to:

- **Develop a targeted approach to tariff implementation on pharmaceuticals**. Medications deemed essential by the FDA and DOD should be considered separately from all other medications. Essential medications have the most direct impact on national security and are therefore the most vulnerable to supply chain shocks.

- **Provide a slow and steady glidepath approach to tariff implementation on pharmaceuticals.** Ensuring that both manufacturers and healthcare providers have sufficient time to respond and adapt to new tariffs is essential. Carefully considered timelines facilitate a smoother transition and allow stakeholders to continue delivering essential healthcare services effectively. While the quick

implementation of substantial tariffs may be a useful policy tool to address imbalances in other supply chains, healthcare products – and in particular essential medications and their associated APIs, raw materials and delivery systems - cannot sustain even brief interruptions in supply without jeopardizing national health security.

Therefore, Premier recommends that any tariffs on pharmaceuticals be announced at least twelve months prior to implementation. An appropriate glidepath approach should increase tariffs at a rate of no greater than 10 percent year-over-year (e.g. 10 percent in year one, 20 percent in year two, 30 percent in year three, etc.) to allow sufficient time for manufacturers to repatriate their supply chains.

- **Clarify the specific pharmaceutical categories that are or are not subject to tariffs**. The pharmaceutical supply chain is complex, and it is therefore imperative that any tariff policy on pharmaceuticals clearly articulates what is or is not subject to tariffs. This requires the inclusion of clear definitions related to finished dose form, APIs, excipients and raw materials in addition to the delivery mechanisms associated with pharmaceuticals such as needles, syringes, glass vials, rubber stoppers, metal crimps, IV fluid bags, etc. It is also important that any tariff policy articulate how medications that are pre-packaged in a certain delivery mechanism will be subject to tariffs – for example: would a pre-filled syringe of a pharmaceutical manufactured in China be subject to a 245 percent tariff on the syringe in addition to the tariff on pharmaceuticals, or would it only be subject to the tariff on the pharmaceutical?

- **Study the impacts of tariffs on the pharmaceutical supply chain.** It is critical to study the ongoing impact of tariffs on the pharmaceutical supply chain and ensure that tariffs are meeting the end goal of spurring domestic ingenuity. Should any unintended consequences be identified, such as increases in costs or shortages, the Department of Commerce must remain nimble to quickly remediate any patient harm.

Premier supports steps to address quality and security concerns as they relate to medical products. However, despite improvements and investment by private sector organizations such as Premier, healthcare supply chains remain vulnerable, and tariff and trade policies must reflect these realities.

IV. ADDITIONAL EFFORTS ARE NECESSARY TO SUPPORT SUPPLY CHAIN RESILIENCY

Premier believes that true supply chain resiliency requires a holistic approach as part of a larger strategy to address the implications of trade policy on products needed in healthcare – particularly those needed during a public health crisis or national security threat.

Tariffs on healthcare can provide an opportunity to reinforce the supply chain, bolster medical product availability, and protect patient care. But they cannot be implemented in a vacuum and must be coupled with actions whose outcomes can be directly correlated to a measurable improvement in the resiliency of the U.S. healthcare supply chain.

Tariffs are intended to spur American ingenuity and promote domestic production, so the funds collected should be leveraged to do exactly that. Policymakers must target collected tariff funds for reinvestments that spur healthcare supply chain innovation. Tariffs on any healthcare items should be directly reinvested to support a strong and resilient healthcare supply chain, not into the Treasury's General Fund. Specifically, opportunities to reinvest tariff revenue to support a strong and resilient healthcare supply chain include:

- **Provide tax incentives to boost domestic manufacturing.** Premier has thought critically about how to incentivize manufacturers to invest in domestic production while also ensuring that domestically manufactured goods are price competitive with globally sourced products. To expand domestic capacity, manufacturers need assurances of longer-term purchasing and a recognition of the required capital investments. Targeted tax incentives can stimulate investments in domestic manufacturing while also

ensuring that domestically manufactured goods are priced competitively with globally sourced products. Therefore, Premier urges for the passage of tax legislation that includes:

- A 30 percent tax incentive for investments in advanced manufacturing equipment or machinery to support the domestic manufacturing of critical medical supplies and drugs.
- A 30 percent tax incentive for investments to upgrade facilities to meet Environmental Protection Agency (EPA) requirements to support the domestic manufacturing of critical medical supplies and drugs.
- To reward entities that have already invested in domestic manufacturing, a 10 percent tax credit on the income generated from the sale of domestically manufactured goods. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products. Guardrails would help ensure companies are not artificially increasing their prices.
- To underscore the intersection between supply chain resilience and national security, only the critical drugs and devices included on the FDA and Department of Defense (DoD) lists of Essential Medicines, Medical Countermeasures, and Critical Inputs, the FDA List of Critical Medical Devices, and the DoD Joint Deployment List should qualify.

- **Authorize trusted trade partnerships.** Premier supports legislation, the Medical Supply Chain Resiliency Act (S. 998 / H.R. 2213), which would permit the establishment of trusted trade partners to diversify sourcing for medical devices and pharmaceuticals and enable timely access to the vital supplies providers need to care for patients during a public health crisis or national security threat. The bipartisan, bicameral bill would authorize the President to enter into trade agreements for the reciprocal elimination of duties and import restrictions on medical goods. Premier, alongside 50+ healthcare organizations, believes trusted trade partnerships in healthcare would not only create new trade and investment opportunities abroad but generate growth and investment in domestic manufacturing and services, insulating some of our most critical supply chains from shocks.

- **Expedite U.S. FDA approvals for domestically manufactured medical supplies.** Accelerating FDA approval processes will help prioritize inspections and regulatory approvals for critical medical supplies and drugs that are manufactured domestically and will improve responsiveness to public health needs, especially in times of crisis. Currently, no expedited pathway exists for domestically manufactured products, and they are reviewed in a first-in, first-out manner meaning that if a Chinese application was submitted first, it would be reviewed before a domestic application. Absent prioritization for domestic manufacturers, on average a new U.S.-based manufacturing facility takes five years to come online and retooling of an existing domestic manufacturing facility takes at least 18 months.

- **Provide differential reimbursement for domestically manufactured medical supplies.** Premier urges the Department of Commerce to work with other federal agencies such as the Centers for Medicare & Medicaid Services (CMS) to consider alternative non-budget neutral policy solutions to pay a differential reimbursement for domestically manufactured medical supplies and drugs, similar to CMS' current policy of paying a differential reimbursement for domestically manufactured NIOSH-approved N95 surgical masks. Broadening payment adjustments for hospitals to purchase domestically manufactured critical medical supplies and drugs can create committed purchasing volume for domestic suppliers and offset higher acquisition costs.

- **Require that federal agencies purchase domestically manufactured medical supplies.** While purchasing requirements for government agencies (e.g. Department of Defense, Department of Veterans Affairs, etc.) exist under The Buy American Act and Berry Amendment, there are many loopholes that permit these agencies to continue to buy globally sourced medical supplies and drugs even when a viable domestic option exists. We must hold agencies accountable for compliance with domestic purchasing of healthcare supplies to support a sustainable domestic manufacturing footprint.

- **Develop a real-time inventory data management system.** A major failure during recent public health emergencies was the lack of downstream visibility into the exact quantities of critical medical supplies and drugs on U.S. soil at any given time, creating yet another domino effect of healthcare product shortages. Premier supported bipartisan legislation in the 118th Congress, the Medical and Health Stockpile Accountability Act of 2023 (H.R. 3577), to establish an automated supply chain tracking application to provide near real-time visibility into the quantity and location of critical medical supplies and pharmaceuticals on U.S. soil. Premier expects to see its reintroduction in the 119th Congress and believes increased transparency and additional data will allow for more robust and critical planning.

- **Reauthorize the Pandemic and All Hazards Preparedness Act (PAHPA).** Reauthorizing PAHPA is vital to protecting our nation's economic well-being, national security and ability to respond to the next public health crisis through a cohesive and holistic national strategy for addressing global health emergencies.

A well-designed and implemented tariff policy represents one leg of a stool to help strengthen our nation's healthcare supply chain, but additional investments and actions, including trusted trade partnerships, tax incentives and appropriate reimbursement are the additional legs necessary to make the stool whole and create a comprehensive multi-pronged approach.

V. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments to the Department of Commerce as it considers the impact of tariff policy on the pharmaceutical supply chain. Premier looks forward to collaborating with the Department of Commerce to address critical supply chain issues and help ensure continuity of access for the critical medications needed to care for Americans.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, please do not hesitate to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.