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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
1401 Constitution Ave, NW
Washington, D.C. 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket ID: BIS-2025-0022; XRIN 0694-XC120)

Dear Director Astle:

Vizient, Inc. appreciates the opportunity to provide feedback to the U.S. Department of Commerce's request for comments (RFC) regarding the imports of pharmaceuticals and pharmaceutical ingredients and their derivative products. Vizient welcomes the administration's interest in determining the effects on national security of these critical imports. However, we do have serious concerns that tariffs on imports of pharmaceuticals and pharmaceutical ingredients could ultimately have the opposite of the intended effect, disrupting critical infrastructure sectors and patient access to life-saving medications.

In addition, we appreciate the recent Executive Order (EO) that aims to provide regulatory relief to promote domestic production of critical medicines. The EO acknowledges many of the concerns Vizient raises below. We look forward to working with the administration and reviewing related policy proposals as the EO is implemented.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics, consulting services and a contract portfolio that represents $140 billion in annual customer purchasing volume to improve patient outcomes and lower costs.

Comments

Vizient's role in the healthcare supply chain puts us in a unique position of having a line of sight into the practices of suppliers and healthcare providers. We utilize data-driven insights to help bolster supply assurance for both healthcare providers and suppliers – the latter similarly relying upon a need for stable demand to ensure available supply. While we have long advocated for a more diversified supply chain, including domestic manufacturing where possible, supply disruptions can and do happen onshore as well. Even well-intentioned tariffs on pharmaceuticals, pharmaceutical ingredients and their derivative products are likely to add

unnecessary volatility to critical supply chains, such as disruptions to manufacturing and price spikes. Such volatility will cause downstream harm to critical sectors, including healthcare and emergency services, among others.

As an alternative to tariffs, Vizient urges the Department of Commerce to collaborate with other stakeholders, including government departments, such as the Centers for Medicare & Medicaid Services (CMS), on a long-term strategy that incentivizes domestic manufacturing and ensures adequate provider reimbursement. Should tariffs be imposed, we recommend using funds collected from tariffs to both support healthcare providers and the costs of domestic manufacturing. In addition to these suggestions, Vizient responds to various questions in the RFC, as outlined below.

The current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States.

Given our insights on the supply chain, Vizient appreciates the interest in determining the current and projected demand for pharmaceuticals in the United States. However, we are also aware of the limitations in obtaining accurate estimates of both current and projected demand. Some factors impacting demand (e.g., orders placed for a product) may be unpredictable, such as the spread of an infectious disease. Alternatively, there may be a high demand for certain products, but production and access to products could be limited for different reasons (e.g., limits on controlled substances) so not all orders placed are actually fulfilled. Vizient encourages the Department of Commerce to carefully consider various reasons which could cause demand to vary.

Further, Vizient reiterates that demand data alone may not accurately depict present or future needs. For example, numerous essential medicines are, unfortunately, routinely in shortage. When in shortage, providers may continue to order the product through different channels, but their orders may not be fulfilled despite patient needs. Further, providers may then use alternative medications when they cannot acquire the preferred option. As a result, it is important that the Department of Commerce work closely with providers to identify these types of circumstances so that the right scope and volume of products is considered in the evaluation.

Vizient encourages the Department of Commerce to consider various datasets in its evaluation and to share, and seek, additional stakeholder feedback throughout the evaluation process. For example, data from IQVIA and the American Society for Health System Pharmacists may be useful in learning more about the pharmaceutical market and drug shortages. In addition, Sg2's Impact of Change provides various forecasts related to healthcare, such as anticipated rises in inpatient and outpatient volume from 2024-2034. While we do not believe any these resources can be used independently to estimate current and projected demand for pharmaceuticals, we encourage the Department to consider a range of resources in its evaluation.

The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.

Vizient appreciates the Department of Commerce's interest in learning more about domestic production of pharmaceuticals and pharmaceutical ingredients. Vizient has long advocated for greater transparency in the pharmaceutical supply chain. Unfortunately, because of the

reticence to disclose this transparency, the full extent of domestic versus foreign manufacturing is unknown – so it is unclear what additional capacity is truly required to meet domestic demand. Before considering tariffs on pharmaceuticals and pharmaceutical ingredients, Vizient suggests the Department of Commerce consider sharing additional information regarding their findings so that stakeholders can learn and comment on assumptions or methodologies utilized. Also, as recommendations are made based on the investigation, Vizient emphasizes the importance of considering how long it would take to build the resources domestically to meet demand. In addition to pharmaceutical manufacturing requiring up-front investments, it is also highly regulated and resources for manufacturing, including pharmaceutical ingredients, may not be readily available. As a result, it can take many years to start manufacturing products domestically and this will assuredly be a costly endeavor. While incentives to support domestic manufacturing would be helpful, we emphasize that several years and additional resources would likely be needed to increase domestic manufacturing. During this time, healthcare providers, government payers and patients should not be expected to absorb the costs associated with increased tariffs.

Additionally, there are myriad other challenges in producing and maintaining access to pharmaceuticals and pharmaceutical ingredients. For example, many pharmaceutical ingredients may be considered hazardous, and their production would be subject to additional regulatory barriers. Similarly, transporting these ingredients domestically may be prohibitive. The feasibility of changing the supply chain and associated risks should be considered when evaluating the ability to produce pharmaceuticals domestically.

It is also important to be aware of the large proportion of pharmaceuticals that are already domestically manufactured. Imposing tariffs on pharmaceutical ingredients could disrupt current manufacturing and deter future initiatives should access to supply be disrupted or costs increase. Vizient is concerned that tariffs on the pharmaceutical supply chain could ultimately harm existing domestic manufacturers and deter future onshoring decisions. Further, efforts should be made to protect existing domestic manufacturing.

The role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients.

Vizient again emphasizes the lack of transparency in the pharmaceutical supply chain. USP's Medicine Supply Map may provide some helpful insights, however, there are significant limitations to its use. For example, the sources of pharmaceutical ingredients are not easily determined, even the country of origin for a specific product may be unknown.

The concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks.

Consistent with our prior comments, Vizient believes that lack of supply chain transparency makes it extremely difficult to provide accurate insights regarding the number of distinct pharmaceutical suppliers. For example, even if there are multiple suppliers, if several of those suppliers use the same contract manufacturer or the same API supplier, then the market may not be as robust as it appears. Therefore, Vizient encourages the Department of Commerce to thoroughly review these types of relationships within the supply chain to have a clearer

understanding of the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks.

In addition, Vizient suggests that the Department of Commerce consider not just the number of suppliers, but also the location, number of facilities, volume of products being produced and location in which those products are warehoused as part of this analysis. Also, factors such as a facility's contingency plans or risk mitigation strategies may also be important to consider should a facility be required to stop or slow production. For example, should a natural disaster occur that prevents a facility from manufacturing in a particular location, it is important to understand the contingent manufacturing options and alternative sources of supply.

While there is a significant lack of supply chain transparency, one helpful way to mitigate short-term access risks is by warehousing more products domestically. Although this approach may not address every supply chain risk, it can often be critical in ensuring that sufficient supply is available to prevent shortages and maintain operations within the healthcare sector while the supply chain recovers. Vizient has successfully deployed this strategy with our healthcare clients and would be happy to speak further about the processes necessary to achieve this goal. We note, however, that additional tariffs on pharmaceuticals may make it more financially challenging for such warehousing to occur.

The feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance.

The lack of visibility in the supply chain makes it difficult to determine the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance. Given these unknowns, Vizient has significant concerns regarding the use of tariffs to bolster the pharmaceutical supply chain. Further, even if domestic capacity is increased, there may still be risks to the supply chain, such as natural disasters, should domestic production be concentrated to one area. As noted above, in addition to domestic production, Vizient encourages the Department of Commerce to also consider opportunities to enhance domestic warehousing of pharmaceuticals, as this can help reduce import reliance should domestic production issues emerge, among other benefits.

Though the Department of Commerce is considering the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients, it is unclear to Vizient to what extent the quality of both the product and facility will be considered in the context of domestic production. Quality-focused efforts such as the Food and Drug Administration's Quality Management Maturity program are positive steps towards a more resilient supply chain that should be utilized in efforts to support domestic manufacturing. As the Department of Commerce is likely aware, quality issues are a key cause of drug shortages. Therefore, domestic capacity should be interpreted broadly to consider both production ability and quality.

To help encourage quality domestic production, particularly if one were to assume the cost of a product would also increase as quality increases, Vizient recognizes the need to ensure providers are adequately reimbursed by payers. As such, we urge the Department of Commerce to work with payers, including Medicare, to identify the feasibility of changes to the reimbursement system so that any increases in costs do not have detrimental effects on providers who cannot absorb cost increases.

Lastly, a supplier's decision to produce domestically depends on numerous factors, including potential legal or regulatory barriers. While Vizient is not addressing whether different regulations, such as environmental regulations, should be eased to enable domestic production, we do believe these regulations can be a significant factor influencing where production can feasibly occur. In addition, the location of pharmaceutical ingredients can similarly impact the feasibility of domestically producing a given product.

Any other relevant factors.

Vizient thanks the Department of Commerce for the opportunity to share other factors that may be relevant to the investigation. While noted above, Vizient emphasizes the importance of considering incentives to support domestic manufacturing and financial support to providers to ensure that they are adequately reimbursed.

In addition, we suggest providing information publicly regarding the tariff costs that are paid by an importer for a given product. Among other reasons, it can be difficult for a provider to validate a claim that tariff policy has resulted in the need to increase the price of a product. Also, while the RFC does not address how funds collected from potential tariffs would be used, we support the use of these funds to support a quality manufacturing infrastructure and to fund providers, either directly (should tariff cost be passed on to them) or through increased reimbursement from payers (at a minimum, Medicare).

To further develop these concepts into policies, Vizient encourages the Department of Commerce to convene key supply chain stakeholders, including manufacturers, group purchasing organizations (GPOs), providers, payers and other government departments. We strongly believe that such measures are needed before any tariffs are proposed. Given the complexity of the supply chain, the limited resources of providers and the critical need to care for patients, we urge the Department of Commerce to refrain from proposing any tariffs on pharmaceuticals and pharmaceutical ingredients.

Vizient thanks the Department of Commerce for issuing the RFC as it provides an opportunity for stakeholder input. As the Department of Commerce's investigation continues, we request the opportunity to share more insights on the essential medicines which are most critical to patient care that may also face even greater access challenges should tariffs be imposed. We also welcome the opportunity to discuss strategies that could be implemented from a reimbursement standpoint to support providers. Thank you for your consideration. Please do not hesitate to contact me at (202) 354-2607 or shoshana.krilow@vizientinc.com if you have any questions or if we can be of assistance.

Sincerely,

Shoshana Krilow
Senior Vice President, Public Policy & Government Relations