Submission by Valisure, LLC

Docket No. BIS-2025-0022 / XRIN 0694–XC120
Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Executive Summary

Valisure, LLC respectfully submits this expert technical analysis in response to the Department of Commerce's request for public comment regarding the Section 232 investigation into the national security implications of pharmaceutical imports. Drawing on extensive independent testing conducted under a Department of Defense-supported initiative, along with empirical supply chain data and strategic risk assessments, this submission demonstrates that the United States' heavy reliance on foreign pharmaceutical manufacturing—particularly from China and India—presents a direct threat to national security and can significantly harm public health, with damages from low-quality generics estimated to exceed $16 billion annually just for chronic disease management.

In the first and only government effort to create actionable transparency to drug quality, independent laboratory testing and quality scoring of DoD essential medicines[1] is already generating the critically missing transparency to fix the broken generic drug market. This DoD study has recently revealed alarming rates of contamination, poor effectiveness, lack of manufacturing transparency, and sourcing vulnerabilities in widely used pharmaceuticals essential to both military and civilian health systems. Based on these findings, Valisure proposes specific policy actions to improve quality and restore American pharmaceutical resilience. This can be achieved by addressing the quality blindness of the current generic market, which often prioritizes only the lowest cost without any value given to manufacturing quality or location. By simply creating objective transparency to pharmaceutical quality, as DoD is currently doing, and reforming procurement protocols to require the use of this data, it is immediately possible to transform the existing drug market and incentivize higher quality and domestic manufacturing. Large private health systems, such as Kaiser Permanente, have already begun to utilize such a system for certain essential medicines. Government reform in this area could significantly accelerate these promising private sector initiatives.

Fortunately, a U.S. generic drug manufacturing base already exists, but is at roughly 50% capacity[2]. This importantly shows that to most effectively and sustainably manufacture more pharmaceuticals in America, the highest priority should be to fix the broken generics market to incentivize the purchasing of quality medications already being made in the U.S. The establishment and utilization of transparency regarding product quality and origin will naturally incentivize increased American manufacturing over time. This market-driven shift could be further accelerated by supportive government initiatives from both DoC and HHS; however, without fixing the fundamental market dynamics, government actions are likely to be ineffective.

Appended to this submission we offer for review the following attachments:

- 4/10/25 Results from quality scoring the first 6 DoD essential medicines
- 4/3/25 Slide deck on DoD drug quality study presented at DoD Symposium
- Draft paper from 20+ healthcare opinion leaders on "Estimation of Economic and Public Health Burden of Low-Quality Generic Drugs for Chronic Disease and Potential Solutions"

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[1] Anna Edney and Riley Griffin. Bloomberg News. *The Pentagon is Skeptical of Cheap Generics Drugs Approved by the FDA* (December 4, 2023) (https://www.bloomberg.com/news/features/2023-12-05/pentagon-is-skeptical-of-cheap-generic-drugs-approved-by-the-fda)

[2] Anthony Sardella. Washington University. *US has capacity to make essential drugs, study finds.* (September 30, 2022) (https://source.washu.edu/2022/09/us-has-capacity-to-make-essential-drugs-study-finds/)

Introduction

Valisure, LLC commends the Department of Commerce for initiating this critical investigation into pharmaceutical import risks under Section 232 of the Trade Expansion Act. The Administration's recognition that pharmaceutical supply chains constitute vital national security infrastructure is timely and essential. As an independent pharmaceutical quality assurance technology company, Valisure is well positioned to offer valuable insights based on our independent data and operational experience analyzing the safety, security, and origin of drug products. Valisure has a unique and proven history of safeguarding consumers and identifying supply chain risk. Our empirical studies have uncovered previously unknown contamination in numerous drugs, leading to recalls and withdrawals of billions of dollars of products in the U.S.[3, 4]

The growing reliance on foreign supplier, especially those considered strategic adversaries like China, poses a significant threat to America's military preparedness, public health, and economic stability. If we do not take swift action to address this issue, these vulnerabilities will only intensify, thereby undermining the Administration's larger goals of achieving American industrial independence and improving public health.

In 2012, FDA identified that the root cause of drug supply problems is "the inability of the [generic drug] market to observe and reward quality,"[5] a conclusion echoed in recent reports. In a December 2023 Senate Finance Committee Hearing, Senator Mike Crapo summarized the expert witness testimonies by stating "Every one of you has made the point that one of the big problems here is that we don't compensate for quality, we compensate for price of product only."[6]

The National Security Threat of Pharmaceutical Import Dependency

The United States has a significant reliance on foreign suppliers, particularly from China and India, for essential pharmaceutical components. These two countries are the primary sources for Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs). It is estimated that approximately 80% of drugs in the US originate from India or China. This concentration of the pharmaceutical supply chain exposes the U.S. to the threat of export restrictions, predatory pricing practices, and geopolitical leverage.

It's important to recognize that the risks associated with relying on foreign sources for essential medicines are not merely theoretical. The COVID-19 pandemic starkly illustrated how global supply chain disruptions can lead to critical medication shortages. Furthermore, there have been explicit threats from Chinese state media regarding the restriction of pharmaceutical exports during trade disputes. In the event of military conflict or a breakdown in diplomatic relations, access to life-saving medicines could be severely impacted. This would pose a significant threat

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[3] Anna Edney. Bloomberg News. *A Tiny Lab Finds Danger on Drugstore Shelves While the FDA Lags Behind*. (November 9, 2022). (https://www.bloomberg.com/news/features/2022-11-09/fda-lags-behind-lab-that-found-benzene-in-dry-shampoos-sunscreen)

[4] Jamie Ducharme. Time Magazine. *Scientists Are Finding Out Just How Toxic Your Stuff Is*. (May 9, 2024). (https://time.com/6975046/toxic-chemicals-in-products-valisure/)

[5] J. Woodcock and M. Wosinska. (2012) *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages.* Clinical Pharmacology & Therapeutics. (https://pubmed.ncbi.nlm.nih.gov/23337525/)

[6] (December 5, 2023) https://www.finance.senate.gov/hearings/drug-shortages-examining-supply-challenges-impacts-and-policy-solutions-from-a-federal-health-program-perspective

to both our military's operational readiness and domestic stability. This issue was recently discussed at the March 11, 2025, Senate Armed Services Committee Hearing on Stabilizing the Military Health System to Prepare for Large-Scale Combat Operations. During this hearing, Senators and witnesses concurred that the United States' over-dependence on China for essential medicines is a serious concern and risk. Major General (ret) Friedrichs also highlighted this in his written testimony, stating that:

> *"In addition to shortages of finished pharmaceuticals, assessments by the Joint Staff have found that deployable assemblages which are expected to be resupplied during large scale combat operations contain medications and/or equipment from potential adversaries, or from a sole source which may not continue provide these items during a conflict. And recent analyses of generic pharmaceuticals have demonstrated variability in the efficacy of some medications."*

Recognizing pharmaceuticals as critical strategic assets, rather than mere commodities, is a vital step in strengthening our national security.

Independent Data Confirms Persistent Quality Failures and Location Opacity

Valisure's work under the Department of Defense-funded "Assessing the Security & Quality of the U.S. Military Health System Pharmaceutical Supply Chain" (PhaSQ) project provides empirical evidence of systemic risks within the current pharmaceutical supply chain of the U.S. military. A 2-Pager summary of the first 6 essential medicines to be analyzed and quality scored under this project is provided as an attachment herein and an overview of findings are below:

- **Of 99 supplier options tested, 66% scored "green" and 13% scored "red."**
- Primary drivers of "red" ratings include detection of toxic elements (arsenic, lead, thallium), carcinogens, and drug release from pills being too fast in some products and too slow in other products.
- **Analysis of price versus quality score shows no correlation. High quality generic drugs are available at low prices.**
- There is evidence that low quality products correlate with overseas manufacturing companies primarily in India and China.
- **In some essential medicines, the majority of drug products sold to DoD are "repackaged," which often masks the true origin of the medications and subverts the intention of TAA-compliance requirements. <u>Independent evaluation of location is needed and the creation of a "location quality" score can solve this problem</u>.** An initial form of this "location quality" scoring is already being generated as part of this project and could be leveraged to incentivize quality and American based manufacturing.

Low-Quality Drugs in the US Substantially Harm Public Health and Cost Billions

This large but significantly underappreciated problem is thoroughly reviewed in the attached current draft paper "Estimation of Economic and Public Health Burden of Low-Quality Generic Drugs for Chronic Disease and Potential Solutions" which is co-authored by 20+ leaders at institutions including the Defense Health Agency, Stanford University, Yale University, Columbia University, NYU Langone Health, and others. Key findings from the paper:

- **Significant economic burden:** The researchers estimate that low-quality generics for chronic diseases cost the U.S. **$16.4 billion in 2023 alone**, potentially reaching **$212 billion over the next 10 years** if not addressed. This cost comes from increased hospitalizations, adverse events (like heart attacks and strokes), and other health problems.
- **Harm to public health:** Low-quality generics can lead to:
    - More hospitalizations due to ineffective medication.
    - Relapses of disease due to sub-potent (weaker than labeled) drugs.
    - Less effective clinical endpoints, leading to more healthcare utilization.
    - Increased risk of heart attacks, strokes, and coronary heart disease.

The issues at hand present significant public health concerns and have a direct impact on national security. Diminished force readiness and deployability are potential critical consequences. As an example, consider the fact that many essential medicines are routinely prescribed to active-duty personnel. These individuals are required to demonstrate 90 days of stability on their prescribed medications. The presence of lower quality generic drugs has the potential to destabilize patients, consequently preventing service members from receiving clearance for deployment.

Foreign Manufacturing Presents Predictable Quality and Strategic Risks

The risks identified by Valisure's testing align with longstanding concerns regarding pharmaceutical manufacturing quality in China and India. Numerous enforcement actions and public reports have documented data falsification, contamination, and failure to meet basic regulatory standards among foreign manufacturers.

New research has shown that such foreign manufactured generic drugs lead to 54% higher rates of serious adverse events compared to domestically manufactured versions.[7]

Low prices achieved through regulatory arbitrage, subsidization, and lower environmental and labor costs create an illusion of cost efficiency, while masking quality risks. In strategic terms, America's current dependence on these problematic supply chains represents a direct challenge to national resilience and operational autonomy.

Independent Verification Is the Foundation of Resilient Supply Chains

To effectively restore American control over pharmaceutical security, we must prioritize a systematic, independent, and objective comparison of product quality, alongside an unbiased evaluation of origin of manufacturing. The cornerstone of this approach is ensuring the independence of both the data and the entities generating it.

Independent laboratories, accredited under ISO 17025 standards and operating without manufacturing or regulatory conflicts of interest, are well-positioned to furnish the U.S. Government with actionable, real-time quality assurance data. This model has already demonstrated its value through its validation by the Department of Defense and its successful

[7] I. J. Noh, J. Gray, G. Ball, Z. Wright and H. Park, (2025) *Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events*," Production and Operations Management, https://journals.sagepub.com/doi/10.1177/10591478251319691

implementation across Europe, where an independent laboratory network collaborates closely with regulatory bodies.

Independent and objective data on the drug quality and location must become a core element of pharmaceutical national security policy.

The Unique Threat of Chinese Pharmaceutical Dominance

China's dominance in pharmaceutical manufacturing presents risks beyond those posed by general foreign reliance. The Chinese government's record of using economic leverage as a geopolitical weapon is well established.[8]

The limited ability of U.S. regulatory bodies to inspect pharmaceutical manufacturing facilities in China presents substantial challenges and further underscores the critical importance of independent product testing to complement and bolster regulatory efforts.

Strategic Recommendations

Valisure respectfully recommends the following actions:

- Leverage DoD's drug quality study to operationalize a national pharmaceutical risk scoring framework based on objective quality and location data to guide procurement, stockpiling, and emergency preparedness strategies.
- Require complete manufacturing origin disclosure at the National Drug Code (NDC) level for procurement and regulatory reporting – enhancing the data available for the risk scoring framework.
- Identify and prioritize essential and high-volume medicines – ensuring pharmaceutical resilience efforts are focused first on the highest impact drugs and avoid less-commonly used and vulnerable drugs, like sterile injectables that have high risk of drug shortages.
- Expand academic research initiatives through National Institutes of Health (NIH) to investigate drug quality and location metrics and their impact – increasing the broader availability of independent data.
- Mandate use of the risk scoring framework in government procurement (DoD and VA) and healthcare programs (Medicare and Medicaid) – accelerating market correction to recognize and incentivize high-quality and American made pharmaceutical products.
- Encourage FDA to utilize the risk scoring framework to optimize its resources (e.g. additional inspections of "red" manufacturers and fewer of "green") and to accelerate quality and American market incentives through objective regulatory actions (e.g. accelerate approvals for "green" manufacturers, increase user fees for "red" manufacturers).

The collective implementation of these recommendations will address the current challenges in the generic drug market and strengthen America's pharmaceutical supply chain, thereby protecting future generations from potential vulnerabilities in accessing life-saving medicines.

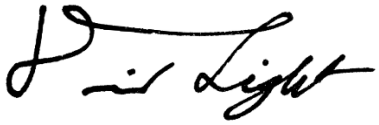
[8] Rosemary Gibson and J. P. Singh, China Rx: Exposing the Risks of America's Dependence on China for Medicines, Amherst, NY: Prometheus Books, 2018

Conclusion

The Trump Administration's commitment to restoring American industrial strength must encompass pharmaceuticals. Without secure, independently reviewed pharmaceutical supply chains, America's strategic autonomy, military readiness, and public health are fundamentally at risk.

Valisure stands ready to support the Trump Administration, Department of Commerce, the Department of Defense, and other federal agencies in implementing these urgently needed reforms.

Respectfully,



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