Submission by Valisure, LLC

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Agency Information Collection Request: Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities.

Executive Summary

Valisure respectfully submits this response to the ASPR Information Collection Request; 30-Day Public Notice Request for comment regarding the Agency's interest to Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities. The pharmaceutical supply chain is heavily reliant on manufacturing in India and China leading to severe quality and reliability risks. This creates a critical need for the Agency to collect information from stakeholders in order to take meaningful actions.

Valisure draws on extensive experience operating independent drug quality testing under a Department of War-supported initiative aimed at being a model for the nation to create actionable transparency to quality, along with approximately four years of working with large health systems like Kaiser Permanente to revise procurement protocols to favor objectively high-quality manufacturers. Such initiatives are already operated at scale and have the potential to transform the generic drug market to incentivize quality and American-made medicines.

Background

In the U.S., approximately 80% of drugs are made in India or China, there are over 300 drug shortages primarily due to manufacturer quality problems, the FDA announces over 3 drug recalls a day, and American researchers estimate that the lowest-quality 10% of generic drugs lead to over $18 billion in public health damages annually in chronic disease management. The U.S. Government Accountability Office (GAO) has considered the FDA's foreign inspection program a "high risk" since 2009 due to limited resources at FDA and the difficulty of inspecting the thousands of facilities in India and China where there are continuing reports of fraud, violations of good manufacturing practices, and drug quality problems reaching the United States. In 2012, FDA identified that the root cause of worsening drug supply problems is a lack of transparency to quality in the generic drug market. Recent analyses and Congressional hearings have reached the same conclusion. This environment has led top health systems in the US, including Kaiser Permanente and the Military Health System, to seek additional quality assurance programs independent from manufacturers. Recent academic articles, investigative reports, and a summary of the DoW quality testing initial results are appended to this submission.

New England Journal of Medicine (3/18/26): Substandard Generic Drugs — Threats to Patient Safety and National Security (pdf attached)

2-Pager Summary (3/6/26): "DoW Drug Quality Scoring (PhaSQ) Project Summary of First 13 Essential Medicines" (pdf attached)

ProPublica (6/23/25): His Kidney Failed. He'll Never Know if a Transplant Drug From a Banned Factory Was to Blame. (pdf attached)

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Recommendations:

OMB should consider as a condition of acceptance for the proposed Information Collection to require the following from the Agency:

- **Form an informal group of stakeholders** with various areas of expertise to advise on information collection activities. Consider Valisure as a member of such a group with unique expertise on the pharmaceutical supply chain.
- **Create a focus area for information collection comprised of generic drug stakeholders** given the substantial risks associated with this especially vulnerable public health supply chain that is the daily baseline treatment for over 150 million Americans. This includes manufacturers of Active Pharmaceutical Ingredients (API), manufacturers of Final Dosage Forms (FDF), repackagers, distributors, wholesalers, health systems, hospitals, pharmacies, doctors, patient advocacy groups, patients, and, most critically, group purchasing organizations (GPOs) that buy direct from manufacturers (these are the ultimate decision makers for the American drug supply chain and there are only 9 entities that account for >90% of all drug purchasing).
- **Focus a collection of interviews on generic drug purchasers and GPOs.** This should specifically include the 6 largest retail purchasers of RedOak (GPO for CVS), WBAD (GPO for Walgreens), ClarusONE (GPO for Walmart), Department of War, Department of Veterans Affairs, and Kaiser Permanente; and 3 largest hospital GPOs of Vizient, Premier, and HealthTrust. As per the consistent conclusions from FDA, Congressional hearings, and expert reports, the key market failure in the US is a lack of quality transparency and the generic market's lack of valuing quality – the information collection from these GPOs should primarily focus on <u>what quality measures are they evaluating for generic drug suppliers and how are they implementing these quality measures?</u>
- **The Agency should partner with FDA to hold a public stakeholder meeting or workshop on drug quality measures.** Such an event should include experts in this field including academic leaders (both private and public), patient advocacy groups, professional organizations, government health organizations, GPOs, organizations currently generating quality measures, and health systems currently implementing quality measures.

Respectfully,

David Light
Co-Founder and President
Valisure, LLC