

Assistant Secretary for Preparedness & Response Washington, D.C. 20201

Mr. Simon Bland Acting Assistant Secretary of Commerce for Export Administration. U.S. Department of Commerce 1401 Constitution Avenue, NW Washington, DC 20230

Dear Mr. Bland,

The Office of the Assistant Secretary for Preparedness and Response (ASPR) requests the participation and support of the Bureau of Industry and Security (BIS) in a multi-year effort to conduct a series of assessments to evaluate the health and competitiveness of the supply chain networks supporting Healthcare and Public Health (HPH) preparedness and response capabilities in the United States.

In 2011, BIS published a prescient report titled "Reliance on Foreign Sourcing in the HPH Sector." Today, COVID-19 has highlighted the critical need to improve our understanding of healthcare supply chain networks while mitigating our reliance upon foreign sources for the production of essential medicines and medical countermeasures. To that end, ASPR is intent on improving its situational awareness of supply chain vulnerabilities while incentivizing resiliencies in domestic manufacturing. With your assistance, the survey-derived data and analysis provided by BIS will greatly enhance ASPR's ability to build a sustainable supply chain behind our HPH industrial base capability.

In order to enable these studies, ASPR intends to provide the requisite funding and technical support needed by BIS. There will also be a project officer assigned by ASPR for each assessment. We have identified the following assessment areas in order of prioritization, the first of which has already been funded in full over a period of three years:

- Study 1: Assess the supply chain for the provision of raw/starting materials, Active Pharmaceutical Ingredients (API) and other consumables required for manufacturing influenza vaccine products
- Study 2: Assess the pharmaceutical supply chain for FDA designated essential medicines identified in Executive Order 13944
- Study 3: Assess the supply chains behind raw/starting materials, API and other required materials for manufacturing high consequence biologic medical countermeasures involved in treating smallpox, anthrax, Ebola, and other diseases

- Study 4: Assess the sterilization capacities supporting biopharmaceutical manufacturing
- Study 5: Assess the biopharmaceutical supply chains supporting single use technologies supporting vaccine production in large quantities
- Study 6: Assess pharmaceutical and device supply chains supporting chemical and radiation/nuclear medical countermeasure efforts

This study partnership represents a priority initiative for ASPR. I will be our point of contact regarding this request. Please contact me at <a href="Robert.Kadlec@hhs.gov">Robert.Kadlec@hhs.gov</a> or 202-205-2882. We appreciate your consideration of this request and look forward to the opportunity to work with BIS.

Sincerely,

Robert P. Kadlec, MD, MTM&H, MS Assistant Secretary for Preparedness and Response