

**Food and Drug Administration Resilient Supply Chain Program (RSCP) Workshop:
“Building Medical Device Supply Chain Resilience: A Healthcare & Public Health
Ecosystem-Wide Collaboration”**

Follow-Up Recommendations from the Infectious Diseases Society of America (IDSA)
July 5, 2022

IDSA appreciates the opportunity to provide recommendations for building medical device supply chain resilience. We welcome continued dialogue and collaboration with FDA and others in the Administration to address the need for a resilient supply chain to ensure health care facilities and personnel have the tools they need to provide optimal patient care and prevent the spread of infectious diseases.

In a pandemic or other public health emergency, it is crucially important that the needs of health care and public health workers are appropriately prioritized to ensure access to supplies that are vital to emergency medical response. As FDA considers the medical device supply chain specifically, IDSA would like to highlight the critical importance of diagnostic testing supplies for public health emergency preparedness and response. Testing capacity is central to understanding how a disease is spreading and mutating, to inform public health and health care system responses, and to guide optimal patient care.

Over the course of the COVID-19 pandemic, laboratories experienced critical shortages of supplies, including nasal swabs, viral transport media and PCR reagents, that could have been averted. It is critical to identify diagnostics supply chain and logistical bottlenecks and ensure that backups and alternatives are in place. This includes the deployment of general-purpose Nucleic Acid Amplification and Nucleic Acid Sequencing devices in clinical settings for ordinary use so that they will be ready and available when the next new pathogen hits. The early deployment of these technologies could feed data directly into the appropriate CDC database for real-time analysis.

Further discussion is needed to examine important factors in test development and supply chain logistics, ensure the inclusion of relevant stakeholders and build a comprehensive plan to ensure diagnostic preparedness.

Specific recommendations for strengthening the diagnostics supply chain to enhance our preparedness are as follows:

- Develop a federally guided supply chain and distribution plan involving all manufacturers of products relevant to diagnostics and pandemic response. The Association of Supply Chain Management should be involved in developing this plan, and the government should contract with suppliers to improve the effectiveness and accessibility of supplies from the Strategic National Stockpile (SNS). COVID-19 demonstrated the inability of SNS to provide supplies to all states simultaneously in a nationwide emergency. We have an opportunity to learn from this experience and make improvements.
- Incentivize domestic manufacturing of diagnostics materials to avert the need for importing a majority of products in the event of a public health emergency.

- Require manufacturers to validate diagnostic products on at least two alternative devices so that laboratories that lack the budget and space to purchase additional instruments or platforms are able to run tests on existing devices. Vendors have an incentive not to do this currently, and laboratory use of unvalidated alternatives can void the device warranty.
- Initiate a national inventory of diagnostic equipment. The federal government should identify choke points and establish and fund a plan to address them, including through backup plans and redundancies to avoid breakdowns in access to testing supplies.
 - Include research labs in this inventory, including labs with smaller machines (e.g., thermocyclers).
- Develop a national database, accessible by all laboratories, to identify available equipment and ensure all resources are utilized.
- Designate pandemic assessment centers – i.e., institutions partnered with state health departments – to coordinate activities to improve responses and alleviate supply chain issues. These partnerships can work strategically to maximize utilization of existing resources and decrease turnaround times on testing.

Strengthening the diagnostic testing supply chain is a critical component of securing our future testing capacity, but it is equally important to invest in our clinical laboratory infrastructure, testing workforce, diagnostics research and development, and regulatory approaches. Thank you again for the opportunity to provide these recommendations. If you have questions about these comments or need more information, please contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.