ASPR

U.S. Department of Health & Human Services
Administration for Strategic Preparedness & Response

ASPR/IBMSC Industry Roundtable on Domestic Manufacturing of APIs/KSMs/FDFs

June 24, 2025

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KEY INFORMATION

In support of the Administration's objectives to secure the nation's medical supply chain and bolster domestic manufacturing of critical medicines and their components (active pharmaceutical ingredients (APIs) and key starting materials (KSMs)), the Administration for Strategic Preparedness and Response (ASPR) is actively engaged with both industry manufacturing partners and other United States Government (USG) agencies. The purpose of the ASPR Industry Roundtable on Domestic Manufacturing of APIs/KSMs/Finished Dosage Forms (FDFs) was to convene key stakeholders across the pharmaceutical manufacturing ecosystem—including industry leaders, federal partners, and academic experts—to assess current capabilities, identify barriers, and explore opportunities for enhancing the domestic pharmaceutical supply chain. The roundtable aimed to support United States (U.S.) national health security by fostering resilient, scalable, and sustainable domestic production of critical medical components necessary for emergency preparedness and routine healthcare delivery.

EXECUTIVE SUMMARY

On June 24, 2025, the U.S. Department of Health and Human Services (HHS), ASPR, through its Center for Industrial Base Management and Supply Chain (IBMSC), hosted an Industry Roundtable focused on the domestic manufacturing of APIs, KSMs, and FDFs. There were 249 attendees (186 Industry/63 Government), and this full-day event brought together leaders from government, industry, academia, and the nonprofit sector to lay the framework for forging a collaborative national strategy aimed at reducing U.S. reliance on foreign pharmaceutical sources and enhancing public health preparedness and economic resilience.

The roundtable proved to be both timely and impactful as it tackled one of the most urgent and complex challenges facing our nation: strengthening the domestic manufacturing of APIs, KSMs, and FDFs.

These components form the foundation of the medications that Americans depend on every single day—and they are essential to both our public health system and our national security. Unfortunately, over 70 percent of the APIs used to produce essential medications in the U.S. are sourced from overseas, primarily from countries like China and India. This level of dependence leaves us vulnerable—not just to market fluctuations and shipping delays, but to geopolitical tensions, trade disruptions, pandemics, and natural disasters. The roundtable aimed to create a plan for reshoring these vital APIs.

The roundtable opened with remarks by ASPR Principal Deputy Assistant Secretary, John Knox, followed by a keynote speech from Arlene Joyner, Deputy Assistant Secretary (DAS) of IBMSC, and a review of the API Study from Robert Nichols, Trade and Industry Analyst at the U.S. Department of Commerce (DOC).

Mr. Knox, offered opening remarks, reminding attendees of the importance of this roundtable, not only to our domestic medical supply chain, but to national defense. He implored attendees to bring their ideas, and most importantly, their hands on experiences to the table, acknowledging that the USG could not tackle such a pressing issue alone.

Mr. Knox was followed by DAS Arlene Joyner, who used her remarks to provide an overview of IBMSC, which she heads. Ms. Joyner provided a summary of the critical projects being spearheaded by the five domains within IBMSC (*Enabling Innovation and Technology, Critical Medical Equipment, Testing and Diagnostic, Defense Production Act (DPA) and Supply Chain Optimization*). She also highlighted the advancements that have been made, to date, by her team as it relates to APIs, KSMs and FDFs.

Echoing Mr. Knox, Ms. Joyner also underscored that this effort was a collective one and encouraged attendees to continue engaging via IBx Connect, ASPR's market research and collaboration platform. IBx Connect collects information from stakeholders on manufacturing solutions that can be applied to platform technologies; drug substance and drug products; personal protective equipment; and testing and diagnostic devices and consumable components. Of particular interest are products and technologies that have progressed into or beyond clinical trials and are currently being produced at scale or utilize an approved platform.

Ms. Joyner was followed by Robert Nichols, Trade and Industry Analyst at DOC. Mr. Nichols provided first wave results from an API study being conducted for IBMSC by the Bureau of Industry and Security, within DOC under the authority of the DPA. These surveys are completed by product manufacturers and aim to understand supply chain vulnerabilities, identify dependencies, and support national security and economic prosperity.

These morning presentations were followed by a series of high-impact breakout sessions that examined key issues, including domestic investment priorities, regulatory harmonization, mapping and visibility of supply chains, and onshoring strategies.

Notable speakers and panelists included both industry and government representatives, such as (list not exhaustive):

- Eric Edwards, CEO of Phlow Corp.
- Dean Kamen, Founder of DEKA
- Ronald Piervincenzi, CEO of U.S. Pharmacopeia
- Grace Graham, U.S. Food and Drug Administration (FDA) Deputy Commissioner; and
- Experts from Defense Advanced Research Projects Agency (DARPA), FDA, the U.S. Department of State, HHS Office of Small and Disadvantaged Business Utilization, and the private sector

Breakout sessions covered critical themes, such as:

- Session 1: Resilience strategies such as onshoring, regulatory pathways, and API visibility
- Session 2: Public-private collaboration, DPA authorities, and agile manufacturing models

Key Takeaways from the breakout sessions include:

Domestic Manufacturing and Investment Opportunities

- Promoting global harmonization to encourage public/private collaborations
- Minimizing regulatory barriers to incentivize Advanced Manufacturing

Advancing Domestic Manufacturing of Pharmaceuticals and Ingredients for National Security

- Rethinking stockpiling strategies as a first option
- Adopting national security strategy posture for APIs and KSMs akin to semiconductors

Onshoring and Nearshoring Strategies

- Using innovation to enable resiliency and reliability
- Prioritizing accessibility and affordability of quality drugs

KSM and API Mapping and Visibility Tools

- Digitizing data is important to visualize and predict barriers on manufacturing, regulatory compliance, and financial investment
- Leveraging the power of AI and Machine Learning to gain visibility and mapping of APIs

Regulatory Harmonization & Fast Track Approval for Domestic APIs

- Balancing regulatory oversight to avoid over-constraining production costs that make domestic manufacturing unviable

- Speeding up approvals by using FDA Preoperational review of facilities before breaking ground and harmonizing regulatory policies to recognize approvals from other countries

Industry-Government Partnerships

- Incentivizing data sharing between USG and Industry
- Kickstarting industry innovation with initial investments, cost-sharing agreements, forgivable loans, and other partnerships

Leveraging DPA to Support the Public Health Base

- HHS's delegated DPA authorities are designed to support health-resource national defense requirements
- The DPA provides unique authorities, such as purchase commitments, to ensure long-term sustainability of domestic capacity for API and KSMs

Agile and Distributed Manufacturing

- Commercial adoption and investment are a significant barrier to development and deployment of agile and distributive manufacturing technologies and their products
- Employing a new "access" model to help partners rise above the bar of entry and adoption of these agile and distributive manufacturing technologies is critical

The event concluded with a plenary session and closing remarks from Ms. Joyner reinforcing the need for both coordinated and sustainable action.

This roundtable marked a pivotal step toward securing America's pharmaceutical supply chain, ensuring that future public health emergencies are met with a robust, agile, and domestic response capability.

ASPR, as part of its mission to safeguard public health and medical preparedness, recognizes the urgent need to strengthen domestic pharmaceutical manufacturing. ASPR will continue to work closely with industry and federal partners such as the White House National Security Council, National Economic Council, Made in America Office, and the U.S. Office of Trade and Manufacturing Policy to further ensure supply chain resilience and national security of critical medicines through our planned stockpiling and reshoring efforts.