What are we trying to do?

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 250414-0065]

XRIN 0694-XC120

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

(x) any other relevant factors.

Summary: Occam Systems will address eight (8) of the elements in XRIN 0694-XC120 with automation and novel workflows leveraging artificial intelligence. The following slides are drawn either directly or with light modification from technical reports that have been completed for DARPA, ARPA-H, and commercial clients.

Contact: James Ferri, President, Occam Systems Incorporated
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(i) current and project demand …

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

Summary: Occam has developed an extensible demand-side prioritization framework based on clinical use, indication, and prescription volume to automatically identify and score both the drug product and drug substance (API).

What did we do? The scoring tool is based on the Medical Expenditures Panel Survey (MEPS). Occam has also developed an enhanced scoring framework based on the Carelon Healthcare Integrated Research Database (HIRD), a key part of the FDA Sentinel initiative. Occam is currently soliciting participants for a useability study of this tool.

When did we do it? August 2024 - **Funding / Agency:** ARPA-H (AY2AX000033)

Funding PoC: Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(ii) extent domestic production can meet …

> (ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

Summary: Occam Systems has developed the ability to define machine-readable chemical manufacturing requirements, a manufacturing asset registry system, and a cloud-based digital enterprise platform to index and optimize new manufacturing solutions for chemicals (pharmaceuticals and pharmaceutical ingredients) important to national security.

What did we do? Domestic pharmaceutical manufacturing requires capital assets, licensure, and chemicals handling capabilities possessed by specialized concerns. We currently curate an asset registry of more than 16,000 assets across more than 100 domestic manufacturing sites. We have demonstrated the ability to automatically assess and allocate supplier equipment assemblies, i.e. manufacturing production lines, against manufacturing requirements. In doing so, we identify candidate solutions for a wide range of supply chain challenges, including complex specialty, fine, and pharmaceutical chemicals. In the DARPA awards below, these analyses were completed for more than 20 drug substances. More importantly, automation in the ARPA-H award accelerates manufacturing requirements explication by more than tenfold, making a full analysis of the entire U.S. portfolio achievable in 6 months or less.

When did we do it? September 2020 -

Funding / Agency: DARPA (HR00112020058) September 2020
DARPA (HR0011SE20224-02) September 2022 -
ARPA-H (AY2AX000033) August 2024 -

Funding PoCs: Anne Fisher, Deputy Director, Defense Sciences Office – now private sector
Ana Saplan, Defense Sciences Office (ana.saplan@darpa.mil)
Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(iii) role of foreign supply chains

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

Summary: Occam developed an automation platform for establishing genealogy of ingredients (drug substance and excipients) in pharmaceutical products and manufacturing provenance.
This has been shared with the FDA Office of Product Quality Assessment: Paresma (Pinky) Patel, Division Director, Office of Product Quality Assessment III at FDA

What did we do? Developed and enhanced AI-tooling and data models to establish route of synthesis and manufacturing location for medicines listed in the National Drug Code (NDC) database. This automation identifies manufacturing location of drug product, drug substance, and (likely) regulatory starting materials.

When did we do it? August 2024 -

Funding / Agency: ARPA-H (AY2AX000033) August 2024 -

Funding PoC: Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(iv) concentration of US imports and … risks

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

Summary: We believe that the automation platform addressed in (iii) also addresses (iv). **We enable direct, quantitative calculation of risk factors associated with manufacturing location and logistical (shipping) risk using real-time data in this platform.**

What did we do? Developed and enhanced AI-tooling and data models to establish route of synthesis and manufacturing location for medicines listed in the National Drug Code (NDC) database. This automation identifies manufacturing location of drug product, drug substance, and (likely) regulatory starting materials.

When did we do it? August 2024 -

Funding / Agency: ARPA-H (AY2AX000033) August 2024 -

Funding PoC: Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(v) impact of foreign govern subsidies

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

Summary: Occam has technology that supports precision analyses of manufacturing margins with respect to current market pricing. We believe this can enable highly resolved strategic planning and policy development, down to single products (medicines or pharmaceutical ingredients.)

What did we do? Occam has developed an automation platform that enables direct calculation of the cost of goods sold for any chemical, including raw materials cost based on real time commercial pricing for raw materials, operating cost (labor and utilities based on regional or municipal rates), and equipment amortization (based on detailed engineering requirements for the manufacturing process line.)
A briefing on these technologies and workflows is available on request.

When did we do it? September 2022 -

Funding / Agency: DARPA (HR0011SE20224-02) September 2022 -
ARPA-H (AY2AX000033) August 2024 -

Funding PoCs: Ana Saplan, Defense Sciences Office (ana.saplan@darpa.mil)
Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(vi) impact of unfair trade …

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

Summary: This item is not directly addressed in this Response

(vii) export restrictions by foreign nations

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

Summary: We believe that the automation platform addressed in (iii) also addresses (vii).

What did we do? Developed and enhanced AI-tooling and data models to establish route of synthesis and manufacturing location for medicines listed in the National Drug Code (NDC) database. This automation identifies manufacturing location of drug product, drug substance, and (likely) regulatory starting materials, as well as supplier redundancy. This combined with the response to (ii) informs the risk posed by foreign nations to weaponize exports.

When did we do it? August 2024 -

Funding / Agency: ARPA-H (AY2AX000033) August 2024 -

PoC: Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(viii) feasibility increasing domestic capacity

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> (viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

Summary: Occam technology can support feasibility analyses and supply chain execution for a wide range chemicals, including pharmaceutical ingredients. We believe this can enable strategic planning, manufacturing execution, and campaign coordination in a large portfolio of manufacturing objectives.

What did we do? Occam has developed an automation workflow that supports the manufacturing lifecycle (process development, manufacturing execution, distribution logistics) that enables strategic coordination of large-scale manufacturing campaigns.
A briefing is available on request.

When did we do it? September 2022 -

Funding / Agency: DARPA (HR0011SE20224-02) September 2022 -
ARPA-H (AY2AX000033) August 2024 –

Funding PoCs: Ana Saplan, Defense Sciences Office (ana.saplan@darpa.mil)
Gina Kost, Deputy Director, Resilient Systems Office (gina.kost@arpa-h.gov)

(ix) impact of trade policy … and resources

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

Summary: Occam technology can support a feasibility analysis and supply chain execution for a wide range chemicals, including pharmaceutical ingredients. We believe this can enable strategic planning, manufacturing execution, and campaign coordination in a large portfolio of manufacturing objectives.

What did we do? Occam has developed an automation workflow supports the manufacturing lifecycle (process development, manufacturing execution, distribution logistics) that enables strategic coordinating of large-scale manufacturing campaigns. A briefing is available on request.)

When did we do it? Funding / Agency DARPA (HR0011SE20224-02) September 2022
ARPA-H (AY2AX000033) August 2024

Funding PoCs: Ana Saplan, Defense Sciences Office (ana.saplan@darpa.mil)
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(x) other relevant factors

(x) any other relevant factors.

Summary: Occam addresses a global chemicals marketplace of more than $5T in annual transactions. We help clients lower cost of goods sold through AI-powered automation in chemical process development and manufacturing supplier optionality with best-in-class data and technology integrations. We develop solutions that address risk management and chemical process development. We enable manufacturing stakeholders from technical personnel to procurement managers, as well as policy makers and strategic advisors with the ability to analyze, design, and optimize supply chains, as well as manufacturing resource requirements and raw materials logistics.

What are we trying to do? The United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security against a wide range of threats. Occam seeks to revolutionize supply chain resilience for critical chemicals and pharmaceuticals through automated supply chain configuration and transformation of the associated procurement processes.

How is it done today? Chemical manufacturing affects the supply of critical materials including pharmaceuticals, semiconductors, and energy storage devices. The supply chains for these transformation-based products is large and complex, making requirements management in manufacturing sourcing processes lengthy and laborious.

What is new in our approach? Occam leverages science-based generative AI and best-in-class technology integrations with a unique collection of multi-discipline tools and methods. The big goal is to shrink the chemicals and materials (and other transformation-based manufactured products) procurement timescale from six (6) months to less than one week.

Who cares? Occam Systems has commercial engagements at scale in the public and private sectors.

What are the risks to execution? Core Occam technology has been technically de-risked through engagements with state and federal government and industry.

Who we work with? Occam is a Delaware C-Corp in Richmond, Virginia with research and development funding from the DARPA, ARPA-H, FDA and commercial clients across large, medium, and small cap chemical and pharmaceutical manufacturers.

(x) other relevant factors

(x) any other relevant factors.

Resilient Chemical Supply Chains.
Supercharged by Artificial Intelligence.

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Summary

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Summary: Occam Systems has addressed eight (8) of ten elements in this RFI XRIN 0694-XC120 with automation and novel workflows leveraging artificial intelligence.

We would be pleased to offer a briefing on any of these technologies on request.

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