STOIC Bio
Cure People + Planet™

Docket No. BIS–2025–0022
XRIN 0694–XC120

Dear Section 232 Investigative Team:

The United States cannot protect its national security if it cannot manufacture the essential inputs for modern medicine. Our pharmaceutical supply chain – from cell culture media to critical vaccine components – remains dangerously dependent on foreign production, long lead times, and centralized systems that are brittle under stress. We've seen the consequences during pandemics, trade disputes, and geopolitical instability. To ensure security, we must reimagine domestic capacity: not only as large factories, but as a distributed, digital, and resilient manufacturing infrastructure that can respond rapidly, flexibly, and locally to the next great challenge.

While large-scale pharmaceutical manufacturing remains essential, the vulnerabilities exposed by recent global disruptions underscore the need to diversify our capabilities. The nation's definition of domestic production capacity must include emerging, **modular technologies that can deliver core pharmaceutical materials on demand and at the point of need.**

These innovations are not speculative. Systems like ours, ***Krakatoa®***, enable the localized production of sterile cell culture media and buffers — critical inputs for biopharmaceutical manufacturing — through an automated, compact platform. By reducing dependence on international shipping and allowing regional or even facility-level production, these systems help eliminate key supply chain bottlenecks while improving responsiveness and reducing environmental impact.

A one-page overview of Krakatoa is attached, highlighting Krakatoa's workflow and relevance to the Department's national security objectives.

Point-of-use manufacturing platforms support national security in several ways:

- **Reducing foreign dependency** for high-volume, high-importance inputs like media, buffers, and excipients
- **Improving responsiveness** to demand surges or disruptions in centralized supply
- **Enabling secure, digital traceability** through integrated process control and monitoring
- **Aligning with modern efficiency and sustainability goals**, minimizing waste and emissions

These solutions are also aligned with broader federal goals related to **manufacturing resilience**, **digital modernization**, and **supply chain transparency**. By embracing these innovations, we not only increase security — we future-proof our pharmaceutical infrastructure.

Accordingly, I urge the Department to:

- Explicitly recognize **modular, automated biomanufacturing systems** as part of the domestic pharmaceutical production base
- Support the development and deployment of **digitally integrated, point-of-use manufacturing infrastructure**
- Coordinate with relevant agencies — including HHS, DOD, and DOE — to align regulatory frameworks and investment strategies that strengthen our industrial base

National resilience in health security does not hinge on stockpiles alone. It is a question of **how flexibly, efficiently, and independently we can produce what we need — when and where it's needed most**. Systems like Krakatoa represent a scalable step toward that future.

Sincerely,
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