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From Stockpile to Supply Chain

Domestic biomanufacturing and defense logistics integration for pharmaceutical supply chain resilience

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Session: Biomanufacturing for Supply Chain Resilience

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The World War II lesson

“However fine the doctor or skilled the surgeon, both were helpless without the drugs and instruments flowing uninterruptedly through the smoothly organized channels of medical supply.”

Lieutenant General Leonard D. Heaton
The Surgeon General, U.S. Army (1959–1969)
Medical Supply in World War II

Translation for 2026 and beyond

Medical excellence does not begin at the bedside. It begins upstream: in raw materials, manufacturing capacity, quality systems, cold-chain storage, inventories, and logistics.

Commercial efficiency created strategic fragility

Raw materials
solvents, precursors, biologic inputs

Key Starting Material (KSM) / Active Pharmaceutical Ingredient (API)
critical upstream manufacturing

Finished dose
sterile fill-finish, formulation

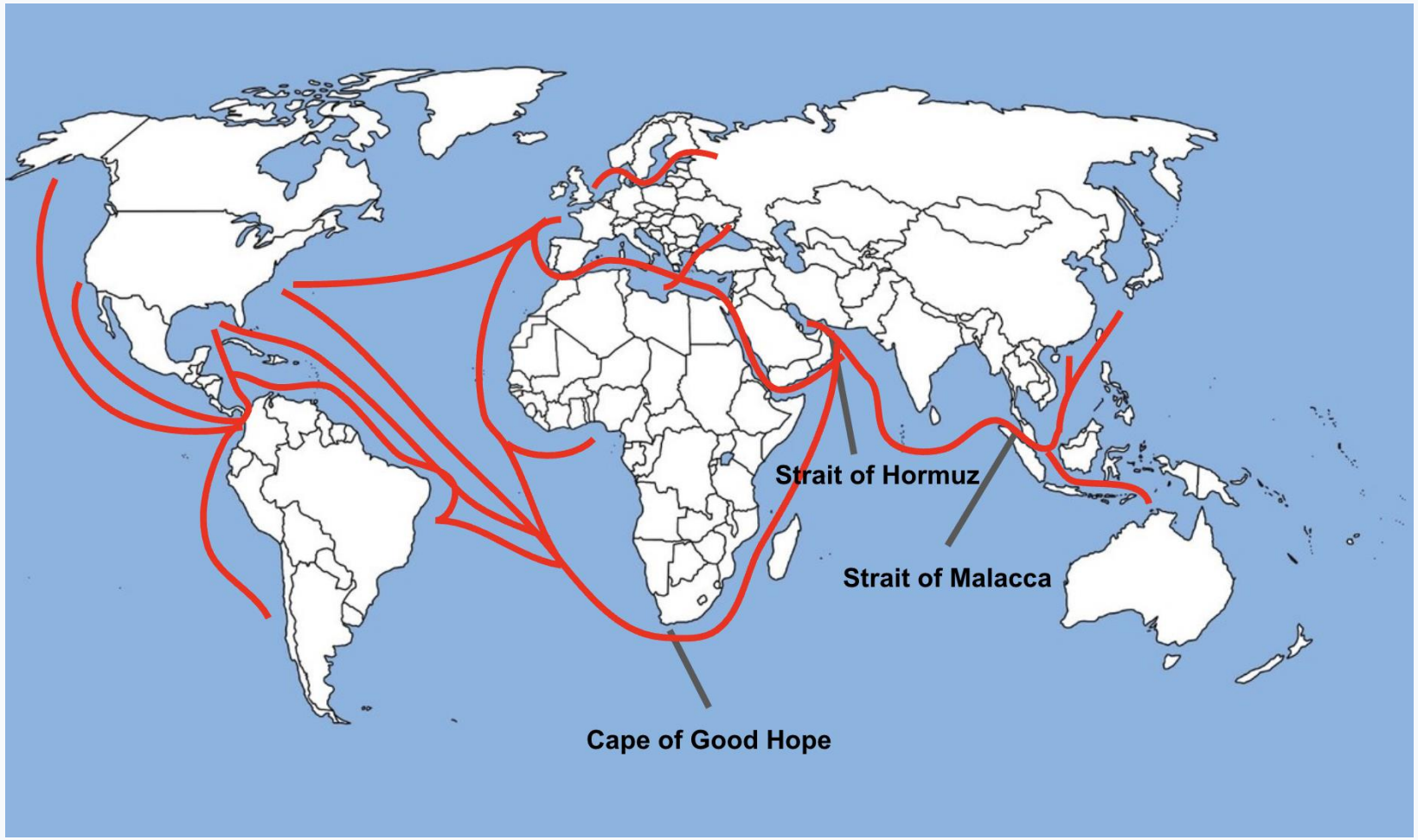
Distribution
cold chain, ports, air cargo

Role of Care
patient-ready medication

Operational risk
In stable markets, global sourcing lowers cost. In a conflict, pandemic, export restriction, quality failure, port closure, or air-cargo disruption, efficiency can become fragility.

Core question
Can we make it, validate it, preserve it, move it, and regenerate it when commercial networks are degraded or denied?

Global pharma transport corridors and chokepoints



Chokepoints to contingency stress test

Strait of Hormuz / Gulf hubs	Strait of Malacca	CONUS last-mile distribution
Gulf disruption	**Indo-Pacific shadow**	**Domestic fragility**
• Air-cargo rerouting delays time-sensitive shipments • Cold-chain assets become stranded at hubs • War-risk premiums hit low-margin generics hardest	• Primary maritime passage between India and China • Critical for API/KSM movement and finished-dose flows • Future conflict could force long reroutes or inventory drawdown	• Just-in-time inventories leave little buffer • Substitution can trigger secondary shortages • Cold-chain failures convert delay into spoilage

LSCO turns transport delay into medical risk

2–8°C

typical cold-chain window for many biologics and vaccines

10–14 days

longer reroutes around major maritime disruption can exhaust thermal buffers

25–30%

global trade commonly cited as moving through Strait of Malacca

System risk

shortage → substitution → error → degraded readiness

India sources approximately 65% of its APIs, KSMs, and pharmaceutical intermediates from China. In a large-scale combat operation (LSCO), China could deliberately leverage this upstream dependence to create downstream shortages of essential medicines in the United States.

The upstream “N-1” problem

China’s control over raw and key starting materials

Downstream diversification can hide a single upstream dependency.

41% of KSMs used in U.S.-approved APIs come solely from China; 16% come from India. Chinese restrictions on inputs moving to India or Europe could cause U.S. shortages indirectly.

Three archetypes of pharmaceutical dependence

1 Small-molecule generics

- Upstream KSM/API concentration
- Low margins + fragile sterile capacity
- Downstream diversity can be illusory

2 Biologics

- Value-chain erosion
- Discovery → trials → manufacturing
- Recovery timelines can be years

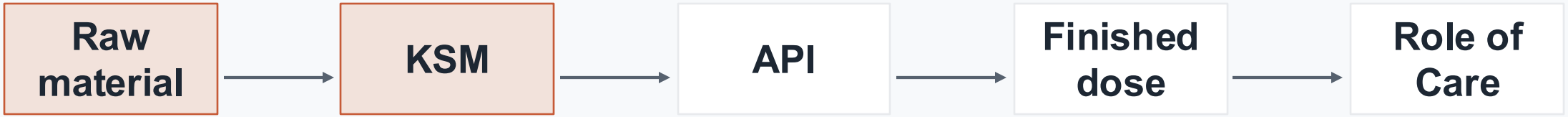
3 R&D infrastructure

- Synthetic DNA and AI-ready biology
- Control of tools shapes future medicines
- Biosecurity + IP risk

The solution cannot be one-size-fits-all. Each archetype needs a different mix of transparency, demand, manufacturing, regulation, and logistics.

Adapted from Council on Foreign Relations *The Pharma Choke Point* archetype model.

Archetype 1: small-molecule generics fail upstream



Medicine	Chokepoint	Concentration	Why it matters
Amoxicillin	6-APA KSM	94% China-controlled	Broad-spectrum antibiotic; pediatric and hospital relevance
Heparin	Crude porcine mucosa / API	74% U.S. supply from China	Surgery, dialysis, trauma, cardiopulmonary care
Acetaminophen	Upstream precursors	70% China-controlled	Analgesic / antipyretic baseline care
Norepinephrine	KSM/API complexity	shortage-prone injectable	Shock and critical care; limited substitution margin

Archetype 2: biologics fail through vertical capacity erosion

32 / 55

late-stage monoclonal antibody programs attributed to Chinese firms

79%

surveyed U.S. biopharma firms reported dependence on China-based contractors for at least some manufacturing

AI + bio

drug discovery speed increases, but scale-up becomes strategic bottlenecks

cold chain

2–8°C requirements make logistics part of the manufacturing problem

Biologics vulnerability is not just about API location; it is about control of process data, cell lines, assays, manufacturing capacity, scale-up, tech transfer, and cold-chain assurance.

Archetype 3: the future supply chain begins with DNA and data

Synthetic DNA	One of three firms accounting for 86% of global synthetic DNA supply is Chinese; the other two have significant China presence.	**Physical input to future therapeutics**
Biological data	AI-ready biological datasets and metadata standards determine model performance and regulatory trust.	**Strategic resource**
Automated labs	Cloud-controlled synthesis and design-build-test cycles can move discovery outside trusted jurisdictions.	**Cyber + IP exposure**
Process data	Digital batch records, comparability packages, and process analytics determine whether scale-up is fast or slow.	**Commercialization bottleneck**

Industrial policy can move capital but not readiness

Pharmaceutical supply chains are now being treated as strategic infrastructure.

Policy tools can push…	Readiness still requires…
Domestic investment	validated KSM/API capacity
Stockpiling	rotating reserves + fill-finish
Supplier shifts	FDA-ready quality systems
Regionalization	cold-chain and theater logistics
Pricing/onshoring deals	Role of Care implementation

Tariffs and incentives can start the conversation. Manufacturing, quality, and logistics determine resilience.

Resilience Tetrad: a specific U.S. strategy for critical medicines

*SAPIR = Strategic Active Pharmaceutical Ingredients Reserve

1. Demand-side anchoring

DoD, VA, and HHS/CMS 5–10 year volume guarantees for priority critical medicines and inputs.

2. SAPIR expansion

Rotating 12-month reserve of priority APIs/KSMs using FIFO replenishment tied to domestic production.

*FIFO = “first in, first out,” meaning older inventory is used or rotated first to prevent expiration and maintain a fresh reserve.

3. Strategic incentives

Priority review vouchers or procurement preference for fully domestic / trusted-allied essential API capacity.

4. Regulatory acceleration

National-security designation for selected API facilities; parallel FDA/EPA engagement while preserving quality.

Reward resilience and drug quality, not only lowest unit price.

Stockpiles buy time; manufacturing buys options

Priority list

operational medicines + civilian criticality

KSM/API reserve

rotating inventory GMP-compliant storage

Fill-finish network

robotics, isolators single-use systems

Release + distribution

QA release pre-positioned logistics

*GMP = good manufacturing practice

*QA = quality assurance

Design principle

An API reserve without pre-qualified finished-dose manufacturing is a warehouse. A fill-finish network without upstream inputs is idle capacity. True resilience requires both.

Near term: 6–18 months of priority KSM/API buffers + allied suppliers + risk communication protocols.

Defense logistics: the missing integrator

Commercial supply chains optimize for efficiency. Defense logistics is designed for mission assurance under degraded conditions.

Buyer	Integrator	Fielding partner	Standards convener	Surge customer
guaranteed demand advance commitments	manufacturing → inventory → theater distribution	operational testing for austere use	resilient design quality + interoperability	stabilize production during disruption

Defense-specific insight

Production without assured delivery is incomplete. Logistics without secured inputs is incomplete. The operational medicine requirement is the integration of both.

Distributed manufacturing must match Role of Care

Role	Manufacturing boundary	Appropriate function
Role 1	No drug manufacturing	Inventory visibility, cold-chain monitoring, reconstitution, last-mile delivery
Role 2	Limited pharmacy preparation	Diagnostics/reagents, emergency compounding, stabilization supplies
Role 3	Controlled preparation / limited fill-finish	Theater hospital: quality checks, selected sterile prep if pre-validated
Role 4	Modular GMP-capable hub	Fill-finish, release testing, cold-chain repair, packaging, distribution
Role 5 / CONUS	Full manufacturing and regeneration	API/FDF production, SAPIR rotation, surge manufacturing, workforce training

Point-of-need manufacturing should be pre-approved, modular, quality-controlled, and matched to clinical risk.

A practical implementation roadmap

0–24 months

Map and buffer

- Identify operational medicine priorities
- Map KSM/API/excipient tiers
- Fill SAPIR for highest-risk inputs
- Qualify allied emergency suppliers

2–5 years

Build and validate

- Fund modular manufacturing nodes
- Pre-qualify fill-finish capacity
- Stand up digital CMC/PAT standards
- Exercise logistics and shortage protocols

5+ years

Scale and integrate

- Mature domestic/allied KSM capacity
- Link production to theater distribution
- Train biomanufacturing workforce
- Include biotech supply in wargames

Success metric: assured access to the right medicine at the right role of care under stress.

Map. Make. Move. Monitor.

Map

upstream dependencies and single points of failure

Make

domestically and with trusted allied redundancy

Move

through defense logistics when commercial routes fail

Monitor

inventory, quality, risk, and shortage signals in real time

The goal is not to make every drug domestically. The goal is to make the most critical medicines, APIs, and KSMs at home or with trusted partners so military medicine can endure disruption.

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Questions

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Discussion prompts

Are we solving the right layer?
FDF vs API vs KSM vs biologics inputs vs logistics

What belongs forward?
Role of Care should determine manufacturing risk tolerance

How do we sustain demand?
AMCs, offtake agreements, SAPIR rotation, allied procurement

How do we avoid bias?
Generic categories, transparent criteria, multiple options, evidence-first

Thank you.