Foreign Dependence: How China Captured America's Drug Supply — and How the U.S. and Democratic Allies Can Lead the Next 50 Years of Life Sciences

Written testimony submitted by the author for the hearing record of the U.S. Senate Special Committee on Aging[1].

Chairman Rick Scott[2], Ranking Member Kirsten Gillibrand[3], and Members of the Committee: thank you for the opportunity to submit testimony for the record on the strategic risks created by America's dependence on foreign life-sciences supply chains—especially those tied to the People's Republic of China[4]—and on the policy architecture needed for the United States and democratic allies to lead the next half-century of life sciences. [5]

This testimony is written in the style of a final, standalone document. Where precise, product-level sourcing or cost data are not publicly available (a recurring problem in this domain), I explicitly note the data gap and provide bounded ranges with clear assumptions. [6]

Executive Summary

America's drug-supply vulnerability is not a single statistic; it is a systems outcome. Over decades, market design (especially in mature generics), procurement practices that reward the lowest price, and a global regulatory architecture that often lacks true inspection parity pushed manufacturing offshore—first upstream (chemical precursors, key starting materials, and active pharmaceutical ingredients), and then downstream into finished dosages. This produced a supply chain that can look "diversified" at the final label and still be dangerously concentrated at the upstream layers that actually determine resilience. [7]

Three hard facts should anchor the hearing record.

First, generic drugs dominate U.S. use (91% of prescriptions), but the U.S. has allowed the industrial base behind generics to erode sharply. The Committee's bipartisan staff report states that since 2002, pharmaceuticals manufactured in the U.S. dropped by 46 percent, and that in 2024 the U.S. manufactured 37% of the pharmaceuticals it consumed (down from 83% in 2002). [8]

Second, exposure is greatest where the public has the least visibility: upstream. The Food and Drug Administration[9] testified that as of August 2019 only 28% of API-manufacturing facilities supplying the U.S. market were in the U.S.; 72% were overseas and 13% were in China. [10] The Committee's report further highlights that the U.S. government has limited information about key starting material (KSM) supply chains because of confidentiality

practices, and that over 40% of generic drugs sold in the U.S. have a single manufacturer—two features that convert normal disruptions into acute shortages. [11]

Third, the national-security dimension is no longer theoretical. The Department of Defense[12]'s FY2023 pharmaceutical supply chain assessment analyzed 1,744 drug families (12,917 NDCs) and found that 22% had unknown API origin; 54% of the DoD pharmaceutical supply chain was rated high or very high risk due to reliance on non–Trade Agreements Act sources (including China and India) or unknown sourcing. [13]

The policy conclusion is straightforward: the U.S. needs a "resilience-by-design" life-sciences strategy that simultaneously (1) hardens essential-drug supply chains and (2) positions the U.S. and democratic allies to win the next 50 years of life sciences—where clinical trial speed, biomanufacturing scale, AI-enabled discovery, and trusted data governance will determine strategic advantage. [14]

This strategy should be built around seven mutually reinforcing pillars:

A federal buyer and payer architecture that rewards reliability and trusted sourcing (not just the lowest price), using defense procurement as a pilot and Medicare as a scale lever. [15]

Full-stack transparency: finished dose, API, and KSM origin disclosure at lot-level (or the closest feasible proxy), with secure but actionable access for government risk analytics. [16]

Targeted reshoring for the most brittle upstream nodes (including fermentation-based antibiotics and selected sterile injectables), complemented by friend-shoring with democratic allies rather than unattainable autarky. [17]

Strategic stockpiles designed for the upstream reality (APIs and—where feasible—KSMs), aligned with the federal government's new Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) direction and paired with advanced manufacturing capacity to "replenish, not just store." [18]

Regulatory modernization: inspection parity tools, risk-based testing, and accelerated pathways for domestically (or trusted-ally) manufactured generics and essential medicines—while maintaining quality floors and avoiding "speed over safety." [19]

A democratic-life-sciences alliance agenda: harmonized standards, coordinated essential-medicine lists, shared surge manufacturing, and joint investment in the critical inputs (chemicals, reagents, single-use bioprocessing components) that underpin both drugs and the broader bioeconomy. [20]

A 50-year innovation posture: trusted biomedical data ecosystems, competitive clinical trial infrastructure, workforce, and commercialization pathways that prevent technology and manufacturing leadership from migrating to China's increasingly integrated life-sciences stack. [21]

Purpose and Scope

The Committee's hearing title—"Foreign Dependence: How China Captured America's Drug Supply"—is accurate but incomplete. China did not merely "capture" finished drugs; the deeper capture is upstream (KSMs, intermediates, APIs, chemical ecosystems), and the broader strategic contest is life sciences as an integrated national capability—including discovery, clinical trials, advanced manufacturing, and data-intensive biology. [22]

Accordingly, this testimony covers two connected domains.

Domain one: essential medicines (especially mature generics and hospital-administered injectables), where supply disruptions harm seniors disproportionately and where procurement dynamics drive fragility. [23]

Domain two: "life sciences overall"—biopharmaceutical innovation, biologics and advanced therapies manufacturing, diagnostics, and the enabling infrastructure (AI, genomics, biosecurity, and capital formation) that will shape prosperity and security for decades. China's current trajectory suggests it is rapidly closing gaps in clinical development and scaling "bioeconomy" capabilities as a strategic priority. [24]

A key methodological note: There is no single authoritative public dataset that maps drug supply chains from KSM to API to finished dosage for all products sold in the U.S. The DoD report, the Committee's staff report, FDA facility counts, and selected industry analyses provide partial slices; they do not fully resolve volume shares at each tier. This "data opacity" is not incidental. It is itself one of the vulnerabilities policy must fix. [25]

Timeline of Dependence and Today's Exposure

The most important timeline is not a list of scandals; it is the cumulative policy and market structure that created incentives to offshore.

In 1984, the Hatch–Waxman Act accelerated generic entry and drove large consumer savings, but it also intensified price competition in mature markets. Over time, many products became "race to the bottom" commodities where reliability and quality investments are poorly rewarded. The Food and Drug Administration[9]'s Drug Shortages Task Force report (2019) identifies core drivers consistent with this: weak incentives to produce low-margin products, limited market recognition of mature quality systems, and regulatory/logistical challenges in recovering after disruption. [26]

In the 1990s and 2000s, upstream chemical synthesis and fermentation migrated toward lower-cost and cluster-based production in Asia. By August 2019, FDA testified that only 28% of API manufacturing facilities supplying the U.S. market were domestic; 72% were overseas and 13% were in China. [10]

By the 2010s, the growth signal is visible in regulatory "plumbing": Drug Master File (DMF) activity for active API shifted heavily toward India and China. The Committee's report cites

that by 2021, India and China together represented 85% of active API DMF filings (India 62%, China 23%), while the U.S. and Europe declined to 4% and 7% respectively. A Duke analysis similarly notes that in 2021, 62% of new API DMFs were submitted from India and 23% from China, and notes that DMFs are a proxy and do not capture production volume. [27]

The COVID-19 period stress-tested the system and revealed that “finished dose” diversification can mask upstream concentration. In 2025, the White House issued an Executive Order directing Administration for Strategic Preparedness and Response[28] to fill the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) with a six-month supply of APIs for roughly 26 “critical drugs,” and to update and develop a plan for a broader list of essential medicines. [29]

Parallel policy tools began to converge:

Defense procurement: The FY2025 Senate NDAA bill text includes Section 887 creating 10 U.S.C. § 4865, restricting DoD procurement of listed generic drugs unless they are manufactured in the U.S. and use U.S. or Trade Agreements Act–designated-country APIs and KSMs, with an availability waiver and a requirement to develop a “defense-relevant generic drug list.” [30]

Medicare incentives: In January 2026, □entity□["organization","Centers for Medicare & Medicaid Services","u.s. medicare agency"]□ issued an ANPRM seeking public input on a “Secure American Medical Supplies” designation and possible payment approaches to offset the added costs of domestic procurement for PPE and “essential medicines,” defining “essential medicines” as the 86 medicines prioritized in the 2022 ASPR resilience assessment. [31]

Trade: In April 2025, the U.S. Department of Commerce[32] initiated a Section 232 national security investigation on imports of pharmaceuticals and pharmaceutical ingredients, including finished drugs, medical countermeasures, APIs, KSMs, and derivative products. [33]

The result is a policy moment in which procurement, payment, and trade tools can be aligned—if Congress and the executive branch choose coherence over single-lever fixes. [34]

Timeline chart

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timeline
  title Key milestones in U.S. drug and life-sciences dependence (selected)
  1984 : Hatch–Waxman accelerates generics and price competition
  2008 : Heparin contamination crisis highlights upstream opacity and quality
risk
  2010-2019 : API facilities supplying U.S. market shift overseas; China
share rises
  2019 : FDA Drug Shortages Task Force identifies structural shortage drivers
  2023 : DoD analyzes 1,744 drug families; reveals high risk and unknown API
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origins
  2025 : EO 14293 targets regulatory relief for domestic critical medicines
manufacturing
  2025 : EO 14336 directs filling SAPIR and building 6-month API reserves
  2025 : Section 232 investigation initiated on pharmaceuticals and
ingredients
  2026 : CMS ANPRM explores Medicare incentives for domestic essential-
medicine procurement
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The heparin crisis is documented by both peer-reviewed epidemiological investigation and FDA safety communications; DoD's supply-chain analysis and the executive and Medicare actions are official U.S. government documents. [35]

Vulnerabilities and Risks

Supply-chain vulnerability is best understood as a set of compounding fragilities. Several are worth elevating into the hearing record because they are actionable.

Single-source and geographic concentration: When a product has one qualified manufacturer, or when multiple manufacturers are clustered in a single region, even minor disruptions can cascade. The Committee report notes that over 40% of generic drugs sold in the U.S. have only one manufacturer. [11]

Opacity at the KSM layer: The Committee report states the U.S. government has limited information about KSM supply chains due to confidentiality practices, making upstream risk hard to assess and mitigate. The DoD report goes further and recommends compelling manufacturers to provide the FDA definitive information on finished drug production location and the sources (and percentages) of APIs and key ingredients, and then storing that data in a repository available to federal stakeholders. [36]

Quality, inspection parity, and regulatory gaps: A globalized supply chain is not inherently unsafe, but it is harder to oversee. The Government Accountability Office[37] has repeatedly highlighted persistent challenges in FDA's foreign inspection program, including issues that recur in inspection workforce capacity and the practical obstacles of foreign inspections. [38] The policy risk is not only "bad actors"; it is a system where purchasers often cannot observe quality differences, so low price dominates. The Committee report explicitly connects purchasers' limited quality information to a market that favors the lowest price, creating incentives to underinvest in mature quality management. [39]

Public health harm from quality variation: A peer-reviewed 2025 empirical analysis (cited by the Committee report) finds substantially higher rates of serious adverse events for generic drugs manufactured in India compared with equivalent U.S.-manufactured generics, with "serious" defined as hospitalization, disability, or death. This does not mean all Indian manufacturing is unsafe; it means manufacturing location can correlate with observable quality outcomes in mature, low-margin products and that policy should reflect that reality with better measurement and incentives. [40]

Systemic shock and coercion risk: Even if China never intentionally "weaponizes" medicines, the combination of geopolitical conflict risk and upstream concentration creates a plausible national emergency scenario. The DoD report emphasizes that DoD uses a just-in-time ordering concept and does not store additional finished drug products; it follows that disruptions from "adversarial actions" or other events can cause shortages affecting operations. [13]

This is why the Executive Order establishing SAPIR emphasizes APIs' longer shelf lives and lower cost relative to finished drugs and directs building six-month API reserves. It also states that only about 10% of APIs by volume used for finished drug products in the U.S. are made domestically, underscoring the upstream exposure. [41]

Two supply-concentration charts

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pie title Active API DMF shares (2021, proxy indicator)
  "India" : 62
  "China" : 23
  "United States" : 4
  "Europe" : 7
  "Other" : 4
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The DMF shares above are reported in the Committee staff report and in a Duke analysis that explicitly notes DMFs are a proxy and do not measure production volumes. [27]

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pie title DoD analyzed essential-medicine APIs by origin (share of NDCs)
  "U.S. domestic" : 25
  "Canada & Mexico" : 3
  "TAA-compliant (outside N. America)" : 18
  "India" : 26
  "China" : 5
  "Other non-TAA" : 1
  "Unknown" : 22
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The DoD figures are from the FY2023 DoD pharmaceutical supply chain assessment (based on 12,917 NDCs linked to 1,744 drug families). [13]

Data gaps that matter

In the public debate, estimates of "China's share of U.S. APIs" vary widely because they often measure different things (facility counts, DMFs, import records, or indirect exposure through third countries), and because KSM and intermediate sourcing is often not visible. A 2025 analysis argues that policy implications differ depending on whether the exposure is at the API stage or deeper upstream in precursors and specialized reagents and notes that some widely repeated "80–90% of all APIs" claims are not well specified. This uncertainty is not a reason to delay action; it is a reason to prioritize supply chain mapping and standardized measurement as the first step. [42]

China's Strategy and the Life-Sciences Frontier

China's capture of upstream pharmaceutical manufacturing must be understood as part of a broader state-enabled strategy to climb the entire life sciences value chain—from basic research to clinical trials to advanced manufacturing and commercialization. The question for U.S. policy is no longer "How do we avoid dependence?" but "How do we build a democratic innovation-and-production system that outcompetes China while remaining aligned with open-market principles and public health?" [43]

Industrial policy tools and tactics

China's strategy is explicit in industrial planning documents and in the consistent use of reinforcing "policy loops": state guidance, subsidies and credit, industrial clusters, procurement preferences, and regulatory modernization.

Made in China 2025: The (translated) State Council-level plan is widely understood as a foundational industrial policy framed around upgrading manufacturing capability and reducing reliance on foreign goods in strategic sectors, including biopharma and high-tech medical devices. [44]

Bioeconomy planning: Scholarly analysis of China's "14th Five-Year Plan for Bioeconomy Development" describes biomedicine, bio-manufacturing, and biosecurity as core pillars of a national bioeconomy agenda—again, not as a narrow sector policy but as an integrated strategic posture. [45]

Regulatory acceleration as a competitiveness tool: China's regulator has publicly emphasized mechanisms that speed clinical trial approvals (including implicit approval frameworks), which can change sponsor behavior and compress development timelines—one of the most durable competitive advantages in life sciences. [46]

Trade and export control leverage: China has modernized export control authorities in ways that can be used across sectors. Even without specific "pharma export bans," the strategic logic is recognizable: if a country can impose coercive leverage through supply chains (critical minerals, key chemicals, or APIs), it gains bargaining power. The U.S. response must assume that risk exists. [47]

Evidence of China's life-sciences ascent

Clinical development share: An IQVIA analysis shows trial starts from China-headquartered companies rising sharply, reaching roughly 30% of Phase I–III trial starts by headquarters location in 2008–2024 data presented in 2025. A separate Nature reporting piece (citing IQVIA) similarly describes a rapid rise over roughly a decade-plus. [48]

Scientific output: The National Science Board[49] reports that in 2022 China produced 27% of global science and engineering publications while the U.S. produced 14% (Scopus-based, fractional counting), underscoring the scale of China's research engine. [50]

AI and IP intensity: The Stanford AI Index reports that as of 2023, China led in total AI patents, accounting for 69.7% of grants. In life sciences—where AI increasingly touches discovery, biomarker development, trial design, and manufacturing optimization—this patent intensity is strategically relevant even when frontier model leadership remains contested. [51]

Capital formation mechanisms: Hong Kong Exchanges and Clearing Limited[52] notes that since the 2018 launch of listing reforms enabling pre-revenue biotech listings (Chapter 18A), 80 such companies had listed via that route as of end-November 2025—illustrating a state-adjacent capital channel for scaling high-risk biotech. [53]

What this means for U.S. strategy

The U.S. cannot treat "drug supply chain resilience" and "life sciences leadership" as separate issues. The same ecosystems that produce upstream dominance (chemicals, manufacturing clusters, workforce, supplier density) also enable rapid scale-up in biologics, vaccines, diagnostics, and advanced therapies. If upstream dependence persists, it will increasingly intersect with high-value innovation domains—especially as biologics manufacturing inputs (single-use systems, specialty resins, media components) become strategic chokepoints. [54]

Democratic Allies: Comparative Map

A U.S. strategy that aims for 100% domestic production of all drugs and inputs would be slow, costly, and—most importantly—unnecessary to achieve resilience. The goal should be "trusted capacity at scale," built across the U.S. and allied democracies, with clear rules for transparency, quality, and surge response. Several ally strategies already point in this direction, creating an opening for coordinated action.

The European Union[55]: The European Commission has advanced a "Critical Medicines Act" agenda explicitly aimed at tackling shortages and boosting resilience, including strategic projects, procurement reforms that incorporate resilience, collaborative procurement, and international partnerships with like-minded countries to reduce single-supplier dependencies. [56]

The Council of the European Union[57] describes the Critical Medicines Act as addressing shortages and improving EU resilience in health crises, indicating that European policy is converging on many of the same tools under discussion in the U.S. (procurement criteria beyond price, strategic project facilitation, and partnerships). [58]

Japan[59]: Japan's economic security framework includes supply chain resilience tools designed for "important items and raw materials," and Japan provides an official English translation of the relevant economic security legislation, emphasizing integrated economic measures for national security. This is directly relevant to pharmaceutical and life-sciences inputs. [60]

Canada[61]: Canada's Biomanufacturing and Life Sciences Strategy is explicitly framed as strengthening domestic life-sciences capability and long-term pandemic resilience; Canada also publicly reports significant investments (over $2.5B across dozens of projects) in biomanufacturing, vaccines, and therapeutics ecosystem capacity. [62]

Australia[63]: Australia operates large, long-horizon public funding instruments for medical research (MRFF), offers targeted industrial strategy work in emerging areas like RNA, and has established national financing vehicles like the National Reconstruction Fund aimed at high-value industry transformation—tools that could be integrated into an allied life-sciences manufacturing and trial ecosystem. [64]

India[65]: India is indispensable in global generics and vaccine manufacturing, making it a crucial partner for "friend-shoring." But India's upstream dependence on China is a structural risk that policy must confront honestly. India's Department of Pharmaceuticals created a Production Linked Incentive (PLI) scheme explicitly to promote domestic manufacturing of critical KSMs, intermediates, and APIs—an acknowledgement that upstream dependence is a strategic weakness. [66]

Comparative table

Ally / Region	Distinct strengths for a democratic life-sciences base	Key weaknesses / risks	Practical "fit" in a U.S.-led resilience architecture
European Union	Emerging Critical Medicines Act toolkit: strategic projects, procurement reform, collaborative procurement, partnerships. [67]	Fragmented procurement authority across member states; cost pressure in generics can still undercut resilience goals. [68]	High: align critical-medicine lists; joint procurement pilots; co-invest in antibiotics and sterile injectables; regulatory harmonization pathways.
Japan	Economic security law framework for stable supply of critical materials and integrated measures; high manufacturing quality culture. [69]	Demographic constraints; may prioritize domestic security use-cases first. [60]	High: trusted upstream and advanced manufacturing nodes; shared standards; joint surge manufacturing planning.
Canada	National BLS strategy + large project investments; proximity to U.S.; integrated innovation ecosystem. [62]	Scale constraints; may need stronger industrial-policy alignment for "full-stack" leadership. [70]	Very high: integrate as key "near-shore" node for biologics, vaccines, and critical inputs; shared workforce and regulatory science.
Australia	MRFF long-horizon	Geographic distance	Medium-high: clinical trial

Ally / Region	Distinct strengths for a democratic life-sciences base	Key weaknesses / risks	Practical “fit” in a U.S.-led resilience architecture
	funding; RNA blueprint; national finance tools for industrial transformation. [64]	from U.S. demand centers; scale limits in manufacturing. [71]	hub potential; specialized biomanufacturing and RNA pilot lines; redundancy and surge capacity.
India	Massive formulation capacity; increasingly explicit industrial policy for upstream API/KSM via PLI and bulk drug parks. [72]	Upstream dependence on China remains large; quality variance signals need strong measurement and incentives. [73]	High but conditional: partner for FDF and vaccines while jointly reducing upstream China exposure; require transparency and quality metrics as entry conditions.

This table is a synthesis of official and published policy documents and the Committee’s and DoD’s findings; it is not a claim that any one partner can solve U.S. resilience alone. [74]

Policy Options, Cost Ranges, and a Roadmap

The policy design challenge is to avoid two failure modes:

The “tariffs-only” trap: trade restrictions without a credible industrial ramp create price spikes and shortages.

The “subsidies-only” trap: grants without durable demand signals create pilot projects that cannot sustain operations.

The recommended approach is a sequenced strategy that uses procurement and payment to create stable demand, invests in targeted domestic and allied capacity, and builds the measurement infrastructure that makes progress auditable.

Core statutory and administrative building blocks already on the table

Defense procurement as the pilot: Section 887 of the FY2025 Senate NDAA bill text creates a ready-made template: a defined list (“defense-relevant generic drugs”), domestic manufacture requirements, API/KSM trusted sourcing rules, a waiver for availability at U.S. market prices, and congressional notification. As written, it operationalizes “trusted sourcing” in a way that can be audited. [30]

Medicare as the scaling lever: CMS’s January 2026 ANPRM is a pivotal signal because it recognizes that hospitals incur higher marginal costs for domestically manufactured PPE and essential medicines and asks how Medicare might offset those costs through designations and payment adjustments. In other words: it contemplates shifting the U.S.

health-financing system from “cheapest wins” toward “secure and reliable wins,” at least for defined categories. [31]

Stockpiles that match the upstream reality: EO 14336 directs ASPR to fill SAPIR with APIs for a defined set of critical drugs and to plan for broader six-month API reserves for an updated essential medicines list. This is an upstream-centric approach that can stabilize the supply chain if paired with replenishment capacity and rotation protocols. [29]

Transparency mandates: both the Committee report and the DoD report converge on a first-order requirement: map supply chains and require disclosure of finished dose, API, and KSM origins (and, ideally, proportions by source). This is the data infrastructure without which both industrial policy and emergency response will remain guesswork. [75]

Policy options table

The table below provides ranges, not point estimates. Facility costs, time-to-build, and operating costs vary by modality (synthetic API vs fermentation, oral solid vs sterile injectable, biologics vs cell therapy), environmental permitting, and the need for qualified workforce. Where public cost data are sparse, I provide “engineering-style” bounds and label them as assumptions rather than verified figures.

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
Federal buyer’s market (DoD pilot → VA/other purchasers) using NDAA-style list + waivers	Creates durable demand for U.S./trusted-origin generics, including API/KSM rules and waivers for availability	Auditable, rapid to pilot; uses existing federal procurement power; can create investment-grade demand	If phase-in is too fast, risk of shortages; if waivers too broad, policy becomes symbolic	Pilot in 12–24 months; scale 3–6 years	Administrative + price premiums; incremental annual cost depends on list size and price differential; should be budgeted as “resilience insurance”
Medicare incentives (CMS SAMS-style designation/payment)	Aligns hospital purchasing with resilience, offsets higher	Scales beyond federal procurement; addresses	Poorly designed measures can be gamed; complexity	Design 1–2 years; scale 3–5 years	Annual payments depend on domestic premium and percent

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
	costs of domestic/trusted supply	the biggest market design failure: procurement rewards price over reliability	burdens hospitals; risk of cost-shifting if not well targeted		thresholds; can be bounded by focusing on the 86-medicine (or updated) list [76]
Full-stack transparency mandate (FDF/API/KSM disclosure; secure federal repository)	Makes upstream reliance measurable and enforceable; enables predictive risk analytics	Essential for prioritizing investments and preventing shortages; reduces "unknown origin" exposure cited by DoD	Industry pushback; confidentiality concerns; requires cyber-secure infrastructure	18–36 months to stand up; continuous thereafter	IT + compliance costs; moderate federal investment relative to manufacturing subsidies; high ROI in avoided crises
Targeted reshoring of brittle nodes (fermentation antibiotics, select sterile injectables, key chemical intermediates)	Builds domestic capacity where strategic risk is highest and substitutes are limited	Reduces "single-region" risk; improves surge capability; aligns with national security	Environmental permits; higher operating costs; risk of stranded assets if procurement incentives vanish	3–10 years (new build); 1–2 years for repurposing existing capacity where feasible [77]	Capital-intensive; "hundreds of millions to low billions" depending on modality (assumption)
Friend-shoring + allied "strategic projects"	Builds trusted capacity across allies; reduces China dependence	Faster than full reshoring; diversifies geographic	Requires harmonized standards and mutual recognition;	2–6 years for meaningful capacity	Public co-investment + policy alignment; cost shared

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
	without excessive domestic cost	risk	politics of "who gets what"	expansion	among partners
Strategic stockpiles (API-first; limited KSM where feasible) + rotation	Creates buffers against shock and coercion; API stockpiles have longer shelf life than finished drugs	Stabilizes near-term resilience	Stockpiles without replenishment can degrade/expire; can distort markets if mishandled	SAPIR actions already directed; expand 1–3 years; maintain indefinitely [78]	Cost depends on number of APIs and six-month volume; should be treated as a portfolio with rotation; EO directs ASPR to develop cost estimates [41]
Advanced manufacturing adoption (continuous, modular, flexible lines)	Improves responsiveness and reduces changeover time; can make domestic production more competitive	Enables "replenish, not just store"; strengthens surge	Requires skilled workforce and regulatory familiarity	2–7 years for scale	Mixed public-private; best treated as "capability investment" rather than per-drug subsidy

The policy rationale for pairing procurement/payment levers with targeted industrial investments is supported by FDA's drug shortage analysis (market incentives) and the Committee's and DoD's findings (opacity and risk). [79]

A prioritized action matrix

This matrix intentionally focuses on actions that (1) reduce near-term risk to seniors and national security and (2) create compounding advantages for long-run life-sciences leadership.

Priority	Action	Why it matters	Lead actors	"Proof" metric within 24 months
Highest	Mandate FDF/API/KSM origin disclosure + federal repository (secure access)	Without data, everything else is guesswork; addresses "unknown origin" risk	Congress + FDA + HHS/ASPR + DoD	Share of essential-medicine NDCs with complete origin disclosure rises sharply (target: >80% of the defined list) [16]
Highest	Implement NDAA-style defense-relevant list procurement rules with phased compliance + waivers	Creates investment-grade demand; produces auditable proof of concept	DoD + Congress	First list published; procurement contracts incorporate API/KSM requirements; waiver rate publicly reported [30]
High	Finalize Medicare "SAMS" design and payment approach targeting essential medicines	Scales market reform beyond defense; aligns incentives for reliability	CMS + Congress (if needed)	Pilot cohort of hospitals; domestic/trusted share rising for defined categories [31]
High	Build SAPIR as API-first stockpile + rotation protocols	Near-term buffer that buys time for manufacturing scale-up	ASPR + OMB + FDA	SAPIR repository operational; first API tranches stored; rotation plan published [78]
High	Launch "Resilient Antibiotics" initiative (domestic + allied fermentation)	Antibiotics and upstream fermentation are recurrent chokepoints	HHS/ASPR + DoD + allies	At least two non-China sources for priority antibiotic APIs/KSMs under contract
Medium	Inspection parity modernization and inspection workforce stabilization	Reduces quality and shortage risks; improves trust in allied supply	FDA + appropriators	Reduced inspection backlog; metrics for foreign inspections improve [80]
Medium	Democratic life-sciences alliance: aligned lists, joint procurement, standards	Converts fragmented efforts into scale; counters China's integrated model	U.S. + allies	First joint critical-medicine list alignment and joint procurement pilot launched [81]

Implementation flowchart

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flowchart TD
  A[Define "Essential & Strategic Medicines" lists\n(health + national
security)] --> B[Mandate transparency\nFDF/API/KSM origin + secure
repository]
  B --> C[Risk scoring & prioritization\nsingle-source, geography, quality
signals]
  C --> D[Demand signals\nDoD procurement rules + Medicare incentives]
  D --> E[Capacity build\nreshore + friend-shore + advanced manufacturing]
  E --> F[Strategic stockpiles\nAPI-first + rotation + replenishment
contracts]
  F --> G[Measure & enforce\nshortage reduction, audit compliance, inspection
parity]
  G --> C
```

This “closed loop” is directly motivated by: (a) the DoD finding of unknown origins and high-risk reliance; (b) the Committee report’s emphasis on mapping and disclosure; and (c) CMS’s recognition that payment systems can offset domestic procurement cost differentials. [82]

Roadmap milestones for 5, 10, 25, 50 years

Within five years: The United States should be able to demonstrate that for every medicine on the essential list (as updated), there is no single point of failure at the API layer across non-adversary jurisdictions, and that the federal government can see upstream provenance in near-real time for those products. This is achievable because both DoD and the Committee report describe existing capacity that could be repurposed within 1–2 years in some cases, even while new facilities may take longer. [83]

Within ten years: The U.S. and allies should have scaled at least several strategically vital “ecosystem nodes” (antibiotics fermentation, sterile injectables redundancy, and selected chemical intermediates) so that adversary supply disruption becomes a manageable shock rather than a national emergency. The Committee report notes estimates that building new manufacturing facilities can take 5–10 years, which is consistent with a decade-scale target for new capacity. [77]

Within twenty-five years: The objective should shift from “repair” to “dominance”: the democratic alliance should lead in advanced biomanufacturing, secure supply chains for both small molecules and biologics, and the clinical and regulatory infrastructure that makes innovation fast and trustworthy.

Within fifty years: The metric is not only manufacturing share; it is strategic leadership in life sciences as a national capability: the ability to discover, trial, manufacture, and distribute new therapies rapidly under trusted governance. China’s rising share of trial starts and its scale in scientific output and AI patents suggest that absent deliberate strategy, leadership could tilt away from democracies. [14]

Metrics to measure success

A resilience strategy must be measurable. I recommend Congress require an annual "Life Sciences Resilience Scorecard" built on auditable metrics:

Supply diversity: For each essential medicine, number of independent manufacturing "families" at API and FDF, and geographic distribution (target: at least three independent suppliers across trusted jurisdictions for high-criticality products).

Upstream visibility: Percent of essential-medicine volume with fully disclosed FDF/API/KSM origin; percent with "unknown" origin (target: approach zero on the essential list). [16]

Shortage performance: Number of ongoing shortages and average shortage duration; FDA and related analyses show multi-year average shortage durations and identify market incentives as a driver, making this a key output metric. [84]

Quality signals: Inspection outcomes, import alerts, and independent testing metrics; the Committee report specifically highlights the need for quality-rewarding procurement and notes evidence linking quality issues to outcomes. [85]

Surge readiness: Time to scale production for a defined set of "critical drugs" under national emergency scenarios; SAPIR fill status and rotation compliance. [86]

Innovation leadership: Share of global phase I–III trial starts by sponsor location; biomedical publication output; and indicators of AI-enabled capability relevant to life sciences. [14]

Legal, Diplomatic, and Unintended Consequences

A strategy this large must anticipate legal friction and second-order effects.

Procurement law and "rules of origin": Section 887's text shows Congress can define procurement rules that focus on manufacturing location and upstream API/KSM sourcing, with waivers that preserve availability. That design reduces legal ambiguity by specifying what counts and by imposing reporting requirements when waivers are used. [87]

Trade law and retaliation: The Section 232 investigation shows one pathway to tariffs or other restrictions. But trade restrictions can trigger retaliation and can backfire if allies are not aligned or if domestic/allied capacity cannot ramp in time. For that reason, "trade" should be used as backstop and leverage—not as the primary engine of resilience. [33]

Diplomatic considerations: Because Europe, Japan, Canada, Australia, and India each have distinct policy tools and domestic constraints, the U.S. should propose a compact with clear mutual benefits: shared surge capacity, shared standards, and shared market access for trusted products. European and Japanese moves toward "economic security" supply chain tools suggest a receptive environment, but coordination is not automatic; it must be negotiated. [81]

Unintended consequence: higher prices without better outcomes. If domestic/trusted sourcing raises prices but does not measurably improve reliability and quality, the policy will lose legitimacy. CMS explicitly acknowledges that domestically manufactured products will generally be more expensive because of higher labor costs, which is why payment design must be tied to measurable reliability and quality metrics. [88]

Unintended consequence: accelerated consolidation. A poorly designed "domestic preference" could inadvertently advantage a small number of incumbents, creating new single points of failure. Mitigation: require multi-supplier contracting, create on-ramps for new entrants (including advanced manufacturing), and require redundancy as a condition of incentives. The Committee report's emphasis on single-manufacturer prevalence underscores why redundancy must be a performance requirement, not merely an aspiration. [39]

Unintended consequence: environmental externalities. Reshoring upstream chemicals and fermentation can increase local environmental burdens. Mitigation: pair reshoring incentives with clean manufacturing requirements and permitting acceleration that does not reduce environmental standards—using the same "smart speed" approach now used in other strategic sectors.

Unintended consequence: shifting dependence rather than reducing it. "Friend-shoring" to India without upstream diversification can still leave the U.S. exposed to China through India's inputs. This is why allied strategy must explicitly include KSM and intermediate diversification, not just finished dose relocation. [89]

Finally, oversight should treat life sciences as both an economic engine and a strategic domain. China's rapid expansion in trials, publications, and AI patents is a warning that the next 50 years will be shaped by nations that can integrate discovery, development, manufacturing, and data governance at scale. The United States and democratic allies can still lead—but only with a coherent, measurable strategy that treats supply chain resilience and innovation leadership as one national project. [90]

References

U.S. Senate Special Committee on Aging staff report, "Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain" (Oct. 20, 2025). [91]

DoD report pursuant to FY2023 NDAA Section 860 on pharmaceutical supply chain risk management (analysis of 1,744 drug families / 12,917 NDCs; high/very-high risk share; unknown origins). [13]

FDA congressional testimony, "Safeguarding Pharmaceutical Supply Chains in a Global Economy" (Oct. 30, 2019) (API facility location shares). [10]

FDA Drug Shortages Task Force report, "Drug Shortages: Root Causes and Potential Solutions" (2019; updated Feb. 2020). [26]

GAO statement and reports on FDA foreign drug inspection challenges. [38]

CMS press release and Federal Register ANPRM on “Secure American Medical Supplies” and domestic procurement incentives for PPE and essential medicines (Jan. 2026). [92]

FY2025 Senate NDAA bill text (S.4638 RS), Section 887 / 10 U.S.C. § 4865 framework (domestic manufacture + API/KSM sourcing; waiver; list). [93]

Executive Order 14293 on regulatory relief for domestic production of critical medicines (May 5, 2025). [94]

Executive Order 14336 directing SAPIR fill and six-month API reserves (Aug. 13, 2025; published Aug. 19, 2025). [29]

Federal Register notice initiating Section 232 investigation of pharmaceuticals and pharmaceutical ingredients (Apr. 16, 2025) and BIS Section 232 investigations page. [33]

European Commission Critical Medicines Act materials and EU Council overview. [95]

Japan “Act on the Promotion of Ensuring National Security through Integrated Implementation of Economic Measures” (official English translation). [60]

Canada Biomanufacturing and Life Sciences Strategy and project investment summaries. [62]

Australia Medical Research Future Fund overview; Australia’s RNA Blueprint; National Reconstruction Fund overview. [64]

India Department of Pharmaceuticals: PLI scheme for KSMs/intermediates/APIs; scheme guidelines. [66]

Peer-reviewed evidence on generic drug manufacturing location and serious adverse events (2025). [96]

NEJM investigation and FDA safety information regarding the 2008 heparin contamination crisis. [97]

IQVIA global trends on clinical trials and China-headquartered sponsor activity. [48]

National Science Board publication output indicators (China and U.S. shares). [50]

Stanford AI Index (AI patent grant shares). [51]

---

[1] [5] [6] [8] [11] [12] [22] [27] [36] [39] [40] [52] [55] [61] [75] [77] [83] [85] [91] https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf

https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf

[2] [7] [23] [26] [79] [84] https://www.fda.gov/media/132058/download

https://www.fda.gov/media/132058/download

[3] [14] [21] [24] [48] [90] The Global Use of Medicines 2025: Outlook to 2029

https://www.iqvia.com/-/media/iqvia/pdfs/events/presentation_global-meds-webinar_public.pdf?utm_source=chatgpt.com

[4] [53] https://www.hkex.com.hk/Join-Our-Market/Biotech?sc_lang=en

https://www.hkex.com.hk/Join-Our-Market/Biotech?sc_lang=en

[9] [51] https://hai.stanford.edu/assets/files/hai_ai-index-report-2025_chapter1_final.pdf

https://hai.stanford.edu/assets/files/hai_ai-index-report-2025_chapter1_final.pdf

[10] [32] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

[13] [16] [25] [82] https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmceuticals1.pdf

https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmceuticals1.pdf

[15] [30] [34] [87] [93] https://www.govinfo.gov/content/pkg/BILLS-118s4638rs/pdf/BILLS-118s4638rs.pdf

https://www.govinfo.gov/content/pkg/BILLS-118s4638rs/pdf/BILLS-118s4638rs.pdf

[17] https://healthpolicy.duke.edu/sites/default/files/2024-11/Building%20a%20Resilient%20and%20Secure%20Pharmaceutical%20Supply%20Chain.pdf

https://healthpolicy.duke.edu/sites/default/files/2024-11/Building%20a%20Resilient%20and%20Secure%20Pharmaceutical%20Supply%20Chain.pdf

[18] [41] [78] [86] https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/

https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/

[19] [38] [80] https://www.gao.gov/products/gao-24-107359

https://www.gao.gov/products/gao-24-107359

[20] [56] [65] [67] [74] [81] [95] https://health.ec.europa.eu/medicinal-products/critical-medicines-act_en

https://health.ec.europa.eu/medicinal-products/critical-medicines-act_en

[28] [62] [70] https://ised-isde.canada.ca/site/ised/en/programs-and-initiatives/health-emergency-readiness-canada/overview-canadas-biomanufacturing-and-life-sciences-strategy/canadas-biomanufacturing-and-life-sciences-strategy

https://ised-isde.canada.ca/site/ised/en/programs-and-initiatives/health-emergency-readiness-canada/overview-canadas-biomanufacturing-and-life-sciences-strategy/canadas-biomanufacturing-and-life-sciences-strategy

[29] https://www.federalregister.gov/presidential-documents/executive-orders/donald-trump/2025

https://www.federalregister.gov/presidential-documents/executive-orders/donald-trump/2025

[31] [59] [76] [88] Federal Register :: Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals

https://www.federalregister.gov/documents/2026/01/29/2026-01730/medicare-program-ensuring-safety-through-domestic-security-with-made-in-america-personal-protective

[33] [47] https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

https://www.federalregister.gov/documents/2025/04/16/2025-06587/notice-of-request-for-public-comments-on-section-232-national-security-investigation-of-imports-of

[35] [97] https://www.nejm.org/doi/full/10.1056/NEJMoa0806450

https://www.nejm.org/doi/full/10.1056/NEJMoa0806450

[37] [94] https://www.federalregister.gov/documents/2025/05/08/2025-08267/regulatory-relief-to-promote-domestic-production-of-critical-medicines

https://www.federalregister.gov/documents/2025/05/08/2025-08267/regulatory-relief-to-promote-domestic-production-of-critical-medicines

[42] https://www.brookings.edu/articles/us-drug-supply-chain-exposure-to-china/

https://www.brookings.edu/articles/us-drug-supply-chain-exposure-to-china/

[43] [44] https://cset.georgetown.edu/wp-content/uploads/t0432_made_in_china_2025_EN.pdf

https://cset.georgetown.edu/wp-content/uploads/t0432_made_in_china_2025_EN.pdf

[45] [54] https://pmc.ncbi.nlm.nih.gov/articles/PMC9995158/

https://pmc.ncbi.nlm.nih.gov/articles/PMC9995158/

[46] https://english.nmpa.gov.cn/2025-10/14/c_1138493.htm

https://english.nmpa.gov.cn/2025-10/14/c_1138493.htm

[49] [71] https://nsc.anu.edu.au/sites/default/files/2024-08/NSC_POP_Future%20Biomade%20in%20Australia_web.pdf

https://nsc.anu.edu.au/sites/default/files/2024-08/NSC_POP_Future%20Biomade%20in%20Australia_web.pdf

[50] https://ncses.nsf.gov/pubs/nsb202333

https://ncses.nsf.gov/pubs/nsb202333

[57] [73] https://pharma-dept.gov.in/sites/default/files/Final%20Report-Survey%20of%20Novel%20Technologies%20for%20Productoion%20of%20APIs.pdf

https://pharma-dept.gov.in/sites/default/files/Final%20Report-Survey%20of%20Novel%20Technologies%20for%20Productoion%20of%20APIs.pdf

[58] [63] https://www.consilium.europa.eu/en/policies/critical-medicines-act/

https://www.consilium.europa.eu/en/policies/critical-medicines-act/

[60] [69] https://www.japaneselawtranslation.go.jp/en/laws/view/4716

https://www.japaneselawtranslation.go.jp/en/laws/view/4716

[64] https://www.health.gov.au/our-work/mrff?language=en

https://www.health.gov.au/our-work/mrff?language=en

[66] [72] https://pharma-dept.gov.in/schemes/production-linked-incentive-pli-scheme-promotion-domestic-manufacturing-critical-key

https://pharma-dept.gov.in/schemes/production-linked-incentive-pli-scheme-promotion-domestic-manufacturing-critical-key

[68] https://health.ec.europa.eu/document/download/2abe4fc8-059e-47d9-a20a-d9e3bfc5dc2c_en?filename=mp_com2025_102_act_en.pdf

https://health.ec.europa.eu/document/download/2abe4fc8-059e-47d9-a20a-d9e3bfc5dc2c_en?filename=mp_com2025_102_act_en.pdf

[89] https://www.aging.senate.gov/imo/media/doc/exiger_a_bitter_pill_pharmaceutical_report.pdf

https://www.aging.senate.gov/imo/media/doc/exiger_a_bitter_pill_pharmaceutical_report.pdf

[92] CMS Seeks Public Input on Strengthening Domestic Supply Chain for PPE, Essential Medicines | CMS

https://www.cms.gov/newsroom/press-releases/cms-seeks-public-input-strengthening-domestic-supply-chain-ppe-essential-medicines

[96] https://journals.sagepub.com/doi/abs/10.1177/10591478251319691

https://journals.sagepub.com/doi/abs/10.1177/10591478251319691