2021–2024 Quadrennial Supply Chain Review

NATIONAL ECONOMIC COUNCIL
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LETTER TO THE PRESIDENT FROM LAEL BRAINARD AND JAKE SULLIVAN

Mr. President:

On behalf of your Council on Supply Chain Resilience, we are pleased to transmit this Review of supply chains for industries critical to national and economic security.

From the food we eat, to the medicines needed to treat patients, to computer chips that underpin nearly every piece of technology we rely on, supply chains produce critical goods and move them to where they are needed. As we saw during the pandemic, when supply chains break down, inflation rises—raising operating costs for businesses and prices for American families. Resilient supply chains are also crucial to our national security, minimizing opportunities for adversaries to exploit dependencies and vulnerabilities due to supply chain chokepoints.

In the early months of your Administration during the throes of the COVID-19 pandemic, supply chains were upended, leading to shortages and high inflation. Supply chains had become a common topic from boardrooms to living rooms. At your direction, it also became a key focus of the federal government led by the Council on Supply Chain Resilience that you established. In partnership with industry, state and local governments, labor, and allies and partners, we moved swiftly to address immediate bottlenecks, build the government's capacity for risk identification and response, and make foundational investments in industries and inputs that underpin the supply side of our economy.

As this Review outlines, our supply chains today are stronger than when you came into office. Prices have come down, shelves are stocked, and our nation is more prepared for future disruptions. We have also reduced our dependencies on critical goods from countries that do not share our values.

There is still more work to be done to strengthen our critical supply chains, particularly for emerging technologies and industries of the future. Threats to our supply chains abound—from an accelerating climate crisis, to cybersecurity vulnerabilities, to regional and geostrategic shifts across the globe. We have put in place a strong foundation of capabilities to prepare for and mitigate these risks, and the Council on Supply Chain Resilience is an innovative body to carry this work forward.

Thank you for your leadership in ensuring America's supply chains are strong and resilient.

Lael Brainard
National Economic Advisor

Jake Sullivan
National Security Advisor

EXECUTIVE SUMMARY

The United States is highly reliant on complex global supply chains, many of which are foundational to the U.S.'s economy and national security. Decades of globalization, efficiency efforts, and underinvestment in resilience have created structural risk in the way goods and inputs make their way to consumers and businesses. These supply chains have been severely tested in recent years—by pandemic, by conflict, and by natural disaster. In some cases, these shocks have forced government and private-sector actors to intervene to avoid major impacts. In others, these shocks have revealed dangerous vulnerabilities and created shortages that have harmed lives and livelihoods, interrupting commerce for both large and small businesses. In all such cases, the world has become more alert to the need for strong and reliable supply chains.

The U.S. Government, at the direction of President Biden and Vice President Harris, has responded to this challenge with a transformational focus on strengthening critical supply chains. In the early days of the Administration, during the throes of the COVID-19 pandemic's disruptions, President Biden launched a whole-of-government effort to assess and to build the resilience of our most critical supply chains: energy, agricultural commodities and food products, medical products, information and communications technology, transportation, and defense. As this Review documents, this work has seen enormous success, thanks to renewed investment in American manufacturing in these sectors, stronger economic relationships with our allies and partners, and improved capabilities within the federal government to monitor and respond to shocks that can disrupt supply chains. Industry and state and local government partners have complemented this work with an invigorated focus on supply chains as well to help ensure that people can get what they need when they need it. Government and industry have found that strengthening supply chains through investment in domestic manufacturing and strategic industrial policy actions is effective and good for the economy—as particularly evidenced by the supply chain healing's direct impact on bringing down inflation. Supply chain resilience is a shared priority with our allies and partners, too. It has become a common feature of diplomatic engagements, which have produced results and laid promising foundations for deeper collaboration and more tactical deliverables in the years ahead.

Four years later, strengthening our critical supply chains by investing in and protecting strategic sectors has become a whole-of-government priority that endures, even as supply chains have mostly recovered from pandemic disruptions. A suite of new offices and resources across the federal government have made this work possible, and the President's Council on Supply Chain Resilience connects these teams and the capabilities they are developing to ensure continued strategic focus. Historic legislation, including the American Rescue Plan, Bipartisan Infrastructure Law, the CHIPS & Science Act, and the Inflation Reduction Act, have provided foundational resources for these efforts. However, many critical sectors will need additional investment in the coming years.

Despite this progress, significant risks remain, and much work is still needed to offset decades of weakening. This work also faces headwinds. Geopolitical tensions create uncertainty in key trade routes and regions. The People's Republic of China continues to distort markets through non-market policies and practices, seeking to dominate key sectors by overwhelming global markets with exports. More extreme weather patterns from climate change will continue to upend supply chains in unexpected places, requiring fortification of the infrastructure and transportation systems that underpin critical supply chains, as well as consideration of climate threats in diversification of supply bases. This Review makes clear that the U.S. Government can have enormously positive influence on our supply chains, and with continued effort and investment, we can tackle these challenges.

BACKGROUND

The Quadrennial Supply Chain Review

Pursuant to Executive Order 14123, this inaugural Quadrennial Supply Chain Review provides an assessment of the supply chains for industries critical to national or economic security. This report to the President documents progress made over the past four years since Executive Order 14017 "On America's Supply Chains."

The Review provides an overall assessment of supply chain resilience, and includes ten reviews prepared by departments and agencies focused on the specific critical supply chains outlined in Executive Order 14017. As directed by Executive Order 14123, the Review also makes a number of recommendations for additional work needed to continue strengthening America's critical supply chains in the future. These recommendations cover deployment of federal incentives and procurement to attract private-sector investment in critical supply chains, and actions to insulate analyses and actions from conflicts of interest, corruption, or the appearance of impropriety. The Review provides a strategic plan that includes diplomatic, economic, security, international development, trade, and other policy actions to guide U.S. engagement with allies and partners to strengthen global supply chain resilience in critical sectors, as well as reforms to domestic and international trade rules and agreements that could be pursued to support supply chain resilience, security, diversity, sustainability, and strength. The Review's recommendations also include education and workforce reforms needed to strengthen the domestic industrial base for critical goods and materials and other essential goods, materials, and services, and steps to ensure that the U.S. Government's supply chain policies support small businesses and family-owned small- and mid-sized farming operations, prevent monopolization, strengthen critical infrastructure, empower workers to advocate for their rights, create quality jobs, consider climate and other health and environmental effects, encourage economic growth in underserved communities and economically distressed areas, and promote the geographic dispersal of economic activity across all regions of the United States. The Review also outlines potential legislative changes that would promote the policy objectives outlined in Executive Orders 14017 and 14123.

FOUR YEARS OF STRENGTHENING AMERICA'S SUPPLY CHAINS

Overview

Since Day One, President Biden and Vice President Harris have been focused on strengthening America's supply chains, especially those critical to America's economic and national security. In February 2021, Executive Order 14017 on America's Supply Chains clearly laid out this direction, asserting that the United States "needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security." It mobilized a whole-of-government effort to assess and then strengthen supply chains that were reeling from disruptions from the COVID-19 pandemic. The federal government—through a series of strategic reviews in 2021 and 2022—took stock of critical supply chains that support our nation's food, health care, connectivity and technology, transportation, energy, and defense. While they documented acute impacts from the pandemic, these reviews also revealed structural vulnerabilities that were decades in the making, the result of years of outsourcing, offshoring, and streamlining. These shifts had the aim of lowering upfront costs and improving regular-order efficiency, but were paired with a deep underinvestment in resilience that left increasingly complex and sprawling supply chains unable to cope with disruption. The granular findings from these strategic reviews also revealed significant opportunities that have inspired and guided federal efforts to make these supply chains more robust and to harness the benefits of strong supply chains for American workers and businesses.

Economic research since the onset of the pandemic has revealed the ripple effects that supply chain disruptions can cause throughout the broader macroeconomy, as evidenced in the U.S. and globally. On top of acute disruptions that can cause shortfalls in supply of critical goods, snarled supply chains were one of the primary drivers of inflation following the onset of the pandemic. An assessment by the Council of Economic Advisers (CEA) in November 2023 estimated that supply chains accounted for most of the excess core inflation that arose in the U.S. during 2021–2023, a trend that set these pandemic years apart from the prior 20 years.[1]

Since these initial strategic reviews, the Biden–Harris Administration has taken historic action to make these critical supply chains stronger, recognizing that—as Executive Order 14017 affirms—pandemics, cyberattacks, climate shocks and extreme weather events, terrorist attacks, geopolitical and economic competition, and other conditions can reduce critical manufacturing capacity, and the availability and integrity of critical goods, products, and services. Thus, a core part of these efforts has been to rebuild American manufacturing in these critical sectors. This work has been fueled by strategically crafted pieces of legislation, including the American Rescue Plan (ARP), Bipartisan Infrastructure Law (BIL), CHIPS & Science Act, and Inflation Reduction Act (IRA). Federal action has been in concert with state and local governments, and in collaboration with allies and partners. And, these actions have been complemented by a renewed private-sector effort on supply chains—a vital element given that, ultimately, private actors control supply chains. Indeed, federal investment has helped drive unprecedented private investment in the workers, manufacturing capabilities, and research needed to keep America's supply chains strong. Since 2021, the private sector has announced over $1 trillion in investments in U.S. manufacturing and power generation. To help these investments succeed, the Administration has also taken bold action—including deploying

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[1] White House Council of Economic Advisers. "Disinflation: Explanation, Supply, Demand, and Their Interaction." *The White House*, November 30, 2023. https://www.whitehouse.gov/cea/written-materials/2023/11/30/disinflation-explanation-supply-demand-and-their-interaction/.

defensive trade tools, where warranted—to level the playing field for American businesses and workers and protect strategic sectors from unfair competition.

In 2023, President Biden established the White House Council on Supply Chain Resilience to cement the federal government's focus on supply chain resilience and coordinate these efforts over the long term. Pursuant to Executive Orders 14017 and 14123, the Council has prepared this inaugural Quadrennial Supply Chain Review to assess progress made over the past nearly four years, and to set forth priorities for future efforts. With continued attention from the U.S. Government and leaders in the public, private, and social sectors, America's critical supply chains will continue to become more resilient to shocks and more reliable for American consumers, businesses, workers, and families.

Supply Chain Resilience and the American Economy

Resilient supply chains are fundamental to a strong economy. When supply chains run more smoothly, inflation declines, and it is easier to keep costs down. Well-functioning supply chains allow for the uninterrupted flow of goods, food, and equipment to businesses and consumers. When supply chains operate well, they also provide certainty to businesses, helping to keep prices in check, and more money in the pockets of American families, workers, farmers, and entrepreneurs. The inverse also holds: when supply chains are brittle and susceptible to disruption, they can lead to shortages, hoarding behavior, and sharp price spikes that increase costs for businesses and raise prices for families.[2]

Supply chains that span multiple national boundaries are now a pervasive feature of the modern production landscape.[3] Productivity gains from specialization, made possible by technological change, have driven a global fragmentation of manufacturing activities across increasingly complex and long supply chains.[4] Producers and buyers have also sought to make supply chains more efficient and cost effective, but potentially in ways that make our industries and our economy less able to withstand shocks. For instance, "just-in-time" production,[5] where supply chains produce goods at a pace just sufficient to meet consumer demand with minimal excess inventory, can come at the expense of investing in multiple suppliers, geographic supplier diversity, workers, and buffer inventory stocks that would improve the ability of supply chains to withstand external shocks.[6] Just-in-time supply chain practices prioritize economic efficiencies and often assume a relatively stable

[2] Council of Economic Advisers. "Unsnarled Supply Chains Appear to Help Ease Goods Inflation." *The White House*, June 8, 2023. https://www.whitehouse.gov/cea/written-materials/2023/06/08/easing-supply-chains/.
[3] Hummels, David, Jun Ishii, and Kei-Mu Yi. "The Nature and Growth of Vertical Specialization in World Trade." *Journal of International Economics* 54, no. 1 (June 2001): 75–96. https://www.sciencedirect.com/science/article/abs/pii/S0022199600000933.
[4] Baldwin, Richard. "Chapter 1: Global Value Chains in a Changing World." In *Global Value Chains in a Changing World*, edited by Deborah K. Elms and Patrick Low, 1–28. Geneva: World Trade Organization, 2012. https://dukespace.lib.duke.edu/server/api/core/bitstreams/1857fdef-8eb2-4df0-93ca-04be04daa6f2/content#page=38.
[5] Golhar, Damodar Y., and Carol Lee Stamm. "The Just-in-Time Philosophy: A Literature Review." *International Journal of Production Research* 29, no. 4 (1991): 657–676. https://www.tandfonline.com/doi/abs/10.1080/00207549108930094.
[6] Cheng, T. C. E., and S. Podolsky. *Just-in-Time Manufacturing: An Introduction.* 1st ed. London: Chapman & Hall, 1993. https://search.worldcat.org/title/just-in-time-manufacturing-an-introduction/oclc/807098789.

supply chain environment with minimal shocks.[7] However, these practices mean suppliers can become overly reliant on a few producers in few countries, leaving them vulnerable to disruptions when unexpected events upend the status quo. In addition, when production of critical key inputs—such as semiconductors—are overly concentrated in a limited number of geographies, it can introduce outsized supply chain risks as regional shocks propagate into broader economic impacts.

Recent experience has starkly demonstrated that modern supply chains that are highly concentrated may be insufficiently resilient. Dependencies across supply chains threaten resilience when discrete shocks affecting just one supply chain segment ripple through the broader global economy. For example, when individual firms halted operations during the pandemic, even in just one part of the world, sectoral supply shocks occurred that drove up prices globally. Information asymmetries across suppliers likely made it more difficult to recover from the shock when suppliers were unable to communicate and coordinate effectively to restart operations. In the transportation and logistics industry, a series of supply chain disruptions and delays at ports led to historically high prices for imports to the United States. The inflationary effect from the supply side was compounded by elevated demand pressures as consumers directed their spending away from services and towards goods.[8]

The correlation between supply chain shocks and inflation is evident when comparing inflation with the Federal Reserve Bank of New York staff's Global Supply Chain Pressure Index (GSCPI), which has become a useful benchmark for understanding the health of the supply chain amid global disruptions. The index summarizes 27 monthly indicators of transportation costs and Purchasing Managers' Index surveys for manufacturing firms in seven major economies.[9] Following the onset of the COVID-19 pandemic, the GSCPI jumped to its highest-ever recorded value by late 2021: more than four standard deviations above its average historical value. Since 2022, the GSCPI has gradually returned to its historical average as shipping bottlenecks were resolved and manufacturing sectors adjusted to changes in global demand. Looking at GSCPI with a six-month lag shows U.S. goods inflation tracking supply chain pressures closely as well (Figure 1).

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[7] Choi, Thomas Y., Torbjørn H. Netland, Nada Sanders, ManMohan S. Sodhi, and Stephan M. Wagner. "Just-in-Time for Supply Chains in Turbulent Times." *Production and Operations Management* (March 15, 2023). https://onlinelibrary.wiley.com/doi/full/10.1111/poms.13979.

[8] di Giovanni, Julian, Şebnem Kalemli-Özcan, Alvaro Silva, and Muhammed A. Yildirim. *Global Supply Chain Pressures, International Trade, and Inflation.* Staff Report No. 1024. New York: Federal Reserve Bank of New York, July 2022. https://www.newyorkfed.org/medialibrary/media/research/staff_reports/sr1024.pdf?sc_lang=en.

[9] Akinci, Ozge, Gianluca Benigno, Ruth Cesar Heymann, Julian di Giovanni, Jan J. J. Groen, Lawrence Lin, and Adam I. Noble. "The Global Supply Side of Inflationary Pressures." *Liberty Street Economics* (blog), Federal Reserve Bank of New York, January 28, 2022. https://libertystreeteconomics.newyorkfed.org/2022/1/the-global-supply-side-of-inflationary-pressures/.

Figure 1: Global Supply Chain Pressure Index and goods inflation

Supply chain shocks are also correlated with other potential macroeconomic impacts of supply chain disruptions. For example, in addition to price spikes, the pandemic-induced supply chain disruptions resulted in sharp declines in U.S. industrial production in manufacturing, sales of goods, and real consumption.[10] Although the pandemic-era supply chain disruptions were unique in breadth and scale, historical evidence demonstrates that some level of supply chain shocks are inevitable, with corresponding economic risks when supply chains are insufficiently resilient. For example, the 2011 Tohoku earthquake and tsunami in Japan resulted in broad economic disruptions that extended beyond Japan's borders. Japanese automotive suppliers shut down temporarily after the earthquake, which affected automotive production around the world, including in the United States.[11] U.S. manufacturing output declined by one percentage point due to linkages to Japanese suppliers,[12] and bank analysts revised Q2 2011 U.S. GDP growth estimates down by 50 basis points annualized.[13] The earthquake's cost to Japanese GDP growth in 2011 was about 50 basis points; although the actual GDP growth impact was larger in Japan, the relative magnitude of these effects reflects the economic importance of these tightly-linked supply chains.

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[10] Alessandria, George, Shafaat Yar Khan, Armen Khederlarian, Carter Mix, and Kim J. Ruhl. "The Aggregate Effects of Global and Local Supply Chain Disruptions: 2020–2022." *Journal of International Economics* 146 (December 2023): 103788. https://www.sciencedirect.com/science/article/pii/S0022199623000740.

[11] Canis, Bill. *The Motor Vehicle Supply Chain: Effects of the Japanese Earthquake and Tsunami.* CRS Report No. R41831. Washington, DC: Congressional Research Service, May 23, 2011. https://crsreports.congress.gov/product/pdf/R/R41831/4.

[12] Boehm, Christoph E., Aaron Flaaen, and Nitya Pandalai-Nayar. "Input Linkages and the Transmission of Shocks: Firm-Level Evidence from the 2011 Tōhoku Earthquake." *The Review of Economics and Statistics* 101, no. 1 (March 2019): 60–75. https://direct.mit.edu/rest/article-abstract/101/1/60/58658/Input-Linkages-and-the-Transmission-of-Shocks-Firm?redirectedFrom=fulltext.

[13] Boehm, Christoph E., Aaron Flaaen, and Nitya Pandalai-Nayar. "Input Linkages and the Transmission of Shocks: Firm-Level Evidence from the 2011 Tōhoku Earthquake." *The Review of Economics and Statistics* 101, no. 1 (March 2019): 60–75. https://direct.mit.edu/rest/article-abstract/101/1/60/58658/Input-Linkages-and-the-Transmission-of-Shocks-Firm?redirectedFrom=fulltext.

Building strong supply chains also brings another important economic benefit: jobs. Investments in American manufacturing can support high-quality, good-paying jobs here in the United States—many of them with the benefits of a union, creating a pathway to the middle class. As an example, investments in the semiconductor supply chain showcase how improving supply chain resilience can also create new economic opportunities for American communities. In the early 2000s, offshoring resulted in the U.S. economy's losing an average of 13,400 semiconductor manufacturing jobs per year.[14] Meanwhile, the U.S. share of global semiconductor manufacturing declined from 37 percent in 1990 to just 12 percent by 2020, leaving the U.S. vulnerable to the types of semiconductor-induced shortages witnessed during the pandemic.[15,16] In response, the Biden–Harris Administration worked with Congress to pass the CHIPS and Science Act, a historic investment in American semiconductor manufacturing capacity. Since then, external estimates are projecting a rebound in domestic manufacturing and a boom in jobs. According to one projection, the United States is expected to triple its capacity to manufacture semiconductors in the decade following the passage of the CHIPS and Science Act—all while potentially creating more than 110,000 new jobs across the industry by 2030.[17]

Supply Chain Resilience and American National Security

Resilient supply chains are fundamental to the United States' vision for a free, open, prosperous, and secure international order. In an era of great power competition and complex shared challenges, bolstering supply chain resilience reduces exposure to national security risks while advancing prosperity for the United States and our allies and partners. In the last four years, as the global economy has recovered from the COVID-19 pandemic, Russia's full-scale invasion of Ukraine, the People's Republic of China's (PRC) non-market policies and practices and economic coercion, and destabilizing activity in the Red Sea, have all threatened the free flow of commerce and fair economic competition. By making U.S. supply chains more diverse and secure, the Biden–Harris Administration has minimized opportunities for adversaries to use economic tools to coerce, intimidate, and destabilize the United States and our allies. Shared challenges like climate change and global pandemics also pose persistent threats to long-term national and economic security.[18] Resilient and agile supply chains that account for these emerging global challenges are crucial to minimize economic ripple effects and prevent costly disruptions.

Improving the security, resilience, and diversity of the core U.S. industrial bases will also keep American communities safer and strengthen the United States' capacity to respond to the pressing challenges of our time. A diverse and resilient energy industrial base will reliably power industries and communities while also helping to reduce emissions; consistent access to medical products will save lives; and safe, resilient, and sustainable food and agriculture supply chains will ensure that both

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[14] Council of Economic Advisers. "U.S. Semiconductor Jobs Are Making a Comeback." *The White House*, March 20, 2024. https://www.whitehouse.gov/cea/written-materials/2024/03/20/u-s-semiconductor-jobs-are-making-a-comeback/.

[15] Semiconductor Industry Association. *Turning the Tide for Semiconductor Manufacturing in the U.S.* October 2020. https://www.semiconductors.org/wp-content/uploads/2020/10/SIA-SUMMARY-OF-BCG-REPORT.pdf.

[16] Federal Reserve Bank of St. Louis. "Did the Computer Chip Shortage Affect Inflation?" *On the Economy* (blog), May 10, 2022. https://www.stlouisfed.org/on-the-economy/2022/may/did-computer-chip-shortage-affect-inflation.

[17] Semiconductor Industry Association. *2024 State of the Industry Report.* October 2024. https://www.semiconductors.org/wp-content/uploads/2024/10/SIA_2024_State-of-Industry-Report.pdf.

[18] The term "national and economic security" is used throughout the report, and "economic security" is understood to be part of "national security".

Americans at home and those in need of humanitarian assistance overseas receive the food they need. A strong information and communications technology (ICT) industrial base is the foundation for the cutting-edge science and technology that will underpin security and prosperity in the 21st century, including the semiconductors in virtually every modern device, and the increasingly connected vehicles on our roads. The transportation industrial base, including historic new investments in modernized transportation infrastructure, will help move critical goods and services across the country and around the world, and the defense industrial base will keep the American people safe and secure. A continued focus on supply chain resilience that builds on the work of the last four years will protect the security of the American people, expand economic opportunity, and lay the groundwork for a more stable and prosperous future.

Our Work to Build Supply Chain Resilience

The Biden–Harris Administration has taken a transformative approach to strengthening supply chains through strategic industrial policy. In 2021, the priority focus was on addressing pandemic-related disruptions and taking stock of vulnerabilities and gaps across critical sectors. The onset of the pandemic in 2020 produced a negative shock to both supply and demand, and while consumer demand quickly recovered, supply challenges persisted amid lockdowns and other snarls. This disruption produced painful inflation and revealed long-standing vulnerabilities in critical sectors such as semiconductors and medical equipment that were overly reliant on foreign manufacturers. The Administration launched the Supply Chain Disruptions Task Force to coordinate the full resources of the federal government to address the acute shocks, undertook strategic reviews of critical sectors, and launched supply chain dialogues with industry and labor, as well as allies and partners. 2021 also saw the passage of ARP and BIL, two important pieces of legislation that began to lay the groundwork for the post-pandemic recovery. 2022 saw the U.S. turn the corner on inflation and congestion in ocean shipping, but brought new global shocks, including Russia's invasion of Ukraine. It also brought the passage of major supply-side investments through the CHIPS and Science Act and IRA. In 2023, Houthi rebels began attacking cargo ships in the critical Red Sea waterway, but—along with a military response in coordination with allies and partners—the Administration's approach to supply chains also began to take stride, with the experienced teams formalized into new supply chain functions at multiple agencies and the launch of the White House Council on Supply Chain Resilience to coordinate supply chain strategy and capabilities across the federal government. The Council has also worked to build and institutionalize the knowledge, data, and capabilities that the U.S. Government has developed through these crises—including strengthening supply chain analytics, risk management, and disruption response.

Improving our response to disruptions

The Administration took office during a time of major supply chain disruptions, including significant congestion in ocean shipping due to pandemic supply and demand imbalances. However, the federal government lacked an existing mechanism to harness federal resources, which were spread across multiple departments and agencies, to effectively address supply chain challenges. In June 2021, President Biden created the Supply Chain Disruptions Task Force (SCDTF) to bring together departments and agencies with a range of relevant tools and authorities, from the Defense Production Act to key data and analytical tools to resources for impacted workers and small businesses. The SCDTF coordinated these federal authorities and resources and also established a process to work with state and local authorities and the private sector in real time. The SCDTF's private–public coordination improved the flow of goods into and around the United States—getting products critical to American families moving again through ports and to shelves.

Even as the country recovered from pandemic-induced supply chain shocks, the SCDTF continued to mobilize to respond to new and unexpected supply chain disruptions. Some departments and agencies bring key tools and authorities to the table, such as the Defense Production Act or resources to support impacted workers and small businesses, while other departments and agencies bring key insights from deep relationships with industry or key data and analytics. The SCDTF coordinated preparations for potential service interruptions on North American railroads and at ports in 2022, 2023, and 2024. It facilitated a rapid response to address supply chain bottlenecks following the sudden shutdown of operations at the Port of Baltimore due to the 2024 collapse of the Francis Scott Key Bridge. It also managed disruptions to the flow of key goods arising from natural disasters, including hurricanes and severe winter storms. In each situation, the SCDTF deployed a tested playbook to convene the core group of federal agencies that handle supply chains, develop a clear workplan, and monitor response efforts until the situation was sufficiently addressed.

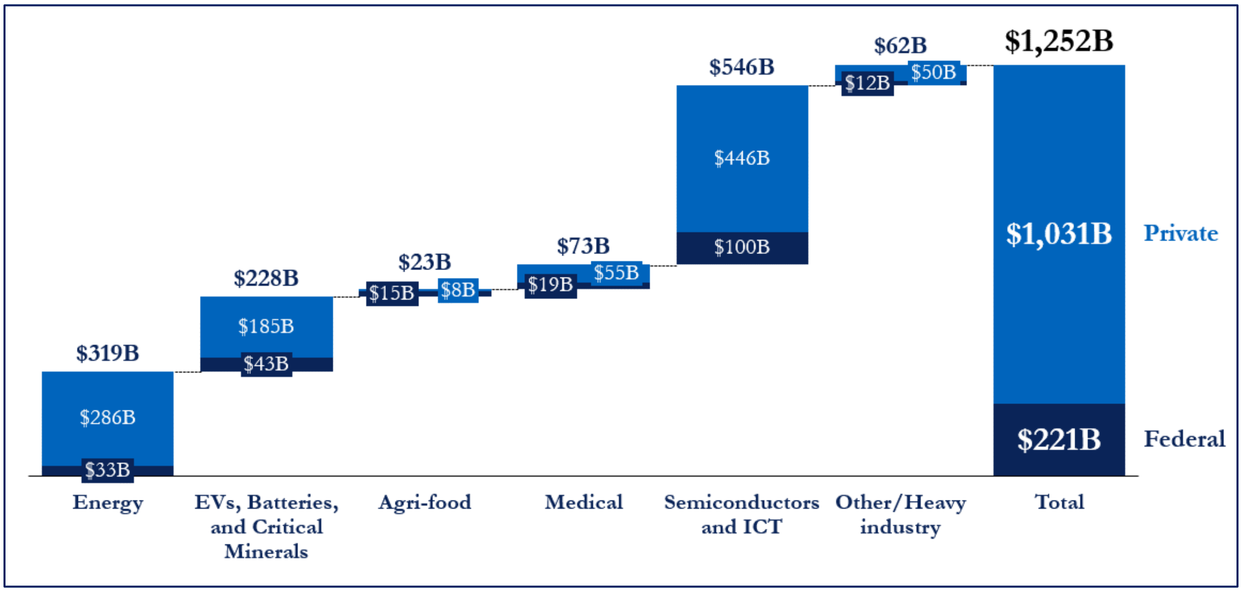
Besides responding to active disruptions, the U.S. Government has also worked to build preparation for potential future ones. Over the past year, multiple federal agencies have run tabletop exercises to examine the actions, authorities, and decision-making timelines for supporting recovery from a disruption. These discussions reinforced the continued importance of contingency planning, interagency cooperation, and communication, including along the United States' geographic borders.

Supply chains are not static, and some level of disruption is inevitable. However, these efforts demonstrate that a rapid, smart federal response—combined with close collaboration with industry, labor, state and local governments, allies and partners, and other groups—can significantly mitigate negative impacts and accelerate resolution.

Investing in American manufacturing

A robust American manufacturing base is at the core of resilient and secure supply chains. Over the past four years, the Biden–Harris Administration has shepherded in a new era of investment in manufacturing. Using strategically allocated resources from major legislation, federal investments—including loans, grants, tax credits, procurements, and other mechanisms primarily funded by BIL, the IRA, and the CHIPS and Science Act—have unleashed over $1 trillion in announced private-sector investment in clean energy and manufacturing since 2021. Of this total, $796 billion is in new American manufacturing. For example, the CHIPS and Science Act is investing nearly $53 billion in U.S. semiconductor manufacturing, research and development, and workforce, driving over $446 billion in announced private investment. Figure 2 illustrates this breakdown across critical sectors.

Figure 2: U.S. Government and private-sector announced investments in critical sectors since 2021



Source: Private investment announcements are from invest.gov as of December 11, 2024. Federal investment announcements reflect loans, grants, preliminary memorandums of terms, certain tax credits, and other awards and allocations by the Departments of Energy, Agriculture, and Health and Human Services, and Commerce since January 20, 2021, as of early December 2024.

These investments have already produced a slew of factories and facilities across the country that benefit multiple critical industrial bases, for example:

- Ultium Cells opened a battery cell manufacturing facility in Warren, Ohio, which employs approximately 2,200 employees and has already produced 100 million battery cells.
- Boom Supersonic invested $500 million in a new factory in Greensboro, North Carolina, to manufacture supersonic airliners.
- Nokia opened a manufacturing facility in Kenosha County, Wisconsin, to produce Buy America–compliant fiber-optic products for broadband investments being funded by BIL.
- Luxwall is investing $165 million in two clean energy manufacturing facilities in Michigan to produce high-volume vacuum-insulating glass, creating 450 good-paying jobs. The Litchfield factory is already online, and the Detroit factory—which is located on the site of a former coal-generation plant and supported by a $31.7-million grant funded by BIL—is anticipated to open in 2026.

The Administration is also providing other kinds of incentives for manufacturers to onshore production of certain critical items. This impact can be seen for solar components and modules—through the 48C Advanced Energy Projects tax credit, $71 million in awards to advance research, development, and demonstration projects, and $7 billion in Solar for All grants to support solar deployment. These actions are energizing domestic solar investment. For example, in 2024, First Solar inaugurated its $1.1-billion photovoltaic (PV) solar module manufacturing facility in Lawrence County, Alabama, which is expected to create over 800 new jobs. Combined with the company's three operating factories in Ohio, First Solar will have a vertically integrated solar manufacturing capacity of 11 gigawatts (GW), and yet another 3.5-GW and $1.1-billion factory is under construction in Louisiana, expected to come online in 2025. Many factories are also currently under construction and projected to come online in 2025 and beyond. For example, in Cedartown, Georgia, SolarCycle is investing $400 million in the largest solar panel recycling facility in the country that will process an estimated 25 to 30 percent of domestic retired solar panels in 2030, as well as $344 million in a solar glass plant with an annual capacity of 6 GW, supported by a $64-million 48C Advanced Energy Projects and 45X Advanced Manufacturing Production tax credits (as disclosed by the taxpayer). These plants are scheduled to be operational in 2025 and 2026 and have already secured partnerships with domestic solar manufacturers.

Importantly, this new American manufacturing capacity is not just for American consumers—it also helps diversify global supply chains through exports. For example, in 2022, the U.S. Export–Import Bank (EXIM) created the Make More in America Initiative (MMIA), allowing EXIM for the first time to support domestic projects that expand the United States' export capacity. Since its creation, MMIA has provided nearly $300 million to companies establishing and returning supply chains to the United States. The Department of the Treasury and Internal Revenue Service (IRS) also announced and finalized rules for the Advanced Manufacturing Production Credit, which will spur U.S. clean energy manufacturing through tax credits and strengthen U.S. energy security.

Additionally, the Biden–Harris Administration recognized the importance of using the power of the federal purse to support American industry. In 2021, President Biden created the Made in America Office (MIAO) in the Office of Management and Budget to help ensure that federal dollars are being leveraged to drive investment, promote good-paying, high quality American jobs, and strengthen the U.S. manufacturing base. In November 2021, as part of BIL, President Biden signed the Build America Buy America Act, which established domestic content preferences for federal financial assistance for infrastructure. The Administration also made the strongest changes to Buy American rules in nearly seven decades by increasing the domestic content threshold for federal procurement from 55 percent to 65 percent in 2024—and that threshold is set to be raised again to 75 percent in 2029.[19] MIAO has also issued guidance on enhanced price preference and industrial mobilization that would help agencies better leverage federal procurement dollars to strengthen domestic sourcing for critical products, mitigate associated supply chain risks, and take a focused approach to supporting domestic industries. Additionally, MIAO has worked to orchestrate a federal procurement "demand signal" across critical industries, including semiconductors, transformers, heat pumps, forgings and castings, renewable energy, broadband, port equipment and infrastructure, EV charging, water infrastructure components, and personal protective equipment (PPE) and textiles.

Creating a level playing field for American businesses to compete and workers to thrive

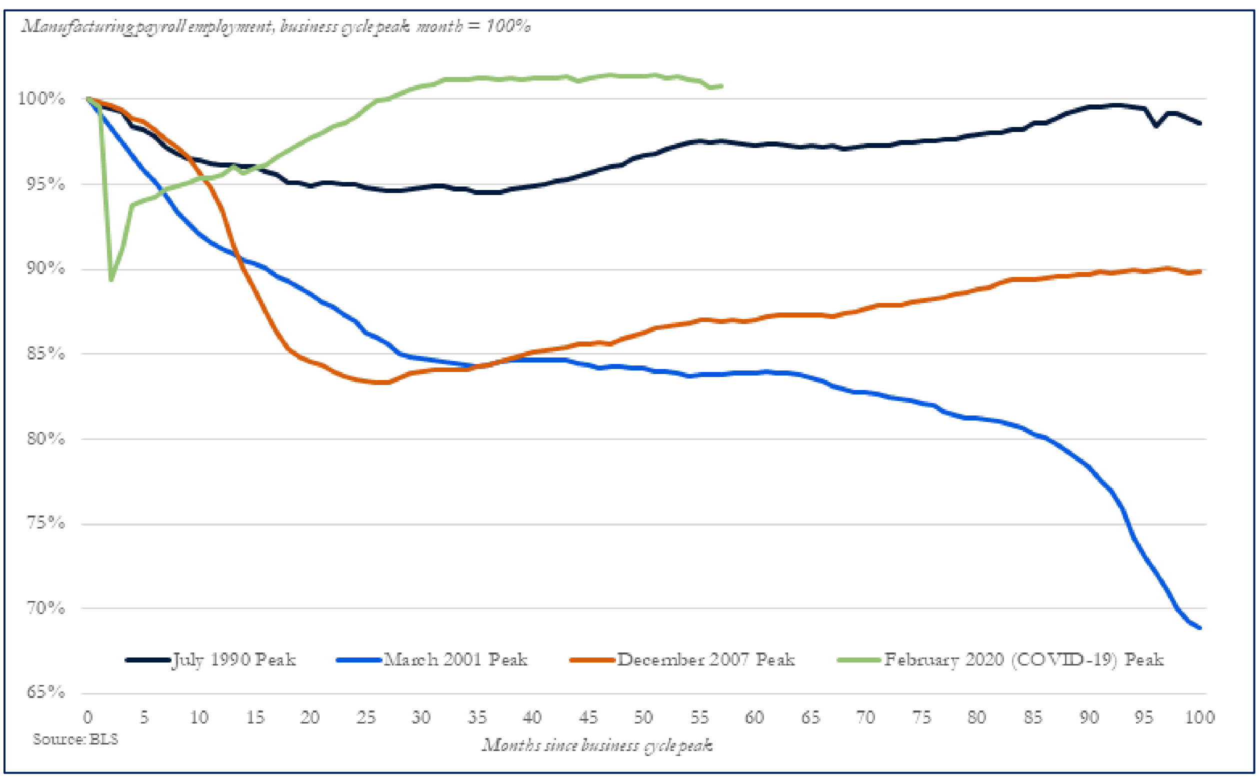
On a level playing field, American businesses and workers can compete and win. Investing in supply chain resilience requires a modern industrial strategy that adapts to the contemporary challenges facing the U.S. economy. Our geostrategic competitors are continuing to engage in non-market policies and practices (NMPP) that undercut our collective resilience—directing actors and resources across their systems to target key industries for dominance by using excessive state subsidies and other forms of state support to dominate critical industries. These actions create non-market excess

[19] Office of Management and Budget. *Guidance for Grants and Agreements.* Rule, 2 CFR Parts 184 and 200. *Federal Register* 88, no. 162 (August 23, 2023): 57468–57490. https://www.federalregister.gov/documents/2023/08/23/2023-17724/guidance-for-grants-and-agreements.

capacity across sectors, dump excess product on the global market at artificially low prices, and drive other manufacturers out of business. The Biden–Harris Administration has developed a strategy to address these NMPP, discussed more in depth later in this Review. Persistent intellectual property theft and forced technology transfers also undermine American businesses' ability to freely innovate and compete. To counteract the burden that China's technology transfer related acts, policies, and practices impose on American businesses and workers, the Biden–Harris Administration raised tariffs on a select number of key sectors to safeguard critical U.S. supply chains in the face of unfair competition. These tariff modifications will protect historic domestic investments under BIL, the CHIPS and Science Act, and the IRA, while also shielding American businesses and workers from unfair trade practices.

Together, these investments and actions have corresponded with a post-pandemic economic recovery unlike any other recovery in recent decades. Overall employment now exceeds pre-pandemic levels, with more than 16 million jobs added since President Biden and Vice President Harris took office. During this Administration, roughly 355,000 new jobs were created each month. American entrepreneurs have filed over 20 million new business applications during this time, the most in any single presidential term in history. In addition, manufacturing has seen a remarkable recovery, with the U.S. economy adding more than 1.6 million manufacturing and construction jobs since January 2021, including 700,000 manufacturing jobs alone. As illustrated in Figure 3, this increase in the manufacturing workforce is historically large and fast compared to other post-recession recoveries in recent decades that saw net declines in the manufacturing workforce. The Biden–Harris economy, thus, has delivered massive gains for American manufacturing

Figure 3: Manufacturing jobs relative to business cycle peak



Strengthening our coordination with allies and partners

The economic reverberations of the COVID-19 pandemic catalyzed a whole-of-government effort to deepen international collaboration on supply chain resilience. Prior to the pandemic, the U.S. Government had few mechanisms to coordinate globally on supply chains. Under the Biden–Harris Administration, the United States has worked with allies and partners to develop channels to warn of potential disruptions, react and respond in real time to acute supply challenges, and diversify long-term trade and investment. The United States alone cannot combat the myriad of challenges that threaten the global economy, and it remains vital to work closely with allies and partners to share information, finance opportunities that support efforts to diversify supply chains and enhance our collective prosperity, and push back against anticompetitive practices that threaten critical industries. Together, the United States and our partners can also shape the rules of the road on important environmental protections and labor standards that underpin all of our markets.

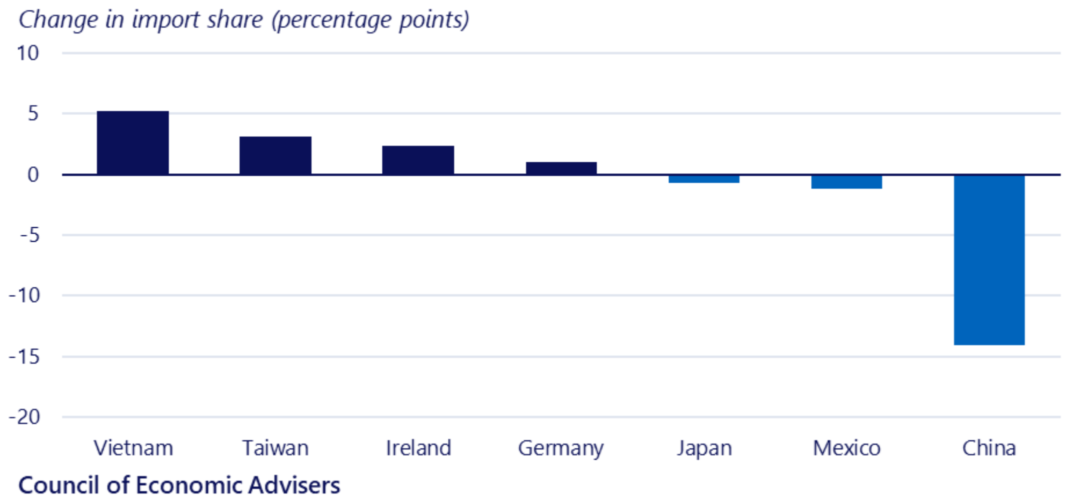
Diversifying supply chain sources is an important element of resilience. Domestic producers alone cannot produce every component of every supply chain. However, overreliance on any one market puts U.S. supply chains at risk of disruption from natural disasters or geopolitical tensions. The U.S. Government must work with partners to develop economic collaboration that minimizes dependencies and chokepoints and improves our mutual resilience.

Recognizing this imperative, the Administration has undertaken robust efforts to strengthen coordination on supply chains with allies and partners over the past four years. In October 2021, President Biden convened over a dozen world leaders to improve international collaboration on supply chain resilience, demonstrating the Administration's commitment to learning from the COVID-19 pandemic to make global supply chains more transparent, diverse, secure, and sustainable. Through initiatives like the Indo-Pacific Economic Framework for Prosperity (IPEF) and Americas Partnership for Economic Prosperity (APEP), the federal government is preparing for potential disruptions, talking to workers and businesses directly about improving labor conditions across supply chains, and making long-term plans for economic resilience in key sectors across the Indo-Pacific and Western Hemisphere.

The U.S. Government is also making long-term investments in global supply chain resilience, partnering with the private sector through the U.S. International Development Finance Corporation (DFC) and EXIM to produce solar energy and unlock access to critical minerals in Angola, develop container ports in Ecuador, and finance health projects worldwide. At the World Bank, the United States and partners are building a pipeline of high-standards critical minerals projects to strengthen and diversify clean energy supply chains through the Resilient and Inclusive Supply Chain Enhancement (RISE) multi-donor trust fund. And the U.S. Trade and Development Agency (USTDA) is working with international customs officials to build awareness of U.S. technologies, solutions, and best practices to support safe, secure, and efficient supply chains. Together, the United States and our partners are strengthening our supply chains and making them more durable, and creating more economic opportunities for Americans and communities worldwide.

The United States' work with allies and partners has shown early evidence of reallocations among foreign sourcing partners are consistent with forging deeper trade relationships with IPEF and EU members to boost resilience across supply chains in general, and in advanced technology products (see Figure 4).

Figure 4: Percentage change in U.S. import share of advanced technology products, by country, 2017–2023



Sources: Trade Data Monitor; CEA calculations.
Note: Advanced Technology Products (ATP) definition from U.S. Census Bureau. Calculated using nominal ATP import values between 2017 and 2023. These countries were selected based on having the highest ATP import shares in 2023 and largest changes in ATP import shares between 2017 and 2023.
As of: July 15, 2024 at 11:30 a.m.

Addressing supply chain risks to critical infrastructure

The mission of protecting critical supply chains is inherently connected to the federal government's longstanding effort to ensure the security and resilience of U.S. critical infrastructure. Critical infrastructure, defined in the Patriot Act of 2001, comprises the physical and virtual assets and systems so vital to the nation that their incapacity or destruction would have a debilitating impact on national security, national economic security, or national public health or safety. Critical infrastructure cannot be secure and resilient without secure and resilient supply chains, and the Administration has taken steps to ensure supply chains are prioritized in federal risk management efforts. In April 2024, President Biden signed a new National Security Memorandum on Critical Infrastructure Security and Resilience (NSM-22) which established a two-year risk management cycle across the sixteen designated critical infrastructure sectors, and tasked the Cybersecurity and Infrastructure Security Agency (CISA) with publishing a National Infrastructure Risk Management Plan. Subsequently, the Secretary of Homeland Security designated the identification and mitigation of supply chain vulnerabilities as one of five priority risk areas which should be addressed as part of the whole-of-government risk management effort. The forthcoming sector-specific risk management plans and National Infrastructure Risk Management Plan, which will be completed in 2025, will communicate to critical infrastructure stakeholders how the U.S. Government will prioritize risk management efforts, including for related supply chain vulnerabilities.

Making supply chain resilience an enduring U.S. Government priority

Disruptions early in the Administration required immediate response. However, the root causes of those disruptions had been years in the making, the result of decades of different policy and private sector decisions. The Administration has affirmed that resilient supply chains are a matter of economic and national security and must remain an enduring focus for the federal government.

Accordingly, across both the White House and federal agencies, the Administration has taken action to integrate and institutionalize supply chain resilience as a lasting priority.

In 2023, President Biden created the White House Council on Supply Chain Resilience to advance this work over the long term. The Council includes representation across the federal government to reflect the multifaceted nature of supply chain resilience. Pursuant to Executive Order 14123, the Council coordinates and promotes federal efforts to strengthen long-term supply chain resilience and American industrial competitiveness. It identifies and provides a coordinated response to address supply chain insecurities, threats, and vulnerabilities, including excessive geographic or supplier concentration. And it facilitates collaboration with allies and partners to foster greater global supply chain resilience.

Supply chain resilience has also become more embedded into the ways that federal agencies operate. The Department of Commerce has launched a Supply Chain Center that is integrating industry expertise and data analytics to develop innovative supply chain risk assessment tools, particularly the new SCALE tool (see more detail on page 29), and sharper "deep-dive" analyses on select critical supply chains to drive targeted actions to increase resilience. Since its inception, the Center has built broad, enduring partnerships across government, industry, and academia. At the Department of Homeland Security (DHS), a new Supply Chain Resilience Center is dedicated to the resilience of supply chains which are crucial for homeland security. Additionally, the Department of Transportation (DOT) has launched an Office of Multimodal Freight Infrastructure and Policy as part of BIL implementation, responsible for maintaining and improving the condition and performance of the nation's multimodal freight network. Dedicated supply chain offices, positions, or both have also been established at the Departments of Health and Human Services (HHS), Energy (DOE), and Defense (DoD). These offices help organize and build agency efforts, including the development of analytical capabilities that help identify and prioritize areas for U.S. Government action. Finally, supply chain resilience remains a priority in the investments and partnerships across the United States' international agencies, with the State Department, the U.S. Agency for International Development (USAID), DFC, USTDA, and EXIM all dedicating resources to improve information-sharing with foreign partners and finance long-term projects that will diversify inputs, create market opportunities, strengthen markets, and minimize the risk of supply chain disruptions in the years to come.

Strengthening supply chains against emerging threats

In the face of new cyber, climate, and other threats, the United States must take innovative approaches to secure supply chains and prevent disruptions that inhibit the flow of goods, raise costs, compromise delivery schedules, contribute to the loss of intellectual property and goods, and result in the delivery of unauthorized or compromised products. Rapid technology developments and the increased digitalization of Americans' day-to-day lives create new risks to our economies. Cyberattacks and cyber actors can undermine critical infrastructure or cause disruptive outages, including through the targeting of supply chain entities. Climate change also poses an existential threat to the planet, threatening the economy, food security, public health, and infrastructure, as well as the manufacturing and logistics systems that underpin global supply chains. Rising sea levels and extreme weather events can disrupt energy and transportation systems, creating shipping backlogs and inhibiting the production and availability of key goods and services. Geopolitical tensions can also cause unexpected disruptions to supply chains, forcing the shipping industry to seek new transit routes or alternate sources for key inputs. Growing dependencies and interdependencies further threaten stability, where supply chain disruptions in one sector could lead to significant cascading impacts across sectors and geographic regions.

Put simply, the United States and the global economy are dealing with challenges that were not encountered in the past. In response to these emerging threats, over the last four years, the Biden–Harris Administration has taken action to prepare and protect communities from risks that could lead to damaging supply chain disruptions. The Administration has led and delivered on the most ambitious climate agenda in history, aligning investments across the public and private sector around climate resilience, ensuring our supply chains can adapt to the challenges of extreme weather and other climate impacts. The U.S. Government has taken executive action to counter maritime cyber threats, secure critical infrastructure,[20] and prevent future cyber incidents. And the United States has built coalitions with our allies and partners across the globe to de-risk against potential geopolitical disruptions.

The work to strengthen supply chains against these challenges must continue, but the Administration's actions over the last four years have helped ensure that critical U.S. industrial bases are more prepared and equipped to deal with the risks of tomorrow, and have laid a strong foundation for this vital work to continue into the future.

Preparing our supply chains to harness emerging opportunities

Although supply chains face new risks, the global economy is also in an unprecedented moment of opportunity. Technological developments including artificial intelligence and information digitization make it easier to monitor and analyze information about supply chains, accelerating our ability to gather insights from complex data and spot disruptions before they occur. In particular, artificial intelligence can help improve forecasting, inventory management, and end-to-end supply chain visibility. Innovation is on the rise as entrepreneurs, startups, and small businesses bring new ideas to life that will help reduce traditional supply chain dependencies and solve global challenges. And workforce development remains a priority, with the Biden–Harris Administration taking action in the last four years to invest in American workers, promote high labor standards and decent work, and create good-paying jobs that will help build the supply chains of tomorrow. To ensure that American supply chains benefit from the opportunities in the modern economy, the next four years should build on the work of the last four years to foster innovation, strengthen the U.S. manufacturing base, strengthen resilience measures, bring together employers and workers to support and train the U.S. workforce, and develop the rules of the road on evolving technology.

[20] This work includes efforts pursuant to NSM–22, through which federal agencies, coordinated by DHS's Cybersecurity and Infrastructure Security Agency (CISA), are conducting a comprehensive effort to identify and mitigate risks to critical infrastructure, including supply chain vulnerabilities This effort includes sector-specific risk management plans and the publication of a National Infrastructure Risk Management Plan.

Engagement with Partners and Stakeholders

Collaboration and coordination with stakeholders inside and outside of government, and up and down supply chains, has been foundational to the Administration's supply chain initiatives.

Engagement with industry and labor stakeholders

From Day One, the Biden–Harris Administration has taken a proactive approach to engaging companies, labor groups, and other private-sector stakeholders on building supply chain resilience.

The Administration has made extensive use of forums large and small to learn from and engage with industry, labor, and other stakeholders. Earlier this year, the Department of Commerce (Commerce), in collaboration with the Council on Foreign Relations, hosted an inaugural Supply Chain Summit, bringing together leaders from government, industry, academia, and civil society to reflect on progress made toward strengthening supply chain resilience. Commerce has also utilized the Advisory Committee on Supply Chain Competitiveness (ACSCC) to discuss supply chain competitiveness with industry and labor leaders, meeting 14 times since 2021 to consider and implement recommendations with the aim of supporting the movement of goods and improving the competitiveness of U.S. supply chains. Similarly, DHS has drawn upon recommendations from the Homeland Security Advisory Council and its Supply Chain Security Leadership Subcommittee to launch and strengthen the work of its Supply Chain Resilience Center (SCRC).

The Administration has also made use of written channels to solicit input from industry and labor stakeholders. Commerce issued a request for comments in the Federal Register on analyzing risk in global supply chains, receiving insights which helped inform the development of Commerce's SCALE tool. The Office of the U.S. Trade Representative (USTR) also gathered input from stakeholders on U.S. supply chain resilience in trade negotiations, enforcement, and other initiatives, convening four public hearings, hearing testimony from over 80 witnesses, and receiving approximately 300 written submissions through a Federal Register notice. These insights have helped inform USTR's development of new trade policy tools and approaches to advance supply chain resilience.

Importantly, this engagement involves ongoing conversations. The Administration has worked to share insights and tools with industry to aid in their resilience efforts and then refine those tools based on feedback and real-world insights. For example, Commerce's new SCALE tool is also being used to further strengthen Commerce's ongoing collaboration with industry, driving more granular conversations about supply chain risk, acknowledging that building resilience in supply chains requires complementary efforts by both the public and private sectors. Engagement with industry stakeholders aims to support companies to better define and factor supply chain risk into their decision-making to enhance supply chain resilience across critical products and industries. These discussions support the private sector in assessing and addressing industry-wide supply chain risks and support fostering a culture of proactive risk management across critical industries, ultimately helping to build U.S. supply chain resilience that supports U.S. jobs and strengthens communities. Additionally, the Department of Labor (DOL) launched the Responsible Business Conduct and Labor Rights InfoHub, a web resource that serves as a central hub for U.S. Government–wide policy, guidance, tools, resources, and outcomes-based approaches to advance responsible business conduct in global supply chains, focusing on labor rights. DOL also updated Comply Chain, its worker-driven social compliance tool, and engaged with private-sector counterparts on integrating this tool into their business practices. And, DOT's Freight Logistics Optimization Works ("FLOW") program has enabled unprecedented sharing of freight data. This public–private partnership brings together U.S. supply chain stakeholders to create a shared, common picture of supply chain networks and facilitate a more reliable flow of goods. Thanks to DOT support, participants are now able to utilize FLOW data to inform their logistics decision-making, helping to avoid bottlenecks, shorten lead times for customers, and enable a more resilient and globally competitive freight network through earlier warnings of supply chain disruption.

Engagement with allies and partners

Over the last four years, the United States has worked closely with allies and partners around the world to improve supply chain resilience, recognizing that durable supply chains require international cooperation with both governments and industry. In October 2021, President Biden convened over a dozen world leaders to improve international collaboration on supply chain resilience, with the Departments of State and Commerce holding subsequent ministerial meetings in July 2022 to further the discussions on managing disruptions and preparing for the future. Following the COVID-19 pandemic and Russia's invasion of Ukraine, G7 leaders committed to building supply chains that are transparent, diverse, secure, sustainable, trustworthy, and reliable, and alongside Japan and the Republic of Korea, the United States launched an early warning system to prepare for supply chain disruptions. The U.S. Government monitors semiconductor supply chains through the U.S.–EU Trade and Technology Council, and innovative partnerships like IPEF and APEP have improved preparedness and deepened economic ties in the Indo-Pacific and Western Hemisphere. Finally, the U.S. Government has partnered with government, industry, and academia in Mexico and Canada to bolster our shared resilience along supply chains in North America.

AN ENDURING VISION FOR STRENGTHENING AMERICA'S SUPPLY CHAINS

The U.S. Government's Approach to Supply Chain Resilience

The U.S. Government is committed to enhancing the resilience of critical supply chains that are integral to the nation's economy, national security, and public health. To achieve this, it is crucial to establish and continually refine a shared understanding of the core drivers of resilience and vulnerability within critical supply chains, each of which is unique and constantly changing.

This Quadrennial Supply Chain Review establishes a common approach and set of definitions, including the identification of critical supply chains and key traits to assess resilience and vulnerability across these critical supply chains. The definitions, elements, and metrics outlined in this Review—which are informed and complemented by an array of academic and industry definitions—are intended to provide the U.S. Government with a shared, fit-for-purpose way to understand and assess criticality, resilience, and vulnerability across supply chains.

Defining criticality

The U.S. Government has prioritized supply chain resilience efforts for supply chains deemed most critical, defined by the extent to which the industries or sectors have—now, or in the future—significance to national security, economic security, and public health. Table 1 below breaks down these three elements into key metrics. This Review focuses on the ten critical industries and sectors outlined by Executive Order 14017: the energy industrial base, transportation industrial base, public health and biological preparedness industrial base, information and communications technology industrial base, defense industrial base, and the production and distribution of agricultural commodities and food products—as well as advanced batteries, critical minerals, pharmaceuticals and active pharmaceutical ingredients, and semiconductors. However, as global events, technological advances, and new risks emerge in the coming years, the U.S. Government will need to continue to refine and update the list of critical supply chains as appropriate, taking into account constantly evolving indicators such as contribution to GDP, exposure to manipulation by foreign adversaries, and price sensitivity.

Table 1: Elements of supply chain criticality

Element	Key Metrics
U.S. national security significance	• **Defense association:** Does this industry or sector significantly contribute to the defense industrial base? • **Coercion incentive and exposure:** Is this industry or sector, compared to others, significantly more likely to be targeted by a country of concern with coercive actions? How exposed is the good/service (or inputs) to commonly used tools of coercion?

Element	Key Metrics
U.S. economic significance	• **Economic impact:** What is the industry or sector's contribution to U.S. gross domestic product, employment, and growth? • **Price sensitivity:** How susceptible are input costs and end prices to sudden changes in availability or trade access (e.g., due to export controls or related economic barriers)? • **Competitive intention:** Have other governments or significant non-U.S. market players expressed or shown intent pertaining to dominance in or manipulation of this industry or sector (e.g., Made in China 2025 sectors)? • **Technological significance:** Does this industry or sector support a key emerging technology area?
Public health and safety significance	• **Public health:** Does this industry or sector provide or support essential food or medicine? Does it involve products identified to be critical (e.g., on the Critical Medical Device List). • **Safety:** Does this industry or sector significantly support public safety? • **Vulnerable populations:** Does this industry or sector provide or support an essential good that disproportionately impacts vulnerable populations (e.g., infants)?

Defining resilience and vulnerability

To ensure a consistent approach to supply chain resilience, the U.S. Government has defined the concepts of resilience and vulnerability, which will be used to guide policy and strategy development. These definitions are informed by and intended to be complementary to those definitions in academia.[21]

Resilience, as defined in this Review, is the ability of a supply chain to adapt to and recover quickly from disruption, including dramatic changes in supply and demand that result from market forces, failures, manipulation, and/or unexpected man-made or natural events. Resilient supply chains quickly restore functionality and minimize long-term negative economic or social impacts. They are flexible, have redundancy built into their systems, and are capable of recovering rapidly from unexpected shocks from natural disasters, geopolitical instability, or technological failures.

[21] Iakovou, Eleftherios, and Chelsea C. White III. "How to Build More Secure, Resilient, Next-Gen U.S. Supply Chains." *Brookings Institution*, December 3, 2020. https://www.brookings.edu/articles/how-to-build-more-secure-resilient-next-gen-u-s-supply-chains/; Khanna, Gaurav, Nicolas Morales, and Nitya Pandalai-Nayar. *Supply Chain Resilience: Evidence from Indian Firms.* NBER Working Paper No. 30689. Cambridge, MA: National Bureau of Economic Research, November 2022. https://www.nber.org/papers/w30689; Baldwin, Richard, Rebecca Freeman, and Angelos Theodorakopoulos. *Hidden Exposure: Measuring US Supply Chain Reliance.* NBER Working Paper No. 31820. Cambridge, MA: National Bureau of Economic Research, October 2023. https://www.nber.org/system/files/working_papers/w31820/w31820.pdf; Ersahin, Nuri, Mariassunta Giannetti, and Ruidi Huang. *Supply Chain Risk: Changes in Supplier Composition and Vertical Integration.* NBER Working Paper No. 31134. Cambridge, MA: National Bureau of Economic Research, April 2023. https://www.nber.org/system/files/working_papers/w31134/w31134.pdf; Baldwin, Richard, and Rebecca Freeman. "Risks and Global Supply Chains: What We Know and What We Need to Know." *Annual Review of Economics* 14 (August 2022): 153–180. https://doi.org/10.1146/annurev-economics-051420-113737.

Vulnerability, in comparison, as defined in this Review, refers to the extent to which a supply chain is exposed and unable to respond effectively to disruption, including dramatic changes in supply and demand brought about by market forces, failures, manipulation, or unexpected man-made or natural events. Vulnerable supply chains lack the agility, redundancy, or security necessary to withstand disruptions without significant economic or operational losses. Assessing resilience and vulnerability, therefore, involves not only identifying risks but also understanding how various supply chain structures—whether domestic, foreign, or global—can withstand these risks and recover.

Resilient supply chains demonstrate seven traits: they are typically transparent, possess at least some degree of domestic capacity, are not overly concentrated geographically, have a diversified supply base, are agile in both manufacturing and logistics, are physically secure, and have good overall economic health, financial stability, and implement strong labor rights protections. Vulnerable supply chains lack many of these key indicators, making it easier and more likely for these industries to experience prolonged negative economic impacts in the aftermath of a disruption. Each of these elements can be assessed using both quantitative and qualitative metrics. Table 2 below outlines key indicators across these seven elements of resilience and vulnerability. Federal agencies have used the below indicators to assess critical supply chains, both to understand progress made over the past four years, as well as to understand key areas to prioritize in the next four years and beyond.

Table 2: Elements of supply chain resilience and vulnerability

Element	Key Metrics
Transparency	• **Data availability**: Does government have access to relevant and timely datasets? Do other stakeholders, including companies, partner governments, and organizations, have access to data at multiple levels of the supply chain (in particular, upstream)? • **Analytics, surveillance, and forecasting**: What capabilities exist to leverage data to predict, anticipate, and monitor disruptions, and inform steps to prevent or mitigate disruptions? • **Public–private collaboration**: Do government and industry have established channels to coordinate?
Domestic Capacity	• **Domestic supply chain representation:** What share and what tiers of the supply chain (including circular economy) exist in the U.S.? • **Supplier ownership:** What is the ownership of domestic capabilities, and/or the nature of foreign investment in the U.S.? • **Intellectual property holdings:** What share of relevant intellectual property is held in the U.S.? • **Research and development activity:** What share of the global research and development space is domestic? Do innovation ecosystems exist to support scale-up of relevant technologies and novel ideas?
Trade Concentration	• **Import reliance**: What share of the good/service (including inputs) is imported? What share is imported from countries of concern or countries in conflict? What is the geographic distribution of sourcing across regions?

Element	Key Metrics
	• **Export reliance**: What share of the good/service (including inputs) is exported? What is the distribution across countries of concern, and allies and partners?
Supplier Diversity	• **Supplier concentration:** Regardless of country location, how many suppliers are there for the same input or process and how concentrated are they (e.g., the Herfindahl–Hirschman Index (HHI))?
Agility	• **Runway**: For how long can a country's entities sustain themselves on existing stockpiles/inventories? • **Manufacturing complexity and lead time:** How many components or process steps are involved in production? How long is a production cycle? • **Manufacturing flexibility:** Do manufacturers use flexible manufacturing processes that can adapt to unexpected changes? Do manufacturers maintain access to sufficient inventory of key materials and components? Do regulations and standards place limits on the ability of manufacturers to adapt to unexpected changes? • **Logistical adaptability**: Are there transportation-related bottlenecks? Are there special storage or transportation requirements (e.g., cold chain)? Are there alternative pathways for transport? Are applicable import/export processes reliable and timely?
Security	• **Security:** How vulnerable are the physical equipment and transportation processes of this supply chain to physical threats (both man-made, including civil risks, and natural, including climate and weather) or cyber and data security threats? How exposed is the supply chain to emerging threats, including climate-driven ones?
Economic Health and Compliance	• **Financial stability:** How sound are the economic operations of key value chain actors? How consistent or predictable are supply and demand? Is there sufficient access to capital to address unexpected disruptions? • **Quality and reliability:** What are the frequency and duration of manufacturing interruptions or delivery delays, including due to quality lapses? • **Compliance:** Are key actors in this supply chain at risk for regulatory violations, such as international labor standards? Do key actors have environmental, social, and governance failures? • **Workforce:** Does this supply chain have a reliable source of labor, now and in the future? Are internationally recognized labor rights protected, including through strong industrial relations?

Importantly, this consistent, expansive, and measurable method of assessing supply chains better enables the U.S. Government to take action to build resilience and mitigate vulnerability. Each element can be addressed through policy or other tools, including data and analytics, stakeholder engagement, dialogue and coordinated action with allies and partners, onshoring, trade, stockpiling, agility, competition policy, cybersecurity measures, sustainability measures, research and development, and more. By systematically understanding and assessing criticality, resilience, and vulnerability, the United States can ensure its supply chains are robust, diversified, and capable of withstanding both current and emerging threats.

Supply chains are dynamic. As such, the U.S. Government's approach to supply chain resilience must also be dynamic, with an ongoing process for evaluation and improvement. As new risks emerge—such as the increasing threat of cyberattacks, climate-related disruptions, and shifting global trade patterns—the U.S. Government must continuously refine and update this framework and these tools. In partnership with the private sector, allies, and international organizations, the U.S. Government will work to build a more resilient and adaptive supply chain ecosystem that supports economic growth, national security, and public health.

The State of America's Supply Chains Today

Overall assessment

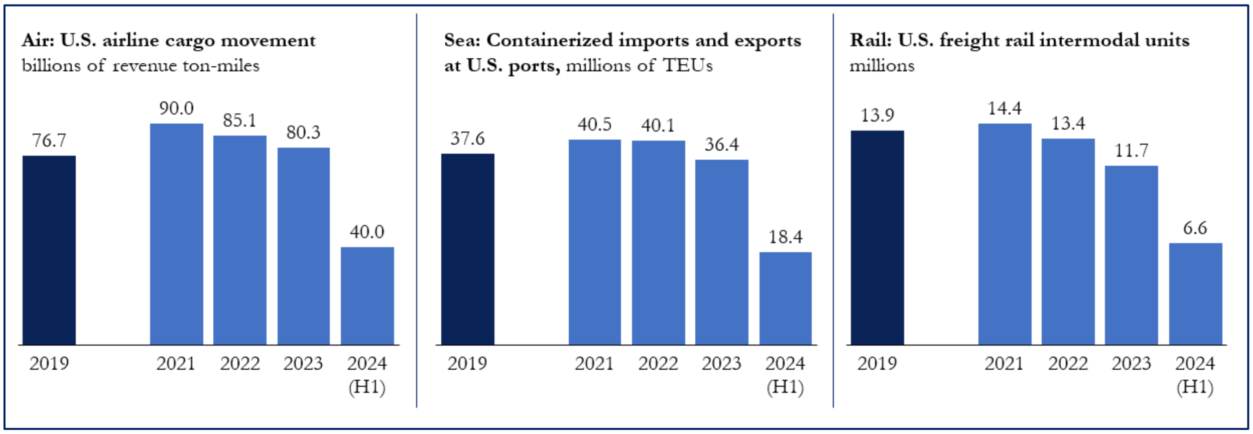
The nation's supply chains are stronger, more secure, and better prepared today to handle disruptions than they were in 2021 or 2022. Table 3 below illustrates the progress made in the Biden–Harris Administration. Lower dwell times and rates for ocean shipping means American businesses get the inputs they need faster and more cheaply, keeping costs down. And stronger retail inventories are both a sign of healthy stocks as well as better preparedness for unexpected supply or demand shocks, so that American families can count on the products they need being available at the store. This progress is just a part of the strength that has allowed the supply chain to continue to move historically strong levels of cargo—by air, land, and sea. See Figure 5.

Table 3: Key supply chain indicators, peak/trough vs. latest available data

	2021 (Peak/Trough)	2024 (Latest Available)	Change
Supply Chain Pressures	4.38 (Dec 2021)	-0.32 (Nov 2024)	-107%
Shipping Prices			
China to East Coast	22,173 (Sep 2021)	5,814 (Dec 2024)	-74%
China to West Coast	20,586 (Sep 2021)	4,301 (Dec 2024)	-79%
Retail Inventories (Millions USD)			
Total excluding autos	598.649 (Jun 2021)	683.242 (Sep 2024)	14%
Food and Beverage Stores	52.247 (Feb 2021)	75.287 (Sep 2024)	44%
Port Dwell			
Dwell times, top 25 U.S. ports	37 hrs (May 2022)	27 hrs (Jun 2024)	-10 hrs
Containerships awaiting berth at all U.S. ports	155 (Feb 2022)	13 (Dec 2024)	-92%

Source: Federal Reserve Bank of New York, U.S. Census, U.S. Department of Transportation

Figure 5: Cargo movement by air, sea, and rail, 2019, 2021–2024



Source: U.S. Department of Transportation
Note: H1 2024 containerized exports includes only Jan–May data.

At the same time, vulnerabilities remain, including in critical sectors. Limited supply chain visibility remains a challenge, meaning that companies still lack sufficient insight into the materials, components, goods and processes across their networks. Many have been investing in technologies to enhance real-time tracking, but more work is needed.

Ten critical industries and sectors

As the rest of this Review details, the federal government has conducted detailed assessments of supply chains for the following industries and sectors:

- **The energy industrial base**: While the U.S. has long been a leading energy economy, maintaining this position and global competitiveness requires substantial and rapid transformation from a focus on producing hydrocarbons to manufacturing energy technologies—especially in light of China's dominance and structural advantages built up over the last decade. Thanks to federal efforts, the U.S. has made substantial progress in advancing a more secure and diversified energy sector industrial base to support an evolving energy system. Over the coming years, more work is needed to drive investment in domestic manufacturing, expand American energy infrastructure, and develop high-skilled, quality jobs in the energy sector workforce.
- **Advanced batteries**: Advanced batteries are critical for U.S. energy security and will play a vital role in affordable, decarbonized, and resilient future transportation and power sectors. Thus, a diversified, secure, and circular supply chain is imperative—including minerals extraction and processing, industrial chemicals, engineered materials, and sophisticated downstream manufacturing operations. U.S. Government action, including BIL, the IRA, and Section 301 tariffs, have helped spur unprecedented investment in the sector. However, supply chain buildout is threatened by market uncertainty and structural challenges. In the years ahead, the U.S. Government must support existing investments, catalyze new investments to onshore critical capabilities, continue leveraging strengths in research and development (R&D) and innovation to compete on next-generation technologies, and facilitate a circular economy model for key input materials.

- **Critical minerals**: Over the past several decades, demand for technologies that are faster, cleaner, smaller, lighter, and smarter has greatly increased the need for mineral commodities. But, as demand for critical minerals increased, U.S. production and processing declined, and global production and processing became increasingly concentrated in fewer countries. In response, recent U.S. Government resilience efforts have focused on building domestic capacity and strengthening U.S. stockpiles, fostering sustainable and transparent critical mineral supply chains, and better identifying supply chain vulnerabilities to reduce risk. Risks remain, however, and in the years ahead, the U.S. Government will focus on further increasing sustainable domestic production of critical minerals, doubling domestic recycling and reprocessing, and working with partners to develop high-standard markets for critical minerals.
- **The production and distribution of agricultural commodities and food products**: The agri-food supply chain is a complex, integrated system from "farm to fork," spanning agricultural and food production, processing, manufacturing, distribution, and consumption, including the inputs needed at each of these steps. Its ever-increasing complexity has exposed new vulnerabilities, which the Department of Agriculture (USDA) has made significant progress in addressing through its Food System Transformation initiative to build resilience through investments to spur domestic production diversification and competition—benefitting consumers, producers of all sizes, and rural communities across the supply chain, from how food is produced to how it is purchased, and all the steps in between. Going forward, USDA will prioritize increasing data availability and coordination, investing in research, and supporting diversified and competitive market opportunities, in order to build a more robust and sustainable U.S. agri-food economy capable of meeting the world's growing demands for affordable and nutritious food.
- **The public health and biological preparedness industrial base**: Disruptive events such as pandemics, manufacturing delays, natural disasters, and product discontinuations have consistently impacted medical care for U.S. patients and revealed supply chain vulnerabilities, prompting a whole-of-government effort to strengthen medical product supply chains and ensure a dynamic, adaptable, and resilient public health and biological preparedness industrial base. The economics of the medical supply chain have generally favored low cost rather than resilient supply chain steps such as diversification and redundancy. Recent decades have also seen an increasing share of production of many essential medicines and medical countermeasures move overseas, resulting in a greater reliance on foreign manufacturing and suppliers and heightening U.S. national health security risks. Over the coming years, HHS will work to build on recent advances to prevent future shortages and hone its ability to mitigate disruptions when they occur.
- **Pharmaceuticals and active pharmaceutical ingredients (APIs)**: Drugs have especially complex production, distribution, purchasing, and contracting systems. Market factors in the function of these systems have led to frequent and persistent shortages of certain medicines—especially low-cost generic medicines—and an increased reliance on foreign countries to manufacture the medicines' finished dosage forms (FDFs), APIs, and key starting materials (KSMs). While HHS has made progress in addressing these longstanding issues, significant additional federal and industry action is needed to address root causes and incentivize investments in resilience so patients can access the medicines they need.

- **The information and communications technology (ICT) industrial base**: ICT infrastructure is highly complex, including networks comprised of both physical and cyber infrastructure, and the geographic concentration of ICT component manufacturing in Asia continues to pose significant risks to global ICT supply chains and the U.S. ICT infrastructure that is vital to maintaining functionality and connectivity across the U.S. and internationally. The U.S. private sector and the U.S. Government, and its allies and partners, have taken steps to identify the most critical supply chain risks in the ICT industry, including risks associated with heavy geographic concentration of component suppliers, and have begun to take steps necessary to build a more durable and resilient ICT manufacturing infrastructure. However, more proactive measures are needed to cover the range of key ICT sectors. By investing in critical component manufacturing, easing certain regulations, and collaborating with allies to diversify sources, the U.S. can increase its ICT supply chain resilience.
- **Semiconductors**: Semiconductor chips are the physical foundation for the binary code that power nearly all digital and consumer electronics goods and services that drive modern life, powering virtually every sector of the economy. Yet, the manufacturing sector of this critical industry over the past few decades had increasingly moved overseas, presenting enormous vulnerability. The historic CHIPS & Science Act of 2022 has catalyzed significant U.S. Government and industry investment in this sector, and as a result U.S. market share for semiconductor manufacturing is projected to increase through the end of the decade. In the years ahead, additional work is needed to improve supply chain transparency and traceability, create a robust talent pipeline for the sector, protect the intellectual property of technologies underpinning the U.S. AI ecosystem, and avoid overconcentration in certain sectors—and to support allies and partners as they grow their own capacity, which can complement and enhance the resilience of the U.S. semiconductor industry and supply chain.
- **The transportation industrial base**: This sector, encompassing road, rail, maritime, air, and pipeline transportation, plays a critical role in supporting national and global commerce, and is undergoing a significant transformation in response to the COVID-19 pandemic and global supply chain challenges. While BIL and other DOT efforts are reshaping the sector, maintaining efficiency, sustainability, and resilience has become increasingly important. In the years ahead, DOT will focus on increasing domestic manufacturing of three key industries—port cranes, shipbuilding, EV manufacturing—as well as increasing supplier diversity in the aerospace industry and advancing data transparency and cybersecurity efforts.
- **The defense industrial base**: Increasingly coercive actions taken by the People's Republic of China, the Russian Federation's invasion of Ukraine, and recent transboundary challenges like COVID-19 have demonstrated the imperative for increased and improved defense capabilities for both the United States and our allies and partners. The first National Defense Industrial Strategy (NDIS), released this year, has articulated DoD's bold vision to achieve a defense industrial ecosystem that is dynamic, responsive, state-of-the art, resilient, and a deterrent to our adversaries.

Analysis from the Department of Commerce's SCALE supply chain diagnostic tool

While the U.S. Government has conducted focused reviews of ten critical industries and sectors, the Administration has also built new capabilities to conduct cross-cutting assessment of resilience and vulnerability. SCALE, a supply chain diagnostic tool developed by the Department of Commerce's Industry and Analysis unit significantly upgrades the U.S. Government's ability to conduct such analysis. The tool employs a comprehensive set of over 40 indicators to assess current or prospective supply chain risk across the U.S. goods economy—431 industries in total. These indicators encompass geopolitical, logistical, technological, and environmental risks, as well as indicators of resilience, such as substitutability and projected recovery times. Using industry-specific thresholds and weights determined by industry and economic experts, SCALE allows the U.S. Government to look across the goods economy at a heat map of risk and assess industries from highest to lowest risk. Beyond identifying economy-wide risks, it ranks the most at-risk industries and products. SCALE also provides a detailed, diagnostic assessment of those risks within specific industries and products, applying an analytical framework across numerous indicators simultaneously. SCALE analysis referenced in this Review is based on the version of the tool launched in September, coinciding with Commerce's inaugural Supply Chain Summit.

SCALE enabled Commerce to conduct its first whole-of-economy analysis of U.S. supply chains, giving the U.S. Government more quantitative insight into structural supply chain challenges that have been decades in the making. The federal government is leveraging SCALE to identify and prioritize sectors and products that are most at risk from supply chain disruption—including sectors that are emerging as increasingly critical to economic and national security. This data-driven approach allows the U.S. Government to pinpoint vulnerabilities, such as reliance on limited suppliers, export markets for critical resources, or dependency on specific transportation methods.

Key findings from the first SCALE analysis of 431 industries are outlined below:

- **Most U.S. goods industries are exposed to structural supply chain risks.** Nearly every industry in the economy scores high in at least one indicator of risk. Lack of substitutability, vulnerability of industry inputs, and concentration of transportation mode are common sources of risk.
- **The U.S. goods economy is interdependent, including dependence on industries and products exposed to high levels of risk**. More than 86 percent of industries are dependent on inputs for other industries that are themselves medium-high or high risk. Interdependencies further threaten stability, where supply chain disruptions in one sector could lead to significant downstream impacts throughout U.S. critical infrastructure and other supply chains. Chemicals, for example, are inputs into 396 out of 431 other industries across the U.S. goods economy. When disruptions occur, these relationships can cause cascading impacts, making it more critical for companies to understand risks not only to their business but to their suppliers as well.
- **U.S. goods industries have poor import diversification.** Many U.S. industries rely heavily on a limited number of countries for key imports, leaving them vulnerable to supply chain disruptions. In fact, nearly 38 percent of U.S. industries are heavily reliant on single-country-sourced products, with more than half of industries having minimal diversification of source countries for their critical inputs. 14 percent of products imported into the United States are, on average over the last five years, almost exclusively imported from a single country. More than 38 percent of industries source over half their imports from China or Russia, and 71 industries are at least 70-percent reliant on adversaries for most of their imports. Limited diversification decreases the resilience of these supply chains in the event of disruption. For many industries, alternative import sources may already be available—over 60 percent of industries have greater import concentration than the world market. For other industries, additional work is required to develop diversified sourcing options.

- **The highest-risk industries cut across the U.S. economy, including electronics, chemicals, and transportation.** These industries rank among the riskiest in the U.S. goods economy. In many cases, vulnerability is driven by high levels of imports from high-risk countries, including China, or from other highly concentrated sources. The specific risks related to many of these industries, and the steps the U.S. Government is taking to address them in collaboration with industry, are addressed in the detailed industry and sector reviews to follow.

Emerging Threats and Opportunities Responsive Actions

Emerging trends

Over the next four years, supply chains may reach a true post-pandemic equilibrium in terms of how industry approaches supply chain efficiency and risk. At the same time, threats from severe weather, conflict, and cyberattacks will continue, requiring government and industry to strengthen their defenses through more agile supply chains. The U.S. Government will be approaching supply chain resilience over the coming years with the following trends top of mind:

- **Post-pandemic industry recalibration.** Following the pandemic, American firms took clear steps to fortify what had been just-in-time supply chains and diversify sourcing from far-flung locations. External surveys have documented industry's progress, including efforts to dual-source inputs and regionalize supply chains, though recent surveys have found signs that industry attention to resilience has leveled off, and some companies are returning to their pre-pandemic inventory practices.[22] In the years ahead, it will be important for the U.S. Government to assess how—and whether—industry continues implementing their resilience efforts, whether by building reliability through deeper inventories and more redundant production locations, by making their supply chains smarter through data and analytics, or by improving their general agility to respond to disruptions.
- **Severe weather disruptions.** 2024 alone has shown the damaging impacts that life-threatening severe weather can also have on supply chains. Heat waves in North America and Europe strained agricultural outputs and halted manufacturing. Hurricanes in the southeastern U.S. crippled production facilities and damaged transportation infrastructure. Flooding in Asia inundated warehouses and factories.[23] The frequency and intensity of severe weather events is set to increase as a result of an accelerating climate crisis. Countries and companies must grapple with these threats and prepare their supply chains accordingly, particularly with respect to geographical concentration and reliance on a particular mode of transportation.

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[22] Alicke, Knut, and Tacy Foster, with Vera Trautwein. "Supply Chains: Still Vulnerable." *McKinsey & Company*, October 14, 2024. https://www.mckinsey.com/capabilities/operations/our-insights/supply-chain-risk-survey; Brown, Marisa. "Preparing for 2024 Supply Chain Challenges and Priorities: Organizations Are Prioritizing Preparedness Against Ongoing Uncertainty." Supply Chain Management Review, March 4, 2024. >https://www.scmr.com/article/preparing_for_2024_supply_chain_challenges_and_priorities<; Dekhne, Ashutosh, and Takshay Aggarwal. "How to Reclaim Supply Chain's Influence as a Driver of Growth." *EY*. Accessed December 11, 2024. https://www.ey.com/en_us/services/supply-chain/boosting-growth-supply-chains-role; Brooks, Chris, Chris Rogers, and Peter Tirschwell. *Look Forward: Supply Chain 2024*. S&P Global, 2024. https://www.spglobal.com/content/dam/spglobal/corporate/en/images/general/look-forward/lookforward_supplychain_2024.pdf.

[23] De Muynck, Bart. "Weather's Wrath: Supply Chains Reel from 2024's Extreme Events." *FreightWaves*, 2024. https://www.freightwaves.com/news/weathers-wrath-supply-chains-reel-from-2024s-extreme-events.

- **Non-market policies and practices.** For many years, the People's Republic of China (PRC) has used comprehensive non-market policies and practices to advance its own economy, including through industrial targeting, non-market excess capacity, large and pervasive state subsidies at the national and local levels, underpriced credit, opaque and discriminatory regulations, and other measures. These actions distort markets, undercut fair competition, produce harmful consequences that create single-market dependencies on the PRC, weaken global supply chains, and can lead to severe and persistent excess capacity. The Biden–Harris Administration has taken action to respond to these problematic behaviors, including by developing a strategy to respond to non-market policies and practices. The Administration has also imposed tariffs on strategic sectors where the PRC has continued to employ non-market policies and practices. However, the United States must continue to work with allies and partners on joint or coordinated responses to the PRC's behavior, protecting investments, and promoting supply chain resilience.
- **Trade measures.** In the months and years ahead, the world could see application of additional tariffs and other trade remedy actions. These actions, regardless of policy basis, could change business decisions in already-shifting global supply chains, and prompt companies to rethink strategies grounded in near-shoring, dual-sourcing, onshoring, and other geography-based supply chain changes.
- **Global conflict.** Protracted conflicts threaten global lives and livelihoods, crossing borders and economies. Russia's full-scale invasion of Ukraine and the conflicts in the Middle East, including along the Red Sea and in Israel and Gaza, have cut people off from economic opportunities as they flee for safety and disrupted the transportation of critical goods. To adapt to these protracted conflicts and minimize economic harm, governments and industry will need to ensure the physical safety of their supply chains, find creative ways to de-risk promising investments, enable livelihoods support to reach people caught in the crosshairs, and invest in the reconstruction and recovery of conflict-affected communities.
- **Cyber.** Many recent cybersecurity incidents have been linked to supply chain risks. These incidents are not isolated events; many recent reports suggest these attacks are increasing in frequency. The combination of digitization and reliance on suppliers to support critical functions creates numerous cybersecurity risks to organizations. Adversaries are increasingly using attack vectors to compromise software supply chains, including the software development process, open-source repositories, update and patching mechanisms, and cloud infrastructure. President Biden's 2021 Executive Order on Improving the Nation's Cybersecurity required software suppliers to attest that the software they provided to the government was developed securely, improved the transparency of where software and its components originate, and included guidelines for reporting incidents when they occur. As governments and industry continue to be more dependent on technology, it is imperative that they recognize the risks associated with the technology supply chain, manage those risks accordingly, and require greater transparency and secure practices from their suppliers.
- **Data and transparency.** Across critical supply chains, the federal government as well as industry have gathered extensive data to monitor flows, measure resilience, and mitigate disruptions. However, the benefits of this work are only beginning to come to fruition, and the complexity and dynamic nature of supply chains continues to make it difficult for companies to effectively monitor materials, components, and goods across their networks. Poor-quality and fragmented data also continue to limit supply chain optimization and obscure risks. Over the past year, the federal government has demonstrated progress through the launch of Commerce's SCALE tool and DOT's FLOW initiative. Over the next

four years, government and industry will likely continue to hone their data sharing and analytics work. Expanding the breadth and depth of available data points is crucial for generating higher-fidelity insights and actionable conclusions, enabling more informed policy decisions and industry actions. Additional industry data collection and data sharing are needed to achieve these goals.

- **Competition.** In many critical industries the consolidation of suppliers and market participants has exacerbated disruptions and limited the ability of supply chains to adapt to changing conditions. President Biden's 2021 Executive Order on Promoting Competition in the American Economy notes the importance of increased choice in supply chains and requires a whole-of-government approach to address concentration and monopolization. Affirmatively working to increase competition and reduce dominance by a small number of firms can help counter the existing trends toward consolidation which hamper the United States' ability to address the other trends in this Review.

Emerging critical sectors

Over the past few years, the federal government has also identified and worked to address risk in other emerging critical supply chains which are expected to grow in importance in the coming years. These include supply chains needed specifically to harness AI. Developing advanced AI systems requires large volumes of advanced chips. Building on work to date on semiconductor supply chains, including President Biden's signing of the CHIPS and Science Act, President Biden in October 2024 issued a National Security Memorandum on AI, which directed additional actions to improve the security and diversity of chip supply chains. The International Trade Administration's Industry and Analysis unit is also actively engaged with the quantum computing industry, including working to better understand the current and future supply chain for this emerging technology. The goal is to help position this critical industry competitively by uncovering and mitigating supply chain risks that could jeopardize the industry's advancement.

Resilience Priorities for the Next Four Years

Following a careful review of progress and outstanding challenges, the federal government has identified four cross-cutting areas of focus for continuing to strengthen critical supply chains over the next four years:

Delivering on the benefits of historic domestic investments. As outlined in Figure 2, the federal government has invested—or is in the process of investing—over $200 billion in the domestic industrial base for critical sectors. That investment has helped engender over $1 trillion in announced investments from private industry. Some of these investments are still being planned, and others are in the early stages of construction. Over the next four years, the federal government must work to create a fertile environment for facilities to be built quickly and to thrive. Doing so will require continued streamlining of permitting processes as well as additional coordination with industry, labor, and communities to provide workforce pathways to these jobs of the future. It also will require close attention to the long-term sustainability and competitiveness of these industries, and additional federal steps where needed to level the playing field for American businesses and workers.

Maintaining and strengthening international supply chain partnerships. The interconnectedness of the global economy means that collaboration with allies and partners on supply chain resilience is more important than ever before. The United States cannot singlehandedly produce every key element in every critical supply chain, but in coordination with our international partners, the U.S. can minimize its vulnerability to disruptions and economic coercion while maximizing collective opportunity. Continuing to engage with G7, IPEF, APEP, and other partners on supply chain preparedness and response efforts will improve American prosperity while protecting American businesses and consumers from disruptive shocks. The United States should also continue working with likeminded partners to friendshore investments, develop global standards, and advance our shared interests to promote overall supply chain resilience.

Harnessing innovation to tackle 21st-century challenges. Efforts to improve resilience today should take into account the needs of tomorrow. The United States should continue to proactively support the use of innovative technology to improve U.S. companies' supply chain analytics, data management, and digitization capacity. Research and development can also yield new findings to make U.S. supply chains more flexible, minimizing dependencies on strategic adversaries for inputs to critical supply chains. Funding for pilot projects, data and analytics tools, and lab work all offer opportunities to harness American innovation and solve for pressing challenges that threaten our supply chains. When the federal government invests in the American people, it invests in the United States' economic future. The U.S. Government must continue preparing American workers for the economy of tomorrow, ensuring they have the technical expertise they need to thrive in the labor force across each core industrial base.

Mobilizing and protecting private investment, including through U.S. Government economic tools. Improving the United States' economic resilience will require using and building upon the full suite of the U.S. Government economic tools to both mobilize and protect private investment. Federal financing agencies like DFC and EXIM can de-risk private investments from market volatility and geopolitical tension, making it easier to diversify sources for U.S. inputs and bring new capacity online. The U.S. Government also needs new tools to deploy patient, flexible capital at speed and scale to underwrite our affirmative economic agenda around the world. Too often, private capital lacks the incentive to invest in projects with long time horizons, large and complex risks, sizable information gaps, or extensive coordination requirements. In these instances, affirmative tools of American economic statecraft must be coordinated and brought to bear to unlock additional resources and drive our economic agenda. The United States must also use the U.S. Government economic toolkit to protect private investments in supply chain resilience, including from the harmful impact of non-market policies and practices that undercut American industries. Targeted use of tools such as sanctions, tariffs, and export controls can counter the impact of and potentially deter non-market policies and practices in key supply chains.

What is Needed to Continue Strengthening America's Supply Chains

To achieve the priorities on the prior pages, the U.S. Government needs continued support. Additional resources and authorities from Congress will be crucial, as will sustained engagement with industry and other external stakeholders. Specific needs are outlined below.

Additional public and private investment in domestic manufacturing in critical sectors. As this Review outlines, significant progress has been made across these ten critical industries and sectors, particularly thanks to U.S. Government investment in domestic manufacturing that has catalyzed private-sector investment. However, the Review also identifies outstanding vulnerabilities, including both existing investments that must be sustained, and outstanding areas in need of federal support—including in emerging critical sectors. In the years ahead, federal agencies and Congress must continue to assess vulnerabilities and opportunities for federal funding to shore up progress and unleash additional industry activity.

Continued support for new federal government supply chain capabilities. The new offices and tools that the U.S. Government has developed are directly responsible for much of the progress outlined in this Review, but they have much still to do, and they need sustained funding to do so. Additionally, for some key sectors, including medical products, agencies need additional authorities to achieve the supply chain visibility they need.

Sustained industry attention to supply chain resilience. While the past four years have demonstrated the power and potential of a robust industrial strategy, ultimately, private actors control supply chains. The past four years have seen tremendous collaboration between government and industry on supply chain resilience, as well as renewed efforts from companies freshly attuned to its importance. For this progress to hold—let alone advance—it is crucial that industry continue to invest in resilience and resist drifting back to pre-pandemic norms. The U.S. Government is counting on continued engagement with industry, including shared data, insights, and warnings, to help the public and private sector better address disruptions.

AMERICA'S CRITICAL SUPPLY CHAINS: A DEEP DIVE

Over the following pages, the Review provides sector-specific assessments, focusing on the supply chains for the ten critical industries and sectors identified in Executive Order 14017:

1. The energy sector industrial base: as assessed by the Department of Energy

2. Advanced batteries: as assessed by the Department of Energy

3. Critical minerals: as assessed by the Department of the Interior and other departments and agencies

4. The production and distribution of agricultural commodities and food products: as assessed by the Department of Agriculture

5. The public health and biological preparedness industrial base: as assessed by the Department of Health and Human Services

6. Pharmaceuticals and active pharmaceutical ingredients: as assessed by the Department of Health and Human Services

7. The information and communications technology (ICT) industrial base: as assessed by the Department of Commerce and the Department of Homeland Security

8. Semiconductors: as assessed by the Department of Commerce

9. The transportation industrial base: as assessed by the Department of Transportation

10. The defense industrial base: as assessed by the Department of Defense

CONCLUSION

In 2021, the Biden–Harris administration took office as global supply chains reeled from the COVID-19 pandemic. Overreliance on individual overseas markets limited U.S. access to key products and inputs, and the federal government lacked the mechanisms and analytics to support a coordinated response. In the four years since, the United States has undertaken historic efforts to invest in supply chain resilience, strengthen the industrial bases critical to American economic and national security, and ensure the federal government has the tools, capacity, and partnerships it needs to support supply chains in the future.

From issuing an Executive Order on America's Supply Chains one month after taking office to creating the White House Council on Supply Chain Resilience and Supply Chain Disruptions Task Force, this Administration has made the economic health and prosperity of supply chains a whole-of-government priority. Over the last four years, the Administration made game-changing investments in critical domestic industries to create good jobs and reduce the vulnerability of supply chains to threats like climate change and economic coercion. The United States has developed innovative whole-of-economy analytical tools to monitor resilience, worked with likeminded international partners to guard against disruptions, and given workers a seat at the table to raise and resolve labor issues within supply chains. And the United States will continue to push back on non-market policies and practices that undercut resilience and threaten fair competition worldwide.

Despite historic progress over the last four years, emerging challenges will continue to threaten global supply chains. Work over the next four years will need to deliver on domestic investments, maintain and expand collaboration with international partners, leverage innovation to create new resilience opportunities, and mobilize and protect investments from market volatility. By building on the historic work of the last four years, the United States can safeguard the enduring resilience of our most critical supply chains for years to come.

Comprehensively Responding to Non-market Policies and Practices

NATIONAL SECURITY COUNCIL
NATIONAL ECONOMIC COUNCIL

DECEMBER 2024

Executive Summary

A whole-of-government effort to enhance the United States' ability to assess and respond to non-market policies and practices has been a cornerstone of the Biden–Harris Administration's efforts to strengthen supply chains and promote economic security. The use of NMPP can harm workers and businesses, distort global markets, hollow America's industrial base, and lead to increased concentration and vulnerabilities in global supply chains. The People's Republic of China's (PRC) use of NMPP, in particular, often allows it to capture a significant, and in some cases monopolistic, share of the global market for critical products and sectors, which displaces foreign competitors and exacerbates supply chain dependencies and vulnerabilities.

The serious impacts of PRC NMPP are frequently felt worldwide, including in the economies of U.S. allies and partners and especially when the PRC seeks to weaponize dependencies to achieve its objectives. Although the PRC is not the only government that uses these unfair trade, industrial targeting, and coercion tactics, the PRC deploys them with unprecedented scale and impact, often with the objective of displacing foreign competitors, establishing monopoly power, and dominating key industries, both in China and globally. This strategy was developed in response to PRC NMPP but could be deployed against any strategic competitor who pursues NMPP.

Under previous Administrations, responses to NMPP were typically limited to one-off trade enforcement actions, which meant that they were reactive, narrowly scoped, and lacked coordination across the U.S. Government and with allies and partners. Given the scope and consequences of the PRC's NMPP, the Biden–Harris Administration has worked to overhaul U.S. efforts to combatting NMPP and to more effectively mitigate the harms outlined above before they happen. The following are essential elements of a comprehensive NMPP response:

- **Systematic and continuous U.S. Government coordination and analysis** to identify sectors vulnerable to NMPP or industrial targeting and early indicators of other countries' use of NMPP;
- **Early and comprehensive U.S. Government action through affirmative and restrictive measures**—including investment, trade actions, procurement, and market standards—capable of nimbly responding to and deterring NMPP or other evolving industrial targeting tactics;
- **Strengthened U.S. NMPP and economic resilience toolkit;** and
- **Collaboration with domestic stakeholders and allies and partners** on analysis, responses, and messaging to limit NMPP and their impacts.

This shift away from insufficient policies of reaction to comprehensive policies of prevention is a hallmark of the Biden–Harris Administration's approach to U.S. supply chain resilience. The strategy outlined on the following pages reflects lessons learned from these efforts and lays out a roadmap for increasing effective U.S. response and coordination in the years to come as strategic competition increasingly plays out in the fields of economics and technology.

I. U.S. Government Coordination and Analysis

The sweeping nature of PRC NMPP and resulting market distortions requires rigorous analysis and regular interagency coordination to focus U.S. Government tools, resources, and authorities to have their highest impact on addressing and deterring future use of NMPP.

Quarterly Convenings and Ongoing Assessments. Quarterly interagency meetings to brief on NMPP activity—and the economic impacts of those policies in global and domestic markets—are necessary to inform and calibrate ongoing U.S. Government efforts. National Security Council and National Economic Council staff should continue interagency convenings at least quarterly to maintain implementation of this overall strategy, including by facilitating discussion of: (1) regularly updated assessments of potential NMPP and impacted products or sectors, (2) NMPP response options and plans, (3) reviews of impact and/or effectiveness of U.S. countermeasures, and (4) engagement with allies and partners.

To inform interagency discussions, the U.S. Government has regularly assessed relevant policy and economic indicators, including, but not limited to:

- National and subnational NMPP;
- Economic indicators, both in the aggregate and for sectors subject to industrial targeting, including those where the United States has already taken action;
- Risks to U.S. supply chains from direct or indirect over-reliance on PRC sources and factors of production;
- Impact of NMPP on allies, partners, and other countries;
- Effectiveness of U.S. countermeasures;
- Other factors, as appropriate.

These assessments and interagency convenings have been instrumental in shaping U.S. responses to NMPP and coordinating actions with allies and partners under the Biden–Harris Administration. To further advance this work, in addition to meeting quarterly, the interagency, led by the Intelligence Community and the Department of Commerce, in coordination with the Department of the Treasury (Treasury), the Council of Economic Advisers, the State Department, and others, should continue to update these assessments as appropriate.

Annual, Public List of At-Risk Sectors. An annual, public list of sectors at risk of NMPP harms should be published by the U.S. Government to facilitate ongoing NMPP response efforts; raise awareness of the PRC's and other strategic competitors' market-distorting policies; signal the potential for U.S. countermeasures; promote coordination with allies and partners; and facilitate stakeholder and congressional engagement.

Based on the assessments described above, the Biden–Harris Administration has pursued NMPP response actions in numerous critical sectors and their supply chains, including the following:

- Iron and steel
- Aluminum
- Solar
- Critical minerals
- Electric vehicles

- Large-capacity batteries
- Semiconductors
- Certain medical products
- Port equipment
- Unmanned aircraft systems
- Shipbuilding

The Biden–Harris Administration's actions in these supply chains are described throughout this Review and provide an important basis from which an annual, public list of sectors at risk of NMPP should be developed going forward. As part of the broader NMPP U.S. Government coordination efforts, the Office of the United States Trade Representative (USTR) should lead development of this list of sectors each year, with input from relevant economic and foreign policy experts within the interagency, as well as feedback from stakeholders.

Sector-Specific Response Plans. The U.S. Government should continue and expand, as needed, the NMPP countermeasure efforts pursued to date and develop response plans for each at-risk sector taking into consideration the comprehensive toolkit described below. USTR and Commerce should work with the interagency to develop these internal plans and update them each year as necessary, based on the effectiveness of U.S. policy responses to date, evolving PRC and other strategic competitors' policies, market conditions in the affected sectors, and stakeholder views.

II. Early and Comprehensive Responses for At-Risk Sectors

Early, comprehensive responses to NMPP are necessary to promote U.S. economic security and resilience. The Biden–Harris Administration has deployed a wide-ranging toolkit to address the strategic and economic impacts of NMPP through the following types of measures. To effectively combat NMPP and promote U.S. economic security, the U.S. Government should continue to consider and leverage this suite of tools, in addition to trade measures.

Supply Chain Transparency and Traceability. Increased supply chain transparency, particularly in critical supply chains, is necessary to identify vulnerabilities and dependencies and tailor NMPP responses to address them and is an important element of a comprehensive NMPP response. Existing traceability requirements, including those incorporated into the forced labor import ban, the Uyghur Forced Labor Protection Act, the Defense Production Act, and sourcing requirements and restrictions on particular tax incentives such as the Inflation Reduction Act Section 30D Clean Vehicle Credit, have demonstrated the capacity for companies to map sourcing and production throughout supply chains, and have contributed to NMPP responses in critical sectors. Going forward, the U.S. Government should build on these measures and incorporate further transparency and traceability requirements, including expanded industry surveys in critical sectors, to enhance the U.S. Government's understanding of U.S. supply chains, potential NMPP impacts, and effective countermeasures.

Domestic Investments and Incentives. Domestic investments and incentives, like the Inflation Reduction Act, Bipartisan Infrastructure Law, and CHIPS and Science Act, and similar investments by allies and partners, can be central to a NMPP response by promoting increased U.S. and allied production when other actions, such as trade enforcement, are insufficient by themselves. However, supply-side policies and investments may be undermined or less effective if not paired with additional countermeasures, particularly for sectors in which markets and prices are set globally.

Procurement. The U.S. Government is the largest purchaser of goods and services in the world, and the Biden–Harris Administration has made it a priority to ensure U.S.-taxpayer-funded purchases benefit U.S. taxpayers and U.S. industries. Although federal procurement alone is typically insufficient to sustain a domestic industry, procurement policies shape markets and can be an important complement to domestic investments and other actions intended to create a level playing field for U.S. producers in the face of NMPP. In his first week in office, President Biden signed Executive Order 14005, *Ensuring the Future is Made in America by All of America's Workers*, to promote consistent application of Made in America laws and to establish the Made in America Office at the Office of Management and Budget to oversee these efforts. Ongoing enforcement of Made in America laws is critical to leveraging procurement policy as part of NMPP responses and in support of industrial and supply chain resilience objectives.

Departments and agencies also have authorities that can require certain standards or domestic sourcing for procured items, as in the case of industrial mobilization authority, which should be considered a potential component of U.S. countermeasures. Furthermore, the Trade Agreement Act (TAA) prohibits procurement purchases from any non-TAA designated countries, unless domestic or TAA suppliers are unable to provide the product or service for TAA covered procurement. The TAA designates the authority to the United States Trade Representative (USTR) to negotiate coverage under TAA. These procurement negotiations could provide an opportunity for the U.S. Government to coordinate with allies and partners to implement similar purchasing prohibitions. In addition, other federal procurement opportunities, such as power purchase agreements, present opportunities to support U.S. producers at risk of NMPP harm and to prevent NMPP-benefiting producers from benefiting from U.S. Government procurement.

Market Standards. Similarly, market standards can play an important role in NMPP responses. Market standards refer to policies that require products to meet certain standards to enter the U.S. market. These can be complemented by voluntary industry standards that the United States and allies and partners encourage private sector entities to adopt. The United States already has market standards that serve a variety of purposes, including to keep U.S. consumers and infrastructure safe and to level the playing field for U.S. producers. Prominent examples include the forced labor import ban, consumer product safety standards, and federal motor vehicle safety standards. Other market standards should also be considered to create a level playing field for U.S. manufacturers. For example, market standards based on economic security criteria could be developed for the incorporation of key components in critical sectors to reduce vulnerabilities. Moreover, trade measures could be put in place to prevent carbon dumping of emissions-intensive goods. Additionally, market standards on labor rights, environmental standards, and traceability of products could help to strengthen U.S. supply chain resilience and competitiveness and promote supply chain diversification, particularly in the clean energy and critical minerals sectors.

III. Strengthening the U.S. NMPP and Economic Resilience Toolkit

In addition to the policies above, the Biden–Harris Administration has deployed trade and national security tools to level the playing field for U.S. businesses and workers. Action to respond to imports will continue to be central to reducing or preventing the harm that results from NMPP.

Title VII of the Tariff Act of 1930, Section 201 and Section 301 of the Trade Act of 1974, and Section 232 of the Trade Expansion Act of 1962 are essential components of the U.S. economic resilience toolkit and crucial to responding to NMPP. Each of these statutes provides important, unique authorities to impose countermeasures, but inconsistencies and a lack of clarity in these and other laws could limit the U.S. Government's ability to effectively respond to NMPP, and updates should be considered.

Import Transparency and Traceability. To most effectively deploy these trade and national security authorities, the U.S. Government should be able to use all federally collected data to strengthen efforts to identify U.S. sectors at risk of NMPP, to determine the likelihood of disruptions based on vulnerabilities in critical supply chains, and to shape NMPP responses. U.S. data collection laws currently limit the ability to share trade, manufacturing, and supply chain data collected for other purposes, even within the U.S. Government. Relevant statutes should be updated to facilitate the collection, collation, and sharing of data on critical sectors, while protecting business confidentiality. In addition, statutory changes are needed to require importers to disclose the components of specific imported final products, or the intended use of imported component parts, when such information is critical to the U.S. Government's ability to craft NMPP response and mitigate NMPP impacts.

Supply Chains. U.S. laws should be strengthened to address systematic use of NMPP by the PRC to achieve market domination of entire supply chains, including final products, intermediate goods, and key components and materials. U.S. economic resilience tools are primarily focused on specific products, without regard to upstream or downstream products that may also be affected by strategic use of NMPP to achieve market domination. For example, Title VII limits the ability of domestic producers of inputs or components to participate in an investigation on a finished product. One exception is Section 232, which allows action to be taken against imports and their derivative products on the basis of a threat to national security but does not explicitly provide for action to be taken throughout a supply chain. Reforms to Section 301, Section 232, and Section 201 could make explicit existing authorities to take action on products throughout a supply chain, including inputs and components as appropriate, wherever located. Relatedly, Section 301 could explicitly recognize the negotiation of sectoral agreements with allies and partners to help achieve these policy goals.

Transnational Subsidies. U.S. laws should be updated to explicitly provide for action against transnational subsidies, which the PRC frequently deploys to achieve domination of global sectors. Under the Biden–Harris Administration, Commerce revoked a prior regulation that was curtailing it from addressing transnational subsidies in countervailing duty proceedings, which is a significant improvement to the U.S. NMPP toolkit. Bipartisan, bicameral legislation pending in Congress would codify Commerce's authority to address transnational subsidies and to address circumstances where shifting production threatens to undermine Commerce's trade enforcement actions.

Circumvention. U.S. trade laws do not all contain circumvention prevention provisions, which can make responses to NMPP vulnerable to evasion. Section 201 and Section 301 could be updated to add circumvention procedures to address the misclassification of products or transshipment through third countries. Furthermore, global or broad trade remedies can help to guard against evasion of NMPP actions achieved by shifting production or export to different countries, and U.S. trade laws could be clarified, as appropriate, to provide this flexibility.

NMPP producers also may seek to avoid U.S. enforcement actions and other border-based measures by investing in U.S.-based operations. The PRC is actively supporting and deploying that tactic in European Union Member States to avoid recently imposed EU tariffs on PRC EV imports. In addition, the United States and other countries have seen an uptick in PRC investment in the solar sector following the imposition of U.S. trade enforcement actions against PRC solar exports and after investigations into circumvention of those duties. The U.S. Government should monitor the threat of these investments in the United States and develop an appropriate policy response, as necessary.

Action Before Harms. Not all trade laws clearly provide for enforcement action before a U.S. industry is affected by NMPP. The standards vary by statute, and, in practice, relief is most often provided only after domestic producers have already experienced demonstrable harm. After-the-fact responses make it harder to achieve full recovery or competitiveness of a U.S. industry, particularly when the PRC has been expending substantial resources to build up a targeted domestic industry before unleashing it on the foreign competition. Title VII allows U.S. firms to seek relief when production is materially retarded by imports, such as when a new domestic industry is seeking to come online but imports are too overwhelming to allow for growth. This provision has been used sparingly, though, and future Administrations should consider how to more aggressively use this tool. To provide for swifter action, Section 201 could be updated to allow for provisional measures, even if time-limited, to be put in place while the International Trade Committee investigatory process is completed. Additionally, Section 301 could be updated to explicitly recognize investigations and action can be taken before domestic producers are harmed by the impact of NMPP and even if there is not yet an existing U.S. industry.

Tariff Code Updates. Furthermore, the Harmonized Tariff Schedule of the United States (HTSUS) could be updated to allow for more precise targeting of imports with trade actions and any tariff rate updates considered by Congress. Certain technical reforms to the HTSUS could help to distinguish among various critical minerals. Other reforms could help to disaggregate tariff lines that comingle products with very different end uses, such as salad spinners and centrifuges for laboratories. More significant changes could also be considered. Modifications to the HTSUS, or authorities to modify the HTSUS, could help to ensure NMPP responses can be effectively implemented to promote American industrial competitiveness and economic resilience.

Updating the U.S. NMPP toolkit will help the U.S. Government better respond to the PRC's evolving tactics and facilitate early, effective action to protect U.S. economic security and create a level playing field for U.S. workers and businesses.

IV. Collaboration with domestic stakeholders and allies and partners

Domestic Stakeholders. Domestic stakeholders, including but not limited to industry, workers' representatives, and state and local governments, should help to shape the overall U.S. Government's NMPP response efforts. Specifically, stakeholder views should be reflected in the annual list of at-risk sectors and the comprehensive response plans. Moreover, stakeholder engagement can help to inform industry about the risks of NMPP and potential approaches to mitigate those risks. USTR and Commerce, in coordination with other departments and agencies, should utilize Federal Advisory Committees and other regular channels of communication with a variety of stakeholders to facilitate ongoing exchanges of information and reinforced messaging on the U.S. Government NMPP response strategy, as appropriate.

Allies and Partners. Coordination of comprehensive NMPP countermeasures with allies and partners will increase their impact and more effectively promote fair competition in the United States and the global market. The Biden–Harris Administration has prioritized NMPP collaboration with allies and partners and on supply chain resilience with significant results. The Group of Seven (G7) countries have issued statements underscoring shared concerns about the threats of NMPP and economic coercion, as well as the importance of economic security, the harms caused by PRC overcapacity, and a commitment to partner on supply chain resilience efforts. Earlier this year, the G7 leaders announced their intention to coordinate efforts on economic resilience, which Canada has committed to taking forward as a central pillar of its presidency next year.

Tariffs on electric vehicles imposed by allies and partners demonstrate the potential and the impact of coordinated action. President Biden announced a 100-percent tariff on PRC electric vehicles in May 2024. In August, Canada announced it would also increase to 100-percent tariffs on PRC electric vehicles and examine the need for tariffs on other products to address NMPP. And after completing its own trade investigation, the European Union began applying tariffs up to 35 percent in October—in addition to the 10-percent duty on imports from all countries—on PRC electric vehicle imports.

To maintain this momentum, ongoing engagement with allies and partners to share assessments and discuss effective policy responses is imperative. The Department of State has coordinated U.S. outreach to allies and partners, including analysis of actions taken by allies and partners to respond to NMPP, and is well suited to continue this work in coordination with the interagency. The future publication of the U.S. annual list of sectors at risk of NMPP harms would serve as a useful basis for these international engagements.

Advancing NMPP concerns in multilateral settings, such as the Organisation of Economic Cooperation and Development (OECD) and the World Trade Organization (WTO), should also be coordinated with allies and partners. These efforts can help to raise awareness of the global economic harms of NMPP and the need to adopt countermeasures to increase supply chain resilience, reduce the risk of economic coercion, and promote a level playing field. This includes work to raise awareness of how NMPP harm developing countries and undermine their industrialization goals, including by impeding efforts to establish new industries and by preventing developing countries from moving up the value chain in sectors of interest. Treasury, USTR, Commerce, and State should maintain these efforts in the future.

Conclusion

Early, comprehensive responses to NMPP have been central to the Biden–Harris Administration's efforts to promote American industrial competitiveness and economic resilience and fair competition throughout the global economy. Continued implementation of this NMPP strategy is essential to creating a level playing field for U.S. industries and workers and to achieving supply chain resilience in the critical sectors identified in this Review.

2021–2024 Four-year Review of Supply Chains for the Energy Sector Industrial Base

U.S. DEPARTMENT OF ENERGY

DECEMBER 2024

EXECUTIVE SUMMARY

The U.S. Government is advancing a more secure and diversified energy sector industrial base to support an evolving energy system. While the United States has long been a leading energy economy, maintaining this position and global competitiveness will require substantial and rapid transformation from a focus on producing hydrocarbons to manufacturing energy technologies.

Leadership in the energy sector industrial base (ESIB) requires action across a diversified set of technologies, infrastructure, and industrial applications. A robust and resilient ESIB requires scaling a broad range of economic activities including extraction and processing of raw and materials for critical components, manufacturing and installation of energy technologies and key components, investment in the electrical grid to carry greater loads, development of new sources of fuel and industrial heat, and workforce development.

The U.S. Government is pursuing a modern industrial and innovation strategy to lead the energy transition. Working with partners around the world, the U.S. is leading a government-enabled, private sector–led approach that invests in our own economic and technological strength, promotes diversified and resilient global supply chains, and sets high standards for labor, the environment, cybersecurity, among other areas.

More secure and resilient supply chains are essential for the national security, economic security, and technological leadership of the United States. The long-standing approach of prioritizing of efficiency and low costs has increased supply chain risks. Foreign entities of concern (FEOC) are playing a larger role in production of critical upstream and midstream materials. Without a robust domestic and allied manufacturing ecosystem, the U.S. may remain reliant on competitor nations, posing a risk to national security and future economic prosperity.

The U.S. has made substantial progress in reinvigorating manufacturing and strengthened our energy supply chains by making them more resilient, robust, diverse, and competitive. In 2022, the U.S. Department of Energy (DOE) published "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition"—the first comprehensive U.S. Government plan to build an ESIB.[24]

The People's Republic of China (PRC) enjoys structural advantages in energy supply chains today, which threaten U.S. economic and national security. While the U.S. and trading partners are making considerable progress towards standing up supply chains for manufactured energy products, future investments must consider the structural advantages in production that PRC has built up over the last decade.

Several key challenges must be navigated to accelerate the pace of progress in building resilience in America's ESIB and its supporting supply chains. An intentional strategy to drive investment into high-priority sectors necessary for U.S. national and economic security, especially where PRC's dominance threatens the U.S. ESIB, will be critical to improve U.S. competitiveness.

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[24] U.S. Department of Energy. "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition," U.S. Department of Energy Response to Executive Order 14017, "America's Supply Chains", February 24, 2022. https://www.energy.gov/policy/articles/americas-strategy-secure-supply-chain-robust-clean-energy-transition.

SECTOR OVERVIEW

Introduction

The United States energy sector industrial base (ESIB) is a sprawling network of activities that enables the energy sector and propels the American economy. This vast, industrial system encompasses a wide range of activities including extraction of hydrocarbons, mining and processing of battery-grade metals, manufacturing and installation of energy technologies, and ultimately recycling or disposal of end-products. The shifts within this sector have ignited growth and investment in new industries, creating millions of well-paying jobs in the process. Indeed, the U.S. energy economy directly employs 8.4 million workers, of which 42 percent are employed in the burgeoning clean energy sector.[25]

Sector Overview

A robust U.S. energy sector is essential for achieving critical national economic and security objectives. First, affordable energy is a cornerstone of economic growth, job creation, and maintenance of a high standard of living. Second, a resilient and secure energy system is critical for ensuring national security. Third, U.S. leadership in the global energy transition and climate change mitigation is paramount to position the United States as a leader both today and in the future, as well as to mitigate the damaging impacts from climate change. A robust U.S. energy sector industrial base is on par with a robust defense industrial base—both are indispensable to the preservation of prosperity, economic vitality, and a secure future.

The challenges ahead to ensuring ongoing strength and resilience of the U.S. ESIB are significant. While the United States has long been a leading energy economy, maintaining this position will require substantial and rapid shift in focus from producing hydrocarbons to manufacturing low carbon energy and grid technologies. The pace of climate change demands a swift diversification of energy resources, and global markets are embracing these technologies at an accelerating pace. New technologies will be indispensable for this transition, from renewable energy generation to energy storage to industrial decarbonization solutions. The Biden–Harris Administration has taken historic steps to accelerate the deployment of these technologies and bolster supply chains, ensuring a resilient and sustainable energy future for the nation. By addressing these challenges, the United States can maintain its leadership in the global energy market and secure a prosperous future for generations to come.

Evolution of the U.S. Energy Sector Industrial Base

The United States energy sector has undergone significant changes in the past two decades and will continue to evolve at an accelerated pace in the next 30 years due to rapid innovation, investment trends in private capital markets, and the urgent need to combat global climate change. Over the last few decades, the ESIB has undergone significant transformation: shifting energy market economics have led to the displacement of coal as the lowest-cost fuel for electricity generation by natural gas and renewable energy; solar and wind capacity have been added to the grid at an unprecedented

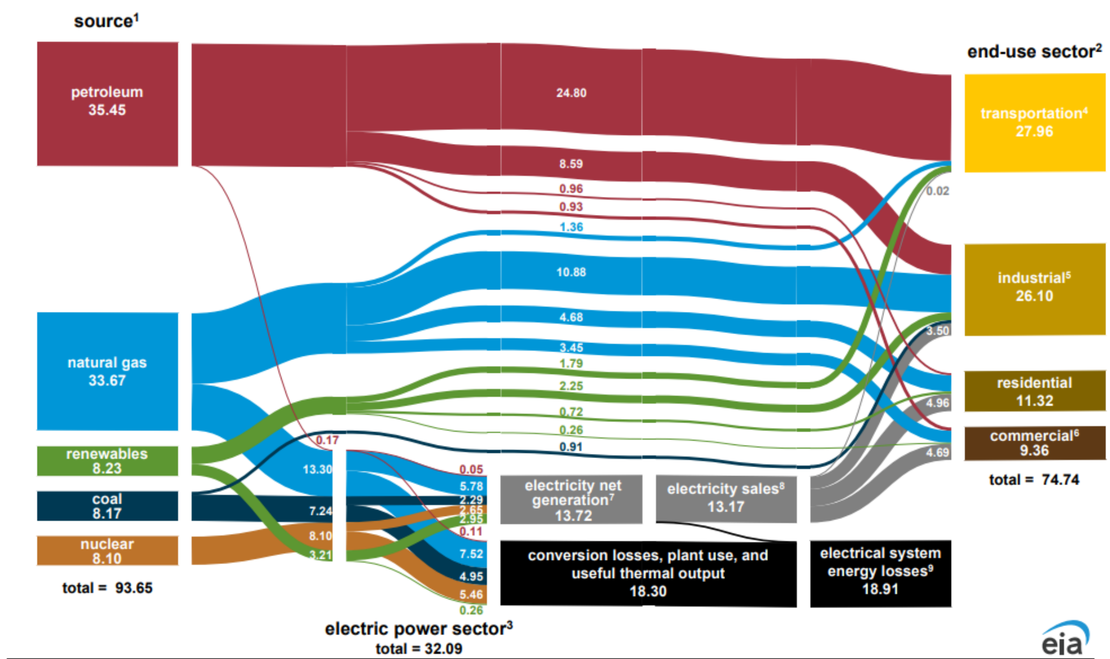
[25] U.S. Department of Energy. Energy.gov. "2024 U.S. Energy & Employment Jobs Report (USEER)," n.d. https://www.energy.gov/policy/us-energy-employment-jobs-report-useer.

pace; advanced batteries have become viable for use in the power and transportation sectors, and grid components have accelerated their shift from an analog to digital model. However, risks have emerged in the system as these changes have taken place. Low-cost production from abroad, at times driven by non-market state policies in the case of energy technologies and noncompliance with international labor standards, has led to the offshoring of supply chains needed to support many of the technologies that are increasingly critical within the U.S. ESIB. Non-market practices by PRC such as overproduction of supply have also distorted global markets. This pattern has had consequences for the American worker, with communities across the United States grappling with deindustrialization as scores of manufacturing facilities jobs moved overseas.

In 2019, the U.S. achieved the long-held goal of producing more energy than it consumed, driven in large part by the development of hydraulic fracturing and horizontal drilling over more than a decade.[26] Today, the U.S. is the leading crude producer in the world, accounting for nearly 20 percent of the world's total oil production and producing more oil annually than any country in human history.[27] In the U.S., as of 2023, about 84 percent of primary energy end-use and 60 percent of electricity generation came from fossil fuels, including petroleum, natural gas, and coal (Figure 1).

Figure 1. U.S. energy consumption by source and sector, 2023[28]

quadrillion British thermal units (quads)



[26] IER. "The United States Was Energy Independent in 2019 for the First Time Since 1957 - IER." IER, May 11, 2020. https://www.instituteforenergyresearch.org/fossil-fuels/gas-and-oil/the-united-states-was-energy-independent-in-2019-for-the-first-time-since-1957/.

[27] U.S. Energy Information Administration. "United States Produces More Crude Oil Than Any Country, Ever - U.S. Energy Information Administration (EIA)," n.d. https://www.eia.gov/todayinenergy/detail.php?id=61545.

[28] U.S. Energy Information Administration. "U.S. Energy Facts Explained - Consumption And Production - U.S. Energy Information Administration (EIA)," n.d., https://www.eia.gov/energyexplained/us-energy-facts/.

While the U.S. energy system remains dependent on fossil fuels, the impacts from climate change have hardened the global consensus that a shift to low-carbon energy solutions is needed. This will require the U.S. to establish a strategy to accelerate energy production and drive towards energy independence with a broad portfolio of technologies. To combat the climate crisis and avoid the most severe impacts of climate change, the United States has made several notable commitments that will require evolution in our energy sector:

- Achieving a 50- to 52-percent reduction from 2005 levels in economy-wide net greenhouse gas pollution by 2030
- Creating a carbon pollution-free power sector by 2035
- Achieving net zero emissions economy-wide by no later than 2050.[29]

While these commitments are one important reason to embrace the development energy technologies, it is equally important to consider that these technologies will drive the energy economy of the future. Countries around the world and private capital markets are increasingly embracing these technologies, and participating in these energy technologies offers substantial economic opportunity in addition to a pathway to meet stated energy transition goals.

A successful shift away from fossil fuels will require a multifaceted approach. While the challenge will be substantial, it is important to note that the U.S. is extraordinarily well-positioned to achieve clean energy independence and to emerge as a global clean energy leader given its unique ability to innovate, exceptional capital markets, and endowment of extraordinary clean energy resources to leverage.

The ESIB encompasses the "how" of the energy transition. No single technology or solution will be sufficient, and the future demands a holistic transformation of the global energy system. Carbon-free energy sources such as geothermal, nuclear, and renewables (e.g., solar and wind power) offer significant potential to drive emissions reductions in the near term. By accelerating investment in these technologies, the U.S. Government can accelerate economically favorable decarbonization while research, development, and demonstration continues in more challenging sectors like chemicals, metals, and aviation.

To face this challenge, the U.S. Government has pursued a modern industrial and innovation strategy, both at home and with partners around the world. This strategy prioritizes investment in American economic and technological strength, promotes diversification of global supply chains to reduce reliance of foreign nations, raises the standards for labor and environmental standards protections, and delivers public goods like better climate, environmental, and health outcomes to the American people. Building a clean-energy economy and navigating the energy transition is one of the most significant challenges—but also one of the most significant growth opportunities—of the 21st century. To harness that opportunity, the United States of America must pursue a deliberate government-enabled, private sector–led strategy to pull forward innovation, drive down costs, and create good jobs. This approach is represented in the Biden–Harris Administration's goals of the energy transition (Infographic).

[29] The White House. "Executive Order on Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability." December 8, 2021. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/12/08/executive-order-on-catalyzing-clean-energy-industries-and-jobs-through-federal-sustainability/.

Infographic: Biden–Harris Administration goals of the energy transition

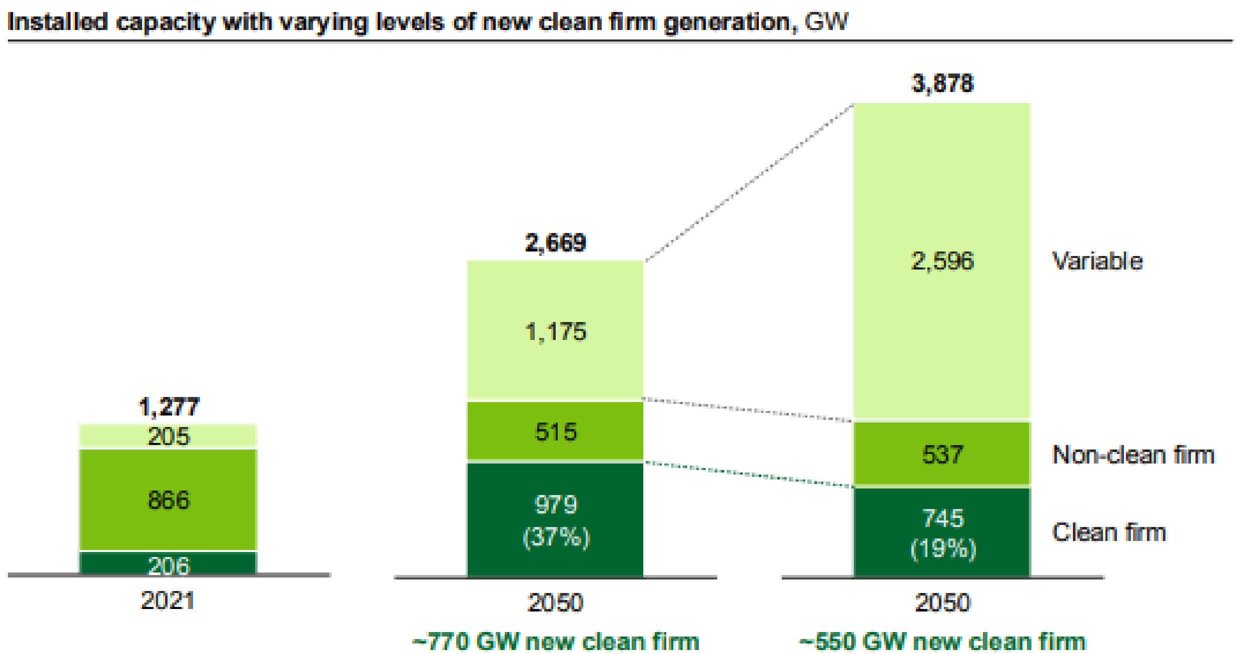
Expanding affordable clean energy for all	Build a more resilient and reliable grid Secure energy system against hazards (e.g., extreme weather, security risk) Provide homes, schools, buildings, and transportation with access to affordable clean energy
Renewing American manufacturing	Secure key U.S. clean energy supply chains including workforce Catalyze new manufacturing and support small- and medium-sized manufacturers Position U.S. energy-intensive industries to supply globally competitive products
Creating jobs and community benefits	Ensure benefits flow to communities at risk of being left behind Create high-quality, accessible, and career-track jobs Partner with state, local, and tribal governments for the clean energy transition
Catalyzing private sector investment	De-risk new clean energy technologies Galvanize broad and deep market demand Deploy co-investment opportunities with the private sector

Technologies for the Energy Sector Industrial Base and Key Trends

Under the leadership of the Biden–Harris Administration—including the passage of the Bipartisan Infrastructure Law (BIL), the Inflation Reduction Act (IRA), and executive branch actions—the U.S. has accelerated the pace of clean technology adoption, catalyzed historic investment in the clean energy manufacturing sector, and initiated transformative projects for industrial decarbonization and carbon management.

The increasing deployment of renewable generating assets and decarbonization technologies improves energy system resilience and insulates the U.S. from shocks in global market prices. Analysis from the Department of Energy shows that power system decarbonization modeling suggests that the U.S. will need about 2,500 GW of new variable renewable energy capacity and ~550–770 GW of additional "clean firm capacity"—nuclear, renewables paired with energy storage, geothermal, hydroelectric power, among others—to reach net-zero. Modeling of power generation by sources in Figure 2 shows two potential scenarios of clean firm power and relative amount of variable generation (e.g., solar, wind) for lowest-cost grid scenario.

Figure 2. System-level modeling shows increasing clean firm capacity complements variable generation for lowest-cost grid, 2023–2050[30]



Building and maintaining the U.S. energy system will require a myriad of technologies, both established and in early development, as well as robust supply chains to support them. Battery cells cannot be made without access to lithium and graphite, transformers and grid components require copper and specialized steel, solar cells are built from polysilicon, and wind turbines require rare earth magnets and specialized castings. The ramp-up in clean energy technologies requires the parallel scaling of critical minerals, materials, and manufacturing in the U.S. and from reliable trading partners.

Beyond securing current clean energy supply chains, it will be critical to look forward and consider how the United States can position itself for success in the next wave of clean energy technologies. This will require efforts to support innovation ecosystem from research and development through commercial deployment. Emerging technologies such as clean fuels, long-duration energy storage, and advanced nuclear, among others, have immense potential to support a resilient and reliable energy system and broader U.S. economy. This holistic approach must be applied to a range of key technologies across the ESIB.

[30] U.S. Department of Energy. "Advanced Nuclear - Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, November 5, 2024. https://liftoff.energy.gov/advanced-nuclear-2/.

Overview of ESIB technologies and supply chains[31] (not exhaustive)

1. Power Generation

Solar. Solar energy is among the cheapest energy generation sources. Due to its favorable costs of deployment, solar is rapidly becoming the dominant form of generating capacity—accounting for 67 percent of all new electricity-generating capacity additions in 2024 H1 alone.[32] Demand for U.S. solar capacity is estimated to increase four-fold from 2020 levels to over 400 gigawatt direct current (GWdc) by 2030,[33] with high case estimates from outside clean energy experts suggesting a range of ~520[34] to 560[35] GWdc. Since the passage of the IRA, U.S. announced solar module assembly projects—nearly 50 GWdc of annual manufacturing capacity—is enough to satisfy 80 percent of domestic demand with U.S.-produced modules by 2026.[36]

While IRA incentives have driven significant progress in building out a domestic solar supply chain, the United States remains reliant on the PRC for the production of key upstream components including polysilicon, ingots, and wafers. In these upstream production steps, current domestic supply is expected to meet only about 30 percent of projected U.S. demand.[37] Closing this gap may prove challenging due to substantial production cost advantages enjoyed by PRC firms. These advantages are driven by multiple factors including lower capital and operating expenditures, vertically integrated business models, a set of favorable state policies, and restrictions on labor rights, including state-imposed forced-labor schemes, that have artificially lowered the cost of production. These include access to low-cost land and utilities, preferential state financing, and a range of trade policy tools. While these advantages are significant, the U.S. has leading solar research and development (R&D) facilities and researchers, including from national laboratories (e.g., NREL) and academic ecosystems, that continue to generate new IP that may enable innovation into new solar technologies.

Wind. Land-based and offshore wind play a key complementary role to solar as part of what will be a diverse, lowest-cost, and low-pollution energy mix. While the U.S. land-based wind market is stable with incremental growth to occur year-over-year, offshore wind is positioned to be a major driver of renewable power generation. Despite recent challenges, the sector is adapting, and improved risk mitigation is being built into industry planning. U.S. offshore wind is now poised for a breakthrough, beginning with the 10–15 GW of projects with a path to final investment decision in

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[31] U.S. Department of Energy. "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition," U.S. Department of Energy Response to Executive Order 14017, "America's Supply Chains", February 24, 2022. https://www.energy.gov/policy/articles/americas-strategy-secure-supply-chain-robust-clean-energy-transition.
[32] Solar Energy Industry Association. "Solar Market Insight Report Q2 2024 – SEIA," August 29, 2024. https://seia.org/research-resources/solar-market-insight-report-q2-2024/.
[33] National Renewable Energy Laboratory. "Standard Scenarios," n.d. https://www.nrel.gov/analysis/standard-scenarios.html.
[34] Solar Energy Industry Association. "Solar Market Insight Report Q2 2024 – SEIA," August 29, 2024. https://seia.org/research-resources/solar-market-insight-report-q2-2024/.
[35] BloombergNEF. "New Energy Outlook 2024 | BloombergNEF | Bloomberg Finance LP," May 30, 2024. https://about.bnef.com/new-energy-outlook/.
[36] U.S. Department of Energy, Loan Programs Office, Energy.gov. "LPO Tech Talk: Solar Photovoltaics Supply Chain," n.d. https://www.energy.gov/lpo/articles/lpo-tech-talk-solar-photovoltaics-supply-chain.
[37] U.S. Department of Energy, Office of Manufacturing and Energy Supply Chains, internal analysis, December 2024.

the next few years.[38] These projects will lay the foundation for consistent long-term deployment, decarbonization, and economic benefit across the country. Longer term, offshore wind can deliver over 100 GW clean power by 2050. There is a clear path to scale, with ~50 GW-worth of U.S. seabed already leased to developers (more planned), and early project deployment advancing rapidly. Delivering over 100 GW by 2050 would require the industry to maintain a steady pace of 4–5 GW deployed per year.[39]

U.S. manufacturing capacity for offshore wind components is still scaling up, leaving a dependency on global sourcing. Like nuclear generation, the wind industry relies on large castings and forgings, specialized and engineered materials, and rare earth metals (e.g., neodymium, dysprosium) used in high-capacity magnets for nacelles. The Jones Act requires U.S.-flagged vessels to install wind turbines, and a shortage of U.S.-flagged installation vessels creates another challenge to rapid deployment. Despite these challenges, the wind industry has received substantial support from recent legislation and policy support. The IRA and BIL created funding opportunities to support offshore wind supply chains including the Qualifying Advanced Energy Project Credit (48C), the Advanced Energy Manufacturing and Recycling Grant program ($750 million),[40] and the Rare Earth Element Demonstration Facility grant program that provides up to $140 million from BIL.

Nuclear. Nuclear power provides a differentiated value proposition for a decarbonized grid; it generates carbon-free electricity, produces firm power that complements renewables, and lowers the need for new transmission and land-use relative to other generation sources. Nuclear power can deliver carbon-free electricity at scale while creating high-paying jobs with concentrated economic benefits for communities. The White House's domestic nuclear energy strategy, "Safely and Responsibly Expanding U.S. Nuclear Energy: Deployment Targets and a Framework for Action," established bold U.S. Government targets for safely and responsibly expanding U.S. nuclear energy, including tripling U.S.-installed nuclear energy capacity from ~100 GW in 2023 to ~300 GW by 2050.[41] The net new capacity gains are anticipated to come from multiple sources, including building new nuclear power plants, and by uprating existing reactors and restarting reactors that have retired for economic reasons. All reactor technologies and sizes will be needed including large, gigawatt-scale reactors, small modular reactors (SMRs), and microreactors.

The build-out of new nuclear power generation capacity in the U.S. would require an increase in capacity for its supporting fuel and component supply chains, as described in the White House domestic nuclear energy strategy, DOE's Pathway to Commercial Liftoff initiative,[42] and DOE's

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[38] U.S. Department of Energy, "Offshore Wind Deployment - Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, August 22, 2024. https://liftoff.energy.gov/offshore-wind-liftoff/.

[39] *Ibid.*

[40] Small and medium-sized manufacturers producing or recycling OSW components—including but not limited to wind turbines, towers, floating offshore platforms, and related equipment—are eligible for up to $100 million to be used to build a new facility or retrofit an existing manufacturing or industrial facility to produce or recycle advanced energy products in communities where coal mines or coal power plants have closed.

[41] White House, "Safely and Responsibly Expanding U.S. Nuclear Energy: Deployment Targets and a Framework for Action." https://www.whitehouse.gov/wp-content/uploads/2024/11/US-Nuclear-Energy-Deployment-Framework.pdf

[42] U.S. Department of Energy, "Pathways to Commercial Liftoff: Advanced Nuclear." https://liftoff.energy.gov/wp-content/uploads/2024/10/LIFTOFF_DOE_AdvNuclear-vX7.pdf

Nuclear Energy Supply Chain Deep Dive Assessment.[43] The U.S. lacks at-scale enrichment capacity for high-assay low-enriched uranium (HALEU), a key input for some nuclear reactor types, and which is largely concentrated in Russia. New DOE programs are investing in domestic enrichment capacity. Investments made possible by the HALEU Availability Program (Section 2001 of the Energy Act of 2020) and the Nuclear Fuel Security Initiative (Section 3131 of the FY2024 National Defense Authorization Act), funded by the IRA ($700 million for the HALEU Availability Program) and the FY2024 Consolidated Appropriations Act ($2.72 billion for the Nuclear Fuel Security Act of 2023), are scaling domestic HALEU and low-enriched uranium capacity. Current production capacity for specialized components—large castings and forgings for advanced reactor components, alloys, specialized equipment to produce reactor components—is also limited and under-developed relative to the forecasted demand. Future nuclear energy deployments must continue to adhere to the highest safety, security, nonproliferation, and labor and environmental protection standards. Efforts must also account for meaningful stakeholder engagement with the public (e.g., communities, intergovernmental, Tribal) to build and sustain the long-term public support of additional domestic nuclear energy.

Geothermal. Geothermal power technology has shown compelling advances—identification of substantial resources, transferability of technology from the oil and gas sector, and decreasing costs of deployment—that can enable it to become a key contributor to decarbonized, firm power generation for the U.S. energy system. Because geothermal leverages technologies developed by the oil and gas sector, particularly horizontal drilling from the U.S. shale boom, the U.S. is well-positioned to be a global leader. Next-generation geothermal technologies—including enhanced geothermal systems and closed-loop geothermal systems—vastly expand the total resource available for geothermal power generation beyond naturally occurring thermal sources and create a unique value proposition as a clean firm technology.[44] In a world where the U.S. grid will need 700–900 GW of additional clean firm capacity by 2050, next-gen geothermal could provide 90 GW by 2050.[45]

Geothermal has an advanced component supply chain, which leverages existing fossil energy networks. However, projects currently face challenges from high up-front costs and early-stage project risks. Technology-neutral tax credits such as the Clean Energy Production Tax Credit (PTC) and the Clean Energy Investment Tax Credit (ITC) can improve the economics of geothermal projects.

2. Clean Fuels

Hydrogen. By some estimates, low-carbon hydrogen can play a role in decarbonizing up to 25 percent of global energy-related CO2 emissions, particularly in industrial and chemicals use cases, as well as in heavy-duty transportation. Today, most of the hydrogen production (~99 percent) is through natural gas reformation (e.g., steam methane reforming or autothermal reforming), either with carbon capture and storage (<5 percent; known as "blue hydrogen") or without (~95 percent

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[43] U.S. Department of Energy, "Nuclear Energy Supply Chain Deep Dive Assessment." https://www.energy.gov/sites/default/files/2022-02/Nuclear%20Energy%20Supply%20Chain%20Report%20-%20Final.pdf.

[44] U.S. Department of Energy, "Next-Generation Geothermal Power - Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, April 17, 2024. https://liftoff.energy.gov/next-generation-geothermal-power/.

[45] *Ibid.*

of total; known as "grey hydrogen")[46]. The U.S. clean hydrogen market is poised for rapid growth, accelerated by historic commitments to America's clean energy economy. Combined, incentives in the IRA and BIL can help make clean hydrogen cost-competitive with incumbent technologies in the next 3–5 years for numerous applications.[47] Clean hydrogen production for domestic demand has the potential to scale from <1 million metric tons per year (MMTpa) to ~10 MMTpa in 2030. Most near-term demand will come from transitioning existing end-uses away from the current ~10 MMTpa of carbon-intensive hydrogen production capacity. If water electrolysis dominates as the production method, up to 200 GW of new renewable power would be needed by 2030 to support clean hydrogen production. The opportunity for clean hydrogen in the U.S., aligned with the DOE National Clean Hydrogen Strategy and Roadmap, is 50 MMTpa by 2050.[48]

As the clean hydrogen economy scales up, domestic electrolyzer manufacturing and supply chains must grow from <1 GW to up to 20–25 GW/year by 2030. So far, $750 million in funding has been awarded across 52 projects to support clean hydrogen electrolysis, manufacturing, and recycling activities**.** Platinum group metals have broad applications across clean energy supply chains but are critical to electrolyzer membranes. Proton exchange membrane (PEM) electrolyzers are currently dependent on foreign supply chains (e.g., iridium—one of the rarest metals in the world—from South Africa; graphite from China for bipolar plates). The Hydrogen and Fuel Cell Technologies Office will administer $1 billion in funding through the Clean Hydrogen Electrolysis Program. The program will establish support for R&D, demonstration, commercialization, and deployment to improve cost and operational efficiency and increase durability of clean hydrogen production through electrolysis. Building CO2 transport and storage infrastructure for blue hydrogen produced with carbon capture, utilization, and storage (CCUS) also represents a sizeable task requiring substantial capital investments.

Sustainable Aviation Fuel. Sustainable aviation fuel (SAF)[49] is a family of synthetic- or biofuels that produce kerosene through pathways other than traditional fossil fuel refining. Because these production processes can have substantially lower carbon intensity and because few alternative fuel sources have sufficient power density to support aviation, SAF will be critical to reduce the 9–12 percent of U.S. transportation GHG emissions driven by air travel.

DOE's SAF Grand Challenge is a public–private program to reduce cost and expand domestic production of SAF, targeting production of 3 billion gallons per year by 2030 with a 50-percent-or-greater reduction in life cycle GHGs. By 2050, the program is targeting 35 billion gallons of annual production.[50] Limited availability of sustainable biofeedstocks, logistics and dedicated infrastructure

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[46] U.S. Department of Energy, "U.S. National Clean Hydrogen Strategy And Roadmap." U.S. National Clean Hydrogen Strategy And Roadmap, 2022. https://www.hydrogen.energy.gov/docs/hydrogenprogramlibraries/pdfs/us-national-clean-hydrogen-strategy-roadmap.pdf.
[47] U.S. Department of Energy, "Clean Hydrogen - Pathways to Commercial Liftoff," Pathways to Commercial Liftoff, December 19, 2023, https://liftoff.energy.gov/clean-hydrogen/.
[48] U.S. Department of Energy, "U.S. National Clean Hydrogen Strategy And Roadmap." U.S. National Clean Hydrogen Strategy And Roadmap, 2022. https://www.hydrogen.energy.gov/docs/hydrogenprogramlibraries/pdfs/us-national-clean-hydrogen-strategy-roadmap.pdf.
[49] U.S. Department of Energy, "Sustainable Aviation Fuel - Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, November 2024. https://liftoff.energy.gov/sustainable-aviation-fuel/.
[50] U.S. Department of Energy, Prepared by the U.S. Department of Transportation, the U.S. Department of Agriculture, U.S. Department of Energy, U.S. Environmental Protection Agency, et al. "SAF Grand Challenge Roadmap." Report. SAF Grand Challenge Roadmap, n.d. https://www.energy.gov/sites/default/files/2022-09/beto-saf-gc-roadmap-report-sept-2022.pdf.

for collection, and high costs of hydrogen required for power-to-liquid fuel production create challenges to commercial viability today. Nevertheless, a relatively strong demand from airlines and corporate travelers has led to relatively strong demand for SAF-certificates, which supports the production of the more sustainable fuel.

3. Energy Storage

Advanced Batteries and Other Energy Storage Applications. Today, the transportation and power sectors together represent more than half of domestic emissions, and batteries are playing a key role in structural changes impacting both sectors. As a result, U.S. battery demand is expected to grow seven-fold from 2023 to 2030 for EV batteries and energy storage systems.[51]

For the electricity grid, batteries are increasingly critical for system and price stability as intermittent, renewable generation is added to the grid and distributed resources are more common. Lithium-ion batteries are likely to play a large role here for relatively short-term energy shifting. However, long-duration energy storage (LDES)[52] will also be critical to effectively firm intermittent power generation over longer periods of time. A range of technologies are being considered including electrochemical solutions like sodium-ion or flow batteries, mechanical solutions like pumped hydropower or compressed air energy storage, thermal solutions such as heat batteries, and even long-term hydrogen storage in salt caverns. For example, DOE awarded ~$150 million to construct a massive iron-air battery intended to help a strained pocket of the New England grid. DOE and DoD partnered together for the Long-Duration Energy Storage Joint Program to deploy LDES demonstrations at military installations to improve resilience. For transportation, the transition from internal combustion engines to battery electric vehicle powertrains will make battery production and innovation key sources of competitiveness for American auto manufacturers.

The anticipated exponential growth in battery production will require a significant increase in raw and processed battery-grade metals. While domestic processing and refining capacity is coming online through federal investments, demand is forecast to outpace the current pipeline of future supply. Even with enough material, U.S. production faces challenges to produce competitively relative to global price benchmarks. This is driven in large part by low-cost Chinese production, which has substantial levels of policy support, including low-cost financing and access to cheap land and utilities, arising from decades of state-driven investment into battery manufacturing and upstream processing.

4. Electricity Grid System

Transmission and distribution network. Electricity is vital to modern life. The U.S. electric grid[53] is a remarkable feat of infrastructure—a network of wires carrying electricity from power plants

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[51] Gohlke, David, et al., Argonne National Laboratory. Energy Systems and Infrastructure Analysis Division, Nuclear Technologies and National Security Directorate, and Transportation and Power Systems Division. "Quantification of Commercially Planned Battery Component Supply in North America Through 2035," 2024. https://publications.anl.gov/anlpubs/2024/03/187735.pdf.
[52] U.S. Department of Energy, "Long Duration Energy Storage – Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, March 2023, https://liftoff.energy.gov/long-duration-energy-storage/.
[53] U.S. Department of Energy, "Innovative Grid Deployment – Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, April 2024, https://liftoff.energy.gov/innovative-grid-deployment/.

across the country into our homes. Assembled over a century by independent utilities, the grid is a vast, yet coordinated, machine. The National Renewable Energy Laboratory (NREL) estimates that transmission capacity would need to more than double in just over a decade to reach the Biden–Harris Administration's goal of 100 percent clean electricity generation by 2035.[54] Unfortunately, the transmission and distribution network that makes up the electric grid is becoming a bottleneck to greater economic development, decarbonization, and equity priorities. Customers are demanding more grid capacity as regional electricity demand grows substantially for the first time in decades to serve a rapid rise in data center buildout, manufacturing needs, and broader end-use electrification.[55] At the same time, heightened threats to the electric grid, often coming in the form of more extreme weather, and load growth driven by electrification increase the importance of making new grid infrastructure both resilient and reliable. Significant capital will be needed for grid modernization and expansion to meet net-zero goals. Regulatory barriers including permitting for approving new transmission lines remain major barriers to deployment.

Grid components. Transformers and grid equipment (e.g., switchgear, transmission circuit breakers) are critical components of a stable and resilient electric grid—the linchpin of U.S. infrastructure and economic vitality. During the COVID-19 pandemic, the grid component manufacturing industry was among those that experienced severe supply chain disruptions, with the electricity sector still reeling from the effects of the disruptions. Rising demand for grid components—driven by increasing electrification across the U.S. and global economies, the build-out of renewable electricity generation, and growth in large-load customers such as data centers—have further stressed supply chains, drawing out lead times and increasing prices. Across transmission and distribution (T&D) equipment, the lead time for components averaged 38 weeks in 2023, nearly double from the year prior, with costs escalating nearly 30 percent year-over-year.[56] Bottlenecks in the supply chains from upstream suppliers to manufacturers among key grid components risks system stability, deployment of clean energy generating assets, and the scale-up of new industrial production and technology facilities.[57] The grid components industrial base and supply chain is highly concentrated among a limited number of manufacturers operating in North America or in key trading partner countries. Vulnerabilities in the transformer and grid components supply chain are primarily driven by limited supply and increasing demand of key engineered materials including grain-oriented electrical steel (GOES), copper, and aluminum. Domestic capacity for distribution transformers is improving due to expansions, making headway on cutting down on lead times.

5. Industrials and Energy Infrastructure

Industrial Decarbonization. The U.S. industrial sector makes products and materials that Americans rely on and that will become increasingly important for the energy transition. Example

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[54] National Renewable Energy Laboratory. "100% Clean Electricity by 2035 Study," n.d. https://www.nrel.gov/analysis/100-percent-clean-electricity-by-2035-study.html.
[55] Wilson, John D., Zach Zimmerman, Rob Gramlich, and Grid Strategies. "Strategic Industries Surging: Driving US Power Demand," 2024. https://gridstrategiesllc.com/wp-content/uploads/National-Load-Growth-Report-2024.pdf.
[56] U.S. Department of Energy, Office of Electricity and Office of Manufacturing and Energy Supply Chains, internal analysis, December 2024.
[57] National Infrastructure Advisory Council. "Addressing the Critical Shortage of Power Transformers to Ensure Reliability of the U.S. Grid.", June 2024. https://www.cisa.gov/sites/default/files/2024-09/NIAC_Addressing%20the%20Critical%20Shortage%20of%20Power%20Transformers%20to%20Ensure%20Reliability%20of%20the%20U.S.%20Grid_Report_06112024_508c_pdf_0.pdf.

products include near-zero emissions steel and aluminum for automobiles and renewable energy generation, cement and concrete for buildings and infrastructure, pulp and paper for packaged goods, glass for windows and containers, and chemicals for fertilizers, pharmaceuticals, and certain plastics. Growing levels of these goods will be needed to satisfy growing demand and to build out infrastructure needed for the energy transition. At the same time, a decarbonized economy will require addressing the production emissions associated with industrial processes, which account for 30 percent of total U.S. emissions when considering both direct energy and electricity use.[58] Across key industrial sectors studied in the DOE's "Industrial Decarbonization" Pathways to Commercial Liftoff Report, ~27 percent of chemicals, ~14 percent of refining, and ~32 percent of cement emissions could be abated with decarbonization levers that have net-positive economics, representing billions of dollars of potential incremental value in the industrials sector.[59] Still, this means that substantial portions of emissions remain non-economical to address and will require further cost reductions through innovation or incentives to fully decarbonize this sector.

Relative to the power sector, industrial decarbonization faces relatively low supply chain risks today. The first wave of industrial decarbonization technologies like efficiency systems required limited process and supply chains. Many more technologies are in the demonstration phase which could create supply chain risks as industrial decarbonization accelerates. Potential supply chain bottlenecks include specialized capital equipment to replace fossil-based energy sources and underlying critical minerals (e.g., high-purity iron ore, material substitutes such as glass pozzolans for supplementary cementitious materials) that are used in this equipment. Electrolyzers, equipment used to produce green hydrogen necessary to decarbonize key processes in iron and chemicals production, are one such example of highly specialized equipment that may face shortages for key input materials including iridium, platinum group metals, and graphite.

Carbon management. Both carbon capture and carbon removal have the potential to eliminate hundreds of millions of tons of CO2 per year. Modeling studies suggest that in order to reach U.S. energy transition goals, 400 to 1,800 MT of carbon dioxide may need to be captured and stored annually by 2050, through both point-source CCUS and carbon dioxide removal (CDR).[60] Today, the U.S. has over 20 MTPA of carbon capture capacity, 1–5 percent of what could be needed by 2050. This scale-up represents a massive investment opportunity of up to ~$100 billion by 2030 and $600 billion by 2050.[61] An increase in the value of the 45Q tax credit—a federal tax credit provided for stored or utilized CO2—has provided a greater incentive to developers and investors for some types of carbon capture projects, though this remains variable by sector. Additionally, the U.S. has excellent geology for storing CO2, world-class engineering and professional talent, and relatively abundant low-cost zero-carbon energy resources that can power CDR projects to maximize net carbon removed. While carbon capture and removal should not supplant the deployment of clean energy or emissions-mitigating improvements across supply chains, these technologies can be part of the solution in achieving climate targets, especially for hard-to-abate sectors.

[58] U.S. Environmental Protection Agency. "Sources of Greenhouse Gas Emissions | US EPA," October 22, 2024. https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions.
[59] U.S. Department of Energy, "Industrial Decarbonization Overview - Pathways to Commercial Liftoff," Pathways to Commercial Liftoff, May 22, 2024, https://liftoff.energy.gov/industrial-decarbonization/overview/.
[60] U.S. Department of Energy, "Carbon Management - Pathways to Commercial Liftoff," Pathways to Commercial Liftoff, February 6, 2024, https://liftoff.energy.gov/carbon-management/.
[61] *Ibid.*

The carbon management sector has lower supply chain risk associated with the common point-source amines and raw material inputs needed for scale-up. However, the U.S. has a limited number of suppliers able to complete the engineering and design of carbon management systems. Furthermore, high investment costs and capital investment are required to reach commercial viability. Demand for captured carbon is not yet sufficient to spur the scale of investments in CCUS and CDR that will be needed to reduce the cost of carbon management, reduce pollution, and meet climate targets.

PROGRESS TO DATE

One-year Review Priorities

In February 2022, DOE released "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition"—the first comprehensive plan to build the U.S. ESIB required to support a rapidly evolving energy system. The report was part of a whole of government approach to chart a course for revitalizing the U.S. economy and domestic manufacturing by securing the country's most critical supply chains.

The review found that without new domestic raw materials production and manufacturing capacity, the U.S. will continue to rely on clean energy imports, exposing the nation to supply chain vulnerabilities while simultaneously losing out on the enormous job opportunities associated with the energy transition. In short, there was ample whitespace and untapped potential in the U.S. to to support greater domestic production of energy technologies poised for exponential growth including solar, wind, nuclear, grid and battery storage, batteries, and hydrogen.

To position the U.S. for action, the report identified 60 actions across seven key areas where the U.S. Government could address risks and vulnerabilities in the energy industrial base that would maximize opportunities for economic growth and improve American quality of life:

- Increase domestic raw material availability
- Expand domestic manufacturing capabilities
- Invest and support the formation of diverse and reliable foreign supply chains to meet global climate ambitions
- Increase the adoption and deployment of clean energy
- Improve end-of-life waste management
- Attract and support a skilled U.S. workforce for the clean energy transition
- Augment supply chain knowledge and decision-making

Since the start of the Biden–Harris Administration, the U.S. Government has made significant progress against each of the seven key areas. Examples include over $77 billion[62] in historic investments in our ESIB manufacturing base along with creating millions of good paying, high-quality jobs for American workers; investments, tax credits, and policy changes that have strengthened our energy supply chains by making them more resilient, robust, diverse, and competitive and increasing access to clean and affordable energy for all Americans.

Progress from 2021 to Present

U.S. Energy Sector Investment: Government Enabled, Private Sector Led

The Bipartisan Infrastructure Law and Inflation Reduction Act have catalyzed historic growth of U.S. clean energy technologies, manufacturing, and the ESIB. Through a suite of public sector tools on both the supply and demand side—incentives for manufacturing across the clean energy supply

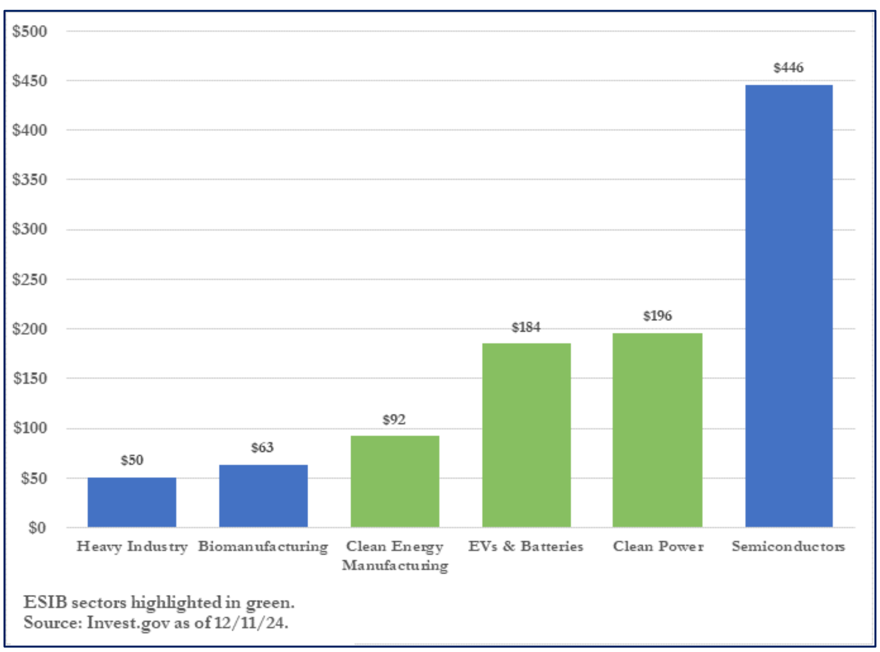
[62] U.S. Department of Energy. Office of Under Secretary for Infrastructure, Office of Manufacturing and Energy Supply Chains. Internal DOE award and project data. Accessed December, 6, 2024.

chain, investments in demonstration projects, loans and loan guarantees for a variety of clean energy technologies, production and investment tax credits for clean energy generation, and public procurement of clean technologies and materials such as through the Sustainability Executive Order, and the Buy Clean Initiative—the Biden–Harris Administration has initiated a government-enabled, private sector–led energy transition.

Public investments and tax incentives have been the catalyst for a complete reimagining of the energy sector: from the most significant expansion of the electrical grid in a century to development of a new clean hydrogen economy; the scaling up of a domestic battery supply chain to industrial decarbonization across heavy industry; carbon management at-scale and across industries; and the development of a U.S. fusion energy strategy with goal of commercialization by 2030. Charged with leading the strategy and implementation of the U.S. energy transition, DOE was allocated ~$90 billion in grant and rebate programs with more than $300 billion in loan and loan guarantee authority to invest in a range of clean energy projects and supply chains. Given the increase in funding and a mandate that stretches from basic research in a lab to funding giga-scale factories, DOE reorganized itself to define and implement this strategy—standing up the Office of the Undersecretary for Infrastructure—to steward public investment in the energy sector industrial base.

Complemented by long-term certainty of production and investment tax credits from the Department of the Treasury, the Biden–Harris Administration has provided the private sector with the necessary tools and foundations for investment. Indeed, the private-sector response has been historic. Since January 2021, private companies have announced more than $1 trillion in new investment, including over $471 billion in clean energy manufacturing, EVs and batteries, and power generation (Figure 3).

Figure 3. Announced U.S. industrial and energy sector industrial base investments since 2021, billions of dollars[63]



[63] The White House, "Investing in America | the White House," December 11, 2024, https://www.whitehouse.gov/invest/?utm_source=invest.gov. Data accessed on December 11, 2024.

Incentives and policy changes have spurred a resurgence of several key manufacturing activities critical to energy transition, such as critical material processing and refining, battery manufacturing, uranium enrichment, and other clean energy technology manufacturing. Evidence of onshoring and friendshoring is apparent in clean energy manufacturing investments and build-out in the United States over the past three years. The federal government has a suite of programs and vehicles for investment in the ESIB. A select subset of some major programs are highlighted below.

- **Investment Tax Credits:** The 48C Advanced Energy Property Credit provides a 30-percent tax credit to boost domestic manufacturing in clean energy supply chains and decarbonize industrial assets. The Treasury Department and IRS have announced nearly $4 billion in selections and are slated to announce another $6 billion by year-end.
- **Production Tax Credits:** Multiple tax credits have been developed to support clean energy manufacturing. The 45X production tax credit (PTC) provides substantial support for domestic clean energy manufacturing for critical materials, battery components, wind, and solar components. The 45X PTC makes U.S. production of battery cells at a lower cost of production than PRC.
- **Consumer Tax Credits:** Multiple tax credits are aimed at incentivizing the uptake of energy technologies to increase consumer adoption including the 30D Clean Vehicle Credit, the 25D Residential Clean Energy Credit, Energy Efficient Home Improvement Credit, among others. Each tax credit increases demand for manufactured energy products including batteries for EV and energy storage, heat pumps, and solar panels for residential or commercial use. Specifically, the 30D tax credit provides a credit for the purchase of electric vehicles subject to certain requirements that encourage resilient supply chains.
- **Capital Grants:** Multiple programs administered by DOE have provided billions in capital to support domestic manufacturing and industrial decarbonization. Notable examples include the Battery Materials Processing and Manufacturing Grants Program, which has committed $5 billion to support approximately 40 projects, the Advanced Energy Manufacturing and Recycling Grants Program, which has provided nearly $700 million in grants to small- and medium-sized manufacturers (SMMs) to build or retrofit manufacturing and industrial facilities in communities where coal mines or coal power plants have closed, and the Industrial Demonstration Program, which deployed $6 billion to large-scale demonstrations at industrial facilities.
- **Debt Financing:** DOE's Loan Program Office has several funding opportunities under the Title 17 Clean Energy Financing Program and the Advanced Technology Vehicles Manufacturing Loan Program (ATVM). $18.7 billion in loans have been committed through Title 17 and $20.6 billion have been committed through ATVM.[64] These programs are intended to deploy or manufacture new energy technologies (Section 1703), repurpose existing energy infrastructure to generate power or reduce emissions (Section 1706), or support the manufacture of advanced technology vehicles and their components.

One area in which these tools are being used to substantial effect is in securing upstream and critical materials supply in the United States and among key trading partners. Through the partnership between DOE and the Department of the Treasury, the U.S. Government has invested nearly $4 billion in projects from critical materials to final manufacturing through the 48C Advanced Energy Property Credit. Supply chain investments included copper and advanced conductor materials for grid components, polysilicon and recycled glass for solar panels, fuel for advanced nuclear reactors,

[64] Figures as of December 10, 2024 and includes conditional commitments.

electrolyzers for hydrogen and sustainable aviation fuel, permanent magnets and steel cable manufacturing for offshore wind, among other technology areas.[65]

Given the strategic importance of the automotive and electric power generation sectors to the U.S. economy, the battery supply chain has received considerable support. DOE, led by the Office of Manufacturing and Energy Supply Chains (MESC) and the Loan Programs Office (LPO), has funded and provided conditional commitments for more than $30 billion in battery supply chain projects for processing and refining from lithium, nickel, and graphite (natural and synthetic) to cathode active material and cell production. Lithium supply is a strategic advantage and an imperative for the country. The U.S. has substantial reserves of untapped lithium resources from hard rock, clays, and brines. For example, analysis funded by DOE through the Lawrence Berkeley National Laboratory found that with expected technology advances, total resources in the region could contain more than 3,400 kilotons (kt) of lithium, enough to support over 375 million batteries for electric vehicles (EVs)—more than the total number of vehicles currently on U.S. roads.[66] In addition, U.S. Geological Survey–led study estimated between 5 and 19 million tons of lithium may be present in brines in southwestern Arkansas—enough to meet projected 2030 world demand for lithium nine times over.[67] The DOE is taking an all-of-the-above investment approach to lithium—funding multiple extraction and processing projects for each geologic type of reserves—that are cost competitive and secure resources.

Domestic investments have been complemented by international coordination and strategy to build out raw material extraction where the materials are located and processing capacity away from its current geographic concentration. For example, U.S. leadership and partnership with allies through the Mineral Security Partnership (MSP)[68] have identified more than 30 projects for critical minerals and materials[69]—focused on extraction, processing and refining, and recycling—that serve as key natural resources for advanced batteries, grid components, electrolyzers, offshore wind, among other technologies.

MSP partners strive to elevate environmental, social, governance (ESG) practices and principles—including responsible stewardship of the natural environment; robust community engagement; fair, safe, and just economic benefits and internationally recognized labor rights for workers, among other necessary actions—in the mining, processing, and recycling sectors.[70] MSP commits to support and invest only in projects that meet high, internationally recognized principles, promote local value

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[65] U.S. Department of Energy. Energy.gov. "Applicant Self-Disclosed 48C Projects," n.d. https://www.energy.gov/mesc/applicant-self-disclosed-48c-projects.

[66] Dobson, P.; Araya, N.; Brounce, M.; Busse, M.; Camarillo, M.; English, L., et al. (2023). Characterizing the Geothermal Lithium Resource at the Salton Sea. UC Davis. Report #: LBNL-2001557. http://dx.doi.org/10.2172/2222403 Retrieved from https://escholarship.org/uc/item/4x8868mf.

[67] Knierim, Katherine J., et al. "Evaluation of the Lithium Resource in the Smackover Formation Brines of Southern Arkansas Using Machine Learning." *Science Advances*, vol. 10, no. 39, 2024, eadp8149. https://doi.org/10.1126/sciadv.adp8149.

[68] Mineral Security Partnership countries include Australia, Canada, Estonia, Finland, France, Germany, India, Italy, Japan, Norway, the Republic of Korea, Sweden, the United Kingdom, the United States, and the European Union (represented by the European Commission).

[69] This Review focuses on midstream processing and refining of critical minerals specifically for energy industrial base applications. Critical minerals are addressed in greater detail in a separate Review.

[70] United States Department of State. "Minerals Security Partnership - United States Department of State," September 30, 2024. https://www.state.gov/minerals-security-partnership/#:~:text=The%20MSP%20is%20a%20collaboration,powering%20the%20clean%20energy%20transition.

addition, and uplift communities, in recognition that all countries can benefit from the global clean energy transition. These principles distinguish the MSP from PRC efforts and give U.S. companies a competitive advantage in bidding for projects. The core investment principles enable resource-rich countries to diversify and stabilize global supply chains while elevating the standard for transparent, ethical business environments. National governments participating in the MSP, private investors representing over $30 trillion in assets under management, and critical mineral industry leaders gathered to launch the MSP Finance Network, advancing a commitment by all MSP partner nations' development finance institutions (DFIs) and export credit agencies (ECAs) to collaborate on investments in global mineral supplies.

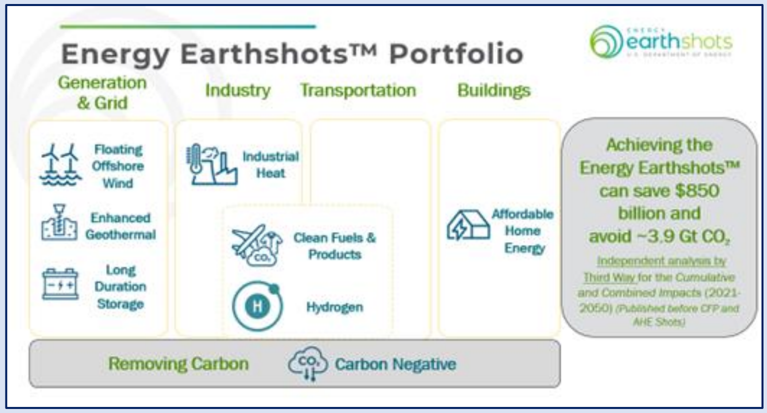
With a private sector–led, government-enabled approach to building strong and resilient ESIB supply chains, greater public and private sector collaboration remains an imperative. DOE recognizes that mobilizing and deploying the trillions of dollars in capital needed for the energy transition requires multiple approaches to scale an industrial base required to reach net-zero by 2050 and continue U.S. energy dominance. These initiatives span multiple focus areas including catalyzing investment to deploy private capital, demand-side initiatives to create a bridge to scale, shape future market activity through leading market analysis on key technologies, and workforce development projects for community-level impact.

Key DOE programs and initiatives

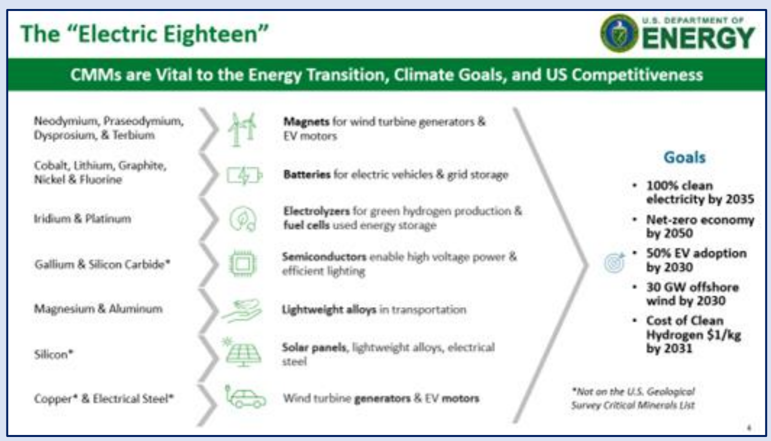
Leading the frontiers of energy innovation. In response to the urgency of the climate crisis, DOE has fast-tracked and expanded research, development, demonstration, and deployment (RDD&D) commercialization for the clean energy transition. From the Energy Earthshots™ Initiative to programs that focus on applied R&D for critical minerals to leading the U.S. strategy to commercialize nuclear fusion, the Office of Science is ensuring that RDD&D and accelerating commercialization of American innovation is a primary driver to not only meet U.S. climate goals and improve competitiveness, but also ensure future supply chains are resilient (Infographic). The electric eighteen are eighteen critical minerals, i.e., any non-fuel mineral, element, substance, or material that the Secretary of Energy determines (i) has high risk for supply chain disruption; and (ii) serves an essential function in one or more energy technologies, including technologies that produce, transmit, store, and conserve energy. The minerals on this list have program support through 48C among other programs.

Infographic: Accelerating Climate Breakthroughs at the Department of Energy

DOE has launched a series of initiatives and cross-cutting programs to bolster RDD&D and expedite the pace of technology commercialization. DOE's Energy Earthshots™ Initiative—which sets technical and cost goals in key next-generation clean energy technologies—is accelerating RDD&D breakthroughs of more abundant, affordable, and reliable clean energy solutions by 2035 to address the climate crisis. Elsewhere within the Office of Science, basic and applied research is being conducted on critical materials supply chains aimed at developing new methods for processing materials, developing synthetic substitutes, and recycling, among other areas.

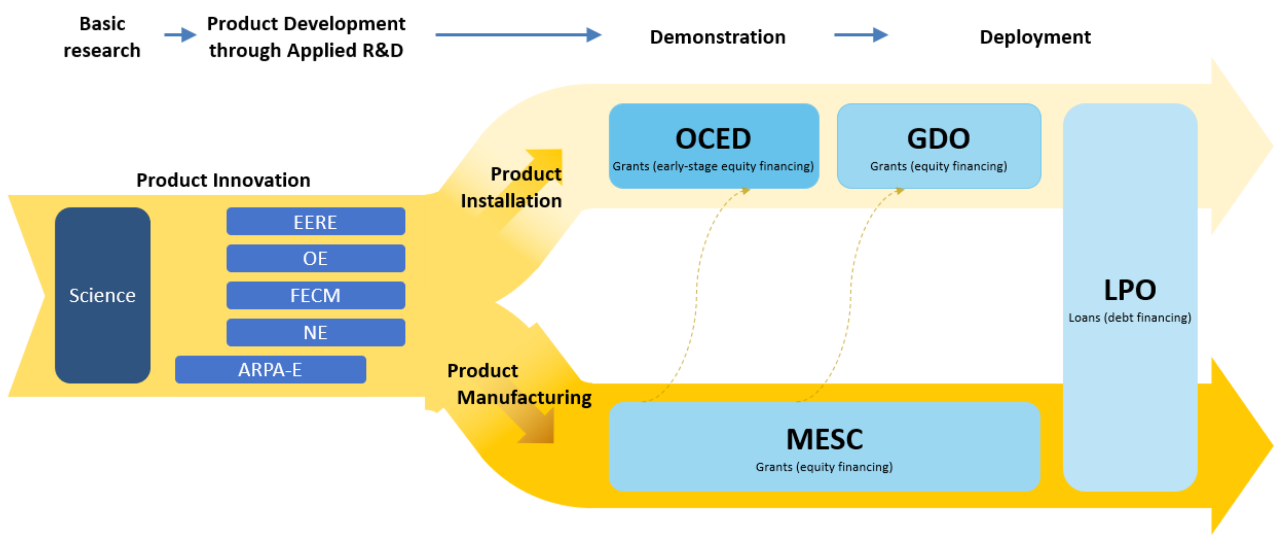


The "Electric Eighteen" critical materials and minerals are the building blocks of the ESIB, and vital to the energy transition to net-zero. DOE has granted funds across the National Lab system to develop the technology to detect and quantify rare-earth elements and critical minerals in unconventional and secondary sources, including five operational small-scale pilots to recover and upgrade to high purity mixed rare earth oxides. In addition, $32 million was awarded to support front-end engineering design to produce critical materials and rare earth elements from conventional coal-based resources, while $140 million was directed to a first-of-a-kind demonstration facility utilizing unconventional sources to extract, separate, and refine critical minerals.



Direct financial and capital support. DOE plays a critical role in funding energy technologies. With close to $90 billion in budget authority and over $300 billion in loan authority from BIL and the IRA, DOE invests in American clean energy innovation. DOE's mandate has expanded from the leading entity funding research and pre-commercialization to funding pilot and at-scale facilities for a range of technologies. Now, DOE is also focused on de-risking and scaling energy technologies and markets, with maximum potential for continued replicability and expansion across more geographies and industries. DOE offices and programs run the full lifecycle of a commercialization to enable American innovators to take an inspiration for a technology and turn it into a viable business. With programs that touch every corner of the economy, DOE has numerous tools to lever up private capital for the energy transition: basic research grants for laboratory exploration, funding to take bench-scale projects to pilot facilities, grants and cooperative agreements that act as non-diluted equity for demonstration projects, and first-of-a-kind (FOAK) investments. In addition to DOE, USDA, EPA, and DOT are providing billions of dollars in support for energy and industrial sector technology deployment.

Infographic: DOE's role in the U.S. energy technology commercialization lifecycle



Demand-side support. DOE has funded and partnered with a consortium of experts to develop demand-side support mechanisms to catalyze the development of key clean energy markets, specifically starting with demand-side support for Clean Hydrogen Hubs (H2Hubs).[71] As demand formation for new energy sources often lags the creation of new reliable supply, developing a hydrogen demand-side initiative is critical to enhancing the early commercial viability of the U.S. hydrogen economy. Demand-side support and other "demand pull" measures bridge the gap between producers, who need medium- to long-term offtake certainty for a significant portion of their projected output to secure financing to build a project, and buyers, who often prefer to buy on a short-term basis for energy inputs that are beginning to be produced at scale, like clean hydrogen.

[71] U.S. Department of Energy. Energy.gov. "DOE Selects Consortium to Bridge Early Demand for Clean Hydrogen, Providing Market Certainty and Unlocking Private Sector Investment," n.d. https://www.energy.gov/oced/articles/doe-selects-consortium-bridge-early-demand-clean-hydrogen-providing-market-certainty.

Catalyzation of private investment. The DOE has developed multiple tools to provide private-sector investors with clear signals about the investment viability of key clean energy technologies. The DOE's established the Pathways to Commercial Liftoff initiative provides public and private sector capital allocators with a perspective on both commercial viability and ultimate total addressable market size across various clean energy technologies.[72] Further, DOE has also taken steps to directly connect private-sector investors with clean energy projects through Office of Manufacturing Energy and Supply Chain's (MESC) Manufacturing Capital Connector (MCC), a financing platform that connects companies applying to DOE-administered clean energy manufacturing programs to a range of potential capital providers seeking high-quality projects.[73]

Supply chain analytics. Across the ESIB, industries and technologies face varying levels of supply chain risk. Multiple departments are undertaking efforts to better understand and gauge resilience within these supply chains. The Department of Commerce's recently launched SCALE tool assesses a broad range of supply chains to identify across more than 40 types of supply chain risk. DOE's MESC has also recently announced its Supply Chain Readiness Level framework intended to deep-dive within energy supply chains to identify key bottlenecks, inform project selection, and ultimately guide the broader policy process. These frameworks represent efforts to drive unprecedented view into these supply chains at granular levels, including risks within specific production steps, competitiveness of domestic manufacturing, and workforce readiness for U.S. projects.

Department of Energy's Supply Chain Readiness Levels

The Supply Chain Readiness Level (SCRL) is a data-driven, technology-agnostic approach to evaluate the resilience of clean energy technologies and their supply chains segments. SCRL assesses readiness at both the overall technology level and individual supply chain segment both today and in 2030.

	RISK FACTORS	ASSESSMENT QUESTION
Supply Reliability Factors	Deployment Viability	Projected global demand relative to all known sources of supply
	Sourcing Risk Management	Projected US & partner demand relative to supply from reliable sources
	Supplier Maturity	Availability of upstream materials/components from established, reliable sources
Commercial Competitiveness Factors	Customer Maturity	Strength of demand at sufficient price levels to make US production viable
	Workforce Readiness	Availability of workers with sufficient skills
	Cost Competitiveness	US competitiveness relative to other global producers

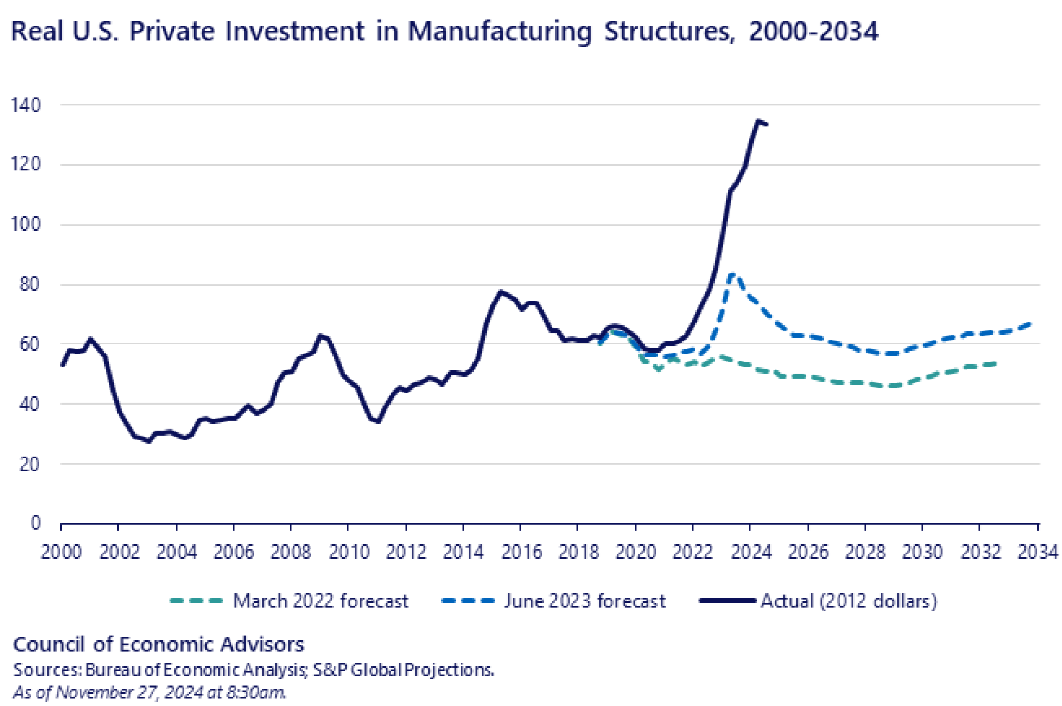
[72] U.S. Department of Energy. "About the Pathways Reports - Pathways to Commercial Liftoff." Pathways to Commercial Liftoff, November 13, 2024. https://liftoff.energy.gov/about-the-liftoff-reports/.
[73] U.S. Department of Energy. Office of Manufacturing and Energy Supply Chains. Energy.gov. "Manufacturing Capital Connector," n.d. https://www.energy.gov/mesc/manufacturing-capital-connector.

Impact of U.S. Energy Sector Industrial Base Investments

The investments made through BIL and IRA are dramatically accelerating demand for and deployment of clean energy technologies. By 2030, the share of electricity from clean sources is projected to reach 80 percent, significantly surpassing pre-IRA estimates. This domestic energy focus strengthens energy security, creates jobs, and reduces reliance on traditional fuel sources. DOE analysis also indicates that U.S. greenhouse gas emissions are projected to decline to 35–41 percent below 2005 levels by 2030, buoyed by the impacts of the IRA, compared to a 27-percent decline in a scenario without BIL and IRA.[74]

While achievement of U.S. climate commitments is laudable, it is equally important to look at the economic impact of not only deploying clean energy but also growing America's role in clean energy manufacturing. Since President Biden took office, inflation-adjusted spending on the construction of manufacturing facilities has more than doubled. This increase has exceeded forecasters' expectations, suggesting that the Investing in America agenda is catalyzing more private-sector funding than initially expected (Figure 6).[75]

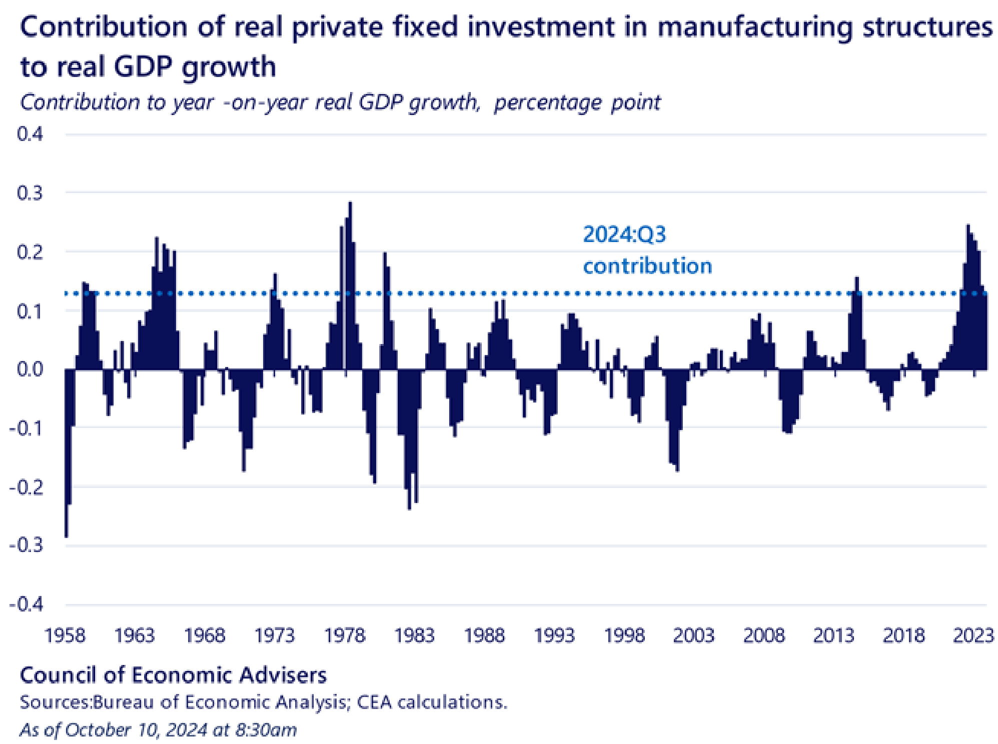
Figure 6. Real U.S. private investment in manufacturing structures, 2000–2034



[74] U.S. Department of Energy. Office of Policy. "Investing in American Energy: Impacts of the Inflation Reduction Act and Bipartisan Infrastructure Law on the U.S. Energy Economy and Emissions Reductions." *Investing in American Energy: Impacts of the Inflation Reduction Act and Bipartisan Infrastructure Law on the U.S. Energy Economy and Emissions Reductions*, n.d. https://www.energy.gov/sites/default/files/2023-08/DOE%20OP%20Economy%20Wide%20Report_0.pdf.
[75] White House, "Building a Thriving Clean Energy Economy in 2023 and Beyond: A Six-Month Update," The White House, July 1, 2024, https://www.whitehouse.gov/briefing-room/blog/2024/07/01/building-a-thriving-clean-energy-economy-in-2023-and-beyond-a-six-month-update/.

The rapid investment in domestic manufacturing of clean energy technologies, as well as in other critical supply chains, has spurred a manufacturing boom in the United States with tangible economic benefits. Manufacturing construction, spurred by these investments, has made substantial contributions to GDP growth in recent quarters, setting new records since data collection began in 1959 (Figure 7). In addition to propelling GDP growth, manufacturing projects create high-quality, enduring jobs, many of which are accessible without college degrees.

Figure 7. Contribution of private nonresidential investment in manufacturing construction as a share of real GDP, 1958 to 2024Q1



Investments in the ESIB are creating substantial benefits for communities that have been impacted by the energy transition. Investments have funneled to energy communities—areas historically reliant on fossil fuels for employment, wages, or tax revenue—demonstrating the economic impact of the energy transition in real time. Analysis shows that Energy Communities[76] have received a $2.4-billion-per-month increase in public and private investment, compared to $1 billion for the rest of the U.S. after the passage of the IRA.[77] According to the study, the investment in energy communities has additional benefits including the creation of high-quality jobs, health, and

[76] The IRA defines energy communities as: (1) A "brownfield site" (as defined in certain subparagraphs of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)); (2) A "metropolitan statistical area" or "non-metropolitan statistical area" that has (or had at any time after 2009) 0.17 percent or greater direct employment or 25 percent or greater local tax revenues related to the extraction, processing, transport, or storage of coal, oil, or natural gas; and has an unemployment rate at or above the national average unemployment rate for the previous year; (3) A census tract (or directly adjoining census tract) in which a coal mine has closed after 1999; or in which a coal-fired electric generating unit has been retired after 2009.

[77] U.S. Department of the Treasury. "The Inflation Reduction Act: A Place-Based Analysis, Updates From Q3 and Q4 2023," November 19, 2024. https://home.treasury.gov/news/featured-stories/the-inflation-reduction-act-a-place-based-analysis-updates-from-q3-and-q4-2023.

environmental benefits. Prior to the Inflation Reduction Act, 68 percent of announced investments in clean technologies were in counties with median incomes below the U.S. aggregate median income. After the IRA, 75 percent of announced clean investments have been in counties with median incomes below the U.S. aggregate median.[78]

Further evidence beyond official U.S. Government data bolsters the case that public investment generates a positive return on investment. A recent analysis from the Clean Investment Monitor suggests that each dollar of federal funding—tax credits, grants, and loans—spurred at least $6 in private investment.[79] The combined pooling of public and private capital delivers outsized, long-term benefits including job creation and community development, lower electricity costs, and reduced carbon emissions. Such findings reinforce the notion that clean energy initiatives offer a compelling solution to environmental and energy challenges while simultaneously driving economic prosperity.

[78] Ibid.

[79] Lily Bermel et al., "Clean Investment Monitor: Q4 2023 Update," January 29, 2024, https://assets-global.website-files.com/64e31ae6c5fd44b10ff405a7/65dfcaebd76fc56445fd7375_Clean%20Investment%20Monitor%20-%20Q4%202023%20Update.pdf.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

Global supply chains for energy technologies have been under pressure since 2020 from the COVID-19 pandemic, the war in Ukraine, and other geopolitical conflicts. Now, the demand for energy technologies with their material and components necessary for final assembly and deployment adds an additional strain to already stretched supply networks. External macroeconomic pressures due to fluctuations in supply, volatility of raw material prices, changes in regulatory environments (e.g., export controls), and cost inflation add additional stress. A government-enabled, private sector–led investment has another crucial impact: it creates more secure and resilient supply chains. A resilient supply chain is one that proactively manages risks and recovers quickly from an unexpected event, or shock.

The long-standing U.S. approach to production, which for years, prioritized efficiency and low costs over security, sustainability and resilience, has resulted in increasing supply chain risk. The search for low-cost production has led to geographic concentrations of key supply chains in a few nations, most notably China, creating the risk of monopolistic behavior and increasing vulnerabilities for United States and its trading partners. Over the last decade, China's Belt and Road Initiative has synced foreign investments in raw material extraction to their domestic manufacturing build-up, making it difficult for U.S. companies to compete with China in global markets. Without a robust domestic manufacturing ecosystem, the U.S. will be reliant on value chains dominated by competitor nations, which poses a risk to national security and future economic prosperity.

As a result of decades of previous production and sourcing decisions, external risks to clean energy supply chains and the ESIB can be classified into two major categories: supply network constraints and sourcing concentration. Supply network constraints are largely a factor of commercial interests or macroeconomic conditions—sourcing investment decisions that focused on lowest cost of production, scarce or limited production of key input sources, price volatility that inhibits critical technology production and deployment, and significant ramp ups in demand outpacing supply. During the COVID-19 pandemic, the fragility of supply chains was laid bare: the lead times of 2 to 4 years for transformers and grid components that typically took weeks,[80] and thousands of pickup trucks sitting lifeless on manufacturers' parking lots without the necessary power electronics.[81] While the Biden–Harris Administration has made significant progress improving the strength and resilience of the ESIB, there are a set of remaining challenges to tackle in the coming years to continue technological progress and the momentum of energy supply chains in transition.

Transparency

Supply chain transparency is a challenge in multiple energy technologies, particularly those dominated by large, vertically integrated original equipment manufacturers (OEMs) (e.g., wind and grid components). In some sectors, high PRC market shares present a challenge to data transparency (e.g., battery and solar sectors). Notably, resources have been devoted to creating data transparency

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[80] Postelwait, Jeff. T&D World. "No Easy Answers: Transformer Supply Crisis Deepens", February 23, 2023. https://www.tdworld.com/substations/article/21258955/no-easy-answers-transformer-supply-crisis-deepens.
[81] Hamblen, Matt. Fierce Electronics. "Covid and chip shortage hit GM pickup assembly", July 22, 2021. https://www.fierceelectronics.com/electronics/covid-and-chip-shortage-hit-gm-pickup-assembly.

in key sectors, led by efforts at U.S. National Laboratories and ongoing efforts by DOE. To inform the U.S. Government's understanding of supply chain risks, DOE's MESC has developed the SCRL framework. SCRL is designed to quantify the strength and resilience of each segment of key energy technology supply chains. As a complement to the Department of Commerce's SCALE tool, the SCRL framework is the product of rigorous, scalable, and data-driven analyses, creating a tool that can be applied consistently across energy technologies to gauge the ability of various supply chains to meet our energy needs.

The application of the tool allows the DOE to better understand impacts of external shocks, including whether supply chains can withstand anticompetitive practices, keep pace with rapid demand growth, demonstrate resilience in the face of geopolitical shocks, and prove durable and competitive over the long-term. Because this framework measures supply chain risk at both the overall technology level and for each individual supply chain segment, SCRL provides a critical diagnostic to inform where investment and policy support is required to address emerging bottlenecks and other energy supply chain risks. By providing a consistent measuring stick and a common language to evaluate supply chains, SCRL can enhance the prioritization and effectiveness of both public and private efforts to build more robust energy supply chains, enhancing U.S. energy independence, national security, and economic well-being.

Domestic capacity

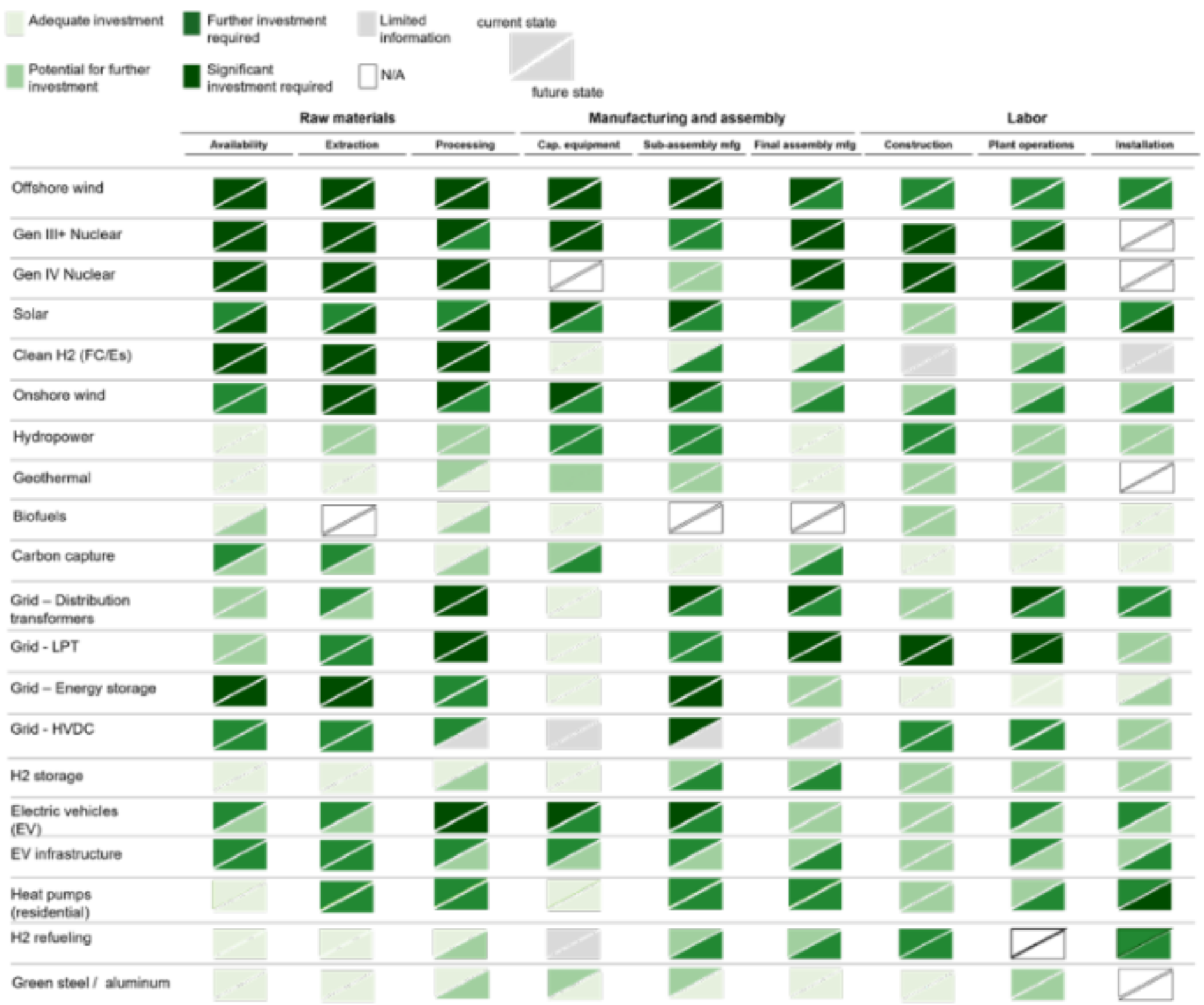
Current and projected demand exceeds current manufacturing capacity for most energy technologies. While this is true for finished goods, shortfalls get more pronounced for upstream production steps. Upstream critical mineral extraction and processing creates a particular bottleneck for U.S. manufacturing across many key ESIB technologies. However, recent investment and policy have created substantial momentum in scaling domestic supply chains, including upstream production. However, it will be critical to ensure projects come to fruition and spur further investment. There are also areas in mature technologies where the United States still lacks manufacturing capabilities or is not competitive compared to other countries. In this case, deploying cutting-edge and innovative technologies could prove to be a viable path to building out supply chains.

As domestic supply chains for new technologies are developed, demand for materials and components often outpaces available supply. For example, large power transformer demand is expected to more than double, from 1,300 to 2,800 units from 2023 to 2030.[82] The limited production of U.S. GOES represents a key bottleneck for meeting required demand.[83] The scale of manufactured components can also add complexity. In the case of offshore wind, the components—blades, towers, and foundations—are large and must be assembled near ports. Building up domestic production takes time with the precise siting of facilities needed to make business cases viable. Supply chain constraints can be challenging when there is a confluence of factors lumped together. However, in most cases, they are market problems—solvable through additional capital or corrective measures taken between suppliers and customers.

[82] Gonzalez, Eva. BloombergNEF. "Research Note: US Risks Power Transformer Supply Gap Becoming a Chasm". November 2023.
[83] U.S. Department of Commerce. U.S. Bureau of Industry and Security. "The Effect of Imports of Transformers and Transformer Components on the National Security", October 15, 2020. https://www.bis.doc.gov/index.php/documents/section-232-investigations/2790-redacted-goes-report-20210723-ab-redacted/file.

In the near term, the U.S. has sizable investment gaps across a variety of energy technologies from upstream materials to final products. Across twenty major technologies, the U.S. has adequate levels of investment for only 3 out of 20 major energy technologies. The gap is further pronounced as supply chains move upstream to critical minerals and materials (Figure 8).

Figure 8. U.S. energy technology and supply chain investment matrix[84]

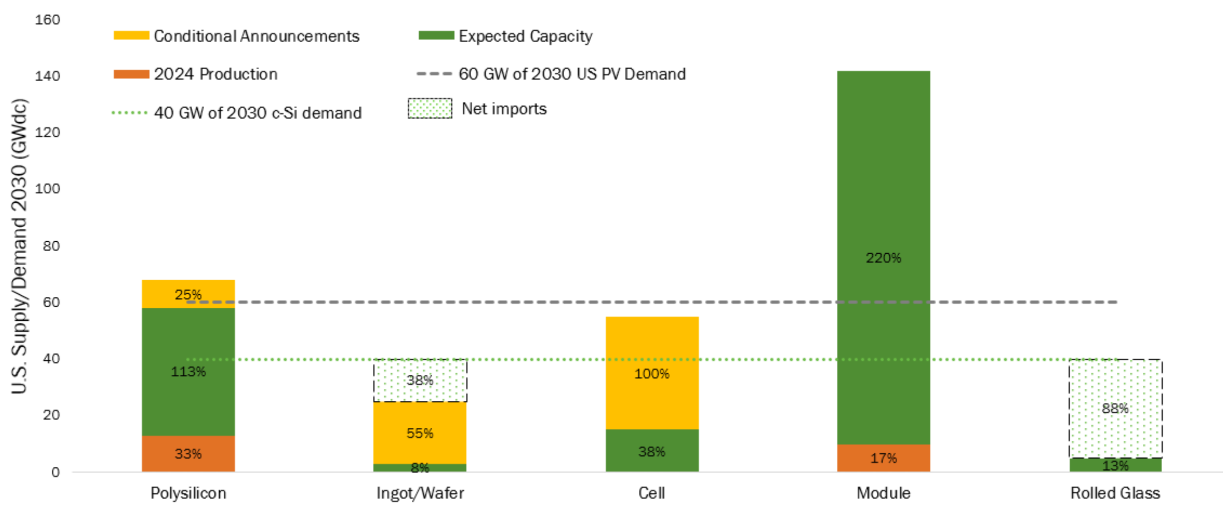


Tax credits for production (e.g., Advanced Manufacturing Production Tax Credit – 45X), investment (e.g., domestic content bonus adders for Clean Electricity Investment Tax Credit – 48E), and consumption (e.g., mineral and component sourcing requirements for Clean Vehicle Credit – 30D) have made a meaningful dent against the PRC's cost advantages in certain areas (e.g., battery cell and pack manufacturing, solar modules). However, sustained, long-term certainty and additional capital is needed to make progress against the cost gap. Support for multiple cost levers—lowering cost of capital, incentives to improve learning rates, additional capital expenditure support, and

[84] Tsisilile Barlock et al., U.S. Department of Energy, Office of Manufacturing and Energy Supply Chains. "Supply Chains Progress Report," *Supply Chains Progress Report*, 2023, https://www.energy.gov/sites/default/files/2023-08/Supply%20Chain%20Progress%20Report%20-%20August%202023.pdf.

additional demand-side support, coupled with targeted tariffs—should be up for consideration. While there has been sizable investment in the overall U.S. ESIB since 2021, the allocation of projects has been uneven across supply chain segments and technologies. Private investments in production across clean energy supply chains have initially focused on downstream production and final assembly (e.g., battery cells and solar modules), leaving gaps in upstream and midstream materials (Figure 9).

Figure 9. U.S. supply and demand by solar component, 2024–2030[85]



The PRC has established considerable structural advantages in building out advantages in energy supply chains across batteries, electrolyzers, solar, wind components, and others. Sustained commitment in the form of additional and lower-cost capital, policy incentives to stimulate investment, advancing commercial relationships with trading partners, and partnership among all levels of government and industry are needed to build at-scale facilities. In the near term, it may not be feasible or economical to onshore all segments of energy supply chains, particularly on the timeframe necessary to meet clean energy and climate goals. In this case, diversifying U.S. import sources by friendshoring to U.S. allies with a comparative advantage to manufacture the needed critical components or nearshoring to countries near the United States is seen as another option to strengthen supply chain resilience by both industry and government. The U.S. will need to further align its foreign policy and international finance tools with both domestic policy and with allies to achieve significant friendshoring.

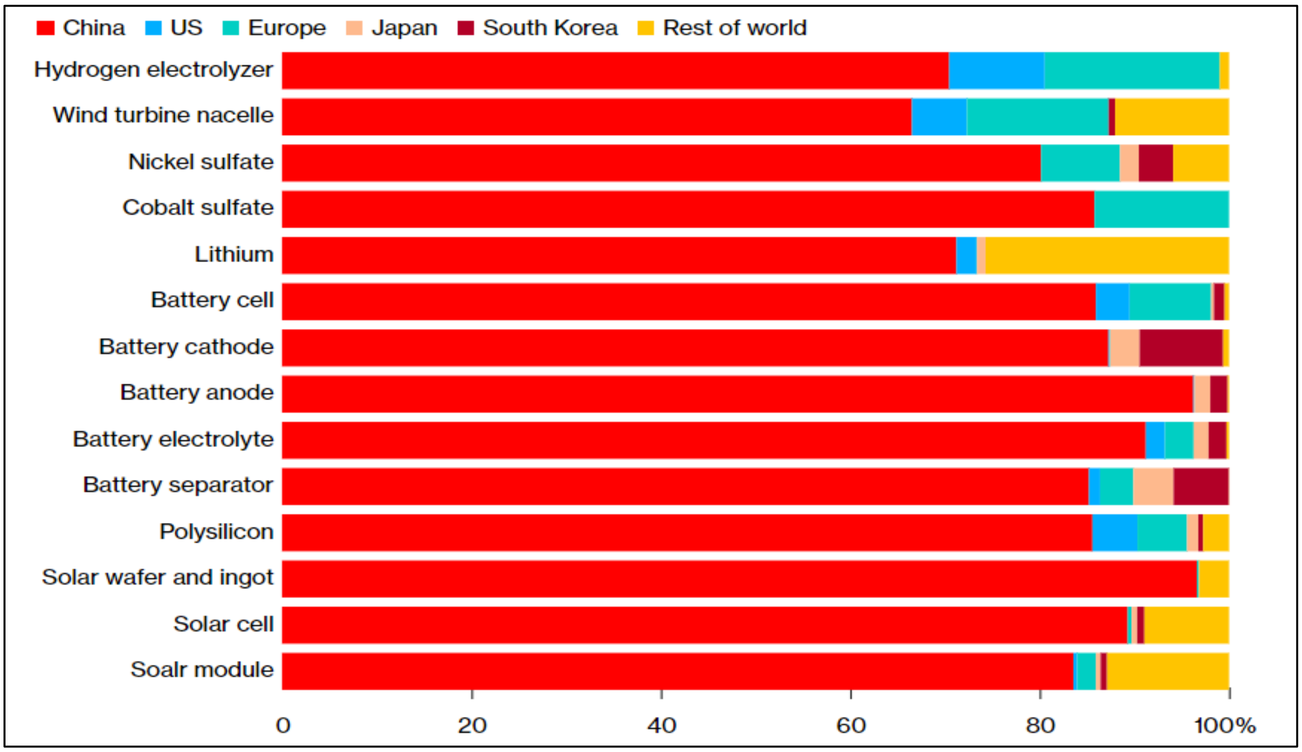
Trade concentration

Trade concentration varies by energy technologies. However, in some key clean energy technologies China plays an outsized role in supply chains, creating potential bottlenecks. For example, these conditions are most pronounced in solar and batteries, though similar risks exist in other sectors including electrolyzers and key upstream inputs such as NOES and GOES. Sourcing concentration represents a structural market problem and a national security risk: low-cost, often subsidized

[85] Internal analysis from the National Renewable Energy Laboratory and U.S. Department of Energy Internal Analysis. December 2024.

production from FEOCs creates sourcing concentration and other associated risks (e.g., cybersecurity for connected grid equipment). U.S. clean energy manufactured products face challenging market conditions due to FEOC-concentrated production and associated supply chains. U.S. and global clean energy supply chains rely on majority of critical upstream materials refined and processed and manufactured components assembled in FEOC countries. Across a survey of clean energy production segments—ranging from raw materials to components, the PRC controls more than 80 percent of raw material processing and manufacturing capacity (Figure 10).

Figure 10. Global manufacturing capacity of energy supply chains by country or region, 2024[86]



While the U.S. and trading partners have made considerable progress towards standing up energy supply chains independent from the PRC, future investments should consider the structural advantages built up over the last decade. The PRC has structurally invested in upstream clean energy critical materials capacity through subsidies and state-controlled finance, which has shifted the supply chains of U.S. innovations to China.

Solar technology was invented in the U.S., but global solar PV manufacturing capacity has increasingly moved to PRC over the last decade. As a result, the PRC's market share across the key production steps (e.g., polysilicon, ingots / wafers, cells, and modules) exceeds ~80 percent.[87] China controls 97 percent of global silicon wafer production, creating sourcing risks in event of trade disruption. The level of geographical concentration of global supply chains presents sizable risks for

[86] BloombergNEF. "China Extends Control of Global Clean Energy Supply Chain", September 10, 2024. https://www.bnef.com/shorts/sje1z4dwx2ps00

[87] International Energy Agency. "Executive Summary – Solar PV Global Supply Chains – Analysis - IEA," IEA, n.d., https://www.iea.org/reports/solar-pv-global-supply-chains/executive-summary.

the U.S. and trading partners. Since the passage of the IRA, U.S. announced solar module assembly projects—nearly 50 GWdc of annual manufacturing capacity—enough to satisfy 80 percent of demand with domestically produced modules.[88] While the U.S. solar manufacturing sector made sizable gains in building out a domestic solar supply chain, there are outstanding resilience challenges ahead that may challenge the longevity of raw material and component production of the U.S. solar industry.

Current PRC production and planned investment—from upstream materials to downstream products—exceed global demand across solar—which will make business cases for investments in the U.S. and allied countries challenging to prove out. This reality is consistent across technologies including batteries and electric vehicles, where PRC has looked to export markets to sell excess supply and right size imbalances within its economy. The risk of dumping of cheap materials and components due to overproduction challenges efforts to build competing U.S. and trading partner production capacity.

Oversupply in the global economy makes cost competitiveness a key challenge for the U.S. and major developed trading partners. Due to both at-scale concentration of production value chains, low environmental standards, protections, or compliance, inadequate enforcement of absence of labor standards, and publicly funded support for these industries, the PRC holds a structural advantage on cost competitiveness. Key U.S. upstream materials (e.g., solar-grade polysilicon for solar) and manufactured products (e.g., crystalline silicon solar modules) are not cost-competitive with PRC production.

Supplier diversity

Supplier diversity varies dramatically by technology, though many sectors experience concentration among a small number of suppliers. The most prominent supplier concentration risks exist in upstream processed and engineered materials such as refined natural graphite for battery anodes, GOES, and production and enrichment for nuclear fuel.

Agility

Responding to supply chain shocks remains a challenge for several key portions of the ESIB due to trade and/or supplier concentration. While these supply chains will always be complex and take time to rewire following shocks, increasing domestic capacity will likely help on this front. However, additional waves of investment will be required to create enduring agility across the ESIB.

Security

As the energy sector has become more globalized and increasingly complex, digitized, and even virtualized, its supply chain risk for digital components—the software, virtual platforms and services, and data—in energy systems has evolved and expanded. All digital components in U.S. energy sector systems are vulnerable and may be subject to cyber supply chain risks stemming from a variety of threats, vulnerabilities, and impacts. This includes digital components in all systems within the ESIB, namely those systems operated by asset owners across different energy subsectors

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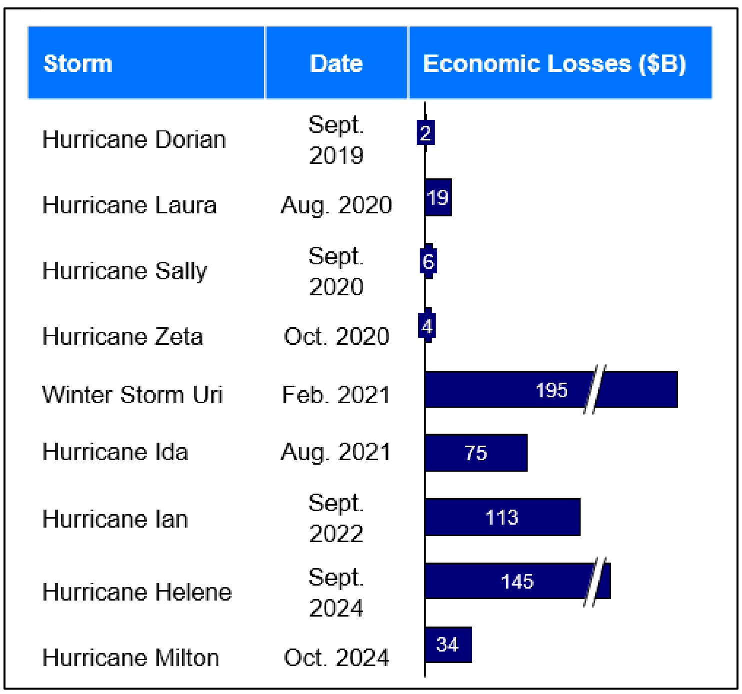
[88] U.S. Department of Energy, Loan Programs Office, Energy.gov. "LPO Tech Talk: Solar Photovoltaics Supply Chain," n.d. https://www.energy.gov/lpo/articles/lpo-tech-talk-solar-photovoltaics-supply-

(e.g., electricity, oil and natural gas, and renewables) and the systems operated by a worldwide industrial complex with capabilities to perform research and development and design, produce, operate, and maintain energy sector systems, subsystems, components, or parts to meet U.S. energy requirements. Supply chain risks for digital components including software, virtual platforms and services, and data have grown in recent years as increasingly sophisticated cyber adversaries have targeted exploiting vulnerabilities in these digital assets. Supply chain risks for digital components in energy sector systems will continue to evolve and likely increase as these systems are increasingly interconnected, digitized, and remotely operated.

Extreme weather and natural hazards are weakening U.S. energy supply chains and supporting infrastructure. Hurricanes, floods, wildfires, severe convective storms and other natural events routinely inflict widespread property damage. Less well publicized and understood are the cascading (negative) effects of such events on the systems that underpin society, including energy, water and transport infrastructure (Figure 11).

Figure 11. Select U.S. extreme weather events and economic losses, 2019–2024[89]



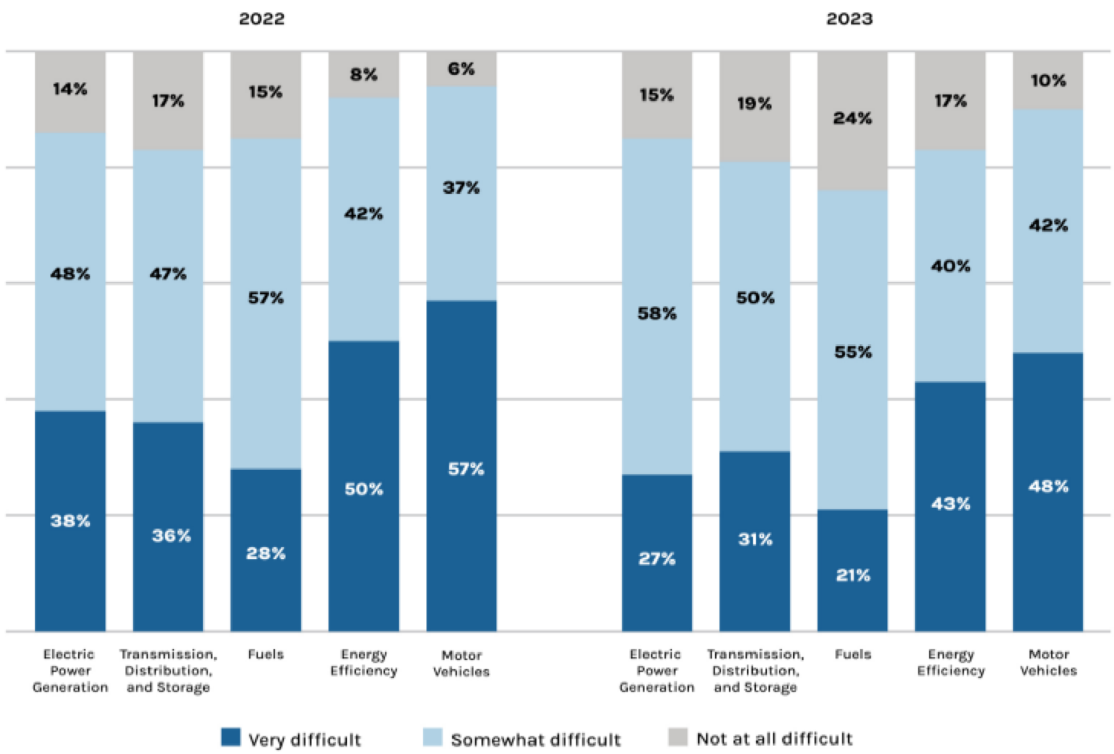
As storms increase in frequency and strength this amount of damage will only further widen the gap between supply and demand and slow down economic development of projects related to manufacturing, housing, technology and infrastructure. Storm damage is increasingly resulting in full-system and substation replacements for investor-owned utilities, cooperatives, and municipal-owned utilities. In the aftermath of Hurricane Ida—utilities estimated $2.6 billion in grid damage and reported nearly 6,000 transformers damaged.[90]

[89] U.S. Department of Commerce. National Oceanic and Atmospheric Administration. National Centers for Environmental Information (NCEI) U.S. Billion-Dollar Weather and Climate Disasters (2024). https://www.ncei.noaa.gov/access/billions/, DOI: 10.25921/stkw-7w73
[90] Entergy Newsroom. "Entergy Provides Update on Hurricane Ida," n.d. https://www.entergynewsroom.com/news/entergy-provides-update-on-hurricane-ida/.

Economic health and compliance

Scaling of supply chains and final assembly requires a sufficient workforce to assemble materials and operate facilities. Data from the 2024 U.S. Energy & Employment Jobs Report (USEER) suggest that ESIB continues to face near term challenges including hiring difficulty, high demand for construction workers to build new production facilities, and specialized skills across the sector (e.g., electricians, welders, heavy equipment operators, and pipefitters). The challenges are particularly acute due to significant competition among energy technologies for the same labor pool and limited specialized knowledge in the U.S. market (Figure 12).

Figure 12. Hiring difficulty by energy sector technology



Targeted investments in education, training, certification, and apprenticeship programs can create pipelines that equip and connect workers with the skills needed to fill high-quality clean energy jobs, while simultaneously reducing constraints on the clean energy manufacturing sector. Additional research is required to identify target models for this training, considering the role of both private and public entities.

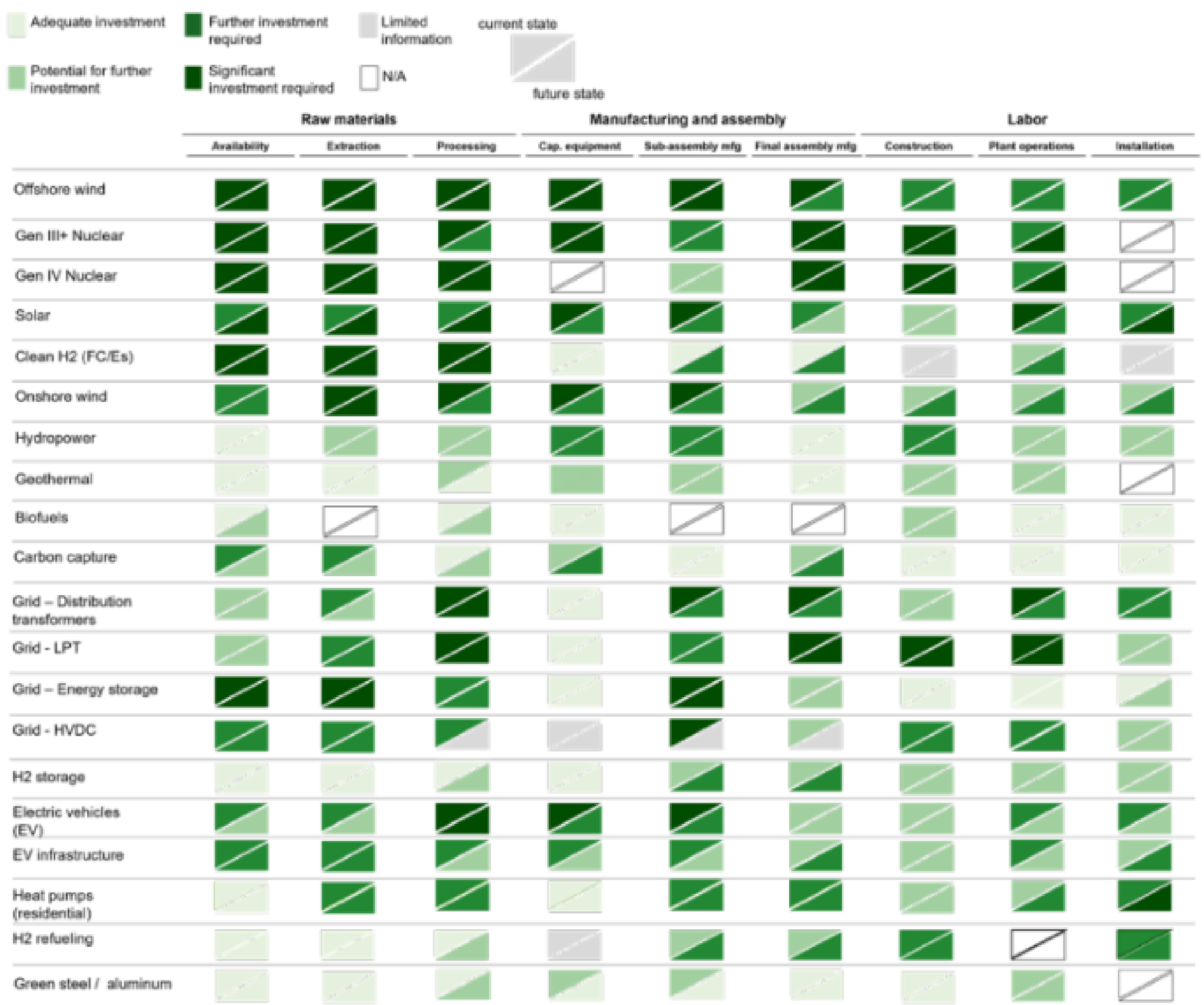
In some supply chain areas, foreign incumbents are in a strong position given strong market share, expertise and IP leading to lower cost operations, enabled by strong policy support. In these areas, robust U.S. policy is needed. U.S. production generally has high standards for labor and environmental compliance relative to global competitors. Requiring trade partners to operate with similar standards may help create a more level economic playing field.

PRIORITIES AHEAD

Four-year Outlook

As the U.S. and other countries around the world strive to diversify the energy industrial base, the extent to which global materials and component supply chains can keep up with new and accelerating sources of demand will be a critical determinant of reaching net-zero targets. While the U.S. has made substantial progress in investments to build out new production capacity, there is more work to do. Estimates on the degree of public and private investment required to establish industry-leading U.S. energy supply chains show five- and ten-year investment ramps fall short across many energy technologies (Figure 12).

Figure 13. U.S. energy technology and supply chain investment matrix[91]



[91] Tsisilile Barlock et al., U.S. Department of Energy, Office of Manufacturing and Energy Supply Chains. "Supply Chains Progress Report," *Supply Chains Progress Report*, 2023, https://www.energy.gov/sites/default/files/2023-08/Supply%20Chain%20Progress%20Report%20-%20August%202023.pdf.

Goal 1. Increase investment in upstream supply chains

The extensive use of processed minerals and materials creates complexity for domestic production of most ESIB outputs including batteries, grid components, electricity generation, industrial decarbonization technologies, among other technologies. Lack of at-scale production and current timelines to production (e.g., 2026–2030 to be operational) for facilities under construction creates risks, including the inability to respond to market developments (e.g., cost declines), technology obsolescence, outdated production techniques, among other areas.

While recent investment and policy have created momentum in scaling domestic supply chains, further investment and support is needed. DOE-led analytical efforts including Supply Chain Readiness Levels and the Critical Minerals Report have identified areas in urgent need of action. The Department of the Interior, through the U.S. Geological Survey's National Minerals Information Center, developed a whole-of-government List of Critical Minerals using a data-driven methodology in 2022. Since publication, the List of Critical Minerals has been used to identify supply risks and work collaboratively to develop solutions to strengthen specific supply chains including where to focus government investments. In parallel, secure trade partnerships will be another critical approach to building resilience and filling supply chain gaps.

Goal 2. Continue to expand manufacturing and production capacity for key components in value chain with focus on systemic vulnerabilities

As demand for ESIB technologies ramps up, there will be a continued focus on increasing the sources and quantity of reliable suppliers domestically and among trading partners. Currently, the U.S. has supplier concentration risk in key technology areas (e.g., grid components) or in some cases sole source suppliers (e.g., grain-oriented electrical steel and amorphous metal for distribution transformers) for upstream materials on several manufactured products essential for ESIB and the clean energy transition. Among other critical materials and metals for clean energy technologies, the U.S. has limited smelting, refining, and recycling capacity for copper, aluminum, and silver, among others, amidst increasing demand. The U.S. needs an additional 400 kt of copper by 2030 with over 50 percent for end-uses in direct support of the energy transition.[92]

Copper smelting is a significant bottleneck (e.g., only two domestic smelters are operational) with unfavorable operating costs (e.g., U.S. producers operate in the fourth quartile of global producers).[93] Moreover, idle production capacity across the value chain for several technologies (e.g., polysilicon and large power transformers) is due to a lack of cost competitiveness with global production. For example, U.S. capacity for producing large power transformers is underutilized at about 40–50 percent of current production line operations despite projections for increasing electrical load growth.[94] Policy supporting the domestic grid supply chain can alleviate these risks. For example, additional targeted funding to bolster manufacturing capacity, as well as potential demand-side support to give suppliers confidence to make investments in expanding production capacity for equipment necessary for grid expansion. In addition, distributed energy resources such

[92] Crooks, Scott, Jonathan Lindley, Dawid Lipus, Richard Sellschop, Eugéne Smit, and Stephan Van Zyl. "Bridging the Copper Supply Gap." McKinsey & Company, February 17, 2023. https://www.mckinsey.com/industries/metals-and-mining/our-insights/bridging-the-copper-supply-gap.
[93] U.S. Department of Energy. Office of Manufacturing and Energy Supply Chains. Internal analysis. December 2024.
[94] Gonzalez, Eva. BloombergNEF. "Research Note: US Risks Power Transformer Supply Gap Becoming a Chasm". November 2023.

as rooftop solar and storage and expansion of technologies such as geothermal for behind-the-meter generation can reduce dependence on grid infrastructure

Goal 3. Improve resilience for specialized materials and capital equipment by increasing domestic production and through trading partners

The challenge of onshoring or friendshoring of key supply chains extends to specialized materials and components along with the capital equipment needed to produce them. Increasing production capacity for specialized components remains a critical gap to close for the ESIB.[95] For example, the U.S. does not have large-scale domestic castings and forgings capabilities to meet demand in offshore wind. Global supply chains may have bandwidth for many sub-components (e.g., bearings), but many will be in high demand with a limited pool of suppliers (e.g., flanges for offshore wind have about seven global suppliers and only 2–3 with the capacity to meet current specifications).[96]

Supply chain challenges have slowed the deployment of offshore wind farms, in addition to other factors. The U.S. also faces limited domestic sourcing of leading- and current-generation capital equipment, tooling, and specialized machinery needed to produce clean energy technologies. The majority of leading-edge solar PV equipment is developed in the PRC or Southeast Asia (e.g., ingot/wafer pullers and diamond wire saws). The increasing size of components—from wind blades to modules—also may make current specs and installation of capital equipment obsolete in the next 2–5 years. Certain technologies require higher-grade equipment than others (e.g., nuclear), which creates potential risk if the necessary components are unavailable. These bottlenecks can be addressed through targeted investment and diplomatic engagement, including strategic trade partnerships with reliable trade partners.

Goal 4. Increased federal investment and program support for workforce development

The U.S. energy workforce overall added over 250,000 jobs in 2023—59 percent of the total share attributed to clean energy and growing 4.9 percent year over year.[97] And for the first time ever, unionization rates in clean energy, at 12.4 percent, surpassed the average rate in the energy sector of 11 percent, driven by rapid growth in unionized construction and utility industries.[98] While the U.S. ESIB workforce has shown promising developments, long-term structural factors may lead to a shortfall in the necessary workers and skills required for U.S. clean energy manufacturing.

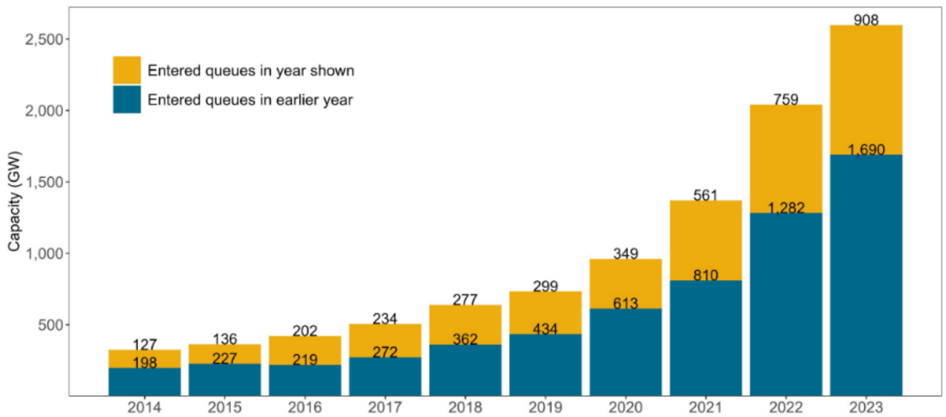
Factors including geographic variations in the labor force, a lack of investment in worker skill development, an aging workforce, and changes in workforce preferences all shape the underlying foundations of the labor market.

[95] U.S. Department of Energy. "America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition," U.S. Department of Energy Response to Executive Order 14017, "America's Supply Chains", February 24, 2022. https://www.energy.gov/policy/articles/americas-strategy-secure-supply-chain-robust-clean-energy-transition.
[96] Ruth Baranowski et al., "Wind Energy Supply Chain Deep Dive Assessment," February 24, 2022, https://www.energy.gov/sites/default/files/2022-02/Wind%20Supply%20Chain%20Report%20-%20Final%202.25.22.pdf.
[97] U.S. Department of Energy et al., "United States Energy & Employment Report 2024," U.S. Department of Energy, 2024, https://www.energy.gov/sites/default/files/2024-10/USEER%202024_COMPLETE_1002.pdf.
[98] Ibid.

Goal 5. Modernize infrastructure to alleviate bottlenecks for downstream demand.

While financial incentives can drive investment, the physical realities of connecting clean energy systems and infrastructure necessary create a risk that could limit deployment. For example, grid interconnection queues increased 27 percent to 2,600 GW—twice as much as the existing U.S. generation capacity—in 2023 (Figure 14).

Figure 14. Total active capacity in interconnection queues, 2023[99]



The increasing backlog of connecting into the grid is exacerbated by the pace of modernization and expansion. DOE released the National Transmission Needs Study, which found the U.S. will need to more than double intra-regional transmission capacity and quadruple interregional transmission capacity by 2035.[100] Estimates have found that large transmission projects can take 20 years to complete. Lack of transparency in the ISO/RTO interconnection backlog and low completion rates for transmission create mixed signals for manufacturers and investors.

While the U.S. needs to clear hurdles to deploy more clean generating assets, there are current investments that can be added to the existing grid network to alleviate current bottlenecks. Deploying advanced grid solutions available today can cost effectively increase the capacity of the existing grid to support 20–100 GW of incremental peak demand when installed individually, while improving grid reliability, resilience, affordability, and sustainability.[101] For consumers, one of the top barriers that prevent them from buying or leasing an EV is charging logistics (61 percent),[102] with evidence showing positive feedback loops with respect to both EV demand and EV charger

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[99] Rand, Joseph, Nick Manderlink, Will Gorman, Ryan H Wiser, Joachim Seel, Julie Mulvaney Kemp, Seongeun Jeong, and Fritz Kahrl "Queued Up: 2024 Edition, Characteristics of Power Plants Seeking Transmission Interconnection As of the End of 2023." (2024). https://emp.lbl.gov/sites/default/files/2024-04/Queued%20Up%202024%20Edition_R2.pdf

[100] U.S. Department of Energy. Energy.gov. "National Transmission Needs Study," n.d. https://www.energy.gov/gdo/national-transmission-needs-study.

[101] U.S. Department of Energy, "Innovative Grid Deployment - Pathways to Commercial Liftoff," Pathways to Commercial Liftoff, May 14, 2024, https://liftoff.energy.gov/innovative-grid-deployment/.

[102] Consumer Reports. "CR Report: Charging the Future—The Role of Retail in Our EV Transition - CR Advocacy," CR Advocacy, March 4, 2024, https://advocacy.consumerreports.org/research/cr-report-charging-the-future-the-role-of-retail-in-our-ev-transition/.

investment.[103] Meaningful progress has been made for EV charging infrastructure build out, with greater expansion needed to make charging ubiquitous and frictionless.[104]

Long-term Resilience Goals

The energy sector industrial base is undergoing rapid transition and will continue to over the coming decades. The United States is poised to emerge from this transition as a leader, maintaining energy independence and its status as an energy superpower. However, a holistic strategy is required to chart this transition as sources of advantage shift to extraction of new minerals and rely on the maintenance of complex supply chains for specialized materials and components.

While the U.S. has driven historical investment through the Inflation Reduction Act and Bipartisan Infrastructure Law, ongoing policy support will be needed to close investment gaps and build the necessary capacity in clean energy supply chains. These efforts must focus on three critical areas:

- **Continuing momentum to build out U.S. energy manufacturing.** This will require ongoing public support in key portions of the supply chain, including both production and recycling capacity, as well as the articulation of a long-term policy orientation to ensure U.S. manufacturing can compete with low-cost production in PRC driven by states support.
- **Building international partnerships to enhance supply chain resilience.** Clean energy supply chains will inevitably have to rely on productive capacity in other nations, due to both resource availability and existing IP. Pursuing an international engagement strategy that considers the competitiveness of U.S. vs. partner production and positions clean energy security prominently within the international agenda will be critical.
- **Activating the U.S. innovation ecosystem to build advantage in emerging technologies.** The competition in energy technologies will continue to grow in the coming decades. The U.S. Government must continue to deploy resources to innovate to improve existing technologies and accelerate the development of next generation solutions. The U.S. has long been a leader in early-stage R&D, and it will need to ensure IP is grown and commercialized within the U.S. ecosystem in the future.

Conclusion

The path to build enduring resilience in clean energy supply chains will be a long one, but the United States has the resources required to take on this challenge. Additional public capital will likely be required to unlock the trillions available in private capital markets in the U.S., and a clear and sustained policy agenda will be required to show investors that the long-term, hard investments in producing clean energy technologies will pay off. Recent actions funded by the Inflation Reduction Act and Bipartisan Infrastructure Law represent a critical step in this direction, and the task ahead is to ensure that the momentum to secure supply chains and preserve American energy independence is maintained.

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[103] The Market for Electric Vehicles: Indirect Network Effects and Policy Design, Shanjun Li, Lang Tong, Jianwei Xing, and Yiyi Zhou, Journal of the Association of Environmental and Resource Economists 2017 4:1, 89-133. https://www.journals.uchicago.edu/doi/10.1086/689702.

[104] U.S. Department of Energy. U.S. Department of Transportation. U.S. Joint Office of Energy and Transportation. "Joint Office Celebrates 200,000 Places to Charge". Joint Office of Energy and Transportation," n.d. https://driveelectric.gov/news/places-to-charge.

2021–2024 Four-year Review of Supply Chains for the Advanced Batteries Sector

U.S. DEPARTMENT OF ENERGY

DECEMBER 2024

EXECUTIVE SUMMARY

Advanced batteries are critical for U.S. energy security and will play a vital role in affordable, decarbonized, and resilient future transportation and power sectors. A diversified, secure, and circular supply chain is imperative for energy security and will position U.S. manufacturing to compete in an industry poised to grow more than five-fold globally and six-fold domestically by 2035.

Advanced batteries are supported by a complex, multi-tiered supply chain that includes minerals extraction and processing, industrial chemicals, engineered materials, and sophisticated downstream manufacturing operations, as well as transportation and logistics. Growing the U.S. market share of emerging high-performance materials and battery chemistries will require further scale-up of advanced industrial and manufacturing capabilities.

The Bipartisan Infrastructure Law (BIL), Inflation Reduction Action (IRA), and Section 301 tariffs have helped spur unprecedented investment in the sector: more than $150 billion in battery manufacturing, creating more than 100,000 jobs. Nearly $33 billion of federal investment has supported onshoring of critical capabilities and commercialization of next-generation battery technologies.[105] Though economics can appear challenging compared to competitors, U.S. operations have a pathway to compete. The U.S. has already made substantial progress in building a pipeline of more than 1,100 gigawatt hours (GWh) per year of manufacturing capacity for battery cells, and the U.S. is investing in the first wave of projects that can help unlock massive domestic mineral resources for use in batteries.

Supply chain buildout is threatened by market uncertainty and structural challenges. Demand uncertainty and price volatility are holding back investment in key sectors. In several key segments, domestic operations face structural production cost disadvantages compounded by non-market policies and practices carried out by foreign governments.

Future priorities for supply-chain resilience include: providing support to existing investments to stabilize markets in the near-term, delivering first-of-a-kind domestic projects to onshore critical capabilities, continuing to build international partnerships to fill residual gaps and enhance the overall competitiveness of the supply chain, leveraging strengths in R&D and innovation to compete on next-generation technologies, and facilitating the emergence of a circular economy model for key input materials.

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[105] Private investment from energy.gov/invest. Public investment tracked by U.S. Department of Energy, including awarded and selected grants, conditionally committed and closed loans, and publicly announced recipients of the 48C Qualifying Energy Project Tax Credit. Public investment figure includes investments in electric vehicles as well.

SECTOR OVERVIEW

Introduction

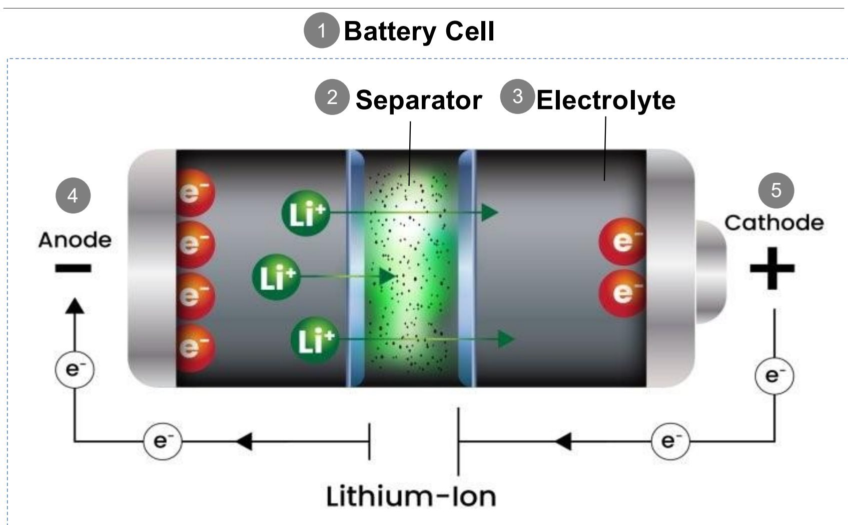
Advanced batteries are a critical technology needed for a resilient, affordable, and secure future energy system. As vital components of electric vehicles, stationary energy storage systems for grid resilience, and advanced electronics, they support fast-growing markets that will play an important role in U.S. economic competitiveness. Advanced batteries are also critical for a range of high-priority defense applications, including unmanned vehicles (particularly UAVs), directed-energy weapons, communications systems, sensors, and electronic warfare and countermeasures.

This Review details the range of advanced battery technologies under development and their associated supply chain inputs, sketches out challenges facing the domestic supply chain, benchmarks progress to date in battery processing and manufacturing, and concludes by identifying priorities for the federal government to pursue going forward.

Sector Overview and Key Trends

Advanced battery chemistries include lithium-ion formulations currently in widespread use (particularly nickel-manganese-cobalt and lithium-iron-phosphate cathode chemistries), as well as emerging formulations like sodium-ion and solid-state chemistries that are at earlier stages of development but may come with benefits related to performance, cost, and material availability. Other alternative chemistries like iron-air and flow batteries are also earlier-stage but may be better suited to stationary storage, including long-duration storage applications. Advanced batteries may likewise include a range of alternative materials that can come with similar performance and supply chain advantages, such as silicon anode blends to supplement graphite and alternative electrolyte and binder formulations. (Figure 1 provides a high-level view of battery cell components, while the manufacturing process and role of key inputs are discussed further below.)

Figure 1. Illustrative structure of a battery cell

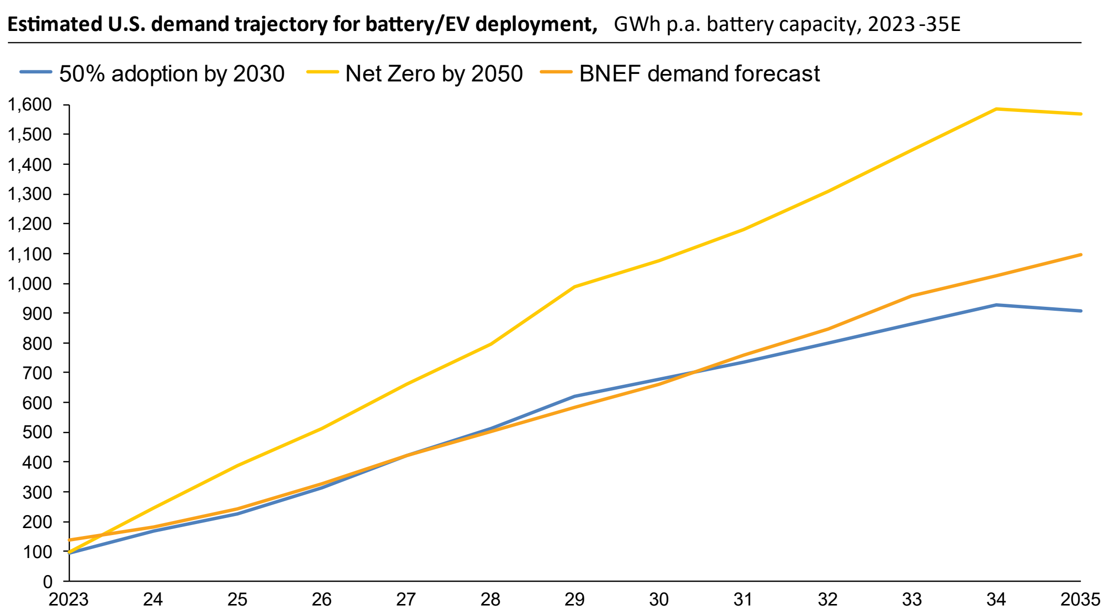


Source: U.S. Department of Energy

Demand for these kinds of advanced batteries continues to grow rapidly. In the U.S., battery deployment could increase by six-fold from 2024 to 2035 (Figure 2). Global deployment could similarly increase by five-fold in the same period. EV adoption is expected to drive 85 to 90 percent of the battery market, with other applications, particularly stationary storage for the grid, accounting for the remainder.[106] Accelerated adoption is a product not just of policy incentives, but also of a strengthening underlying value proposition for EVs, stationary storage, and other use-cases, reflected in market-driven demand forecasts (e.g., "BloombergNEF demand forecast" in Figure 2) and rapid growth in battery deployment across global markets. The battery market will be a key engine of growth for advanced manufacturing and presents an important opportunity to create middle class jobs, grow an advanced manufacturing industrial base, and ensure future energy security and economic competitiveness.

For the automotive industry specifically, cost and performance improvements in EVs are likely to drive continuing growth in market share. Successful integration of advanced batteries will accordingly be critically important for the long-term competitiveness of U.S. automakers and for the long-term health of the U.S. automotive manufacturing base, which directly employs roughly 1.1 million American workers,[107] accounts for roughly 7 percent of U.S. manufacturing output,[108] and provides peacetime support for a range of dual-use industrial capabilities, such as metal-working, that are vital for defense production.

Figure 2. Battery deployment trajectories



Source: Illustrative scenarios, based on analysis of Administration targets and Net Zero scenarios from Argonne National Laboratory. Other scenario from BloombergNEF.

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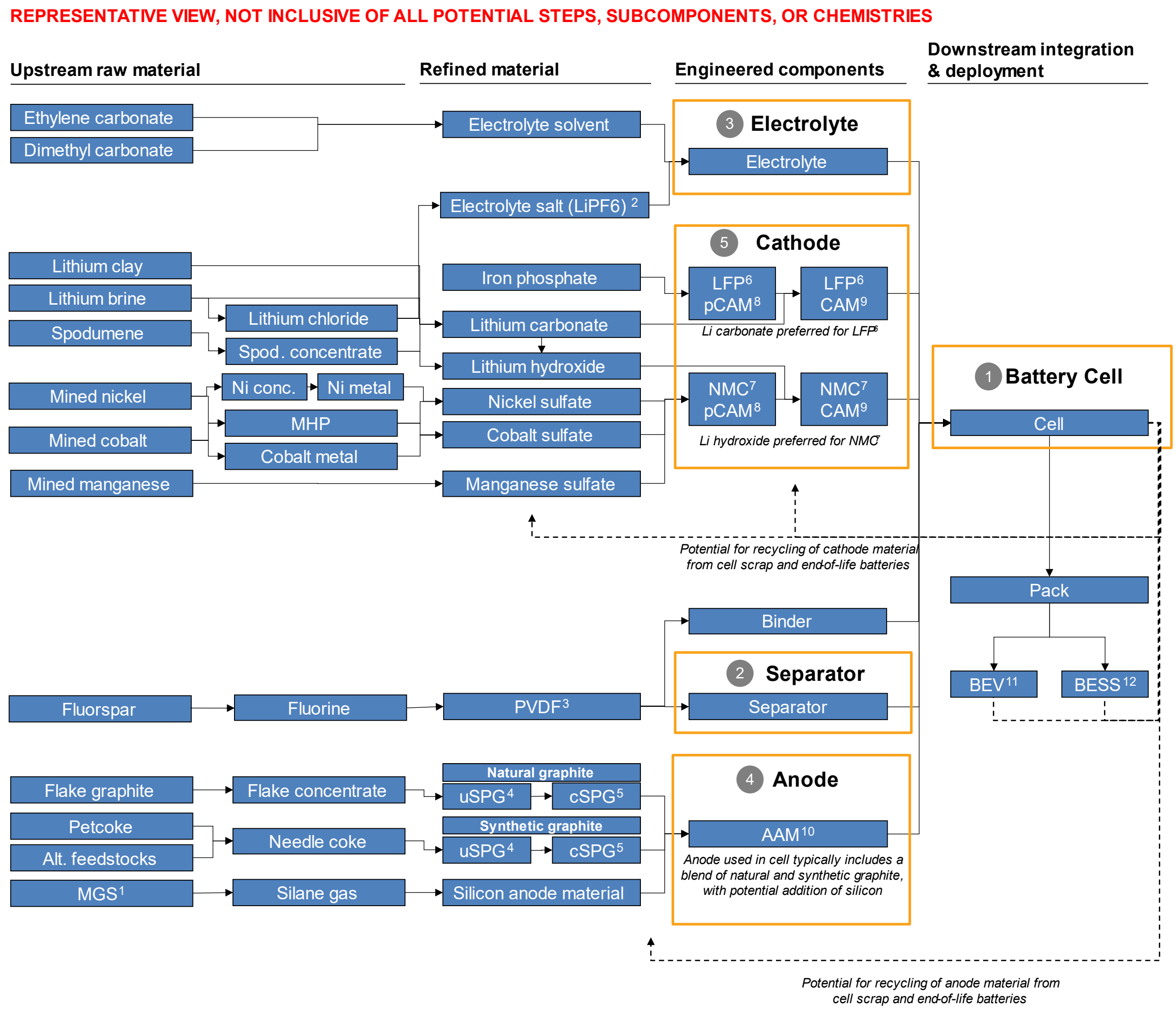
[106] U.S. demand estimates based on forecasts from Argonne National Laboratory. Other estimates based on "Economic Transition Scenario" battery deployment forecasts from BloombergNEF (updated July 2024, latest available).
[107] "Automotive Industry: Employment, Earnings, and Hours." Bureau of Labor Statistics (2024). https://www.bls.gov/iag/tgs/iagauto.htm.
[108] Measured by value added to GDP. "Value Added by Industry." Bureau of Economic Analysis (2024).

Figure 3. Battery supply chain map



Note: Battery supply chain map. Representative view, not inclusive of all steps, subcomponents, or chemistries. Notes: 1. MGS = Metallurgical Grade Silicon. 2. LiPF6 is common, but other electrolyte salts may also be used. 3. PVDF = Polyvinylidene Fluoride, polymers used as binders and in separator material. 4. uSPG = Uncoated Spherical Purified Graphite. 5. cSPG = Coated Spherical Purified Graphite. 6. LFP = Lithium-Iron-Phosphate cathode chemistry. 7. NMC = Nickel-Manganese-Cobalt chemistry. 8. pCAM = cathode precursor. 9. CAM = Cathode Active Material. 10. AAM = Anode Active Material. 11. BEV = Battery Electric Vehicle. 12. BESS = Battery Energy Storage System (e.g., for stationary storage).

Advanced batteries sit at the end of a complex, multi-tiered supply chain that cuts across mining, chemicals, and advanced manufacturing (representative view in Figure 3). Upstream raw materials include critical minerals, extracted through a variety of potential routes,[109] carbon feedstocks, and industrial chemicals. In the midstream, raw materials are refined and processed in capital-, energy-, and reagent-intensive operations to produce refined materials specialized for use in batteries. These intermediate inputs are further processed into precursors and then major engineered components

[109] This chapter focuses on midstream processing and refining of critical minerals specifically for battery applications. Critical minerals are addressed in greater detail, including extraction, in a separate chapter.

like cathode and anode active material, electrolyte, separator material, and binders. Specifically, critical minerals like lithium, nickel, cobalt, manganese, and phosphate are refined and used in the cathode; natural graphite, synthetic graphite, and, increasingly, silicon are blended in the anode. Lithium and other salts are combined with specialized chemical solvents to produce electrolyte. These major components are assembled at large-scale manufacturing plants into battery cells. Cells are then assembled into battery packs for use in EVs, stationary storage systems, advanced electronics, and other applications.

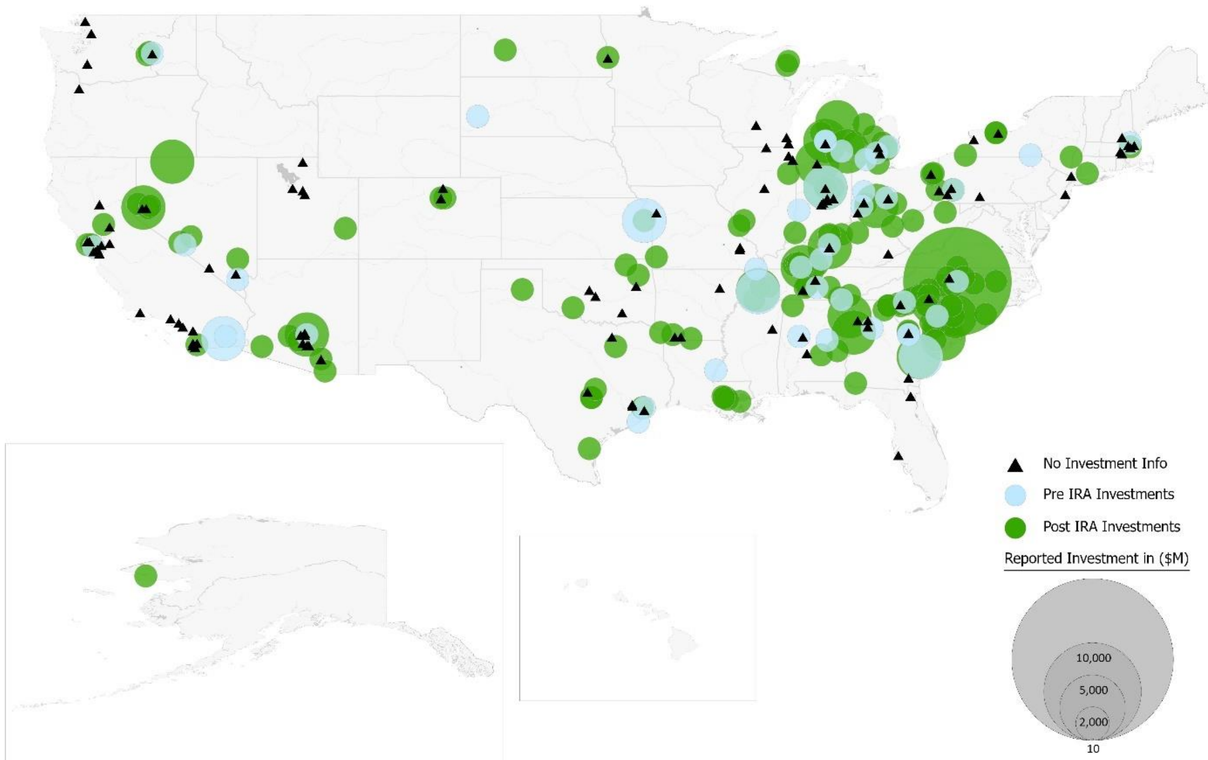
The battery manufacturing ecosystem is also increasingly adopting a "closed-loop" or "circular economy" model, particularly for scarcer and higher-value input materials, in which recycling is an integral part of a secure supply chain. Scrap from manufacturing lines and eventually the large volume of material from end-of-life batteries may be collected and treated by pyrometallurgical, hydrometallurgical, or direct recycling processes to extract constituent materials, particularly critical minerals and electrode active materials (e.g., cathode material).[110] In this way, the domestic manufacturing base can better secure access to scarce materials while improving sustainability and often reducing cost as well.

[110] See, e.g., National Renewable Energy Laboratory's Battery Recycling Supply Chain Analysis portal. "Battery Recycling Supply Chain Analysis." National Renewable Energy Laboratory. https://www.nrel.gov/transportation/battery-recycling-supply-chain-analysis.html.

PROGRESS TO DATE

Progress from 2021 to Present

Figure 6. U.S. investments in the battery supply chain



Source: Energy.gov/invest. As of December 2024.

Significant progress has been made over the past four years in strengthening supply chains and building the foundations of an American industrial base for advanced batteries. Since 2021, the U.S. has seen more than $150 billion of announced investment in the batteries supply chain, with projects potentially creating more than 100,000 manufacturing jobs across the country (Figure 6).

The impact is being felt in key segments of the supply chain. The U.S. has developed a pipeline of cell manufacturing projects with more than 1,100 GWh per year of capacity, enough to supply on the order of 11 to 17 million light-duty EVs[111] (discussed in more detail in a case study at the end of this Review). These downstream operations can anchor a thriving industrial base and allow American manufacturers to begin benefitting from some of the same advantages of colocation and economies of scale enjoyed by foreign competitors. In the upstream and midstream, the U.S. is developing a pipeline of mining, refining, and subcomponent manufacturing projects that are beginning to onshore critical capabilities, and associated technical knowledge, and close domestic supply gaps. These projects include investments that could bring competitive advantages to the domestic supply chain, including novel lithium projects that can help unlock massive, economically

[111] Assuming 65 to 100 kWh per EV battery pack.

competitive domestic resources (discussed in detail in a case study at the end of this Review) as well as advanced recycling technologies that could address other supply chain vulnerabilities.

Government action has played a vital role in catalyzing development of this industrial base. The U.S. Department of Energy, Department of the Treasury, and other agencies have provided more than $33 billion of direct investment in the form of grants, conditional loan commitments, and investment tax credits.[112] (Figure 7 gives a view of companies that have received federal investment.) Federal funding has supported commercial-scale projects across the full value chain, ranging from minerals processing, production of precursors and electroactive materials, and downstream cell and battery production. The Department of Energy has provided additional support for fundamental R&D and continues to support a thriving research ecosystem at the National Labs focused on advanced batteries. Investments to date include the following:

- Under the Department of Energy Office of Manufacturing and Energy Supply Chains (MESC) Battery Materials Processing and Manufacturing Grants Program, DOE has committed approximately $5 billion to approximately 40 projects.
- Since the start of 2022, the Loan Program Office's (LPO) Advanced Technology Vehicle Manufacturing (ATVM) Loan Program has closed approximately $5.5 billion of battery-related loans, with another $22 billion in projects reaching conditional commitment.
- The Export–Import Bank of the U.S. has approved a loan package of up to $50 million for long-duration energy storage company ESS Inc. and another $51 million to battery manufacturer Electrovaya USA.[113]
- The Economic Development Administration has invested more than $66 million in Tech Hubs in New York, Nevada, and South Carolina.

The Inflation Reduction Act (IRA) provides further economic investment to domestic operations. The 45X advanced manufacturing production tax credit created by the IRA provides support to domestic manufacturers across the value chain of battery components and the refining or recycling of critical minerals. The 48C qualifying advanced energy project credit helps offset upfront capital expenditures for manufacturing projects in the battery supply chain. The 30D tax credit for electric vehicles both supports end demand for batteries and, through content requirements, creates demand for materials from the U.S., North America, and countries with which the U.S. has a free trade agreement, as well as ex-PRC materials.

Based on its finding that China has persisted, and in some cases become more aggressive, in its use of harmful forced technology transfer–related acts, policies and practices, in September 2024, the Office of the U.S. Trade Representative also imposed 25-percent tariffs on certain batteries and battery components from China, helping to further offset disadvantages from the PRC's non-market policies and practices.

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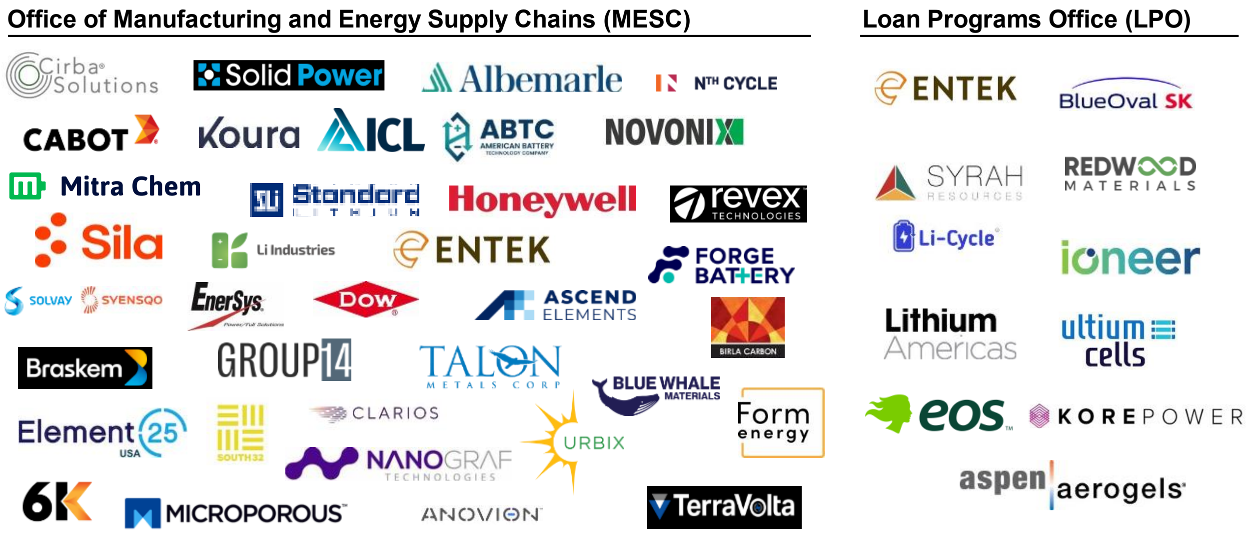
112 Value of investment tax credits estimated based on companies that have voluntarily announced their receipt of the 48C ITC.

113 "Export-Import Bank of the United States Board of Directors Approves Fifth Make More in America Transaction." Export-Import Bank of the United States (2024). https://www.exim.gov/news/export-import-bank-united-states-board-directors-approves-fifth-make-more-america-transaction.

Figure 7. Example recipients of federal investment



Note: Companies with projects funded by the Department of Energy Office of Manufacturing and Energy Supply Chains and Loan Programs Office.

Outside of direct funding and economic support, the federal government has worked to build the institutional infrastructure for long-term engagement and is helping to shape a supportive ecosystem in which domestic projects can succeed. Efforts to date include the following:

- The Department of Energy Office of Manufacturing and Energy Supply Chains is developing a range of analytical tools to improve market transparency, situational awareness of key vulnerabilities, and assessments of U.S. economic competitiveness at different parts of the supply chain.
- The Department of the Interior, through the U.S. Geological Survey's National Minerals Information Center, has developed sophisticated understanding and models of the supply chains for the critical minerals needed for advanced batteries.
- Led by DOE, The Federal Consortium for Advanced Batteries (FCAB) encourages cooperation and coordination across Federal agencies that are interested in ensuring a domestic supply of lithium batteries and are committed to accelerating the development of a robust and secure domestic industrial base.
- Led by DOE, the Conference on Critical Materials and Minerals (CCMM) is a G7 + Australia forum for technical exchanges and government-to-government discussions aimed at enhancing security of supply, R&D, cooperation, standards, and multinational cooperation.
- The White House, Department of Energy (through MESC), and other agencies are continuing to engage and coordinate with industry on supply chain challenges through the American Battery Materials Initiative and other forums.
- The Department of State is leading international engagement and coalition-building with likeminded nations through forums like the Minerals Security Partnership,[114] deepening relationships and helping to mobilize investment to diversify and secure supply chains while promoting high environmental, social, and governance standards.

[114] "Minerals Security Partnership." U.S. Department of State. https://www.state.gov/minerals-security-partnership/.

- The Department of Commerce is continuing to engage key countries in the battery supply chain through the Net Zero World Initiative. After hosting the Net Zero World Industry Forum in December 2022 alongside DOE, Commerce co-hosted both the Battery Energy System Seminar and the Battery to Electric Vehicle Workshop in Jakarta in May 2024 with Indonesia's Ministry for Energy and Mineral Resources. These initiatives advertised U.S. technological solutions to energy storage challenges and solicited input for roadmap reports that continue to guide U.S. policy.
- The Department of Commerce also leads efforts in the IPEF Supply Chain Council, established under The IPEF Supply Chain Agreement that entered into force in February 2024. During its meeting in September 2024, the Council established an Action Plan team on critical minerals, with a focus on batteries, under the IPEF Supply Chain Council. Action Plan teams are a core activity under the Council and will work to compile recommendations to increase the resilience and competitiveness of critical sectors and key goods of mutual interest among IPEF countries. Commerce is leading U.S. participation on this Action Plan team, which will build on the successes of the Critical Minerals Dialogue and establish a workplan on by the end of 2024.
- DOE has led bilateral engagement to increase access to critical minerals and materials for the battery supply chain (e.g., U.S.–Canada Joint Action Plan for CM Cooperation, focused on the battery supply chain, and work with Australia and others on international standards that support U.S. competitiveness).

U.S. support has been substantial but varies meaningfully in how it materializes and impacts underlying unit economics in different parts of the battery supply chain. This Review includes two case studies to illustrate in more detail how U.S. firms are building a robust industrial base: one focused on battery cells to represent downstream manufactured components and one focused on lithium chemicals to represent upstream and midstream activities. Each case study shows how the U.S. Government is working to overcome distinct challenges at each step of the battery production process and enabling the private sector to build out more robust and resilient supply chains.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

This section offers a view of the challenges that will have to be overcome to build a secure, resilient battery supply chain. The first subsection provides a high-level assessment of supply chain resilience and vulnerability across the supply chain using the standard framework. The second considers eight particularly important challenges in greater detail.

2024 Resilience and Vulnerability Assessment

Transparency

The advanced batteries supply chain has limited transparency today due to challenges with data availability and market maturity. A lack of established ex-PRC exchanges and indices for price and the limited commoditization of many midstream components makes it challenging to track supply, demand, and price dynamics across the supply chain.

Government is investing in building additional capabilities to monitor supply-chain and industrial-base resilience for advanced batteries, including DOE MESC's "Supply Chain Readiness" assessment tool. Government and industry are also developing channels to facilitate communication, including the American Batteries Materials Initiative, Minerals Security Partnership, and Argonne National Laboratory's Li-Bridge partnership.[115]

Domestic capacity

The U.S. has made progress in onshoring downstream manufacturing capacity in key areas, with a pipeline of cell manufacturing plants that could provide more than enough capacity to meet 2030 demand. However, domestic capacity remains more limited midstream and upstream, and limited domestic capacity for refining and electrode active material production makes it difficult to onshore recycling capabilities and build a domestic circular economy.

A pipeline of domestic projects is developing that could meet a significant share of domestic demand across tiers of the supply chain, but challenges related to a difficult market environment, delivery of first-of-a-kind projects, and fundamental availability of resources (e.g., critical minerals) will have to be navigated (discussed in greater detail in the pages ahead). Finally, residual import reliance can be further mitigated by deepening strategic relationships with international partners and diversifying international sources of supply.

Trade concentration

The U.S. has significant import reliance today, particularly in upstream and midstream portions of the supply chain. The PRC has significant global market share (~70–90 percent) for many battery-grade refined minerals and engineered subcomponents, while ex-PRC options for subcomponents are largely concentrated in Japan and the Republic of Korea (ROK).

[115] "Li-Bridge." Argonne National Laboratory. https://www.anl.gov/li-bridge.

U.S. and partner countries (such as Canada, Australia, Japan, ROK, the European Union, United Kingdom, and countries in southern Africa) are investing to diversify the supply chain and reduce import dependence. Significant progress to date has been made in onshoring cell manufacturing, and an ex-PRC supply pipeline is also developing for upstream and midstream. To come online, projects must navigate challenges discussed in the rest of this section.

Supplier diversity

Production has traditionally been dominated by a smaller set of large tier-1 battery majors, with many based in the PRC, Japan, and ROK.

The supply base is now diversifying with new entrants. These include both established companies in "adjacent" sectors (e.g., chemicals, oil and gas) standing up battery-focused production and smaller companies, including junior miners and start-ups bringing novel technologies and production approaches to market.

Agility

The supply chain has some potential for material substitution over longer timelines (e.g., alternative chemistries for the cathode and anode), but operations generally require retooling, new investment, and potentially investment in development of new IP and product validation to pivot, limiting their ability to do so quickly in response to unexpected supply disruptions.

Security

In its current state, the supply chain has security risks from geographic concentration. Global production of input materials is concentrated in the PRC and other countries in East Asia, and individual countries still account for disproportionate shares of the global supply of critical minerals like cobalt. Risks from geographic concentration are heightened by the potential for adversarial policy actions, such as export restrictions.

The developing pipeline of domestic and international projects offers an opportunity to diversify the supply mix and hedge against risk. However, the formation of geographic clusters (e.g., for domestic battery cell production, as discussed in the case study at the end of this Review) may create additional risk from geographic concentration of operations.

Economic health and compliance

U.S. manufacturers are commercially well-positioned in parts of the supply chain where they can benefit from policy support, domestic resource endowments, technological advantages, or potential for differentiation on quality and performance (e.g., cell, lithium, and subset of cost-advantaged or high-performance projects elsewhere).

However, much of the supply chain faces challenging market headwinds relative to competitors (particularly established PRC firms). Key drivers include cost and IP advantages of incumbent firms, structural disadvantages on cost of capital and key inputs, market volatility and demand uncertainty, market immaturity and opacity, and workforce constraints, both in construction and operation of large-scale manufacturing projects.

Challenges in Focus

The U.S. has started from a position of limited domestic capacity across the steps of the supply chain. Early global demand for batteries and battery critical minerals, constituent materials, and battery components has largely been met by foreign producers, including the PRC, which has built a dominant market share at key chokepoints (see Figure 4). Batteries are expected to become an increasingly critical part of the energy ecosystem, making it imperative to reduce foreign reliance, even as the rapid growth of the sector makes doing so even more challenging. Building out a secure domestic supply chain will require the U.S. to overcome several cross-cutting challenges, including:

(a) Aggressive PRC actions to support its domestic industry

PRC firms have a commanding market share today in many segments of the battery supply chain, benefitting from decades of state-backed investment, subsidies, and incumbency in developing a strong industrial base. At important chokepoints like midstream minerals processing and subcomponent manufacturing, PRC firms account for roughly 70 to 90 percent of global production capacity today (Figure 4), giving them significant leverage to shape market dynamics. In many parts of the supply chain, PRC firms have significantly increased capacity to exceed both to domestic and even to projected global demand,[116] and the resulting oversupply has helped hold down prices and crowd out potential entrants. This dynamic has already been seen in other sectors targeted as strategic priorities by Chinese industrial policy, including steel, aluminum, and solar panels, with similarly damaging results for domestic industry.[117]

China's longstanding non-market industrial policies and practices have played an important role in building up this entrenched position. Advanced battery research and development and manufacturing, including coverage of the full supply chain, has been treated as a strategic sector by the PRC government, which has supported its domestic industry previously through years of mandatory joint ventures requirements that facilitated technology transfer and government-approved whitelists that explicitly preference domestic battery manufacturers. The PRC continues to release policies including with massive subsidies for consumer demand, manufacturer sales requirements, favorable access to land, utilities, and other inputs, and large supplies of low-cost capital (a particularly important lever to bolster competitiveness in capital-intensive battery supply chains, discussed in more detail in challenge (c)).

Building on these subsidies, PRC firms are investing to maintain their position in the market in the long term. Firms have announced plans to build production capacity that would provide 80 to 90 percent global market share at key points in the supply chain into the 2030s.[118] PRC operations are also investing heavily in the next generation of advanced battery technologies (e.g., sodium-ion) and account for the bulk of planned capacity buildout and deployment of these technologies today.

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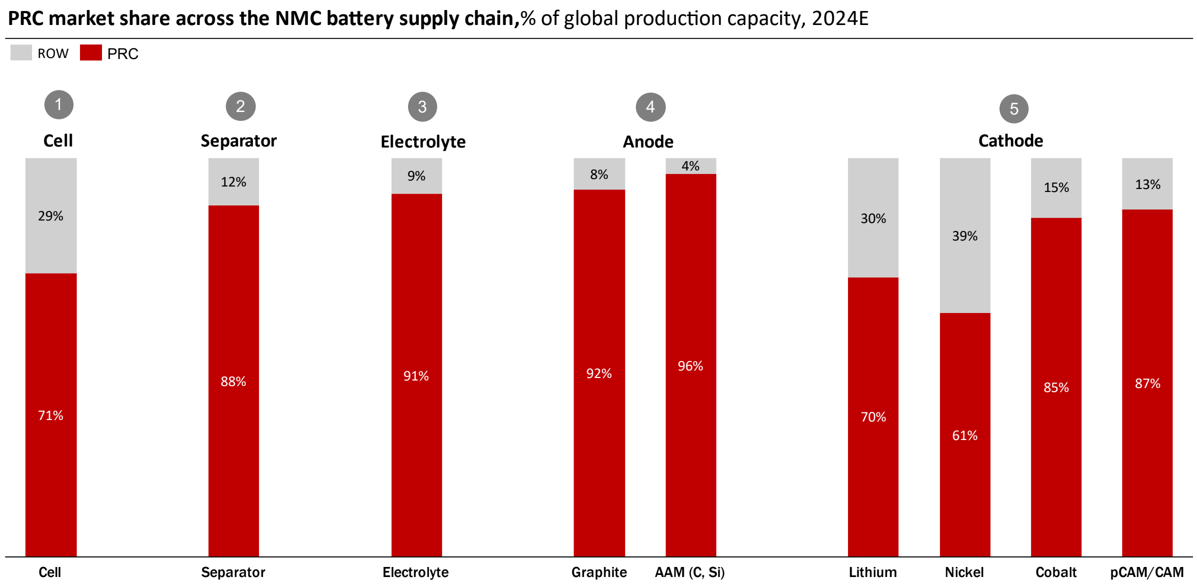
116 E.g., BloombergNEF is tracking nearly 6 TWh of battery capacity announced in PRC for 2025, compared to estimated *global* demand of under 2 TWh. Though significant portions of this announced capacity may be delayed or canceled, even a fraction of this pipeline of projects coming to fruition would represent a significant overbuild. Colin McKerracher. "China Already Makes as Many Batteries as the Entire World Wants." BloombergNEF (2024). https://about.bnef.com/blog/china-already-makes-as-many-batteries-as-the-entire-world-wants/.

117 Discussed in *2023 Report to Congress on China's WTO Compliance*. U.S. Trade Representative (2024).

118 Based on announced project capacity tracked by BloombergNEF.

Figure 4. PRC market share across the battery supply chain



Note: PRC market share across the battery supply chain. Lithium, nickel, cobalt, and graphite from BloombergNEF 2024E refined mineral supply figures for lithium carbonate and hydroxide, nickel sulfate, cobalt sulfate, and both natural and synthetic graphite. All others from BloombergNEF-tracked "fully commissioned" facilities. Est. market share does not include operations outside of PRC that may be owned by Chinese companies, therefore likely understates true PRC market share.

(b) Structural cost disadvantages

PRC firms benefit from structural advantages on cost, bolstered by state industrial policy. These include lower costs of labor, environmental compliance, and key inputs. The strong incumbent position of PRC operations has brought additional important benefits, including mature domestic markets with firm demand, well-established upstream supply chains, and strong positioning on IP and technical knowledge.

Mature PRC operations have realized significant cost benefits from vertical integration, colocation of operations, economies of scale, and long-term learning effects. For example, concentrating sequential parts of the supply chain in geographic clusters helps PRC firms dramatically reduce the costs associated with logistics while enabling quicker material qualification and process improvement. Similarly, by co-locating with chemical plants as part of large industrial complexes, PRC refining and cathode manufacturing operations can secure low-cost access to reagents that may be waste products of other chemical processes while more easily monetizing the waste byproducts of their own operations.

Conversely, midstream gaps in U.S. domestic supply chains, such as slower buildout of cathode precursor and material plants, can deny domestic firms the structural advantages of colocation, requiring domestically produced material to be shipped overseas for intermediate processing, and challenge the business case for long-term investment.

PRC operations also benefit from significant investment in IP and technical knowledge amassed through years of operating at scale. U.S. companies trying to break into the market often must partner with foreign firms to secure IP or invest heavily in developing new IP for themselves, at added cost. Limited technical experience can increase the cost of first-of-a-kind domestic projects, which can incur additional costs in fine-tuning and ramping production for the first time, as well as increase the perceived risk of projects to potential investors.

(c) Limited domestic resource supply

For some critical inputs, particularly raw materials like critical minerals, the U.S. has limited domestic resources available for battery manufacturing, creating a dependence on foreign sources of supply. In some cases, such as nickel and cobalt, the U.S. has limited domestic mineral deposits that can be economically developed. In other cases, such as natural graphite, the U.S. has large-scale mineral deposits but faces lengthy development timelines to bring mining capacity online. Without appropriate mitigations, reliance on foreign sources of supply can create risk downstream in the supply chain and to the broader economy by leaving operations vulnerable to supply shocks, both from unexpected disruptions like natural disasters and bottlenecks in global shipping and logistics, and from adversarial state policy, such as export controls.[119] The lack of upstream resources can also compound cost disadvantages in the midstream by limiting opportunities for vertical integration and colocation of operations.

(d) High capital costs for new domestic projects

U.S. operations are especially disadvantaged by high capital costs, relative to other countries and to the PRC in particular. Capital repayment can be one of the largest drivers of unit costs, particularly in the midstream, where projects are often at greater than $1 billion scale, and projects can be anywhere from two to seven times more expensive to build in the U.S. compared to the PRC and other countries. Higher U.S. capital costs are a result of constraints in the construction sector (including shortages in the trade workforce, also discussed in challenge (h)), significantly slower timelines for project delivery (typically multiple years compared to 6 to 12 months), and a higher baseline cost of doing business. First-of-a-kind domestic projects are particularly exposed to these pressures because of the unique challenges in initial project delivery and commissioning (see challenge (g)).

High project delivery costs are compounded further by the high return expectations of U.S. investors and the high cost of capital for many domestic project developers. Due to China's large-scale industrial policy support and non-market policies and practices, PRC firms can leverage cheap, in some cases, effectively free, capital from state-owned financial institutions and other low-cost providers, allowing them to overbuild capacity relative to domestic demand and compete more readily in low-price environments. In contrast, to attract private capital, U.S. projects must deliver a highly competitive return to investors, particularly in parts of the supply chain perceived as high-risk like minerals processing, which requires higher prices for their refined and manufactured products. Projects that would break even on operating cost in a low-price environment can nonetheless

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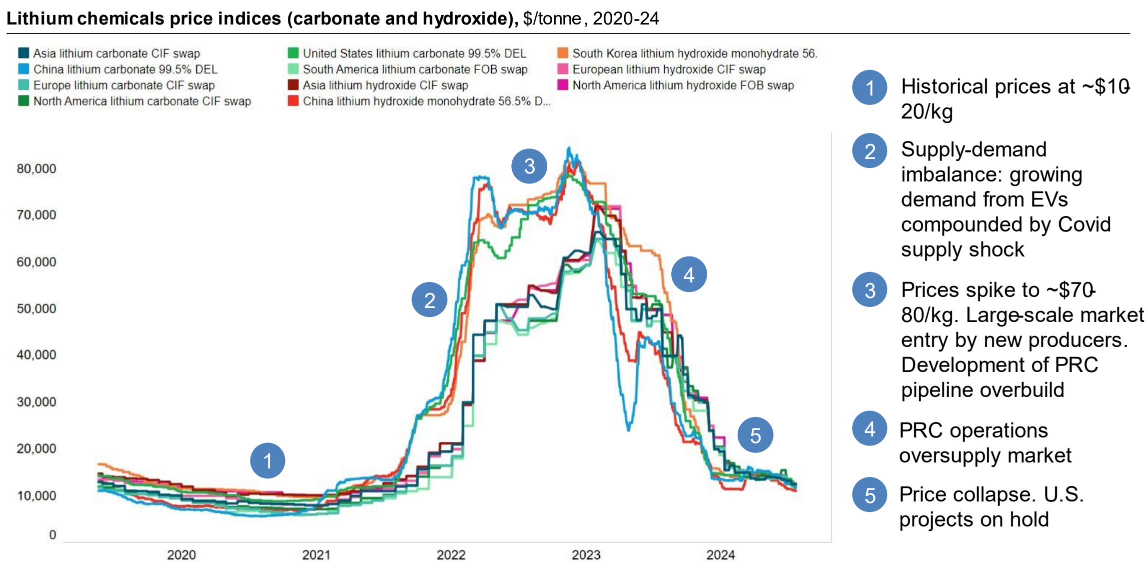
[119] *E.g.*, potential risk to domestic manufacturing from PRC export controls on graphite. Sybil Pan. "China's Jan-Feb graphite exports plunge amid export controls." Fastmarkets (2024). https://www.fastmarkets.com/insights/chinas-jan-feb-graphite-exports-plunge-amid-export-controls/.

struggle to generate sufficient margin to repay capital with a competitive return, deterring domestic investment and slowing buildout of the domestic industrial base.

(e) Market volatility and demand uncertainty

Market volatility is another major threat to the development of the domestic industrial base. Supply-demand imbalances catalyzed in part by pandemic-related disruption drove dramatic increases in price in 2022, particularly for battery minerals, but market conditions today are characterized by relative oversupply and overcapacity across much of the global supply chain, particularly driven by PRC activities. Though EV sales have continued to grow, fluctuating demand in some markets has created short-term uncertainty about future need for battery materials, with a resulting impact on prices and project development. For some key inputs, prices have fallen by as much as 80 percent since their peak in 2022, driven by uncertainty about the trajectory of the future demand ramp-up and mass-buildout of low-cost capacity by PRC firms. (As an illustrative example, Figure 5 maps price dynamics over the last four years for battery-grade lithium chemicals, showing the run-up in prices as supply tightened in 2022 and 2023, followed by a price collapse in response to softening short-term demand and oversupply by PRC operations.)

Figure 5. Recent market volatility: collapse in lithium prices



Note: Recent market volatility: collapse in lithium prices. Price data and visual from BloombergNEF (data reported through July 2024).

The resulting low-price environment has hurt the investment case for new U.S. and ex-PRC projects, causing companies to delay or cancel capacity expansions in some cases. The prospect of future volatility serves as an additional deterrent to private investors, who may now require higher returns and shorter payback periods commensurate to the perceived risk of projects operating in a market with high levels of demand and price volatility, all of which make it more difficult for domestic projects to attract capital. This dynamic is a particular challenge for projects in the early stages of commissioning and material qualification with OEMs, when their financial position is at especially high risk (discussed in more detail in challenge (g)).

(f) Immature, opaque markets

Challenges with market volatility are compounded by the relative immaturity and opacity of markets for many key battery components and inputs. Some are not listed on commodities exchanges and have no public trading price. While mature, commoditized markets offer financial instruments and other mechanisms for hedging against price volatility and risk of downcycles, markets for battery components like refined mineral products and specialty chemicals tend to be shallower and insufficiently developed for these tools and approaches to mitigating risk. Opacity also increases the difficulty of monitoring market activity and identifying potential supply–demand imbalances, including policies of overcapacity, and other related vulnerabilities.

Market data are limited for many segments of the battery supply chain, particularly midstream products like cathode and anode materials, electrolyte, and other subcomponents. Markets have limited liquidity, poor price transparency, and less mature indices and exchanges for pricing, trading, and hedging. Existing indices are largely centered on the Chinese market, and thus are particularly susceptible to price-manipulation activities. Farther downstream, products are likelier to be bespoke and non-commoditized, making it still more difficult to monitor supply and hedge against risk of disruption. These challenges have encouraged recent consideration of measures to monitor global metals markets at the Commodities Future Trading Commission.[120]

(g) First-of-a-kind project risks

Once developers secure funding, they may still face significant challenges related to project delivery for first-of-a-kind domestic operations. In the construction and commissioning stages, because the domestic industry is starting from a limited foundation, U.S. operations often rely on foreign engineering knowledge and equipment suppliers (including from the PRC) to deliver initial projects, or else they must develop their own IP at higher risk, higher cost, and on longer timelines. Compounding the challenge is the fact that companies developing projects are often smaller and new entrants in the market, with limited experience and higher delivery risk.

New operations face additional delays and related funding challenges from the need to qualify material with potential downstream customers. Suppliers must generally build a full-scale facility to undergo qualification, incurring significant upfront capital expense (on the order of hundreds of millions or billions of dollars), but may not see revenue for as much as 12 to 18 months while the qualification process is underway. Smaller, new-entrant companies are especially exposed to these pressures, as they are unlikely to have existing operations and prequalified material and, with smaller balance sheets, also struggle to secure the working capital needed to bridge extended qualification periods.

(h) Constrained workforce in key technical occupations and geographies

Both construction and ongoing operation of projects are challenged by constraints in the available workforce. Limited labor supply in key construction trades (e.g., welders, pipefitters, and electricians) can increase construction costs and timelines for domestic projects, and limited supply

[120] "CFTC's Energy and Environmental Markets Advisory Committee to Meet February 13." U.S. Commodity Futures Trading Commission (2024). https://www.cftc.gov/PressRoom/Events/opaeventeemac021324.

of skilled manufacturing labor in some regions can similarly constrain production ramp-up. Workforce challenges are compounded in cases where projects must be built in more remote areas, as is often the case for the upstream and midstream supply chain (e.g., processing facilities that must be adjacent to mineral resources).

PRIORITIES AHEAD

Four-year Resilience Goals and Priorities

Overview

More progress remains to be made, both to fully capitalize on opportunities in areas like cell manufacturing and lithium refining, and to ensure a secure and resilient supply chain for other inputs. Ensuring the large pipeline of domestic projects comes to fruition, developing strong supply chains and a resilient industrial base, and capitalizing fully on U.S. opportunities to compete and win will require a concerted effort by government, industry, investors, labor, and local communities.

However, with targeted policy and concerted action, the U.S. is well-positioned to build resilient supply chains that can deliver energy security and economic opportunity. The U.S. can capitalize on domestic strengths to build a vibrant domestic manufacturing base for advanced batteries, onshore critical supply-chain capabilities, and realize economic benefits for workers and communities, while deepening relationships with international allies and partners, leveraging complementary strengths to secure supply chains and improve economic competitiveness.

Goal 1: Stabilize markets and firm demand to backstop domestic investment

Demand and price uncertainty, particularly the risk of a persistent low-price environment driven by PRC overcapacity, are key deterrents to domestic and 'friendshored' investment in mining, refining, manufacturing, and recycling projects.

Priority action 1.1: Move towards firmer offtake commitments from industry

Firmer offtake commitments by downstream industry, particularly automotive OEMs and battery Tier 1s, can help unlock needed capital for domestic projects across the value chain.

Priority action 1.2: Provide clarity and consistent enforcement of content requirements

Clarity on and consistent enforcement of domestic and 'friendshored' content requirements can further improve the credibility of the demand signal to industry and capital markets.

Priority action 1.3: Leverage stockpiles to mitigate demand uncertainty

Stockpiling of selective critical minerals may have positive impacts including price stabilization and increased certainty for investors. These benefits are substantial and would likely play a role to enhance national security, but further engagement is needed on potential approaches and focus for stockpiling efforts. The Departments of Energy, State, and Defense have executed a memorandum of agreement formalizing an interagency partnership on stockpiling of critical minerals needed for energy technologies to advance this dialogue.[121]

[121] "U.S. Departments of Energy, State and Defense to launch Effort to Enhance National Defense Stockpile with Critical Minerals for Clean Energy Technologies." Office of International Affairs, U.S. Department of Energy (2022). https://www.energy.gov/ia/articles/us-departments-energy-state-and-defense-launch-effort-enhance-national-defense.

Goal 2: Successfully deliver first-of-a-kind domestic projects

Targeted action will be needed in the next four years to ensure domestic projects are successfully delivered and critical supply-chain capabilities successfully onshored.

Priority action 2.1: Help project developers address barriers to delivery

Developers will have to navigate challenges related to permitting, workforce constraints, and fine-tuning operations that may be active for the first time at true commercial scale. Government has a key role to play as a facilitator and partner to ensure the success of investments.

Priority action 2.2: Facilitate successful engagement with communities

Community buy-in is particularly critical for project success. Government facilitation can ensure close collaboration between project developers and community, labor, and Tribal stakeholders to ensure projects earn and maintain support and license to operate from fenceline communities.

Goal 3: Continue strengthening international partnerships to address residual gaps in the supply chain

In parts of the supply chain where the U.S. lacks critical IP or technical knowledge, faces particularly acute structural disadvantages, or has limited domestic resources (e.g., certain critical minerals), deeper international partnerships will be essential to ensure the availability of affordable and competitive ex-PRC supply. International partnerships also ensure U.S. interests continue to be represented and PRC influence does not go unchecked and unchallenged around the world.

Priority action 3.1: Continue to advance multilateral and bilateral engagement

The U.S. can build on existing multilateral and bilateral forums and relationships to deepen partnerships on supply-chain security. Forums like the Minerals Security Partnership and Net Zero World Initiative, as well as ongoing multilateral and bilateral with key allies and partners, allow for international coordination to build secure battery supply chains.

Priority action 3.2: Facilitate joint ventures for U.S. projects

For domestic projects, joint ventures allow U.S. firms to leverage partnerships on IP and ensure successful delivery. Government action can help facilitate engagement between domestic firms and international partners and can attract investment in domestic projects.

Priority action 3.3: Provide investment to scale supply chains with partners

Where other countries may be more competitively positioned, the U.S. and its partners can build shared, mutually beneficial supply chains that leverage different strengths to compete more effectively, while advancing complementary goals for economic development, integration, and security. Potential areas of focus could include refining of battery-grade nickel and cobalt chemicals, low-cost anode material, and cathode precursors, where the U.S. has limited domestic resources or may face structural headwinds to onshoring.

Goal 4: Expand pools of patient capital for projects

Patient capital is often critical for project success, especially in a low-price environment where foreign competitors often have access to cheap capital from state-backed financial institutions. Mobilizing patient capital from both public and private sources can support buildout of a domestic and "friendshored" supply chain even in the face of challenging market headwinds.

Priority action 4.1: Continue to provide low-cost financing and capital support to projects

Additional government lending and grantmaking can help unlock the business case for further supply-chain investment, improving commercial viability of projects even in the face of challenging market headwinds.

Priority action 4.2: Create conditions for strategic private investment

With firmer demand, more mature markets, and demonstrated success on first-of-a-kind projects, government action can attract additional private capital from strategic investors on more favorable terms to projects.

Priority action 4.3: Mobilize patient capital for investment in partner countries

It will be important to grow these pools of capital for projects in partner countries as well. Development finance institutions and multilateral development banks can play an important role in mobilizing capital behind projects in emerging markets, while advancing complementary objectives for economic development.[122] Coordination between government finance arms playing at different parts of the supply chain can serve as a "force multiplier" to enable project success and facilitate greater investment.[123]

Goal 5: Facilitate market maturation

The long-term health of the industrial base will benefit from a more mature market for inputs, including development of trusted indices, deep, liquid markets, and improved price-transparency—all of which can enable improved situational awareness of vulnerabilities and more effective hedging against market risk. Market maturation will be led and driven by the private sector, but government attention can help ensure the market develops favorably in the long term.

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[122] For example, the International Development Finance Corporation (DFC) has invested $55 million in nickel and cobalt mining for battery markets in Brazil. "Sourcing critical minerals to support the global clean energy transition." U.S. International Development Finance Corporation. https://www.dfc.gov/investment-story/sourcing-critical-minerals-support-global-clean-energy-transition.

[123] For example, the Department of Energy Loan Programs Office (LPO) and DFC have effectively partnered to support complementary parts of the supply chain for graphite anode, with DFC financing an upstream graphite mine in Mozambique and LPO financing a project in Louisiana to refine that mined graphite feedstock to anode-grade material. Interagency collaboration helped streamline project diligence, and funding both parts of the supply chain helps to de-risk both projects. "DFC Makes More Than $9.1 Billion in Financial Commitments for Fiscal Year 2023." U.S. International Development Finance Corporation (2023). https://www.dfc.gov/media/press-releases/dfc-makes-more-91-billion-financial-commitments-fiscal-year-2023. "LPO Offers First Conditional Commitment for Critical Materials Project for Syrah Vidalia to Support Domestic EV Supply Chain." Loan Programs Office, Department of Energy (2022). https://www.energy.gov/lpo/articles/lpo-offers-first-conditional-commitment-critical-materials-project-syrah-vidalia.

Priority action 5.1: Improve market liquidity and foster use of non-PRC market indices

Creating market liquidity as projects bring supply to market and encouraging use of trusted, U.S.-centric or non-PRC indices can help accelerate this process. Market maturation will be led and driven by the private sector, but government attention can help ensure the market develops favorably in the long term.

Goal 6: Invest in workforce development and domestic talent pipeline

The ability to build robust and resilient U.S. supply chains will also depend on a strong domestic workforce, both for construction and long-term operation of projects.

Priority action 6.1: Invest in recruitment and training

Investments in training and growing local talent pipelines will be crucial to enable project success, particularly in regions with constrained labor supply, while ensuring that economic benefits flow to fenceline communities. A coordinated approach can leverage federal and state resources, local educational and labor organizations, and industry investment for maximal result. The Department of Commerce Economic Development Administration has already invested $21 million in a Nevada Tech Hub focused on lithium-ion batteries and EV components[124] and $45 million in a South Carolina and Georgia Tech Hub focused on grid resilience (including battery energy storage systems),[125] and EDA designated another Tech Hub in New York focused on battery manufacturing.[126] The Department of Energy's Vehicle Technologies Office and Argonne National Laboratory are taking additional steps to coordinate with industry in developing a comprehensive workforce development program for battery manufacturing through the Battery Workforce Challenge.[127]

Goal 7: Support movement towards a circular economy for battery materials

A mature industry can leverage recycling and circular economy models to address residual supply gaps, further strengthen the supply chain, and improve the sustainability of U.S. operations. DOE's Office of Energy Efficiency and Renewable Energy has developed a draft strategic framework that lays out how a circular economy for batteries could be structured. Overall, RMI has estimated that recycled content could meet roughly 45 to 55 percent of U.S. demand for lithium, nickel, and cobalt

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[124] "Biden-Harris Administration's Tech Hubs Program Awards Approximately $21 Million to Nevada Tech Hub to Strengthen the Region's Capacity as a Global Leader in Lithium Batteries and Electric Vehicle Materials." U.S. Economic Development Administration (2024). https://www.eda.gov/news/press-release/2024/07/02/Nevada-Tech-Hub.

[125] "Biden-Harris Administration's Tech Hubs Program Awards Approximately $45 Million to SC Nexus for Advanced Resilient Energy in South Carolina to Strengthen the Region's Capacity as a Global Leader in Clean Energy." U.S. Economic Development Administration (2024). https://www.eda.gov/news/press-release/2024/07/02/Nevada-Tech-Hub.

[126] "New Energy New York (NENY) Battery Tech Hub." U.S. Economic Development Administration. https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs/2023/New-Energy-New-York-Battery-Tech-Hub.

[127] "Battery Workforce Challenge Programs." Argonne National Laboratory. https://www.anl.gov/taps/step/battery-workforce-challenge-programs.

by 2040.[128] As the supply of material in circulation from manufacturing scrap and end-of-life batteries grows, government and industry action can position domestic firms to capitalize on the opportunity to bring additional cost-competitive supply to market.

Priority action 7.1: Continue to support commercialization of novel recycling technologies

Government support can help deliver first-of-a-kind projects and commercialize novel, low-cost recycling technologies. DOE MESC and LPO have already selected a combined $3.5 billion of advanced recycling projects for grants and loans, helping to build the initial tranche of projects that can de-risk recycling technologies and lay the groundwork for longer-term buildout.

Priority action 7.2: Foster broader market ecosystem needed for a successful circular economy

Areas of focus can include support for necessary logistics and infrastructure, facilitating joint ventures and colocation of recycling operations with battery manufacturing clusters, and, longer term, incentives to encourage and facilitate recycling of end-of-life materials by consumers. The Department of Energy's Vehicle Technologies Office has selected $85 million of projects focused on improving the economics and logistics of transporting and processing end-of-life batteries,[129] as well as $14 million of projects to increase participation by consumers in existing battery recycling programs.[130] EPA is developing voluntary battery labeling guidelines and battery collection best practices in order to increase the number of batteries available for recycling.[131]

Goal 8: Continue to invest in R&D and commercialization of the next generation of advanced battery technologies

Traditional U.S. strengths in innovation will be vital to ensure long-term competitiveness and continuing technological leadership.

Priority action 8.1: Continue investment in R&D and commercialization

Public and private efforts can provide ongoing support to perfect and scale the next generation of advanced battery technologies, including alternative chemistries, high-performance substitute materials, novel recycling approaches, and high-efficiency, low-impact extraction, refining, and processing techniques for input materials. Government action can play a key role in accelerating progress at all stages of technology development. Public investment in basic research through DOE, DOD, the National Laboratories, National Science Foundation, and other agencies can advance foundational battery science and complement private-sector R&D efforts. Later-stage grants and loans can facilitate initial scale-up and commercialization of emerging technologies.

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[128] "Battery Circular Economy Initiative Dashboard." RMI. https://rmi.org/battery-circular-economy-initiative/resources/dashboards/?dashboard=0.
[129] "Funding Selections: Bipartisan Infrastructure Law Battery Recycling, Reprocessing, and Battery Collection Funding Opportunity." U.S. Department of Energy. https://www.energy.gov/eere/vehicles/funding-selections-bipartisan-infrastructure-law-battery-recycling-reprocessing-and.
[130] "Biden-Harris Administration Announces Nearly $45 Million to Slash Electric Vehicle Battery Recycling Costs." U.S. Department of Energy (2024). https://www.energy.gov/articles/biden-harris-administration-announces-nearly-45-million-slash-electric-vehicle-battery.
[131] "Battery Collection Best Practices and Battery Labeling Guidelines." U.S. Environmental Protection Agency. https://www.epa.gov/infrastructure/battery-collection-best-practices-and-battery-labeling-guidelines.

Priority action 8.2: Continue to pursue international partnerships on advanced battery science and technology

Deeper international partnerships on science and technology, particularly with nations that have their own robust advanced battery ecosystems, can help further speed development, commercialization, and deployment of advanced technologies across friendly markets.

Priority action 8.3: Pursue policies that are technology-agnostic and preserve a competitive marketplace

The federal government can pursue technology-agnostic policies and affirmatively fund and scale multiple technologies to create a market environment that preserves competition and enables the emergence and scale-up of the next-generation of advanced batteries.

Conclusion

As batteries continue to grow in importance to the global energy system, diversifying and strengthening supply chains will be both critical for energy security and a significant opportunity for the U.S. economy and international cooperation. Building battery supply chains can strengthen the U.S. economy, create opportunities for American workers, and deepen U.S. ties with likeminded partners around the globe.

CASE STUDIES

Cell Manufacturing

The U.S. is onshoring substantial capacity for downstream cell manufacturing, operations that account for much of the value-add in finished batteries and serve as 'anchor tenants' for the rest of the supply chain. Domestic cell capacity is scaling rapidly, supported by strong underlying economics and a robust policy regime. Announced U.S. projects represent $94 billion in potential investment, supporting more than 62,000 manufacturing jobs. These projects would provide more than 1,100 GWh of annual cell manufacturing capacity by 2030, enough to meet demand from 50-percent EV penetration of light-duty vehicle sales and expected scale-up of stationary storage, with hundreds of GWh of residual capacity for other uses and potential export. In total, the U.S. and ex-PRC pipeline could meet 100 percent of ex-PRC demand, with U.S. production potentially increasing 18-fold from 2021 to 2030 (Figure 6). Though not all announced projects are likely to come to fruition and a haircut is expected on ultimate capacity additions, projects representing roughly 690 GWh per year of capacity are already active or under construction, and the robust project pipeline is indicative of strong tailwinds for this portion of the industrial base.

This domestic pipeline includes a mix of established tier 1 suppliers, including experienced Korean and Japanese battery majors that can leverage existing IP to accelerate development while deepening ties with key partners and allies, as well as new entrants bringing domestically developed technologies to market at scale. The largest projects are often joint ventures between tier 1s and automotive companies, with closely integrated technical partnerships and cell specifications tailored to meet the unique requirements of each OEM and vehicle model. Smaller operations may be focused on scaling novel technologies or meeting demand from niche, high-performance markets.

Onshoring of cell production is undergirded by a strong competitive advantage on unit economics. With production tax credits and recent tariff modifications, domestic manufacturers of nickel-manganese-cobalt (NMC) batteries could have a landed-cost advantage of 45 percent or more relative to foreign competitors. Figure 8 provides a more detailed breakdown of estimated U.S. vs. PRC production costs.[132] At baseline, U.S. manufacturers likely operate at a premium relative to Chinese production due to lower costs of labor, capital, and other inputs, but the policy regime has offset this disadvantage to create a level playing field. At $35/kWh, the 45X production tax credit for cell manufacturing can offset the conversion cost (operating cost net of materials) for cell production and the cost to repay invested capital with a healthy return, providing an advantage over competitors.[133] In some cases, projects have also been supported by direct federal investment, including $12.5 billion in closed and conditionally committed loans from the Department of Energy Loan Programs Office, focused on large-scale joint ventures between established battery majors and American automotive OEMs, and $450 million in announced selections from the Department of Energy Office of Manufacturing and Energy Supply Chains, focused on commercializing and scaling

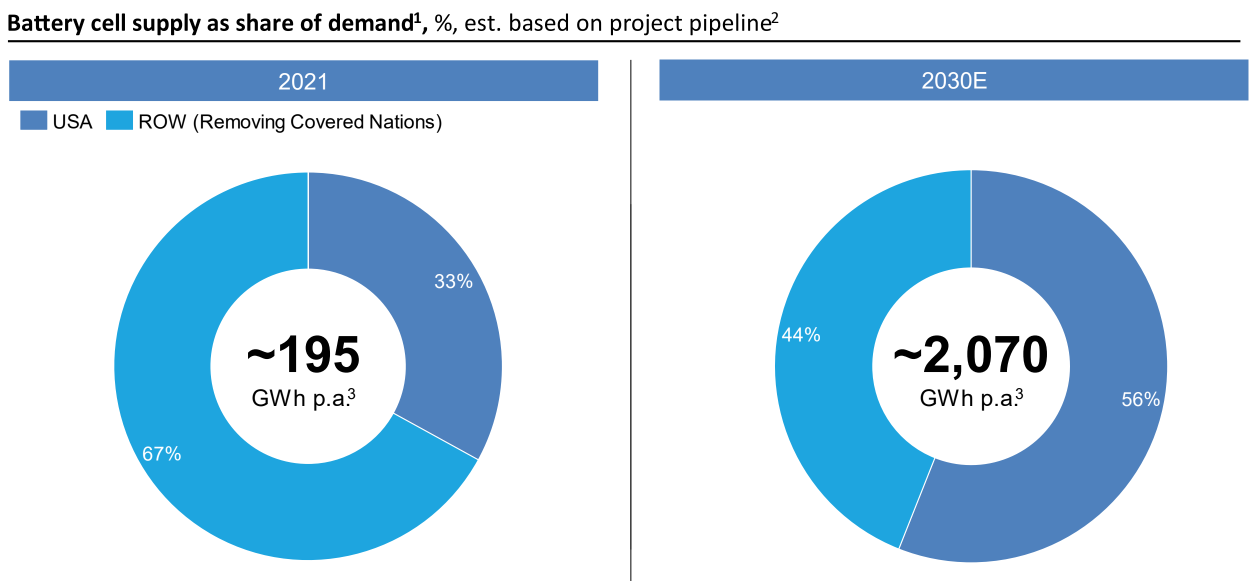
[132] Bottom-up cost estimate based on Argonne National Laboratory 'BatPaC' cost model, including power, labor, materials, other operating costs, and capital recovery. Discussed in Figure 8. "BatPaC: Battery Manufacturing Cost Estimation." Argonne National Laboratory. https://www.anl.gov/partnerships/batpac-battery-manufacturing-cost-estimation.

[133] Modeling based on cost analysis from BloombergNEF suggests potential for a similar cost advantage for U.S.-made lithium-iron-phosphate battery cells, which are generally cheaper to produce and thus see a proportionally greater impact from the production tax credit. Source: BloombergNEF "Bottom-Up Battery Cost Model" ("BattMan 3.1.0"), DOE analysis of representative capital recovery scenarios and potential impact of 45X tax credit.

manufacturing of novel technologies for high-performance and long-duration stationary storage markets.

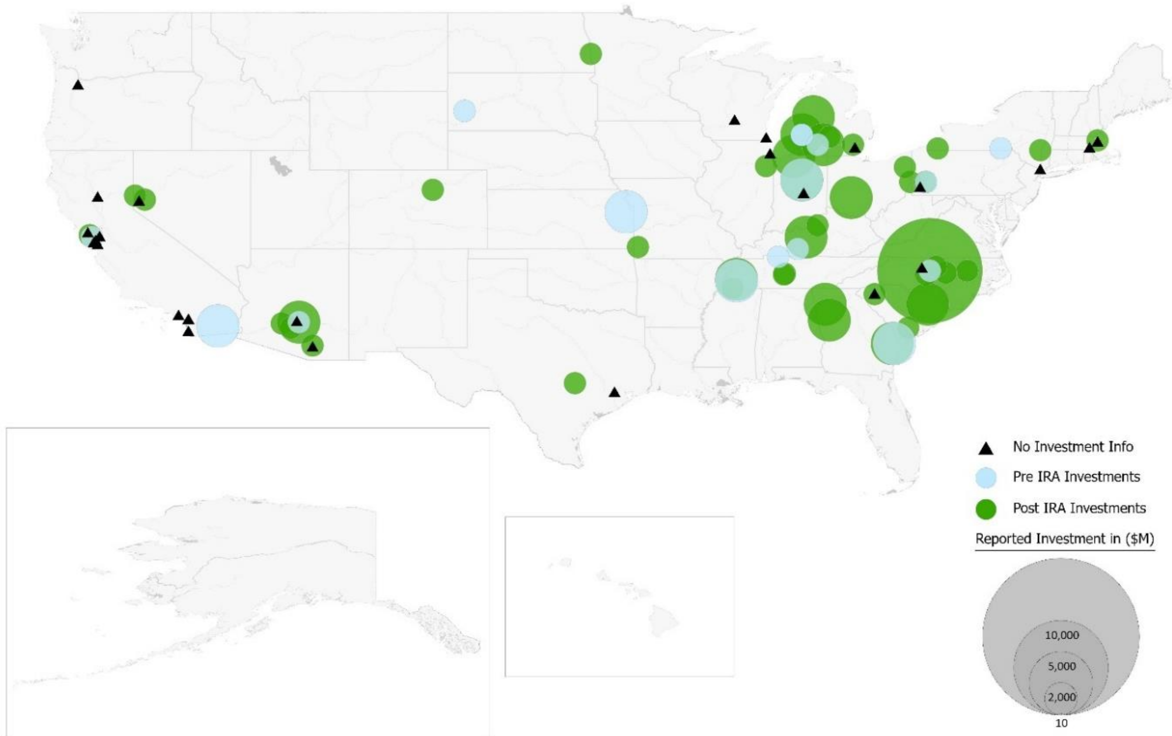
Regional clusters are forming where there is proximity to critical infrastructure and labor. Projects have generally been drawn to areas that offer access to low-cost power and short timelines to interconnect, a ready supply of trained labor, and cost-efficient logistics like rail and water transport. Developers cite affordable and abundant power supply as a particularly critical enabling factor, as well as strong workforce development programming by state and local authorities. Clusters are forming in the Southeast, catalyzed by ready access to power and labor, the Midwest, leveraging existing automotive and battery manufacturing infrastructure, and the Southwest, where there is an existing gigafactory presence (see Figure 7).

Figure 6. Improving supply chain resilience for cell manufacturing



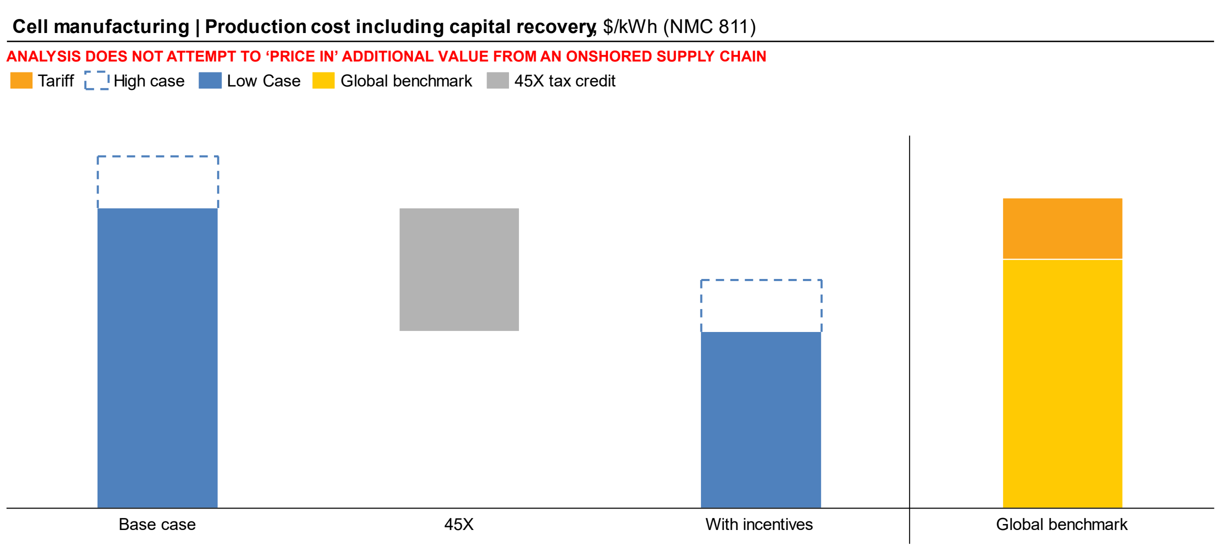
Note: Improving supply-chain resilience for cell manufacturing, measured by battery cell supply share of demand for market outside covered nations. Notes: 1. Representing globally available supply, adjusted to remove PRC supply net of PRC domestic demand (assuming PRC domestic demand is met out of domestic supply). 2. Project pipeline is based on tracked projects operating, announced, and under construction. 3. Figure represents global demand for battery cells, adjusted to remove PRC demand. Sources: DOE internal project data, Argonne National Laboratory, BloombergNEF project trackers.

Figure 7. project map, cell manufacturing



Source: U.S. investments in battery cell manufacturing projects. Source: Energy.gov/invest. As of Dec. 2024.

Figure 8. Representative unit economics, cell manufacturing



Note: Representative unit economics for cell manufacturing (NMC 811). Bottom-up cost estimate based on Argonne National Laboratory "BatPaC" Battery Manufacturing Cost Model, including power, labor, materials, other operating costs, and capital recovery. 'High' and 'low' scenarios reflect different assumptions for capital recovery (high vs. low benchmarks for capital intensity, hurdle rate, and payback period). 45X impact modeled as $35/kWh reduction in cost. 'Global benchmark' is based on estimated PRC-centric costs, with the addition of estimated freight cost and 25-percent tariff to reflect landed cost of imported material. To isolate the cost of the cell manufacturing step (i.e., conversion), materials for both U.S. and global benchmark estimates are assumed to be procured at global commodity prices; with domestic sourcing of materials, base case cost of cell manufacturing may be higher.

Challenges remain for the domestic cell industry to navigate: Uncertainties about the exact timing and trajectory of the demand ramp-up could lead to investment being delayed or project aspirations being scaled back in the short and medium term. Many cell producers are additionally looking to adopt lower-cost lithium-iron-phosphate chemistries already widely used by PRC manufacturers and being commercialized in other countries as well. But onshoring and scaling this technology will likely require joint ventures or additional investment to develop new IP with a significant learning curve to ramp production of a less-familiar chemistry. The scale of the buildout could also strain local labor and power markets, as projects have significant power demand and can employ thousands of skilled manufacturing workers.[134] The federal government is working across agencies and in collaboration with state and local authorities to identify potential bottlenecks and proactively target mitigations. Despite these challenges, U.S. firms enjoy a strongly supportive ecosystem and are well-positioned to compete in battery cell production as the market continues to develop.

Lithium Refining

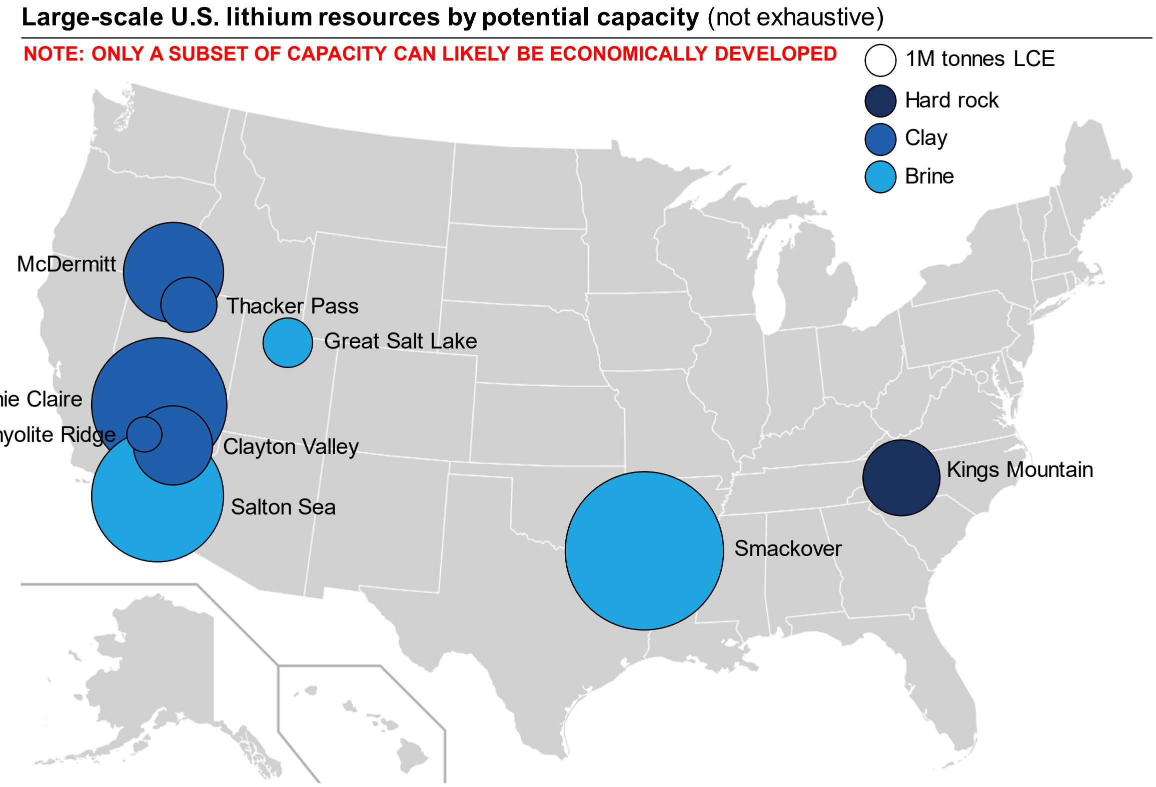
Lithium extraction and refining are other areas of the supply chain where the U.S. is well-positioned to compete given its substantial lithium reserves, and firms are taking the first steps towards building a robust domestic industrial base.

The U.S. has massive domestic lithium resources and reserves, potentially enough to supply tens of millions of EV batteries per year and meet domestic demand several times over (Figure 9). These resources fall into three categories:

- The U.S. has some but more limited "hard-rock" spodumene mineral deposits from which lithium can be extracted and processed to battery-grade chemicals by conventional, widely used means.
- The U.S. has larger resources and reserves in 'unconventional' clay and brine deposits that can be unlocked at competitive cost by scaling novel extraction and processing routes like direct lithium extraction (DLE). Initial deployments may come with scaling risk as technologies are fine-tuned for the unique conditions of U.S. clay and brine deposits, but successful commercialization and scale-up of these approaches is a massive opportunity to unlock domestic supply. The U.S. has additional shallow brine resources that can be extracted by 'conventional' means of evaporation.
- Finally, advanced recycling techniques can allow for recovery of lithium in waste cathode material from manufacturing scrap or end-of-life batteries (This category is discussed in less detail here given its earlier stage of development and limited immediate supply potential, but the U.S. Department of Energy is making significant investments in first-of-a-kind domestic operations to commercialize and scale these technologies.)

[134] E.g., the Department of Energy-supported [Ultium Cells] and [Blue Oval SK] projects could create a total of 12,600 operations jobs across six facilities. "Ultium Cells." Loan Programs Office, U.S. Department of Energy. https://www.energy.gov/lpo/ultium-cells. "LPO Announces Conditional Commitment for Loan to BlueOval SK to Further Expand U.S. EV Battery Manufacturing Capacity." Loan Programs Office, U.S. Department of Energy. https://www.energy.gov/lpo/articles/lpo-announces-conditional-commitment-loan-blueoval-sk-further-expand-us-ev-battery.

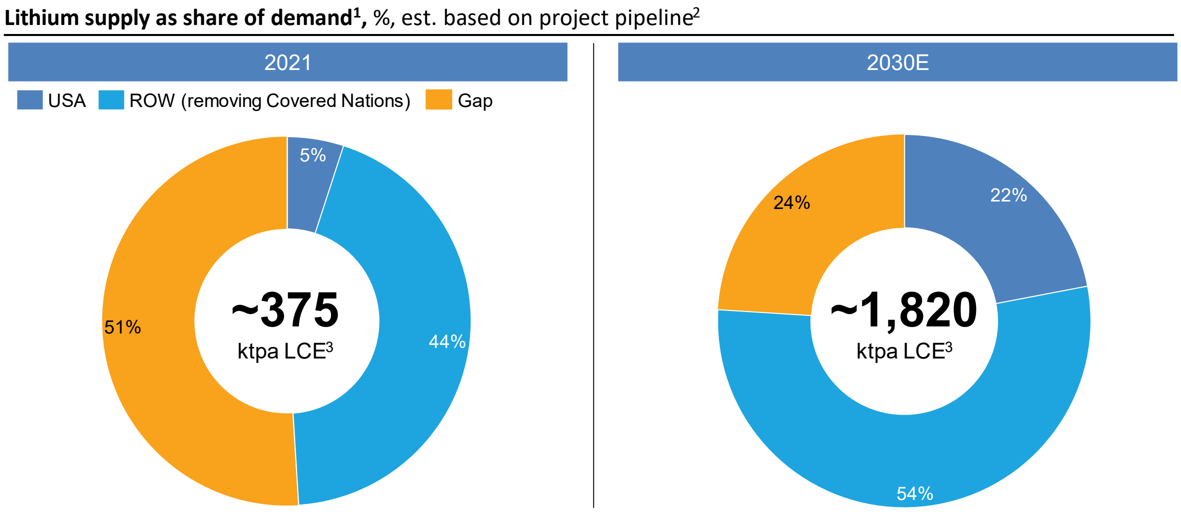
Figure 9. Large-scale U.S. lithium deposits



Note: Illustrative view of large-scale U.S. lithium deposits (not exhaustive of all domestic deposits). Includes measured, indicated, and inferred resources and reserves. Projects and deposits are in various stages of development. Many are pre-production. Only a subset of capacity can likely be economically developed.

A pipeline of domestic projects is developing to tap these resources, including first-of-a-kind deployments to extract and refine lithium from unconventional brine and clay resources, scaling production on domestic hard rock deposits, and first-of-a-kind advanced recycling operations. Active, under construction, and announced projects could meet roughly 50 percent of potential U.S. demand in 2030, and, if fully realized, the overall pipeline of ex-PRC lithium projects could reduce dependence on PRC from 51 percent in 2021 to 24 percent by 2030, even as demand increases by nearly five-fold (Figure 10), while further development of U.S. resources and reserves could support far more than the capacity expansion that would be required to meet remaining domestic demand.

Figure 10. Improving supply chain resilience for lithium extraction and refining



Note: Improving supply-chain resilience for lithium extraction and refining, measured by refined lithium supply share of demand for market outside covered nations. Notes: 1. Representing globally available supply, adjusted to remove PRC supply net of PRC domestic demand (assuming PRC domestic demand is met out of domestic supply). 2. Project pipeline is based on tracked projects operating, announced, and under construction. 3. Figure represents estimated global demand for refined lithium, adjusted to remove PRC demand. Sources: DOE internal project data, Argonne National Laboratory, BloombergNEF project trackers.

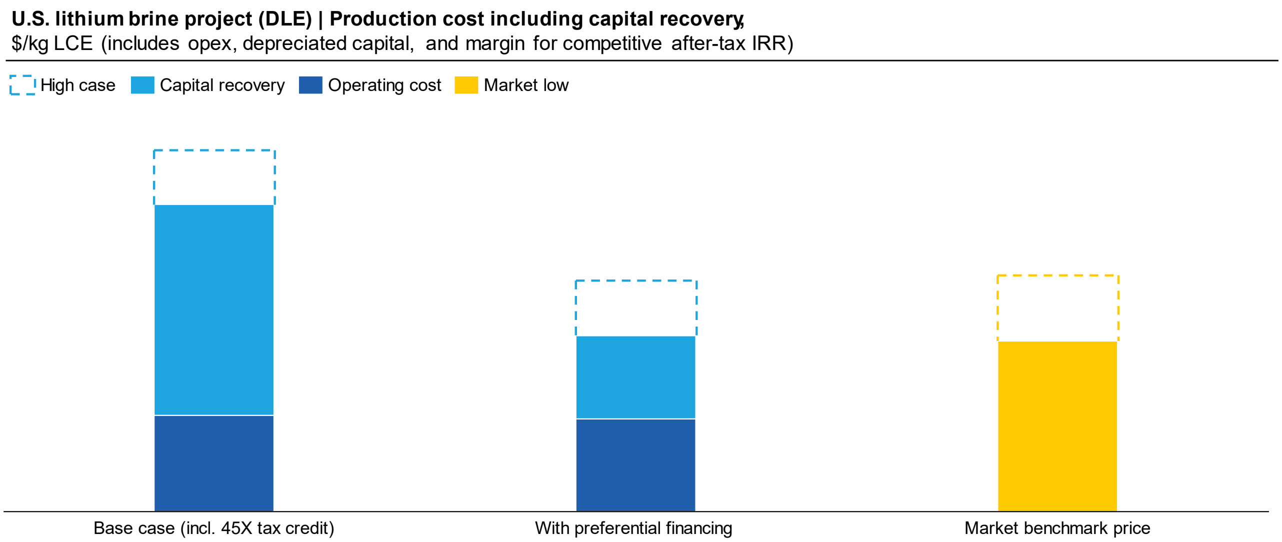
Although U.S. projects today can appear economically challenged relative to competitors, they have a pathway to compete. Figure 11 shows the potential unit cost buildup for a representative brine project using DLE, with the impact of potential levers to improve economics. Projects could be highly competitive on operating cost, potentially in the first and second quartiles of the global cost curve. Brine and clay projects can achieve extremely low operating costs per metric ton of refined lithium through novel approaches like DLE, once initial technology and scaling risk are addressed, and, for some projects, monetization of byproducts. Though cost positioning for hard-rock operations can be challenging, they can achieve meaningful cost reductions and more competitive positions in the cost curve through vertical integration with mining assets.

The primary challenge on the unit economics of domestic lithium projects is capital cost. U.S. projects are highly capital intensive, and the current low-price environment makes it difficult for projects to repay upfront capital quickly and with the high return expected by traditional mining and minerals investors. In contrast, competing PRC developers benefit from lower upfront capital costs, a function of cheap land, reduced construction costs both at baseline and from learning effects realized in a mature, experienced industry, as well as from access to cheap debt and other investment from state-owned and low-cost capital providers.

To unlock development, projects can build a capital stack that includes more patient capital, from investors that are willing to accept longer payback periods and more modest returns. Potential sources of this kind of capital include government debt and grants—which are particularly important for higher-risk first-of-a-kind deployments—and strategic investment from large-balance-sheet majors, including through joint ventures with end customers like automotive OEMs and players in 'adjacent' industries like oil and gas—which have the advantage of being able to secure lower-cost private debt for projects. With more patient capital in the mix, projects can likely deliver a competitive return to investors even at prices in the current range of $10–15/kg (see the "With preferential financing" scenario in Figure 11).

The federal government has been stepping forward to provide this low-cost capital to enable an initial tranche of projects. The Department of Energy Loan Programs Office has closed a loan for $2.26 billion to Lithium Americas' Thacker Pass and conditionally committed $700 million to Ioneer's Rhyolite Ridge, two large-scale clay projects that can help validate the commercial viability of substantial lithium resources in Nevada. The DOE Office of Manufacturing and Energy Supply Chains has similarly announced selection of two brine projects in the Smackover formation, one developed by TerraVolta Resources and the other by Standard Lithium and Equinor, to receive $450 million in grants. Successful delivery of these initial projects can eventually help unlock significant scale-up in the 2030s as the first set of projects add capacity at existing sites and the validation of their approaches catalyzes follow-on project development with support from strategic private investment.

Figure 11. Illustrative cost breakdown, lithium processing operation



Note: Illustrative cost breakdown for a U.S. lithium processing operation (brine DLE). Range of operating costs estimated based on third-party benchmarking of U.S. DLE brine projects and assuming 10-percent reduction in estimated eligible costs from the 45X production tax credit for minerals processing. Capital recovery is based on range of published capex figures for domestic projects, with representative financing scenarios. 'Base case' estimates margin needed for 20-percent after-tax IRR with 5-year payback period to approximate expectations of a traditional mining investor. 'With preferential financing' reflects a set of scenarios that assume additional support from federal grants, low-cost federal loans, and more patient private capital, significantly reducing the margin needed for capital recovery. 'Market benchmark price' reflects the range of prices currently observed in the market.

2021–2024 Four-year Review of Supply Chains for Critical Minerals

U.S. DEPARTMENT OF THE INTERIOR

U.S. DEPARTMENT OF COMMERCE

U.S. DEPARTMENT OF DEFENSE

U.S. DEPARTMENT OF ENERGY

U.S. DEPARTMENT OF STATE

U.S. DEPARTMENT OF THE TREASURY

U.S. ENVIRONMENTAL PROTECTION AGENCY

NATIONAL SCIENCE FOUNDATION

U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

DECEMBER 2024

EXECUTIVE SUMMARY

Over the past several decades, demand for technologies that are faster, cleaner, smaller, lighter, and smarter has greatly increased the need for mineral commodities. Industries that use minerals—such as clean energy infrastructure, electric vehicles, aerospace, defense, and electronics—are essential to national security and the clean energy transition.

In 2021, Executive Order 14017's 100-day Supply Chain Review concluded that over the last sixty years, as demand for what would become known as critical minerals increased, U.S. production and processing declined, and global production and processing became increasingly concentrated in fewer countries. During the period from 2021 to present, the Biden–Harris Administration has deployed historic new funding, authorities, and incentives to reduce supply chain risks and vulnerabilities. These investments in increasing resilience have enabled the nation to weather more recent shocks and disruptions to critical mineral supply chains without significant impacts to the national economy.

The 100-day Supply Chain Review and subsequent One-year Review identified three thematic areas for federal investments in critical mineral supply chain resilience: (1) building capacity for domestic production of critical minerals and strengthening U.S. stockpiles, (2) fostering sustainable and transparent critical mineral supply chains, including by expanding options for recycling and recapture of minerals waste, as well as manufacturing scrap and end-of-life products, and promoting high sustainability standards with allies and (3) identifying supply chain vulnerabilities and working with industry, allies, and partners to reduce supply risk.

There has been historic progress since 2021 in all three of these areas, leading to increased critical mineral supply chain resilience. Multiple facilities are now in operation to recover or recycle critical minerals. Since 2021, the United States has advanced trade partners' capacity and experience in recycling critical minerals, increasing the availability of sustainably produced materials and goods in the global marketplace. Additionally, since 2021, U.S. agencies have significantly advanced methods for identifying supply chain vulnerabilities through the development and use of the 2022 List of Critical Minerals. Multiple government agencies have made direct and indirect investments that are increasing domestic supply and processing capabilities in the critical minerals sector.

However, more remains to be done, both within and outside the U.S. Government, to ensure robust and resilient mineral supply chains. There are still vulnerabilities to be addressed in areas such as trade concentration, supplier diversity, and domestic capacity. The significant progress related to labor standards and transparency of supply chains needs to be continued. Over the next four years, increased threats due to export barriers or controls from other countries, as well as rapidly increasing demand for critical minerals may challenge our ability to meet the needs of the clean energy transition as well as national security objectives and consumer products demand.

Three goals are outlined to reduce the risks associated with the four-year outlook: 1) increasing sustainable production of critical minerals in the United States, 2) doubling domestic recycling and reprocessing of critical minerals from waste or mine tailings, and 3) working with partners to develop high standard markets for critical minerals. Achieving these goals will lead to a robust and sustainable U.S. minerals sector that not only meets the demands of emerging technologies but also promotes secure access for all sectors to the essential raw materials needed for innovation and growth.

SECTOR OVERVIEW

Introduction

Minerals are the foundation of all modern economies. Industries that rely heavily on critical minerals—such as clean energy production, storage, and transmission; electric vehicles; aerospace; defense; and electronics—are essential to national security and the clean energy transition. As described in the Mineral Commodity Summaries 2024,[135] these and other industries that use nonfuel mineral materials contributed $3.84 trillion to the U.S. economy in 2023[136] (14 percent of U.S. GDP). Combined, the U.S. nonfuel mineral industry, including mining and processing of raw materials and recycling, employed approximately 1.32 million workers across all 50 States as of 2023. In 2023, the U.S. was a net exporter of raw mineral materials and a net importer of processed mineral materials.

This sector focuses on minerals and materials identified as critical under the Energy Act of 2020[137] and the Strategic and Critical Materials Stock Piling Act.[138] The determination of criticality is a mechanism to monitor mineral supply chains through repeated assessments of risk and resilience, based on factors that include the potential for supply chain disruption, the economic impact of disruption, and global trade exposure. In 2023–2024, the imposition of a series of export controls by foreign producers has illustrated the vulnerability of these critical minerals' supply chains to disruption through coercive action.

Evolution of the Sector through 2020

Over the past several decades, demand for technologies that are faster, smaller, lighter, and smarter has greatly increased the need for mineral commodities. For example, today's mobile phone is a pocket-sized, touch-sensitive, wireless computer that contains lithium and cobalt in the battery, tantalum in its capacitors, and germanium and gallium in the microchips. High-strength alloys such as aluminum-lithium have made aircraft lighter and more fuel efficient. Superalloys incorporating cobalt, rhenium, tantalum, and hafnium allow jet turbines to operate at higher temperatures, also reducing fuel consumption. Technological innovations such as these, combined with the energy transition and infrastructure reinvestment, are increasing demand for a broadening range of mineral commodities.[139]

Modern mineral supply chains are complex and global. They run from geologic exploration through mining, processing, manufacturing and assembly into products, followed by recycling of waste materials and products at the end of their use. In 2020, the Energy Act provided a whole-of-government, cross-sectoral definition of a critical mineral. In 2021, Executive Order 14017's 100-day Supply Chain Review concluded that, over the last sixty years, as demand for critical minerals

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[135] USGS 2024, *Mineral Commodity Summaries 2024*, https://pubs.usgs.gov/periodicals/mcs2024/mcs2024.pdf.
[136] USGS, "USGS Releases Mineral Commodity Summaries 2024, finds US Mineral Production Jumped 4 billion to exceed 105 billion dollars", Technical Announcement, January 31, 2024, https://www.usgs.gov/news/technical-announcement/usgs-releases-mineral-commodity-summaries-2024-finds-us-mineral.
[137] The Energy Act of 2020, in *H.R.133 - 116th Congress (2019-2020): Consolidated Appropriations Act, 2021,* Congress.gov, "" December 27, 2020. https://www.congress.gov/bill/116th-congress/house-bill/133.
[138]The Strategic and Critical Materials Stock Piling Act, Strategic and Critical Materials Stock Piling Act Amended through FY2024.pdf
[139] USGS Mineral Commodity Summaries 2024 Figure 2.

increased, U.S. production and processing declined, and global production and processing became increasingly concentrated in fewer countries. In 1954, the United States was at least 25 percent reliant on imports for 21 mineral commodities.[140] By 2019 that number had risen to 58 mineral commodities,[141] including 48 on the current List of Critical Minerals.[142]

Key Sector Trends from 2021 to Present

The past four years have seen unprecedented shocks to mineral supply chains, including disruption of titanium and other critical mineral supplies in the aftermath of Russia's invasion of Ukraine;[143] China's imposition of export controls on supplies of antimony, gallium, germanium, and graphite;[144] market shocks such as the London Metal Exchange cancellation of $12 billion in nickel trades;[145] and dramatic disruptions to global supply chains during the COVID-19 pandemic.[146] Impacts included shipment delays, price volatility, stock drawdowns, and unmet demand, and were felt throughout the entire supply chain. These shocks are occurring during a time of increasing global demand for critical minerals.[147] For example, by 2030, the International Energy Agency projects a doubling or tripling of global demand for minerals critical to clean energy technologies.[148]

During this period, the Administration has deployed historic new funding, authorities, and incentives to reduce supply chain risks and vulnerabilities. Executive Order 14017 drove an early response to supply chain turbulence, creating a crucial focus on critical minerals including rare earth elements. The Bipartisan Infrastructure Law (BIL) invested over $9 billion in critical mineral supply chains, and the Inflation Reduction Act's (IRA) tax incentives reenergized domestic critical mineral production, processing, and manufacturing. The CHIPS and Science Act invested $52 billion in the domestic semiconductor industry.[149] Multiple uses of the Defense Production Act have supported crucial critical minerals facilities, such as for efforts to diversify the nation's supply of rare earth

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140 Fortier, S.M., DeYoung, J.H.J., Sangine, E., and Schnebele, E.K., 2015, "Comparison of U.S. net import reliance for nonfuel mineral commodities—A 60-year retrospective (1954–1984–2014)",*U.S. Geological Survey* Fact Sheet *2015-3082,* 4p, http://dx.doi.org/10.3133/fs20153082.

141 U.S. Geological Survey, 2020, *Mineral commodity summaries 2020*, U.S. Geological Survey, 204 p, https://doi.org/10.3133/mcs2020

142 USGS, "U.S. Geological Survey Releases 2022 List of Critical Minerals", National News Release, February 22, 2022, https://www.usgs.gov/news/national-news-release/us-geological-survey-releases-2022-list-critical-minerals

143 U.S. Department of the Treasury, "Targeting Key Sectors, Evasion Efforts, and Military Supplies, Treasury Expands and Intensifies Sanctions Against Russia", Press Releases, February 24, 2023, https://home.treasury.gov/news/press-releases/jy1296

144 "China's Curb on Exports of Strategic Minerals", Reuters, August 15, 2024, https://www.reuters.com/markets/commodities/chinas-curbs-exports-strategic-minerals-2024-08-15/

145 Sam Tobin, Eric Onstad and Pratima Desai," LME cancelled nickel trades to "save" Tsingshan, London court told" Reuters, June 20, 2023,https://www.reuters.com/markets/commodities/lme-cancelled-nickel-trades-save-tsingshan-london-court-told-2023-06-20/#:~:text=The%20London%20Metal%20Exchange%20cancelled%20%2412%20billion%20worth,the%20exchange%20told%20London%27s%20High%20Court%20on%20Tuesday.

146 U.S. Geological Survey, *Mineral Commodity summaries 2023: U.S. Geological Survey*https://pubs.usgs.gov/periodicals/mcs2023/mcs2023.pdf

147 "Critical minerals demand has doubled in the past five years- here are some solutions to the supply crunch" World Economic Forum, May 16, 2024, https://www.weforum.org/agenda/2024/05/critical-minerals-supply-crunch-iea/

148 IEA, "Global Critical Minerals Outlook", IEA, https://www.iea.org/reports/global-critical-minerals-outlook-2024/outlook-for-key-minerals

149 "Funding Updates", NIST, September 27, 2024, https://www.nist.gov/chips/funding-updates

elements. DOE has allocated $4.8 billion to projects promoting battery manufacturing, processing, and recycling,[150] and can provide additional financial support through the Loan Programs Office.[151]

Coordinated through the Critical Minerals Subcommittee (CMS) of the National Science and Technology Council, these historic investments have revitalized materials research for next-generation energy production and storage; modernized mapping of the nation's critical mineral resources both still in the ground and in mine waste; strengthened strategic trade relationships; reexamined permitting procedures for both efficiencies and sustainable outcomes; and established fundamental underpinnings to the sector, including the supply chain analysis needed to prioritize all of these efforts as well as the workforce and educational pipelines required for a modern critical minerals supply chain. These investments in increasing resilience have enabled the nation to weather recent supply chain shocks and disruptions without long-term impacts to the national economy.

[150] "Bipartisan Infrastructure Law: Battery Materials Processing and Battery Manufacturing Recycling Selections", Department of Energy, 2024, https://www.energy.gov/mesc/bipartisan-infrastructure-law-battery-materials-processing-and-battery-manufacturing-recycling.
[151] "Critical Materials Projects", Department of Energy, https://www.energy.gov/lpo/critical-materials-projects.

PROGRESS TO DATE

One-year Review Priorities

The 100-day Supply Chain Review[152] and subsequent One-year Reviews[153] focused federal investments in critical mineral supply chain resilience on: (1) building capacity for domestic production of critical minerals and strengthening U.S. stockpiles, (2) fostering sustainable and transparent critical mineral supply chains, including by expanding options for recycling and promoting high sustainability standards with allies, and (3) identifying supply chain vulnerabilities and working with industry, allies and partners to reduce supply risk. These areas have seen tremendous progress since 2021 and remain central priorities even as the state of critical mineral supply chains continues to evolve.

Progress from 2021 to Present

Since 2021, significant progress has been made towards increasing critical mineral supply chain resilience. Particular progress has been made in domestic capacity through mapping the nation's critical mineral potential and decreasing the challenges of mine permitting and development; in sustainable supply chains by expanding critical mineral recycling capacity and bolstering the recapture of minerals from mine waste and in reducing supply risk by strengthening partnerships with industry and allies and expanding supply chain forecasting models to target investments in resilience. From 2020 to 2023, net reliance on imports has decreased for 8 of the 50 commodities on the whole-of-government List of Critical Minerals.[154]

1) **Building capacity for sustainable domestic production of critical minerals and strengthening U.S. stockpiles**

1.a Mapping the Nation's Critical Minerals

In 2019, only one percent of the United States had modern mapping of buried mineral deposits. As of 2024, accelerated by BIL funding, the Department of the Interior (DOI) U.S. Geological Survey (USGS) Earth Mapping Resources Initiative (Earth MRI) has remapped over one-third of the nation's subsurface, and launched mapping of critical minerals in mine waste in 16 states. Earth MRI has identified previously unknown deposits of minerals critical to energy storage, including rare earth elements and cobalt. In addition, Earth MRI's state partnerships are rebuilding the domestic minerals workforce. Multiple State Geological Surveys are receiving new funding from their state legislatures, reopening their energy and minerals divisions, learning new techniques in their fields, and providing students mapping, teaching, laboratory, and field opportunities that develop geoscience skills. Furthermore, the Bureau of Ocean Energy Management's National Offshore

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[152] "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth", The White House, June, 2021, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[153] "Executive Order on America's Supply Chains: A Year of Action and Progress", The White House Washington, https://www.whitehouse.gov/wp-content/uploads/2022/02/Capstone-Report-Biden.pdf

[154] U.S. Geological Survey, *Mineral Commodity summaries 2023: U.S. Geological Survey,* https://pubs.usgs.gov/periodicals/mcs2023/mcs2023.pdf

Critical Minerals Inventory project is collaborating with USGS and the National Oceanic and Atmospheric Administration to map, explore, and characterize portions of the federal seabed that contain accessible critical mineral resources.

BIL funding is also introducing innovative new techniques to critical minerals mapping. The USGS, the Defense Advanced Research Projects Agency, and the Advanced Research Projects Agency–Energy have leveraged monetary prizes and artificial intelligence "hackathons" to accelerate mapping of the nation's critical mineral resources by 10-fold, with a goal to ultimately accelerate by 100-fold.

1.b Expanding Domestic Production and Processing

Domestic production and processing capacities are being supported by both commercial and government initiatives. In 2022, the IRA established a new Advanced Manufacturing Production Credit (45X), enabling the tax system to incentivize the domestic production of components used in renewable energy generation, storage, and related manufacturing. The tax credit is available to domestic producers of a variety of critical minerals produced in the U.S. In October 2024, the Department of the Treasury and the IRS issued final rules for the Advanced Manufacturing Production Credit that will accelerate the build-out of domestic critical minerals supply chains. The final rule provides clarity that domestic processors of Applicable Critical Minerals can now count indirect and direct material costs (as well as upstream mining conducted by the same taxpayer) when claiming the 45X tax credit.

In addition, Department of Defense (DoD) funding has bolstered domestic capacity, including supporting separation and processing of heavy rare earth elements. DoD funding has also developed a new domestic capability to manufacture magnets made with rare earth elements and helped to increase titanium powder production for defense supply chains. These actions and facilitation by SelectUSA, housed at the Department of Commerce (DOC), have attracted foreign companies to make significant critical minerals investments in the U.S. DoD investments in mining projects through the Defense Production Act Investment (DPAI) program continue and expand support for domestic production of critical minerals and are helping to build resilient supply chains.[155]

In 2023, the Department of Energy's (DOE) Loan Programs Office (LPO) made commitments to projects at Thacker Pass[156] and Rhyolite Ridge[157] to advance domestic production and processing of lithium and boron and strengthen the U.S. battery supply chain. BIL also funded $6 billion in battery manufacturing and recycling grants through DOE to support battery material manufacturing and recycling capability.[158] Also, in 2023 the board of the Export–Import Bank of the United States (EXIM) approved a $4.7-million direct loan to a small business to support expansion of their

[155] "Announcements", Industrial Base Policy, https://www.businessdefense.gov/ibr/mceip/dpai/dpat3/announcements.html.

[156] "LPO Announces Conditional Commitment to Lithium Americas Corp. to Help Finance the Construction of a Lithium Processing Plant in Nevada | Department of Energy", Department of Energy, March 14, 2024, https://www.energy.gov/lpo/articles/lpo-announces-conditional-commitment-lithium-americas-corp-help-finance-construction.

[157] "LPO Announces Conditional Commitment to Ioneer Rhyolite Ridge to Advance Domestic Production of Lithium and Boron, Boost U.S. Battery Supply Chain | Department of Energy", Department of Energy, January 13, 2023, https://www.energy.gov/lpo/articles/lpo-announces-conditional-commitment-ioneer-rhyolite-ridge-advance-domestic-production.

[158] "Battery Materials Processing Grants", Department of Energy, https://www.energy.gov/mesc/battery-materials-processing-grants.

capabilities to support direct lithium extraction projects domestically and internationally,[159] potentially opening up new sources of lithium supply.

The National Economic Council (NEC) and Council on Environmental Quality (CEQ) lead the Critical Minerals Permitting Interagency Working Group (IWG) that includes DOI, USDA, EPA, and DOE to track critical minerals projects permitting and implement efficiencies related to federal reviews and approvals. The White House Council on Native American Affairs Critical Minerals Working Group including DOI, DOE, EPA, and USACE established and consulted with Tribes on the National Tribal Critical Minerals Initiative to improve Tribal consultation, engagement and outcomes related to critical mineral projects.

CASE STUDY: RESILIENCE IN THE RARE EARTHS SUPPLY CHAIN

The rare earth elements (REE) are a chemically-related class of mineral commodities whose supply chains tie into the clean energy sector, defense and many manufacturing industries. In 2020, demand for Neodymium Iron Boron magnets were rapidly growing as sales of hybrid and electric vehicles grew and off-shore wind turbine projects were planned. At the same time, the U.S.'s top import source for many of the processed and separated REEs was China. The U.S. Government has recognized the major vulnerabilities in the REE supply chain and has been addressing the gaps with a whole-of-government approach.

- Tax credits provided to a REE magnet manufacturing facility through the Inflation Reduction Act's 48C tax credit, which was publicly disclosed by the company.
- Steady production of Rare Earth Oxide concentrate over the past few years and increasing production of separated Neodymium/Praseodymium in 2024 at the Mountain Pass mine.
- Construction of MP Materials' Fort Worth, Texas manufacturing facility in 2022 with expectations to commence commercial production of precursor materials in 2024 and finished magnets by late 2025. MP Materials announced plans to supply General Motors
- Ongoing R&D funded by DOE into REE extraction, separation and refining technologies as well as into substitute materials have resulted in dozens of patents in the last 4 years.

1.c Raw Material Stockpiling

The National Defense Stockpile (NDS) Program is modernizing the nation's strategic and critical material stockpile, acquiring materials that are more reflective of a 21st-century economy and defense industrial base. In FY2025, the annual materials plan for potential acquisitions[160] includes critical minerals such as antimony, the rare earth elements, titanium and tungsten as well as materials such as grain oriented electrical steel and NdFeB magnet blocks. Executive Order 14051[161] and

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159 "Export-Import Bank of the United States Approves First-Ever Term Financing for Domestic Manufacturing", EXIM, August 31, 2023, https://www.exim.gov/news/export-import-bank-united-states-approves-financing-for-first-ever-domestic-manufacturing

160 Defense Logistics Agency-Strategic Materials, FY2025 Annual Materials Plan (AMP), https://www.dla.mil/Strategic-Materials/Reports/

161 "Designation To Exercise Authority Over the National Defense Stockpile", Federal Register, October 31, 2021, https://www.federalregister.gov/documents/2021/11/03/2021-24183/designation-to-exercise-authority-over-the-national-defense-stockpile.

updates to the Stock Piling Act (50 U.S.C. § 98 et seq.)[162] have expanded authorization for releasing material from the NDS, although Title 50 still limits use of the Stockpile to defense and national emergency needs (which include essential civilian needs).

2) Fostering sustainable and transparent critical mineral supply chains, including by expanding options for recycling and promoting high sustainability standards with allies

2.a Research and Development to Strengthen the Circular Economy

Federally-funded research has targeted the need to adapt engineering practices across the manufacturing life cycle. The National Institute of Standards and Technology (NIST) has developed novel decision-making tools and methods to support the transition to a circular economy.[163, 164, 165, 166, 167] For instance, NIST has analyzed potential pathways for recovering critical minerals and materials during the manufacturing and end-of-life stages of photovoltaics, which are the fastest growing clean energy technology and whose production relies on a steady supply of copper and silicon[168].

Since 2021, the Department of Energy (DOE) has funded research to develop battery technologies and cerium-based magnets that reduce the need for scarce and critical minerals in electric vehicles (EVs), wind turbine generators, and other clean energy technologies. The interagency Materials Genome Initiative[169] is collaborating to identify and support pathways for reducing the cost and development time of discovering, optimizing and deploying new materials across all sectors of the U.S. economy that might offer better performance and reduce demand for critical minerals.

DOE's National Laboratories are a key player in research and development for critical minerals production. Recently a 9-lab consortium was awarded $75 million to set up a Critical Materials Supply Chain Research Facility.[170] Inventions produced through the research and development performed by these labs will be manufactured substantially in the U.S., which spurs domestic manufacturing.

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162 THE STRATEGIC AND CRITICAL MATERIALS STOCK PILING ACT (50 U.S.C. § 98 et seq.) (As amended through Public Law 117-263 the National Defense Authorization Act for Fiscal Year 2023)

163 Reslan, M. , Last, N. , Mathur, N. , Morris, K. and Ferrero, V. (2022), "Circular Economy: A Product Life Cycle Perspective on Engineering and Manufacturing Practices", Procedia CIRP, 2022, https://doi.org/10.1016/j.procir.2022.02.141, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=933397.

164 Mathur, N. , Last, N. and Morris, K. , "A process model representation of the end-of-life phase of a product in a circular economy to identify standards needs", Frontiers in Manufacturing Technology, April 18, 2023, https://doi.org/10.3389/fmtec.2023.988073, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=935155.

165 Ferrero, V., Hapuwatte, B. and Morris, K., "Adapting Modern Product Design to the Circular Economy", The ASME 2022 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference, August 14-17, 2022, https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=934318.

166 "Circular Economy Closed Loop Recovery", NIST, https://www.nist.gov/programs-projects/circular-economy-closed-loop-recovery.

167 Chatterjee, A., Minsk, O., Triebe, M. J., Hapuwatte, B. M., Kietzer, D., Kittali-Weidner, S., ... & Mathur, N. (2024). "Investigating the use of network analysis metrics to benchmark Industrial Symbiosis development", Journal of Cleaner Production, 143078.

168 Mathur, N., Hapuwatte, B., & Morris, K. C. (2023). "A proposed integrated model to assess product recovery pathways: the case of solar photovoltaics", . Procedia CIRP, 116, 83-88.

169 "About the Materials Genome Initiative", Materials Genome Initiative (mgi.gov), https://www.mgi.gov/about.

170 "DOE Invests $75 Million to Strengthen Nation's Critical Minerals Supply Chain", Department of Energy April 2, 2024, https://www.energy.gov/fecm/articles/doe-invests-75-million-strengthen-nations-critical-minerals-supply-chain.

2.b Advancing Waste Reprocessing for Critical Minerals

Every state, and every country, has legacy waste from extractive industries. Since 2021, the Administration, State, Tribal, and private sector partners have advanced the geoscience, technology, and policy development required to reuse mine waste and waste from energy production as a resource. These advancements are answering the question of how much of that waste could be used to strengthen critical mineral supply chains and are informing federal and private sector investments in waste reprocessing, environmental management, and waste site reclamation. And there have already been successes: rare earth elements are being extracted from acid mine drainage at treatment facilities in West Virginia (see case study below).

CASE STUDY: EXTRACTING MINERALS FROM ACID MINE DRAINAGE

Abandoned mines are often a source of acid mine drainage (AMD), which pollutes waterways and can result in the disappearance of animal life from a river or stream. However, AMD can also contain rare earth elements, and recovering those offers the promise of a new source of critical minerals that could also help offset the cost of expensive treatment plants.

In April 2024, with funding from the DOE and the DOI Office of Surface Mining Reclamation and Enforcement, the West Virginia Department of Environmental Protection (WVDEP) began operations at the Richard Mine AMD Treatment Facility in Monongalia County, West Virginia. The facility treats AMD using a process developed by the University of West Virginia's Water Research Institute that allows for the collection of light and heavy rare earth oxides before the cleaned drainage is released into Deckers Creek.

This is the second such facility built by the State of West Virginia, and it represents a significant step forward in addressing the dual challenge of environmental restoration and resource recovery. By reclaiming critical minerals from polluted water, the Richard Mine facility not only improves local ecosystems but also contributes to the nation's clean energy supply chain. The network of facilities recovering critical minerals from AMD also includes a project funded by DoD which started in 2023 at a copper mine in Butte, Montana.

BIL funding is accelerating development of the USGS National Mine Waste Inventory. The Inventory is essential to identify opportunities to extract critical minerals from mine waste; inform mine waste management decisions and restoration and reclamation efforts; and inform DOE's investments in technology development for mineral extraction. Interagency and intergovernmental partnerships are bringing together existing data on abandoned mine lands. The Federal Mining Dialogue[171] and State Geological Surveys are actively working to demonstrate the on-the-ground potential to recover critical minerals through reprocessing mine waste. For example, the USGS, the Quapaw Nation, and other partners identified recoverable zinc and germanium in solid mine

[171] The Federal Mining Dialogue (FMD) is a cooperative initiative among federal environmental and land management agencies for cleaning up contamination, addressing safety hazards, and minimizing pollution from abandoned and inactive hard rock mining and mineral processing sites.

wastes[172] at the Tar Creek site in Oklahoma, which could expedite cleanup efforts for the region's toxic legacy from lead and zinc mining.

More broadly, DOE, DOI, and EPA have advanced research on critical minerals from unconventional sources such as energy and mine wastes[173,174], oil and gas production wastewaters[175], and geothermal brines. For example, the USGS and the Arkansas Department of Energy and Environment leveraged artificial intelligence techniques and the National Produced Waters Database to evaluate lithium in the oil and gas-rich Smackover Formation of southwestern Arkansas, estimating the formation contains between 5 and 19 million tons of lithium—a significant portion of the estimated global need.

2.c Advancing Domestic Recycling

Critical mineral recycling programs play an increasingly important role in resilience to supply chain disruptions. For example, the Defense Logistics Agency Strategic Material Recovery and Reuse Program (SMRRP) mitigated a shortfall in germanium by partnering with Anniston Army Depot to recover germanium from waste. SMRRP also recycles super-alloys used in Air Force planes. These efforts bolster the security of U.S. supplies of minerals like nickel, cobalt, tungsten and niobium, by building capacity to recycle and include them in the NDS in times of need.

The DOE and DOE National Labs have funded new, retrofitted, and expanded commercial-scale domestic facilities to demonstrate battery material production, processing, recycling and manufacturing. The Battery Materials Processing and Battery Manufacturing and Recycling Program is funding 25 projects across 14 states that are creating over 6,000 operating jobs and over 13,000 construction jobs nationwide; one facility is already operational. DOE's Loan Programs Office (LPO) is investing in plants to recycle lithium-ion batteries[176] and end-of-life battery components and production scrap[177] into the production of new batteries.

In 2024, DOE launched the Electronics Scrap Recycling Advancement Prize (E-SCRAP), which competitively funds solutions to increase the production and use of critical minerals recovered from electronic scrap. The Prize takes solutions from idea to implementation, supporting competitors from prototype development to real-world implementation and commercial scaling.

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172 "Germanium redistribution during weathering of Zn mine wastes: Implications for environmental mobility and recovery of a critical mineral", Applied Geochemistry, August 2022, https://doi.org/10.1016/j.apgeochem.2022.105341.
173 Kolker, A, Lefticariu, L., Anderson, S.,"Energy-related rare earth element sources", U.S. Geological Science, 2024, (usgs.gov), https://pubs.usgs.gov/publication/70231903.
174 McDevitt, B., Cravotta III, C., McAleer, R., Jackson, J., Jubb, A., Jolly, G., Hedin, B., Warner, N., "Evaluation of coal mine drainage and associated precipitates for radium and rare earth element concentrations", ScienceDirect, July 15, 2024, https://www.sciencedirect.com/science/article/pii/S0166516224001046?via%3Dihub.
175 E.D. Attanasi, T.C. Coburn, & P.A. Freeman, "Machine learning approaches to identify lithium concentration in petroleum produced waters", Springer Nature Link, https://link.springer.com/article/10.1007/s13563-023-00409-8.
176 "LPO Announces a Conditional Commitment for Loan to Li-Cycle's U.S. Battery Resource Recovery Facility to Recover Critical Electric Vehicle Battery Materials" Department of Energy, February 27, 2023, https://www.energy.gov/lpo/articles/lpo-announces-conditional-commitment-loan-li-cycles-us-battery-resource-recovery.
177 "LPO Offers Conditional Commitment to Redwood Materials to Produce Critical Electric Vehicle Battery Components From Recycled Materials", Department of Energy, February 9, 2023, https://www.energy.gov/lpo/articles/lpo-offers-conditional-commitment-redwood-materials-produce-critical-electric-vehicle.

2.d Advancing Global Recycling

Since 2021, the United States has worked with trade partners to advance their capacity and experience in recycling critical minerals, increasing the availability of sustainably produced trade materials and goods in the global marketplace. For instance, the Department of State has worked through the Minerals Security Partnership (MSP) to support projects such as a manganese recycling project in Czechia, a rare earth magnet recycling facility in the United Kingdom, and a project that advances cooperation on germanium offtake and processing between Belgian company Umicore and STL, which operates mines in the Democratic Republic of Congo. Since 2021, DOC's International Trade Administration (ITA) has also made progress towards facilitating international trade in recycled materials, including through a public–private partnership between the Market Development Cooperator Program and the Recycled Materials Association to expand recycling exports. ITA has also conducted interagency and industry outreach on new e-waste requirements under the Basel Convention, an international agreement on hazardous waste, to inform industry efforts to recover critical minerals from e-waste.[178]

The Department of State is also leading policy and investment directions to support robust critical minerals recycling sectors throughout the Indo-Pacific region. In 2024, Indo-Pacific partners will take stock of existing efforts, complete characterization and inventorying of mine waste, and identify information and resources needed to further evaluate the potential to extract valuable minerals from above-ground mine waste. In addition, the Department of State will support Indo-Pacific Economic Framework for Prosperity (IPEF) countries in recycling projects and improved data collection.

2.e Advancing Global Information Sharing and Common Standards for Waste Management and Recycling

Since 2021, the Administration has strengthened international partnerships to improve information sharing and transparency, ultimately forging a path forward towards more secure and sustainable global supply chains.

For instance, the Department of State brought together experts from key trading partners on e-waste and lithium-ion battery management and recovering critical minerals through recycling. The exchange enhanced trading partners' capabilities to increase e-waste and lithium-ion battery collection, strengthen legislative frameworks, and incorporate standards for responsible recycling. The Department of State is facilitating additional conversations with key trading partners to build recycling capacity to recover critical minerals and diversify supply chains.

The Department of Labor is funding technical assistance projects that promote labor rights in critical mineral supply chains. For example, the Improving Workers' Rights in the Rural Sectors of the Indo Pacific with a Focus on Women[179] is improving labor conditions in the region and seeking to improve worker health and safety in nickel supply chains. Through the Promotion of Labor

[178] "New International Requirements for Electrical and Electronic Waste", U.S. Environmental Protection Agency, https://www.epa.gov/hwgenerators/new-international-requirements-electrical-and-electronic-waste.

[179] "Improving Workers' Rights in the Rural Sectors of the Indo Pacific with a Focus on Women", U.S. Department of Labor, https://www.dol.gov/agencies/ilab/improving-workers-rights-rural-sectors-indo-pacific-focus-women.

Standards in the Democratic Republic of Congo[180] project, we are strengthening the capacity of the labor inspectorate to identify and address labor violations in the mining and construction sectors.

3) Identifying supply chain vulnerabilities and working with industry, allies and partners to reduce supply risk

3.a Identifying Supply Chain Vulnerabilities

Since 2021, U.S. agencies have significantly advanced methods for identifying supply chain vulnerabilities. One example of this is the development and use of the 2022 List of Critical Minerals. USGS led development of this whole-of-government the list using a data-driven methodology that utilized data from industry and other countries. Since publication, the List of Critical Minerals has been used to identify supply risks and work collaboratively to develop solutions to strengthen specific supply chains.

The importance of this kind of multi-sectoral analysis was demonstrated in 2024, when the Francis Scott Key Bridge collapsed. At the request of the National Security Council, the Department of Commerce's Industry & Analysis' Office of Critical Minerals and Metals provided an analysis of the impact of the Port of Baltimore closure on the U.S. aluminum industry. They found that Alcoa, the world's eighth largest producer of aluminum, imports alumina for its Massena, New York, aluminum smelter via the Port of Baltimore. The smelter accounts for approximately 15 percent of U.S. aluminum production. As a result of the analysis, alumina shipments have been prioritized for entry into the harbor as it has gradually reopened.

3.b Enhanced International Transparency

Enhanced international transparency is allowing the U.S. to benefit from better information-exchange, including by enhancing the ability to identify supply chain risks and actively support diversified supply chains.

The Critical Minerals Mapping Initiative (CMMI),[181] a partnership between the USGS, Geoscience Australia, and the Geological Survey of Canada, is developing a harmonized classification of mineral systems and beginning in 2024 is expanding the partnership to enable data sharing with additional nations.[182] In 2022, the partnership released the Critical Minerals in Ores database and portal,[183] which offers access to consistent geochemical data from global ore deposit samples.

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180 "Support the Promotion of Labor Standards in the Democratic Republic of Congo (DRC)", U.S. Department of Labor, https://www.dol.gov/agencies/ilab/support-promotion-labor-standards-democratic-republic-congo-drc.
181 Geology, Geophysics, and Geocheminstry Science Center, "Critical Minerals Mapping Initiative (CMMI)", U.S. Geological Survey, https://www.usgs.gov/centers/gggsc/science/critical-minerals-mapping-initiative-cmmi.
182 Hofstra, A., Lisitsin, V., Corriveau, L., Paradis, S., Peter, J., Lauzière, K., Lawley, C., Gadd, M., Pilote, J., Honsberger, I., Bastrakov, E., Champion, D., Czarnota, K., Doublier, M., Huston, D., Raymond, O., VanDerWielen, S., Emsbo, P., Granitto, M., and Kreiner, D., "Deposit Classification Scheme for the Critical Monerals Mapping Initiative Global Geochemical Database, U.S. Geological Survey Open-File Report 2021-1049, 60p., https://pubs.usgs.gov/publication/ofr20211049.
183 Champion, D., Raymond, O., Huston, D., VanDerWielen, S., Sexton, M., Bastrakov, E., Schroder, I., Butcher, G., Hawkins, S., Lane, J., McAlpine, S., Czarnota, K., Britt, A., Granitto, M., Hofstra, A., Kreiner, D., Emsbo, P., Kelley, K., Wang, B., Case, G., Graham, G., Lauzière, K., Lawley, C., Gadd, M., Pilote, J-L., Létourneau, F., Lisitsin, V., Haji Egeh,

The C5+1 is composed of the United States and Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan. Early in 2024, the Department of State inaugurated the C5+1 Critical Minerals Dialogue[184] to increase the region's involvement in global critical minerals supply chains, strengthen economic cooperation, and advance the clean energy transition, while protecting Central Asia's unique ecosystems.

3.c Diversifying Global Supply Chains

Multiple government agencies have committed to diversifying global supply chains of critical minerals and supporting projects in the critical minerals mining sector. These agencies—EXIM, the International Development Finance Corporation, and DoD—have announced awards, issued letters of interest, and approved projects that bolster rare earth, nickel, cobalt and graphite supply chains. DoD's Defense Production Act Title III program allows for grants in Canada, the UK and Australia.[185]In September 2024, the Office of the U.S. Trade Representative imposed additional 25-percent tariffs on certain critical minerals from China, which is intended to encourage China to eliminate its unfair trade practices while also promoting diversification of critical minerals supply chains and counteracting unfair trade practices.[186] The Department of Commerce has assisted with private sector engagement, partnering with allies (e.g., Canada) to promote government funding/policy opportunities (e.g., DoD Defense Production Act funding) that U.S. and allied industry can leverage.

President Biden and G7 Leaders announced the Partnership for Global Infrastructure and Investment[187] at the 2021 G7 Leaders' Summit to provide a private sector-driven, sustainable and transparent option for low-and middle-income countries seeking infrastructure investment to accelerate inclusive economic development. PGI is a whole-of-government approach to infrastructure investment in emerging markets to support a number of sectors, including critical mineral supply chains. By investing in infrastructure projects to ensure western and allied markets have access to critical minerals, PGI enhances critical mineral supply chain security. The partnership has already facilitated a strategic partnership in Tanzania for a company to open a multi-metal processing facility, expecting to begin shipping battery-grade nickel by 2026 and will also work to identify additional opportunities across the region for critical mineral inputs to the new facility.

President Biden and G7 leaders launched the Partnership for Resilient and Inclusive Supply-chain Enhancement (RISE) at the annual meetings of the World Bank and the International Monetary Fund (IMF) in October 2023. RISE is a multi-donor trust fund at the World Bank designed to

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A, "Critical Minerals in Ores - geochemistry database", Geoscience Australia, https://pid.geoscience.gov.au/dataset/ga/145496.

184 "Inaugural C5+1 Critical Minerals Dialogue among the United States and Kazakhstan, the Kyrgyz Republic, Tajikistan, Turkmenistan, and Uzbekistan", United States Department of State, February 9, 2024, https://www.state.gov/inaugural-c51-critical-minerals-dialogue-among-the-united-states-and-kazakhstan-the-kyrgyz-republic-tajikistan-turkmenistan-and-uzbekistan/.

185 "FY2024 NDAA: Defense Industrial Base Policy", Congressional Research Service, January 8, 2024, https://crsreports.congress.gov/product/pdf/IN/IN12221

186 "USTR Finalizes Action on China Tariffs Following Statutory Four-Year Review", United States Trade Representative, September 13, 2024, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/september/ustr-finalizes-action-china-tariffs-following-statutory-four-year-review

187 "Fact Sheet: Partnership for Global Infrastructure and Investment at the G7 Summit", The White House, May 20, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/20/fact-sheet-partnership-for-global-infrastructure-and-investment-at-the-g7-summit/.

diversify global clean energy product supply chains by building out the capacity of low- and middle-income countries to engage in midstream and downstream activities in the sector. The goal is to build out a robust, high-standard pipeline of projects in the critical minerals space that the World Bank Group or development finance institutions (DFIs), such as DFC, can finance. The RISE workplan focuses on southern and eastern Africa, leading an advanced pilot program in Zambia, and also initiating country-level roadmap projects for the DRC and Malawi. RISE is exploring potential future work in Latin America, Europe and Central Asia, and India.

The DFC is directly supporting development of rare earth oxides for allies' supply chains in South Africa through a $50 million in equity investment in TechMet, that will support the development of the Phalaborwa Rare Earths project[188]

Challenges and Opportunities

The path to build and maintain resilience requires continuous supply chain monitoring, long-term planning, and sustained reinvestment in key underpinnings of the sector. The 100-day Supply Chain Review identified a technically-skilled workforce as essential to robust critical mineral supply chains. Accordingly, the CMS is coordinating supportive investments in several parts of the education and training ecosystem. The U.S. Department of Labor has begun to examine deficits in skilled labor for industry, DOE is examining gaps in energy technology and manufacturing education and workforce, the National Science Foundation is developing new support to universities for basic research in key technology areas including materials, and the USGS is developing new support to universities in applied geoscience and supply chain education and research. All of these are essential to building the critical minerals workforce of the future.

A key structural challenge in this sector is the timeline for building new capacity and expanding existing capacity. For example, investments in materials engineering and substitution take time to mature into the manufacturing setting, and increasing production capacity requires significant investments, logistics, and permitting. Critical minerals also rely on transportation infrastructure to move raw materials to manufacturing facilities and to transport intermediate and finished goods that incorporate critical mineral inputs throughout the supply chain. In addition, which minerals meet the risk criteria to be identified as critical depends on a variety of factors, including shifts not only in supply and demand but also in technology design. Advancements in battery and manufacturing technology are happening quickly, generating rapid shifts in the minerals needed to build the infrastructure of the future. While certain minerals (e.g., cobalt) may be highly sought after now, they may be obsolete for certain applications (e.g., batteries) in a matter of years.

Finally, in this as in many other with globally diversified supply chains, there are challenges centered around U.S. economic competitiveness, especially when countries with non-market economies and those with anti-competitive practices have a large role in the supply chains. With critical minerals, we see higher capital and operating costs, and longer project timelines for development with the U.S. than in some other countries.

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[188] "DFC Reaffirms Commitment to Scaling Investment in African Infrastructure and Critical Minerals", U.S. International Development Finance Corporation, February 12, 2024, https://www.dfc.gov/media/press-releases/dfc-reaffirms-commitment-scaling-investment-african-infrastructure-and

Federal agencies are taking actions in many of these priority areas. In addition, increased coordination will be needed outside the U.S. Government with local and State entities, Tribes, private industry, labor organizations, international groups, and foreign governments. This coordination will leverage the capacities of these other groups to strengthen the critical minerals supply chain and reduce supply risks.

Engagement with Industry

For the United States and for trading partners, critical mineral supply chains are developed, maintained, and enhanced by private industry. The private sector operates mines and processing plants, manufactures the resulting products, manages transportation of both the raw materials and finished goods, and creates or implements technical innovations that both increase and reduce reliance on mineral commodities sourced from vulnerable supply chains.

The supply chain investments described above comprise a new degree of government engagement with private industry. Each loan, grant, permit, and research partnership represents both the recognition of supply chain vulnerability that can be reduced through private–public partnerships and the identification of industry partners who can be the foundation of future resilient supply chains.

Industry has been responsive in providing mining, manufacturing, and trade information to support greater transparency and more accurate analysis of supply chain status by U.S. Government agencies. Industry has also responded in the research realm, building on government investments by focusing the dynamic American innovation ecosystem on the once neglected technological challenges of mining and materials science. Finally, industry has responded to partnership opportunities with the U.S. and other governments as well as Tribal, community, and non-governmental organization (NGO) interests to promote mining standards that advance sustainability as noted in the Interagency Working Group (IWG) on Mining Laws, Regulations, and Permitting report, "Recommendations to Improve Mining on Public Lands."[189]

This IWG, comprised of experts in mine permitting and environmental law from across the U.S. Government, was formed by the Department of the Interior in response to Executive Order 14017. The IWG was charged with reviewing laws, regulations, policies, and permitting processes pertaining to hard rock mineral development, as well as addressing the mandate of the Bipartisan Infrastructure Law (Public Law 117-58), which requires the Department of the Interior and the U.S. Department of Agriculture to identify legislative and regulatory recommendations to increase the timeliness of permitting activities for exploration and development of domestic critical minerals.

Engagement with Allies and Partners

The U.S. Government has strengthened engagement with allies and partners around the globe to improve the resilience of mineral commodity supply chains, increase the supply of critical minerals, and ensure robust, transparent, and sustainable mineral production. Efforts draw on established international multilateral partnerships such as the G7, but also include new partnerships such as

[189] Biden-Harris Administration Interagency Working Group on Mining Laws, Regulations, and Permitting "Recommendations to Improve Mining on Public Lands", September 2023, https://www.doi.gov/sites/default/files/mriwg-report-final-508.pdf

PGI, the Minerals Security Partnership (MSP) and the Indo-Pacific Economic Framework for Prosperity (IPEF), as well as direct investments through the DPA to qualified countries such as Canada. These efforts are aimed at building and expanding resilient, transparent supply chains that are based on extensive local engagement, respect for the environment and conservation, and safe, high-standard- labor practices. Investments supported both solely by the U.S. Government and jointly with other allies and partners are moving forward in countries around the world and span the entire length of critical minerals supply chains.

CASE STUDY: INDO-PACIFIC ECONOMIC FRAMEWORK FOR PROSPERITY

The U.S. Government is collaborating with international partners in the IPEF Critical Minerals Dialogue which was announced by IPEF leaders in November 2023. The objective of this initiative is to launch an international dialogue that meaningfully advances efforts to strengthen IPEF critical mineral supply chains and promote regional competitiveness in clean energy technologies and other relevant industries that rely on critical minerals. IPEF partners have identified four priority areas of focus (workstreams).

- **Workstream 1** focuses on mineral resource mapping brings together technical experts from IPEF partner countries to collaborate and share technical expertise, tools, and best practices for mineral mapping.
- **Workstream 2** focuses on trade promotion and enables partners to understand trade flows and facilitate more competitive and resilient critical mineral supply chains.
- **Workstream 3** focuses on mineral recovery and recycling. Mineral recovery from mine waste, mine tailings, and mineral refining by-products and recycling of critical minerals are key to developing sustainable critical mineral supply chains and maximizing mineral resources. IPEF partners are performing analysis to assess potential for mineral recovery and recycling and provide technical assistance and capacity building on advancing those technologies.
- **Workstream 4** focuses on raising international standards for labor and environmental protections. The extraction and processing of critical minerals is resource-intensive, and the sector has a history of abuses. IPEF partners are making efforts to implement strong, enforceable labor and environmental protections across IPEF critical mineral supply chains and share best practices on community and stakeholder engagement.

In addition, the IPEF Supply Chain Agreement in September 2024 established an Action Plan team on critical minerals, with a focus on batteries, under the IPEF Supply Chain Council. Action Plan teams are a core activity under the Council and will work to compile recommendations to increase the resilience and competitiveness of critical sectors and key goods of mutual interest among IPEF countries. The Action Plan on critical minerals will build on the successes of the Critical Minerals Dialogue and establish a workplan on by the end of 2024.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

In the last four years the U.S. has made historic advances in how it assesses the resilience and vulnerability of mineral supply chains globally, with a focus on how those vulnerabilities affect the U.S. Under the Energy Act of 2020, the USGS and the CMS updated the whole-of-government List of Critical Minerals using a new data-driven and cross-sectoral methodology to assess supply risk. This assessment uses quantitative data on domestic capacity, trade concentration, supplier diversity, security and U.S. economic health and enables the U.S. Government to scan the horizon for mineral supply chain risks. Also under the Energy Act of 2020, the DOE released the first Critical Materials list for energy using a new methodology that considered projected scenarios for clean energy adoption. The DoD also maintains a list of strategic and critical materials for the National Defense Stockpile under the Strategic and Critical Materials Stock Piling Act. Together these lists monitor aspects of resilience and vulnerability described below and form the basis for forward-looking supply chain analysis.

In 2024 the interagency community developed several innovations that will be incorporated into the resilience and vulnerability assessments above, in particular developing new forward-looking supply chain analysis and forecasting capabilities. DOC's Industry & Analysis (I&A) unit conducted supply chain assessments of minerals in strategic sectors such as semiconductors and electric vehicles, identifying current and potential alternative sources and policy recommendations to mitigate short-term supply disruptions as well as mid-to-long term policy solutions. I&A also draws from an internally developed SCALE tool, which weighs structural supply chain risks to drive policy recommendations to advance supply chain resilience. USGS developed a new model to quantify the potential economic impacts of mineral commodity supply disruptions both to individual sectors and to the overall U.S. gross domestic product. Moreover, DOE conducted new Supply Chain Readiness assessments that characterize global supply-demand balance, cost curves and economic competitiveness of the U.S. and allied operations for energy minerals.

These latest models and more that are in development will contribute to and support updates to the whole of government List of Critical Minerals and future quadrennial reporting requirements. As noted above, minerals supply chains are complex and global; thus, resilience and vulnerability must be considered globally even while focusing on national interests.

Transparency

The U.S. has established robust and transparent data on mineral supply chains for about 100 minerals in 180 countries and across 236 manufacturing sectors. Over the past four years, the U.S. Government has enhanced supply chain transparency through interagency partnerships, data sharing, and agencies leveraging economic data and each other's modeling efforts. The USGS 2022 whole-of-government List of Critical Minerals and the DOE Critical Materials List for energy both feature transparent rankings of supply risks and have provided the Administration a strong evidence base for historic investments in mineral supply chains.

Despite this significant progress, opportunities for further transparency remain, particularly downstream from the mining stage. Production data at refinery and downstream stages is reported less frequently, and not all countries adhere to the same reporting standards. This lack of data reduces transparency as materials are transformed and assembled into parts, components, and products such as cell phones, aircraft, and satellites. Agencies are committed to addressing these data gaps to enhance transparency and resilience across sectors.

Domestic capacity

Across the U.S., every state participates in the mineral economy and has opportunities to contribute to increased domestic capacity. The USGS Earth MRI program and multilateral partnerships such as the CMMI and the IPEF are identifying which minerals could feasibly be mined and processed in the U.S. and which minerals will require the U.S. to rely on strategic trade relationships. The Mineral Commodity Summaries 2024 show there is no domestic primary production for at least 14 critical minerals and the group of rare earth elements. There are also multiple critical mineral commodities for which there is no domestic secondary (recycled) production[190]. The data also show that for at least seven critical minerals and the group of rare earth elements, the U.S. had three or fewer producers. Further downstream, progress has been made to increase capacity in key supply chains, such as for lithium-ion batteries, neodymium iron boron magnets, and semiconductors. Current and targeted investments to fill these gaps, such as for lithium,[191] are expanding domestic capacity and are expected to improve supply chain resilience by 2030.

Trade concentration

Trade is extremely important to the U.S. mineral economy. In 2023, the U.S. was a net exporter of raw mineral materials (with exports valued at $10.6 million and imports valued at $5.9 million), and a net importer of processed mineral materials (with exports valued at $101 billion and imports valued at $203 billion). The degree of reliance on trade and the nature of supporting trade agreements are crucial determinants of risks associated with trade concentration. In 2023, there were 15 mineral commodities for which the U.S. was 100-percent net import reliant and 16 additional commodities for which the U.S. was more than 75-percent net import reliant. The U.S. Government is taking steps to decrease risks associated with trade concentration, such as investing in domestic capacity and establishing strong partnerships with allies who are potential trade partners for critical minerals.

Supplier diversity

Mineral production is highly concentrated in a few countries. Supplier diversity is very low for many mineral commodities at either the raw material production step, the processing step or both. When mineral production is concentrated in a few countries, U.S. importers have limited options. In the risk assessment for the List of Critical Minerals a single point of failure in the supply chain is

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[190] U.S. Geological Survey, "Mineral Commodity Summaries 2024", U.S. Geological Survey, 2024, https://pubs.usgs.gov/periodicals/mcs2024/mcs2024.pdf

[191] "Fact Sheet: Biden- Harris Administration Takes Further Action t0 Strengthen and Secure Critical Mineral Supply Chain", The White House, September 20, 2024,https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/20/fact-sheet-biden-harris-administration-takes-further-action-to-strengthen-and-secure-critical-mineral-supply-chains/

considered a significant risk factor. The critical minerals beryllium, nickel, and zirconium are produced domestically but have a single point of failure. This lack of domestic competition creates opportunities for the government to take steps to fund and increase supplier diversity through competitions, regulatory approvals, or other interventions.

Agility

Agility varies widely across supply chains in the minerals sector. Since critical minerals are used globally in almost all sectors, there is a wide range of manufacturing complexity, lead times and supply chain flexibility. The NDS provides additional agility for the defense industrial base in response to a war or national emergency. More broadly, the U.S. Government is developing early warning systems for priority critical minerals to increase the sector's agility.

At the raw material stage, the least agile critical mineral supply chains are byproduct minerals.[192] Market incentives do not strongly influence byproduct mineral production. However, at the secondary production stage, which includes recycling and recovery, current DOE investments to develop cost-competitive recycling processes[193] are adding to domestic capacity to draw from secondary materials. These investments particularly benefit byproduct critical minerals, which may be more readily available in mine wastes than through primary production. In addition, BIL investments in the USGS National Mine Waste Inventory include byproduct mineral mapping, which is identifying targets for research and development and for regulatory innovation to enable mine waste reprocessing.[194]

Security

Mining, refining and processing facilities are large operations with significant dependencies on energy, water, and transportation infrastructure. Because mines are tied to geological ore deposits and therefore impossible to relocate, the raw materials portion of critical mineral supply chains has low resilience to security risks. For example, there are titanium, zirconium and rare earth mineral deposits located in regions prone to hurricanes. Internationally, the USGS and the DOC's I&A have reported on risks for tin, tungsten and tantalum mined in conflict regions on the African continent.[195] The critical mineral sector is vulnerable to environmental and geopolitical risks that can disrupt transportation. These risks are intensified in developing countries, where inadequate last-mile infrastructure can lead to delays and bottlenecks. Regions with underdeveloped, roads, ports, and railways frequently lack the capacity or stability needed to ensure reliable delivery.

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[192] Nassar, Nedal T., Thomas E. Graedel, and E. M. Harper. "By-product metals are technologically essential but have problematic supply." Science advances 1, no. 3 (2015): e1400180.
[193] "Critical Materials Projects", Department of Energy, https://www.energy.gov/lpo/critical-materials-projects
[194] "Earth Mapping and Resources Initiative (Earth MRI), U.S. Geological Survey, https://www.usgs.gov/special-topics/earth-mri
[195] U.S. Geological Survey, "Mineral Commodity Summaries 2024", U.S. Geological Survey, 2024, https://pubs.usgs.gov/periodicals/mcs2024/mcs2024.pdf

Economic health and compliance

Given that metal prices can be highly volatile,[196] the industrial sectors that are closely tied to mineral commodities must find ways to remain agile in order to navigate through market cycles, changes in the regulatory environment, tax and trade policies, and geopolitical events that can change quickly despite workforce training and capital requirements that require years to develop. As noted above under Challenges and Opportunities, geopolitical competition can play out within the global supply chains creating economic challenges for the U.S. related to structural differences and anti-competitive economic practices in some foreign countries. Pulling from the U.S. Department of Labor and other government sources, the USGS publishes summary data on employment tied to the mining, metals and minerals industries. The overall size of the U.S. workforce for nonfuel mineral mining, chemicals, primary metals and related industries had recovered from the 2020–2021 downturn by 2023.[197]

CASE STUDY: FORMALIZING THE ARTISANAL COPPER-COBALT SUPPLY CHAIN IN THE DRC

In November 2024, USAID/DRC will sign a $2-million grant with The Impact Facility to pilot a new model of responsible artisanal cobalt operations in order to legally export artisanal cobalt for the first time from the Democratic Republic of the Congo (DRC). Through this Program, USAID funding will strengthen the field operations of the Entreprise Générale du Cobalt (EGC), the state entity tasked with cleaning up DRC's artisanal cobalt sector, so that EGC can scale this model to dozens of other sites and carry out their mandate after the Program is over. The Program seeks to unlock up to $50 million in investment through long-term offtake agreements with international buyers.

Through a consortium approach, the Impact Facility will work in close partnership with Enterprise Generale du Cobalt (EGC) and the Responsible Minerals Initiative (RMI). The Impact Facility serves as the secretariat of the Fair Cobalt Alliance (FCA)—a multi-stakeholder initiative that brings together 20+ actors from across the cobalt supply chain, including industrial miners, battery manufacturers, downstream companies, and other non-profit organizations. Established through a 2019 government decree, EGC's mandate is to export artisanal cobalt and strategic minerals and ensure that this production meets high standards of social and environmental responsibility and traceability. RMI is an industry association and standard setter, bringing together some of the leading organizations collaborating in this sector with the shared objective of formalizing and professionalizing artisanal cobalt operations in the DRC.

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[196] Trevor Hart and Ugo Platania,"2024 Global Metals and Mining Outlook", KMPG, 2024, https://assets.kpmg.com/content/dam/kpmgsites/xx/pdf/2024/09/mining-metals-outlook-2024.pdf.coredownload.inline.pdf
[197] U.S. Geological Survey, "Mineral Commodity Summaries 2024", U.S. Geological Survey, 2024, https://pubs.usgs.gov/periodicals/mcs2024/mcs2024.pdf

PRIORITIES AHEAD

Four-year Outlook

The United States has put in place significant federal infrastructure to monitor critical mineral supply chains' risks, vulnerabilities, and resilience, and to drive historic investment to strengthen supply chains. These whole-of-government risk assessments and coordinated actions are essential underpinnings to critical mineral supply chains. Over the next four years, increased threats from export barriers or controls from other countries as well as exponential increased demand for critical minerals may challenge our ability to meet the needs of the clean energy transition as well as national security objectives and consumer products demand. However, over that same period of time, federal investments and policy advances will be bearing fruit. There will be improved tools to monitor supply chain health, enabling agile and targeted responses to future challenges and making supply chain investments more efficient and effective. There will be an increasing supply of critical minerals produced domestically and by friendly nations, from both conventional sources such as new mines and unconventional sources such as mine waste and recycling. Technological advances will develop products which reduce the amount of or even replace the critical minerals currently required. These accomplishments will counter current and the potential increased stressors, both within and outside the federal system, to move towards robust and resilient supply chains across the minerals ecosystem.

Four-year Resilience Goals and Priorities

Overview

Over the next four years, continued progress toward the 100-day review's priorities will reduce the risks and vulnerabilities outlined in the previous section. The goals and priority actions below carry on the lines of effort identified in the 100-day Supply Chain Review.

Goal #1: Increase sustainable production of critical minerals in the United States. New mapping is revealing previously unknown domestic critical mineral potential both still in the ground and in mine waste. To capitalize on this potential, following EO 14017, the Biden Administration recommended fundamental reform of the Mining Law of 1872, which governs access to mineral resources on hundreds of millions of acres of public land in the United States. In addition, the Administration recommended improved engagement with communities and consultation with Tribes to improve community and Tribal outcomes and reduce time consuming litigation.

Priority action 1.1. Enact policies to modernize mining policy in the United States to achieve the best outcomes for communities and Tribes impacted by mining, America's clean energy and climate goals, and certainty for industry.

Priority action 1.2. Accelerate mapping of the nation's domestic mineral potential; complete mapping of 50 percent of the subsurface and complete the National Mine Waste Inventory for 20 states by 2028.

Priority action 1.3. Complete a national assessment of lithium resources in the United States and implement investments and policies that accelerate the production and processing of lithium from domestic sources, increasing that production by a factor of four by 2028.

Priority action 1.4. Identify and close research gaps to provide information needed to support decision-making on seabed mining policy options and strengthen regulations pertaining to federal management of seabed minerals.

Goal #2: Double domestic recycling and reprocessing of critical minerals from mine wastes, manufacturing scrap, and end-of-life products. Waste streams ranging from electronics recycling to mine waste are a potential source of critical minerals. Rapid public- and private-sector progress is being made in quantifying this potential, and in technology and standards to facilitate its development. By tapping into the waste, by-products, and end-of-life products including critical materials at all stages of the supply chain, we create more domestic sources for critical minerals (including some that we do not have access to at the mining step) and create more domestic manufacturing opportunities.

Priority action 2.1: Establish programs to incentivize repurposing and recycling. In particular, expand nascent recycling streams that are not currently collected, such as EV batteries.

Priority action 2.2: Leverage partnerships with States, industry and non-governmental organizations to open mine waste processing operations at sites with or near significant critical mineral resources as identified in the National Mine Waste Inventory (priority action 1.2).

Priority action 2.3: Pass legislation to remove unnecessary hurdles to the reprocessing of mine wastes.

Goal #3: Work with partners to develop high standard markets for critical minerals. Establishing high standards for trade in critical minerals, working in conjunction with the MSP, with trade partners will advance resilient, diverse, safe, equitable, transparent, and sustainable critical mineral supply chains.

Priority action 3.1: Develop downstream standards requirements for a subset of critical minerals to establish the high standard marketplace requirements.

Priority action 3.2: Work with producers, existing standards bodies, and metal exchanges to promote traceability of products to ensure standards are being met at each step in the supply chain.

Legislative and Budgetary Objectives

Increasing the amount of domestic mining will require increasing public trust in domestic mining laws and regulations. Therefore, a significant priority is to achieve fundamental mining reforms, which would require Congress to pass legislation to significantly amend the Mining Law of 1872. More moderate reforms can still improve public confidence, community outcomes, and industry certainty. Excess claim maintenance fees, for example, can be redirected toward abandoned mine remediation (Priority 1.3) and community impact assistance. Tribal consultation requirements can ensure that Tribes are meaningfully engaged prior to mining proposals moving forward. Additionally, incentives can encourage positive industry actions, such as establishing benefit agreements with communities and Tribes, seeking free, prior, and informed consent from Tribal Nations, and adhering to the highest global industry standards.

Good Samaritan legislation governing liability for remediation of mine wastes has passed both chambers of Congress in different sessions of Congress, and if enacted could help third parties address legacy pollution from abandoned hard rock mines (Priority 1.3). As Congress contemplates full passage of Good Samaritan legislation, it would be productive to engage industry, NGOs, federal agencies, Tribes, and other partners to determine ways to appropriately allow for additional reprocessing of mine wastes while ensuring that proper environmental and consultation safeguards remain intact.

Another priority is to provide and sustain the level of federal investment required to expand domestic capacity for the long term. The 100-day Supply Chain Report called for increased support to the USGS National Minerals Information Center; the need for data collection and risk assessment has grown only more acute since that report. Accordingly, the President's Budget Request for 2025 calls for additional investment in supply chain forecasting and scenario analysis by the USGS, in addition to complementary support for supply chain analysis by Commerce. In addition, specific stages of critical minerals supply chains require investment. For raw materials production and secondary materials reprocessing, BIL funding is accelerating, but will not complete, the USGS national mapping of domestic critical mineral resources both still in the ground and in mine waste (Priority 1.2); and investments by DOE in recycling will require some years to grow and mature secondary markets for critical minerals (Priorities 2.1 and 2.2). Similarly, one hurdle to efficient permitting is the lack of sufficient funding from Congress for mine permitting agencies, such as the DOI Bureau of Land Management or U.S. Forest Service and review agencies such as EPA. Additional funding should be provided, particularly for staff with mining expertise and staff needed to conduct cultural resource surveys and consult with Tribes (Priority 1.1).

Long-term Resilience Goals

A resilient U.S. minerals economy must not only survive but thrive in the face of emerging challenges. Long term strategic resilience goals for critical minerals articulated in the Executive Order 14017 1-year capstone report[198] have guided the substantial progress made over the last four years and frame the four-year goals specified above. These goals are:

Goal #1: Secure and expand sustainable critical mineral mining and processing capacity in the United States and strengthen U.S. stockpiles

The U.S. will cultivate a robust and sustainable domestic minerals industry that not only meets the demands of emerging technologies but also promotes secure access for all sectors, including renewable energy, defense, and advanced manufacturing to the essential raw materials needed for innovation and growth. To this end the U.S. will champion initiatives that bolster sustainable domestic production of minerals and incentivize investment in innovation. By doing this the U.S. will establish the foundation for domestic production that is both sustainable and commercially viable with high standards that will require diverse, safe and equitable, transparent, and sustainable critical mineral supply chains. Strengthening stockpiles will remain a long-term goal under NDS and the Strategic and Critical Materials Stock Piling Act; specific mineral commodities that would benefit from a stockpiling approach are expected to evolve over time and continued monitoring of supply chain risks and vulnerabilities will enable the U.S. Government to adapt stockpiling strategies as needs change.

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[198] "Executive Order on America's Supply Chains: A Year of Action and Progress", The White House Washington, https://www.whitehouse.gov/wp-content/uploads/2022/02/Capstone-Report-Biden.pdf

Goal #2: Expand options for recycling and recapture of minerals from waste or mine tailings in support of circular critical mineral supply chains

Federal, State, Tribal, and private-sector decision-makers will have the modern mapping of domestic critical mineral resources needed to strategically invest in sustainable domestic primary production. Permitting process coordination and efficiencies will result in increased domestic secondary production through reprocessing of critical minerals from mine waste and recycling. The U.S. will establish transparent and circular critical mineral supply chains by adopting high market standards and advancing technological innovation to implement those standards. Over the coming decade, new trade partners will also achieve high standards. Innovations such as the Digital Product Passport will be widely used to verify, support, and scale high-standard markets across global supply chains.

Goal #3: Work with partners to develop and diversify mining and processing of critical minerals and reduce supply risk

The U.S. has strong trade relationships and has opportunities to diversify import sources further. Partnerships with industry, allies, and other partners will be informed by robust and comprehensive mineral supply chain data and forecasting to ensure global supply chains are adaptive, transparent, and equipped to withstand global market fluctuations and geopolitical challenges. In addition, innovations and improvements in domestic primary and secondary production, processing, and manufacturing will be mirrored in allied and partner countries through coordinated government actions, such as the MSP, and the advances made by the multinational firms which already span the U.S. and partner countries.

Conclusion

The United States has established significant federal infrastructure to monitor critical mineral supply chains; regularly evaluate those supply chains' risks, vulnerabilities, and resilience; and drive coordinated action to strengthen supply chains as needed. These processes, coordinated throughout whole-of-government bodies and processes form the essential underpinnings to critical mineral supply chains. More remains to be done, both within and outside the federal system, to ensure robust and resilient supply chains. However, the historic investments and achievements over the last four years have laid the groundwork for further domestic production of critical minerals, sustainable and transparent critical mineral supply chains, and new partnerships with industry, allies and partners to reduce supply risk.

2021–2024 Four-year Review of Agri-food Supply Chains

U.S. DEPARTMENT OF AGRICULTURE

DECEMBER 2024

EXECUTIVE SUMMARY

The agri-food supply chain is a complex, integrated system from "farm to fork," spanning agricultural and food production, processing, manufacturing, storage, distribution, and consumption, including the inputs needed at each of these steps. The agri-food supply chain also touches on other critical sectors—such as information and communications technology, manufacturing, energy, and transportation—and faces many of the same challenges as those sectors. However, the agri-food supply chain also faces unique challenges. Most U.S. households are food secure, meaning they have consistent, dependable access to enough food for active, healthy living, but temporary or sustained local, national, or global disruptions to the agri-food supply chain can cause immediate impact for American households due to the frequent need to purchase and consume food. In addition, many agri-food products are impacted by seasonality, environmental shocks, and perishability.

Technological developments in agriculture have been influential in driving production changes in the farming sector for over the past century. Innovations in animal and crop genetics, chemicals, equipment, and farm organization have enabled continuing output growth without adding much to inputs. As a result, even as the amount of land, labor, and other inputs used in farming declined, total farm output nearly tripled between 1948 and 2021. However, the ever-increasing complexity and consolidation of the agri-food supply chain has exposed new vulnerabilities, which USDA laid out in its 2022 USDA Agri-Food Supply Chain Assessment: Program and Policy Options for Strengthening Resilience. While many of these challenges are ongoing, USDA has made significant progress over the past two years in addressing these known issues through its Food System Transformation initiative.

Through landmark investments, new rules and enforcement, and a wide-ranging realignment of policies, USDA's actions to strengthen the agri-food supply chain have benefited consumers, producers, and rural communities across the supply chain, from how food is produced to how it is purchased, and all the steps in between. In addition, USDA tackled a range of interconnected policy considerations—competition, climate, fairness, accessibility, and equity—to ensure a balanced strengthening of the food system across specific segments of the agri-food supply chain: Food Production, Food Processing, Fair and Competitive Markets, Food Distribution and Aggregation, and Trade.

Looking ahead to 2025–2028, USDA has outlined key actions to further strengthen the agri-food supply chain including:

- Increasing data availability, transparency, and coordination to better monitor, diagnose, and respond to supply chain disruptions;
- Advancing transdisciplinary research, development, technological innovation, and delivery of solutions particularly for local and regional supply chains and small and mid-sized producers; and
- Supporting expanded competitive market opportunities that support more diversified and distributed supply chains while returning value to communities.

These will lead to a more robust and sustainable U.S. agri-food economy capable of meeting the world's growing demands for affordable and nutritious food in the face of new and emerging challenges. Through targeted actions, all segments along the agri-food supply chain will have the resources and policy framework in place needed to support their continued innovation and growth.

SECTOR OVERVIEW

Introduction

U.S. agriculture and food systems (including production, processing, and distribution) are extensive, open, interconnected, diverse, and complex. These descriptors are even more apt when one considers that the agri-food sector is interconnected with not only animal and plant health but environmental and human health as well. The agri-food sector is foundational to the U.S. economy and way of life. Agriculture, food, and related industries contributed roughly $1.530 trillion to the gross domestic product in 2023, and in 2022 accounted for 10.4 percent of total U.S. employment, including around 2.6 million farm jobs and another 19.6 million jobs in food- and agriculture-related industries.[199] USDA estimates that (in 2022) each dollar of agricultural exports stimulated another $1.09 in business activity.[200] Further, every household in the United States depends on food and agricultural products.

Sector Overview

As an identified critical sector under Executive Order 14017 on America's Supply Chains, and National Security Memorandum (NSM) 16 on Strengthening the Security and Resilience of United States Food and Agriculture and NSM-22 on Critical Infrastructure Security and Resilience, the agri-food supply chain plays an outsized role in impacting public health and safety as well as the U.S. economy. The U.S. agriculture sector extends beyond the farm business to include a range of related industries such as: food and beverage manufacturing; food and beverage stores; food services and eating/drinking places; textiles, apparel, and leather products; and forestry and fishing. Expenditures on food accounted for 12.9 percent of U.S. households' spending, on average, in 2023, an increase from 12.8 percent in 2022. The share of household expenditures on food ranked third behind housing (32.9 percent) and transportation (17.0 percent). Vulnerabilities along any of these points of the agri-food supply chain create vulnerabilities for food security, public health, and the economy.

The agri-food supply chain is also increasingly global in scope and interconnected, as evidenced by the growth in agricultural trade. With U.S. agricultural output growing faster than domestic demand for many products, U.S. farmers and agricultural firms have been relying on export markets to sustain prices and revenues. As a result, U.S. agricultural exports have grown steadily over the past 25 years—reaching $174 billion in 2023, up from $57.3 billion in 1998. During the same period, total agricultural imports more than quintupled in value, reaching $195 billion in 2023. In addition, many agri-food products are impacted by seasonality, environmental stress, pests and diseases, and perishability. And given the uniqueness and breadth of the agri-food sector, federal agencies such as USDA and the Food and Drug Administration (FDA) have complementary program and regulatory

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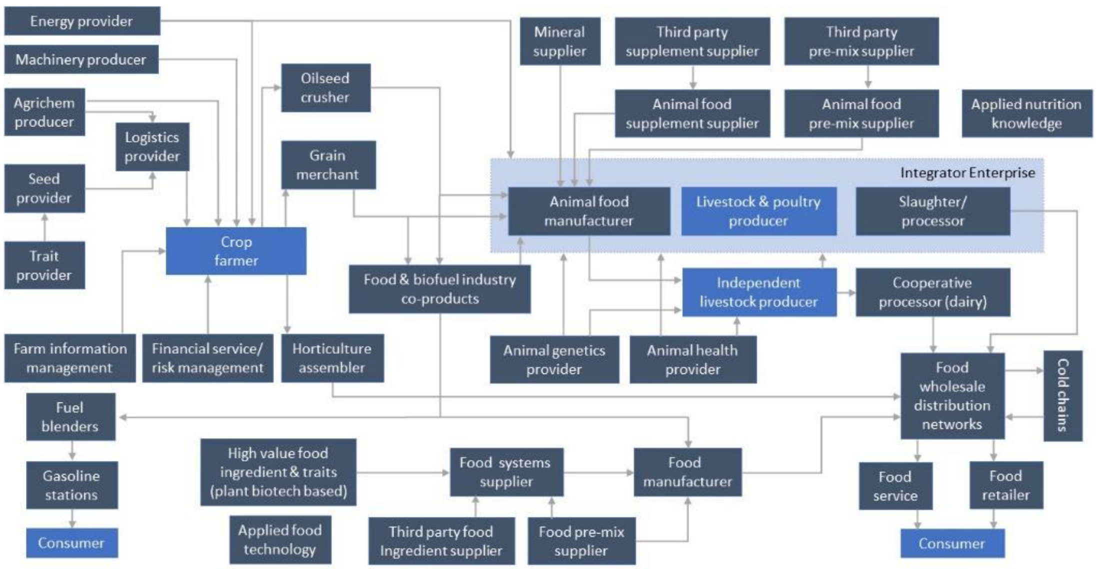
[199] U.S. Department of Agriculture, Economic Research Service, *Ag and Food Sectors and the Economy*, 2004, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/.

[200] U.S. Department of Agriculture, Economic Research Service, *Ag and Food Sectors and the Economy*, 2004, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/.

responsibilities in agri-food supply chains.[201] While this Review primarily focuses on USDA's agri-food supply chain work, FDA regulates foods other than meat, poultry, and some egg products, and has taken additional steps to support the continuity of these supply chains.

Infographic: The agri-food supply chain



Evolution of the Sector through 2020

During the past century, the U.S. farm sector has experienced transformative change–from a localized system of inputs and outputs, largely constrained by the limitations of particular geographic regions, to today's complex, interrelated global agri-food sector, which has both increased the productive capacity of geographic regions as well as removed localized constraints on inputs and production through technological developments.

Technological developments in agriculture, primarily catalyzed by long-term federal and private sector investments in R&D, have been influential in driving changes in the farm sector. Early 20th-century agriculture was labor intensive and took place on many small, diversified farms in rural areas where more than half the U.S. population lived. Agricultural production in the 21st century, on the other hand, is concentrated on a smaller number of large, specialized farms in rural areas where less than a fourth of the U.S. population lives. Innovations in animal and crop genetics, chemicals, equipment, and farm organization have enabled continuing output growth without adding much to inputs. As a result, even as the amount of land, labor, and other inputs used in farming declined, total farm output nearly tripled between 1948 and 2021.[202]

The increasing complexity of the agri-food supply chain has been necessary to sustain population growth as well as changing preferences as income levels increase. However, this has also exposed the

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[201] U.S. Department of Agriculture, Agricultural Marketing Service, *USDA Agri-Food Supply Chain Assessment,* 2022, https://www.ams.usda.gov/sites/default/files/media/USDAAgriFoodSupplyChainReport.pdf

[202] U.S. Department of Agriculture, Economic Research Service, *Farming and Farm Income*, 2024, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/farming-and-farm-income/

agri-food supply chain to increasingly complex vulnerabilities. On one hand, for example, subsistence farming reduces risks against external shocks, as the entire supply chain from end to end is managed directly on the farm. However, this systems approach is also the most vulnerable to a single major disruption occurring at the farm-level. On the other hand, as the agri-food supply chain involves an increasing number of actors and becomes more diversified and geographically integrated, it becomes more resilient to individual farm-level disruptions, but overall becomes more exposed and vulnerable to different types of disruptions.

Key Sector Trends from 2021 to Present

The 2022 *USDA Agri-Food Supply Chain Assessment: Program and Policy Options for Strengthening Resilience* identified key vulnerabilities impacting the agri-food supply chain in six priority areas, all of which remain key concerns in 2024:

- Concentration and Consolidation in Agri-Food Production, Manufacturing, and Distribution
- Labor Needs
- Ecological and Climate Risks to Crops
- Livestock and Poultry Disease Threats
- Transportation Bottlenecks
- Trade Disruptions

Since 2022, the dynamic within and across these key concerns continues to shift in conjunction with world events. For example, conflict in the Red Sea starting in 2023 has resulted in significant adjustment of transportation routes, impacting the flow of U.S. agricultural goods to critical export markets. As another example, extreme weather events in 2024 resulted in targeted U.S. agricultural production losses and the need to invest in supply chain recovery for affected commodities. Given the continued impacts of externalities on the food system, the agricultural sector will need to remain nimble and diversified to meet both known and unknown challenges ahead.

PROGRESS TO DATE

One-year Review Priorities

The One-year Review's recommended actions to address these vulnerabilities include:

- Strengthen data and market intelligence to enhance USDA's understanding of supply chains and address disruptions early, reducing impacts on individuals and communities;
- Diversify critical supply chain infrastructure, expand local and regional programs, and enable more and better market opportunities for producers and expanded and reliable choices for consumers;
- Support a level playing field to enable competition through stronger rules under the Packers and Stockyards Act and partnerships with the Federal Trade Commission and Department of Justice;
- Improve working conditions and overcome critical labor shortages in farm and affiliated agri-food industries;
- Support research and assistance that helps the agricultural sector mitigate and adapt to climate change;
- Strengthen monitoring, surveillance, prevention, research, and response preparedness related to animal and crop pest and disease threats;
- Rebuild critical transportation infrastructure for moving bulk commodities and specialty products;
- Support diversified options for agricultural exports, which stimulates local economic activity, helps maintain a competitive edge globally, and supports producers' bottom lines; and
- Embed equity principles throughout USDA's actions to ensure programs, services and decisions reflect the values of equity and inclusion.

Progress from 2021 to Present

Food System Transformation

The lessons from recent food supply chain disruptions such as the pandemic and the Russian invasion of Ukraine made clear that USDA must help strengthen the food system across the entire supply chain. No single policy effort on its own is sufficient to build resilience in the agri-food supply chain as many issues—competition, climate, fairness, accessibility, and equity—are interconnected and must be balanced. Thus, USDA developed its comprehensive Food System Transformation initiative to tackle the underlying vulnerabilities exposed by the pandemic-induced disruptions.

USDA's guiding principles in building a more resilient agri-food supply chain remain:

- Providing more and better competitive market options for consumers and producers while prioritizing sustainability.
- Creating a fairer food system that challenges market dominance and helps producers and consumers gain more power in the marketplace by creating new, more and better local market options to combat the perils of a food system increasingly dominated over the past 50 years by a few corporate players.

- Making nutritious food more accessible and affordable for consumers to alleviate food insecurity and ensure every American family has access to affordable, nutritious foods.
- Emphasizing equity to remove barriers and create more economic opportunities for rural, underserved, and persistently impoverished communities.

To achieve these goals, USDA implemented landmark investments, new rules and enforcement, and a wide-ranging realignment of policies to benefit consumers, producers, and rural communities across the supply chain, from how food is produced to how it is purchased, and all the steps in between. Specifically, USDA targeted the following segments of the agri-food supply chain: Food Production, Food Processing, Fair and Competitive Markets, Food Distribution and Aggregation, and Trade. Progress under each segment is further outlined in the following sections.

Food Production

A resilient food supply chain relies on a diverse supplier base of farmers and ranchers who are positioned to reliably supply food in the face of changing markets. Small and mid-size operations struggle in particular to access markets and a fair share of the food dollar, and there are still many barriers to entry for new farmers. These producers also must have access to competitively priced inputs to be successful. The 2022 USDA Agri-Food Supply Chain Assessment identified strengthening local and regional food systems and advancing value-added market opportunities such as climate-smart and organic as essential steps to diversify the number and scale of farm and food businesses and, in turn, to address concentration and consolidation issues as well as the ecological and climate risks faced by the sector. Therefore, USDA has focused on supporting the next generation of farmers; increasing access to domestically-produced fertilizer; and expanding options for American farmers to process locally, sell locally, and adopt practices that are both good for their businesses and the climate. USDA investments and tools to support food production since 2021 include:

- **Ensuring stability for current, new, and future farmers and associated workforce challenges.** Given the aging farm population, investments to support current producers to remain in farming and to encourage new entrants are critical for maintaining the production aspect of the supply chain alongside the surrounding rural agricultural communities. Such support included over $161 million through the Farming Opportunities and Outreach (FOTO) program to encourage and assist socially disadvantaged, veteran, and beginning farmers and ranchers in the ownership and operation of farms and ranches through education and training; and promote equitable participation in the agricultural programs of USDA. Additionally, The Enhancing Program Access and Delivery for Farm Loans Rule improved Farm Loan Programs to increase opportunities for farmers and ranchers to access credit and meet their financial goals.
- Given the ongoing shortages of U.S. farm workers and other agriculture labor challenges essential to keep supply chains operational, USDA invested **up to $65 million in grants through the Farm Labor Stabilization and Protection Pilot Program** to provide support grants for agricultural employers to implement robust labor standards and promote safe, healthy work environments for both U.S. workers and workers hired under the seasonal H-2A visa program.
- **Up to $900 million in grants through the new Fertilizer Production and Expansion Program** to spur domestic competition and combat rising fertilizer costs that more than doubled between 2021 and 2022 in the face of import threats and global unrest. FPEP

supports independent, innovative and sustainable American fertilizer production to supply American farmers. Grants to eligible applicants support expanding the manufacturing and processing of fertilizer and nutrient alternatives and their availability in the United States.

- **Over $11 billion in rural energy investments through the Inflation Reduction Act** to support clean, reliable energy in rural America through electric cooperatives and to launch renewable energy and energy efficiency projects for almost 3,700 farms and small businesses, like rural grocery stores, in our agri-food supply chain. Stable, affordable, accessible energy alongside food production, processing, and rural communities is critical for maintaining a robust supply chain as building robust energy resources at the local level helps shield the agri-food sector from energy price and supply swings.
- **Addressing climate change.** More than $3.1 billion through the Partnerships for Climate-Smart Commodities effort, which seeks to build and expand market opportunities for American commodities produced using climate-smart practices through pilot projects. In addition, developing the Greenhouse Gas Technical Assistance Provider and Third-Party Verifier Program to facilitate farmer, rancher, and private forest landowner participation in voluntary carbon markets, allowing them to access a new income stream through carbon credit sales, ensuring agri-food production practices contribute toward the long-term resilience of the sector through combatting climate change.
- **Up to $300 million in a new Organic Transition Initiative** to provide comprehensive support for farmers to transition to organic production, and invest in expanded capacity for certified organic production, aggregation, processing, manufacturing, storing, transporting, wholesaling, distribution, and marketing needed resulting in increased domestic availability and market diversification of U.S. organic goods.

Food Processing

During disruption to the agri-food supply chain, consolidated processing can create supply bottlenecks, which leads to a drop in efficient processing capacity for crops and livestock. Small and midsize farmers often struggle to compete for processing access and are left without an avenue for getting their specialty crops or animals to market. Building more geographically distributed capacity builds resilience in the face of market disruptions, provides more choices for producers to create value-added products and sell locally, and supports new economic opportunities and job creation in rural communities. USDA investments and tools to address processing and other challenges in the middle of the agri-food supply chain include:

- **The Food Supply Chain Guaranteed Loan Program (FSCGL)**, which provided guaranteed loans of up to $40 million for qualified lenders to finance food systems projects, specifically for the start-up or expansion of activities in the middle of the agri-food supply chain. The program provided $781 million in loan guarantees to 51 independently-owned businesses for infrastructure in food aggregation, processing, manufacturing, storage, transportation, wholesaling, and distribution to increase capacity and create a more resilient, diverse, and secure U.S. agri-food supply chain.
- **Investing up to $420 million through the Resilient Food Systems Infrastructure program** to fund projects in partnership with all 56 states and territories that expand capacity for the collection, processing, manufacturing, storing, transporting, wholesaling, and distribution of food products, including specialty crops, dairy, grains for human consumption, aquaculture, and other food products, other than meat and poultry.

- **Build a Fairer, More Competitive, and More Resilient Meat and Poultry Supply Chain.** By expanding independent meat and poultry processing capacity, supporting workers, and delivering technical assistance through $1 billion in investments, USDA has supported the Biden–Harris Action Plan for the Meat and Poultry Supply Chain. USDA's myriad financial and technical assistance programs diversified the meat and poultry processor sector to tackle concentration and consolidation and ensure livestock producers have more options across this supply chain. These programs include strengthening financing capacity for independent meat and poultry processing facilities, supporting grants for small and midsized operations to improve infrastructure and enable them to sell local products across state lines, expanding supply chain information and resources to processors, and delivering standardized training to ensure a well-trained processing workforce.

Fair and Competitive Markets

Clear, transparent standards ensure markets function fairly and competitively for consumers and producers alike. Fair and competitive markets have long been the cornerstone of the American economy. Competition ensures that American farmers, ranchers, and those who grow our nation's food have the freedom to choose among different suppliers, employers, and retailers to buy and sell their product and the products they need. It spurs many businesses to innovate, improves opportunities for producers and workers, and increases resilience in the nation's food supply. However, entrenched market power remains an obstacle to achieving lower prices for consumers and fairer practices for producers.

USDA's comprehensive report, *Agricultural Competition: A Plan in Support of Fair and Competitive Markets*, as required by President Biden's Executive Order 14036 on Promoting Competition in the American Economy, details USDA's strategy for a more resilient agri-food supply chain by addressing concentration and consolidation and promoting competition in agricultural markets—including not only actions and initiatives to promote competition in meat and poultry markets, but also other key agricultural sectors like fertilizer and seeds. Highlights of USDA's efforts include:

- **Developing new data visualization tools.** The Livestock Mandatory Reporting (LMR) Live Cattle Data Dashboard and the Cattle Contracts Library pilot provide user-friendly access to cattle market information to support stakeholders' work to efficiently market their agricultural products. The enhanced insight gained from these powerful tools places producers on a more equal footing with large volume data users and fosters a fairer and more competitive marketplace.
- **Making value-added markets more accessible.** Official voluntary grades, including USDA Prime and USDA Choice, accurately communicate meat quality across the supply chain. While more than 90 percent of fed beef in the U.S. is officially graded, the service is almost exclusively used in larger packing operations. By launching a Remote Grading Pilot for Beef, USDA increased accessibility of the service to independent beef packers, allowing them to better communicate the value of their products with customers.
- **Fair market rulemaking** to reinforce market fairness includes publishing new rules to reinvigorate USDA's century-old fair and competitive market laws under the Packers and Stockyards Act; defining what is required for meat products to be labeled as a "Product of the USA"; and strengthening the National Organic Program.
- **Partnering with the Department of Justice (DOJ)** to enforce antitrust laws vigorously. This includes standing up a new one-stop shop at FarmerFairness.gov to make it easier for

stakeholders to report complaints of potential violations, with confidentiality protections and whistleblower protections against retaliation for reporting criminal antitrust concerns.

- **Establishing an innovative partnership with the State Attorneys General** to share resources and enhance enforcement of unfair and anticompetitive practices in food and agriculture.
- **Establishing the Farmer Seed Liaison initiative**, which works with the U.S. Patent and Trademark Office (USPTO) to enhance transparency into the patent system for farmers and plant breeders and to promote policies that increase access to seeds for research and breeding.

Food Distribution and Aggregation

Having the right infrastructure in the right places is key to USDA's efforts to shorten the agri-food supply chain, provide more income opportunities for producers and more options for consumers to buy locally produced products. These efforts include:

- **Investing $400 million to create twelve Regional Food Business Centers** that provide coordination, technical assistance, and capacity building support to small and mid-size food and farm businesses, particularly focused on processing, distribution and aggregation, and market access challenges.
- **Incorporating locally produced foods in nutrition assistance programs.** Delivered billions to strengthen local and regional supply chains for school nutrition and feeding programs which secured local and regional markets for local farmers and ensured students, young children and neighbors in need received nutritious, reliable meals. Taken together, efforts such as providing states, territories, and tribes with a mechanism to directly purchase foods from local, regional, and underserved producers, increasing State agency capacity and grants across Farm-to-School Institution programs, and assisting schools through supply chain assistance funds allows producers to expand, invest in infrastructure, and solidify new connections and markets.
- **Providing nearly $2 billion in funding to support food for emergency food providers for The Emergency Food Assistance Program (TEFAP)** through the Commodity Credit Corporation to help nutrition assistance organizations such as food banks as they continue to deal with supply chain challenges and elevated food costs.
- **Reimagining Resilient Agri-food Supply Chains.** Recognizing the need to identify ways to develop a more robust and resilient national agri-food supply chain, the National Institute of Food and Agriculture funded more than 30 projects through various competitive programs, resulting in an online toolkit and online course to train Extension professionals to improve local and regional supply chain participants' abilities to respond during disruptions.
- **Creating Local and Regional Food Systems Resilience resources.** The experiences gained from navigating the complexities of the COVID-19 crisis underscored the need to cultivate resilience and equity at the grassroots level. The Local and Regional Food Systems Resilience Playbook, an interactive web-based resource, is designed to broaden food systems leaders' understanding of the distinct strengths and vulnerabilities of local and regional food supply chains during disruptions. To foster greater data efficacy and literacy in these supply chains, USDA and its partners also developed the Food and Agriculture Mapper and Explorer—an open-access data resource designed to increase accessibility to U.S. local and regional food systems data. The platform offers tools for planning, evaluating, and responding to future supply chain disruptions.

Trade

Keeping existing markets open and fair, maintaining sales to our largest trading partners, and expanding and diversifying into new markets is critical for the health and resilience of the U.S. agri-food supply chain. USDA supports efforts to develop and enforce rules-based agricultural trading system with our global trading partners, creating new or expanded opportunities for $3 billion in U.S. agricultural exports since 2021, and preserving access for more than $20 billion in U.S. agricultural exports. USDA's efforts to increase the resilience of the agri-food supply chain through new, expanded, and reopened markets include the following initiatives:

- 14 USDA Agribusiness Trade Missions, 59 USDA-endorsed USA Pavilions at Trade Shows, and 10 Virtual Trade Events since 2022 connected over 2,400 U.S. companies with potential buyers overseas in nearly 5,000 business-to-business meetings during these events, generating nearly $5.56 billion in 12-month projected sales.
- The Export Credit Guarantee Program (GSM-102) makes available approximately $5 billion in guarantees annually to support sales to non-traditional markets in Africa, Asia, Latin America, the Middle East, and Turkey. Over the past three years, the program has supported an average of $2.9 billion in exports with approximately 90 percent of the sales going to countries in Latin America.
- The Facility Guarantee Program (FGP) makes available approximately $500 million in guarantees annually to support infrastructure improvements in countries where demand for U.S. agricultural products may be limited due to inadequate storage, processing, handling, or distribution capabilities. The program provides credit guarantees to facilitate the financing of manufactured goods and U.S. services to improve or establish agriculture-related facilities in emerging markets.
- The Agricultural Trade Promotion (ATP) program and Regional Agricultural Promotion Program (RAPP) help diversify export markets away from the top mature export destinations. ATP provided $300 million to encourage the development of new markets to reduce the U.S. reliance on exports to any single market and mitigate the adverse effects of countries' unjustified tariff and non-tariff barriers. RAPP further expands on this effort by providing $1.2 billion over five years through Commodity Credit Corporation funds to support additional investments in market development and enable U.S. agriculture exporters to break into new markets.
- The Assisting Specialty Crop Exports (ASCE) initiative will provide $65 million for projects that, through an innovative partnership with the specialty crops sector, will help support global exports and expand to new markets by breaking down unnecessary non-tariff trade barriers that hinder U.S. exports of fruits and vegetables, tree nuts, horticultural crops, and other products.
- The Department of Commerce International Trade Administration (ITA) Commercial Service (CS) collaborates with USDA/FAS under the guidance of a Memorandum of Understanding. CS and FAS have enjoyed a long history of working together to promote U.S. exports of agribusiness products and services around the world. This relationship enhances U.S. competitiveness, sustains economic growth, and advances the American value proposition overseas. CS takes the lead for export promotion of several products overseas, including agricultural machinery and agricultural chemicals.

Challenges and Opportunities

Several notable challenges developed as USDA worked to implement the recommendations from its 2022 *USDA Agri-Food Supply Chain Assessment: Program and Policy Options for Strengthening Resilience* to address key vulnerabilities. Many of these challenges developed in relation to strengthening data and market intelligence in order to enhance USDA's understanding of supply chains and address disruptions early.

First, USDA realized the need for additional visibility on the agri-food supply chain beyond its traditional end points to where it intersects with other critical sectors—public health and biological risks, national security, transportation, information and communications technology, and critical minerals. For example, agricultural exports are dependent on the freight transportation network to move products from the nation's interior to export ports and ultimately to overseas markets. However, neither USDA nor FDA possess the regulatory authority to compel data collection from transportation service providers that would greatly enhance market transparency for our stakeholders and reduce overall supply chain vulnerabilities, such as location data on ocean shipping containers.

Understanding these interdependencies among different critical-sector supply chains is crucial to ensuring the success of individual sector supply chains and requires collaboration across federal agencies. This was evidenced during the March 2024 collapse of the Francis Scott Key Bridge in Baltimore, whereby the resulting supply chain disruptions did not fit squarely into specific individual critical sectors, but rather overlapped among many different supply chains, requiring a coordinated effort through the Supply Chain Disruptions Task Force among USDA, DOT, SBA, DOE, FDA, Commerce, State-level agencies, and others. In addition to the need for data sharing in the face of different incidents—whether a transportation disruption or a biological threat of concern to the biodefense community, there are also challenging scientific, legal, and security issues that agencies must tackle together.

Second, many supply chain disruptions do not originate within the United States nor are they exclusive to the U.S. agri-food supply chain. USDA has identified the need for additional visibility into the agri-food supply chain beyond U.S. borders, particularly with Canada and Mexico, which are deeply integrated with the U.S. supply chain through proximity, shared land-borders, trade, and the transportation network. Supply chain disruptions impacting these countries, such as recent labor disputes, migration issues, border closures, transportation service disruptions, and other trade disruptions can potentially have large ripple effects across the U.S. agri-food supply chain, and vice versa. Throughout these recent disruptions, there were several opportunities to develop working relationships and some data sharing with Canadian and Mexican counterparts. However, more formal cooperation and transparency on cross-border issues is necessary for building resilience within the U.S. agri-food supply chain.

Third, while much data sharing between USDA and the private sector is well established, there are emerging areas in which additional data sharing could provide greater insight and early warnings of supply chain disruptions. These areas often involve data that are closely held by individual companies reluctant to lose a competitive advantage by sharing such information. Thus, no individual company is incentivized to share its data, even though widespread data sharing among all companies would provide them a relative advantage on managing supply chain disruptions impacting the agri-food sector as a whole. Furthermore, clear visibility into supply chain disruptions often requires voluntary data sharing from the private sector to government. This approach limits its responsive efforts and oversight only to what is voluntarily shared, potentially creating data gaps in visibility and increased vulnerability. For example, recent industry consolidation has limited the availability of grain price data in certain geographic regions, limiting the analytical capacity to monitor and detect potential disruptions that are often signaled through such price data.

Engagement with Industry

Over the past four years, USDA has engaged frequently and actively with the public and impacted industries. Specific examples include public requests for information related to food supply chain resilience as a whole; meat and poultry processing; competition in seeds, retail, and fertilizer sectors; and climate smart agriculture and forestry practices. USDA also conducted listening sessions with the public on topics including farm labor, emerging technologies, and access to research. Additional industry engagements include cabinet and sub-cabinet level discussions related to acute supply chain disruptions impacting the flow of agricultural goods via water and rail; distribution challenges for school meal and nutrition assistance programs; and opportunities to reduce transportation bottlenecks to support U.S. export competitiveness.

Engagement with Allies and Partners

USDA has actively engaged with partners on key supply chain concerns, especially those related to climate. Most notably, in 2021, the United States, led by USDA, in partnership with the United Arab Emirates, launched the Agriculture Innovation Mission for Climate (AIM for Climate / AIM4C) as a joint initiative to address climate change and global hunger by uniting participants to significantly increase investment in, and other support for, climate-smart agriculture and food systems innovation over five years (2021–2025). AIM for Climate's network of more than 800 partners features governments and non-governments, including private research, education and extension institutions and international organizations, companies, or other NGOs. This effort included a three-day summit in 2023 that brought together key domestic and international public and private sector partners. Through this effort, AIM for Climate partners have increased investment in climate-smart agriculture and food systems innovation to more than $29.2 billion (2021–2025, over a 2020 baseline), which includes over $4.3 billion from the United States. AIM for Climate is a five-year initiative and now, in its fourth year, it is critically important for partners to work together toward institutionalizing progress. To support this, AIM for Climate and the United Nations Foundation led the development of the AIM for Climate Report: Cultivating Transformative Investments in Climate-Smart Agriculture and Food Systems Innovation.[203] Released in September 2024, the report commemorates collective action by AIM for Climate partners, encourages institutional change, and provides recommendations for AIM for Climate partners to persist in making critical efforts for years to come. As AIM for Climate prepares to sunset in 2025, AIM for Climate partners are encouraged to embrace and champion the report recommendations in 2025 and beyond.

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[203] "AIM For Climate Report: Cultivating Transformative Investments in Climate-Smart Agriculture and Food Systems Innovation," AIM for Climate, published September 2024, https://www.aimforclimate.org/report/.

More Fertilizer, Better Service, Less Carbon!

Since 1997 Town & Country Supply Association merged with two other cooperatives to provide high quality fertilizer products and on-site services at competitive prices to Montana's farmers and ranchers. The rural community of Lockwood, Montana, is home to Town & Country's Mega Fertilizer Plant. At this plant, members of the agricultural cooperative can order custom aggregated fertilizer to match their personalized needs. However, the plant's success quickly outgrew its capacity for raw materials.

In early 2024, Town & Country received a $2.9-million USDA Fertilizer Production Expansion Program (FPEP) grant to help expand this production facility and soon after, construction began. This project includes a 36,700-square-foot addition as well as two railcar storage tracks. It is projected that in five years, the new and improved facility will have the capacity to produce and distribute 132,000 tons of raw materials. All of this is designed with the goal to serve the co-op's customers better.

"We need to be able to provide these products in a timely manner and at a cost-effective price too," said Town and Country Supply Association's Chief Executive Officer Wes Burley. "That's something else that the facility gives us, we are able to go out there and contract product with our suppliers and then turn around and contract product to our growers."

By upgrading the automatic bagging system, they will also be better able to sell bags of fertilizer to cater to the needs of all members and expand their market in a less labor-intensive way. The expansion and improvements made to the fertilizer plant are not only increasing volume, but also allow for the growth of partnerships. Supply partners can ship fertilizer out of this facility and get product delivered to their needed locations, shipping as far as Idaho. This assists partners who struggle to get rail cars into their own facilities.

Long-term sustainability is a mission Town & Country Supply Association is proud of. With the modernization of the facility, the co-op is projected to decrease their CO_2 emissions by over 14 million pounds per year. This is equivalent to taking almost 1,400 vehicles off the road. This dramatic decrease is due to the expanded rail delivery capacity, decreasing their need for truck transportation.

In addition to reducing greenhouse gas emissions, these improvements will allow for expanded services from expert agronomists, helping growers minimize unnecessary fertilizer application. This means farmers are more precise when applying fertilizer, and with Montana's diverse landscape, that means less waste. Burley notes farming is "expensive enough as it is" without using more inputs than necessary.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

Since 2022, USDA's Food System Transformation initiative has laid the foundation for a more resilient agri-food supply chain through developing new capabilities within the seven key elements of resilience and vulnerabilities of the agri-food supply chain. USDA's capabilities to address identified vulnerabilities show relatively high resilience in terms of Transparency–through a wide range of enhanced data tools and multiple avenues of public–private engagement, Trade Concentration–through investments to spur domestic competition in fertilizer production and robust efforts to diversify export markets, and Agility–through abundant and diverse domestic production, recent developments in biotechnology/biomanufacturing to complement conventional production methods, and numerous nutrition assistance programs to purchase commodities in order to address emergency food assistance needs. There are, however, identified gaps in resilience for each of these elements, notably for Transparency—the data limitations described under *Challenges and Opportunities;* Trade Concentration—the need to determine which farm-level inputs (and their degree of import reliance) are the most critical; and Agility—unforeseen shocks of unknown duration to the transportation system, which directly impact the resilience of the agri-food supply chain.

Other elements show a more mixed outlook for developed capabilities relative to risk exposure. Domestic Capacity reveals U.S. agricultural production exceeds domestic needs and therefore remains reliant on well-functioning global supply chains and trading partners acting in good faith. Supplier Diversity reveals vulnerability to the relatively high levels of concentration in many seed, livestock, and food retail markets, but also relative increases in resilience in these sectors through recent efforts by USDA to implement new rules and investments to expand the middle of the supply chain and strengthen local and regional food systems. Security shows the agri-food supply chain is exposed to a wide range of vulnerabilities from biological pests/diseases, climate change, cyberattacks, and intentional harm, and USDA's capabilities are largely geared toward incentivizing the private sector to adopt voluntary best practices to address identified security threats. Finally, Economic Health and Compliance indicates farm income and wealth is resilient, with many Federal support programs, but faces challenges from declining productivity—linked to decreased investment in research and development, labor shortages, and economic shocks that continue to ripple through the sector (e.g., labor and transportation disruptions leading to lost sales and lost market share for exports).

Transparency

Data Availability & Analytics, Surveillance, and Forecasting

Economic information and market intelligence form a critical knowledge base that provides resilience in anticipating and monitoring supply chain disruptions. USDA works directly with the agri-food sector to provide free, unbiased production, price, and sales information to assist in the marketing and distribution of farm commodities. Wholesale, retail, and shipping data give farmers, producers, and other agricultural businesses the information needed to evaluate market conditions, make purchasing and selling decisions, and evaluate transportation costs in the face of near real-time changes to the agri-food supply chain. However, additional data are needed to provide better transparency on cross-sectional vulnerabilities, which are those where the agri-food supply chain connects and overlaps with other critical sectors, including public health and biological risks, national security, transportation, information and communications technology, and critical minerals. For example, agriculture is highly dependent on pesticides, fertilizers, and farm equipment as inputs into the production process. However, the chemical and manufacturing industries, which are traditionally outside of the agri-food sector, have better visibility into key metrics for these inputs—price, availability, and supply chain challenges—than the agri-food sector. Understanding the inter-dependencies involving multiple supply chains is crucial to ensuring no segments or nodes of the agri-food supply chain—much less the overall U.S. supply chain of critical sectors—are excluded. At the same time, the Federal government must ensure that too much transparency through data sharing does not become a vehicle for anticompetitive practices.

USDA routinely collects and monitors key indicators to anticipate and monitor disruptions. Swings in prices, such as input prices and commodity prices at the wholesale and retail levels, may signal anomalies or disruptions to the agri-food supply chain. Several examples of these key data indicator series for analytics, surveillance, and forecasting are summarized below.

- USDA's My Market News and Datamart websites provide commodity specific data to the public on over 1,500 reports that are updated daily, weekly, monthly, and annually with up-to-the-minute information that assists producers, consumers, and other businesses in making informed marketing and production decisions. Reports covering key wholesale, retail and shipping data help stakeholders evaluate market conditions, identify trends, make purchasing decisions, monitor price patterns, evaluate transportation equipment needs, and accurately assess movement. USDA also supports organic production and market data collection and dissemination and associated surveys and analysis through the Farm Bill's Organic Data Initiative.
- USDA's National Agricultural Statistics Service conducts 400+ annual farm-level surveys on topics covering production and supplies of food and fiber, prices paid and received by farmers, farm labor and wages, farm finances, chemical use, and changes in the demographics of U.S. producers. USDA's Office of the Chief Economist uses this data to develop long-range forecasts of global supply and demand for agricultural commodities. These forecasts help market participants gauge imports and exports, prices and farm income, storage and transportation demand, and potential shortfalls where government assistance in the agri-food supply chain may be needed. In addition, USDA's weekly crop progress report provides insight in monitoring the effects of drought, heat, precipitation, and other climactic disruptions on agricultural production.
- USDA's World Agricultural Outlook Board (WAOB) serves as the focal point for economic intelligence and the commodity outlook for U.S. and world agriculture. It coordinates, reviews, and approves the monthly World Agricultural Supply and Demand Estimates report, as well as the Department's annual, ten-year agricultural commodity market projections. The WAOB also releases annual projections covering agricultural commodities, trade, and aggregate indicators of the sector for the next decade, providing market intelligence for both policy makers and industry to better prepare the supply chain for anticipated demands and usage.
- USDA's AgTransport open data platform provides access to data, monitoring the movement of agricultural products across the country and around the world. The platform contains numerous datasets and dashboards about movements by rail, truck, barge, and ocean vessel

(both bulk and container) used to transport agricultural products. These datasets cover key indicators on rates and volumes as well as service metrics that can help identify and evaluate the extensiveness of supply chain disruptions to the agri-food sector.

Public–Private Engagement

Supply chain resilience is built on strong relationships. Maintaining open communication between the public and private sectors helps cultivate strong relationships among all partners—individuals, communities, regions, sectors, and institutions. While USDA can provide high-level support to improve the functioning of the agri-food supply chain, much of the supply chain rests in the hands of individuals and businesses throughout the private sector—producers, processors, aggregators, distributors, and others—as well as academia and NGOs. Without strong stakeholder relationships, USDA would not be able to provide targeted and responsive support to the agri-food sector.

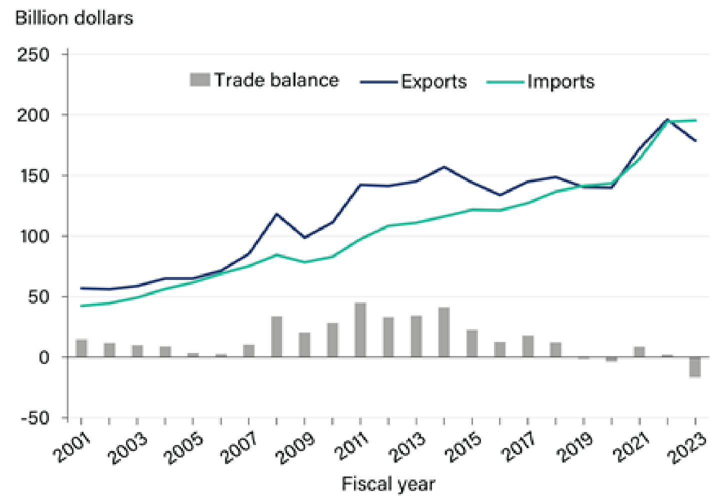
USDA maintains multiple established channels to communicate with stakeholders, with some examples summarized below.

- **Field-based operations:** The vast majority of USDA's nearly 100,000 employees are located in field-based roles providing connections and context with stakeholders and partners. Specific engagement includes direct interaction with farmers and ranchers, regulatory and quality grading presence in a wide variety of processing facilities, and coordination with state plant and animal health officials. USDA also maintains a corps of Foreign Service Officers stationed at posts around the world who are positioned to assist on global market issues.
- **Coordination with Land-Grant Universities:** The Cooperative Extension System operated by the Land-Grant University System, with substantial funding provided by USDA's National Institute of Food and Agriculture (NIFA), provides non-formal education and learning activities to farmers, ranchers, communities, youth, and families throughout the nation to meet emerging challenges, adapt to changing technology, improve nutrition and food safety, prepare for and respond to emergencies, and protect the environment.
- **Intentional Stakeholder Outreach:** USDA and FDA are co-chairs for the Food and Agriculture Sector's Government Coordinating Council (GCC), which provides coordination of agricultural security and food defense strategies and activities; policy review and development; and communication across government and between the government and the private sector. The GCC acts as the counterpart and partner to the private industry-led Food and Agriculture Sector Coordinating Council (SCC). Through close coordination, GCC and SCC plan and coordinate activities between the government and private-sector on prevention, preparedness, response, and recovery systems to ensure the resilience of the nation's agri-food critical infrastructure and the continued ability to provide agricultural products, human and animal food products, and secure associated supply chains.

Domestic capacity

Domestic Supply Chain Representation

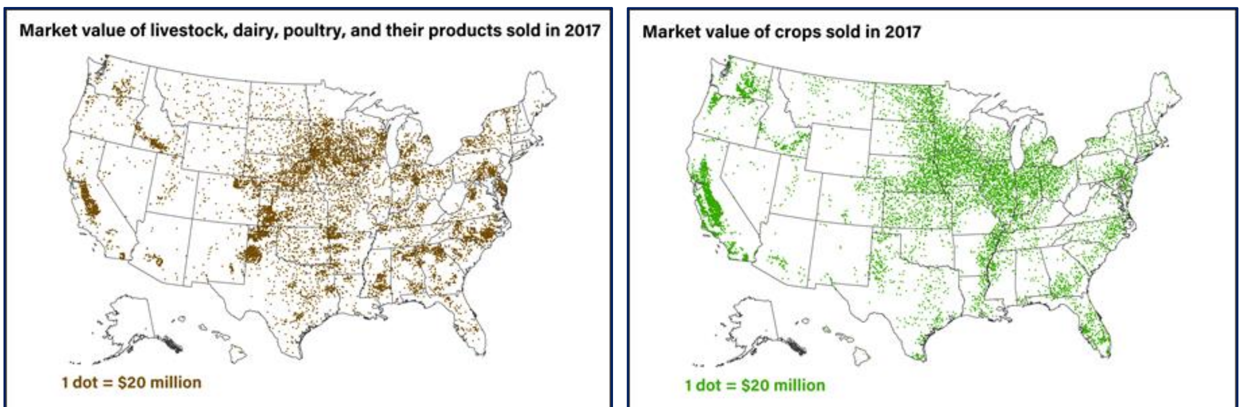
Figure 1: U.S. agricultural trade, 2001–2023



Note: Values are not adjusted for inflation. The trade balance is equal to the value of exports minus the value of imports. When the balance is negative, imports exceed exports.
Source: USDA, Economic Research Service using data from U.S. Department of Commerce, Bureau of the Census.

The United States is committed to global agricultural trade, as both a major exporter and a major importer of agricultural goods. However, the value of agricultural imports has grown more rapidly than exports over the past decade, largely driven by the strong U.S. dollar and consumer preferences for year-round produce selections. U.S. production that exceeds domestic consumption in grains and feeds, soybeans, livestock products, tree nuts, fruits, vegetables, and other horticultural products results in net U.S. exports. Sweeteners and processed sugar, confections, coffee, cocoa, and tropical fruits are groups of products extensively imported. Several categories of fruits, nuts, and vegetables are also frequently imported. The United States tends to have a lower reliance on imports for unprocessed bulk commodities such as feed grains, livestock, and oilseeds. The total import share of consumption across all food and beverages between 2011 and 2021 was 15 percent, steadily growing over the period.

Figure 2: Market value of livestock, poultry, and their products, and crops sold in 2017



Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, 2017 Census of Agriculture.

Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, 2017 Census of Agriculture.

The United States has significant domestic fertilizer production capacity, supplying over 80 percent of its needs through domestic production, especially for nitrogen and phosphate fertilizers. In 2022, the United States produced 15.1 million tons of nitrogen and 6.2 million tons of phosphorus. However, U.S. production of potash is under 0.5 million tons annually, necessitating a heavy import reliance on potassium-based fertilizers.

USDA has several tools to ensure the supply and distribution of domestic food production through multiple food assistance programs. The collective goals of the programs are to provide food insecure people with access to a more nutritious diet and to improve the eating habits of the nation's children.

Supplier Ownership

The domestic agri-food supply chain spans a diverse set of infrastructure—such as farms and ranches, grain elevators, farm supply wholesalers, testing laboratories, manufacturing and processing facilities, and restaurants and supermarkets. Continued integration of the world's economy opens additional opportunities for domestic agribusinesses abroad but also exposes them to new risks, which, without adequate awareness and intentional oversight, may increase the vulnerability of the domestic agri-food supply chain.

A 2022 report by the congressionally mandated U.S.–China Economic and Security Review Commission stated that foreign acquisition of major domestic agribusinesses may "confer undue leverage over U.S. supply chains" and lead to restructuring of supply chains that negatively affects domestic producers and service providers.[204] The report identified risks of intellectual property theft, illicit technology transfer, and foreign control of the agri-food supply chain as part of a coordinated and deliberate policy of the Chinese government to address its domestic food security challenges by increasing productivity through illicit technology transfer and overseas diversification of its agri-food supply chains.

Whether foreign owned assets over critical domestic infrastructure necessary to the agri-food supply chain are more vulnerable than U.S.-owned assets during supply chain disruptions is unclear. USDA has several tools for monitoring and buffering against inappropriate control by a foreign-based company over the domestic supply chain.

- The Committee on Foreign Investment in the United States (CFIUS) plays an important role in reviewing certain foreign direct investment transactions for national security considerations—this includes certain transactions that could result in control of a U.S. business by a foreign person, non-controlling but non-passive investments in certain U.S. businesses, and certain real estate transactions. The Secretary of Agriculture is not a full member of CFIUS, but the Consolidated Appropriations Act, 2024 (P.L. 118-42, §787), enacted in March 2024, requires the Secretary of Agriculture to be included as a member of CFIUS on a case-by-case basis with respect to covered transactions involving agricultural land, agriculture biotechnology, or the agriculture industry (including agricultural transportation, agricultural storage, and agricultural processing), as determined by the chair

[204] U.S. China Economic and Security Review Commission, *Staff Research Report: China's Interests in U.S. Agriculture: Augmenting Food Security Through Investment Abroad*, (Washington, DC: GPO, 2022), 3. https://www.uscc.gov/annual-report/2022-annual-report-congress.

of CFIUS in coordination with the Secretary of Agriculture. USDA's continued involvement with CFIUS can help evaluate the potential risks and vulnerabilities from foreign purchases of strategic U.S. agri-food assets.

- The Agricultural Foreign Investment Disclosure Act (AFIDA) of 1978 sets forth regulations to establish a nationwide system for the collection of information pertaining to foreign ownership in U.S. agricultural land. The regulations require foreign investors who acquire, transfer, or hold an interest in U.S. agricultural land to report such holdings and transactions to the Secretary of Agriculture.
- Additional capacity across the supply chain at the local and regional level builds resilience against disruptions that may otherwise incapacitate largescale but more concentrated firms. USDA has focused extensive efforts to build more distributed, local capacity in the middle of the supply chain with small and mid-sized entities through investments, regulatory policy, and data initiatives.

Intellectual Property Holdings

Intellectual property is a key driver of innovation among producers and can represent a symbol of quality assurance among consumers. In agriculture, intellectual property laws provide several forms of protections—including plant patents, plant variety protection certificates, and utility patents—which can cover a wide range of innovations, including those relating to plant varieties, parts of plants, methods of breeding, methods for identifying or isolating naturally occurring traits, specific modified gene sequences, genetically engineered traits, and more. USDA has developed multiple tools in collaboration with the private sector, universities, and other federal agencies to overcome the limitations of intellectual property holdings and support genetic diversity of agriculturally important plants, summarized below.

- A major source of genetic diversity for both the public and the private sector is USDA's Agricultural Research Service (ARS) National Plant Germplasm System (NPGS), which exists in the public domain free of intellectual property rights and restrictions. This collection maintains over 600,000 unique plant accessions that can be integrated into the commercial supply to increase resilience against pest and disease pressures and evolving environmental conditions. In 2023, the NPGS released the National Strategic Germplasm and Cultivar Collection Assessment and Utilization Plan to "identify the resources and research necessary to address the significant backlog of characterization and maintenance of existing accessions." Maintaining and characterizing the collection provides both the public and the private sector means to efficiently integrate sources of genetic diversity into commercial cultivars without having to spend time and resources identifying the traits they need. Additionally, the 2023 plan suggested an increased budget necessary for managing this crucial collection.
- Every year, USDA distributes billions of dollars to enhance resilience along the agri-food supply chain through investments in plant breeding and research across multiple agencies, including the Agricultural Research Service and the National Institute of Food and Agriculture's Plant Breeding, Genetics and Genomics Programs. USDA published a statement in 2024 encouraging the sharing of germplasm and the dissemination of important plant research developed with federal funds, citing that such research is essential for the

expedited translation of research results into knowledge, products, and procedures to improve agricultural research, education, and extension. To that end, USDA urges funding recipients to plan their research, intellectual property protection, licensing, and material transfer strategies with this goal in mind.

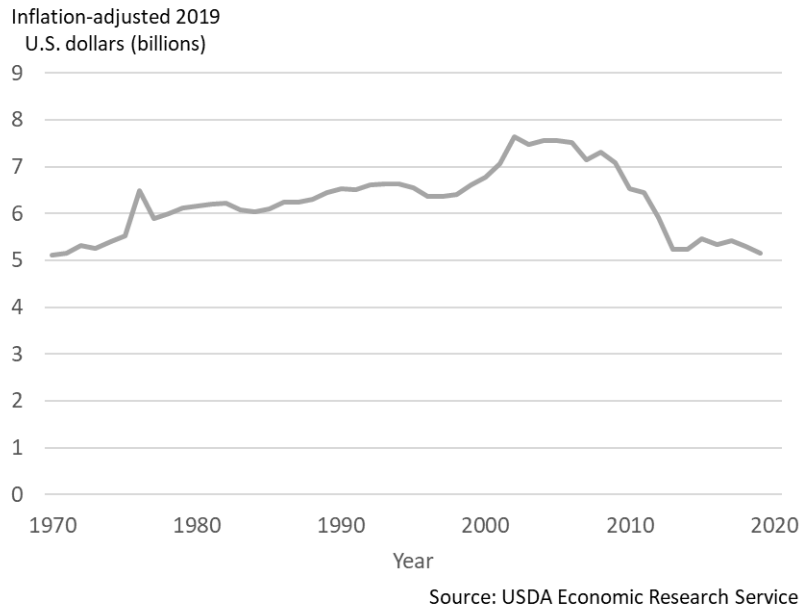
- A new interagency working group with USDA, U.S. Patent and Trademark Office, the Department of Justice, and the Federal Trade Commission brings the farmers' voices to federal agencies to identify issues of outsize market power in the seed industry. The working group is committed to promoting fair competition.
- In 2023, after a robust public comment period regarding the intersection of intellectual property rights and antitrust in the seed industry, USDA released the report More and Better Choices for Farmers: Promoting Innovation and Fair Competition in Seed and Other Agricultural Inputs. The report identified concerns raised by farmers and breeders, including accessing information, understanding patentability requirements and the scope of intellectual property rights. The report provides recommendations that address the concerns raised, such as enhancing transparency. This report identified public concerns that dominant input firms have leveraged intellectual property rights to consolidate market power, reduce transparency along the supply chain, and engage in practices that hinder farmers and independent seed suppliers' ability to choose products tailored to their needs.

Research and Development Activity

Studies have shown that public investment in agricultural research and development (R&D) has been the primary driver of improvements in agricultural productivity and has resulted in large economic benefits with annual rates of return between 20 and 60 percent.[205] Globally, productivity growth accounts for a rising share of the increase in agricultural production, easing pressure on natural resources to supply the rising demand for food and agricultural commodities. However, U.S. public agricultural R&D expenditures, when adjusted for the rising cost of conducting research, have declined by about one-third since peaking in 2002, and the United States is falling behind other major countries in investment in agricultural R&D.[206] Using alternative public R&D investment scenarios, USDA analysis on future productivity growth found that declines in public R&D have a more pronounced effect in the long-run than in the short-term, and even if public R&D investment recovers, future productivity growth would take some time to resume, due to the lag between research investment and application.[207]

[205] U.S. Department of Agriculture, Economic Research Service, *Economic Returns to Public Agricultural Research*, 2007.
[206] U.S. Department of Agriculture, Economic Research Service, *Agricultural and Food Research and Development Expenditures in the United States*, 2022.
[207] U.S. Department of Agriculture, *U.S. Agricultural Productivity Growth: The Past, Challenges, and the Future*, 2015.

Figure 3: Investment in U.S. public agricultural R&D



Public agricultural R&D is supported through federal–state partnerships, which provide an important complement to business R&D in increasing U.S. agri-food system productivity. USDA's research and science program is implemented across multiple agencies.

- USDA intramural and extramural research programs protect, secure, and improve the agri-food and natural resources systems. The "USDA Science and Research Strategy, 2023–2026: Cultivating Scientific Innovation" outlines USDA's highest scientific priorities—Accelerating Innovative Technologies and Practices; Driving Climate-Smart Solutions; Bolstering Nutrition Security and Health; Cultivating Resilient Ecosystems; and Translating Research into Action. The strategy is designed to foster public engagement on research strategies while delivering research that is inclusive, equitable, accessible, innovative, and competitive in order to build the most resilience into the future through R&D investment.
- USDA support for research and innovation enhances supply chain resilience by protecting the nation's food supply from emerging threats of pests and diseases, adapting crops and livestock to changing climate conditions, developing new farm practices that conserve natural resources and enhance soil health, improving food nutrition and safety, and stimulating opportunities for biomanufacturing. However, declining levels of investment in agricultural research by the Federal Government have put long-term supply chain resilience in jeopardy.

Trade concentration

Import Reliance

A wide range of inputs and ingredients, many of which are not immediately associated with food or agriculture, are critical to the functioning of the agri-food supply chain. Limited access to imports of products like pallets, packaging, vitamins, and machinery have all strained agri-food supply chains in recent memory. These impacts are highly variable. What is critical to one firm might not be needed for another firm.[208] Given the breadth of the sector, there is no comprehensive list of critical inputs and ingredients, so continued coordination between Federal agencies and industry members on on-going basis and during individual disruptions is necessary to understand key import reliance vulnerabilities.

USDA has focused policy options on addressing vulnerabilities to the fertilizer sector, given recent price volatility. Fertilizers are particularly vulnerable to disruptions, because there are few producers, and exporters are limited to a handful of countries. Combined, China, Russia, the United States, India, and Canada produce more than 60 percent of the world's fertilizer nutrients.[209] Disruptions from any major exporter may cause significant fertilizer shortages and increases in prices. For example, in recent years, fertilizer export restrictions and supply and logistics issues have disrupted supply chains and price stability.

The United States is a significant producer of nitrogen and phosphorus yet imports nearly 20 percent of all its fertilizers, mostly large quantities of potassium-based fertilizers—over 80 percent of potash is imported due to the heavy concentration of potash mines outside the U.S.—and some smaller amounts of nitrogen and phosphate fertilizers. Crop production relies on these three macro fertilizers in some combination, which have limited substitutability. Fertilizer prices account for nearly one-fifth of U.S. farm cash costs, with an even greater share for corn and wheat producers. Fertilizer accounts for an estimated 36 percent of a farmer's operating costs for corn, and 35 percent for wheat on average. While imported fertilizer can provide lower market prices and greater availability, disruptions to supplies and costs can also severely impact operating costs as well as farmers' production choices and ability to sustain crop production.

USDA has made significant investments through its Fertilizer Production and Expansion Program to spur domestic competition in fertilizer production and combat rising fertilizer costs.

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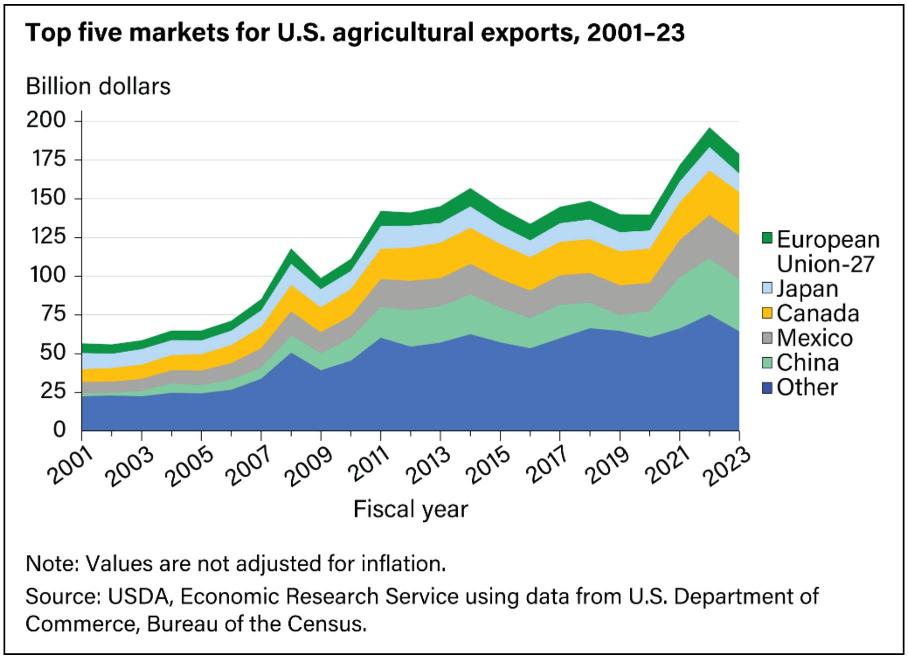
[208] U.S. Department of Homeland Security, Public-Private Analytic Exchange Program, *Threats to Food and Agricultural Resources*, 2021, https://www.dhs.gov/sites/default/files/publications/threats_to_food_and_agriculture_resources.pdf
[209] U.S. Department of Agriculture, *Impacts and Repercussions of Price Increases on the Global Fertilizer Market*, 2022, https://fas.usda.gov/sites/default/files/2022-09/IATR%20Fertlizer%20Final.pdf.

Export Reliance

Approximately 20 percent of U.S. agricultural production is exported, providing important cash receipts for farmers and generating economic opportunities for rural America. Although the last three years of U.S. exports have been at their highest values ever, reaching a record $196 billion in 2022, exports have also become slightly more concentrated in the top six markets. In 2023, the top three destinations accounted for nearly half of all exports, and the top 6 markets accounted for 67 percent of U.S. exports. Geopolitical turmoil or natural disasters that could potentially shut off one of these major markets risks the loss of significant income for rural America, making export market diversification a goal to ensure the resilience of U.S. agriculture. For several major export commodities, the risk to producers is even greater due to high concentration in just a few key markets. For soybeans—the top U.S. agricultural export valued at $28 billion in 2023—the top three trading partners accounted for 77 percent of exports.

Figure 4: Top five markets for U.S. agricultural exports, 2001–23



USDA operates numerous market development programs, trade missions and events, credit guarantee programs, and trade capacity building programs in an effort to diversify export markets, allowing the U.S. agri-food sector to be more nimble and less dependent on a few major trading partners.

- The Foreign Agricultural Service (FAS) routinely works to facilitate trade by opening new markets, expanding existing markets, and addressing unjustified tariff and nontariff trade barriers imposed by trading partners on U.S. agricultural products. FAS works closely with DOC's International Trade Administration to support the work of the Office of the U.S. Trade Representative (USTR) in on U.S. Government interventions advocating for a rules-based trading system at the World Trade Organization, and with other U.S. Agencies in ensuring the continued integrity of international standard setting bodies. FAS also provides analysis and support to USTR for the monitoring and enforcement of free trade agreements, and advocacy with trading partners to resolve unjustified barriers impeding U.S. exports.
- FAS manages a variety of programs aimed at expanding export markets, such as the Market Access Program ($200 million per year); Foreign Market Development Program ($34.5 million per year); Agricultural Trade Promotion ($300 million in 2019); and the Regional Agricultural Promotion Program ($1.2 billion multi-year; beginning 2024).

Supplier diversity

Supplier Concentration

A challenge to supply chain resilience in the agri-food sector is the relatively high levels of concentration in particular markets. Market concentration—measured by the share of industry sales held by the largest firms—has increased sharply over the last four decades in many seed, livestock, and food retail markets. In 2018–20, two seed companies accounted for 72 percent of planted corn acres and 66 percent of planted soybean acres in the United States. In 2019, the four largest meatpackers accounted for 85 percent of steer and heifer slaughter and 67 percent of hog slaughter. Most poultry farmers and livestock producers face even higher levels of concentration in the local markets in which they sell their products. In most metropolitan areas, five to six store chains account for most supermarket sales.

USDA has conducted and published peer-reviewed analyses of concentration and competition in three agribusiness sectors: crop seeds, meatpacking, and food retailing.[210] Over the past several decades, concentration in each of these sectors has significantly increased and been the subject of antitrust investigations. Findings from these analyses include:

- Opportunities to commercialize innovations in agricultural biotechnology and stronger protection for intellectual property rights over seed and related agricultural biotechnology innovations were a major driver of seed sector consolidation. This was accompanied by more private research and development investment in crop agriculture, rapid diffusion of improved crop varieties to farmers, and higher farm productivity. Stronger scientific and marketing links between seeds and agricultural chemicals were followed by a series of mergers among firms in these industries.
- At the same time that U.S. seed markets became more concentrated, seed prices rose significantly, especially for genetically modified (GM) varieties. However, the evidence is mixed on whether market concentration led to higher seed prices or whether other factors may have been more important determinants of seed price inflation. Between 1990 and 2020, the average price farmers paid for seed rose by 270 percent, compared with commodity price inflation of 56 percent. For crops planted predominately with GM seed (corn, soybeans, and cotton) seed prices rose by an average of 463 percent. Despite their higher cost, GM crop varieties brought significant productivity gains to farmers, partly through higher yield but also by lowering farm production costs as genetic traits substituted for other inputs.
- Meatpacking price "spreads" (the margin between what meatpackers pay farmers for live animals and charge retailers for meat products) have increased significantly in beef over the past decade, which may reflect firms' exercising market power to raise profits. Higher price spreads and USDA financial support are attracting new entrants into the industry, which could increase competition in the sector.
- U.S. antitrust reviews played important roles in agri-food industry restructuring. To maintain market competition and incentives to innovate, antitrust reviews led to divestitures of some company assets in mergers involving the "Big Six" seed-chemical global leaders (BASF,

[210] U.S. Department of Agriculture, Economic Research Service, *Concentration and Competition in U.S. Agribusiness*, 2023.

> Bayer, Dow Agrosciences, DuPont, Monsanto, Syngenta). Merger reviews have stopped or altered a few meatpacking mergers, but have not been sufficient to halt consolidation in that industry. Food retail mergers frequently attract antitrust scrutiny, including recent cases such as the merger between grocery stores Kroger and Albertsons. These enforcement actions have tended to focus on mergers rather than conduct, and there has yet to be a major monopolization case brought that would potential structurally separate existing food industry monopolies.

The food retail sector is less concentrated than livestock and poultry processing but still presents challenges to supply chain resilience at the point of sale of retail food to consumers. Moreover, some retail firms exercise considerable buyer power, which can affect competition and market access for processors and producers up the supply chain. The top four food retailers (CR4) accounted for 34 percent of total sales in 2019.

In response to these findings, USDA has prioritized investments to expand the middle of the supply chain and strengthen local and regional food systems to build agri-food supply chain resilience. These investments to expand the middle of the supply chain will provide more options for both producers and consumers and make the food system more resilient and less reliant on limited options. USDA has also published new rules to foster fairer and more competitive markets and increased enforcement coordination with the Department of Justice.

Agility

Manufacturing Complexity and Lead Time

Conventional agricultural production has limited flexibility in adapting to supply and demand shocks. Switching agricultural production from one commodity to another requires a long lead time, typically months to years, depending on the production cycle of the specific crop or livestock. Agricultural production and marketing cycles are fixed periods determined by the time between when a crop is planted or a live animal is born until a product is marketed. This process requires advanced planning and often significant investment in specialized equipment and infrastructure. The production cycle is dependent on fixed factors, such as sufficient temperature, sunlight, and irrigation conditions, and the application of specialized inputs, such as seed and fertilizer for crops and feed for livestock, at specific intervals of the production cycle as well as continuous monitoring and treatment for disease and pest threats. Thus, the conventional agricultural sector cannot quickly ramp up production to meet short-term needs. However, releasing crops from storage, substitution between similar crops/livestock, and "imports" (whether from other States or foreign countries) can provide flexibility in the short term while production cycles adjust to new supply and demand characteristics over the longer-term. Additionally, significant research development, and commercialization advances in Controlled Environment Agriculture, biotechnology, and biomanufacturing of food and ingredients are expected to complement conventional production practices and contribute to year-round production that enhances nutrition security.

The USDA Science and Research Strategy 2023–2026 supports research on biotechnology and biomanufacturing capacity in food and agriculture to reach the bold societal goals for advancing the U.S. bioeconomy to support a sustainable circular economy. Active research supported by both public and private sectors are ongoing to address critical scientific challenges and societal issues including public acceptance and regulatory policy development to ensure safe food.

Manufacturing Flexibility

Disruptions in food production and manufacturing pose extraordinary challenges to ensuring food and nutrition security, and circumstances in local communities remain unpredictable.

For example, an apple surplus paired with the closure of a key processor during the 2023 harvest prevented many processors, who still had full storage warehouses from a surplus the previous year, from purchasing new crop apples, leaving growers with insufficient market opportunities and orchards full of apples left to rot. However, USDA purchased $10 million of apples from West Virginia growers, saving them from waste, and donated the fresh produce to hunger-fighting charities across the country. This creative approach to an unexpected supply chain problem provided financial support to growers, prevented food waste, and increased food and nutrition security through access to fresh fruit.

Logistical Adaptability

The nation's extensive transportation system underlies the resilience of the agri-food supply chain. Agricultural products are the single largest user of freight services in the United States, comprising 24 percent of freight services across all modes by tonnage and 27 percent of all ton-miles.[211] The four major modes—barges, ocean vessels, trucks, and railroads—operate as a seamless network, both complementing and competing with one another, to deliver products efficiently and economically within ever-changing domestic and global markets. However, while this system of inland waterways, ocean ports, containers, highways and bridges, trucking, and railroads, is resilient to most localized disruptions, it remains vulnerable to system-wide shocks. These systemic shocks include drought, flooding, border-crossing slowdowns, and labor disruptions, as well as localized failures resulting from infrastructure degradation or damage.

Drought in the Mississippi River watershed in fall 2022 and fall 2023 led to a reduction in the ability to ship corn and soybeans via barge on the river. Because barge transportation is the most economical mode of transportation for long-distance shipments, a bottleneck that disrupts barge shipping can potentially result in higher shipping costs for grain exporters. In that same time period, low water levels in the Panama Canal and Houthi attacks on vessels transiting the Red Sea greatly reduced access to major trade routes. The Panama Canal is a key route for shipments of U.S. grains to Asian markets, which means increased shipping costs and impacts on U.S. exports.

Labor strikes and lockouts across ports can also disrupt supply chains, leading to delays, increasing congestion, and increasing logistical costs for shippers. Even the threat of a strike is enough to induce uncertainty among many businesses, which can lead to delays due to rerouting, increased logistical costs, and ultimately disruptions to agricultural commodity exports. Stakeholders also report that slowdowns at U.S.–Mexico border crossings due to increased enforcement activity by state and Federal authorities has caused delays and disruptions in the flow of rail and truck freight for agricultural commodities.

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211 U.S. Department of Agriculture, Agricultural Marketing Service, *The Importance of Highways to U.S. Agriculture*, 2020, https://www.ams.usda.gov/sites/default/files/media/Main_Highway_Report.pdf

USDA participates in government-wide efforts to support logistical adaptability across the agri-food supply chain.

- USDA has remained actively involved in data sharing and coordination with partners at the Department of Transportation and Army Corps of Engineers and has engaged extensively on transportation matters impacting the agri-food sector with independent agencies, such as the Federal Maritime Commission and Surface Transportation Board.

Security

The agri-food supply chain is extensively interconnected, diverse, and complex. It is one of many heavily interdependent infrastructure sectors that experiences potential security threats from ecological and climate risks, pests and disease, cyberattacks, and intentional harm to physical infrastructure. Both the public and private sectors have paid extensive attention to fortifying the sector to enhance its resilience to potential threats. National Security Memorandum (NSM) 16 on *Strengthening the Security and Resilience of United States Food and Agriculture* and NSM-22 on *Critical Infrastructure Security and Resilience* outline policy and activities for the Federal Government and private sector to strengthen the resilience of the agri-food sector against security vulnerabilities. However, because the majority of the agri-food sector is owned and operated by non-federal entities in the private sector, no single policy framework or operational approach at present exists to address food and agriculture as a single sectoral function.

The agri-food supply chain is vulnerable to the effects of climate change across its entire continuum—from production to consumption. Natural disasters and extreme weather events, limited water resources, loss of pollinators, and an increased likelihood for exposure to pests and pathogens are exacerbated by climate change with the potential to decrease future agricultural productivity. Agricultural production is projected to decline in regions with increased frequency and duration of climate change impacts, according to the Fourth National Climate Assessment.[212] The increased frequency and severity of extreme weather events such as hurricanes, floods, and fires have negatively affected working lands and increased the risk of secondary disturbances such as erosion, invasive species, poor water quality, and telecommunications disruptions, as well as community and animal health.[213]

Pests, invasive species, pathogens, and diseases can disrupt agricultural trade and have substantial economic and environmental impacts. Transboundary animal diseases (TADs) can infect livestock and poultry and quickly spread through a vulnerable population, potentially leading to heavy losses and severe trade consequences. The threat to the agri-food supply chain is further complicated by any widespread disease—such as COVID-19, the 2009 H1N1 swine influenza, or zoonotic diseases (capable of spreading between animals and humans), which can cause significant human morbidity

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[212] U.S. Government Accountability Office, *Climate Change: Options to Enhance the Resilience of Agricultural Producers and Reduce Federal Fiscal Exposure*, 2023, https://www.gao.gov/assets/d23104557.pdf.
[213] Food and Drug Administration, U.S. Department of Agriculture, Department of Homeland Security, *National Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture: 120-Day Food and Agriculture Interim Risk Review,* March 2023, https://www.fda.gov/media/170114/download?attachment.

and mortality. Disease outbreaks can impact the availability of workers for the production and inspection of crops and livestock and impact the supply chain.[214]

The widespread adoption of data-driven and connected devices in the agri-food sector provides valuable insights to enable more efficient production but also creates significant security vulnerabilities and a target rich environment for cyberattacks.[215] Some cyber threat actors target agribusinesses due to the value and wealth of information the sector holds while other actors are opportunistic, focusing their attacks on sectors where businesses may have relatively weak cybersecurity postures; this is especially true in ransomware campaigns.[216] Nation states and other threat actors are also seeking to compromise critical infrastructure, including in the food and agriculture sector, to disrupt operations and possibly, the health, safety, and economic activity of a community.[217] The growing reliance on data analytics and cloud technologies has also increased the use of third-party providers, raising additional supply chain risks for the security and privacy of data.

Security incidents impacting other critical sectors can severely disrupt the agri-food supply chain, compromising its integrity. Disruptions to production, storage, or transportation, for example, could lead to rerouting and delivery delays for perishable items and contamination of food products, putting consumers at risk.[218] Damage and interruptions to production and processing at farms and facilities may reduce harvest yields or prevent the ability to process crops and food products efficiently, causing delays along the entire supply chain, and could also cause economic and public health impacts.[219] Given critical interdependencies on water and wastewater, energy, and transportation systems, an attack on one of these sectors could have cascading impacts on the food and agriculture sector.[220]

Given that the agri-food supply chain is almost entirely owned by private industry, USDA's strategies, outside of and separate from regulatory responsibilities, are largely driven by incentives and by ensuring the availability of the latest programs, services, resources, and tools to help the agri-food sector pursue voluntary security efforts that result in effective and sustainable solutions.

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[214] Terrorism, Infrastructure Protection and the U.S. Food and Agricultural Sector: Hearing before the Senate Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, 107th Cong., XX Sess., (2001) (Statement of Dr. Peter Chalk, Policy Analyst, RAND Washington Office).

[215] U.S. Department of Agriculture, Agricultural Marketing Service, Grain Inspection Advisory Council, *Cyber Security Discussion Paper,* 2024. https://www.ams.usda.gov/about-ams/giac-may-2024-meeting/cybersecurity.

[216] "Farm-to-Table Ransomware Realities – Exploring the 2023 Ransomware Landscape and Insights for 2024," *The Food and Agriculture-Information Sharing and Analysis Center*, April 2024, https://www.foodandag-isac.org/resources.

[217] Cybersecurity & Infrastructure Security Agency, *Defending OT Operations Against Ongoing Pro-Russia Hacktivist Activity*, 2024, https://www.cisa.gov/sites/default/files/2024-05/defending-ot-operations-against-ongoing-pro-russia-hacktivist-activity-508c.pdf.

[218] US Department of Homeland Security, Public-Private Analytic Exchange Program, *Threats to Food and Agricultural Resources*, 2021, https://www.dhs.gov/sites/default/files/publications/threats_to_food_and_agriculture_resources.pdf.

[219] Food and Drug Administration, U.S. Department of Agriculture, Department of Homeland Security, *National Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture: 120-Day Food and Agriculture Interim Risk Review,* March 2023, https://www.fda.gov/media/170114/download?attachment.

[220] US Department of Homeland Security, Public-Private Analytic Exchange Program, *Threats to Food and Agricultural Resources*, 2021, https://www.dhs.gov/sites/default/files/publications/threats_to_food_and_agriculture_resources.pdf.

The following examples summarize the wide spectrum of efforts USDA and partner organizations have undertaken against various security threats:

- USDA and FDA are co-Sector Risk Management Agencies in NSM-22 and work collaboratively across the agri-food supply chain to build greater resilience to the potential vulnerabilities it faces.
- USDA continues to implement a wide array of activities as called for in NSM-16. This includes holding a Food and Agriculture Sector Vulnerability Workshop with participants from the GCC and SCC.
- USDA and FDA continue to encourage agri-food companies to participate in the Food and Ag- Information Sharing and Analysis Center (ISAC), previously the Food and Agriculture Special Interest Group (SIG), which provides participating companies with threat intelligence, analysis, and effective security practices that help companies detect attacks, respond to incidents, and share indicators so they can better protect themselves and manage risks to their companies and the agri-food supply chain.
- FDA and USDA have identified four Key Activity Types (KATs)—bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities—as the most vulnerable processing activities. These four KATs consist of points, steps, or procedures consistently ranked as the most vulnerable, regardless of the food commodity assessed, and reflect significant vulnerabilities to intentional adulteration caused by acts intended to cause wide scale public health harm. In FDA-conducted inspections of food defense plans in support of FDA's Intentional Adulteration regulation, private industry facilities are widely using the KATs to identify vulnerable points in their production processes.
- USDA’s Climate Hubs is a unique cross-agency program that develops and delivers science-based, region-specific information to producers, stakeholders, and USDA staff to reduce climate risks and enable climate-informed decision-making. The Climate Hubs translate USDA’s research and science, especially on climate impacts on supply chain vulnerabilities, into management and action on-the-ground linking with extension, natural and agricultural resource managers, and USDA field staff. By working with both external partners and with USDA agencies, individual Hubs can help train agencies’ staff on regional climate risks, adaptation options, and ways to use tools and data to manage those risks and assess options. This will help support and improve climate literacy and engagement on climate risk to supply chains and procurement.
- USDA’s Food Safety Inspection Service (FSIS) encourages regulated entities to develop a food defense plan and implement food defense best practices identified through vulnerability assessments. FSIS performs food defense tasks in all regulated establishments to identify vulnerabilities that may lead to intentional contamination of product. The data from the tasks are used to measure the percentage of establishments that maintain food defense practices, which allows FSIS to better understand how food defense practices are being implemented by industry. This understanding then guides how FSIS provides outreach and education activities aimed at improving uptake of preparedness and threat mitigations in regulated facilities.

- USDA's Animal and Plant Health Inspection Service (APHIS) operates a National Veterinary Stockpile (NVS) program providing support to States, Tribes, and Territories responding to outbreaks of animal diseases. The NVS helps protect the nation's food supply by quickly providing necessary resources during an animal disease outbreak. Within 24 hours, the NVS can provide veterinary countermeasures—including certain types of animal vaccines, antivirals, supplies, equipment, and response support services—to animal health officials in affected areas. With NVS support, officials can set up immediate measures to contain and eradicate the disease, minimizing the animal losses, market disruptions, and other economic damages that result from an outbreak.
- The Department of Homeland Security's Cross-Border Threat Screening and Supply Chain Defense (CBTS) Center of Excellence (COE) is creating a comprehensive mapping database of known threats, pinpointing the factors that significantly influence agricultural and food security, including climate change, natural disasters, invasive species, emerging diseases, trade policies and socioeconomic factors. The research team, led by Texas A&M University, is also studying the impacts of pests and pathogens on crops vs. livestock and how all these threats impact public health, economics, and the environment.

Economic health and compliance

Financial Stability

Measures of farm income, wealth, and other financial indicators have been strong for the agricultural sector since 2020. The past three years generated much higher aggregate farm income than historical levels. Driven by strong global demand, high commodity prices, and ad hoc support payments, the U.S. farm sector experienced rising farm incomes that reached a record high in 2022 of more than $200 billion. However, net farm income in 2024 is forecast to be 27.6 percent below the 2022 record high but 15.2 percent above its 20-year average (2004–23) of $121.5 billion in inflation-adjusted dollars.[221]

Farmers are facing softening prices and production costs that remain elevated, as well as higher financing costs. U.S. agricultural exports have been strong but are expected to continue to face fierce competition from other global producers, especially South America. In addition, there are growing concerns regarding weaker demand from China, the world's largest agricultural importer, due to ongoing macro-economic problems. Weaker output prices relative to elevated input prices is leading to concerns of tightening margins and lower farm incomes for U.S. producers.

Recent credit data paints a concerning picture, especially for crop producers. Farm income has retracted sharply since the 2022 record high, loan repayment rates are down slightly, and loan demand has risen notably. This tightening is particularly pronounced in areas reliant on crops, while cattle-heavy regions see less impact. Lenders report concerns about working capital deterioration due to low crop prices. While strong cattle prices provide some relief, continued low crop prices throughout 2024 could lead to further tightening of credit conditions and potentially squeeze farm borrowers.

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[221] U.S. Department of Agriculture, Economic Research Service, *Farm Sector Income & Finances: Highlights from the Farm Income Forecast*, 2024.

The Federal Government provides financial stability to the agricultural sector through Direct Government Farm Payments. Typically, most direct payments to farmers and ranchers are administered by USDA using the Farm Bill or related authorities. Direct payments can also come from supplemental programs authorized by the U.S. Congress. In addition, USDA's Farm Loan Programs offer eligible farmers and ranchers access to credit to start, purchase, sustain, and expand family farms. These loans are temporary and designed for farmers and ranchers to graduate to commercial credit.

Quality and Reliability

Total factor productivity (TFP) provides a broad measure of the economic health and performance of an economy or economic sector. TFP indexes indicate the rate of improvement in technology, efficiency and economic competitiveness. Between 1948 and 2021, average annual growth rates in real output and TFP for the aggregate farm sector were 1.46 percent and 1.49 percent, respectively. For the past decade or so, however, there has been a significant slowdown in the rates of output and TFP growth. Between 2013 and 2021, annual growth rates in output and TFP for the aggregate farm sector averaged only 0.28 percent and 0.51 percent, respectively, indicating TFP was growing at only about one-third of its long-run average. However, between 2019 and 2021, TFP experienced a resurgence, growing by over 5 percent/year. This resurgence may be due to short-run factors, such as recovery from previous drought years, in which case it would likely be short-lived.

Possible reasons for a slowdown in long-run agricultural TFP growth include (i) insufficient investment in agricultural R&D; (ii) adverse weather conditions, which could be due to climate change; (iii) outbreaks of new pests and diseases; and (iv) regulatory barriers or consumer apprehensions toward application of some new technologies in agriculture.

Compliance

The United States agri-food supply chain is one of the safest in the world, but preventing foodborne illness remains a major public health challenge. Foodborne illnesses can cause a range of health issues as well as lead to long-term diseases and even death. Non-compliance with food safety guidelines can disrupt the agri-food supply chain by weakening the workforce (through foodborne illness) and by necessitating product recalls (as companies must identify and locate affected products). USDA estimated the annual economic burden of foodborne illnesses (including the social costs of medical care, lost productivity, and premature death) to be $17.6 billion in 2018 dollars.[222] Proper compliance with food safety guidelines ensures operational efficiency in the agri-food supply chain, minimizes waste, and keeps consumers safe.

USDA maintains compliance on food safety guidelines across multiple agencies and aspects of the agri-food supply chain related to food processing and food distribution. USDA's guidelines include requirements applicable to: meat and poultry processing regulations; food safety practices; food labeling standards; sanitary performance standards; quality assurance standards; export regulations; biotechnology regulations; crop and livestock insurance regulations; animal and plant health

[222] U.S. Department of Agriculture, Economic Research Service, *Updating Economic Burden of Foodborne Diseases Estimates for Inflation and Income Growth*, ERR-297, 2021.

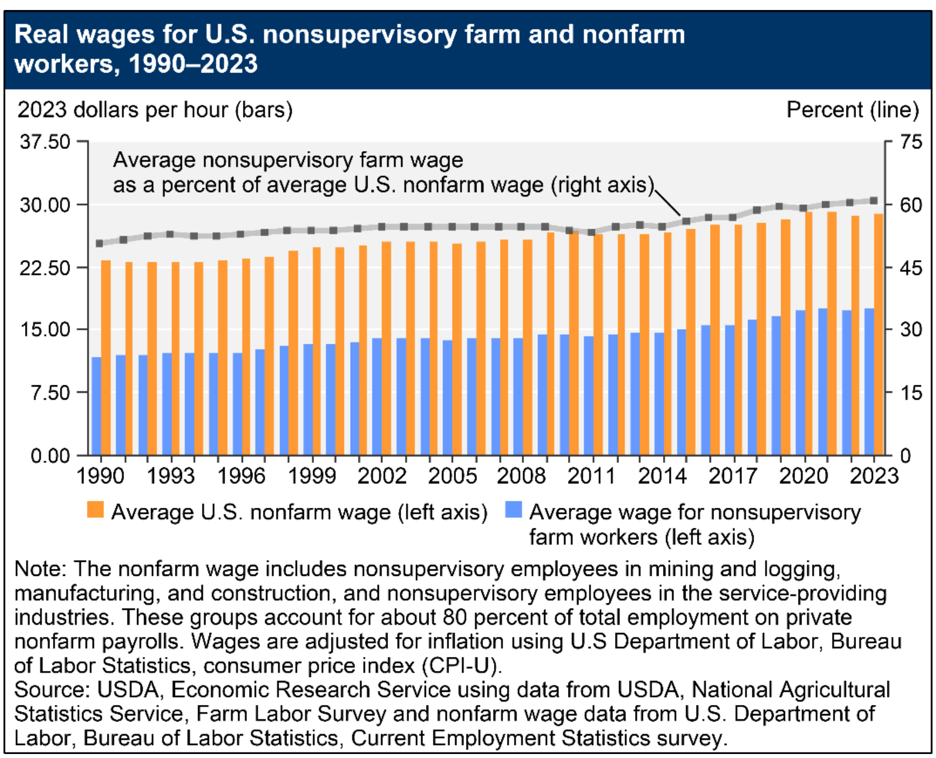
regulations; food distribution regulations; rural development regulations; grain inspection regulations; organic regulations; and the Packers and Stockyards Act regulations.

USDA ensures its rules and regulations are transparent and science based, providing opportunities for the agri-food industry to participate in the rule-making process. USDA informs and establishes accountability through published regulations, notices and directives, agency initiatives, and research-based industry guidelines. USDA engages stakeholders in vital conversations—about developing standards and resources needed to support compliance—through monthly stakeholder meetings, industry roundtables, webinars, presentations at conferences, and individual establishment engagement. If an incident occurs, USDA works quickly to restore compliance with regulatory requirements to protect U.S. agriculture and the integrity of the agri-food supply chain.

Workforce

For many decades, immigrants have played an essential role in U.S. agriculture. By some estimates, around 70 percent of farmworkers in crop agriculture are immigrants, primarily from rural Mexico, and about 60 percent of them are not authorized to work legally in the United States. However, there are many indications suggesting that the supply of workers from rural Mexico is declining. For example, farmers have increasingly reported labor shortages, farm wages are rising in all regions, and there has been a significant increase in the employment of H-2A guest workers. Some likely causes for this decline in labor supply are falling fertility rates in rural Mexico, the stronger enforcement of U.S. immigration laws, and better employment opportunities in the Mexican economy.

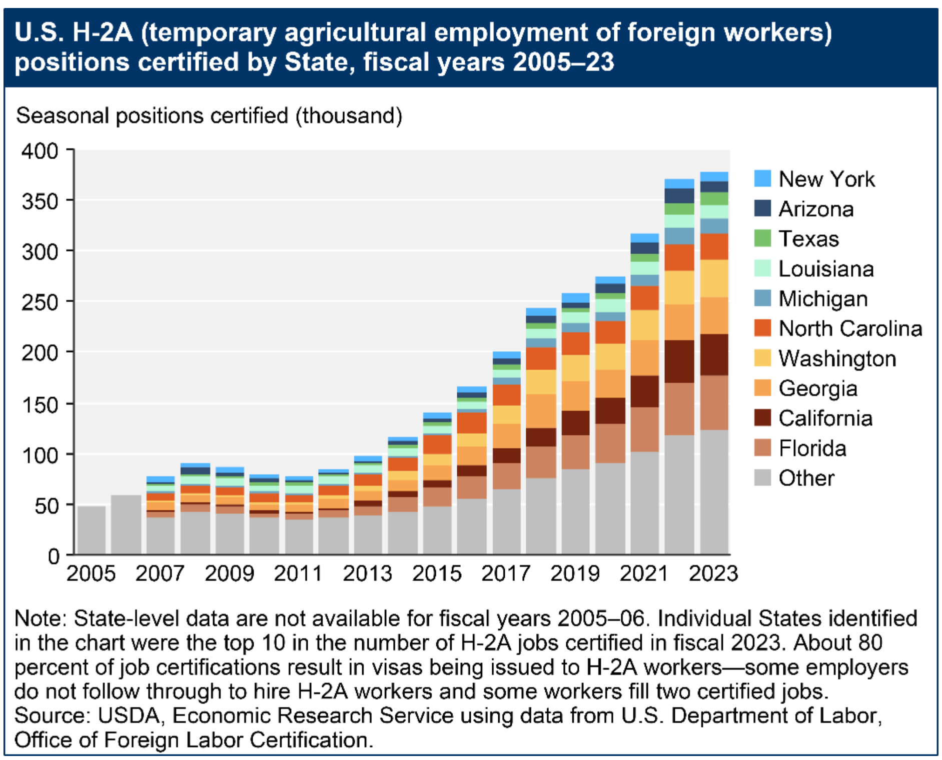
Figure 5: Real wages for U.S. nonsupervisory farm and nonfarm workers, 1990–2023



Labor-intensive agricultural industries are most sensitive to falling labor supply. In crop production, fruits and vegetables, as well as nursery and greenhouse production, are particularly labor-intensive. Within livestock, the most labor-intensive industries are aquaculture and dairy. Producers in these industries are adjusting to a decreasing farm labor supply by employing several strategies. For example, if they decide not to decrease production, they can try to substitute labor with capital by mechanizing. However, mechanization technology is not yet available for many crops and can be expensive in other cases, so it is often not a viable solution.

For some producers, hiring guest workers through the H-2A program is a better option. The H-2A Agricultural Guest Worker Program allows producers to hire non-immigrant foreign workers to fill temporary or seasonal agricultural jobs. The program has grown rapidly in recent years, partially addressing the tightness of the labor market stemming from the decline in the supply of U.S. farm labor. The U.S. Department of Labor (DOL) certified around 378,000 temporary jobs in fiscal year (FY) 2023 under the program, more than seven times the number certified in FY 2005.

Figure 6: U.S. H-2A (temporary agricultural employment of foreign workers) positions certified by state, fiscal years 2005–2023



H-2A employment has increased in all regions and sectors of the country since 2010, with the greatest concentrations in States with large, seasonal, and labor-intensive agricultural sectors, especially in fruit and vegetable agriculture. Increases in H-2A employment were much smaller in livestock and nursery compared to other labor-intensive sectors. This may stem from the fact that, while these two sectors contain large and labor-intensive industries, such as dairy, jobs in these industries tend to be year-round and thus don't qualify for H-2A employment. It is worth noting that employers in labor-intensive agriculture-related industries, also heavily exposed to declines in labor supply, such as meat processing, are ineligible to participate in the H-2A program.

PRIORITIES AHEAD

Four-year Outlook

In the next four years, the agri-food supply chain will undoubtably continue to face a range of challenges that will require intentional and coordinated response. As climate risks continue to grow, an increase in weather-related natural disasters and the increased movement of pest and disease concerns will continue to threaten crop and animal production. These scenarios may unfold at a time when farm income is projected to soften, meaning they may have an even larger impact on the stability of rural communities. Other factors, including shifting market power concentration, changing global market dynamics, evolving technologies, and impacts to transportation flows, may also have substantial impacts to food and agriculture supply chains. Continued U.S. investment in transportation infrastructure can help alleviate many bottlenecks for food and agriculture products domestically but functioning global markets will be key for the overall health of the sector. As additional market consolidation occurs across the sector, scrutiny should be given to proposed mergers and acquisitions of any transactions that are directly or indirectly related to food and agriculture. Moreover, additional attention should be paid to the conduct and market structure in the industry to arrest potentially unfair or anticompetitive practices regardless of merger transactions. Emerging technologies present new opportunities to better predict, monitor, and respond to potential supply chain disruptions, but such tools will work best with full coordination across all levels of government as well as the private sector.

Four-year Resilience Goals and Priorities

Overview

Thanks to significant investments by Congress through the American Rescue Plan, Inflation Reduction Act, and Bipartisan Infrastructure Law, USDA has made significant initial progress on many needs related to supply chain resilience over the past four years. The actions laid out in this section focus on lessons learned and logical next steps for this significant body of work. Additionally, many of the actions outlined in the 2022 USDA Agri-Food Supply Chain Assessment remain relevant.

Priority 1: Increasing Data Availability, Analysis, and Coordination

Goal: The U.S. Government needs a robust and integrative data analysis and coordination platform that quickly and clearly links multidisciplinary data sets critical for agri-food supply chains.

Current reality: Currently, the government lacks government-wide indicators and sufficient data and research to plan for, react to, and resolve agri-food supply chain issues in real-time, which is vital given the perishable, seasonal, and essential nature of food.

Path forward: Strengthening the resilience of our country's agri-food supply chains will require: 1) enhanced data and market intelligence to address disruptions early, reducing impacts on individuals and communities, and 2) increased federal coordination on agri-food supply chain disruptions as part of the nation's critical infrastructure.

USDA can better anticipate and respond to supply chain constraints including those related to market concentration and just-in time procurement approaches by increasing data analysis and sharing related to critical supply chain components, where information is not commonly captured or currently shared across government and with stakeholders (e.g., additional transportation data, partnering with other federal agencies who have agri-food data to amplify the collective ability to assess supply chains), and supporting ongoing required responses for policy and program input on agri-food supply chains to government wide initiatives.

USDA's existing AgTransport open data platform provides a framework for the type of additional data platform that could be leveraged and enriched to include additional key indicators to detect, analyze, and communicate supply chain disruptions to the agri-food sector.

USDA will continue close coordination with other Departments and Agencies, such as the Department of Transportation and FDA, to continue to enhance this work. USDA will also continue to work with private sector partners to expand available data sources. With additional resources, USDA could further develop and implement more robust data tools and insights to help inform understanding of agri-food supply chains.

Priority 2: Investing in Research

Goal: Now more than ever, USDA research programs need to be adequately funded to help the U.S. agri-food sector meet and respond to critical supply chain threats. Science and innovation are necessary to overcome these challenges and must underpin policy interventions, while nonproprietary, publicly-funded research keeps new knowledge available and accessible to all.

Current reality: Given the breadth and intersecting nature of issues critical to food and agriculture supply chains, public sector research is incredibly necessary to better understand and directly ignite opportunities to improve resilience in continually shifting value chains. As noted in this Review, research funded by the public sector remains a primary driver of improvements to agricultural productivity, and investment in such research has fallen.

Path forward: Over the next four years, it is critical to invest in systems-level, as well as foundational research in agricultural production and products, for integrated Extension activities to transfer research findings to producers and consumers, and for continued development of the skilled workforce needed to spur the agricultural enterprise. Focused investments in these topics should be made in the three major complementary components of AFRI: 1) Sustainable Agricultural Systems, 2) Foundational and Applied Science, and 3) Education and Workforce Development.

Agriculture science and innovation should drive the future of sustainable and resilient agriculture systems by filling scientific gaps that are unmet by current programs. To accomplish this goal, USDA's Science and Research Strategy[223] provides a road map for this work. As outlined in that strategy, specific areas for increased focus include:

- Accelerating Innovative Technologies & Practices: USDA must rapidly catalyze the development of new technologies and practices that are innovative, resilient, and commercially viable.
- Driving Climate-Smart Solutions: USDA must advance research that addresses risks from long-term and acute climate stressors and improves climate resiliency.
- Bolstering Nutrition Security & Health: USDA must deliver science-based information to support food accessibility while continuing to drive innovative solutions.
- Cultivating Resilient Ecosystems: USDA must support research that helps to create a resilient, healthy, and viable production ecosystem that reliably provides food, feed, fuel, and fiber for all while enhancing quality of life and conserving natural resources for future generations.
- Translating Research into Action: USDA science and research must respond to the needs of the diverse communities the Department serves, be accessible to all, and be translated into action in communities across the nation.

Strategies for accomplishing this work include fostering an environment to evaluate high risk, high reward bid ideas that stretch across scientific disciplines; creating an environment that incentivizes diversity and creativity of thought; and supporting innovations that enable risk-based and scientifically sound policymaking.

Priority 3: Supporting Diversified and Competitive Market Opportunities

Goal: More resilient agri-food supply chains should be built on more diversified and more competitive markets that allow for more flexibility and adaptability in the face of disruption.

Current reality: The pandemic and associated market disruptions highlighted the rigidness and consolidated nature of most current agri-food supply chains, from initial crop input markets through consumer-facing products.

Over the past four years, USDA has made significant strides to implement programs to address these key issues.

USDA has invested heavily in opportunities to build more and better market opportunities including by investing in critical infrastructure through the Fertilizer Production Expansion Program, Resilient Food System Infrastructure grants, and a suite of meat and poultry processing investments. USDA also launched resources such as the Local and Regional Food Systems Resilience Playbook to showcase how such food systems are an essential part of the frontline response in the face of a disruption. Playbook recommendations to equitably coordinate recovery, build and safeguard

[223] U.S. Department of Agriculture, Research, Education, and Economics, *USDA Science and Research Strategy*, *2023 – 2026,* 2023, https://www.usda.gov/sites/default/files/documents/usda-science-research-strategy.pdf.

infrastructure, and maintain markets through redirection of products and innovation remain core to agri-food supply chain response and resilience. As the investments made by these programs mature, the next four years provide a critical opportunity to continue to monitor and assess the impact of these investments, including conducting a gap analysis where additional investments in infrastructure are still needed.

Every year, USDA also purchases billions of dollars of food for use in nutrition assistance programs. Over the last four years, USDA has worked to leverage this procurement power and diversify the existing supplier base by advancing equity in federal procurement; launching tools to support small business participation; and partnering directly with states and Tribal governments to close gaps in local supply chains and deliver hundreds of millions of dollars' worth of local foods to food banks, schools, and other nutrition assistance programs. This work has established new supply chain relationships, helped new and small businesses expand their reach, and broadly helped build flexibility into agri-food supply chains. The next four years offer a pivotal opportunity to continue and expand this work. To ensure that producers and other stakeholders have ready access to the right tools to grow their businesses, especially as local and regional programs grow and data and research expands, USDA needs to provide more targeted technical assistance to help them navigate the available resources, provide them with data and information using our local and regional expertise to better inform their decision-making on the ground, and connect them with strategic partners that can enhance the success of their food and farm businesses while removing chokepoints from the supply chain as a whole.

USDA has also made regulatory improvements across a variety of spaces to better establish a level and competitive playing field, most notably under the Packers and Stockyards Act which governs livestock and poultry markets. As these rules have only recently gone into effect, the next four years are a critical time for enforcement to ensure the rules are applied as intended.

Path forward: The next four years offer a pivotal opportunity to continue and expand this work. These critical investments and actions are beginning to provide real transformation to the sector, but the coming years present a critical opportunity to continue to monitor and assess the impacts of this work, including conducting a gap analysis where additional investments in infrastructure are still needed while providing ongoing support for current awardees.
USDA also needs to have sustained resources to provide continued targeted technical assistance to help farm and food businesses navigate the available resources, provide them with data and information using local and regional expertise to better inform their decision-making on the ground, and connect them with strategic partners that can enhance the success of their businesses while removing chokepoints from the supply chain as a whole.

Continuing work that connects farmers and food companies with local markets, like through the Local Food for Schools and the Local Food Purchase Assistance programs, will continue to build market relationships and strengthen supply chain links, further strengthening local and regional supply chains.

Fully enforcing the Packers and Stockyards Act, including new rules that have recently gone into effect, and other antitrust statutes in this sector remains key.

Legislative and Budgetary Objectives

All the actions laid out above will require resources from Congress to carry out, both to continue existing programs as well as to ensure adequate agency staffing to allow for full program delivery. Multiple bills introduced in the 118th Congress contemplated these and related issues. USDA continues to offer and provide technical assistance to Congress at their request as they consider legislation in light of the expiration of the 2018 Farm Bill (P.L. 115-334).

Long-term Resilience Goals

Over the last century, the U.S. agri-food sector has intentionally become incredibly efficient and productive. The cost for this productivity has been resilience. Despite record-breaking farm income in recent years, typically about 7 percent of our farms receive 85 percent of that income while 93 percent of our farms are sharing 15 percent of the income. This has led to a situation in which half of farm households had negative farm income and 84 percent of farm families obtain the majority of their income from off the farm. That leaves small and mid-sized farms behind, weakens local rural economies, and threatens our food security and safety.

These market factors have led to bigger farms and fewer farmers and a general message for both farmers and food processors, that to succeed, a business needs to either get bigger or get out of the market. Since January 1981, the U.S. has lost nearly 545,000 farms and 155.6 million acres of farmland. That number of farms is equivalent to the loss of every farm in North Dakota, Minnesota, Wisconsin, Illinois, Iowa, Nebraska, Oklahoma, Missouri, and Colorado in 2023. This consolidation means more potential bottlenecks and more risk of disruption in the agri-food supply chain.

To build long term resilience, a distributed and resilient food system needs to make economic sense. Continued investments in diversifying farmer income including through creating opportunities in carbon markets and the bioeconomy; building strong and flexible supplier relationships in local and regional food systems; maintaining stable and reliable global markets; addressing labor needs; and investing intentionally in transportation infrastructure are all necessary to support long term supply chain resilience in this sector.

Conclusion

The agri-food sector is vital to the economic stability, national security, and public health and safety of the United States. As this sector continues to experience transformative change through an increasingly complex supply chain which touches on other critical sectors, USDA will work closely with other Federal agencies, with State, local, tribal and territorial governments, and with the private sector to address vulnerabilities and strengthen the resilience of our agri-food supply chain. By building on progress made through the Food System Transformation initiative, USDA's long-term vision will increase data availability and coordination, invest in research, and support diversified and competitive market opportunities to further increase supply chain resilience. These actions will continue to provide producers and rural communities with the tools and resources they need to face new challenges and ensure a more robust and sustainable U.S. agri-food economy capable of providing affordable and nutritious food well into the future.

2021–2024 Four-year Review of Supply Chains for the Public Health and Biological Preparedness Industrial Base

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DECEMBER 2024

EXECUTIVE SUMMARY

A resilient public health and biological preparedness industrial base is vital to the nation's ability to deliver effective health care.[224] Disruptive events such as pandemics, manufacturing delays, natural disasters, and product discontinuations have consistently impacted medical care for U.S. patients and revealed supply chain vulnerabilities. The economics of the medical supply chain have generally favored low cost rather than resilient supply chain steps such as diversification and redundancy. Recent decades have also seen an increasing share of production of many medical products move overseas, resulting in a greater reliance on foreign manufacturing and suppliers, and heightening U.S. national health security risks. At the same time, supplier and purchaser concentration have undermined resilience at home, prompting shortages and quality issues. The Coronavirus Disease 2019 (COVID-19) pandemic highlighted a number of these vulnerabilities, as global demand shifts and supply chain disruptions created significant challenges to delivering effective health care.

Recognizing these challenges, the Biden–Harris Administration pursued a whole-of-government effort to strengthen medical product supply chains. Two executive orders signed by President Biden in 2021 directed federal agencies to review a range of sectors, including the public health and biological preparedness industrial base, and identify strategies to respond to future threats.

Since 2021, HHS has worked with industry and across government to increase investment and expand capacity in domestic manufacturing, and to improve medical product supply chain transparency. These actions played a central role in responding to the COVID-19 pandemic and have better prepared the United States for future threats to medical product supply chains.

Despite advances made to promote robust supply chains, additional risks and opportunities remain. To promote resilience throughout the medical product supply chain, a strategic approach that includes the following HHS actions is needed:

- Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product supply chains.
- Increase availability and utilization of actionable insights into critical medical product supply chains for HHS.
- Strengthen HHS response to shortages and supply chain disruptions.
- Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other steps.

These advancements will require additional authorities and resources as well as continued collaboration with industry and other stakeholders. Importantly, the funding, investments, and public–private coordination that were mobilized in response to COVID-19 have demonstrated what progress is possible. With continued investment, the U.S. Government and the broader participants in the public health industrial base can make these supply chains even stronger so that Americans can count on receiving the health care they need.

224 For this chapter we use the terms "public health industrial base," "public health and biological preparedness industrial base," and "medical product supply chains" interchangeably, and defined as entities manufacturing, producing, or distributing pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins), non-pharmaceutical interventions (e.g., medical devices, including diagnostics, ventilators, personal protective equipment), and critical foods.

SECTOR OVERVIEW

Introduction

A resilient public health industrial base is vital to the nation's ability to deliver effective health care. In 2021, President Biden issued two Executive Orders aimed at strengthening supply chains. The first, Executive Order 14001 on a Sustainable Public Health Supply Chain, focused primarily on preparedness, directing agencies to develop a strategy to respond to future pandemics and threats through increased domestic production of key supplies.[225] The second, Executive Order 14017 on America's Supply Chains, directed reviews of several critical sectors, including a 100-day review of the supply chain for pharmaceuticals and active pharmaceutical ingredients (APIs), as well as a broader one-year review of the public health and biological preparedness industrial base. These activities mobilized a broader supply chain effort by HHS, complementing the ongoing response to the COVID-19 pandemic. Since then, HHS, in coordination with interagency partners, has continued to focus on strengthening supply chains for medical products, including pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins), non-pharmaceutical interventions (e.g., medical devices, including diagnostics, ventilators, personal protective equipment (PPE)), and critical foods (including infant formula and medical foods).

A resilient medical product supply chain is less likely to face disruption and better able to withstand and mitigate the disruptions that do occur. Robust preparedness, mitigation, response, and recovery strategies are critical to ensure the necessary medical countermeasures (MCMs) and other supplies remain available to the public. Resilience requires an expanded industrial base with diversification in sourcing of raw materials, equipment, and other supplies—both in terms of redundancy in manufacturing capacity and in the balance of domestic and diversified, foreign sourcing—as well as investment in reliable, efficient, and sustainable manufacturing practices. Mitigation and prevention tools such as buffer inventory, programmed additional capacity, and risk mitigation plans are also essential to ensure the nation is ready to respond to a public health emergency. Resilience is also enabled by reliable, efficient, and sustainable purchasing, payment, manufacturing, transportation, logistics, and distribution practices. Moreover, proactive monitoring, assessment, and communication of risks and vulnerabilities to prevent or mitigate shortages or supply chain disruptions are crucial, especially for those products at highest risk of supply chain disruptions, such as generic drugs. Strong partnerships with industry and other stakeholders are needed to facilitate and promote collaboration. Building a resilient supply chain also requires creating a system where all actors have adequate incentives and responsibility to ensure improved resilience across the supply chain. This means creating a system where the private sector competes not just on price but also on strengthening supply chain resilience.

Resilient and sustainable supply chains are central to protecting the nation's public health, security, and economic well-being. Increasing economic sustainability of U.S.-based manufacturing requires providing predictability in production costs, pricing, and volume sold. It also requires increasing government and private sector flexibility to adapt and scale up in times of crisis. Building resilience through supplier diversification involves exploring ways to support and reward domestic manufacturing capabilities, including the use of Made in America and Buy American laws and related tools. This includes substantial investments to support domestic manufacturing, as well as

[225] Exec. Order No. 14001, 3 C.F.R. Vol. 86, No. 15, (7219-7222) (January 21, 2021). https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain.

innovative advanced manufacturing solutions to enable scalable, cost-effective, and environmentally sustainable solutions. It also requires strengthening linkages with partners that utilize resilient supply chain management practices.

This Review outlines outstanding vulnerabilities, progress HHS has made over the past four years, and priorities ahead for the public health industrial base. It includes HHS learnings and approaches to strengthening supply chain resilience, and discusses the infrastructure, resources, and authorities that may be needed to accomplish forward-looking goals. A corresponding review provides a deep dive into the supply chains for pharmaceuticals and APIs.

Sector Overview

The public health industrial base includes all entities manufacturing, producing, or distributing medical products, including MCMs,[226] medical devices, medical equipment, pharmaceutical products, and other products designed to improve patient outcomes.[227] The infrastructure required for the public health industrial base also includes the associated workforces, such as those in research and development (R&D) facilities, manufacturing facilities that produce essential medicines,[228] MCMs, and critical inputs for the health care and public health sector (Figure 1). In addition, organizational purchasers of these products, including hospitals, pharmacies, and long-term care facilities, as well as group-purchasing organizations (GPOs) and other organizations that facilitate contracting, also play an important role in the public health industrial base.

The public health industrial base, unlike the defense industrial base, is driven by the private market, which creates unique challenges, such as incentivizing domestic industry to maintain capacity that might be less economical than foreign competitors. The public health industrial base is a large, and complex sector and provides a strategic source of employment, research, capital, and the goods it manufacturers.[229] Some of the factors that contribute to the insecurity of the public health industrial base include: foreign dependencies for components of its public health supplies, particularly from countries from India and China; competition for economies of scale;[230] workforce challenges; complex and expensive startup costs that serve as barriers to entry and expansion. The contributing factors to the PHIB complexity present unique obstacles and therefore, distinct solutions to rectify the problem.[231]

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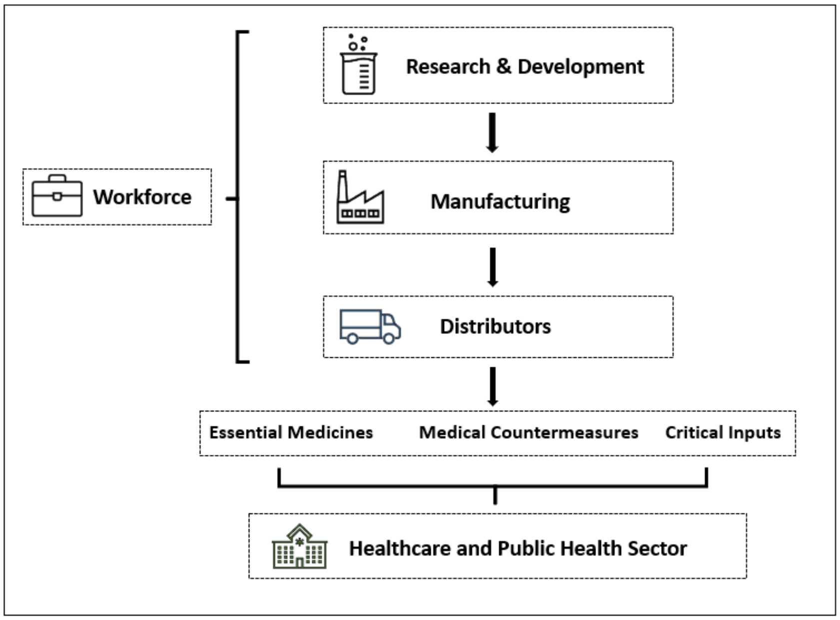
[226] Medical countermeasures include both pharmaceutical interventions (e.g., vaccines, antimicrobials, supportive care, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., medical devices—including diagnostics—ventilators, PPE, and patient decontamination) as well as other needed medical products that may be used to prevent, mitigate, or treat the adverse health effects of an intentional, accidental, or naturally occurring public health emergency.
[227] U.S. Department of Health and Human Services, *Public Health Supply Chain and Industrial Base One-Year Review: In Response to Executive Order 14017* (February 2022), https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx
[228] For purposes of this Review, "essential medicines" is broadly defined as priority life-saving medicines. This may include among others, medicines in the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs published in October 2020, as well medicines in the Essential Medicines Supply Chain and Manufacturing Resilience Assessment report published by ARMI in May 2022.
[229] U.S. Department of Health and Human Services*, Public Health Supply Chain and Industrial Base One-Year Review: In Response to Executive Order 14017* (February 2022), https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.
[230] "Economies of scale exist when increased size of production capacity results in lower unity costs," see Alesch, D. J. & Dougharty*,* L. A. *Economies-of-Scale Analysis in State and Local Government*. https://www.rand.org/pubs/reports/R0748.html
[231] U.S. Department of Health and Human Services, *Public Health Supply Chain and Industrial Base One-Year Review: In Response to Executive Order 14017* (February 2022), https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

Figure 1. The public health and biological preparedness industrial base[232]



The public health industrial base manufacturing sector represents 2.5 percent of the United States gross domestic product (GDP).[233,234] In 2023, the public health industrial base manufacturing sector employed 770,971 workers across 20,309 manufacturing establishments in the United States.[235] These estimates do not include R&D and other activities associated with the industrial base and are likely an underestimate.[236,237] The public health industrial base is a critical sector for the U.S., not only because of its centrality to the health of the U.S. population and to national health security, but also for its contribution to the GDP and labor market.

232 Figure is a representative view and is not inclusive of all processes, subcomponents, and regulatory bodies of the public health industrial base.
233 "Value added by Industry as a Percentage of Gross Domestic Product," U.S. Bureau of Economic Analysis, accessed December 10, 2024, https://apps.bea.gov/iTable/?reqid=150&step=2&isuri=1&categories=gdpxind
234 Defined as the 'Value added by Industry as a Percentage of Gross Domestic Product' from Medical Equipment and Supplies Manufacturing, Pharmaceutical and Medicine Manufacturing, Basic Chemical Manufacturing, Other Chemical Manufacturing, and Navigational, Measuring, Electromedical, and Control Instruments Manufacturing.
235 Including , NAICS 325199 All Other Basic Organic Chemical, 325412 Pharmaceutical Preparation, 325413 In-Vitro Diagnostic Substance, 325414 Biological Product (except Diagnostic), 325998 All Other Miscellaneous Chemical Product and Preparation, 334510 Electromedical and Electrotherapeutic Apparatus, 334516 Analytical Laboratory Instrument, 334517 Irradiation Apparatus, 339112 Surgical and Medical Instrument, and 339113 Surgical Appliance and Supplies, Manufacturing, All Counties 2023 Annual Averages, All Establishment Sizes. See "Quarterly Census of Employment and Wages. Employment and Wages Data Viewer," U.S. Bureau of Labor Statistics, accessed December 10, 2024, https://data.bls.gov/cew/apps/data_views/data_views.htm#tab=Tables.
236 Industry-sponsored studies suggest that the biopharmaceutical industry accounted for 17.6 percent of all domestic U.S. business R&D performance in 2022. See PhRMA. *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* (May 2022), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.
237 FDA data show there are 7,969 facilities (3,540 domestic and 4419 foreign) involved in the development and marketing of human drugs, and more than 23,000 prescription products approved for marketing.
See U.S. Food and Drug Administration, *FDA at a Glance: FDA Regulated Products and Facilities* (October 2024). https://www.fda.gov/media/182749/download.

To strengthen the public health industrial base and ensure the U.S. has the resources needed to prepare for and respond to public health emergencies, HHS often works in collaboration with other departments, such as the Departments of Defense (DOD), Commerce (DOC), Veterans Affairs (VA), Agriculture (USDA), and Labor (DOL), to address cross-cutting issues and to strengthen the supply chains to ensure the U.S. has the resources needed to prepare for and respond to public health emergencies. Within HHS, a Supply Chain Resilience and Shortage Coordinator ("the Coordinator"), a role announced in 2023, coordinates the development and implementation of strategies to enhance supply chain resilience. The Coordinator works most closely with the Administration for Strategic Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) in these efforts. ASPR leads the development, acquisition, stockpiling, and distribution of MCMs. As deeply underscored by the COVID-19 pandemic, in addition to the research and development of MCMs, the U.S. must ensure products are manufactured and stockpiled to be ready when needed. ASPR established the Center for Industrial Base Management and Supply Chain (IBMSC) to coordinate activities within HHS related to the expansion and sustainment of the medical product industrial base supply chain, and ASPR maintains the Strategic National Stockpile (SNS), the nation's largest repository of emergency medicines and supplies to help the country prepare for, respond to, and recover from public health emergencies. Additionally, ASPR's Biomedical Advanced Research and Development Authority (BARDA) works with private- and public-sector partners to support the advanced research, development, and procurement of MCMs that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. The FDA leads routine response efforts for shortages of regulated products (including pharmaceuticals, biological products, and medical devices), in coordination with industry and other HHS and U.S. Government partners, as appropriate. For example, the Office of Supply Chain Resilience (OSCR) within the Center for Devices and Radiological Health (CDRH) Office of Strategic Partnerships and Technology Innovation (OST) proactively identifies and addresses potential risks to medical device supply chains, creating vulnerability assessments and informing use of potential mitigations.

Additional HHS agency efforts to develop MCMs to combat public health threats and to strengthen medical product supply chains occur within the National Institutes of Health (NIH), including its Advanced Research Projects Agency for Health (ARPA-H) which invests in high-impact solutions to health challenges and is generally interested in supply chain data analytics, medical logistics, and advanced manufacturing innovation. Also, the Centers for Medicare & Medicaid Services (CMS) establishes payment policies for certain medications, medical devices, and PPE.

Evolution of the Sector through 2020

Shortages of life-saving medical products have been an ongoing public health concern for decades. Market participants throughout the supply chain have lacked appropriate incentives to adopt practices that foster resilience through diversification, redundancy, and investment in newer technology and mature quality systems. Concentration in medical product markets has increased negotiating power for certain intermediaries. This negotiating power has generally been used to drive lower margins for manufacturers, who have implemented cost reduction strategies leading to a less diversified and redundant manufacturing base (including reliance on sole-source suppliers), leaner inventories, and smaller investments advanced manufacturing technologies.

Over recent decades, manufacturers of many medical products have increasingly relied on overseas production and suppliers, driven by competition for economies of scale[238] and the lowest-available cost. U.S. drug manufacturing, especially for generic drugs, became undercut by low-cost competition from manufacturers in India and China, which included medicines and medical devices as a key industry in its Made in China 2025 strategy, released in 2015. These shifts have reduced diversity across supply chains and made the U.S. increasingly reliant on other countries for many essential medicines and medical devices, as companies operating overseas can often outcompete U.S.-based production due to lower overhead costs, fewer regulatory requirements, and increased financial incentives.[239]

These challenges became highly visible with the onset of the COVID-19 pandemic, which tested the U.S. public health industrial base and strained global supply chains, exposing critical vulnerabilities in the nation's ability to deliver effective health care during times of high demand. Offshore manufacturing and just-in-time inventory management were vulnerabilities that stretched supply chains beyond their capacities and created shortages, resulting in significant disruptions for manufacturers and consumers, and putting health care workers and patients at risk.

Key Sector Trends from 2021 to Present

The U.S. Government and the private sector have made historic investments of over $18 billion and $55 billion respectively in bolstering domestic manufacturing capacity and capabilities for medical products since 2021. According to U.S. Census Bureau data the U.S. is experiencing an upward trend in total value of goods shipped by manufacturers in the public health industrial base sector, with the $335 billion produced in 2020 and increasing to $446 billion and $490 billion in 2022 and 2023, respectively.[240,241] Additionally, estimates from the Department of Commerce suggest that U.S. exports increased from $135 billion in 2020 to $197 billion and $209 billion in 2022 and 2023, respectively.[242,243] Increased healthcare spending, for example due to innovative and costly new treatments and products, plays a role in these upward trends.[244] For some products, such as inexpensive generic drugs, supply chain disruptions and shortages have persistently impacted patient care.

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238 Daniel J. Alesch and L. A. Dougharty, *Economies-of-Scale Analysis in State and Local Government* (RAND Corportation, 1971), https://www.rand.org/pubs/reports/R0748.html.

239 Exec. Order No. 14036, 3 C.F.R. Vol. 86, No.132, (36987-36999) (January 21, 2021). https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf.

240 U.S. Census Bureau, Manufacturers' Value of Shipments: Electromedical, Measuring, and Control Instrument Manufacturing [A34KVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A34KVS.

241 U.S. Census Bureau, Manufacturers' Value of Shipments: Pharmaceutical and Medicine Manufacturing [A25BVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A25BVS.

242 "USA Trade Online," U.S. Department of Commerce, accessed December 10, 2024, https://usatrade.census.gov/index.php.

243 "Annual Survey of Manufacturers," U.S. Department of Commerce, accessed December 10, 2024, https://1www.census.gov/econ/overview/ma0300.html.

244 "National Health Expenditures Fact Sheet," Centers for Medicare & Medicaid Services, accessed December 16, 2024, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

Recognizing the importance of resilience, supply chain entities including manufacturers, group purchasing organizations, wholesalers, and health systems have launched and increased utilization of innovative partnerships designed to create supply chain resilience assessment programs, improve contracting models, and further supply chain collaboration.[245,246] As discussed later in this Review, while these nascent and innovative models hold promise not only to increase the supply chain resilience of the pharmaceutical sector but also to sustain the industrial base, they are not yet widely adopted.

245 "About Us," Healthcare Industry Resilience Collaborative (HIRC), accessed December 9, 2024. https://hircstrong.com/about-us/.
246 "CivicaRx," accessed December 9, 2024, https://civicarx.org/.

PROGRESS TO DATE

One-Year Review Priorities

In 2021 and 2022, HHS conducted a first-of-its-kind assessment of the public health industrial base pursuant to Executive Order 14017. This One-year Review[247] outlined the sectors' supply chain vulnerabilities, particularly those materializing during the COVID-19 pandemic. It emphasized the importance of ensuring adequate supply of PPE and durable medical equipment, testing and diagnostics, pharmaceuticals, vaccines, and other items in shortage.

The One-year Review priorities include recommendations to build long-term resilience, covering the following nine themes: (1) manufacturing and industrial base investments; (2) stockpiling, allocation, and coordination; (3) innovation; (4) trade policy and buy American/federal procurement; (5) regulations, policy, and standards; (6) workforce development; (7) global partnerships and standards; (8) governance; and (9) external stakeholder engagement and coordination. The One-year Review also highlighted the importance of working with allies and partners to achieve the stated goals of increasing supply chain transparency, diversity, security, and sustainability. These recommendations mirrored those outlined in 2021's National Strategy for a Resilient Public Health Supply Chain, developed in concert with DHS, DOD, and VA, pursuant to Executive Order 14001.

Progress from 2021 to Present

Since these initial reviews, HHS has made significant progress in strengthening the public health industrial base. A series of initiatives—some focused on the COVID-19 response, and others oriented toward broader preparedness—have helped shepherd a stronger domestic industrial base and better public and private coordination toward responding to public health emergencies and other disruptions.

Investing in domestic manufacturing

The most important work that HHS has led over the past four years has been to support the growth of America's domestic public health industrial base. Since the beginning of the Administration, HHS has invested over $18 billion toward domestic manufacturing across the entire public health industrial base—part of the more than $19 billion that the U.S. Government has invested in this sector since 2020, when the COVID-19 response began. These investments have focused on expanding manufacturing capacity to produce PPE and medical equipment in preparation for future public health emergencies and establishing novel or advanced manufacturing methods to quickly adapt and scale up production.

The Defense Production Act (DPA) authorizes the President to expedite and expand the supply of materials and services from the U.S. industrial base needed to promote the national defense. Title III of the DPA is one of the most potent tools to support expansion of the domestic production capacity, and enabled the U.S. Government to make these investments, with funding from CARES Act and American Rescue Plan. These efforts have also extended beyond COVID-19 to broader

[247] U.S Department of Health and Human Services, *Public health supply chain and industrial base one-year review in response to Executive Order 14017* (February 2022), https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx.

medical products needed for acute care. In 2023, President Biden issued a Presidential Determination broadening HHS's authorities under Title III of the DPA to enable investment in domestic manufacturing of essential medicines, MCMs, and other critical inputs.[248] This action provided additional flexibility to promote the onshoring of essential manufacturing capabilities, which will further strengthen the nation's response to public health emergencies. Since this Presidential Determination, HHS announced two DPA Title III funded awards focused on modernizing and expanding manufacturing capacities of key starting materials (KSMs) and APIs.

Investing in advanced manufacturing

HHS has also invested in ensuring that re-shored manufacturing capabilities are competitive, adaptable, and innovative. "Advanced manufacturing," as it is known in the sector, enables the U.S. to produce high-quality products efficiently, quickly adapt to changing market demands, innovate new products, and maintain a strong domestic manufacturing base, while also allowing businesses remain competitive globally. To this end, IBMSC has been building and sustaining a domestic advanced pharmaceutical manufacturing ecosystem, and additional investments have been directed at developing and deploying agile and distributed drug substance and drug product manufacturing technologies. IBMSC has also been investing in new partnerships to improve the responsiveness and resilience of domestic pharmaceutical supply chains. These investments to address supply chain vulnerabilities include agile, continuous, and distributed domestic production of APIs and finished dose form drugs whose use are more prevalent in the care of acute care patients. IBMSC investments also include the demonstration of population-scale production for essential medicines in shortage. FDA helps to facilitate uptake of advanced manufacturing technologies through the Center for Drug Evaluation and Research's Emerging Technologies Program (ETP) and Center for Biologics Evaluation and Research's Advanced Technologies Team (CATT).

Additional targeted investments will spur innovations, including the development and deployment of novel manufacturing platforms, and the scale-up of these technologies will help develop domestic manufacturing. This work will address the critical need to onshore and sustain the production of certain API and finished dosage forms (FDF). To catalyze domestic pharmaceutical development, HHS will: (1) enhance competitiveness in the private sector through increased technological efficiencies (e.g., automation, a novel regulatory framework) to decrease production costs; (2) enable process intensification and scale-up, and (3) improve data sharing and security to maximize collaboration and minimize redundancy in R&D efforts. To accomplish these goals, it is necessary to strengthen HHS partnerships with private partners and within government. Gains in automation and efficiency will not reduce the need for skilled labor, but instead will create additional employment opportunities, enhance workers' safety by reducing exposure to hazardous environments and promote an enterprise that is safe, highly productive, and sustainable.

Enhancing HHS supply chain visibility

Whether production is domestic or overseas, visibility into supply chains for the public health industrial base is critical for enabling rapid response, operational resilience, and optimal resource

[248] The White House, "FACT SHEET: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors," news release, November 27, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/.

allocation. With enhanced visibility, public health entities can anticipate disruptions, prevent and respond to shortages, and swiftly adapt to changing demands or geopolitical challenges. This capability mitigates risks such as supply bottlenecks and counterfeit products, as well as fosters data-driven decision-making, bolstering trust and collaboration across stakeholders. These efforts safeguard public health by empowering the system to maintain uninterrupted access to critical medicines, equipment, and resources, even under unpredictable circumstances. With this vision in mind, HHS has taken several steps to increase supply chain visibility:

- ASPR launched the trial of a supply chain risk management (SCRM) tool for increased generalized supply chain visibility. This tool seeks to organize medical product supply chain requirements from different manufacturers and is under evaluation through May 2025.
- ASPR's Supply Chain Control Tower (SCCT) has made progress toward developing enhanced U.S. Government visibility of select critical public health supply networks. Since 2021, the SCCT has coordinated and collaborated with nine key medical distributors, seven of whom signed corresponding Data Use Agreements for the monitoring of SCCT's Master Product List (MPL) 2.0, developed based on the SCCT's Product Inclusion Criteria List (PICL). Through this development, the SCCT has built a capability to enable supply chain monitoring of specific products being managed by those distributors.
- FDA's Center for Devices and Radiological Health (CDRH) established its Office of Supply Chain Resilience which houses medical device data, analytics, and modeling capability, enables the proactive addressing of medical device supply chain vulnerabilities, and fosters collaboration. FDA has supported resiliency in the medical device sterilization landscape and conducted assessments that inform the implementation of FDA and interagency regulatory actions (e.g., the FDA evaluation of Chinese manufactured plastic syringes).
- The Risk Assessment and Management Program (RAMP) taskforce, led by ASPR's Office of Critical Infrastructure Protection (CIP), has led conversations with public, private, and U.S. Government partners to identify risks to the broad health and public health sectors and discuss consequences of and likelihood of risks. This work is ongoing and is expected to be completed in two parts in October 2024 and January 2025.

Progress by product type

Over the past four years, the U.S. Government has deployed these tools across various product types that were needed during the COVID-19 pandemic and remain critical products for acute care and response to future public health emergencies.

PPE and medical equipment

Health care workers rely on PPE to safeguard themselves and their patients against the spread of infectious disease or illness. Thus, having reliable domestic production for these products, particularly during public health emergencies, is essential. Prior to the COVID-19 pandemic, PPE and its key chemicals and components were not produced by U.S.-based industries, and the PPE supply chain was not a focus for the U.S. Government.

Since 2021, the U.S. Government has invested $1.15 billion in PPE capacity and raw materials across 21 contracts to:

- <u>Produce 191.7 million nitrile gloves per month</u>. Several HHS contracts have resulted in an increased domestic production capacity for gloves including the capacity to manufacture

191.7 million gloves per month by January 2025. HHS also awarded contracts for critical production materials for gloves including nitrile butadiene rubber (NBR) with a contract for 90,000 metric tons each, enough raw material for an additional 840 million nitrile gloves per year, and two key chemicals, methylacrylic acid and acrylonitrile (Table 2).

- Produce an additional 1.5 million gowns per year. Freeman Manufacturing Co. was contracted to increase domestic production capability of disposable gowns by 1.5 million gowns annually. Additionally, IBMSC is currently working with BARDA's BioMaP Consortium team to invest more than $302 million towards projects related to manufacturing and assembling gowns domestically.
- Increase production of surgical masks by 136 million per year, and production of N95 medical grade masks to 160 million respirators/month. HHS awarded seven contracts to increase domestic production of surgical masks, filter media, and N95 respirators, reaching the U.S. Government target investment of 160 million N95s monthly. U.S. Government investments also increased domestic production capability of melt-blown fibers, which will enable the increased production of 483 million surgical masks per month and/or 160 million N95 respirator masks per month.
- Increase ventilator filter production capacity from 485,000 units per month to 650,000 units per month. U.S.-based Pall Corporation was contracted to increase ventilator filter production by adding a new production line in Fall 2021.

Importantly, this manufacturing capacity must have demand to be sustained. The federal government has taken great strides over the past four years to support domestic PPE manufacturers through both public-sector and private-sector demand sources:

- Federal procurement of domestically made PPE. The federal government has made significant progress in identifying total PPE needs, modeling potential demand, and aligning the procurement strategies of the biggest federal purchasers of PPE. The Bipartisan Infrastructure Law's "Make PPE in America Act" section included new requirements for HHS, DHS, and VA to procure wholly domestically made PPE through long-term contracts in order to help catalyze domestic investments toward a robust, secure, and wholly domestic PPE supply chain. Additionally, the Defense Logistics Agency (DLA), while not included in the Make PPE in America Act, also procures PPE subject to the Berry Amendment. To organize federal demand, OMB's Made in America Office (MIAO), in coordination with DLA, HHS, DHS, and VA held a "Make PPE in America Industry Day" to facilitate an exchange of information about government opportunities and industry capabilities for 100 percent domestic manufactured PPE. The MIAO also co-hosted two Civilian Service Acquisition Workshops (CSAW), to align and continue cross-agency efforts to organize domestic PPE procurement, releasing a white paper providing industry with insight into agency PPE requirements and specifications, PPE demand, procurement methodologies and strategies, and domestic sourcing challenges. A unified federal voice to industry with respect to demand and strategy will increase confidence that the U.S. Government is committed to creating a sustainable domestic industrial base.
- Private-sector procurement of domestically made PPE. Hospitals need to be able to access a reliable supply of PPE that are delivered on a timely basis in order to protect health care

workers and their patients, and sustaining domestic production of these products is important for helping to maintain that assurance. To that end, CMS has developed policies that support health care providers in purchasing domestically produced products, which can cost more than foreign-sourced PPE. Through the CY2023 OPPS final rule, CMS has provided payment adjustments to hospitals for their share of the additional cost of domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators. Additionally, in the CY2025 Hospital OPPS final rule, following a comment solicitation, CMS stated that it intends to propose modifications in 2026 rulemaking, including an expansion of the payment adjustments to domestic non-surgical N95 respirators and domestic nitrile gloves, as well as a new payment methodology for calculating the payment adjustments.

Testing and diagnostics

Diagnostics and testing are paramount for accurately assessing the state of an emerging and evolving biological threat. COVID-19 brought about shortages in some raw testing materials needed for millions of testing kits. In response, ASPR supported the domestic industrial base for the manufacturing of COVID-19 over-the-counter tests by executing multiple rounds of direct procurement for the diagnostic stockpile. The U.S. Government has invested $2.2 billion (40 contracts) in testing capacity and raw materials to:

- Increase domestic production of diagnostics tests and materials. ASPR conducts targeted investments in the supply and manufacturing of testing materials and upstream components, or raw materials used in the making of diagnostic materials, for the U.S. market. ASPR executed 40 contracts that have increased the domestic industrial base for the manufacturing of diagnostic tests. These investments are spread across swab manufacturers, pipette tips, laboratory reagents, and raw materials. During the COVID-19 pandemic, all of these materials were in short supply and no domestic sources were available for some. A plant in Wisconsin is coming online in Fall 2024, as a direct result of the efforts of IBMSC and ASPR. These efforts increased production capacity of pipette tips by more than 463 million per month, increased domestic pipette tip filter production by more than 50 percent, and enabled manufacturing of more than 780 million swabs per month.
- Stockpile and deploy COVID-19 over-the-counter tests. These investments have allowed HHS to distribute more than 990 million at-home COVID-19 test kits directly to U.S. homes, and ship over 285 million rapid antigen tests and 1 million point-of-care polymerase chain reaction COVID-19 tests to nursing homes, federally qualified health centers, and long-term care facilities since the close of the public health emergency. ASPR awarded several contracts to increase availability and maintain a stockpile of diagnostic supplies, and ASPR currently manages a stockpile consisting of several hundred million COVID-19 over-the-counter tests. These tests are sent weekly to over 20,000 locations including federally qualified health centers, food banks, schools, long-term care facilities, state, territorial and tribal governments, and section 202 housing. ASPR partners with NGOs such as Feeding America, National Association of County and City Health Officials, and the Big Cities Health Coalition to facilitate continuous access to diagnostics for vulnerable, uninsured, or

under-insured populations. Twelve domestic companies are making monthly deliveries to the stockpile until mid-2025.

Vaccines, therapeutics, and other pharmaceuticals

As the COVID-19 pandemic and global mpox outbreak demonstrated, reliable supply of pharmaceuticals and related materials are essential for ensuring access to life-saving vaccines and treatments. Over the past four years, BARDA has invested over $2 billion in key industry partners to expand domestic biopharmaceutical manufacturing surge capacity. Investments include support of the National Biodefense Strategy goal to establish and maintain domestic capability and capacity to produce sufficient quantities of vaccines within 130 days of the determination of a biological incident (Table 1). These investments will increase the manufacturing capacity for the raw materials, critical ingredients, consumables, and production lines required to produce COVID-19 (and future) vaccines and therapeutics. Similar investments by IBMSC are also highlighted in Table 1. Investments in vaccine and therapeutic supplies and raw materials allowed the U.S. to:

- Deliver 984 million COVID-19 doses to the United States population through May, 2023 and continue to produce updated COVID-19 vaccines.[249]
- Donate more than 185 million vaccine doses to other nations.
- Increase syringe and needle capacities by more than 70 million syringe/needle sets per month from July 2020-July 2024.

Table 1. HHS contracts awarded in the public health and biological preparedness industrial base to produce domestic vaccines and therapeutics since 2021

Product(s)	Year(s)	Total Investment	Contract Goal
Vials (BARDA)	2022	$306.4 million	Support new construction of a domestic glass vial facility and expand existing facilities to address the shortage of domestic vial manufacturing capacity.
Needles and Syringes (BARDA)	2020, 2021	$144 million	Expand production of safety needles and syringes necessary to support the COVID-19 response.
Single Use Technologies (BARDA)	2021	$261.7 million	Expand capacity of single-use manufacturing systems that are critical components in vaccine and therapeutic production.
Raw Materials (BARDA)	2021, 2022	$552 million	Expand manufacturing capacity of raw materials used in vaccine production.
Drug Substance and Drug Product Manufacturing (IBMSC)	2021, 2022, 2023, 2024	$831 million	Establish the on-shoring of large scale and hybrid manufacturing
DPA Title III – Upstream Pharmaceutical Materials (IBMSC)	2024	$83 million	Expand manufacturing capacity of raw materials used in vaccine production.
DPA Title III – Critical Inputs (Sterilization) (IBMSC)	2024	$38 million	Expand formulation, filling, and finishing manufacturing capacity for Biosafety Level 1 and 2 containment.

[249] Centers for Disease Control and Prevention, *Justification of Estimates for Appropriation Committees* (September 2024), FY-2025-CDC-congressional-justification.pdf

Fill-Finish	2021, 2022	$974.9 million ($190.4 million from IBMSC and $784.5 million from BARDA)	IBMSC: supplement traditional needle syringe vial manufacturing during pandemic and enable rapid FF during PHEs BARDA: expand formulation, filling, and finishing manufacturing capacity for Biosafety Level 1 and 2 containment.

Supporting advanced vaccine manufacturing. During this time, HHS has also supported continued innovation in vaccine manufacturing. Using American Rescue Plan (ARP) funding, FDA's Center for Biologics Evaluation and Research (CBER) launched a demonstration project for messenger RNA (mRNA) vaccine manufacturing, which focuses on best practices in integrated and continuous vaccine manufacturing. Production of these and other vaccines may benefit from several advanced manufacturing techniques. For example, distributed manufacturing in decentralized or mobile units could allow vaccines to be produced near the site of distribution, thus reducing the cost and risks of transportation and cold-chain management. This work may also be relevant for multiple types of vaccines, including those targeting influenza and other pathogens. Additionally, the U.S. International Development Finance Corporation (DFC) invests in private sector solutions in low- and middle-income countries to advance U.S foreign policy priorities and create development impact. Health is a priority sector and includes investments in health manufacturing and supply chains, services and infrastructure, and technology. DFC has expanded vaccine and other medical countermeasure manufacturing investments to secure supply chains and bolster global health security. For example, DFC provided a €100-million loan in 2021 to Aspen Pharmacare to support expansion of vaccine manufacturing capacity in South Africa, particularly for fill-and-finish of COVID-19 vaccines for distribution across Africa. DFC provided a follow-on €110-million loan in 2024 to support further expansion of manufacturing capacity including production of childhood vaccines, insulin, and other essential medicines. Aspen has a partnership with Serum Institute of India that leverages this manufacturing capacity to produce four childhood vaccines in Africa. Aspen was co-financed by the International Finance Corporation (IFC), the German DFI DEG, and the French DFI Proparco.

Incentivizing pharmaceutical supply chain resilience and combatting drug shortages. HHS has also taken steps to support efforts by health care providers and other supply chain participants to make their supply chains more resilient. In August 2024, CMS issued a final rule that provides separate payment under the Inpatient Prospective Payment System (IPPS) for small, independent hospitals to establish and maintain a "buffer stock" of essential medicines so that they can better weather supply chain disruptions and continue to provide patients with the care they need. CMS also noted in the Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) final rule that CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130). Additionally, HHS has analyzed broader, longer-term solutions for supply chain resilience, particularly with respect to drug shortages. In April 2024, HHS published a white paper ("HHS White Paper") discussing factors underlying drug shortages and policy concepts to address them. It described two proposed programs that would bring transparency into the market, link purchasing and payment decisions to supply chain resilience practices and incentivize investments in supply chain resilience and diversification in the supply chains—including domestic manufacturing.[250] The corresponding four-year review of supply chains for pharmaceuticals and APIs provides a deeper dive into this work.

Whole blood and blood products

There are ongoing challenges within the U.S. supply chain for whole blood collection bags used to collect whole blood and blood components for transfusion. In addition, there are a limited number of suppliers for apheresis platelet collection systems. In October 2024, FDA issued guidance[251] on transfusion methods and processes that manufacturers can adopt to alleviate platelet shortages and diversify the blood bag supply chain. HHS and FDA continue to engage with manufacturers and blood centers to identify possible solutions, including diversification and manufacturing quality improvements. FDA supports and is actively engaged in research efforts to identify novel pathogen reduction technologies for whole blood. At the same time, FDA continues to encourage R&D of innovative blood products, and after partnering with the DOD, on August 8, 2024, FDA issued an Emergency Use Authorization (EUA) for U.S. military forces for the treatment of hemorrhage or coagulopathy during certain emergencies when plasma is not available or practical.[252]

Challenges and Opportunities

HHS identified a number of supply chain challenges during the COVID-19 pandemic, including inadequate domestic manufacturing capacity and capabilities, which led to a greater reliance on manufacturers and suppliers located outside the United States. These shortages of life-saving medicines, medical devices, medical food, and other vital components, including key starting materials, emphasized the need to ensure dynamic, adaptable, and resilient supply chains. Additional challenges included unprecedented global demand for limited supplies, temporary manufacturer closures to comply with COVID-19 mitigation efforts, and transportation delays disrupting the timely delivery of medical products. However, identification of these challenges has presented opportunities to strengthen existing supply chains and redouble U.S. Government efforts to help promote more robust supply chains capable of withstanding future public health threats. These opportunities include expanding the domestic public health industrial base, continued medical product stockpiling, identifying gaps and shortages while addressing vulnerabilities, and incentivizing pandemic preparedness.

Innovative solutions have been proposed or launched to increase the resilience of the industrial base. These include:

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[250] U.S. Department of Health and Human Services, *Policy considerations to prevent drug shortages and mitigate supply chain vulnerabilities in the United States* (2024), https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf

[251] U.S. Food and Drug Administration, "Guidance for Industry, Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method." Federal Register Vol. 89, No. 202. (October 18, 2024). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-development-blood-collection-processing-and-storage-systems-manufacture-blood).

[252] Peter W. Marks, *letter to Octapharma USA Inc,* August 8, 2024, https://www.fda.gov/media/180723/download#:~:text=This%20EUA%20is%20important%20for,associated%20with%2C%20an%20imminently%20life%2D

- Hospital membership-based and long-term committed contracting models that include supply guarantees and purchase guarantees, fixed prices, buffer stocks, sourcing from diverse and vetted suppliers, and other steps.[253,254]
- Supply chain resiliency assessment programs that have developed or are in the process of developing standards and best practices to increase resiliency and transparency in the pharmaceutical supply chains.[255,256,257,258]

While these nascent and innovative models hold promise not only to increase the supply chain resilience of the pharmaceutical sector but also to sustain the industrial base, they are not widely adopted. Barriers to adoption include cost, lack of awareness, lack of infrastructure, and the voluntary nature of these models. The HHS White Paper published in April 2024, outlines potential steps that could be taken to increase use of approaches like these. While HHS has made significant strides in shoring up the system's ability to respond to shortages and supply chain disruptions, more impactful and enduring solutions require additional actions from all supply chain participants.

Engagement with Industry

HHS has engaged with experts in the private sector to improve supply chain transparency. Engagements include:

- Critical Infrastructure Partnership Advisory Council/health care and public health sector: HHS carries out multiple activities with federal and external partners (including industry and trade groups) through the Joint Supply Chain Resilience Work Group's task groups, such as developing strategies and conducting studies to better inform partners and support policy changes.
- Industrial Base Expansion (IBx) Connect: Through IBx Connect, ASPR coordinates market research to find innovative solutions that address vulnerabilities in our Nation's public health and medical industrial base and supply chains and seek insights on advanced manufacturing to guide public health resilience strategies. For example, ACI, a presenter to IBx Connect, showcased their high-speed, automated production line in Florida, capable of producing up to 1.8 million N95 masks daily. This capacity far exceeds typical industry standards, where scalability and speed are often limited. ACI's innovations underscored the potential for rapid, resilient PPE manufacturing in the U.S., shaping ASPR's strategic vision for future initiatives, supply chain resilience, and acquisition planning.

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253 Sonal Parasrampuria et al., *Impacts of a Nonprofit Membership-Based Pharmaceutical Company on Volume of Generic Drugs Sold and Drug Prices: A Case Study* (Washington, D.C.: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, July 2024), https://aspe.hhs.gov/sites/default/files/documents/172d065c60a40a7c77b3fb46eef0e4f4/sdp-nonprofit-quantitative-ib.pdf.

254 "CivicaRx," accessed December 9, 2024, https://civicarx.org/.

255 "About Us," Healthcare Industry Resilience Collaborative (HIRC), accessed December 9, 2024. https://hircstrong.com/about-us/.

256 "USP Medicine Supply Map," U. S. Pharmacopeia (USP), accessed December 1, 2024. https://www.usp.org/supply-chain/medicine-supply-map.

257 "CHSR Department of Defense Pharmaceutical Supply Chain Portfolio," Uniformed Services University of the Health Sciences (USU), accessed December 1, 2024, https://chsr.usuhs.edu/pharmaceutical-supply-chain

258 "Healthcare Supply Chain," Resilinc, accessed December 10, 2024, https://www.resilinc.com/industry/healthcare-life-sciences/.

- Manufacturability and Resilience (M&R) Program: BARDA continues to extend and improve biopharmaceutical industry and inter-agency relationships that are crucial to the nation's PHE responses. Routine discussions with biopharmaceutical suppliers, integrators, and industry trade groups, as well as independent horizon scanning activities, ensures that BARDA is well-positioned to take action in addressing challenges, gaps, and opportunities that could affect HHS's ability to respond to the next PHE, as well as continue advanced research and development of innovative MCMs.
- Office of Supply Chain Resilience, Office of Strategic Partnerships and Technology Innovation, CDRH: This office works with external stakeholders to capture information necessary to understand potential supply chain vulnerabilities and identify opportunities for building resilience. The CDRH medical device program has a data, analytics and modeling capability that supports integration of disparate data sources from internal and external sources. This capability supports real-time supply chain analyses and has been used to inform the Interagency and stakeholders on potential supply chain disruptions. FDA is also currently exploring working to establish new novel vehicles (e.g., public–private partnerships) for collaboration with medical device stakeholders. These partnerships are critical to identifying and understanding vulnerabilities and subsequently working to build resiliency in medical device supply chains. The FDA routinely works across agencies to support supply chain activities (see the corresponding *Four-year Review of Supply Chains for Pharmaceuticals and APIs* for additional detail).

HHS also continues to engage with experts from within HHS and across the government to share information to enhance transparency of U.S. supply chains, among other goals. Engagements include:

- The SCCT as described above has leveraged interoperable technology and shared interagency and private partner data.
- In response to the National Security Memorandum (NSM-22) released in April 2024 by the White House, ASPR Division of Critical Infrastructure Protection stood up the RAMP taskforce comprising public and private sector subject matter experts as well as U.S. Government interagency partners (Cybersecurity Infrastructure Security Agency, BARDA, IBMSC, CMS, FDA, DHS, The Office of Climate Change and Health Equity [HHS], The Office of the Chief Information Officer [HHS], among many) to develop the required sector-wide assessment.[259]

Engagement with Allies and Partners

While investing in American manufacturing is a priority, HHS recognizes that the U.S. cannot and should not manufacture every medical product and input. Thus, coordination with allies and partners has been crucial. These discussions have focused on closer collaboration on supply chain visibility as well as potential nearshoring and friendshoring strategies so that supply chains for the public health industrial base can be stronger globally. In 2024, the State Department, Executive Office of the President (EOP), and HHS worked with partners from Japan, India, the Republic of Korea and the European Medicines Agency to launch a Track 1.5 Biopharmaceutical Supply Chain

[259] Exec. [Off.] of the President. "National Security Memorandum on Critical Infrastructure Security and Resilience." April 30, 2024. https://www.whitehouse.gov/briefing-room/presidential-actions/2024/04/30/national-security-memorandum-on-critical-infrastructure-security-and-resilience/.

(BIO-5) consortium, aimed at fostering onshoring and friendshoring of critical API.260 HHS has participated in a number of additional meetings with global partners to discuss supply chain resiliency with a goal of developing allied redundancy, for example the 2024 OECD High-Level Conference on Building Resilient Medical Supply Chains and the 2023 Building a High Quality US-Mexico Pharmaceutical Supply Chain. Additionally, the DFC works closely with development finance institutions (DFIs) as well as global and regional health organizations to strengthen pandemic preparedness and health system resilience. For example, DFC along with other G7 DFIs, European Investment Bank (EIB), International Finance Corporation (IFC), and MedAccess signed a memorandum of understanding (MoU) for the Surge Financing Initiative for MCMs. These DFIs are working closely with global and regional health organizations to establish the collaboration frameworks and innovative financing mechanisms needed to support more rapid and equitable pandemic response. Building on lessons from the COVID-19 pandemic, the initiative will focus on the procurement, production, and distribution of vaccines, therapeutics, diagnostics, and other MCMs for low- and middle-income countries.

Discussions between HHS and global partners extend beyond investments. For example, HHS has engaged with the Organisation of Economic Co-operation and Development (OECD), the Mexican federal government, Mexico institute, Mexican Association of Pharmaceutical Laboratories (AMELAF) and trade associations on redundancy in medical supply chains[261] and with the Health Emergency Preparedness and Response Authority (HERA) on a joint task force to improve pandemic prevention, preparedness, and response, especially surrounding MCMs, antimicrobial resistance, and improving cancer prevention and detection.[262]

260 White House. "FACT SHEET: Biden-Harris Administration's Actions to Advance American Biotechnology and Biomanufacturing," news release, May 25, 2024, https://www.whitehouse.gov/ostp/news-updates/2024/06/25/fact-sheet-biden-harris-administrations-actions-to-advance-american-biotechnology-and-biomanufacturing/.
261 The Wilson Center, "Building a high quality US- Mexico pharmaceutical supply chain," video panel discussion, October 17, 2023, https://www.wilsoncenter.org/event/building-high-quality-us-mexico-pharmaceutical-supply-chain
262 U.S. Department of Health and Human Services, "Joint press release on the launch of EU-U.S. health task force," press release, May, 17, 2023, https://www.hhs.gov/about/news/2023/05/17/joint-press-release-launch-eu-us-health-task.html.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

HHS, along with other U.S. Government partners, including through the work of the HHS Supply Chain Resilience and Shortages Coordinator, is moving toward a standardized method of assessing resilience and vulnerability in the public health and biological preparedness industrial base. The following represents HHS's initial assessment for this sector to provide insights into the vulnerability and resilience of the public health and biological preparedness industrial base, as well as to facilitate partnerships across the U.S. Government and private industry toward resilient supply chain actions.

Some assessment criteria are supplemented by DOC's 2024 SCALE supply chain risk tool which estimates risk factors of sector-specific industries as categorized by The North American Industry Classification System (NAICS; see Appendix Table 1 for inclusion criteria). Scores are derived from dozens of inputs and data sets that feed into three factors: vulnerability, the exposure of an industry to disruption; resiliency risk, the difficulty an industry faces in responding to disruption; and criticality, the significance of the industry to the national economy, national security, and public health and safety of the American people.[263] SCALE analysis found that five out of thirteen health-related industries were identified at high risk, suggesting that the industrial base is vulnerable to supply chain disruptions.[264,265,266] Further, SCALE data identified multiple health-related industries as moderately critical to the national economy. Over the following pages, HHS analyzes these findings through various elements of resilience and vulnerability.

Visibility

Much of the data on the medical product supply chain are proprietary (e.g., confidential commercial or trade secret information), resulting in limited end-to-end medical product insights for government or industry. Depending on their roles, different HHS Operating and Staff Divisions have access to a range of data. Some of these datasets are provided via HHS authorities. For example, in its regulatory role, FDA has broad access to compliance, inspection, safety, and efficacy data as it pertains to human and veterinary drugs, biological products, medical devices, foods, cosmetics, and products that emit radiation. However, much of these data are proprietary and not available to other HHS components. Other data are provided voluntarily by the private sector through data-sharing agreements. An example is the Supply Chain Control Tower, set up in collaboration with medical product distributors during the COVID-19 pandemic response in order to increase visibility into inventories and orders for certain critical products.

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263 DOC SCALE supply chain risk tool 2024.

264 These included: "All Other Basic Organic Chemical Manufacturing", "All Other Miscellaneous Chemical Product and Preparation Manufacturing," "Surgical Appliance and Supplies Manufacturing," "Medicinal and Botanical Manufacturing," and "Pharmaceutical Preparation Manufacturing.

265 Office of Management and Budget, *North American Industry Classification System United States, 2022* (Washington, D.C.: Executive Office of the President, 2022), https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf.

266 Medical products in these NAICS categories are likely to include supporting materials for vaccine and therapeutics manufacturing, non-biological pharmaceuticals designed for individual dosage forms, chemical products that support testing and diagnostics, surgical tools, PPE and durable medical equipment.

In the years prior to the COVID-19 pandemic, HHS's level of monitoring varied across critical medical supply chains. For instance, the SNS had very limited supply chain data and visibility, as its role had not been required under mission operating assumptions. Further, while the FDA has monitored and managed drug shortages, some products (such as PPE, raw materials, and other inputs) have historically had little ongoing monitoring or visibility at the Federal level.[267]

During the COVID-19 pandemic, industry engagement and willingness to share data created opportunities to build visibility into the medical product supply chains through collaborations with FDA and ASPR—and in some cases this collaboration has continued or even expanded. The SCCT was created in March 2020 with COVID-19 supplemental funding to provide visibility into critical medical supply chains to support U.S. Government decision-making and actions on planning acquisition, prioritization, allocation, and targeted distribution and actions on planning. The SCCT continues to operate today and has expanded the set of products it tracks, thanks to continued collaboration with medical product distributors. In addition, through direct engagement with manufacturers and other industry organizations, HHS has been able to develop deep visibility into supply chains for select products to support specific response or domestic capacity-building initiatives—these products have included COVID-19 products including vaccines and over-the-counter tests, as well as, more recently, infant formula and intravenous solution bags. Furthermore, using COVID-19-supplemental funding, FDA has built a robust medical device supply chain program. This program has leveraged external and internal FDA data, relationships with external partners and the interagency to not only respond to imminent shortages but also predict potential impacts of supply chain disruptions, weather events, geopolitical issues, and other causes of medical device supply chain disruptions.

All of this collaboration has demonstrated the importance and possibility of public–private data-sharing for the purpose of strengthening supply chains and responding to disruptions. It also helps illustrate how this transparency could be expanded or codified. HHS would benefit from additional access to public health and medical supply chain data and insights from entities such as manufacturers, distributors, and group purchasing organizations (GPOs). As stated previously, currently, much information sharing from third parties is voluntary. Availability of additional insights could be gained through expanded external partnerships, or through additional authority provided by Congress to HHS.

Additional data and other information that could improve supply chain insights that require legislative authorization include:

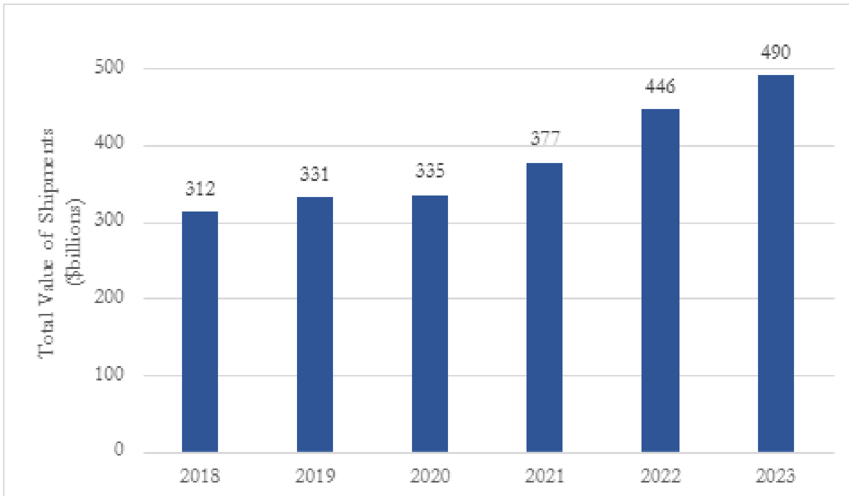
- Industry supply chain resilience plans, inventories, and safety stocks
- Sourcing of raw materials and inputs, particularly foreign sourcing
- Drug substance and drug product manufacturing volume information and reporting
- Complete registration and listing requirements
- Distribution data on prescription drugs and certain biological products
- Manufacturer notifications to HHS of an unusual increase in demand
- Labeling of original manufacturers for API and finished drug products

[267] Exec. [Off.] of the President. "National Strategy for a Resilient Public Health Supply Chain." https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.

Domestic capacity

The total value of goods shipped by domestic manufacturers of drugs, biological products, and medical devices was valued at nearly $490 billion in 2023, an increase from $312 billion in 2018, and represented about seven percent of the $6.9 trillion of the total values of goods shipped by all manufacturing industries in the United States (Figure 3).[268,269] These data suggest that domestic production has increased in the last few years.

Figure 3: Total value of shipments of drugs, biological products, and medical devices (in 2018 dollars)



However, based on market research, limited domestic capacity continues to negatively impact the resilience of the public health and biological preparedness industrial base. The previous section outlines the significant investment that HHS has made toward building domestic production capacity for a variety of medical products. Certain industry players, from small producers to large manufacturers, have also undertaken major investments to build American-made medical products.

To assess the state of the domestic public health industrial base, HHS has also taken great strides to monitor levels of domestic manufacturing capacity for key products in this sector, especially those deployed during the COVID-19 response and those for which HHS has invested in domestic manufacturing capacity. However, as outlined in the previous section on transparency, much of this data comes from voluntary industry sharing, and thus HHS does not have consistently up-to-date visibility into domestic manufacturing levels. Still, HHS is able to generalize the current state of domestic capacity for certain product types:

- PPE: As the COVID-19 pandemic ended, demand for PPE decreased, and lower costs of international competition and domestic availability of raw materials are posing greater challenges for domestic manufacturers. The box on the following page outlines domestic capacity and market conditions for key PPE types.

[268] U.S. Census Bureau, Manufacturers' Value of Shipments: Electromedical, Measuring, and Control Instrument Manufacturing [A34KVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A34KVS.
[269] U.S. Census Bureau, Manufacturers' Value of Shipments: Pharmaceutical and Medicine Manufacturing [A25BVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A25BVS.

- Durable medical equipment: The U.S. Government invested $5 million to build a new ventilator filter manufacturing line. This increased ventilator filter production capacity from 485,000 units per month to 650,000 units per month.
- Testing and diagnostics: The supply chains for raw materials remain fragmented across a variety of domestic and foreign suppliers.

DOMESTIC CAPACITY FOR PPE

The COVID-19 pandemic led to a substantial increase in domestic PPE production, driven by both U.S. Government and private investments. However, as demand for PPE has softened, companies are evaluating the feasibility of maintaining domestic capacity. Below, based on market research, is an assessment of the factors that may drive a decrease in domestic capacity.

N95 Respirators: While most manufacturers considered themselves to be domestically competitive, there have been concerns regarding global competitiveness due to pricing, lower demand for PPE, and protectionism in overseas markets. Additionally, specific components of N95 respirators, including headbands and specialty foam products, create bottlenecks in complete domestic sourcing. New or modified regulatory actions, such as providing clearer definitions for sourcing requirements and enforcing existing quality standards, can help address these barriers.

Nitrile Gloves: Nitrile gloves are overwhelmingly sourced from Malaysia, China, and Thailand and also rely on chemical inputs from China and other countries. However, new domestic nitrile glove capacity has come online in recent years. International competition offers products at significantly lower prices, which impacts domestic manufacturers' ability to obtain market share and remain commercially viable. Access to skilled labor further limits manufacturers, impacting time to source and the ability to hire, train, and retain skilled workers. There has been support for trade actions to increase competitiveness, including increased tariffs for foreign-produced gloves and regulatory action against suspected dumping practices. Today, the largest challenge for wholly domestic nitrile glove production is the lack of domestic availability for nitrile butadiene rubber (NBR) raw materials.

Nitrile Butadiene Rubber: The dumping of Chinese-produced nitrile gloves and NBR into the U.S. market poses a significant challenge. In the short term, the U.S. will need to source Acrylonitrile and Butadiene from foreign sources as the domestic supply is constrained. The availability of lower-cost products from global suppliers further discourages purchasers from buying domestic materials due to a higher cost of goods than foreign producers. In addition, expanding U.S. raw material supply capacity will require hundreds of millions of dollars in capital investment. Domestic producers are unlikely to commit to this level of investment until U.S. PPE manufacturing achieves self-sufficiency.

Nonwoven Fibers: Fibers spun from resins replace fabric fibers in certain PPE products. Foreign suppliers benefit from local labor rates, cost of raw materials and polymers, and access to lower-cost shipping options, leaving domestic producers struggling to compete on price. While the U.S. textile and apparel industry is capable of producing nearly any required PPE product, certain products rely on select input materials for use in production that must be imported, with China often being the dominant or sole supplier of these materials.

Trade concentration

The 100-day Review indicated that dependence on foreign nations such as India and China are a key vulnerability for the industrial base sector. Foreign anticompetitive practices—such as state subsidies to businesses and labor, price fixing, or state-ownership of raw materials—can provide further economic advantages to foreign locations over the U.S. During the COVID-19 pandemic, China interrupted exports of critical medical supplies, such as PPE, medical devices, antibiotics, and APIs, to the United States, which contributed to production shortages.[270] In addition, the U.S. imported 72 percent of face masks from China in 2019 and closer to 85 percent in 2020, and experienced large shares of imports from China for a broad range of medical supplies (nitrile gloves, disposable gowns, surgical masks, melt blown fiber to make masks and ventilators).[271]

Based on data from 2021, China and India were among the top suppliers—ranking 4th and 5th, respectively—of drugs, biological products, and medical devices into the United States.[272,273] Additional reliance on China and India also exists in the supply of raw materials farther upstream in the supply chain. The data suggest there is continued reliance on foreign manufacturing which is geographically concentrated, and continued risk to the resilience of the public health industrial base supply chains.

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[270] Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues*, R46304 (Washington, DC: Library of Congress, April 6, 2020), https://crsreports.congress.gov/product/pdf/R/R46304/1.
[271] Exec. [Off.] of the President. *National Strategy for a Resilient Public Health Supply Chain.* (July, 2021). p 72. https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.
[272]"USA Trade Online," U.S. Department of Commerce, accessed December 10, 2024, https://usatrade.census.gov/index.php.
[273]"Annual Survey of Manufacturers," U.S. Department of Commerce, accessed December 10, 2024, https://www.census.gov/econ/overview/ma0300.html

Indicators of Resiliency and Risk for Syringes as Identified by Department of Commerce's SCALE Tool

In November 2023, the FDA announced the ongoing evaluation of potential medical device failures associated with plastic syringes manufactured in China. Warning letters describing violations were distributed to three entities with sole or partial reliance on foreign production in March 2024. Beyond isolated quality issue disruptions, HHS examined specific indicators of supply chain vulnerability, resilience risk, and criticality to the U.S. population's well-being through the Department of Commerce's SCALE supply chain risk tool for NAICS 339112 - Surgical and Medical Instrument Manufacturing, the industry containing syringes. Four product categories, Syringes Overall (HS 901831), Hypodermic Syringes (HS 9018310040), Non-Hypodermic syringes (HS 9018310080), and Syringe Parts (HS 9018310090) were scored medium to high-risk for adversary dependence, substitution difficulty, and international climate change vulnerability, reinforcing the importance of recent domestic investments in needles and syringes made by ASPR ($144 million as noted in Table 1). This need was highlighted by others in the global public health sector (e.g., U.S. International Development Finance Corporation and USAID's 2023 report[†] on next steps for international financing solutions for MCM surge manufacturing and delivery).

[†] U.S. International Development Finance Corporation. *Advancing DFI Financing for a More Equitable Response to Health Emergencies. Retrieved from:* *https://www.dfc.gov/sites/default/files/media/documents/DFI%20Surge%20Financing%20for%20MCM_Options%20Report.pdf*

Supplier diversity

Strategies to create a robust and resilient public health and biological preparedness industrial base include diversification of supply, both domestic manufacturing and diversity in foreign sourcing. Lack of diversity in terms of the geographic location of suppliers and consolidation in overall production of critical medicines and medical devices outside the U.S. can leave the domestic supply chain vulnerable to single points of failure, external events such as natural disasters or geopolitical events.[274] These single points of failure highlight the need for affirmative promotion of competitive entry outside of crisis times. For example, in 2017 Hurricane Maria disrupted several factories of a major manufacturer of IV bags, leading to widespread shortages. Hurricane Helene in 2024 impacted operations of a facility that produces 60 percent of IV solutions used in the U.S. In addition, a limited number of manufacturers per product also leads to risks, as demonstrated in what HHS has seen in the PPE and testing and diagnostics markets.[275]

- **PPE**: With warehouses in the U.S. holding excess inventory, glove manufacturers in Asia—where most nitrile gloves are produced—have experienced a decline in orders. However, as the excess nitrile gloves in the U.S. are sold down, these manufacturers are likely to experience an increase in orders. This greater demand, combined with a limited number of

[274] Executive Office of the President, *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017* (June 2021), https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[275] Rena M. Conti and Ernst R. Berndt, "Four Facts Concerning Competition in U.S. Generic Prescription Drug Markets," NBER Working Paper No. 26194 (National Bureau of Economic Research, August 2019), https://doi.org/10.3386/w26194.

producers, may give them leverage to raise prices, a shift in the market that would foster a need for greater diversity of domestic manufacturing.

- **Testing and Diagnostics:** The overall testing landscape in the U.S. relies on the same materials as other sectors, creating potential bottlenecks for ramping production due to shared up-stream suppliers. There is also a lack of diversity of product types in many of the diagnostic channels leading to competition between manufacturers for the same materials.
- **Pharmaceuticals:** A detailed analysis of sole-supplier reliance is presented in the corresponding *Four-year Review of Supply Chains for Pharmaceuticals and APIs*.

Agility

Resilient supply chains involve fostering processes necessary to adapt and recover from disruptions. This means being agile, and have the supplies needed to respond rapidly when a supply chain disruption occurs. Stockpiling and inventories, as well as flexible manufacturing, are critical to ensuring that medical product supply chains are able to respond quickly to public health emergencies. The U.S. continues to prepare for public health emergencies through procurement and stockpiling of supplies, medicines, and devices for lifesaving care. For example, the SNS procures and stores products that are not supported by the commercial market and commercially available products that may experience increased demand during times of emergency, as well as helps facilitate their distribution when not available through commercial channels. However, the SNS does not have sufficient funding to store enough product to provide adequate agility for all SNS products. Other stockpiles such as the safety stock of hospitals and distributors also provide agility to the supply chains.

The United States medical product supply chains typically run on a just-in-time inventory model, often containing no more than a 30-day supply under normal conditions. As a result, commercially available products may not exist in necessary quantities or be positioned for rapid distribution and use during public health emergencies. Despite these challenges, HHS can move medical personnel, equipment, and supplies across the nation within hours. To that end, the SNS maintains contracts with commercial transportation partners that possess the resources and capabilities to meet the most difficult delivery timelines. SNS transportation arrangements are designed to maintain MCM security and efficacy in extreme environments so that deployed products are safe to dispense during a public health emergency. Similarly, medical device manufacturers leverage a system and complex network of suppliers in a tier-structure based on the manufacturer being discussed: Tier 1 suppliers sell goods to the manufacturers, Tier 2 suppliers sell to Tier 1, and so on.[276] One major manufacturer of medical devices stated that across all lines of business, it had 100,000 Tier 1 suppliers alone.[277]

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[276] Sophie Luo, "What Is a Tier 1 Company or Supplier?" Insight Solutions Global, December 18, 2018, https://insightsolutionsglobal.com/what-is-a-tier-1-company-or-supplier/

[277] Peggy G. Chen et al., *Medical Device Supply Chains: An Overview and Description of Challenges During the COVID-19 Pandemic* (RAND Health Care, September 2021), https://aspe.hhs.gov/sites/default/files/documents/e48047020834c0c34cf6baf08a9428d0/PR-A328-2-medicaldevices.pdf.

CASE STUDY: COVID-19 AT-HOME TESTING KITS

ASPR oversaw the procurement and stockpile mission of COVID-19 tests as well as distributed hundreds of millions of tests to tens of thousands of Long-Term Care Facilities, Community Health Centers, Schools, Housing and Urban Development sites, Food Banks and Centers for Community Living. From FY 2020 through FY 2024, ASPR invested more than $14.62 billion in testing and diagnostics manufacturing capacity expansion and test procurements. In January 2022, President Biden announced a first-of-its-kind effort to make one billion free at-home COVID-19 tests available to the public to ensure any person who needed or wanted tests could obtain them. ASPR managed the budgets, interagency agreements, and operations and logistics activities that enabled the delivery of more than 990 million at-home tests distributed to the American public through the Covidtests.gov program, in conjunction with the United States Postal Service. The majority of COVID-19 tests were contracted or purchased through a U.S. company.

Overall, the total value of the SNS inventory grew by approximately 50 percent during the COVID-19 response, in large part due to the procurement of PPE and ventilators using COVID-19 supplemental funds. However, products procured during the COVID-19 response have begun to expire. Without an increase in SNS's annual appropriation, the SNS will be unable to continue to replace expiring products, which will reduce holdings and the agility of the PPE supply chain.

The testing and diagnostics domain may have challenges to quickly ramp up production, if needed, for several reasons. First, the market for over-the-counter COVID-19 or influenza tests is relatively new and therefore unstable, and manufacturers lack the agility to throttle manufacturing rates in response to market demand, specifically at the consumer level. Also, there are fewer manufacturers since the end of the pandemic. Additionally, novel agents or new biological threats would not be detectable by existing point-of-care or over-the-counter technology. The timeline for the development, regulatory review, and manufacturing ramp up for a test against a novel agent remains too long to be immediately effective. While there are clinical trial risks for higher complexity tests such as laboratory or point-of-care devices such as nucleic-acid amplification tests, there are currently no federal government requirements to maintain the diagnostic materials or raw materials used in the manufacturing of tests. Without government support, ramp-up times will remain high.

Security

A wide range of security risks exist, including prolonged loss of transportation, energy outages, cyberattacks, and geopolitical tensions, as described in additional detail in the corresponding *Four-year Review of Supply Chains for Pharmaceuticals and APIs*.

Extreme weather events driven by climate change can disrupt the production, stockpiling, and distribution of medical supplies, increasing demand for these products and further stressing supply chains. For example, in 2021, winter storms in Texas caused power outages at chemical plants, which led to disruptions to raw materials used in medical products such as diagnostics, gowns and face shields.[278] SCALE data suggest that overall, the industrial base risk associated with climate change is medium to high. Detailed data based on the Federal Emergency Management Agency (FEMA) National Risk Index (NRI) scores demonstrate that medical product manufacturing facilities in the U.S. are located disproportionately in areas at high risk for natural hazards such as earthquakes, tornados, hurricanes, and storms.[279] Specifically, more than a quarter of device manufacturers are in areas categorized as very high or relatively high risk using the NRI's Composite Risk score).

FDA/CDRH has documented nearly 500 cyber-security vulnerabilities identified in medical devices as well as their response,[280] while FDA has committed to upholding safety and effectiveness standards in AI-enabled medical products across the life cycle.[281] SCALE data point to moderate cyber risk in pharmaceutical supply chains and the sector that includes hand sanitizers.[282]

Additional infrastructure risks include disruptions to transportation and logistics systems, including ocean shipping and air freight. Supply chain transportation disruptions could result in significant recovery time. For example, four health-related industries scored high-risk against port concentration and domestic port vulnerability by the SCALE tool. Additionally, even industries with modest scores were estimated to take six months to recover from transportation shocks in the supply chain. Across all health-related industries, there were 51 products (at the HS 6-digit level) identified by SCALE that scored high for port concentration risk and 76 that score medium-high. Of the 51 high-risk products, 30 have an average of at least $1 million in general imports through a single domestic port.

High-value medical devices are often shipped by air due to their value and the need for rapid delivery and additional security. Limited availability of cargo space during crises can hinder the transport of medical products, especially when demand spikes. In December 2020, there was a notable 13.71 percent year-on-year increase in worldwide cargo flights, largely driven by the urgent need to transport PPE and medical supplies amid the evolving pandemic.[283]

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278 Christopher M. Matthews, Austen Hufford, and Collin Eaton, "Texas Freeze Triggers Global Plastics Shortage," *The Wall Street Journal*, March 17, 2021, https://www.wsj.com/articles/one-week-texas-freeze-seen-triggering-monthslong-plastics-shortage-11615973401.

279 Allison Kolbe and Trinidad Beleche, *Linking Medical Product Manufacturing Locations with Natural Hazard Risk: Implications for the Medical Product Supply Chain* (Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, July 2024), https://aspe.hhs.gov/sites/default/files/documents/2cf7713763c222cbb8caaf5015126735/aspe-data-point-natural-hazards-manufacturing.pdf.

280 U.S. Food and Drug Administration, "CDRH Recognizes 10-Year Anniversary of Cybersecurity Program and Continued Steps to Help Ensure Medical Device Cybersecurity," press release, October 4, 2023. https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-recognizes-10-year-anniversary-cybersecurity-program-and-continued-steps-help-ensure-medical.

281 U.S. Food and Drug Administration, *Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together* (March 2024), https://www.fda.gov/media/177030/download?attachment

282 Specifically, the risk was 60.4 for 325412 - Pharmaceutical Preparation Manufacturing and 62.2 for 325611 - Soap and Other Detergent Manufacturing.

283 Lucy Budd and Stephen Ison, "The impact of COVID-19 on air cargo logistics and supply chains," in *Transportation Amid Pandemics,* ed. Junyi Zhang and Yoshitsuga Hayashi (Elsevier, 2023), 183-188, https://doi.org/10.1016/B978-0-323-99770-6.00020-X.

Economic health and compliance

Understanding the economic health and regulatory compliance of the industrial base includes monitoring the stability of operations and the predictability of supply and demand, and identifying key actors or factors that affect them. Sustained funding through annual U.S. Government appropriations is required to ensure that the public health and biological preparedness industrial base is incentivized to both develop and sustain production of essential medical products. However, sufficient funds to build, maintain, and drive innovation remain critical challenges. The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Multi-Year Budget for Fiscal Years (FY) 2023–2027 projects an estimated overall funding need of $79.5 billion over the five-year period, an increase of $15.5 billion over the FY 2022–2026 report. This funding is required to conduct advanced research and development, regulatory review, procurement and stockpiling, as well as replenishment of MCMs. If funding continues at the FY 2023 level over the projected five-year period, the report estimates a shortfall of $46.4 billion from the total projected need.

Additionally, cybersecurity risks in supply chains are related to the misuse of biotechnology and synthetic nucleic acids. Advances in computing technology have made it easier to purchase synthetic nucleic acids produced by third parties (rather than cultivated in a research lab).[284] Non-regulated pathogens and toxins (e.g., those not covered directly by the Foreign Select Agent Program [FSAP] and/or the BIS Commerce Control List [CCL]) in addition to other types of novel nucleic acid sequences (e.g., new microbial organism or toxin that has the potential to threaten public health, agriculture, plants, animals, animal or plant products, or the environment) if sold to individuals with no legitimate scientific and peaceful purpose for the materials.[285]

Another aspect of economic stability of public health and biological preparedness industrial base supply chains is having a reliable source of labor, including maintaining an adequate workforce for pharmaceutical manufacturing with the specialized knowledge needed and wage competition from other U.S. STEM fields.[286] This need places additional pressure on manufacturers to relocate operations offshore in order to remain competitive.

Manufacturing quality issues, which can result in recalls or other compliance actions, present a continuing threat to availability of medical products and may signal vulnerabilities in manufacturers' economic health. The following demonstrate the types of available data on manufacturing quality issues. The FDA Data Recalls Dashboard shows there have been fluctuations but an overall decrease in the number of recalls (Figure 4) and warning letters issued (Figure 5) since 2020.[287] Finally, Figure 6 shows trends in FDA inspection outcomes for the fiscal years 2019–2023, and show an increase in the absolute number of inspections that result in an Action Indicated

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[284] Emily Mullin, "The US is Cracking Down on Synthetic DNA," *WIRED*, May 6, 2024, https://www.wired.com/story/synthetic-dna-us-biden-regulation/.

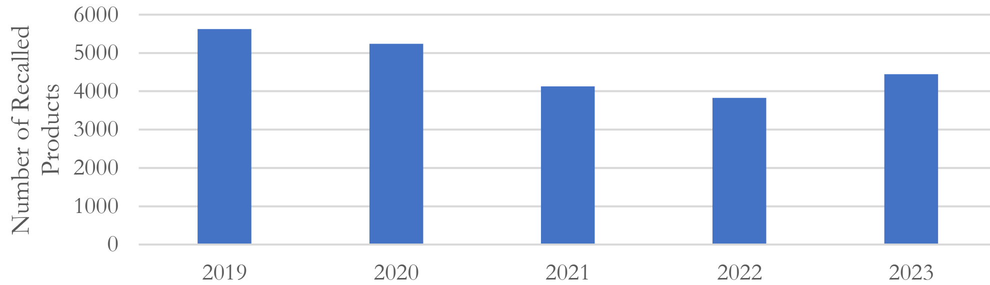
[285] Administration for Strategic Preparedness and Response, *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* (U.S. Department of Health and Human Services, 2010), https://aspr.hhs.gov/S3/Pages/Screening-Framework-Guidance-for-Providers-of-Synthetic-Double-Stranded-DNA.aspx.

[286] Administration for Strategic Preparedness and Response & ARMI, *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* (2022), https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.

[287] "Recalls," U.S. Food and Drug Administration, accessed December 9, 2024. https://datadashboard.fda.gov/ora/cd/recalls.htm

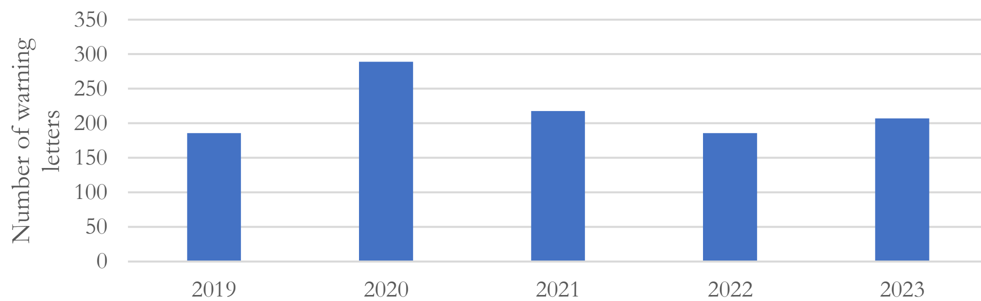
classification, which means regulatory and/or administrative actions are recommended, although a decrease in the percentage of total inspections resulting in an Action Indicated classification.

Figure 4: Total recalled products of drugs, biological products, and medical devices



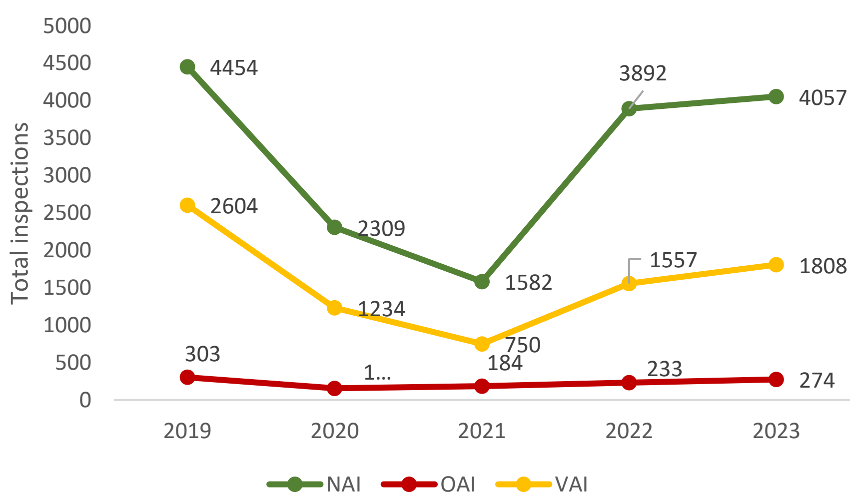
Source: U.S. Food and Drug Administration Data Dashboard

Figure 5: Total warning letters for drugs, biological products, and medical devices by fiscal year



Source: U.S. Food and Drug Administration Data Dashboard

Figure 6: Inspections classifications for drugs, biological products, and medical devices by fiscal year



Note: NAI=No Action Indicated, VAI=Voluntary Action Indicated, OAI=Official Action Indicated.
Source: U.S. Food and Drug Administration Data Dashboard

PRIORITIES AHEAD

Four-year Outlook

America's public health industrial base involves many actors, and additional surveillance and data sharing across the U.S. Government could promote early identification of supply chain risks and vulnerabilities. Market structure, resources, and data gaps limit HHS, U.S. Government, and other stakeholders' end-to-end visibility into supply chains. Many recognize the need to prioritize strategies and implementation actions for critical medical products in the face of constrained resources, including identifying medical products that could be prioritized for enhanced visibility and investments. Further, the market lacks information and competes on lowest price rather than supply chain resiliency, which limits the ability to enhance the overall resilience of the industrial base.[288] Importantly, beginning in 2024 HHS will be guided in its work to enhance supply chain resilience by the newly created Coordinator and the first ever draft *HHS Action Plan for Addressing Shortages of Medical Products and Strengthening the Resilience of Medical Product Supply Chains (draft HHS Action Plan).*

Four-year Resilience Goals and Priorities

Overview

In this Section we provide a high-level description of HHS priorities for the next four years, organized within four major goals. Further details on HHS actions are presented in the forthcoming draft *HHS Action Plan for Addressing Shortages of Medical Products and Strengthening the Resilience of Medical Product Supply Chains (draft HHS Action Plan).*

Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product supply chains

Fostering greater coordination and communication within HHS and across the U.S. Government will enhance efforts to set and ultimately achieve specific supply chain objectives. A formalized coordinating function also enables continual scanning for any strategic gaps in the approach being deployed to achieve these objectives. Additionally, strengthening partnerships with non-government domestic stakeholders are essential steps in mapping the supply chain and addressing shortages. Conversations with global partners and multilateral and bilateral agreements are also central to ensuring that shared access to needed supplies is maintained and near-shore capacities are available to diversify and sustain the supply chain, especially in times of crisis.

Increase availability and utilization of actionable insights into critical medical product supply chains for HHS

Enhancing insights into the medical product supply chains will require a mix of strategies to expand HHS and private-sector capabilities and data to monitor and conduct risk assessments of the supply chains. This includes leveraging existing information and identifying technologies and platforms to facilitate analysis of these data, as well as identifying gaps where additional data is needed to inform

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288 FDA Drug Shortages Task Force. *Drug shortages: Root causes and potential solutions* (2020), https://www.fda.gov/media/131130/download

decision-making. Additionally, mapping critical components of the pharmaceutical supply chain (e.g., stockpiles, raw materials, components, manufacturers, distributors, and end-users), and proactively identifying threats and potential responses are essential components of strengthening the supply chain.

Strengthen HHS response to shortages and supply chain disruptions

Unforeseen events that stress even the most resilient supply chains are unavoidable, and the U.S. Government must be prepared to respond to disruptions. HHS response efforts can be strengthened by identifying mechanisms, strategies, technologies, policy levers, and funding that supports greater pharmaceutical supply chain resilience. Specific actions include outlining R&D priorities and optimizing resources; encouraging the adoption of novel technologies that promote quality and could enable more domestic manufacturing; developing procedures, processes, plans, frameworks, and mechanisms that facilitate an all-of-government response to supply chain disruptions and other threats; and promoting workforce development and engagement to make sure the U.S. has the expertise needed to support a resilient supply chain.

Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other steps

Market participants throughout the supply chain have lacked appropriate incentives to adopt practices that foster resilience through diversification, redundancy, and investment in newer technology and mature quality systems. Incentivizing the private sector to compete not just on price but also on strengthening supply chain resilience is critical. U.S. and allied drug manufacturing is often undercut by foreign competition. While the United States does not need to produce every drug itself, it does need increased international cooperation and domestic production capacity for key drugs. Supply chain resilience can be strengthened by identifying critical industrial capacity gaps, and subsequent mechanisms, technologies, funding, strategies, and policy levers to address them. Further promoting onshoring, ally-shoring, and "Buy in America" initiatives will work to expand the domestic industrial base and increase supplier diversification.

Legislative and Budgetary Objectives

Many causes of disruptions are unpredictable or occur at nodes in the supply chains where HHS may have limited visibility, resources, or authority. Additional budget authority is needed to sustain certain existing HHS activities, many of which were supported by COVID-19 supplemental funding. HHS has also proposed a number of complementary legislative initiatives to improve the Department's capabilities in achieving the stated priorities. These proposals span a number of HHS agencies and would provide them with new or additional authorities to better address potential supply chain disruptions. A number of other proposals would advance ASPR's efforts to increase the supply of essential medicines, including acquiring innovative commercial products, funding development and large-scale manufacturing of a product, and acquiring or constructing non-federally owned facilities. Other changes would require new or additional information sharing between industry and HHS. Additional details regarding resources and other legislative efforts that would support HHS actions are detailed in the forthcoming draft *HHS Action Plan*.

Long-term Resilience Goals

HHS will continue to strengthen the resilience of the public health industrial base through innovative solutions, such as Supply Chain Optimization, Agile Manufacturing, Next-Generation Disease Testing, Manufacturing and Deployment of Critical Medical Equipment, and DPA Title III by promoting development of new disease testing platforms, improving infrastructure and advancing technologies for rapid scale-up of medical supplies or decrease costs, speeding production, and improving access to critical medical products. Certain markets, like PPE, continue to be highly volatile with continued competition from global suppliers; some domestic companies shut down lines, facilities, and even laid off their work force. Another major priority for HHS is to ensure the sustainability and commercial viability of the investments made in this sector since the COVID-19 response.

Conclusion

Frequent supply chain disruptions have highlighted significant vulnerabilities in the U.S. public health industrial base, and historic efforts were made to strengthen its resilience. HHS will continue to invest in technology and infrastructure to improve insights into the supply chains, increase domestic capacity, and diversify the industrial base. HHS remains committed to identifying risks and vulnerabilities, and building more resilient medical product supply chains by incentivizing resiliency and improving communication and coordination within government and with key partners. Achieving these goals requires significant funding and resources as well as continued efforts across the U.S. Government, Congress, the private-sector, and other stakeholders to overcome the anticipated and unknown challenges. These efforts must remain a priority to protect the nation's public health and increase the economic sustainability and competitiveness of the nation.

APPENDIX

Appendix Table 1. Inclusion criteria for NAICS codes used in the SCALE tool analyses

NAICS	2022 Industry Title	Examples of Sector Relevant Industry Products
325199	All Other Basic Organic Chemical Manufacturing	Non-API and biochemical compounds used in pharmaceutical manufacturing
325412	Pharmaceutical Preparation Manufacturing	Substances intended for diagnostic and/or internal and external consumption in dose forms
325413	In-Vitro Diagnostic Substance Manufacturing	Substances used for diagnostic tests performed in test tubes, petri dishes, machines, etc.
325414	Biological Product (except Diagnostic) Manufacturing	Vaccines, toxoids, blood fractions, and culture media
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	Manufacturing materials
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	Products such as magnetic resonance imaging equipment, medical ultrasound equipment, pacemakers, etc.
334516	Analytical Laboratory Instrument Manufacturing	Instruments and instrumentation systems for laboratory analysis of chemical or physical composition, etc.
334517	Irradiation Apparatus Manufacturing	Irradiation apparatuses and tubes for medically diagnostic, medically therapeutic, industrial, research and scientific evaluation applications.
339112	Surgical and Medical Instrument Manufacturing	Medical devices such as syringes, hypodermic needles, catheters, etc.
339113	Surgical Appliance and Supplies Manufacturing	Surgical PPE, safety devices, hospital beds, etc.
325411*	Medicinal and Botanical Manufacturing	Uncompounded medicinal chemicals and their derivatives generally for pharmaceutical preparation manufacturing
325611*	Soap and Other Detergent Manufacturing	Hand Sanitizer, cleansers, and glycerin
339114*	Dental Equipment and Supplies Manufacturing	Cutting instruments, orthodontic appliances, and substances such as enamels, wax, etc.

** Indicates industries that may contain non-health related products, but were selected for partial relevance for the Public Health and Biologic Industrial Base and are included in aggregated averages.*

2021–2024 Four-year Review of Supply Chains for Pharmaceuticals and Active Pharmaceutical Ingredients

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DECEMBER 2024

EXECUTIVE SUMMARY

Improving the resilience of the nation's human drug supply chains is essential for public health and the national security and economic prosperity of the United States. This Review, a complement to HHS's four-year review of supply chains for the public health and biological preparedness industrial base, focuses on the pharmaceutical[289] and active pharmaceutical ingredients (APIs) supply chains, which are complex, global, and vulnerable to disruptions.

Global supply chains and complex production, distribution, purchasing and contracting systems can all contribute to disruptions in the supply chains that lead to medicine shortages that can sometimes persist for years. Market factors, particularly cost pressures and concentration among organizations that facilitate pharmaceutical purchasing contracts, have led to decreased investments in diversification, redundancy, newer quality systems, and other steps that can help prevent shortages. Over the past 30 years, the generic pharmaceutical market, which accounts for 90 percent of the drugs prescribed to Americans, has consolidated and increasingly outsourced its production to countries with lower labor and manufacturing costs.

In 2021, HHS conducted a 100-day review of pharmaceutical and API supply chains, which outlined vulnerabilities in the sector and ways to build resilience.[290] The HHS White Paper also provides additional insight into the root causes of drug shortages in particular, building on years of HHS research into this topic. This work has identified three primary challenges to resilience in this sector:

- the complexity, and global nature of pharmaceutical and API supply chains and the corresponding dependence on foreign sourcing;
- limited incentives to reward supply chain resilience in the market, and
- lack of supplier diversity.

To address these challenges and promote resilience throughout the pharmaceutical and API supply chains, HHS and the broader U.S. Government have taken a number of actions since 2021, including increasing domestic production capabilities and visibility into certain pharmaceutical product supply chains. However, the sector still faces challenges, and more work is needed. Over the next four years, the U.S. Government work will focus on doing the following:

- Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product supply chains.
- Increase availability and utilization of insights into critical medical product supply chains.
- Strengthen HHS response to shortages and supply chain disruptions.
- Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other steps.

To promote more robust supply chains capable of addressing future public health challenges, additional opportunities remain. Advancements will also require additional authorities and resources going forward to ensure sustained change.

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289 In this Review, drugs and pharmaceuticals are used interchangeably.

290 Exec. [Off.] of the President, *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth, 100-day reviews under Executive Order 14017* (June, 2021), https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

SECTOR OVERVIEW

Introduction

This Four-year Review focuses on the supply chains for human drugs, particularly small-molecule drugs and therapeutic biological products, including their active pharmaceutical ingredients (APIs).[291] A corresponding HHS *Four-year Review of Supply Chains for the Public Health and Biological Preparedness Industrial Base* more broadly discusses the supply chains for certain pharmaceuticals and APIs,[292] personal protective equipment (PPE), medical equipment, and testing and diagnostics, as well as certain vaccines.

HHS has made progress strengthening the resilience of the pharmaceutical and API sectors since 2021 when President Biden issued two related executive orders. Executive Order 14001 on A Sustainable Public Health Supply Chain[293] focused on preparedness, directing certain agencies to develop a strategy to respond to future pandemics and threats through increased domestic production of key supplies for sustainable public health supply chains. Executive Order 14017 on America's Supply Chains directed certain federal agencies to conduct a 100-day supply chain review ("100-Day Review"), as well as a subsequent review one year later ("One-Year Review") for a range of sectors.[294] Additionally, this Review outlines HHS's learnings and approaches to strengthening supply chain resilience, describes goals for the next four years, and discusses the infrastructure, resources, and authorities that may be needed to accomplish these goals.

Within HHS, the U.S. Food and Drug Administration (FDA) leads response efforts for shortages of pharmaceuticals and APIs. Under the FDA's regulatory purview are over 20,000 human prescription drugs,[295] 90 percent of which are generics[296]—up from 36 percent in 1994[297]—and most products have foreign manufacturing sites for their APIs and finished dosage form (FDF).[298] These capabilities center on information gathering to determine whether a shortage exists, planning and implementing strategies to mitigate or prevent shortages, as well as assessing manufacturers' compliance with various reporting requirements.

Other HHS agencies maintain a constant watch function for potential and emerging public health threats, including their potential impacts on certain medical products. The Administration for

[291] This Review does not focus on the supply chains for vaccines, cell therapies, blood products, and their APIs, due to the nature of these products and the distinct features in their supply chains.
[292] The public health and biological preparedness industrial base includes pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins), non-pharmaceutical interventions (e.g., medical devices, including diagnostics, ventilators, personal protective equipment) and critical foods.
[293] Exec. Order No. 14001, 3 C.F.R. Vol. 86, No. 15, (7219-7222) (January 21, 2021). https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain.
[294] Exec. Order No. 14001, 3 C.F.R. Vol. 86, No. 15, (7219-7222) (January 21, 2021). https://www.federalregister.gov/documents/2021/01/26/2021-01865/a-sustainable-public-health-supply-chain.
[295] U.S. Food and Drug Administration. *FDA at a Glance: FDA Regulated Products and Facilities.* (2024). https://www.fda.gov/media/182749/download.
[296] U.S. Food and Drug Administration, *Office of Generic Drugs 2023 annual report* (Febuary 2024). https://www.fda.gov/media/175664/download.
[297] Maas, S. *Competition in Generic Drug Markets*. (2017). NBER. https://www.nber.org/digest/nov17/competition-generic-drug-markets.
[298] Center for Drug Evaluation and Research. *Fiscal year 2023 report on the state of pharmaceutical quality.* (2024). https://www.fda.gov/media/179254/download?attachment.

Strategic Preparedness and Response (ASPR) supports and coordinates targeted expansion and sustainment of domestic manufacturing of essential medicines[299] as well as medical countermeasures (MCMs),[300] and also manages the Strategic National Stockpile (SNS) and the Supply Chain Control Tower (SCCT). The Centers for Medicare & Medicaid Services (CMS) establishes payment policies for certain medication reimbursements, and may authorize waivers or adjust certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements during an emergency. CMS also contracts with private companies to provide prescription drug benefits to beneficiaries under the Medicare Part D program. To facilitate Department-level coordination across these and other HHS partners and programs, the HHS Supply Chain Resilience and Shortage Coordinator sits in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and oversees the HHS Supply Chain Resilience and Shortage Working Group.

Sector Overview

The United States pharmaceutical and API sector is critical to public health and national security

The pharmaceutical manufacturing sector represents approximately one percent of the United States Gross Domestic Product (GDP).[301,302] In 2023, the pharmaceutical manufacturing sector employed 272,871 workers earning an average annual wage of $130,498 across 5,406 manufacturing establishments in the United States.[303] These estimates do not include research and development (R&D), and other activities associated with the pharmaceutical and API sector and are likely an underestimate.[304,305]

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299 For purposes of this Review, 'essential medicines' is broadly defined as priority life-saving medicines. This may include among others, medicines in the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs published in October 2020, as well medicines in the Essential Medicines Supply Chain and Manufacturing Resilience Assessment report published by ARMI in May 2022.

300 Medical countermeasures, or MCMs, are FDA-regulated products (biological products, drugs, devices) that may be used in the event of a potential public health emergency. Examples of MCMs include drugs, vaccines, and devices such as diagnostic tests and personal protective equipment.

301 "Value added by Industry as a Percentage of Gross Domestic Product." U.S. Bureau of Economic Analysis. https://apps.bea.gov/iTable/?reqid=150&step=2&isuri=1&categories=gdpxind

302 Defined as the 'Value added by Industry as a Percentage of Gross Domestic Product' from Pharmaceutical and Medicine Manufacturing.

303 NAICS 325412 Pharmaceutical Preparation & 325414 Biological Product (except diagnostic), Manufacturing, All Counties 2023 Annual Averages, All Establishment Sizes, see *"*Quarterly Census of Employment and Wages. Employment and Wages Data Viewer.*"* U.S. Bureau of Labor Statistics. https://data.bls.gov/cew/apps/data_views/data_views.htm#tab=Tables.

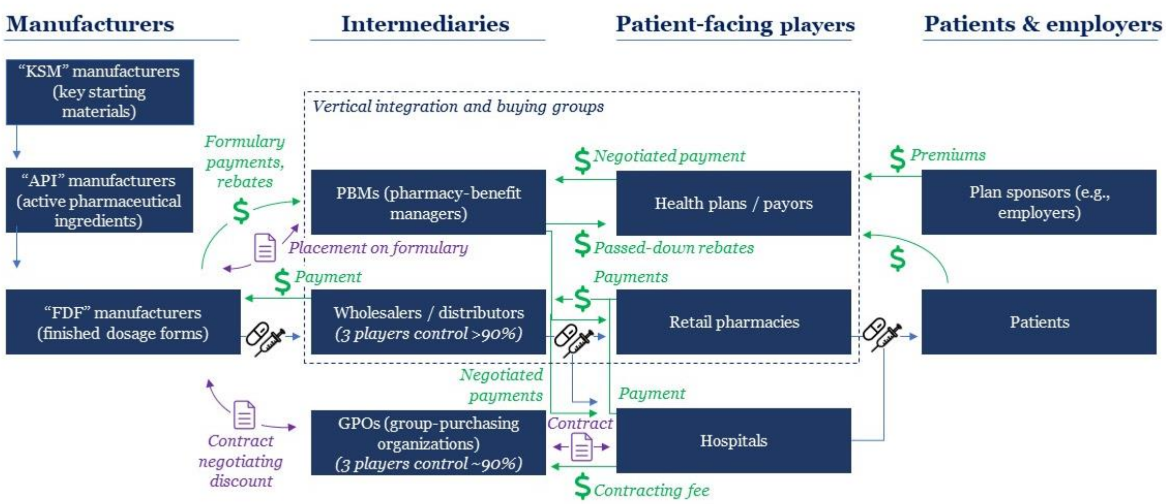
304 Industry-sponsored studies suggest that the biopharmaceutical industry accounted for 17.6 percent of all domestic U.S. business R&D performance in 2022. See PhRMA. *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates.* (May 2022). https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

305 FDA data show there are 7,969 facilities (3,540 domestic and 4419 foreign) involved in the development and marketing of human drugs, and more than 23,000 prescription products approved for marketing. See U.S. Food and Drug Administration. *FDA at a Glance: FDA Regulated Products and Facilities*. (2024). https://www.fda.gov/media/182749/download.

From raw materials to finished dosage forms to end-users

The pharmaceutical sector is a global and complex network of activities and services (contractual relationships, manufacturing, distribution, purchasing, reimbursement, shipment, product dispensing, administration, regulatory oversight) involving many entities (suppliers, manufacturers, distributors, wholesalers, group purchasing organizations (GPOs), pharmacy benefit managers (PBMs), pharmacies, providers, payers, patients, and regulatory agencies) (Figure 1).

Figure 1. From raw materials to finished dosage form to end-users



Note: This diagram represents a notional, simplified view. Actual value chains vary by program, drug, and more.

The pharmaceutical manufacturing supply chain generally starts with suppliers of raw materials, such as solvents, reagents, and other chemicals that are combined by a series of reactions and then purified by a process designed to result in the desired API, or API intermediate,[306] of high purity and free of harmful impurities. A drug manufacturing facility then combines the APIs with various inactive ingredients (actual ingredients depend on final dosage form type, but can include water, lactose, and microcrystalline cellulose), then shapes and/or fills into the FDF (e.g., tablet or liquid). A single API, such as a synthetically made API, may be produced using dozens of different chemicals, while a single drug product often has multiple ingredients, including many inactive ingredients, and a container-closure system (e.g., a glass vial). Once an FDF is manufactured, the path to the end-user can be similarly complex. Distribution from the manufacturer to patients can involve direct distribution to health care facilities or may include intermediaries such as wholesale distributors or third-party logistics providers. Some FDFs may be obtained without a prescription (i.e., over-the-counter) through pharmacies or grocery stores, while others require a prescription or

306 API Intermediate: A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. API intermediates may or may not be isolated. API intermediates are only those produced after the point that a company has defined as the point at which the production of the API begins, as defined by U.S. Food and Drug Administration, "Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Guidance for Industry." (FDA-1995-D-0288). (September, 2016). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q7-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients-guidance-industry.

administration by a health care provider in a diverse set of health care settings (e.g., acute care hospitals, rehabilitation centers, nursing homes), and other long-term care facilities, specialized outpatient centers (e.g., hemodialysis, chemotherapy), or a physician's office.

Resilient and sustainable medical product supply chains are central to protecting the nation's public health, security, and economic well-being. The reliability and resilience of the pharmaceutical supply chains have been influenced by factors that include: (1) increasing reliance on foreign countries to manufacture the medicines, active pharmaceutical ingredients, and their key starting materials; (2) global supply chains and complex production, distribution, purchasing, and contracting systems; (3) market factors such as cost pressures and market concentration that decrease diversification, redundancy and investments in newer quality systems or increased capacity. These factors play a major role in the generics market where profit margins are often low. Moreover, the concentration of power in a few dominant distributors, intermediaries, and manufacturers can create recursive incentives toward more consolidation in other parts of the system.

For generic drugs, market participants throughout the supply chains lack appropriate incentives to adopt practices that foster resiliency, such as diversification, redundancy, and investment in newer technology and mature quality systems. As a result, market participants frequently compete based on lowest price rather than resiliency. Concentration in pharmaceutical purchasing and distribution plays a role in these trends, however the individual contribution is unclear. Concentration among organizations that facilitate pharmaceutical purchasing contracts for generic drugs creates negotiating power for intermediaries, which has generally been used to drive lower cost for purchasers such as hospitals and retail pharmacies, resulting in lower margins for manufacturers. This concentration gives the most negotiating power to intermediaries (e.g., Group Purchasing Organizations (GPOs), Pharmacy Benefit Managers (PBMs), and wholesalers), which some argue have applied strong downward price pressures to generic drugs through harmful contracting practices, including low-price clauses that allow middlemen to unilaterally walk away from a contract if they find a lower price from another manufacturer.[307] For some pharmaceuticals, wholesalers negotiate drug acquisition costs, set drug sales prices to pharmacies, charge fees based on list prices, and compete in specialty drug distribution.[308] Researchers and others have expressed concerns that concentration among GPOs[309] and PBMs[310] may be undermining price competition and limiting hospital access to medical products.[311,312] In addition, manufacturers and purchasers such as hospitals, pharmacies, and others, express a lack of understanding around GPO and PBM

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[307] U.S. Food and Drug Administration. *Drug Shortages: Root Causes and Potential Solutions*. (2019). https://www.fda.gov/media/131130/download.

[308] Seeley, E. *The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending*. (July 20, 2022.) The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending.

[309] Bruhn, W.E., Fracica, E.A., and Makary, M.A. "Group Purchasing Organizations, Health Care Costs and Drug Shortages." *JAMA,* 320 no. 18 (2018): 1859-1860, https://doi.org/10.1001/jama.2018.13604.

[310] Guardado, J.R. "Policy Research Perspectives-- Competition in Commercial PBM Markets and Vertical Integration of Health Insurers and PMBs: 2023 Update." *American Medical Association.* (2023): https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf.

[311] Ventola, L.C. "The Drug Shortage Crisis in the United States. Causes, Impacts and Management Strategies." *P&T* 36 no. 11 (2011).

[312] American Economic Liberties Project, Center for Economic and Policy Research, Demand Progress Education Fund, Free to Care, Our Revolution, Physicians Against Drug Shortages, Practicing Physicians of America, Public Citizen, Revolving Door Project, *letter to The Federal Trade Commission.* (2022, November 22). https://www.economicliberties.us/wp-content/uploads/2022/11/2022-11-22-AELP-FTC-6B-GPO-Letter-Final.pdf.

contracting practices beyond their own experience.[313,314] Overall, these intermediaries create a complex and opaque layer between the health care organizations that must deliver these low-cost generic drugs to patients and the manufacturers that produce them. Hospitals and other health care organizations also play a role in these trends. They, too, face economic pressures, which can lead to pursuit of lowest-cost sources for generic drugs, without adequate consideration for whether the hospital is then reliant on a single source producer and whether the producer(s) have the resources and commitment to invest in resilient manufacturing processes. Hospitals and other health care organizations may advocate for their GPOs, PBMs, or wholesalers to pursue lowest-cost sources without adequate consideration for resiliency. Together, these pressures can further push manufacturing costs and/or profit margins to potentially unsustainable levels, and lead to supplier consolidation that is more vulnerable to disruptions.

Given these challenges, innovative solutions have been proposed or recently launched to address these issues. These include:

- Hospital membership–based and long-term committed contracting models that include supply guarantees and purchase guarantees, fixed prices, buffer stocks, sourcing from diverse and vetted suppliers, and other steps.[315,316,317,318]
- Supply chain resiliency assessment programs that have recently developed or are in the process of developing standards and best practices to increase resiliency and transparency in the pharmaceutical supply chains.[319,320,321,322]

While these nascent and innovative models hold promise not only to increase the supply chain resilience of the pharmaceutical sector but also to sustain the industrial base, they are not widely adopted. Barriers to adoption include cost, lack of awareness, lack of infrastructure, and the voluntary nature of these models. The HHS White Paper published in April 2024 outlines potential steps that could be taken to help increase use of approaches like these. While HHS has made significant strides in shoring up the system's ability to respond to shortages and supply chain disruptions, more impactful and enduring solutions require additional actions from all supply chain participants, and the U.S. Government.

313 "About Us," HIRC, accessed on December 9, 2024. https://hircstrong.com/about-us.

314 US Pharmacopiea. *The Medicines Supply Chain: Increasing Visibility to Strengthen Preparedness*. (March 14, 2022). https://qualitymatters.usp.org/increasing-visibility-in-the-medicines-supply-chain.

315 Parasrampuria, S., Beleche, T., Murphy, S., and Adetunji, O. *Impacts of a Nonprofit Membership-Based Pharmaceutical Company on Volume of Generic Drugs Sold and Drug Prices: A Case Study.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. (July 2024). https://aspe.hhs.gov/sites/default/files/documents/172d065c60a40a7c77b3fb46eef0e4f4/sdp-nonprofit-quantitative-ib.pdf.

316 "CivicaRx," accessed December 9, 2024. https://civicarx.org/.

317 "ProvideGx," Premier, accessed December 11, 2024. https://premierinc.com/providegx.

318 "HealthTrust's SIMS Contracting Strategy Addresses Drug Shortages," HealthTrust Performance Group, accessed December 11, 2024. https://healthtrustpg.com/thesource/pharmacy/drug-shortages/healthtrusts-sims-program-addresses-drug-shortages/.

319 "About Us," HIRC, accessed on December 9, 2024. https://hircstrong.com/about-us.

320 "USP Medicine Supply Map," U. S. Pharmacopeia (USP), accessed December 1, 2024. https://www.usp.org/supply-chain/medicine-supply-map

321 "CHSR Department of Defense Pharmaceutical Supply Chain Portfolio," Uniformed Services University of the Health Sciences (USU), accessed December 1, 2024. https://chsr.usuhs.edu/pharmaceutical-supply-chain/.

322 "Healthcare Supply Chain," Resilinc. https://www.resilinc.com/industry/healthcare-life-sciences/.

Evolution of the Sector through 2020

Over the past 30 years, pharmaceutical manufacturing has become an increasingly global enterprise, and the generic pharmaceutical market has consolidated and increasingly outsourced its production to countries with lower labor and manufacturing costs. Generic drugs make up 90 percent of all prescription medications filled, 17.5 percent of all prescription drug spending,[323] and is estimated to have saved the U.S. health care system $2.9 trillion dollars in the past decade.[324] As the U.S. drug market shifted toward lower-priced generic drugs, manufacturers came under increasing cost pressure. Manufacturers of older generic drugs face intense price competition, uncertain revenue streams, and, for certain sterile products, high investment requirements, all of which limit potential returns.[325] This led manufacturers to relocate more of their facilities overseas, particularly China and India, where labor, energy, and transportation costs are lower, or where nations provide incentives, including foreign subsidies and manufacturing support programs.[326]

Key Sector Trends from 2021 to Present

Where Are Our Drugs and Their Components Produced?

Data submitted to FDA as part of product applications show that, while there has been little change between 2021 and 2024 with respect to the percent of manufacturing facilities that make FDF or API in the United States (Figure 2),[327,328] there has been an increase in the percent of generic drug manufacturing facilities making FDFs and APIs in the U.S. Although these data are limited in demonstrating risk of supply chain disruptions because the data do not include production amount for listed drugs, the results suggest there may have been an increase in domestic capability to manufacture generic FDFs and APIs. It is important to note that FDA has data for API and FDF facilities but does not have comprehensive data about the production of all chemicals used in the synthesis of drugs. FDA has some data on regulatory starting materials, which are upstream from API; generally, many of these chemicals are produced outside of the United States with a majority being produced in China.

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323 Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report.* (September, 2023). https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

324 U.S. Food and Drug Administration. *Office of Generic Drugs 2023 annual report.* (2024). https://www.fda.gov/media/175664/download.

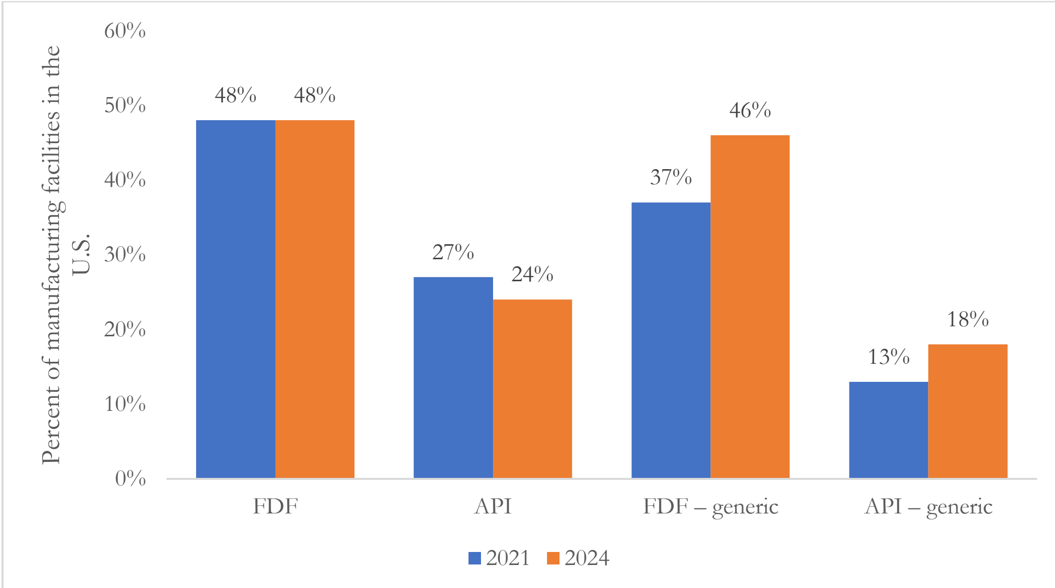
325 U.S. Department of Health and Human Services. *Policy considerations to prevent drug shortages and mitigate supply chain vulnerabilities in the United States.* (2024). https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.

326 For example, India's Strengthening of Pharmaceutical Industry Scheme, see "Strenghtening of Pharmaceutical Industry (SPI) Scheme for MSMES," Invest India, UPDATED July 29, 2022. https://www.investindia.gov.in/team-india-blogs/strengthening-pharmaceutical-industry-spi-scheme-msmes.

327 Facility location by country or region generated from data submitted to FDA as part of product applications.

328 "Abbreviated New Drug Application (ANDA)," U.S. Food and Drug Administration, updated on December 16, 2022. https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda

Figure 2. Percent of FDA-registered manufacturing facilities located in the United States, 2021–2024



Note: Facility location by country or region generated from data submitted to FDA as part of product applications.

Drug Shortages

As a result of congressional and HHS actions, manufacturers now notify FDA earlier than in the past about certain manufacturing interruptions and discontinuances that can lead to shortages. These early notifications give FDA time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent a shortage. Figures 3 and 4 show the trends for new and prevented drug shortages starting in 2010.[329] During calendar year (CY) 2023, FDA's Center for Biologics Evaluation and Research (CBER) and CDER worked with manufacturers to successfully prevent 236 drug shortages using a range of available tools, including regulatory flexibility and discretion when appropriate. Despite this work, during this same period, 55 new drug shortages were identified by CDER[330] and CBER,[331] as compared to a peak of 251 new drug shortages during 2011. Shortages of CDER-regulated products decreased, but there was an increase in CBER-regulated product shortages due to manufacturing problems and quality procedures at one manufacturing facility. Appendix Figures 1 and 2 show the main causes of new shortages in 2023 included manufacturing issues, increase in demand, and availability of APIs, and that at least half of FDF and API shortages of involved foreign manufacturing locations.

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[329] U.S. Food and Drug Administration. *Drug Shortages report.* (2023). https://www.fda.gov/media/179156/download?attachment=

[330] CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

[331] CBER regulates biological products that include allergenics, blood and blood components, gene therapy, human tissues and cellular products, vaccines, and xenotransplantation products.

Figure 3. Number of new drug shortages per calendar year (from CY 2010 to CY 2023)

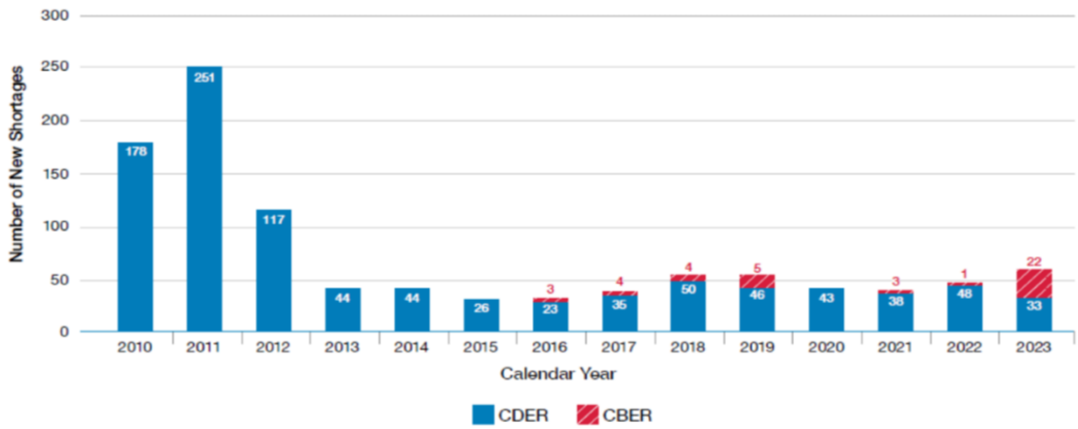
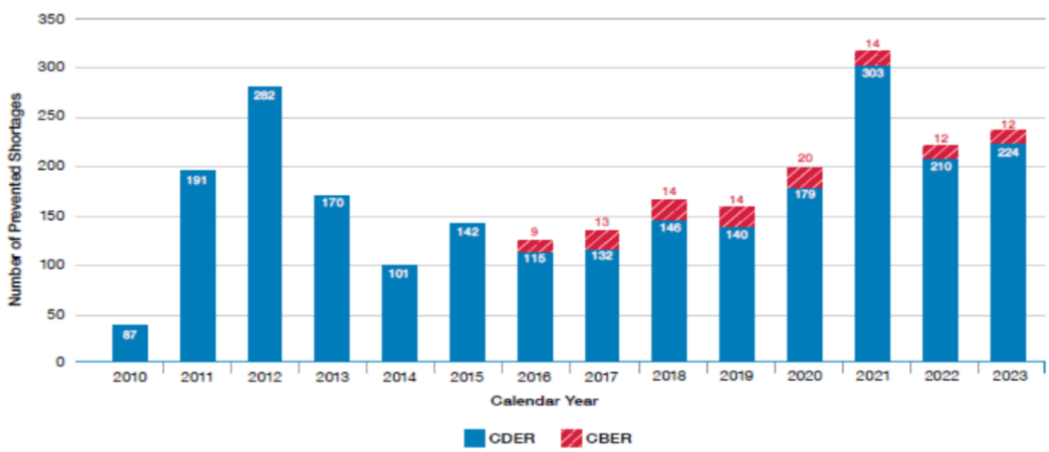


Figure 4. Number of prevented drug shortages per calendar year (from CY 2010 to CY 2023)



PROGRESS TO DATE

100-day Review Priorities

Based on the analysis conducted in 2021, HHS highlighted two priority objectives to build a more robust and resilient supply chain that relied on quality, diversity, and redundancy:

- Improve supply chain transparency and incentivize resilience; and
- Increase the economic sustainability of U.S. and allied drug manufacturing and distribution.

HHS developed three strategies to meet those objectives and delineated specific actions and timelines for implementation. These strategies were:

- Boost local production;
- Build emergency capacity; and
- Promote international cooperation and partner with allies.

HHS outlined its plan to leverage available tools and partnerships to seed investments that promote greater U.S. production and to develop new technologies that will reduce costs and increase the resilience of U.S. and allied production. Some of the key actions include incentives to create redundancy for sterile injectable production, leverage the DPA and current PPPs to identify critical medicines, establish novel platform production technologies, create a rating system to incentivize drug manufacturers to invest in achieving quality management maturity, and improve information and data collection.

HHS's strategy to build emergency capacity involved the creation or expansion of a virtual strategic stockpile of API reserve and other critical materials managed by the SNS, including finished doses.

With the growing dominance of competitor nations, HHS highlighted the importance for the United States to work with its like-minded regulatory partners to develop secure and resilient supply chains that are not overly reliant on material or manufacturing from countries that lack a shared interest in mutually beneficial supply chain arrangement. To that end, HHS described actions to work through already established international regulatory collaboration and harmonization organizations, as well as to leverage other bilateral and multilateral agreements and engagements to strengthen drug and API supply chains cooperation.

Progress from 2021 to Present

HHS has made strides to increase transparency into the pharmaceutical and API supply chain risks. Improved insights into the supply chains have also resulted in identification of essential medicines that should be prioritized to expand domestic production or to build emergency capacity. In addition, HHS has promoted the development and adoption of advanced manufacturing technologies and made significant investments to boost local production of APIs and KSMs, and to increase the economic sustainability of domestic manufacturing.

Improve supply chain transparency and incentivize resilience

- **Enhancing Visibility into Supply Chain Risks:** Leveraging multiple internal and external data sources, HHS created the Supply Chain Analytic Network System (SCANS), a tool that visualizes drug supply chains based on the data that is submitted in periodic regulatory submissions.[332] SCANS automates data collection, organization, and visualization, enabling FDA to quickly assess the supply chains of its pharmaceutical products. With the recent finalization of the guidance on production amount reporting,[333] following new requirements added by the Coronavirus Aid, Relief, and Economic Security (CARES) Act,[334] FDA's Center for Drug Evaluation and Research (CDER) expects this production amount data will facilitate increased transparency into the upstream pharmaceutical supply chains and provide a more complete understanding of key manufacturers based on market share. Although reported annually, this could improve FDA's overall awareness and broader U.S. Government and industry investment decision-making related to long-term risk factors for drug shortages. For active products listed in FDA's electronic Drug Registration and Listing System (eDRLS), less than half of National Drug Codes (NDCs) have drug amount reports submitted by manufacturers (Appendix Figure 3). However, CDER and FDA actions are improving reporting over time. FDA has made enhancements to the reporting portal to make submission easier. In addition to education, outreach, and delinquency notifications, FDA will act, as appropriate, to ensure compliance with CARES Act Drug Amount Reporting.
- **Assessing the Resilience of the Pharmaceutical Supply Chains:** Section 3101 of the CARES Act directed HHS to partner with the National Academies of Sciences, Engineering, and Medicine (NASEM) to assess the security and resilience of the U.S. medical product supply chains.[335,336] NASEM published its report on resilience in America's prescription drug supply chains in 2022.[337,338]
- **Developing an Essential Medicines List to Guide Investments that Incentivize Resilience:** In 2021, HHS assembled several consortia of public health experts and clinicians in the government, non-profit, and private sectors to review the Essential Medicines List published in 2020 in response to Executive Order 13944.[339] An evaluation of

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332 Data on new facilities will be submitted in amendments and amount data will be submitted annually.

333 U.S. Food and Drug Administration. "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act." (FDA-2021-D-1031) (February, 2024). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-amount-listed-drugs-and-biological-products-under-section-510j3-fdc-act.

334 The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) made amendments to the FD&C Act to require that each, compounded, or processed by such person for commercial distribution.

335 Text - S.3548 - 116th Congress (2019-2020): CARES Act, S.3548, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/senate-bill/3548/text.

336 "Security of America's Medical Product Supply Chain - Committee Meeting 2 and Public Workshop", NASEM, December 1-3, 2020. https://www.nationalacademies.org/event/12-01-2020/security-of-americas-medical-product-supply-chain-committee-meeting-2-and-public-workshop.

337 Ibid.

338 Park, M., Conti, R.M., Wosińska, M.E., Ozlem, E., Hopp, W.J., Fox, E.R. "Building resilience Into US prescription drug supply chains." *Health Affairs Forefront.* (2023): https://ramaonhealthcare.com/building-resilience-into-us-prescription-drug-supply-chains/

339 U.S. Food and Drug Administration, "FDA Publishes List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive," Press Release, October 30, 2020. https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive.

the critical drugs list was completed in 2022 and was followed by a report that included a prioritized list of 86 medicines that the government can target, as well as strategies and implementation actions, to increase supply chain resilience.[340] This list has been used by HHS to inform strategies to ensure domestic supply and production of essential medicines, as well as to promote practices that enhance pharmaceutical supply chain resilience (see subsection *Incentivizing Pharmaceutical Supply Chain Resilience* within this Review for additional details). For example, HHS is working with interagency partners, through industrial-based assessment and inquiries, to identify APIs that are at risk and critical to drug manufacturing.[341] HHS is also investing in technology and infrastructure development to improve domestic capacity to produce APIs for a variety of essential medicines (see the corresponding *Four-year Review of Supply Chains for the Public Health and Biological Preparedness Industrial Base* for further information).

- **Increasing Transparency of Quality Management Maturity:** FDA continues to develop a program to promote Quality Management Maturity (QMM) at drug manufacturing establishments. The QMM program would encourage manufacturers of CDER-regulated drugs to implement quality management practices that go beyond current good manufacturing practice (cGMP) requirements. The adoption of advanced quality management practices supports more reliable drug supply chains. In 2023, FDA published a white paper[342] that discussed practice areas in the prototype assessment protocol, a manuscript that discussed lessons learned from the QMM pilots.[343] FDA also gathered public input on the QMM program.[344] FDA is currently conducting a QMM Prototype Assessment Protocol Evaluation Program with nine manufacturers. Assessments will be completed by the end of CY 2024 and learnings will be used to refine the protocol, rubric, and scoring algorithm.

Increase the economic sustainability of U.S. and allied drug manufacturing and distribution

- **Advancing Manufacturing Capabilities:** HHS has invested in the development of advanced manufacturing capabilities to lower the cost of domestic manufacturing of critical supplies and reduce foreign dependency, as well as promote global competitiveness. FDA has recently published a draft strategic plan outlining several examples of how it plans to facilitate the use of innovative manufacturing technologies.[345] FDA's CDER Emerging Technology Program (ETP) has facilitated the approval of 22 applications that use advanced manufacturing (some including continuous manufacturing). In addition, FDA's 18,000

340 Administration for Strategic Preparedness & Response, "Essential medicines report now available," Press Release, May, 2022. https://aspr.hhs.gov/newsroom/Pages/Essential-Medicines-May22.aspx
341 U.S. Department of Health and Human Services, "ASPR Partners with Commerce Department to Ensure Availability and Security of Active Pharmaceutical Ingredient Supply Chain," Press Release, July, 2024. https://aspr.hhs.gov/newsroom/Pages/Active-Rx-Ingredient-Supply-Chain-July2024.aspx.
342 See "CDER. *Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development*. (2023). https://www.fda.gov/media/171705/download
343 Maguire, J., Fisher, A., Harouaka, D., Rakala, N., Lundi, C., Yambot, M., Viehmann, A., Stiber, N., Gonzalez, K., Canida, L., Buhse, L., & Kopcha, M. "Lessons from CDER's Quality Management Maturity Pilot Programs." *AAPS J*, 25 no. 1. (2023):14, https://doi.org/10.1208/s12248-022-00777-z.
344 U.S. Food and Drug Administration, "Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments." Federal Register Vol 88. (September 13, 2023). https://www.federalregister.gov/documents/2023/09/15/2023-20015/quality-management-maturity-program-for-drug-manufacturing-establishments-establishment-of-a-public.
345 "Completed PDUFA VII Deliverable," U.S. Food and Drug Administration, updated on November 22, 2024. https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vii-deliverables.

square foot advanced pharmaceutical manufacturing research facility in Ammendale, Maryland, opened in 2024.[346] This facility will improve CDER's capability to conduct mission-relevant testing, research, and training for FDA staff in emerging technologies.

- **Expanding Domestic Manufacturing of Key Starting Materials and APIs for Essential Medicines:** To build a domestic advanced pharmaceutical manufacturing ecosystem, investments made by ASPR through the IBMSC have been directed at developing and deploying agile drug substance and drug product manufacturing technologies as well as establishing new partnerships to improve the responsiveness and resilience of the domestic pharmaceutical supply chains. These investments to address KSM, API, and finished drug product supply chain vulnerabilities include domestic agile, continuous, and distributed production of APIs and finished dose form drugs whose use are more prevalent in the care of acute care patients presenting with respiratory illness. IBMSC investments also included the demonstration of population scale production for essential medicines in shortage. Domestic expansions from these investments are listed in Appendix A, and include (among others):
    - Opening a cGMP compliant manufacturing facility in 2022;
    - Successful demonstration of pharmacy on demand capability for finished drugs at a health system in Mississippi in 2023; and
    - Successful completion of procurement processes that will increase production capacity for essential medicines including six APIs (acetaminophen, hydrocortisone, tretinoin, morphine, hydromorphone, and atropine), sterile saline, and paralytics.
- **Incentivizing Domestic Production:** CMS has recently developed policies that support domestically produced critical health care products by providing payment adjustments to hospitals that purchase, when available, domestically produced medical products.[347] These policies have been adapted within the pharmaceutical sector from "Buy American" iron, steel, manufactured products and construction materials requirements for Federal agencies to procure domestic materials and products to bolster America's industrial base, protect national security, and support high-paying jobs.[348] In addition, in August 2024 CMS issued a final rule that provides separate payment under the Inpatient Prospective Payment System (IPPS) for small, independent hospitals to establish and maintain a buffer stock of essential medicines to foster a more reliable, resilient supply of essential medicines. CMS also noted in the CY2024 Outpatient Prospective Payment System (OPPS) final rule that as part of the agency's initial efforts, CMS intends to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply (88 FR 82130).[349] The HHS White Paper published in April 2024

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[346] U.S. Food and Drug Administration. *Advanced Manufacturing Research Facility (AMRF). CDER's Cutting-Edge Lab for Evaluating Innovative Drug Manufacturing Technologies*. (2024). https://www.fda.gov/drugs/science-and-research-drugs/advanced-manufacturing-research-facility-amrf.

[347] Centers for Medicare & Medicaid, "New Domestic N95 Respirator Payment Adjustments. Medicare Learning Network (MLN) Fact Sheet (MLB8990453)" news release, May, 2024. https://www.cms.gov/files/document/mln8990453-new-domestic-n95-respirator-payment-adjustments.pdf.

[348] [Off.] of Management and Budget, Exec. [Off.] of the President. Memorandum for the Heads of Executive Departments and Agencies. (October 25, 2023) https://www.whitehouse.gov/wp-content/uploads/2023/10/M-24-02-Buy-America-Implementation-Guidance-Update.pdf.

[349] Centers for Medicare & Medicaid Services, "Fact Sheet: FY 2025 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule –- CMS-1808-F," Press

discusses factors underlying shortages and HHS's actions to address them, as well as policy concepts for consideration. This includes collaboration with the private sector to develop and implement a Manufacturer Resiliency Assessment Program (MRAP) and a Hospital Resilient Supply Program (HRSP). As described, the combination of these programs would bring transparency into the market, link purchasing and payment decisions to supply chain resilience practices, and incentivize investments in supply chain resilience and diversification in the supply chains—including domestic manufacturing—at a scale that would drive impactful change in the market.

Challenges and Opportunities

In 2021, HHS emphasized the importance of having the appropriate tools to maintain oversight and awareness of the pharmaceutical supply chains to be able to proactively prevent and mitigate potential shortages or supply chain disruptions, consistent with statutory authorities, as well as to be able to influence key factors—quality, diversity, and redundancy—that are fundamental to building robust and resilient pharmaceutical supply chains.

Opportunities and challenges with enhancing visibility into the pharmaceutical and API supply chains

The CARES Act granted FDA authority to require manufacturers of drugs and APIs to develop, maintain, and implement, as appropriate, a redundancy risk management plan (RMP) that identifies and evaluates risks to the supply of the drug for each establishment in which the drug or its API are manufactured. FDA issued draft guidance in May 2022.[350] Effective implementation of RMPs present an opportunity to monitor the pharmaceutical and API supply chains as they can facilitate more informed decisions, and supply chain risk management.

Although the majority of drug shortages have historically been linked to quality and CGMP requirements issues, more than half of 2023 shortages were due, in part, to increases in demand. Currently, manufacturers are not required to notify FDA about shortages related to increases in demand, and this hampers FDA efforts to prevent or mitigate them, as demonstrated by COVID-19 pandemic-era shortages in albuterol and pediatric amoxicillin. In addition, some medicines are controlled substances and require collaboration with other U.S. Government partners to help mitigate demand-related shortages by ensuring appropriate production limits (also known as quotas) are set by the Drug Enforcement Administration (DEA).[351] Similarly, discussed in the 2021 report, FDA's ability to appropriately monitor, and assess the impact of, quality issues remains limited.[352]

Release, 2024. https://www.cms.gov/newsroom/fact-sheets/fy-2025-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective-0.

[350] U.S. Food and Drug Administration, "Draft Guidance Document. Risk Management Plans to Mitigate the Potential for Drug Shortages." Federal Register Vol 87. (May, 2022). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-management-plans-mitigate-potential-drug-shortages.

[351] U.S. Food and Drug Administration & Drug Enforcement Administration, *joint letter to Healthcare Providers.* (2023, August 1). https://www.dea.gov/sites/default/files/2023-08/DEA%20and%20FDA%20Issue%20Joint%20Letter%20to%20the%20Public.pdf.

[352] Exec. [Off.] of the President. *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth. 100-day reviews under Executive Order 14017.* (June, 2021). https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

For example, APIs and finished drug products do not always include the identity of the original manufacturer in their labeling.[353] In addition, the report discussed challenges in monitoring certain foreign manufacturers. FDA is working to address this gap through rulemaking to implement Section 2511 of the FY2023 Food and Drug Omnibus Reform Act, which clarified FDA's authority to request this information.[354,355] There is also limited visibility into KSM supply chains, complicating efforts to identify sourcing vulnerabilities.

Opportunities and challenges in increasing the economic sustainability of U.S. pharmaceutical manufacturing through advanced manufacturing capabilities

There is an opportunity to use end-to-end continuous manufacturing for both API and drug product manufacturing. Continuous manufacturing offers the potential to reduce drug shortages and increase or maintain drug quality, while keeping the industrial base globally competitive in this market. There are also a variety of novel analytical and drug production technologies that may be utilized in this area, including portable and modular manufacturing platforms (e.g., pharmaceuticals on demand), and using 3D-printing technologies for solid dosage forms. Despite the promise of advanced manufacturing technologies (AMTs), there has been slow uptake, especially among generic drugs. Barriers in uptake include: the cost of AMTs outweigh the return on investment for generic manufacturers; lack of private incentives; regulatory barriers; and misalignment of certain AMTs with the fast turnover, large portfolio nature of generic drug manufacturing.[356]

The scale-up of novel technologies will help the domestic pharmaceutical industry address the critical need to onshore the production of APIs and FDFs. Once established, it will be critical to sustain this new domestic pharmaceutical ecosystem. HHS will work to catalyze domestic pharmaceutical development by enabling factors to enhance competitiveness. These efforts will be outlined in the *Priorities Ahead* section of this Review. Gains in automation and efficiency improvements will not reduce the need for skilled labor, but instead will create employment opportunities throughout the supply chains. Gains and improvements will also enhance workers' safety by reducing exposure to hazardous environments and ensuring an enterprise that is safe, highly productive, and sustainable. Although these activities will expand the ability to produce critical medicines domestically and increase competitiveness, supply chain vulnerabilities beyond the manufacturing level will persist.

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353 This legislative proposal is included in the FY2024 FDA budget request, See U.S. Food and Drug Administration. *FY 2024 FDA Budget Summary.* https://www.fda.gov/media/166050/download.

354 This section expands an existing registration requirement for foreign establishments that manufacture, prepare, or otherwise process drugs or medical devices that are imported into the United States. Under this section, such a foreign establishment must register with the FDA even if the drug or medical device in question undergoes further processing at another foreign establishment before importation into the United States.

355 H.R.2617 - 117th Congress (2021-2022): Consolidated Appropriations Act, 2023, H.R.2617, 117th Cong. (2022), https://www.congress.gov/bill/117th-congress/house-bill/2617.

356 Wosińska, M., Conti, R., & Reynolds, E. *Technology Solutions for Improving the Resilience of Generic Prescription Drug Manufacturing.* (2024). https://www.brookings.edu/articles/workshop-summary-technology-solutions-for-improving-the-resilience-of-generic-prescription-drug-manufacturing/.

Engagement with Industry

ASPR's Biomedical Advanced Research and Development Authority (BARDA) Biopharmaceutical Manufacturing Preparedness (BioMaP) Consortium Industry Day was held on January 20, 2022. BioMAP now includes partners across the drug and vaccine manufacturing supply chains, including manufacturers of raw materials, consumables, and suppliers of fill-finish services, to transform and build core capabilities for biodefense. The initial effort focuses on medical countermeasure (MCM) manufacturing and the role that public–private partnerships can play in strengthening the nation's biomanufacturing infrastructure. It will support ongoing efforts to expand the industrial supply chains for MCM production, manufacturing, and implementation. The consortium's goal is to establish the physical infrastructure, manufacturing platforms, and supply chains capable of producing enough vaccines for the entire U.S. population within 130 days and the global population within 200 days after recognition of a potential emerging pandemic threat. It expands the ability to domestically produce the therapeutics and vital supplies to halt future pandemics.

Engagement with Allies and Partners

Concerns continue surrounding the global supply chains and the United States' reliance on overseas manufacturing. To foster international cooperation to combat drug shortages, in CY 2023, there were four quarterly meetings held with the FDA's foreign counterparts.[357] FDA continues to work closely with its colleagues in foreign regulatory authorities and directly with manufacturers to understand what the future impact on supply disruptions might be. While FDA is not currently aware of shortages caused by restrictions on exports, FDA continues to monitor for any impact on supplies related to exports of pharmaceuticals, raw materials, and components. Should the situation change, FDA would continue to rely on established relationships with its foreign counterparts to inform the shortage surveillance programs to inform the public and to mitigate the impact of supply constraints.

FDA has also developed strategic partnerships with global stakeholders, including the World Health Organization (WHO), to ensure access to safe drug products. FDA is highly involved in the technical, policy, and strategic implementation of WHO's Member State Mechanism on Substandard and Falsified Medical Products (the Mechanism). The Mechanism addresses substandard and falsified medical products to protect public health and promote access to affordable, safe, efficacious, and quality medical products. FDA serves as a vice-chair for the Americas region on its Steering Committee and sits on many of the Mechanism's working groups. Currently, FDA is leading a prioritized activity on strengthening the supply chains of excipients at high risk of contamination. In addition, the State Department, the Executive Office of the President (EOP) Office of Pandemic Preparedness and Response Policy (OPPR) and Domestic Policy Council (DPC), and HHS worked with partners from Japan, India, the Republic of Korea and the European Medicines Agency[358] to launch a Track 1.5 Biopharmaceutical Supply Chain (BIO-5) consortium, aimed at fostering onshoring and friendshoring of critical APIs.

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[357] U.S. Food and Drug Administration. *Report to Congress Drug Shortages CY 2023, (Required by Section 506C–1 of the Federal Food, Drug, and Cosmetic Act).* (2023). https://www.fda.gov/media/179156/download.

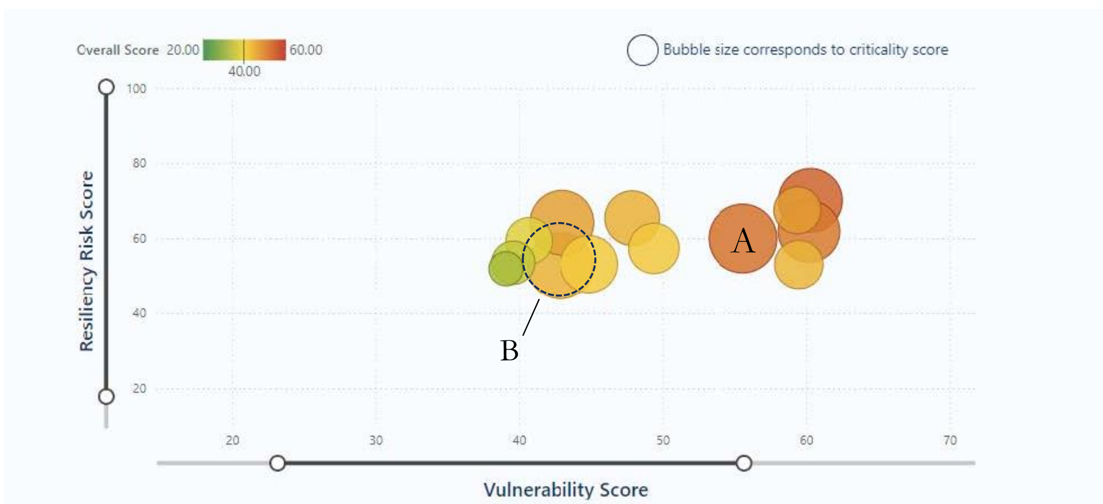
[358] White House. "FACT SHEET: Biden-Harris Administration's Actions to Advance American Biotechnology and Biomanufacturing." June 25, 2024 https://www.whitehouse.gov/ostp/news-updates/2024/06/25/fact-sheet-biden-harris-administrations-actions-to-advance-american-biotechnology-and-biomanufacturing.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

In 2021, HHS concluded that the pharmaceutical supply chains have difficulty responding to disruptions and that these vulnerabilities led to widespread shortages of drugs critical for treating patients in acute and intensive care settings. Based on current data and this assessment, the pharmaceutical and API supply chains remain susceptible to supply chain disruptions. Specifically, using the Department of Commerce's 2024 SCALE supply chain risk tool,[359,360] which assesses a wide range of supply chains and identify more than 40 types of supply chain risks across sector-specific industries as categorized by the North American Industry Classification System (NAICS), five out of 13 possible health-related industries were identified as high risk, with "Pharmaceutical Preparation Manufacturing" and "Biological Product (except Diagnostic) Manufacturing" being among the highest ranked in terms of criticality and vulnerability (Figure 5).[361,362,363] Further, SCALE data suggest that the Pharmaceuticals and Biological Products industries are considered critical based on the number of essential medicine products in these industries.

Figure 5. Scatter plot of select health-related industries by vulnerability, resiliency risk, and criticality



359 Some assessment criteria are supplemented by Department of Commerce's 2024 SCALE supply chain risk tool estimates risk factors of sector-specific industries as categorized by NAICS. Scores are derived from dozens of inputs and data sets that feed into three factors: vulnerability, the potential for product supply chains to experience risks; resiliency risk, an estimate of how much time a product supply chain will need to return to normal when facing disruption; and criticality, how important an industry supply chain is to the national economy, national security, and public health and safety of the American people. High scores (0-100) translate to a higher magnitude (i.e., more vulnerable, higher risk to resilience, and very critical to the U.S. population's well-being).

360 DOC SCALE supply chain risk tool 2024

361 NAICS Code: 325412 Pharmaceutical Preparation Manufacturing | NAICS Association

362 NAICS Code Description - 325414 - Biological Product (except Diagnostic) Manufacturing

363 Medical products in the Pharmaceutical and Biological Product Industries are likely to include, allergen and antitoxin manufacturing, bacterial and viral vaccine manufacturing, blood and plasma products, and preparation manufacturing for a great number of medicines, some including anesthetics, antidepressants, cardiac, contraceptive, cold remedies, diuretic, dietary, central nervous system stimulants, insulin, and vitamins.

Figure 5 Notes (previous page):
A: NAICS 325412 - Pharmaceutical Preparation Manufacturing
B: NAICS 325414 - Biological Product (except Diagnostic) Manufacturing
Scores are between 0 and 100 where higher values translate to a higher magnitude of importance to the national economy.
Source: Department of Commerce SCALE supply chain risk tool 2024

Transparency

No single HHS component (or other federal agency) has full end-to-end insight into the supply chains of all drug products, and there are limitations on how certain proprietary data to which HHS has access can be shared or used. Depending on their roles, different HHS Operating Divisions and Staff Divisions have access to a range of data that could potentially enhance insights into the pharmaceutical and API supply chains. These data include manufacturing site information, manufacturing volume, inspection and compliance information, safety and efficacy, and manufacturer notifications submitted to FDA as required by various laws and implementing regulations. FDA also receives information from manufacturers, wholesalers, or suppliers or other stakeholders. Although much of the data is proprietary (e.g., confidential commercial or trade secret information) that may not be shared publicly, FDA makes various data publicly available, which are based on shortage notifications, inspections, and registration information, among others.[364,365,366,367] HHS is able to monitor and respond to supply chain disruptions and drug shortages by means of notifications to FDA from manufacturers, hospitals, patients, and IQVIA data. SCANS does not currently include CARES Act volume information reporting data; however, with the recent finalization of the guidance on amount reporting, CDER expects to be able to incorporate CARES Act amount information reporting into SCANS in the future.

In its response role, ASPR has access to distributor data on certain MCMs (see the corresponding *Four-year Review of Supply Chains for the Public Health and Biological Preparedness Industrial Base* for additional information), and CMS, in its regulatory and public payer roles, has access to certain hospital and patient drug utilization data. HHS has worked with other Federal agencies to identify manufacturing challenges with KSMs, APIs, and FDF drugs that the United States does not produce at scale domestically, and to map out geographic origins and reliance on KSMs. However, there is still limited overall visibility into the supply chains of KSMs compared to FDF and APIs. HHS sponsors and engages in multiple platforms to provide channels for public and private engagement to enhance visibility. These platforms facilitate data sharing and increased visibility into supply chain vulnerabilities and resilience.[368,369,370]

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364 "Data Dictionary," U.S. Food and Drug Administration, accessed December 1, 2024. https://open.fda.gov/data/datadictionary.

365 "FDA Drug Shortages: Current and resolved drug shortages and discontinuations reported to FDA," U.S. Food and Drug Administration, accessed December 8, 2024 https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

366 "FDA Data Dashboard," U.S. Food and Drug Administration. https://datadashboard.fda.gov/ora/index.htm

367 "Drug Establishments Current Registration Site," U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site.

368 H.R.3204 - 113th Congress (2013-2014): Drug Quality and Security Act. (2013, November 27). https://www.congress.gov/bill/113th-congress/house-bill/3204.

369 "Partnership for DSCSA Governance," PDG. https://dscsagovernance.org/.

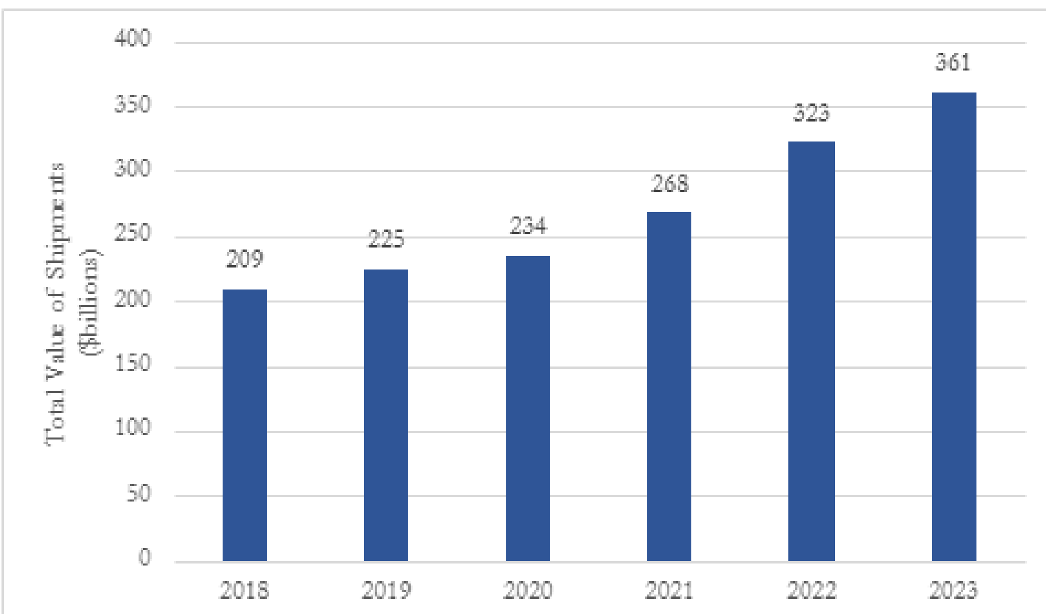
370 Cybersecurity & Infrastructure Security Agency. *Healthcare and Public Health Sector Working Groups.* (2024). https://www.cisa.gov/resources-tools/groups/healthcare-and-public-health-sector-working-groups.

Major gaps in HHS's access to relevant data include inventory management at the manufacturer level and explicit information on manufacturer physical, cyber, and environmental security which feed information on manufacturer-level supply and demand. In addition, FDA generally does not receive notice or adequate information from drug manufacturers regarding increases in demand, or data that identifies the suppliers and the extent of the reliance, which would better enhance FDA's visibility into the pharmaceutical supply chain.[371,372] Insight into the supply chain is needed not just at the federal level, but for the many stakeholders and organizations, including Federal, state, local, tribal, and territorial (SLTT) authorities, that are part of the pharmaceutical and API supply chains.

Domestic Capacity

FDA has data for API and FDF facilities but does not have comprehensive data about the production of all chemicals used in the synthesis of drugs. FDA has limited data on regulatory starting materials, which are upstream from API; generally, many of these are produced outside of the U.S., with a majority being produced in China. The total value of goods shipped by domestic pharmaceutical and API manufacturers was valued at $361 billion in 2023, an increase from $209 billion in 2018, and represented about 5 percent of the $6.9 trillion of the total value of goods shipped by all manufacturing industries in the United States (Figure 6).[373,374]

Figure 6: Total value of shipments of drugs and biological products (in 2018 dollars)



[371] "FY25 Legislative proposals," U.S. Food and Drug Administration. https://www.fda.gov/media/176924/download.
[372] Exec. [Off.] of the President. "National Strategy for a Resilient Public Health Supply Chain." https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.
[373] U.S. Census Bureau, Manufacturers' Value of Shipments: Pharmaceutical and Medicine Manufacturing [A25BVS], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/A25BVS.
[374] U.S. Bureau of Labor Statistics, Consumer Price Index for All Urban Consumers (CPI-U). https://www.bls.gov/cpi.

Trade Concentration

The 100-day Review indicated that dependence on foreign nations such as India and China is a key vulnerability for the U.S. pharmaceutical and API supply chains. Foreign anticompetitive practices—such as state subsidies to businesses and labor, price fixing, or state-ownership of raw materials—can provide further economic advantages to foreign locations over the U.S.
During the COVID-19 pandemic, China interrupted exports of critical medical supplies, such as antibiotics and APIs, to the United States, which contributed to production shortages.[375] India and China were among the top suppliers—ranking 4th and 13th respectively—of pharmaceutical and API products into the United States in 2021.

By contrast, the share of exports was roughly 18 percent throughout the 2018–2020 period, increasing to around 24 percent from 2021 to 2023. China ranked as the second largest nation of U.S. exports in 2021, with India ranked 21st ($0.64 billion). In addition, 90 to 95 percent of generic sterile injectables used for critical acute care in the U.S. rely on KSMs and drug substances from China and India.[376] While India and China compete for market share of these essential medicines, other data indicate that India imports over 80 percent of its API from China.[377] The data suggests that some progress has been made at reducing reliance on foreign manufacturing of pharmaceutical and API products at the sector level.[378,379] However, reliance on geographically concentrated production such as that from China and India continues to pose risks to the resilience of the pharmaceutical and API supply chains.

Supplier Diversity

Strategies to create a robust and resilient pharmaceutical supply chain include diversification of supply, both in domestic manufacturing and diversity in foreign resourcing. Lack of geographic diversity among suppliers, and consolidation in overall production of APIs and FDFs outside the United States, can leave domestic supply chains vulnerable to external events.[380] In addition, a limited number of manufacturers per drug also leads to risks.[381] The median number of drug manufacturers per a unique drug/dosage form is between two and three, indicating highly concentrated markets. Furthermore, the share of drug-product markets in both oral and non-orally

[375] Congressional Research Service. *COVID-19: China Medical Supply Chains and Broader Trade Issues.* (April, 2020). https://crsreports.congress.gov/product/pdf/R/R46304/1.
[376] U.S. Senate Committee on Homeland Security & Government Affairs. *Short Supply. The Health and National Security Risks of Drug Shortage.* (March 2023). https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.
[377] "India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global market," BioSpectrum, updated September 1, 2024. https://www.biospectrumindia.com/interviews/17/25075/india-is-well-positioned-to-reduce-its-dependence-on-imported-apis-and-potentially-challenge-chinas-dominance-in-the-global-market.html#:~:text=Despite%20various%20government%20initiatives%2C%20India,related%20to%20cost%20and%20scale
[378] "USA Trade Online," U.S. Department of Commerce. https://usatrade.census.gov/index.php
[379] "Annual Survey of Manufacturers," U.S. Department of Commerce. https://www.census.gov/econ/overview/ma0300.html
[380] Exec. [Off.] of the President. *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth. 100-day reviews under Executive Order 14017.* (June, 2021). https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
[381] Conti., R.M., & Berndt, E. *Four Facts Concerning Competition in U.S. Generic Prescription Drug Markets, The National Bureau of Economic Research.* Working Paper No. 26194 (NBER, 2019). https://www.nber.org/papers/w26194.

formulated categories supplied by two or fewer manufacturers grew from 2005 to 2015 but is more pronounced among non-orally formulated drugs.[382] Sterile injectables have been associated with a higher risk of shortage compared to branded or oral formulations.[383] Separate analysis shows that 44 percent of essential medicines that are injectables are solely reliant on foreign manufacturing facilities for API, and that essential medicines in other dosage form categories have even greater reliance on foreign API manufacturing.[384] Further, competition for economies of scale and the lowest available cost have contributed to offshoring production of many raw materials and finished products consolidated in specific countries, reducing diversity across the supply chains and driving competition against U.S.-based production.

CASE STUDY: U.S. MARKET SHARE TRENDS OF INJECTABLE AND ORAL DRUG MANUFACTURERS.

An analysis of 2019–2023 national sales data from IQVIA for analgesics, nutrients and supplements, anti-infectives, antineoplastic agents, and all other therapeutic classes indicate that, across most of the classes, the top five manufacturers of injectable drugs hold roughly 60 percent of the market combined.[*] In some cases, a single manufacturer can hold more than 40 percent of the total market share (e.g., analgesics and anti-infectives) Although there is greater supplier diversity among oral generic drugs, market concentration is still a concern for branded oral generics. The data indicate there has been a decrease in market concentration for injectable antineoplastic agents and generic injectable analgesics from 2019 to 2023, but the other markets have experienced little to no change, and in some cases market concentration has increased (e.g., generic injectable anti-infectives and nutrients and supplements).

**ASPE Analysis on Injectable Supplier Diversity in the Pharmaceutical Market, 2019–2023, using IQVIA National Sales Perspective data. Accessed October 25, 2024.*

Agility

Resilient pharmaceutical and API supply chains involve fostering processes necessary to adapt, recover, and persist from disruptions. This means being agile, or being able to build flexibility and have the supplies needed to respond rapidly when a supply chain disruption occurs. Industry emphasis on cost-cutting has led to a large-scale acceptance of just-in-time inventory management (often containing no more than 30-day supply under normal conditions), which leads to limited stock on hand or excess manufacturing capacity to help withstand disruptions or allow for rapid distribution and use. Despite these challenges, HHS has moved critical pharmaceuticals during an emergency response. See the corresponding *Four-year Review of Supply Chains for the Public Health and Biological Preparedness Industrial Base* for examples.

[382] Berndt, E., Conti, R.M., & Murphy, S.J. *The Landscape of U.S. Prescription Drug Markets.* Working Paper No. w23640 (NBER, 2017). https://www.nber.org/system/files/working_papers/w23640/w23640.pdf

[383] Exec. [Off.] of the President. *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth. 100-day reviews under Executive Order 14017.* (June, 2021). https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

[384] U.S. Food and Drug Administration . *Report on the State of Pharmaceutical Quality.* (July, 2023).

For some U.S. companies, complex and expensive startup costs, including those associated with infrastructure and lengthy regulatory and approval processes, are challenges to building or expanding manufacturing capabilities. Some manufacturers face reduced incentives to upgrade equipment, improve supply chains, or expand capacity, which contributes to dependency on a limited group of suppliers.[385] Likewise, domestic environmental and regulatory authorities can pose significant barriers to entry and further complicate expanding the industrial base.

HHS lacks access to data, such as how quickly manufacturers produce or deliver orders, experience changes in demand, and inventories from hospitals and distributors, that could provide further insights into the agility of the pharmaceutical and API supply chains. While some private companies are willing to share their insights, others are reluctant to do so, such as wholesale distributors who collect data on drug demand. For these reasons, among others, FDA has included a legislative proposal in the FY2025 budget request to require drug manufacturers to notify FDA of an increase in demand that the manufacturer will likely be unable to meet for certain drugs.

Security

The resilience and vulnerability of the pharmaceutical and API supply chains are also affected by exposure to physical disasters (human made and natural), and cyber and data security threats, which affect access and availability of supplies.[386] SCALE data scored the Biological Products industry moderately (39) against cyber security risk, while the corresponding risk was high (60.4) for the Pharmaceuticals industry. Physical hazards may adversely affect manufacturing processes and availability by compromising storage conditions (e.g., heat stress, deteriorating infrastructure, and reducing water quality). HHS conducted an analysis of FEMA's National Risk Index (NRI) data linked to manufacturer location data to illustrate how risk from multiple natural hazards are associated with the location of drug manufacturers.[387] More than a quarter of drug manufacturers are in areas categorized as very high or relatively high risk using the NRI's Composite Risk score. Other HHS analysis shows this estimate is higher (34 percent) when looking at the subset of drugs that are considered essential.[388] When examining specific hazard types, 58 percent of drug manufactures are in areas at very high or relatively high risk in two or more hazards such as tornadoes, hurricanes, earthquakes, and other extreme weather events. The analysis also showed that many facilities are located in areas of high natural hazard risk, particularly on the West Coast, throughout the Midwest, and in the South. These risks make manufacturing pharmaceutical facilities, equipment, and their products vulnerable to damage. SCALE data partially replicated these findings by scoring Pharmaceuticals high (71.4) for International Risk from Climate Change, whereas Biological Manufacturing scored low (29.7).

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385 Exec. [Off.] of the President. *Building resilient supply chains, revitalizing American manufacturing, and fostering broad-based growth. 100-day reviews under Executive Order 14017.* (June, 2021). https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
386 Pharmaceutical supply chains include manufacturing of APIs.
387 Kolbe, A. & Beleche, T. *Linking Medical Product Manufacturing Locations with Natural Hazard Risk: Implications for the Medical Product Supply Chain.* (2024). https://aspe.hhs.gov/sites/default/files/documents/2cf7713763c222cbb8caaf5015126735/aspe-data-point-natural-hazards-manufacturing.pdf.
388 U.S. Food and Drug Administration. *Report on the State of Pharmaceutical Quality.* (2023). https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/report-state-pharmaceutical-quality.

Geopolitical, natural disaster, and man-made disruptions may also cause shocks at the import and delivery segments of the Pharmaceutical and Biological Product Industry supply chains. SCALE data scored Pharmaceutical and Biological Product Industries high against Domestic Port of Entry Vulnerability (75, 71.1), risk associated with Transportation Mode (83.5, 84.8), and Elasticity (90.4, 89.6). Based on these data and other available information, we assess that the U.S. is extremely vulnerable to disruptions of international imports.

CASE STUDY: TRADE CONCENTRATION RISKS STRESSED THE PHARMACEUTICAL AND API SUPPLY CHAINS DUE TO TEMPORARY WORK STOPPAGE

On October 1, 2024, domestic ports from Maine to Texas experienced a work stoppage by dock workers as more than 50,000 members the International Longshoreman's Association protested the failure for the union and United States Maritime Alliance, or USMX, to make contracting agreements. The work stoppage has temporarily ended, with the union and USMX extending previous contracts to January 15, 2025. The disruption lasted for two full business days, but the U.S. Government and private industry were preparing for large-scale potential impact across industries. HHS worked closely with federal partners to monitor and address potential impacts. Pharmaceutical APIs that could potentially be used for the domestic manufacturing of anti-inflammatory drugs, corticosteroids, insulin, oxytocin, antibiotics, antimalarials, asthma treatments, hypotension treatments, stimulants used to treat ADHD and narcolepsy, and drugs for oncology research and development were all identified by SCALE as having high concentration of imports to a single, U.S. eastern port. Had the work stoppage persisted, disruptions would have been exacerbated by the effects of Hurricane Helene and Hurricane Milton. Further diversification of not only manufacturing facility locations, but also logistics networks and distribution systems would improve supply chain agility and reduce the vulnerability of these specific APIs and other manufacturing ingredients and supplies.

Economic Health and Compliance

Understanding the economic health and manufacturing compliance of pharmaceutical and API supply chains includes monitoring the stability of operations and the predictability of supply and demand, and identifying key actors or factors that affect them. Over the past decade, many generic pharmaceutical companies operating in the United States have closed operations or are operating with significant idle capacity.[389] Further, as profit margins erode, lower cost production options are explored, which can result in production and supply issues that create vulnerability to shortages and susceptibility to low re-investment.[390] A company's financial instability can also translate to reduction in the ability for manufacturers to address expensive compliance issues, update equipment or infrastructure, or fill requisite positions, all which of which may increase the risk of recalls, noncompliance actions, and other events that can lead to supply chain disruptions or shortages.

[389] Sardella. *U.S. Generic Pharmaceutical Manufacturer Available Capacity Research Survey*. Washington University Olin School of Business. Center for Analytics and Business Insights. (2022).

[390] Sardella. *US Generic Pharmaceutical Industry Economic Instability. Understanding Drivers of Economic Uncertainty in the US Generic Pharmaceutical Industry and Its Implications on Supply Instability.* (2023). https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf.

HOW A COMPANY'S ECONOMIC HEALTH RESULTED IN A SHORTAGE OF ALBUTEROL

In February 2023, Akorn Pharmaceuticals, one of two domestic manufacturers of liquid albuterol, abruptly shut down its three plants after its second bankruptcy proceedings in three years. The other domestic firm, Nephron, that could increase liquid albuterol supply of the same dose (0.5 percent) to the U.S. market also experienced manufacturing issues that limited its supply. This event came at a time when liquid albuterol was already in short supply and on FDA's shortages list. FDA determined that Akorn's bankruptcy would likely exacerbate the shortage, as it was the major manufacturer for a specific dose and vial size. FDA worked with manufacturers in the supply chain to understand and mitigate related impacts, and with outsourcing facilities to compound the specific product to increase supply. FDA also explored other available regulatory levers to increase supply, including the use of regulatory discretion and temporary importation.

Recent data shows there has been an increase in the total volume of reports submitted to FDA by application holders, consumers, patients, and health care professionals, some of which were for quality-related issues. These can signal vulnerability in the economic health of manufacturers. Overall, the total volume in post-market quality defect PQD reports increased by five percent to 17,086 in FY2023, with quality-related customer complaints and Biological Product Deviation Reports seeing the greatest growth in volume. Additionally, except for FY2023, the number of drug products recalled has increased since FY2018, with more than half of the recalls being attributable to CGMP deviations (Appendix Figure 4).[391] The number of warning letters and those issued for reasons related to drug quality have also increased (Appendix Figure 5). Import alerts help stop certain products from entering the United States. During FY2023, FDA added 93 companies to import alerts for reasons related to drug quality. Most of these import alert additions were associated with sites in China (33 percent), South Korea (18 percent), and India (16 percent).

[391] "Recalls," U.S. Food and Drug Administration. https://datadashboard.fda.gov/ora/cd/recalls.htm.

PRIORITIES AHEAD

Four-year Outlook

As noted previously, America's pharmaceutical and API supply chains are global, complex, and involve many actors. Greater supply chain insight through strengthened surveillance and data sharing across the U.S. Government could promote early identification of supply chain risks and vulnerabilities. Market structure, resources, and data gaps limit HHS, U.S. Government, and other stakeholders' ability to have end-to-end visibility into the supply chains for pharmaceuticals and APIs sold in the United States. Many recognize the need to prioritize strategies and implementation actions for ensuring the availability of critical pharmaceutical and APIs in the face of constrained resources. These actions include the challenging task of identifying products that could be prioritized for enhanced visibility. Further, continued lack of visibility into quality management maturity of the manufacturing process for pharmaceuticals and APIs means that the market lacks information to reward manufacturers that invest in supply chain resiliency, which will continue to hamper the ability to enhance supply chain resilience.[392]

The complexity of pharmaceutical and API supply chains will continue to introduce many opportunities for shortages and supply chain threats (e.g., extreme whether events or deliberate security attacks), which are difficult or impossible to predict. This diverse set of threats will continue to introduce many challenges for HHS and the U.S. Government, as well as for suppliers, purchasers, and other stakeholders that play a crucial role in facilitating an effective response. Moreover, other supply chains such as energy, fuel, durable goods, and agriculture, are increasingly intersecting with pharmaceutical and API supply chains and warrant careful consideration in understanding their role in building resilience in the pharmaceutical and API supply chains as these sectors evolve. For example, the pharmaceutical industry, which spends more than $1 billion on energy consumption every year and generates 55 percent more emissions than the automotive industry, is increasingly adopting advanced energy management solutions to reduce costs and increase profits. Energy management solutions not only impact manufacturing, but also R&D formulation, packing, and filling practices, all of which can impact supply chain resilience.[393,394]

The resilience of pharmaceutical and API supply chains is highly influenced by several factors, including the degree of dependence on foreign sources, low-cost competition from other countries, and market concentration. However, there is also recognition that the pharmaceutical industry needs to rethink its innovation strategy to deliver results that the market and patients demand, which may require innovating in each aspect of the business model for companies to break the cycle of margin compression and below-market returns.[395] This could translate into increased adoption of practices that expand and diversify the industrial base and enable it to adapt and scale up in times of

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392 FDA Drug Shortages Task Force. *Drug shortages: Root causes and potential solutions.* (2020). https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions (accessed May 8, 2024).

393 "Pharma Companies Cutting Energy Consumption to Gain a Competitive Advantage," Centrica Business Solutions. https://www.centricabusinesssolutions.com/us/blogpost/pharma-companies-cutting-energy-consumption-gain-competitive-advantage.

394 "Energy Efficiency in Biotech and Pharma," Mantis Innovation, updated December 6, 2018, https://blog.mantisinnovation.com/energy-efficiency-in-biotech-and-pharma.

395 "Next in Pharma 2024: Reinventing for Returns. Top C-Suite Agenda Topics that will Help Shape the Year," PWC. https://www.pwc.com/us/en/industries/pharma-life-sciences/pharmaceutical-industry-trends.html.

crisis.[396,397] Further, while advanced manufacturing technologies have the potential to lower cost and improve efficiencies, their adoption is low for many reasons, including financial awareness, and regulatory considerations. These technologies also require substantial up-front investments and a time lag before realizing any returns on investment, which may contribute to low adoption.

Finally, a crucial step to improve supply chain resilience and addressing shortages relies heavily on building on existing partnerships as well as establishing new relationships to ensure all stakeholders can play a role in solving current and future challenges. Enhanced coordination and collaboration can drive improvements across all components of the supply chain but will require sustained commitment, engagement, and leadership from all involved.

Four-year Resilience Goals and Priorities

Overview

This section provides a high-level description of HHS priorities for the next four years, organized within four major goals. Further details on HHS goals and actions will be presented in the forthcoming draft *HHS Action Plan for Addressing Shortages of Medical Products and Strengthening the Resilience of Medical Product Supply Chains (draft HHS Action Plan).*

Strengthen HHS's integrated approach to coordination, communication, and partnerships focused on improving the resilience of medical product supply chains

Fostering greater coordination and communication within HHS and across the U.S. Government will enhance efforts to set and ultimately achieve specific supply chain objectives. A formalized coordinating function also enables continual scanning for any strategic gaps in the approach being deployed to achieve these objectives. Efforts to expand domestic and international coordination are also central to increasing supply chain resilience. These strategies will require a mix of communication and coordination activities to ensure information on supply chain disruptions and shortages are available. Strengthening these partnerships with stakeholders within and beyond the U.S. Government will work to improve domestic and global preparedness, mitigation, response, and recovery activities.

Increase availability and utilization of actionable insights into critical medical product supply chains for HHS

A critical component of increasing supply chain resiliency is recognizing and addressing information gaps in the available data to better inform decision-making for HHS and the private sector. This includes examining current data sources and performing thorough risk assessments to identify potential weaknesses. Improved data availability and utilization across HHS can also promote supply chain resilience by increasing visibility into supply chain risks and vulnerabilities. Additional actions include provisions in the CARES Act requiring firms to report additional information to FDA, which may improve transparency and provide a more complete understanding of key manufacturers

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[396] Exec. [Off.] of the President. "National Strategy for a Resilient Public Health Supply Chain." https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.

[397] National Academies of Sciences, Engineering, and Medicine. *Building resilience into the nation's medical product supply chains.* Washington, DC: The National Academies Press. (2022). https://doi.org/10.17226/26420 (accessed May 8, 2024).

based on market share. This information could improve FDA's awareness of supply chain vulnerabilities that could be long-term risk factors for drug shortages, and domestic infrastructure investment could be prioritized based on the criticality of an essential medicine and supply chain reliability.

Strengthen HHS response to shortages and supply chain disruptions

Shortages and supply chain disruptions can occur unexpectedly, impacting even the most resilient systems. To mitigate these impacts when the occur, HHS can work to develop robust response measures. Specific actions include refining HHS standards and systems to expand HHS's ability to surge and adapt during a response; incentivizing the adoption of novel technologies or approaches that enable quick transition, rapid scaling, or efficient manufacturing practices; expanding emergency or excess capacity to minimize the impacts of shortages or supply chain disruptions; and maintaining and enhancing the resilience, safety, and security of the HHS workforce, facilities, and assets to ensure long-term viability of effective response capabilities for shortages and/or supply chain disruptions.

Incentivize investment in supply chain resilience through increased supply chain diversification, redundancy, and other steps

Market participants throughout the supply chain have lacked appropriate incentives to adopt practices that foster resilience through diversification, redundancy, and investment in newer technology and mature quality systems. Utilizing demand-side incentives to encourage the private sector to compete not just on price but also on strengthening supply chain resilience is critical. The U.S. and allied countries also face challenges in drug manufacturing from foreign competition. While self-sufficiency across all drug products is not necessary, increasing domestic production of certain products and manufacturing technologies is crucial. For example, there is an opportunity to use end-to-end continuous manufacturing to reduce the number of drug shortages and increase or maintain drug quality, while keeping the domestic industrial base competitive. There are also a variety of novel analytical and drug production technologies that may be utilized, including portable and modular manufacturing platforms (e.g., pharmaceuticals on demand), and using 3D-printing technologies for solid dosage forms. These investments, along with increasing the competitiveness of the U.S. workforce through human capital investments, will work to strengthen and improve supply chain resilience.

Legislative and Budgetary Objectives

Many causes of disruptions are unpredictable or occur at nodes in the supply chain where HHS may have limited visibility, resources, or authority. Current budget authority is not sufficient to sustain certain HHS activities, many of which were supported by COVID-19 supplemental funding. In many cases, especially for acute responses, engagement from other HHS and U.S. Government partners, industry, and external stakeholders is critical for an effective response, and some capabilities such as funding to purchase licenses to access proprietary market data or to build and maintain existing data platforms require sustained funding or new authorities to continue. HHS has proposed a number of complementary legislative initiatives to improve the Department's capabilities in achieving the stated priorities. For example, the April 2024 HHS White Paper describes policy concepts that would require Congressional action to develop and implement two programs, a

Manufacturer Resiliency Assessment Program and a Hospital Resilient Supply Program. These programs would provide increased payment to hospitals that take steps to identify and reduce risks in their supply chains such as by contracting with more reliable suppliers, diversifying their supply chains, and holding buffer inventories. Additional details regarding resources and other legislative efforts that would support HHS actions are detailed in the forthcoming draft *HHS Action Plan*. HHS will continue to develop and make recommendations to Congress seeking statutory authorization and funding to increase HHS's ability to collect and share information, as well as to expand its predictive and surveillance capacity to enhance visibility into the supply chains.

Long-term Resilience Goals

The pharmaceutical and API supply chains are complex, global, and vulnerable to disruptions. Building resilient supply chains requires the U.S. Government to undertake a comprehensive, multifaceted approach to induce sustained enhancements that drive resilience throughout the entire supply chain. This will require sustained and active engagement from the private sector, including purchasers, intermediaries, and manufacturers, as well as the public sector, including Congress. Long-term solutions to address the reliability of the pharmaceutical and API supply chains will in turn contribute towards improving patient health and wellbeing by increasing access to essential pharmaceuticals by reducing the impact of shortages and supply chain disruptions.

Conclusion

Frequent supply chain disruptions have highlighted significant vulnerabilities in the U.S. pharmaceutical and API supply chains, and historic efforts were made to mitigate and resolve the resulting disruptions and shortages. The assessment in this Review revealed that while the U.S. Government has taken notable strides to address vulnerabilities and disruptions to these supply chains, more needs to be done to increase the resilience of these supply chains. HHS will continue to invest in technology and infrastructure development to improve insights into these supply chains and increase the domestic capacity to produce pharmaceuticals and APIs used for a variety of essential medicines. HHS remains committed to increasing its capacity to identify risks and vulnerabilities, strengthening the response to shortages and supply chain disruptions, building more resilient public health supply chains by incentivizing investments in resilient practices, and improving communication and coordination within government and with key external partners. Achieving these goals requires significant funding and resources, as well as continued efforts across the U.S. Government, the private-sector, and other stakeholders, and must remain a priority to protect the nation's public health and increase the economic sustainability and competitiveness of the nation as a whole.

APPENDICES

Appendix A. Summary of ASPR's Investments to Expand the Domestic Industrial Base for Pharmaceuticals and APIs

- ASPR utilizes Pharmacy on Demand technology (PoD) to develop a rapid response capability to produce KSMs, APIs, and final dosage form drugs.
    - On Demand Pharmaceuticals opened a CGMP-compliant manufacturing facility in February 2022.
    - ODP is also spearheading the development of automated and deployable PoD machines to promote a more secure supply of essential medicines when needed.[398]
    - Demonstrated PoD capability for final formulated medicines in a modular platform at a health system in Tupelo, MS in September 2023.
- ASPR uses CONTINUUS Pharmaceuticals Inc.'s proprietary integrated continuous manufacturing (ICM) technology to enable rapid, on-demand production of medicines from API to final dosage form without interruption in a fully-automated, small-footprint facility.
- In December of 2022, Office of Naval Research (ONR), in coordination with HHS, issued an Other Transaction for $30 million to develop and validate distributed manufacturing capacities for sterile 0.9N saline on demand. This technology will be developed, validated, and transitioned to the FDA and Walter Reed Hospital for further evaluation. This effort was funded by the American Rescue Plan Act of 2021.
- In June of 2024, ONR, in coordination with ASPR/IBMSC, issued an Other Transaction for $19 million to onshore production of a paralytic that went into shortage during the COVID-19 pandemic and continue to sustain CGMP capacities for agile and continuous drug substance and drug product manufacturing.
- ASPR leverages technologies to produce biologically derived small molecule APIs for essential medicines. In June of 2024, ASPR/IBMSC, in coordination with ASPR/BARDA, awarded two task orders on an Other Transaction Consortium Agreement for the biologically-derived production of six APIs, including acetaminophen, hydrocortisone, tretinoin, morphine, hydromorphone, and atropine. Final production capacities are on track to be established by September 2026.
- ASPR establishes Qualification Processes for Point-of-Need Pharmaceutical Products (EQUIP-A-PHARMA) program, which, seeks to demonstrate a real-time digital regulatory approval framework for multiple finished drug products produced on a single reprogrammable hardware platform. The program is currently supporting five pilot agile pharmaceutical manufacturing sites that will not only establish additional agile manufacturing capacities for drug substances and drug products in the US, but also generate the data required to inform the creation of a future regulatory framework for agile drug manufacturing.
- ASPR leverages HHS's delegated Defense Production Act Title III authorities to make investments in onshoring of KSM and API manufacturing as well expansion of domestic X-

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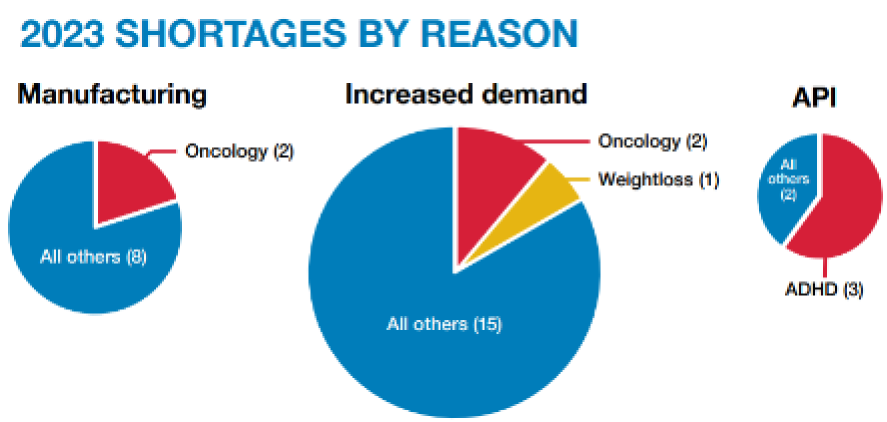
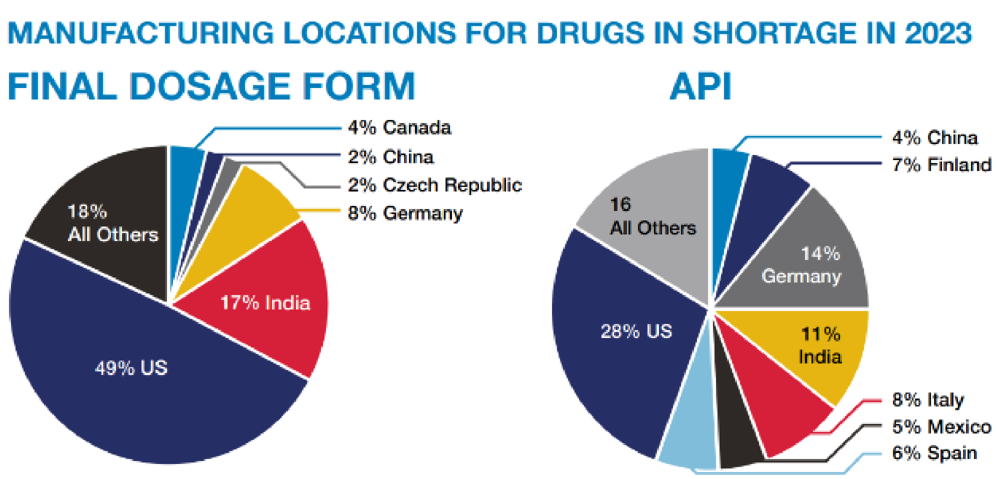
[398] "On Demand Pharmaceuticals Commissions State-of-the-Art, cGMP Medicine Manufacturing Facility," PR Newswire, updated February 15, 2023. https://www.prnewswire.com/news-releases/on-demand-pharmaceuticals-commissions-state-of-the-art-cgmp-medicine-manufacturing-facility-301483128.html#:~:text=(ODP)%2C%20an%20innovative%20technology,chemicals%20to%20final%20drug%20product.

ray sterilization capacity. The first effort is focused on establishing domestic capacities for KSM and API manufacturing, including population-scale manufacturing of albuterol, lorazepam, desmopressin acetate, pinephrine, norepinephrine, phenylephrine, artemisinin (KSM for artesunate) and oripavine (KSM for opioid reversal agents like naloxone). The second effort focuses on establishment of two new X-ray sterilization facilities in addition to expansion of a third existing X-ray sterilization facility. This investment ensures that the U.S. Government can produce and supply the nation with the necessary vaccines and therapeutics in response to current or future public health threats.

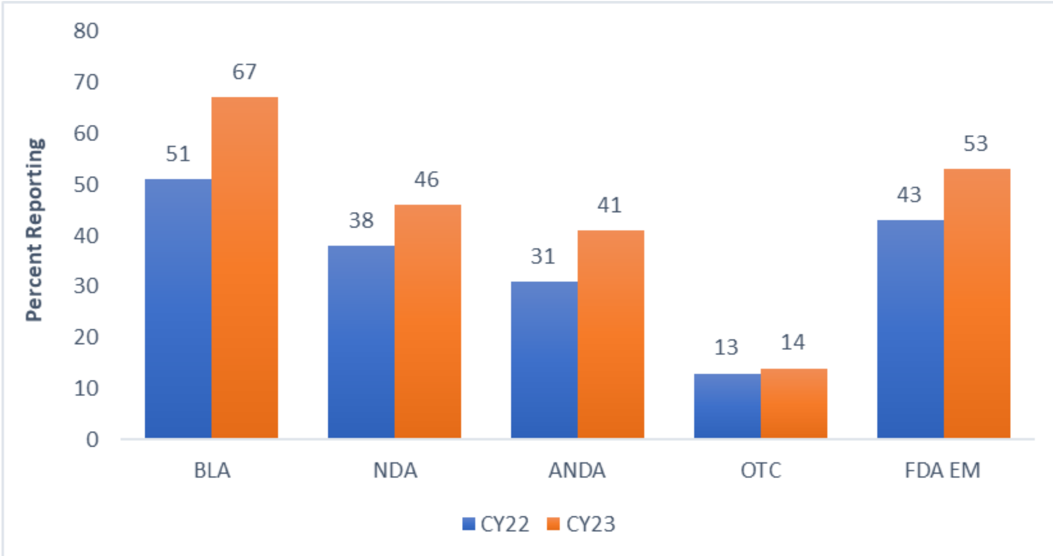
Appendix Figure 1. Main causes of shortages, 2023



Appendix Figure 2. Manufacturing locations for FDFs and APIs in shortage in 2023

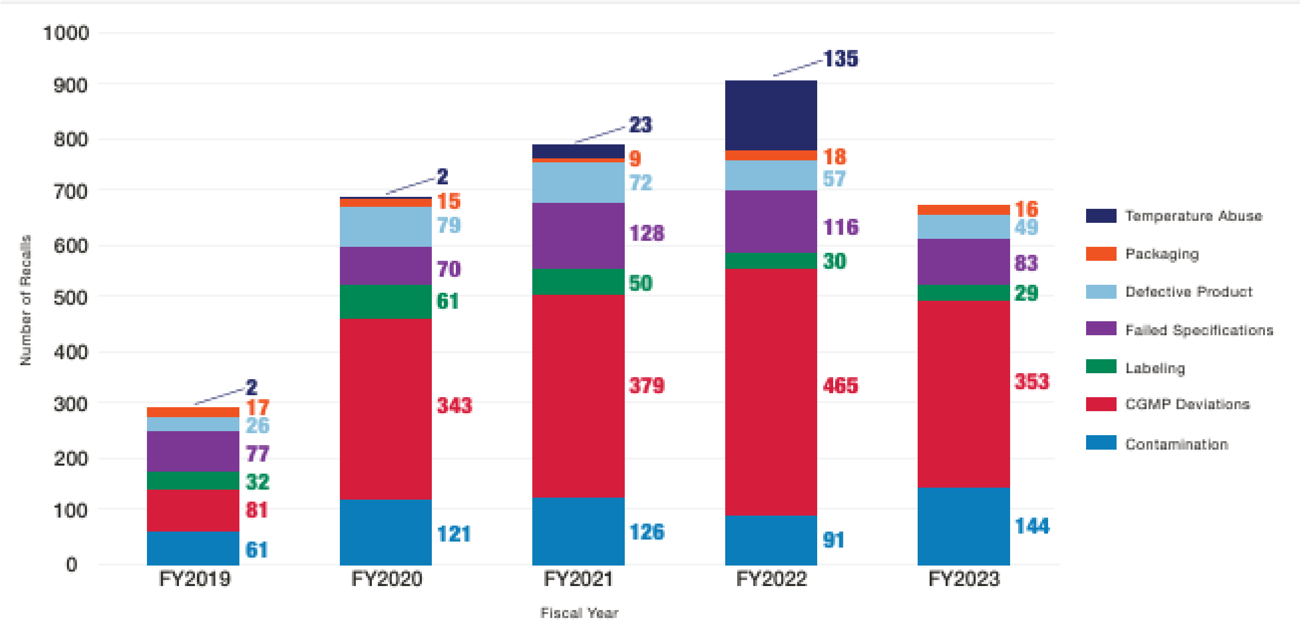


Appendix Figure 3. FDA/CDER-regulated product submissions reporting drug amount information, CY22–CY23



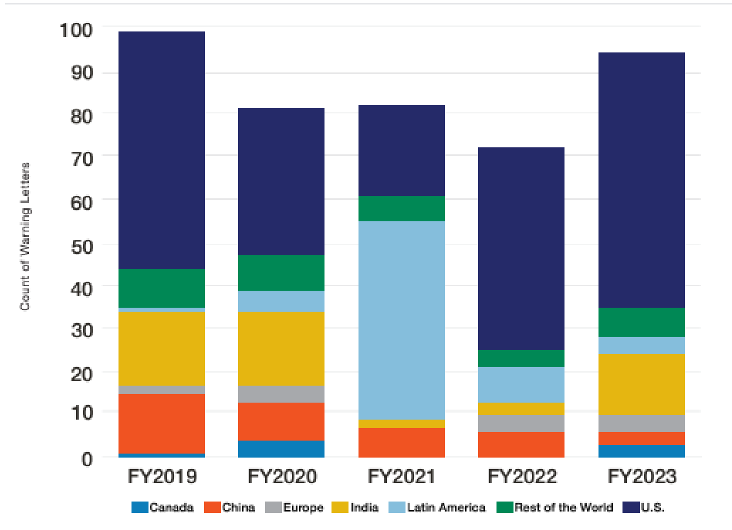
Notes: Counts include CDER-regulated product reports submitted by product type for CY22 and CY23 as of 09/30/2024. BLA: Biologics License Application; NDA: New Drug Application; ANDA: Abbreviated New Drug Application; OTC: Over-the-counter; FDA EM: EO 13944 List of Essential Medicines.

Appendix Figure 4: Total recalled drug products attributable to CGMP deviations



Notes: The CDER Catalog is a subject of all recalls; it excludes compounded drugs and those marketed without an approved application.
Source: CDER Product Catalog

Appendix Figure 5: Total warning letters for drugs attributable to CGMP deviations



Source: CDER Site Catalog

2021–2024 Four-year Review of Supply Chains Supporting the Information and Communications Technology Industrial Base

U.S. DEPARTMENT OF COMMERCE

U.S. DEPARTMENT OF HOMELAND SECURITY

DECEMBER 2024

EXECUTIVE SUMMARY

The United States information and communications technology (ICT) industry serves as a foundational bedrock of the nation's economic and national security. Natural disasters, geopolitical challenges, and the COVID-19 pandemic have created a strong impetus for ICT companies, as well as the federal government, to increase global ICT supply chain resilience through a variety of means.

U.S. ICT infrastructure is highly complex, including both physical and cyber infrastructure. The geographic concentration of ICT component manufacturing in Asia continues to pose significant risks to global ICT supply chains and U.S. ICT infrastructure. In addition, vertical specialization and industry consolidation have led to single-source supplier concentration risks. While the United States remains the leader in design and innovation for the ICT sector, China dominates manufacturing, although some specialized components that require more advanced technical processes are produced in other regions.

Since 2021, ICT companies have prioritized supply chain resilience in response to global disruptions, cybersecurity risks, and changing geopolitical dynamics. On the transmission side of the ICT industry, the terrestrial U.S. communication infrastructure remains resilient against physical and cyberattacks. The submarine U.S. communication infrastructure has a similar resilience posture, but faces additional challenges from competition with other industries and regulatory burdens. On the software side, secure development practices help to reduce risk, while hardware manufacturers continue to address the heavy geographic concentration of component suppliers.

The U.S. Government also made significant strides building ICT resilience. Key initiatives have bolstered U.S. semiconductor manufacturing ($52.7 billion from the CHIPS and Science Act) and expanded high-speed internet access ($42.5 billion from the Bipartisan Infrastructure Law), while placing a renewed emphasis on software security. Furthermore, the U.S. Government has increased its capacity to assess and diagnose supply chain risks across critical sectors by leveraging the risk management and analytics forecasting expertise housed within the respective supply chain centers that have been established within the Departments of Commerce and Homeland Security.

The United States may need further proactive measures to strengthen key ICT sectors. By investing in critical sectors, easing certain regulations, and collaborating with allies, the United States can increase its supply chain resilience across the ICT industrial base. Examples of specific priorities include bolstering the U.S. printed circuit board industry, addressing the non-market policies and practices that China deploys to support its manufacturing base, and continuing to work toward implementation of the Federal Acquisition Security Council (FASC), Executive Order 14028 ("Improving the Nation's Cybersecurity"), and National Security Memorandum 22 on Critical Infrastructure Security and Resilience.

The U.S. Government can further strengthen ICT supply chains by examining market and resilience issues through vehicles such as Executive Orders, and developing policies and best practices that promote resilience, through the use of attestation tools, bills of materials, and initiatives such as CISA's Secure by Design.

SECTOR OVERVIEW

Introduction

Core networks within the U.S. communications infrastructure are vital to maintaining internet functionality and connectivity across regions and internationally. Given the network's role in transporting large volumes of internet traffic and connecting various service providers, any disruption or vulnerability within these core networks could have significant impacts on the overall stability and security of the U.S. communications infrastructure. Therefore, ensuring the robustness and resilience of these core networks is critical to sustaining reliable services.

Executive Order 14017 on "America's Supply Chains" required the Secretary of Commerce and the Secretary of Homeland Security, in consultation with the heads of appropriate agencies, to submit a report on supply chains for critical sectors and subsectors of the ICT industrial base: "Assessment of the Critical Supply Chains Supporting the U.S. Information and Communications Technology Industry" (hereinafter "One-year Review of the ICT Industry"). That Order also set in place a process for reviewing action under the Order and conducting quadrennial supply chain reviews. This Review provides an update on the progress and status of ICT sector supply chain resilience since the February 2022 publication of the One-year Review of the ICT Industry. Specifically, this update provides an overview of the ICT sector, highlights the resilience and vulnerabilities of the sector as well as those of specific hardware and software products, details industry progress to date, and notes the key priorities that the sector's stakeholders should continue to address in the coming years. This update does not provide a discussion of Artificial Intelligence (AI), as AI was not addressed in the One-year Review of the ICT Industry and given that AI-related risks and resilience are already being addressed in a variety of forums, guidelines, and responses, including Executive Order 14110 - Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, as well as the President's Memorandum on Advancing the United States' Leadership in Artificial Intelligence; Harnessing Artificial Intelligence to Fulfill National Security Objectives; and Fostering the Safety, Security and Trustworthiness of Artificial Intelligence.

The heavy concentration of ICT component manufacturing in Asia, particularly in China, continues to pose significant risks to global supply chains and U.S. communications infrastructure. The reliance on single-source suppliers and the geographic concentration of production creates vulnerabilities that could disrupt the supply of critical components. This situational landscape underscores the need for diversification of manufacturing locations and suppliers to reduce dependency on a few concentrated sources and areas, thereby enhancing the resilience of the ICT sector.

Sector Overview

The ICT sector and sub-sector roles can be illustrated utilizing the DHS ICT Framework[399] that was developed pursuant to Executive Order 13873: Securing the Information and Communications

[399] "Executive Order 13873 Response: Methodology for Assessing the Most Critical Information and Communications Technologies and Services," Cybersecurity and Infrastructure Security Agency (CISA), published April 2020, https://www.cisa.gov/sites/default/files/2023-01/eo-response-methodology-for-assessing-ict_v2_508_0.pdf.

Technology and Services Supply Chain. The ICT Framework is organized into five roles (Local User Access, Transmission, Storage, Processing, and System Management) and 11 sub-roles, shown in figure 1 below.

Figure 1. DHS ICT Framework

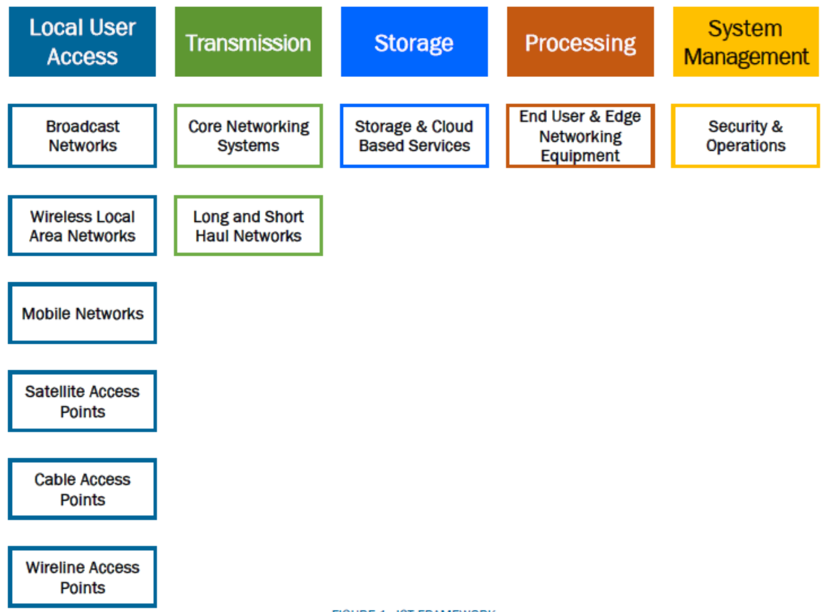


FIGURE 1—ICT FRAMEWORK

DHS identified 61 ICT elements, including hardware, software, and services that support these 11 sub-roles of the ICT Framework and make up the supply chain of the ICT sector. These elements include items such as transmitters, base station subsystems, satellite buses, uplink facilities, core servers, core infrastructure, fiber optic cable, servers, mobile devices, computers, and systems software.

This updated assessment focuses on the supply chains of the select number of critical components, devices, and software foundational to multiple facets of the nation's ICT industrial base that were discussed in the One-year Review of the ICT Industry response. In addition to criticality, the components, devices, and software were selected to exemplify broader trends impacting the U.S. ICT supply chains and to identify opportunities for the U.S. Government and industry to build resilience.

The ICT industry is essential to the U.S. economy, and it represents a major source of high-quality jobs for American workers. Positions in the ICT field had a median wage of $104,420 in May 2023, a striking 46 percent higher than the median wage of $49,060 across all occupations.[400] The computer systems design and related services sector employed over 2.5 million people, or about 1.6 percent of

[400] "Computer and Information Technology Occupation," U.S. Bureau of Labor Statistics, last modified August 29, 2024, https://www.bls.gov/ooh/computer-and-information-technology/home.htm.

the total workforce in 2023.[401,402] The ICT industry also provides manufacturing jobs at more than 1,200 active manufacturing sites in the United States.[403] Though impressive, this data only conveys a portion of the ICT industry's impact on the United States economy as the technologies that ICT enables, such as enterprise software systems, contribute greatly to empowering business tools like e-commerce. The ICT industry's supply chains are deemed to be "critical" based on a combination of the following elements:

U.S. National Security Significance: All 16 critical infrastructure sectors rely on ICT networks, devices, and services for various levels of functionality, without which the entirety of U.S. national security interests would be degraded.[404] Following CISA's definitions of the critical infrastructure sectors, this section will separately discuss the Information Technology (IT) Sector as well as the Communications Sector. In the rest of this Review, they will be grouped together as ICT.

- Defense Association: The Defense Industrial Base Sector has critical dependencies on most of the core ICT functions.
- Coercion Incentive and Exposure: The IT Sector faces state-sponsored advanced persistent threat (APT) actors that are well resourced and engage in sophisticated malicious cyber activity targeted at prolonged system and network intrusion.[405] APTs seek to position themselves on IT and communications networks for espionage, data theft, and system and network disruption or destruction.[406] APT attackers use tactics, techniques, and procedures (TTP) to remain undetected on victim networks to conduct long-term cyber campaigns.[407] Real-world examples of publicly reported incidents include Volt Typhon,[408] Salt Typhoon,[409] and Flax Typhoon.[410]

U.S. Economic Significance:

- Economic Impact: The ICT Sector has an outsize impact on the U.S. economy, given that it serves as the critical backbone utilized by all 16 critical infrastructure sectors. The digital economy, which includes ICT goods and services, represented $2.41 trillion in 2021—about 9.8 percent of the gross domestic product (GDP). The digital economy also grows faster than the overall economy. From 2016 to 2021, the overall economy expanded at a rate of

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401 "Occupational Employment and Wage Statistics," U.S. Bureau of Labor Statistics, last modified April 3, 2024, https://www.bls.gov/oes/current/naics4_541500.htm.
402 "Labor Force Statistics from the Current Population Survey," U.S. Bureau of Labor Statistics, last modified January 26, 2024, https://www.bls.gov/cps/cpsaat01.pdf.
403 Bloomberg data for telecommunications and technology industries combined, retrieved from dashboard created by the Office of Trade and Economic Analysis within the International Trade Administration.
404 The White House, "National Security Memorandum on Critical Infrastructure Security and Resilience," effective April 30, 2024, https://www.whitehouse.gov/briefing-room/presidential-actions/2024/04/30/national-security-memorandum-on-critical-infrastructure-security-and-resilience/.
405 "Nation-State Cyber Actors," The Cybersecurity and Infrastructure Security Agency (CISA), accessed December 19, 2024, https://www.cisa.gov/topics/cyber-threats-and-advisories/nation-state-cyber-actors.
406 CISA, "Nation-State Cyber Actors."
407 "Advanced Persistent Threat Activity Exploiting Managed Service Providers," CISA, last modified June 30, 2020, https://www.cisa.gov/news-events/alerts/2018/10/03/advanced-persistent-threat-activity-exploiting-managed-service.
408 "PRC State-Sponsored Actors Compromise and Maintain Persistent Access to U.S. Critical Infrastructure," CISA, published February 7, 2024, https://www.cisa.gov/news-events/cybersecurity-advisories/aa24-038a.
409 "*Salt Typhoon* Hacks of Telecommunications Companies and Federal Response Implications," Congressional Research Service, last modified November 15, https://tinyurl.com/3knjm44h.
410 "US Disrupts 'Raptor Train' Botnet of Chinese APT Flax Typhoon, Security Week, published September 19, 2024, https://www.securityweek.com/us-disrupts-raptor-train-botnet-of-chinese-apt-flax-typhoon/.

just 1.9 percent, while the digital economy surged by 5.6 percent, with a notable 10.0 percent increase between 2020 and 2021.[411]

- Price Sensitivity: ICT markets are highly competitive, and price competition is common for companies to retain market share. Companies offering highly commoditized products and services are typically more price sensitive than those offering differentiated or highly technical products and services. Additionally, companies that can offer reliable and secure supply can command a premium. Companies with higher fixed costs are likely more sensitive to price given the need to cover those costs.
- Competitive Intention: China presents a number of challenges to the ICT sector. Per a May 14, 2023, White House Fact Sheet, "China's unfair trade practices concerning technology transfer, intellectual property, and innovation are threatening American businesses and workers." China is also flooding global markets with artificially low-priced exports, while the Chinese government implements state-imposed forced labor schemes of Uyghurs, Kazakhs, Kyrgyz, and other Muslim ethnic minority groups.[412] The Made in China 2025 roadmap also articulates goals to increase global market share in key ICT industries including wireless mobile communication, optical communication equipment, and high-performance computers and servers.[413] On September 18, 2024, the Office of the United States Trade Representative (USTR), published a Notice of Modification: China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property and Innovation to further impose additional section 301 duties or increase the rate of existing section 301 duties, on certain products of China in strategic sectors; and increase tariff rates for certain tungsten products, wafers, and polysilicon.[414,415]
- Technological significance: The IT Sector functions encompass the full set of processes involved in creating IT products and services, including R&D, manufacturing, distribution, upgrades, and maintenance. The IT Sector is composed of the following key components that create the products and services that underpin much of the U.S. economy:
    - Hardware: IT hardware includes manufactured physical components of IT systems, such as computers, peripherals, communication and audiovisual equipment, semiconductors, and other electronic components. Much of the physical infrastructure underlying the IT Sector is housed in data centers, which include components like servers, routers, and information storage systems. The United States has data centers in over 1,600 locations.

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411 "New and Revised Statistics of the U.S. Digital Economy 2005-2021," Bureau of Economic Analysis, published November 2022, https://www.bea.gov/system/files/2022-11/new-and-revised-statistics-of-the-us-digital-economy-2005-2021.pdf.

412 "Against Their Will: The Situation in Xinjiang," U.S. Department of Labor, Bureau of International Labor Affairs, accessed December 10, 2024, https://www.dol.gov/agencies/ilab/against-their-will-the-situation-in-xinjiang.

413 "Roadmap of Major Technical Domains for *Made in China 2025*," The State Strategic Advisory Committee for Building China into a Manufacturing Superpower, translated September 9, 2020, https://cset.georgetown.edu/wp-content/uploads/t0181_Made_in_China_roadmap_EN.pdf.

414 Office of the U.S. Trade Representative, "China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property and Innovation," Federal Register Vol. 89 No. 181, published September 18, 2024, https://www.federalregister.gov/documents/2024/09/18/2024-21217/notice-of-modification-chinas-acts-policies-and-practices-related-to-technology-transfer.

415 Office of the U.S. Trade Representative. "USTR Increases Tariffs Under Section 301 on Tungsten Products, Wafers, and Polysilicon, Concluding the Statutory Four-Year Review," published December 11, 2024, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/december/ustr-increases-tariffs-under-section-301-tungsten-products-wafers-and-polysilicon-concluding.

- Software: Software comprises the instructions that govern the functioning of hardware. It includes programs and data, with the software industry producing both general-purpose published or packaged software and custom-developed products and services. Software is essential to managing and understanding the vast amounts of data generated by modern technology.
- Internet and IT Networks: The IT Sector's basic functions are required to maintain or reconstitute computer networks (e.g., internet, local networks, and wide area networks) that connect the sector's physical, discrete components and facilitate their associated services. The internet, a global system of interconnected networks, is supported by the IT Sector in close collaboration with the Communications Sector.
- IT Services: IT services include development, integration, operations, communications, and security. Specific functions include cybersecurity, data science, web development, database administration, and IT user support.

- The services and applications provided by the Communications Sector include voice, video, and data. Voice services consist of FM/AM/UHF/VHF/HF radio, 911 and Enhanced 911 (E911) capabilities, Voice Over Internet Protocol (VOIP) services, air traffic control, intermodal, and satellite radio. Data services include HTTP, email, text messaging, remote transfer, managed/hosted/cloud services, social networking, and GPS navigation/tracking/timing.

Public Health and Safety Significance:

- Public Health: The Healthcare and Public Health Sector is increasingly reliant on IT. This sector depends on secure IT systems for notifiable disease reporting and the secure sharing of patient data. Additionally, medical devices and systems rely on ICT components like Operational Technology (OT), printed circuit boards (PCBs) and firmware for their use.
- Safety: The Emergency Services Sector relies on networks for emergency operations center connectivity, interconnecting land mobile radio networks, backhauling traffic, operating public alert and warning systems, and receiving emergency 911 calls.

The ICT sector is foundational to the nation's economic and national security. ICT products and services underpin the support systems used by all critical infrastructure sectors and the U.S. Government. Secure and resilient ICT supply chains ensure that vital functions such as power generation, emergency communications, data transmission, gas lines, medical devices, and industrial control systems can function.

Presidential Policy Directive 21 (PPD-21) and the subsequent National Security Memorandum 22 (NSM-22) identify the nation's 16 critical infrastructure sectors, all of which are critically important to our nation's economy, national security, as well as public health and safety. While all critical infrastructure sectors are important, some portions of the ICT sector are particularly interconnected and have dependencies that can cascade significantly across other critical infrastructure sectors during a disruption.

To that end, ICT critical infrastructure sectors are included in the Department of Homeland Security's Federal Emergency Management Agency's (FEMA) Community Lifelines framework and their services are also detailed in CISA's National Critical Function (NCF) framework. The NCF framework indicates that the functionality of "Connect, Distribute, Manage, and Supply" are functions of government and the private sector so vital to the United States that their disruption, corruption, or dysfunction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof. The ICT sectors facilitate these NCFs.

In addition, the FEMA Guide to Continuity of Government itself calls for the necessity of having critical resources available to conduct its operations plan, including various communications methods, and technologies, including cell phone service.

Overview of ICT Manufacturing Production

A primary conclusion reached in the One-year Review of the ICT Industry was that the U.S. ICT market and production structure, with its geographic concentration of manufacturing in Asia as well as reliance on concentrated manufacturing sources, created significant risk. Low manufacturing profit margins and the need for mass production drove ICT manufacturing to Asia over the previous decades, and favorable attributes such as lower labor costs, subsidies, infrastructure benefits, and availability of capital and land attracted high volume, consumer product electronics manufacturing service (EMS) assembly to China.

Vertical specialization and industry consolidation has further led to supplier single-source concentration, which is also typically centered in Asia. Given that any one product may contain thousands of components, economies of scale are created when an ICT manufacturer can mass produce and specialize in one component. Today, many of these components are manufactured in Asia, and in particular China, Japan, the Republic of Korea, and Taiwan. Production of low-value components followed assembly to China, as low-value component producers were urged to provide just-in-time product and low-cost delivery to the assembly plants.

Overview of ICT Transmission

U.S. communications infrastructure is a complex collection of networks comprised of both physical infrastructure such as buildings; networking components; fiber; satellites; towers; antennas; and cyber infrastructure, including routing and switching software, operational support systems, and user applications. Communications networks are owned and operated by service providers in three main functional areas: services and applications, core networks, and access networks. Of these three main functional areas, the core networks are the most critical and essential for internet functionality.[416]

The core networks—in both their terrestrial and submarine varieties—transport a high volume of internet traffic over substantial distances and/or between different service providers or carriers. These networks connect U.S. regions by maintaining data centers and internet exchange facilities (IXFs) and using land-based fiber, coaxial cable networks, and submarine fiber optic cable systems to connect to international networks.

[416] "Cybersecurity: Internet Architecture is Considered Resilient, but Federal Agencies Continue to Address Risks," U.S. Government Accountability Office, published March 3, 2022, https://www.gao.gov/products/gao-22-104560.

Evolution of the Sector through 2020

While the United States remains the leader in the design and innovation for the ICT sector, China leads in manufacturing.[417] Over the previous three decades, the U.S. private sector ceded manufacturing of much of the ICT supply chain to Asia, and the U.S. ICT industry evolved from being vertically integrated to one that is highly outsourced. For example, beginning in the 1980s, original equipment manufacturers (OEMs) pulled back from designing and manufacturing their own computer chips and software and began outsourcing manufacturing and software development to specialized technology companies. As a result, OEMs were able to focus on design and innovation of new and improved technologies, making the United States the world's leader in technology innovation, but at the cost of increasing reliance for hardware manufacturing on other countries.

In the 1990s, as ICT OEMs divested their manufacturing operations, contract manufacturing companies acquired these production facilities and consolidated the market. They began offering a comprehensive range of production services, including specialized design and manufacturing for both components and software.[418] As of 2020, 43 percent of the electronics assembly market was outsourced to contract manufacturers. The remainder was assembled by OEMs for their brand products.[419]

Over time, this vertical specialization and segmentation of the ICT industrial base has led to geographic specialization whereby certain products and services are sourced from single regions or countries,[420] and due to economies of scale, an ICT manufacturer may mass produce and specialize in one component. Today, although most manufacturing occurs in Asia, some specialized components that require more advanced technical processes are still produced outside of Asia.

Key Sector Trends from 2021 to Present

Since 2021, ICT companies have prioritized supply chain resilience in response to global disruptions, cybersecurity risks, and changing geopolitical dynamics. Key trends include shifting to onshoring, nearshoring, and regional diversification to reduce reliance on distant suppliers, inventory management, along with investing in real-time monitoring and supplier transparency. All these efforts take time, but the shift is underway. The key trends include:

Proactive Risk Classification: ICT companies may continue to refine their supply chain risk management approach given the financial burden experienced as a result of supply disruptions during the pandemic. Companies may consider deploying a systematic classification of risks, continually analyze developments and events that are happening around the world and undertake the development of a response strategy to improve supply-chain resilience strategically.

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417 "Executive Order 14017 on Securing America's Supply Chains," CISA, accessed December 9, 2024, https://www.cisa.gov/executive-order-14017-securing-americas-supply-chains.
418 Esther de Haan and Irene Schipper, "CSR Issues in the ICT Hardware Manufacturing Sector".
419 Randall Sherman, "Now Available! The Worldwide OEM Electronics Assembly Market – 2021 Edition,". Nevada City: New Venture Research, July 2021, https://newventureresearch.com/wp-content/uploads/OEM2021-RS.pdf.
420 Timothy Sturgeon, Presentation on "Supply chain resilience and smart reshoring in massively modular industries: The case of ICT," Virtual Forum for Risks in the Information Communication Technology Supply Chain, (Bureau of Industry and Security, October 29, 2021).

Map the Corporate Supply Chain: ICT companies may want to develop a detailed map of junior-tier suppliers as a critical step to detect hidden relationships that impede adding resilience. After mapping upstream suppliers, purchasers of ICT products must also be aware of the production locations and financial stability of each participant in the value chain that supplies a critical component or constitutes a potential logistical bottleneck.

Broaden Supplier Network and Regional Footprint: To eliminate and reduce the risk of single source for raw materials or critical product components when possible, companies can increase resiliency and redundancy in their networks by dual-sourcing supply from multiple or lower-risk regions.

Potential Development of Standardized Mapping and Other Illumination Tools: While there is a strong consensus about the need to more effectively map the locations of sub-tier suppliers and to identify upstream logistical bottlenecks, currently there is no standard methodology for doing so. The ICT sectors may thus benefit from the development of standardized approaches to supply chain mapping that would place appropriate focus on sub-tier suppliers or logistical bottlenecks that are most critical; would care for legitimate vendor concerns about being pressed to provide proprietary information; and would settle on common formats for providing maps and other information.

Work to Shift the Optimal Amounts of Inventory Held: Many ICT manufacturers try to minimize their inventory of components, thereby holding down costs by keeping stockpile inventories low and delivering goods as needed. This is the opposite of the "just in case" methodology that calls for holding more inventory in reserve. ICT companies may want to explore holding more buffer inventories and also working with their suppliers to hold inventory at their warehouses, through a Vendor Managed Inventory system. Furthermore, ICT manufacturers should continue to ensure that they utilize meaningful metrics, such as orders delivered complete, accurate, and on-time, as well as time-related metrics like days of inventory and cycle time.

Plan Alternatives in Logistics and Transportation: During an adverse event, almost every mode of transportation can be affected. To reduce the impacts of transportation and logistics issues, ICT companies can engage in scenario planning for different types of events and map out the alternatives that can allow for the supply chain to be restored as efficiently as possible. To further assist in these efforts, companies can utilize technology platforms that provide real-time, blockchain visibility into available logistics capacity. Companies can also study logistics patterns to help identify alternative providers for each key route.

PROGRESS TO DATE

One-year Review Priorities

The One-year Review of the ICT Industry included specific recommendations to strengthen supply chain resiliency. To revitalize the U.S. ICT manufacturing base, the report recommended supporting the private sector to expand domestic manufacturing capacity through financial incentives and procurement preferences. Other recommendations included promoting supply chain risk management practices through illumination, procurement, and monitoring efforts, as well as improving international collaboration to advance shared interests. Given the importance of investing in future ICT technologies, processing, and manufacturing as well as a skilled workforce, the assessment also highlighted the need to sustain the research and development (R&D) ecosystem while supporting programs that attract, educate, and train the ICT workforce. Finally, the report recommended promoting environmental standards, strengthening public–private engagements, and guiding long-term policy through further studies.

Progress from 2021 to Present

Resilient and secure ICT supply chains are critical to U.S. economic and national security, and this update has highlighted several vulnerabilities, including a lack of domestic production capacity for many product categories, overreliance on single-source and regional suppliers, as well as cyber and design risks.

The U.S. Government has made significant strides building ICT resilience through a combination of programs, incentives, policies, and collaboration with the private sector. Key initiatives include the Build America, Buy America Act under the Bipartisan Infrastructure Law (also known as the Infrastructure Investment and Jobs Act (IIJA)), and the CHIPS Act of 2022, which has bolstered domestic semiconductor manufacturing and reduced reliance on foreign sources. The U.S. Government also implemented incentives to encourage the development of critical infrastructure, including funding to the Department of Commerce for broadband expansion - the $42.45 billion Broadband Equity, Access, and Deployment (BEAD) Program and cybersecurity enhancements. Buy America requirements for BEAD boosted resiliency by driving private investment in U.S. domestic production, with close to 90 percent of the funding expected to be spent on equipment manufactured in the United States.[421]

In addition, the Public Wireless Supply Chain Innovation Fund (Innovation Fund) is a $1.5 billion competitive grant program aimed at accelerating the adoption of open and interoperable networks. These investments are designed to foster competition and innovation, lower costs for consumers and network operators, and strengthen our supply chains. To date, Commerce has invested more than $140 million across 17 awards to drive testing and evaluation of Open RAN technologies. In the coming weeks, the Department will award hundreds of millions of dollars in additional grants to further accelerate commercialization and innovation of this technology through the program's second funding opportunity.

[421] "An American-Made Internet for All," National Telecommunications and Information Administration (NTIA), published February 23, 2024, https://www.ntia.gov/blog/2024/american-made-internet-all.

Entities awarded funds through the Innovation Fund must employ and integrate cybersecurity into the design, development, operation, and maintenance of their solutions to ensure the future of critical infrastructure information technology (IT) and operational technology (OT). In FY24 the Innovation Fund published 2 Notice of Funding Opportunities (NOFO). The first NOFO established 3 testing and evaluation labs for the ecosystem to leverage for testing cybersecurity designs as well as other open radio access network parameters. Each awardee is incorporating cybersecurity in accordance with the above requirements. The second NOFO focused on the Radio Unit (hardware) and required partnerships amongst vendors and mobile network operators to enhance the features of Radio Units, including cybersecurity. Further NOFOs may be announced in the future.

Policies like the National Cyber Strategy, released in March 2023 and Executive Order 14028: Improving the Nation's Cybersecurity, emphasized securing the digital, software, and cyber landscape, with agencies like the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA) leading efforts to promote Secure by Design practices and enhance open-source software security.

Furthermore, public–private partnerships like CISA's ICT Supply Chain Risk Management (SCRM) Task Force and NIST's Software and Supply Chain Assurance Forum have been pivotal, fostering collaboration between government entities and ICT companies and organizations to address supply chain vulnerabilities by creating products, tools, templates, and reports that increase U.S. ICT resilience in the face of evolving threats. The U.S. Department of Commerce's new Supply Chain Center (housed in the Industry and Analysis business unit) and industry offices have carried out deep dive supply chain analysis and produced policy recommendations to increase the resiliency of the broadband, quantum computing, and AI data center industries, while the Department of Homeland Security's new Supply Chain Resilience Center is conducting assessments on submarine cables and other critical infrastructure.

Additional efforts to build resilience since 2021 for the selected components and devices that were identified in the One-year Review of the ICT Industry are detailed below. The discussion will cover the following topics:

- Cybersecurity Supply Chain Risk Management (C-SCRM)
- Supply Chain Analysis
- Upstream Components
- Downstream Products
- Software
- Firmware / Internet of Things

C-SCRM

Since 2008, NIST has conducted research and collaborated with a large number and variety of stakeholders to produce information resources that help public and private sector organizations identify, assess, and respond to cybersecurity risks in their ICT supply chains. By statute[422], federal agencies must use NIST's C-SCRM and other cybersecurity standards and guidelines to protect non-national security federal information and communications infrastructure. Stemming from the SECURE Technology Act and EO 14028, in May 2022 NIST updated its flagship supply chain publication, SP 800-161, Revision 1, C-SCRM Practices for Systems and Organizations. SP 800-161, Revision 1 integrates C-SCRM into risk management activities by applying a multilevel, C-SCRM-specific approach, including guidance on the development of C-SCRM strategy and implementation plans, C-SCRM policies, C-SCRM plans, and risk assessments for products and services. Additionally, NIST released a Quick-Start Guide for C-SCRM) as a complement to the enhanced role of C-SCRM in the NIST Cybersecurity Framework (CSF) 2.0's new Govern Function. The Guide provides an overview of C-SCRM and provides a set of recommended activities to establish an organization's C-SCRM capability and define supplier requirements. The CSF's new release highlights the essential role of C-SCRM in organizational governance and provides control statements to assist organizations in identifying current and desired C-SCRM outcomes. Additionally, based on the wide adoption of SP 800-161, Revision 1, NIST released draft SP 1326, Due Diligence Assessment Quick-Start Guide. This new publication provides an implementation-ready approach to conducting the minimum amount of investigative rigor on potential suppliers. Identifying the primary risk factors that an acquirer should consider can enable quick turnarounds with limited resources.

Supply Chain Analysis

The U.S. Department of Commerce established the Supply Chain Center in the Industry & Analysis (I&A) business unit, which works with I&A's industry offices to identify, monitor, and address supply chain vulnerabilities and strengthen resilience throughout the ICT industry. I&A has conducted supply chain risk assessments for several ICT industries, including:

- AI Data Centers: I&A conducted a detailed analysis of the under-appreciated supply chain risks for materials used to construct and operate AI data centers in the United States. I&A leveraged industry expertise, company relationships, and the SCALE supply chain analytical tool to assess risks associated with a range of critical AI data center components, including highly advanced printed circuit boards, leading-edge chips, backup generators, and emerging cooling technologies.
- Broadband: Using this same methodology, I&A examined the fiber equipment supply chain for broadband, necessary to support the BEAD program's $42.5 billion investment in expanding U.S. broadband access. This analysis provides a baseline for ongoing monitoring of the fiber supply chain, especially for products waived under the Buy America requirements, and which also support adjacent industries like data centers and high-performance computing.
- Quantum Computing: I&A conducted an assessment of the quantum computing supply chain, including chokepoints that would affect commercialization and U.S. competitiveness of this critical emerging industry. I&A staff engaged quantum computing companies, industry associations, the venture capital community, national laboratories, and U.S. Government agencies, as well as leveraging its industry expertise and internal data tools.

[422] Office of Management and Budget, "Federal Acquisition Supply Chain Security Act of 2018," Federal Register Vol. 85 No. 170, published September 1, 2020, https://www.federalregister.gov/documents/2020/09/01/2020-18939/federal-acquisition-supply-chain-security-act.

DHS also established a Supply Chain Resilience Center (SCRC), which focuses on key technologies that facilitate data and goods' safe and secure movement across our borders. In the ICT sector, the SCRC will utilize an assessment developed by CISA for submarine cables and collaborate with other U.S. public and private stakeholders to enhance resilience in this key market. The SCRC will then analyze cable production issues and capabilities to uncover insights, pinpoint critical challenges, and propose potential solutions to address supply chain vulnerabilities associated with submarine cables.

There are efforts underway to strengthen the ICT workforce and these efforts can help to advance the workforce recommendation from the One-year Review on the ICT Industry: these policies and actions build on each other. Since the BEAD program's launch, states are including workforce plans in their BEAD proposals. As of December 2024, nearly one third of eligible entities (e.g., states and territories) have allocated over $300 million in BEAD funding to workforce development initiatives.[423] Industry groups are also expanding their own workforce programming to support broadband deployment. Notable examples include the National Skills Coalition's effort to expand access to broadband careers, the Wireless Industry Association's continued work on the Telecommunications Industry Registered Apprenticeship Program, as well as the Telecommunications Industry Association's new Broadband Nation program.[424]

Upstream Components

Printed Circuit Boards

Unassembled (bare) PCBs are the map for the placement and interconnection of semiconductors, passive components, and electronic connectors that enable the electronic functions of an end product. Semiconductors and other components do not work until they are assembled onto a PCB.

Over the last 25 years, the U.S. share of global PCB manufacturing has plummeted from 30 percent to five percent.[425] U.S. PCB production focuses primarily on low-volume, high-mix specialty boards for industrial, medical, defense, and aerospace applications. Chinese and Taiwanese companies lead in this industry, with Taiwan, China, Japan and South Korean companies making up more than 90 percent of the top 100 companies.

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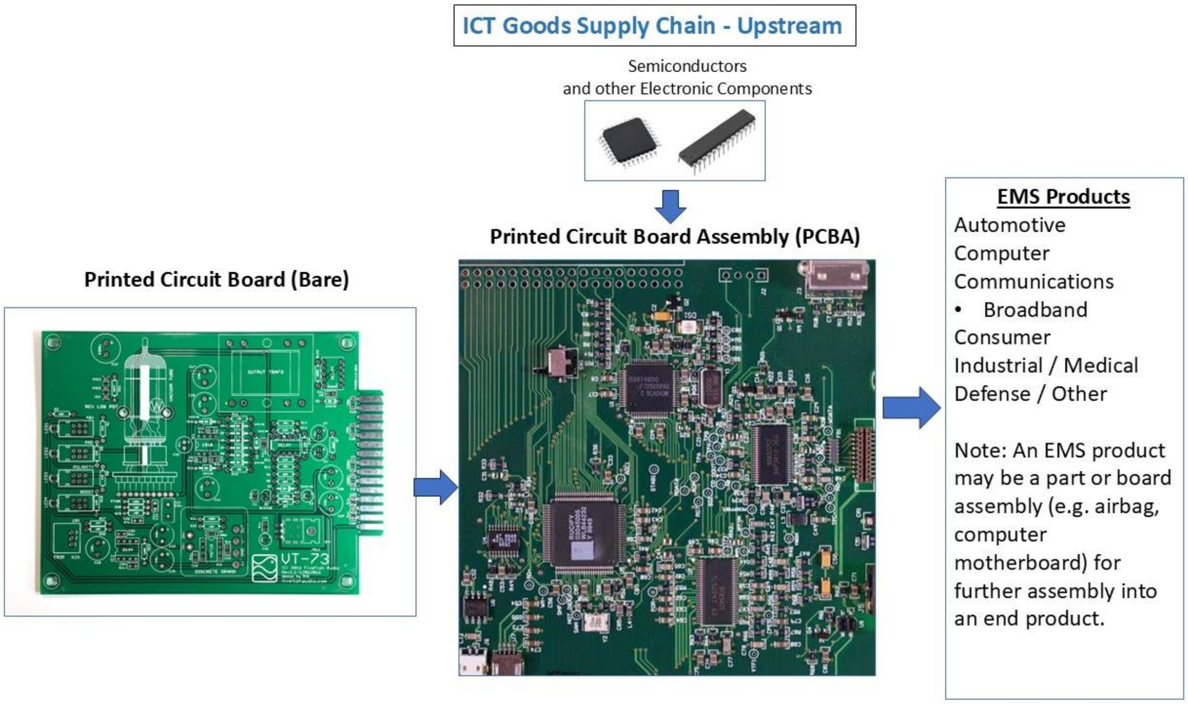
423 "Ramping Up the BEAD Workforce: 5 Things States, ISPs, and Construction Firms Can Be Doing Now," National Telecommunications and Information Administration (NTIA), published December 4, 2024, https://www.ntia.gov/blog/2024/ramping-bead-workforce-5-things-states-isps-and-construction-firms-can-be-doing-now.

424 "Expanding Access to Broadband Careers and Building Digital Skills: Next Steps in State Policy Advocacy," Johnson, M., Bergson-Shilcock, A., published April 24, 2024, https://nationalskillscoalition.org/blog/future-of-work/expanding-access-to-broadband-careers-and-building-digital-skills-next-steps-in-state-policy-advocacy/; https://www.tirap.org/; https://tiaonline.org/what-we-do/technology-programs/broadband-nation/.

425 "Notice of Request for Public Comments on Risks in the Information Communications Technology Supply Chain," U.S. Department of Commerce, Federal Register Vol. 86 No. 179, published September 20, 2021, https://www.federalregister.gov/documents/2021/09/20/2021-20229/notice-of-request-for-public-comments-on-risks-in-the-information-communications-technology-supply.

Figure 2. ICT goods supply chain – upstream[426]



The PCB supply chain includes chemicals, equipment, and material constituents that are heavily reliant on offshore sourcing. There are notable vulnerabilities sourcing key materials, including high-performance laminates, polytetrafluoroethylene laminates, copper foil, mechanical drill bits, and solder mask.

In March 2023, President Biden issued a determination authorizing the use of Defense Production Act to support the nation's domestic Printed Circuit Boards and Advanced Packaging defense industrial base. More than $100 million in manufacturing investment was awarded to the PCB industry through the Defense Production Act in FY 24; however, Congress needs to continue to fund the program for it to continue.[427]

Policy efforts related to that determination are also underway. The 2021 National Defense Authorization Act prohibits U.S. Department of Defense (DOD) acquisition of PCBs and PCB assemblies (PCBAs) used for mission critical defense functions from China, Russia, North Korea, and Iran.[428] DOD is currently developing guidance on PCB and PCBA acquisition for DOD procurers. These efforts could provide greater demand for U.S. domestic production of PCBs.

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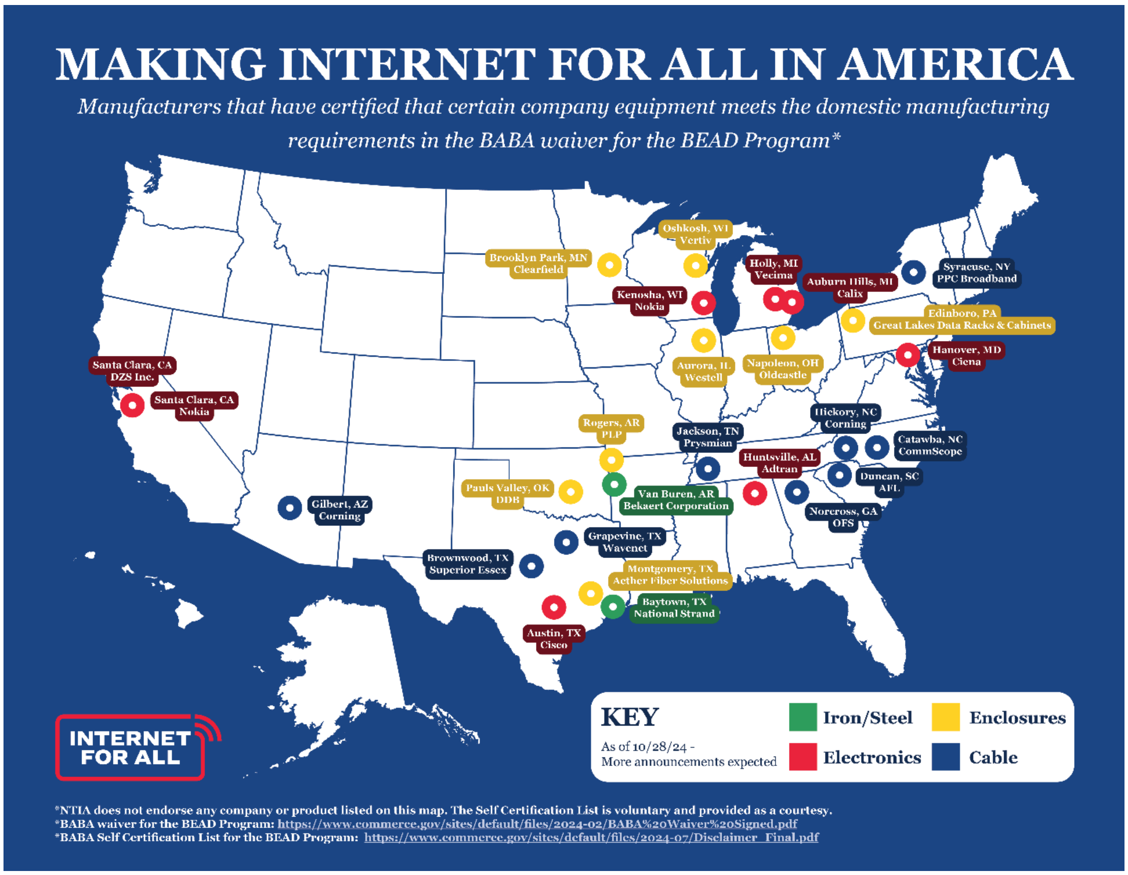
426 U.S. Department of Commerce, International Trade Administration, Industry & Analysis, Office of ICT, "ICT Goods Supply Chain – Upstream," February 1, 2024.
427 "IPC Persisting on Defense PCB Funding; Lend Your Voice Today," IPC, accessed October 18, 2024, https://www.ipc.org/blog/ipc-persisting-defense-pcb-funding-lend-your-voice-today-0.
428 Public Law 116-283 § 841, (2021).

Fiber Optic Cable

The Infrastructure Investment and Jobs Act (IIJA) was signed into law on November 15, 2021. IIJA includes the $42.5 billion Broadband Equity, Access, and Deployment (BEAD) program, which is managed by the U.S. Department of Commerce's National Telecommunications and Information Administration (NTIA). Aligning with a recommendation from the One-year Review on the ICT Industry, IIJA implemented significant Buy America requirements for its programs.[429] For example, the BEAD program requires that broadband equipment items such as optical fiber, fiber optic cable, key electronics, enclosures, and iron and steel products among others, are manufactured in the United States.[430]

Figure 3. Build America, Buy America (BABA) Self-certification List[431]



[429] "What Is Build America, Buy America?" Office of Management and Budget, Made in America Office, accessed October 16, 2024.

[430] "Build America, Buy America," Office of Acquisition Management, U.S. Department of Commerce, accessed October 16, 2024, https://www.commerce.gov/oam/build-america-buy-america; "Broadband Equity Access and Deployment Program," BroadbandUSA, NTIA, accessed December 10, 2024, https://broadbandusa.ntia.doc.gov/funding-programs/broadband-equity-access-and-deployment-bead-program.

[431] "Build America Buy America: Companies Self-Certify Domestic Production for the BEAD Program," Arbuckle, W., NTIA, October 16, 2024, https://www.ntia.gov/blog/2024/build-america-buy-america-companies-self-certify-domestic-production-bead-program.

The Buy America requirement will boost supply chain resilience by driving investment in U.S. domestic production, while reducing reliance on producers in Asia. Private investment in manufacturing, in turn, creates U.S. jobs and mitigates the risk to U.S. supply chains for fiber optic cable and other key broadband products used throughout the lifecycle of BEAD funding. NTIA announced industry commitments to create thousands of jobs and new products in the United States that are used for building high-speed internet networks, with participation from companies such as Adtran, AFL, Calix, CommScope, Corning, Nokia, PPC Broadband, and Prysmian.[432] As one example, Corning announced a new $100 million investment to manufacture optical fiber and cable in Gilbert, Arizona.[433]

Downstream Products

Routers, Switches, and Servers

The demand for routers, switches and servers is growing due to expanded 5G connectivity and the rise of artificial intelligence.[434] The U.S. Government launched initiatives to advance supply chain resilience for communications equipment. For example, U.S. domestic manufacturing of networking equipment will be supported by the Buy America provisions included under the BEAD program.[435] In 2024, Nokia partnered with Sanmina to produce Buy America-compliant networking products (optical line terminals and optical network terminals) in the United States.[436]

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432 "Internet for All," NTIA, published February 23, 2024, https://www.ntia.gov/blog/2024/american-made-internet-all.

433 "Corning to Build New Optical Cable Manufacturing Facility in Gilbert," Digital Newsroom, August 30, 2022, Corning To Build New Optical Cable Manufacturing Facility in Gilbert | News | Gilbert, Arizona; "Corning brings $100M manufacturing facility, 250 jobs to Gilbert," *AZ Big Media*, September 6, 2022, https://azbigmedia.com/business/corning-brings-100m-manufacturing-facility-250-jobs-to-gilbert/.

434 "Worldwide Server Market Summary and Outlook, 4Q23," International Data Corporation (IDC) commissioned analysis, published December 2023; https://www.delloro.com/news/service-provider-router-and-aggregation-switch-market-poised-for-growth-after-inventory-correction/.

435 Note: Routers and switches are waived from the Buy America requirement under the BEAD BABA waiver.

436 "Nokia makes its first Buy America products at Wisconsin factory," Hardesty, L., Fierce Network, April 24, 2024, https://www.fierce-network.com/broadband/nokia-produces-its-first-buy-america-products-wisconsin-factory

CASE STUDY: EXIM'S CHINA AND TRANSFORMATIONAL EXPORTS PROGRAM (CTEP)

The One-year Review of the ICT Industry also included a recommendation for the federal government to consider enhancing financial support offered by the Export–Import Bank of the United States (EXIM) for friend- and near-shoring of ICT components that are unlikely to be produced domestically. Through EXIM's China and Transformational Exports Program (CTEP), launched in December 2020, EXIM has expanded the availability of financing for U.S. goods and services exports in the transformational export areas of semiconductors, quantum computing, high performance computing, and wireless communications, as well as for any U.S. ICT exporter facing PRC competition. In January 2023, the EXIM Board approved a 5G policy clarification that permits maximum EXIM financing for 5G-related transactions with less than 51 percent U.S. content, provided that the exporter submits an actionable plan describing a pathway for U.S.-based job expansion. Through this approach, EXIM is able to provide financing for trusted vendor wireless communications components - including products that are unlikely to be produced domestically in the near-term - while overseas exporters agree to examine how they can increase U.S. investment, manufacturing, and job protection to ultimately strengthen U.S. onshoring efforts. In September 2024, the EXIM Board approved the first transaction under this low content framework, committing $313 million under a co-financing agreement with Finnish export credit agency, Finnvera, to support the export of Nokia goods and services to be used by India's Reliance Jio as it builds out its 5G nationwide network.

End-User Devices

Risks causing supply chain disruptions include counterfeiting, unauthorized production, tampering, theft, and insertion of unexpected software and hardware in end-user devices. A delivered device has integrity if it is genuine and all changes to the device were authorized and expected throughout the entire life cycle from creation to ownership. However, many organizations currently lack the ability to cost effectively identify trustworthy products, meaning they are genuine and have not been inappropriately altered.

Published in December 2022, NIST SP 1800-34, Validating the Integrity of Computing Devices, aims to address some challenges associated with these risks by demonstrating how organizations can verify that the internal components and system firmware of the computing devices they acquire are genuine and have not been unexpectedly altered during distribution or operational use.

Displays

Following the One-year Review of the ICT Industry, the trend to innovate display technologies has continued, and China's efforts to dominate the industry continue. Organic Light-Emitting-Diode (OLED) displays are replacing traditional Liquid Crystal Display (LCD) panels in smartphones and tablets and are now being used in handheld gaming devices and wearables. Cutting-edge micro display technologies are being used in consumer and military Augmented Reality and Virtual Reality products.

The One-year Review highlighted the rapid growth of the Chinese LCD manufacturing sector. A similar story is now playing out with OLED innovation and manufacturing. China is quickly catching up with Korean and Japanese firms in OLED and is investing heavily in developing and manufacturing cutting edge micro displays. China's growing dominance in OLED and investments in micro displays should continue to be monitored to avert potential future supply chain disruptions and single source vulnerabilities. For supply chains in which the federal government has substantial purchasing power, Made in America laws and other procurement tools could potentially spur increased investment in domestic supply chains.

Hardware Bill of Materials (HBOM)

To address the economic and security risks associated with equipment components that may be untrusted, compromised, or subject to availability risks, the ICT SCRM Task Force published, in 2023, the Hardware Bill of Materials Framework for Supply Chain Risk Management.[437]An HBOM is a list of all the physical pieces or components used to build a product. HBOMs are an important part of supply chain risk management because they allow organizations to make informed decisions by evaluating the hardware supply chain before purchasing new products or technology. The Framework includes a consistent naming methodology for attributes of components, a format for identifying and providing information about the different types of components, and guidance of what HBOM information is appropriate depending on the purpose for which the HBOM will be used.[438] The Framework includes a consistent naming methodology for attributes of components, a format for identifying and providing information about the different types of components, and guidance of what HBOM information is appropriate depending on the purpose for which the HBOM will be used. An HBOM could potentially be used as a product list to prioritize for Made in America laws and related incentives.

Software

Software has been the focal point of many ICT supply chain risk reduction efforts, and the development and expansion of security initiatives equips developers and producers with recommendations to better secure their systems.

Software Bill of Materials

A Software Bill of Materials (SBOM) is a formal record containing the details and supply chain relationships of various components used in building software, allowing for better visibility into the trustworthiness and security of the overall software stack. These components, including libraries and modules, can be open source or proprietary, free or paid, and the data can be widely available or access-restricted. A more comprehensive understanding of the individual components included in the software helps uncover potential vulnerabilities and allows for a swift response to address the identified threats or vulnerabilities that could put the entire software stack at risk of exploitation.

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[438] "Hardware Bill of Materials Framework for Supply Chain Risk Management," CISA, published September 25, 2023, https://www.cisa.gov/resources-tools/resources/hardware-bill-materials-hbom-framework-supply-chain-risk-management.

In a 2024 study by BlackBerry, 41 percent of organizations request proof of cybersecurity compliance, such as SBOMs, from their supply chain partners, demonstrating an increased reliance on SBOMs to ensure robust supply chain security measures.[439] By highlighting SBOM as a best practice incurring benefits like enhanced recall ability, organizations are also increasing their understanding of risks such as licensing requirements, compliance rules, and developer security and maintenance practices.[440]

CISA is advancing SBOM implementation by promoting SBOM as a transparency and productivity tool throughout the software ecosystem and encouraging widespread adoption for software producers, software selectors, and software operators.[441] DHS is also enhancing and refining SBOM technology and best practices through programs like the Silicon Valley Innovation Program, a DHS Science and Technology Directorate-led initiative that partners with startups to energize the market with SBOM-enabled software supply chain visibility tools.

Secure by Design

The concept of Secure by Design applies to technology products built in a way that reasonably protects against malicious cyber actors gaining access to devices, data, and connected infrastructure.[442] CISA urges software manufacturers to prioritize Secure by Design principles in their 2023 joint guidance, Shifting the Balance of Cybersecurity Risk: Principles and Approaches for Secure by Design Software.

Products designed with Secure by Design principles prioritize the security of customers as a core business requirement, rather than merely treating it as a technical feature. During the design phase of a product's development lifecycle, implementing Secure by Design principles can significantly decrease the number of exploitable flaws prior to entering the market for widespread use.

As of November 2024, 251 companies have signed CISA's voluntary pledge to make a good-faith effort to work towards the following Secure by Design goals: increase the use of multifactor authentication, eliminate default passwords, reduce entire classes of vulnerabilities, increase adoption of security patches, publish a vulnerability disclosure policy, report common weakness enumeration fields, and enable evidence of intrusions.[443,444] Although there is no single solution to end the persistent threat of malicious actors exploiting vulnerabilities in software, Secure by Design principles are proven to help protect against the root causes perpetuating these vulnerabilities.[445]

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439 "The State of Software Supply Chain Security [Research]," BlackBerry, published June 6, 2024, https://blogs.blackberry.com/en/2024/06/supply-chain-cybersecurity-survey-research.
440 "SVIP & CISA: Enhancing Software Security with SBOMs," DHS Science and Technology Directorate, published April 16, 2024, https://www.youtube.com/watch?v=sNjVQaK5QW4.
441 "SBOM FAQ," CISA, accessed December 9, 2024, https://www.cisa.gov/resources-tools/resources/sbom-faq.
442 "Shifting the Balance of Cybersecurity Risk: Principles and Approaches for Secure by Design Software," CISA, National Security Agency, Department of Justice, et al., published April 13, 2023, https://www.cisa.gov/sites/default/files/2023-10/SecureByDesign_1025_508c.pdf.
443 "Secure by Design Pledge Signers," CISA, accessed December 9, 2024, https://www.cisa.gov/secure-design-pledge-signers
444 "Secure by Design Pledge," CISA, accessed December 9, 2024, https://www.cisa.gov/sites/default/files/2024-05/CISA%20Secure%20by%20Design%20Pledge_508c.pdf.
445 "Shifting the Balance of Cybersecurity Risk: Principles and Approaches for Secure by Design Software," CISA, last modified October 25, 2023, https://www.cisa.gov/sites/default/files/2023-10/SecureByDesign_1025_508c.pdf

CISA and FBI's [Product Security Bad Practices] document further articulates certain software development approaches that pose unacceptable risks in 2024.

Secure Software Development

Secure software development practices are equally as important to the Software Development Life Cycle to ensure that the software being developed is well-secured. Stemming from EO 14028, NIST developed and issued SP 800-218, Secure Software Development Framework (SSDF) Version 1.1: Recommendations for Mitigating the Risk of Software Vulnerabilities, which provides a core set of secure software development practices that help software producers reduce the number of vulnerabilities in released software, mitigate the potential impact of the exploitation of undetected or unaddressed vulnerabilities, and address the root causes of vulnerabilities to prevent future recurrences. Executive Order 14028 and OMB memorandum M-22-18 require agencies to only use software from suppliers that attest that the software they provide to the government was developed using NIST's SSDF. The companion NIST SP 800-218A, Secure Software Development Practices for Generative AI and Dual-Use Foundation Models: An SSDF Community Profile, augments the secure software development practices and tasks defined in SSDF version 1.1 by adding practices, tasks, recommendations, considerations, notes, and informative references that are specific to AI model development throughout the software development life cycle.

Software Acquisition Guide

In August 2024, the ICT SCRM Task Force published the Software Acquisition Guide for Government Enterprise Customers: Software Assurance in the Cyber-Supply Chain Risk Management (C-SCRM) Lifecycle.[446] The Software Acquisition Guide focuses on "Secure by Demand" elements by providing recommendations for agency personnel, including mission owners, contracting staff or requirements offices, to engage in more relevant discussions with their enterprise risk owners (such as Chief Information Officers and Chief Information Security Officers) and candidate suppliers, so that better, risk-informed decisions can be made associated with the acquisition and procurement of software and cyber-physical products. The Acquisition Guide builds on existing U.S. Government cybersecurity guidance to address four phases of software ownership: software supply chains, development practices, deployment, and vulnerability management. Importantly, the Acquisition Guide consolidates relevant software assurance guidance and frameworks into a single document and enables stakeholders to easily navigate through these requirements in a clear, concise manner.

Firmware/Internet of Things

Continuous progress has been made to highlight risk mitigation practices that prove effective at reducing risk from persistent threats from firmware, including those affecting Internet of Things (IoT) devices. The IoT Improvement Act of 2020 includes a requirement that U.S. Government entities are prohibited from acquiring IoT products that do not comply with NIST SP 800-213 cybersecurity requirements. Additionally, CISA routinely provides new and ongoing risk mitigation

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[446] "Software Acquisition Guide for Government Enterprise Consumers: Software Assurance in the Cyber-Supply Chain Risk Management (C-SCRM) Lifecycle," CISA, published August 1, 2024, CISA, https://www.cisa.gov/resources-tools/resources/software-acquisition-guide-government-enterprise-consumers-software-assurance-cyber-supply-chain.

best practices, including recent IoT risk resilience and mitigation best practices which often reference Federal interagency guidance:

- Inventory IoT Devices, Systems, and IoT-Related Data*:* Organizations should know and document the number, location, and technical details (e.g., software, firmware, hardware) of the IoT devices and systems across their networks. NIST SP 1800-5 – IT Asset Management provides more information on how organizations can create or augment their asset inventory.
- Include IoT in Risk Management Planning: Organizations using IoT in their ecosystem to collect, analyze, or transmit information should understand and document the potential risks from IoT deployments. Organizations can refer to CISA's Shields Up webpage and CISA's Cybersecurity Performance Goals (CPGs) for recommendations and resources for reducing risks.
- Plan for and Deploy Resilient IoT Systems*:* Organizations should assess the potential for access, tampering, damage, and destruction (human or environmental) of IoT devices and develop security controls relative to the threats. Physical security considerations with IoT can be found in NIST IR 8228 – Considerations for Managing IoT Cybersecurity and Privacy Risks. Example implementations of secure network onboarding and lifecycle management of IoT devices are found in NIST SP 1800-36, Trusted Internet of Things (IoT) Device Network-Layer Onboarding and Lifecycle Management: Enhancing Internet Protocol-Based IoT Device and Network Security.
- Build IoT Security into Acquisition and Vendor Contracts: Organizations can reference NISTIR 8228 to learn about challenges they may face when integrating an IoT device and use this information to inform the device requirements identification process and the subsequent procurement and integration processes. Additionally, NIST 800-213 provides background and recommendations to help organizations consider how an IoT device they plan to acquire can integrate into a system. IoT devices and their support for security controls are presented in the context of organizational and system risk management. CISA's Internet of Things Acquisition Guidance Document also provides information on solutions for common challenges and identifies factors to consider before purchasing or using IoT devices, systems, and services.
- Ensure Appropriate Authentication, Access, and Password Practices: Organizations should build appropriate authentication processes and employ role-based access to devices, systems, and collected data. Organizations may also consider implementing zero trust concepts for their networks and may refer to NIST SP 800-207, draft SP 1800-35, and CISA's Zero Trust Maturity Model.
- Make Data Security and Privacy a Key Component for IoT: Organizations should categorize data based upon sensitivity and impact to operations and then secure data using encryption and access controls, pursuant to the aforementioned recommendations.
- Segment IoT Networks from Critical Networks: Segmenting IoT networks from primary networks and into alternate networks is a key defense tactic against IoT security threats. For further information, reference CISA's graphic Layering Network Security Through Segmentation.
- Regularly Monitor IoT Networks and Sub-Nets: Organizations should ensure IoT devices and networks are included in monitoring and response processes. CISA maintains the authoritative source of vulnerabilities that have been exploited. Organizations should refer to CISA's KEV Catalog.

- Conduct Vulnerability Assessments, Patch and Update IoT Systems: Organizations should continually assess vulnerabilities, update, and patch software and hardware regularly. CISA provides Vulnerability Scanning services to assess the health of internet-accessible assets.

Additionally, NIST publication reports NISTIR 8259 – Foundational Cybersecurity Activities for IoT Device Manufacturers, NISTIR 8259A – IoT Device Cybersecurity Capability Core Baseline, and NISTIR 8259B – IoT Non-Technical Supporting Capability Core Baseline provide recommendations for the manufacturers of IoT products for minimum technical and process-based baseline cybersecurity requirements for IoT products. This baseline has been adopted for consumer products by the FCC's U.S. Cyber Trust Mark program and also for the IoT Improvement Act of 2020. It is important to note that the NISTIR 8259 series is updated regularly to reflect the advancements in technology and the threat landscape.

Challenges and Opportunities

Promoting a more secure and resilient ICT supply chain will continue to require significant effort from the U.S. Government, the private sector, and other non-governmental partners. ICT is a global industry and ICT supply chain vulnerabilities are not confined to the United States. Addressing these challenges successfully will require close coordination and collaboration with international allies and partners. The priority areas described below provide an opportunity to address the vulnerabilities and risks identified in the assessment, and to strengthen supply chain resiliency overall.

Lower production costs available in certain countries can make it challenging for U.S. domestic manufacturing to compete globally. According to International Labor Organization data, the United States has comparatively high hourly labor costs of $42.78 for overall manufacturing activity.[447] Similarly, a 2020 joint study by KPMG and the Manufacturing Institute found that U.S. primary costs (including labor, real estate, energy, corporate taxes, and interest rates) were on average 16 percent higher than in the 16 other markets studied. The United States ranked fifth in the overall cost of manufacturing operations globally.[448]

In addition, efforts to revitalize the U.S. ICT Manufacturing Base must be implemented in a manner consistent with federal human rights protections. Section 307 of the Tariff Act of 1930 prohibits U.S. imports of any product that was mined, produced, or manufactured wholly or in part by forced labor. Forced labor risks exist in many parts of the ICT supply chain, including in the mining of raw materials as well as in manufacturing processes. As of 2018, out of the world's 90 naturally occurring elements, 50 are used in more than 8.5 billion computing devices.[449] The top mining locations for these minerals, such as the Democratic Republic of Congo, China, and Brazil, all have documented cases of forced labor, making it challenging for U.S. manufacturers to source necessary materials while also ensuring their supply chain contains no components sourced from forced labor.[450]

[447] "Statistics on labor costs," International Labor Organization, accessed December 9, 2024, https://ilostat.ilo.org/topics/labour-costs/.
[448] "Cost of manufacturing operations around the globe," Manufacturing Institute, KPMG, accessed December 9, 2024, https://www.themanufacturinginstitute.org/wp-content/uploads/2020/10/cost-manufacturing-operations-globe.pdf, 8.
[449] "What Raw Materials Are Used to Make Hardware in Computing Devices?" Andrew Wheeler, September 29, 2018, https://www.engineering.com/story/what-raw-materials-are-used-to-make-hardware-in-computing-devices.
[450] "Better Trade Tool," United States Department of Labor, published 2021, https://www.dol.gov/agencies/ilab/better-trade-tool.

Engagement with Industry

Since 2021, the U.S. Government has continued to engage the ICT industry on supply chain resilience to promote awareness and adoption of risk mitigation techniques, identify best practices for securing ICT supply chains, and create voluntary mechanisms for improving the sustainability of operations.

For example, the core work of the International Trade Administration (ITA) requires ongoing engagement with private sector stakeholders and conversations include supply chain challenges. The Office of Manufacturing Industries, within the International Trade Administration's Industry and Analysis unit, is the U.S. Government's leading advocate for advancing the competitive position of U.S. manufacturing industries in the global market. The team includes analysts, trade specialists and economists who conduct extensive stakeholder outreach to inform their research and analysis. For each of the three ICT-related supply chain risk assessments conducted by Industry and Analysis (on AI data centers, broadband, and quantum computing), analysts engaged with industry stakeholders to understand specific supply chain challenges they were facing. ITA, together with the United States Trade Representative, also jointly administers, an Industry Trade Advisory Committee on the Digital Economy. This provides an integral link between the U.S. ICT industry and the U.S. Government.

NIST continues to lead the Software and Supply Chain Assurance (SSCA) Forum, which is an international public–private partnership focused on sharing information to better enable organizations to better respond to cybersecurity risks in their supply chains. SSCA Forum events are two to three days long and have been held at least three times per year since 2003. The SSCA Forum provides a venue for government, industry, and academic participants from around the world to share their knowledge and expertise regarding software and supply chain risks, effective practices and mitigation strategies, tools and technologies, and any gaps related to the people, processes, or technologies involved.

Additionally, the various working groups of CISA's ICT SCRM Task Force which is comprised of over 300 members from the private and public sectors, have met approximately 480 times since 2021 to discuss and develop products, tools, and reports that increase ICT supply chain resilience.

Engagement with Allies and Partners

Allies and partners have been essential in U.S. Government efforts to advance ICT supply chain resiliency, security, and diversity for critical products. At the Department of Commerce, this engagement has been complemented by existing bilateral and multilateral dialogues with international partners. The dialogues below are led or driven by Commerce's International Trade Administration. They provide communication channels to tackle issues important to industry. ITA's industry analysts take part in these dialogues to bring industry stakeholder perspective to the conversations and to drive meaningful results that will enhance the competitiveness of U.S. industry:

- South Asia: U.S.–India Commercial Dialogue.
- Southeast Asia: U.S.–Singapore Partnership for Growth and Innovation.
- East Asia and the Pacific: U.S.–Japan Economic Policy Consultative Committee (a.k.a. "Economic 2+2"), Japan–U.S. Commercial and Industrial Partnership, U.S.–Korea Supply Chain and Commercial Dialogue, U.S.–Taiwan Technology Trade and Investment Collaboration, and U.S.–Australia Strategic Commercial Dialogue (SCD).

- Western Hemisphere: Supply Chains Working Group within the U.S.–Mexico High Level Economic Dialogue.
- Europe: U.S.–EU Trade and Technology Council.

Additionally, the Indo-Pacific Economic Framework for Prosperity (IPEF) Supply Chain Agreement includes workstreams on semiconductors as well as critical minerals with a focus on batteries, supply chain logistics, and supply chain data and analytics. Commerce also leads U.S. participation in the Quad Critical and Emerging Technology Working Group.

Additionally, in the context of the EU–U.S. Cyber Dialogue, in 2023 the U.S. Department of Homeland Security and the European Commission's Directorate-General for Communications Networks, Content and Technology announced their intention to launch dedicated workstreams in the fields of Information Sharing, Situational Awareness, and Cyber Crisis Response; Cybersecurity of Critical Infrastructure and Incident Reporting Requirements; and Cybersecurity of Hardware and Software. The workstreams are expected to invite and involve as appropriate other relevant institutions and agencies working on cyber issues, including the European External Action Service, the Directorate-General for Defence, Industry, and Space, and the U.S. Department of State.

CASE STUDY: DFC SUPPORT FOR TELSTRA ACQUISITION OF DIGICEL PACIFIC

DFC cooperated with its Trilateral Infrastructure Partners (TIP) partners, Japan Bank for International Cooperation (JBIC) and Export Finance Australia (EFA), to support Australian telecom company Telstra's acquisition of Digicel Pacific's telecom network and assets. Telstra's acquisition of Digicel Pacific is supporting the delivery of high-quality telecommunication services in the region. Digicel Pacific is the leading telecommunications service provider in the Pacific, holding more than 60 percent market share with over 2.5 million subscribers in Papua New Guinea, Fiji, Vanuatu, Samoa, Tonga and Nauru.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

While the United States remains the leader in design and innovation, ICT component manufacturing is still heavily concentrated in Asia, and this reliance on concentrated manufacturing sources creates a significant risk for global supply chains and U.S. communications infrastructure. While there have been some shifts in production to countries in Asia other than China, many of the inputs and components required for manufacturing and assembly still originate from China. The U.S. private sector and the U.S. Government, and its allies and partners, have identified this risk and have begun to take steps necessary to build a more durable and resilient manufacturing infrastructure, both within the United States and elsewhere.

On the transmission side, the terrestrial U.S. communication infrastructure remains resilient and able to withstand physical and cyberattacks as owners and operators have systems in place to ensure route diversity, redundancy, and protective/restorative measures. The submarine U.S. communication infrastructure has a similar resilience posture but faces additional challenges from the inherent nature of the underwater environment, competition with other industries for seabed use and supply of critical components, and increasing regulatory burdens. On the software side, the ubiquitous use of open-source software requires focused effort to manage risk, as 84 percent of codebases contain at least one known open-source vulnerability and 74 percent of those codebases contain high-risk vulnerabilities.[451] Agencies such as the CISA are working to ensure that software systems, including those that use open-source software, are Secure by Design.

Hardware Production

New capabilities in supply chain data analytics offer insights on supply chain risks for hardware such as fiber optic cable and printed circuit boards.[452] According to Department of Commerce analysis, informed in part by application of the SCALE supply chain analytical tool, fiber optic cable manufacturing shows low levels of resiliency, such as the low adaptability of the sector to market fluctuations, and high vulnerability to adversary industrial strategy, given the industry's geopolitical importance to countries of concern. The Chinese government has included optical communication equipment, such as fiber optic cable, in its plans to upgrade China's manufacturing base.[453] In the case of printed circuit boards, low substitutability means there are few, if any, alternatives available in the case of a supply chain disruption. This is partially because each PCB is custom-made for use, and some types of PCBs are only available from certain manufacturers, who in turn rely on specialized equipment and materials.

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[451] "2024 Open Source Security and Risks Analysis Report." Synopsys, published 2024, https://www.synopsys.com/software-integrity/resources/analyst-reports/open-source-security-risk-analysis/thankyou.html#UXabout2024Ossra.

[452] U.S. Department of Commerce Supply Chain Center, SCALE risk assessment tool. Results for NAICS 335921 (Fiber Optic Cable Manufacturing) and NAICS 334412 (Printed Circuit Board Manufacturing) were selected for SCALE analysis because they directly match the target industries covered in this chapter. Other industries highlighted in this chapter do not fall within a single six-digit NAICS code, on which SCALE analysis is based.

[453] "Made in China 2025," Kennedy, S., Center for Strategic & International Studies, June 1, 2015, https://www.csis.org/analysis/made-china-2025; https://cset.georgetown.edu/wp-content/uploads/t0181_Made_in_China_roadmap_EN.pdf.

The Department of Commerce's Industry and Analysis unit, utilizing the deep industry knowledge of its industry analysts along with the results of the SCALE tool, has also identified the following additional insights on the vulnerability and resilience of several ICT component manufacturing industries:

Computer terminals and peripherals, electronic components, telephone apparatuses, audio and video equipment, printed circuit board assemblies, and printed circuit boards industries are all vital industries in the defense industrial base sectors defined in the FY20 Industrial Capabilities report from the Department of Defense.[454] Each of these ICT industries respectively have been awarded a significant average contract value from 2019 to 2023. Computer terminals and peripherals were awarded on average a contract value of $134.43 million, electronic components awarded on average $1.10 billion, telephone apparatuses $353.94 million, audio and video equipment $113.34 million, printed circuit board assemblies $83.49 million, and printed circuit boards $271.32 million.

In 2017, printed circuit board assemblies contributed 0.0879 percent of the total value added in the U.S. economy. Since then, the industry's contribution to the GDP has grown at a moderate rate of 2.44 percent on average from 2018 to 2021. Other ICT manufacturing industries are growing more rapidly. In particular, the fiber optic cable industry's contribution to U.S. GDP on average from 2018 to 2021 grew at a rate of 5.04 percent while the audio and video equipment industry grew even more dramatically at an average rate of 9.66 percent over the same time frame.

Fiber optic cables, routers, switches, servers, printed circuit board assemblies, audio video equipment, and computer terminals and peripherals all feature heavily in China's Made in China 2025 industrial strategy, while China also provides a significant share of global exports of these products,[455] suggesting that China could further increase its market share to the detriment of U.S. suppliers in these industries.

Finally, printed circuit board assemblies support medical supply chain products that are identified to be on the Critical Medical Device List.[456] The ICT industry is broadly important for public health: according to a survey of medical technology firms, two-thirds of respondent companies have semiconductors and firmware or embedded software in over half of their products.[457]

Transparency

Transparency is critical to ensure supply chains remain resilient in the face of disruptions. As described throughout this Review, the U.S. Government is investing in new capabilities to track supply chain data in the ICT sector and beyond. Recognizing that public–private engagement is

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454 "Fiscal Year 2020 Industrial Capabilities Report to Congress," U.S. Department of Defense, January 14, 2021, https://www.defense.gov/News/Releases/Release/Article/2472854/dod-releases-industrial-capabilities-report/.

455 "Roadmap of Major Technical Domains for Made In China 2025," State Strategic Advisory Committee for Building China into a Manufacturing Superpower, accessed December 9, 2024, https://cset.georgetown.edu/wp-content/uploads/t0181_Made_in_China_roadmap_EN.pdf.

456 "Critical Medical Device List Recommendations Report," U.S. Department of Health and Human Services, accessed December 9, 2024, https://files.asprtracie.hhs.gov/documents/critical-medical-device-list-recommendations-report.pdf.

457 Bill Murray and Stephen Bradley, "The Semiconductor Chip Shortage Hits Medtech: Strategies to Build Resilient Supply Chains," *AdvaMed*, September 23, 2021, Medtech POV Blog, https://www.advamed.org/2021/09/23/the-semiconductor-chip-shortage-hits-medtech-strategies-to-build-resilient-supply-chains/.

another essential means to bolster transparency, government and industry have established many channels to coordinate. At the International Trade Administration, engagement with industry and other stakeholders is ongoing through a wide range of industry engagement including the Industry Trade Advisory Committees (ITACs), Advisory Committee on Supply Chain Competitiveness (ACSCC), the Commerce Department's work with the President's Export Council (PEC), and ongoing industry office outreach.

Domestic Capacity

The United States had nearly 10,000 firms and approximately 820,000 employees involved in computer and electronic product manufacturing in 2022.[458] In 2022, the United States technology sector contributed nearly two trillion U.S. dollars to the country's overall gross domestic product (GDP), making up approximately 9.3 percent of total GDP. The technology sector's yearly share of total GDP has remained relatively consistent since 2018.[459]

At the same time, the United States is a global leader in upstream device design as well as research and development (R&D). As of 2022, firms based in the United States accounted for approximately 42 percent of the worldwide research and development (R&D) spending by hardware companies in the ICT sector.[460] Additionally, five U.S. firms were among the top ten technology hardware and equipment companies with the highest spending on R&D worldwide in 2022.[461]

Trade Concentration

In 2018–2019, the United States placed tariffs on several Chinese goods, many of which include ICT components and equipment. These tariffs contributed to a reduced U.S. trade deficit with China. Although the trade balance with China has decreased, USTR's Four-Year Review of Actions Taken in the Section 301 Investigation: China's Acts, Policies, and Practices Related to Technology Transfers, Intellectual Property, and Innovation points out that indirect trade between the United States and China continues to a degree not evident in official bilateral flows.[462]

The average value of imports from 2018 to 2021 for computer terminals and peripherals and audio video equipment exceeded that of the U.S. domestic production base. For computer terminals and peripherals, average import value during this period outpaced domestic production by a factor of 2:1. For audio video equipment, the disparity was starker, with the U.S. average import value exceeding domestic production by a factor of approximately 8:1.

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458 U.S. Census Bureau, "Manufacturing: Summary Statistics for the U.S., States, and Selected Geographies: 2022," accessed December 10, 2024, https://data.census.gov/table/ECNBASIC2022.EC2231BASIC?q=EC2231BASIC.
459 Statista, "Tech sector as a percentage of total gross domestic product (GDP) in the United States from 2017 to 2022," accessed December 10, 2024, https://www.statista.com/statistics/1239480/united-states-leading-states-by-tech-contribution-to-gross-product/.
460 "Information and communication technology (ICT) research and development (R&D) expenditure worldwide in 2022, by country or region," European Commission, published July 4, 2024, https://www.statista.com/statistics/732308/worldwide-research-and-development-information-communication-technology/.
461 European Commission, "R&D expenditure."
462 "USTR Finalizes Action on China Tariffs Following Statutory Four-Year Review," Office of the U.S. Trade Representative, published September 13, 2024, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/september/ustr-finalizes-action-china-tariffs-following-statutory-four-year-review. See chapter three for a discussion of these trade dynamics.

Across the past five years, computer terminals and peripherals and audio video equipment have diversified their import sourcing to reduce the share of imports coming from countries of concern. For computer terminals and peripherals, the share of imports from adversary countries reduced from 42.8 percent in 2018 to 29.9 percent by 2023, while for audio video equipment the reduction was greater, falling from a 45.5-percent share of imports from adversary countries to a 21.6-percent share by 2023.

Computer terminals and peripherals, audio video equipment, and other key ICT components such as fiber optic cables, printed circuit board assemblies, and telephone apparatuses feature heavily in China's Made in China 2025 strategy to upgrade its manufacturing base. While China continues to hold the largest share of world export value across many of these hardware categories, a healthy diversity of alternative suppliers are available as potential trading partners for the United States to further decouple these imports.

Supplier Diversity

Supplier diversity varies across ICT industry segments. There is a medium amount of supplier concentration for the ICT components examined in this Review, with slightly increased supplier concentration for audio video equipment as well as computer terminals and peripherals. Broadly defined, electronics has more globally concentrated trade than any other manufactured goods sector, due in part to mobile phone and laptop production in China.[463] Limited supplier diversity can make trade disruptions more harmful due to reliance on concentrated sources.

Agility

While very few ICT components are heavily concentrated in a single or few ports, there is nevertheless a medium-high level of natural hazard risk to the varied points of entry. The notable exception to this general diversity of entry ports is for cathode ray tubes, which come in through only a small number of ports.

Conversely, there is heavy concentration of the mode of transportation for audio video equipment, LCDs and other displays, and printed circuit board assemblies. The vast majority of these components are coming into the U.S. by air.

Security

Based in part on information from the Department of Commerce's SCALE tool, the computer terminals and peripherals and electronic components industries reflect low cybersecurity resiliency. Companies associated with these industries have demonstrated high incidence rates of compromised systems and security incidents.

Further, the Department of Commerce assesses medium to medium high risk across ICT components for their vulnerability to climate change. The current landscape of U.S. import sources for these components is moderately weighed towards countries that are both particularly vulnerable

[463] "Global trade: The complication of concentration," McKinsey Global Institute, published January 12, 2023, https://www.mckinsey.com/mgi/Our-Research/The-complication-of-concentration-in-global-trade.

to climate related hazards and possess low readiness to improve their climate change-related resilience measures.

Economic Health and Compliance

With the notable exception of fiber optic cables, ICT components are heavily imported from countries that have low compliance with internationally recognized labor standards outlined by the International Labor Organization. Moreover, U.S. imports of audio and video equipment, printed circuit boards, and telephone apparatuses are especially exposed to risk of forced/child labor due to U.S. import of these products from countries known to use these types of labor in the production process. While the share of U.S. imports coming from countries demonstrating low compliance has reduced over the past five years, in 2023 it was still at a third or more for each of these industries.

For the manufacture of computer terminals and peripherals as well as telephone apparatuses there is a high dependence on high-skilled labor in the industry. For the former this share is 65.9 percent while for the latter it is 52.2 percent of employment in the industry. The large percentage of workers whose role requires either higher education or long-term training makes it more difficult to quickly replace and maintain the industry's workforce. Historically for ICT component industries, there has been a low incidence of domestic labor strikes and lockouts.

Transmission

CISA assesses that U.S. communications infrastructure is resilient and able to endure single physical and cyberattacks as owners and operators have systems in place to ensure route diversity, redundancy, and protective/restorative measures. Communications infrastructure nevertheless faces a variety of risks that can disrupt services on a national level, potentially impacting the confidentiality, integrity, and availability of U.S. communications.[464] While not exhaustive, this assessment identifies core network components whose disruption could cause national level impacts, including:

- Data Center: Facility housing servers, storage infrastructure, and networking devices. Data centers contain IXF, which are critical to operation of core networks. Data center owners and operators ensure redundancy of on-site components.
- IXF: A building or areas within a data center containing communications equipment to facilitate the interconnection of Internet Service Provider (ISP)[465] networks and the exchange of internet traffic. IXFs improve overall internet speed, connectivity, and cost and may include infrastructure from ISPs, Content Delivery Networks (CDNs),[466] Internet Exchange Points (IXPs),[467] and telecommunication networks.[468] IXFs house many different communication provider networks that are operated with separate, segregated network

[464] "Cybersecurity: Internet Architecture is Considered Resilient, but Federal Agencies Continue to Address Risks," U.S. Government Accountability Office, published March 3, 2022, https://www.gao.gov/products/gao-22-104560.
[465] An ISP is a company that provides subscribers with access to the internet.
[466] A CDN is a group of geographically distributed servers that speed up the delivery of web content by bringing it closer to where users are.
[467] An IXP is a physical location through which internet infrastructure companies such as ISPs and CDNs connect with each other.
[468] A telecommunication network supports services such as telephony and data communications access.

infrastructures.[469] This network segregation makes it extremely difficult for malicious actors to execute a cyberattack which would allow them to disrupt operations or move laterally to other networks within an IXF. In general, cyberattacks against IXF-housed systems and networks require a high degree of sophistication and capability and as a result, common attacks such as DDoS are not that effective.[470,471]

- Submarine Cable Infrastructure: Submarine cables serve as the backbone for domestic and international communication and end at cable landing stations (CLSs)[472] near the shoreline. Submarine cables connect to land-based fiber optic cables to carry international traffic domestically. Damage to deep-lying cables can take several weeks to months to repair, depending on the location of the damage, availability and placement of cable repair ships, varying requirements for permits, weather and safety conditions, and other factors. Unintentional disruptions of a single submarine cable are common and communications infrastructure owners and operators have protocols in place to quickly and automatically re-route network traffic through other regional submarine cables until the damaged cable can be repaired. This may strain other submarine cables as their loads increase, potentially increasing latency. Damage to highly utilized cables, cables to/from small islands with fewer alternative systems, or multiple cables simultaneously could force data to be widely re-directed and increase the throughput for other submarine cables, potentially leading to widespread disruption of services dependent on low latency, such as digital payment processing. Additionally, because the cable repair supply chain has been developed to address damage occurring at a "normal" expected rate from non-malicious activity, it is not clear how resilient submarine networks would be to coordinated attacks that target multiple systems. Risk of widespread, multi-system outages are also increased in areas where cables cluster as they traverse chokepoints.
- For cable materials, U.S. manufacturers' generally preferred material, beryllium copper, has been banned in the European Union, so other manufacturers such as HMN Tech, whose predecessor company was majority-owned by Chinese telecom giant Huawei Technologies, have begun moving towards using titanium. U.S. hyperscalers may also have a preference for titanium, given its improved thermal qualities and resistance. Additionally, domestic U.S. cable manufacturers and vendors have expressed concerns about the availability of the high voltage relay supply chain because of competing interests with the electric vehicle market which orders them in exponentially higher numbers. Industry has not experienced a shortage, but could if there is an adverse event or crisis.
- Fiber Optic Infrastructure: Consists of circuit and packet switched networks via fiber optic cable that connect cities within the United States. Fiber optic networks can carry up to 1,000 times more data than traditional copper networks, and devices like transceivers, amplifiers, couplers/splitters, and multiplexers are needed to support the increased bandwidth. Fiber optic cable connects to coaxial and copper networks that comprise private enterprise data and telephony networks, which is the core backbone of the Internet and the public switched telephone network. Damage to a single fiber optic cable will cause minimal disruption and a

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469 "Internet Architecture is Considered Resilient, but Federal Agencies Continue to Address Risks," U.S. Government Accountability Office, March 3, 2022, https://www.gao.gov/products/gao-22-104560.
470 "DDoS Never Dies? An IXP Perspective on DDoS Amplification Attacks," Kopp et al., published March 2021, https://arxiv.org/pdf/2103.04443.pdf.
471 "A study on efficient detection of network-based IP spoofing DDoS and malware-infected Systems," Seo, J. W. and Lee, S. J., published October 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5081987/.
472 The CLS hosts the submarine line terminal equipment that aids in the reception and transmission of data.

temporary, localized outage because communications infrastructure operators have protocols in place to quickly and automatically re-route network traffic. However, if a disruption were to interrupt or damage multiple fiber connections in a concentrated location, consequences would be greater. For example, if a disruption occurs near a major metropolitan area, it could cause widespread internet access disruptions and regional routing failures since most circuit-rerouting paths to bypass a disrupted fiber outage involve another path or route in the same localized area.

- Satellite Infrastructure: U.S. communications infrastructure relies heavily and increasingly on satellite systems for position, navigation, and timing (PNT), Global Position System (GPS), communications, and other functions. The growing use and reliance on satellite infrastructure increases the U.S. communication attack surface and the opportunities for adversaries to corrupt the supply chains that serve them. Older satellites often rely on legacy ground station technology that is challenging for satellite operators to secure, and it is difficult for operators to keep pace with emerging cyber threats to space-based systems.
- Ground Station: A terrestrial facility designed to communicate with satellites and spacecraft. Satellite ground stations rely on land-based fiber optic cables to carry traffic domestically. Unlike terrestrial networks where data is automatically redirected during an outage, a ground station disruption could block access to satellites and greatly increase recovery times. U.S. satellites and the terrestrial ground stations that support them rely on those supply chains to source thousands of parts, manufactured both inside and outside the U.S., offering adversaries opportunities to introduce and later exploit vulnerabilities in satellite infrastructure.[473,474]

Open Source Software

Resources such as CISA's Known Exploited Vulnerabilities (KEV) Catalog or the NIST Vulnerability Database (NVD) track and provide a repository of software vulnerabilities, including those present in Open Source Software (OSS).[475,476] ICT systems commonly rely on OSS both directly and indirectly—when OSS is incorporated by vendors within proprietary software. Vulnerabilities can arise from development mistakes that generate vulnerabilities and from malicious compromises. Examples of such compromises in OSS include embedding cryptominers in open source packages, modifying source code with protestware that deletes users' files, employing

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473 " Job One for Space Force: Space Asset Cybersecurity," Falco, G., Harvard Kennedy School Belfer Center for Science and International Affairs, published July 2018, https://www.belfercenter.org/publication/job-one-space-force-space-asset-cybersecurity.

474 "Defending Spacecraft in the Cyber Domain," Bailey B., et al., The Aerospace Corporation, published November 2019, https://csps.aerospace.org/papers/defending-spacecraft-cyber-domain.

475 "National Vulnerability Database," NIST, last modified August 27, 2024, https://nvd.nist.gov/.

476 "Known Vulnerabilities Catalog," CISA, accessed December 9, 2024, https://www.cisa.gov/known-exploited-vulnerabilities-catalog.

typosquatting to take advantage of human error, and dependency confusion attacks to trick software installer scripts to download malicious code.[477,478,479]

The ICT supply chain's significant reliance on OSS requires governments and ICT manufacturers to continue their efforts to safeguard OSS security. In September 2023, CISA published its Open Source Software Security Roadmap, laying out how CISA is working to help enable the secure use of OSS in the federal government and bolster the security of the broader OSS ecosystem. As part of this work, CISA has structured its OSS security work around addressing two distinct classes of OSS vulnerabilities and attacks:[480]

Cascading Effects of Vulnerabilities in Widely Used OSS

As evidenced by the Log4Shell vulnerability, the ubiquity of OSS can cause vulnerabilities to have particularly widespread consequences. Given the prevalence of OSS across the federal government and critical infrastructure, any widespread vulnerability represents risk that should be reduced. Similar to the potentially large impact of vulnerabilities in widely used closed-source software, the widespread and distributed nature of OSS can magnify the impact of OSS vulnerabilities.

Supply Chain Attacks on Open Source Repositories Leading to Compromise of Downstream Software

The second category of risks is the malicious compromise of OSS components, leading to downstream compromises. Examples include an attacker compromising a developer's account and committing malicious code, or a developer intentionally inserting a backdoor into their package.

In response to high-profile vulnerabilities like Log4shell, the White House convened the Open Source Software Security Initiative (OS3I) interagency working group. The White House released an end-of-year report on OS3I's work, Securing the Open-Source Software Ecosystem, which details how numerous Federal agencies are working hand-in-hand with the open source software community to strengthen the security of the open-source software ecosystem.[481]

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477 "'CuteBoi' Detected Preparing a Large-Scale Crypto Mining Campaign on NPM Users," Aviad Gershon, published July 6, 2022, https://checkmarx.com/blog/cuteboi-detected-preparing-a-large-scale-crypto-mining-campaign-on-npm-users/.

478 "How Shady Code Commits Compromise the Security of the Open-Source Ecosystem," Trend Micro Research, published July 11, 2022, https://www.trendmicro.com/en_us/research/22/g/how-shady-code-commits-compromise-the-security-of-the-open-sourc.html.

479 "What is typosquatting and how typosquatting attacks are responsible for malicious modules in npm," Tal, L., published January 12, 2021, https://snyk.io/blog/typosquatting-attacks/.

480 "CISA Open Source Software Security Roadmap," CISA, published September 12, 2023, CISA Open Source Software Security Roadmap | CISA.

481 "Securing the Open-Source Software Ecosystem: End of Year Report." Open-Source Software Security Initiative, published January 2024, https://www.whitehouse.gov/wp-content/uploads/2024/01/Securing-the-Open-Source-Software-Ecosystem-OS3I-End-of-Year-Report-MASTERCOPY.pdf.

PRIORITIES AHEAD

Introduction

The U.S. may need proactive measures to strengthen certain key ICT sectors, such as the printed circuit board (PCB) industry, in response to China's advancements. Possible enhanced legislative efforts demonstrate a growing recognition of the need for government support. By investing in critical sectors, easing regulations, and collaborating with allies, the U.S. can reinforce its supply chain resilience against anti-competitive practices from countries like China. Importantly, the U.S. Government can continue to bolster ICT supply chain resilience and security by continuing to examine important market and resilience issues through vehicles such as Executive Orders and develop policies and best practices that promote resilience, such as Secure by Design initiatives.

Four-Year Outlook

The United States will likely need to take proactive steps to bolster the U.S. PCB industry and address the non-market policies and practices that China deploys to support its manufacturing base. Legislative proposals like the Protecting Circuit Boards and Substrates Act and recommendations to potentially expand the CHIPS Act to include PCBs indicate an awareness of the potential value of government support.[482] China's strategic goals under its Made in China 2025 plan highlight the urgency for the United States to enhance its manufacturing capacity and defend against anti-competitive policies and practices. By increasing investment in key sectors, easing regulations, and fostering international cooperation with allies, the United States can strengthen its supply chain resilience and mitigate vulnerabilities in critical industries.

Additionally, the U.S. Government should advance supply chain resilience through the ongoing work detailed in various Executive Orders and mandates (including Made in America laws) as well as continue to support software vendors that use secure software development practices through initiatives such as CISA's Secure by Design program.

It is important that the government remain vigilant about the continued threats to ICT resilience and continue to meet these challenges head on by creating new policies or initiatives that respond to the evolving threat landscape as well as continue the mechanisms and mandates already in place to apply steadfast consistency to reduce ICT supply chain threats. To that end, the federal government will continue to focus on these key areas to counter the aforementioned challenges:

Federal Acquisition Security Council (FASC)

The Federal Acquisition Security Council (FASC), established in 2018 by the Federal Acquisition Supply Chain Security Act (FASCSA), had appropriated funds under the 2023 NDAA extending to 2033. The mission of the FASC is to provide leadership and coordination for supply chain risk activities critical to improving the security, reliability, and resiliency of federal ICT systems

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482 "Protecting Circuit Boards and Substrates Act," U.S. Congress, House, HR 3249, 118th Cong., effective May 11, 2023, https://www.congress.gov/bill/118th-congress/house-bill/3249/text; "Assessment of the Status of the Microelectronics Base," U.S. Department of Commerce, Bureau of Industry and Security, accessed December 9, 2024, https://www.bis.doc.gov/index.php/other-areas/office-of-technology-evaluation-ote/industrial-base-assessments.

and acquisition programs. CISA continues to lead the FASC Information Sharing Agency and facilitates the FASC Task Force. The FASC has statutory requirements in additional legislation to include the FASCSA, American Security Drones Act of 2023, and the Secure and Trusted Communications Networks Act of 2019. Under FASCSA, the FASC is responsible for identifying and recommending development by NIST of supply chain risk management practices for executive agencies; identifying and developing criteria for sharing supply chain risk information; and, recommending the exclusion and removal of products, services, and suppliers identified as being high-risk to federal information systems. Additionally, under Section 5949 of the 2023 NDAA, the FASC (to include Commerce, NIST, DHS, and CISA) is responsible for (1) issuing recommendations to mitigate supply chain risks relevant to Federal Government acquisition of semiconductor products and services, and (2) making recommendations to the Federal Acquisition Regulatory Council and the heads of executive agencies for any needed regulations to mitigate supply chain risks.

Executive Order 14028: Improving the Nation's Cybersecurity

Executive Order 14028 was issued in May 2021 to provide a comprehensive and coordinated effort to strengthen the cybersecurity posture of the U.S. Government and its critical infrastructure.[483] The executive order requires software suppliers to attest that the software they provide to the government is developed securely, improves the transparency of where software and its components originate, and provides guidelines for reporting incidents when they occur.

National Security Memorandum 22

As part of the National Security Memorandum (NSM) on Critical Infrastructure Security and Resilience, the Secretary of Homeland Security, acting through the Director of CISA as the National Coordinator for the Security and Resilience of Critical Infrastructure (National Coordinator), is tasked to develop and submit to the president every two years a National Infrastructure Risk Management Plan which will be informed by individual sector-specific risk assessments, risk management plans, and a cross-sector risk assessment.[484] CISA will coordinate with the Sector Risk Management Agencies (SRMAs) to fulfill their roles and responsibilities to implement national priorities and to identify and assess sector and cross-sector risk. As part of the NSM Sector Risk Assessment (SRA) process, each SRMA shall develop sector-specific risk assessments and sector-specific risk management plans. The Sector-specific Risk Assessments identify the most significant critical infrastructure risks to their sector, including key cross-sector risks and interdependencies. The Information Technology and Communications sectors will produce an SRA, which will help to identify and inform ICT supply chain resilience efforts going forward.[485]

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483 The White House, "Executive Order 14028 on Improving the Nation's Cybersecurity," effective May 12, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/05/12/executive-order-on-improving-the-nations-cybersecurity/.
484 The White House, "NSM."
485 The White House, "NSM."

Four-Year Resilience Goals and Priorities

Overview

The U.S. Federal Government should pursue a multi-pronged approach to fortify this sector in the face of future geopolitical headwinds and economic challenges. This will involve a concerted effort comprising investment, research and development, workforce training, engagement with industry, and coordination with allies and partners. They should consider the following priority actions as part of a comprehensive, long-term strategy to increase ICT supply chain resilience:

Goal 1: Develop programs and approaches that support PCB and PCBA industries in the United States

The Defense Production Act funding and other Department of Defense efforts have helped maintain a small domestic PCB industry for secure and trusted PCBs, but this demand alone cannot sustain a robust U.S. PCB industry. The Department of Defense continues to pursue efforts to maintain domestic capability and industry know-how, while pursuing ongoing supply chain assessment and risk management, targeted technology development, and the development of proactive technology assurance measures.

Priority Action 1.1: Encourage a Robust Printed Circuit Board Industry

Some industry leaders have asked for Congress to adopt the House-passed funding at the House-passed funding level of $618.6 million for the Defense Production Act and $1.08 billion for the Industrial Base Analysis and Sustainment program which includes funding for the U.S. PCB industry.[486] Industry leaders have also indicated that tax credits for the purchase or acquisition of PCBs fabricated in the United States could help generate more demand for U.S. manufactured PCBs for commercial purposes. Industry efforts to include PCBs in a CHIPS Act expansion are also underway, aligning with a previous recommendation from the U.S. Department of Commerce.

Goal 2: Enhance the United States' competitiveness in manufacturing communications equipment.

Priority Action 2.1: Strengthen Manufacturing Competitiveness for Fiber Optic Cables

As addressed in the One-year Review of the ICT Industry, China's non-market excess capacity continues to be a concern. When persistent patterns of overinvestment, facilitated by state support, lead Chinese producers to export their goods at low or below-market prices, international competitors may struggle to stay in business. Market-oriented competitors may also opt not to enter particular markets or decline investments they otherwise would make, further concentrating production in China. The Chinese government's Made in China 2025 strategy targets a 60 percent international market share for Chinese optical communications equipment by 2025, and China is

[486] IPC, PCBAA, to House and Senate Committees on Appropriations, published February 6, 2024, [IPC-IndustryLetter_FY24Appropriations.pdf.]()

producing nearly 38 percent of the global research in advanced optical communications.[487] The U.S. Government should continue to engage with the private sector and ensure that federal policies are aligned with manufacturing competitiveness in this industry.

Priority Action 2.2: Foster Resilient Supply Chains for Routers, Switches, and Servers

International trade can provide opportunities to enhance the supply chains for routers, switches, and servers. Further research could study the feasibility of friend-shoring (for example, India, Vietnam, and the United Kingdom are three countries identified for their strengths in communications equipment manufacturing).[488] There is also ongoing work within NIST around cybersecurity requirements for consumer-grade routers and other Internet of Things (IoT) devices.[489] For example, NIST IR 8425, Profile of the IoT Core Baseline for Consumer IoT Products, identifies cybersecurity capabilities commonly needed for the consumer IoT sector and small businesses. Router manufacturers can follow these and other best practices to protect their products from cyberattacks and thus strengthen the overall resilience of ICT networks. IR 8425 will form the basis for the U.S. Cyber Trust Mark labeling program, which could increase the demand for trustworthy products and foster a more diverse supply chain. NIST IR 8425A outlines the recommended minimum requirements and standards for consumer routers.[490]

Priority Action 2.3: Bolster Workforce Readiness in the ICT Sector

Despite new developments in the industry, there is also debate about workforce readiness. While wireless industry representatives noted that workforce shortages have eased, several stakeholders still expressed concerns about the availability of a skilled domestic broadband workforce.[491] The U.S. Government should continue exploring options to strengthen the workforce, including public–private apprenticeship programs.

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[487] "Competing Visions for the Future of the Internet: China's Strategy to Control the Highways of Connectivity," Alex Botting and Ines Jordan-Zoob, Wilson Center, published May 9, 2024, https://www.wilsoncenter.org/article/competing-visions-future-internet-chinas-strategy-control-highways-connectivity.

[488] Consumer Technology Association & Kearney, *Building a Resilient U.S. Consumer Technology Supply Chain* (Consumer Technology Association 2023), Building a resilient US consumer technology supply chain | Kearney.

[489] "Recommended Cybersecurity Requirements for Consumer-Grade Router Products," Fagan, M., Megas, K., Watrobski, P., et al., published April 17, 2024, https://www.nist.gov/cyberframework; https://csrc.nist.gov/pubs/ir/8425/a/ipd.

[490] "Biden-Harris Administration Announces Cybersecurity Labeling Program for Smart Devices to Protect American Consumers," The White House, published July 18, 2023, https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/18/biden-harris-administration-announces-cybersecurity-labeling-program-for-smart-devices-to-protect-american-consumers/.

[491] Meeting between the International Trade Administration and the Wireless Infrastructure Association, July 2024.

Goal 3: Strengthen resilience of end-user devices through policy coordination with allied partners.

Priority Action 3.1: Conduct Further Study on Global Cooperation within the Display Supply Chain

The 2024 U.S. List of Critical Sectors and Key Goods for Potential Cooperation under the IPEF Supply Chain Agreement includes audiovisual technology, particularly displays.[492] More study into the display supply chain, particularly for advanced display technology, is needed as current industry trends indicate the next few years will be critical to avoiding dependency on a single country.

Goal 4: Enable the secure use of open source software through CISA's Open Source Security Roadmap objectives.

Open source software is increasingly vital to the software development market due to efficiency and innovative benefits. This increased reliance on OSS also increases the chances of malicious cyberattacks that target OSS. Aligning with the National Cybersecurity Strategy,[493] between FY 24-26, CISA, given its responsibilities to defend and secure federal government information systems and coordinate a national effort to secure and protect against critical infrastructure risks, will play a key role in enhancing OSS resilience through its *CISA Open Source Software Security Roadmap.*[494]

Priority Action 4.1: Establish CISA's Role in Supporting the Security of OSS

CISA will mature its working relationship with the OSS community to build a secure and resilient open source ecosystem in line with CISA's mission to identify and reduce risks to the federal government and critical infrastructure.

Priority Action 4.2: Drive Visibility into OSS Usage and Risks

CISA will identify the greatest risks of OSS libraries that are most used to support critical functions across the federal government and critical infrastructure and prioritize activities to mitigate and reduce these risks.

Priority Action 4.3: Reduce Risks to the Federal Government

The U.S. Government must establish processes to manage its usage of OSS and means of contributing back to the OSS the United States depends upon.

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492 "U.S. Identifies Critical Sectors and Key Sectors for Potential Cooperation under the IPEF Supply Chain Agreement," U.S. Department of Commerce, published August 23, 2024, https://www.commerce.gov/news/press-releases/2024/08/us-identifies-critical-sectors-and-key-goods-potential-cooperation.

493 The White House, "NSM 22."

494 "Software Security Roadmap."

Priority Action 4.4: Harden the OSS Ecosystem

CISA will advance efforts to harden the broader OSS ecosystem, specifically focusing on OSS components identified in *Priority Action 4.2*.

Goal 5: Encourage hardware and software best practices to ensure more secure products

Priority Action 5.1: Promote Secure by Design Principles

CISA will continue to promote its Secure by Design principles that call for hardware and software vendors to design products out of the box securely and with security features such as multifactor authentication, logging, and single sign on available at no additional cost. CISA encourages all software manufacturers to take the Secure by Design Pledge and demonstrate how they are taking ownership of their customers' security outcomes.

Priority Action 5.2: Provide Tools and Resources to Reduce and Manage Software Vulnerabilities

CISA will continue to provide updates to its KEV catalog - the authoritative source of vulnerabilities that have been exploited in the wild. Organizations should use the KEV catalog as an input to their vulnerability management prioritization framework. NIST will regularly update its NIST Vulnerability Database with standards-based vulnerability management data. Additionally, updates to the Software Acquisition Guide for Government Enterprise Customers: Software Assurance in the Cyber-Supply Chain Risk Management (C-SCRM) Lifecycle will likely occur when the Federal Acquisition Regulation guidance is published, further enhancing the Acquisition Guide's ability to provide enhanced software assurance.

Priority Action 5.3: Promote Cybersecurity Certification and Labeling Initiatives

The Federal Communication Commission's U.S. Cyber Trust Mark program encourages manufacturers to voluntarily adhere to minimum security standards and provides transparency to customers. Additionally, the U.S. Government has signed an agreement with the Euro Commission on a Joint Action Plan to work towards mutual recognition between the U.S. Cyber Trust Mark and the EU Cyber Resilience Act. Both efforts focus on more secure products in the marketplace.

Long-term Resilience Goals

Establishing long-term ICT supply chain resilience will be dependent not only on near-term action to stimulate nascent manufacturing industries, but also forward-looking policy to ensure flexibility and account for contingencies. Input from the private sector is critical in all of these endeavors. In order to achieve success, it will be critical to focus on the following key goals:

- **Revitalize U.S. ICT Manufacturing**: Encourage domestic investment and production of critical ICT products, such as PCBs and semiconductors. Federal procurement and Made in America Laws for both procurement and federal financial assistance are several methods to pursue this objective.

- **Encourage Critical Mineral Production**: To ensure the resilience of the U.S. supply chain and reduce dependence on foreign sources, it is crucial to encourage domestic production of critical minerals. These minerals, such as lithium, cobalt, and rare earth elements, are essential components in ICT technologies ranging from semiconductors to advanced manufacturing. While environmental protection remains a priority, a balanced approach is needed to expedite the responsible extraction of critical minerals.
- **Build Resilience through Secure and Transparent Supply Chains**: Foster supply chain risk management practices by implementing hardware and software assurance best practices in federal procurement, in addition to Made in America laws and tools such as enhanced price preferences and industrial mobilization.[495]
- **Collaborate Internationally for Supply Chain Security**: Enhance international partnerships to secure and diversify supply chains for critical products, improve trade enforcement, and promote participation in global standards development, ensuring shared interests in the ICT sector are advanced.
- **Invest in Future ICT Technologies**: Support research and development (R&D) efforts through federal programs and legislation to bring emerging technologies to market and advance manufacturing innovations.
- **Strengthen the ICT Workforce**: Expand initiatives to attract, educate, and train the ICT workforce by enhancing computer science education and creating multiple pathways, including apprenticeships, technical education, and community college programs. Align grant funding with employer-led partnerships to ensure training meets industry demands.
- **Engage Industry Stakeholders**: Strengthen public–private collaborations to raise awareness and encourage the adoption of risk mitigation strategies and best practices for securing the ICT supply chain.
- **Continue Monitoring the ICT Industrial Base and Assess and Mitigate Supply Chain Risk**: Conduct ongoing studies on critical ICT products like PCBs and related microelectronics to track industry trends and inform future policy planning. Continue regular engagement with stakeholders and trading partners to provide analysis and U.S. Government assistance, as appropriate.

[495] "Strengthening Domestic Sourcing for Critical Items," Office of Management and Budget, effective March 13, 2024, https://www.whitehouse.gov/wp-content/uploads/2024/03/Strengthening-Domestic-Sourcing-for-Critical-Items.pdf.

Conclusion

The resilience of the U.S. ICT sector is vital for both economic stability and national security, and to avoid challenges highlighted by the COVID-19 pandemic. The sector faces vulnerabilities, primarily due to the heavy reliance on foreign manufacturing, especially in Asia, a lack of fidelity in supply chain illumination and transparency as well as cybersecurity risks. However, significant strides have been made through government initiatives like the CHIPS Act, the Bipartisan Infrastructure Law, and various cybersecurity efforts that aim to bolster domestic production and safeguard ICT critical infrastructure. Collaboration between the public and private sectors has also proven essential in addressing supply chain risks and enhancing resilience.

Looking forward, the next four years will be crucial for the U.S. to further strengthen its ICT supply chain. Priorities include increasing domestic manufacturing of printed circuit boards, addressing the non-market policies and practices that China deploys to support its manufacturing base, and continuing efforts to secure both hardware and software systems. Through continued legislative action, investment, and international collaboration, the U.S. can mitigate risks, improve its ICT infrastructure, and ensure long-term supply chain resilience in an increasingly interconnected and digital world.

2021–2024 Four-year Review of Supply Chains for the Semiconductors Sector

U.S. DEPARTMENT OF COMMERCE

DECEMBER 2024

EXECUTIVE SUMMARY

Semiconductor chips are the physical foundation for the binary code that power nearly all digital and consumer electronics goods and services that drive modern life. Semiconductors power virtually every sector of the economy—including energy, healthcare, agriculture, consumer electronics, manufacturing, defense, and transportation.

Given the importance of this sector, in February 2021 President Biden ordered a 100-Day review under Executive Order 14017 to assess risks in the semiconductor supply chain and outline recommendations aimed at addressing those risks.[496] Since the report's release, the U.S. Government worked to address identified risks, including passing and implementing the CHIPS and Science Act of 2022 (CHIPS Act), conducting additional analysis of the domestic industrial base, and enhancing engagements with international partners. During this time the United States has seen over $446 billion in private investment announced by semiconductor and electronics companies since the beginning of the Biden–Harris Administration, catalyzed in large part by public investment.[497]

Challenges and Opportunities: The United States has succeeded in attracting a notable number of new investments, including from all five leading-edge semiconductor companies in the world. Although the current U.S. market share for leading-edge chip capacity remains relatively small, it is projected to increase through the end of the decade as many of these new investment projects complete construction and begin full-scale production. Nonetheless, most leading-edge production capacity, which will be used for advanced technologies such as artificial intelligence (AI) and supercomputing, is likely to remain in Taiwan given TSMC's dominance in the foundry sector. The base for contract outsourced assembly, packaging, and test companies also remains highly geographically concentrated. As such, while progress has been made in diversification of key semiconductor supply chain chokepoints, opportunities to further advance supply chain resiliency exist.

Priorities: The dynamic nature of the semiconductor industry necessitates continued efforts over the next four years to address and achieve the following goals:

- Enhance transparency and traceability of the supply chain;
- Support allies and partners as they grow their capacity to produce critical assembly, testing, and packaging (ATP) inputs;
- Continue to develop domestic initiatives creating a robust talent pipeline covering all skill and educational levels that can meet the demand for the rising number of semiconductor research and development (R&D), design, and manufacturing positions;
- Foster the development of technologies underpinning the U.S. AI ecosystem;
- Ensure a level playing field for U.S. and allied semiconductor manufacturers to drive investment in a resilient and diverse supply of chips that underpin national security and critical manufacturing sectors;
- Continue to execute and expand upon the CHIPS for America Vision for Success.

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496 "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," The White House, accessed January 24th, 2024, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

497 "Investing in America," The White House, accessed on November 25th, 2024, https://www.whitehouse.gov/invest/?utm_source=invest.gov.

SECTOR OVERVIEW

Introduction

Semiconductor chips are the physical foundation for the binary code that power almost all digital and consumer electronics goods and services that drive modern life. Semiconductors power virtually every sector of the economy—including energy, healthcare, agriculture, consumer electronics, manufacturing, defense, and transportation. Their outsized impact on citizens' daily lives became clear during the COVID-19 pandemic. A burst in semiconductor-enabled global communication enabled the video calls and collaborative software that kept critical work and entertainment flowing when public health required social distancing. At the same time, a shortage of chips limited the production of goods like personal vehicles and medical devices.

Against this backdrop, in February 2021 President Biden ordered a 100-Day review under Executive Order 14017 to assess risks in the semiconductor supply chain and outline recommendations aimed at addressing those risks. Since the report's release,[498] the U.S. federal government worked to address identified risks, including passing and implementing the CHIPS and Science Act of 2022 (CHIPS Act), conducting additional analysis of the domestic industrial base, and enhancing engagements with international partners. During this time the United States has seen over $446 billion in private investment announced by semiconductor and electronics companies since the beginning of the Biden–Harris Administration, catalyzed in large part by public investment.[499] This Review showcases the progress made toward strengthening critical semiconductor supply chain segments over the past four years, assesses the current state of supply chain resilience, and lays out a resilience agenda for the next four years.

Sector Overview

The semiconductor industry is a major engine for U.S. economic growth and job creation. Its technology remains key to virtually all sectors of the U.S. economy. In 2023, worldwide demand for semiconductors by end use was: mobile phones (32 percent), computers (25 percent), industrial (14 percent), automotive (17 percent), and consumer electronics (11 percent).[500] By at least one measure, applications that directly support U.S. national security and critical infrastructure make up about nine percent of semiconductor demand.[501] Integrated circuits are a general purpose technology that enhance many types of technologies. Semiconductors and printed circuit boards are essential for the manufacturing of many finished devices that are on the Critical Medical Device List developed by

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498 "BUILDING RESILIENT SUPPLY CHAINS, REVITALIZING AMERICAN MANUFACTURING, AND FOSTERING BROAD-BASED GROWTH: 100-Day Reviews under Executive Order 14017," The White House, accessed January 24th, 2024, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

499 "Investing in America," The White House, Accessed on November 25th, 2024, https://www.whitehouse.gov/invest/?utm_source=invest.gov.

500 "Semiconductor Industry Association Factbook: 2024 Factbook", Semiconductor Industry Association (SIA), accessed October 30, 2024, https://www.semiconductors.org/wp-content/uploads/2024/05/SIA-2024-Factbook.pdf.

501 "Supply Chain Briefing to the U.S. Department of Commerce," Semiconductor Industry Association (SIA), accessed November 13th, 2024.

the U.S. Department of Health and Human Services[502] and to the operation of virtually every military system, including communications and navigations systems as well as important weapons systems ranging from the F-35 Joint Strike Fighter to the Javelin missile. Globally, defense and other government use accounts for approximately one percent of worldwide consumption of semiconductors.[503] Semiconductors are key to the development and operation of the "foundational technologies of the 21st century" identified in the October 2022 National Security Strategy, which include artificial intelligence (AI), biotechnology and biomanufacturing, advanced computing and quantum technologies.[504]

The United States continues to maintain its position as a leader in the global semiconductor sector. Companies headquartered domestically generated $264 billion in sales in 2023, accounting—as they have for the past three decades—for approximately half of worldwide semiconductor revenue.[505]

According to the most recent data from the Bureau of the Census, about 684 firms located in the United States were involved in semiconductor device manufacturing in 2021, and an additional 147 firms manufactured the equipment used to make semiconductors.[506] The majority of these firms are small: only 67 semiconductor device manufacturers and 24 semiconductor machinery manufacturers have 500 employees or more. Measured by value added, however, these two semiconductor industry sectors contributed $39 billion to the U.S. economy in 2021, accounting for approximately 1.4 percent total U.S. manufacturing value added.[507]

The Semiconductor Industry Association (SIA) estimates that the U.S. semiconductor industry contributes $246 billion to U.S. GDP and directly employs around 345,000 workers, with approximately two-thirds (68 percent or 236,000) of this workforce being engaged in semiconductor manufacturing.[508,509] U.S.-based companies maintain approximately half of their facilities internationally, and several large non-U.S. companies have a significant U.S. presence.[510] However, all semiconductor companies rely on a highly globalized supply chain with significant regional concentrations.

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502 "Critical Medical Device List: Summary and Recommendations," U.S. Department of Human & Health Services, accessed November, 29th, 2024, https://files.asprtracie.hhs.gov/documents/critical-medical-device-list-recommendations-report.pdf.

503 Semiconductor Industry Association Factbook: 2024 Factbook", Semiconductor Industry Association (SIA), accessed October 30, 2024, https://www.semiconductors.org/wp-content/uploads/2024/05/SIA-2024-Factbook.pdf.

504 "National Security Strategy", The White House, accessed October 29th, 2024, https://www.whitehouse.gov/wp-content/uploads/2022/10/Biden-Harris-Administrations-National-Security-Strategy-10.2022.pdf.

505 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.

506 Covered by North American Industry Classification System (NAICS) 334413 and 333242, respectively. "2021 SUSB Annual Data Tables by Establishment Industry" (U.S. Census Bureau, December 2023).

507 "2021 Annual Survey of Manufactures (ASM)," NAICS 333242 and 334413 (U.S. Census Bureau, 2022).

508 Dan Martin and Dan Rosso, "Chipping Away: Assessing and Addressing The Labor Market Gap Facing the U.S. Semiconductor Industry", *Semiconductor Industry Association and Oxford Economics*, July 2023.

509 Michael Reid and Falan Yinug, "Chipping In. The Positive Impact of the Semiconductor Industry On the American Workforce and How Federal Industry Incentives will Increase Domestic Jobs", *Semiconductor Industry Association and Oxford Economics*, May 2021.

510 "Assessment of the Status of the Microelectronics Industrial Base in the United States," U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.

Two different business models generally define the way in which semiconductor companies operate. Integrated device manufacturers (IDMs) are companies with vertically-integrated operations that undertake the design, fabrication, and packaging processes internally, although typically in physically separate spaces. In the "fabless-foundry" model, each stage of the production process is conducted by distinct companies, with "fabless" vendors developing semiconductor designs, "foundries" undertaking fabrication activities on behalf of many different design companies, and outsourced semiconductor assembly and test (OSAT) companies performing the finishing steps of assembly, testing, and packaging.

Integrated circuits (ICs), fabrication equipment, testing equipment, and wafers are each featured in the Made in China 2025 Policy, an industrial strategy promoting Chinese high-tech manufacturing and innovation on a global scale. For testing equipment and fabrication equipment, China has not managed to capture a notable share of the global export market. This is not the case for wafers, where from 2018 to 2022 China held an average of 22.1 percent of the global export market, nor integrated circuits, where over the same period China held 19.1 percent of the global export market.

Evolution of the Sector through 2020

The modern semiconductor was first commercialized in 1959 in the United States, as Jack Kilby of Texas Instruments made one of the earliest ICs using germanium and Robert Noyce of Fairchild Semiconductor invented the first true monolithic IC with silicon using the planar process. The U.S. Air Force and NASA were the main consumers of such microchips during the early 1960s. Over the next two decades, IDMs were the dominant business model in the semiconductor industry. By the late-1980s, dedicated IC foundries emerged as a new means of outsourcing the manufacturing of chips, a business model pioneered by the Taiwanese authorities and the Taiwan Semiconductor Manufacturing Company (TSMC). The foundry model allowed manufacturers to achieve efficiency of scale and focus on improving their production processes. Fabless companies, which outsource the fabrication to foundries, prioritized optimizing the design, R&D, and IP development of their products. As the foundry model overtook the IDM model, U.S. share of semiconductor manufacturing drastically declined, due to a combination of labor costs, foreign government support programs, specialization, and innovative business decisions by foreign companies.

The COVID-19 pandemic demonstrated the importance of semiconductors to meet the world's most urgent challenges including their use in enabling technology for finding treatments, caring for patients, working and studying from home, and ordering groceries and other essential products. Shortages of certain semiconductors during the pandemic also revealed the importance of ensuring reliable, resilient supply chains for these vital products. The industry has since recovered from a global chip shortage which occurred in 2021–2022; however, geographic overconcentration of manufacturing in several key supply chain sectors—including leading-edge foundry manufacturing and contract assembly, test, and packaging (ATP)—remains a key challenge to supply chain resiliency. Many of the materials, tools, and equipment used to manufacture semiconductors are also available from limited sources, and the production of leading-edge semiconductors requires multi-billion-dollar investments, thus limiting where these investments can be economically viable.

While the United States maintains a dominant market share in areas such as electronic design automation, design, and equipment manufacturing, the U.S. share of global chip fabrication capacity declined from 37 percent in 1990 to just 12 percent in 2021. As the cost of innovation increased, the semiconductor supply chain became more globalized in search of both specialization and cost-savings in different parts of the world. U.S. companies, including major fabless semiconductor companies, depend on foreign sources for semiconductor fabrication and packaging, especially in Asia, creating a supply chain risk.

Key Sector Trends from 2021 to Present

Since 2021, the semiconductor industry has benefited from an investment boon as economies worldwide have increased public spending on semiconductors, catalyzing hundreds of billions of private sector investments in the industry.

- United States: President Biden signed the CHIPS and Science Act on August 9, 2022, providing incentives for domestic semiconductor manufacturing and programs promoting semiconductor research and development in the United States.
- Europe: In September 2023, the European Union launched its own incentive program with the entry into force of the European Chips Act. The European Chips Act plans to double European chip manufacturing by 2030.
- East Asia: China, Japan, South Korea, and Taiwan all announced billions of dollars' worth of direct funding, loans, and tax credits to semiconductor manufacturing and research and development from 2022 to 2024.

Spurred by these announcements, economies in South Asia, Southeast Asia, and the Americas have also unveiled initiatives to attract semiconductor supply chain investments.

The growing markets for artificial intelligence (AI), automotive, and industrial chips have in part propelled this increased interest in semiconductor industry investments. Strong demand for AI chips is driving competition in the industry as companies vie to develop processors that can compute information more quickly, efficiently, and cost effectively than current market leaders. In August 2024, U.S. imports from Taiwan reached an all-time monthly high due to strong demand for semiconductors that enable AI and high performing computing applications.[511] Auto manufacturers are also demanding more semiconductors to support the production of electric vehicles and to enhance autonomous driving capabilities, increasing competition for the sensor chips and compound semiconductors that will power tomorrow's cars.

[511] "Taiwan exports hit record in August on AI, U.S. reaches record again," *Reuters*, September 9, 2024, https://www.reuters.com/world/asia-pacific/taiwan-exports-hit-record-august-ai-us-reaches-record-again-2024-09-09/#:~:text=In%20August%2C%20exports%20to%20the,previous%20month%27s%20slide%20of%2013.5%25.

PROGRESS TO DATE

100-day Review Priorities

The 100-day Review under Executive Order 14017 released during the United States' recovery from the global pandemic in June 2021 outlined key areas of strength and vulnerabilities in the domestic semiconductor industry.[512] It provided a series of recommendations aimed at bolstering the domestic semiconductor industry:

1. Promote investment, transparency, and collaboration, in partnership with industry, to address the semiconductor shortage. While the private sector must take the lead in addressing the shortage in the near term, the U.S. Government can assist in mitigating the current shortage by redoubling partnerships with industry to facilitate information flow between semiconductor producers and suppliers and end-users; strengthening engagement with allies and partners to promote fair semiconductor chip allocations and increased investment and to increase production; and advancing the adoption of effective semiconductor supply chain management and security practices by companies.

2. Fund the Creating Helpful Incentives for Production of Semiconductors (CHIPS) for America provisions in the Fiscal Year (FY) 2021 National Defense Authorization Act (NDAA), which authorized programs to: (1) incentivize manufacturing through federal financial assistance to construct, expand, or modernize semiconductor-related facilities to support semiconductor fabrication, ATP, and advanced packaging; and (2) advance R&D technology prototyping via a new National Semiconductor Technology Center (NSTC).

3. Strengthen the Domestic Semiconductor Manufacturing Ecosystem through legislative action to implement the ideas put forth in President Biden's American Jobs Plan[513] by providing incentives to support key upstream industries—including semiconductor manufacturing equipment, materials, and gases—and downstream industries to offset high operational costs in the United States; continued support for investment in the United States through programs like the Department of Commerce International Trade Administration's SelectUSA; and support for manufacturing through a new Department of Commerce National Institute of Standards and Technology (NIST) Manufacturing USA Institute, as requested in the President's 2022 Budget.

4. Support Manufacturers, Particularly Small and Medium-Size Businesses via R&D resources to prove emerging technologies and financing to move from the lab to market and address capital needs for growth.

5. Build a Diverse and Accessible Talent Pipeline for Jobs in the Semiconductor Industry through significant investments to grow and diversify the STEM talent pipeline, the Department of Labor's Employment and Training Administration sector-based pathways and training programs,

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512 "BUILDING RESILIENT SUPPLY CHAINS, REVITALIZING AMERICAN MANUFACTURING, AND FOSTERING BROAD-BASED GROWTH: 100-Day Reviews under Executive Order 14017," The White House, accessed August 24th, 2024, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
513 "FACT SHEET: The American Jobs Plan," The White House, accessed September 15th, 2024, https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/31/fact-sheet-the-american-jobs-plan/.

public/private investments to help fund workforce development, and changes in immigration policies to attract the world's best and brightest minds.

6. Engage with Allies and Partners on Semiconductor Supply Chain Resilience by encouraging foreign foundries and materials suppliers to invest in the United States and other allied and partner regions to provide a diverse supplier base, pursuing R&D partnerships, and harmonizing policies to address market imbalances and non-market actors.

7. Protect the U.S. Technological Advantage in Semiconductor Manufacturing and Advanced Packaging by ensuring that export controls support policy actions to address national security and foreign policy concerns related to the semiconductor manufacturing and advanced packaging supply chain and that foreign investment reviews consider national security considerations in the semiconductor and advanced packaging supply chain.

Progress from 2021 to Present

Since the release of the 100-day Review in June 2021, the U.S. Government has worked to address identified risks, including through the passage and implementation of the CHIPS and Science Act of 2022 (CHIPS Act), additional analysis of the domestic industrial base, and enhanced engagements with international partners. Progress since 2021 is as follows:

- **Promote investment, transparency, and collaboration, in partnership with industry, to assess supply chain resilience and address semiconductor shortages**: The Department of Commerce established a Semiconductor Alert Mechanism (SAM) to facilitate information sharing by industry about emerging supply chain challenges. The Department has also established information sharing mechanisms with partners such as the European Union to advance a multilateral response to any emergent crises. On January 18, 2024, the Department of Commerce also issued a Defense Production Act survey to identify how U.S. companies are sourcing mature-node semiconductors, also known as legacy chips.[514] A report showcasing the survey's findings were publicly released on December 6, 2024.[515]
- **Implement the CHIPS Act and Strengthen the Domestic Semiconductor Manufacturing Ecosystem:** With the announcement and subsequent enactment of the CHIPS Act, the United States has seen over $446 billion in private investment announced since the beginning of the Biden–Harris Administration.[516] The law appropriated $39 billion in incentives for investment in commercial manufacturing facilities of semiconductors, equipment or materials in the United States, $11 billion to develop a robust domestic R&D ecosystem, and created a 25-percent investment tax credit for capital expenses for manufacturing of semiconductors and semiconductor manufacturing equipment. In October 2024, the Department of the Treasury and the Internal Revenue Service (IRS) issued final rules for the investment tax credit. The final rules gave taxpayers the clarity needed to

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[514] "BIS DEPLOYS ASSESSMENT ON THE USE OF MATURE-NODE CHIPS", U.S. Department of Commerce, Bureau of Industry and Analysis, accessed December 05, 2024, https://www.bis.doc.gov/index.php/documents/about-bis/newsroom/press-releases/3437-2024-01-18-bis-press-release-legacy-chip-survey-final/file.

[515] "BIS Publishes Assessment on the Use of Mature-Node Chips", U.S. Department of Commerce, Bureau of Industry and Analysis, accessed December 09, 2024, https://www.bis.gov/press-release/bis-publishes-assessment-use-mature-node-chips.

[516] "Investing in America," The White House, accessed on November 25th, 2024, https://www.whitehouse.gov/invest/?utm_source=invest.gov.

continue making and finalizing investments in U.S. semiconductor manufacturing and semiconductor manufacturing equipment. The investment tax credit, along with the $50 billion in CHIPS for America funding administered by the Department of Commerce, are integral incentives to achieve the domestic economic and national security goals. Accordingly, the Department of Commerce and the Department of the Treasury coordinate closely to make sure these incentives—including the national security guardrails—work together. In just over two years since the passage of the CHIPS Act, the Department of Commerce has announced over $36 billion in proposed funding across 20 states, over $10 billion of which has been awarded, and has proposed to invest billions more in research and innovation.

- **Support Manufacturers, Particularly Small and Medium-Size Businesses:** Announced November 19, 2024, Department of Commerce and the Semiconductor Research Corporation Manufacturing Consortium Corporation (SRC) entered negotiations for the Department to provide SRC $285 million to establish and operate a CHIPS Manufacturing USA Institute will dedicate work to developing digital twin technology. The program will establish a shared facility for large and small-to-medium manufacturers that will bolster research aimed at significantly reducing U.S. chip development and manufacturing costs. On September 19, 2024, the Biden–Harris Administration awarded nearly $5 million to 17 small businesses across nine states under the Small Business Innovation Research (SBIR) Program. The SBIR Phase I awards will fund research projects to explore the technical merits or feasibility of an innovative idea or technology for developing a viable product or service for introduction in the commercial microelectronics marketplace.[517]
- **Build a Diverse and Accessible Talent Pipeline for Jobs in the Semiconductor Industry:** The Department of Commerce is committed to ensuring that the semiconductor industry can attract and equip the workforce needed for growing the domestic industry. The Department is allocating workforce funds across its investment portfolio and has announced over $200 million in proposed funding to create and expand workforce training programs and wraparound services for both construction and facilities workers. In addition, the Department of Commerce will make an expected $250 million investment into the National Semiconductor Technology Center's (NSTC) Workforce Center of Excellence over the next 10 years to engage with employers, strategic partners, and stakeholders to better understand the critical needs of the industry and strengthen and expand the semiconductor workforce through education and training and activities that promote effective workforce ecosystems. Through a cross-agency partnership, the U.S. National Science Foundation and the Department of Commerce also signed a non-binding memorandum of understanding to build the National Network for Microelectronics Education, starting with jointly providing $30 million over the next five years to establish and fund the network's coordination hub.
- **Engage with Allies and Partners on Semiconductor Supply Chain Resilience:** Since the release of the 2021 100-day review, the U.S. Government bolstered its work with allies and partners around the world to build resilience in the semiconductor supply chain, both in responding to potential acute disruptions and by addressing institutional vulnerabilities through diversification and global cooperation. For example, the CHIPS Act's International Technology Security and Innovation (ITSI) Fund, which is administered by the Department of State, has thus far partnered with eight countries—Costa Rica, Panama, Vietnam,

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[517] "Biden-Harris Administration Awards nearly $5 million to Small Businesses to Bring New CHIPS Technology to the Commercial Market", U.S. Department of Commerce, November 28, 2024, https://www.commerce.gov/news/press-releases/2024/09/biden-harris-administration-awards-nearly-5-million-small-businesses.

Indonesia, India, Kenya, the Philippines, and Mexico—to promote semiconductor supply chain security and diversification. Bolstered by U.S.-led platforms such as ITSI, many U.S. partners launched roadmaps for attracting semiconductor suppliers that can complement and support new manufacturing investments in the United States. The United States is also cooperating with 13 Indo-Pacific partners on semiconductor supply chain resilience under the IPEF Supply Chain Agreement.

- **Protect U.S. Technological Advantage in Semiconductor Manufacturing and Advanced Packaging:** The Department of Commerce continually assesses and updates export control policies. In October of 2022, the Department began implementing controls on the export of key types of semiconductor-related technologies to China. The Department of Commerce refined and expanded these controls in October 2023 and April 2024. Given the rapidly evolving nature of technology in this space, the Department plans to review these controls annually to assess their impact and ensure long-term effectiveness.

Challenges and Opportunities

Although the United States has succeeded in attracting a notable number of new investments, the United States' market share for leading-edge chip capacity remains relatively small. Most of the fabrication capacity for leading-edge chips, which will be used for the next generation of advanced technologies such as AI and supercomputing, will likely remain in Taiwan despite new investments announced for U.S. advanced chip fabrication. According to one report, TSMC's overseas plants, including its new investments in the United States, Japan, and Germany, will contribute less than 10 percent of the company's global fabrication output.[518] Larger IDMs, including Samsung and Intel, have begun offering contract-foundry services at advanced logic nodes. However, these competitors have struggled to keep pace with Taiwan's dominance in the foundry sector. Reports in November 2024 indicate that Samsung Electronics' Foundry Division plans to shut down about 50 percent of its facilities by the end of 2024,[519] whereas Intel's Foundry unit's revenue declined 8 percent between the third quarters of 2023 and 2024.[520] The base for contract OSAT companies is also highly geographically concentrated. Eight of the top ten OSAT companies are based in Taiwan or China, with the other two headquartered in the United States (Amkor) and Singapore (UTAC).[521] As such, while progress has been made in diversification of key semiconductor supply chain chokepoints, opportunities to further advance supply chain resiliency exist.

Engagement with Industry

In implementing the recommendations of the 100-Day supply chain report, the U.S. Government developed multiple tools to promote transparency and collaboration in partnership with industry in semiconductor supply chains, as detailed on the following pages.

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518 Anton Shilov, "TSMC's overseas expansion will only contribute 10% of the foundry's production capacity: Report" *Tom's Hardware*, June 30, 2024, https://www.tomshardware.com/tech-industry/tsmcs-overseas-expansion-will-only-contribute-10-of-the-foundrys-production-capacity-report.

519 Kim Eun-jin, "SK Hynix to Deliver HBM4 to NVIDIA Six Months Ahead of Schedule - Businesskorea", BusinessKorea, November 11, 2024, https://www.businesskorea.co.kr/news/articleView.html?idxno=228553#google_vignette.

520 "Intel Reports Third-Quarter 2024 Financial Results", *Intel Corporation (INTC),* October 31, 2024, https://www.intc.com/news-events/press-releases/detail/1716/intel-reports-third-quarter-2024-financial-results.

521 "Measuring distortions in international markets", Organisation for Economic Co-operation and Development (OECD), November 21, 2019.

Semiconductor Alert Mechanism (SAM): The Department of Commerce established the SAM to enable early reporting of potential disruptions to the semiconductor supply chain and support faster problem solving through coordination with our trading partners and the private sector. Companies, manufacturers, and other interested parties can submit information regarding any new, ongoing, or potential disruptions to semiconductor manufacturing supply chains around the world. Submitted information helps the Department of Commerce assess bottlenecks and mobilize U.S. Government resources to reduce chokepoint risks.

Industrial Base Surveys: The Department of Commerce issued a request for public comment to facilitate information flow between semiconductor producers, suppliers, and end-users to address the semiconductor shortage.[522] The resulting data provided visibility into levels of demand for semiconductors, which were especially elevated for legacy logic and analog chips.

Following the enactment of the CHIPS Act and based on direction contained in that Act, the Department of Commerce used the Defense Production Act (DPA) to collect data from pertinent companies representing over 95 percent of U.S. semiconductor revenue. The development of this survey was guided by the 100-day review and discussions with experts across the U.S. Government and industry. The resulting report—*Assessment of the Status of the Microelectronics Industrial Base in the United States*—released in December 2023, provided new insights on the resilience of the domestic semiconductor industry.[523]

On the release of this assessment, the Secretary of Commerce announced a follow-up DPA survey on the use of legacy chips and reliance on China-manufactured chips in critical U.S. supply chains.[524] The legacy chips collection was focused on companies in key industries with concentrated use of legacy chips—aerospace/defense, automotive, biomedical, information and communications technology, and industrial—and gathered information on companies' visibility into the origins of semiconductors contained in their products. The legacy chips collection additionally gathered information from chip suppliers with experience using China-based foundries to gain insight into the extent of their use, availability of alternatives, and differences in cost. The results of the survey are informing next steps in building strong, diverse, and resilient semiconductor supply chains.

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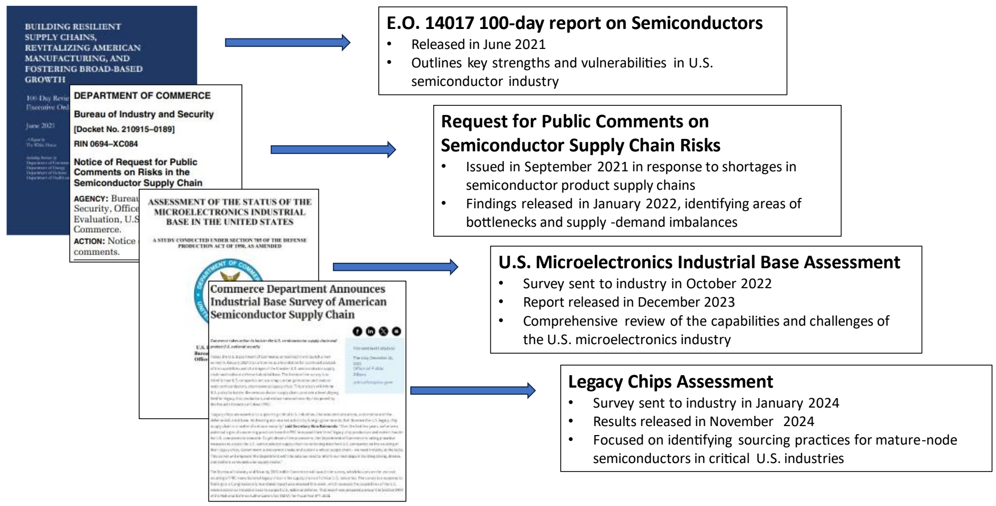
[522] "Federal Register: Notice of Request for Public Comments on Risks in the Semiconductor Supply Chain", The National Archives and Records Administration, accessed December 05, 2024, https://www.federalregister.gov/documents/2021/09/24/2021-20348/notice-of-request-for-public-comments-on-risks-in-the-semiconductor-supply-chain.

[523] "Assessment of the Status of the Microelectronics Industrial Base in the United States," U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.

[524] "BIS DEPLOYS ASSESSMENT ON THE USE OF MATURE-NODE CHIPS", U.S. Department of Commerce, Bureau of Industry and Analysis, accessed November 13, 2024, https://www.bis.doc.gov/index.php/documents/about-bis/newsroom/press-releases/3437-2024-01-18-bis-press-release-legacy-chip-survey-final/file.

Infographic: Recent Commerce semiconductor industrial base studies

Recent Commerce Semiconductor Industrial Base Studies



Proactive Risk Assessment: The Department of Commerce's Supply Chain Center is undertaking proactive risk assessments of the semiconductor supply chain, employing the first-of-its-kind SCALE supply chain risk assessment tool to utilize a comprehensive set of indicators to assess supply chain risks in the semiconductor industry and across the economy, with an emphasis on the national and economic security-related risks most relevant to the U.S. Government. The Department of State is also developing tools to improve semiconductor supply chain mapping to support broader risk assessment efforts in this industry.

Export Control Measures: The Department of Commerce enacted export controls on the most powerful computing capabilities—namely large-scale AI models and very powerful supercomputers, which are built on advanced semiconductors. These capabilities present concerns to U.S. national security given their potential to allow the People's Liberation Army (PLA) to use AI to significantly improve the speed and accuracy of military decision-making, planning, and logistics. They can also enhance cognitive electronic warfare, radar, signals intelligence, and jamming; improve calculations in weapons design and testing, including for weapons of mass destruction (WMD); and create human rights concerns when they are used to support applications like facial or gait recognition surveillance systems for human rights abuses.

The Department of Commerce continually assessed and updated export control policies. In October 2022, the Department began implementing controls on key types of semiconductor-related technologies to the PRC. The Department of Commerce refined and expanded these controls in October 2023 and April 2024. Given the rapidly evolving nature of technology in this space, the Department plans to review these controls annually to assess their impact and ensure long-term effectiveness.

Assistance for Downstream Industries: The Department of Commerce leveraged its industry relationships to engage companies in several industries dependent on semiconductors to connect those companies with semiconductor fabricators and manufacturers. For instance, several U.S. medical technology companies reached out to the Department of Commerce for assistance in identifying partners from which they could obtain legacy semiconductors during a period of acute shortage in 2021–2022. The Department worked across teams to assist these medical technology companies in obtaining needed semiconductors for products such as ventilators, MRI machines and CT scanners. Although medical technology end uses account for only 1–2 percent of total semiconductor purchases, helping manufacturing facilities work at full capacity allowed these products to assist many U.S. citizens address serious health conditions during the COVID-19 pandemic.

CHIPS R&D Programs: The Department of Commerce continues to make significant progress advancing the four historic R&D programs created by the CHIPS and Science Act's $11 billion in funding: 1) the CHIPS National Semiconductor and Technology Center (NSTC); 2) the CHIPS National Advanced Packaging Manufacturing Program (NAPMP); 3) the CHIPS Manufacturing USA Program; and 4) the CHIPS Metrology Program. The CHIPS R&D programs, informed by industry's needs, deliver strategic investments complementing targeted incentives that will not only bring semiconductor manufacturing back to the United States, but keep it here for good with a robust R&D ecosystem.

The Department of Commerce expects to invest over $5 billion of CHIPS funds in the NSTC over the next decade. The NSTC was established as a public–private consortium by the Secretaries of Commerce, Defense, and Energy, the Director of the National Science Foundation, and the CEO of Natcast. Operated by Natcast, a purpose built non-profit, the NSTC brings together government, industry, customers, suppliers, educational institutions, entrepreneurs, and investors to accelerate the pace of new innovations from idea to marketplace.

Address Metrics and Analytics Challenges: The Department of Commerce's CHIPS Metrology Program is building partnerships between researchers and industry to address the microelectronics industry's grand challenges and has already funded over $210 million across over 55 projects to develop new instruments, methods, data analysis, models, and simulations. The CHIPS Metrology Program aligns its R&D portfolios based on the needs of NIST's "strategic" seven grand challenges[525] and leverages NIST's proven measurement science expertise to conduct research on measurements that are accurate, precise, and fit-for-purpose for the production of microelectronic materials, devices, circuits, and systems.

Engagement with Allies and Partners

Since the release of the 2021 100-day Review, the U.S. Government bolstered its work with allies and partners around the world to build resilience in the semiconductor supply chain, both in responding to potential acute disruptions and by addressing institutional vulnerabilities through diversification and global cooperation.

Under the U.S.–EU Technology and Trade Council (TTC), the United States and European Union established a joint early warning mechanism for semiconductor supply chain disruptions and a transparency mechanism for reciprocal sharing of information about public support provided to the

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525 U.S. Department of Commerce National Institute of Standards and Technology, "NIST Report Outlines Strategic Opportunities for U.S. Semiconductor Manufacturing", September 1, 2022**,** https://www.nist.gov/news-events/news/2022/09/nist-report-outlines-strategic-opportunities-us-semiconductor-manufacturing#:~:text=Six%20of%20the%20seven%20grand,supply%20chain%3B%20improving%20tools%20for.

semiconductor sector. These arrangements formalize lines of communication to rapidly respond to potential supply chain disruptions and enhance transparency of public support provided to the semiconductor sector.

The United States is working with the G7 Semiconductor Point-of-Contact Group established in 2024 to share information between key allies about policies to promote a resilient semiconductor supply chain globally.

The U.S. Government holds regular bilateral and multilateral dialogues focused on semiconductor supply chain resiliency with international partners whose territories contain three-fourths of the world's semiconductor production capacity. These engagements include the U.S.–India initiative for Critical and Emerging Technology, Japan–U.S. Commercial and Industrial Partnership (JUCIP), U.S.–Korea Supply Chain and Commercial Dialogue (SCCD), U.S.–Korea–Japan Trilateral, U.S.–Australia Strategic Commercial Dialogue (SCD), U.S.–Singapore Partnership for Growth and Innovation (PGI), U.S.–Singapore Critical and Emerging Technology Dialogue, and the U.S.–Taiwan Technology Trade and Investment Collaboration (TTIC) Framework. These engagements foster collaboration and exchange of best practices on research priorities, semiconductor investments, workforce development, private sector cooperation, and crisis management.

The United States is working with partners, particularly those in IPEF and APEP, to develop attractive semiconductor ecosystems to diversify conventional ATP and materials supply chains that are capable of supporting investments coming online in the United States. At the September 2024 IPEF Supply Chain Council meeting, the Council established an Action Plan team on semiconductors, which will develop actionable recommendations aimed at increasing the supply chain resilience and competitiveness of critical sectors and key goods of mutual interest among IPEF countries.

The State-managed ITSI Fund, in partnership with the Organization for Economic Co-operation and Development (OECD), manages a semiconductor forum building collaboration among 50 economies. The forum is key to exchanging information on investments in the semiconductor sector and has published a taxonomy that streamlines data exchange and early warning communication between members.

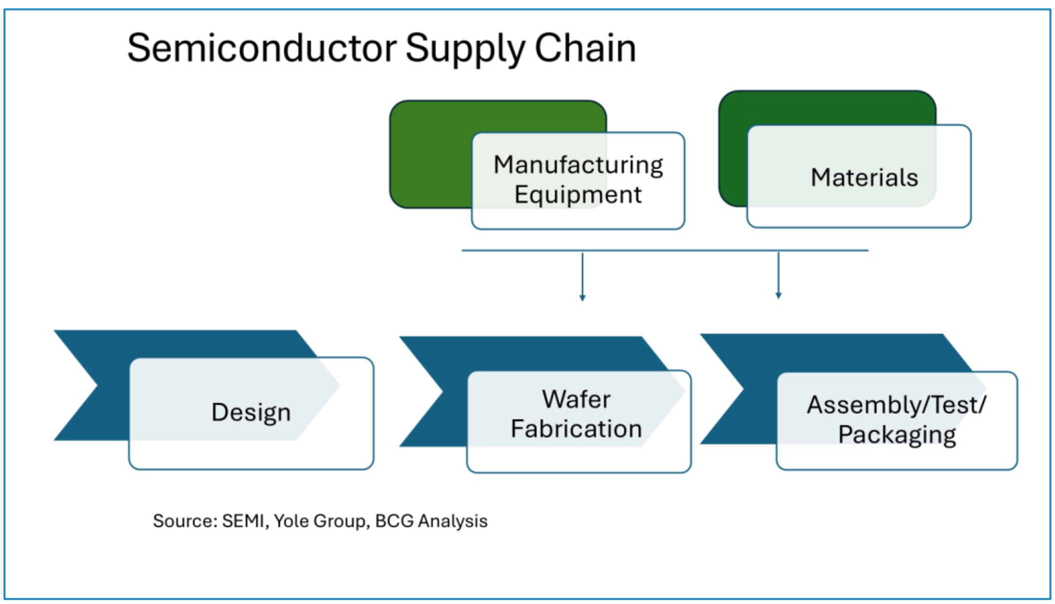
At the tenth North American Leaders Summit (NALS) in January 2023, the United States, Canada, and Mexico committed to strengthening and expanding strategic supply chains in and across North America as part of the competitiveness pillar. In May 2023, Secretary Raimondo participated in the first-ever trilateral semiconductor forum with industry, academia, and cabinet-level officials from all three governments in Washington, D.C., to inform policies and encourage increased investment in semiconductor supply chains across North America. The Department of Commerce is also working on a mapping exercise with Canada and Mexico to outline and identify existing areas of strength, opportunities for complementary growth/expansion, existing areas of weakness, and ways to fill gaps and mitigate vulnerabilities in the semiconductor supply chain.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

The U.S. semiconductor supply chain is on track to be both more globally diversified and more dependent on domestic sources than in the pre-COVID-19 period. This has been the result of the passage and implementation of the CHIPS Act, enhanced analysis of the domestic industrial base, and augmented engagements with international partners and industry stakeholders over the last four years. Between 2013 and 2022, for instance, private sector investment in wafer fabrication reached $720 billion. Two years after the enactment of the CHIPS Act, these global investments are now projected to reach around $2.3 trillion by 2032, and the United States is expected to capture 28 percent of these capital expenditures, compared to just 9 percent had the pre-CHIPS Act pace of investment continued. [526] Nevertheless, continued work will be necessary to build upon these efforts and address the long-standing and new risks that characterize this dynamic and globally integrated industry, including global supply concentration of critical inputs, the disruption of emerging technologies, workforce needs, and natural hazards.

The Department of Commerce's supply chain risk assessment framework (SCALE) has been employed to inform the risk assessment of the semiconductor supply chain. The SCALE tool compares industries across the U.S. goods economy and diagnoses structural risks to their supply chains to inform and help prioritize U.S. Government efforts to reduce risk and improve resilience and expand engagement with industry on supply chain risk. Such risks are assessed across several categories that characterize industries' risks, including criticality, vulnerability, and resiliency.



[526] Varadarajan et al. "Emerging Resilience in the Semiconductor Supply Chain", (Semiconductor Industry Association and Boston Consulting Group, May 2024)

Transparency

According to industry stakeholders, end-product manufacturers often find it difficult to discern from where the chips they source originate or whether they are prone to supply chain and security vulnerabilities. Equipment and electronics manufacturers source from a complex network of upstream vendors, distributors, and assemblers, which obscures the exact origins of the semiconductors in their products. Traceability is especially lacking for mature-node semiconductors that, by volume, comprise most of the semiconductors consumed by the defense, transportation, medical, and telecommunications sectors. These semiconductors are in some cases substitutable and sold off-the-shelf from distributors, with cost being the main differentiator. Moreover, the sourcing of a product's semiconductors can provide a comparative advantage for a company. This incentivizes end-product manufacturers to conceal their supply chains and keep their intellectual property from being replicated by competitors. This lack of transparency into the origin of chips for critical U.S. Government infrastructure poses considerable risks to U.S. national security and supply chain resiliency.

Agility

While imports across semiconductor associated products are not overly concentrated in their port of entry to the United States, there is a medium high risk of natural hazard disruptions occurring at most ports importing wafers and certain optical instruments for testing. For fabrication equipment, the level of risk of natural hazard disruptions at most ports is high.[527]

Conversely, there is more acute risk to a subset of these products due to their heavy use of air transportation into the United States. Both dynamic random-access memory (DRAM) integrated circuits (ICs)—which are used to store data—and optical instruments for inspecting wafers are imported almost entirely via air, making these products' supply chains especially vulnerable to disruptions to this mode of transportation.

Security

The Department of Commerce has not identified a high cybersecurity risk associated with either semiconductor and related device manufacturing or the semiconductor machinery manufacturing industries. Public companies associated with these two industries have not demonstrated high incidence rates of compromised systems or other security incidents.

Further, the Department assesses medium risk across wafers, fabrication equipment, ICs, and testing equipment for their vulnerability to climate change.[528,529] The current landscape of U.S. import sources for these components is moderately weighed towards countries that are both particularly vulnerable to climate related hazards and possess low readiness to improve their climate change-related resilience measures.

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527 A "significant risk" is derived from SCALE internal risk assessment quantitative modeling and entails that there is low confidence that sector supply chain will be able to meet demand.

528 A "medium risk" is derived from SCALE internal risk assessment quantitative modeling and entails that there is reasonable to strong confidence that sector supply chain will be able to meet demand.

529 See fabrication; assembly, test, and packaging (ATP), and manufacturing equipment for more details about wafers, fabrication equipment, ICs, and testing equipment

Economic health and compliance

The Department of Commerce identifies the financial health of the public companies in this sector to be relatively weak. Semiconductor machinery manufacturing companies have an especially low firm level current ratio, a measurement of liquidity, indicating that these companies are on average less capable of paying short-term obligations and at higher risk of experiencing liquidity issues. This observation carries through, though to a lesser extent, for public companies manufacturing semiconductors and related devices.

Imports of wafers and integrated circuits both carry with them the risk of child or forced labor having been employed in the supply chain. Section 307 of the Tariff Act of 1930 prohibits U.S. imports of any product that was mined, produced, or manufactured wholly or in part by forced labor. Moreover, a notable percentage of U.S. imports of both products come from countries known to use these types of labor in the production process.

For the semiconductor and related device manufacturing industry, 43.4 percent of the workforce is employed in a high-skilled occupation, according to data from the Bureau of Labor Statistics.[530] Nearly half of the employment in this industry requires either higher education or long-term training. This makes it more difficult to quickly replace and maintain the industry's workforce in the event of a disruption.

While some resiliency and vulnerability assessments can be made across the semiconductor supply chain as a whole, since the United States' role in the semiconductor industry varies across the different stages of the production process, the report will also consider each of the five segments that comprise the industry: design; fabrication; assembly, test, and packaging (ATP); input materials; and manufacturing equipment:

Design

Overview

During this initial phase of semiconductor production, the desired functionality, performance, capabilities, and objectives of the chip are determined, along with the blueprint of circuits needed to achieve those objectives. Design activities are carried out by specialized "fabless" semiconductor design companies, which do not have manufacturing capabilities, and by IDMs.

The 100-Day review of risks in the semiconductor supply chain identified several vulnerabilities in the U.S. semiconductor design ecosystem, including: a reliance on limited sources of Intellectual Property (IP) cores; labor-related constraints such as a shortage of skilled workers and an increasing dependance on foreign labor and design teams based outside the United States; and a dependence by U.S. fabless companies on foundries primarily located in East Asia to manufacture their products. While the U.S. semiconductor design ecosystem remains robust and the investments catalyzed by the CHIPS Act established a foundation to help address existing risks in the semiconductor industry, additional progress remains to be made to ensure the long-term resilience of the domestic fabless sector.

[530] U.S. Bureau of Labor Statistics, "Occupational Employment and Wage Statistics", https://www.bls.gov/oes/.

Domestic capacity

The United States continues to have world-leading design capabilities with 27 percent of the world's design facilities and 32 percent of design engineers.[531] As of 2022, U.S.-headquartered companies held 51 percent of the global design market by revenue,[532] with U.S.-based fabless companies accounting for nearly three-quarters of global fabless revenue.[533] U.S. companies have a ubiquitous presence in the design of central processing units (CPUs) and graphics processing units (GPUs), with companies such as Intel, Qualcomm, Apple, NVIDIA, and AMD commanding leading shares in these segments. The United States also remains a world leader in two design-enabling segments: (1) Intellectual Property (IP) cores—licensed blocks of proven circuit layouts to perform a given function—and (2) electronic design automation (EDA) software—programs that assist designers in mapping millions or billions of patterned circuits. In 2022, the United States accounted for 68 percent of the total value added in IP cores and EDA.[534]

Trade concentration

Some foreign players play key roles in the design market in specific sub-sectors. As of 2021, Korean-headquartered semiconductor companies maintained a 59-percent market share of memory-related design revenues, largely driven by IDMs.[535] Meanwhile, the European and Chinese industries play a notable role in the design market for discrete, analog, and other (DAO) chips at 18 percent and 13 percent of global revenues, respectively.[536] The United States maintains 65 percent of global market share in the logic design sector as well as 68 percent of global market share in the EDA and Core IP sectors.[537]

Supplier diversity

Although a large share of design segment market share is held by U.S.-headquartered companies, the breakdown of physical design activity across the globe is highly diversified. The United States is home to 27 percent of the world's design facilities, 21 percent of facilities are in Europe, 12 percent are in China, 7 percent are in India, 6 percent are in Taiwan, 4 percent are in South Korea, and 23 percent are elsewhere globally. As such, the physical design activity location segment is notably diversified.[538] As design costs at the cutting edge continue to rise, the ability of design companies to continue to invest in R&D continues to depend on sales growth, largely outside of the United States.

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[531] Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.
[532] Ibid.
[533] "Assessment of the Status of the Microelectronics Industrial Base in the United States," U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.
[534] Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.
[535] Ramiro Palma et al. "The Growing Challenge of Semiconductor Design Leadership", *Semiconductor Industry Association and Boston Consulting Group*, November 2022.
[536] Ibid.
[537] Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.
[538] Ibid.

Security

Hardware design threats can be introduced at various stages of the design flow, whether unintentional design flaws that can be created by synthesis and optimization processes or intentional malicious modifications introduced during the design phase.[539] While widescale security flaws and instructions have not been reported in the design phase, significant vulnerabilities remain across this step of the value chain. Design companies must work with manufacturers to ensure that both parties are responsible for security threat detection. Companies can work with governments, standards institutes, researchers, and other business representatives across the industry to build consensus and collaboration in order to develop industry-wide approaches to ensure security across all stages of the design process.

Economic health and compliance

The People's Republic of China' (PRC)'s National Integrated Circuit Funds I, II, and III have allocated billions of dollars of support to develop new domestic design and EDA capabilities since 2014. Such level of state-directed support threatens to disrupt the design market and jeopardize U.S. companies' competitiveness over the long term. Already, there are over 3,000 fabless design companies in China. Several of the country's manufacturers in the automotive and mobile device sectors are establishing units to design custom semiconductors. [540] Some Chinese companies have reportedly created EDA tools capable of designs at line-widths above 14 nanometers (nm).[541] The PRC also prioritized support for the open-source RISC-V instruction set architecture, believing this tool has advantages that could allow Chinese entities to commercialize associated technologies ahead of the United States and other economies.[542]

Other countries are also seeking to compete with the United States in the design segment through increased government subsidies. India is providing $600 million worth of preferential tax treatment for design-related activities through its Design Linked Incentive Program. South Korea pledged $1.3 billion over ten years to support AI and power chip design.[543] The advent of generative AI is increasing demand for specialty semiconductors, including AI accelerators, opening the door to new design vendors from regions that also have a robust pipeline of engineers or whose governments are supporting the development of design capabilities in this technology space.[544]

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539 Securing the Chip Design Flow to Tackle Cyber Threats and Ensure Hardware Integrity | (SEMI, February 2024).

540 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.

541 Triolo, Paul. "A New Era for the Chinese Semiconductor Industry: Beijing Responds to Export Controls" *American Affairs Journal* February 2024.

542 Cheung, Sunny. "Examining China's Grand Strategy For RISC-V" (The Jamestown Foundation, December 2023)

543 Ramiro Palma et al. "The Growing Challenge of Semiconductor Design Leadership", *Semiconductor Industry Association and Boston Consulting Group*, November 2022.

544 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", Semiconductor Industry Association and Boston Consulting Group, May 2024.

Fabrication

Overview

In the fabrication stage, designs are etched into wafers—typically silicon—through a process that can encompass between 400 and 1,400 steps and take 14 to 20 weeks to complete. The fabrication facilities, or "fabs," are the most capital-intensive segment in the value chain, as they require highly specialized equipment and inputs.[545] Fabs can be owned by IDMs making their own chip designs or by contract manufacturing foundries that only fabricate other companies' designs.

The perceived technology generation to which a semiconductor belongs is often determined by the physical size of its circuit layouts, called a "node." There are no exact definitions for categorizing each generation of node and the semiconductor industry famously sharply increases the performance of its products roughly every two years. For this Review, references to leading-edge nodes are those that are below 7 nanometers (nm) and current generation chips are considered to have nodes between 10 and 26 nm. Legacy, or mature nodes refer to chips produced at 28 nm and above.

Leading-edge logic semiconductors are the highest value chips and are used in the most advanced technology applications and emerging industries, including AI, Internet of Things (IoT), and mobile communication devices. In other segments of the industry, such as memory or analog chips, leading-edge technology may rely more on specialized design or materials rather than the node on which a chip is produced. Legacy chips comprise the majority of semiconductor production volume and are broadly used in critical and consumer-facing industries including defense, transportation, medical devices, and telecommunications.

Domestic capacity

In 2023, U.S.-based companies accounted for 10 percent of the global wafer fabrication capacity, down from 12 percent in 2019 as other countries continued to build fabs at a faster rate.[546] Thanks to its robust IDM-based fabrication capacity, the United States has strong production capabilities in current generation logic and analog semiconductors, and a small but important manufacturing footprint in the memory segment.

However, in 2023 the United States lacked fab capacity at the most advanced technology nodes and was losing global market share in mature node logic chips. Through the implementation of the CHIPS Act of 2022, the U.S. Government is working to reverse these trends. The law appropriated $39 billion to incentivize investment in commercial facilities for manufacturing semiconductors, equipment, and materials in the United States. Its implementation and expected impact are already changing the outlook of the industry. One analysis estimates that, without investments supported by the CHIPS Act, the U.S. share of global capacity would have continued to slowly decrease to 8

[545] Ramiro Palma et al. "The Growing Challenge of Semiconductor Design Leadership", Semiconductor Industry Association and Boston Consulting Group, November 2022.
[546] Estimate based on output capacity aggregated at the national level. SEMI, "World Fab Forecast—2Q 2024," June 7, 2024.

percent by 2032.[547] However, since the start of the Biden–Harris Administration, semiconductor companies including IDMs and foundry operators planned or announced over $446 billion worth of new domestic semiconductor projects.[548]

With the CHIPS Act's investments, the United States is now projected to produce approximately 20 percent of the world's leading-edge logic chips by 2030, up from zero produced today.[549] A total of approximately 21 additional new fabs and production lines are expected to come online by the end of the decade. [550]The new fabs built will spur the growth of regional industry clusters, or geographically compact areas with multiple commercial scale fabs owned and operated by one or more companies; a large, diverse, and skilled workforce; nearby suppliers; R&D facilities; utilities; and specialized infrastructure. Each cluster will have the scale, infrastructure, and other competitive advantages required to ensure that chipmakers view continued expansion in the United States as economically attractive and core to their business models.[551]

Overall, the United States is now projected to grow its share of global semiconductor capacity to 14 percent by 2032, [552] tripling its domestic semiconductor manufacturing capacity in wafers per month from 2022 to 2032. The United States attracted production expansions from all five of the world's leading-edge logic, memory, and advanced packaging companies. No other economy in the world has more than two of these companies producing leading-edge chips on its shores.

Supplier diversity

Until recently announced investments begin full-scale production, leading-edge foundry capabilities inside the United States will remain limited. Global revenue from semiconductors designed to execute AI workloads is expected to total $71 billion in 2024, an increase of 33 percent from 2023.[553] Leading-edge fabrication and advanced packaging capabilities able to produce AI chips will continue to be concentrated in East Asia, leaving the supply chain less resilient to supply chain disruptions. In addition to Samsung, TSMC remains the largest manufacturer of chips capable of enabling cutting edge AI applications. However, TSMC's advanced fabrication and packaging capabilities are reportedly already booked through 2026,[554] and other leading-edge manufacturers are still working to secure customers and enable their own capacity over the next several years, indicating tight supply. Risk assessments by the Department of Commerce also find notable environmental risks, given that TSMC's fabs in Taiwan are not fully shielded from natural disasters and the effects of climate

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547 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.
548 The White House, "Investing in America," Accessed on November 25th, 2024, https://www.whitehouse.gov/invest/?utm_source=invest.gov.
549 Estimate based on forecasted output capacity aggregated at the national level. SEMI, "World Fab Forecast – 2Q 2024," June 7, 2024.
550 Estimate based on output capacity aggregated at the national level. SEMI, "World Fab Forecast – 2Q 2024," June 7, 2024.
551 U.S. Department of Commerce, "Vision for Success: Commercial Fabrication Facilities," February 2023.
552 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", Semiconductor Industry Association and Boston Consulting Group, May 2024.
553 Gartner. "Global Forecast Worldwide Semiconductor Revenue to Grow 17% in 2024". Gartner Forecasts Worldwide Semiconductor Revenue to Grow 17% in 2024.
554 Gareffa Anthony, "TSMC's 3nm process production lines booked through 2026: Apple, Qualcomm, NVIDIA, and AMD" *TweakTown*, June 10, 2024, https://www.tweaktown.com/news/98758/tsmcs-3nm-process-production-lines-booked-through-2026-apple-qualcomm-nvidia-and-amd/index.html.

change, and imports tend to arrive through West Coast ports with moderate vulnerability to natural hazards.

To date, the CHIPS Act has allocated more than $3.5 billion to increase the domestic production of legacy chips. Despite those investments, the global share of production capacity for legacy node chips is projected to steadily increase in East Asia. China increased its global legacy logic capacity share to 38 percent in the second quarter of 2024, up from 29 percent since the 2021 report.[555] PRC provides pervasive subsidies in pursuit of industrial policy targets that enable chip companies headquartered there to offer, on average, 20 to 30 percent lower prices compared to their non-Chinese competitors.[556] This can crowd out legacy chip production in other countries.

Agility

Additionally, transportation in supplier countries can be a risk, particularly in less developed economies. As fabs rely on both raw materials and finished goods coming from global sources, they need dependable access to major ports and airports to quickly export and import materials. Even fabs located near airports need to have strong transportation infrastructure for last-mile transportation, including roads for trucks to move between the fab and the airport. Transportation infrastructure is vulnerable to disruption through natural disasters and geopolitical crises, among other risk factors.

Economic health and compliance

New investments in the U.S. fabs will require employees to fill approximately 67,000 positions in the semiconductor industry by 2030 across all skill and educational levels.[557] A labor market gap could keep the industry from achieving and leveraging its full potential and undermine the long-term success of U.S. efforts to enhance the supply chain resilience.

Assembly, Testing, and Packaging (ATP)

Overview

After the "front-end" fabrication referenced in the previous section, wafers become finished chips through the "back-end" process of assembly, test, and packaging (ATP). Printed wafers are sliced into individual pieces of silicon—called dies—which are in turn enclosed in a protective container that provides power and signal interconnects to enable the integrated circuit to be incorporated into a larger electronic device. Chips are also rigorously tested for functionality at multiple stages before being shipped to electronic device manufacturers.[558]

The semiconductor packaging process encompasses many technologies broken into two broad categories: conventional and advanced packaging. Conventional packaging techniques focus on

555 Estimate based on data from the SEMI, "World Fab Forecast – 2Q 2024," June 7, 2024.
556 David et al., "Foundational Fabs" *Silverado Policy Accelerator*, October 2023.
557 Martin, Dan Martin and& Dan Rosso, Dan, "Chipping Away: Assessing and Addressing The Labor Market Gap Facing the U.S. Semiconductor Industry", (Semiconductor Industry Association and Oxford Economics, July 2023).
558 Varas et al. "Strengthening the Global Semiconductor Supply Chain In An Uncertain Era," *Boston Consulting Group and Semiconductor Industry Association* April 2021.

attaching direct interconnects and casings for a single die. This relatively lower-profit-margin, higher-labor-intensity segment historically takes place in low-to-middle income countries, a dynamic likely to remain unchanged moving forward.

Advanced semiconductor packaging techniques are those used to combine multiple dies internally connected to each other in addition to external connections to a circuit board, a more capital-intensive and innovation-driven process. AI chips, which require rapid data exchange between computing and memory elements, are driving rising demand for advanced packaging, particularly 2.5 and 3D packages that combine chips on a vertical axis.[559] According to Allied Market Research, the advanced packaging market was valued at $48.5 billion in 2023 and is estimated to reach $119.4 billion by 2032.[560]

Domestic capacity

The United States accounts for only 5 percent of global ATP.[561] Despite this small share, the United States has a strong footprint in the advanced packaging subspace thanks to the internal capabilities of domestic semiconductor companies including Intel, Texas Instruments, Micron, and GlobalFoundries.

A recent survey finds that U.S.-based companies outsource approximately 60 percent of all ATP.[562] To further increase the U.S. share of the back end of semiconductor manufacturing, the Department of Commerce, through the CHIPS Act, began to make investments in ATP and in particular advanced packaging supply chains.[563,564] The Department is supporting the development of glass substrates that may be used in advanced packaging,[565] as well as supporting 3D High Bandwidth Memory production and 2.5D packaging.[566]

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559 Fitzgerald et al. "Advanced Packaging Is Radically Reshaping the Chip Ecosystem," *Boston Consulting Group*, May 20, 2024.
560 "Advanced Packaging Market Size, Share, Competitive Landscape and Trend Analysis Report, by Type, by End user : Global Opportunity Analysis and Industry Forecast, 2024-2032: Advanced Packaging Market Research, 2032," *Allied Market Research*, August 2024.
561 "State of the U.S. Semiconductor Industry," *Semiconductor Industry Association*, 2023.
562 "Assessment of the Status of the Microelectronics Industrial Base in the United States," U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.
563 "U.S. Department of Commerce Announces Preliminary Terms with SK hynix to Advance U.S. AI Supply Chain Security," *U.S. Department of Commerce National Institute of Standards and Technology*, August 6, 2024, https://www.nist.gov/news-events/news/2024/08/us-department-commerce-announces-preliminary-terms-sk-hynix-advance-us-ai-0.
564 "Biden-Harris Administration Announces Preliminary Terms with Amkor Technology to Bring Cutting-Edge Advanced Packaging Technology to the U.S. for Leading-Edge Semiconductors," *U.S. Department of Commerce National Institute of Standards and Technology,* July 26, 2024, https://www.nist.gov/news-events/news/2024/07/biden-harris-administration-announces-preliminary-terms-amkor-technology.
565 "Biden-Harris Administration Announces Preliminary Terms with Absolics," *U.S. Department of Commerce National Institute of Standards and Technology*, May 23, 2024, https://www.commerce.gov/news/press-releases/2024/05/biden-harris-administration-announces-preliminary-terms-absolics.
566"Biden-Harris Administration Announces Preliminary Terms with Amkor Technology," July 26, 2024; "Biden-Harris Administration Announces Preliminary Terms with Samsung Electronics," April 15, 2024; "Biden-Harris Administration Announces Preliminary Terms with Intel," March 20, 2024.

The CHIPS Act also appropriated $11 billion to the Department of Commerce to support extensive semiconductor R&D programs, including the CHIPS National Advanced Packaging Manufacturing Program (NAPMP), which is accelerating the transfer of innovations in packaging, equipment, and process development into manufacturing.[567] On October 18, 2024, the Department of Commerce released a notice of funding opportunity to invest up to $1.6 billion in an open competition for new R&D activities to establish and accelerate domestic capacity for semiconductor advanced packaging, as outlined in the vision for the NAPMP.[568] On November 21, 2024, the Department of Commerce entered negotiations to invest up to $300 million in advanced packaging research projects in Georgia, California, and Arizona to accelerate the development of cutting-edge technologies essential to the semiconductor industry.[569]

CHIPS NAPMP funded activities, coupled with CHIPS manufacturing incentives, will establish a vibrant, self-sustaining, and profitable domestic packaging industry where advanced node chips manufactured in the United States and abroad can be packaged in appropriate volumes within the United States and innovative designs and architectures are enabled through leading-edge packaging capabilities.

Trade concentration

The ATP value chain remains concentrated in Asia (93 percent of global value added), and particularly in China (30 percent) and Taiwan (28 percent).[570] The United States is likely to remain dependent on foreign-based capacity to meet most of its ATP demand, especially for conventional ATP given that the relatively lower-profit-margin and higher-labor-intensity nature of the segment is expected to continue making low-to-middle income countries more attractive destinations to perform this process. The United States must remain a leader in advanced packaging innovations and commercialization to play a larger role in ATP as these technologies gain wider adoption.

Supplier diversity

As shown by the case studies below, various efforts have been taken over the last few years to support allies and partners as they grow their capacity to produce inputs that can complement and enhance the resilience of the U.S. semiconductor industry and supply chain:

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567 "CHIPS for America The Vision for the National Advanced Packing Manufacturing Program," *U.S. Department of Commerce CHIPS Research and Development Office*, November 20, 2023, https://www.nist.gov/system/files/documents/2023/11/19/NAPMP-Vision-Paper-20231120.pdf.

568 "Biden-Harris Administration to Invest Up to $1.6 Billion to Establish and Accelerate Domestic Capacity Advanced Packaging," *U.S. Department of Commerce National Institute of Standards and Technology,* July 09, 2024, https://www.commerce.gov/news/press-releases/2024/07/biden-harris-administration-invest-16-billion-establish-and-accelerate.

569 CHIPS for America Announces up to $300 million in Funding to Boost U.S. Semiconductor Packaging," *U.S. Department of Commerce National Institute of Standards and Technology,* November 21, 2024, https://www.commerce.gov/news/press-releases/2024/11/chips-america-announces-300-million-funding-boost-us-semiconductor.

570 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.

CASE STUDY: THE INTERNATIONAL TECHNOLOGY SECURITY AND INNOVATION (ITSI) FUND

The United States is committed to support allies and partners as they grow their capacity to produce critical ATP inputs into the semiconductor supply chain. The CHIPS Act's International Technology Security and Innovation (ITSI) Fund, which is administered by the Department of State, has thus far partnered with eight countries—Costa Rica, Panama, Vietnam, Indonesia, India, Kenya, the Philippines, and Mexico—to support semiconductor supply chain security and diversification. Bolstering partners' ATP capacity would help diversify the supply chain and offer more options to on-shore fabrication companies. ITSI programs are increasing the critical hard and soft skills of professors, engineers and students, and improving the overall investment climate in partner countries. Bolstered by U.S.-led platforms such as ITSI, many U.S. partners launched roadmaps for attracting semiconductor suppliers that can complement and support new manufacturing investments in the United States.

CASE STUDY: EXIM'S SUPPORT FOR THE SEMICONDUCTOR INDUSTRY AND DOMESTIC MANUFACTURING

The Export–Import Bank (EXIM) approved a final commitment of more than $11.3 million to support financing of nitrogen generator plants for Productos del Aire de Guatemala (PAGSA). The nitrogen will be used to support Intel's ATP Costa Rica operations. The nitrogen equipment will be manufactured mostly by Cosmodyne in Seal Beach, California.

EXIM took the opportunity of the application to lean into the broader U.S. Government support of friendshoring and supporting a U.S. industrial giant in Intel.

Agility

According to supply chain analyses conducted by the Department of Commerce, testing equipment shows relatively low risk compared to other segments of the semiconductor supply chain. The highest risk lies in the limited substitutability among different types of testing equipment, particularly for coordinate-measuring machines and photomask inspection instruments. Additionally, some products, such as wafer inspection instruments, face vulnerabilities due to their primary entry through West Coast ports via air. However, this risk is not widespread across the category.

Security

As ITSI programs work to diversify ATP capacities and bring new countries into the supply chain, the United States must also ensure that it is closing any loopholes that could be exploited to gain access to semiconductor technology and know-how. The ITSI Fund is also engaging the partner countries on technology protection programs. This capacity-building effort involves governments, private sector industry, and research institutions to strengthen regulatory environments, implementation practices, and enforcement measures that safeguard semiconductors and associated sensitive technology from diversion and misuse. ITSI programming includes developing and strengthening export controls and controls on technology transfer, enhancing research security best practices, identifying and closing cybersecurity vulnerabilities and improving physical security at semiconductor facilities, improving IP protections, and enhancing the understanding of and compliance with U.S. export control regulations on semiconductors and advanced technology.

Semiconductor Materials/Raw Materials

Overview

The manufacturing of semiconductors requires the input of hundreds of different types of materials, with those inputs accounting for over $60 billion per year in sales.[571] Semiconductor input materials include wafer fab materials (wafers, photoresists, targets, process gases, chemicals), assembly and packaging related materials (bonding wire, substrates, lead frames, encapsulants), as well as various minerals (such as gallium, germanium, fluorspar, arsenic, and copper.).[572] Due to the infinitesimal size of semiconductors' physical features, in most cases each input material must also be of ultra-pure quality to avoid defects in the manufacturing process.

Domestic capacity

The United States continues to play an important role in the overall market of semiconductor materials. U.S.-, Japan-, and Germany-based suppliers hold most of the market share for wafer fabrication materials used in the deposition and etch processes such as—spin-on dielectrics, chemical mechanical planarization (CMP) slurry, atomic level deposition materials, chemical vapor deposition, and physical vapor deposition targets. Chinese companies supply less than 5 percent share of these materials. For other materials such as wet chemicals and gases, sourcing tends to occur closer to the fabrication site, meaning that these materials tend to be sourced from U.S.-based suppliers for domestic fabrication facilities, and from non-U.S.-based suppliers for non-U.S. facilities. Semiconductor manufacturers indicated that on average, they acquired 69 percent of their semiconductor materials used at facilities located inside the United States from U.S.-based suppliers, compared to 20 percent at non-U.S. facilities.[573,574]

Under the CHIPS Act, the Commerce Department released funding opportunities for the construction, expansion, or modernization of commercial facilities for semiconductor materials and manufacturing equipment. These incentives aim to strengthen the resilience of the semiconductor supply chain, advance U.S. technology leadership, and support vibrant domestic semiconductor clusters. Through the CHIPS Act, the Commerce Department has also made investments in helping to reverse the need for importing supply chain materials, including through critical onshoring of substrates, front opening unified pops (FOUPs), liquid filter membranes, filters, purifiers, wafers,

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571 "Semiconductor Industry Association Comments on CHIPS Program Office Request for Information," *87 Fed. Reg. 61570*, November 14, 2022, https://www.regulations.gov/comment/DOC-2022-0001-0096.
572 "Ryan Berg et. al., Mineral Demands for Resilient Semiconductor Supply Chains," *Center for Strategic and International Studies,* May 16, 2024.
573 "Assessment of the Status of the Microelectronics Industrial Base in the United States," U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.
574 Saif Khan et al., "The Semiconductor Supply Chain: Assessing National Competitiveness" *CSET*, January 2021, https://cset.georgetown.edu/publication/the-semiconductor-supply-chain/.

and polysilicon production.[575] Additional future awards of $500 million for small-scale supply chain materials and manufacturing equipment are forthcoming.

Trade concentration

Bare wafer production represents the highest risk among the four semiconductor supply chain categories analyzed by the Department of Commerce. This risk is driven by its relevance to Made in China 2025 policy and China's substantial and growing share of global exports. In 2019, China accounted for approximately 6 percent of total U.S. wafer imports, a share that more than doubled to 13 percent in 2023, according to U.S. Census Bureau data.[576] While the U.S. does not heavily rely on a single source for imports, there are notable risks related to transportation modes, as most wafers enter the United States via air, and the vulnerability of major ports of entry. Additionally, wafers exhibit moderate risk across many indicators, including import dependence on adversaries, and concentration of global supply.

China also plays a central role in the production and processing of semiconductor minerals such as gallium (Ga) and germanium (Ge), which are key for the fabrication of non-silicon wafers used for power, radio frequency, and light-emitting diode (LED) semiconductors. In 2023, China produced 98 percent of the world's refined primary (low purity) gallium output.[30] In 2022, China produced 60 percent of the world's germanium output.[577]

The PRC has leveraged this market dominance to disrupt global mineral supply chains through export licensing requirements, beginning with restrictions on gallium /germanium exports implemented in August 2023. According to a United States Geological Survey (USGS) study on the potential effects of the export restrictions on the United States, a complete restriction of China's net exports of gallium and germanium could cause U.S. GDP to decrease by approximately $3.1 billion and $0.4 billion, respectively, if disrupted separately, and $3.4 billion if disrupted simultaneously.[578] While there are natural deposits of primary commodities from which gallium and germanium can be produced, such as aluminum and zinc, companies subject to free market pressures have been reluctant to make the additional investments necessary to recover the trace byproducts used in semiconductor manufacturing given the much smaller demand relative to the primary commodity.

Supplier diversity

In an industry survey conducted by the Department of Commerce in 2023,[579] respondents expressed significant concerns about the availability of domestic sources of three categories of materials: bare

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[575] "Biden-Harris Administration Announces Preliminary Terms with GlobalWafers to Significantly Increase Production of Silicon Wafers in U.S.," *U.S. Department of Commerce National Institute of Standards and Technology,* July 17, 2024, https://www.nist.gov/news-events/news/2024/07/biden-harris-administration-announces-preliminary-terms-globalwafers.

[576] "USA Trade Online," *U.S. Census Bureau,* https://usatrade.census.gov/.

[577] SCALE has HS 2804290050 Other Rare Gases inclusive of these gases - it does not flag high risk vulnerabilities to this code outside of our adversary dependence. 28 percent of our imports in 2023 came from China, up from 6 percent in 2018. In large part these replaced imports from Russia of 19 percent in 2018 down to 0 percent in 2023. Import dependence on these countries of concern spiked in 2021 at 43 percent, but have returned to approximately 2018 level (26 percent in 2018 vs 28 percent in 2023).

[578] "Quantifying potential effects of China's gallium and germanium export restrictions on the U.S. economy," *United States Geological Survey (USGS),* October 15, 2024.

[579] More information provided in the "Engagement with Industry" section

wafers, gases, and wet chemicals. Within gases, the survey found that helium, nitrogen, hydrogen chloride, neon, nitrogen trifluoride, and hydrogen presented the most frequent acquisition concerns. Concerns for wet chemicals were more dispersed. Survey respondents identified 78 unique chemicals of concern, led by sulfuric acid and isopropyl alcohol. Ultra-high purity forms of both chemicals are heavily imported. Additionally, with minimal ATP operations in the United States, there are limited domestic sources for assembly and packaging materials.[580]

Transparency

U.S. downstream companies may not be fully aware of their exposure to material chokepoints in China. For example, with gallium and germanium, U.S. companies source processed gallium/germanium indirectly from midstream partners like Belgium, Germany, and Japan, several steps removed from China's gallium/germanium metal production choke points.

Economic health and compliance

Many chemistries in the family of polyfluoroalkyl substances (PFAS)—or "forever chemicals"—are used throughout the semiconductor manufacturing process. Industry organizations have acknowledged the dangers of certain PFAS and have encouraged companies to remove non-essential uses. [581] In June 2024, the World Semiconductor Council reported the complete phase-out of intentional uses of perfluorooctanoic acid (PFOA) to the United Nations Stockholm Convention.[582] Industry maintains, however, that semiconductors cannot currently be manufactured without PFAS, which are used at multiple steps in production process. The lack of suitable PFAS substitutes in the semiconductor manufacturing process has caused concern among companies about potential future supply chain disruptions as they observe growing restrictions on the use, production and import of PFAS in multiple jurisdictions. The United States Environmental Protection Agency (EPA) is among regulators assessing the impacts of PFAS, and clarifies in its Framework for Addressing New PFAS and New Uses of PFAS that, in the semiconductor sector, certain PFAS can be used "when exposures and releases can be mitigated, which is critical for important sectors like semiconductors."[583]

The transport of dangerous or hazardous cargo also requires compliance with guidelines for proper handling and storage; temperature-controlled cargo relies heavily on temperature-controlled air freight services and cold storage facilities.

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[580] "Assessment of the Status of the Microelectronics Industrial Base in the United States," *U.S. Department of Commerce Bureau of Industry and Security Office of Technology Evaluation*, accessed August 24th 2024, https://www.bis.doc.gov/index.php/documents/technology-evaluation/3402-section-9904-report-final-20231221/file.
[581] "Semi PFAS Mission Statement," *SEMI.*
[582] "Global Semiconductor Industry Announces Phaseout of Intentional Uses of PFOA," *Semiconductor Industry Association,* July 09, 2024.
[583] "Framework for Addressing New PFAS and New Uses of PFAS," *United States Environmental Protection Agency,* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/framework-addressing-new-pfasand#:~:text=EPA%27s%20Framework%20for%20Addressing%20New%20PFAS%20and%20New,be%20harmful%20to%20human%20health%20and%20the%20environment.

Semiconductor Manufacturing Equipment (SME)

Overview

The tools used to manufacture circuits on semiconductor wafers are some of the most complex and expensive equipment used in any manufacturing process. After reaching $105.91 billion in 2023, sales of semiconductor manufacturing equipment (SME) are expected to grow moderately in 2024 to $109.47 billion for 2024 and projected to reach $128 billion in 2025.[584]

There are two primary segments of SME. The first is wafer fabrication equipment, which includes wafer processing, fab facilities, and mask/reticle equipment. Sales of wafer fabrication equipment is projected to reach $98 billion in 2024 and reach $112.78 billion in 2025.[585] On average, wafer fabrication equipment accounts for roughly 80 percent of the cost of a new fab, which itself can cost tens of billions of dollars.[586]

The second segment is equipment for assembly, test, and packaging (ATP), which is further split into semiconductor packaging equipment and semiconductor test equipment. Semiconductor packaging equipment sales are expected to rise from $4.43 billion in 2024 to $5.98 billion in 2025 and sales of higher value and more sophisticated semiconductor test equipment are expected to jump from $6.73 billion to $8.77 billion over the same period.[587]

Domestic capacity

U.S. companies lead in the wafer fabrication equipment market, accounting for 46 percent of the overall market.[588] In ATP equipment, although U.S. companies only account for 5 percent of semiconductor packaging equipment market, they represent 30 percent of the semiconductor test equipment market.[589] As mentioned under the materials section, the Commerce Department released funding opportunities under the CHIPS Act for the construction, expansion, or modernization of commercial facilities for semiconductor materials and manufacturing equipment. The investment tax credit created under the CHIPS Act also provides a 25-percent credit for capital investments in facilities that manufacture semiconductor manufacturing equipment.

Trade concentration

Fabrication equipment presents a lower risk compared to wafers and semiconductor devices, with generally diversified sourcing and relatively low geopolitical risk. According to data from the U.S. Census Bureau, fabrication equipment and testing equipment have seen reductions in their import share from countries of concern since 2018, from 9.8 percent to 6.2 percent in 2023 for the former and 5.0 percent to 0.8 percent in 2023 for the latter.[590] The primary concerns are related to domestic port vulnerabilities and global supply concentration. Imported fabrication equipment predominantly

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[584] "Global Total Semiconductor Equipment Sales Forecast to Reach Record $109 billion in 2024," *SEMI,* July 9, 2024.
[585] Ibid.
[586] "World Fab Forecast 2nd Quarter Dataset," *SEMI,* 2024.
[587] "Global Total Semiconductor Equipment Sales Forecast to Reach Record $109 billion in 2024," *SEMI,* July 9, 2024.
[588] Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.
[589] Ibid.
[590] "USA Trade Online," *U.S. Census Bureau,* https://usatrade.census.gov/.

enters the United States through Los Angeles, a port exposed to significant risks from earthquakes, wildfires, and heat waves. Non-U.S. suppliers are concentrated in the Netherlands, Japan, and Singapore, although the United States also plays a substantial role as an exporter.

Supplier diversity

Manufacturers supplying SME are diversified, with multiple companies producing competing versions of most lithography, deposition, and etch tools. Japanese companies capture the second most share after U.S. companies, with 26 percent of the wafer fabrication equipment market.

One glaring exception to this market diversity is the production of the extreme ultraviolet (EUV) lithography tool, a technology that is currently only manufactured by one company in the Netherlands and used to produce the most advanced chips. The company's dominance in EUV and other advanced lithography tools makes the Netherlands the third largest semiconductor wafer fabrication equipment producer, with 18-percent market share.[591] The remaining share is rounded out by companies in Europe, South Korea, China, and Southeast Asia. [592]

Economic health and compliance

U.S. semiconductor equipment producers remain dependent on foreign sales. China is the largest market for semiconductor manufacturing equipment, with sales to China expected to exceed $35 billion for 2024, followed by Taiwan and South Korea.[593] The PRC's push to reduce the country's reliance on foreign semiconductor vendors could negatively impact U.S. companies' revenue streams and market share. The PRC stated its intention to support the domestic production of semiconductor manufacturing equipment as early as 2016 in the State Council's "13th Five-Year National Science and Technology Innovation Plan,"[594] which lists SME manufacturing development as a major national science and technology project.[595] This policy signaled that SME manufacturers could enjoy blanket benefits that come with future policies directed at semiconductor companies, such as tax breaks and bureaucratic support.[596] Chinese analysts predict that investment into "key bottleneck equipment" for advanced wafer manufacturing and advanced packaging will be a focus for the PRC's National Integrated Circuit Fund Phase III, launched in May 2024.[597] Although Chinese companies are not among the top providers of most types of equipment, they can manufacture legacy equipment and to some extent serve the Chinese semiconductor industry.

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591 "ASML Holding Revenue 2010-2024," *ASMI Financials Macrotrends*, Accessed August 13, 2024.

592 Raj Varadarajan et al., "Emerging Resilience in the Semiconductor Supply Chain", *Semiconductor Industry Association and Boston Consulting Group*, May 2024.

593 "Global Total Semiconductor Equipment Sales Forecast to Reach Record $109 billion in 2024," *SEMI,* July 9, 2024.

594 "China's 13th Five-Year Plan," *U.S.-China Economic and Security Review Commission,* Chapter 1, Section 3, November 2016. https://www.uscc.gov/sites/default/files/Annual_Report/Chapters/Chapter%201%2C%20Section%203%20-%2013th%20Five-Year%20Plan.pdf

595, "国务院关于印发十三五"国家科技创新规划的通知(Translation: The State-Council Notice on the Publication of the National 13th Five Year Plan for Science and Technology Innovation PRC State Council)", accessed November 22, 2024 https://www.gov.cn/zhengce/content/2016-08/08/content_5098072.htm

596 "重磅！2022年中国半导体设备行业政策汇总及解读（全）政策助推半导体设备国产化进程 (Translation: Qianzhan Industrial Research Institute)" accessed, November 22. 2024, https://finance.sina.com.cn/roll/2022-10-05/doc-imqmmtha9850820.shtml

597 Tong Luo and Yu Ze Wang, "国家集成电路大基金三期成立，重点关注半导体设备 及相**关零部件投**资机会 (Kaiyuan Securities)", accessed, November 21, 2024, https://pdf.dfcfw.com/pdf/H3_AP202405271634725470_1.pdf?1716843777000.pdf

PRIORITIES AHEAD

Four-year Outlook

Thanks to the efforts taken over the last four years to strengthen the U.S. semiconductor supply chain, the domestic semiconductor industry is expected to be more resilient over the next four years than the pre-2022 trendlines indicated. The United States' ability to rely on additional resilient sources of supply will steadily increase as semiconductor companies' new investments come online and enhanced cooperation with allies yields higher global supply diversification. Despite this progress, the dynamic and globally integrated nature of the industry will make it necessary to build upon these efforts over the next four years and address both long-standing and new vulnerabilities that may impact the U.S. semiconductor ecosystem such as the overconcentration of production of critical inputs, including legacy chips and materials; lack of supply chain transparency; workforce requirements; and geopolitical competition.

In addition to addressing physical supply chains, the CHIPS Act created initiatives that are helping develop new manufacturing knowledge. The National Science Foundation's Regional Innovation Engines are catalyzing and fostering innovation ecosystems across the United States to advance critical technologies including semiconductors.[598] In addition, the Regional Technology and Innovation Hubs (Tech Hubs) program through the Department of Commerce's Economic Development Administration is investing assets and resources in regions across the country with the potential to become globally competitive in the technologies and industries of the future, such as semiconductors and microelectronics.[599] These programs are boosting innovation that will allow the next generation of technologies to impact manufacturing and allow the United States to remain competitive in the global industry, in semiconductors as well as other technologies.

Through the CHIPS Manufacturing USA Institute,[600] the Department of Commerce will establish a first-of-its kind institute focused on the development, validation, and use of digital twins for semiconductor manufacturing, advanced packaging, assembly, and test processes. The Institute will use integrated physical and digital assets to tackle important semiconductor-industry manufacturing challenges and unlock the full potential of digital twins for the semiconductor industry while benefitting manufacturers of all sizes. The new Institute will have both regionally focused programs and meaningful cross-region participation, which will best meet the CHIPS R&D program goals of strengthening U.S. technology leadership, accelerating ideas to market, and realizing a robust semiconductor workforce.

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598 "About NSF Engines," *U.S. National Science Foundation,* https://new.nsf.gov/funding/initiatives/regional-innovation-engines/about-nsf-engines

599 "Regional Technology and Innovation Hubs (Tech Hubs)," *U.S. Economic Development Administration*, https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs.

600 "CHIPS for America Announces New Proposed $285 Million Award for CHIPS Manufacturing USA Institute for Digital Twins, Headquartered in North Carolina" U.S. Department of Commerce National Institute of Standards and Technology, November, 19, 2024, https://www.nist.gov/news-events/news/2024/11/chips-america-announces-new-proposed-285-million-award-chips-manufacturing.

Four-year Resilience Goals and Priorities

[Goal 1] Enhance transparency and traceability of the supply chain and prevent executive agencies from obtaining semiconductor products from entities owned or controlled by the government of a country of concern:

The Department of Commerce is working with the U.S. Government interagency to implement Section 5949 of James M. Inhofe National Defense Authorization Act for Fiscal Year 2023. Section 5949 prohibits executive agencies from obtaining semiconductor products from entities owned or controlled by the government of a country of concern and requires the Department of Commerce, in coordination with the interagency, to assess the risk posed by covered semiconductor products in federal systems. Among other provisions, the law requires the Secretary of Commerce to establish a microelectronics traceability and diversification initiative that will coordinate analysis of and response to Federal Government microelectronics supply chain vulnerabilities.

[Goal 2] Support allies and partners as they grow their capacity to produce critical assembly, testing, and packaging (ATP) inputs that can complement and enhance the resilience of the U.S. semiconductor industry and supply chain:

Through the ITSI Fund, the Department of State is delivering training and curricula through Arizona State University in partner countries to expand the ATP segment of the supply chain and a second program is expanding the workforce and supplier ecosystems within Americas Partnership for Economic Prosperity (APEP) member countries. In parallel to these efforts, ITSI programs are also ensuring partner countries—alongside their relevant industry and academia—have the necessary tools in place to protect semiconductor-related research, intellectual property, and hardware from diversion and end-uses of concern. Facilitating the adoption of measures to mitigate the misuse of semiconductor technology is foundational for attracting investments intended to expand ATP supply chains. Engaging these partner countries to fortify their technology protection measures is essential as every country involved in the supply chain plays a role in ensuring its security.

[Goal 3] Continue to develop domestic STEM talent to strengthen the workforce for semiconductor R&D, design, and manufacturing:

Through the CHIPS Act, the Department of Commerce is allocating dedicated workforce funds across its investment portfolio to create and expand workforce training programs and wraparound services for both semiconductor fabrication staffing and facility construction. This funding —over $200 million of which has been included in preliminary and final awards to date—will start the process of building up the semiconductor ecosystem workforce, but sustained efforts are necessary to maintain the United States' edge in leading edge manufacturing.

The U.S. Government should continue to build upon efforts to partner with local research ecosystems, academia, economic development associations, industry, and non-profit organizations to expand opportunities for domestic semiconductor workforce development.

[Goal 4] Foster the development of technologies underpinning the United States' artificial intelligence (AI) ecosystem:

New and shifting paradigms in the deployment of AI—and the semiconductor technologies underpinning it—could transform global supply chains and national security. The United States' competitive edge in AI development will be at risk absent concerted government efforts to promote and secure domestic AI progress, innovation, and competition.

The U.S. Government should work to promote new and innovative capabilities in semiconductor design, tooling, and production that expand the domestic market and promote competition among U.S. semiconductor companies that develop technologies for AI chips. The U.S. Government must aim to support an ecosystem for AI chip companies that uplifts innovators, removes barriers for small-to-medium sized companies to enter the market, and encourages market competition across the domestic value chain. This includes avoiding pushing markets unnecessarily towards concentrated or vertically integrated structures to ensure that the supply chain remains modular and able to serve new and innovative entrants.

The U.S. Government must also work to ensure that the United States remains the most attractive destination for global talent and home to the world's most sophisticated advanced semiconductor manufacturing facilities.

[Goal 5] Ensure a level playing field for U.S. and allied semiconductor manufacturers to drive investment in a resilient and diverse supply of chips that underpin national security and critical manufacturing sectors:

The United States has ongoing requirements for mature node and legacy semiconductors. Many defense systems remain in service for decades beyond their initial design, and sustainment of these systems requires continued ability to manufacture parts that are no longer cutting edge. Other critical industries such as transportation, medical devices, and telecommunications infrastructure rely on chips fabricated at mature process nodes. One result of the PRC's investment in its indigenous semiconductor sector has been a rapid build out of fab capacity for mature node semiconductors. In just six years, from 2018 to 2024, China nearly doubled its global share of legacy logic production capacity from 20 percent to 38 percent. Based on announced new fabs, this share will grow to just over half of the world's capacity (51 percent) by 2029.[601]

Although industries that most heavily use mature node chips account for only 24 percent of the overall semiconductor market by revenue, semiconductor companies predict that the health care, industrial, automotive, aerospace, and defense markets will grow the fastest between now and 2032 (ranging from 8 to 14 percent CAGR respectively).[602] The Department of Commerce has observed potential signs of concerning practices from the PRC to expand their firms' legacy chip production and make it harder for U.S. companies to compete in the international market.[603] In September 2024, the Office of the U.S. Trade Representative (USTR) announced increases in tariffs to 50 percent in

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[601] Estimate based on forecasted output capacity aggregated at the national level. SEMI, "World Fab Forecast – 2Q 2024," June 7, 2024.
[602] BIS 9904 Report.
[603] "Commerce Department Announces Industrial Base Survey of American Semiconductor Supply Chain*," U.S. Department of Commerce*, December 21, 2023, https://www.commerce.gov/news/press-releases/2023/12/commerce-department-announces-industrial-base-survey-american.

2025 for semiconductors made in China, based on its finding that the PRC has persisted in its use of harmful forced technology transfer practices. Additionally, the U.S. Government has launched joint efforts with international partners to explore the effect of non-market policies and practices on the semiconductor industry.

To remain resilient, U.S. supply chains for critical technologies that use mature-node chips—defense, communications, medical devices, transportation—will require continued investment domestically and in allied countries that may be undermined by other countries' nonmarket policies and practices.

The U.S. Government must continue to address the lack of transparency in the supply chain and continue to assess and ultimately leverage its trade and supply chain analysis tools to prevent risks associated with the geographic overconcentration of production.

[Goal 6] Continue to execute and expand upon the CHIPS for America Vision for Success:

Shortly after passage of the CHIPS Act, the Department of Commerce outlined a strategy for revitalizing the domestic semiconductor industry, protecting U.S. national and economic security, preserving U.S. leadership in the industries of the future, creating good-paying jobs, and building strong communities here in the United States. This Vision for Success included:

- Creating at least two new large-scale leading-edge logic clusters;
- Establishing multiple high-volume advanced packaging facilities;
- Producing high volume memory (DRAM) chips and R&D;
- Increasing production for current-and mature-node chips;
- Building a resilient semiconductor supply chain.

The Department of Commerce is on track to achieve every objective. The United States is now expected to have a diversity of technology that it has not had in decades. All five leading-edge logic and DRAM semiconductor manufacturers are now expected to expand in the United States. By comparison, no other economy in the world has more than two. CHIPS investments are also supporting multiple downstream investments in critical advanced packaging capabilities and upstream investments silicon wafers that are foundational to modern semiconductor manufacturing.

The Department of Commerce will continue to implement the $39 billion in manufacturing incentives provided in the CHIPS and Science Act by continuing to allocate the remaining funding and convert preliminary memorandum of terms into direct funding agreements. These agreements will support more than $450 billion in private investment and help create over 125,000 manufacturing and construction jobs. This includes allocating $500 million in available incentives to strengthen supply chain resilience, advance U.S. technological leadership, and support vibrant U.S. fab clusters.

Legislative and Budgetary Objectives

Safeguard U.S. Leadership in Semiconductor Design: The United States should ensure activities under this segment of the value chain, including R&D, instruction set architecture design, microarchitecture implementation, and EDA, can continue to thrive domestically. Congress should consider mechanisms to bolster semiconductor design research and development to ensure valuable intellectual property is created and secured in the United States while guaranteeing high-paying jobs for American workers.

Workforce Development: Congressional support for STEM education and workforce development would amplify existing efforts to develop the United States talent base for the semiconductor industry.

Enhance U.S. Capabilities to Analyze the Semiconductor Market and Supply Chain: The United States must invest in resources that can enable the Department of Commerce to enhance its ability to assess and forecast the market dynamics of the semiconductor industry, including supply and demand trends, semiconductors provenance, procurement, and usage. Additional funding is required to procure pertinent datasets, augment industry analyses, and effectively implement the microelectronics traceability and diversification initiative set forth in Section 5949 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023. These resources are critical to increase visibility into and assessment of the supply chain and support export control measures that can enable the government to better identify supply chain vulnerabilities and enhance its ability to take potential steps to address them.

Enhance EXIM Ability to Take Risk: Through its China and Transformational Exports Program (CTEP), the Export-Import Bank of the United States (EXIM) has an explicit mandate from Congress to support the semiconductor and semiconductor equipment industries, and EXIM has nearly $100 billion of lending capacity still available out of its total $135 billion in financing authority.[604] This financing could support both overseas projects related to supply chain diversification and complement CHIPS in growing the domestic supply chain via EXIM's Make More in America (MMIA) domestic finance initiative.[605] However, EXIM operates under a congressionally mandated two percent default rate cap that effectively freezes EXIM's lending if the two percent cap is breached. Congress exempting CTEP transactions, as requested in EXIM's FY 2025 Congressional Budget Justification, would allow EXIM to take appropriate risk in supporting the transformational export areas, including the semiconductor industry, to ensure support for a single large project if it were to default would not jeopardize EXIM's overall operations.

Long-term Resilience Goals

Competitiveness of the U.S. Semiconductor Industry: The long-term competitiveness of the semiconductor industry will continue to be tested as new developments, technologies, and business practices emerge. Ensuring that the U.S. semiconductor ecosystem can adapt to supply chain and

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[604] "CTEP - China and Transformational Exports Program Strategic Context," *Export-Import Bank of the United States*, https://www.exim.gov/about/special-initiatives/ctep/strategic-context-congressional-mandate.
[605] "Make More in America Initiative," *Export-Import Bank of the United States,* https://www.exim.gov/about/special-initiatives/make-more-in-america-initiative.

market changes and remain competitive will help enable that the United States can continue to play a key role in this critical industry moving forward.

Diversified Supply Chains: Diversified supply chains are still a long-term goal for semiconductor supply chain resilience. Initiatives such as the CHIPS Act have started to redirect investments along the semiconductor value chain, but manufacturing capacity in certain segments of the industry remains regionally concentrated or is growing more so, creating vulnerabilities. Diversification of manufacturing of mature-node semiconductors and of conventional packaging would particularly strengthen the sector's resilience.

Robust Upstream and Downstream Ecosystems: Resilient supply chains require resilient upstream material markets as well as reliable downstream markets. For the semiconductor industry, this may mean ensuring that the industry maintains access to the inputs such as minerals, materials, and wafers that semiconductor manufacturers rely on, and for the U.S. Government this may work to ensure that these items are not subject to unfair trade measures or other restrictions. Additionally, long-term resilience will also require semiconductor manufacturers to have continued access to downstream markets for personal electronics, industrials, and automobiles.

Sustainability: As semiconductor manufacturing increases worldwide, the demand for energy, water, and resources to operate fabrication facilities also increases. In addition, concerns continue to arise regarding the potential environmental and health impacts of certain inputs for semiconductor manufacturing such as PFAS. The semiconductor industry is working to address such challenges to reduce manufacturing costs and to better comply with regulatory requirements targeting PFAS waste and other materials. Continued progress on reducing the footprint of the industry will be key for its long-term resilience.

Conclusion

Over the last four years, the U.S. Government has taken a variety of steps to reduce the vulnerabilities and enhance the resilience of the U.S. semiconductor industry. Ongoing efforts to implement the CHIPS Act, assess and update export controls, increase engagement with industry, and develop tools to assess the supply chain have contributed to mitigation of the risks identified in the June 2021 100-Day supply chain review. Since that time, the United States has enjoyed a historic development of over $446 billion in private sector investment for new semiconductor production. Given the complex, dynamic, and globally integrated nature of the semiconductor industry, continued work will be necessary to build upon existing efforts and address long-standing and new risks in the supply chain including global supply concentration of critical inputs, the disruption of and uncertainties around emerging technologies, workforce needs, and natural hazards. Over the next four years, the United States must focus on meeting a series of key goals to further reinforce the progress made to date and strengthen the domestic semiconductor ecosystem, including (1) enhancing transparency and traceability of the supply chain; (2) growing the capacity of allies and partners to produce critical ATP inputs; (3) continuing to develop domestic STEM talent to strengthen the workforce for semiconductor R&D, design, and manufacturing; (4) strengthening and protecting the technologies underpinning the United States' artificial intelligence (AI) ecosystem; and (5) ensure a resilient supply of chips that underpin our country's critical needs.

2021–2024 Four-year Review of Supply Chains for the Transportation Industrial Base

U.S. DEPARTMENT OF TRANSPORTATION

DECEMBER 2024

EXECUTIVE SUMMARY

The U.S. transportation industrial base is undergoing a significant transformation, driven by the need to address vulnerabilities exposed by recent disruptions, such as the COVID-19 pandemic and global supply chain challenges. The United States Department of Transportation (DOT) released its first Supply Chain Assessment of the Transportation Industrial Base in February of 2022. This sector, encompassing road, rail, maritime, air, and pipeline transportation, plays a critical role in supporting national and global commerce. However, maintaining resilience has become increasingly important to meet future demands and safeguard the U.S. economy.

Since 2021, major developments have emerged that are reshaping the transportation sector. The Bipartisan Infrastructure Law (BIL) provided historic funding to modernize ports, rail systems, and highways; ease freight congestion and improve multimodal connectivity. Alongside these infrastructure improvements, advancements in electric vehicles (EVs), predictive analytics, and data-sharing platforms such as the DOT Freight Logistics Optimization Works (FLOW) initiative have enhanced supply chain visibility, efficiency, and coordination. Sustainability initiatives have focused on reducing emissions, adopting alternative fuels, and implementing green technologies across transportation modes.

Workforce development is another priority, as the sector addresses labor shortages through the expansion of apprenticeships and improvements to the Commercial Driver's License (CDL) process. Programs like the Women in Trucking Advisory Board aim to promote diversity and inclusion, helping to build a more robust and sustainable workforce.

Looking ahead to 2025–2028, DOT has outlined key priority actions to further strengthen the industrial base:

- Strengthen domestic manufacturing of port cranes to reduce reliance on foreign suppliers through onshoring initiatives, financial incentives, and regional partnerships with ally and partner nations.
- Support domestic shipbuilding and nearshoring to boost ship production by considering federal incentives and workforce development programs, while also prioritizing military and commercial shipbuilding to enhance national and economic security.
- Expand domestic EV manufacturing to focus on increasing the production of batteries and critical components domestically, reducing dependency on foreign entities of concern in international supply chains. This effort will be supported by sustainable mining and recycling practices in collaboration with global partners.
- Increase supplier diversity in aerospace manufacturing.
- Improve data transparency to enhance supply chain resilience by expanding the use of the Freight Logistics Optimization Works (FLOW) platform.

These strategic actions emphasize the need for collaboration between the public and private sectors to build a more resilient, adaptable, and sustainable transportation network. Through targeted investments, policy alignment, and international partnerships, the U.S. transportation industrial base is positioned to meet future challenges, support national security, and drive economic growth and innovation in the years ahead.

SECTOR OVERVIEW

Sector Overview

The transportation industrial base is the collective network of industries, businesses, organizations, and infrastructure supporting transportation systems. This term covers sectors and activities related to various modes including road, rail, air, and maritime. The transportation industrial base includes passengers and cargo transportation industries, warehousing, and support activities. Establishments in these sectors use transportation equipment or facilities as productive assets. These sectors contribute significantly to the U.S. economy, accounting for 6.7 percent of GDP and 16.0 million jobs, equating to 10.3 percent of the U.S. labor force. Trucking companies alone account for over 1.86 million companies.[606]

The type of equipment depends on the mode of transportation, including the following:

- Air transportation (including traditional aviation and emerging unmanned and advanced air mobility)
- Rail transportation (such as passenger or freight line-haul and freight shortline railroads)
- Water transportation (such as coastal, inland, and Great Lakes cargo transportation)
- Truck transportation
- Transit and ground passenger transportation (such as urban and rural transit systems, commuter rail, and bus or other motor vehicle transit systems)
- Pipeline transportation
- Last-mile delivery transportation (including biking and walking)

In addition, the transportation industrial base includes industries engaged in manufacturing equipment for transportation of passengers and cargo by land, air, and water. Important products produced by establishments in this major group include motor vehicles, aircraft, ships, boats, railroad equipment, and miscellaneous transportation equipment. The transportation equipment manufacturing subsector consists of these industry groups:

- Motor vehicle manufacturing
- Aerospace and aircraft product and parts manufacturing
- Railroad rolling stock and train control and communications manufacturing
- Ship building and repair
- Other transportation equipment manufacturing
- Support activities for transportation (such as rail and locomotive maintenance; bridge, tunnel, and highway operations and maintenance; airport operations; and port and harbor operations and marine cargo handling)

Equipment manufacturing in this sector also includes other general-purpose machinery, such as locomotive and ship cranes and truck trailer and cargo container chasses. Several elements of the overall industrial base directly impact the transportation industry, such as engine, turbine, and power transmission equipment and computer, electrical, semiconductor, and communications equipment. This industry also includes activities related to heavy and civil engineering construction projects.

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[606] "Industries at a Glance: Trade, Transportation, and Utilities," Bureau of Labor Statistics, last modified December 6, 2024, https://www.bls.gov/iag/tgs/iag40.htm

These include highway, street, bridge, and distribution line construction; new transportation infrastructure work, reconstruction, rehabilitation, and repairs; construction projects involving water resources (e.g., dredging), development of marine facilities, and dock construction; and building construction.[607] Yet, the transportation industrial base is more than just hardware and concrete. It encompasses a wide range of support services. Support services, including logistics and supply chain management, play a crucial role in orchestrating the seamless flow of goods. Warehousing, freight forwarding, and transportation management are integral to optimizing supply chain resiliency.

Technology and innovation are driving forces within the transportation industrial base, shaping advancements in areas such as electric vehicles, unmanned systems, drones, digital infrastructure, and predictive analytics.[608] Regulatory agencies establish standards for safety, environmental impacts, and compliance across the transportation sector, ensuring adherence to regulatory requirements. Workforce development initiatives focus on training and education programs to cultivate skilled professionals, such as engineers and technicians, essential for the operation and maintenance of transportation systems.[609]

Evolution of the Sector through 2020

The resilience of the U.S. transportation industrial base evolved throughout the 20th and early 21st centuries, driven by changing economic policies, technological innovations, and geopolitical realities. From locally concentrated production in the early 1900s to globalized networks by the 2000s, the transportation supply chain oscillated between vulnerabilities, learning valuable lessons from wars, economic shifts, and pandemics.

1900s–1940s: Domestic Supply Chains and Early Resilience. In the early 20th century, the U.S. transportation industrial base was predominantly domestic and vertically integrated. Companies controlled every step of production, from raw materials to finished products. Most industries were clustered geographically, like Detroit's automotive sector, which relied on local suppliers for steel, rubber, and glass. Railroads served as the primary transportation backbone, connecting industrial hubs and ports. Even during the Great Depression, U.S. industries remained operational by relying on nearby resources. During World War II, the transportation industrial base proved critical to the war effort, with U.S. factories rapidly shifting to military production.[610]

1950s–1970s: Globalization Begins and Infrastructure Expands. After World War II, the transportation industrial base began to globalize, spurred by the rebuilding of Europe and Japan through programs like the Marshall Plan (1948). The rise and widespread adoption of container shipping in 1956 further transformed global logistics, reducing port loading times from days to hours. The launch of the Interstate Highway System in 1956 enhanced domestic transportation by linking cities and industrial centers, improving freight efficiency. During this era, the labor-intensive

607 Agency Reports to Congress, U.S. Department of Transportation, last updated March 4, 2015, https://www.transportation.gov/government/government-affairs/agency-reports-congress
608 An Analysis of the Operational Costs of Trucking: 2023 Update, American Transportation Research Institute, effective June 2023, https://irp.cdn-website.com/7bc682fd/files/uploaded/ATRI-Operational-Cost-of-Trucking-06-2023.pdf
609 Employment in Transportation: Monthly Employment in the Transportation and Warehousing Sector, Establishment Data, last updated November 2024, https://data.bts.gov/stories/s/Employment-Transportation-Total/2z63-wprv
610 The American Homefront and WWII, National Park Service, last updated October 2007, https://www.nps.gov/subjects/nationalhistoriclandmarks/upload/WWII_and_the_American_Home_Front-508.pdf

manufacturing began to shift to emerging economies like Japan, particularly the automotive and electronics industries, reflecting the growing reliance on international suppliers. Potential new vulnerabilities began to emerge as supply chains stretched across borders.

1980s–1990s: Offshoring and Just-in-Time Manufacturing. The 1980s marked a turning point as companies increasingly off-shored production to countries with lower labor costs, including China and Mexico. U.S. firms sought to reduce costs by outsourcing manufacturing of consumer goods, electronics, and automotive components. The signing of NAFTA (1994) accelerated nearshoring within North America, integrating supply chains between the U.S., Canada, and Mexico. For example, the automotive industry began to rely on Mexican assembly plants for vehicle and parts production. Simultaneously, companies adopted Just-in-Time (JIT) manufacturing, a system pioneered by Toyota that relies on reduced inventory levels, with parts arriving exactly when needed to minimize storage costs. While this approach increased efficiency, it also made supply chains more vulnerable to disruptions because a network of local suppliers undergirded JIT manufacturing as initially implemented. By the end of the 1990s, offshoring was widespread, and the transportation industrial base became deeply interconnected with global trade networks, introducing new risks, as disruptions in distant countries could ripple through U.S. supply chains.

2000s–2010s: Peak Globalization and Growing Vulnerabilities. The early 21st century marked the height of globalization, making the U.S. increasingly dependent on overseas suppliers for everything from consumer goods to industrial components. The increased dependence on overseas suppliers contributed to economic globalization, offering lower costs and greater efficiencies for many businesses. However, it also exacerbated the decline of U.S. manufacturing, increased job displacement in several industries, and made the U.S. economy more vulnerable to global supply chain disruptions.

Global events during this period revealed the fragility of these global supply chains. The 9/11 terrorist attacks (2001) disrupted air travel and freight movement, highlighting vulnerabilities in just-in-time logistics. In 2011, the Tohoku earthquake and tsunami in Japan disrupted global automotive and electronics production, costing companies billions of dollars. These events emphasized the risks of relying on distant suppliers and just in time inventory. Meanwhile, the rise of e-commerce demanded faster and more flexible transportation networks.

2010s–2020: Trade Tensions, COVID-19, and the Resilience Imperative. In the late 2010s, geopolitical tensions and natural disasters further exposed supply chain vulnerabilities. Following a determination by the Office of the U.S. Trade Representative (USTR) that China employed a series of technology transfer-related acts, policies, and practices that are unreasonable or discriminatory and burden or restrict U.S. commerce, the United States imposed tariffs on a wide range of goods made in China. In response, companies began diversifying supply sources and exploring nearshoring alternatives in Mexico and other countries. The COVID-19 pandemic in 2020 was a watershed moment for the U.S. transportation industrial base, exposing severe weaknesses in global supply chains. Lockdowns, port closures, and transportation delays caused shortages of essential goods, from personal protective equipment (PPE) to semiconductors. Shipping costs surged by 500 percent during the pandemic, as bottlenecks at major ports disrupted the flow of goods and impacted the pricing and availability of goods for consumers. These disruptions prompted companies and governments to re-evaluate their reliance on overseas suppliers.

The globalization of the U.S. transportation industrial base from the 1900s through 2020 reflects a journey from domestic production and vertical integration to globalized, highly efficient networks. In 2020, the U.S. transportation sector faced a turning point. The disruptions caused by COVID-19 and trade tensions prompted a shift toward reshoring, nearshoring, and supply chain diversification. Governments and industries began prioritizing resilience over pure efficiency, investing in domestic manufacturing and digital supply chain management tools to prepare for future disruptions. As the transportation industrial base continues to evolve, balancing global integration with local resilience will be essential for maintaining stability and competitiveness in an uncertain world.

Key Sector Trends from 2021 to Present

Since 2021, several key trends reshaped the transportation industrial base, emphasizing efficiency, resiliency, and sustainability in response to global disruptions and long-term economic demands. Notably, the continued expansion of intermodal transportation has integrated rail, trucking, and maritime networks to optimize freight flows. This growth, driven by rising e-commerce and consumer demand, has led ports and inland terminals to develop better facilities to reduce bottlenecks and improve efficiency. Additionally, technological advancements are revolutionizing the sector. The rapid adoption of improved data analytics and new digital platforms, bolstered by new investments in charging infrastructure and digital tools, is reshaping transportation.

Sustainability is central, with global climate change agreement driving efforts to promote green transportation through alternative fuels, electric vehicles (EVs), and emission-reduction technologies. The rail, maritime, aviation, and trucking sectors are adopting sustainable practices to meet federal and international climate goals, enhancing environmental stewardship throughout the transportation network.

Addressing workforce challenges in trucking has been a priority. DOT has expanded apprenticeship programs and streamlined the Commercial Driver's License (CDL) process to attract new drivers. Establishing the Women in Trucking Advisory Board highlights efforts to enhance diversity and inclusion. Simultaneously, the sector is investing in workforce development programs to upskill employees for emerging technologies.

The importance of supply chain resilience and collaboration has grown in light of recent disruptions. Public–private partnerships are playing a key role in addressing congestion hotspots and improving coordination across the supply chain. Programs like Freight Logistics Optimization Works (FLOW) foster data-sharing between shippers, carriers, and ports, creating more adaptable and responsive logistics networks.

Modernization efforts extend to rail, air and maritime systems, with the BIL dedicating $66 billion to rail upgrades for safety improvements, capacity expansion, and system modernization and $15 billion for airport infrastructure improvements. Ports are also receiving support through the Port Infrastructure Development Program (PIDP), which funds infrastructure upgrades to increase capacity and improve the efficiency of U.S. ports.

These trends reflect a transportation industrial base that is evolving to meet the challenges of today while preparing for the demands of tomorrow. The sector's emphasis on innovation, sustainability, collaboration, and workforce development ensures that it remains resilient, adaptable, and prepared to support economic growth and global trade in the years ahead.

PROGRESS TO DATE

One-year Review Priorities

In the February 2022 *Supply Chain Assessment of the Transportation Industrial Base: Freight and Logistics*, the Biden–Harris Administration identified several key priorities aimed at addressing vulnerabilities exposed by the COVID-19 pandemic and trade disruptions. The focus was on building a more resilient and sustainable supply chain to support U.S. economic growth and ensure the smooth movement of goods in the future.

The 2022 Review places significant emphasis on infrastructure investment and modernization. The BIL allocated historic levels of funding to upgrade ports, railroads, highways, and bridges. These investments aim to increase capacity and reduce bottlenecks, particularly in congested areas like ports, to improve the speed and efficiency of freight movement.

Recognizing the impact of labor shortages across the transportation sector, the Administration prioritized workforce development and labor support. This includes investing in training programs for new workers, improving job stability and working conditions, and ensuring safety for supply chain workers, such as truck drivers and port employees. One notable example was the Trucking Action Plan, which led to 2021 registering as the best year for trucking employment growth since 1994 and December 2021–February 2022 as the best three-month stretch for long distance truck hiring since the 1990s.

The report also emphasized the need for data-driven supply chain management, encouraging companies to adopt digital tools like AI, blockchain, and real-time dashboards to monitor logistics and forecast potential disruptions. Improved data sharing between public and private sectors is seen as crucial for enhancing visibility and managing crises more effectively.

To further strengthen the resilience of freight networks, the assessment advocated for multimodal and intermodal connectivity. To achieve this, BIL programs including (Nationally Significant Multimodal Freight & Highway Projects) INFRA, PIDP, and the Consolidated Rail Infrastructure and Safety Improvements (CRISI) Program invested in freight infrastructure projects to make the movement of goods more flexible and efficient, reducing delays and transportation costs.

Finally, the report highlighted the importance of public–private coordination and international partnerships to build resilience. Developing "friend-shoring" alliances with trusted trading partners will maintain the efficiencies of trade while promoting economic resilience. The Administration also aimed to convene stakeholders across sectors to align infrastructure and policy improvements that will better prepare the U.S. for future disruptions.

These priorities reflected a strategic shift towards redundancy and resilience, balancing efficiency with preparedness to create a transportation system that can withstand future challenges while supporting sustainable economic growth.

Progress from 2021 to Present

Since 2021, significant progress has been made in building resilience within the U.S. transportation industrial base supply chain. DOT, alongside federal, state, and private sector partners, has launched key initiatives aimed at strengthening infrastructure, improving supply chain visibility, and enhancing the ability of the transportation network to withstand disruptions. Major investments through BIL, as well as targeted efforts to address workforce challenges and freight congestion, have positioned the U.S. transportation system to be more adaptable and resilient in the face of ongoing global challenges. These initiatives reflect a coordinated approach to bolstering the critical systems that support the movement of goods and services across the nation.

Responding to the Covid-19 Crisis

In response to the COVID-19 crisis, DOT has taken a series of strategic measures to address freight congestion and enhance the resilience of the transportation industrial base. Recognizing the challenges caused by supply chain disruptions, DOT directed emergency funding and implemented regulatory and collaborative strategies to support key freight corridors, ports, and intermodal facilities.

One critical effort involved emergency infrastructure funding to alleviate bottlenecks. The Port of Savannah is a notable example, where DOT funded a project by the Georgia Ports Authority to create pop-up container yards. This initiative, supported by a reallocation of over $8 million, converted existing inland facilities in Georgia and North Carolina into five temporary container yards.

In addition to infrastructure upgrades, DOT provided regulatory flexibility to address pandemic-induced disruptions. Temporary waivers—such as relaxing hours-of-service rules for truck drivers and lifting weight restrictions on highways—enabled faster freight movement and ensured that essential goods were delivered without delays. These regulatory adjustments played a crucial role in maintaining transportation flow under challenging conditions.

DOT also focused on collaborative efforts with key industry stakeholders, including freight carriers, logistics providers, and trade associations. This collaboration facilitated the sharing of data, best practices, and insights to identify congestion hotspots and optimize freight movements. Such partnerships allowed the transportation sector to better manage disruptions and minimize bottlenecks across supply chains.

Bipartisan Infrastructure Law

Federal investment has been a pivotal driver of infrastructure improvements in the freight transportation sector. With the enactment of BIL, signed into law in November 2021, significant resources have been allocated to address critical infrastructure needs, including those related to port congestion, rail, highways and bridges, and intermodal investments. This historic investment in the nation’s infrastructure aims to modernize and expand freight transportation systems. BIL makes the largest single Federal investment in our ports in American history, on top of new funds for airports, freight rail, and other critical supply chain infrastructure, which created jobs and strengthened our economy. BIL's $1.2 trillion made it the largest infrastructure bill in U.S. history, nearly double the funding made available through the Fixing America's Surface Transportation (FAST) Act.

In addition to historic funding levels, through this Administration DOT has transformed how it invests in the nation's transportation supply chains, by launching the Office of Multimodal Freight Infrastructure and Policy (Multimodal Freight Office) to oversee the maintenance and improvement of the nation's freight network and supply chains. This new office within the Office of the Under Secretary of Transportation for Policy was established and funded by Congress to carry out the national multimodal freight policy. Among other duties, Congress specified that the Office should promote and facilitate the sharing of information between the private and public sectors with respect to freight issues through the FLOW program, conduct research on improving multimodal freight mobility, assist cities and States in developing freight mobility and supply chain expertise, update the National Freight Strategic Plan, and liaise and coordinate with other Federal departments and agencies.

CASE STUDY: JOINT OFFICE OF ENERGY AND TRANSPORTATION

The Joint Office of Energy and Transportation (Joint Office) supports the deployment of zero-emission, convenient, accessible, and equitable transportation infrastructure. The Joint Office was created through the Bipartisan Infrastructure Law and facilitates collaboration between the U.S. Department of Energy (DOE) and the U.S. Department of Transportation (DOT).

The Joint Office supports the buildout of a nationwide network of electric vehicle chargers, zero-emission fueling infrastructure, and zero-emission transit and school buses by aligning resources and expertise to achieve this strategic goal through unifying guidance, technical assistance, and analysis for the following programs: National Electric Vehicle Infrastructure Formula Program, Charging and Fueling Infrastructure Discretionary Grant Program, Low or No Emission Vehicle Program for Transit, and Clean School Bus Program.

In 2021, the Joint Office was formed by the passage of the Bipartisan Infrastructure Law (Infrastructure Investment and Jobs Act). In its first year, the Joint Office hired expert staff, established the Electric Vehicle Working Group to coordinate industry stakeholders, and saw approval of NEVI plans from all 50 states. In its second year, the Joint Office established the National Charging Experience (ChargeX) Consortium to improve charging accessibility and reliability, convened the Electric Vehicle Working Group and activated the first NEVI-funded stations. Throughout 2024, the Joint Office has provided funding for community charging, transit to make electric transportation an easy choice for anyone.

America's Trucking Workforce

In response to challenges faced by America's trucking workforce, DOT has undertaken several initiatives to enhance recruitment, training, and diversity within the industry. DOT has significantly expanded trucking apprentice programs across the country. These programs offer structured training and mentorship opportunities for aspiring truck drivers, aiming to attract more individuals to pursue careers in trucking. By doubling the number of these programs, DOT seeks to address staffing issues experiences by trucking companies. Additionally, DOT has implemented measures to streamline the process of obtaining a CDL Recognizing the bureaucratic hurdles and barriers that often deter individuals from entering the trucking profession, DOT has worked to simplify CDL application procedures, making it easier for aspiring truck drivers to acquire the necessary credentials.

DOT has also taken steps to promote gender diversity and inclusion within the trucking industry. To this end, DOT has established a Women in Trucking Advisory Board, which focuses on advocating for policies that support gender equality, addressing gender-specific challenges, and encouraging greater participation of women in trucking careers. Financial support has also been provided by DOT to assist states in expediting the issuance of CDLs. Grants totaling over $44 million have been allocated to states, enabling them to enhance their CDL issuance systems, improve training programs, and streamline administrative processes.

Aerospace Resiliency Task Force

The Consolidated Appropriations Act of 2023 required DOT to establish the Aerospace Supply Chain Resiliency (ASCR) Task Force. The purpose of the Task Force, as established by the Act, is to "Identify and assess risks to United States aerospace supply chains, including the availability of raw materials and critical manufactured goods, with respect to major end items produced by the aerospace industry; and the infrastructure of the National Airspace System; and identify best practices and make recommendations to mitigate those risks and support a robust United States aerospace supply chain."

The first meeting of the Task Force was held in January 2024 and based on the statutory provisions, the Task Force submitted its Report to Congress in November of 2024. DOT will submit a separate Report to Congress, within 180 days of the Task Force report, regarding the status or implementation of recommendations of the Task Force.

The key findings of the report include that our aerospace supply chain is vulnerable to labor shortages, obstacles in critical materials, and the health of supporting infrastructure. Investment in these three areas, well beyond today's current levels, will be needed to ensure that the aerospace supply chain is able to operate in the presence of supply chain disruptions. Unlike other parts of the economy in the U.S., the aerospace supply chain is uniquely dependent on the smooth operation of, and collaboration across regulatory entities, especially the Federal Aviation Administration (FAA). In many cases, key work can only be done by people who have required credentials, repairs and maintenance often require additional government oversight, and the personnel responsible for oversight are subject to Congressional authorization and appropriation timelines. Because the aerospace supply chain is tied to global operations, global interoperability requirements, and bilateral or multi-lateral agreements, actions taken in the U.S. cannot be seen as independent of the broader global environment.

Challenges and Opportunities

Since 2021, DOT has faced several challenges in implementing the goals outlined in the *Supply Chain Assessment of the Transportation Industrial Base*. While meaningful progress has been made, infrastructure bottlenecks, global supply chain disruptions, and cybersecurity risks complicated the recovery and modernization efforts. Alongside these challenges, new opportunities emerged, driven by collaboration between public and private sectors, infrastructure investments, and evolving strategies like nearshoring.

Challenges and Setbacks: A Complex Recovery

One of the most pressing challenges has been operational bottlenecks, particularly at key U.S. ports. For example, the Ports of Los Angeles and Long Beach faced severe congestion in 2021 and 2022 due to a sharp increase in import container volume, following a COVID-19 induced decline. Recent research estimates that sectoral supply chain bottlenecks were responsible for a significant share of total observed U.S. inflation from 2021 to 2022 and that supply chain disruptions during the pandemic were a large component of cross-industry inflation for producers.[611] Despite emergency measures funded by BIL, including expanded rail links and new storage capacity, these challenges persist, particularly, with rail cargo, when there are changes in cargo demand.

As DOT pushed for enhanced data-sharing platforms to improve visibility across supply chains, some stakeholders were reluctant to share sensitive data, slowing down adoption of real-time tracking and predictive tools. Although DOT launched the Trucking Action Plan to recruit drivers, expand apprenticeships, and improve working conditions, the sector continued to struggle with retention. Bottlenecks in the trucking industry delayed deliveries, contributing to a ripple effect throughout the transportation network.

Emerging Opportunities: Collaboration and Resilience

Amid these setbacks, new opportunities emerged, driven by public–private collaboration and infrastructure modernization and workforce development. Programs like FLOW, which brought together freight carriers, cargo owners, logistics providers, port operators, and trade associations, successfully improved supply chain visibility. This partnership model allowed stakeholders to share data and coordinate efforts to reduce congestion and mitigate the ripple effects of supply chain crises.

BIL also provided much-needed investment to modernize ports, railways, and intermodal facilities. The INFRA grant program alone allocated $8 billion to highway and freight projects, while BIL also provided $2 billion for the PIDP program, and $5 billion for the CRISI program. These and other programs will build infrastructure for a more resilient supply chain for the coming decades.

DOT's emphasis on workforce development began to yield results as well. Through partnerships with the Department of Labor, the Trucking Action Plan introduced new apprenticeship programs and launched a pilot initiative for drivers between the ages of 18 and 21. These efforts aimed to stabilize the trucking workforce and create long-term career pathways to attract and retain talent.

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611 Comin, Johnson, and Jones, "Supply Chain Constraints and Inflation", *NBER Working Paper Series* August 2024

CASE STUDY: FREIGHT LOGISTICS OPTMIZATION WORKS (FLOW)

Freight Logistics Optimization Works (FLOW) is a public–private partnership among industry and government to build a forward-looking, integrated view of supply chain conditions in the United States. FLOW data helps forecast how current capacity and throughput will fare against future demand, helping participating companies anticipate changes in supply chain throughput and take proactive step to mitigate previously unanticipated delays.

The FLOW program collects purchase order information from importers in addition to logistics supply, demand, and throughput data from participants (e.g., beneficial cargo owners, ocean carriers, ports, terminals, motor carriers). The United States Department of Transportation (USDOT) anonymizes, regionally segments, and aggregates the data. Participants then receive FLOW data that provides a broad, daily view of the current conditions of the overall logistics network, beyond what they may observe within their own operations.

Participants use FLOW data to develop more responsive operations strategies to improve their supply chain throughput and resilience. Because importer POs drive the demand for logistics services, aggregating future demand data (e.g., purchase orders, incoming container volumes, origin and/or destination regions) coupled with regional supply and throughput data across different transportation modes (ocean, truck, rail) enables participants to forecast how current capacity and throughput will fare against the future demand. Participants then use this insight to optimize operations and ensure healthy throughput.

By sharing aggregated regional data from multiple participants, FLOW provides a broad and timely level of transparency beyond the visibility and scope of any single company's operations. Participants can use this data to better understand how regional logistics capacity can service current and future demand, as well as how demand fluctuations may impact their own utilization of assets and logistics throughput. Because demand data is shared in advance of when respective logistics services would be required, supply-side optimizations such as modifying supply capacity levels, service level mixes, and service expectations can be made by participants in a more proactive and responsive manner. This in turn can help the industry mitigate bottlenecks and service-level volatility.

This newfound visibility has been useful as the United States has faced continued supply chain challenges including the Francis Scott Key Bridge Collapse, rerouting of cargo due to major global events, and overall validation of trends in the industry. This has allowed participating companies to utilize FLOW data in concert with their existing processes to better understand and prepare for supply chain disruptions.

Engagement with Industry and Communities

The Administration has engaged with the supply chain industry regularly since 2021 through the Supply Chain Disruptions Task Force. DOT's Multimodal Freight Office, established in 2023, has engaged shippers, ocean carriers, ports and terminal operators, motor carriers, rail carriers, intermodal equipment operators, warehousing companies, and environmental justice community groups. This regular engagement has allowed the Multimodal Freight Office to be viewed as an important partner and a first call for industry to make when they need to engage DOT. The Multimodal Freight Office's FLOW program assisted DOT in responding to supply chain disruptions like the Francis Scott Key Bridge collapse and subsequent temporary closure of the Port of Baltimore, by sharing how cargo flows were diverting to other ports on the east coast.

Engagement with Allies and Partners

DOT has played a leading role in multilateral fora. Along with its G7 partners, DOT has prioritized supply chains during 2024 under the Italian presidency of the G7 and will further sharpen its focus during the G7 Canadian presidency in 2025 through the work of the newly established Supply Chain Working Group. The working group explores areas of mutual cooperation to strengthen transportation resiliency that include digital innovation and infrastructure, disruption and crisis management, and clean transportation. Another critical forum for advancing supply chain resiliency is the Indo-Pacific Economic Framework for Prosperity (IPEF), which is comprised of 14 member countries including the United States. Under IPEF, the member countries established the Supply Chain Council (SCC) and the Crisis Response Network (CRN). The SCC will facilitate collaboration to develop actionable policies and recommendations aimed at enhancing supply chain resilience across the IPEF region. The CRN is focused on addressing immediate supply chain disruptions, such as an emergency simulation exercise that involved a supply chain disruption impacting the import and use of certain chemicals by IPEF countries.

The Multimodal Freight Office has worked closely with the new supply chain office at Transport Canada as we work to solve similar challenges and find areas of collaboration. Representatives of the Multimodal Freight Office have visited allied ports including Rotterdam on trade missions to facilitate continued collaboration between the U.S. and Europe. Other engagements include engagement with associations who represent European logistics companies on lessons learned from the Supply Chain Disruptions Task Force and allied foreign manufacturers to think through ways of boosting shipbuilding and crane manufacturing. The Biden–Harris Administration also announced the Icebreaker Collaboration Effort, or ICE Pact, which is a trilateral arrangement between the United States, Canada, and Finland to collaborate on the production of polar icebreakers and other capabilities.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

Improving the resiliency, and identifying the vulnerabilities, of the transportation industrial base supply chain in the United States involves implementing a range of measures to mitigate risks, enhance flexibility, and strengthen the ability to withstand and recover from disruptions.

Transparency

Achieving transparency across the transportation industrial base supply chain has several challenges. One major issue is data availability, which is fragmented across various stakeholders, systems, and formats. Efforts to collect data are often delayed due to inconsistencies in quality and standards. Additionally, concerns about data privacy and security can inhibit the sharing of sensitive transportation data, particularly between public and private entities.

Another challenge is the complexity of analytics and forecasting, including integrating data from disparate sources and systems is complex resulting in difficulties and uncertainties in developing predictive modeling. DOT has worked to address transparency issues through a variety of data collections from the Bureau of Transportation Statistics (BTS) as well as the FLOW program, which works together with industry in a data trust construct to forecast ocean freight congestion at U.S. ports.

Domestic capacity

The U.S. transportation industrial base is vulnerable due to reliance on foreign suppliers for key commodities like semiconductors, rare earth elements, and batteries. Limited domestic production, fragile global logistics, and geopolitical tensions, such as U.S.–China trade disputes, exacerbate risks, while workforce shortages and policy gaps hinder supply chain resilience. Many sectors rely on imported components and materials that are not available from domestic or other nearby sources. An over-reliance on foreign sources can increase vulnerability to disruptions such as natural disasters, geopolitical tensions, and supply chain bottlenecks. Balancing the need for increased domestic manufacturing with the need for imports to support domestic industry requires a strategic approach, such as identifying critical components and technologies for domestic production, workforce capacity, and assessing the capacity of industries.

This approach includes prioritizing strategic sectors essential for national security, economic stability, and supply chain resilience, and focusing on building domestic and regional capabilities in these high-priority areas. This can support economic and practical viability, while improving the resiliency and efficiency of the transportation industrial base supply chain. Supplier ownership, including ownership by foreign entities of concern of key components in critical sectors like maritime and automotive may raise concerns about national security and supply chain resilience. Domestic immigration policy may affect supply chain components coming from the Global South, as many components from Mexico/Central America are trucked through the same ports of entry. Backlogs at the US-Mexico border could pose difficulty for domestic production.

Trade concentration

The U.S. transportation industry relies heavily on imported components and materials, making it vulnerable to global supply chain disruptions. In 2021, transportation equipment imports totaled $382.5 billion, with Mexico, Japan, and Canada supplying 58.1 percent of these imports. The industry's dependence was starkly highlighted by the 2021 global semiconductor shortage, which led to an 18.9 percent decline in U.S. vehicle production. Concentrated trade relationships and dependence on foreign suppliers amplify the risks posed by supply chain interruptions. Import reliance and trade concentration have implications beyond economic considerations, extending to national security. The transportation sector plays a critical role in supporting defense transportation systems, and disruptions in the supply chain could hinder the nation's ability to respond effectively during crises or conflicts. The U.S. transportation industrial base's dependence on importing from a single foreign market or region can weaken resilience in the face of supply chain disruptions or strategic challenges.

In several sectors there is a reliance on a few countries for critical components like semiconductors and electronic systems. This reliance led to widespread production delays and shortages during the COVID-19 pandemic. Similarly, in aircraft manufacturing, disruptions in the supply chain for crucial components like engines and avionics systems could halt production globally. Maritime shipping faces challenges due to the concentration of shipbuilding and port equipment manufacturing in specific countries, including China.

Supplier diversity

The current state of diversity within the U.S. transportation industrial base varies significantly across sectors. Supplier diversity, crucial for supply chain resilience and robustness, is assessed by the number of suppliers for specific inputs or processes and the concentration among these suppliers. High supplier concentration, particularly for critical components like engines and advanced electronic systems, makes the supply chain highly vulnerable to disruptions if key suppliers face operational issues. Manufacturers must often qualify their suppliers of highly advanced parts and systems, and it would likely not be cost effective for a manufacturer to pursue qualifying multiple suppliers, particularly among smaller, less experienced suppliers that may have difficulty meeting the specifications.

The maritime industry relies on a few manufacturers for specialized equipment like port machinery, engines, and navigation systems, increasing supply chain vulnerability due to the technological sophistication required for these products. Similarly, the aerospace industry experiences high supplier concentration for specialized equipment like airplanes and control systems. A small number of suppliers dominate these markets, resulting in significant risks to supply chain stability. Infrastructure dependencies further limit the number of suppliers, exacerbating concentration issues.

High entry barriers, including significant capital investment, technological expertise, and compliance with regulatory standards, restrict new entrants into these markets. Existing large suppliers benefit from economies of scale, making it difficult for smaller or new suppliers to compete, thus maintaining high concentration levels and reducing supplier diversity.

Agility

The agility of the U.S. transportation industrial base's supply chain is important for effectively responding to disruptions. This agility depends on existing stockpiles, manufacturing process complexity and lead times, manufacturing system flexibility, and the adaptability of logistics networks. The COVID-19 pandemic exposed vulnerabilities due to just-in-time inventory practices, highlighting susceptibility to prolonged disruptions.

Manufacturing processes within the transportation industrial base are highly complex, involving numerous components and intricate production steps. Lead times for advanced components, such as electronic systems, can extend from months to years due to availability, stringent quality control, and certification requirements. The transportation industrial base frequently encounters bottlenecks at major ports and distribution hubs, exacerbated by the global supply chain crisis. Addressing these bottlenecks requires significant improvements in port infrastructure and logistics management. Alternative transportation pathways vary by industry; some sectors can reroute shipments to mitigate delays, while others are constrained by specific transportation modes or routes.

CASE STUDY: AEROSPACE SUPPLY CHAIN RESILIENCY TASK FORCE

The Task Force identifies and assesses risk to the United States aerospace supply chains, including the availability of raw materials and critical manufactured goods, with respect to major end items produced by the aerospace industry; to identify and assess risks to the infrastructure of the National Aerospace System; and to identify best practices and make recommendations to mitigate those risks and support a robust United States aerospace supply chain.

The Task Force engages with the aerospace industry to document trends in changes to production throughput and lead times of major end items produced by the aerospace industry. The Task Force also determines the extent to which United States aerospace supply chains are potentially exposed to significant disturbances, including the existence of and potential for supply chain issues such as chokepoints, bottlenecks, or shortages that could prevent or inhibit the production of flow of major end items and services.

The Task Force is tasked with exploring new solutions to revolve supply chain issues using the existing aerospace infrastructure and aerospace infrastructure, manufacturing capabilities, and production capacities in small or rural communities. The Task Force is evaluating the potential for introduction and integration of advanced technology to address these supply chain issues and utilize to the maximum extent practicable existing supply chain studies, reports, and materials in crafting its recommendation to address, manage, and relive the critical aerospace supply chain challenges in the United States. The Task Force has submitted its report to Congress.

Security

The security status of the nation’s transportation industrial base's supply chain demands continuous evaluation and enhancement due to various threats. Critical infrastructure, including ports, railways, and airports, implement advanced security measures like surveillance systems, physical barriers, and security personnel. However, the network's complexity challenges comprehensive security.

Manufacturing facilities and transport hubs face risks of industrial sabotage, mitigated by strict access controls, employee background checks, and robust security protocols. Despite these measures, insider threats persist, necessitating ongoing vigilance and updates.

Natural and man-made disasters such as hurricanes, floods, wildfires, and major infrastructure failures, are risks to the transportation infrastructure. Recent events, such as the collapse of the Francis Scott Key Bridge in Baltimore, MD, recent train derailments, the Gulf Coast hurricanes, migrant crisis at the US-Mexico border, and western wildfires, highlight these vulnerabilities. Efforts to enhance resilience include reinforcing infrastructure, emergency response plans, and climate-resilient technologies, yet catastrophic risks remain, requiring continuous investment. Heavy reliance on digital systems makes the transportation sector vulnerable to cyberattacks. Cyber resilience is being improved through measures like encryption, multi-factor authentication, and continuous monitoring, but the sector remains a target for sophisticated attacks, such as ransomware.

Economic health and compliance

The economic health of the transportation industrial base supply chain depends on several factors, including financial stability, quality and reliability, compliance, and workforce dynamics. The transportation industry faces volatility driven by factors like fluctuating fuel prices, currency exchange rates, and the global trade frictions. Capital-intensive requirements for infrastructure upgrades, fleet expansions, and technology integrations can create financial strains. Revenue uncertainty can be exacerbated by economic downturns, shifts in consumer behavior, and unforeseen disruptions such as pandemics or natural calamities.

Aging infrastructure coupled with deferred maintenance poses risks ensuring consistent quality and reliability within transportation networks. Capacity constraints at critical transportation hubs or across various modes can increase congestion, delays, and undermine service reliability. Furthermore, reliance on complex technological systems introduces risks of technical failures or malicious cyberattacks, jeopardizing the reliability of transportation operations.

PRIORITIES AHEAD

Four-year Outlook

Between 2025 and 2028, the U.S. transportation industrial base will face a range of challenges as it strives to build more resilient and sustainable supply chains. These efforts could require balancing efficiency with preparedness to mitigate risks such as geopolitical tensions, climate change, and cybersecurity threats, while also seizing opportunities through reshoring, nearshoring, infrastructure investment, and digital transformation.

One of the primary risks in the coming years will be managing geopolitical tensions, especially between the U.S. and China. As China continues to deploy non-market policies and practices that prompt responses from the United States and like-minded trading partners, companies will need to increase resiliency in their sourcing strategies to reduce their exposure to those policies and practices.

At the same time, climate-related risks will become more pressing. The frequency and severity of hurricanes, wildfires, and floods are expected to increase, posing a threat to critical infrastructure such as ports, highways, and railways. Additionally, environmental regulations aimed at reducing carbon emissions and noise may accelerate the transition to alternative fuels and cleaner logistics systems. This will create challenges but also opportunities, as businesses that adopt sustainable practices will benefit from improved operational efficiency and regulatory compliance.

Another major concern is the growing threat of cyberattacks on transportation infrastructure. As the industry continues to digitize, the risk of cyberattacks increases, threatening to disrupt logistics networks or compromise data security. Protecting these digital systems will require robust cybersecurity frameworks and closer collaboration between public and private sectors to prevent and mitigate potential disruptions.

Four-year Resilience Goals and Priorities

Through the *Supply Chain Assessment of the Transportation Industrial Base*, DOT spotlighted a range of actions that it envisions as supporting a resilient 21st-century freight and logistics supply chain for America. Since publication of the report, DOT continues to investigate resiliency and vulnerability issues in the Transportation Industrial Base supply chain, has implemented several actions to address these issues, and has identified priority actions over the next four years in this sector.

Priority 1: Foreign-Manufactured Cranes

Addressing the issues associated with Chinese-manufactured cranes requires a comprehensive policy and strategic response. In 2024 the White House announced the U.S. Port Security Initiative to reverse our dependence on Chinese State-owned enterprises that manufacture U.S. port equipment in the Peoples Republic of China (PRC). The initiative includes 25 percent tariff rate on ship-to-shore (STS)-cranes manufactured in the PRC, an Executive Order that strengthens U.S. Government authorities in the port environment, and a Maritime Security Directive that provides regulatory oversight of STS-cranes. To mitigate the supply gap this would inevitably create in the United States, the U.S. Government identified international suppliers from allied nations and developed economic incentives that would lead to a commitment by a Japanese firm, its U.S. based subsidiary, and a global infrastructure private equity firm to invest in the United States and onshore their ship-to-shore gantry crane manufacturing. The announcement expands the Japanese firm's port crane manufacturing in the United States, including the essential ship to-shore gantry cranes that have not been produced in the United States in over 30 years. This deal creates a clear path to rebuild critical U.S.-based port crane manufacturing capabilities. The announcement also provided the Administration momentum to carry its message forward into forthcoming engagements, including the House Homeland Security Committee on the cybersecurity of the nation's ports, the President's State of the Union Address, and the April 2024 Japan State Visit. Following the initial announcement, crane manufacturers from other like-minded partners in Finland and Switzerland have expressed their willingness to make a similar commitment.

While there are several allied countries, such as Japan, South Korea, Germany, and Finland, involved in crane manufacturing, crane manufacturing is dominated by non-allied countries. For example, in February 2024 the Department of Homeland Security published Directive 105-4; *Cyber Risk Management Actions for Ship-to-Shore Cranes Manufactured by People's Republic of China Companies*, noting: "PRC [Peoples Republic of China]-manufactured STS cranes make up the largest share of the global ship-to-shore crane market and account for nearly 80 percent of the STS cranes at U.S. ports. The dominance of foreign-manufactured cranes carries significant economic implications, particularly for the domestic manufacturing sector. Domestic crane manufacturers have and continue to face strong competition from foreign counterparts, which often benefit from lower production costs and state subsidies.

Cranes are a vital type of infrastructure that facilitate the safe and efficient transfer of cargo between multiple modes of transportation, especially at ports and intermodal facilities across the United States. Rising containerized cargo transportation worldwide has resulted in an increased need for cranes at U.S. ports to handle increased cargo volumes that directly support the U.S. economy. Common types of cranes used at ports specially designed to load and offload goods include overhead/hammerhead cranes, ship-to-shore (STS) cranes, overhead traveling cranes, rubber tire gantry cranes, cantilevered rail-mounted gantry cranes, rail-mounted gantry cranes, automatic stacking cranes, and mobile harbor cranes. As demand for these types of equipment has increased, U.S. ports are increasingly reliant on foreign-manufactured cranes due to the lack of available, domestically manufactured alternatives.

CASE STUDY: CRANE MANUFACTURING

The Administration continues to deliver for the American people by rebuilding the United States industrial capacity to produce port cranes with trusted partners. America's prosperity is directly linked to maritime trade and the integrated network of ports, terminals, vessels, waterways, and land-side connections that constitute the Nation's Marine Transportation System (MTS). This complex system supports $5.4 trillion worth of economic activity each year, contributes to the employment of more than 31 million Americans, and supports nearly 95 percent of cargo entering the United States.

The Administration will invest into U.S. port infrastructure over the next 5 years through the President's Investing in America Agenda, including the Bipartisan Infrastructure Law and the Inflation Reduction Act.

PACECO Corp., a U.S.-based subsidiary of Mitsui E&S Co., Ltd (Japan), is planning to onshore U.S. manufacturing capacity for its crane production. PACECO has a deep history in the container shipping industry, manufacturing the first dedicated ship-to-shore container crane in 1958 as PACECO Inc., and it continued U.S.-based crane manufacturing until the late 1980s. PACECO intends to partner with other trusted manufacturing companies to bring port crane manufacturing capabilities back to the U.S. for the first time in 30 years, pending final site and partner selection.

In addition to PACECO Corp., Konecranes, a Finnish-based port equipment manufacturer, is announcing its plans to establish and grow a consortium of U.S. partners, including steel structure providers and other manufacturers, to build ship-to-shore (STS) cranes in the United States to serve North American ports. Konecranes is committed to growing its workforce in the United States as demand for cranes produced by trusted vendors increases. Konecranes estimates that every STS crane built in the United States will require the production of 1,500 tons of U.S.-made steel and over 100,000 labor hours for the whole value chain.

The Administration continues to support this effort through collaboration with ports, manufacturers, and capital providers to create the necessary conditions for onshoring crane manufacturing. Through continued action, the Biden–Harris Administration is laying out a roadmap for how to rebuild industries critical to the American supply chain and doing so alongside its allies and partners.

Priority 2: Shipbuilding and Repair

The U.S. shipbuilding and repair industry depends on foreign suppliers for essential raw materials, components, and equipment necessary for constructing vessels. These suppliers provide materials like steel and aluminum, engines, propulsion systems, electronics, navigation equipment, specialized machinery, advanced materials, composites, and outfitting components. While domestic suppliers provide many items, foreign sources play a vital role in supplying specialized materials and components that contribute to the construction of modern vessels.

This dependency exposes the industry to vulnerabilities, particularly during periods of geopolitical tension, where disruptions in the supply of critical components can result in production delays and increased cost. A robust domestic shipbuilding and repair industry is critical for national and economic security, ensuring the country's ability to build and maintain a fleet of vessels for defense, maritime security, and emergency response.

Domestic shipyards, and their ability to quickly expand production, if needed, are essential for constructing naval vessels, Coast Guard ships, and other maritime assets vital for safeguarding national interests and protecting maritime borders. Swift procurement and coordination within the supply chain can prevent production delays, while continuous workforce training and efforts to expand the current workforce can ensure the availability of skilled labor.

In 2024 the White House took steps to strengthen U.S. shipbuilding capacity through the Icebreaker Collaboration Effort (ICE) Pact, a trilateral arrangement with Canada and Finland to collaborate on the production of polar icebreakers. The objective is to advance U.S. economic and national security interests at the same time. ICE Pact does that by strengthening our shipbuilding and industrial capacity while simultaneously pushing back against Russia and China and strengthening our international alliances.

From an economic perspective the arrangement gives the U.S. Coast Guard an opportunity to leverage Finnish and Canadian design and construction expertise, as it seeks to build a fleet of American-made icebreakers. The arrangement also pushes demand from foreign partners to American shipyards, providing the yards with an opportunity to expand their long-term order books. This arrangement will help American yards compete for a significant share of that orderbook and help the United States lead the world in the design, construction, and delivery of polar icebreakers.

ICE Pact also advances U.S. national security in four remarkable areas: 1) cements the increasingly close ties between Finland and the United States—sending a signal to Russia about our continued ability to leverage international alliances; 2) it re-directs orders for icebreakers away from Chinese yards and into those of our own, further degrading Chinese economic security; 3) strengthens transatlantic security and economic ties because much of the equipment U.S. shipyards rely on is made by Finnish companies; 4) and it will allow the United States to project power into the polar regions to enforce international norms and treaties that promote peace and prosperity in the Arctic and Antarctic.

For the United States, the value proposition is to bring world class expertise to U.S. shipyards to help them compete on the world stage and to strengthen U.S. national security by developing a competitive edge in technologies with geostrategic importance. It also demonstrates U.S. commitment to international alliances and reinforces the signal to Russia and China that U.S. strategic alliances are strong, continue to evolve, and are here to stay. An MOU to finalize the arrangement was signed by the United States, Canada, and Finland in November 2024.

CASE STUDY: SHIPBUILDING

The Biden–Harris Administration has committed to supporting the entire American shipbuilding supply chain and enhancing the security of the global maritime environment through collaboration with our allies and partners. This includes cooperation with allied nations, incentivizing private investment, and strategic public investments.

The United States, Canada, and Finland announced the Icebreaker Collaboration Effort or "ICE Pact" – a trilateral arrangement to collaborate on the production of icebreakers, alongside allies and partners, labor, and industry. Due to the capital intensity of shipbuilding, long-term, multi-ship orderbooks are essential to the success of a shipyard. The governments of Canada, Finland, and the United States intend to leverage their own shipyards in Canada, Finland, and the United States to build polar icebreakers for their own use, as well as extend an invitation to allies and partners to purchase polar icebreakers for their needs.

Bollinger Shipyards will play a critical role in ICE Pact and its efforts to strengthen the polar capabilities of the United States and its allies through the creation of a fleet of polar icebreakers. Bollinger is currently under contract to build three Polar Security Cutter (PSC) heavy polar icebreakers for the United States Coast Guard and has invested over $20 million in private capital in its shipyard.

Davie Shipbuilding, Canada's largest shipbuilder, intends to make a new long-term commitment to American shipbuilding, given the Biden–Harris Administration's leadership. This includes a major investment in a U.S. shipyard, and Davie is currently building the world's largest orderbook of heavy icebreakers for ICE Pact partner, Canada. Davie also owns Helsinki Shipyard in Finland, which has built over 50 percent of the world's icebreaker fleet.

The U.S. Maritime Administration continues to support shipbuilding through several grant programs and other programs of record, including the Small Shipyard Grant program. The funds will help shipyards modernize, increase productivity, and expand local job opportunities.

One notable example is the Philly Shipyard, who has utilized an innovative on-site apprenticeship training process, supported by the award of a MARAD Small Shipyard Grant in 2009 and 2021. Before this grant, Philadelphia's Shipyard had seen their employee numbers drop below 100 personnel. With the 5-ship contract awarded in 2020 the workforce has now recovered and built a workforce of over 1500 personnel, plus contractors, that allowed it to competitively gain contracts for at least 4 more commercial ships providing a long-term career pathway for its workforce. This includes Great Lakes Dredge & Dock Corp. (GLDD), who are currently building The Acadia, the first subsea rock installation vessel being built in the U.S.

The Philly Shipyard has since been purchased by Hanwha Systems and Hanwha Ocean, who bring expertise to support growth of the shipyard as a leading commercial shipyard in the United States. Recently, Philly Shipyard announced construction on first of three Matson Aloha Class LNG-fueled containerships.

Priority 3: Electric Vehicle Infrastructure

The transportation industrial base is undergoing a significant transformation toward electric-powered equipment, driven by environmental concerns, technological advancements, and regulatory mandates. However, despite the momentum gained by electric-powered equipment, several challenges remain, particularly concerning domestically sourced components and infrastructure.

A major challenge is the dependency on foreign sources for critical components in electric-powered equipment. The supply chain is limited by domestic availability of critical materials like lithium, cobalt, graphite, and nickel. While the U.S. may produce some components domestically, the supply chain often relies on foreign countries for essential materials like lithium-ion batteries, rare earth metals, and specialized electronics. Dependency on foreign sources can expose the transportation sector to geopolitical risks, supply chain disruptions, and fluctuations in commodity prices. In addition, the cost of producing batteries and sourcing other raw materials critical to vehicle production domestically can be higher than in countries with lower labor costs and less stringent environmental regulations. This disparity can make U.S.-made batteries less competitive on the global market. Additionally, the U.S. battery manufacturing industry has not yet achieved the economies of scale seen in countries like China, where government incentivized large-scale production reduces per-unit costs as a result of Chinese industrial support.

Further complicating the supply chain is the lack of adequate critical minerals and refining facilities. Most of these activities are concentrated overseas, particularly in China, which has established a dominant position in the global battery supply chain. Building and upgrading domestic processing facilities requires substantial financial investment and time, along with the development of specialized expertise to ensure the production of high-quality battery components. Additionally, regulatory hurdles and permitting processes can delay the establishment of new manufacturing facilities, further constraining domestic production.

Priority 4: Aerospace Manufacturing

The supply chain within the United States aviation transportation industrial base faces a series of significant challenges that can impact its efficiency, reliability, and overall resilience. These issues have become particularly evident in recent years due to a combination of factors, including the COVID-19 pandemic, geopolitical tensions, and technological demands.

The industry's heavy reliance on a complex, global supply chain is a fundamental issue. This dependence makes the aviation sector particularly susceptible to geopolitical tensions and economic fluctuations. In addition, essential materials like advanced composites, aluminum, and titanium are crucial for building lightweight and fuel-efficient aircraft. Any disruption in their supply chain can have far-reaching consequences for the industry, affecting production schedules and cost structures.

Major areas of concern are the concentration of key suppliers and difficulty for an aerospace supplier trying to enter the market. A small number of suppliers dominate the production of specialized aircraft components, leading to high concentration risk. If any of these suppliers face operational or financial difficulties, the entire supply chain can be disrupted. The lack of alternative suppliers exacerbates this issue, as does the influence of high capital costs, which discourages opportunities for numerous suppliers of critical components, limiting the industry's flexibility in responding to such disruptions. Additional challenges are identified in the Aerospace Supply Chain Resilience Task Force, including ongoing workforce concerns.

Priority 5: Digital Infrastructure

Within the transportation industrial base, data functions as a key commodity, underpinning the entire supply chain's efficiency and resilience. Data analysis begins with descriptive analytics, where historical data is examined to understand trends and patterns. Advanced analytics, including predictive and prescriptive analytics, follow. Predictive analytics forecast future events, such as demand trends or potential disruptions. Prescriptive analytics recommends specific actions based on these predictions to optimize operations and strategic planning.

In the transportation industrial base supply chain, issues in data and data analysis can impact efficiency, resilience, and overall performance. The complexity of this industry, comprising manufacturers, suppliers, logistics providers, and regulatory bodies, exacerbates these challenges. Data plays a crucial role in decision-making, operations, and strategic planning, but its availability is often compromised by fragmented data sources, inconsistent data quality, and limited real-time data.

Increased vulnerability to disruptions arises from the lack of predictive analytics and data integration, leading to severe operational disruptions during crises. Strategic decision-making is hindered by inadequate data and knowledge, affecting organizations' ability to identify trends, and forecast demand. Even when data is available, knowledge gaps can hinder its effective utilization. These gaps arise from insufficient analytical capabilities, a lack of predictive analytics, and limited knowledge sharing among stakeholders.

Resilience Goals and Priorities for the Transportation Industrial Base

The Resilience Goals and Priorities for the U.S. transportation industrial base reflect a strategic commitment to building a stronger, more adaptable, and future-ready transportation system. These goals are designed to address vulnerabilities exposed by recent global disruptions and ensure that the transportation sector can efficiently support economic growth, national security, and supply chain stability.

Goal 1: Strengthen Domestic Manufacturing Capabilities and Production of Port Cranes.

Performance Measure: Increase cranes and critical crane components produced domestically or by allied nations.

- Priority Action 1.1: Measure cranes and crane components, such as control systems, hydraulic parts, and steel structures, that are imported compared to those manufactured domestically or by partners nations.
- Priority Action 1.2: Collaborate with allied countries to promote manufacturing relocation to domestic or allied regions, enhancing regional supply chain resilience.
- Priority Action 1.3: Provide financial incentives, infrastructure development support, or regulatory assistance to encourage onshoring and nearshoring of manufacturing.
- Priority Action 1.4: Provide regulatory assistance to encourage onshoring and nearshoring of crane manufacturing operations.
- Priority Action 1.5: Engage with international partners to support crane manufacturing.

- Priority Action 1.6: Provide technical support and capacity-building programs to assist crane manufacturers in navigating international trade regulations and accessing foreign markets effectively.

Goal 2: Increase shipbuilding and shipbuilding components produces domestically or by allied nations

Performance Measure: Grow the domestic and allied shipbuilding industry.

- Priority Action 2.1: Examine the need for specific financial support to promote local sourcing and production of the domestic shipbuilding industry.
- Priority Action 2.2: Collaborate with maritime agencies to develop allied sourcing strategies.
- Priority Action 2.3: Advocate for a domestic supply chain with shipbuilding associations.
- Priority Action 2.4: Conduct detailed evaluation of the U.S. shipbuilding sector to identify challenges, alongside analysis of global trade patterns and market demands for ships, maritime equipment, and components.
- Priority Action 2.5: Provide support and training to domestic producers to improve their capabilities and meet international standards.
- Priority Action 2.6: Engage with international partners to support ships, maritime equipment, and components manufacturing.

Goal 3: Increase the Use of Domestically Sourced Materials, Components, and Services in the EV Manufacturing Industry.

Performance Measure: Grow the EV manufacturing industry located in the U.S. or allies.

- Priority Action 3.1: Review the contribution of U.S. companies in the EV manufacturing industry, including raw material extraction, component manufacturing, assembly, distribution, installation, and recycling.
- Priority Action 3.2: Examine public and private investment initiatives and incentives aimed at bringing manufacturing and supply chain activities back to the U.S.
- Priority Action 3.3: Adopt content requirements or incentives encouraging the use of domestically sourced materials, components, and services in EV infrastructure projects.
- Priority Action 3.4: Continue Committee on Foreign Investment in the U.S. (CFIUS) reviews to assess and mitigate national security risks posed by foreign investments in domestic EV infrastructure firms.

Goal 4: Increase the Number and Diversity of Suppliers in the Aerospace Manufacturing Industry

Performance Measure: Grow supplier resiliency providing critical inputs or processes within the aerospace manufacturing industry.

- Priority Action 4.1: Market Share Analysis: Measure the market share of different suppliers to assess the level of competition.
- Priority Action 4.2: Evaluate the number and diversity of suppliers in the market.
- Priority Action 4.3: Monitor performance metrics to identify the best-performing suppliers and ensure competitive pricing and quality.
- Priority Action 4.4: Measure the effectiveness of incentive programs designed to promote supplier resiliency.

- Priority Action 4.5: Develop policy and programs aimed at increasing the domestic and allied supplier base for aircraft manufacturing.
- Priority Action 4.6: Track initiatives and programs aimed at engaging and supporting a diverse supplier base.

Goal 5: Improve the Transparency of Data Collection and Analysis in the Transportation Industrial Base Supply Chain.

Performance Measure: Triple the Number of Industry Participants voluntarily sharing data with DOT by 2028.

- Priority Action 5.1: Employ supply chain visibility platforms to provide a comprehensive view of the entire supply chain, from raw materials to finished products.
- Priority Action 5.2: Utilize predictive analytics to forecast potential disruptions or failures in the supply chain, allowing for proactive measures to mitigate risks.
- Priority Action 5.3: Develop and promote industry standards through participation in industry consortia to improve data interoperability, ensuring that best practices are followed across the digital infrastructure supply chain.
- Priority Action 5.4: Alert stakeholders through early warning systems to potential risks and disruptions, such as component shortages or logistical delays.
- Priority Action 5.5: Provide stakeholder engagement fora to provide a platform for ongoing dialogue and collaboration.

Legislative and Budgetary Objectives

Since 2021, the U.S. Government has set ambitious goals to bolster the transportation industrial base, including strengthening domestic manufacturing, promoting nearshoring, and increasing transparency across supply chains. Achieving these objectives may require new authorities and resources from Congress to overcome key constraints while seizing new opportunities.

Goal 1: Strengthen Domestic Manufacturing Capabilities and Production of Port Cranes
The U.S. currently relies heavily on foreign manufacturers, particularly from China, for port cranes, leaving American ports vulnerable to geopolitical tensions and trade disruptions. Transitioning toward domestic crane production presents several challenges. Building the necessary manufacturing infrastructure is expensive, requiring investments in specialized equipment and a skilled workforce. Furthermore, the current shortage of skilled labor in the industrial sector complicates efforts to scale production rapidly. However, BIL presents opportunities to boost domestic manufacturing by funding port infrastructure projects and incentivizing U.S. production. Additionally, streamlined regulatory pathways could help accelerate the establishment of domestic manufacturing capabilities.

Goal 2: Support Onshoring, Nearshoring, and Allied-Shoring for the Domestic Shipbuilding Industry
The domestic shipbuilding industry faces stiff competition from heavily subsidized foreign shipyards, particularly in China. U.S. shipyards also suffer from fragmented supply chains, with many components sourced internationally, making it difficult to sustain production and meet demand. Congress can play a critical role in supporting onshoring and nearshoring by expanding funding for military and Coast Guard contracts, stabilizing shipyard operations. The United States–Mexico–

Canada Agreement (USMCA) presents an opportunity to build regional supply networks, making the industry less reliant on overseas suppliers. Federal workforce programs will also be essential, as skilled labor remains a bottleneck in the shipbuilding sector, requiring investment in apprenticeships and technical training programs.

Goal 3: Increase the Use of Domestically Sourced Materials, Components, and Services in EV Manufacturing

While the U.S. is ramping up EV production, the industry remains dependent on imported lithium, rare earth elements, and battery components, which are critical for EV batteries. China currently dominates these markets, posing a significant risk to the U.S. supply chain. Domestic sourcing is constrained by long permitting processes and environmental regulations that slow down the development of new mining operations and battery manufacturing plants. The CHIPS Act and BIL offer some funding to boost domestic production, but additional incentives and expedited permitting processes should be considered by Congress. Collaborations with Canada and Australia—key sources of critical minerals—also present an opportunity to align sustainability goals with reliable sourcing practices.

Goal 4: Increase the Number and Diversity of Suppliers in the Aerospace Manufacturing Industry

The aerospace industry is highly consolidated, with a few dominant suppliers controlling most of the market. This can create supply chain vulnerabilities, as disruptions at any of these large suppliers can impact the entire sector. Expanding contracts for smaller aerospace firms could also promote supplier diversity. However, ensuring quality and compliance across a more diverse supplier base will require certification of new suppliers through technical assistance programs to support smaller firms through the certification process. New products would also require certification and adoption by the industry, and workforce development will be critical.

Goal 5: Improve the Transparency of Data Collection and Analysis in the Transportation Industrial Base Supply Chain

Efforts to improve supply chain transparency have been slowed by fragmented data systems and reluctance from private sector stakeholders to share sensitive information due to competitive and cybersecurity concerns. The FLOW initiative is a step toward building a real-time data-sharing platform across transportation networks. However, expanding this effort requires additional congressional support to develop secure data infrastructure and create incentives for private companies to participate. Congress may need to introduce legislation that encourages data collection practices across sectors, ensuring interoperability between systems while addressing cybersecurity risks. Furthermore, new data privacy frameworks will be essential to balance transparency with the protection of proprietary information.

Long-term Resilience Goals

The transportation industrial base will require a multi-faceted strategy over the next decade to ensure it can withstand geopolitical, environmental, and economic challenges. Guided by recent disruptions and opportunities, the sector must focus on regionalized supply chains, sustainable practices, technological innovation, cybersecurity, and supplier diversity to build long-term resilience. This high-level vision outlines the specific goals needed to achieve these outcomes, ensuring the U.S. transportation industrial base remains competitive and secure in a rapidly changing world.

1. Build Secure Regional and Domestic Supply Chains

The transportation industrial base must address vulnerabilities caused by global supply dependencies by onshoring, nearshoring, and friend-shoring. Increased reliance on Mexico, Canada, and other trusted partners and allies will reduce the risks posed by distant suppliers and increase the agility of supply chains. This shift is crucial for key sectors like shipbuilding, port infrastructure, aerospace, and EVs, which currently rely on components sourced from overseas. Examples include:

- Shipbuilding and Port Infrastructure: The U.S. must modernize domestic shipyards and increase local production of critical components such as engines and steel to reduce reliance on foreign suppliers like China. Federal investments will be needed to support the production of domestic port cranes and intermodal equipment, minimizing exposure to geopolitical tensions.
- Resiliency at Borders: Border crossings create bottlenecks for commerce. In recent years, numerous disruptions at the border with Canada and Mexico from various causes have caused cascading supply chain impacts. DOT will continue to work with Canada and Mexico to improve the resiliency and efficiency through infrastructure improvements, data analysis, and joint exercises in cooperation with state and local authorities. The opening of the Gordie Howe International Bridge in Detroit, Michigan, will offer critical redundancy at the busiest border crossing between the U.S. and Canada.
- Electric Vehicles: Battery production must be expanded within North America to ensure that future EV supply chains are secure. Regional partnerships with Mexico and Canada, supported by the USMCA, and with other trusted trading partners, will help build more integrated and flexible supply networks that can respond quickly to disruptions.

2. Improve Supply Chain Transparency and Digital Security

Building resilient supply chains requires real-time data integration and improved visibility across transportation networks. Expanding programs like FLOW will allow public and private stakeholders to monitor and manage operations seamlessly. However, this increased reliance on digital platforms will require a strong focus on cybersecurity to protect critical infrastructure from attacks. Examples include:

- Integrated Digital Platforms: Developing national data-sharing frameworks will ensure that both public and private organizations can coordinate efforts to prevent and mitigate disruptions. Predictive analytics and AI-powered forecasting tools will allow stakeholders to anticipate risks and adjust operations proactively.
- Cybersecurity Enhancements: As more systems become interconnected, cybersecurity will be paramount. Federal funding and partnerships will be required to develop secure data-sharing protocols and protect critical transportation infrastructure from cyber threats and data breaches.

3. Promote Supplier Diversity and Inclusivity

A diverse supplier network will reduce the risks associated with reliance on a small number of dominant suppliers. Encouraging participation from small, minority-owned, and disadvantaged businesses across transportation sectors will improve the resilience and adaptability of supply chains. This goal will require both financial incentives and regulatory assistance to lower the barriers for new suppliers entering the market.

Examples include:

- Increased Federal Contracts for Small Businesses: Expanding government contracts to include additional small and minority-owned businesses will promote diversity across industries such as aerospace, automotive, and shipbuilding. This approach will also create new economic opportunities for underrepresented communities.
- Supplier Certification Programs: Certification initiatives will help new suppliers meet industry standards, building trust and reliability in the transportation sector. These efforts will strengthen the supply chain by increasing the availability of critical components from multiple sources.

Conclusion

The U.S. transportation industrial base plays a vital role in supporting economic growth, national security, and supply chain stability. Recent global disruptions, such as the COVID-19 pandemic and geopolitical tensions, have exposed vulnerabilities in this complex network, prompting a shift toward more resilient, sustainable, and adaptive systems. Investments through BIL and other federal initiatives reflect a strategic focus on modernizing infrastructure, promoting domestic manufacturing, and enhancing supply chain transparency.

The long-term vision for the transportation industrial base emphasizes resilience, sustainability, technological innovation, supply chain transparency, and inclusivity. Achieving this vision will require ongoing public–private collaboration, international partnerships, and strategic investments from Congress and industry leaders. By integrating advanced technologies, promoting sustainable practices, planning for potential disruptions, and building diverse supply networks, the U.S. transportation sector can position itself as a global leader in innovation and preparedness. This comprehensive approach will ensure that the transportation industrial base is ready to meet future challenges while safeguarding economic and national security interests.

Looking ahead, the sector aims to:

- Strengthen domestic production capabilities, especially in key areas like port cranes, shipbuilding, and electric vehicle infrastructure.
- Enhance supply chain resilience by promoting nearshoring and regional partnerships with allied nations, and working with partners to plan for and mitigate future disruptions
- Improve workforce development through expanded apprenticeships and initiatives to attract a diverse talent pool.
- Adopt advanced technologies and foster public–private collaboration for better data sharing, predictive analytics, and cybersecurity.

The outlined priorities and actions are designed to address current weaknesses and ensure that the transportation industrial base remains a global leader. Achieving these goals will require a coordinated effort across public and private sectors. Through strategic investments, enhanced infrastructure, and technological innovation, the U.S. transportation industrial sector is well-positioned to meet future challenges and secure its long-term competitiveness and resilience.

2021–2024 Four-year Review of Supply Chains for the Defense Industrial Base

U.S. DEPARTMENT OF DEFENSE

DECEMBER 2024

EXECUTIVE SUMMARY

With the publication of the 2022 National Defense Strategy (NDS), Secretary Austin charted the Defense Department's way forward through this decisive decade. Increasingly coercive actions taken by the People's Republic of China demonstrate its intent to reshape the Indo-Pacific region and broader international system to fit its authoritarian preferences, and the Russian Federation's invasion of Ukraine underscores the acute threat it poses. These threats, along with transboundary challenges like COVID-19, demonstrate the imperative for increased and improved defense capabilities for both the United States and our allies and partners. In observing these events, we've learned a great deal about the challenges within our defense industrial base, the network of organizations, facilities, and resources that provides our government with materials, products, and services for defense purposes, and the critical importance of maintaining a robust, resilient, and dynamic defense industrial ecosystem. The U.S. Government now has an opportunity to address those challenges, including increasing our production capacity and strengthening our supply chains.

Building off the NDS, the Defense Department released the first National Defense Industrial Strategy (NDIS) in January 2024. The NDIS articulates the bold vision and associated priorities over the next three to five years to achieve a defense industrial ecosystem that is "dynamic, responsive, state-of-the art, resilient, and a deterrent to our adversaries." The NDIS outlines the vision for ensuring the Department can continue this support and produce at a pace and scale needed to meet the ever-growing demands we face now and into the future.

It is important to note that some of the work was already in progress prior to the NDIS release. Over the last four years, the Department has been working to get better supply chain visibility in critical areas, while ensuring that we work better with industry to achieve our national security goals. While the current state of the industrial base has some visible challenges the FY2025 NDIS Implementation Plan (NDIS-IP) details the ongoing and planned actions taken by DoD to achieve the vision set forth in the NDIS and to address key challenges to the U.S. industrial base. Our commercial and organic defense industrial base (DIB), skilled manufacturing workforce, and American ingenuity produce high-end systems and products that provide our Armed Forces with a competitive advantage. The NDIS-IP prescribes the necessary steps to align future investments in industrial capacity and resilience across the Military Services and the Office of the Secretary of Defense.

These efforts show our unwavering commitment to ensuring that the defense industrial base is resilient and ready to withstand a war time scenario or epidemic such as COVID-19.

SECTOR OVERVIEW

Introduction

The DIB comprises tens of thousands of suppliers across the nation and the globe who provide the capabilities needed to train and equip our warfighters. The DIB is part of the global supply chain and faces unique challenges, including long lead times, an insufficient workforce, geopolitical shocks (such as the global pandemic and the Russian Federation's invasion of Ukraine), and a focus on efficiency over resilience in production and fulfillment (e.g., "just-in-time management"). Furthermore, the DIB faces other unique challenges, including inadequate domestic production, small or erratic demand, over-customization, lack of adequate data, and obsolescence. The National Defense Strategy (NDS) states that building a resilient ecosystem is vital to national defense.

A robust and resilient industrial base provides the enduring foundation for military advantage. While America continues to generate the world's most capable weapons systems, it must have the capacity to produce those capabilities at speed and scale to maximize our advantage. Accordingly, the 2022 NDS prioritizes strengthening the industrial base to "ensure that we produce and sustain the full range of capabilities needed to give U.S., allied, and partner forces a competitive advantage." Doing so builds on lessons learned in recent decades and the enduring advantage of the global international economic order, which has proven to be a major strength for the U.S. and our allies. Over the past century, U.S. industrial might overwhelmed the Axis powers in World War II and contributed significantly to deterring the Soviet Union during the Cold War. The "peace dividend" and "procurement holiday" that followed saw dramatic cuts in military force structure, weapons production, and corresponding stockpiles of munitions and materials. Most notably, the traditional DIB consolidated in the wake of the Secretary of Defense's meeting with major prime contractors and their suppliers in 1993 at what became known as the "Last Supper."

Today the U.S. needs to shift from policies rooted in the 20th century that supported a narrow defense industrial base, capitalized on the DoD as the monopsony power, and promoted either/or tradeoffs among cost, speed, and scale. Instead, the U.S. must build a modernized industrial ecosystem that includes the traditional defense contractors—the DIB primes and sub-tier defense contractors who provide equipment and services—and also includes innovative new technology developers; academia; research labs; technical centers; manufacturing centers of excellence; service providers; government-owned, contractor-operated (GOCO) facilities; and finance streams, especially private equity and venture capital. As we build a modernized industrial ecosystem, we remain mindful of the environment in which private industry operates and look to work with them to tackle adverse impacts which can manifest during change and modernization.

Accordingly, building a more robust, modernized defense industrial ecosystem will require a dynamic effort across the U.S. Government to create the legal and policy conditions that allow new entrants into the defense production and services community. We must solicit entrants of all types: large and small, domestic, and foreign, and those with no previous relationship to the DoD or defense production. This will require reinvigoration and the development of new dialogues and relationships. The DoD must consider the impact of government policies and decisions on industry, just as its adherents must appreciate their critical role in providing for the defense of the nation and consider the impact of their business practices on national security.

Critical Sectors of the Defense Industrial Base

Given the breadth and scale of defense supply chains, this Review highlights four of five sectors in which critical vulnerabilities post the most pressing threat to national security. These focus areas are:

- Kinetic Capabilities
- Energy Storage and Batteries
- Castings and Forgings
- Microelectronics
- Strategic and Critical Materials (see the Four-Year Review of Supply Chains for Critical Minerals)

Kinetic Capabilities

U.S. national security depends on current and future kinetic capabilities to successfully prosecute combat operations against foreign adversaries. The resilience and adaptability of prime contractors and sub-tier suppliers are key to this defense-unique private sector of the economy. Current efforts focus on addressing critical vulnerabilities in supply chains for both existing programs and future requirements, such as hypersonic weapons. Various methods of strengthening the DIB are being used, including direct investment in domestic suppliers and pursing multi-year procurements to encourage private investment in facilities and lower-tiered suppliers.

Evolution of the Sector through 2020

For the last 20 years, DoD has focused kinetic weapon procurements on meeting current operational needs (e.g., Operation Inherent Resolve) and reducing inventory shortfalls incurred during the operations against the Islamic State of Iraq and Syria (ISIS). The result of this approach is an inconsistent pattern of procurement that undercuts the sustainment and resiliency of the defense industrial base.

Key Sector Trends from 2021 to Present

Missiles have no commercial markets, and the defense sector alone cannot drive demand for components. Studies are in progress to explore the ramifications of investing in multiple sources to strengthen the supply chain for critical items and investments in business which onshore capabilities are underway. Organic Industrial Base (OIB) facilities have plans to be modernized in ways which will expand their capacity and flexibility, allowing them to be more agile in responding to gaps in the private side of the DIB. These are all necessary steps in strengthening the kinetic capabilities supply chain; however, these efforts must be supported for several years to come to fruition, and further efforts should continue to be made.

An institutional shift is required to take advantage of this period of increased competition with U.S. near-peer competitors. There are advances in technology that can be integrated into our systems and into our DIB. Just as new system technologies require an acceptance of cost and schedule risk to meet higher performance goals, the DoD must find ways of encouraging modernization and innovation in production, despite short-term effects in cost and schedule. Technologies exist to improve quality, footprint, and flexibility in production. Many of these technologies would benefit existing suppliers or enable smaller companies to enter the market.

Insight into the kinetic capability supply chain is limited. However, efforts are being made to increase visibility into lower tiers of the supply chain. This visibility will help the DoD and industry partners identify fragile domestic suppliers, sole-source dependencies, foreign sourcing, limited supply chain visibility, outdated U.S. Government guidance and specifications, and limited demand.

Energy Storage and Batteries

Advanced lithium-ion batteries are key to fielding and sustaining many critical legacy and future advanced military capabilities. Consequently, it is vital that the United States secures access to a robust DIB free of adversary interference. To this end, the DoD is working with its internal, interagency, international, and industry partners to build and strengthen the lithium-ion battery industrial base domestically and with our allies and partners.

Evolution of the Sector through 2020

Twenty years ago, the People's Republic of China (PRC) made it a national priority to obtain dominance in the lithium-ion battery market and has achieved great success to date. China is particularly dominant in the areas of ore processing and cell production at low cost, which provides a decisive market advantage.

U.S. efforts to secure the domestic lithium battery industry began in earnest in June 2021 with the publication of the National Blueprint for Lithium Batteries by the U.S. Department of Energy (DOE). This national-level strategy is administered through the efforts of the Federal Consortium of Advanced Batteries (FCAB), whose core membership and executive oversight is made up of Deputy Assistant Secretaries from the Departments of Energy, Defense, State, and Commerce.
The National Blueprint established a way forward that has been supported by investments from the Bipartisan Infrastructure Law and the Inflation Reduction Act, infusing direct U.S. investment and encouraging hundreds of millions of dollars in private-sector investments that are a major boon for the small but growing U.S. lithium battery industry.

The Department continues making investments in analytics to better understand our own requirements and supply chain risks, improve standardization to aggregate demand signals where practicable, expand existing testing capabilities, and identify and test battery modules for use in future DoD platforms.

Key Sector Trends from 2021 to Present

We continue to make progress against the challenges in the energy storage and batteries sector, though the challenges still remain. These challenges include:

- **PRC's Supply Chain Dominance:** PRC dominates the global advanced battery supply chain from the raw materials to components and cell production, resulting in a heavy reliance by domestic battery companies on PRC-produced precursors.

- **Custom Design Standards:** Many of the systems currently used by DoD components are reliant on custom designs that are generally not standardized with commercial-use batteries. The proliferation of custom designs disaggregates demand, impedes DoD's ability to influence industry standards, and increases risks from single- or sole-source suppliers and obsolescence.
- **Acquisition Policy:** Despite a preference for domestic sources, present acquisition regulations provide limited mechanisms for prioritizing domestic and allied sources of lower-echelon components within the bill of materials for items such as batteries.
- **Supply Chain Data:** Inadequate data management practices that relate to batteries as components of larger systems hamper standardization efforts, investment planning, and key supplier relationships.
- **Infrastructure:** As advanced batteries become larger and more complex, the DoD needs to grow and mature its battery safety testing and certification processes for qualifying the increasing numbers of fielded and future systems, and to characterize failures and performance attributes to augment safety and reliability of the advanced batteries we use.
- **Organization and Structure:** DoD has historically lacked a central organization for addressing cross-service battery challenges and to collaborate and coordinate with industry and other key stakeholders.

These challenges have served to guide the Department's efforts and are included in the February 2023 release of the DoD Lithium Battery Strategy 2023–2030. This strategy is the coordinating vehicle for internal, interagency, international, and industry efforts to secure the battery defense industrial base. Target outcomes of defined lines of effort (LOEs) in the DoD Strategy will:

- Provide DoD program offices with safe, effective, affordable, and standard energy storage options.
- Ensure access to battery systems when the supply chain is threatened.
- Reduce the total time required to develop, certify, and field safe advanced energy storage-enabled systems.
- Reduce the logistical burden associated with providing advanced batteries to the warfighter and sustaining them in the field and,
- Support the Department's climate objectives.

Castings and Forgings

Casting, forging, and machine tools (CFMT) are manufacturing capabilities that focus on applied metallurgy and metalworking. Casting is the process used to create geometrically complex parts by pouring molten or high-temperature metal or composites into a mold. Forging is the process in which thermal and mechanical energy is applied to metal to change its shape and internal properties while in a solid state. A machine tool is a nonportable power tool, such as a lathe or milling machine, used for cutting or shaping metal, wood, or other material.

The casting, forging, and machine tools industry is vital to the production and sustainment of combat capability. Our defense industrial base must be able to quickly design, manufacture, and repair—at scale—hardware parts for DoD systems. It must also have timely access to the ability to do the same for the machines used to make those parts.

America's ability to produce castings, forgings, and machine tools to support military operations depends on the health of the commercial casting, forging, and machine tools industry in the United States and its international partners. This is because commercial firms and the workers they employ conduct the overwhelming share of DoD metal fabrication. DoD uses its OIB capabilities to produce only those cast and forged products that commercial firms cannot or, for economic reasons, will not.

Evolution of the Sector through 2020

In the early 1980's, the United States was the global production leader in the CFMT sector. Meanwhile, nations such as Japan, Germany, and Italy increasingly led innovation in the design and production of metalworking systems. The vast majority of casting and forging (C&F) metal fabrication progressively moved offshore, overwhelmingly to China, which produced steel at four times U.S. production rate. Waves of financially driven consolidation in the United States and over 20 years of government-subsidized growth by Chinese casting, forging, and machine tools firms caused the loss of thousands of U.S. firms and hundreds of thousands of American jobs.

The COVID-19 pandemic crystalized the downside of over-reliance upon global supply chains to offset a lack of domestic production. Production and transoceanic shipping delays caused lead times for cast and forged products to surge dramatically—two- or three-year lead times became common. This was especially true for large cast and forged components used in the machine tools that are essential for producing virtually all modern hardware products. Meanwhile, China continued to execute a deliberate strategy to gain control of the upstream supply chain—the raw and refined materials used in the production of castings and forgings—threatening the success of current and emerging defense programs. Resulting the nation's processes and infrastructure for developing, qualifying, and certifying new materials and new production methods shrank precipitously and slowed to a crawl.

Key Sector Trends from 2021 to Present

Executive Order 14017 identified key challenges in capability and capacity, acquisition and program protection policy, and technical data policy. DoD demand, which, according to a 2022 study commissioned by DoD, currently makes up less than 20 percent of the domestic C&F market, is highly variable depending on the number and size of major programs in production, and often centers on low-density requirements. According to a major consulting organization, the domestic C&F industry has invested more than $15 billion in overall capacity in recent years. DoD-sponsored capital improvement efforts must, therefore, be tightly targeted based on an assessment of the combination of the fragility of the specific suppliers and the criticality of the products they supply to DoD.

In recent years the castings and forgings sector has seen growth with the global casting, forging, and stamping category valued at $397.7 billion. Factors driving this growth include the expansion of the aircraft industry, increase in infrastructure construction projects, and the demand for lightweight and fuel-efficient vehicles. Still today the Asian Pacific region dominates the metal forging market, with a market share of 52.09 percent in 2023.

Microelectronics

Microelectronic components and systems are ubiquitous across DoD, commercial, and critical infrastructure sectors. DoD leverages a wide variety of microelectronics technologies, and components to meet mission requirements. In terms of market share, DoD represents approximately one percent of the domestic microelectronics market. Thus, DoD microelectronics applications are typically characterized as low-volume and high-mix. This is anathema to the microelectronics manufacturing industry, which is predicated on high-volume, low-mix production to sustain economic viability. This incongruence is the source of multiple challenges DoD still faces in the access to and implementation of microelectronics technologies in DoD platforms. These challenges include:

- Limited ability to influence outcomes in the commercial microelectronics sector due to diminished market presence.
- Reduced ability to access microelectronics technologies targeting high volume commercial applications.

Microelectronics technology is a primary enabler of the asymmetric technological advantage the U.S. Armed Forces enjoy over potential adversaries. Microelectronics are not only important to defense; microelectronics also play a critical role in the security and economic prosperity of the United States.

Evolution of the Sector through 2020

The strategic posture of the United States, relevant to microelectronics, is dominated by the decades of offshoring that diminished the domestic microelectronics ecosystem. In 1992, the U.S share of global semiconductor manufacturing stood at 37 percent. By 2022, the U.S share had declined to 12 percent.[612] The primary beneficiary of the decline in U.S semiconductor manufacturing has been the Asia-Pacific region. Currently, 88 percent of semiconductor production, and 98 percent of the assembly, packaging, and testing capability associated with semiconductor products is located in the Asia-Pacific region, primarily in Taiwan, South Korea, Malaysia, and China.[613] The migration of semiconductor manufacturing to the Asia-Pacific region, and the subsequent decline in domestic manufacturing, represents a substantive security and economic threat for the United States and many allied nations.

Key Sector Trends from 2021 to Present

Semiconductors power virtually every sector of the economy—including energy, healthcare, agriculture, consumer electronics, manufacturing, and transportation. Semiconductor types range

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612 Boston Consulting Group "*Strengthening US Semiconductor Manufacturing*". Industry report. 2020.

613 Boston Consulting Group and Semiconductor Industry Association. "Strengthening the Global Semiconductor Supply Chain in an Uncertain Era." April 2021. p.38. https://www.semiconductors.org/strengthening-the-global-semiconductor-supply-chain-in-an-uncertain-era/.

from logic, memory, application-specific integrated, silicon-photonic chips, and RF-analog chips.[614] Usages for semiconductors include microcontrollers, image sensors, display drivers, automobiles, satellites, and cruise missiles. The primary industries for semiconductor chips include Communication, PC/Computer, Automotive, Consumer, Industrial, and Government.

Between 2022 and 2023 the automotive and industrial end markets saw an increase in sales with automotive becoming the third-largest end market in 2023. PC/Computer and Communication end markets also accounted for the largest share of semiconductor sales in 2023. Sales to the communications industry, however, increased by 2 percentage points while the PC/computer decreased to 25 percent of sales.[615] Additionally, an increase in the demand for chips critical to AI systems was also seen, especially in the second half of 2023.

Demand for mature nodes remains high and is expected to continue growing due to their criticality for many products that have civilian and military applications.[616] For example, in the automotive sector, the number of chips per vehicle has doubled since 2017 and is expected to increase in the future. Additionally, this increase in chips per vehicle is happening while higher performance chips are becoming popular. The popularity of high-performance chips has triggered heavy investments in this area resulting in underinvestment in mature nodes. Considering supply chain issues, the output of mature semiconductors for automotive applications is not keeping pace with current demand.[617]

Restoration of domestic manufacturing capacity should continue to be prioritized to reduce dependence on foreign sources for microelectronics. Congress should continue to support new incentives and increasing existing incentives to promote domestic semiconductor manufacturing, printed circuit board manufacturing, development of new sources of raw materials, and microelectronics packaging, assembly, and test capability. CHIPS funding alone is insufficient to restore domestic semiconductor manufacturing capacity to a level that meets national security and economic objectives. This will require additional investment from the commercial sector. Creating a favorable investment environment should be a priority.

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614 Logic chips are the 'brains' of electronic devices—they process information to complete a task. Among Logic chips, CPUs (central processing units) are the 'original' chips.
Memory chips store information. There are two types of Memory: volatile and non-volatile. Volatile Memory chips, such as DRAM (Dynamic Random Access Memory), are the 'working memory' chips that save data only while the device's power is turned on.
ASICs are simple, single-purpose chips used for performing repetitive processing routines such as scanning a barcode.
Silicon photonics is a technology for fabricating optical and electronic integrated circuit on silicon microchip.
RF-analog chips, or radio frequency-analog chips, are integrated circuits (ICs) that combine radio-frequency (RF), analog, and digital electronics.

615 Semiconductor Industry Association. *AI, Auto, Industrial Markets Spurred Rebound in Chip Demand During Second Half of 2023*. March 2024. https://www.semiconductors.org/ai-auto-industrial-markets-spurred-rebound-in-chip-demand-during-second-half-of-2023/.

616 Mature nodes are typically regarded as those produced at nodes at the 28 nanometers (nm) level or above.

617 Center for Strategic & International Studies. *The Strategic Importance of Legacy Chips*. 03 March 2023. https://www.csis.org/analysis/strategic-importance-legacy-chips

PROGRESS TO DATE

One-year Review Priorities

Over the past year the Department has created its own strategy for the defense industrial base building off of Executive Order 14017 and the National Defense Strategy. The 2023 National Defense Industrial Strategy (NDIS) outlines the challenges and vulnerabilities in the defense industrial base, four strategic priorities, and twenty-five associated actions for building a more resilient defense industrial ecosystem and ensuring the necessary industry and global collaboration to mitigate the risk of inaction to our national security. The strategic priorities of the NDIS are:

- **Resilient Supply Chains:** The DIB can securely produce the products, services, and technologies needed now and in the future at speed, scale, and cost.
- **Workforce Readiness:** A skilled and sufficiently staffed workforce that is diverse and representative of America.
- **Flexible Acquisition:** Acquisition strategies that strive for dynamic capabilities while balancing efficiency, maintainability, customization, and standardization in defense platforms and support systems.
- **Economic Deterrence:** Fair and effective market mechanisms that support a resilient defense industrial ecosystem among the U.S. and close international allies and partners and contribute to economic security and integrated deterrence.

To build resilient supply chains, DoD has prioritized five focus areas of particular importance to national security. These focus areas were identified with input from the Services, senior leaders from the Office of the Secretary of Defense, and guiding strategies and policies such as the Defense Planning Guidance and Executive Order 14017. The areas are:

- **Kinetic Capabilities:** Current missiles systems and advanced and developing missile capabilities including hypersonic weapons technology and directed energy weapons.
- **Energy Storage and Batteries:** High-capacity batteries, with a particular focus on lithium batteries.
- **Castings and Forgings:** Metals or composites developed into key parts and tools through high-intensity processes.
- **Microelectronics:** State-of-the-practice (SOTP) and legacy microelectronics as well as state-of-the-art (SOTA) microelectronics.
- **Strategic and Critical Materials** (please see the Four-Year Review of Supply Chains for Critical Minerals)

The NDIS Implementation Plan is the next granular step toward realizing our shared vision of developing a more resilient defense industrial ecosystem. It aligns with the strategic vision of the NDIS by addressing consequential risks in critical areas and presenting six key initiatives to mitigate the risks in the near, medium, and long term and make the strategy real.

The DoD's commitment to achieving the NDIS vision through partnership and continuous investment is accurately conveyed by our increased investment in defense industrial capacity and resilience. In FY 2024, DoD injected $74.6 billion toward modernization of the defense industrial ecosystem in critical areas. These critical investments are also evident in the FY 2025 President's Budget Request. Although DoD's FY 2024 budget and FY 2025 budget requests clearly signal the

Department's NDIS vision prioritization, additional investment is required in future budget cycles to achieve NDIS modernization and expansion objectives.

Progress from 2021 to Present

Following the call for a comprehensive review of supply chains in the DIB via Executive Order 14017. The Department released its 2021 Industrial Capabilities Report, which responded to the Executive Order and provided a One-year Review of the critical sectors identified in order. In this 2021 report the Department identified foundational recommendations to enhance and grow the industrial base. These recommendations were made to ensure the Department's overall ability to make strategic informed acquisition and sustainment decisions. These recommendations were (1) build domestic production capacity, (2) engage with partners and allies, (3) mitigate foreign ownership, control, or influence, (4) conduct data analysis, (5) aggregate demand, (6) develop common standards, and (7) update acquisition policies. These actions all worked together to provide the Department with a strategic roadmap to renew the DIB and maintain its positions as the world leader in innovation into the 21st century.

Within this Review, the Department also identified four strategic enablers that are also important to mission success. Fragility or gaps in these enablers create operational and strategic risk and addressing the challenges in each is critical to building overall supply chain resilience. The strategic enablers are (1) workforce, (2) manufacturing, (3) cyber posture, and (4) small business. Since, DoD has taken an enterprise-wide approach to effectively address these strategic enablers and boost collaboration with the appropriate partners.

As a result of these recommendations, DoD wrote the first-ever NDIS, which put into action the push for an enterprise-wide approach to address supply chain resiliency collaboratively with our international, interagency, and industry partners. Subsequently, the NDIS implementation actions reflect DoD's renewed focus on bolstering the health and resilience of the industrial base and mitigating short-, medium-, and long-term risks spurred in part by world events, such as the COVID-19 pandemic and Russia's invasion of Ukraine. In response, funding for the Defense Production Act (DPA), a major vehicle for DoD investment in industrial base resilience, increased from an average of about $74 million per year from 2014 to 2019, to $734 million per year from 2020 to 2023.

Resilient Supply Chains

- DoD awarded $20 million in DPA funds to South32 for the Hermosa Project, which will sustainably produce battery-grade manganese in Santa Cruz County, Arizona. Manganese is an essential material used in batteries for DoD and civilian applications. DPA funds will enable the acceleration the Hermosa Project to deliver ore up to two years earlier than originally planned. Once completed, South32 will be the first sustainable, domestic producer of battery-grade manganese.
- DoD awarded $6.4 million and $8.4 million in to Canadian companies Fortune Minerals Limited and Lomiko Metals, Inc., respectively, to build resilience in the cobalt and graphite supply chains and support the U.S.–Canadian Joint Action Plan on Critical Minerals. These awards represent the first DPA awards using the expanded definition of DPA domestic sources.

- The U.S. Army opened a new modular metal parts facility in Mesquite, Texas, to increase domestic production capability and help achieve the goal of producing 100,000 155-millimeter artillery shells per month, meeting growing requirements.
- DoD released the Defense Industrial Base Cybersecurity Strategy, which will enhance the cybersecurity of our defense industry stakeholders, while improving U.S. posture and resiliency against attacks.
- DoD, using Defense Production Act Title III authorities, awarded the American Center for Manufacturing Innovation a $75-million contract to establish a munitions campus pilot that will allow companies of all sizes to participate in a shared facility to reduce costs and lower barriers to entry.
- DoD has also invested $25 million to date for the Energy Storage Systems Campus (ESSC), which is being led by the University of Texas at Dallas with a consortium of partners. The ESSC, which is a Manufacturing Capability Expansion and Investment Prioritization (MCEIP) Pathfinder project designed to address cross-service and interagency needs in critical minerals and battery supply chains, will help build a shared-use facility outside of Dallas, Texas, expanding the capacity of current battery chemistries while accelerating the development and production of next-generation batteries.
- DoD created the Office of Strategic Capital (OSC) to attract and scale private capital in support of DoD priorities and released OSC's first Investment Strategy.
- DoD's Manufacturing Capability Expansion and Investment Prioritization (MCEIP) Office issued multiple awards in areas such as domestic mining and production of lithium, expanding the graphite supply chain, and critical chemicals. These investments represent the continuation of DoD's five-year investment plan to secure supply chains for minerals and materials critical to the defense and commercial sectors. The critical chemicals awards help onshore the supply chain for military grade chemicals used in defense systems, including non-energetic chemicals and precursors for both energetic and non-energetic chemicals.

Workforce Readiness

- DoD's MCEIP Office awarded $20 million to Austal USA, and its subsidiary Austal USA Advanced Technologies, to enhance U.S. Navy shipbuilding capabilities and address gaps in the submarine workforce.
- Over the past decade, DoD's commitment of $954 million to its nine Manufacturing Innovation Institutes has resulted in approximately $2 billion of committed non-federal cost share and over $1.2 billion of committed federal project work.
- DoD allocated $61.7 million to the DoD Research and Education Program for Historically Black Colleges and Universities and Minority Serving Institutions program, which helps increase the number of under-represented minorities in defense-related fields.
- In order to tackle the shortage of a skilled submarine production workforce, the Navy and its industry stakeholders held regional submarine workforce talent signing days, celebrating more than 2,700 individuals starting careers with maritime industry suppliers.
- DoD continued to support career pathways in manufacturing through the America's Cutting Edge program, which offers free online training as well as the opportunity for hands-on, in-person training, setting workers on career paths in the machine tool industry.
- CHIPS and Science Act funding included $13.2 billion to DoD to support domestic prototyping and fabrication of microelectronics for the military, workforce development,

and a tax credit incentive that will create tens of thousands of construction and high-skilled manufacturing jobs.

Submarine Industrial Base (SIB)

The characteristics of navy shipbuilding and sustainment impose and unique workforce requirements on the industry, with its most acute defense-related workforce challenges tied to nuclear submarine production. The public and private shipbuilding and refitting yards have suffered from the same defense spending contraction as other defense producers and the broad decline in U.S.-based shipbuilding has reduced the overall market need for shipbuilding expertise. As a result, the domestic shipbuilding industry is struggling to maintain an adequately sized and skilled workforce. These conditions are now being met head-on by the Department's aggressive plan to simultaneously modernize its nuclear-powered strategic ballistic missile and attack submarine fleets, spiking the requirement for workers skilled in most of the traditional submarine construction trades. This enterprise also requires unique skill sets and extensive training—such as nuclear welding—that is proving difficult to acquire outside of U.S. Navy programs. For example, the Navy ended Fiscal Year 2022 short 1,200 workers across its four public shipyards. Notably, there are only two shipyards capable of servicing nuclear systems—which have no civil counterpart—putting additional pressure on the workforce as they require rare but niche skills in their labor pool. The Executive Director for the Strategic Ballistic Missile Submarine Program Executive Office noted that over the next ten years, the SIB alone will need to hire nearly 100,000 trained workers at both primary construction yards and 17,000 people at vendors supporting across the SIB supply chain—a massive increase. The Interagency Taskforce in Fulfilment of Executive Order 13086 dated September 2018 section on shipbuilding notes some of these deficiencies in the SIB. A July 6, 2023, report issued by the Congressional Research Service titled "Navy Virginia (SSN-774) Class Attack Submarine Procurement: Background and Issues for Congress" provides an updated report on the status of the SIB, especially noting its projected hiring needs.

* Shipbuilding History. The Decline of U.S. Shipbuilding. January 21, 2016. Accessed 28 August 2023.
**The Interagency Taskforce in Fulfillment of Executive Order 13086 noted some of these SIB deficiencies in its September 2018 report. A July 6, 2023 report issued by the Congressional Research Service titled, "Navy Virginia SSN-774) Class Attack Submarine Procurement: Background and Issues for Congress" provides an updated SIB view, noting is project hiring needs.

Flexible Acquisition

- The U.S. Partnership for Assured Electronics and the Defense Business Accelerator promote public–private partnerships, accelerating development of emerging technologies by leveraging private sector market forces and incentives.
- DoD established the Defense Industrial Base Consortium Other Transaction Authority (DIBC OTA) to accelerate production and enable DoD to adopt state-of-the art commercial prototypes more swiftly. As the first DoD OTA to include research, prototype, and production activities, the DIBC OTA is a vehicle for whole-of-government investment to expand domestic capabilities and diversify the supplier base in critical areas.
- DIBC OTA issued a Request for White Papers for the Distributed Bioindustrial Manufacturing Program (DBIMP). The Department has since made awards to 34 proposers

valued at a total of $60.2 million to deliver business and technical plans for building U.S. bioindustrial manufacturing production facilities.

- Working with Congress, DoD secured FY24 authorities and resources to execute multi-year procurements for six critical munitions: Advanced Medium Range Air-to-Air Missile (AMRAAM), Naval Strike Missile (NSM), Guided Multiple Launch Rocket System (GMLRS), PATRIOT Advanced Capability-3 Missile Segment Enhancement (PAC-3 MSE), Long Range Anti-Ship Missile (LRASM), and Joint Air-to-Surface Standoff Missile (JASSM).
- The Defense Innovation Unit's Replicator Initiative accelerates delivery of innovative capabilities to the Warfighter by removing systemic roadblocks and overcoming challenges faced by commercial industry. By leveraging non-traditional technology ecosystems, alongside more traditional sources of defense capability, the DoD is adapting to integrate emerging technologies and methodologies to add the most military value while working to diversify and expand the base of American industry and technology companies.

Economic Deterrence

- For only the second time in the 74-year history of the Defense Production Act, Congress expanded the definition of a domestic source for DPA Title III Awards in the FY 2024 National Defense Authorization Act, allowing companies and projects in the United Kingdom and Australia, in addition to the United States and Canada, to be considered as domestic sources for DPA funds.
- DoD announced the Regional Sustainment Framework, which aims to optimize regional maintenance, repair and overhaul by aligning the U.S., its international partners, and industry in a more closely linked collaborative network to drive enhanced coordination for Warfighter readiness capabilities.
- DoD and international partners and allies endorsed announced a Statement of Principles for Indo-Pacific Defense industrial Base Collaboration at the 2024 Shangri-La Dialogue in Singapore. Underscoring the importance of defense industrial resilience, by adopting this statement of principles, the United States and global allies will pursue collaborative actions bilaterally and multilaterally to enhance shared defense industrial resilience in the Indo-Pacific.
- The U.S. and Japan restructured the Systems and Technology Forum into the Defense Industrial Cooperation, Acquisition, and Sustainment (DICAS) Forum in June 2024. This new initiative allows both nations to leverage their respective industrial bases to establish an allied defense co-production capacity.
- Secretary of the Navy announced the formation of the Maritime Economic Deterrence Executive Council. This council is a component of the national Maritime Statecraft approach that calls for strengthening industries that are vital to enhancing U.S. maritime power.
- This year, President Biden ordered divestment of MineOne's real estate and equipment in Cheyenne, Wyoming. The property located near Francis E. Warren Air Force Base is majority-owned by a company directly linked to the PRC. This is the first Presidential Determination blocking adversarial foreign ownership since 2018 and a first directed against adversarial investment near a military installation, underlining the importance of economic deterrence tools in support of national defense.

Engagement with Industry

Whether from defense and software primes, small business contractors, the many newly established defense technology firms, service firms, or other companies not traditionally considered defense firms, industry partner contributions are a fundamental pillar to NDIS success. By innovating advanced technologies and accelerating research and development efforts, industrial stakeholders play a major role in modernizing the defense industrial ecosystem. Their agility shortens the concept to deployment timeline, ensuring rapid access to cutting-edge technologies and enhancing mission effectiveness. Industrial contributions support national defense and economic growth, while also driving job creation and enhancing their growth, innovative capabilities, and economic impact. NDIS implementation partnership will increase insight into DoD strategic priorities and investments and enable complementary industry action.

As one example of the ways DoD is innovating to expand and increase opportunities for industry engagement, the MCEIP directorate awarded the Defense Industrial Base Consortium (DIBC) Other Transaction Agreement (OTA). This consortium managed MCEIP vehicle is designed to accelerate DoD's access to technologies typically reserved for commercial development and enhance MCEIP's mission of addressing defense supply chain issues, developing the industrial workforce, sustaining critical production, commercializing Research and Development efforts, and rapidly scaling emerging technologies to build a robust, resilient defense industrial base.

MCEIP hosted the inaugural DIBC Symposium in San Diego. The event, which centered on enhancing collaboration with the defense industrial base to build capacity and capabilities, brought together more than 500 participants from the U.S. Government, industry, and investors, as well as industry partners from Australia, Canada, and the United Kingdom. Panel discussions included representatives from the Departments of Defense, Energy, and Commerce, the Defense Logistics Agency, and stakeholders from private capital firms, which offered insight into strategic priorities and future investments plans in five critical sectors: strategic and critical materials, kinetic capabilities, energy storage and batteries, castings and forgings, and microelectronics. Industry and Investor Sector panels focused on the perspectives of these groups as they make buying and investment decisions, the challenges in working with DoD, and how to improve communications.

Engagement with Allies and Partners

International partnerships hold significant importance in modernizing and securing the defense industrial ecosystem. These partnerships enhance global supply chain security, ensuring access to critical resources and components that may not be readily available domestically. They also improve situational awareness through shared intelligence and data. Additionally, the defense industrial bases of North America and Europe are already interconnected. By opening new markets for U.S. defense products and technologies, international collaboration supports the domestic defense industry while fostering new job opportunities and economic activity in participating countries. Furthermore, strategic alliances can enhance global stability, promote diplomatic relationships, and expedite collaborative efforts in addressing security concerns. Bilateral and multilateral partnerships and alliances including NATO will continue to be vital for defense industrial cooperation. Engaging closely with the U.S. on NDIS implementation will allow our international partners to better understand the DoD's strategic priorities and anticipate areas for future focus and collaboration. Increased cooperation will enable the U.S. to work with its international partners to amplify the effect of national or bilateral initiatives.

RESILIENCE AND VULNERABILITY ASSESSMENT

Overview

To defend the nation and deter America's adversaries, the Department of Defense (DoD) ensures that our armed forces have reliable access to every industrial and material advantage benefitting national security. DoD has the responsibility to ensure that the nation is prepared to—with all possible speed—manufacture and deliver superior defense platforms and weapons systems to the armed forces. The DoD requires a healthy Defense Industrial Base (DIB) built on resilient, diverse, and secure supply chains to meet those needs. In this section, we highlight outstanding resilience and vulnerability challenges for the DIB and its underlying sectors.

Defense Industrial Base

Overview

DoD and its partners have significant assets to build resilience in the face of supply chain risks and constraints, including national resolve around supply chain resilience; a renewed focus within the Executive Branch; resourced programs for addressing industrial base challenges; unrivaled information resources; interagency information sharing; co-development, co-production, and leveraged resourcing with allies; capital-driven markets with patriotic suppliers; the American spirit of entrepreneurship; and cutting-edge research and development (R&D) innovation ecosystem.

DoD's research and procurement revolve around broad-based stakeholder coalitions and public–private partnerships that catalyze economic growth across many communities. Despite current supply chain challenges, this market-based approach will outpace adversaries' reliance on state-directed command-and-control of their innovation and production capacity.

Transparency

For several decades, the DoD has entrusted supply chain visibility and risk management to companies in the private sector that provide it with defense capabilities. Consequently, the DoD has limited visibility into some sub-tiers of defense supply chains. As supply chains have become more global in scale, prime contractors have lost some visibility into the sub-tiers of their supply chains, especially below third-tier levels. To combat these challenges, the DoD continues to invest in supply chain illumination data and services to improve visibility and transparency within defense supply chains.

Domestic capacity, trade concentration, and supplier diversity

Over time, many domestic suppliers have lost business or have exited the market due to numerous factors, including unstable DoD procurement and competitive pressure from foreign nations, particularly the PRC. For example, the PRC's lower production costs make importing materials more profitable for U.S. companies than manufacturing the same material domestically. It also reduces the likelihood of U.S. private capital investment in the domestic market.

Within the Energy Storage and Batteries sector, specifically, the PRC continues to dominate the global advanced battery supply chain, including graphite, lithium hydroxide, electrolyte, lithium carbonate, anodes, cathodes, and finished cells. Materials and components manufactured domestically are often reliant on PRC-produced precursors and intermediate products or are fragile suppliers and single-point failures within the supply chain.

Additionally, the Services have experienced casting and forging (C&F) capability and capacity challenges that can be attributed in large part to the impacts of economic efficiency-driven offshoring and waves of industry consolidation since the mid-20th century. Although some suppliers have updated equipment to meet the Services' needs, many commercial and OIB C&F plants employ aging equipment or are limited by existing facilities, infrastructure, and, for commercial firms, state and federal operating permits. U.S. supply chains currently rely upon significant materials and products from foreign manufacturers. Multiple U.S. sources report that the PRC and other foreign suppliers often deliver completed items for the same cost a U.S. forge will pay for raw materials needed to produce parts of an item.

Moreover, the lack of a stable domestic industry for smaller logic semiconductors impacts next-generation capability development, but U.S. Government investment is improving outlooks. In 2023, authorized under the 2022 CHIPS and Science Act, the Defense Department awarded nearly $240 million to eight "innovation hubs" as part of the Microelectronics Commons, which will benefit both the Department and the United States by spurring development of a domestic microelectronics manufacturing industry. The Microelectronics Commons Program is a network of regional technology Hubs acting on a shared mission to expand the national leadership in microelectronics. With $2 billion in funding for Fiscal Years 2023 through 2027, the program aims to leverage these regional hubs to accelerate domestic hardware prototyping and "lab-to-fab" transition of semiconductor technologies.

Agility

Many elements of the traditional DIB have yet to adopt advanced manufacturing technologies, as they struggle to develop business cases for needed capital investment. This directly impacts DoD's ability to reduce manufacturing lead times and lifecycle costs, and to increase readiness. Advanced manufacturing automation streamlines and compresses development and production processes, reduces human intervention, lowers unexpected downtime, and improves overall manufacturing performance. Today's advanced manufacturing automation is the result of decades of symbiotic interactions between the public and private sectors and separate independent private sector-driven advances. Through new initiatives like Advanced Manufacturing (AdvM) Forward as well as continued work in advanced manufacturing applications in production and sustainment of key components, the DoD seeks to produce more advanced technologies in the U.S. through investments in regional manufacturing ecosystems. DoD will expand efforts to incentivize, invest in, and otherwise promote the use of advanced automation technologies by defense suppliers to reduce total life cycle costs and increase readiness, and, as appropriate, to fill workforce gaps.

Security

Dependence on adversarial sourcing poses a mounting national security challenge to the DIB and the components, systems, platforms, and munitions it produces. Counterfeit or substandard items could foster system failures while computing and networking technology "backdoors" may serve as intelligence pathways. Further, even if materials and parts are uncompromised, sole-source dependence on adversary-produced materials and parts present an obvious vulnerability. Various investigations have confirmed adversarial infiltration into defense supply chains is substantial. Some critical capabilities remain dependent on prohibited adversarial suppliers. Over the last decade, the DoD has struggled to curtail adversarial sourcing and burnish the integrity of defense supply chains. Despite these efforts, dependence on adversarial sources of supply has grown. DoD continues to lack a comprehensive effort for mitigating supply chain risk. Policy concerning prohibited sources today remains piecemeal, inadequate to address the current complexity of the DoD supply chain, and is often difficult to execute and enforce. Predictably, this approach has delivered only marginal results with DoD continuing to procure items from adversarial sources in line with low-cost free market principles but not in line with national security and resilience-oriented principles. As detailed in the National Security Strategy and NDS, the PRC is the United States' pacing challenge. DoD must work with Congress, other executive departments, and global Allies and partners to eliminate defense industrial dependencies emanating from the PRC. The defense of the nation must not be held at risk by reliance on those who might seek to undermine it.

Economic health and compliance

The DoD must balance the needs for speed and scale with cost and requires resilient, healthy, diverse, dynamic, and secure supply chains to ensure the development and sustainment of capabilities critical to national security. Currently, the health of sub-tier suppliers, manufacturing capacity, and lack of visibility into our critical supply chains create unique challenges that must be addressed to meet national security objectives. This is a particularly acute issue for small businesses who face various obstacles in helping DoD meet its challenges. Unreliable cash flow to small businesses makes the DIB more fragile and less secure, and this is driven by a range of issues from appropriation delays to commonly used contracting practices. Regulations and business practices can be difficult to understand, costly to implement, and in a myriad of ways often create barriers to doing business with DoD. Some of these barriers include confusing points of entry into defense markets, improper bundling and consolidation of contracts, and convoluted regulations. These barriers strain the relationship between the DoD and small businesses. By working with both large and small businesses and more strategically utilizing the OIB, the DoD will achieve a more resilient, modernized industrial ecosystem that is economically and environmentally sustainable, receives predictable demand signals, and does not depend on adversarial foreign sources of capital, technology, raw materials, and critical inputs.

PRIORITIES AHEAD

Four-year Outlook

While outlining a strategy is key, implementation is essential for mission success. The DoD aims to incentivize the development of a modernized, resilient defense industrial ecosystem that has resilient supply chains, a ready workforce, taps into the Department's flexible acquisition policies, and promotes economic deterrence for the United States and her close allies. After engagement and study with key players in the U.S. industrial base, including both traditional and non-traditional companies, Department leadership determined that the following six initiatives needed senior leadership's focused attention. These six cross-cutting areas are not the sole responsibility of any one Department component, but instead require work across the Department enterprise to drive change.

The six cross cutting areas are as follows:

- Indo-Pacific Deterrence
- Production and Supply Chains
- Allied and Partner Industrial Collaboration
- Capabilities and Infrastructure Modernization
- New Capabilities Using Flexible Pathways
- Intellectual Property

These areas all ensure that we have the means to produce at scale, make sure our data is safe, and collaborate with international partners and industry resulting in a more robust, efficient, and bottleneck free supply chain. The Department is committed to providing clear direction on the Department's priorities for defense industrial capacity building and resilience to allies and partners, industry, Congress, and the interagency.

Four-year Resilience Goals and Priorities

Overview

The Department has a bold vision to achieve a defense industrial ecosystem that is "dynamic, responsive, state-of-the art, resilient, and a deterrent to our adversaries over the next three to five years. With the publication of the National Defense Industrial Base Strategy, we outlined the vision for ensuring the Department can continue this support and produce at a pace and scale needed to meet the ever-growing demands we face now and into the future. The following priorities are aligned with these priorities and are hoped to be achieved within 3 to 4 years.

Production and Supply Chains

To shore up vital supply chains and build resilience in critical technology sectors and manufacturing strength, the United States must gain robust situational awareness of vulnerabilities.

The Department is using supply chain risk identification programs—including those underway prior to the NDIS and new, complementary ones—to create a robust defense supply chain vulnerability risk assessment capability. To this end, OSD and the Military Services are collaborating in a variety of different ways with commercial suppliers, other government agencies, allies, and strategic partners.

Assessing Supply Chain Risk Vulnerabilities

The Department is currently developing and expanding the tools used to illuminate supply chain adversarial influence on and risks to DoD supply chains. Using tools like the Industrial Base assessment Tool (IBAT) coupled with creating a method to prioritize DoD efforts to high risk industries DoD is on the way to being able to better identify risks in the defense supply chain. Additionally, creating security classification guides, understanding the qualification process as barrier to entry, tracking army assets, and updating Military Specifications.

The combination of supply chain assessment and threat detection capabilities aims to thwart the sourcing of counterfeit or substandard items of any kind. This is particularly true for sourcing from adversaries, which could foster system failures while leaving unsecure computing "backdoors" that could serve as hostile intelligence pathways into DoD systems. Furthermore, verifiable identification and prevention of sole-source dependence, particularly involving adversary-produced materials and parts, is essential to mitigating production vulnerabilities. Supply chain assessment enables better identification of foreign intelligence and insider threats to DoD capabilities, the industrial base, and defense-related supply chains. This ultimately strengthens the U.S. ability to identify, deny, and disrupt adversarial foreign intelligence and insider threats to national security–related supply chains.

Beyond these protective goals, deep supply chain situational awareness can enable alternatives and dramatically shorten production lead times and improve material responsiveness for crisis events. This will ensure that the domestic industrial base can produce weapons at the capacity needed for the future fight.

The intended outcomes of the barriers to entry study center on policy changes that improve industry participation in critical defense supply chains and increase industrial base production. Measurements of success include a better understanding of which contracting vehicles (e.g., fixed price contracts vs. work completed, etc.) are preferable and enable small businesses to enter the industrial base ecosystem. This will include identifying the ideal contracting timelines for small businesses and qualification costs to entry. Additional outcomes include viable policy changes and proposals such as reductions in qualification costs through changes to the Federal Acquisition Regulation (FAR) costing requirements, accounting and pricing methodologies, and more equitable contracting opportunities for small businesses.

Adversarial Capital

Adversarial capital is strategic investments in key U.S. and allied defense industries to harvest critical technologies, gain access to pioneering innovation and research and development efforts, leverage opaque private–public reporting structures to mask ultimate beneficial ownership, and capitalize on dual-use technologies that may be used to close the gap in the U.S. military's comparative advantage. Adversarial capital is weaponized financial capital and is an important component of our pacing threats' strategies. The goal of adversarial capital is to gain access to, influence over, or even control of pioneering innovation and research and development efforts, often involving financially struggling companies. Adversarial capital surreptitiously bypasses national security review by leveraging opaque private–public reporting and transaction review structures to mask the ultimate beneficiaries of ownership. Worse, adversarial capital is difficult to counter because adversaries employ sophisticated techniques and strategies and continually adapt tactics to stay ahead of detection and regulations. When it succeeds, adversarial capital leapfrogs years of painstaking research and development, foils intellectual property protection, and results in adversaries gaining at the expense of U.S. national security.

Successful interventions will shield the United States' most innovative small businesses from increasing attempts by foreign actors to influence or disrupt business operations using adversarial capital. Specifically, this LOE will establish effective mechanisms to counter disguised ownership and persistent, adaptive efforts by adversaries.

Stockpiling

Stockpiling is a core element of DoD's vision for creating more resilient supply chains. Stockpiles range from inputs for defense production—including strategic minerals, critical chemicals, critical parts, and technology components—to finished goods, including broad sets of weapons and other munitions, medical supplies, and other hardware and supplies. These inventories act as shock absorbers for the supply chain and help to mitigate near-term risks, including from unanticipated demand spikes or supply chain disruptions. However, recent geopolitical events revealed that our national stockpiles are inadequate and that replenishing existing stockpiles needs urgent attention. To mitigate vulnerabilities in the supply chain, the Department is embracing an expanded approach to stockpile and inventory planning.

Working with industry, DoD is expanding existing and establishing new stockpiles of the critical parts, finished goods, and commodities needed to meet production requirements for conducting sustained campaigns against adversaries.

To cope with prolonged conflicts, protracted lead times in scaled production capacity, and unpredictable market fluctuations (e.g., delays in domestic raw materials output), it is imperative that our various stockpiles hold adequate reserves of both inputs toward defense production and finished goods ready in sufficient quantities for the warfighter. This is particularly true for areas that had been long neglected, including, but not limited to, stocks of strategic and critical materials and munitions.

Maritime Economic Deterrence

As highlighted in the NDIS economic deterrence strategic pillar, fair and effective market mechanisms support a resilient maritime defense industrial ecosystem among the U.S. and our partners and allies. Maritime economic deterrence involves strategic actions taken by nations to safeguard their economic interests and maintain stability in the maritime regions. Maritime economic deterrence focuses on mitigating adversarial foreign investment risks, innovation and technology protection, supply chain integrity initiatives, and the coordination and protection of research efforts across the government and private sector.

This LOE will align foreign investment, critical technology, supply chain, industrial base, and critical infrastructure to address economic deterrence across the Navy. MEDEC's efforts will better align foreign investment, critical technology, supply chain, industrial base, and critical infrastructure to address strategic economic deterrence across the Navy. The MEDEC team will develop a cohesive Navy strategy inclusive of policy, resourcing, organizational, and offensive recommendations by the end of 2024 to address economic security and deterrence issues.

Allied and Partner Industrial Collaboration

Strengthening the AUKUS Trilateral Security Partnership

AUKUS is an enhanced trilateral security partnership among Australia, the United Kingdom, and the United States that promotes a free and open Indo-Pacific that is secure and stable, guided by a shared commitment to the international rules-based order. AUKUS is focused on the development and delivery of advanced capabilities to the warfighter and is broken down into two Pillars. Pillar I is Australia's acquisition of a conventionally-armed, nuclear-powered submarine (SSN) capability. The delivery of the submarine capability is through the "Optimal Pathway," which outlines the plan to sell three, with an option of up to five, U.S. Virginia-class submarines, followed by the joint construction with the United Kingdom of a new SSN class, SSN AUKUS. In addition to the $5.4 billion invested in the U.S. SIB since 2021, the U.S intends to invest $11.4 billion in the SIB across the next five years to accelerate the production rate of U.S. submarines as quickly as possible.

Pillar II is focused on the delivery of advanced warfighting capabilities to promote security and stability in the Indo-Pacific region, in addition to creating an enabling ecosystem which will facilitate deep industrial base cooperation and collaboration and support joint co-development, -production, and -sustainment. Initial areas of collaboration include advanced cyber, artificial intelligence and autonomy, hypersonics, quantum technologies, electronic warfare, and undersea warfare capabilities.

Co-Development and Co-Production of Priority Defense Systems

The NDIS underscores production diplomacy as a key aspect of bolstering the defense ecosystem. Co-development, co-production, and co-sustainment of major defense platforms and critical weapons systems with partners and allies is key to that effort. Utilizing global manufacturing capabilities to manufacture U.S. and foreign products domestically and in allied and partner nations is integral to building a modernized, resilient defense industrial ecosystem and to enabling interoperability and interchangeability. A prime example of integrating domestic and foreign munitions production capabilities is the decision to manufacture Guided Multiple Launch Rocket System (GMLRS) munitions in Australia under Australia's Guided Weapons and Explosive Ordinance enterprise. These efforts are also intended to strengthen overall manufacturing capabilities.

Facilitating International Industrial Collaboration

The Foreign Military Sales (FMS) program is a critical tool used to achieve U.S. foreign policy objectives. FMS often includes locally sourced production and capabilities support that contributes to host nation economic productivity, while deepening defense and industry relationships with the U.S. Accelerating the responsiveness of the FMS system, in cooperation with allies and partners is important as we work to alleviate bottlenecks. Alleviating bottlenecks in the FMS process requires a multi-faceted approach. Key strategies include streamlining the approval process, enhancing interagency coordination, and modernizing information systems. This will improve communication and transparency with both foreign buyers and domestic manufacturers and reduce delays caused by misunderstandings and/or incomplete information.

To advance this effort, the Secretary of Defense established a Foreign Military Sales Tiger Team (TT) which identified key pressure points that can delay progression of a specific case throughout the security cooperation case lifecycle—both inside and outside of the Department. As a result, the Department established an enduring governance board, the Continuing Process Improvement Board (CPIB) to oversee FMS system improvement.

Capabilities and Infrastructure Modernization

Nuclear Modernization

The DoD is committed to modernizing the U.S. nuclear enterprise. This includes the aircraft, missiles, and other platforms required for delivering nuclear capability. The Department of Energy is responsible for the infrastructure required to build nuclear weapons. The DoD is undertaking an extensive, multifaceted effort to sustain aging systems and weapons and modernize across the spectrum of U.S. nuclear weapons capabilities. The nuclear modernization budget includes the new stealth bomber (B-21 Raider), updates to submarine-launched missiles, new strategic submarines, updates to existing gravity bombs, updates to the existing Cold War nuclear command-and-control network, F-35 modifications, cruise missiles, and new intercontinental ballistic missiles (ICBMs).

As a result of these efforts, the Department will diversify its supplier base by developing a new method of automation to optimize the manufacturing of reactive materials and ensure the safe handling of combustible metal powers while preserving the warhead's enhanced performance. Additionally, DoD will secure the supply chain of critical components to energy systems, lower costs, and create an enduring research tool for separators.

Improving maintenance, repair, overhaul, and upgrade

Production is not the only contributor to deterrence and industrial resilience. Once systems are manufactured and fielded, the Department expends resources on maintaining, repairing, overhauling, and upgrading systems. Known as Maintenance, Repair, Overhaul and Upgrade (MRO&U), DoD MRO&U programs allow existing systems to be maintained, modified and improved. In May 2024, the DoD announced the Regional Sustainment Framework (RSF) as a blueprint aimed for empowering a globally connected, distributed, and resilient maintenance, repair, and overhaul (MRO) ecosystem. The RSF is intended to bring existing and potential weapon system MRO capability and capacity closer to the forward point of need, and to augment traditional strategies to improve readiness.

RSF implementation requires stakeholders to prioritize sustainment efforts for critical platforms, identify gaps in regional support solutions, and establish conditions now to support contingency planning and execution. Targeted weapons systems will be selected based on relevance to operational plans, a comprehensive review of Foreign Military Sales cases and other cooperative programs, the potential for MRO collaboration with industry, allies and international partners, along with other criteria such as strategic importance, international relevance, maintenance needs, retrograde considerations, and international industry capacity. The priority for implementation of the

Regional Sustainment Framework aligns with the National Defense Strategy. Therefore, initial focus will be on projects within the Indo-Pacific, with follow-on projects in the European theater.

RSF aligns with the National Defense Strategy (NDS) and underpins the Department's efforts to develop distributed MRO capabilities closer to the point of need by collaborating with allies and partners, including the U.S. and international defense industrial bases. RSF has three primary goals: (1) prevail in a contested logistics environment, (2) enhance military readiness, and (3) strengthen regional partnerships.

New Capabilities using Flexible Pathways

Replicator Initiative

Replicator is a DoD-wide process that accelerates the delivery of innovative capabilities to warfighters at speed and scale. The first iteration of Replicator (Replicator 1), announced in August 2023, will deliver all-domain attritable autonomous systems (ADA2) to warfighters at a scale of multiple thousands across multiple warfighting domains within 18–24 months, or by August 2025. The DoD is creating a new meaning of "state of the art" with the use of ADA2 systems, which are less expensive, put fewer people in the line of fire, and can be changed, updated, or upgraded with greatly reduced lead times. Successive iterations of Replicator will apply lessons learned to address additional capability gaps beyond ADA2 systems, including their simplified control and employment using advanced human-machine interface.

The goal of the Replicator initiative is to create a repeatable process by which the DoD can quickly field innovative capabilities in large quantities leading to shorter lead times for these capabilities. Replicator aims to leverage emerging technologies, particularly autonomous systems and adjacent enablers like artificial intelligence and human-machine interfaces, to achieve several strategic objectives: increased operational capability, technological superiority, and cost effectiveness.

Second, the Replicator initiative also seeks to achieve and maintain technological superiority through continuous development of cutting-edge technologies, such as artificial intelligence and robotics. Lastly, technological advantage will be reinforced by accelerated development and fielding of battlefield systems to establish and maintain the advantage against adversary forces.

Rapid Defense Experimentation Reserve (RDER)

The NDIS draws the link between production, DoD acquisition practices, and the warfighter. The United States must fully support the Joint Force—the five military services plus combatant commands—to ensure the nation's defense. The Rapid Defense Experimentation Reserve (RDER) initiative takes prototypes offered by the military services and combatant commands, verifies their production readiness and operational utility, and pushes the most promising applications to full production.

RDER will bring three benefits to the DoD: (1) RDER will enable the Department to bring new capabilities to the Joint Force, transitioning systems and approaches more quickly, (2) RDER will better align current experimentation efforts to the Joint Warfighting Concept (JWC), and (3) RDER will leverage end-to-end mission analysis and experimentation to capitalize quickly on innovative ideas.

Overall, the RDER initiative aims to transform the way the DoD approaches technology development and deployment, making it more responsive to the fast-paced nature of modern warfare and ensuring that the U.S. military remains equipped to handle a wide range of current and future challenges.

Flexible Acquisition Pathways

The primary desired outcome of working to create flexible acquisition pathways is to streamline the procurement process, which is critical to the Department's success. Flexible acquisition pathways, such as OTAs and MTAs, significantly streamline the procurement process by reducing bureaucratic hurdles and enhancing the speed and flexibility of contracting, allowing the DoD to engage more effectively with nontraditional defense contractors, academic institutions, and small businesses. By facilitating rapid prototyping and the swift fielding of mature technologies, these streamlined processes ensure that innovative solutions can be developed and deployed much faster than through traditional methods. This not only accelerates the deployment of advanced technologies but also broadens the pool of potential innovators and suppliers, ultimately enhancing the DoD's ability to maintain a technological edge and respond swiftly to emerging challenges.

Legislative and Budgetary Objectives

The DoD continues to work with Congress to develop new authorities for improved supply chain resilience within the DIB. For example, working with Congress, DoD secured FY 2024 authorities and resources to execute multi-year procurements for six critical munitions: Advanced Medium Range Air-to-Air Missile (AMRAAM), Naval Strike Missile (NSM), Guided Multiple Launch Rocket System (GMLRS), PATRIOT Advanced Capability-3 Missile Segment Enhancement (PAC-3 MSE), Long Range Anti-Ship Missile (LRASM), and Joint Air-to-Surface Standoff Missile (JASSM). Additionally, for only the second time in the 74-year history of the Defense Production Act, Congress expanded the definition of a domestic source for DPA Title III Awards in the FY 2024 National Defense Authorization Act, allowing companies and projects in the United Kingdom and Australia, in addition to the United States and Canada, to be considered as domestic sources for DPA funds. Moving forward, the DoD will continue to work with Congress to develop authorities that address current and emerging supply chain resilience risks within the DIB.

Long-term Resilience Goals

Indo-Pacific Deterrence

Fair and effective market mechanisms that bolster the U.S. allied, and partner defense industries and overall economic stability are critical in supporting broader integrated deterrence within the Indo-Pacific region. Robust economic activity supports increased and growing military capabilities and capacities, meaningfully contributing to economic deterrence. By investing in the Indo-Pacific, the U.S. also sends a strong message of reassurance to our regional partners, enhancing the integrated deterrence effect. The impact of economic deterrence is compounded by the fear of materially reduced access to U.S. markets, technologies, and innovations by sowing doubt in the minds of potential aggressors as the U.S. and our allies and partners markets with resilient supply chains. These resilient, interconnected, larger markets increase U.S. and our allies' self-sufficiency and interoperability. This defense industrial ecosystem collaboration and interoperability strengthens economic deterrence by compounding potential aggressors' fears of losing access to U.S. and likeminded allied and partner markets, technologies, and innovations.

Additionally, U.S. investments in the Indo-Pacific defense industrial ecosystem helps to reassure regional partners of continued U.S. commitment while the increased military capabilities and capacities from allied and partner collaboration strengthens military deterrence. The overall effect of increased regional market integration, investments, and greater military capability and capacity strengthens integrated deterrence and promotes a free and open Indo-Pacific. The promise of collaborative and complementary investments in theater-relevant capabilities, leveraging the strength of our network for mutual benefit, brings optimism and hope for a more secure future.

Supplementing Key Munitions and Missiles

U.S. material support to Ukraine has revealed challenges in maintaining, reconstituting, and increasing production of U.S. munitions stockpiles. Failure to maintain, and potentially increase, these stockpiles risk operational capability and force readiness. DoD requires increased capacity to ensure sufficient production of new, advanced munitions.

OUSD(A&S) has undertaken multiple initiatives to supplement key munitions and missiles by focusing on increasing capacity and capabilities across the munitions industrial base, diversifying the defense industrial vendor base, and modernizing production techniques. First, at the behest of the Nuclear Weapons Council, OASD Industrial Base Policy (OASD(IBP)) is working with other DoD offices to incentivize vendor participation in the nuclear defense industrial base and mitigate the risks inherent in a fragile industry dependent on single and sole source suppliers. Second, efforts to collaborate on hypersonics under AUKUS Pillar II will help increase the capability and capacity of AUKUS partner nations and create redundancy in suppliers as the critical technologies required begin to ramp up to full production. The conventional hypersonics and nuclear industrial bases are starting to converge due to similar advanced material requirements for nuclear weapon modernization and next-generation hypersonic missile performance. OASD(IBP) maintaining these efforts ensures that progress made in one sector of the industrial base will support, rather than compete with, the other.

In the next four years, DoD is working to expand global munition production capacity, reduce manufacturing lead times, improve resiliency, and enhance surge capacity of missiles and munitions. These efforts will ensure that we have increase production, reduced lead times overall improving material responsiveness for crisis events. Lastly, these efforts will aid in increasing redundancy in supplies for key hypersonics components. While these are a priority now—estimated completion is longer term.

Submarine Industrial Base

The submarine industrial base (SIB) is increasingly strained, yet crucial, as the Navy ramps up production of the Columbia class and needs to achieve an increase production of Virginia-class submarines to two per year. Achievement of these construction rates is essential for the Columbia class to come online to replace the aging Ohio class ballistic missile submarines, meet the Navy's force need of 66 attack submarines, and to support our commitments under the AUKUS partnership.

SIB investments are targeted across five key lines of effort (LOE): (1) workforce growth and development; (2) supplier development; (3) shipbuilder infrastructure; (4) strategic outsourcing; and (5) manufacturing technology. This end state will be realized through the Navy's production goal of one Columbia-class and two Virginia-class submarines per year. The Navy is committing significant resources in these key areas to strengthen the extended supply chains, improve material availability, meet construction and sustainment demands, and support our commitments to AUKUS. Many of these critical actions will take time to matriculate into increased production and sustainment capacity.

Production and Supply Chains

Onshoring Critical Production Capacity

Since the end of the Cold War, considerable portions of U.S. civilian manufacturing, and some of the U.S. defense sector's sub-tier supply chain, have moved offshore, driven by lower labor costs and advantageous access to certain resources. Over time, distortionary, unfair international trade practices and outright trade agreement violations amplified these offshoring trends. Such practices include illegal subsidies, currency manipulation, dumping practices, failure to enforce environmental regulation, cyber espionage, and predatory investments and acquisitions from adversaries. Adversarial domination of critical markets and important industrial sectors negatively affects U.S. control of commodity pricing, as well as access to materials in strategically critical areas. Defense industrial base consolidation and contraction compounded these efforts as did the decades' long focus on counterterrorism rather than near-peer conflicts. The result is significantly increased risk and cost to U.S. and allied defense supply chains.

The Department is currently addressing this priority by developing prohibited sourcing policy, revitalizing domestic manufacturing or critical materials, investing in modern production infrastructure, workforce, and process improvements. With this we hope to facilitate the onshoring of critical industries will ensure healthy, competitive, sustainable, reliable, scalable domestic industrial capabilities, capacities, and supply chains.

Industrial Cybersecurity

Numerous state and non-state actors have come to see cyberspace means as a powerful force multiplier. U.S. adversaries seek to use malicious cyber capabilities to achieve asymmetric advantages, targeting U.S. critical infrastructure, undermining U.S. economic security, and degrading U.S. military superiority. Hostile cyberattacks pose an outsized danger to defense industry intellectual property and supply chains. Secure, reliable defense technology research and development and industrial base production is simply not possible without robust industrial cybersecurity.

The Department is currently addressing this priority by creating architecture for DIB cyber risk. As directed by the President in National Security Memorandum 22, the Department serves as the Sector Risk Management Agency for the defense industrial base. In this role, the Department interfaces with industry, monitors and prioritizes threats, oversees incident management, and provides technical assistance, among other duties. Cybersecurity is one such area of collaboration with the DIB. The Department's industry-related cybersecurity initiatives include the Defense Industrial Base Cybersecurity Program, the DoD Cyber Crime Center's DoD-DIB Collaborative Information

Sharing Environment, the National Security Agency's Cybersecurity Collaboration Center, and the Enduring Security Framework. The Defense Industrial Base Cybersecurity Program alone sustains a voluntary partnership with over 1,000 companies and has shared roughly 600,0000 cyber threat incident indicators since its establishment in 2008.

The primary desired outcome is to foster a defense industrial ecosystem, including for-profit and government-owned, that is adequately shielded from adversarial cyberattack. It can securely research and develop technologies that confer and sustain enduring advantage, such that production operates without cyber disruption. Foreign intelligence and insider threats to DoD capabilities, the industrial base, and defense-related supply chains will be identified, and hostile intelligence will be denied and disrupted. Underpinning this strategic approach will be an approved DIB Cybersecurity Strategy Implementation Plan in FY 2025 that guides DoD execution. Successfully executing this LOE will enable the DoD to build upon and improve the coordination of regulations, policies, requirements, programs, services, pilots, public–private efforts, and interagency initiatives to combat the varied and evolving cyber threats facing the defense industrial base.

Joint Production Accelerator Cell (JPAC)

JPAC spearheads efforts to increase munitions, weapons platforms, and other materials production rapidly by coordinating across the Department and with other agencies and production partners. JPAC is the successor to the Munitions Industrial Deep Dive (MIDD) organization that was formed in response to the Ukraine crisis. JPAC is a tactical, problem-solving cell that leverages analytical processes and current authorities to be less crisis-driven and empower more proactive, forward-looking decision-making to support more responsive weapons production. The organization focuses on three main efforts: scaling production in line with Department priorities through direct investment in suppliers; building surge capacity, including identifying opportunities to introduce and leverage new production techniques, advanced manufacturing, and digital engineering; and engaging allies and partners to identify and address global production constraints. JPAC's efforts have directly contributed to $2 billion in investments in the weapons industrial base.

Capabilities and Infrastructure Modernization

Organic Industrial Base

The NDIS specifically highlights the organic industrial base (OIB), the network of government-owned industrial facilities overseen by the DoD. These facilities ensure that the weapons systems and equipment built by the commercial defense industrial base stay operational for decades. Weapons systems include arsenals, ammunition plants, overhaul maintenance facilities, and shipyards. Building a resilient defense industrial ecosystem will ultimately require a robust, modernized organic industrial base.

The Army's OIB Modernization Implementation Plan consists of a 15-year approach to modernize and support enduring and to "sunset" legacy systems, including a total of $9.5 billion in funding through FY 2023–2028. It includes five LOEs which address facilities, tooling and processes, workforce, network, cyber, and energy and the environment.

The Army OIB modernization and workforce training programs will enhance critical infrastructure and production machinery longevity and resilience while increasing innovation and expansion into other production lines. The benefits will include reduced facility maintenance costs, lessened downtime for repairing broken machinery, and increased productivity with lower long-term costs associated with inefficiencies within current program operations.

In addition to the Army's efforts, the Air Force has an OIB construction flexible acquisition initiative, which allows for construction on OIB facilities administered by private contractors and on OIB facilities not wholly operated by private contractors.

Through the OUSD(R&E) ManTech program, the Manufacturing Innovation Institutes (MIIs) launched an OIB Modernization project call that will offer up to $2.5 million to five MII-member winners. These contracts include projects related to robotic non-contact 3D inspection replacing tank ammunition, extended reality, artificial intelligence-assisted paint masking, maskless robotic painting with real-time control, closed-loop technical data exchange, and cybersecure data compliance for integrated sensors and shop floor digitization.

The Air Force construction initiative will speed facility development and construction times.

Intellectual Property and Data Analysis

Intellectual Property Coordination

OUSD(A&S) will advocate for clear, effective, and flexible IP acquisition laws, policies, and regulations. This will include supporting policy updates across the Department to ensure IP imperatives are appropriately integrated across DoD interests with specific focus upon patent data rights.

As called for in the NDIS, DoD aims to enhance the competitive environment to the maximum extent possible. DoD will leverage its market power to incentivize vendors to enter into agreements that encourage the competitor to develop business models and provide corresponding offers that better balance both parties' interests in ensuring return on their technology investments.

A key desired outcome will be enhanced legal and regulatory authorities that provide clear and consistent application of IP policy and statute for the workforce. Enhanced efforts to tailor development, planning, and execution of IP strategies that improve on-demand access to data with the necessary license rights will be complemented by improved legal and regulatory actions increasing the workforce's ability to develop business and IP strategies will further strengthen the initiative. The acquisition workforce will ultimately be able to integrate IP strategies with open systems architectures to achieve Modular Open Systems Approaches in critical programs.

The DoD will improve communications and transparency with industry in program planning while fostering an environment and culture during execution that allows for improved on-demand access to data with the necessary license rights.

Deliver Capabilities for Enterprise Business and Join Warfighting Impact

OUSD(A&S) will drive transparent engagement and collaboration with industry and create opportunities to foster balanced communication and relationships founded on the understanding of industry and government's mutual need to remain innovative and sustainable. The DoD will build clear and consistent messaging that conveys that IP must be approached as both a necessary commodity for program life cycle product support and a necessary investment in industry for future innovation. OUSD(A&S) will pursue this task through existing forums, and support for other industry and professional events.

OUSD(A&S) will promote the DoD's adoption of open systems architectures and virtual modeling methodologies across critical programs. These techniques use large language models and other data analytics methods to effectively use data to gain data-driven insights into the health of programs and the industrial base in order to make effective program decisions.

Advance the Data, Analytics, and AI Ecosystem

Effective data management and analysis can be a force multiplier. The Department strives to better leverage data, analytics, and the AI ecosystem to improve planning and sub-tier visibility in the defense industrial ecosystem. Ultimately, the Department aims to swiftly use new and emerging analytic tools to improve decision-making. OUSD(A&S) will ensure access to cross-functional resources and tools to plan and execute IP best practices. The IP Cadre provides guidance and support directly to programs through job aids, desk references, best practices, automated tools, and other resources to ensure the workforce can execute the Department's intent related to IP. Additionally, the IP Cadre serves as a cross-functional team of experts to directly advise programs primarily through peer reviews.

Further, OUSD(A&S) will enhance business analytics and warfighting capabilities with data, analytics, and artificial intelligence technologies for improved decision advantage and outcomes.

Conclusion

The United States and its allies and partners require modernized defense industrial capacity that strengthens national defense, and that reassures and supports those countries in the direct path of adversarial influence and aggression. This position of modern industrial strength is a core enduring advantage that will contribute substantially to Integrated Deterrence—not just for the Department but across the U.S. Government and with allies and partners.

The Department took two giant steps forward with publication of the 2023 National Defense Industrial Strategy and the 2024 NDIS Implementation Plan. The challenge ahead will be to maintain the momentum on building DIB resiliency and ensure U.S. Government efforts support the shared goals on strengthening, diversifying, and protecting defense-critical supply chains. To achieve these goals, DoD and its partners will need to concentrate on three key points:

Using the NDIS Implementation to guide defense industrial base policy and resourcing. The Implementation Plan is a living document that will be updated every six months to measure progress and assess remaining risk in the 15 discrete "risks of inaction." Consistent attention on the effects of Department, interagency, and allied and partner actions will ensure that the entire enterprise is driving down risk in the highest-priority areas.

Sufficiently resourcing the DIB. Congress and DoD have worked cooperatively throughout the COVID-19 pandemic and the war in Ukraine to provide funding and exercise certain authorities to expedite closing supply chain gaps and respond to these emergencies. The U.S. Government should sustain these efforts and avoid replicating mistakes from the past whereby inconsistent focus and funding led to a lack of industry engagement and diminished DIB capacity and capability at the time of need.

Addressing future DIB supply chain requirements. As discussed throughout this Review, DoD has focused investment in the five key sectors identified in Executive Order 14017 and emphasized in the NDIS. To ensure the DIB is ready to produce weapon systems and capabilities for the future fight, DoD must look ahead to anticipate industrial requirements pertinent to meeting the pacing threat.

These actions are a commitment to both the public and private sectors for focused, dedicated efforts to build and secure the industrial capability and capacity necessary to ensure our military has the materiel available to deter our potential adversaries, and if necessary, defeat them in battle. This call to action may seem a great cost, but the consequences of inaction or failure are far greater.