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concerning

"Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security."

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Members of the Commission and Commission staff, thank you for the opportunity to testify on the critical topic of supply chains and our nation's security.

My name is Dr. Monica Gorman, and I am a Managing Director with Crowell Global Advisors, the global policy consulting firm affiliated with Crowell & Moring LLP. From September 2022 until January 2025, I served as the Special Assistant to the President for Manufacturing & Industrial Policy at the White House National Economic Council. I also served as Deputy Assistant Secretary of Commerce for Manufacturing within the International Trade Administration from March 2021 until September 2022.

Prior to government service, I worked for approximately 18 years as a corporate executive in the apparel and footwear industry. I directly managed corporate teams around the world and tackled business challenges related to both global sourcing and U.S. manufacturing. Much of my private sector career has been dedicated to strengthening and improving manufacturing supply chains, whether through effective understanding and management of quality, product safety, labor and environmental risks, as well as through the evolution of sourcing strategies to effectively account for geopolitical and other risks. My testimony is based on a myriad of public reports, several of which I directly coordinated or contributed to during my government service, as well as other public reporting and direct observations from my public and private sector experience.

Background

More than five years have passed since the start of the global COVID-19 pandemic. Supply chain disruptions caused by pandemic-related lockdowns and abrupt shifts in supply and demand for goods and services are now well-known. However, the supply chain risks that led to pandemic-induced disruptions did not arise overnight. Over the past few decades, technological advancements, free trade agreements, and accessible, cost-efficient transportation networks led many American companies to pursue highly efficient, lower cost manufacturing around the world. This resulted in increasing geographic concentration of production over time into the most efficient, cost-effective locations, most notably in China. When the pandemic unexpectedly upended these smoothly functioning systems, it revealed critical industry dependencies on

foreign suppliers in key sectors, from semiconductors and pharmaceuticals to batteries and defense-related materials, particularly from the People's Republic of China (PRC).

Much attention has been focused on supply chains since the pandemic, including by the Biden Administration from 2021-January 2025. It is now clear that historical global supply chain efficiencies came at a price to the economic and national security of the United States. 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.[1] National security risks stemming from American industry dependence on PRC and other adversarial nations for critical products, materials, and components have been extensively documented in reports over the past five years.[2] Federal agencies have stepped up data collection and established new offices focused on supply chain risks. New coordinating mechanisms across the executive branch, including the White House Supply Chain Disruptions Task Force and the White House Council on Supply Chain Resilience established by the Biden Administration, galvanized a whole-of-government response to address both near-term supply chain disruptions and longer-term risks.

Yet, much more work remains to be done. The PRC continues to seek to dominate global markets with non-market policies and practices[3] that drive industry dependence on PRC suppliers. Although U.S. companies utilizing global supply chains have a greater recognition today of the importance of supply chain resilience than in pre-pandemic years, corporate financial and business goals drive a continued focus on efficiency and cost, particularly as memories of pandemic-era disruptions fade. As such, the rebalancing of industry footprints and a continued reduction in critical sector dependencies on the PRC will require ongoing focus from

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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/.

[2] See: The White House, *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth,* 100-Day Reviews under Executive Order 14017, https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf?utm_source=sfmc%E2%80%8B&utm_medium=email%E2%80%8B&utm_campaign=20210610_Global_Manufacturing_Economic_Update_June_Members; Administration for Strategic Preparedness and Response, Public Health Supply Chain and Industrial Base One-Year Report, February 2022, https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx; U.S. Department of Transportation, *Supply Chain Assessment of the Transportation Industrial Base: Freight and Logistics*, February 2022, https://www.transportation.gov/sites/dot.gov/files/2022-02/EO%2014017%20-%20DOT%20Sectoral%20Supply%20Chain%20Assessment%20-%20Freight%20and%20Logistics_FINAL.pdf; U.S. Department of Commerce, multiple industrial base assessments, https://www.bis.doc.gov/index.php/other-areas/office-of-technology-evaluation-ote/industrial-base-assessments; U.S. Department of Defense, *Securing Defense-Critical Supply Chains,* February 2022, https://media.defense.gov/2022/Feb/24/2002944158/-1/-1/1/DOD-EO-14017-REPORT-SECURING-DEFENSE-CRITICAL-SUPPLY-CHAINS.PDF; U.S. Department of Energy, *America's Strategy to Secure the Supply Chain for a Robust Clean Energy Transition*, February 2022, https://www.energy.gov/policy/articles/americas-strategy-secure-supply-chain-robust-clean-energy-transition; U.S. Department of Agriculture, *USDA Agri-Food Supply Chain Assessment: Program an Policy Options for Strengthening Resilience,* February 2022, https://www.ams.usda.gov/sites/default/files/media/USDAAgriFoodSupplyChainReport.pdf; and The White House, National Security Council and National Economic Council, *2021–2024 Quadrennial Supply Chain Review*, December 2024, https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/12/20212024-Quadrennial-Supply-Chain-Review.pdf.

[3] *Quadrennial Supply Chain Review*, pp. 38-45.

policymakers and private sector actors to create incentives and spur actions that prioritize the resilience of critical U.S. sectors.

U.S. Government Agency Coordination and Information Gathering on Supply Chains

Outside of the Department of Defense and the U.S. military, private companies oversee and manage supply chains – not the U.S. government. Prior to the COVID-19 pandemic, U.S. government knowledge and expertise on industry supply chains was limited and generally siloed deep within individual agencies and departments.

Institutional Coordination and Policymaking

The disruptions stemming from the COVID-19 pandemic galvanized an unprecedented level of federal government attention to supply chains. President Biden signed Executive Order 14017 on *Securing America's Supply Chains*[4] in February 2021, mobilizing a whole-of-government focus on supply chain risks and dependencies in critical industries. Executive Order 14017 ordered four "100 day" reports, published in June 2021, that assessed supply chain risks in four immediate priority sectors, as well as six in-depth industrial base assessments, published in February 2022.

These reports kicked off and subsequently informed a plethora of policy processes, legislative negotiations, institutional responses, and agency-level actions that encompassed nearly all departments and agencies and continued throughout the remainder of the Biden Administration. Many of these actions – such as the negotiations that led to the passage of the CHIPS & Science Act – are well-known to the Commission. Others, including new institutional initiatives to coordinate supply chain activities across the federal government or to establish permanent supply chain-focused positions and programs within multiple agencies, have received less public attention.

In June 2021, the White House established the Supply Chain Disruptions Task Force (SCDTF) to coordinate a whole-of-government response to the most acute supply chain crises of the day.[5] The SCDTF continued throughout the Biden Administration, coordinating federal government responses to a wide range of unexpected and urgent disruptions, ranging from the 2021-22 infant formula shortage and port disruptions to the 2024 Key Bridge collapse and temporary closure of the Port of Baltimore. The SCDTF played an essential coordinating role to bring all relevant agencies to the table to problem-solve together in real-time, assess and activate appropriate authorities and resources, and include necessary stakeholders at relevant times throughout the process.

Several federal departments and agencies have recognized the need to institutionalize supply chain capabilities as a more permanent function. The U.S Department of Commerce (Commerce) established the Supply Chain Center (SRC) with the Industry & Analysis division of the International Trade Administration. The U.S. Department of Homeland Security (DHS)

[4] Executive Order 14017, https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains.

[5] https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities/

established the Supply Chain Resilience Center (SCRC) within the DHS Policy function, and the U.S. Department of Energy (DOE) established the Office of Manufacturing & Energy Supply Chains (MESC). The U.S. Department of Health & Human Services (HHS) also created a Supply Chain Resilience and Shortages Coordinator, funded through May 2025, to coordinate strategies across different HHS operating divisions to address drug shortages and strengthen supply chain resilience for pharmaceuticals and other medical products.[6]

Throughout the Biden Administration, coordination of agency-level efforts on supply chains was led by the National Security Council and National Economic Council at the White House through the interagency policy committee (IPC) process. Other functions within the Executive Office of the President, including but not limited to the Domestic Policy Council, the Office of Science & Technology Policy (OSTP), the Office of Management and Budget (OMB), and the Office of the COVID-19 Response were regularly involved in policy processes related to specific industry supply chains or issues. Because most U.S. industries rely upon supply chains in some form, nearly all federal departments and agencies were involved in some aspect of supply chain policymaking.

The cross-cutting nature of supply chains creates coordination challenges across the federal government, particularly when multiple agencies and authorities are required to address a specific issue effectively. Recognizing the need for more permanent executive branch attention to and coordination of supply chain policy (particularly to address longer-term structural challenges as pandemic-era disruptions subsided), President Biden launched the White House Council on Supply Chain Resilience in November 2023 to ensure Cabinet-level attention and coordination on supply chain vulnerabilities for the long term. This Council was affirmed in Executive Order 14123 of June 14, 2024,[7] which also mandated a quadrennial review to the President every four years assessing the nation's critical supply chains. The first quadrennial review was published in December 2024.

Supply Chain Data Collection & Analysis

The White House typically leads executive branch coordination and policymaking, but the data that informs these processes are generally collected at the agency and department level. Departments and agencies collect data in a myriad of ways: by statute (e.g. by the Food and Drug Administration (FDA) as the regulator); through mandatory import and export documentation (e.g. by Customs and Border Protection (CBP)); through Defense Production Act (DPA) survey authority (e.g. by Commerce's Bureau of Industry & Security (BIS)); from Census data; through data supplied directly from federal contractors (e.g. to the U.S. Department of Defense (DOD)); internal tools and modeling (e.g. from DOE's National Laboratories); trade action investigations (e.g. Section 232 or 301); or through voluntary requests for information (RFIs). Additional data may be obtained voluntarily from private sector entities through Section 708 committees or other novel means (e.g. voluntary reporting of inventory data by medical product distributors to the

[6] An April 2025 GAO report reiterated the need for an HHS coordinating mechanism on drug shortages: https://www.gao.gov/products/gao-25-107110

[7] Executive Order 14123, https://www.federalregister.gov/documents/2024/06/21/2024-13810/white-house-council-on-supply-chain-resilience.

HHS Supply Chain Control Tower during the COVID-19 public health emergency), as well as from private data sets purchased by the U.S. government.

The institutionalization of supply chain functions within Commerce and DOE during the Biden Administration established new analytical capabilities to assess supply chain risks.

In Fall 2024, Commerce's Supply Chain center unveiled its SCALE tool, which 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 utilizes trade data to enable the U.S. Government to look across the goods economy at a heat map of risk and assess industries from highest to lowest risk. SCALE helps 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 a limited number of suppliers or dependencies on specific transportation methods.[8]

Beyond identifying economy-wide risks, the SCALE tool can also rank the most at-risk industries and products. SCALE provides a detailed, diagnostic assessment of those risks within specific industries and products, applying an analytical framework across numerous indicators simultaneously.[9]

DOE's MESC office also launched a Supply Chain Readiness Level (SCRL) framework, a data-driven, technology-agnostic approach to evaluate the resilience of clean energy technologies and related supply chains. SCRL is based on 6 risk factors: deployment viability, sourcing risk management, supplier maturity, customer maturity, workforce readiness, and cost competitiveness.[10]

Despite significant progress in strengthening government analytical capabilities, particularly at Commerce and DOE, supply chain data – particularly at the sub-industry, material, and component levels – remains incomplete. Supply chain data is held primarily by the private sector and guarded closely by companies for competitiveness and confidentiality reasons. Trade data collected by CBP is governed by the Harmonized Tariff Schedule of the United States (HTSUS), which is not nearly as granular as corporate data captured in a product's bill of materials. While more detailed industry data may be obtained by the U.S. government through Defense Production Act (DPA) surveys or other forms of mandatory reporting, these mechanisms typically provide "moment-in-time" snapshots that do not capture the ongoing dynamic changes that characterize industry supply chains.

Persistent Supply Chain Dependencies related to the People's Republic of China

[8] *Quadrennial Supply Chain Review*, p. 30
[9] *Ibid.*
[10] *Quadrennial Supply Chain Review*, p. 68

In December 2024, the Biden Administration published the first Quadrennial Supply Chain Review, as mandated by Executive Order 14123, which assessed four years of federal government work on supply chains, including progress made, challenges encountered, and opportunities still ahead. The report is comprehensive and includes lengthy discussion about critical ongoing U.S. supply chain dependencies with respect to the People's Republic of China (PRC).

Data gaps. While the federal government has made progress in analyzing data for supply chain risks, notable gaps remain, particularly with respect to understanding upstream dependencies on the PRC. Gaps are especially apparent for base materials, components, parts, and processing that go into a final imported product (or larger imported component), as this information is not collected by CBP and not typically reported by companies to the federal government. For example, the FDA has data on facilities producing active pharmaceutical ingredients (APIs) and finished dose forms (FDFs) for new and approved drugs, but it does not have comprehensive information about the manufacturers that produce the chemicals used in the synthesis of those drugs (known as key starting materials (KSMs)), even though it is generally believed that the majority of KSMs are produced in the PRC.[11] Similar challenges exist in understanding critical minerals, industrial parts and tooling, other industrial chemicals, etc.

U.S. domestic demand continues to outstrip anticipated domestic supply. Countering the PRC's dominance in certain industries will require sustained effort to expand domestic supply, beyond current federal investment that is already catalyzing domestic manufacturing in certain key industries, such as semiconductors. For example, in the solar industry, the PRC's market share across the key production steps (e.g., polysilicon, ingots / wafers, cells, and modules) exceeds ~80 percent.[12] In the case of battery production, anticipated growth will require a significant increase in raw and processed battery-grade metals. Even though domestic processing and refining capacity is coming online with federal investments, demand is forecast to outpace the current pipeline of future supply, and U.S. producers will struggle to price competitively relative to global benchmarks. [13]

For example, DOE has estimated that for upstream production steps in certain renewable energy supply chains, domestic supply is expected to meet only about 30 percent of projected U.S. demand.[14] PRC firms continue to operate with substantial production cost advantages, driven by lower capital and operating costs, vertically-integrated business models, favorable state policies, fewer labor and environmental restrictions and favorable government policies that include access to low-cost land and utilities, preferential financing, and a range of trade policy tools. Market incentives are likely to continue to lure U.S. companies towards PRC firms, particularly for upstream inputs, unless or until alternative supply is competitively available at scale.

Competitive pressures for U.S. manufacturers vis-à-vis PRC firms. PRC structural advantages create price pressures for finished goods that challenge the competitiveness of U.S.

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[11] *Ibid*, p. 221

[12] 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.

[13] *Quadrennial Supply Chain Review*, p. 57

[14] U.S. Department of Energy, Office of Manufacturing and Energy Supply Chains, internal analysis, December 2024. See also *Quadrennial Supply Chain Review*, p. 53.

producers. DOE has noted that significant production capacity across the value chain for several energy technologies (e.g., ranging from polysilicon to large power transformers) remains idle 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.[15] Idle capacity is not limited to the energy sector. Countering PRC dominance will therefore require not only supply-side incentives to expand manufacturing capacity, but also demand-side support to assure suppliers that a market exists for their product and large-scale investments in U.S. production can be sustained over time.

Barriers to Effective Interagency Coordination

A variety of legal, technical, and institutional barriers complicate coordination of supply chain policy across the executive branch. These barriers are especially apparent when it comes to sharing data within and/or between agencies. However, they also arise between departments and agencies that may not agree on which resources or authorities are best utilized to achieve certain supply chain objectives, or even within a single agency between different internal bureaus or operating divisions that disagree on policy priorities. These challenges require strong leadership both at senior agency levels and the White House to ensure effective coordination of resources.

Legal Barriers

Data sharing within and between agencies is often hindered by confidentiality requirements. Information may be business confidential – or may have been collected for a purpose unrelated to supply chains – which then limits the ability of an agency to utilize that data for supply chain risk management purposes. Legal barriers often limit the sharing of data even within agencies, such as between Commerce's BIS and International Trade Administration (ITA) bureaus, or between the FDA and other HHS operating divisions, such as the Administration for Strategic Preparedness and Response (ASPR).

Technical Barriers

Because departments and agencies collect industry data under different authorities and for different purposes, data sets are typically not directly comparable. Moreover, outdated information technology systems hinder data-sharing, both within and between departments and agencies.

Institutional Barriers

Institutional barriers to data-sharing also exist within departments and agencies. For example, at HHS, no single HHS component (or any other federal agency, for that matter) has full end-to-end insight into the supply chains of pharmaceutical products. Yet different HHS operating divisions and staff divisions have access to a range of data that, if pulled together, could potentially enhance insights into pharmaceutical and API supply chain risks significantly. These data include manufacturing site information, manufacturing volume, inspection and compliance information,

[15] Gonzalez, Eva. BloombergNEF. "Research Note: US Risks Power Transformer Supply Gap Becoming a Chasm". November 2023.

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. In its response role, ASPR has access to distributor data on certain medical countermeasures (MCMs) as well as volume and production data from U.S. manufacturers supported by funding from ASPR. The Centers for Medicare and Medicaid Services (CMS), in its regulatory and public payer roles, has access to certain hospital and patient drug utilization data.[16] However, there are strict limitations – even within HHS – as to how certain proprietary data can be shared or used,[17] so to date, these data have not been pulled together to provide an end-to-end view on medical product supply chains.

Institutional barriers also hinder effective interagency coordination on supply chain policymaking. In addition to data-sharing challenges, departments and agencies often disagree substantively on priorities as well as which authorities and resources to utilize for a particular supply chain issue. No permanent institutional mechanism currently exists to coordinate work on risk analysis or policy recommendations between specific supply chain experts in one agency, such as Commerce's Supply Chain Center, with industry experts in another agency, such as the DOE or HHS. The Biden Administration addressed this need through the White House Council on Supply Chain Resilience, but it is unclear if the Trump Administration intends to continue leveraging the Council's coordinating role. Ideally, a statutory coordinating mechanism would provide a more permanent solution.

Blind Spots and Opportunities to Strengthen U.S. Government Data Collection

Upstream materials, components, and processes represent some of the most significant blind spots in current U.S. government understanding of supply chain risks. Agencies rely on trade data and other reported data, but the origin of the materials and components incorporated into finished products (including where those materials and components are processed) are not normally disclosed.

Chemicals (including Key Starting Materials for Pharmaceuticals)

Utilizing its SCALE tool, the Department of Commerce reported in December 2024 that chemicals serve as inputs into 396 out of 431 other industries across the U.S. goods economy. However, little is understood about how and where these chemicals are currently made, as well as what alternative manufacturing options exist if disruptions were to occur. What is clear, however, is that disruptions in the supply of core component chemicals could cause cascading impacts.[18]

The lack of information is particularly notable in the case of key starting materials (KSMs), which are chemical derivatives upstream from APIs. The FDA has data on API and FDF facilities but not for the chemicals used in the synthesis of drugs. Yet, it is understood that most KSMs are

[16] https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf?utm_source=sfmc%E2%80%8B&utm_medium=email%E2%80%8B&utm_campaign=20210610_Global_Manufacturing_Economic_Update_June_Members
[17] *Quadrennial Supply Chain Review*, p. 232
[18] *Quadrennial Supply Chain Review*, p. 30.

produced outside of the U.S., with a majority presumed to be produced in the PRC.[19] For example, 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.[20]

Castings and Forgings

Casting and forging operations are necessary to provide tooling and precision parts to a wide range of industries, from automotive and aerospace to energy. However, the PRC continues to dominate the castings and forgings sector – especially for commercial applications – offering a wide range of materials, sizes, and applications unmatched by any other country.

A reliable casting and forging industry is essential to U.S. military readiness, as it produces critical parts for tanks, warships, submarine, fighter aircraft, helicopters, missiles, and other warfighting equipment. A small network of domestic castings and forgings operations supplies the Department of Defense,[21] but the industry in the U.S. has been declining. The final report of the bipartisan Commission on the National Defense Strategy published last year found that, over the past two decades, more than 241 forging plants have closed or consolidated, mostly due to foreign competition.[22]

A survey conducted in 2024 by the accounting firm Wipfli found that 60 percent of forging companies that were evaluated reported that they sell products to the defense industry. The independent assessment by the also found that roughly half of the 41 forging companies surveyed are operating only at a 52 percent capacity utilization level, suggesting that commercial demand for casting and forgings is not utilizing available domestic capacity (most likely because foreign producers offer more competitive pricing).[23]

U.S. manufacturing dependencies on PRC imports

U.S. manufacturers also rely on PRC suppliers for a variety of imported materials, components, and equipment to keep production lines in the United States running. Commerce's SCALE tool found that more than 38 percent of U.S. industries source over half their imports from the PRC or Russia, and 71 industries are at least 70 percent reliant on adversaries for most of their imports.[24]

However, these data are not detailed enough to analyze specific dependencies. External reports have called out particular areas of concern: a March 2025 paper from Oxford Economics

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[19] *Ibid*, p. 233
[20] 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.
[21] The U.S. Army hosted a castings and forgings summit in 2022: https://www.army.mil/article/256347/army_hosts_castings_forgings_summit_to_modernize_manufacturing_capabilities.
[22] https://www.nationaldefensemagazine.org/articles/2024/12/20/viewpoint-us-forging-companies-overlooked-for-too-long#:~:text=%E2%80%9CCasting%20and%20forging%20are%20fundamental,for%20the%20propellers%20of%20warships.
[23] *Ibid.*
[24] *Quadrennial Supply Chain Review*, p. 30

highlighted U.S. industry on Chinese electrical and communication equipment, as well as imports of Chinese medical and non-medical instruments.[25] Other reporting has emphasized U.S. manufacturer dependence on Chinese imports of motors, precision gears, hydraulic systems, and control modules.[26] However, the federal government lacks a systemic view of the U.S. industries and products most at risk: more systematic data by industry is needed to more fully assess U.S. manufacturing dependencies on PRC imports.

Opportunities to expand data collection authorities and tools

Updating the Harmonized Tariff Schedule of the United States (HTSUS). The current HTSUS is not granular enough in most categories to distinguish between different types of products imported under the same code. Certain technical reforms to the HTSUS could improve the U.S. government's ability to distinguish between imports of certain kinds of critical minerals or chemicals. Other reforms could help to disaggregate tariff lines that comingle products with very different end uses, such as salad spinners and centrifuges for laboratories. Updating the HTSUS would allow for more precise targeting of imports with trade actions as well as any tariff rate updates considered by Congress.[27]

Strengthening FDA's data collection. Although FDA collects significant information from pharmaceutical and medical device manufacturers, significant gaps persist, including a lack of inventory data at the manufacturer level as well as information on manufacturer physical, cyber, and environmental security. In addition, FDA generally does not receive notice or adequate information from drug manufacturers regarding sudden increases in demand (a common cause of shortages), or data that identifies the extent to which drug manufacturers rely on specific suppliers.[28] HHS also lacks access to data showing how quickly manufacturers produce or deliver orders, how frequently they experience changes in demand, as well as inventories from hospitals and distributors. While some private companies are willing to share their insights, others are reluctant to do so. To this end, FDA had 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.[29]

Under new FDA reporting requirements added by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[30] FDA's Center for Drug Evaluation and Research (CDER) expects to receive more production volume data will facilitate increased transparency into the upstream pharmaceutical supply chains and provide a more complete understanding of key manufacturers based on market share. However, of the 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. In addition, the data required to be submitted

[25] Oxford Economics, *Research Briefing: Tariffs will weigh heavily on business equipment investment*, April 15, 2025, Tariffs-will-weigh-heavily-on-US-business-equipment-investment.pdf.
[26] Matthew Lekstutis, "The Impact of Tariffs on Industrial Manufacturing," *Industrial Equipment News,* March 3, 2025, https://www.ien.com/operations/article/22934857/the-impact-of-tariffs-on-industrial-manufacturing.
[27] *Quadrennial Supply Chain Review*, p. 44
[28] *Quadrennial Supply Chain Review*, p. 233
[29] *Quadrennial Supply Chain Review*, p. 236
[30] 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.

under CARES do not enable FDA to determine which drug product manufacturers are relying on a given API supplier, or how much of a manufacturer's API is being supplied by any given API supplier. Therefore, if an application holder has listed more than one API supplier in its application, FDA still does not know whether the application holder is relying on each supplier equally or is only relying on a single supplier, making it difficult for FDA to predict how a disruption in one API supplier, or API suppliers from one region (such as the PRC), will affect the manufacturer's ability to produce the drug products that require that API.[31]

Public-Private Engagement on Supply Chain Resilience

Private industry communicates and collaborates with U.S. government departments and agencies in a variety of ways, including through federal advisory committees chartered under the Federal Advisory Committee Act (FACA), other agency committees, informal engagement, formal responses to Requests for Information (RFIs) and Federal Register Notices (FRNs).

Federal advisory committees operate with full transparency, with public access to meetings and work product. Following the pandemic, both Commerce's Advisory Committee on Supply Chain Competitiveness (ACSCC) and the DHS Supply Chain Security Subcommittee, part of the Homeland Security Advisory Council (HSAC), made formal recommendations to the Secretaries of Commerce and Homeland Security, respectively, on supply chain risks.[32] These recommendations encompassed both manufacturing supply chains and logistics networks, as well as the need for more interagency coordination. In a number of cases, the Committees' recommendations went well beyond the authorities of Commerce or DHS and implicated other departments and agencies (e.g., DOD, the Department of Transportation, the Veterans' Administration). However, the federal government lacks a process to formally share recommendations made to one cabinet secretary with other cabinet secretaries whose departments or agencies may be implicated.

Public transparency limits certain aspects of federal advisory committee work, as participating companies cannot discuss confidential data in open settings. If competitors are present on the same committee (as well as companies in customer-supplier relationships), they are also limited in the level of detail that can be shared in the same room.

Many companies do engage extensively with federal officials on an informal and ongoing basis. However, they may be reluctant to provide certain kinds of data to the government – particularly on key business risks related to China - without a legal requirement to do so. Companies may also be wary of providing information around business risks if they do not fully understand how the government will use the data. Supply chain data held by companies is also very granular and dynamic – and constantly changing. Companies are understandably reluctant to share such information without the ability to provide federal officials with relevant context.

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[31] https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf?utm_source=sfmc%E2%80%8B&utm_medium=email%E2%80%8B&utm_campaign=20210610_Global_Manufacturing_Economic_Update_June_Members, p. 235.

[32] For the U.S. Department of Homeland Security, see: https://www.dhs.gov/publication/supply-chain-security-leadership-subcommittee-final-report. For the U.S. Department of Commerce, see: https://www.trade.gov/recommendations-advisory-committee-supply-chain-competitiveness

Because supply chains are primarily managed by the private sector, however, new mechanisms for public-private collaboration should be explored. Successful initiatives involving voluntary data sharing, such as HHS's Supply Chain Control Tower (SCCT),[33] could serve as models for other sectors, provided all parties are clear on the purpose of the initiative and agree how data will be utilized.

Assessing the effectiveness of U.S. policy tools to address supply chain dependencies

The U.S. government has a variety of policy tools available to address supply chain dependencies. However, they tend to be incomplete, insufficient, and time-consuming. Certain tools, such as trade enforcement measures, were designed for a different industrial era and are difficult to deploy at the speed and scale needed to address China's non-market policies and practices.

To address supply-side needs, the U.S. government can provide direct funding incentives through legislative authorization and appropriation (e.g. the 2022 CHIPS & Science Act) and/or through Defense Production Act (DPA) funding. The CHIPS Act is driving rapid expansion of U.S. manufacturing of semiconductors, and DPA funding has been crucial to support a variety of industries critical to the national defense, including production of medical products related to the COVID-19 pandemic response.

However, federal funding is insufficient to build out critical industries to commercial scale. Ideally, federal funding catalyzes much more private investment into critical sectors; however, private capital in the U.S. often lacks the incentive to invest in large-scale manufacturing projects with long time horizons, complex risks, or extensive coordination requirements.[34] More creative policymaking is needed to ensure that private capital consistently follows federal funds to sustain and grow supply-side investments in critical domestic industries over time.

Federal purchasing also sends an important signal to the private sector about U.S. government priorities. When done through transparent and predictable contracting, federal purchasing can provide a valuable and reliable baseline level of orders for U.S. manufacturers. Yet, federal purchasing alone is typically insufficient to sustain manufacturing at scale in most industries, especially outside of defense applications.

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[33] The HHS Supply Chain Control Tower (SCCT) was established in March 2020 to provide visibility into critical COVID-19 medical supply chains to support U.S. Government decision-making and distribute medical supplies to where they were most needed. The SCCT program leverages voluntarily reported information from manufacturers, distributors, and healthcare providers, as well as U.S. Government entities such as the Strategic National Stockpile and FEMA, to monitor the availability and supply of critical medical products, such as select personal protective equipment, pharmaceuticals, new COVID-19 therapeutics, point-of-care tests, and needles and syringes. Given the federal investment already made into the SCCT, opportunities exist to assess its potential to expand into other critical medical product supply chains, particularly pharmaceuticals prone to shortages. However, with the end of the COVID-19 public health emergency, the SCCT's future is unclear. For more information, see: https://bidenwhitehouse.archives.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf?utm_source=sfmc%E2%80%8B&utm_medium=email%E2%80%8B&utm_campaign=20210610_Global_Manufacturing_Economic_Update_June_Members, p. 233.

[34] *Quadrennial Supply Chain Review*, p. 34

In the case of COVID-era investments in personal protective equipment (PPE), for example, some domestic manufacturers that received federal funds during the pandemic have been forced in recent years to shut down lines, facilities, and even lay off their work force due to renewed competition and price pressures from foreign suppliers, particularly in China. Even with the passage of the Make PPE in America Act as well as HHS's commitment to sustain the commercial viability of COVID-era investments in domestic PPE manufacturing,[35] the reality is that federal purchasing alone is insufficient to sustain these manufacturing investments. Federal purchasing can catalyze an industry and signal U.S. government support to commercial actors, but it should ideally be paired with other mechanisms to incentivize private sector purchasing to sustain these industries over time.

In certain industries, particularly the defense and medical sectors, the U.S. government holds key levers to influence both demand- and supply-side incentives, although these are rarely coordinated. At HHS, for example, in addition to the FDA's regulatory functions and ASPR's industrial base investments through its Industrial Base Management and Supply Chain (IBMSC) office, CMS establishes payment policies for medications and other medical products paid under the Medicare and Medicaid programs. CMS also contracts with private companies to provide prescription drug benefits to beneficiaries under the Medicare Part D program. Medicare policies can be considered by private insurers and can be influential in determining reimbursement standards.

In the 2023 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS implemented a novel rule related to N95 respirators to provide additional payments to hospitals that purchase domestically manufactured NIOSH-approved surgical N95 respirators. These payments were meant to offset the higher cost of U.S.-made N95s compared to non-domestic alternatives and incentivize hospitals to seek out U.S.-made respirators in lieu of foreign (including PRC-made) products. Unfortunately, uptake of these incentive payments by private sector actors has been relatively minimal, reportedly due to the narrow construct of the rule and burdensome paperwork requirements. Nevertheless, the concept of utilizing CMS payment policies to incentivize public reimbursement for and reward private sector purchasing of more resilient (and non-PRC dependent) medical products remains an opportunity for further exploration.

Strategic coordination with allies and partners

Strengthening U.S. manufacturing in critical sectors is essential, but U.S. manufacturing alone cannot replace supply chain dependencies on the PRC. To build lasting supply chain resilience, the United States needs to bolster U.S. manufacturing while also incentivizing integrated, agile, and diversified supply chains within and across borders. Deliberate, sector-specific trade agreements with like-minded countries that promote regulatory harmonization would foster more balanced supply chain ecosystems and expand market access for U.S. manufacturers. Sector-specific agreements could incorporate incentives to promote localized manufacturing of upstream materials or intermediate components with country partners, further reducing dependencies on third-country (including PRC) sources.

[35] *Ibid*, p. 212

U.S. legislators have made an initial foray into this space: the Medical Supply Chain Resiliency Act introduced on March 12 by Sens. Thom Tillis (R-NC), Chris Coons (D-DE), John Cornyn (R-TX), and Michael Bennet (D-CO)[36] would authorize the president to enter into trade agreements for the reciprocal elimination of duties or other import restrictions with respect to medical goods. The bill is an encouraging example of the trade strategies needed to diversify supply chains for pharmaceuticals and medical devices and incentivize U.S. investment by expanding export markets for American manufacturers.

Information and Communications Technology and Services (ICTS) Rulemaking

Executive Order 13873 of May 15, 2019 on *Securing the Information and Communications Technology and Services Supply Chain (ICTS)* enables Commerce to undertake rulemaking to protect the security, integrity, and reliability of information and communications technology and services provided and used in the United States against critical national security threats.[37]

On January 16, 2025, the Bureau of Industry and Security (BIS) issued a final rule to address national security concerns about ICTS in connected vehicles.[38] The rule prohibits the importation and sale of certain connected vehicle hardware or software that has been designed, developed, manufactured, or supplied by entities subject to influence by the PRC or Russian governments. It also prohibits manufacturers that are owned by, controlled by, or subject to the jurisdiction or direction of PRC or Russia from selling in the U.S. connected vehicles that incorporate certain software or hardware, regardless of whether such hardware or software is linked to those countries.

In light of the ICTS rulemaking, global automakers and suppliers are now required to restructure their supply chains to comply with the new rules and eliminate hardware and software integrated into Vehicle Connectivity Systems (VCS) and software integrated into the Automated Driving System (ADS) with a PRC nexus. PRC automakers are also now effectively shut out of the U.S. market. Notably, certain PRC automakers that were previously exploring investments in Mexico have now scaled back or abandoned those plans in the wake of the ICTS rule.[39]

ICTS rulemaking is a newer policy tool, but its application to connected vehicles suggests that it may have potential to be applied to other information and communication technology sectors where PRC dominance in supply chain components represents a grave national security risk to the United States.

Incentivizing Resilience

Supply chain risks did not regularly arise in mainstream discourse until the COVID-19 pandemic disrupted global value chains. During the depths of the pandemic-induced supply chain crisis,

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[36] https://www.tillis.senate.gov/services/files/9FCE603A-3E90-4773-A974-3359D76D61F5

[37] Executive Order 13873, https://www.federalregister.gov/documents/2019/05/17/2019-10538/securing-the-information-and-communications-technology-and-services-supply-chain.

[38] https://www.federalregister.gov/documents/2025/01/16/2025-00592/securing-the-information-and-communications-technology-and-services-supply-chain-connected-vehicles?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

[39] Bloomberg News, "China's BYD Pauses Mexico Factory Plans Until After US Election," September 3, 2024, https://www.yahoo.com/news/china-byd-pauses-mexico-factory-215426505.html?guccounter=1

many companies took a fresh look at their sourcing and inventory patterns and enhanced their ability to identify risky suppliers and customers. Dual sourcing of components and products became more common, and warehouses often held "just-in-case" inventory. However, as the crisis faded, some industries have begun to revert to pre-pandemic historical sourcing and inventory patterns, again prioritizing cost over resilience. [40]

Financial markets do not currently have a systematic way to measure and price in the cost of supply chain risks. Companies do not routinely "stress-test" supply chains against various risk scenarios, even though the frequency and severity of supply chain disruptions has been increasing over time.[41] Significant opportunity exists for creative policymaking that incentivizes private sector actors to consider supply chain risks more fully during the normal course of business – and not just when a supply chain crisis hits.

Conclusion

Functioning supply chains are a lot like being in good health. They are easy to take for granted until a crisis hits. Yet as the pandemic-induced disruptions revealed, supply chains left solely to the design of global market forces – particularly when a country such as the PRC is seeking to dominate global markets through non-market policies and practices – yield dangerous dependencies and chokepoints that threaten the economic and national security of the United States.

The U.S. federal government should continue to utilize all policy tools and also explore new ones to address the lessons learned from the pandemic-era supply chain crisis and ensure that pre-pandemic patterns do not once again become the normal course of business in the United States. Building supply chain resilience will require sustained focus and accountability from both public and private sector actors. This must be a long-term play.

This testimony has highlighted a number of potential policy solutions to strengthen work already underway across the federal government – as well as how to support or expand promising initiatives. Because supply chain issues cut across so many different federal departments and agencies, it will be crucial to consider authorization and funding for a permanent coordination mechanism. Ongoing accountability to Congress and the public is also critical; the quadrennial reviews outlined in Executive Order 14123 are a start, but Congress may want to consider more frequent reporting to ensure the federal government's continued prioritization of and focus on critical supply chains.

Federal departments and agencies have access to a wealth of data related to supply chains, but as this testimony has outlined, data remains incomplete – particularly with respect to upstream materials and components. Updating the HTSUS to support more granular data collection, as well as expanding specific agency authorities (such as at the FDA), and establishing mechanisms to share data legally within and across agencies for supply chain risk assessment purposes would

[40] Brian Anstey, Cengiz Bayazit, Yogesh Malik, Asutosh Padhi, Nick Santhanam, and Stijn Tollens, "Why now is the time to stress-test your industrial supply chain," McKinsey & Company, July 27, 2020, https://www.mckinsey.com/capabilities/operations/our-insights/why-now-is-the-time-to-stress-test-your-industrial-supply-chain
[41] *Ibid.*

significantly improve U.S. government visibility into core supply chain risks and inform more fulsome policy responses.

Opportunity also exists to foster more public-private sector collaboration, including around novel concepts that could incentivize more business attention to pricing in supply chain risk, especially as it relates to the PRC. The private sector could also be engaged to help clarify what demand-side levers would be most influential to helps sustain federal investments in critical industries and enable them to compete more effectively with PRC firms.

Lastly, as this testimony has noted, the United States cannot eliminate economic and national security risks in critical supply chains alone. Continuing to build out domestic manufacturing in critical industries is essential, but the United States also needs to work strategically with allies and other country partners to expand cross-border production for upstream materials, components, and processes currently concentrated in the PRC. The future resilience of America's supply chains will depend on robust systems that incorporate U.S. manufacturing into a network of trusted suppliers across allied countries that are strong, agile, and not overly reliant on any one country.