REVITALIZING AMERICAN HEALTHCARE: UNLOCKING TAX INCENTIVES TO BOOST DOMESTIC MANUFACTURING

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EXECUTIVE SUMMARY

U.S. dependence on foreign sources for critical medical products and essential medicines is well established.[1] Because the healthcare supply chain is vital to ensuring patient care, any disruption can quickly create ripple effects that jeopardize the availability of life-saving medications and essential medical products. Recent events including floods, ice storms, and shipping challenges in the Red Sea and Panama Canal have underscored the vulnerability of the supply chain that healthcare providers and patients rely on for their everyday needs.

Recently, the broader issue of supply chain challenges due to overdependence on foreign suppliers has garnered attention from policymakers and thought leaders. The goal of this paper is to examine key factors contributing to the current situation and provide an overview of possible policy levers, including the use of targeted tax incentives that could increase domestic production of medical supplies.

The healthcare supply chain is vast and highly complex, involving tens of thousands of products of varying levels of sophistication. This speaks to the need for thoughtful and targeted policy solutions. One effective strategy is to focus on key subsets of products that are essential to healthcare providers and their ability to deliver care to patients. This includes existing lists of essential medicines and critical medical products maintained by the federal government, per the appendices of this paper.[2] Developed through collaboration between government and the commercial market, these lists can guide policy decisions by identifying healthcare products of greatest importance.

This white paper examines the U.S.'s reliance on foreign sources for critical medical products and essential medicines, the obstacles to reshoring production, potential policy responses, and lessons learned from recent case examples. Some key findings include:

- The U.S. has a high foreign dependency upon critical medical products and pharmaceuticals, such as personal protective equipment (PPE) from China and pharmaceutical imports from the European Union (EU).
- Significant cost differentials exist between domestic manufacturing and foreign production, presenting challenges to reshoring healthcare product manufacturing.
- Case studies demonstrate that targeted tax credits and incentives can create conditions that drive increased domestic production by helping offset manufacturers' costs and improve competitiveness across various sectors.

1 From *The Medical Device Industry in the United States*, by E. M. Lake, 2022, in Medical Devices: A Public Health Perspective, National Academies Press (https://www.ncbi.nlm.nih.gov/books/NBK583730/).

2 See Appendices A-D.

INTRODUCTION

Supply chain disruptions can severely limit the availability of critical medical products and essential medicines for healthcare providers and the patients they serve. Recent product disruptions following natural disasters, public health emergencies, and transportation disturbances have shone a spotlight on the U.S. medical supply chain and the extent to which it depends upon foreign components and finished products, particularly those coming from East and Southeast Asia.

This overdependence and the lack of domestic alternatives have raised geopolitical, national security, and public health concerns from policymakers and thought leaders. For example, in a House Subcommittee on Health hearing on strengthening domestic manufacturing in June 2025, Representative Buddy Carter (R-GA) said "our nation's reliance on adversarial countries for essential medications and health care products…not only jeopardizes our national security and patient safety but also highlights the urgent need to increase domestic and friend-shored manufacturing."[3] Additionally, Senator Mark Kelly (D-AZ) noted that "the less reliant we are on other countries for the goods we need, the stronger and more resilient our economy will be."[4] Meanwhile, the American Hospital Association (AHA) "believes it is necessary to strengthen the domestic supply chain for essential pharmaceuticals and other medical products and recognizes the value of reducing reliance on international sources."[5]

The medical and pharmaceutical supply chains are complicated and interdependent with raw material availability, processing and production, a multitude of transportation and global logistics, as well as the shifting needs of medical professionals. Each of these elements can create ripple effects—both upstream and downstream—if there are unforeseen disruptions.

Due to the layered complexity of healthcare supply chains, and the dependence on foreign production, there have been a myriad of proposals from stakeholders, consultants, and legislators on how to incentivize domestic manufacturing of critical healthcare products. This white paper will focus on critical medical products such as gloves, gowns, and masks, as well as essential medicines. Information on the complete lists of these products can be found in the appendices.[6] This paper will provide insights into the following:

- Overview of foreign overdependency on critical medical products and essential medicines;
- The challenges to reshoring the manufacturing of healthcare products;
- Policy paths forward;
- Use of tax policies for manufacturing outside of the contiguous U.S.;
- Lessons learned from case studies and the policies utilized to incentivize domestic production;
- Considerations on achieving domestic resiliency through evaluation of previous initiatives; and
- Recommendations to support and sustain domestic production of critical medical products and essential medicines to increase supply chain resiliency, and decrease the potential ramifications of supply chain disruptions due to foreign dependency.

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3 From *Chairman Carter Delivers Opening Statement at Subcommittee on Health Hearing on Strengthening Domestic Manufacturing and Our Health Care Supply Chain*, Office of Rep. Earl L. "Buddy" Carter (R-GA), June 11, 2025 (https://buddycarter.house.gov/news/documentsingle.aspx?DocumentID=15705).

4 From *Sen. Kelly Statement on Urgency of Passing Legislation to Tackle Inflation, Strengthen Supply Chains*, Office of Sen. Mark Kelly (D-AZ), July 13, 2022 (https://www.kelly.senate.gov/newsroom/press-releases/sen-kelly-statement-on-urgency-of-passing-legislation-to-tackle-inflation-strengthen-supply-chains/).

5 From *AHA Statement to House Energy & Commerce Subcommittee on Health Hearing for June 11, 2025*, American Hospital Association, June 11, 2025 (https://www.aha.org/testimony/2025-06-11-aha-statement-house-energy-commerce-subcommittee-health-hearing-june-11-2025).

6 See Appendices A-D.

OVERDEPENDENCY ON FOREIGN SOURCES IS A KEY CHALLENGE FOR THE U.S. HEALTHCARE SUPPLY CHAIN

The U.S. relies significantly on foreign sources of medical supplies and pharmaceuticals—not only for the products themselves, but also for the critical materials and components needed to produce them. For example, the U.S. healthcare system currently relies on Chinese producers for over 50% of certain categories of critical medical products, such as gauze, gowns, and nitrile gloves.[7] In the event of a disruption in supply from China, U.S. stockpiles of these products would be rapidly exhausted, putting the health of Americans at risk and jeopardizing the stability of our healthcare system.[7] Foreign reliance for some PPE products is even higher. It is estimated that 90% of N95 masks are imported, primarily from China.[8]

With respect to pharmaceuticals, the EU collectively accounted for 62% of total U.S. pharmaceutical imports in 2024, highlighting the EU's critical role in the U.S. medical supply chain.[9]

The U.S. has historically had a negative trade balance for many medical products:

- In 2020, the U.S. imported nearly $94 billion in human and animal drugs and exported $32 billion.[10]
- Dependence on overseas production is especially notable for active pharmaceutical ingredients (APIs) for generic drugs, as according to the Food and Drug Administration (FDA), for the 2020 fiscal year only 26% of facilities manufacturing APIs for U.S. consumption were located within the U.S.[10]

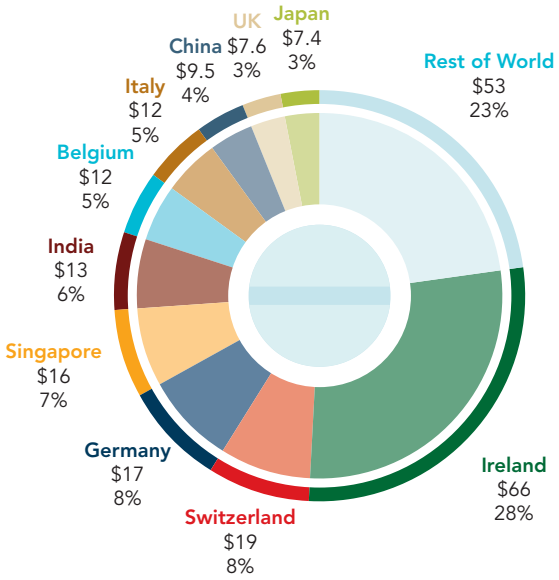


Figure 1. Top Exporters of Medicinal and Pharmaceutical Products to the U.S. in 2024.[9]
U.S. Imports (Billions US$) and Share of Total (%)

- Although observing less of a gap between import and export revenue, medical device manufacturing has also become increasingly reliant on foreign supply chains, with the U.S. importing $68 billion and exporting $59 billion in medical devices in 2020.[10]

This foreign dependence exposes U.S. businesses to risks associated with foreign supply chain disruptions and market uncertainties.[11] For example, in 2024, the temporary

7 From *Medical Manufacturing: A Critical Supply Chain At Risk*, by T. K. Devine, 2025, American Affairs (https://americanaffairsjournal.org/2025/02/medical-manufacturing-a-critical-supply-chain-at-risk/).

8 From *Journal of general internal medicine*, by Dai, T., Bai, G., & Anderson, G. F. (2020). (https://pmc.ncbi.nlm.nih.gov/articles/PMC7326307/).

9 From *Top Exporters of Medicinal and Pharmaceutical Products to the US in 2024*, by Voronoi, 2024 (https://www.voronoiapp.com/trade/-Top-Exporters-of-Medicinal-and-Pharmaceutical-Products-to-the-US-in-2024-4197).

10 From *The Medical Device Industry in the United States*, by E. M. Lake, 2022, in Medical Devices: A Public Health Perspective, National Academies Press (https://www.ncbi.nlm.nih.gov/books/NBK583730/).

11 From *The Supply Chain Crisis: What's Behind It & What To Do About It*, by K. G. Dougherty, 2021, Third Way (https://www.thirdway.org/report/the-supply-chain-crisis-whats-behind-it-what-to-do-about-it).

pause in production at Eugia Pharma Specialties' facility in Hyderabad, India, led to shortages of medical products for U.S. consumption.[12] By building more robust and diverse supply chains, the U.S. can improve security for domestic manufacturers, businesses, and patients.

The healthcare industry can be directly affected by vulnerabilities in other sectors whose supply chains depend heavily on foreign sources. This can put the U.S. in vulnerable situations, as was observed when China enacted an export ban on key minerals, such as gallium, which impacted the semiconductor and defense industries.[13] Semiconductors are important to the medical product industry as well, as they are a key part of computerized tomography (CT) scans, ultrasound imaging, and magnetic resonance imaging (MRI), among other medical products.[14]

The following sections discuss the challenges of reshoring manufacturing and outline potential policy options to address them. Furthermore, tax policy case studies that have proven successful in incentivizing domestic production are discussed. The lessons learned from these use cases will provide a strong base for the closing policy recommendations.

12 From *The Supply Chain Disruption Report*, 2024, End Drug Shortages Alliance (EDSA) (https://info.enddrugshortages.com/External/WCPages/WCWebContent/webcontentpage.aspx?ContentID=2112).

13 From *Medical Manufacturing: A Critical Supply Chain At Risk*, by T. K. Devine, 2025, American Affairs (https://americanaffairsjournal.org/2025/02/medical-manufacturing-a-critical-supply-chain-at-risk/).

14 From *The Role of Semiconductors in Medical Devices*, 2023, Microchip USA. (https://www.microchipusa.com/industry-news/the-role-of-semiconductors-in-medical-devices).

RESHORING OPPORTUNITIES AND CHALLENGES

Reshoring, the multi-sector practice of bringing manufacturing and services back to a country from overseas, can help balance trade and budget deficits and shrink unemployment. Reshoring allows for this by creating well-paying manufacturing jobs and helping develop a skilled workforce. Furthermore, research indicates that reshoring can benefit manufacturers as it has the potential to reduce total product costs, improve balance sheets, and increase the effectiveness of product innovations while reducing the risks associated with foreign supply chain reliance.[15] In the context of healthcare delivery specifically, reshoring can protect against disruptions in the availability of critical supplies due to geopolitical circumstances, natural disasters or other factors.

There has been support in Congress and across administrations to encourage onshoring of various manufacturing sectors, including chips, steel, and semiconductors. These efforts have encompassed committed government contracts, with the government entering into multi-year contracts with domestic manufacturers to provide a stable demand signal, as well as utilizing tax policy to incentivize domestic production. Specific examples of enacted legislation include:

- Tax Cuts and Jobs Act, 2017
  - Lowered corporate tax rates from 35% to 21%,[16] which some studies indicate can result in companies increasing their investment in U.S. manufacturing.[17,18]
- Infrastructure Investment & Jobs Act, 2021[19]
  - Focused on using government purchasing power and contracting to require that federally funded infrastructure projects use 100% U.S.-produced iron, steel, manufactured products, and construction materials.
  - To build manufacturing capacity in the U.S., the bill required a two-year minimum federal contract for procuring domestically made PPE for the departments of Homeland Security, Health and Human Services (HHS), Veterans Affairs (VA), Defense (DoD), and Education.
- CHIPS and Science Act, 2022[20]
  - Included a provision that provides $24 billion in tax credits for domestic chip production.
  - Included $52.7 billion for semiconductor manufacturing and workforce development.
- One Big Beautiful Bill, 2025[21]
  - Permanently extends 100% bonus depreciation so companies can immediately deduct the full cost of new equipment and property, lowering upfront costs for reshoring.

15 From *Reshoring Advanced Manufacturing Supply Chains to Generate Good Jobs*, by S. Ezell & M. Muro, 2022, Brookings Institution (https://www.brookings.edu/articles/reshoring-advanced-manufacturing-supply-chains-to-generate-good-jobs/).

16 From *The TCJA: Key Facts on the 2017 'Trump Tax Cuts' and What's Extended for 2025*, by Kate Schubel, Kiplinger, July 9, 2025 (https://www.kiplinger.com/taxes/what-is-the-tcja).

17 From *The 2025 Tax Debate: The Corporate Tax Rate and Pass-Through Deduction, Bipartisan Policy Center*, 2025 (https://bipartisanpolicy.org/explainer/the-2025-tax-debate-the-corporate-tax-rate-and-pass-through-deduction/).

18 From *Tax Policy and Investment in a Global Economy*, by G. Chodorow-Reich, M. Smith, et al., National Bureau of Economic Research Conference Paper, 2024 (https://conference.nber.org/conf_papers/f191672.pdf).

19 From *H.R. 3684 — Infrastructure Investment and Jobs Act*, 117th Congress, Library of Congress, 2021-2022 (https://www.congress.gov/bill/117th-congress/house-bill/3684).

20 From *The CHIPS and Science Act: Here's What's in It*, by J. Badlam, et al., McKinsey & Company, October 4, 2022 (https://www.mckinsey.com/industries/public-sector/our-insights/the-chips-and-science-act-heres-whats-in-it).

21 From *One Big Beautiful Bill Signed Into Law – What It Means for You and Your Business*, by Kreischer Miller Team, Kreischer Miller, July 6, 2025 (https://www.kmco.com/insights/one-big-beautiful-bill-signed-into-law-what-it-means-for-you-and-your-business/).

- Raises the Section 179 expensing limit to $2.5 million, making it easier to expense manufacturing equipment investments.
- Restores improved interest expense deductions, reducing the cost of financing U.S. manufacturing expansions.
- Allows immediate deduction of domestic research and development (R&D) expenses (while research abroad must be amortized), encouraging innovation in the U.S. It creates a new 100% first-year bonus depreciation for newly constructed manufacturing facilities (qualified production property), cutting costs for building factories domestically through 2029.

Additionally, policymakers have partnered at the federal and state levels to attract companies to their states. Two examples include:

- Michigan—Grand River Aseptic Manufacturing (GRAM)[22]
  - GRAM received $120 million in federal contracts from DoD and HHS to expand fill finish capabilities.
- Ohio—Intel[23]
  - Ohio offered Intel an estimated $2 billion in cash grants, infrastructure support, and tax incentives to construct two multibillion-dollar chip labs in New Albany, OH.

Encouraging and expanding domestic production provides opportunities for widespread domestic economic growth and can assist geographic areas experiencing high unemployment rates. Domestic production is also important in maintaining a geographically diverse manufacturing footprint, which increases supply chain resiliency. Supply chain resiliency is generally defined as the ability to mitigate disruptions, so product still flows through the supply chain to healthcare providers. This is achieved by "diversification of supply—both redundancy of manufacturing capacity and a balance of domestic and diversified foreign sourcing."[24] While the examples discussed above are broad in scope, the general concept is relevant to the healthcare sector. However, these concepts do not capture all the unique attributes of the healthcare supply chain.

The medical product supply chain is complex. Policy solutions to incentivize domestic production of medical products need to account for its unique challenges and nuances and recognize that medical products and pharmaceutical supply chains are different than others. Healthcare supply chains have significantly globalized since the 1970s for various reasons, including cost containment around lower prices, lower labor costs, and less regulatory burden. Therefore, some key challenges specific to healthcare must be addressed to effectively incentivize the reshoring of production of these products, which are discussed in more detail in the following sections.

First, there is often a substantial price differential for domestically sourced medical products versus foreign products because production costs overseas are significantly lower, thus putting domestic producers at a disadvantage. Foreign manufacturers often benefit from several cost-saving factors, including lower labor costs, reduced operational expenses, fewer regulatory and compliance burdens, and greater economies of scale.[25] These lower costs enable foreign-made goods to be sold at or below the price of U.S.-made products, which creates an unfavorable marketplace for domestic manufacturers.[25]

It is estimated that domestically produced generic drugs and PPE may cost 20-50% more than foreign sourced products.[25]

In the pharmaceutical industry, it has been observed that India can offer chemical industry infrastructure costs that are 40% lower and fixed production costs that are 20% lower than in the U.S.[25] U.S. healthcare providers are likely to purchase foreign-made or foreign-dependent products, especially given their lower cost and high accessibility.[25] Despite interest in domestically produced products, the need to keep overhead costs low by managing procurement costs makes it financially difficult for providers.

22 From *Michigan Life Sciences Manufacturer to Spend $160 Million on Expansion*, by Nolan Beilstein, Thomasnet, May 11, 2022 (https://www.thomasnet.com/insights/michigan-life-sciences-manufacturer-to-spend-160-million-on-expansion/?msockid=1915ff324cc36680336be9264d5a6741).

23 From *Ohio Promised $2.1 Billion in Incentives to Lure Chipmaker Intel*, by M. Tobin & M. Niquette, Yahoo Finance, January 28, 2022 (https://finance.yahoo.com/news/ohio-promised-2-1-billion-214702142.html?guccounter=1).

24 From *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States*, by U.S. Department of Health and Human Services, White Paper, Office of the Secretary, April 2, 2024 (https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf).

25 From *The Medical Device Industry in the United States*, by E. M. Lake, 2022, in Medical Devices: A Public Health Perspective, National Academies Press (https://www.ncbi.nlm.nih.gov/books/NBK583730/).

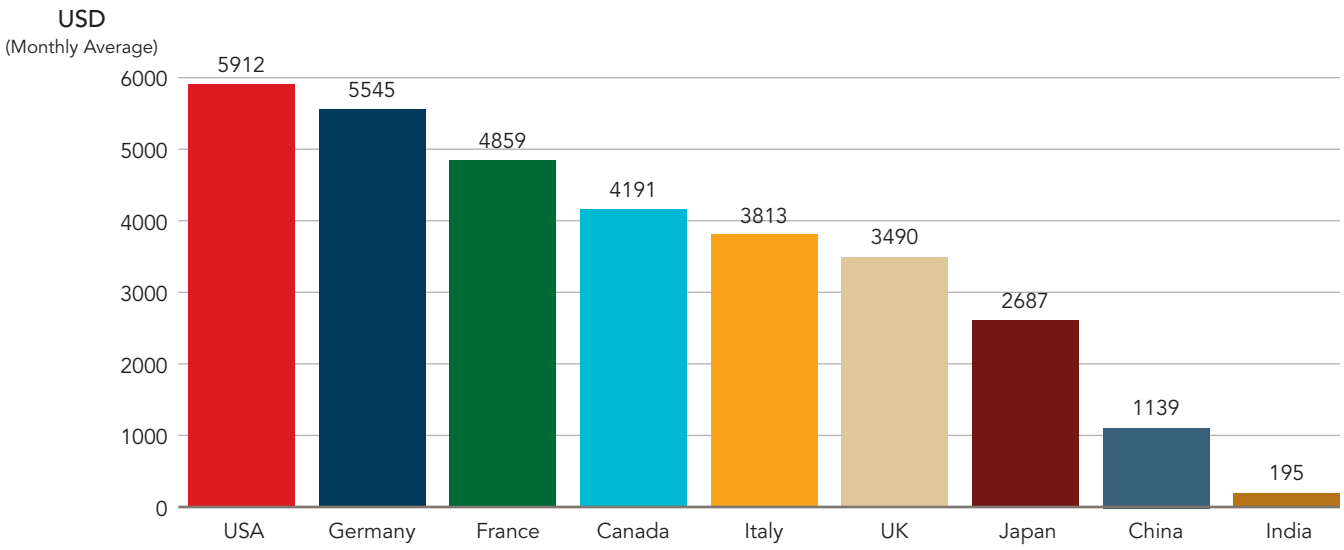


Figure 2. Average monthly manufacturing wages.
Canada, United Kingdom, United States of America and India data is for 2023. Germany, France, Italy and China data is for 2022. Japan data is for 2021.[26]

Second, in most countries—most notably India and China—labor costs are significantly lower than in the U.S. Manufacturing wages in China were 20% of manufacturing wages in the U.S., and manufacturing wages in India were 3% of U.S. wages in 2024.[26]

With significantly lower labor costs, foreign manufacturers can offer more competitive pricing, encouraging companies to shift production offshore rather than keeping it at home. This trend puts additional pressure on U.S. producers, as they are increasingly undercut by lower-cost competitors abroad.

Third, the U.S. has much stricter licensing, inspection, and compliance requirements than many other countries with oversight carried out by federal, state, and local agencies. While the level of regulation and enforcement can vary widely from one location to another, as well as between industries, there is an inherent incentive for companies to manufacture and produce abroad to save on compliance and operational costs.

The U.S. has historically been more consistent than other countries in the enforcement of environmental regulations. Compliance can entail high costs, permit systems, detailed reporting, and regular inspections. Non-compliance can result in substantial penalties. By contrast, many other countries, especially in Asia, tend to maintain less stringent environmental regulations or enforce them inconsistently.[27]

Figure 3: Regulatory Compliance Costs per Employee per Year for Manufacturers, 2022 (in 2023 Dollars).

**The average compliance costs for manufacturers to comply with federal regulations ($29,100 per employee, per year) is more than double the rate seen for all U.S. businesses ($12,800 per employee, per year). For small manufacturers with fewer than 50 employees, compliance costs per employee are more than three times the average of all firms.[28]*

26 From *US Wages vs Wages in China and India*, by Apollo Research, 2023, Apollo Academy (https://www.apolloacademy.com/us-wages-vs-wages-in-china-and-india/).

27 From *Why Doesn't the United States Have a European-style Welfare State?*, by A. Alesina, E. Glaeser, & B. Sacerdote, 2018, Review of Environmental Economics and Policy (https://www.journals.uchicago.edu/doi/10.1093/reep/rex013).

28 From *Regulations Executive Summary, by National Association of Manufacturers*, 2023, https://nam.org/wp-content/uploads/2023/10/Regulations-Exec-Summary.pdf.

Consequently, complying with environmental standards in the U.S. is more costly than meeting—or not meeting—standards in many other countries. This pushes companies to move their operations and associated environmental impact abroad, shifting pollution rather than eliminating it.[29] Given these challenges, the manufacturing industry would greatly benefit from long-term regulatory compliance support to strengthen and incentivize domestic production while maintaining environmental goals.

Lastly, the sheer diversity of the healthcare supply chain presents challenges, as a wide array of products are needed to support patient care. Medical procedures and surgeries can only be performed if all the needed supplies and equipment are available to the healthcare provider at the right time. A disruption in a single product's supply chain can undermine the larger healthcare community's ability to provide needed patient care.

It is important to note that products beyond medications and devices, including PPE and surgical instruments, are also essential parts of the healthcare supply chain. For example, cleaning products are critical for the prevention of infection and move through the medical product supply chain.[30]

"Unlike industries that can zero in on a narrower range of related products, a healthcare supply chain needs to account for particularly stringent regulatory and compliance standards and could include everything from pens, laptops, and printing paper to perishable drugs and blood, X-ray machines, and surgical implants."[31]

The previously mentioned challenges frame the need to find solutions to minimize the hurdles for domestic manufacturers. Incentivizing a level playing field and focusing on the most critical products and essential medicines would allow the U.S. to be less dependent on foreign produced medical products for patient care.

29 From *Research: When Environmental Regulations are Tighter at Home, Companies Emit More Abroad*, by Harvard Business Review, 2019 (https://hbr.org/2019/02/research-when-environmental-regulations-are-tighter-at-home-companies-emit-more-abroad).

30 From *The Role of Supply Chain in Healthcare*, by E. Nuber, 2022, ECRI Blog (https://home.ecri.org/blogs/ecri-blog/the-role-of-supply-chain-in-healthcare).

31 From *Healthcare Supply Chain Management*, by A. Jenkins, 2025, NetSuite (https://www.netsuite.com/portal/resource/articles/erp/healthcare-supply-chain-management.shtml).

THE POLICY PATH FORWARD FOR UNIQUE HEALTHCARE SECTOR SOLUTIONS

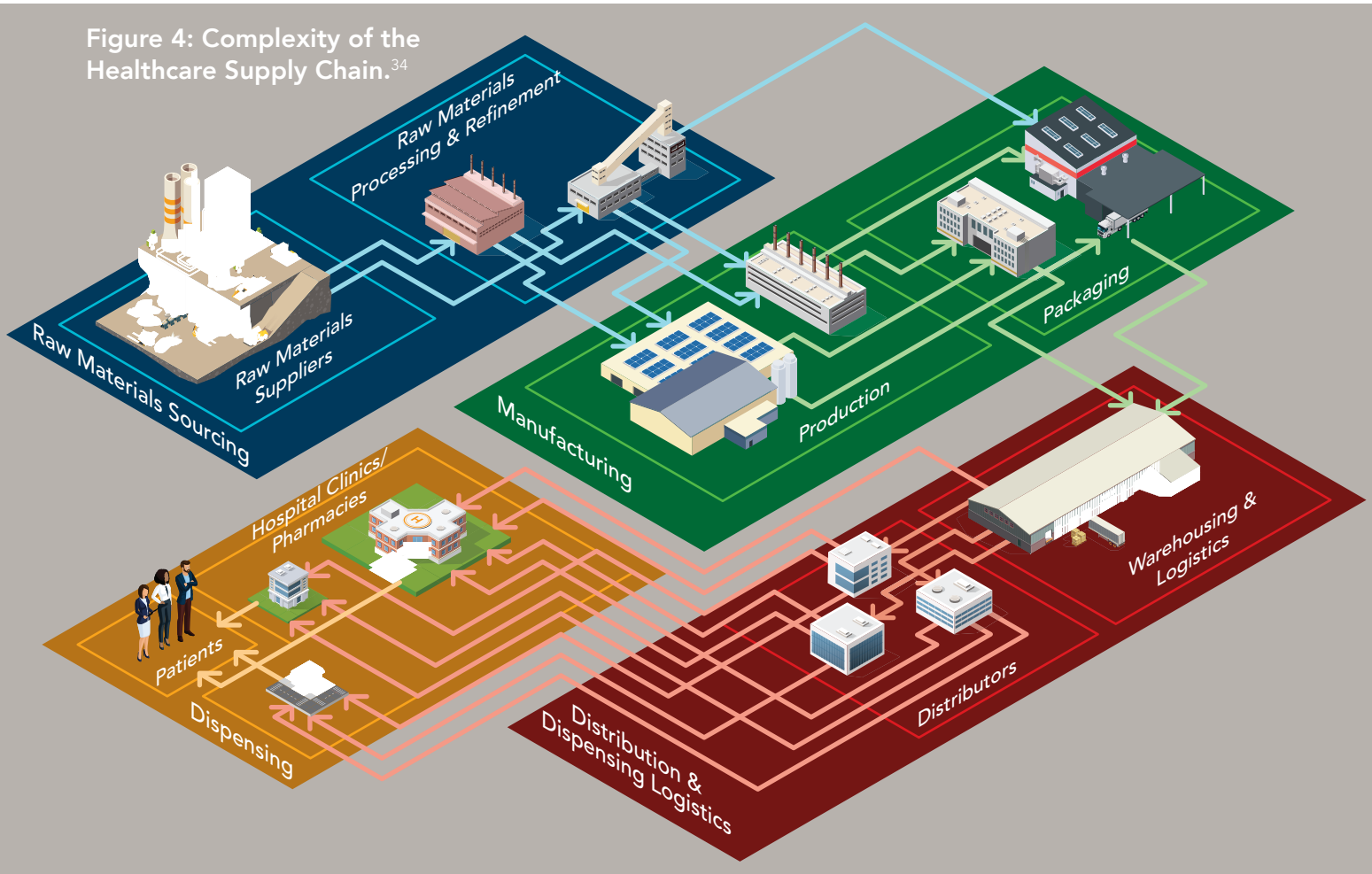
The graphic in Figure 4 illustrates the complex and interconnected nature of the healthcare supply chain, which moves tens of thousands of medical products to support patient care. The expansive nature of the supply chain and the multiple factors involved argue for identifying targeted approaches to solve specific problems. If the intent is to reduce overreliance on specific classes of products that are essential to healthcare providers, one strategy would be to target solutions that focus on existing lists of critical medicines, supplies, and devices already established by the federal government, specifically the FDA's list of Essential Medicines, Countermeasures and Critical Inputs and also the DoD's list of Essential Medicines, Medical Countermeasures and Critical Inputs.[32] These lists identify medicines, medical countermeasures, and critical inputs that must be available in appropriate dosage forms, when applicable, to meet patient needs. They are intended to ensure that the nation is prepared for public health emergencies and protected against potential threats.[33]

32 See Appendices A and B.

33 From *Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs*, by U.S. Food and Drug Administration, May 23, 2022 (https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs).

34 From *Healthcare Supply Chain*, by Healthcare Ready, December 30, 2019 (https://healthcareready.org/healthcare-supply-chain/).

Figure 4: Complexity of the Healthcare Supply Chain.[34]



Previously enacted federal legislation aimed at increasing domestic production across other manufacturing sectors has shown the positive impact federal tax incentives can have on company behavior and achieving that goal. As discussed previously, the CHIPS and Science Act, 2022[35] and the Tax Cuts and Jobs Act, 2017[36] resulted in job growth, increased domestic production, and improved national security.

However, healthcare products are different due to their life-sustaining and life-saving impact on patients as well as their role in protecting providers and the public. Recognizing this unique importance, policymakers are interested in legislative solutions to increase domestic production of critical healthcare products to ensure national and public health security. Building on the success of earlier domestic manufacturing bills that utilized tax incentives as a model, lawmakers have introduced several bills focused specifically on healthcare. These proposals target the pharmaceutical industry and the raw materials needed to support domestic production.

Focusing on the essential medicine and critical product lists will allow government incentives to target products that are the most important to saving lives and protecting the public during an emergency.[37] It will make the domestic production of these products more competitive and sustainable and will:

- Enable manufacturers to engage within this highly competitive pricing landscape by offsetting higher production costs;
- Encourage stable, long-term investment capacity; and
- Provide consistent demand through mechanisms such as tax credits, subsidies, or guaranteed purchasing programs.

Cost Differential of Domestic Production

While increased domestic production can enhance the resiliency of the supply chain for critical healthcare products and essential medicines, the cost differential between U.S. manufacturing and production abroad remains a significant hurdle for companies considering onshoring. Tax incentives and financial support offer a way to address this challenge by helping companies of all sizes offset the costs of expanding domestic production. The use of the Defense Production Act in 2020 demonstrated how increasing domestic manufacturing capabilities may require financial incentives to offset cost differentials.[38] This was a temporary solution, highlighting the need for and value of long-term policy solutions that incorporate federal tax incentives.

Partnerships with state and local governments can also help narrow the cost gap between domestic and foreign production. As discussed in the use case section, such partnerships can encourage companies to expand domestic operations by using a regional workforce and investing in local economies.

In addition, focused assistance to support the higher cost of labor in the U.S.—particularly relative to countries in Asia—could help offset this differential and strengthen the domestic workforce, all while increasing domestic production.

Labor

Given the upward trend in U.S. labor costs,[39] there is a growing need for intervention to support domestic companies. Strategic policies or incentives could help level the playing field, allowing U.S.-based companies to remain competitive with foreign manufacturers in the long term.

Beyond labor cost differentials, a key hurdle to domestic manufacturing is the lower availability of labor, especially skilled labor. To address this, partnerships with local educational institutions can be developed to establish a direct pipeline of skilled laborers in the geographical area they are needed. Quality Electrodynamics (QED), discussed in the use case section, is an example of a company that has successfully adopted this approach. Furthermore, additional tax incentives for manufacturing in qualified opportunity zones can bolster local economies and encourage the revitalization of these areas.

Through expanding domestic manufacturing, the U.S. can further establish itself as a leader in production in the global market. Increased domestic production creates opportunities for innovation and furthers the utilization and development of advanced manufacturing practices. The use of domestic advanced manufacturing practices can also support jobs that offer comparatively better pay. Therefore, incentivizing investment in these manufacturing practices domestically can further bolster the economy and labor force in the U.S.[40]

The next section summarizes tax incentive case studies and highlights key takeaways and policy insights that provided the basis for the tax incentive policy recommendations that follow.

35 From *012*, by J. Badlam, et al., McKinsey & Company, October 4, 2022 (https://www.mckinsey.com/industries/public-sector/our-insights/the-chips-and-science-act-heres-whats-in-it).

36 From *The TCJA: Key Facts on the 2017 'Trump Tax Cuts' and What's Extended for 2025*, by Kate Schubel, Kiplinger, July 9, 2025 (https://www.kiplinger.com/taxes/what-is-the-tcja).

37 See Appendices A-D.

38 From *Defense Production Act*, 2025, FEMA (https://www.fema.gov/disaster/defense-production-act).

39 From *US Labor Costs Rise From Year Earlier By Least Since 2021*, by A. Saraiva, 2025, Bloomberg (https://www.bloomberg.com/news/articles/2025-01-31/us-labor-costs-rise-from-year-earlier-by-least-since-2021?embedded-checkout=true).

40 From *National Strategy for Advanced Manufacturing*, by Executive Office of the President, National Science and Technology Council, 2022, U.S. Department of Energy (https://www.energy.gov/sites/default/files/2024-03/National-Strategy-for-Advanced-Manufacturing-10072022.pdf).

USE OF TAX POLICIES FOR MANUFACTURING OUTSIDE OF THE CONTIGUOUS U.S.

The U.S. is not the only country to experiment with incentives for manufacturers to onshore. The EU has worked on policies to incentivize reshoring as well. An evaluation of European reshoring practices from 2014-2018 showed that reshoring increased productivity in small and medium-sized enterprises, especially when shifting production domestically from distant, developing countries such as certain ones in Asia.[41]

China has demonstrated success in the use of tax policies to encourage domestic manufacturing across various industries. These policies include a value-added tax (VAT) policy that allows eligible companies to receive accumulated, deferred VAT credits applicable to many industries including manufacturing.[42] China also offers a reduced corporate income tax rate to certain high-tech manufacturing companies that are identified as needing key support from the state, with one of eligible fields being biology and medical technologies.[42] Additionally, China has increased tax incentives for R&D investments across the MedTech sector and these policies have yielded immense success. As a result, China has increased its share of global exports across many product categories including MedTech, medical consumables, and medical syringes which in turn has had the largest impact on U.S. exports as compared to other countries.[43]

Ireland has also demonstrated significant success in encouraging the onshoring of manufacturing, especially with pharmaceutical production. The tax incentives offered in Ireland include:[44]

- A 12.5% corporation tax rate on active business income;
- A 30% credit on eligible R&D expenditures in addition to the normal 12.5% revenue deduction available for the R&D expenditure; and
- Accelerated tax depreciation allowances for certain energy efficient equipment.

These policies have led to an increase in pharmaceutical onshoring, due to the favorable tax environment the country has created. In fact, Ireland is now the world's third-largest exporter of pharmaceuticals, demonstrating how long-term government investment can impact industry behavior.[45]

Lastly, Puerto Rico demonstrated past success with encouraging the onshoring of pharmaceutical manufacturing. Puerto Rico implemented the Section 936 tax credit, which allowed U.S. companies operating there to receive a federal tax exemption and helped establish the island as a hub for pharmaceutical and medical device manufacturing. This led to large-scale investments in production facilities, research, and workforce development.[46] At one point, over 50 manufacturing facilities were located in Puerto Rico and 80% of the medicines they produced were consumed by patients in the U.S.[47] Unfortunately,

41 From *COVID-19 and the Geopolitics of Global Health Supply Chains*, by S. Tagliapietra & A. Shapiro, 2023, Global Affairs (https://www.tandfonline.com/doi/full/10.1080/21681376.2023.2199054).

42 From Tax Incentives for Manufacturing Companies in China in 2024. *China Briefing*, May 7, 2024. https://www.china-briefing.com/news/manufacturing-tax-incentives-in-china-in-2024/.

43 From Brown, A., et al. (2023, November). *Investigating state support for China's medical technology companies.* MERICS. https://merics.org/sites/default/files/2023-11/MERICS_Report_MedTech%20State%20Support_November%202023_final.pdf.

44 From Tax Credits and Incentives. PwC Ireland, February 10, 2025. https://taxsummaries.pwc.com/ireland/corporate/tax-credits-and-incentives.

45 From Key Players in Ireland's Pharmaceutical Manufacturing Space. https://www.idaireland.com/latest-news/insights/pharmaceutical-manufacturing-companies-ireland.

46 From Tax Policy: Puerto Rico and the Section 936 Tax Credit. U.S. General Accounting Office, June 1993. https://www.gao.gov/assets/ggd-93-109.pdf.

47 From *Puerto Rico's Prescription Drug Industry Hindered by Hurricane*, by Lisa Robinson, WBAL-TV, October 12, 2017 (https://www.wbaltv.com/article/puerto-ricos-prescription-drug-industry-hindered-by-hurricane/12840780).

Hurricane Maria hit Puerto Rico in 2017 and devastated the island's infrastructure, creating shortages of essential healthcare products such as saline bags and IV solutions.[48] A key lesson from Puerto Rico's experience is that, while locating pharmaceutical manufacturing close to the U.S. decreased foreign dependence, it did not necessarily create supply chain resiliency because production was concentrated in a single geographic area.

48 From *FDA Works to Help Relieve the IV Fluid Shortages in Wake of Hurricane Maria*, U.S. Food and Drug Administration, November 14, 2017 (https://www.fda.gov/drugs/drug-safety-and-availability/fda-works-help-relieve-iv-fluid-shortages-wake-hurricane-maria).

LESSONS LEARNED FROM TAX POLICY USE CASES

As discussed, there is significant bipartisan interest in expanding domestic manufacturing efforts within the U.S. Furthermore, recent bipartisan legislation and sustained policymaker interest demonstrate a clear opportunity to apply the lessons learned from previous iterations of federal tax incentive policy.

The following examples highlight the impact financial support can have in increasing and strengthening domestic production in the U.S. While these cases studies are drawn from varying industries, they highlight ways in which financial incentives can be used to create a stronger and more resilient supply chain. These cases demonstrate the importance of a strong labor force, government partnerships, and the benefits financial support can provide in offsetting the costs of domestic production.

Case Studies[49, 50, 51, 52, 53, 54]

Edgewell Personal Care

Case Type: Reshoring from Canada to Delaware

Industry: Personal Care Products

Incentive Type: State grant from DE to assist with relocation and workforce training costs

Size of Award: $3 million

Result: Investment of $90 million and creation of 160 jobs

Impact/Benefit:

- Enabled faster distribution and lower transportation costs (90% of their customers are in the U.S.).
- Shifted to U.S.-based suppliers to reduce shipping time and costs.
- Combined operations under one regulatory and physical location, which increased operational efficiency.

49 From 2019 Manufacturing and Investment Report, by International Trade Administration, 2022, in *U.S. Department of Commerce* (https://www.trade.gov/sites/default/files/2022-07/2019ReinvestmentReport.pdf).

50 From Research & Development Tax Credit Examples, by StenTam, n.d., in *StenTam* (https://stentam.com/research-development-tax-credit-examples/).

51 From Clean Electricity Investment Credit, by Internal Revenue Service, n.d., in *IRS* (https://www.irs.gov/credits-deductions/clean-electricity-investment-credit).

52 From MACRS Overview for Businesses, by A. Langone & S. Fields, 2024, in *EnergySage* (https://www.energysage.com/business-solutions/macrs-overview/). Updated August 27, 2024.

53 From Opportunity Zones, by Internal Revenue Service, 2022, in *IRS.gov* (https://www.irs.gov/newsroom/opportunity-zones). Updated April 2022.

54 From The Section 45X Advanced Manufacturing Production Credit, by Nicholas E. Buffie, 2024, in *Congressional Research Service Reports*, U.S. Congress (https://www.congress.gov/crs-product/IF12809).

Quality Electrodynamics

Case Type: Expansion

Industry: Manufacturer of MRI radiofrequency coils

Incentive Type: Local incentive from Mayfield Village, OH to encourage QED to remain; grant from JobsOhio tied to job creation

Size of Award: $400,000 (local incentive); up to $2.1 million (JobsOhio)

Result: Investment of $3.1 million, retention of 145 jobs, creation of 30 jobs

Impact/Benefit:

- Continued access to a strong local supply chain and MRI industry cluster.
- Enhanced collaboration with local universities including education/internship programs.
- Established the QED Research Center, advancing R&D and innovation.

MedPharmCo

Case Type: R&D Tax Credit

Industry: Developer of drug and medication delivery systems

Incentive Type: Federal R&D tax credit; state level credit

Size of Award: $40,000 (federal tax credit)

Qualifying Activities:

- Developing new medical devices, specifically drug and medication delivery routes. Includes development, testing, and commercial production.
- Creating and testing device prototypes through patient compassionate use scenarios.
- New methodologies for drug/device delivery.

Clean Energy Industry

Clean Electricity Investment Credit

- Emissions-based incentive that is neutral and flexible between clean electricity technologies.
- Base amount is 6% of the qualified investment.
- Credit can be increased by specified amounts for facilities meeting prevailing wage and registered apprenticeship requirements; certain domestic content requirements for steel, iron, and manufactured products; or if located in an energy community.

Clean Electricity Production Credit

- Provides companies a per kilowatt-hour (kWh) incentive for generating electricity from certain renewable energy sources.
- Credit can be increased by specific amounts for facilities meeting certain domestic content requirements for steel, iron, and manufactured products or if located in an energy community.

Accelerated Deprecation (MACRS)

- Allows renewable energy systems to be depreciated over a 5-year schedule, thus reducing taxable income more quickly.
- Often paired with a tax credit.

Renewable Energy and Opportunity Zones

- Opportunity zones are economically distressed communities.
- For larger, renewable energy plants, tax advantages are offered for investing in renewable energy projects located in these designated areas.

The Section 45X Advanced Manufacturing Production Credit

- Subsidizes the production of solar energy components, wind energy components, battery components, inverters, and critical minerals.
- Businesses may only claim the credit for goods produced in the U.S. or its territories.

CASE	INDUSTRY	INCREASED DOMESTIC PRODUCTION	INCREASED INVESTMENT	INCREASED JOB CREATION
Edgewell Personal Care	Personal Care Products	✓	✓	✓
Quality Electrodynamics	Manufactures Radiofrequency Coils Used in MRI Scanners	✓	✓	✓
MedPharmCo	Developer of Drug and Medication Delivery Systems	✓	✓	✓
Clean Energy Industry	Renewable Energy	✓	✓	✓

Key Takeaways

In the previous use cases, commonalities included:

- The use of tax incentives to encourage domestic production.
- Understanding how to access local labor, especially skilled labor and how to increase availability of domestic skilled laborers.
- Partnerships with state and local governments.
- The ability to, and cost of, navigating and complying with the regulatory landscape from a local, state, and federal level.
- The higher costs associated with domestic reshoring and production.

To address the need for skilled labor, QED partnered with local universities to develop internship programs and educational initiatives. They also established a Research Center to promote R&D activities and innovation.[55] Many of these companies and industries, in addition to benefitting from federal incentives, partnered with state and local governments to promote their reshoring and/or expansion efforts in a manner that boosted the local economy.

When it comes to regulatory compliance, many companies have struggled to navigate the different levels of regulations and the varying requirements amongst agencies. Furthermore, companies reported that when it came to their ability to maintain compliance with U.S. regulations, uncertainty in the changing landscape was a major factor in their ability to reshore.[55] The difficulty in navigating regulatory compliance issues, as well as other factors leading to increased domestic costs, were a major factor for companies deciding whether to expand U.S. production.

Despite these challenges, the companies and industries mentioned previously experienced success in their domestic production efforts due, in part, to the financial assistance offered to them. In many of these cases, this has resulted in a positive effect on both local and state economies and provided for improved company performance and results.

Return on Investment

Targeted financial incentives to encourage domestic manufacturing have resulted in tangible benefits to the public, including decreased unemployment rates due to the creation of jobs and enhanced economic growth due to investment by manufacturers. For example, Ireland lowered its standard corporate tax rate from 40% to 12.5% over the course of the 12 years leading up to 2003[56] and Ireland's unemployment rate went from 15.77% in 1991 to 4.48% in 2003.[57] The $3 million grant offered to Edgewell Personal Care resulted in an investment of $90 million, which is just one example of the return on investment (ROI) that such financial incentives can generate. As these cases and many others demonstrate, tax incentives to encourage domestic production can create a compelling ROI for taxpayers.

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55 From 2019 Manufacturing and Investment Report, by International Trade Administration, 2022, in *U.S. Department of Commerce* (https://www.trade.gov/sites/default/files/2022-07/2019ReinvestmentReport.pdf).

56 From *Tax Rates*, Irish Legal Blog (https://legalblog.ie/tax-rates/).

57 From *Ireland Unemployment Rate* (1991–2024), MacroTrends (https://www.macrotrends.net/global-metrics/countries/irl/ireland/unemployment-rate).

CONSIDERATIONS TO ACHIEVE DOMESTIC RESILIENCY BASED UPON PREVIOUS INITIATIVES

As discussed throughout this paper, there has been strong interest in increasing domestic production of critical healthcare products and essential medicines to improve healthcare supply chain resiliency. Numerous case studies—both domestic and international—showcase successful initiatives. At the same time, not all policies to incentivize domestic manufacturing have achieved their intended outcomes. Both situations provide opportunities to assess and incorporate lessons learned in future policy proposals.

One example is the CHIPS and Science Act, 2022. This legislation lacked provisions to help manufacturers navigate compliance with Environmental Protection Agency (EPA) requirements which led to unforeseen delays and costs associated with onshoring for manufacturers.[58] Future legislation that considers regulatory streamlining provisions will provide greater certainty and support to manufacturers, thus encouraging domestic onshoring on a wider scale.

Additionally, The Homeland Investment Act—a part of American Jobs Creation Act (AJCA) of 2004—aimed to incentivize domestic investment, research and development, and job creation in the U.S. by temporarily cutting taxes on profits U.S. multinationals could bring back from abroad. This policy did not account for a company's need for long-term support to move production and alter supply chains. The legislation provided a short-term incentive (2004-2005) which resulted in the absence of a lasting push for domestic investment.[59] Policy that can provide long-term supports to manufacturers and make their investments worthwhile and effective would allow for longer-term success of onshoring.

As discussed previously regarding Puerto Rico's experience with Hurricane Maria, it is important to avoid manufacturing concentration in one geographic region. Another example was the impact of Hurricane Helene in September 2024, on an IV solution manufacturer in the U.S. One large plant in North Carolina accounted for 60% of the U.S. market. The flooding of the facility stopped all production and took until February 2025, for the facility to return to its pre-hurricane production status and until May 13, 2025, for the company to restore its inventory levels.[60] However, it wasn't until August 8, 2025, that the FDA announced the IV solution shortage was over.[61] Domestic manufacturing is important for the healthcare supply chain and the providers and patients it serves. Domestic manufacturing incentives should be combined with a diversification strategy—even within the U.S.—for supply chain resiliency.

Lastly, a key element of success is to ensure policies are evaluated and lessons learned are incorporated into future policies. Policymakers have a role in collecting this information, hearing from subject matter experts, and incorporating insights to shape more effective legislation. Requiring reports to Congress is a common method utilized, and new legislative initiatives often require a report to Congress from the agency responsible for overseeing the new policy or program or from an entity such as the Government Accountability Office (GAO). The last reauthorization of national preparedness programs in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 required multiple reports on vaccine development, adequacy of the national blood supply, and response capabilities of healthcare providers.[62]

58 From Chipping Away at American Manufacturing. American Compass, June 11, 2025. https://americancompass.org/chipping-away/

59 From "Watch What I Do, Not What I Say: The Unintended Consequences of the Homeland Investment Act." Dhammika Dharmapala, C. Fritz Foley, and Kristin J. Forbes, *Journal of Finance*, 66, 753 (2011). https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1540-6261.2011.01661.x

60 From *Hurricane Helene Updates*, Baxter International Inc., May 13, 2025 (https://www.baxter.com/baxter-newsroom/hurricane-helene-updates).

61 From A Statement from FDA Commissioner Marty Makary, M.D., M.P.H.: Announcing Resolution of the IV Saline Solutions Shortage, U.S. Food and Drug Administration, August 8, 2025 (https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-announcing-resolution-iv-saline-solutions-shortage).

62 Public Law 116-22.


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POLICY RECOMMENDATIONS

The successful bipartisan history of using tax incentives to encourage domestic production in other sectors suggests that the healthcare sector could benefit from similar policies. Accordingly, this white paper makes the following recommendations to increase domestic production of critical medical products and essential medicines:

- Federal tax incentives should be provided for domestic production of the critical medical products and essential medicines listed in the appendices. Manufacturers should also receive a tax credit on the income generated from the sale of domestically manufactured goods as further incentive to sustain and grow the current U.S. manufacturing presence. Such practices have been successful in the past, as demonstrated by the previous case studies.

- Federal tax incentives should be provided for manufacturers to offset labor costs as well as investments in advanced manufacturing equipment or machinery. These can be expected to lead to the increased development and utilization of skilled labor forces.

- To address concerns with regulatory complexity in the U.S. due to the multi-agency requirements companies must comply with, efforts to promote regulatory streamlining should be enacted to ensure companies are able to account for and meet all regulatory requirements, including environmental ones.

- Legislative initiatives should include reports to Congress that require an assessment of impact and effectiveness in incentivizing domestic production.

The relatively higher costs of domestic production and labor can be effectively addressed through targeted financial incentives. Partnerships to enhance the accessibility of skilled labor, as well as resources to navigate complex regulations, are also critical to success.

In conclusion, federal tax incentive policy—thoughtfully structured to avoid disrupting product availability or reducing output—should be a critical component of efforts to encourage the onshoring of critical medical product manufacturing. Such policies will help build a more resilient healthcare supply chain, strengthen national security, and improve the ability of the U.S. to respond to public health emergencies.

APPENDIX A: FDA ESSENTIAL MEDICINES, MEDICAL COUNTERMEASURES AND CRITICAL INPUTS

The FDA's list includes 227 drug and biological products, essential medicines, and medical countermeasures.[63]

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Drug Category: Gastrointestinal Agents			
Famotidine	Oral / IV	API only	
Lactulose	Liquid	API only	
Loperamide	Oral	API only	
Pantoprazole	IV	API only	
Drug Category: Anticonvulsants			
Phenytoin	IV	API only	
Levetiracetam	Oral / IV	API only	
Drug Category: Antiemetics			
Ondansetron	IV	API only	
Drug Category: Anticoagulants / Antiplatelet			
Alteplase	IV	API only	
Apixaban	Oral	API only	
Aspirin	Oral	API only	
Ticagrelor	Oral	API only	
Enoxaparin	SQ	API, heparin, crude heparin	
Heparin	IV	API and crude heparin	
Protamine	IV	API, source proteins	
Vitamin K	IV	API only	
Andexanet Alfa Injection	IV	Genetically modified variant of human FXa	
Argatroban	IV	API only	
Drug Category: Antimetabolite			
Hydroxyurea	Oral	API only	
Drug Category: Chemotherapeutic			
Cyclophosphamide	IV	API only	

63 From *Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of Executive Order 13944*, by U.S. Food and Drug Administration, 2020, U.S. Department of Health and Human Services (October 3). (https://www.fda.gov/media/143406/download?attachment).

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Drug Category: Antihistamines			
Diphenhydramine	IV	API only	
Drug Category: Antihypertensives / Cardiovascular			
Adenosine	IV	API only	
Atropine	IV	API only	
Amiodarone	IV	API only	
Amlodipine	Oral	API only	
Diltiazem	Oral / IV	API only	
Esmolol	IV	API only	
Furosemide	Oral / IV	API only	
Hydrochlorothiazide	Oral	API only	
Hydralazine	Oral / IV	API only	
Labetalol	IV	API only	
Mannitol	IV	API only	
Metoprolol	Oral / IV	API only	
Nitroglycerin	Oral / IV	API only	
Nitroprusside	IV	API only	
Dobutamine	IV	API only	
Phenoxybenzamine	Oral	API only	
Drug Category: Anti-malarial			
Artesunate	IV	API only	
Drug Category: Anti-Microbial			
Amikacin	IV	API only	
Amphotericin B	IV	API, +	
Ampicillin	IV	API only	
Azithromycin	IV	API only	
Cefepime	IV	API only	
Ceftazidime	IV	APIs only	
Ceftazidime-Avibactam	IV	APIs only	
Ceftriaxone	IV	API only	
Clindamycin	IV	API only	
Daptomycin	IV	API only	
Doxycycline	Oral / IV	API only	
Fluconazole	Oral / IV	API only	
Micafungin	IV	API only	
Linezolid	IV	API only	
Levofloxacin	Oral / IV	API only	
Meropenem	IV	API only	
Metronidazole	Oral / IV	API only	
Piperacillin / Tazobactam	IV	APIs only	

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Penicillin G	IV	API only	
Rifampin	IV	API only	
Trimethoprim/Sulfamethoxazole	Oral	APIs only	
Vancomycin	Oral / IV	API only	
Voriconazole	IV	API, +	
Tobramycin Ophthalmic Solution 0.3%	Solution / Topical	API only	
Drug Category: Psychiatric Agents			
Haloperidol	IM	API only	
Benztropine	Oral / IV	API only	
Olanzapine	Oral	API only	
Drug Category: Antipyretics			
Acetaminophen	Oral	API only	
Ibuprofen	Oral	API only	
Drug Category: Analgesics			
Codeine	Liquid	API only	
Fentanyl	IV	API only	
Hydromorphone	Oral / IV	API only	
Morphine	IV / Elixir	API only	
Lidocaine/Epinephrine	Solution for SQ local	APIs only	
Drug Category: Antiseptics / Disinfectants			
Chlorhexidine	Solution / Topical	API only	
Povidone-Iodine 10% Solution	Solution	API only	
Topical/surface alcohol-based sanitizers	Topical	API only	
Drug Category: Antivirals			
Acyclovir	IV	API only	
Valganciclovir	Oral	API only	
Foscarnet	IV	API only	
Oseltamivir	Oral / liquid	API only	
Peramivir	IV	API only	
Darunavir/cobicistat	Oral	APIs only	
Drug Category: Ophthalmic /Glaucoma			
Timolol Maleate Ophthalmic Solution 0.5%	Solution	API only	
Drug Category: Pulmonary			
Albuterol	MDI / NEB	NEB: API only MDI: API, critical device components, +	
Ipratropium Bromide	MDI / NEB	NEB: API only MDI: API, critical device components, +	
N-acetylcysteine	IV Solution	API only	
Drug Category: Chemotherapy / Immunosuppressants / Immunomodulators			
Tacrolimus	Oral	API, +	

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Mycophenolate Mofetil	Oral / suspension	API only	
Drug Category: human granulocyte colony-stimulating factor			
Filgrastim	SQ	API only	
Drug Category: Anticholinergic Secretions			
Glycopyrrolate	IV	API only	
Drug Category: Dialysis Agents			
Continuous Renal Replacement Solution	Solution	API only	
Drug Category: Glycemic Control			
Glargine	SQ	API and master cell bank storage	
Insulin regular	IV	API and master cell bank storage	
Dextrose 50% Injection	IV	API only	
Drug Category: Paralytics			
Cisatracurium	IV	API only	
Rocuronium	IV	API only	
Vecuronium	IV	API only	
Succinylcholine	IV	API only	
Drug Category: Reversal Agents			
Glucagon	IV	API only	
Flumazenil	IV	API only	
Methylene Blue	IV	API only	
Naloxone	IV	API only	
Sugammadex	IV	API only	
Fomepizole	IV	API only	
Drug Category: Sedatives / Hypnotics			
Dexmedetomidine	IV	API only	
Etomidate	IV	API only	
Ketamine	IV	API only	
Lorazepam	IV	API only	
Midazolam	IV / IM	API only	
Propofol	IV	API, +	
Drug Category: Anesthetic			
Isoflurane	gas	API only	
Drug Category: Malignant Hyperthermia			
Dantrolene	IV	API only	
Drug Category: Steroids			
Dexamethasone	IV	API only	
Hydrocortisone	Oral / IV	API only	
Methylprednisolone	IV	API only	
Drug Category: Endocrine			
Levothyroxine	IV	API only	

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Propylthiouracil	Oral	API only	
Zoledronic acid	IV	API only	
Desmopressin acetate	IV	API only	
Drug Category: Vaccines			
Rabies Vaccine	IM	Rabies Virus Strain Flury Lep Antigen, or Virus strain PM-1503-3M Antigen	
Tetanus Vaccine	IM	Clostridium tetani toxoid antigen	
Drug Category: Vasopressors			
Epinephrine	IV / Prefilled Syringe	API, autoinjector (4 applications)	
Norepinephrine	IV	API only	
Phenylephrine	IV	API only	
Vasopressin	IV	API only	
Drug Category: Volume Expanders			
Dextrose 5% Water	IV	API only	
Dextrose 10% Water	IV	API only	
Lactated Ringers (LR)	IV	API only	
Sodium Chloride 0.45%	IV	API only	
Sodium Chloride 0.9%	IV	API only	
Sodium Chloride 3%	IV	API only	
Drug Category: Additives			
Calcium Gluconate	IV	API only	
Magnesium Sulfate	IV	API only	
Potassium Chloride	Oral / IV	API only	
Sodium bicarbonate 5% injection	IV	API only	
Thiamine	IV	API only	
Cyanocobalamin 1000 mcg ml	IM	API only	
Sodium Phosphate	IV	API only	
Drug Category: Nutrition			
Intralipid 20%	IV	API, +	
Trophamine (AA for infants)	IV	API only	
Zinc	IV	API only	
Cupric Chloride	IV	API only	
Drug Category: Other			
Octreotide	IV	API, +	
Hemin for injection	IV	Hemin from processed red blood cells	
Anticoagulants in Blood Bags and storage solutions	IV	Citrate, phosphate, dextrose, adenine	

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Drug Category: Blood and Blood Products			
Source plasma	Further Mfr	Human plasma	
Transfusable Blood Components: WB, RBC, Platelets, Plasma, Cryo	IV	Human venous blood	
S/D Plasma (Octaplas)	IV	Pooled human plasma	
Drug Category: Fractionated Plasma Products			
Albumin	IV	Pooled human plasma	
C-1 esterase inhibitor	IV	Pooled human plasma, or milk of transgenic rabbits	
Factor VII, VIII, X, XIII products	IV	Pooled human plasma or recombinant DNA technology	
Activated Factor VII	IV	Pooled human plasma or recombinant DNA technology	
von Willebrand Factor	IV	Pooled human plasma or recombinant DNA technology	
Protein C	IV	Pooled human plasma or recombinant DNA technology	
Antithrombin	IV	Pooled human plasma or recombinant DNA technology	
Anti-inhibitor coagulant complex	IV	Pooled human plasma or recombinant DNA technology	
Fibrin sealant products	Topical / Intra-Operative	Fibrinogen Human, Human Thrombin	
Prothrombin complex concentrate	IV	Human Source Plasma	
Fibrinogen products	IV	Human plasma-derived fibrinogen concentrate	
Thrombin products	IV	Prothrombin and thromboplastin of bovine origin; human coagulation protein produced through recombinant DNA technology; or pooled human plasma	
Drug Category: Immune Globulins			
Immune Globulin	IV / IM / Subcutaneous	Pooled human plasma, immunoglobulin G	
Drug Category: Hyperimmune Globulins			
Botulism immune globulin	IV	Pooled human plasma from persons who were immunized with recombinant botulinum vaccine for serotypes A and B	
Rabies immune globulin	IV	Plasma from human donors immunized with rabies vaccine	
Tetanus immune globulin	IV	Plasma of human donors immunized with tetanus toxoid	
Drug Category: Animal-Derived IG Products			
Anti-thymocyte globulin products	IV	Immunoglobulin G, obtained by immunization of rabbits with human thymocytes	
Black widow spider anti-venin (Latrodectus mactans)	IV	Normal horse serum from immunized horses	
Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) Equine	IV	Purified F(ab')2 plus F(ab')2-related immune globulin fragments derived from equine plasma	

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Centruroides Immune Fab (scorpion)	IV	Plasma of horses immunized with venom of 4 species of scorpions	
Crotalidae Immune Fab (North American rattlesnakes)	IV	Plasma from horses immunized with venom of North American rattlesnake	
Crotalidae Polyvalent Immune Fab (rattlesnake, water moc, cottonmouth)	IV	Immune globulins obtained from healthy sheep immunized with North American snake venom (multi)	
Coral Snake Antivenom (antivenin) (Micrurus fulvius)	IV	Plasma from horses immunized with North American Coral Snake (Eastern Coral & Texas Coral Snakes)	
Digi Immune Fab (digoxin)	IV	Immune globulin fragments from blood of healthy sheep immunized with digoxin derivative	
Drug Category: Unapproved Drugs Initiative			
Potassium Iodide - OTC for Radiation Emergency but also could be used thyroid storm	Oral Solution	API only	
Activated charcoal - not approved	Oral		
Selenium	IV	Neonate selenium deficiency	
Drug Category: Chemical Threat MCMs			
Atropine AI	IM	API and Autoinjector	x
Diazepam	IM or IV	API only	x
Dual chamber atropine/pralidoxime AI - See Antidote Treatment Nerve Agent Autoinjector (ATNAA - DoD) and DuoDote (civilian)	IM	APIs and Autoinjector	x
Hydroxocobalamin	IV	API only	x
Naloxone HCl AI	IM	API and Autoinjector	x
Pralidoxime chloride & AI	IM or IV	API and Autoinjector	x
Pyridostigmine bromide	Oral (30 mg)	API only	x
Sodium nitrite	IV	API only	x
Sodium thiosulfate	IV	API only	x
Drug Category: Radiologic-Nuclear Threat MCMs			
Calcium diethylenetriamine pentaacetate (DTPA)	IV	API only	x
Ferric Hexacyanoferrate (Prussian blue; Radiogardase)	Oral	API only	x
Pegfilgrastim (Neulasta)	SQ	API, master cell bank storage, +	x
Sargramostim (Leukine)	SQ	API only	x
Zinc diethylenetriamine pentaacetate (DTPA)	IV	API only	x
Hematopoietic Progenitor Cells- Cord Blood (HPC-C)	Injectable	Human Cord Blood	x
Drug Category: Biological Threat MCMs			
Amoxicillin	Liquid / Oral	API only	x
Ciprofloxacin HCl	liquid / Oral	API only	x
Imipenem	IV	API only	x
Levofloxacin	Liquid	API only	x

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Moxifloxacin HCl	Oral / IV	API only	x
Obiltoxaximab	IV	API only and master cell bank storage	x
Omadacycline	Oral / IV	API only	x
Raxibacumab	IV	API only and master cell bank storage	x
Tecovirimat	Oral	API only	x
Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	Injectable	Human Adenovirus E Serotype 4 Strain CL-68578, Human Adenovirus B Serotype 7 Strain 55142 Antigen	x
Anthrax Immune Globulin Intravenous	Injectable	Human plasma from donors who are immunized with Anthrax Vaccine Absorbed	x
Anthrax Vaccine, Adsorbed	Injectable	Bacillus anthracis Strain V770-NP1-R Antigens	x
Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) Equine	Injectable	Plasma obtained from horses that have been immunized with specific serotype of botulinum toxoid and toxin	x
Botulism Immune Globulin	Injectable	Pooled human plasma from persons who were immunized with recombinant botulinum vaccine for serotypes A and B	x
Cholera Vaccine, Live Oral	Oral	Vibrio cholerae CVD 103-HGR Strain Live Antigen	x
Dengue Tetravalent Vaccine, Live	Injectable	Chimeric yellow fever dengue (CYD) virus serotypes 1, 2, 3, and 4	x
Ebola Zaire Vaccine, Live	Injectable	Recombinant viral vaccine consisting of a vesicular stomatitis virus (VSV) backbone deleted for the VSV envelope glycoprotein and substituted with the envelope glycoprotein of the Zaire ebolavirus (Kikwit 1995 strain)	x
Japanese Encephalitis Vaccine	Injectable	Japanese Encephalitis Virus Strain SA 14-14-2 Antigen	x
Smallpox and Monkeypox Vaccine, Live, Non-Replicating	Injectable	Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non- replicating orthopoxvirus	x
Plague Vaccine	Injectable	Yersinia pestis organisms grown in artificial media	x
Smallpox (Vaccinia) Vaccine, Live	Injectable	Vaccinia Virus Strain New York Board of Health Live Antigen	x
Typhoid Vi Polysaccharide Vaccine	Injectable	Salmonella Typhi TY2 VI Polysaccharide Antigen	x
Typhoid Vaccine Live, Oral Ty21a	Oral	Salmonella typhi TY21A Live Antigen	x
Vaccinia Immune Globulin Intravenous (Human)	Injectable	Human plasma containing antibodies to vaccinia virus	x
Yellow Fever Vaccine	Injectable	Yellow Fever Virus Strain 17D-204 Live Antigen	x
Inmazeb	Injectable	APIs only and master cell bank storage	x
Drug Category: Pandemic Influenza MCMs			
Baloxavir marboxil	Oral	API only	x
Zanamivir	Inhaled	API, Diskhaler constituent parts including body, wheel, needle level, and mouthpiece tray, base foil laminate and aluminum lid foil constituting rotadisk, +	x
Influenza A (H5N1) Monovalent Vaccine Adjuvanted	Injectable	Hemagglutinin (HA) of the influenza virus strain A/turkey/Turkey/1/2005 NIBRG-23, a reverse genetics-derived reference strain	x

DRUG NAME	DOSAGE FORMS	CRITICAL INPUTS	MCM USE ONLY
Influenza A (H5N1) Virus Monovalent Vaccine Adjuvanted	Injectable	Hemagglutinin (HA) of the influenza virus strain A/Indonesia/05/2005 (H5N1)	x
Influenza Virus Vaccine, H5N1	Injectable	H5N1 suspension formulated to contain hemagglutinin (HA) of A/Vietnam/1203/2004 (H5N1, clade1)	x
Drug Category: Burn and Blast Injuries			
Bacitracin	Topical	API only	x
Bacitracin / Polymyxin B	Ophthalmic	API only	x
Oxycodone HCl	Oral	API only	x
Silvadene (silver sulfadiazine)	Topical	API only	x
Transfusable blood and blood components	Injectable	Human venous blood	x
Anticoagulants in Blood Bags and storage solutions	Injectable	Citrate, Phosphate, Dextrose, Adenine	x
Drug Category: COVID-19 (Material Threat Determination in place)			
Tigecycline	IV	API only	x

APPENDIX B: DOD ESSENTIAL MEDICINES, MEDICAL COUNTERMEASURES AND CRITICAL INPUTS

There are 40 essential medicines on the DoD Essential Medicine List.[64] Key examples include:

DRUG	TREATMENT
Apixaban	Anticoagulant
Cefepime	Broad-spectrum antibiotic
Continuous renal replacement (CRRT) solution	Dialysis-like fluid used in CRRT
Dextrose 50% injection	Emergency glucose administration
Diltiazem	Calcium channel blocker (rate control and antihypertensive)
Dobutamine	Inotrope for heart failure
Hydromorphone	Opioid analgesic
Intralipid 20%	Fat emulsion; used as nutrition and antidote
Metoprolol	Beta-blocker (rate control, antihypertensive)
Norepinephrine	Vasopressor
Pantoprazole	Proton pump inhibitor/prevents bleeding
Phenylephrine	Vasoconstrictor
Rocuronium	Neuromuscular blocker (paralytic)
Sodium bicarbonate	Buffer; corrects metabolic acidosis
Adenovirus vaccine	Prevents adenovirus respiratory illness

64 From *Securing the Pharmaceutical Supply Chain: The Critical Role of Pharmacy in National Health Security*, by M. G. Ndukwe & R. H. Carter, 2025, Journal of the American Pharmacists Association. (https://www.japha.org/article/S1544-3191(25)00106-2/pdf).

APPENDIX C: FDA LIST OF CRITICAL MEDICAL DEVICES

The FDA's list of critical medical devices includes 96 medical devices and products, along with their critical inputs.[65]

PROCODE	PREFERRED NAME	CRITICAL INPUTS
BTO	Tube, Tracheostomy (W/Wo Connector)	Connectors, valves, balloon cuffs
BTR	Tube, Tracheal (W/Wo Connector)	Connectors, valves, balloon cuffs
CAW	Generator, Oxygen, Portable	Molecular sieve, oxygen sensor, pressure chamber, pneumatic valves, mechanical
DQA	Oximeter	Red and infrared LEDs, photodetector
JOH	Tube Tracheostomy And Tube Cuff	None
EOQ	Bronchoscope (Flexible Or Rigid)	Optics (e.g., camera)
KTI	Bronchoscope Accessory	None
BTM	Ventilator, Emergency, Manual (Resuscitator)	Mechanical bellows, gas filters (particulate/viral/bacterial), connectors for gas pathway,
BZE	Heater, Breathing System W/Wo Controller (Not Humidifier Or Nebulizer	None
FLS	Apnea Monitor	Sensor
BZH	Peak Flow Meter	Flow sensor
CBK	Ventilator, Continuous, Facility Use	Sensors (flow, pressure, volume), expiratory pressure regulator, BZE
BYS	Oxygenator, Long Term Support Greater Than 6 Hours	Oxygenator fiber
MHX	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)	ECG electrodes/leads, SpO2 sensors, Blood pressure cuff/ pump and tubing,
PZS	Dual Lumen ECMO Cannula	None
QJZ	Extracorporeal System For Long-Term Respiratory / Cardiopulmonary Failure	Pump impeller, oxygenator fiber
FIL	System, Dialysate Delivery, Single Pass	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
FIZ	Meter, Conductivity, Non-Remote	Conductivity sensor
FJD	Detector, Leak, Blood	Leak sensors
FJF	Detector, Air Bubble	Air sensors
FJI	Dialyzer, Capillary, Hollow Fiber	Dialyzer membrane
FJK	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve	None

65 From *Device Medical Countermeasures and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944*, by U.S. Food and Drug Administration, 2020, U.S. Department of Health and Human Services (October 3). (https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs).

PROCODE	PREFERRED NAME	CRITICAL INPUTS
FKB	Connector, Blood Tubing, Infusion T	None
FKP	System, Dialysate Delivery, Single Patient	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
KDI	Dialyzer, High Permeability With Or Without Sealed Dialysate System	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
KDL	Set, Perfusion, Kidney, Disposable	None
MQS	System, Hemodialysis, Access Recirculation Monitoring	FID FKJ FLA KDI KOC KPO MPB MSY NQJ
MSE	Hemodialyzer, Re-Use, Low Flux	Dialyzer membrane
MSF	Hemodialyzer, Re-Use, High Flux	Dialyzer membrane
PSX	Chlorine Meter	Chlorine sensor
FMF	Syringe, Piston	None
FMI	Needle, Hypodermic, Single Lumen	None
FRN	Pump, Infusion	Pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, air-in-line detector), FPB
MEA	Pump, Infusion, PCA	Pumping mechanism, accessories under MRZ (anti free flow detector, pressure sensor, air-in-line detector), FPB
MRZ	Accessories, Pump, Infusion	None
FLL	Thermometer, Electronic, Clinical	Temperature sensor
FMG	Stopcock, I.V. Set	None
FOZ	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	None
FPA	Set, Administration, Intravascular	None
FPB	Filter, Infusion Line	Filter
FPK	Tubing, Fluid Delivery	None
KPE	Container, I.V.	None
PND	Midline Catheter	None
PWH	Administrations Sets With Neuraxial Connectors	None
PYR	Neuraxial Administration Set - Intrathecal Delivery	None
KXG	Applicator, Absorbent Tipped, Sterile (Swabs, General Hospital)	None
FYE	Dress, Surgical	None
FYF	Cap, Surgical	None
FXO	Suit, Surgical	None
FXP	Cover, Shoe, Operating-Room	None
FYA	Gown, Surgical	None
FRF	Medical Recirculating Air Cleaner	Filteration media
CAH	Filter, Bacterial, Breathing-Circuit	Filteration media
FMC	Patient Examination Glove	None
FME	Gown, Examination	None
FXX	Mask, Surgical	None
FXY	Hood, Surgical	None
FXZ	Helmet, Surgical	None
FYB	Gown, Patient	None

PROCODE	PREFERRED NAME	CRITICAL INPUTS
FYC	Gown, Isolation, Surgical	None
KGO	Surgeon's Gloves	None
LGM	Chamber, Patient Isolation	Air filter, air supply blower
LGN	Chamber, Patient Transport Isolation	Air filter, air supply blower
LYU	Accessory, Surgical Apparel	None
LYY	Latex Patient Examination Glove	None
LYZ	Vinyl Patient Examination Glove	None
LZA	Polymer Patient Examination Glove	None
MSH	Respirator, Surgical	Filtration medium
OIG	Powder-Free Guayle Rubber Examination Glove	None
OPA	Powder-Free Non-Natural Rubber Latex Surgeon's Gloves	None
OPC	Powder-Free Polychloroprene Patient Examination Glove	None
OPH	Radiation Attenuating Medical Glove	None
OXZ	Pediatric/Child Facemask	None
NZW	Vascular Access Flush, Heparin	None
NGT	Vascular Access Flush, Saline	None
MGR	Dressing, Wound And Burn, Interactive	None
OEA	Non-Surgical Isolation Gown	None
NQR	Sealant, Dural	None
JJH	Clinical Sample Concentrator	None
JKA	Tubes, Vials, Systems, Serum Separators, Blood Collection	None
JSM	Culture Media, Non-Propagating Transport	None
KDT	Container, Specimen Mailer And Storage, Sterile	None
OEP	Influenza A Virus Subtype Differentiation Nucleic Acid Assay	DNA primers, DNA probes, polymerase
OTG	Non-SARS Coronavirus Multiplex Nucleic Acid Assay	DNA primers, DNA probes, polymerase, KDW, KST, LXG
OZE	Influenza A And Influenza B Multiplex Nucleic Acid Assay	DNA primers, DNA probes, polymerase
PFT	Reagents For Molecular Diagnostic Test Systems	None
PRA	Virus Nucleic Acid-Based Detection Assay	DNA primers, DNA probes, polymerase
PPM	General Purpose Reagent	None
PSZ	Devices Detecting Influenza A, B, And C Virus Antigens	Cartridges
QBD	Microbial Nucleic Acid Storage And Stabilization Device	None
QDS	MERS-CoV And Common Respiratory Pathogens Semi-Quantitative And Quantitative Multiplex Nucleic Acid Detection System	DNA primers, DNA probes, polymerase
QID	Device To Detect Antigens Of Biothreat Microbial Agents In Human Clinical Specimens	Cartridges, nitrocellulose membrane
QIF	Device To Detect And Identify Biothreat Microbial Agents In Human Clinical Specimens	DNA primers, DNA probes, polymerase
OOI	Real Time Nucleic Acid Amplification System	General purpose equipment (LXG)
LIO	Device, Specimen Collection	None
OCC	Respiratory Virus Panel Nucleic Acid Assay System	DNA primers, DNA probes, polymerase

APPENDIX D: DOD JOINT DEPLOYMENT LIST

The DoD Joint Deployment List consists of several documents including the Joint Deployment Formulary (JDF), the Time-Phased Force and Deployment List (TPFDL), and the Joint Deployment and Distribution Enterprise (JDDE). It has been reported that the "DoD has a high dependence on foreign material and trade agreements to maintain current pharmaceutical capabilities."[66]

The JDF encompasses a wide range of medications and medical supplies that are sent on all operations and deployments. Products include:[67]

- Analgesics - for pain management
- Antibiotics - to treat bacterial infections
- Antivirals - for viral infections
- Vaccines - to prevent disease outbreaks
- Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasures - for defense against CBRN threats

The TPFDL are components of an operation plan that vary from operation to operation. They often include:[68]

- Medical units (e.g. field hospitals, surgical teams, etc.),
- Medical equipment and supplies,
- Items on JDF, and
- Medical assemblages

The JDDE plays a role in organizing and executing global patient movement, medical logistics, and supporting health systems during deployments and crises.[69]

66 From *FY23 NDAA Sec. 860: Risk Management for DoD Pharmaceuticals*, by U.S. Senate, Office of Senator Elizabeth Warren, 2023. (https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmceuticals1.pdf).

67 From *Joint Deployment Formulary (JDF)*, by Defense Health Agency, 2023, U.S. Department of Defense. (https://www.health.mil/-/media/Files/MHS/Policy-Files/SignedandDatedDHAPM643008JointDeploymentFormularyJDF.ashx).

68 From *Deployment Health Guide: A Soldier's Handbook for Recognizing and Managing Health Threats During Deployment (ATP 4-02.8)*, by U.S. Army Public Health Center, 2025, U.S. Department of the Army (April). (https://api.army.mil/e2/c/downloads/2025/04/16/af071d4f/25-08-648-deployment-handbook-apr-25-public.pdf).

69 From *DoD Instruction 5158.06: Director of the Defense Health Agency (DHA)*, by U.S. Department of Defense, 2018 (November 15). (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/515806p.pdf?ver=2018-11-15-150218-933).

APPENDIX E: BIOGRAPHIES OF THE AUTHORS

James G. Scott, JD

James "Jim" G. Scott, President & CEO of Applied Policy, founded the company in 2009 from a desire to apply his in-depth knowledge of federal health policy and help healthcare providers and companies succeed. As a respected member of the health policy community, he offers valuable experience and access to key players in government and industry.

Prior to founding Applied Policy, Jim helped introduce optimal Medicare coding and coverage for all Hoffmann-La Roche pharmaceutical products. While at Roche, he also worked to resolve Medicare and Medicaid reimbursement issues at the federal level and served as the pharmaceutical manufacturer's principal contact with the Centers for Medicare & Medicaid Services (CMS).

Jim served as Senior Legislative Advisor at CMS, advising the CMS Administrator on congressional intent in implementing the Medicare Modernization Act of 2003 and engaging Members of Congress in the implementation process. He received agency-wide awards for his work with Congress in 2005 leading to successful implementation of the new Medicare prescription drug benefit and with congressional appropriators on the Fiscal Year 2006 President's Budget request.

Prior to his service with CMS, Jim was an Assistant Counsel with the Office of the Legislative Counsel of the U.S. Senate, where he was a principal drafter of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 along with other Medicare legislation. Jim and his work were recognized through the unanimous passage of a Senate Resolution and in numerous statements by Senators and Representatives printed in the Congressional Record.

Jim serves on the Board of Directors of the Alliance for Aging Research, founded the Northern Virginia Health Policy Forum, and is a member of the Steering Committee of the Partnership for a Healthier Alexandria.

Linda Rouse O'Neill

Linda Rouse O'Neill is Vice President of Health Policy at Applied Policy. Her understanding of regulatory and legislative issues affecting the healthcare sector is informed by more than 30 years of experience in government affairs and healthcare policy. Linda specializes in Medicare reimbursement for medical devices, preparedness and medical product supply chain.

Before joining Applied Policy, Linda spent 14 years at the Health Industry Distributors Association (HIDA), rising to Senior Vice President of Supply Chain Policy. Throughout her tenure, she worked closely with medical product manufacturers and distributors to address key supply chain challenges, including tariffs, transportation, domestic production, and Medicare reimbursement. She also cultivated strong partnerships with the Administration for Strategic Preparedness and Response (ASPR), managing a $2 million collaborative agreement.

Linda previously worked on Capitol Hill as a legislative assistant to a member of the Senate Finance Committee, analyzing and advising on health legislation and amendments. Her focus on rural provider reimbursement during this period extended to serving as co-staff director for the Senate Rural Health Caucus. She later served as Director of Federal Affairs for one of the nation's largest group purchasing organizations, leading policy initiatives on value-based purchasing, hospital infection control and unique device identification.

Linda holds a Bachelor of Arts in American history and journalism from the University of Albany and a Master of Arts in legislative affairs from The George Washington University.

Sabrina Luther

Sabrina Luther is a Health Policy Associate at Applied Policy where she performs research and analysis on a variety of topics, focusing primarily on durable medical equipment and medical diagnostics.

Sabrina holds an Honors Bachelor of Arts in Biological Sciences and Liberal Studies from the University of Delaware Honors College where she graduated cum laude, with minors in Public Health and Public Policy. She also studied at Sidney Kimmel Medical College at Thomas Jefferson University.

Sabrina's work in health policy is informed by her understanding of clinical perspectives and her experience in qualitative and quantitative research and analysis. She has previously been recognized for her work investigating adolescent attitudes towards breast-feeding and has successfully employed projection models to evaluate the cost effectiveness of a hospital's GI program protocol.

William Rogers, MD

Dr. William "Bill" Rogers brings more than 40 years of clinical experience to his role as Applied Policy's Chief Medical Officer. He spent 15 of those 40 years managing emergency departments, giving him a detailed understanding of the impact of regulation and reimbursement policy, which he shares with the clients of Applied Policy.

Prior to joining Applied Policy, Bill spent 14 years at CMS, during which time he served as an interface between the agency and the clinicians who care for Medicare patients. In this role, he was involved in the breadth of CMS functions, from writing regulations to ensuring that audit activities were fair and effective. He served as the ICD-10 Ombudsman, and he chaired the Physician and Allied Health Open Door Forum, the Ambulance Open Door Forum, and the First Fridays meeting with medical specialty groups and other stakeholders with an interest in CMS policy.

Bill also served on the Recovery Audit Contractor New Issues Review Board and directed the Physicians Regulatory Issues team. As director of the Physicians Regulatory Issues team, Bill served as an interface between clinicians and the Medicare and Medicaid programs. He coordinated the resolution of problems brought to his team by medical specialists, mid-level providers, ambulance services, rural health clinics and many other entities which in one way or another provide care to Medicare and Medicaid beneficiaries.

While at CMS, Bill continued to practice emergency medicine as a Clinical Assistant Professor at Georgetown University. In January of 2017, he moved to New Orleans, where he served as the Director of Emergency Services at the New Orleans VA medical center and is a Clinical Assistant Professor of Medicine at LSU. As a colonel in the U.S. Air Force, Bill served as State Air Surgeon for the D.C. Air National Guard.

Simay Okyay McNutt, MPH

Simay Okyay McNutt is a Senior Health Policy Manager at Applied Policy, leading the durable medical equipment and MedTech portfolio. Simay specializes in strategy development for federal market access including coding, coverage and reimbursement in Medicare and Medicaid.

At Applied Policy, Simay has overseen numerous successful Medicare coverage expansions of medical technologies and completed dozens of successful coding applications. Her experience includes an emphasis on health policy and advocacy, developed through her work in collaborative strategy building.

Simay currently serves on the Policy Committee for American Public Health Association's Aging and Public Health Section. Prior to joining Applied Policy, she worked as a certified clinical medical assistant at a clinical practice. Simay graduated with a double major with a Bachelor of Science in Biological Chemistry and a Bachelor of Arts in Women, Gender and Sexuality from the University of Virginia. She holds a Master of Public Health from the Milken School of Public Health at George Washington University.

Sampat Nidadavolu, M.S., MBA

Sampat Nidadavolu is a Health Policy Manager at Applied Policy, specializing in medical devices. Prior to joining Applied Policy, Sampat worked at Palmetto GBA for over five years as the Biomedical Engineer for the Pricing, Data Analysis, and Coding (PDAC) contract. In this role, he supported the review of applications for Healthcare Common Procedure Coding System (HCPCS) code assignment and conducted research and analysis for CMS. His work focused on identifying testing and national and international standards for medical devices to aid in accurate HCPCS code assignments. Sampat also analyzed emerging technologies, including digital scanning and 3D printing, and explored such engineering concepts as durability and rigidity in policy contexts. His work contributed to the development of precise coding guidelines and improved policy decision-making.

Earlier in his career, Sampat served as an Application Support Engineer at Siemens, where he collaborated with clients across industries, utilizing simulation modeling to perform engineering analyses and support a range of projects.

Sampat earned a Bachelor of Science and a Master of Science in Biomedical Engineering from the University of Connecticut. He holds a Master of Business Administration from the University of South Carolina, where he also completed a Graduate Certificate in Business Analytics.

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