2024
eBOOK

Reshoring manufacturing: Progress and challenges

ENDEAVOR BUSINESS MEDIA

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When the pandemic hit and Americans found themselves looking to China for critical supplies, the idea of reshoring — a concept that had drifted along the currents of the manufacturing sector for over a decade — embedded itself into the country's discourse with renewed vigor.

While the reshoring movement had started in 2010 as a mission to "bring good, well-paying manufacturing jobs back to the United States," its most recent revival positions the initiative as a strategic opportunity to improve product quality and consistency, combat the risk of geopolitical disruptions and take advantage of lucrative federal contracts and local tax incentives.

Reshoring has found some of its most fervent supporters inside the halls of both Congress and the White House, with leaders putting forth a rush of 'America first' legislation.

With government policies, initiatives and funding in place across all sectors of manufacturing, now comes arguably the most vital phase of U.S. domestic manufacturing efforts — implementation.

As the manufacturing sector juggles timelines, logistics and budgets, will domestic manufacturing prove self-sustaining?

This ebook aims to provide a collective analysis of reshoring efforts across several major manufacturing industries — wastewater, pharmaceutical, semiconductor, chemical and plastics — to paint a cohesive picture of the country's reshoring challenges and progress.

— Karen Langhauser,
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A RECKONING FOR MANUFACTURERS

Build America, Buy America's intentions are noble, but its implementation and guidance stand on rocky ground for original equipment manufacturers in the water sector

"A noble cause, but it's never been made here."

"We make everything in the U.S., except the electronics."

"U.S. manufacturing can't keep up with the demand."

These are example quotes, themes and statements one tends to hear when asking original equipment manufacturers (OEMs) serving the industrial water sector to share their sentiments on Build America, Buy America (BABA), a domestic preference law codified in the Infrastructure Investment and Jobs Act (IIJA), the largest infrastructure investment package in United States history.

BABA implementation could prove a critical step toward reshoring the country's lost manufacturing

competencies. Manufacturers agree that domestic preference of U.S. manufacturing can be the shot in the arm for the U.S. economy. It will establish pride in U.S. infrastructure, create American jobs and grow the working middle class.

What they do not agree with is the timeline and implementation of the domestic preference law, particularly in regard to the manufactured products category. In the water sector, this category of the law pertains to engineered products used to manage municipal water in industrial facilities, such as blowers, headworks equipment, control cabinets, metering devices, packaged systems and more.

The refrain from manufacturers who make these products and equipment echo the same sentiment. "I don't know if you've ever heard the phrase, 'Ready, fire, aim,' but that's how I feel BABA was implemented," said Paul Gifford, director of infrastructure products for Mueller Water Products. "I'm glad it's happening. I just wish it wasn't so hard."

Tom McCurdy, Aerzen USA regional sales manager and vice chair of the Water and Wastewater Equipment Manufacturer's Association (WWEMA) — the voice of water manufacturers on Capitol Hill — echoes that sentiment. "The whole idea is great on the campaign trail, but implementing it is another thing entirely," said McCurdy.

"We're happy that they're taking this initiative," said Marian Widdel, administrative manager for Lakeside Equipment Corporation. "We just wish that they had kind of thought it out a little better, a little more thoroughly, but we're happy that they're taking the initiative of bringing [manufacturing] back to the USA."

Nuts and bolts and little headaches

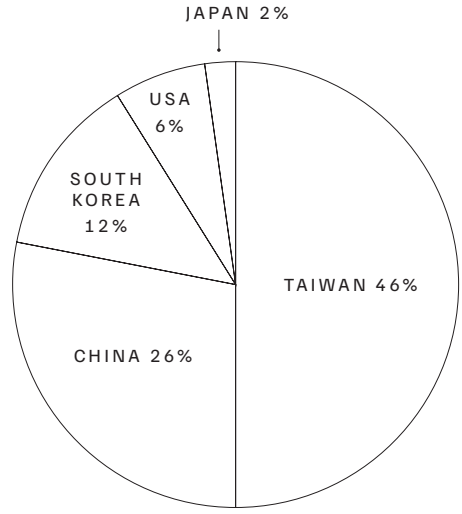
BABA went into effect on May 2022, requiring 55% of products used in federally funded projects — even if as little as $1 had been used — to be domestically manufactured.

This calculation to reach 55% is done through the cost of components of a product without the inclusion of labor. Guidance on the scale at which this calculation should be done — down to individual components on a circuit board or the board with the small components on it, for example — went unanswered for more than a year.

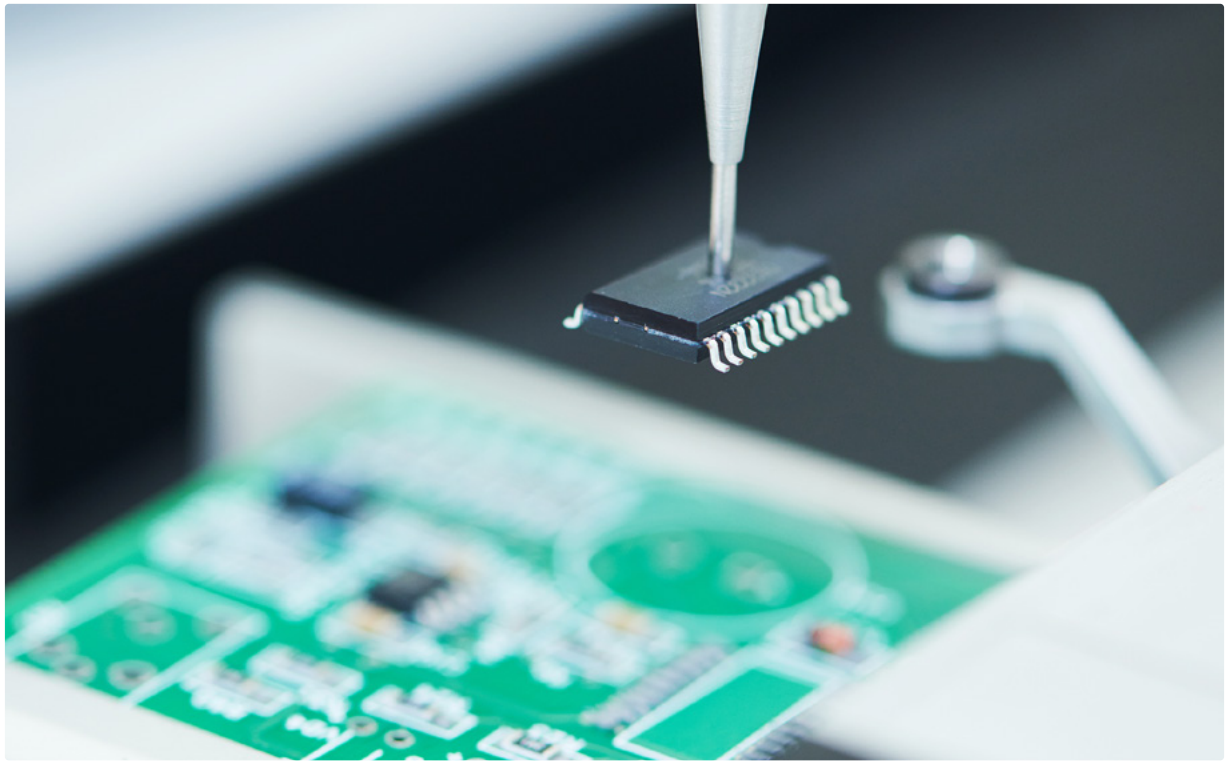
For manufactured products in the water sector, guidance was necessary. OEMs were left questioning how to calculate 55% of a manufactured product like a blower when it has hundreds of components, how far down they go when considering something a component, and what about things such as nuts and bolts?

To compensate, U.S. EPA established a waiver for projects that utilities had initiated prior to the effective date, which allowed

Global semiconductor foundry capacity by country 2023



While the total capacity of semiconductor manufacturing looks bleak for the U.S. in 2023, the CHIPs Act and onshoring of manufacturing has primed America to earn 17% market share for mature and advanced semiconductors by 2027, according to TrendForce.



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those projects to ignore the rules of BABA because they started planning on it prior to the law going into effect. Even something as simple as an inquiry into the design of the project with an engineer qualified for these waivers. Because water infrastructure projects have such long timelines, water and wastewater utilities, engineers, consultants and manufacturers have been able to ignore the law for the better part of the past two years.

But those projects will dry up, and manufacturers are wise to the challenges with onshoring manufactured products in the U.S. when so much of the water industry's innovation comes from overseas. Furthermore, water projects will be competing for the same resources as the transportation sector, which received ten times as much funding as the water sector in the IIJA.

Mueller's Gifford said one of the challenges is simply the nuts and bolts for products. Like the waiver previously mentioned, EPA also established the "Minor (Ferrous) Components of Iron and Steel Product General Applicability Waiver." This waiver allows a product to ignore nuts and bolts up to 5% of product material cost when it is in the public interest to do so. This waiver, however, does not always apply, which creates complications in some instances.

"We had one product, a brass product, that just had one screw that was imported, a steel screw, and for that project we couldn't use that screw," Gifford said. "And finding that particular screw [manufactured in the U.S.], it took us months to find somebody who was making that."

Mueller has invested millions into its U.S. manufacturing capabilities, including a brass foundry that began construction in 2019 that would employ 250 people, making it one of the largest finished-goods brass foundries in the world.

For manufacturers like Mueller, BABA is a headwind, but a surmountable challenge. For others, it could be a reckoning.

> **The whole idea is great on the campaign trail, but implementing it is another thing entirely.**
>
> – Tom McCurdy

Semi-ready semiconductor manufacturing

Brands that have a long and proud history of being U.S.-made, such as Mueller Water Products and Lakeside Equipment Corporation, are better prepared than others.

In the case of Mueller, it onshored all its capabilities, consolidated manufacturing, and built a brand-new foundry in Decatur, Illinois, to ensure its products would meet BABA requirements. Lakeside, on the other hand, continued to leverage its in-house U.S. staff in Bartlett, Illinois, to design its products, which are then constructed at a facility in Iowa that proudly sources Made in USA materials. Lakeside Equipment has taken pride that it designs, sources and builds its equipment in the U.S. with these partners — business relationships that date back to the 1930s.

Where these companies say they run into issues with BABA is with the introduction of electronic equipment such as semiconductors. Units that have automation capabilities, sensors that collect and relay data to SCADA systems, or any other use of controllers are considered vital for their businesses to remain competitive.

"That's our main concern right now is that control panel," Widdel said. "Those components, those PLCs, the VFDs, they just aren't made in the United States. And so as much as we would love to say, 'Yeah, bring it on,' we're not exactly sure where to find what we need. Our control manufacturer is always looking."

The demand for these kinds of components and capabilities continues to grow, but U.S. semiconductor manufacturing is not yet prepared for prime time. Industry Week, an Endeavor Business Media brand, reported that the U.S. only makes 12% of the globe's total chips, down from 37% in the 1990s. As a result, manufacturers in the U.S. have relied heavily on imports from Asia, where almost 90% of the most advanced and profitable chip designs are manufactured, according to data from TrendForce, an organization that conducts research on business trends.

Evidence of this imbalance of production capability was most noticeable during the COVID-19 pandemic, in which chip prices surged. A notable example were computer graphics cards produced by Nvidia, which jumped to double or triple their MSRP during periods of the pandemic due to shortages from manufacturing shutdowns in Asia.

With the injection of $50 billion for water infrastructure in the 2022 IIJA, utilities have sought better automation and have placed a renewed focus on artificial intelligence and machine learning technologies. As such, a surge in demand for semiconductors is imminent if not already present.

The CHIPS Act has spurred the construction of semiconductor plants in the U.S., but they are not yet ready to meet that demand.

"You can't just snap your fingers and say, 'OK, let's go,'" Widdel said. "You have to give it the time to build and form and become reliable and get their name out there … and then have the supply chain for that. But you know what that does to our supply chain? Longer lead times, and all those things that now we face because everybody is here and everybody's getting the same piece of equipment."

With limited domestic capabilities, manufacturers in the water sector that are integrating chips into their systems anticipate bottlenecks in the supply chain. Data from TrendForce shows the U.S.

has a 12% market share for advanced process nodes (≤16/14 nanometer nodes) but the U.S. is primed to increase that to 17% by 2027.

"Having talked to the meter guys, we have the same problems with electronics, [and] communications gear in that we don't make any of those things," Gifford said. "It's all purchased [by] buying printed circuit boards, and where those components came from, we didn't know."

Gifford said a great deal of his and his teams' work over the past two years was focused on identifying where the individual components of its products were sourced, a practice that had never been done before. He said some of the smarter products — automation and data relaying equipment — that use semiconductors and circuit boards do not comply with BABA. Despite the U.S. poured and smelted brass, adding these boards into a smart meter shift the cost structure of the product into non-compliance.

"That is probably pretty typical across the technology space," Gifford said, "and so customers are probably seeking waivers for those products when projects include them. How long that goes on? I don't know."

U.S. affiliate scrambles to protect American workers

While domestic manufacturers have some gripes with supply chain and the nuanced language of the law, international manufacturers with a presence in the United States are concerned for the future of their U.S.-based business lines.

As vice chair of WWEMA, McCurdy has been highly involved in the association's conversations on Capitol Hill and with U.S. EPA about BABA because the law directly impacts the business for which he is employed, Aerzen USA. Aerzen is a German-based blower manufacturer. Some of its products' components are manufactured in the U.S. while others are manufactured in Germany, shipped to the U.S. and are assembled by American workers.

McCurdy stressed that the realities Aerzen is facing are being faced by some of its competitors in the blower space, but that the manufactured products category extends beyond just blowers and into many other categories of engineered equipment in the U.S.

Those products include headworks and degritting equipment manufactured by Huber, the North American member of The Huber Group based in Bavaria, Germany. Henk-Jan van Ettekoven, president of Huber Technology, said he and his parent company took the matter of BABA seriously from the jump and invested in U.S. manufacturing capabilities.

"We planned and invested a total of $50 million in complete manufacturing for ALL HUBER products so that we are in compliance," van Ettekoven said. "This was done with an aggressive schedule and we are fully operational."

For Huber, which unveiled its new Denver, North Carolina facility in April, the greatest challenges in this transition were hiring of personnel, transforming measurements from metric to imperial and a limited one-year span for knowledge transfer while still maintaining regular orders of business.

The pain point for companies like Aerzen is the inability to count labor in the calculations to reach the 55% domestic preference threshold.

"In Coatesville, Pennsylvania, we have 100-some odd people there," he said. "If we could no longer participate in the U.S. market because of the domestic compliance issue, we're talking about laying off U.S. workers, which is completely counter to the intent of the bill to put more Americans to work."

Adding to Aerzen's business challenges with BABA, more than one blower company has claimed complete BABA compliance, meaning EPA cannot issue a general non-availability waiver for the category of blower products. A non-availability waiver can be issued by EPA if certain products are not made in the U.S. or if the supply chain is not sufficient to handle the demand.

> **Any action that positively addresses America's decaying infrastructure is better than no action.**
>
> – Paul Gifford

"These guys at EPA, they have to thread a needle here," McCurdy said. "They know what works for the industry. They went through it with ARRA [American Recovery and Reinvestment Act], with the whole substantial transformation aspect of it. They went through it with the AIS [American Iron and Steel] Act where they completely exempted manufactured products, but that's all off the table."

Faced with this looming problem, McCurdy and the U.S. team at Aerzen are looking for ways to reposition or adjust its market strategy to remain relevant to the U.S. market while minimizing the challenges it foresees with BABA.

Some of the products in Aerzen's catalog already likely comply with BABA. The air-end of the blower, McCurdy said, is imported from Germany where it is manufactured with precision casting, molds, forgings for tight tolerances. The rest comes from domestic suppliers.

Aerzen purchases the package components from Germany where the company can buy them by the thousands for bulk discounts. Aerzen could consider sourcing them locally, but it would come at increased costs.

"It raises our cost because we're not buying in quantity and we have to watch the quality of manufacturing very closely to make sure that it meets our overall package quality standards," McCurdy said. "Depending on the size, it can add 30 to 50% to the cost."

Another option is repositioning its products to be purchased and specified by another manufacturer into a larger overall product. In doing so, it could mean that larger product complies because the mix of foreign and domestic components have shifted the cost structure into the realm of compliance. Aerzen has not made any final determinations on how it will address BABA.

The waiver well is running dry

Gifford said he expected 2024 to be the year in which he would start seeing BABA compliance added to bid documentation and project specifications, but the uptake has been slower than anticipated. The general applicability waiver for projects initiated prior to May 2022 has seemingly staved off the inclusion of this compliance language.

"BABA requirements haven't really hit a huge percentage of jobs yet," Gifford said, "but they're going to start to see that soon, probably in the next six to 12 months. Companies that are importing are going to notice the impact of not having domestic product."

Widdel shared a similar sentiment to the current waivers.

"We've had a couple [projects] that have come through with waivers because of public need," Widdel said. "They can't wait, and that public need one is the big one."

The public need waiver to which Widdel referred is the "Public Interest: Small Project General Applicability Waiver," which waives BABA for small projects when it is in the best interest of the public to do so.

The timeline for these infrastructure projects is years long. The number of projects initiated after the May 2022 effective date may finally be reaching the stage where BABA compliance is being requested more often. From a business opportunity and growth standpoint, Gifford said the IIJA does

not always have an additive effect on the market's buying power. Utilities in several cases have replaced the bond or loan for which they were previously going to apply with the federal funding they have received instead. In other cases, utilities have used federal funding to make a project bigger rather than conduct or initiate additional projects on separate timelines.

BABA only applies to projects that receive federal funding, meaning local bank loans, certificates of deposits or bonds alone would not necessitate BABA requirements. Grants or loans from the Department of Energy, funding from Housing and Urban Development, or even the most common vehicle, Drinking Water and Clean Water State Revolving Funds, all do force BABA compliance, however. Gifford expects to see BABA included on every specification over the long term.

"With AIS, utilities get it in their specifications, and they just leave it there," Gifford said. "When they get switched over to BABA … they'll just leave it."

Despite those challenges, manufacturers all recognize the good BABA will create over the long term. The pains now are worth the future vision they can see for America.

"Any action that positively addresses America's decaying infrastructure is better than no action," Gifford said. "BABA requirements will ensure that the USA will have the capability, if not the capacity, to build our own infrastructure, including all the critical components, which in the end makes it a stronger nation."

Michael Annino | Shutterstock-AI

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MINING THE RESHORING RUSH

It's time for the U.S. to sift through domestic drug manufacturing efforts

When the pandemic hit and Americans found themselves looking to China for critical medical supplies, the idea of reshoring — a concept that had drifted along the currents of the manufacturing sector for over a decade — embedded itself into pharma discourse with renewed luster.

Reshoring found some of its most fervent supporters inside the halls of Congress, with leaders touting the idea as a catch-all cure to pharma's longstanding supply chain ills and putting forth a rush of legislation. The solution also had a champion in the White House, with President Trump, just months into the pandemic, issuing a controversial 'Buy American' executive order mandating that essential drugs and medical supplies purchased by the federal government be manufactured domestically.

The country's reshoring fever has persisted into the Biden administration, with the president invoking the Defense Production Act, a Truman-era policy, to unlock government investment in the domestic manufacturing of essential medicines, countermeasures and critical inputs last November.

Phlow's Virginia-based manufacturing infrastructure is strategically designed to support R&D and manufacturing scale up for small and large commercial volumes.

As Mark Twain once said, "During the gold rush it's a good time to be in the pick and shovel business." And for the handful of pharma stakeholders willing to get on board with the reshoring effort, the government — through the Department of Health and Human Services' (HHS) Administration for Strategic Preparedness and Response (ASPR) — has offered lucrative incentives. ASPR's Biomedical Advanced Research and Development Authority (BARDA) has awarded contracts totaling more than $2.1 billion to expand domestic production of pharma ingredients and related supplies for pandemic response and build future capacity. ASPR's newly created Office of Industrial Base Management and Supply Chain (IBMSC) has invested over $17 billion across 87 contracts to expand the U.S. industrial base for key materials and products.

"There's certainly a lot of activity in this space right now and a tremendous amount of money that's being thrown at it. And you're seeing bits and pieces of it take hold," says Bikash Chatterjee, president and chief science officer at Pharmatech Associates, a USP company.

The government's investments into generic drugs and APIs have created an air of excitement surrounding the westward migration of manufacturing. But health care economists, such as Marta Wosińska, who currently serves as a senior fellow at the Brookings Institution Center on Health Policy, are worried about what comes next.

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>
> – Marta Wosińska

"If I were a manufacturer and the government were to offer me a bunch of money to build a facility, I would be asking a lot of questions about whether that's going to be enough for me to be competitive in the market after," says Wosińska.

While many of the companies who received these contracts have managed to deliver on their initial promises, they are now faced with the daunting task of remaining self-sustaining as the dollars dry up.

Now comes arguably the most vital phase of U.S. domestic manufacturing efforts — figuring out where to get the most lasting bang for our reshoring bucks.

"There's an opportunity for the U.S. government to be much more strategic about this. Think about which supply chains, which players, and how to think holistically about not only infrastructure but also follow-on," says Wosińska. "If it's not systematic, the government can very easily end up spending a bunch of money and accomplishing very little."

With the pandemic finally in our rearview, the U.S. has what many industry insiders see as a golden opportunity to candidly assess pharma's reshoring progress — and create a more formal plan for supply chain resilience.

Panning the lists

Given the sheer enormity of the pharma market, it's easy to imagine how quickly spending on domestic manufacturing will escalate if left unchecked.

"There are around 2,800 generic API molecules on the U.S. market. There's tens of thousands of drugs on file with the FDA. So where do you start?" asks Kevin Webb, chief operating officer at the API Innovation Center (APIIC), a St. Louis-based nonprofit formed in 2021 to help lead U.S. efforts to reshore APIs. "Initially it was just 'throw a lot of money at it, fix the problem.' But now the position that the administration and Congress is taking is that we need to be more tailored in our approach."

Among the supply chain issues currently in need of resolution, no problem has garnered more widespread attention than drug shortages — which has made shortage lists an attractive starting point for reshoring efforts. Currently, the FDA is tracking over 120 drug shortages (reported at the molecular entity level). According to the American Society of Health-System Pharmacists (ASHP), ongoing and active shortages have reached a record high in the U.S. Per ASHP's list, which reports shortages at the drug preparation level, there were 323 active shortages during the first three months of 2024 — largely involving the same molecules that FDA is tracking.

Because the lists include vital drugs such as chemotherapies, antibiotics and emergency medicines used on hospital crash carts, finding a fix has resulted in a flood of Congressional hearings, reports and proposed policy solutions. But the idea of reshoring has been a consistent part of these discussions, and in some ways, constantly pushing domestic manufacturing as the remedy for all that ails the pharma supply chain has diluted the movement's mission.

"When I testified with Senate Finance Committee, we were talking about shortages of generic sterile injectables, which are largely made in the U.S. and in Europe. But senators make their statements and

it seemed like their solution often was 'we should onshore' as if that alone would solve the problem," says Wosińska.

Wosińska, who served as economic advisor to the U.S. Senate Finance Committee and has spent over a decade doing policy work on drug shortages and supply chain resilience through positions at the FDA and HHS, is among those trying to help the government prioritize its supply chain spending. And for Wosińska, using reshoring as the primary means to trim the drug shortages list doesn't add up. According to Wosińska, current persistent shortages are caused by a race-to-the-bottom in pricing, not geopolitical risk, which makes reshoring a mismatched solution.

The countless drug shortage reports that have been released by various organizations and sectors of the government have reached similar conclusions: Factors that cause drug shortages are multifaceted and thus, solutions need to reflect the nature of each of those factors.

Because it stands at the intersection of so many supply chain issues, reshoring continuously runs the risk of losing focus, which makes the need to create a refined, targeted list crucial to the movement's momentum.

"We need to be strategic about which supply chains to prioritize for government support. Let's assess which products, if lacking, would have the largest consequences for our health care system," says Wosińska.

Efforts to do that have been underway. Currently there are a multitude of lists attempting to define 'essential' medicines. FDA's list, posted in October 2020, includes 227 drug and biological products deemed essential medicines, medical countermeasures and critical inputs. ASPR, in response to an executive order from President Biden, solicited input from various stakeholders to down select FDA's list to create a prioritized list of medicines that the government could target for domestic manufacturing. The list, published in a resilience assessment report in May 2022, included 86 medicines. At the time the report was created, half of those medicines were on a drug shortage list, highlighting the persistent and alarming overlap between shortages and essential medicines.

Those closest to the problem are calling for further refinement of reshoring targets, which would establish a 'vulnerable' medicines list. This list would look at the already established essential medicines lists overlaid with all possible supply chain vulnerabilities, creating a continually updated 'super list' of the most essential medicines facing the highest risk of shortage.

"You have to talk about vulnerable generics such as those that have been on the ASHP or FDA drug shortage list or a combination thereof and then further classify those drugs for which there is no American manufacturer and there is no clinical alternative," says Eric Edwards, co-founder and CEO at Phlow Corp.

Shortly after its inception in 2020, Phlow, a certified B Corp pharma manufacturer, made national headlines when it was awarded a $354 million contract from BARDA to procure medication for the Strategic National Stockpile (SNS) as well as build domestic infrastructure for advanced manufacturing of essential medicines.

"We need a global supply chain for resiliency, but we have lost our pharmaceutical sovereignty for these medicines, and we need to make them here again as a matter of national public health security," says Edwards.

Upstream and down

With efforts underway to narrow the reshoring list, experts stress the need to simultaneously broaden its scope.

LEGISLATION & DIRECTIVES

Coronavirus Aid, Relief and Economic Security Act

MARCH 2020

The CARES Act included several provisions regarding the supply chain: Additional drug/API shortage and sales volume reporting requirements, a mandate to develop redundancy risk management plans for each drug/API establishment, and a study on the national security and public health threats related to the pharma supply chain.

Ensuring Essential Medicines, Medical Countermeasures and Critical Inputs are Made in the U.S.

AUGUST 2020

The 'Buy American' executive order directed federal agencies to identify vulnerabilities in the supply chain, support domestic production through various investments, and prioritize the procurement of essential medicines, countermeasures and critical inputs from U.S. manufacturers. It also directed the FDA to identify a list of essential medicines.

America's Supply Chains

FEBRUARY 2021

The EO initiated a government 100-day review of U.S. industrial supply chains, among them pharmaceuticals and APIs. The order directed HHS to create a one-year report on the public health supply chain and industrial base outlining successes and strategies.

Advancing Biotech and Biomanufacturing Innovation for a Sustainable American Bioeconomy

SEPTEMBER 2022

The EO laid out a vision for a whole-of-government approach to advance biotech. It launched a National Biotechnology and Biomanufacturing Initiative to ensure that the U.S. had the domestic capacity to make bio-based products. Included was also a $40 million investment in biomanufacturing for APIs, antibiotics and relevant KSMs needed for essential medications and pandemics.

"If you onshore APIs, but your starting ingredients still come from China, then what problem did you solve?" probes Wosińska. "When you are thinking about domestic manufacturing, it's a more complex system."

Currently, much of federal policy focus has been on repatriating generic drugs and APIs, but stakeholders have realized that in order to achieve true sovereignty, reshoring efforts must reach further into the supply chain — both upstream and down.

Phlow's government-backed program initially focused on surge response to the pandemic. The company procured 2 million doses of medications from various manufacturers in shortage for patients hospitalized with COVID-19 and delivered them to the SNS. But in doing so, Phlow recognized that the SNS was not set up to facilitate the rapid production of essential medicines because it was lacking starting materials and ingredients.

Working alongside BARDA and ASPR, Phlow built a Strategic API Reserve (SAPIR) to store and supply critical starting materials and active ingredients that can be rapidly converted to finished essential medicine if needed. Phlow also built two new facilities, a kilo-scale facility and a metric-ton scale facility, that are both capable of manufacturing necessary components to make drugs: key starting materials (KSMs), intermediates and APIs.

Biden's use of the Defense Production Act last November specifically acknowledged the importance of these KSMs, a crucial component of APIs, in supply chain security by including a $35 million investment in their domestic production.

Also vital to the drug supply chain are excipients, which are included alongside the APIs in formulations and are necessary to enhance stability and bioavailability of the finished drug products.

A deep dive into pharma supply chains for the purpose of repatriating its various

LEGISLATION & DIRECTIVES

Consolidated Appropriations Act

DECEMBER 2022

The omnibus appropriations bill included $1.7 trillion in fiscal year 2023 discretionary government funding, as well as a number of other health care provisions. The bill contained important reforms relevant to the FDA, including FDORA, which directed the agency to establish advanced manufacturing centers of excellence and an advanced manufacturing technologies designation program.

Bold Goals and Priorities to Advance American Biotechnology and Biomanufacturing

MARCH 2023

In response to the executive order issued in September 2022, this initiative set ambitious national targets for the next two decades to help establish R&D priorities. Specifically for pharma, it aimed to deploy broad synthetic biology and biomanufacturing capabilities in the U.S. within five years to produce 25% of all APIs for small molecule drugs.

Actions to Strengthen America's Supply Chains

NOVEMBER 2023

During the inaugural meeting of the White House Council on Supply Chain Resilience, 30 actions designed to strengthen supply chains across multiple industries were unveiled. Among them, the use of the Defense Production Act to make more essential medicines in the U.S. and mitigate drug shortages. This included $35 million for investments in domestic production of KSMs for sterile injectable medicines and the designation of a new Supply Chain Resilience and Shortage Coordinator.

constituents requires visibility into said supply chains — historically a stumbling point in the U.S. According to Edwards, while the country has made progress towards comprehending the API supply chain, that's where visibility ends. "We have a long way to go to truly understanding where the key starting materials and some of these constituent components are being manufactured."

Phlow has been working for years on mapping the extended supply chain for essential medicines, leveraging a variety of publicly available databases as well as private information from market research firms, manufacturers, distributors and others.

While the Federal Food, Drug and Cosmetic Act requires all API manufacturing facilities serving the U.S. market to register their locations with the FDA, the agency has lacked data on the actual volume of APIs that facilities are producing and how much is entering the U.S. market. When the Coronavirus Aid, Relief and Economic Security (CARES) Act was signed into law in March 2020, the $2.2 trillion economic stimulus bill included a provision that requires all manufacturers of drugs and APIs to report drug volume details to the FDA via a dedicated portal.

Taking that idea a step further, last year, legislators introduced a bipartisan bill — Mapping America's Pharmaceutical Supply (MAPS) Act — that would require HHS to update its essential medicines list, creating a federal database to map the origin of each drug, the location of the facilities involved in the production of the KSMs and excipients needed to produce the APIs and finished dosage forms, as well associated inspections and recall alerts.

"We've done a lot of work, but we still need to do more, especially as you start trying to go upstream and downstream across this opaque essential medicine

supply chain," says Edwards. "It's a critical task because to find an effective cure, you have to have an accurate diagnosis."

All that glitters

When it comes to building domestic manufacturing infrastructure, Uncle Sam has dug deep, trying to mitigate the supply disruptions caused by the pandemic while also investing in future capacity. But as with any government-backed model, there are concerns about long-term sustainability once the initial funding is drained.

Among those worries is the concern that if the government stands up facilities and then thrusts them into the open market, the companies will eventually fall victim to the same systemic economic issues that drove them offshore to begin with. In short, are we pouring money into a broken system?

"The mistake is thinking that if we build a new manufacturing plant, it's going to solve everything. It won't. Those companies that the government has funded or put money into, they risk falling into the same trap that everyone else has fallen," says Webb.

No one knows this better than the companies that are living this reality.

"Having the government step in and finance the build-out of advanced manufacturing facilities in the U.S. is an essential part of reshoring. But it's not everything," says Salvatore Mascia, founder and CEO of CONTINUUS Pharmaceuticals. "Once you build a facility, unless you have a take-off contract providing financial incentives to make these generic medications, then it's not going to be enough to resolve these problems."

In January 2021, the Department of Defense awarded CONTINUUS a $69.3 million contract to develop domestic production capabilities for critical APIs and final dosage generics using the company's proprietary integrated continuous manufacturing (ICM) technology. CONTINUUS, which was spun out of the Novartis-MIT Center for Continuous Manufacturing in 2012, had earmarked a portion of the money to build a first-of-its-kind GMP facility for critical generic sterile injectables — but things didn't go as planned.

The company ran into permitting issues linked to FEMA regulations, which triggered a 12-month delay and the decision to change the location of the expansion to a more expensive site. As the project budget increased, CONTINUUS struggled to attract interest from outside investors, eventually running out of money to build the plant, voiding a portion of the contract.

While all was not lost — CONTINUUS was able to use its ICM technology and develop the key synthetic manufacturing routes of some pandemic drugs that were in shortage in its lab and deliver these synthetic routes to the U.S. government, providing proof of concept for the company's platform — the situation highlights that federal infrastructure investments alone may not be enough to create a thriving domestic manufacturing sector.

Mascia says the economic realities of producing low-revenue generic drugs make for a difficult pitch to outside investors. The company has since pivoted away from generic drugs and is instead working with large pharma/innovators on new products.

"When we were working with U.S. government, our goal was to be a generic company — we wanted to build a GMP facility and commercialize generic products," says Mascia. "What we are focusing on right now involves working with pharma companies on new molecular entities that are not facing all this financial constraint."

Phlow, which represents both the greatest reshoring success story and the government's largest individual investment, has a government contract can be extended for up to a total of $812 million

For the top 100 generic medicines consumed by U.S. citizens, 83% have no U.S.-based source and another 11% have only one U.S.-based source.

– Cortellis Generics Intelligence, Clarivate

over 10 years to help maintain the company's system and supplies. However, the company's objective is to establish a sustainable commercial business.

To that end, in early 2022, Phlow launched a CDMO business to serve government entities as well as commercial pharma customers. With the U.S. government already a committed customer, Phlow has generated some commercial interest, delivering CDMO services in its lab and supporting customers with programs for both generic and innovator products.

But despite Phlow's laudable achievements, Edwards acknowledges the need for ongoing government support and says that certain incentives "would be huge" as the company continues to navigate the market.

"Government subsidies for us are just a starting point to help catalyze reshoring efforts for the essential medicines industrial base. But the government also must provide incentives to domestic manufacturers who are focused on going back to high quality manufacturing," says Edwards.

Those incentives could include things like tax breaks or loans to companies willing to repatriate the manufacturing of FDA approved medications. They also don't necessarily have to be in the form of cash. In its "Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain," the Association for Accessible Medicines suggests that the FDA could create regulatory efficiencies by forming an internal, intra-agency working group focused on helping to expedite reviews and approvals to onshore pharma manufacturing. Another option would be for the FDA to create regulatory vehicles that help reward domestic-made drugs. Creating a 'first generic that uses U.S. components' designation that comes with an exclusivity period could go a long way for companies in the highly competitive generics market.

Restoring luster to AMTs

Success in the reshoring movement hinges on the industry's ability to not only build back its capabilities when it comes to the generic drug supply chain, but also (to borrow the phrase) build back better.

"When you look at why companies moved overseas in the first place — lower labor rates, lax environmental regulations and heavy government subsidies — we can't compete against that, nor should we," says Webb. "In order to bring that back to the U.S., we need better technology and improved efficiencies. We have to be cost competitive."

To that end, no discussion of reshoring is complete without the mention of advanced manufacturing technologies, with the most popular tool being continuous manufacturing. Much like reshoring, continuous manufacturing is commonly offered up as a fix for pharma supply chain issues. The FDA in particular, through its Emerging Technologies Program as well as its newly created Advanced Manufacturing Technologies Designation Program, has supported the idea that continuous manufacturing, over time, could help prevent drug shortages caused by product quality and manufacturing problems.

"Thinking about onshoring the old way doesn't make sense. You still have all the process segmented and the underlying problems of batch manufacturing," says Mascia. "If you are going to onshore, you need to onshore in a new way."

But the idea of replacing outdated batch processing methods has existed in the pharma industry with marginal uptake for over two decades. While there have been a handful of innovator drugs approved using continuous methods, the generics industry has been a tougher sell.

On the innovator side, the robust ROI on branded drugs has enabled capex investments into different advanced development and manufacturing approaches. Yet for the highly competitive, low-margin generics industry, continuous might seem like an economic mismatch. "The generics industry, they don't touch that. There's been no incentives to invest in advanced technologies, so they've remained antiquated," says Edwards.

Last year, the Brookings Institute convened a group of experts from academia, industry, government and nonprofits to explore technology options for improving the resilience of generic drug manufacturing. During the workshop, generic drug leaders voiced concerns that the cost efficiencies captured by continuous manufacturing still fall short when compared with current models for generic drug production, including sourcing from foreign producers.

But continuous manufacturing proponents, Chatterjee among them, insist that with technology costs coming down and regulatory uncertainty surrounding those technologies lessened, there is a role for continuous to play in generic drug manufacturing.

"There's more than a wealth of generic drugs out there that could benefit from continuous, but it's just that activation energy to get management to realize that the upside far outweighs the downside," says Chatterjee. "The government is trying to incentivize folks to push in that direction to overcome their fears."

It's here that the reshoring movement has given continuous manufacturing new luster.

The infusion of government funds associated with reshoring has enabled companies like Phlow to de-risk that leap for generics. Phlow's goal, according to Edwards, is to take the best of what's happening with innovator drugs and apply it to generics, where the chemistry hasn't been looked at for decades.

And the results have been encouraging. Using continuous-flow processes and other green chemistry approaches, Phlow has been able to cut costs and waste, improve quality and yield, and offer a more environmentally friendly alternative to batch manufacturing for several different generic compounds.

"New chemistry, new process, new catalysts, new solvents and putting it into a manufacturing environment that requires less manual steps to take out some of that expensive labor. Now you're starting to become more cost competitive," says Edwards.

CONTINUUS has developed its own form of advanced manufacturing that the company calls integrated continuous manufacturing (ICM). Rather than just making the finished drug using a continuous process, ICM offers a single continuous end-to-end chain — from KSM to API to final dosage. The process is designed to increase quality and efficiency while reducing manufacturing costs and the exposure of supply chain components to geopoltical risks.

Those efficiencies alone, however, have not been enough to attract investment from the generics space. According to Mascia, CONTINUUS was able to develop a full end-to-end process for metformin, a key generic drug, through which the company demonstrated numerous operational benefits, including better speed and quality. But the client wasn't willing to invest in building a facility for continuous production of metformin, given the low profitability of the drug.

"That's where the hang-up is — capex activation energy," says Mascia. "And that's why it's important to have the government invest in this, because unless the government steps in and makes that investment, private investors will not do it for a low-profitability product."

Buying in

While the recent pitch for domestic manufacturing has hooked a diverse group of players — equipment suppliers, government, academic institutions, nonprofits, specialty manufacturers — global pharma companies have conspicuously kept their distance.

When the FDA solicited public commentary from stakeholders regarding the essential medicines list the agency had been directed to create through President Trump's 'Buy American' order, the industry wasted no time making it clear that forcing a domestic supply chain (in a pandemic no less) would likely just worsen problems.

"Use of overly broad and blunt instruments, such as the executive order, to encourage domestic manufacturing does not account for the realities, challenges, and nuances of pharmaceutical supply chains, or the actual risks of supply shortages. Such actions may actually result in market disruptions and product shortages," said Sarah Lieber, Sanofi's North America head of global regulatory affairs, in a written commentary.

While timing a domestic manufacturing mandate with a global pandemic that wreaked havoc on supply chains certainly didn't encourage the pharma industry to embrace the reshoring movement, the pandemic did provide a unique opportunity to reintroduce the idea of repatriating the drug supply. According to Chatterjee, the pandemic also allowed the U.S. government to demonstrate that it could catalyze the pharma industry if the government was a customer.

"Now that the subsidies are gone for vaccines, for example, the attractiveness around that sector is definitely far less. So there's going to have to be some component of government support that's going to drive the industry to get real traction," says Chatterjee.

At Phlow, Edwards is quick to point out that building a domestic supply chain is "not a call towards removing diversity in our supply chain" and to clarify what 'buy in' from the pharma industry might look like.

"The role large global pharma companies can play in this movement is to come alongside Phlow and help the U.S. government understand the problems and contributors to these supply chain challenges and align on the right incentives that need to be in place to secure a resilient supply of these critical essential medicines," says Edwards.

Even without a ringing endorsement from big pharma, APIIC's Webb feels that the government's efforts over the past four years to identify stakeholders and "hardwire a domestic network" was money well spent towards navigating future supply chain shocks.

"Are we doing this better than we were a couple years ago? Yes — because now people are asking the right questions."

Michael Annino | Shutterstock-AI

Sarah Shinton
Research Associate, Americans for a Clean Energy Grid, for IndustryWeek

THE SUCCESS OF U.S. CHIP MANUFACTURING HINGES ON OUR ELECTRIC GRID

Advanced semiconductor equipment requires 10 times more power; our grid is not up to the task

In 2022, the White House signed the CHIPS and Science Act into law, a bipartisan effort to increase domestic advanced semiconductor manufacturing. The legislation made a historic $52 billion investment in American semiconductor research, manufacturing and workforce development.

Over a year later, new projects are facing construction delays and permitting issues, raising concerns over efforts to expand domestic manufacturing despite legislative support. Worse yet, the country might be unable to generate enough electricity to power new fabrication plants, leaving billions of dollars in federal funds stranded and one of its most critical supply chains vulnerable.

The U.S. imports most of its advanced semiconductor chips from Taiwan, a trend the Biden Administration is trying to reverse as Chinese

aggression towards the island grows. Just over 100 miles from mainland China, headquartered in the Hsinchu Science Park, is the Taiwan Semiconductor Manufacturing Company (TSMC), the world's leading semiconductor manufacturer.

Controlling more than 90% of the global market for the most advanced processors, TSMC has a stranglehold over the chips found in everything from consumer electronics to military technology. The prevalence of semiconductors in modern life leaves the U.S. in a dire position if exports from Taiwan become disrupted — a predicament that has prompted efforts to reshore manufacturing.

Producing these small chips stateside presents one large challenge: The amount of electricity it takes to make them.

Electricity demands increase exponentially

TSMC has already begun construction on a 1,000-acre facility north of Phoenix, touted by President Biden as a crucial step towards creating a "vibrant domestic semiconductor ecosystem." However, producing these small chips stateside presents one large challenge: The amount of electricity it takes to make them.

While manufacturing semiconductors has always been energy-intensive, the process is becoming even more so as chips are developed to be smaller and more powerful. The most advanced semiconductors require extreme ultraviolet (EUV) lithography machines, which use ultraviolet light produced by rapid-fired lasers to burn fine details on silicon wafers.

The Dutch company ASML, the only company producing these machines, just tripled its orders from manufacturers last quarter, indicating that the semiconductor industry is trending towards chips that use this technology. However, these machines consume 10 times as much power as earlier generations of equipment. Due to the vast amount of power needed to run EUVs, TSMC now consumes more electricity than some U.S. states.

An 'eyewatering' surge

Taiwan already faces its own electricity challenges because of semiconductor manufacturing. Experts predict the island's reserve capacity may dip below the recommended 10% emergency margin the government says is necessary. Similar to data centers, semiconductor manufacturing creates large pockets of demand in the areas where fabrication plants are located. A rapid increase in load presents challenges for grid operators who maintain the delicate balance between electricity supply and demand, preventing curtailments or worse, blackouts.

Just the first phase of TSMC's Phoenix facility will create 200 megawatts of demand, the equivalent of powering nearly 30,000 households. The manufacturing giant plans to build up to five additional fabs on the same site. Information from the Arizona Public Service Company (APS) places the final demand from plant operations at an eyewatering 1,200 megawatts. With TSMC saying production will begin in a few short years, APS has little time to accommodate this surge in demand. This facility

Many utilities are already scrambling to update their integrated resource plans, with some expecting loads 17 times greater than forecasted just a year ago.

is just one out of dozens scheduled to open over the next few years, with a total of 21 fabrication plants planned for construction nationwide.

Slow replacement factor

The vast amount of electricity needed to onshore this new manufacturing comes at a time when America's power grid is increasingly unreliable as the country undergoes rapid changes.

In the past decade, natural gas plants started displacing pricier coal-fired ones as fracking reached previously inaccessible gas sources. The fracking revolution lowered the price of natural gas by nearly 50% in the mid-2010s, leading to a proliferation of gas plants. Now, wind and solar farms are increasingly replacing coal, nuclear and even gas plants. However, many regulators are raising alarms that power plants are being retired faster than they are replaced, leaving the country at risk of electricity shortages.

These mass retirements are also happening while electricity demand nationwide is increasing from data center growth, expansions in manufacturing and intensifying weather conditions. Over the past year, the five-year load growth forecast nearly doubled, jumping from 2.6% to 4.7%. While this increase may seem modest, it represents a stark departure from the 1% annual growth that decision-makers have come to expect over the past 20 years. Many utilities are already scrambling to update their integrated resource plans, with some expecting loads 17 times greater than forecasted just a year ago. Without expanding the high-capacity transmission system, our grid will struggle to meet this demand.

More pressure on Taiwan

Taiwan's election back in January demonstrated the vulnerability of semiconductor supply chains. Shortly before the election, China's Taiwan Affairs Office called the vote a choice between "war" and "peace," describing the now president-elect, William Lai, from the Democratic People's Party, as an "instigator." After Lai's victory, China sent additional warships to patrol waters near Taiwan, with Beijing expected to continue ratcheting up the pressure.

Chinese Premier Li Qiang recently unveiled a report with tougher language around reunification, dropping the word "peaceful" found in previous state documents. While an actual invasion is not imminent, concerns around Taiwan's future persist, demonstrating the desperate need to manufacture more semiconductors domestically and the urgency of generating more power to support this onshoring.

The Biden Administration says it would like to make semiconductors in America again. While the shift towards reshoring production will inevitably be long and gradual, electricity shortages may hamper this effort. Taiwan's recent election should be a wake-up call — we need a grid that can power American manufacturing, or we risk facing cataclysmic supply chain disruptions.

Michael Annino | Shutterstock-AI

Jonathan Katz
Executive Editor, Chemical Processing

RESHORING CRITICAL CHEMICAL PRODUCTION TO FORTIFY U.S. SUPPLY CHAINS

Lacamas Laboratories and ACMI discuss their partnership to secure domestic production of a key defense department material

The Biden administration has taken strong action to address risks to America's supply chains and economic security posed by over-reliance on imports from China, particularly for critical materials. On May 14, President Biden announced plans to increase tariffs on Chinese imports valued at $18 billion, citing China's "unfair, non-market practices" that threaten U.S. economic security.

Securing domestic supply chains for key materials has been an ongoing priority. Even before the new tariffs, the U.S. Department of Defense (DoD) launched a major initiative to re-establish U.S. production capabilities for 22 essential

chemicals used in defense applications like munitions as well as vital commercial sectors such as agriculture and pharmaceuticals. This includes energetic materials, non-energetic chemicals, precursors and stabilizers/moderants that had previously been solely sourced from China.

The DoD launched the program through its Defense Production Act Title III Program in collaboration with the American Center for Manufacturing and Innovation (ACMI) in Austin, Texas. ACMI has several campuses throughout the U.S. that provide advanced manufacturing equipment and technologies for companies looking to reshore production.

One of the companies collaborating with ACMI on the DoD initiative is Lacamas Laboratories in Portland, Oregon. Lacamas received a $86.2 million contract to establish U.S. production of 4-nitroanisole and 1,3,5-trichlorobenzene, salicylic acid and sebacic acid and diphenylamine, ethyl centralite and methyl centralite. ACMI selected Lacamas over other suppliers because of the company's capabilities, which included in-house process design and production, in addition to their interest in supporting the DoD program, according to an ACMI spokesperson.

In early May, Lacamas announced a major milestone — it had successfully delivered proof-of-concept for the program by restarting domestic production of an essential chemical input that had not been manufactured in the United States for 15 years. With this critical first step achieved, Lacamas is now scaling up to a continuous production process and has plans to build a new manufacturing plant in Portland.

I recently spoke with ACMI program manager Victor Boelscher and Lacamas Labs CEO Allen Erickson to discuss the effort. The following is an edited version of that conversation.

VICTOR BOELSCHER
Program Manager,
ACMI

ALLEN ERICKSON
CEO,
Lacamas Labs

Can you provide some background on this initiative and how both of you became involved?

Boelscher: ACMI finds and evaluates DoD needs, and then we help facilitate that process with folks who may not have been in the DoD space before. It helps companies in multiple ways. We help them with the speed of contracting with the DoD; that's normally not a very quick process. And we help fulfill the DoD's need of anchoring, reshoring and onshoring critical technology that's been out of the country for sometimes a decade or more. That is a serious security risk to the defense industrial base.

Erickson: Almost all of the critical chemicals used by the DoD now are from China. If China were to shut down its exports, the United

This Lacamas Labs facility has produced 50 to 100 kilograms of materials for the Department of Defense. The company is now moving that to a batch process and is proceeding with plans to scale that to a continuous manufacturing process.

States would be really in a bad way. We sort of saw that during the COVID-19 pandemic when suddenly, a whole pile of medicines that we thought were just ordinary day-to-day sort of things disappeared. The same thing happened in the chemical world. So, we're very dependent on China for the backbone of our defense department, as well as our day-to-day basic chemicals.

This initiative is aimed at bringing back those critical chemicals that the defense department needs. But there's a bigger picture of that, too. I think when you look at just the day-to-day household chemicals, they're all coming out of China, too. So while this initiative is focused on defense, there's a wider world out there.

Can you explain what type of chemicals you're developing for the DoD?

Erickson: Right now, we're making 1,3,5-trichlorobenzene. The DoD uses this material and can only source it from Asia. So, we›ve developed a batch route to start with, and we›re successfully making high-purity, good-quality material. We're now converting that to a continuous process.

Why wasn't this particular material already being produced in the U.S.?

Erickson: As offshoring increased, manufacturers of these intermediate-scale raw materials could not compete with overseas

manufacturers with their lower costs, often associated with lower labor costs and lower environmental regulations. With this competition, they closed their doors or switched product offerings. Lacamas' chemistry expertise allowed us to develop a manufacturing process that is both commercially viable and meets the more stringent environmental regulations of the United States.

> **Almost all of the critical chemicals used by the DoD now are from China. If China were to shut down its exports, the United States would be really in a bad way.**
>
> – Allen Erickson

When you talk about scalability challenges, what's significant about the way you're manufacturing the product?

Erickson: We've looked at old chemistry and adapted it to the present day. So, in the old days, this kind of chemistry was done, but without all the instrumentation and things we have today. Using the instrumentation and the knowledge that we have, we've been able to take a chemistry that was fairly dirty in the old days, clean it up and cut down on the environmental footprint of this material. We really cut down on the use of chlorinated hydrocarbons and, at the same time, delivered a high-quality material in an economical fashion.

You said you've been able to do it more sustainably. Are you talking about material substitution or is that something to do with the actual manufacturing process?

Erickson: Well, I think it's both. We're looking at using solvents that are environmentally benign instead of ones that are long-lasting sort of beasties. At the same time, when you run a continuous process, it seems you can recycle a lot of things back around, so you just don't have this huge pile of trash at the back end, as well as your product. You want to take everything you can and just recycle it back into the origin of that. And then, if you can get your processes to be higher yielding, that means they make less trash. Everybody wants to make higher-yielding projects because that reduces costs and also means lower environmental impact.

What are the next steps for this project?

Erickson: The DoD has given us more money to take this forward. We made the samples. We took that to the pilot plant. We've made 50 to 100 kilos of good-quality material in that pilot run, and now we›re taking that forward. That's a batch process we›ve made, and now we're backing up and doing further research on that, trying to convert that into a continuous process. Continuous processes are higher yielding and more sustainable, but they're more work. Typically, you start off with a laboratory batch process. You go to a pilot batch process, and you scale to the plant batch.

Then, once that's all working, you'll take what you've learned and make it into a sustainable continuous process.

What's your timeline for scaling production?

Erickson: That's going to happen this year, and shortly after that, we will be building a plant to make this material here in Portland, Oregon. Then, the DoD will start taking that material in about a year or two. But I'd like to point out that ACMI put us on the track to do this. Without them, I don't think we would've gone down this path. The defense industry is contracted into a few large companies that aren't interested in taking on these relatively small projects. ACMI has been able to parse these things out and then alert us to these opportunities, and then we took that and ran with it.

Do you see partnerships like that being increasingly important in the chemical industry to secure domestic supplies?

Boelscher: The Lacamas program was a pilot for us. It was a critical-chemicals pilot. We identified three chemicals to go on trial. This is a $5 million contract. Because of the success we had there, we were awarded a $15 million contract to continue it, and that's going to include at least 10 more companies, depending on what we can fit into the budget.

And so, this idea of finding a DoD need and then looking to see how commercially available it is, and then bringing folks in that aren't familiar in the DoD space, make it easy for the DoD to contract instead of going through a huge file of proposals. We do that work, and then we partner, and Lacamas is one of the initial success stories.

Erickson: These government proposals are typically 100 pages long. ACMI goes through them and then cuts them down to English. They gave us sufficient cash in that grant to get us off the ground. And then, that's moved forward into an actual plant for the DOD.

Do you see applications beyond defense? Are there potential consumer applications for this as well?

Erickson: One of the things that drove us in this direction was that we were sourcing out of Asia for an intermediate we make for the pharmaceutical world. It's one of the major pharmaceutical companies here for a major pharmaceutical need. So, we're expecting that a substantial amount of material that we make here will go not just to the DoD but also into the pharmaceutical world.

Michael Annino | Shutterstock-AI

Karen Hanna
Senior Staff Reporter, Plastics Machinery & Manufacturing

SUPPLY CHAIN VULNERABILITIES DRIVE PLASTICS INDUSTRY RESHORING

Plastics processors and supply chain experts see a competitive shift, as global uncertainty creates demand for shorter supply chains

Years-long turmoil in the supply chain saw ships parked for weeks at port while store shelves were stripped of essentials in the midst of the COVID-19 pandemic. For advocates of made-in-America manufacturing, the case for producing goods closer to the sources of demand and raw-material supply couldn't have been more apparent.

At Premier Plastics' two plants in Salt Lake City, seven thermoforming lines were running two shifts a day, five days a week in 2023. But the company was accustomed to running three shifts — if only it could find enough workers. Company founder Jim Holbrook said he'd like to hire more people, in part to accommodate

A VARIETY OF FACTORS AFFECT A COMPANY'S DECISION TO RESHORE MANUFACTURING

Which of the following factors would positively contribute to a decision to reshore manufacturing operations to the United States? (Top five factors)

	SMALL COMPANIES	MEDIUM-SIZE COMPANIES	LARGE COMPANIES
1	Quality of goods	Quality of goods	Labor costs
2	Delivery lead times	Labor costs	Logistics costs
3	Logistics costs	Reduced carbon footprint	Labor availability
4	Ease of conducting business	Delivery lead times	Delivery lead times
5	Quality of goods	Logistics costs	Reduced carbon footprint

Factor appears once in top five factors across company sizes.

Factor appears twice in top five factors across company sizes.

Factor appears three times in top five factors across company sizes.

Note: Small = less than $250 million, medium = $250 million to $5 billion, large = more than $5 billion

Source: Kearney analysis

Research for Kearney's "Reshoring Index" report from 2021, revealed a number of factors – other than cost – that play a role in reshoring decisions

burgeoning growth from customers eager to bring work back from overseas.

"That's the big one for most of our clients that we were talking to. They're either not even able to get product, or what they're getting is not of the quality that they have had in the past," Holbrook said.

To boost capacity, the company added a SencorpWhite thermoformer and a form-fill-seal machine that can load cartons automatically.

Long-awaited return

More than 40 years after the U.S. manufacturing sector peaked at 19 million-plus jobs, made-in-America advocates see a reversal in the forces that once shipped production out of the country. Now, they say, it's becoming clearer that reshoring would bring greater predictability, while producing benefits in terms of cost and environmental impact.

Reshoring Initiative

The Reshoring Initiative — which began in 2010 as one man's mission to reverse job losses — lately has been tracking victories, with ballpark figures of the number of reshored jobs and jobs created by foreign investment in the U.S. increasing from 6,000 in the year of its founding to 260,000 in 2021.

> **They no longer can put the [help-wanted] sign up and expect decent people to walk in; they have to work, they have to train within the company, they have to work with the community college to get the smart students to get them in.**
>
> – Harry Moser

In 2022, 350,000-plus jobs came back, Reshoring Initiative founder and President Harry Moser said. And in 2023, 819 cases of reshoring and foreign direct investment (FDI) led to 287,000 announced jobs, according to the latest report issued in July 2024.

While it's sometimes difficult to distinguish jobs created by expansion from those created by reshoring, Moser has confidence that at least 90% of the jobs included in his figures are the result of reshoring or FDI — when a company with a headquarters based outside the U.S. expands in the U.S.

According to the Reshoring Initiative's 2023 annual report, reshoring continues to outpace FDI, "indicating that the country and domestic companies finally recognize the value of local production that FDI realized long ago."

Since its founding, the organization has tallied nearly 2 million jobs created through reshoring or FDI.

The initiative aims to even the trade deficit, which would mean reshoring about 6 million manufacturing jobs — a goal Moser said he believes is achievable, as long as the country and companies can provide a way to train workers to fill them.

"They no longer can put the [help-wanted] sign up and expect decent people to walk in; they have to work, they have to train within the company, they have to work with the community college to get the smart students to get them in," he said. "And the ones that do that are doing fine."

Efforts to bring jobs back to the U.S. will shorten the supply chain, provide markets and consumers with stability and reduce carbon footprint, among other benefits, said Greg Kozera, director of marketing for Shale Crescent USA, a nonprofit that promotes shale gas resources in Pennsylvania, Ohio and West Virginia.

"Here's how you can reduce your emissions and your costs at the same time," Kozera said. "What an opportunity! You can be more cost-competitive; you can cut your costs, reduce your supply chain, create a more dependable product line and save money … when you localize those supply chains."

Trouble on the water

The pandemic called into question a simple formula that has worked for many businesses in the U.S. for decades. Tariffs beefed up during the Trump administration, pandemic-related shutdowns and supply chain clogs affected companies both big and small.

Plastics parts makers were no exception.

In 2016, when he started a stand-up paddleboard business, Rob Bossen joined so many others to follow a time-worn road map: Source goods from overseas, where labor is cheaper, and sell them where disposable incomes are higher. Seven years later, while Grey Duck Outdoor is still dependent on paddleboards from China, it's also diversifying — as Bossen worked with two other people to build canoes in the Boundary Waters Canoe Area Wilderness in Roseville, Minnesota.

The vulnerabilities exposed by the pandemic hit home for him, in ways he could never have predicted. As supply shortages and plant shutdowns in China rocked the supply chain, Bossen realized

Decatur Mold Tool & Engineering

An employee works at an electrical discharge machining cell at Decatur Mold Tool & Engineering, which is expanding in the hopes that the addition of automation can make it more globally competitive.

he couldn't absorb the costs of shipping foam boards thousands of miles around the world. Instead, he passed "a massive, massive price increase" onto his customers.

"Containers were just sitting off port for weeks at a time. ... It used to cost between six and 10 thousand [dollars] for me to land a container into Minneapolis, and that ballooned to $30,000 with tariffs and ocean freight and rail costs. When you're talking about a paddleboard that you can put, let's say, 120 paddleboards in a container, when it goes from six to $10,000 to $30,000, you're looking at a couple-hundred-dollar difference, just literally in freight costs," he said.

The global issues also have had ripple effects in tiny North Vernon, Indiana, where mold maker Decatur Mold Tool & Engineering had plans to add 14,000 square feet to its production space.

"In the past, we have built quite a bit of our molds in China; we actually have an arm in China. Beginning with the tariff, and then moving into COVID and supply chain pressures, we have found that our customers are much more willing to consider a domestically built mold," majority owner and President Rhonda Lustenberger said.

Plastics' potential

Given how many of its jobs currently are performed elsewhere, plastics manufacturing — with its automation and mega volumes — has been among the industries most affected by reshoring.

"We see reshoring both to the U.S. and to Mexico," said Vanessa Malena, president of Engel North America, York, Pennsylvania. "Higher tariffs, rising shipping costs, supply chain concerns and political unknowns abroad make reshoring a good choice for many companies. Based on these circumstances, China is no longer the more economical choice. It has also become more challenging to do business with China because of the heightened regulations stemming from the effects of the ongoing pandemic."

The U.S. imports about $53 billion in plastic-based products a year, according to a report released in December 2022 by Shale Crescent USA. Of the $500 billion in goods China ships to the U.S., about 5% are made from plastic — a number that's risen from $8 billion worth in 2010 to about $25 billion now. In all, since 1985, it has shipped $8 trillion in consumer goods to the U.S., with most of the volume making the trip in the last decade.

As the value and number of goods produced in China have risen, the number of U.S. manufacturing jobs has fallen.

The U.S. Bureau of Labor Statistics makes available data regarding plastics and rubber manufacturing dating to 1990. Between then and 2022, the number of jobs peaked at 959,100 in 2000 and cratered at 607,500 in 2009; at the end of 2022, it stood at 749,800.

But the category now is experiencing growth, ranking No. 10 in a list compiled by the Reshoring Initiative of the industries with the most reshored jobs since 2010, with 47,766. The list includes a number of industries that are heavily dependent upon plastics: Transportation equipment is No. 1, with 368,522 jobs; followed by computer and electronic products, with 184,496; machinery, 152,659; medical equipment and supplies, 139,451; and electrical equipment, appliances and components, 60,434. Primary metal products, apparel and textiles, and chemicals also made the top 10.

To businesses looking for manufacturers, Shale Crescent USA's Kozera asks one question:

"Can you make it?" he asked. "If you can make it, you can probably make it less expensive than they can over there."

Paying for predictability

As the world emerges from the pandemic, Moser and others said businesses are reassessing the costs and tradeoffs of a global supply chain.

"It used to be a system that worked very well but had a lot of glitches in it, and now it's a system that doesn't work very well," said Moser, who worked in the machining industry for years before retiring as president of AgieCharmilles, Lincolnshire, Illinois, and founding the Reshoring Initiative. "And because we've had the experience of Fukushima, COVID, the Suez Canal, Russia/Ukraine, and, hanging over it, China — the risk of some kind of a decoupling or kinetic event over Taiwan … companies are deciding … '[We've] got to get this stuff out of China.' "

In an era that's seen the word "unprecedented" become a cliché, Luo said businesses now are more willing to pay extra for predictability. "Black swan" events have inspired a new mindset. In a Kearney analysis of small, medium-sized and large companies open to reshoring, a number of factors unrelated to cost stand out, including product quality, lead times and carbon footprint.

"I think before [the] pandemic, everyone's focusing on costs; you have to be the lowest cost," Luo said. "However, during the pandemic, because of the uncertainties in the supply chain, supply chain resilience [and] agility become also a very important perspective for companies to design their supply chain."

Making your case

In finding ways to grow domestically, Holbrook, Bossen and Lustenberger are bucking a decades-long movement that placed one factor above all others: price.

> **If you can make it, you can probably make it less expensive than they can over there.**
>
> – Greg Kozera

For some, it's still a sticking point. But Moser, Kozera and Luo say manufacturers now can offer new arguments to offset cost concerns.

At Westec Plastics Corp., Livermore, California, which employs 80 to 90 people, business development manager Mustafa Hossaini said customers are more open to considering domestic production. They're drawn to advantages like improved communications and a shorter supply chain, with better assurance of access to materials.

"We've definitely seen a strong uptick in quoting opportunities. Now the challenge is, there is a little sticker shock. So, customers say, 'We want to reshore, we want to get out of Asia, we want to get out of China.' And then when you quote them a project, when they actually see the tooling costs, and they see the production costs, the contract manufacturing costs, maybe even the lead times, sometimes, you might not hear from them again," he said.

To help brand owners and manufacturers better quantify the benefits of reshoring, the Reshoring Initiative has developed a calculator that Moser says makes the math more palatable — by exposing to prospective customers costs that otherwise are opaque or overlooked. The initiative's Total Cost of Ownership Estimator is available to manufacturers, such as molders, looking to make their pitch vs. imports. Meanwhile, its Import Substitution Program helps manufacturers identify potential downstream customers.

With the costs of shipping and tariffs, imports once considered "cheap" aren't such a good deal anymore, Moser said.

"Price difference is big, and companies go for the price," he said. "But, as the companies start to do the math correctly, and look at all of the costs and risks, when they start adding in the duty and the freight and the carrying cost of inventory, even without thinking about decoupling with China, even without putting in the Section 301 tariffs, 20 to 30% of what they're importing — this is broad industry, not just plastics — 30% of what's being imported would be more profitably sourced here."

Considering all the other factors, Tony Firth, VP of sales and marketing for IMM maker Tederic North American Machinery, based in Palmetto, Florida, said the priority on price is changing.

"This reshoring is not price-driven. Rather, it is a function of low confidence in the stability of global supply chains," he said.

Products with the best economics for reshoring include those that are especially expensive to ship, as well as items that can be made in high volumes with relatively little labor. Alternatively, they might require frequent design changes.

Items that could be subject to wild swings in demand — such as toys based on movies or cartoons — also should be made close to their consumer base "because they need a supply chain to be short, so they will be able to capture the upside of the market," Kearney's Luo said.

With highly automated processes, items as simple as plastic cutlery can be made more cheaply in the U.S., she said.

Technology levels the playing field

In its report touting U.S. competitiveness, Shale Crescent USA takes issue with an offshoring trend that valued volume discounts over innovation, stating, "Labor, utilities and land were cheap in Asia, and especially China. Asian countries had a culture that was both hard-working and quick to capitalize on imitation versus innovation."

Winning jobs back will require a return to innovation, according to manufacturers and made-in-America advocates.

"Given the fact that our wages are three times as high as China and seven times or something as high as India, you have to automate the heck out of it to get the economics to work," Moser said.

That's the route Decatur Mold is beginning to take, with three new automated machining lines in the works. The company, which makes and repairs molds for plastic parts used by a number of industries, including the automotive, consumer goods and health-care sectors, employed about 140 people as of 2023. It added its first robot at the end of 2020.

By September 2023, the company hoped to have installed two new relatively large Makino mills served by a Fanuc robot, a third mill served by a Fanuc and an electrical discharge machining cell served by an Erowa robot, Lustenberger said.

"The goal is to really decrease the gap in costs between the U.S., between building here, and low-cost countries where our customers might be tempted to go," she said.

Can a mold maker really take tooling jobs away from overseas?

"Never say never," said Lustenberger. "I knew it would be hard, but I do feel like the direction we're going, we have a really good shot at getting that gap pretty close."

Lustenberger said she believes the new automation will lower costs — and allow her company and its customers to gain greater control over quality, and give them the flexibility and agility to deal with the changing supply chain.

"I think that's going to be a significant piece of the puzzle because people will be able to bring things to market more quickly, because we're taking time off of that supply chain, and you don't have to worry about global disruptions, whatever that looks like," she said.

Ultimately, she'd like to add to the number of people she's able to employ in her 6,000-some-person town and ensure that Decatur Mold is strong when she hands it off to the next generation.

A focus on automation — like that taken by Decatur Mold — could provide the path forward, supply chain experts say.

"No question that millions of jobs can be brought back just by companies doing the math correctly," Moser said.

RESOURCES

Helpful links

VIDEO

INDUSTRYWEEK PRODUCTION PULSE

Reshoring manufacturing: Pharma, trucking and plastics insights

HERE

PODCAST

OFF-SCRIPT, A PHARMA MANUFACTURING PODCAST

Mining pharma's reshoring rush

HERE

EHANDBOOK

WATERWORLD EHANDBOOK

Build America, buy America

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Flood control trends

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