U.S. GENERIC PHARMACEUTICAL MANUFACTURER
AVAILABLE CAPACITY RESEARCH SURVEY

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Summary

While drug shortages are not new, even peaking prior to COVID-19, the pandemic exposed the fragility of the U.S. medical supply chains and has placed a focus on building enhanced resiliency. A recent White House report\(^1\) concluded that the pharmaceutical supply chain vulnerabilities, which can and has led to drug shortages of essential and critical medicines, are driven in part by insufficient U.S. manufacturing capacity. But, at the same time, the pharmaceutical industry made headlines announcing the closure of several U.S. manufacturing plants, in part as a result of foreign government investments, lower offshore operating costs and labor rates, intense pricing pressure, and dependency on offshore sources for raw materials.\(^2\) How do we account for this incongruency?

The establishment and maintenance of a baseline of existing U.S. drug manufacturing capacity, together with the expansion of domestic production, provides an opportunity to create a more resilient and stable U.S. pharmaceutical supply chain. To foster such resiliency, a generic pharmaceutical industry-wide understanding of manufacturing capacity in the United States, the market conditions which led to the fragility of the U.S. pharmaceutical supply chain, and how quickly the industry could respond to reshoring critical and essential medicines is critical to developing strategies and policy recommendations to strengthen domestic manufacturing.

Between May 3, 2022 - Jun 10, 2022, a total of 18 manufacturers selling generic pharmaceuticals in the U.S. were contacted, with 13 companies participating in the research, for a response rate of 72%. Combined, these companies operate 37 manufacturing sites in the U.S., nearly 25%\(^3\) of the generic drug manufacturing infrastructure.

The findings of this study conclude that there is readily available manufacturing capacity in the United States for consideration for reshoring our most important essential and critical drugs, with the following findings/recommendations:

1. The United States holds existing available infrastructure that can be leveraged to strengthen the U.S. pharmaceutical supply-chain.
2. Repurposing currently idle capacity can enable U.S.-based manufacturing of critical and essential medicines to address shortages, enable supply chain resiliency and allow for supply within a 24-36 month timeframe.
3. Funding of advanced manufacturing technologies, such as continuous flow and on-demand manufacturing capabilities in idled manufacturing sites offers the ability to reduce production cost, create new work force development opportunities, and increase the economic sustainability of U.S. drug manufacturing through federal policy.

Keeping the nation’s drug supply chain secure, robust and resilient is essential for the national security and economic prosperity of the United States. Leveraging the available capacity of our national assets offers the ability to manufacture essential and critical medicines within the United States. But it will also be necessary to address the market factors which led the generic
pharmaceutical manufacturers to increasingly offshore its production capabilities in the first place. Only then can a meaningful difference in strengthening our domestic pharmaceutical supply chain take place. Utilizing current excess U.S. manufacturing capacity combined with additional recommendations, offers the opportunity to strengthen the national drug supply chain and build resiliency.

**Introduction**

Recent research into the U.S. drug supply chain has revealed a system vulnerable to disruption as it is overly reliant on foreign production and sourcing of critical drug Active Pharmaceutical Ingredients (APIs) and drug products for a significant percentage of the generic medicines consumed by U.S. citizens. With over 91% of medicines used by U.S. patients being generics, secure supply of generic drugs is of vital importance to the health security of our nation. For example, recent research revealed 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.

Fragile supply chains and drug shortages can have a significant impact on the U.S. healthcare system. A longitudinal trends study in U.S. drug shortages by Hawley et al. (2015) revealed a majority of shortages are for drugs used for lifesaving intervention or high-acuity conditions. This is consistent with the recently published Food and Drug Administration (FDA) List of Essential Medicines, which focused on those medications needed most by patients in U.S. acute care medical facilities specializing in short-term treatment for severe injuries or illnesses, or those with urgent medical conditions. The impact of drug shortages can also be felt beyond the emergency department. Acute lymphoblastic leukemia, the most common childhood cancer, is curable in 90% of cases; however, 82% of medications used in treatment were in short supply between 2009-2019. The substitution of agents lacking sufficient evidence can lead to reduced efficacy, increased cost, poor drug tolerance, reduced quality of life, drug toxicity, and death.

On average, pharmaceutical companies maintain a high inventory level, typically 75-days, which minimized supply disruptions experienced during the pandemic. It is estimated that during COVID-19, this higher inventory and increased transportation created an incremental industry cost of near $1B. But the pandemic also exposed the fragility of U.S. medical product supply chains, leading to certain drug shortages of single-sourced essential and critical medicines. These vulnerabilities are a threat to national security and compromise the U.S. health care supply chain. This isn’t a recent phenomenon, nor happened as a result of COVID-19, but the current drug shortage vulnerability has been a national challenge many years in the making, and both the FDA and World Health Organization maintain a drug shortage list entitled the “essential medicine” list. For several decades, pharmaceutical manufacturers have increasingly moved production out of the United States, particularly to developing nations, benefiting from lower labor, energy, and transportation cost, and fewer environmental regulations. A recent FDA analysis of national drug shortages, published in 2019 and updated in 2020, highlights three root causes of the U.S. pharmaceutical manufacturing exodus: low profitability, low value for quality and continuous improvements, and complex, global supply chains.

On February 24, 2021, President Biden signed Executive Order 14017 to secure America’s critical supply chains, launching a 100-day review and strategy development process to address
vulnerabilities in the supply chains of four key product categories, including pharmaceuticals. The final report, published in June 2021, stated “keeping the nation’s drug supply chain secure, robust, and resilient is essential for the national security and economic prosperity of the United States.”

The White House report concludes that pharmaceutical supply chain vulnerabilities, which can and has led to drug shortages of essential and critical medicines, are driven in part by insufficient U.S. manufacturing capacity, which has declined over several decades, and misaligned incentives in private markets which fail to reward firms for investing in quality, sustainability, or long-term productivity. To sustain a robust pharmaceutical supply chain, per the report, we must be able to manufacture high-quality products for the U.S. market, diversify manufacturing locations, and have built-in redundancy, such as multiple manufacturers for each drug product and its precursors (i.e., active pharmaceutical ingredients).

This is no easy task. According to PhRMA, the innovator pharmaceutical industry trade group, it takes between five to ten years to establish a new manufacturing facility, and even longer to onshore an entire manufacturing network. Costs associated with the establishment of a new manufacturing plant can cost as much as $2 billion. Making changes to even one element of a supply chain can take years to implement and have significant costs.

Generic drugs account for 92% of prescriptions dispensed in the U.S., despite representing only 16% of the pharmaceutical industry revenue. Generics also represent most of the essential and critical drugs in shortage. Over the past 30 years, the generic pharmaceutical industry has consolidated and increasingly offshored its production to countries with lower labor and manufacturing costs in response to low profit margins. Factors that put U.S.-manufactured pharmaceuticals at a competitive disadvantage include foreign government investments, lower offshore operating costs and labor rates, and dependency on offshore sources for raw materials.

One resiliency building option available for consideration is to invest in existing U.S. facilities including facilities that are operating at less than full capacity or have been recently shuttered. A robust pharmaceutical supply chain has at least three critical features:

1. Ability to manufacture high-quality products for the U.S. market.
2. Diversification of the drug supply chain, such as relying on a geographically diverse set of manufacturers.
3. Redundancy of the supply chain, such as the existence of multiple manufacturers for each product and its precursors.

The benefits may include:

- Faster time to production, which is critical in times of surge demand;
- Avoids single-source point of failure;
- Certainty of supply;
- Minimizes impact of global supply disruption;
- Improved supply chain transparency;
- Creates redundant capacity for essential and critical medicines;
- Eliminates costs of building new facilities, and
- Leverages facilities experienced in operating under FDA cGMP requirements.
However, a thorough review of available U.S. excess and available industry capacity has been difficult to quantify. As such, our research focuses on quantifying the available U.S. excess capacity that could be repurposed and leveraged, and drug product and API manufacturing that could be activated to produce generic medicines in the U.S. and build national resilience.

This study sought to understand what the pharmaceutical manufacturing capacity for generic medicines was in the U.S., how much excess capacity existed within these plants to manufacture essential or critical medicines, and how quickly could the generic manufacturers respond to ramp up production if needed. The results of the study have been anonymized, and no individual manufacturer data are disclosed.

**Methodology**

We conducted a survey of 13 generic pharmaceutical manufacturers and fielded between May 3, 2022 - Jun 10, 2022. The companies were a mix of U.S. and foreign-domiciled entities, and combined, operate 37 manufacturing sites in the U.S., representing nearly 25% of the country’s generic pharmaceutical manufacturing capacity.³

Each participant completed a nine-question Finished Dose (FD) Manufacturing survey, including an optional eight-question API Manufacturing survey. All companies could also participate in further research measuring North American manufacturing capacity (Canada, Mexico) for both FD and API. Each respondent was also offered the opportunity to participate in an in-person interview with the researcher to review/discuss their survey responses.

A total of 18 manufacturers selling generic pharmaceuticals in the U.S. were contacted, with 13 companies participating in the research, for a response rate of 72%. Two declined since they did not have a North American manufacturing presence, and three did not respond. Eleven of the 18 respondents participated in a follow up call with the researcher. One participant only partially completed their survey, so it was necessary to apply a survey response average for their incomplete survey responses. Only one of the 13 participants had manufacturing operations in Canada or Mexico, therefore due to the inconclusiveness of the data, these results are not included in the final paper.

All research respondents were senior level personnel, mostly from commercial operations or supply chain management functions, including President U.S. Operations; EVP and SVP Business Unit Operations; U.S. Site Leads; SVP Generic Operations; and Global Supply Planning.
Research Findings

Production Capacity. The use of medicines in the U.S. – based on defined daily doses\(^1\) – has grown 9.6% over the past 5 years to an estimated 194 billion days of therapy in both retail and non-retail settings in 2021.\(^6\) The 37 U.S. generic pharmaceutical manufacturing sites surveyed for this study have a total production capacity of 60.31 billion doses, defined as an oral solid (capsule/tablet) or injection, that a patient would take as a daily treatment for their medical condition. On an annual basis, overall, these sites are producing at just half of their production capacity, with an aggregate excess capacity of nearly 50%.

And by retooling or repurposing dormant or low volume manufacturing lines, the result determined 57% of the manufacturing sites with excess capacity could be operational within one year to produce essential medicines. Nearly an additional 30 billion doses of essential and critical medicines could be produced in the United States without incurring the expense of building a new manufacturing plant.

Utilization Rate. Often defined as a ‘race to the bottom’ industry, generic drug manufacturers operate in a market of intense pricing pressure.\(^4\) Over the past few decades, sectors of the healthcare system, including hospital systems, GPOs, wholesalers, and the pharmaceutical industry, have consolidated to achieve efficiencies and increase negotiating power with suppliers and customers.\(^1\)

Generic manufacturers have also been negatively impacted by brand company actions with heavy rebating and patent protection strategies that limit market access opportunities. The relationships between the innovator brand companies and pharmacy benefit managers (PBMs) can often block generics on public and private managed care contracts.\(^16\)

Combined, excess manufacturing capacity shouldn’t come as a surprise. What is surprising is the magnitude.

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\(^{1}\) Defined daily doses (DDD) are based on World Health Organization (WHO) definitions, which is the assumed average maintenance dose per day for a drug used for its main indication in adults. A limitation of this study is the ability to coorelate the definition of production capacity by dose with the WHO estimated DDD.
Only two of the 37 manufacturing sites are producing at full capacity. And while 70% of the sites are producing above 50% capacity, 30% are less than 50% utilized. Over 13% of the sites are less than 30% utilized. Notably, these are existing FDA-inspected and approved, cGMP plants, requiring limited, if any upgrades necessary to meet minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product.

**Manufacturing Location.** The 37 surveyed manufacturing sites are dispersed over 12 states, which represent a strong and diversified infrastructure across the country. Leveraging domestic manufacturing creates redundant capacity, and increases end-to-end supply chain coordination, security and transparency. These sites also account for 12,000 direct manufacturing jobs, according to the survey responses.

As stated in the White House report, a key criterion for sustaining a robust supply chain is diversity in manufacturing locations across the country, and one which can recover quickly from an unexpected event.

While there are many benefits to a global supply chain, COVID-19 also demonstrated it is vulnerable to disruption. By leveraging the strength of a diversified pharmaceutical manufacturing sector, it can greatly reduce transportation costs and create the redundancies necessary to withstand future supply-chain shocks, which often result from trade disputes, a changing international geo-political landscape, weather disruptions and global pandemics.

**Full Production Availability.** As part of the deliverables of the White House 100-day pharmaceutical supply chain report, the National Forum to Secure America’s Supply Chain for Essential Medicines prioritized 86 medicines as most critically needed for acute patient care.
A further analysis of those 86 prioritized medicines identified 58.1% as intravenous (IV) injected medications, 17.4% as both oral solid or IV medications, and 11.6% oral solid tablets. The remainder were delivered as either solution, subcutaneous injection, topical, nebulizer, gas or intramuscular (IM).

Over 87% of the prioritized medicines are either injectable or oral solid dose, both readily produced by the generic manufacturers which participated in this research. Respondents indicated idle capacity could be immediately repurposed to begin manufacturing critical and essential medicines. Once manufacturing lines are repurposed, manufacturers indicated 57% of the generic pharmaceutical sites could be at full production within one year, and 86% within two years.

This offers potentially tremendous advantages compared to a 5-10 year timeframe and $2 billion required to build new pharmaceutical plants that would achieve similar production capacity. Repurposing idle production lines could make a meaningful difference in achieving U.S.-based manufacturing and lessening the nation’s overreliance on foreign-sourced finished dose pharmaceuticals and strengthen our national and public health security within two years.

**Essential Medicines Capacity.** In response to Executive Order 13944, the FDA published its list of essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. To accomplish this goal, the executive order seeks to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing our dependence on foreign manufacturers of these products.

The disappearance of domestic production of essential antibiotics impairs our ability to counter threats ranging from pandemics to bio-terrorism, as emphasized by the FDA’s analysis of supply chains for active pharmaceutical ingredients, is but one example of our nation’s health security risk.

Nearly 60% of the surveyed generic pharmaceutical manufacturers are already producing FDA identified essential medicines. The excess manufacturing capacity of these same manufacturers can be quickly repurposed within one to two years to expand manufacturing allowing the FDA to meet
most, if not all of their essential and critical medicine needs.

**Overcoming Barriers to Building Resiliency**

The U.S. pharmaceutical industry continues to shutter U.S. manufacturing sites. Over the past year, the pharmaceutical industry made headlines announcing the closure of several U.S. manufacturing plants, eliminating hundreds of well-paying jobs in the process. The most notable example is the announcement by Viatris, Inc. in August 2021, to close the former Mylan plant in Morgantown, West Virginia, in operation since 1965, with a loss of over 1,400 jobs. With more plant closings to follow. In October 2021, Viatris also announced the closing of its San Carlos, California plant, eliminating 95 jobs. In March 2022, Merck announced the pending closure of its Active Pharmaceutical Ingredient manufacturing plant in Danville, Pennsylvania, effective 2024, eliminating 300 jobs. Some of these plant closings could affect the availability of FDA-deemed essential medicines.18-21

While some of these facilities became too costly to update to meet current good manufacturing practices (cGMP) and FDA compliance requirements, the closures reflect the current market dynamics for generics in the U.S. marketplace.

**Current Market Dynamics and the Economics of Reshoring Generic Medicines**

Generic medicines are substitutable for each other and for the brand they follow. Pharmacies can substitute products from different manufacturers at the pharmacy, and wholesalers use bids and tenders to continually push costs ever downward. As a result, many generic medicines are less than a dollar a dose and for common solid dose tablets, manufacturing costs are frequently less than 10 cents. The API component of these medicines can be pennies or fractions of pennies per dose, and API procurement by the FDA manufacturers is highly competitive.

A study by Sood et al., (2017) evaluated the flow of a hypothetical $100 expenditure on prescription drugs covered under private insurance through the U.S. retail distribution system and demonstrated that only $17 was directly attributed to production costs. The remainder was absorbed within the supply chain, which includes manufacturers,
insurers, pharmacies, pharmacy benefit managers and wholesalers. For generic drugs, the
intermediaries realized a greater percentage of gross profit margins than the manufacturers.\textsuperscript{22}

However, through advancements in new innovative manufacturing equipment, such as
continuous flow manufacturing and on-demand manufacturing capabilities, it is expected that
pharmaceutical production costs will continue to decline, further reducing the cost of U.S.-based
production and for reshoring\textsuperscript{23} and enabling the development of fully U.S.-made products for
total development costs ranging from $3 to $5 million.

The active component of medicines that results in the medicinal affect is the API. API
manufacturing in the U.S. is a critical to enabling the production of U.S.-based finished drug
products. As such, our research included an evaluation of the economic viability of researching,
developing and producing drug API in the U.S. based on cost information provided by
respondents. These discussions with generic manufacturers during the interview process
revealed:

- On average, drug API development costs are estimated at $2 to $4 million, for conventional synthetic
  chemistry products.
- The development of the finished generic dosage form similarly ranges
  from less than $1 million for very simple oral solid tablets to $3 million for simple sterile injectables
  in vials, to far greater than $10 million for complex or long-acting injectables.
- The majority of medicines in shortages are in tablet or vial formats, implying a range of $1 to
  $3 million per product for development.
- In a combined development program, efficiencies could produce a U.S.-made, FDA-filed
  finished dose product with total development costs ranging from $3 to $5 million.

The application of continuous manufacturing into existing excess capacity offers a promising
path for building resiliency. Estimates as high as a 30-50\% reduction in Cost of Goods Sold
(COGS) seem possible, in a far smaller footprint with less labor – nullifying many advantages
ex-U.S. manufacturers enjoy. Industry 4.0 proponents believe that automation of traditional
manufacturing processes can make these gains even greater, when the right technologies extend
across the supply chain.

However, innovators in the U.S. lack access to commercial scale, FDA-approved cGMP facilities
and the commercial, quality, regulatory and physical infrastructure required to bring products to
the commercial market. Efforts by entities such as the API Innovation Center @ Cortex a non-
profit organization, overcome this gap and help innovators work together with large existing manufacturers to de-risk commercialization, increasing the potential successful production in the U.S. Further, the leaders in chemistry may not have access to leaders in control systems or equipment engineering or training programs for these new technologies. There is a substantial gap between bench scale proof-of-concept and commercial scale cGMP production that requires bridging.

Upon further analysis of market and industry cost data provided during the research, leveraging current underutilized facilities could enable U.S.-based commercialization for cents per finished dose tablet differences, or 10-20% more per monthly bottle from foreign sourced materials. In 2020, the average generic medicine co-pay was $6.61\textsuperscript{24}. Feasibility, essential and critical medicines could be re-shored with an incremental out-of-pocket cost for a U.S.-sourced generic prescriptions between $0.66 cents - $1.32 per month.

**Talent Recruitment**

While not part of the research, a common finding that emerged during the one-on-one interviews with plant management was the importance of their frustration in finding workers to hire. And not just qualified candidates. There was a general concern of management being unable to attract and retain technicians and operators to work in their manufacturing plants. The pharmaceutical industry is not immune to the post-COVID hiring challenges facing most employers in the United States today. In states such as Ohio, a strong pharmaceutical manufacturing base, employers are often vying for the same candidate, or employee, leading to high turnover and a spike in wages. While not necessarily limiting a plant’s full capacity potential, a reduction in labor has resulted in eliminating some 2nd and 3rd shifts until hiring needs are met.

**Conclusion and Recommendations**

The findings of this study conclude that there is readily available excess manufacturing capacity in the United States for consideration for reshoring our most important essential and critical drugs. Recognizing the need for a public funding, existing capacity and manufacturing facilities offer an opportunity to build supply chain resiliency less expensively than building new manufacturing plants, and within one year of retooling. To strengthen our domestic pharmaceutical manufacturing, the findings suggest the following for consideration:

1. **The United States holds existing available infrastructure that can be utilized to strengthen the pharmaceutical supply-chain.** A critical industry to our national and public health security, pharmaceutical manufacturers are pivotal within the ecosystem of innovation, research, and job growth. Each time one of these plants is shuttered, it has a ripple effect beyond the impacted community. The ‘brain drain’ of institutional knowledge in R&D, innovation, operations management, and quality, to name a few, that leaves the community, the state, or the country makes the nation a little more vulnerable to over-reliance on foreign-sourced pharmaceuticals. Relationships and connections with small and medium-sized businesses, and universities, and technical schools within this ecosystem are severed. Rebuilding for resilience at a national level requires that we maximize the value of our existing world-class pharmaceutical infrastructure as we build for growth and sustainability.
2. **Repurposing currently idle capacity can enable U.S.-based manufacturing of critical and essential medicines to address shortages, enable supply chain resiliency and allow for supply within a 24-36 month timeframe.** Capacity is readily available. These are not shuttered plants; but fully operational, FDA-inspected and approved, cGMP factories already producing many of our nation’s most important drugs. They are compliant with federal and state environmental regulations, provide living-wage manufacturing jobs, and the industry is an important contributor within the healthcare innovation ecosystem. Any solution to healthcare security requires a critical mass of domestic manufacturing infrastructure to protect domestic interest.²⁵ An important first-step in addressing our shortage of critical and essential drugs would begin by creating incentives with manufacturers to produce these less profitable drugs, which would be significantly less expensive than building new pharmaceutical manufacturing plants, or the collective loss as these jobs are moved offshore and factories continue to close.

3. **Funding of advanced manufacturing technologies, such as continuous flow and on-demand manufacturing capabilities in idled manufacturing sites offers the ability to reduce production cost, create new workforce development opportunities, and increase the economic sustainability of U.S. drug manufacturing.** Advanced manufacturing lowers costs by condensing processes that used to take months of expensive work into a few days. It also promotes the use of automation and robotics to shrink labor costs while improving quality controls to minimize waste. In addition to being less expensive, continuous manufacturing can expedite regulatory checks without compromising oversight²³, improves manufacturing agility, and utilizes a smaller environmental footprint. The FDA also recognizes that the adoption of advanced manufacturing techniques would reduce production costs and increase the resilience of U.S. production, enabling a competitive advantage to ensure a stable supply of critical drugs.²⁶ The placement of new, advanced technologies in idled sites would boost production, build emergency capacity and help minimize the risk for existing manufacturers to invest in upgrading equipment to expand production lines. Advanced manufacturing also creates new opportunities to develop a trained workforce with deep knowledge and hands-on experience with these critical new skills, specifically in communities of color, necessary to produce high-quality drugs and long-term sustainability of a strengthened U.S. pharmaceutical supply chain.

4. **Increase the economic sustainability of U.S. drug manufacturing.** Over the past 30 years, the generic pharmaceutical industry has consolidated and increasingly offshored its production to countries with lower labor and manufacturing costs in response to low profit margins. This downward spiral placed tremendous economic pressure on manufacturers’ ability to make large investments to modernize quality systems, such as upgrading manufacturing equipment or rebuilding aging facilities. Needed are federal policy tools to increase the economic sustainability of U.S. drug manufacturing.¹ Recommendations, include leveraging the governments collective buying power to reform procurement protocols; regionalize and expand strategic national stockpile to include essential medicines and their API; establish long-term demand for generic medicines at a sustainable price to encourage domestic production expansion; and streamline regulatory procedures to make adding new production capacity faster and easier.²
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