Professional Perspective

Potential Costs of Reshoring Pharmaceutical Manufacturing

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On Feb. 24, 2021, President Joe Biden issued an Executive Order on America's Supply Chains, founded on the increasingly accepted principle that the U.S. needs "resilient, diverse, and secure supply chains to ensure [its] economic prosperity and national security." Even before the Covid-19 pandemic, U.S. policymakers had grown increasingly concerned about the extent of the nation's reliance on foreign-supplied medical products and the potential public health and national security risks it posed.

The severe shortages in critical medical supplies that arose quickly with the emergence of Covid-19, exacerbated by export restrictions imposed by foreign governments, dramatically justified such concerns.

Pandemic-related supply chain disruptions exposed the degree to which the U.S. relies on foreign supplies of critical medical products, including active pharmaceutical ingredients (API), finished pharmaceuticals, personal protective equipment (PPE), and other key medical supplies. In the U.S., pandemic-related medical product shortages have intensified the calls for the "reshoring" of American medical product manufacturing capacity that had moved abroad in previous decades.

Under the executive order, federal agencies are currently undertaking a 100-day review to identify supply chain risks for four key product types, including pharmaceuticals, and to recommend strategies to mitigate those risks. While we await the formal findings of that review, an assumption underlying it—and undergirding ongoing policy discussions—is that reshoring pharmaceutical manufacturing will ensure greater resilience in the event of global pandemics like Covid-19, lessen dependence on foreign suppliers in countries such as China and India, and strengthen the U.S. economy by rebuilding domestic manufacturing capacity and ensuring U.S. leadership in research and development.

Benefits of Reshoring

There are several potential benefits to reshoring pharmaceutical manufacturing. One advantage is reduced vulnerability to supply shocks caused by export controls imposed by foreign governments to prioritize domestic needs or even to gain political leverage. Another advantage is economic: the reshoring of drug production may generate high-quality, relatively high-paying jobs.

Less frequently mentioned, reshoring can offer more consistent FDA oversight over drug production quality, potentially leading to fewer manufacturing shutdowns and associated supply disruptions due to poor quality drugs that FDA can prohibit from being imported into the U.S. It is easier and cheaper for FDA to inspect domestic manufacturing facilities than foreign facilities. FDA can inspect domestic facilities much more frequently than foreign facilities, and faces fewer obstacles in doing so, such as foreign visa requirements and the logistical need to pre-announce foreign inspections.

Risks and Potential Consequences of Reshoring

While proposals to bring drug manufacturing back to the U.S. are extremely attractive, they are not without risk. Before undertaking reshoring in earnest, it is important to consider thoughtfully whether such proposals are realistic, the potential adverse consequences of reshoring, and strategies to mitigate any perils. Below, we first explore adverse consequences related to costs and then consider the interplay between reshoring and drug pricing.

Regulatory and Manufacturing-Related Costs

Obstacles to realizing significant reshoring may include the difficulty of obtaining necessary raw materials in the U.S., the significant costs of moving manufacturing, especially of low-margin API and generic drug products, to the U.S., and the high cost of real estate and labor. Other factors include the amount of time and effort required to construct and outfit, transfer manufacturing operations to, and obtain requisite regulatory approvals for such facilities before they can be fully operational. Finally, increased FDA oversight and scrutiny over domestic facilities could lead to higher manufacturing compliance costs.

In addition, a narrow focus on ensuring a primarily domestic pharmaceutical supply chain risks interfering with and damaging existing supply chains, contracts, and relationships thus jeopardizing supply chain capacity and redundancy.

Globalization of supply chains can have a protective function. The U.S. is not immune from natural disasters or other problems that can shut down production and cause serious supply chain shocks.

Consider the shortages of sterile IV saline in late 2017, after drug manufacturing factories in Puerto Rico were damaged by Hurricane Maria. In response, the FDA approved the importation of IV saline products from overseas to ameliorate the shortages. Consolidating manufacturing in the U.S., with a resultant loss in global supply chain relationships, could undermine efforts to strengthen supply chain security if taken too far.

Moreover, once the Covid-19 pandemic is no longer an immediate threat, it is difficult to gauge whether the current level of attention will persist and whether new domestic production facilities will be self-sufficient or will need significant long-term government funding. If reshored pharmaceutical production were to prove unsustainable in the long run, excessive loss of global supply chain relationships could prove extremely detrimental.

Key Considerations: Obtaining regulatory approvals for domestic facilities; higher costs associated with domestic manufacturing, including from potentially increased regulatory scrutiny; and damaging existing relationships with foreign supply sources needed in the event of a domestic shortage; profitable manufacturing not sustainable.

Drug Pricing-Related Costs and Considerations

The general expectation is that reshoring is likely to lead to increased drug production costs arising from the higher costs of domestic real estate, regulatory compliance, re-training a domestic workforce in manufacturing, and employee wage rates that exceed those in India and China. It also is possible that businesses may be subject to greater taxes in the U.S., as compared to under foreign tax regimes.

There are significant business and legal consequences when manufacturers have higher drug production costs that merit close consideration. For example, manufacturers that have committed to limiting drug price increases to the rate of inflation may have difficulty doing so if they have not accurately anticipated and built into internal estimates the potentially significant costs of reshoring.

Further, raising drug prices can result in reputational harm, particularly during a time when drug pricing is already subject to extreme, and bipartisan, scrutiny. Raising drug prices may also result in heightened patient cost-sharing—a consequence no stakeholder desires—although the connection between drug pricing and patient cost-sharing for a drug is often attenuated.

There are other manners in which higher drug prices can have particular "sting" based on the current legal framework for drug pricing and reimbursement under government health-care programs. These programs are significant players in the health insurance market, as the U.S. government pays for nearly 50% of domestic health-care spending.

Most pharmaceutical manufacturers elect to participate in the Medicaid drug rebate program (MDRP), a program under which state Medicaid programs are obligated to cover a drug for Medicaid enrollees and, in exchange, the manufacturer must pay a rebate on all drug units paid for by state Medicaid programs. Participation in the MDRP is a prerequisite for coverage of a drug under the Medicaid drug rebate and Medicare Part B programs.

Given the high utilization of many therapies under one or both of these programs, there is a strong incentive to opt in to the program. Manufacturers that join the MDRP also must participate in the 340B drug pricing program and the Secretary of Veterans Affairs Federal Supply Schedule (VA/FSS) program. As a result, the vast majority of pharmaceutical manufacturers participate in these government health-care programs.

Under each government health-care program, the federal government pays drug prices that are tied to commercial market prices for drugs. As commercial market prices change, so does manufacturer rebate and other financial liability under government health programs. For instance, under the MDRP, pharmaceutical manufacturers pay rebates on each unit of a drug reimbursed by a state Medicaid agency, including an inflationary penalty, in the event a drug's price increases faster than the rate of inflation.

In light of the Medicaid inflationary penalty, a drug with a price that has increased quickly over time could be subject to a substantial rebate. The Medicaid statute currently caps the Medicaid rebate at 100 percent of AMP for the drug, although the Covid-19 relief legislation will eliminate this rebate cap starting in 2024. Eliminating that cap will cause even more dramatic financial consequences for pharmaceutical manufacturers that increase prices in excess of the inflation rate.

Drug Pricing Legislation

Various federal drug pricing bills that have been introduced in Congress propose their own penalties pegged to the rate of inflation. For instance, the House-passed bill, H.R. 3, would require pharmaceutical manufacturers to pay the federal government a rebate if their prices for drugs covered under Medicare Part B and Part D increase faster than the rate of inflation. A similar proposal in the Senate Finance Committee garnered a majority of votes.

The upshot is that even pharmaceutical manufacturers that have committed to measured price increases that do not exceed the rate of inflation may struggle to adhere to those commitments if the costs of reshoring are too high. In the event that there are iterative increases in drug prices over time as manufacturers slowly transition to reshoring, manufacturers may confront nuanced –but nonetheless painful–consequences.

Pharmaceutical manufacturers also may have enhanced compliance and reporting obligations under the increasing number of state laws that mandate reporting triggered by price increases. For instance, California, Oregon, and Maine (among various other states) require manufacturers to report various information to state agencies if the price of their drugs increases beyond specified thresholds. One state also has proposed imposing an excise tax on drugs with prices that increase faster than the rate of inflation, although no such measure has yet been enacted.

And, of course, higher drug prices may have adverse consequences for patients. Patient cost sharing is nominal under the Medicaid program but can feature prominently in other forms of health coverage.

Stakeholders need to carefully model these costs of reshoring. Beyond the costs of a more-expensive domestic workforce, workforce training, and enhanced regulatory oversight, there may be spill-over costs associated with drug price increases. The Covid-19 relief bill will amplify these costs, as could other bills moving through Congress if they ultimately are enacted. These spillover costs are not easily mitigated under the current legal framework for federal health-care program drug pricing and reimbursement.

In that case, the legal framework may require reconsideration. At a minimum, the federal government would be wise to think through ways to lower the overall costs of reshoring, through direct subsidies or tax breaks, or to moderate its approach by seeking to reshore only certain types of products.

Key Considerations: Potential federal inflation-based or other penalties on account of increased drug costs; compliance-related costs related to regulatory costs in connection with price increases; potential reputational costs of price increases; additional potential costs in the future as drug pricing federal and state legal framework evolves.

Alternative Approaches to Ensuring Supply Chain Security

While we await the result of the supply chain review under the recent executive order, it is not too early to start thinking about how much and what type of pharmaceutical manufacturing reshoring would be advisable. One approach would be to focus such efforts on drugs that are relatively complex to manufacture. The Biden administration may want to consider providing targeted loans, as suggested by the chief executive of U.S. Pharmacopeia (USP) at a Food and Drug Law Institute webinar on reshoring, to incentivize reshoring by companies that specialize in complex drug manufacturing or emerging technologies.

The idea would be to target areas where the U.S. would have a competitive advantage that would enable it to manufacture products at a lower cost or else demand higher prices. Targeting loans in this way may be preferable to subsidizing the onshore production of low-tech, low-value products for which production may be economically unsustainable.

FDA has already indicated its support for the adoption of advanced manufacturing techniques, such as continuous manufacturing rather than traditional batch manufacturing, and has highlighted the potential public health value of advanced manufacturing techniques during the Covid-19 pandemic. The hope is that continuous manufacturing, which is more efficient than batch manufacturing, can reduce the costs of manufacturing, which may make domestic production more competitive and therefore more viable in the long run. Additional regulatory guidance may be required to implement these new methods.

Another option for ensuring the viability of reshored production is to provide long-term government contracts to domestic manufacturers at sustainable prices to ensure stockpiles of medically necessary products are adequately maintained. In essence, the government would ensure a market for domestically produced products that might otherwise be unable to

compete due to the high cost of manufacturing. As noted above, however, the success of such an approach depends on the predictability and durability of the government support.

Another proposal for ensuring supply chain resilience that does not rely on reshoring, from the Association for Accessible Medicine (AAM), is to spread manufacturing capacity throughout allied foreign countries. AAM has developed a blueprint for strengthening the supply chain, which suggests that the U.S. Trade Representative, working with HHS, should negotiate a plurilateral agreement with U.S. allies to promote a cooperative approach to securing the U.S. supply chain and ensuring diversity of supply among allied foreign partners.

Others have emphasized that supply chain resilience also rests, in part, on ensuring manufacturing quality, as poor quality is a significant driver of shortages. To that end, FDA is likely to continue to support and operationalize CDER's Quality Management Maturity Program, which is developing a ratings system for manufacturing facilities that would incentivize such facilities to invest in quality maturity.

The assumption underlying this program is that medical products manufactured in highly compliant facilities with mature quality systems, that receive high ratings from FDA based on predetermined quality metrics, will be able to justify higher prices, thus averting a race to the bottom with respect to quality driven by pricing pressures. Industry will have to be prepared for increased FDA scrutiny, and the reputational risks associated with a sub-par quality rating if CDER's Quality Management Maturity Program is operationalized.

Key Considerations: Potential need for additional regulatory guidance to implement advanced manufacturing methods; need to engage in diplomatic relations if the AAM model is adopted; increased regulatory scrutiny and potential reputational risk associated with quality ratings; potential need for long-term government subsidies to ensure viability of domestic production.

Conclusion

The Covid-19 pandemic has significantly intensified the attention and scrutiny directed at the fragility of the nation's supply chain for medical products. Acute shortages of critical medical products, including pharmaceuticals, have forced the U.S. to take a hard look at short- and long-term solutions to supply chain vulnerabilities.

Remediating the supply chain shortcomings that the pandemic has revealed will require serious thought and effort. Targeted solutions focused on onshoring higher technology manufacturing and a limited list of the most critical drugs and medical supplies, and stockpiling domestically produced products, will likely play an important role.

However, policies that pressure American companies to reshore too great a portion of their foreign drug manufacturing capacity could have adverse consequences that need to be considered carefully. Such policies could lead to skyrocketing drug prices that will cause significant pain for drug manufacturers participating in government health-care programs, unless the government agrees to significant subsidies to offset the high costs of reshoring, which may not be sustainable.

Further, higher drug prices could lead to myriad adverse effects—including but not limited to potentially higher costs to consumers and the overall health-care system, reputational damage to manufacturers, that some may argue is undeserved in this instance, and a fundamental disconnect from broad-based, bipartisan federal and state efforts to lower drug prices.

Thus, before initiating major reshoring efforts, the government should consider carefully the full range of consequences that could flow from such action, and whether reshored manufacturing will be sustainable for the long-term. Such an analysis is critical to ensure that the benefits of reshoring outweigh its risks.