The FUJIFILM Biotechnologies facility in Holly Springs, N.C.

Pharmaceutical Onshoring in the Fifth District

As pharmaceutical manufacturers look to bring production back to the United States, the Fifth District is attracting billions of dollars in cutting-edge life sciences investments.

By Matthew Wells

Virginia's Shenandoah Valley is known for its bucolic landscape and proximity to some of the country's most scenic wilderness. Amid the farms and fields, adventurers on their way to Shenandoah National Park or the Blue Ridge Parkway might be unaware, however, of the valley's long history in producing some of the most innovative medicines and vaccines used to treat diseases and illnesses across the globe.

Last October, that reputation received a boost when pharmaceutical giant Merck announced plans to construct a $3 billion, 400,000-square-foot facility in Elkton, Va., in the heart of the valley. The facility will host the firm's Center of Excellence for Pharmaceutical Manufacturing, focusing on the testing and development of complex medicines and pharmaceutical ingredients, potentially creating over 500 full-time jobs and 8,000 construction jobs.

Merck has been producing medicines in the Shenandoah Valley for nearly 85 years, where it "has been a beacon of innovation in our proud legacy of delivering leading-edge science for patients," noted Sanat Chattopadhyay, executive vice president and president of Merck Manufacturing Division, in announcing the new facility. "We're proud to be part of the Elkton community, where generations have contributed to our important work with determination, accountability, teamwork and grit."

The project is part of a more than $70 billion multiyear expansion of Merck's U.S. manufacturing and research and development footprint, which reflects a broader effort by pharmaceutical firms and policymakers to bring production back to the United States after it shifted overseas in the late 2000s. In the last two decades, the growth of overseas production facilities has been substantial: Anaïs Galdin, an economist at Dartmouth College, noted in a recent working paper that in the early 2000s, only 15 percent of factories supplying the United States market were located overseas, but by 2020, that number had grown by more than 80 percent.

Problems with overseas supply chains have led to significant shortages, however, particularly for medicines needed in the wake of emergencies. Policymakers have also pointed to national security concerns that come with being reliant on China, a global competitor for these medicines, and reshoring efforts, which began prior to the COVID-19 pandemic, have since accelerated.

IMAGE: FUJIFILM BIOTECHNOLOGIES

But the process of bringing pharmaceutical production back to the United States is not straightforward or risk-free. Onshore production is still subject to domestic supply shocks, which could translate into significant supply chain volatility. Labor dynamics, regulatory requirements, and firms' financial considerations are also complicating factors, even as federal and state governments take steps to ease the process and identify potential incentives.

Regions across the Fifth District, including the Shenandoah Valley and areas in and around Research Triangle Park in North Carolina, are responding to the onshoring push by creating or expanding the necessary infrastructure and building talent pipelines to position themselves as natural landing sites for these new investments.

Merck's Elkton expansion is just one of several such investments that pharmaceutical firms announced or started in 2025 alone. In March, Merck also opened a $1 billion vaccine production facility in Durham, N.C. That same month, Johnson & Johnson broke ground on a more than $2 billion plant in Wilson, N.C., where it will produce medicines for cancer, as well as immune and neurological diseases. In September, Eli Lilly and Company announced a $5 billion investment for a plant in Goochland County, Va., to develop ingredients to treat cancer and autoimmune diseases and for advanced therapies. Also in October, AstraZeneca announced a $4.5 billion project in Albemarle County, home to the University of Virginia, which will go toward the construction of two factories dedicated to medicines and therapies for cancer and chronic diseases. All told, pharmaceutical firms committed at least $23 billion in 2025 to solidify and expand their presence in the Fifth District.

THE DRIVE TO ONSHORE

Pharmaceutical supply chains have three phases. First is the production of raw materials, known as active pharmaceutical ingredients, or APIs. U.S. Pharmacopeia, a nonprofit that sets quality standards for pharmaceuticals and provides data and analysis on the supply of medicines, found in 2024 that over half of the APIs for prescription medicines in the United States came from India and the European Union (EU). APIs for generic drugs, which make up 90 percent of the United States' prescription drug volume, primarily came from India, while 43 percent of branded pharmaceutical APIs came from the EU. Only 12 percent of total API volume used in the United States was produced domestically.

The second phase is the manufacturing of the product in what is known as finished dosage form (FDF), which typically combines the APIs and any inactive ingredients into a deliverable form such as a pill or injectable. According to U.S. Pharmacopeia, the United States is the largest manufacturer of injectable FDFs, with 45 percent of global production volume, followed by the EU with 19 percent. For pills, India produces 60 percent of the global volume, with the United States second at 22 percent.

As with these two phases, the third phase, distribution, is spread all over the globe. This global supply chain reflects countries' different comparative advantages, as firms locate each step of the production process in countries or regions with plentiful labor and resources appropriate for that step. This abundance allows firms to reduce costs relative to regions where those inputs are not as plentiful. In the case of pharmaceuticals, firms realized that there was a large supply of workers abroad, particularly in places like India and China, and that APIs could be produced overseas more efficiently (that is, more cheaply) than in the United States. Similar to other industries, pharmaceutical firms also moved abroad to capitalize on lower land, energy, tax, and environmental and workplace safety compliance costs.

While firms benefitted from these reduced costs, there were trade-offs. Offshoring created unique supply chain vulnerabilities, sometimes leading to shortages of crucially needed medications in the United States. Global public health emergencies or natural disasters have caused surges in global demand, reducing availability in the United States for certain periods. Also, problems with overseas manufacturing quality have regularly constrained supply. The U.S. Food and Drug Administration (FDA), for example, found that 60 percent of all U.S. cases of supply interruption stemmed from quality control issues, which can range from errors in labeling to contaminated production processes. The COVID-19 pandemic also led countries like China to shutter manufacturing facilities, as well as the ports used to ship those products around the world. In 2016, an explosion in China at the only global production facility of APIs for a particular antibiotic led to worldwide shortages, and a 2007 shortage of an antibiotic made from pig intestines stemmed from an infectious disease that devastated China's pig herds.

In her research, Galdin found that drugs produced in Asia are 54 percent more likely to experience a shortage relative to those produced in the United States, and those shortages are an average of 130 days longer than those impacting medicines manufactured domestically.

These shortage problems are heightened when there are few sources of an API. Maria Nieradka, who studies life sciences supply chains at Gartner, a business research and advisory firm, notes that APIs are frequently the most expensive component of a drug, leading many manufacturers to rely on a single source to reduce costs.

Onshoring could mitigate some of these supply chain issues. The federal government has long expressed concerns over the role pharmaceutical access could play in contentious politics with other countries, especially China. Domestic manufacturing of those medicines would eliminate the possibility that other countries could use access to crucial treatments as leverage against the United States. Further, manufacturing entirely in the United States could make regulatory compliance within that jurisdiction easier, although that might mean new compliance issues in other countries should firms export domestically produced medicines abroad.

POLICY SUPPORT

Moving production back to the United States does not automatically alleviate the shortage problem, as it could even reduce supply diversification. John Murphy III, president and CEO of the Association for Accessible Medicines, a generic manufacturing advocacy group, argues the economics of

generic medicines (which, again, make up 90 percent of the U.S. market) are driven by efficiency, not redundancy.

This suggests domestic production could still be exposed to supply shocks. Murphy cites Hurricane Helene, which hit western North Carolina in 2024, as an example of how onshoring by itself might not solve supply chain issues. "Ninety percent of the U.S. supply of sterile saline produced domestically comes from one plant in western North Carolina. When it was knocked offline, we were stuck with no alternatives in the United States, and we had to import saline from China during that period," he recalls. "Onshoring without a plan to imbue resiliency and redundancy doesn't help us in the context of natural disasters or outbreaks." Domestic onshoring coupled with expanded production in countries that have good trade relations with the United States would be one potential way to increase redundancy.

Also, firms originally moved their manufacturing abroad to reduce costs, and those higher domestic costs still exist. Murphy notes that for generic manufacturers, those costs can be a strong deterrent to bringing production back onshore. Generics are priced low and produced in high volume, meaning thin profit margins with little left for new capital investments in the United States. "If I'm a generic manufacturer and I have a facility in Canada and a facility in India, and I'm producing at 100 percent capacity for the demand that I'm seeing in the global market, how do I justify a $1 billion facility in the United States to my board of directors or to a bank?" he says.

"Onshoring without a plan to imbue resiliency and redundancy doesn't help us in the context of natural disasters or outbreaks," says Murphy.

In Congressional testimony last June, Murphy called for the government to play a more active role in assisting firms to relocate onshore, drawing a parallel with the $280 billion CHIPS and Science Act of 2022, which boosted domestic semiconductor manufacturing by smoothing the permitting process, providing manufacturing incentives, and granting a tax credit for necessary capital expenses. (See "Semiconductor Industrial Policy and the Fifth District," *Econ Focus*, Third Quarter 2023.)

In response to a May 2025 executive order to encourage firms to onshore, the FDA developed the PreCheck Program, which would streamline the application process for the construction of new facilities. It would first institute more frequent communication with manufacturers at different stages of the process, including facility design, construction, and preproduction; and streamline development of approvals for the chemistry and development portions of the application.

Nieradka sees these moves as a step in the right direction, noting that they could make the process more predictable and improve the timing for bringing manufacturing back to the United States. "I think it's a big opportunity, and I think life science companies are going to be really attracted by it," she says.

The FDA also created a new pilot process, the Abbreviated New Drug Application, to expedite applications for drugs made with APIs sourced entirely in the United States. For this to work as intended, however, API suppliers would also have to move back to the United States. Because they operate on thin margins like pharmaceutical firms, convincing them to bring production onshore might also require additional government investments and incentives.

Tariff dynamics further complicate the effort to bring pharmaceutical production back to the United States. Despite early indications it intended to apply tariffs to both generic and brand name medicines made abroad, the Trump administration ultimately exempted generics. On the other hand, President Donald Trump announced a 100 percent tariff on brand name pharmaceutical imports unless the manufacturer was actively building capacity in the United States. The administration also carved out an exception for brand name medicines produced in the EU, setting that rate at 15 percent.

While many of the larger companies have been able to move quickly by expanding existing facilities, John Crowley, CEO of the Biotechnology Innovation Organization said that a 100 percent tariff "for any company without 'shovels in the ground' would devastate our nation's small and mid-sized biotechnology companies." Alex Schriver, senior vice president at the Pharmaceutical Research and Manufacturers of America also expressed concern, arguing "every dollar spent on tariffs is a dollar that cannot be invested in American manufacturing or the development of future treatments and cures." The pharmaceutical firms themselves have been vague about how tariffs influenced their plans, but they committed over $351 billion in new investments in the United States in 2025.

THE DRAW OF THE FIFTH DISTRICT

As firms return to the United States, they likely will look for locations where they can minimize costs, particularly those costs that led them to move much of their production abroad previously. This means finding sites with preexisting infrastructure and a talent pool suitable for pharmaceutical research and production. If firms do not have to start operations from scratch and can leverage plentiful training and education programs already in place, the move onshore may be more attractive.

Research Triangle Park (RTP) in North Carolina is one such location. In the 1940s, Duke University, the University of North Carolina, and North Carolina State University began engaging in collaborative research with private industries with a goal of keeping talent in the state. After a failed bid to attract Merck, leaders of the project adopted the RTP name in the 1950s and began with a technology-heavy focus that gradually expanded to include health and biological science firms.

That effort paid off, as RTP now has around 24,000 employees across more than 675 life science companies. This clustering increases efficiency by allowing firms to share infrastructure, and they are also able to share innovations and technology with lower transaction costs than if they were geographically dispersed.

Just as important, these firms can draw on a common

talent pool through initiatives they developed in partnership with the state's postsecondary education systems. Laura Rowley is the vice president for life sciences economic development with the North Carolina Biotechnology Center, a state-funded nonprofit company founded in 1984 to strengthen the research capacity of the state's universities and companies and encourage development of the biotech industry in North Carolina. "If companies have access to an established system for recruiting from community colleges and universities, it can be a lot easier than starting at zero in a new market," she says of firms looking to set up operations in the RTP. "Having more of that system structure, where you're able to benefit from shared services rather than isolated activities at each institution, can increase efficiencies."

NCBioImpact is another public-private partnership providing connectivity across biomanufacturing training programs throughout the University of North Carolina and the North Carolina Community College system. Its member institutions provide many of these hands-on programs, which are specifically tailored to companies' needs, from those that are well-established global brands to smaller firms that are just getting started.

These collaborative programs include a biomechatronics apprenticeship program recently launched at three NC Life Sciences Apprenticeship Consortium member companies — Eli Lilly, FUJIFILM Biotechnologies, and CSL Seqirus — to train students for industrial maintenance positions at these firms. Rowley explains that these positions, which are responsible for keeping the advanced equipment running at these facilities, don't require a degree, but do require a knowledge of biomanufacturing and skilled trades. This knowledge, which is gained through coursework at local community colleges, is then paired with on-the-job training at these facilities.

Virginia's Shenandoah Valley pharmaceutical footprint is not on the same scale as North Carolina's, but it shares some common traits that Merck has found attractive. Jay Langston is the executive director of the Shenandoah Valley Partnership, the region's economic development and marketing organization. He suggests that when Merck first established operations in the valley in 1941 to produce vitamins for soldiers, it was drawn to the location by its proximity to Washington, D.C. It also had existing transportation assets, such as rail lines and waterways, which were used to ship medicines needed for the war effort. It was also close to the University of Virginia. "It was a classic sort of economic development story in many ways," says Langston. "It was the right place, at the right time, with the right assets."

Those assets have only grown in the years since. Food and beverage manufacturing has also been a huge driver of the valley's economy, and Langston notes that the technology and skills necessary to produce food and pharmaceuticals are similar. In particular, the technology that drives both automation and sanitation are the same, and both industries rely on the same subcontractors to build their manufacturing infrastructure. "There's a lot of synonymous activities between those two industries, and I think that is what has helped Merck over time."

Merck has expanded its Elkton operations several times over the years. Its decision to commit to its 2019 expansion was made easier after it secured an agreement with nearby James Madison University and Blue Ridge Community College to develop programs geared toward ensuring a pipeline of local talent to meet its short- and long-term workforce needs. The programs include STEM opportunities for middle schoolers, high school and college internships, apprenticeships, associate and bachelor's degree courses and technical certificates, and professional development programs for current Merck employees. At the same time, however, Langston acknowledges these programs are not the whole story when it comes to creating that workforce; those workers also need somewhere to live. "We need to consider housing development as a foundational part of economic development," he says, noting that two local manufacturers recently could not hire key talent because of lack of housing. (See "What's Driving Rural Population Growth?" *Econ Focus*, Third Quarter 2025.)

MAKING THE MATH WORK

As these firms and others look to bring production back to the United States with the goal of a resilient and secure supply chain, they will be relying heavily on technological innovations allowing them to develop and manufacture medicines, vaccines, and other complex therapies more efficiently. Artificial intelligence could help determine which costly clinical trials are more likely to succeed, and in the context of manufacturing, identify potential issues before they occur, which can reduce a drug's time to market. Process innovations will also be key, such as the move to continuous manufacturing from traditional batch production, which will allow firms to check quality and consistency in real time rather than waiting for a batch to be completed.

For onshoring to make sense, manufacturers need to address ongoing cost concerns, particularly for much-needed generic medicines and API production. But if those costs can be overcome, states like North Carolina and Virginia, with their existing manufacturing and workforce pipelines dedicated to producing lifesaving medicines, may offer a launchpad for further domestic pharmaceutical production. **EF**

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