Case Study: BioFabrication Cluster - Two Years After the Building Back Better Regional Challenge Winner Award

In September of 2022, the Economic Development Administration (EDA) awarded under the Build Back Better Regional Challenge (BBBRC) a total of roughly \$1 billion to 21 regional coalitions across the country. Created through the American Rescue Plan Act of 2021, the BBBRC solicited proposals from communities across the country aimed at transforming local economies through collections of complementary and integrated projects. Among these 21 awardees is the BioFabrication Cluster—a New Hampshire-based coalition set on revolutionizing healthcare and reducing medical costs through the engineering of human cells, tissues, and ultimately organs.

1. Background

At the start of the 20th century, the city of Manchester, New Hampshire, had arguably fully lived up to its namesake in England, having industrialized its regional economy and established a booming textile cluster led by the Amokseag Manufacturing Company. At its peak in the early 1900s, Amokseag operated 25,000 looms and created more than 50 miles of cloth per hour, eventually becoming the largest textile mill in the United States. Its impact on the region's labor market was even more pronounced; by the time World War I began in 1914, the company employed more than 17,000 people, or more than half the working population in Manchester at the time. For all intents and purposes, Manchester was a textile town that revolved around the Amokseag Manufacturing Company.

Yet despite the domestic textile manufacturing preeminence that Manchester held for nearly half a century, tectonic national economic changes eroded many of the advantages held by the region at the time. Southern states, for example, whose economies had been traditionally reliant on agriculture began to industrialize through increased mechanization, and comparatively lower wages in the South put tremendous competitive pressure on already industrialized and highly unionized areas of the country, such as New England. Nearly nonexistent in the latter part of the 19th century, the Southern textile manufacturing industry by the 1920s had completely surpassed New England in total annual production of yarn and cloth.³ By 1935, the Amoskeag Manufacturing Company had permanently closed its doors and marked the beginning of the decline of Manchester's textile industry.

Domestic competition proved to be relatively tame compared to the onslaught of textile and apparel imports to the United States that accompanied the rapid acceleration of globalization following the end of World War II. In an effort to more deeply integrate the global economy and as a result increase the costs of potential future armed conflict, the United States and a slew of other countries in 1947 signed the General Agreement on Tariffs and Trade (GATT), which laid out the foundation for a more open multilateral global trading order. While ostensibly allowing the laws of comparative advantage play out on an international scale and thus increase production efficiency and volume, the introduction of the GATT introduced an entirely new level of competition on American textile manufacturers and their

¹ Todd Bookman. "Made in New Hampshire: Manufacturing's Rise and Fall in Manchester." New Hampshire Public Radio. 27 March 2017. Available at www.nhpr.org/nh-news/2017-03-27/made-in-new-hampshire-manufacturings-rise-and-fall-in-manchester.

² Ibid.

³ "Southern Labor Archives: Work n' Progress – Lessons and Stories: Part III: The Southern Textile Industry."

⁴ World Trade Organization. "The General Agreement on Tariffs and Trade (GATT 1947)." Available at www.wto.org/english/docs e/legal e/gatt47 01 e.htm.

employees from countries with lower operating margins such as Japan, Hong Kong, Egypt, and India.⁵ Such acute pressures were felt not just among the remaining textile manufacturers in New England but across geographies and sectors in the United States.

This updated international trading framework was buoyed by technological advances in production, logistics, communication, and transportation, as firms became more productive given fixed inputs and more adept at sourcing materials and labor in international markets. The United States government was temporarily successful in its attempt to stem the inbound flow of relatively inexpensive textiles from abroad through signing on to the quota system in the internationally negotiated Multifiber Agreement (MFA) in 1974. This agreement, however, was ultimately superseded in 1994 when the Uruguay Round of Trade Negotiations established the World Trade Organization and with it the gradual dismantling of the MFA's system of import quotas. The supersequence of the MFA's system of import quotas.

By 2022, manufacturing of nondurable goods, which includes textiles and clothing, represented just 2% of the gross domestic product (GDP) of the Manchester metropolitan statistical area (MSA). Overall manufacturing employment as a share of total employment declined from a recent peak of 14.6% in 1997, when the former textile quota system was in the process of phasing out, to just 6.8% in 2023, representing a total loss of nearly 6,000 jobs. 10

2. The BioFabrication Cluster

Fortunately for the Manchester region and the workers within it, the long decline in the textile manufacturing sector was around this same time beginning to become offset by the government-initiated rise of a new sector focused on the research and development of biofabrication, or the automated engineering and production of cells, tissues, and organs. In response to the Manufacturing USA program—a 2016 federal initiative aimed at creating a network of American research institutes that focus on advancing cutting-edge technologies—the Manchester-based Advanced Regenerative Manufacturing Institute (ARMI) created BioFabUSA and was ultimately awarded an \$80 million grant through the Department of Defense to develop the first-ever biofabrication foundry manufacturing program. ¹¹

These efforts to establish a more robust transplant supply chain are long overdue. Despite some 43,000 transplants taking place in 2023, more than 103,000 people were on the national transplant waiting list

⁵ Joseph Pelzman. "The Multifiber Arrangement and Its Effect on the Profit Performance of the U.S. Textile Industry." *The Structure and Evolution of Recent U.S. Trade Policy*. January 1984. Available at www.nber.org/books-and-chapters/structure-and-evolution-recent-us-trade-policy/multifiber-arrangment-and-its-effect-profit-performance-us-textile-industry.

⁶ Mark Mittelhauser. "Employment trends in textiles and apparel, 1973-2005." *Monthly Labor Review*. Bureau of Labor Statistics. August 1997. Available at www.bls.gov/opub/mlr/1997/article/employment-trends-in-textiles-and-apparel-1973-2005.htm.

⁷ Pelzman. "The Multifiber Arrangement and Its Effect on the Profit Performance of the U.S. Textile Industry."

⁸ Simon Lester. "The Agreement on Textiles and Clothing." The World Trade Organization: Legal, Economic and Political Analysis. 2005. Available at link.springer.com/chapter/10.1007/0-387-22688-5 9.

⁹ Author's calculations of U.S. Bureau of Economic Analysis. "Real GDP by County and Metropolitan Area." Available at www.bea.gov/data/gdp/gdp-county-metro-and-other-areas

¹⁰ Author's calculations of Bureau of Labor Statistics. "Local Area Unemployment Statistics," "State and Area Employment, Hours, and Earnings." Available at www.bls.gov/regions/northeast/nh_manchester_mn.htm#eag.

¹¹ Department of Defense Manufacturing Technology Program. "BioFabUSA: Advanced Regenerative Manufacturing Institute." Last updated 30 September 2023. Available at www.dodmantech.mil/About-Us/Manufacturing-Innovation-Institutes-MIIs/BioFabUSA/.

that year. ¹² Currently, nearly 20 people die every day waiting to reach the top of this list—a reality that was exacerbated during the height of the COVID-19 pandemic when hospitals were focused primarily on combatting the novel coronavirus. ¹³ And like other disparate dimensions of healthcare that were exacerbated during 2020, transplants too are plagued by racial and ethnic inequities. While annually 58% of white patients on the waiting list receive a transplant, the same figures for Black, Hispanic, and Asian patients are respectively just 38%, 36%, and 32%. ¹⁴

In an effort to build on the initial successes of ARMI and alleviate the disparities present in the healthcare system, the City of Manchester in 2021 submitted an application to the Economic Development Administration's Build Back Better Regional Challenge. This bold vision laid out strategies to firmly cement the burgeoning biomanufacturing sector in southern New Hampshire. The result was the BioFabrication Cluster, a coalition composed of local government entities, nonprofit organizations, and institutes of higher education focused on using the momentum behind this emerging sector to ensure that the economic benefits of its success were widely shared among all populations within the region—especially those with limited physical or professional proximity to ARMI. The BioFabrication Cluster's vision is one of strengthening the tissue engineering supply chain, physically revitalizing existing spaces to develop late-stage clinical and commercial manufacturing, and developing an inclusive workforce roadmap for well-paying employment opportunities in biofabricaion.

The coalition is simultaneously seeking to build out the regional biofabrication private-sector ecosystem and working to showcase the real-world applicability of engineered tissues. To foster private-sector involvement in the commercialization of regenerative therapies and technologies needed for automated manufacturing, the BioFabrication Cluster is establishing the BioFab Startup Lab to provide acceleration services and incubation space to high-potential early-stage companies and entrepreneurs. Similarly, the coalition is developing the Logistics Network for Cell, Tissue, and Organ Delivery, focused on rapid delivery of biologic products and in the process greatly expand future demand for such biofabricated products.

Simultaneously, to accommodate the increasing demand for physical space among the region's growing biofabrication cluster, ARMI is renovating 100,000 square feet of a historic mill. When completed, the collective space will meet the regional need for advanced manufacturing training as well as a space equipped with the necessary assets, such as clean rooms, for late-stage clinical and commercial manufacturing of cell-based products.

Finally, to meet the growing demand for a skilled biofabrication workforce, Southern New Hampshire University, along with other regional education partners, is expanding the pipeline into this career path through the Work & Learn project, which will facilitate the removal of transportation and technology barriers as well as increase education and job-readiness assets. Central to these workplans is the emphasis on equitable access, recruitment, and job placements, as New Hampshirites of historically disadvantaged backgrounds traditionally face greater barriers to economic success.

3. Year-Two Marker

After two years of planning and implementation, the BioFabrication Cluster is showing significant progress in achieving its vision of anchoring the biofabrication sector firmly within southern New

¹² "Organ Donation Statistics." Health Resources & Services Administration. Last updated March 2024. Available at www.organdonor.gov/learn/organ-donation-statistics.

¹³ Ibid.

¹⁴ Ibid.

Hampshire. Reorienting an entire regional economy—especially one with as storied a history as Manchester's—is no small feat, yet continued public- and private-sector investments indicate that this strategy is paying off.

The BioFab Startup Lab has made notable strides in establishing a vibrant private-sector ecosystem within Manchester. To date, the coalition has created a new curriculum for and accepted 13 startups into its program. Promisingly, firms are successfully beginning to progress though Food and Drug Administration clearance of clinical evaluation and raise outside capital, setting the stage for future commercialization. The Startup Lab's Investment Summit, held in October 2023, attracted investors already investing in the industry and those wanting to learn more. The sold-out event set the stage for an even larger gathering, the Second Annual BioFab Investment Summit, in October 2024.

While renovations of the training facility are still in the final planning stages, the coalition has determined that there are broader uses for the space once complete. One potential application will be to conduct registered apprenticeship trainings in partnership with the Community College System of New Hampshire. Such efforts will complement the Work & Learn initiative, which is continuing to gather momentum. As of September 2024, Southern New Hampshire University, in partnership with the University of New Hampshire and Manchester Community College, has conducted regional analyses to identify necessary technology upgrades, worked to stand up a highly sought-after middle- and high-school technology readiness afterschool program, and begun securing internships at private-sector life sciences firms for college students. UNH also launched the STEM MoBILE – a mobile lab that serves underresourced communities and schools to expose children and adults alike to the biofabrication industry and the emerging career pathways.

In an effort to continue to build on the successes accrued over the past decade, ReGen Valley, a consortium of 40 organizations led by ARMI, was selected to receive supplementary funding under EDA's Regional Technology and Innovation Hubs program. This additional \$44 million will be used to create a globally competitive biofabrication cluster, scale commercialization capacity, increase awareness and adoption of regenerative therapies among clinicians and the public writ large, and continue to increase the accessibility of jobs in the biofabrication industry for residents across the Manchester-Nashua metropolitan statistical area.

4. Conclusion

In order to solicit the widest possible range of proposals from prospective applicants to the Build Back Better Regional Challenge, the Economic Development Administration maintained an intentional agnosticism about what form regional and industrial development should take. Instead, applicants were encouraged to define their visions of economic transformation and demonstrate feasibility, scalability, and community excitement. The BioFabrication Cluster is a testament to how federal investments in such visions can lead to extraordinary results in relatively short periods of time. As the BBBRC reaches this important milestone, the returns generated from this series of initial federal investments will not only ensure that all residents of southern New Hampshire have the opportunity for upward economic mobility, but it will also advance technology that has the potential to save countless lives.