REPORT

American Innovation, Manufacturing, and Resilience

BOYD Biomedical

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The look on Dr. Zeidel's face was frighteningly serious. "I've seen young people die horrible deaths," he said, looking directly at me. We were only a few minutes into the interview, and a tear fell out of the corner of my eye. I wiped it away quickly. The camera lights were bright. I don't think he saw it. Get your shit together, I thought to myself.

July 28, 2020, was a surreal day for me. I had not set foot in Beth Israel Deaconess Hospital in Boston since 2014 when my wife and I practically lived in their Neonatal Intensive Care Unit with our premature twin daughters for months. So there was a sort of raw emotion when I walked into the hospital, which I wasn't expecting. I thought to myself; I became a parent here.

But this time, I was visiting for an entirely different purpose. Our firm, a medical device manufacturer, was involved in the emergency response efforts in Massachusetts, and we were filming a documentary about it called Project Frontline. I was there to interview the Physician in Chief, Dr. Mark Zeidel. The topic was somber; we were discussing the explosion of the coronavirus pandemic in Massachusetts. I had only met Dr. Zeidel over Zoom, but we had logged many hours in our Massachusetts Emergency Response Team meetings, which began in March. So, I knew what kind of person I was sitting in front of. Dr. Zeidel wasn't someone whose time you wasted normally, and certainly not now.

Dr. Zeidel wears a bowtie and a lab coat and speaks with specific authority and credibility earned through experience. He's the kind of person who doesn't need to rush when he speaks because everyone is listening and giving him space to finish his point. I began the interview by asking Dr. Zeidel to introduce himself. He did, and then he told his story. For over an hour, I sat, and I listened. I never had to ask another question. It was a story about the dramatic and frightening early days of the pandemic when we were building field hospitals in conference centers and packing dead bodies into refrigerated trucks. We were discussing the crisis in Massachusetts, but his story was about all of us, and it was about our future.

I thought to myself, this man sitting in front of me is the Physician in Chief at one of the best hospitals in the world. He is making decisions about what people will wear in the COVID ward. He teaches at Harvard Medical School. Yet, our business, our industry, our Country ultimately failed him. We put him in this position. Why? Was this all because we moved our manufacturing overseas? Were hospital procurement practices to blame? Was it even something we could change? I felt that everyone had resigned to the idea that we don't manufacture products in America anymore, even in advanced industries, like medical devices. And it seemed that no one even cared.

In Response to Crisis

> *"What we did as a healthcare community when we came together was remarkable. The first level of the crisis — reacting to the punch. What I wonder is what long-term societal changes this creates."*
>
> *— Brian Johnson, President of MassMEDIC*

Since the early months of 2020, we've been producing a documentary about the manufacturing response to the pandemic, giving me a unique opportunity to have thoughtful discussions with business leaders across health care systems, industry, and academia. There is reason to be optimistic about our future, but there is work to be done, and manufacturing is at the center of it.

Building a bright future for manufacturing in America is a complex problem. The answers are embedded in decades of decisions, and consequences, across a dynamic and complex ecosystem of actors. These answers will not occur independently or in the absence of a national strategy. We need to be thoughtful and strategic, but most of all, we need to act with long-term intent.

Our firm, Boyd Technologies, was thrust into the coronavirus emergency response efforts in Massachusetts due to our access to advanced materials and manufacturing know-how. For example, we could source materials, make masks, and supply components used in vaccine production. As a result, we were asked to become part of the Massachusetts Emergency Response Team (M-ERT) which held its first meeting on March 20, 2020. The goal was to generate a manufacturing response to the crisis.

During this time, in the spring of 2020, the coronavirus pandemic was exploding in Massachusetts. There were 26 new confirmed cases on March 15th, but by April 30th, Massachusetts had already recorded over 3,500 deaths. These numbers seem less dramatic as we are now two years into the pandemic, with over 20,000 deaths in Massachusetts. Yet, this was an incredibly frightening time. Testing was limited, hospitals were unprepared, and our medical equipment supply came to an alarming halt. For a period of time in Massachusetts, a State world-renowned for its Healthcare, our hospitals relied on donated products to stay operational. Some ran out completely.

By the end of 2020, the M-ERT was responsible for producing 9 million isolation gowns, 3 million N95 respirators, 5 million face shields, and over 10,000 ventilators in Massachusetts. Alongside this effort, Massachusetts granted over $16 million in funding to manufacturers who could establish long-term manufacturing capabilities for these items. (MassTech.org 2021) It was the largest manufacturing response by volume of FDA compliant products from any State in the Country.

But two years later, these results are a bit murkier. Impressive as it was, the initial response in Massachusetts was still only a crisis response, a short-term burst of energy and economic stimulus, with incomplete evidence about its long-term sustainability and impact.

Today, the key players have returned to their domains. But we should not leave our experience in Massachusetts behind. Instead, we need a long-term commitment to a regional and national strategy for leadership in innovation, advanced manufacturing, and resilience. Our experience reveals important ideas which could be instructive to this effort.

- Innovation is collaborative and multidisciplinary. It occurs inside ecosystems sustained by long-term investments and requires government support.
- Manufacturing is an essential ingredient to innovation. Investing in it directly increases our total innovative capacity, and neglecting it reduces our total innovative capacity.
- Corporate agility is capacity for innovation and resilience — it's the same thing. Resilient, innovative companies will thrive in Industry 4.0, not just during the next crisis.

Innovation Ecosystems

> *"The perspective is neither macro nor micro, but more meso, where individual firms are seen as part of a broader network of firms with whom they cooperate and compete. The system of innovation can be technological, interfirm, regional, national, or global. From the meso perspective, the network is the unit of analysis (not the firm)" (Mazzucato, 2015).*
>
> *— Mariana Mazzucato*

The study of business clusters and ecosystems is neither a new concept nor a singular one. It can be traced back to Alfred Marshall's "industrial districts" in 1890. Since then, there have been numerous business and economic interpretations of these and their benefits to society. One of those interpretations is the "innovation ecosystem," which consists of a network of actors working towards the commercialization of new ideas and concepts.

Massachusetts is home to an innovation ecosystem that concentrates on biomedical innovations developed in labs, commercialized in industry, and consumed in hospitals. The resilience exhibited during the crisis response in Massachusetts was a direct result of its already existing innovation ecosystem.

Massachusetts's biomedical ecosystem comprises world-class academic institutions and healthcare systems and is one of the world's most recognized industry clusters. These three actors — Academia, Healthcare Systems, and Industry — are critical to this innovation ecosystem. But so is the State, or in our case Commonwealth, who, alongside these actors, plays a crucial role through three types of public organizations — innovator institutions, broker institutions, and educators (Reynolds et al., 2021).

Innovator Institutions are accelerator institutions that focus on identifying and funding the advancement of novel technologies and startups. Broker Institutions act as facilitators to increase the connectivity of actors in the ecosystem. And Educator Institutions work to upscale the capabilities of the individual organizations in the ecosystem. These public organizations are an entry point into the market for new companies. They foster interconnectedness within the ecosystem and support the continual improvement of the actors in the ecosystem through education (Reynolds et al., 2021).

Academia, Industry, Healthcare Systems, and the State fill essential roles in our innovation ecosystem. Each serves a different purpose and is necessary to maintain and grow the ecosystem's total innovative capacity. But, innovation ecosystems, viewed as a single entity, are a spiderweb of complexity. They have no clear mandate, nor do they have any explicit rules of engagement. Instead, organizations are singular and self-serving, driven by individual missions and enabled by internal capabilities. The ecosystem consists of individual actors, but it needs to be interconnected and collaborative to be successful, which is the critical role of the State.

All of this makes the innovation ecosystem a difficult entity to measure. It is a cacophony of strategies, capabilities, resources, and activities, and singular metrics such as jobs, wages, patents, or R&D spend, used alone, are insufficient. They overemphasize one aspect of the ecosystem and underemphasize another. And so, we need to appreciate the importance of all four actors in the system — Academia, Healthcare Systems, Industry, and the State — and in doing so, measure and support them with equal attention along a long-term time scale.

Take the experience of the emergency response effort to coronavirus here in Massachusetts. State entities (MassMEDIC, Mass Life Sciences Center, Mass Tech Collaborative, MassMEP, AFFOA), Academia (MIT, WPI, UMass Lowell), Healthcare (Beth Israel Deaconess Medical Center, Mass General Brigham), and Industry (countless manufacturing firms) collaborated in the crisis response. But these entities were all here, before the pandemic, thanks to sustained investment over decades focused on building an innovation ecosystem. Without them, our response to this crisis would have had far less impact.

In our firm, it is almost an everyday experience to engage with new technologies born from the collaborative efforts of Academia, Healthcare, and the Institutions supported by the Commonwealth. This ecosystem was already in place when the pandemic arrived. It simply needed to be focused on a common adversary and given authority to move faster than its typical bureaucracy allows. In the absence of a crisis, we need a national strategy to pursue long-term investments in regionalized innovation ecosystems across the Country.

Manufacturing Innovation

> *"Manufacturing is often highly integral to the innovation process, and the common assumption that the United States can prosper as an 'innovator' without manufacturing is a dangerous one" (Pisano & Shih, 2012).*
>
> *— Willy Shih*

Today, a 50-year-old American has been completely consumed with a negative narrative about manufacturing for their entire lives. This was not only their guidance counselor telling them manufacturing was a dead-end career. Our culture has romanticized a narrative of leaving rural America and escaping the production floor for half a century. At the time, this was a valid criticism of manufacturing, and it seeped into every corner of our lives.

The prosperity of the Industrial Revolution eventually reached a point of diminishing returns. We treated manufacturing, and its people, as external to the innovation ecosystem. We viewed manufacturing as a cost and never a benefit, and our relationship with it became reductive. The only competitive advantage we could extract from it was to reduce it. So we chased these diminishing returns overseas and abandoned the notion that manufacturing could deliver value beyond the labor market.

But today, markets have evolved. Advanced manufacturing is an exciting growth market that provides tremendous value to the economy in addition to jobs. It is not dark, dirty, and dangerous anymore. Instead, it is bright, clean, and innovative. This is especially true in advanced materials, biotechnology, medical devices, and other advanced technology industries.

To appreciate the relationship between manufacturing and innovation, we need to change our mindset in America in three critical ways. The first is to understand manufacturing's relationship to R&D-based innovation. We view ourselves as world leaders in this type of pipeline innovation. Without manufacturing, we cannot sustain this status. The second is to understand manufacturing-led innovation. Manufacturing itself is its own model of innovation. We need to pursue innovation that comes from the factory floor. And the third is to decouple manufacturing from jobs as the sole metric we use to determine its success.

When innovation occurs in non-manufacturing led activities like research and development, what we call pipeline innovation, manufacturing is still a critical component in the commercialization of that idea. Manufacturing supports prototyping, pilot production, demonstrating and testing products, and early-stage small run production during commercial scale-up (Bonvillian & Singer, 2018).

In Massachusetts, our strength in R&D is supported by this type of manufacturing. Prototyping and early-stage scale-up of new technologies rely on sophisticated manufacturers who can provide just-in-time products and services (E. Reynolds et al., 2021). In other words, the innovation ecosystem we are so proud of in Massachusetts relies heavily on close relationships with manufacturing firms that can engage in new product design and development.

New discoveries, concepts, and prototypes do not become commercialized innovations without manufacturing capabilities. The problem in Massachusetts and America is that new novel products are often commercialized here but then moved overseas for high-volume long-term production. This makes it harder and harder for domestic manufacturers to achieve long-term financial success and reinvest profits into new capabilities. Moreover, it diminishes the ability of manufacturing firms to keep pace with technological advancements and reduces our overall innovative capacity.

Innovation also occurs as a manufacturing-led activity. Production technologies, new processes, and products themselves can emerge from the experience of manufacturing. In large part, this experience is generated by manufacturing knowledge that is tacit — the experience of doing. The relationship between learning and making is a vital iterative part of the innovation process. Next-generation products are developed with input from manufacturing. Even in today's hyper-connected, technology-enabled world, transferring tacit knowledge around the world is tough to do. Tacit knowledge still walks on two feet (Bonvillian & Singer, 2018).

Finally, if we only measure jobs, states like Massachusetts come across as underwhelming. Manufacturing accounted for 6.7% of employment in Massachusetts in 2018 — compared to 12.6% in industrial heartland states like Ohio (Reynolds et al., 2021). To most, manufacturing and Massachusetts seem like an odd fit. And yet, Massachusetts is home to the Massachusetts Manufacturing Innovation Initiative (M2I2), the Country's largest state-run manufacturing grant program (Reynolds et al., 2021). It is specifically targeted at advancing innovations into the market. As a result, in Massachusetts, there is an understanding that manufacturing plays a role in its reputation as an innovator and not exclusively as a job creator.

Unfortunately, policy-making operates in short-term election cycles while manufacturing and innovation require long-term strategies to yield results. The quick fix in manufacturing policy-making is to start by subsidizing legacy manufacturing technologies already at scale. Unfortunately, we do this for the singular purpose of acquiring jobs quickly rather than patiently building innovative capacity. In doing so, we become an ecosystem of junkies, not innovators.

Instead, we should incentivize manufacturing that is part of the innovation ecosystem. We should invest in manufacturing that is part of the apparatus that can discover and develop technologies. But we should also incentivize investment in manufacturing that can support scale-up and long-term commercial production. In doing so, we will increase our total innovative capacity as a country.

Resilience & Innovation

> *"The pursuit of 'efficiency' — getting the most with the least investment of energy, time, or money — was once a laudable goal, but being effective in today's world is less a question of optimizing for a known (and relatively stable) set of variables than responsiveness to a constantly shifting environment. Adaptability, not efficiency, must become our central competency" (McChrystal et al., 2015).*
>
> *— General Stanley McChrystal*

The philosophical backbone which drove the Industrial Revolution came from Frederick Winslow Taylor's doctrine "The Principles of Scientific Management." When these management best practices were paired with the technological advances of industrial engineering, the Industrial Revolution delivered us from an agrarian economy to an industrial one. And we prospered. Industry 4.0 is completely different.

Today, the technological advances of the Digital Revolution have similarly changed the world. Supply chains, ecosystems, industries, and whole economies have an increasingly dense and diverse array of connected elements. This interconnectedness has escalating nonlinearity, complexity, and unpredictability (McChrystal et al., 2015). Simply stated, the cause and effect we encounter today are inside of hyper-connected networks with vastly more potential inputs and outputs. As a result, it is increasingly impossible to predict and prepare for potential risks and their outcomes.

But today's technology challenges go beyond just digital technologies into new hard technologies fueling the IoT. Product portfolios have exploded in size and diversity due to the convergence of these technologies. Advanced materials, flexible hybrid electronics, advanced sensors, miniaturization, 3D printing, and robotics provide an incredibly diverse array of possibilities for product innovation.

Because of this, markets have evolved from mass-markets to masses-of-markets. Consumers won't accept one-size-fits-all anymore. Toys look like you, clothing can be customized online to fit your dimensions, and drugs are built to match your genetics. We no longer live in an environment of predictability and scarcity where we succeed by optimizing and capturing value from competitors. Today, we live with an abundance of opportunities and resources available to us, and we succeed by co-creating value.

The reality for corporations today is that the pace and diversity of technological advancement have completely surpassed corporate adaptability. Markets are hyper-segmented, product lifecycles are shorter, and change occurs rapidly. Our old management paradigms simply can't keep up.

This has made our supply chains increasingly complex supply networks under the constant stress of instability. While these technological advances and the Digital Revolution have given us a tremendous ability to innovate, track, measure, and communicate at light speed, they have simultaneously created more instability and unpredictability, not less.

And yet, these technological advances do not have a similar widely adopted managerial sibling to "The Principles of Scientific Management." As a result, we don't have a best practice to deal with this complexity. In large part, we still rely heavily on command-and-control hierarchies and management practices that seek out reductionist efficiencies. The antidote to today's complexity is prioritizing agility and adaptability in our organizations and moving beyond the Industrial Revolution's obsession with hierarchy and efficiency.

Today organizations need the capacity to absorb stress, recover critical functionality and thrive in altered circumstances (Schuster et al., 2021). Or, more opportunistically, they need the capacity to identify opportunities, develop critical functionality, and pursue new markets. Perpetually changing externalities are a constant — instability is the new normal — the satisfaction of a permanent fix no longer exists. Agility and adaptability are the solutions, whether the problem is a newly identified market opportunity or a global crisis.

The coronavirus pandemic broke global supply chains. Yet, two years later, we continue to struggle with raw materials, manufacturing capacity, and the delivery of manufactured goods. Strategies like dual sourcing, inventory buffers, risk simulation, and management are used to reduce complexity and create predictability. Today they are being proposed to fix our supply chain woes.

But we no longer live in an environment of predictability and scarcity. Instead, we live with an abundance of opportunities available to us, and how corporations capture value has shifted. We have moved from a product-centric model to a customer-centric model. The product-centric model, born from the Industrial Revolution, was focused on how many customers a product could be sold to — mass markets. In the mass-market context, businesses were optimized by increasing efficiency, reducing cost, and maximizing product profit — the reductionism of the Industrial Revolution.

Industry 4.0 is a customer-centric model. We are now focused on how many products we can sell to a particular customer. In this context, businesses are optimized by increasing the customer's lifetime value, reducing customer churn, and maximizing customer profit. As a result, product portfolios need to cover more than just a target market. They need to cover a customer's lifetime. This value capture model has significant implications on how we structure businesses and their supply chains.

De-risking product-centric supply chains is not the same as building resiliency into customer-centric ones. Strategies like dual sourcing can diversify supply networks and reduce dependency on interconnected elements. But a reduction of interconnectedness in a supply chain could also mean a reduction in capacity for innovation and resilience. Too often, we view our supply chain in terms of what we give and take, as cogs in a machine with inputs and outputs. Instead, we need to shift our mindset to relationship building and view the supply chain as parts of a collaborative network.

Corporate agility and adaptability require additive, not reductive, strategies. Strategic supplier management, increased transparency, integrated planning, labor flexibility, and even co-investments are better suited to increase our capacity for innovation and resilience. It doesn't matter if the purpose is to survive a crisis or pursue innovation.

New Normal

> *"We have to get to a place where we are permitting at the public policy level, just as we do in the private sector, a willingness to try new things. One of the things about innovation is that you have to also raise your tolerance for failure, and politics punishes failure" (NPR [How I Built This], 2020).*
>
> *— Deval Patrick*

Our experience in Massachusetts revealed evidence of three core ideas — that innovation is collaborative and multidisciplinary, manufacturing is an essential ingredient to innovation, and corporate agility is capacity for innovation and resilience because they are the same thing.

As we move into our third year of the coronavirus pandemic, policymakers, business leaders, and the public are anxious to see action that strengthens our supply chains and builds a more resilient economy. To do so, we need to recommit ourselves to global leadership in innovation, advanced manufacturing, and resilience. That will only come from additive, not reductive strategies.

Strategies that lead to sustained innovation, manufacturing, and resilience will require a long-term vision and commitment. Accomplishing that will also require tolerance for failure. Failure is a natural and necessary ingredient for economies to move through growth, crisis, and rebuilding cycles.

Today, as we move out of crisis and into rebuilding, I'm conflicted about how much has changed. Companies that responded to the crisis with solutions for PPE and testing have struggled, and many have even failed. Hospitals are experiencing acute staffing shortages due to burnout and will have financial troubles for years to come. Priorities and bureaucracies once again separate Dr. Zeidel's world and my world.

On the other hand, public awareness of supply chains and advanced manufacturing is at an all-time high. There is a public willingness to rethink how we approach our new normal. There are also many success cases from Companies making PPE, diagnostics, therapies, and vaccines. Healthcare has gained momentum towards becoming more inclusive and distributed, and new technologies that facilitate this are finding a receptive audience.

As we saw in Massachusetts, when we expressed our collaborative gene across healthcare systems, academia, industry, and government, we became capable of operating as one cohesive organism towards a strategic end. Leaders need to develop and talk consistently about our regional and national strategies for innovation, advanced manufacturing, and resilience. This will empower the actors in the system to act in service of that destination. If we can do that, we may find that we are at the beginning of this great American experiment and not the end.

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