Written Testimony of
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INTRODUCTION

Chair Cantwell, Ranking Member Wicker, Chair Baldwin and Ranking Member Sullivan, and distinguished members of the subcommittee good afternoon. I am honored, and humbled, to be invited to share a perspective on the some of the important Department of Commerce investments and policies that help small and medium sized manufacturers compete effectively in today's global marketplace. Thank you for the opportunity to be with you today.

My name is Kelvin Lee. I am the Institute Director at NIIMBL, the **National Institute for Innovation in Manufacturing Biopharmaceuticals**, a Department of Commerce-sponsored manufacturing innovation institute. NIIMBL is one of 16 current institutes in the Manufacturing USA Network. NIIMBL's unique sector focus is on biopharmaceutical manufacturing innovation - the technologies and workforce needed to leverage the power of biology to make life-improving and life-saving medicines. Biopharmaceutical medicines include everything from therapeutic proteins and antibodies that treat autoimmune and neurodegenerative diseases, as well as the latest cell therapies that some see as cures for pediatric cancer, in addition to gene therapies where a single dose of medicine can be the difference between a normal life or several difficult years for a newborn child ultimately resulting in death from a motor neuron disease.

AMERICAN MANUFACTURING AND THE MANUFACTURING USA PROGRAM

Manufacturing is central to America's economic power and national security. It accounts for about 11% of the gross domestic product [1,2] and employs almost 13 million people in good paying jobs [3]. Historically, the US has led the world both in basic research that leads to new technologies, as well as in the manufacturing of high-value advanced technology products such as computer chips, aircraft, and medicines. However, US leadership in advanced technology industries is not guaranteed [4] and over the past two decades, our country has lost its leadership position in manufacturing. I believe this loss of advanced manufacturing leadership is a threat to our economic prosperity and national security. We invent things here, but they are made elsewhere. I think all of us who have experienced the last two years of limited product availability because of supply chain issues can appreciate the benefits of inventing things here and making things here. I want to emphasize how important it is that we make things here.

The Manufacturing USA Program, authorized by the Revitalize American Manufacturing and Innovation Act of 2014, as amended [5], establishes large-scale public-private partnerships to drive manufacturing innovation for advanced technology products. The purposes of the program include: improving competitiveness of US manufacturing; stimulating US leadership in advanced manufacturing research, innovation, and technology; facilitating the transition of innovative technologies into scalable, cost-effective, and high-performing manufacturing capabilities;

facilitating access by manufacturing enterprises to capital-intensive infrastructure; and accelerating the development of an advanced manufacturing workforce; among others.

Each of the Manufacturing USA innovation institutes is a large-scale public-private partnership that creates a precompetitive ecosystem to advance technologies that have already demonstrated proof of concept but have not been matured and de-risked enough to be adopted into commercial manufacturing processes. Many, but not all, of these innovative technologies are being cultivated by small and medium enterprises who must navigate the so-called Valley of Death as they seek financial support to continue to mature their technologies and as they ultimately look for customers or for opportunities to be acquired or go public. **Manufacturing USA institutes are a proven, efficient, and effective model for de-risking and demonstrating these innovative technologies** regardless of whether they are being developed by universities, small companies, or large companies.

The institutes are end-to-end ecosystems for technology and workforce development in advanced manufacturing. They include state and local governments, Manufacturing Extension Partnership Centers, community colleges focused on training the workforce, universities pursuing applied research and pushing technologies into the marketplace, small and medium enterprises advancing their technologies, vendors in the supply chain, and end-user manufacturing companies selling products such as semiconductors, airplanes, biopharmaceuticals, automobiles, or robotics systems, just to name a few.

By working inside a Manufacturing USA institute, small companies can receive non-dilutive funding to collaboratively advance and demonstrate their technology. Small companies can work with big companies that may be future customers, they can work with large suppliers who may be interested to acquire the technology, and they can work with academic and government scientists to understand and improve the technology. Academic institutions can ensure that workforce training programs are aligned with industry needs and that new research discoveries, often funded by various US Government research agencies, can be developed into valuable products for society. Large companies can de-risk new technologies in a shared, precompetitive arena accelerating their adoption into new products, processes, and services. And state and local governments pursue their interests for regional economic development and job creation.

Today more than 2300 organizations, based in all 50 states, have joined at least one of the 16 Manufacturing USA innovation institutes, of which 63% are manufacturing firms and over 1000 are small to medium businesses [6]. To give a sense of the scale, in FY2021 alone, these organizations were actively working on more than 700 technology projects among the institutes and engaged over 90,000 people in advanced manufacturing workforce skills development [6]

The 16 institutes that comprise the Manufacturing USA Network each have one of three primary sponsoring agencies: the Department of Commerce, the Department of Defense, or the Department of Energy. NIIMBL is sponsored by the National Institute of Standards and Technology (NIST) within the Department of Commerce.

NIIMBL

I realize that my comments have been at a conceptual level, and I want to share something more specific that speaks to how an institute can function. NIIMBL is focused on biopharmaceutical manufacturing. Unlike traditional small molecule generic medicines which are primarily regulated based on the product itself, biopharmaceuticals are regulated based on the manufacturing process. The biopharmaceutical manufacturing industry is extremely risk averse to implement new manufacturing technologies into their processes because it is difficult to know

what questions health authorities may have about how a new technology works. Answering those questions can delay speed to market and speed to patient and as a result, businesses often make decisions to rely on previously accepted approaches rather than newer approaches.

Moreover, companies must navigate a globally diverse environment of regulations - each country's health authority maintains its own expectations and process for approving medicines. Here in the United States that responsibility rests with the Food and Drug Administration. In Canada the responsibility rests with HealthCanada, in Switzerland the responsibility is with SwissMedic, and so on. An approval to use an updated manufacturing process in one country does not ensure approval in another country and so relying on older existing approaches is a better business decision than employing different manufacturing processes (one conventional and one innovative) to make the same product for use in different countries. As a result, companies tend to choose traditional manufacturing technologies and approaches for which there is broad understanding and experience even if innovative approaches are available. However, once a new manufacturing technology is accepted and adopted somewhere within the industry, other companies are quick to embrace those approaches because they confer improved efficiency, reliability of supply, and other benefits to companies and patients. Within our community, we talk about the notion that when it comes to manufacturing technologies, companies would rather be a fast second to implement a new technology rather than to be first. By de-risking technologies, our goal at NIIMBL is to have all companies go first together.

The NIIMBL mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards to enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing US competitiveness in this industry [7]. While the US is a global R&D leader in this space, US biopharmaceutical manufacturing productivity is 40% lower in 2020 than it was in 2006 – a bigger drop than any other manufacturing sector [5]. The US biopharmaceutical trade deficit was $3.4 billion in 2000 and an astonishing $85.7 billion in 2020 – only two decades later [5]. Examples of countries that lead in biopharmaceutical manufacturing and workforce development include Ireland, United Kingdom, Germany, Switzerland, and Singapore.

An example of how NIIMBL works. One area in which NIIMBL seeks to transform biopharmaceutical manufacturing is in the evolution from batch to continuous processing – an evolution that many other industrial sectors have gone through such as oil refining, metal smelting, paper, automobiles, and foods. The benefits of continuous manufacturing relate to efficiency, flexibility, cost, and speed, among others. The current state of the art commercial monoclonal antibody manufacturing processes are batch processes. Bioreactors are used to grow cells that express an antibody. Those materials are collected, purified, and formulated into vials, IV bags, or syringes. The resulting antibody treatments are targeted for patients with various forms of cancer, autoimmune disorders, metabolic and infectious diseases. It is very likely that every person in this room has either received an antibody treatment or knows someone who has had their life improved, or saved, by such a treatment.

Antibodies can be made by continuous manufacturing. Most of the companies I talk to have demonstrated that capability in their own facilities using their proprietary continuous manufacturing processes. The technology works, yet commercial production is still by batch processing rather than by continuous processing. To move the field forward, NIIMBL brings together diverse companies including drug developers, vendors and suppliers of equipment, small businesses, and academics, to work on a non-proprietary continuous manufacturing testbed. Within NIIMBL, hundreds of subject matter experts from dozens of companies collaborated over the past two years to design a continuous manufacturing process that is

generally (but not specifically) the same as the proprietary platforms in the company labs – with the notable exception that the NIIMBL process is shared. Scientists from different companies can work alongside each other and with those from academia and government to turn the proverbial knobs on the equipment to develop a shared understanding of how continuous manufacturing works. They can take those learnings back inside their own companies to gain confidence in this approach. Vendors and suppliers can work on standardized solutions to streamline supply chains. And small companies with innovative technologies can test their technologies in the testbed to show the improvements that can be made.

We see the desire by companies, and by the US Government, to increase domestic biopharmaceutical manufacturing capacity going forward. Our vision for the future of continuous manufacturing is a future where there are smaller, less expensive, more flexible, and more geographically distributed manufacturing facilities. A future where first-generation continuous manufacturing factories are being built in the US, while NIIMBL works on demonstrating second and third generation continuous manufacturing paradigms. This future will result in a more resilient supply of medicines, increased patient access and more and better jobs. Our NIIMBL continuous manufacturing testbed, not to mention 100+ other technology innovation projects at NIIMBL, are going to help us realize this vision.

Neither NIIMBL, nor any of the Manufacturing USA innovation institutes, can meet the global competitiveness challenges of today by advancing technology alone. Our country must also focus on workforce development. NIIMBL's workforce development programs are designed to ensure that these new factories, which are ideally geographically distributed around the country, can be staffed by skilled workers who are also located around the country. All Americans should have an opportunity to gain the skills needed to work in this important industry, or in advanced manufacturing careers generally, and all Americans should have access to those opportunities near their communities. Realizing this vision for the American manufacturing worker is vital to having a resilient economy. But workforce development needs aren't only a concern for large manufacturing companies. Small companies need skilled, agile workers; and even the US Government will benefit directly, and indirectly, from a much greater focus and investment on people acquiring industry-relevant manufacturing skills.

FOUR CONSIDERATIONS FOR THE FUTURE AS OPPORTUNITIES TO IMPROVE

America's long-standing ability to meet and overcome any crisis is rooted in a spirit of innovation, a capability to manufacture, and a people with skills and a commitment to succeed. Multiple global events over the past few years have challenged America's ability to respond rapidly to threats and there are gaps to be addressed to ensure America's national, economic, health, and energy security in the face of such threats and the rise of more technologically advanced competitors. As Chair of the Manufacturing USA Institute Directors Council, I believe we must create a coordinated set of strategic investments, including policy and regulatory updates, that build upon existing institutions, address gaps, and anticipate future needs.

1) Enhance and expand upon the successes of the Manufacturing USA Program.

The Manufacturing USA Program is an established, effective, and proven program that promotes US competitiveness. Institutes have demonstrated significant amounts (2.8 to 1) of non-Federal co-investment for every Federal dollar [6]. However, our investment as a nation for advanced manufacturing innovation is relatively small compared to other countries. Relative to the need, institutes have very limited resources available to support ecosystem development and workforce development for their sectors. For example, the United Kingdom has a similar program called the Catapult Network. Their broad-based initiative includes three institutes that work in the same technical area as NIIMBL. Based on a variety of public sources and press

releases, we estimate that the UK government invested about $1 billion USD for biopharmaceutical manufacturing innovation for the period of 2015 to May 2021. That amount is roughly 12 times more in absolute dollars than the US investment in NIIMBL over that same time period and about 90 times more investment than the US when normalized to GDP. The other Manufacturing USA innovation institutes almost certainly have similar examples. Other countries want to be the home of global innovation and manufacturing and the US must scale our investments appropriately to ensure our economic and national security.

Beyond the issue of funding for any single institute, the collection of institutes is intended to serve as a network providing a national competitive advantage. By ensuring complementarity of technology sectors, institutes can collaborate on technologies allowing each ecosystem the ability to bring their own expertise and capabilities to help address each other's needs. For example, CESMII, the Department of Energy-sponsored Smart Manufacturing Institute could provide valuable expertise to support NIIMBL's future vision of continuous manufacturing. As a network, we have not yet achieved our potential because of resource constraints. Moreover, the authorization of exciting new innovation-centered programs such as DOC's Regional Technology and Innovation Hubs and the NSF's Technology, Innovation, and Partnerships Directorate risks duplication of effort. **I urge the Subcommittee to 1) work with appropriators to ensure there are adequate resources for DOC to provide more support to all institutes for their own work and to collaborate across the network, and 2) ensure new initiatives build upon existing successes, maximize coordination, and minimize duplication.**

2) Capital Investment in Demonstration Facilities.

A key gap in US competitiveness relates to manufacturing scale-up infrastructure in this country. Manufacturing USA innovation institutes seek to mature and de-risk technologies to the point of commercial adoption. However, as a technology matures the cost to make such demonstrations also increases, largely influenced by the need to test the technology in real-world manufacturing environments. Such environments have high utilization rates by companies and therefore are not available for testing purposes. Investments to create such infrastructure around the nation for various sectors, would help Manufacturing USA innovation institutes move technologies from proof of concept all the way through commercial realization. Without such infrastructure, manufacturing technologies may mature to a point, then move overseas for final demonstration and adoption as competitor nations benefit from early-stage US technology development. The ability and investment to establish such specialized research and testing facilities here in the US will support small manufacturers de-risking their technology. It can also be the basis for a national network of workforce training facilities that would provide the US with world-leading workforce training capabilities. **I recommend the Subcommittee consider explicit language authorizing DOC to invest and create such specialized research and testing facilities through the Manufacturing USA Program.**

3) Advance a National-Scale Manufacturing Careers Campaign and Program.

I believe that any advanced manufacturing innovation strategy without a clear emphasis on workforce and talent development will fail. Current Manufacturing USA innovation institutes have an incredible range of effective programs that connect people to skills, leading to careers. NIIMBL's eXperience program partners with historically black colleges and universities and other minority serving institutions to introduce students to biomanufacturing careers. Our friends at the DoD-sponsored LIFT institute run Operation Next, an innovative training and credentialing program to transition active-duty soldiers nearing the end of their service into high demand manufacturing fields. The FlexFactor program run by the NextFlex institute is a highly successful STEM outreach program to introduce students to advanced manufacturing technology careers – it's so successful that many other institutes, including NIIMBL, are working

to adapt the FlexFactor framework to their own industry sector. Despite these great programs, meeting the workforce needs of today, and tomorrow, can't be done by inspiring or training on a local level alone. The US needs a significant upgrade in how we think about manufacturing careers. The impression of dirty, dark, and dangerous environments still persists, even though, for example, a biopharmaceutical manufacturing facility is clean, cool, and quiet. Only the US Government has the resources and power to change this perspective rapidly. Without such a change, and an available and ready workforce, companies will continue to build their factories where they can get talent and that poses risks to our competitiveness. I understand that solutions to this important question are both within the Committee's jurisdiction and might also require collaboration with others. **I recommend the Subcommittee explore ways to significantly expand advanced manufacturing workforce and talent development programs by Manufacturing USA institutes including a national campaign to promote manufacturing careers that would be available to all Americans.**

4) OTAs: Ensuring Efficient and Effective Use of Federal Resources Aligned with the Goals.
Across the 16 institutes, there are a variety of contracting vehicles that have been used by the Department of Commerce, Department of Defense, and Department of Energy to work with the institutes. Some of these vehicles are Cooperative Agreements and others rely on Other Transactional Authority (OTAs). The industry-led nature of the work of the institutes, including an emphasis on working with small manufacturers to advance their technologies, is well-aligned with the concept of OTAs which were established as ways to permit Federal agencies to work with non-traditional contractors and small businesses to prototype and advance technologies and allow close collaboration between the Federal agency and the partner. Our experience is that the use of Cooperative Agreements is not as efficient nor effective for working within ecosystems as large as a Manufacturing USA innovation institute such as NIIMBL, and its use can create disincentives to participation by companies. **I urge the Subcommittee to find ways to have the DOC Manufacturing USA Program adopt the use of existing other transactional authority for DOC-sponsored institutes to facilitate enhanced interactions between institutes and small and large businesses.**

CONCLUSIONS
I am grateful to have the opportunity to share my perspective on American manufacturing, the role of small to medium enterprises, Manufacturing USA, and our global competitiveness. Our history as leaders of research and development of advanced technologies and a domestic capability for manufacturing those technologies was no accident. Our country's significant investment in early-stage science and technology together with an entrepreneurial and innovative mindset, and a skilled and capable workforce made us the greatest nation in the history of the planet. However, the world is changing, technologies are advancing, and other countries are investing and implementing policies that have eroded our leadership position. We must not wait!

As Marv Levy, Hall of Fame NFL coach of the Buffalo Bills from the 1980s-90s, is attributed to have said: "If you don't change with the times, the times are going to change you".

[1] https://data.worldbank.org/indicator/NV.IND.MANF.ZS
[2] https://www.brookings.edu/research/global-manufacturing-scorecard-how-the-us-compares-to-18-other-nations/
[3] https://www.nam.org/facts-about-manufacturing/
[4] https://itif.org/publications/2021/11/22/going-going-gone-stay-competitive-biopharmaceuticals-america-must-learn-its/
[5] 15U.S.C.§278s
[6] https://www.nist.gov/publications/manufacturing-usa-highlights-report-2022
[7] https://www.niimbl.org