Written Testimony of

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INTRODUCTION

Chair Babin, Ranking Member Lofgren, Chair Obernolte, Ranking Member Stevens, Chair Weber, Ranking Member Ross, and distinguished members of the subcommittees, good morning. I am honored to be invited to share a perspective on the important topic of strategic priorities in biotechnology as we collectively pursue the Golden Age of Innovation. 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, National Institute of Standards and Technology (NIST)-sponsored manufacturing innovation institute. NIIMBL is one of 18 institutes in the Manufacturing USA Network. The Manufacturing USA Program, authorized by the bipartisan Revitalize American Manufacturing and Innovation Act of 2014, as amended [1], 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 [1].

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, to the latest cell therapies that some see as cures for pediatric cancer. Biopharmaceuticals include gene therapies where a single dose of medicine can be the difference for a newborn child between a normal life or several difficult years and eventual early death from a motor neuron disease.

As a Manufacturing USA institute, NIIMBL is a public-private partnership focused on advanced manufacturing innovation. 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 and security [2]. The US is a global research leader in this space. However, we have not been successful in promoting advanced manufacturing innovation and realizing the benefits of domestic manufacturing. US biopharmaceutical manufacturing productivity was 40% lower in 2020 than it was in 2006. This represents a bigger drop than any other manufacturing sector [3]. The US biopharmaceutical trade deficit has grown over the past two decades from $3.4 billion in 2000 to an astonishing $85.7 billion in 2020 [3]. NIIMBL de-risks biomanufacturing innovations by partnering industry stakeholders (large and small) with academics and federal scientists so they can collaboratively innovate and also build a US biopharmaceutical manufacturing workforce to fill the needed jobs in advanced manufacturing. Every public dollar invested in NIIMBL is matched by at least one private sector dollar. This model for unleashing American innovation, a model also pursued by two sister biomanufacturing innovation institutes (BioMADE and BioFabUSA) as well as the 15 other Manufacturing USA institutes, is proving effective as described by NIST with nearly 3000 member organizations leveraging $539 million in funds to collaborate on over 900 major applied research projects in the Manufacturing USA network [4,5]. But there is much to be done.

AMERICAN INNOVATION AND ADVANCED MANUFACTURING IN A GLOBALLY COMPETITIVE ENVIRONMENT

Manufacturing is central to America's economic power and national security. It accounts for about 11% of the gross domestic product [6,7] and employs almost 13 million people in well-paying jobs [8]. 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 continued leadership in advanced technology industries is not assured. **Over the past two decades, our country has lost its leadership position in manufacturing.** In 1980, the US manufactured over 40% of global high-technology goods. Today this is a mere 18% [9]. When it comes to high value products, including biotechnology-based products, we invent things here, but they are made elsewhere and imported. I believe this loss of advanced manufacturing leadership is a threat to our economic prosperity and national security. One cannot expect to address a trade deficit without manufacturing and it can be argued that one cannot be truly independent of coercion without advanced manufacturing capabilities [10]. Indeed, we forged a long history of leadership in advanced industries only to subsequently lose our competitive advantage to the more effective industrial policy and more patient private sector capital of other countries [11]. Biopharmaceutical manufacturing is not an isolated case. There are precedents. It has happened in telecom, semiconductors, solar panels, and chemicals [11]. We must act now to respond to today's strategically competitive environment. *By way of analogy, it's as if we are getting ready to enter a football season knowing that the team that wins the season's championship will have decades of future winning seasons – seasons made up of security, power, wealth, and prosperity. We need to act now to be ready for the competition before us.*

While our country debates strategy and seeks to understand how we lost our advanced manufacturing leadership, other countries are building upon strategic, long-term approaches to techno-economic leadership. As one example, China has followed a deliberate path as explained in a recent ITIF report [10]: the "first step being to attract foreign investment", the "second step was to attempt to learn from foreign companies", the "third step was to support Chinese companies in their efforts to copy and incorporate foreign technology," and the final step to "enable Chinese firms to become independent innovators" [10]. Today, the US leads in global production for only three of ten advanced industries; whereas China leads in seven of ten

[10]. Two decades ago, the US led in 60 out of the 64 critical technologies that the Australian Strategic Policy Institute's Critical Technology Tracker covered, while China led in three at that time; today, China leads in 57 out of 64 critical technologies while the US leads in seven [12]. In a recent NIST report [9] it is noted that China has built enough solar panel factories to supply the world and they have built enough auto factories to make every car sold in China, Europe, and the US, among other impressive developments in semiconductors and electric vehicles. According to observations in the report, China is focused on innovation and self-reliance. Overcapacity also allows them to focus on growth of developing countries which has other geopolitical implications for the US. **We need policies that provide sustained, robust, and significant investments or we risk being dominated in many of these fields [9] including biotechnology.** Competitors are building their innovation capacity and are already performing at a high level. *In the quest to win the football championship, the competitor is already fielding one of the strongest teams with a proven playbook and a deep bench of great players and coaches that already outperform others.*

AMERICAN INNOVATION AND COMPETITIVENESS IN BIOTECHNOLOGY

The US has been a leader in basic research in the life sciences. The US led the Human Genome Project and created global data-sharing platforms. Agencies such as the NSF, NIST and NIH, fund foundational research that fuels the innovation pipeline. And these investments, and the subsequent value created by bringing basic research discoveries into products and services have led to wealth, economic prosperity and health security benefits for the past several decades. *Our team has had success in the past.*

However, as the National Security Commission on Emerging Biotechnology (NSCEB) report [13] highlights, "**our innovation edge is eroding**." In 2010, the US published 45% of the top cited papers in synthetic biology and China published 13%; by 2023, China published 60% of the top papers while the US published only 7% [13]. In 2012, the US had 218 of the top 10% most cited publications in biotechnology and China had 139; by 2022, China had 671 such top-cited papers while the US published only 145 such papers [14]. In 2023, Chinese publications accounted for 19% of all publications in the field of biomanufacturing and 26% of all publications in top cited journals making China first in the world in terms of overall publications and high-impact publications in biomanufacturing [14]. Moreover, their H-index (a measure of impact and quantity) was #1 among countries for biomanufacturing [14]. In 2023, Chinese publications accounted for 21 of all publications in the field of novel antibiotics and antivirals and 28% of all papers in top-cited journals, whereas the US was 14% [14]. Their H-index in novel antibiotics and antivirals was also #1 among nations. China is a leader in quantity and in quality of publications. *The competitor team is running more plays and scoring more touchdowns than other teams.*

Across a variety of measures including patents, new drugs, out-licensing deals for drugs, clinical trials, and even development of laboratory space for biotechnology R&D [10,11,15,16], China is either a leader, a US peer, or a rapidly rising nation depending on the metric. Indeed, "**China views biotech as a key emerging industry critical to the country's global competitiveness, and has developed a national biotechnology strategy to bolster its industry's innovation capabilities"** [14]. They are implementing their strategy, in the case of biopharmaceuticals, to move from a system that replicates discoveries and manufactures them, to a system that creates new treatments and manufactures them. Investment bank Stifel projects that 37% of big pharmaceutical companies' licensed molecules this year will come from China alone [16]. Stifel sees a future where China could potentially dominate categories such as

cancer therapies and autoimmune diseases [16] (beyond their leadership mentioned above in novel antibiotics and antivirals). In 2024, China outpaced the US in clinical trials, 7100 to 6000, in the World Health Organization's International Clinical Trials Registry Platform [17]. *Their team has a great stadium, dedicated and vested ownership, and their players and coaches are training relentlessly to win every game.*

In the US, the federal government plays a foundational role in funding and de-risking biotechnology R&D. Basic research is the foundation of biotechnology innovation. Without it, there will be no pipeline of discoveries to translate into products - products that are essential for our security (food, public health, and defense) and our economic prosperity (job creation, value creation, and global competitiveness). By providing sustained, robust, and predictable funding for basic research, the US government can ensure private investors will want to focus their capital here in the US and that the American people and our shared values are protected. Strengthening federal investment in basic research can also create the skilled workforce needed to be a global leader. From R&D scientists making new discoveries, products, and processes to those working on the manufacturing floor running bioreactors in a cleanroom making a cure for pediatric cancer, the US cannot be a leader in biotechnology without a world-leading workforce. *One cannot expect to have a successful team without having draft picks, a strong scouting infrastructure, effective training camps, success in developing young players, and a strong start to each game.*

The needs go beyond basic research. Many promising biotechnology innovations fail to reach the market due to lack of support getting across the so-called valley of death. Once proof of concept is established, perhaps in a federal lab or at a small start-up company, there is a long road of technology maturation, de-risking, and demonstration that must be followed prior to commercial success. This technology scale-up is often where ideas and technologies fail – not because they lack merit but because they lack support. Government programs such as the Manufacturing USA institutes, Department of Energy laboratories, SBIRs, and many other programs support the translation of basic research through scale-up and commercialization, although they have not been adequately funded. *A team cannot expect to win championships without investing in some experienced veterans, coaches, and a culture of playing the second half of each game strong in all phases of the game.*

An interesting perspective comes from Rob Atkinson at ITIF [10] who writes that "China looks at investing in advanced technology industries the way the West looks at investing in military weapons systems. **Economic returns are not the goal; power and security are.**"

RECOMMENDATIONS

The time to act is now. 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. So what is to be done to recapture US leadership in biotechnology? OSTP Director Kratsios recently commented that our pursuit of a Golden Age of Innovation requires us to maintain American technological leadership which will be best achieved through a strategy of both promotion and protection [18]. The NSCEB report [13] clearly articulates several important recommendations aligned with the concept of promoting and protecting US biotechnology interests. I will highlight a few key actions:

1) **We must ensure a more coordinated and strategic approach to biotechnology activities** within the government. Biotechnology research, development, and

commercialization intersects with diverse agency missions. Each has an important and complementary role to play with unique perspectives and experiences that are needed to forge a more focused, intentional strategy to ensure we promote and protect our biotechnology interests. The need for such an office has been expressed both by the NSCEB report [13] as well as a recent National Academics of Science, Engineering, and Medicine consensus study report [19].

2) We must **significantly increase federal support for basic biotechnology research** through relevant science agencies to ensure a robust pipeline of discoveries. US leadership in basic life science research will have significant impacts on our public health, our energy needs, and access to a healthy food supply. The value of US leadership extends to helping define global standards and norms to promote a global bioeconomy where dependence on any one country for critical products is avoided [20]. These investments will also turn the tide and help us develop the talent pool needed to be the premier destination for biotechnology talent.

3) We must **increase support for programs that support scale-up and commercialization of technologies** by explicitly calling out biotechnology as a critical and emerging technology area and investing in public-private partnerships that facilitate technology maturation across the valley of death. Such investments will leverage private sector knowledge and capital to promote an accelerated pace of biotechnology innovation in the US.

4) We must **invest in the creation of technology scale-up demonstration facilities to facilitate technology scale-up and innovation** – taking discoveries and turning them into products of value to society. A gap exists for de-risking and demonstrating new technologies and the creation of these specialized facilitates will promote adoption and commercialization of innovative technologies. Such facilities can also provide foundational infrastructure for workforce training programs.

5) We must **invest in a range of workforce development programs** from operator skills training for some, to opportunities for advanced research for others, to ensure that we have the needed talent pool to fill the high paying jobs that this field creates.

6) We must **secure and protect our biotechnology supply chains and critical inputs** to ensure resilience in times of crisis or conflict. We can partner with allies to reduce risks and ensure the US is better positioned to respond to any biotechnology-related national security issues.

CONCLUSIONS

I am grateful to have the opportunity to share my perspective today. I believe that if we are informed about the opportunity and the risks, that we will choose to update our policies to enable a more strategic and nimble response to today's strategic techno-economic competition. Our nation's history as leaders of biotechnology research and development was no accident: we achieved prominence through robust and purposeful investment in early-stage basic research, academic-industry partnerships, a creative and dedicated workforce, and a healthy innovation system populated by innovators and entrepreneurs who create value from basic discoveries. However, the world has changed, technologies are advancing, and other countries have

invested and implemented policies that leave us behind. This changing landscape for innovation has eroded our leadership position. We need to act. As the NSCEB report noted "**countries that win the innovation race tend to win actual wars, too**" [13].

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] 15U.S.C.§278s
[2] https://www.niimbl.org
[3] https://itif.org/publications/2021/11/22/going-going-gone-stay-competitive-biopharmaceuticals-america-must-learn-its/
[4] https://www.manufacturingusa.com/sites/manufacturingusa.com/files/2025-05/Mfg_USA_Overview_2025_05_30.pdf
[5] https://nvlpubs.nist.gov/nistpubs/ams/NIST.AMS.600-14.pdf
[6] https://data.worldbank.org/indicator/NV.IND.MANF.ZS
[7] https://www.brookings.edu/research/global-manufacturing-scorecard-how-the-us-compares-to-18-other-nations/
[8] https://www.nam.org/facts-about-manufacturing/
[9] https://nvlpubs.nist.gov/nistpubs/ams/NIST.AMS.600-17.pdf
[10] https://itif.org/publications/2024/09/16/china-is-rapidly-becoming-a-leading-innovator-in-advanced-industries/
[11] https://itif.org/publications/2024/02/29/not-again-why-united-states-cant-afford-to-lose-biopharma-industry/
[12] https://www.aspi.org.au/report/aspis-two-decade-critical-technology-tracker-the-rewards-of-long-term-research-investment/
[13] https://www.biotech.senate.gov/
[14] https://itif.org/publications/2024/07/30/how-innovative-is-china-in-biotechnology/
[15] https://www.cbre.com/press-releases/rapid-expansion-of-international-life-sciences-markets-with-strong-growth-in-china
[16] https://www.stifel.com/newsletters/investmentbanking/bal/marketing/healthcare/biopharma_timopler/2025/BiopharmaMarketUpdate_033125.pdf
[17] https://www.axios.com/2025/05/29/china-biotech-boom-us-drug-trials
[18] https://www.whitehouse.gov/briefings-statements/2025/05/remarks-by-director-kratsios-at-the-national-academy-of-sciences/
[19] https://nap.nationalacademies.org/catalog/25525/safeguarding-the-bioeconomy
[20] https://www.state.gov/wp-content/uploads/2024/11/ISAB-Report-on-Biotechnology-in-the-PRC-MCF-Strategy_Final.pdf