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House Select Committee on the Chinese Communist Party Hearing
Growing Stakes: The Bioeconomy and American National Security
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Good morning, Chairman Gallagher, Ranking Member Krishnamoorthi, and distinguished members of the Committee. Thank you for the opportunity to appear before you today to discuss the importance and impact of biotechnologies on U.S. national security and geopolitical competition with China.

I am a physician, and Senior Fellow at In-Q-Tel (IQT), a non-profit venture capital investor for U.S. national security agencies. IQT's mission is to anticipate, identify, evaluate, and leverage commercial technologies emerging from innovative startup companies to address U.S. national security needs. I joined IQT in 2014 as an Executive Vice President to lead the company's initiative in biotechnology. Prior to IQT, I was honored to serve as Under Secretary of Science and Technology in the Department of Homeland Security (2009-13), and as Assistant Secretary of Energy for Environment, Safety and Health (1993-97). In the decade between those positions, I was CEO of the Johns Hopkins Center for Biodefense Studies, and Founder and CEO of the University of Pittsburgh Center for Biosecurity. I held academic appointments at these institutions as Professor of Public Health and Professor of Medicine and Public Health, respectively.

My testimony addresses four points: 1) the economic and technological importance of the "biorevolution" now underway; 2) China's determination to dominate biotechnologies and its strategy to achieve this; 3) the nature, advantages and vulnerabilities of America's ecosystem for biotechnological innovation; and 4) Suggestions for how the Federal Government might strengthen U.S. competitiveness in biotechnology and build a bioeconomy capable of competing with China's ambitions. I would be happy to elaborate further during the hearing or in writing if the Committee would find that useful.

First, global economic competitiveness will increasingly depend on a nation's bioeconomy – its ability to develop and use biotechnologies to produce food and energy, improve human health, design and manufacture essential products and ensure resilient supply chains.

Over the past decades, advances in the life sciences and increasing computational capacities have converged to create a "revolution" in our ability to understand and to predictably manipulate living systems. This "biorevolution," and the new technologies it is producing, will

have a deep and lasting impact on a broad range of industries beyond biomedicine - including agriculture, manufacturing, energy and planetary health.

Biomedicine has already been greatly augmented by the biorevolution. Cell-based cancer therapies, and genes engineered to cure inherited diseases, and new vaccines against ancient disease scourges like malaria are examples of how profoundly biotechnologies are impacting human health. But biotechnologies will also dramatically change agricultural production and practices, industrial design and manufacture, and environmental stewardship.

Biotechnologies will be essential to solving some of the world's biggest and most urgent problems such as ensuring food security, improving supply chain resiliency, preventing and curing disease, and mitigating the effects of climate warming. Some biotechnological advances will pose significant market, regulatory and ethical challenges.

As biotechnologies emerge and mature, they will transform the global economy, as the digital revolution did before it. Biotechnologies will likely propel significant economic growth, affecting as much as 20% of global economic activity by 2040, based on bioeconomy growth rates relative to gross domestic product (GDP).[1]

The McKinsey Global Institute estimates that 60% of the physical inputs to the global economy could be produced biologically based on existing science, and that the Biorevolution, in its fully fledged form, could have a $4 trillion annual impact on the world economy over the next 10-20 years.[2] They estimate over half of this impact would be on industries other than human health. A recent analysis by TD Cowen is "ahead" of McKinsey's $4T estimate, assessing that synthetic biology in particular is at a commercial inflection point, and will grow to a mid-single digit trillion dollar market by 2025.[3] Other countries recognize the economic advantages that biotechnologies can yield and are moving to establish and strengthen their own bioeconomies.

Second, China is determined to become the dominant global force in biotechnology and is aggressively pursuing a comprehensive and ambitious strategy to accomplish this. The Chinese Communist Party (CCP) sees biotechnologies as essential to its economic future and integral to its ambition to surpass the power and influence of the United States. It is directing a great portion of its biotechnology efforts towards solving some of its most urgent domestic problems. These include the need to expand and improve a grossly inadequate health care system, and the need to ensure food security in the face of dwindling resources, extreme weather and growing demand.

[1] U.S. National Intelligence Council, *Global Trends 2040: a More Contested World*, March 2021

[2] McKinsey Global Institute, *The Bio Revolution – Innovations Transforming Economies, Societies and Our Lives*, May 2020

[3] TD Cowen, *Is Synthetic Biology Reaching a Tipping Point*?, Cowen and Company, LLC; June 23, 2023.

The CCP has long recognized biotechnologies to be "critical strategic technologies" and has been aggressively pursuing an ambitious and comprehensive strategy to dominate the global bioeconomy. This strategy includes utilizing civilian-military fusion funding schemes, building extensive infrastructure for biotech research and development (R&D), establishing multiple programs to entice top scientists and biotech managers from abroad, and incentives designed to generate its own domestic talent pipeline.

China understands the importance of melding the life sciences and biotechnologies with advanced analytics, and has systematically amassed huge biological data collections containing genomic data of humans, plants and animals, as well as human clinical data. The CCP has directed its giant internet agencies to assist in applying machine learning and artificial intelligence to these data to accelerate biological research and biotechnology development. Towards this end, China has established 17 "biomedical industrial clusters" which co-locate life sciences research universities with companies focused on advancing artificial intelligence (AI) to generate research that combines biology and AI.[4]

Through most of the past decades, China has benefited – via legitimate and illicit means – from the basic research discoveries made by U.S. and European scientists. The CCP's strategy was to focus on translation of these scientific discoveries into useful products and solutions. In recent years, the CCP has promoted more basic science research, but retains a focus on developing technology to solve specific problems. The CCP and the Chinese Academy of Science have significantly reorganized the countries science funding agencies and research organizations in pursuit of greater productivity, particularly in synthetic biology, which underpins much of the Chinese biotech strategy for improving health care and agricultural productivity.

China is also making extraordinary progress in building a sophisticated pharmaceutical industry, a goal of Xi Jinping made explicit in the "Made in China 2025" strategy.[5] Since 2015, China has made significant changes to its regulatory policies, bringing them more in line with U.S. standards. In the past twenty years, China has evolved from a manufacturer of generic drugs (of uneven quality), to becoming a producer of innovative drugs for the global market, posing a genuine challenge to U.S. pharmaceutical preeminence.[6]

The quality and quantity of Chinese scientific publications in biology and biotech have increased significantly over the past decade. This is not simply the result of China stealing knowledge and technologies developed by the West, but a reflection of the importance the CCP places on excelling in biotechnology. CCP spending on R&D has increased doubled since Xi Jinping gained power in 2012. It may be prudent and necessary to restrict some Chinese companies or researchers from operating in the U.S., but such bans and strictures alone will not secure the U.S. bioeconomy. We must outcompete China's scientific research and technology development.

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[4] A. Puglisi, Chow, D.: *China's Industrial Clusters – Building AI-Driven Bio-Discovery Capacity*; Center for Security and Emerging Technology, June 2022.

[5] Nature Biotechnology, *The Next Biotech Superpower*." Vol.37, Nov. 2019

[6] S. Barbosu, ITIF, Not Again: *Why the United States Can't Afford to Lose Its Biopharma Industry,* Feb.29, 2024

A 2022 report by the Australian Strategic Policy Institute (ASPI)[7] compared Chinese progress in 44 key strategic technologies to that of the Quad countries from 2018-22. The analysis included three areas of biotechnology: synthetic biology, biomanufacturing and medical countermeasure development. China was found to have significant leads in synthetic biology and biomanufacturing, based on comparisons of a country's number of top research papers within a tech area and the locations of the institutions which produced them. The report assessed that U.S. was the global leader in countermeasure development.

China is directing much of its efforts in biotechnology towards forging solutions to urgent domestic problems - specifically, to improving health care and bolstering China's food security.

Health Care –
China's 1.4 billion people bear a huge burden of disease. China has over 100 million diabetics, has the world's highest incidence of lung cancer, and is beset by ongoing epidemics of neck and esophageal cancer. By 2050, 30% of the population will be over 65 years old and increasingly susceptible to chronic diseases such as heart disease, stroke, dementia, etc. Yet health care in China suffers from inadequate and inequitable access to drugs and medical technologies, and insufficient numbers of trained medical professionals. In China's rural areas, health care is all but non-existent.

Xi Jinping regards delivering health care as essential to the CCP's credibility, as announced in the "Healthy China 2030" policy agenda. The CCP's health strategies are complex, but include an emphasis on developing digital health services to increase access to care; ambitious efforts to use genomics and "precision medicine" to identify and reduce disease risks and to develop new drugs, for cancer in particular; and a long-term strategy to create a world class pharmaceutical sector to service the huge Chinese drug market and gain market share of global pharmaceutical development and sales.

Pharmaceuticals and biomedical technologies - CCP policies, including a major revision of China's FDA in 2015 to more closely mimic the U.S. FDA regulatory framework, have been instituted to help Chinese biotech and Pharma companies "move up the value chain", develop pharmaceuticals to meet China's enormous domestic needs, and eventually become designers of innovative new drugs competitive in global markets. CCP policies typically advantage Chinese firms engaged with foreign biotech and pharma companies which are attracted to China as the world's second largest pharma market, where modern drugs, especially cancer drugs, developed by multinational pharmaceutical corporations are in high demand. China's large patient populations also make China an attractive site for clinical trials.

[7] Australian Strategic Policy Institute, *The Global Race for Future Power: Who is Leading the Critical Technology Race?,* Report no. 69, 2023

Chinese biopharma companies have benefited from recruitment of highly trained and managers from multinational pharmaceutical companies experienced in the complex process of moving an experimental drug through clinical trials and regulatory procedures. Chinese drug companies have long been adept at manufacturing small molecule drugs, but they have moved into biological drugs as well and are becoming increasingly innovative.[8] Chinese biopharma companies are beginning to produce first-in-class pharmaceuticals such as the monoclonal antibody which recently achieved FDA approval for a type of blood cancer. China's progress in pharmaceutical design and manufacturing has been rapid and impressive, but these are still early days for China's pharmaceutical innovation ecosystem which has attained only limited scale and profitability. To succeed, Chinese biopharma firms must continue to integrate their processes into global regulatory systems, and maintain funding support, which today comes mostly from China.

Food insecurity is a long-standing issue in China, which has a history of destabilizing famines. Today, limited arable land and water, widespread pollution, an ageing rural population, and the effects of climate warming and extreme weather threaten China's food supply. The CCP's food security strategy includes using synthetic biology techniques to engineer more productive and resilient food crops. China is also attempting to apply engineered biology to create food animals with more protein-rich muscle. Xi Jinping has endorsed efforts to biomanufacture meat from animal stem cells to provide new protein sources to meet growing demands. These efforts are reflected in China's strong lead in publishing research papers describing the use of CRISPR-based gene-editing techniques.

Third: The U.S. bioeconomy is the world's largest. America's biotechnology innovation ecosystem is the envy of the world, but it has vulnerabilities associated with translating basic biological research into products, especially in areas other than human health. Building a robust and diverse U.S. bioeconomy that can continue to compete globally across key industrial sectors will require the Federal Government to identify top national biotechnology goals, and to actively engage and support the private sector in meeting those goals.

The U.S. cannot assume that its current competitive position in the global bioeconomy will hold. Not only is China making a credible bid to "own" the biorevolution, other countries also recognize that biotechnologies can build economic power and address major problems - and are investing accordingly. Moreover, the rapid and accelerating rate of discovery in the life sciences means that unexpected, break-out technologies could suddenly disrupt the competitive landscape. To maintain its lead in biotechnology and to out-compete China, the

[8] C. Simone, *Biocentury,* Nov. 8, 2023: "China's Strength is Innovation on Innovation – Western Partners are Lining Up".

U.S. should apply to the bioeconomy key lessons from historical support for defense-related technologies.

The United States has been the "innovation engine" of the biorevolution. Decades of U.S. Government funding for the National Institutes of Health (NIH) and the National Science Foundation (NSF) generated the basic biological research which is the scientific core of today's biotechnologies, particularly those related to biomedicine and human health. The U.S. also has the advantage of a unique combination of institutions that together encourage and protect scientific innovation: research universities, an extensive and dynamic environment of start-up companies and venture capital firms, strong financial institutions, and a well-developed regulatory system that protects intellectual property and public safety while guarding against fraud and snake oil.

The U.S. should apply to the bioeconomy key lessons from historical support for defense-related technologies. Since World War II, this unique innovation landscape and generous government support for R&D, especially in the physical sciences, enabled American industry to leverage the intellectual property generated by defense R&D into unrivaled global military superiority – and allowed U.S. industry to dominate related commercial technology, particularly in telecommunications and information/computational technologies.

The Federal Government's investments funded basic research, but also supported an expansive array of *translational infrastructure - facilities, programs and projects* - which were essential to converting scientific insights into operational technologies and useable products. Similar to China's current national investments in Bio-AI research hubs, genomic data bases, synthetic biology institutes, etc., the post-war U.S. translational infrastructure included national laboratories, test ranges, giant telescopes, research reactors, linear accelerators, space programs, ocean mapping projects, etc. These infrastructure investments were critical to U.S. leadership in commercial technologies emerging from the physical sciences.

The United States needs an analogous approach for biotechnology. Such an approach might include establishing regional biofoundry hubs to spur biomanufacturing development; initiatives to accelerate efficient fermentation processes at large scales; deep sequencing of select microbes used as bioengineering chassis a; initiatives to develop exemplars of how to organize and secure large biological data collections, etc.

The few government translational initiatives in biology have been powerful: the Human Genome Project (~$3B over 13 years) is estimated to have generated a direct and indirect economic impact of $796B in 15 years and spurred the development of advanced equipment, tools and analytical techniques that facilitated the growth of the genomics industry and catalyzed commercial innovation across many sectors. [9] The agricultural "Green Revolution" (1960-80s) brought U.S. agriculture to unprecedented levels of agricultural productivity. But

[9] Battelle Memorial Institute, *Economic Impacts of the Human Genome Project – How a $3.8B Investment Drove$796B in Economic Impact, Created 310,000 Jobs and Launched the Genomic Revolution*, May, 2011

Government support for translational infrastructure within the life sciences has not approached that provided for the physical sciences.

In the U.S., most innovative biotechnologies emerge from in small biotech companies whose founders have an idea about how to translate a scientific finding (or many) into a technology or useful product that can be successfully marketed. These "start-ups" are typically funded by venture capital firms, and serially financed as performance milestones are achieved. Venture capital-financed biotech startups are also found in Europe and Southeast Asia, but the U.S. "VC" ecosystem is the world's largest. Venture Capital financing has clear advantages: it can move fast, take risks, and help founders to build viable companies. VC firms often acquire valuable perspective on the innovation landscape itself. But most venture capital firms are not built for long-term, high-risk, high-reward investments. Historically, efforts seeking transformative technological change require the vision and "patient capital" which comes only from government.

A successful biomedical start-up may be bought by a large pharmaceutical firm, which has the capital and expertise to finance clinical trials, navigate the regulatory process and market the new drug. Alternatively, the start-up may enter the private equity markets. In either event, success delivers excellent financial returns to the venture capitalists. This system has been highly successful, although it includes significant risk – only ten out of 100 drugs entering clinical trials achieve FDA approval, and it takes about ten years to achieve this. It is also extremely expensive: estimates are that the cost of bringing a new drug to market is about $2B.

Venture capital investments in all biotech startups peaked in 2021 at about $28 billion, and then declined for the next two years. About 85% of venture capital biotech funding is invested in biomedical companies. IQT's experience indicates that biotech startups that are not focused on the biomedical or health sectors have a harder time raising capital – in part because the markets for such highly innovative products are nascent and unproven.

Platform companies - startups seeking to create fundamental infrastructure and technologies which could be used across multiple products or operations – are also struggling in an investment climate that prioritizes rapid returns. Investors' lack of appetite for non-biomed biotech products has led some startups to seek financing from abroad, including from Sovereign Funds from Saudi Arabia and elsewhere – essentially giving investor countries access to important technology platforms without having to bear the underlying research and development costs.

The deep knowledge of biological processes achieved by decades of basic research in the life sciences gives American scientists and innovators a significant advantage in building the bioeconomy. But the U.S. biotech innovation ecosystem, financed principally by venture capital, is not well suited to take on ambitious, risky, longer-term projects, or to finance and build the essential infrastructure required to create a robust and diversified national bioeconomy. The current ecosystem of U.S. life sciences research and biotechnology innovation is not well positioned to compete with the CCP's ambitions for Chinese biotechnology dominance.

Fourth: Three successive presidential administrations have endorsed the importance of building a strong U.S. bioeconomy, [10] [11] [12]and Congress has declared biotechnology to be a sector "strategically critical" to national security. The relevant documents from three (very different) presidencies all identify the same elements as essential building blocks of a strong bioeconomy: support for basic research, a strong talent pipeline, adequate infrastructure, and a robust and secure biological data foundation.

What is lacking is a clear and articulated vision of what the Nation needs to achieve via biotechnologies, what problems it must solve, what priorities should apply, and how the essential prerequisites – research, talent, infrastructure and biological data - should be constructed or strengthened to maintain U.S. economic competitiveness and protect U.S. power in this Age of Biology.

The expertise and experience needed to design and execute a roadmap to building the bioeconomy resides in the private sector. Only the private sector - the small companies, large corporation, financial institutions and universities, ideally in collaboration with international partners – can actually *build* the bioeconomy. But identifying and articulating the biotechnology *goals, capabilities and priorities* which the country must achieve to maintain economic competitiveness and national power is the responsibility of the Federal Government, and the Government must effectively engage and enlist the private sector in realizing such goals.

Having observed global biotechnology innovation for ten years from my position at IQT, I have no doubts that U.S. companies, together with businesses of allied countries, can establish a bioeconomy that will bring great economic and social benefits to the world. But as has been the case for previous technological revolutions, success - *especially on a time frame consistent with China's ambitions and evident progress* - will require the strategic direction, oversight and patient capital that only governments can provide.

Respectfully, I would like to offer for the Committee's consideration, the following list of possible actions that would strengthen U.S. biotechnology development and the U.S. bioeconomy.

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[10] The National Bioeconomy Blueprint, April 1, 2012, https://www.obamawhitehouse.archives.gov

[11] Summary of the 2019 White House Summit on America's Bioeconomy, Oct. 7, 2019; https://www.trumpwhitehouse.archives.gov

[12] Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe and Secure American Bioeconomy, Sept. 12, 2022; https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-om-advancing-biotechnology-and-biomanufacturing-innovation

- Fully fund the science appropriation for the CHIPS and Science Act.

- Build out biomanufacturing capacity in the U.S., including the construction of a network of regional biofoundries available to industry and academia, with provisions for training in foundry operations.

- Work with industry to reduce the costs and increase the efficiency and scale of manufacturing gene therapies to make such life-saving treatments generally available, especially to children.

- Congress should support a national strategic investment in the infrastructure, computing resources, and standards needed to drive the bioeconomy. This is an area in which China has a clear strategic advantage, and which directly impairs the ability of U.S. industry and academia to efficiently make scientific discoveries and translate them into technologies. The Interagency Working Group on Data for the Bioeconomy, in consultation with the private sector, produced a 2023 report, *Vision, Needs, and Proposed Actions for Data for the Bioeconomy Initiative,* which presents useful starting points for actions to design and build a federal data infrastructure consistent with the needs of the U.S. bioeconomy.

- As recommended by the 2020 U.S./China Economic and Security Review Commission, in collaboration with allies, to ensure the availability of vital drugs and medical equipment, either by securing existing supply chains, developing alternate substitutions for some products (possibly via synthetic biology manufacture), or establishing needed drug manufacturing processes within the U.S. and allied countries.

- To strengthen U.S. innovators' access to large biological data caches, and to attract public attention to biotechnologies, Congress could support An international effort to sequence and interpret the genomes of key collections of non-human species (e.g. all 462 known mammals in the Northern hemispheres, all saltwater mammals, critical forest species, etc.). Such an effort would advance genomic sequencing and interpretation, advance the development and application of advanced analytics in genomic sequencing, aid progress in synthetic biology, and establish and exemplar of biological data collection and curation.

- As recommended by the 2020 U.S. - China Economic and Security Review Commission, in collaboration with allies, to ensure the availability of vital drugs and medical equipment, either by securing existing supply chains, developing alternate substitutions for some products (possibly via synthetic biology manufacture), or establishing needed drug manufacturing processes within the U.S. and allied countries.

- Congress could, in consultation with industry and academia, initiate 2-3 ambitious and highly visible projects designed to advance key biotechnology platforms, solve a big

problem, and display the importance of modern biotechnologies to excite public interest in the bioeconomy. Such "mission driven" projects might include:

- An international effort to sequence and interpret the genomes of key collections of non-human species (e.g. all 462 known mammals in North America). Such an effort would advance genomic sequencing and interpretation, advance the development and application of advanced analytics in genomic sequencing, aid progress in synthetic biology, and establish and exemplar of biological data collection and curation.

- The U.S. could lead an international Plant Genome Project – an effort to create a genomic data base for food crops. As of 2021, only 10% of the nearly 700 historically cultivated food crops have been genetically sequenced. Such an effort would greatly aid efforts to enhance the yields and resilience of existing crops and provide keys to unlocking new and beneficial crop traits.

- Invest with industry in a large-scale, precompetitive public-private partnership to develop biomarkers of disease. This could boost disease diagnosis and treatment, accelerate drug development, and reduce the costs and risks of clinical trials.

I want to thank the Committee for its time, and its attention to protecting and advancing the U.S. bioeconomy.